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Leading a new era of precision oncology

Oncofocus®

Precision Oncology

ONCOFOCUS® TEST REPORT

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	-		
Surname	-	**Requester**	-
Forename	-	**Contact details**	-
DOB	-	**Date requested**	-
Gender	-		
Histology #	-	**Tumour %**	80%
Primary site	Breast	**Tumour %**	-
Tumour subtype	Metastatic Breast Cancer	**(macrodissected)**	
Tissue Type	Lymph Node		

Comment:
The DNA and RNA extracted from this sample were of optimal quality. The Oncofocus assay on which the sample was run met all assay specific quality metrics.

Oncofocus currently targets 505 genes covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are currently linked to 687 anti-cancer targeted therapies/therapy combinations.

- A variant of unknown significance was identified in the ATR gene: p.(E560*) c.1678G>T. There is little published functional data on this particular variant, however, if it does cause ATR aberration, then the therapies identified in this report would be indicated.
- A variant of unknown significance was identified in the TP53 gene: p.(G112fs) c.335delG. There is little published functional data on this particular variant, however, if it does cause TP53 aberration, then the therapies identified in this report would be indicated.

Within the 'Current Clinical Trials Information' section of this report, starting on page 56, the NCT numbers are hyperlinks to the clinicaltrials.gov webpages which should be accessed to gain further trial specific information

Sample Cancer Type: Breast Cancer

Indicated Contraindicated

Clinically Significant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
ERBB2 amplification	trastuzumab (Celltrion)[1] trastuzumab (Celltrion) + chemotherapy[1] trastuzumab (Samsung Bioepis)[1] trastuzumab (Samsung Bioepis) + chemotherapy[1] trastuzumab[1,2] trastuzumab + chemotherapy[1,2] ado-trastuzumab emtansine[1,2] lapatinib + aromatase inhibitor[1] lapatinib + chemotherapy[1,2] lapatinib + trastuzumab[1] pertuzumab + trastuzumab + chemotherapy[1,2] trastuzumab (Celltrion) + anastrozole[1] trastuzumab (Samsung Bioepis) + anastrozole[1] trastuzumab + anastrozole[1] trastuzumab (Biocon)[2]	trastuzumab (Celltrion)[1] trastuzumab (Celltrion) + chemotherapy[1] trastuzumab (Samsung Bioepis)[1] trastuzumab (Samsung Bioepis) + chemotherapy[1] trastuzumab[1,2] trastuzumab + chemotherapy[1,2] trastuzumab (Biocon)[2] trastuzumab (Biocon) + chemotherapy[2] trastuzumab containing regimen	165

Sources included in relevant therapies: EMA[1], FDA[2], ESMO, NCCN

Referring pathology dept: -

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Clinically Significant Biomarkers (continued)

Indicated **Contraindicated**

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
	trastuzumab (Biocon) + chemotherapy[2] lapatinib + letrozole[2] neratinib[2] trastuzumab + hormone therapy + chemotherapy trastuzumab + hormone therapy pertuzumab + trastuzumab hormone therapy lapatinib + trastuzumab + aromatase inhibitor pertuzumab + trastuzumab + hormone therapy + chemotherapy trastuzumab + aromatase inhibitor trastuzumab + fulvestrant trastuzumab + tamoxifen		
ERBB2 p.(S310F) c.929C>T	Clinical trials and/or off-label	ado-trastuzumab emtansine	18
ATR p.(E560) c.1678G>T*	Clinical trials and/or off-label	Clinical trials and/or off-label	10
FGF19 amplification	Clinical trials and/or off-label	Clinical trials and/or off-label	5
TP53 p.(G112fs) c.335delG	Clinical trials and/or off-label	Clinical trials and/or off-label	4
FGF3 amplification	Clinical trials and/or off-label	Clinical trials and/or off-label	4
CCND1 amplification	Clinical trials and/or off-label	Clinical trials and/or off-label	4

Sources included in relevant therapies: EMA[1], FDA[2], ESMO, NCCN

Hotspot variants with >10% alternate allele reads are classified as 'detected' with an assay sensitivity and positive predictive value(PPV) of 99%. Copy number variants; amplifications of CN> 6 with the 5% confidence value of ≥4 after normalization and deletions with 95% CI ≤1 are classified as present when the tumour% >50% with a sensitivity of 80% and PPV 100%. Gene Fusions are reported when occurring in >40 counts and meeting the thresholds of assay specific internal RNA quality control with a sensitivity of 92% and PPV of 99%. Supplementary technical information is available upon request.

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Tier Criteria Met

Genomic Alteration	Tier Classification for Breast Cancer
ERBB2 amplification Tier: IA	IA: Biomarker predicts response or resistance to EMA or FDA approved therapies in this cancer type IA: Biomarker is included in ESMO or NCCN guidelines that predict response or resistance to therapies in this cancer type IIC: Biomarker predicts response or resistance to EMA or FDA approved therapies in other cancer types IIC: Biomarker is included in ESMO or NCCN guidelines that predict response or resistance to therapies in other cancer types IIC: Biomarker is an inclusion criteria for clinical trials
ERBB2 p.(S310F) c.929C>T Tier: IIC	IIC: Biomarker is included in ESMO or NCCN guidelines that predict response or resistance to therapies in other cancer types IIC: Biomarker is an inclusion criteria for clinical trials
ATR p.(E560) c.1678G>T* Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
FGF19 amplification Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
TP53 p.(G112fs) c.335delG Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
FGF3 amplification Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials
CCND1 amplification Tier: IIC	IIC: Biomarker is an inclusion criteria for clinical trials

Reference: Li et al. *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists.* J Mol Diagn. 2017 Jan;19(1):4-23.

Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + capecitabine + cisplatin	◑	◑	○	○	✖
trastuzumab + cisplatin + fluorouracil	◑	◑	○	○	✖
trastuzumab + paclitaxel	◑	◑	✖	◑	✖
trastuzumab + carboplatin + docetaxel	◑	◑	✖	●	✖

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab	◑	◑	✖	○	● (III)
trastuzumab + cyclophosphamide + docetaxel + doxorubicin	◑	◑	✖	✖	✖
trastuzumab + cyclophosphamide + doxorubicin + paclitaxel	◑	◑	✖	✖	✖
trastuzumab + docetaxel	◑	✖	✖	◑	✖
trastuzumab (Celltrion)	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + capecitabine + cisplatin	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + carboplatin + docetaxel	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + cisplatin + fluorouracil	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + cyclophosphamide + docetaxel + doxorubicin	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + cyclophosphamide + doxorubicin + paclitaxel	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + docetaxel	◑	✖	✖	✖	✖
trastuzumab (Celltrion) + paclitaxel	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis)	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + capecitabine + cisplatin	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + carboplatin + docetaxel	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + cisplatin + fluorouracil	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + cyclophosphamide + docetaxel + doxorubicin	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + cyclophosphamide + doxorubicin + paclitaxel	◑	✖	✖	✖	✖

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab (Samsung Bioepis) + docetaxel	◑	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + paclitaxel	◑	✖	✖	✖	✖
ado-trastuzumab emtansine	●	●	●	●	● (IV)
pertuzumab + trastuzumab + docetaxel	●	●	●	●	✖
lapatinib + capecitabine	●	●	✖	●	✖
lapatinib + trastuzumab	●	✖	●	●	● (II)
lapatinib + aromatase inhibitor	●	✖	✖	●	✖
trastuzumab (Celltrion) + anastrozole	●	✖	✖	✖	✖
trastuzumab (Samsung Bioepis) + anastrozole	●	✖	✖	✖	✖
trastuzumab + anastrozole	●	✖	✖	✖	✖
trastuzumab (Biocon)	✖	◑	✖	✖	✖
trastuzumab (Biocon) + capecitabine + cisplatin	✖	◑	✖	✖	✖
trastuzumab (Biocon) + carboplatin + docetaxel	✖	◑	✖	✖	✖
trastuzumab (Biocon) + cisplatin + fluorouracil	✖	◑	✖	✖	✖
trastuzumab (Biocon) + cyclophosphamide + docetaxel + doxorubicin	✖	◑	✖	✖	✖
trastuzumab (Biocon) + cyclophosphamide + doxorubicin + paclitaxel	✖	◑	✖	✖	✖
trastuzumab (Biocon) + paclitaxel	✖	◑	✖	✖	✖
pertuzumab + trastuzumab + chemotherapy	✖	●	●	●	● (IV)
neratinib	✖	●	✖	✖	● (II)
lapatinib + letrozole	✖	●	✖	✖	✖
trastuzumab + chemotherapy	✖	✖	●	●	● (IV)
trastuzumab + hormone therapy + chemotherapy	✖	✖	●	●	● (II)

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
pertuzumab + trastuzumab + paclitaxel	✖	✖	●	●	✖
trastuzumab + vinorelbine	✖	✖	●	●	✖
pertuzumab + trastuzumab	✖	✖	●	✖	● (II)
pertuzumab + trastuzumab + capecitabine	✖	✖	●	✖	✖
pertuzumab + trastuzumab + nab-paclitaxel	✖	✖	●	✖	✖
pertuzumab + trastuzumab + vinorelbine	✖	✖	●	✖	✖
trastuzumab + hormone therapy	✖	✖	●	✖	✖
trastuzumab + taxane	✖	✖	●	✖	✖
trastuzumab containing regimen	✖	✖	○	✖	✖
trastuzumab + capecitabine	✖	✖	✖	◑	✖
trastuzumab + carboplatin + paclitaxel	✖	✖	✖	◑	✖
hormone therapy	✖	✖	✖	●	✖
lapatinib + trastuzumab + aromatase inhibitor	✖	✖	✖	●	✖
pertuzumab + trastuzumab + carboplatin + docetaxel	✖	✖	✖	●	✖
pertuzumab + trastuzumab + hormone therapy + chemotherapy	✖	✖	✖	●	✖
trastuzumab + aromatase inhibitor	✖	✖	✖	●	✖
trastuzumab + chemotherapy (other)	✖	✖	✖	●	✖
trastuzumab + cyclophosphamide + docetaxel	✖	✖	✖	●	✖
trastuzumab + fulvestrant	✖	✖	✖	●	✖
trastuzumab + tamoxifen	✖	✖	✖	●	✖
trastuzumab + capecitabine + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + carboplatin + docetaxel + fluorouracil	✖	✖	✖	○	✖
trastuzumab + cisplatin + docetaxel	✖	✖	✖	○	✖

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Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + cisplatin + docetaxel + fluorouracil	✖	✖	✖	○	✖
trastuzumab + cisplatin + paclitaxel	✖	✖	✖	○	✖
trastuzumab + docetaxel + fluorouracil + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + fluorouracil	✖	✖	✖	○	✖
trastuzumab + fluorouracil + irinotecan	✖	✖	✖	○	✖
trastuzumab + fluorouracil + oxaliplatin	✖	✖	✖	○	✖
ado-trastuzumab emtansine, trastuzumab	✖	✖	✖	✖	● (IV)
pertuzumab + chemotherapy	✖	✖	✖	✖	● (IV)
ado-trastuzumab emtansine, pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
antiHER2 therapy + chemotherapy	✖	✖	✖	✖	● (III)
GB-221	✖	✖	✖	✖	● (III)
GBR 200 + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
HLX02 + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
lapatinib + chemotherapy, pyrotinib + chemotherapy	✖	✖	✖	✖	● (III)
lapatinib + chemotherapy, trastuzumab + chemotherapy, trastuzumab deruxtecan	✖	✖	✖	✖	● (III)
lapatinib + hormone therapy + chemotherapy	✖	✖	✖	✖	● (III)

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
palbociclib + pertuzumab + trastuzumab + anastrozole, palbociclib + pertuzumab + trastuzumab + exemestane, palbociclib + pertuzumab + trastuzumab + fulvestrant, palbociclib + pertuzumab + trastuzumab + letrozole, palbociclib + trastuzumab + anastrozole, palbociclib + trastuzumab + exemestane, palbociclib + trastuzumab + fulvestrant, palbociclib + trastuzumab + letrozole, pertuzumab + trastuzumab + anastrozole, pertuzumab + trastuzumab + exemestane, pertuzumab + trastuzumab + fulvestrant, pertuzumab + trastuzumab + letrozole, trastuzumab + anastrozole, trastuzumab + exemestane, trastuzumab + fulvestrant, trastuzumab + letrozole	✖	✖	✖	✖	● (III)
pertuzumab + ribociclib + trastuzumab + anastrozole, pertuzumab + ribociclib + trastuzumab + chemotherapy, pertuzumab + ribociclib + trastuzumab + exemestane, pertuzumab + ribociclib + trastuzumab + fulvestrant, pertuzumab + ribociclib + trastuzumab + letrozole, pertuzumab + ribociclib + trastuzumab + tamoxifen	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + aromatase inhibitor + chemotherapy + filgrastim + radiation therapy + surgical intervention, pertuzumab + trastuzumab + aromatase inhibitor + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + tamoxifen + chemotherapy + filgrastim + radiation therapy + surgical intervention, pertuzumab + trastuzumab + tamoxifen + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
pyrotinib + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo	✖	✖	✖	✖	● (III)
SYD-985	✖	✖	✖	✖	● (III)

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + chemotherapy, trastuzumab (Tanvex Biopharma) + chemotherapy	✖	✖	✖	✖	● (III)
trastuzumab + chemotherapy, trastuzumab + hormone therapy	✖	✖	✖	✖	● (III)
GnRH agonist + chemotherapy, letrozole + chemotherapy	✖	✖	✖	✖	● (II/III)
lapatinib + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II/III)
ado-trastuzumab emtansine + pertuzumab + surgical intervention	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine, ado-trastuzumab emtansine + chemotherapy, ado-trastuzumab emtansine + pertuzumab, ado-trastuzumab emtansine + pertuzumab + chemotherapy	✖	✖	✖	✖	● (II)
atezolizumab + cobimetinib + chemotherapy	✖	✖	✖	✖	● (II)
atezolizumab + pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)
atezolizumab + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
avelumab + trastuzumab + chemotherapy + acetaminophen + antihistamine, avelumab + trastuzumab + utomilumab + acetaminophen + antihistamine, avelumab + trastuzumab + utomilumab + chemotherapy + acetaminophen + antihistamine, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
denosumab, pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
lapatinib + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib + chemotherapy, RC-48	✖	✖	✖	✖	● (II)
lapatinib + radiation therapy	✖	✖	✖	✖	● (II)

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
lapatinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
lapatinib + trastuzumab, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib, selatinib ditosilate + chemotherapy	✖	✖	✖	✖	● (II)
MCLA-128 + trastuzumab, MCLA-128 + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
neratinib + trastuzumab + crofelemer + loperamide	✖	✖	✖	✖	● (II)
neratinib, neratinib + fulvestrant	✖	✖	✖	✖	● (II)
palbociclib + trastuzumab	✖	✖	✖	✖	● (II)
palbociclib + trastuzumab + hormone therapy, palbociclib + trastuzumab + letrozole	✖	✖	✖	✖	● (II)
palbociclib + trastuzumab, palbociclib + trastuzumab + letrozole	✖	✖	✖	✖	● (II)
palbociclib, palbociclib + trastuzumab	✖	✖	✖	✖	● (II)
pembrolizumab + chemotherapy, pertuzumab + trastuzumab, SGN-LIV1A + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
pembrolizumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + chemotherapy + surgical intervention	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + hormone therapy	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + letrozole, pertuzumab + trastuzumab + tamoxifen	✖	✖	✖	✖	● (II)
poziotinib	✖	✖	✖	✖	● (II)
trastuzumab + chemotherapy + placebo, trastuzumab + Tucatinib + chemotherapy	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + chemotherapy, trastuzumab + chemotherapy + pegfilgrastim	✖	✖	✖	✖	● (II)
trastuzumab + letrozole	✖	✖	✖	✖	● (II)
trastuzumab + TVB-2640 + chemotherapy	✖	✖	✖	✖	● (II)
varlitinib + chemotherapy	✖	✖	✖	✖	● (II)
WOKVAC + dendritic cell vaccine	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine + neratinib	✖	✖	✖	✖	● (I/II)
ado-trastuzumab emtansine, ado-trastuzumab emtansine + chemotherapy	✖	✖	✖	✖	● (I/II)
AZD-5069 + durvalumab	✖	✖	✖	✖	● (I/II)
CART-HER-2	✖	✖	✖	✖	● (I/II)
copanlisib + trastuzumab	✖	✖	✖	✖	● (I/II)
ibrutinib + trastuzumab, trastuzumab	✖	✖	✖	✖	● (I/II)
interferon gamma + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I/II)
masitinib + chemotherapy	✖	✖	✖	✖	● (I/II)
MCLA-128	✖	✖	✖	✖	● (I/II)
neratinib + chemotherapy	✖	✖	✖	✖	● (I/II)
neratinib + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I/II)
palbociclib + pertuzumab + trastuzumab + anastrozole	✖	✖	✖	✖	● (I/II)
palbociclib + Tucatinib + letrozole	✖	✖	✖	✖	● (I/II)
ruxolitinib + trastuzumab	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
TAS0728	✖	✖	✖	✖	● (I/II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + natural killer cell treatment	✖	✖	✖	✖	● (I/II)
trastuzumab, trastuzumab + natural killer cell treatment	✖	✖	✖	✖	● (I/II)
abemaciclib + pertuzumab + trastuzumab + hormone therapy + loperamide, abemaciclib + pertuzumab + trastuzumab + loperamide	✖	✖	✖	✖	● (I)
AdHER-2	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + palbociclib	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + pembrolizumab	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + pertuzumab + taselisib, ado-trastuzumab emtansine + taselisib, pertuzumab + taselisib + trastuzumab, pertuzumab + taselisib + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + poziotinib	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + utomilumab, trastuzumab + utomilumab	✖	✖	✖	✖	● (I)
allitinib + chemotherapy	✖	✖	✖	✖	● (I)
ARX-788	✖	✖	✖	✖	● (I)
atezolizumab + PRS-343	✖	✖	✖	✖	● (I)
BAT-8001	✖	✖	✖	✖	● (I)
BI-CON-02	✖	✖	✖	✖	● (I)
BTRC-4017A	✖	✖	✖	✖	● (I)
dacomitinib + gedatolisib	✖	✖	✖	✖	● (I)
darolutamide	✖	✖	✖	✖	● (I)
everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib	✖	✖	✖	✖	● (I)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
FATE-NK100 + trastuzumab	✖	✖	✖	✖	● (I)
GBR 1302	✖	✖	✖	✖	● (I)
Hemay022	✖	✖	✖	✖	● (I)
Hemay022 + exemestane	✖	✖	✖	✖	● (I)
M-7824 + chemotherapy	✖	✖	✖	✖	● (I)
MP-0274	✖	✖	✖	✖	● (I)
pembrolizumab	✖	✖	✖	✖	● (I)
pertuzumab + taselisib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (I)
pertuzumab + tocilizumab + trastuzumab, tocilizumab + trastuzumab	✖	✖	✖	✖	● (I)
PF-06804103	✖	✖	✖	✖	● (I)
pirotinib	✖	✖	✖	✖	● (I)
PRS-343	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)
RC-48	✖	✖	✖	✖	● (I)
RG-7461 + trastuzumab	✖	✖	✖	✖	● (I)
SGN-LIV1A + trastuzumab	✖	✖	✖	✖	● (I)
TAS-116	✖	✖	✖	✖	● (I)
ZW-25	✖	✖	✖	✖	● (I)

ERBB2 p.(S310F) c.929C>T

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
ado-trastuzumab emtansine	✖	✖	✖	○	✖
afatinib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Referring pathology dept: -

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ERBB2 p.(S310F) c.929C>T (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
atezolizumab + cobimetinib + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
neratinib	✖	✖	✖	✖	● (II)
neratinib + fulvestrant	✖	✖	✖	✖	● (II)
neratinib + fulvestrant, neratinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
neratinib + trastuzumab	✖	✖	✖	✖	● (II)
neratinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
neratinib, neratinib + trastuzumab	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
TAS0728	✖	✖	✖	✖	● (I/II)
darolutamide	✖	✖	✖	✖	● (I)
everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib	✖	✖	✖	✖	● (I)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)
pirotinib	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)
varlitinib + chemotherapy	✖	✖	✖	✖	● (I)

ATR p.(E560*) c.1678G>T

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
durvalumab + olaparib	✖	✖	✖	✖	● (II)
niraparib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

ATR p.(E560*) c.1678G>T (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
olaparib	✖	✖	✖	✖	● (II)
prexasertib	✖	✖	✖	✖	● (II)
talazoparib	✖	✖	✖	✖	● (II)
avelumab + talazoparib	✖	✖	✖	✖	● (I/II)
BAY-1895344	✖	✖	✖	✖	● (I/II)
VX-970, VX-970 + chemotherapy	✖	✖	✖	✖	● (I/II)
nivolumab + veliparib	✖	✖	✖	✖	● (I)

FGF19 amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
INCB-54828, INCB-54828 + chemotherapy, INCB-54828 + pembrolizumab, INCB-54828 + trastuzumab	✖	✖	✖	✖	● (I/II)
INCB-62079	✖	✖	✖	✖	● (I/II)
TAS-120	✖	✖	✖	✖	● (I/II)
E-7090	✖	✖	✖	✖	● (I)
INCB-54828	✖	✖	✖	✖	● (I)

TP53 p.(G112fs) c.335delG

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
adavosertib + olaparib	✖	✖	✖	✖	● (II)
atezolizumab + cobimetinib	✖	✖	✖	✖	● (I/II)
VX-970, VX-970 + chemotherapy	✖	✖	✖	✖	● (I/II)
LY3143921	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✖ No evidence

FGF3 amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
INCB-54828, INCB-54828 + chemotherapy, INCB-54828 + pembrolizumab, INCB-54828 + trastuzumab	✖	✖	✖	✖	● (I/II)
TAS-120	✖	✖	✖	✖	● (I/II)
E-7090	✖	✖	✖	✖	● (I)
INCB-54828	✖	✖	✖	✖	● (I)

CCND1 amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
abemaciclib	✖	✖	✖	✖	● (II)
palbociclib	✖	✖	✖	✖	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

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Relevant Therapy Details

Current EMA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated 👎 Not recommended 🛡 Resistance

EMA information is current as of 2018-10-01. For the most up-to-date information, search www.ema.europa.eu/ema.

ERBB2 amplification

◑ trastuzumab (Celltrion), trastuzumab (Celltrion) + docetaxel, trastuzumab (Celltrion) + paclitaxel, trastuzumab (Celltrion) + capecitabine + cisplatin, trastuzumab (Celltrion) + carboplatin + docetaxel, trastuzumab (Celltrion) + cisplatin + fluorouracil, trastuzumab (Celltrion) + cyclophosphamide + docetaxel + doxorubicin, trastuzumab (Celltrion) + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer

Label as of: 2018-09-18

Variant class: ERBB2 amplification or ERBB2 overexpression

Reference:

https://www.ema.europa.eu/documents/product-information/herzuma-epar-product-information_en-0.pdf

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◑ trastuzumab (Samsung Bioepis), trastuzumab (Samsung Bioepis) + docetaxel, trastuzumab (Samsung Bioepis) + paclitaxel, trastuzumab (Samsung Bioepis) + capecitabine + cisplatin, trastuzumab (Samsung Bioepis) + carboplatin + docetaxel, trastuzumab (Samsung Bioepis) + cisplatin + fluorouracil, trastuzumab (Samsung Bioepis) + cyclophosphamide + docetaxel + doxorubicin, trastuzumab (Samsung Bioepis) + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer

Label as of: 2018-09-10

Variant class: ERBB2 amplification or ERBB2 overexpression

Reference:

https://www.ema.europa.eu/documents/product-information/ontruzant-epar-product-information_en.pdf

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◑ trastuzumab, trastuzumab + docetaxel, trastuzumab + paclitaxel, trastuzumab + capecitabine + cisplatin, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + cyclophosphamide + docetaxel + doxorubicin, trastuzumab + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer

Label as of: 2018-09-06

Variant class: ERBB2 overexpression or ERBB2 amplification

Reference:

https://www.ema.europa.eu/documents/product-information/herceptin-epar-product-information_en.pdf

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ERBB2 amplification (continued)

ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2018-09-19 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Reference:
https://www.ema.europa.eu/documents/product-information/kadcyla-epar-product-information_en.pdf

lapatinib + aromatase inhibitor

Cancer type: Breast Cancer **Label as of:** 2018-09-07 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Other criteria: ER positive, PR positive

Reference:
https://www.ema.europa.eu/documents/product-information/tyverb-epar-product-information_en-0.pdf

lapatinib + capecitabine

Cancer type: Breast Cancer **Label as of:** 2018-09-07 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Reference:
https://www.ema.europa.eu/documents/product-information/tyverb-epar-product-information_en-0.pdf

lapatinib + trastuzumab

Cancer type: Breast Cancer **Label as of:** 2018-09-07 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Other criteria: Hormone receptor negative

Reference:
https://www.ema.europa.eu/documents/product-information/tyverb-epar-product-information_en-0.pdf

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2018-10-05 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Reference:
https://www.ema.europa.eu/documents/product-information/perjeta-epar-product-information_en-0.pdf

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ERBB2 amplification (continued)

trastuzumab (Celltrion) + anastrozole

Cancer type: Breast Cancer **Label as of:** 2018-09-18 **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

Reference:

https://www.ema.europa.eu/documents/product-information/herzuma-epar-product-information_en-0.pdf

trastuzumab (Samsung Bioepis) + anastrozole

Cancer type: Breast Cancer **Label as of:** 2018-09-10 **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

Reference:

https://www.ema.europa.eu/documents/product-information/ontruzant-epar-product-information_en.pdf

trastuzumab + anastrozole

Cancer type: Breast Cancer **Label as of:** 2018-09-06 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Other criteria: ER positive, PR positive

Reference:

https://www.ema.europa.eu/documents/product-information/herceptin-epar-product-information_en.pdf

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Current FDA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated 👎 Not recommended 🛡 Resistance

FDA information is current as of 2018-10-01. For the most up-to-date information, search www.fda.gov.

ERBB2 amplification

◑ trastuzumab (Biocon), trastuzumab (Biocon) + paclitaxel, trastuzumab (Biocon) + capecitabine + cisplatin, trastuzumab (Biocon) + carboplatin + docetaxel, trastuzumab (Biocon) + cisplatin + fluorouracil, trastuzumab (Biocon) + cyclophosphamide + docetaxel + doxorubicin, trastuzumab (Biocon) + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer

Label as of: 2017-12-01

Variant class: ERBB2 overexpression or ERBB2 amplification

Indications and usage:

OGIVRI™ is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761074s000lbl.pdf

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◑ trastuzumab, trastuzumab + paclitaxel, trastuzumab + capecitabine + cisplatin, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + cyclophosphamide + docetaxel + doxorubicin, trastuzumab + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer

Label as of: 2018-10-17

Variant class: ERBB2 amplification or ERBB2 overexpression

Indications and usage:

HERCEPTIN® is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Select patients for therapy based on an FDA-approved companion diagnostic for HERCEPTIN®.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103792s5347lbl.pdf

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ERBB2 amplification (continued)

ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2018-09-20 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Indications and usage:

KADCYLA® is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125427s102lbl.pdf

lapatinib + capecitabine

Cancer type: Breast Cancer **Label as of:** 2017-04-06 **Variant class:** ERBB2 overexpression

Indications and usage:

TYKERB® is a kinase inhibitor indicated in combination with:

- capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
- Limitation of Use: Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB® in combination with capecitabine.
- letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

TYKERB® in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022059s022lbl.pdf

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ERBB2 amplification (continued)

lapatinib + letrozole

Cancer type: Breast Cancer **Label as of:** 2017-04-06 **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

Indications and usage:

TYKERB® is a kinase inhibitor indicated in combination with:

- capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
- Limitation of Use: Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB® in combination with capecitabine.
- letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

TYKERB® in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022059s022lbl.pdf

neratinib

Cancer type: Breast Cancer **Label as of:** 2018-06-28 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Indications and usage:
NERLYNX® is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208051s002lbl.pdf

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2018-09-20 **Variant class:** ERBB2 amplification or ERBB2 overexpression

Indications and usage:

PERJETA® is a HER2/neu receptor antagonist indicated for:

- Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- Use in combination with trastuzumab and chemotherapy as
  - neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
  - adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125409s121lbl.pdf

trastuzumab (Biocon)

Cancer type: Breast Cancer **Label as of:** 2017-12-01 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Other criteria: ER negative, PR negative

Indications and usage:

OGIVRI™ is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761074s000lbl.pdf

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ERBB2 amplification (continued)

trastuzumab (Biocon) + carboplatin + docetaxel, trastuzumab (Biocon) + cyclophosphamide + docetaxel + doxorubicin, trastuzumab (Biocon) + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer **Label as of:** 2017-12-01 **Variant class:** ERBB2 overexpression or ERBB2 amplification

Other criteria: ERBB2 negative, PR negative

Indications and usage:

OGIVRI™ is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761074s000lbl.pdf

trastuzumab, trastuzumab + carboplatin + docetaxel, trastuzumab + cyclophosphamide + docetaxel + doxorubicin, trastuzumab + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer **Label as of:** 2018-10-17 **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, PR negative

Indications and usage:

HERCEPTIN® is a HER2/neu receptor antagonist indicated for:

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Select patients for therapy based on an FDA-approved companion diagnostic for HERCEPTIN®.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103792s5347lbl.pdf

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Current ESMO Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated 👎 Not recommended 🛡 Resistance

ESMO information is current as of 2018-08-16. For the most up-to-date information, search www.esmo.org.

ERBB2 amplification

● trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, PR negative

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- ERBB2(+) Non-Luminal Cancer; Except very low risk, such as T1aN0 (Neoadjuvant therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Primary Breast Cancer [Ann Oncol (2015) 26 (suppl 5): v8-v30.]

● trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Primary Breast Cancer (Neoadjuvant therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Primary Breast Cancer [Ann Oncol (2015) 26 (suppl 5): v8-v30.]

● trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Luminal B ERBB2-positive Breast Cancer; Except low-risk T1a (Neoadjuvant therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Primary Breast Cancer [Ann Oncol (2015) 26 (suppl 5): v8-v30.]

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ERBB2 amplification (continued)

trastuzumab + hormone therapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive

ESMO Level of Evidence/Grade of Recommendation: V / A

Population segment (Line of therapy):
- Luminal B ERBB2-positive; If contraindication or refusal of chemotherapy (Neoadjuvant therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Primary Breast Cancer [Ann Oncol (2015) 26 (suppl 5): v8-v30.]

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ado-trastuzumab emtansine

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer; Progression after one line of trastuzumab-based therapy (Second-line therapy) (Preferred)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

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pertuzumab + trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer; Previously untreated with anti-HER2 therapy (First-line therapy)
- Advanced Breast Cancer; Previously treated (in the (neo)adjuvant setting) with anti-HER2 therapy (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

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pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

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ERBB2 amplification (continued)

trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer; Previously treated in the adjuvant setting (First-line therapy)
- Advanced Breast Cancer; Untreated with trastuzumab (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

trastuzumab + taxane

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer; Pertuzumab is not given (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

trastuzumab + vinorelbine

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Advanced Breast Cancer; Pertuzumab is not given (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

lapatinib + trastuzumab

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

Other criteria: ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):
- Advanced Breast Cancer; First-line therapy was endocrine therapy and anti-HER2 therapy (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

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ERBB2 amplification (continued)

lapatinib + trastuzumab

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):
- Advanced Breast Cancer; Progression on trastuzumab-based therapy (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

pertuzumab + trastuzumab

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

Other criteria: ER positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):
- Advanced Breast Cancer; First-line therapy was endocrine therapy and anti-HER2 therapy (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

pertuzumab + trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: I / B

Population segment (Line of therapy):
- Advanced Breast Cancer (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

pertuzumab + trastuzumab + capecitabine

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: II / A

Population segment (Line of therapy):
- Advanced Breast Cancer (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

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ERBB2 amplification (continued)

● pertuzumab + trastuzumab + vinorelbine

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: II / A

Population segment (Line of therapy):
- Advanced Breast Cancer (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

● pertuzumab + trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: II / B

Population segment (Line of therapy):
- Advanced Breast Cancer; Previously untreated with the combination of chemotherapy + trastuzumab + pertuzumab (After first-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

● pertuzumab + trastuzumab + nab-paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 positive

ESMO Level of Evidence/Grade of Recommendation: II / B

Population segment (Line of therapy):
- Advanced Breast Cancer (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESMO-ESO-ESMO Advanced Breast Cancer [Ann Oncol (2018) 00: 1–24.]

○ trastuzumab + capecitabine + cisplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Not specified

Reference: ESMO Clinical Practice Guidelines - ESMO-Gastric Cancer [Ann Oncol (2016) 27 (suppl 5): v38-v49.]

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ERBB2 amplification (continued)

trastuzumab + cisplatin + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

ESMO Level of Evidence/Grade of Recommendation: I / A

Population segment (Line of therapy):
- Not specified

Reference: ESMO Clinical Practice Guidelines - ESMO-Gastric Cancer [Ann Oncol (2016) 27 (suppl 5): v38-v49.]

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trastuzumab containing regimen

Cancer type: Esophageal Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

ESMO Level of Evidence/Grade of Recommendation: II / B

Population segment (Line of therapy):
- Not Specified

Reference: ESMO Clinical Practice Guidelines - ESMO-Oesophageal Cancer [Ann Oncol (2016) 27 (suppl 5): v50-v57.]

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pertuzumab + trastuzumab

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Summary:

ESMO Clinical Practice Guidelines include the following supporting statement:
- "The role of dual HER2 blockade (including a combination of trastuzumab and pertuzumab) is not well proven and such treatment is not recommended for routine use, although it may be discussed on a case-by-case basis."

Reference: ESMO Clinical Practice Guidelines - ESMO-Primary Breast Cancer [Ann Oncol (2015) 26 (suppl 5): v8-v30.]

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Current NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated 👎 Not recommended 🛡 Resistance

NCCN information is current as of 2018-08-16. For the most up-to-date information, search www.nccn.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/international_adaptations.aspx.

ERBB2 amplification

● pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (First-line therapy) Preferred

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

● trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER negative, PR negative

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3 and pN0 or pN1m; Tumor >1 cm (Not specified)
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; pN0 or pN1mi (≤2 mm axillary node metastasis), pT1, pT2, or pT3; Tumor >1 cm (Not Specified)
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes) (Not Specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER negative, PR negative

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3 and pN0 or pN1m; Tumor >1 cm (Not specified)
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER positive, PR positive

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; Tumor >1 cm (Not specified)
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; Tumor >1 cm (Not specified)
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ado-trastuzumab emtansine

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; With or without prior endocrine therapy within 1 yr; Premenopausal or Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ado-trastuzumab emtansine

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; With or without prior endocrine therapy within 1 year; Premenopausal or Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

hormone therapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3; Tumor ≤0.5 cm including microinvasive; pN1mi or Tumor 0.6-1.0 cm (Not specified)
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

hormone therapy

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3; Tumor ≤0.5 cm including microinvasive; pN1mi or Tumor 0.6-1.0 cm (Not specified)
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

lapatinib + aromatase inhibitor

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

lapatinib + capecitabine

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

lapatinib + trastuzumab

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer; Without cytotoxic therapy (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

lapatinib + trastuzumab + aromatase inhibitor

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + carboplatin + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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pertuzumab + trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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pertuzumab + trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node positive (one or more metastases >2 mm to one or more ipsilateral axillary lymph nodes) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (First-line therapy) (Preferred)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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pertuzumab + trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (First-line therapy) Preferred

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + aromatase inhibitor

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + capecitabine

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

trastuzumab + carboplatin + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

trastuzumab + carboplatin + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; pT1, pT2, or pT3, and pN0 or pN1mi (node metastasis ≤2 mm axillary); Tumor ≤0.5 cm including microinvasive pN1mi or Tumor 0.6-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

---

trastuzumab + chemotherapy (other)

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + cyclophosphamide + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + docetaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

---

trastuzumab + fulvestrant

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3; Tumor ≤0.5 cm including microinvasive; pN1mi or Tumor 0.6-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3; Tumor ≤0.5 cm including microinvasive; pN1mi or Tumor 0.6-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Low-risk stage I Breast Cancer; Particularly those not eligible for other standard adjuvant regimens due to comorbidities (Not specified)
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + tamoxifen

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV Invasive Breast Cancer; No prior endocrine therapy within 1 year; Postmenopausal (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + vinorelbine

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, ER positive, PR negative, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or Stage IV Invasive Breast Cancer (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3 and pN0 or pN1m; Tumor ≤0.5 cm including microinvasive; pN0 (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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trastuzumab + hormone therapy + chemotherapy

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3; Tumor ≤0.5 cm including microinvasive; pN0 (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3 and pN0 or pN1m; Tumor ≤0.5 cm including microinvasive; pN0 (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

trastuzumab + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 overexpression

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic Histology; Node metastasis ≤2 mm axillary; pT1, pT2, or pT3 and pN0 or pN1m; Tumor ≤0.5 cm including microinvasive; pN0 (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

trastuzumab + capecitabine + cisplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

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ERBB2 amplification (continued)

trastuzumab + capecitabine + cisplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

---

trastuzumab + cisplatin + fluorouracil

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

---

trastuzumab + cisplatin + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

---

trastuzumab + carboplatin + paclitaxel

Cancer type: Endometrial Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Advanced or Recurrent Uterine Serous Carcinoma; Stage IA-Stage IV (Adjuvant therapy) (Preferred if tolerated)

Reference: NCCN Guidelines® - NCCN-Uterine Neoplasms [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + capecitabine

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + capecitabine

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + capecitabine + oxaliplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + capecitabine + oxaliplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + carboplatin + docetaxel + fluorouracil

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + carboplatin + docetaxel + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + carboplatin + paclitaxel

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + carboplatin + paclitaxel

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + cisplatin + docetaxel

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + cisplatin + docetaxel

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + cisplatin + docetaxel + fluorouracil

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + cisplatin + docetaxel + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + cisplatin + paclitaxel

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + cisplatin + paclitaxel

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + docetaxel

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + docetaxel

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + docetaxel + fluorouracil + oxaliplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + docetaxel + fluorouracil + oxaliplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + fluorouracil

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

○ trastuzumab + fluorouracil + irinotecan

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + fluorouracil + irinotecan

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

○ trastuzumab + fluorouracil + oxaliplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

○ trastuzumab + fluorouracil + oxaliplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

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ERBB2 amplification (continued)

trastuzumab + paclitaxel

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

---

trastuzumab + paclitaxel

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Metastatic Adenocarcinoma; Local therapy is not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

---

trastuzumab

Cancer type: Head and Neck Cancer **Variant class:** ERBB2 positive

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Recurrent Metastatic Salivary Gland Tumors; Distant metastases (Therapy for recurrence)

Reference: NCCN Guidelines® - NCCN-Head and Neck Cancers [Version 2.2018]

---

pertuzumab + trastuzumab + cyclophosphamide + docetaxel + doxorubicin

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Summary:

NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided."

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided."

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

---

trastuzumab + cyclophosphamide + docetaxel + doxorubicin

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided."

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

---

trastuzumab + cyclophosphamide + doxorubicin + paclitaxel

Cancer type: Breast Cancer **Variant class:** ERBB2 amplification or ERBB2 overexpression

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided."

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 1.2018]

---

trastuzumab + capecitabine + cisplatin + epirubicin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):

- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

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ERBB2 amplification (continued)

trastuzumab + capecitabine + cisplatin + epirubicin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

trastuzumab + capecitabine + epirubicin + oxaliplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

trastuzumab + capecitabine + epirubicin + oxaliplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

trastuzumab + cisplatin + epirubicin + fluorouracil

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

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ERBB2 amplification (continued)

trastuzumab + cisplatin + epirubicin + fluorouracil

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

trastuzumab + epirubicin + fluorouracil + oxaliplatin

Cancer type: Esophageal Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2018]

trastuzumab + epirubicin + fluorouracil + oxaliplatin

Cancer type: Gastric Cancer **Variant class:** ERBB2 overexpression

Summary:
NCCN Guidelines® include the following supporting statement(s):
- "Trastuzumab is not recommended for use with anthracyclines"

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 2.2018]

ERBB2 p.(S310F) c.929C>T

ado-trastuzumab emtansine

Cancer type: Non-Small Cell Lung Cancer **Variant class:** ERBB2 mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Non-Small Cell Lung Cancer; Emerging targeted agents

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 6.2018]

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Current Clinical Trials Information

Clinical Trials information is current as of 2018-09-04. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

ERBB2 amplification

No NCT ID - see other identifier(s)
Observational Study for Treatment Outcome in Patients with HER2-positive Metastatic Breast Cancer who Received Pertuzumab Combination Chemotherapy

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000012210

Population segments: HER2 positive, Line of therapy N/A, Stage IV

Phase: IV

Therapy: pertuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Observational Study of Pertuzumab in Combination with Trastuzumab and Docetaxel in Patients with Metastatic HER2-Positive Breast Cancer that have the History of Trastuzumab Treatment

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000012444

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
The Clinical Study of PLD Plus Trastuzumab and Paclitaxel as Neoadjuvant Therapy for HER2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifier: ChiCTR1800016222

Population segments: First line, HER2 positive, Neoadjuvant, Stage II, Stage III

Phase: IV

Therapy: trastuzumab + chemotherapy

Location: China

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ERBB2 amplification (continued)

NCT02419742
An Indian Multicentric Open Label Prospective Phase IV Study to Evaluate Safety and Efficacy of Trastuzumab in Her2 Positive, Node Positive or High Risk Node Negative Breast Cancer as Part of a Treatment Regimen Consisting of Doxorubicin, Cyclophosphamide, With Either Docetaxel or Paclitaxel (AC-TH) or Docetaxel and Carboplatin (TCH)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: CTRI/2015/05/005789, ML28714

Population segments: HER2 positive, Line of therapy N/A, Stage I, Stage II, Stage III

Phase: IV

Therapy: trastuzumab + chemotherapy

Location: India

NCT02305641
Post-marketing surveillance of kadcyla in breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: ML29629

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: IV

Therapy: ado-trastuzumab emtansine

Location: Republic of Korea

No NCT ID - see other identifier(s)
The effect of trastuzumab emtansine (T-DM1) to the platelets for HER2-positive advanced breast cancer patients

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000014750

Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV

Phase: IV

Therapies: ado-trastuzumab emtansine, trastuzumab

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A Phase III, Double-blind, Multicenter Clinical Study of Recombinant HER-2 Humanized Monoclonal Antibody (GB221) or Placebo Combined with Capecitabine for the Treatment of HER-2-Positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CTR20160389, GENOR GB221-003

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: III

Therapy: GB-221

Location: China

No NCT ID - see other identifier(s)
A Prospective, Multicenter, Randomized, Double-blind, Parallel-group Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in patients diagnosed with HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: CTRI/2017/02/007892, GBR 200-301

Population segments: HER2 positive, Line of therapy N/A, Stage IV

Phase: III

Therapies: GBR 200 + chemotherapy, trastuzumab + chemotherapy

Location: India

NCT03084237
A Phase III Clinical Study To Evaluate Safety and Immunogenicity Of HLX02 In Comparsion With Herceptin And Docetaxel In Patients With Previously Untreated HER2 -overexpressing Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 2017-CT0418, CTR20160526, EudraCT Number: 2016-000206-10, HLX02-BC01, PHRR171108-001718

Population segments: First line, HER2 positive, Stage IV

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: III

Therapies: HLX02 + chemotherapy, trastuzumab + chemotherapy

Location: China

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ERBB2 amplification (continued)

NCT01619111
A multicenter, prospective, randomized phase III trial comparing an antineoplastic therapy alone versus an antineoplastic therapy plus lapatinib in patients with initially HER2-negative metastatic breast cancer and HER2-positive circulating tumor cells

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: D-III, DETECT III, EudraCT Number: 2010-024238-46

Population segments: Bone mets, First line, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: III

Therapy: lapatinib + hormone therapy + chemotherapy

Location: Germany

NCT02344472
DETECT V / CHEVENDO CHemo- Versus ENDOcrine Therapy in Combination With Dual HER2-targeted Therapy of Herceptin (Trastuzumab) and Perjeta (Pertuzumab) in Patients With HER2 Positive and Hormone-receptor Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CHEVENDO, D-V, Detect V, DRKS00008184, DV, EudraCT Number: 2014-002249-22

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Stage IV

Other inclusion criteria: Hormone receptor positive

Phase: III

Therapies: pertuzumab + ribociclib + trastuzumab + anastrozole, pertuzumab + ribociclib + trastuzumab + chemotherapy, pertuzumab + ribociclib + trastuzumab + exemestane, pertuzumab + ribociclib + trastuzumab + fulvestrant, pertuzumab + ribociclib + trastuzumab + letrozole, pertuzumab + ribociclib + trastuzumab + tamoxifen

Location: Germany

NCT02514681
A Randomized, Open-label Phase III Trial to Evaluate the Efficacy and Safety of Pertuzumab Retreatment in Previously Pertuzumab, Trastuzuamb and Chemotherapy Treated Her2-Positive Metastatic Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: JBCRG-M05, M05 PRECIOUS, PRECIOUS, UMIN000018202, UMIN000021514

Population segments: HER2 positive, Second line, Stage I, Stage II, Stage III, Stage IV

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

NCT02625441
A Randomized Phase III Study Comparing Trastuzumab, Pertuzumab Plus Docetaxel (TPD) Followed by 3 Cycles of Chemotherapy to the Current Standard Regimen as the Treatments of Early Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: BOLD-1, EudraCT Number: 2015-002323-25, FBCG-01-2015

Population segments: Adjuvant, HER2 positive, Neoadjuvant, Stage I, Stage II

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Location: Finland

NCT03588091
A Randomized, Muticenter Double-blind Phase III Study of Neoadjuvant Pyrotinib Plus Trastuzumab and Docetaxel Compared With Placebo Plus Trastuzumab and Docetaxel in Women With HER2 Positive Early Stage or Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CTR20180941, HR-BLTN-III-NeoBC

Population segments: First line, HER2 positive, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: Hormone receptor status

Phase: III

Therapies: pyrotinib + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo

Location: China

NCT01785420
A Phase III Double Blind Randomized Placebo Controlled Study of Trastuzumab as Short Duration Preoperative Therapy in Patients with HER2-neu Positive Operable Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: TMH Project-982

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Phase: III

Therapy: trastuzumab

Location: India

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A Randomized, Double-Blind, Multi-Centre, Parallel Group Study Comparing Two Humanized Monoclonal Antibodies that Target HER2 Receptors in Combination with Weekly Paclitaxel Administered as First-Line Treatment in Patients with HER2-Positive Metastatic Breast Cancer (Phase I/III)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: CTRI/2015/08/006085, TZ-01-002

Population segments: First line, HER2 positive, Stage III, Stage IV

Phase: III

Therapy: trastuzumab + chemotherapy

Location: India

No NCT ID - see other identifier(s)
A Randomized Controlled Trial Comparing Primary Tumor Resection Plus Systemic Therapy with Systemic Therapy Alone in Metastatic Breast Cancer (JCOG1017, PRIM-BC)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: JCOG 1017, JCOG1017, PRIM-BC, UMIN000005586

Population segments: Estrogen receptor positive, First line, HER2 negative, HER2 positive, Stage IV

Other inclusion criteria: ER negative

Phase: III

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
A Randomized Controlled Trial Comparing Primary Tumor Resection Plus Systemic Therapy with Systemic Therapy Alone in Metastatic Breast Cancer (JCOG1017, PRIM-BC)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: JCOG 1017, JCOG1017, PRIM-BC, UMIN000005586

Population segments: Estrogen receptor positive, First line, HER2 negative, HER2 positive, Stage IV

Phase: III

Therapy: trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

NCT03556358
A Randomized, Double-blind, Parallel Group, Phase III Trial to Compare the Efficacy, Safety, and Immunogenicity of TX05 With Herceptin in Subjects With HER2 Positive Early Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: EudraCT Number: 2017-004190-13, TX05-03

Population segments: Adjuvant, HER2 positive, Stage II, Stage III

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: III

Therapies: trastuzumab + chemotherapy, trastuzumab (Tanvex Biopharma) + chemotherapy

Location: Hungary

NCT01950182
A Multicentre, Randomized Study of Trastuzumab Combined With Chemotherapy or Endocrine Therapy as the First Line Treatment for Patients With Metastatic Luminal B2 Breast Cancer Subtype

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifier: SYSUCC-002

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Stage IV

Other inclusion criteria: ER positive, PR positive

Phase: III

Therapies: trastuzumab + chemotherapy, trastuzumab + hormone therapy

Location: China

No NCT ID - see other identifier(s)
A Phase III Study Comparing T-DM1 with Pertuzumab, Trastuzumab and Docetaxel in Elderly Patients with Advanced Stage HER2 Positive Breast Cancer (JCOG1607, HERB TEA study)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: HERB TEA, JCOG1607, UMIN000030783

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: III

Therapies: ado-trastuzumab emtansine, pertuzumab + trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Adjuvant Dynamic marker- Adjusted Personalized Therapy trial optimizing risk assessment and therapy response prediction in early breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: ADAPT, ADAPT Umbrella, EudraCT Number 2011-001462-17, WSG-AM06

Population segments: Adjuvant, HER2 negative, HER2 positive, Stage I, Stage II, Triple receptor negative

Phase: III

Therapy: antiHER2 therapy + chemotherapy

Location: Germany

NCT03080805
A Randomised, Open-label, Parallel Controlled, Multicentre, Phase III Clinical Trial of Pyrotinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer:

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: CTR20170251, HR-BLTN-III-MBC

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: III

Therapies: lapatinib + chemotherapy, pyrotinib + chemotherapy

Location: China

NCT03523585
A Phase III, Multicenter, Randomized, Open-label, Active-controlled Study of DS-8201a, an Anti-HER2-antibody Drug Conjugate, Versus Treatment of Investigator`s Choice for HER2-positive, Unresectable and/or Metastatic Breast Cancer Subjects Pretreated With Prior Standard of Care HER2 Therapies, Including T DM1

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: DS8201-A-U301, EudraCT Number: 2018-000221-31, JapicCTI-184017

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: III

Therapies: lapatinib + chemotherapy, trastuzumab + chemotherapy, trastuzumab deruxtecan

Locations: Japan, United States

US States: CA, NY

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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ERBB2 amplification (continued)

NCT02947685
A Randomized, Open Label, Phase III Trial to Evaluate the Efficacy and Safety of Palbociclib + Anti-HER2 Therapy + Endocrine Therapy vs. Anti-HER2 Therapy + Endocrine Therapy After Induction Treatment for Hormone Receptor Positive (HR+)/HER2-Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2017-0182, 2017-0361, AFT-38, AFT-38/HCC 17-132: PATINA Trial, AFT-58 (PATINA), EudraCT Number: 2017-000419-17, NCI-2017-00206, PATINA

Population segments: Estrogen receptor positive, HER2 positive, Maintenance/ Consolidation, Progesterone receptor positive, Stage IV

Other inclusion criteria: ER positive, PR positive

Phase: III

Therapies: palbociclib + pertuzumab + trastuzumab + anastrozole, palbociclib + pertuzumab + trastuzumab + exemestane, palbociclib + pertuzumab + trastuzumab + fulvestrant, palbociclib + pertuzumab + trastuzumab + letrozole, palbociclib + trastuzumab + anastrozole, palbociclib + trastuzumab + exemestane, palbociclib + trastuzumab + fulvestrant, palbociclib + trastuzumab + letrozole, pertuzumab + trastuzumab + anastrozole, pertuzumab + trastuzumab + exemestane, pertuzumab + trastuzumab + fulvestrant, pertuzumab + trastuzumab + letrozole, trastuzumab + anastrozole, trastuzumab + exemestane, trastuzumab + fulvestrant, trastuzumab + letrozole

Location: United States

US States: FL, IA, IL, KS, KY, MD, ME, MI, MO, NC, NJ, OK, OR, PA, SC, VA, WA

US Contact: Jane S. Lanzillotti [617-735-7511; jlanzillotti@alliancefoundationtrials.org]

NCT03493854
A Phase III, Randomized, Multicenter, Open-Label, Two-Arm Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Combination With Chemotherapy in Patients With HER2-Positive Early Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2017-004897-32, WO40324

Population segments: Adjuvant, Estrogen receptor positive, HER2 positive, Neoadjuvant, Progesterone receptor positive, Stage II, Stage III

Other inclusion criteria: Hormone receptor positive

Phase: III

Therapies: pertuzumab + trastuzumab + aromatase inhibitor + chemotherapy + filgrastim + radiation therapy + surgical intervention, pertuzumab + trastuzumab + aromatase inhibitor + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + tamoxifen + chemotherapy + filgrastim + radiation therapy + surgical intervention, pertuzumab + trastuzumab + tamoxifen + chemotherapy + radiation therapy + surgical intervention

Locations: Argentina, Belgium, Germany, Italy, Russian Federation, Spain, United Kingdom, United States

US States: CA, NM

US Contact: Reference Study ID Number WO40324 www.roche.com/about_roche/roche_worldwide.htm [888-662-6728; global-roche-genentech-trials@gene.com]

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ERBB2 amplification (continued)

NCT03264547
A Phase III Clinical Study to Compare the Combination Therapy of Eribulin Mesylate + Pertuzumab + Trastuzumab With Paclitaxel or Docetaxel + Pertuzumab + Trastuzumab (EMERALD)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EMERALD, JBCRG-M06, UMIN000027938

Population segments: First line, HER2 positive, Stage III, Stage IV

Phase: III

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

NCT03262935
A Multi-centre, Open-label, Randomized Clinical Trial Comparing the Efficacy and Safety of the Antibody-drug Conjugate SYD985 to Physician`s Choice in Patients With HER2-positive Unresectable Locally Advanced or Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2017-001994-18, IRAS ID:230951, SYD985, SYD985.002, TULIP

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: III

Therapy: SYD-985

Locations: Denmark, France, Italy, United States

US States: AL, FL, KS, MD, NC, OH, OR, PA, TX, VA

US Contact: Dr. Evelyn van den Tweel [clinicaltrials@synthon.com]

NCT02221999
A Prospective, Randomized, Open-label Comparison of Preoperative Weekly Paclitaxel and Cisplatin With or Without Endocrine Therapy in Patients With Operable Hormone Receptor Positive and Triple Negative Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: RenJiH-BC-002, SHPD002

Population segments: Estrogen receptor positive, HER2 negative, Neoadjuvant, Progesterone receptor positive, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ER positive, PR positive

Phase: II/III

Therapies: GnRH agonist + chemotherapy, letrozole + chemotherapy

Location: China

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ERBB2 amplification (continued)

NCT03085368
A Randomized Controlled Trial of HER-2 Positive Breast Cancer Patients Treated With Lapatinib and Paclitaxel vs Herceptin and Paclitaxel With Sequential and Synchronous Anthracycline

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Population segments: First line, HER2 positive, Stage III, Stage IV

Other inclusion criteria: Hormone receptor status

Phase: II/III

Therapies: lapatinib + chemotherapy, trastuzumab + chemotherapy

Location: China

NCT02568839
PREDIX HER2 - Neoadjuvant Response-guided Treatment of HER2 Positive Breast Cancer. Part of a Platform of Translational Phase II Trials Based on Molecular Subtypes

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2014-000808-10, PREDIX HER2, PREDIXHER2

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Phase: II/III

Therapies: ado-trastuzumab emtansine, pertuzumab + trastuzumab + chemotherapy

Location: Sweden

NCT02326974
The Impact of HER2 Heterogeneity on the Treatment of Early-stage HER2-positive Breast Cancer: a Phase II Study of T-DM1 in Combination with Pertuzumab in the Preoperative Setting.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 14-409, NCI-2015-00454

Population segments: HER2 positive, Maintenance/Consolidation, Neoadjuvant, Stage 0, Stage I, Stage II, Stage III

Phase: II

Therapy: ado-trastuzumab emtansine + pertuzumab + surgical intervention

Location: United States

US States: MA, MO, TN

US Contact: Dr. Ian Krop [617-632-6973; IKROP@PARTNERS.ORG]

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ERBB2 amplification (continued)

NCT03417544
A Phase II Study of Atezolizumab in Combination With Pertuzumab Plus High-dose Trastuzumab for the Treatment of Central Nervous System Metastases in Patients With Her2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 17-546, NCI-2018-00401

Population segments: CNS mets, HER2 positive, Line of therapy N/A, Stage IV

Phase: II

Therapy: atezolizumab + pertuzumab + trastuzumab

Location: United States

US State: MA

US Contact: Dr. Nancy Lin [617-632-3800; nlin@partners.org]

NCT03125928
Single Arm, Phase IIA Clinical Trial Assessing The Safety And Efficacy of Atezolizumab in Combination With Paclitaxel, Trastuzumab, and Pertuzumab in Patients With Metastatic HER-2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 17-1010, BR-093, NCI-2017-00929

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Stage IV

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: II

Therapy: atezolizumab + pertuzumab + trastuzumab + chemotherapy

Location: United States

US State: PA

US Contact: Dr. Lori J. Goldstein [215-214-1515; lori.goldstein@fccc.edu]

NCT03414658
A Randomized, Phase II Study Comparing Trastuzumab and Vinorelbine in Combination With Avelumab or Avelumab and Utomilumab (41BB/CD137 Agonist), in Patients With HER2-positive Metastatic Breast Cancer Who Have Progressed on Prior Trastuzumab and Pertuzumab

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 17-455, AVIATOR, NCI-2018-01455, TBCRC 045, TBCRC045

Population segments: First line, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapies: avelumab + trastuzumab + chemotherapy + acetaminophen + antihistamine, avelumab + trastuzumab + utomilumab + acetaminophen + antihistamine, avelumab + trastuzumab + utomilumab + chemotherapy + acetaminophen + antihistamine, trastuzumab + chemotherapy

Location: United States

US State: MA

US Contact: Project Manager [617-632-5313; ctopm@dfci.harvard.edu]

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ERBB2 amplification (continued)

NCT02682693
Investigating Denosumab As An Add-on Neoadjuvant Treatment For RANK-Positive Rr RANK-negative Primary Breast Cancer And Two Different Nab-Paclitaxel Schedules ; 2x2 Factorial Design (GeparX)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: EudraCT Number: 2015-001755-72, GBG 88, GeparX

Population segments: HER2 negative, HER2 positive, Neoadjuvant, Stage II, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapies: denosumab, pertuzumab + trastuzumab + chemotherapy

Location: Germany

NCT01730677
Randomized Phase II Study of Lapatinib Plus Vinorelbine Versus Vinorelbine in Patients With HER2 Positive Metastatic Breast Cancer Progressed After Lapatinib and Trastuzumab Treatment

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: NCCCTS-11-583

Population segments: Fourth line or greater, HER2 positive, Stage IV, Third line

Phase: II

Therapy: lapatinib + chemotherapy

Location: Republic of Korea

NCT03500380
A Randomized, Multicenter, Phase II Study of the Efficacy and Safety of Recombinant Humanized Anti-HER2 Monoclonal Antibody-MMAE Conjugate For Injection in Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: CTR20180492, RC48-C006

Population segments: First line, HER2 positive, Stage III, Stage IV

Phase: II

Therapies: lapatinib + chemotherapy, RC-48

Location: China

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ERBB2 amplification (continued)

NCT03273595
A Prospective, Open-label, Multicentre, Real-word Study of Lapatinib Plus Chemotherapy Versus Trastuzumab Plus Chemotherapy as Neoadjuvant Therapy for Women With HER2-positive and p95HER2-positive, PI3K Mutation, or PTEN Loss Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: KY20162048-1

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: Hormone receptor status, PTEN underexpression

Phase: II

Therapies: lapatinib + chemotherapy, trastuzumab + chemotherapy

Location: China

NCT03273595
A Prospective, Open-label, Multicentre, Real-word Study of Lapatinib Plus Chemotherapy Versus Trastuzumab Plus Chemotherapy as Neoadjuvant Therapy for Women With HER2-positive and p95HER2-positive, PI3K Mutation, or PTEN Loss Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifier: KY20162048-1

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: Hormone receptor status

Phase: II

Therapies: lapatinib + chemotherapy, trastuzumab + chemotherapy

Location: China

NCT01622868
Phase II Randomized Study of Whole Brain Radiotherapy/Stereotactic Radiosurgery in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of NRG Oncology and KROG

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 20140570, KROG1103, N 41516, NCI-2012-01977, NRG/RTOG 1119, RTOG 1119, RTOG-1119

Population segments: CNS mets, First line, HER2 positive, Second line, Stage IV

Phase: II

Therapy: lapatinib + radiation therapy

Locations: Republic of Korea, United States

US States: CA, FL, GA, IA, IN, KS, MI, MN, MO, MS, NY, OH, OR, PA, SC, VA, WA, WI

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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ERBB2 amplification (continued)

NCT02238509
A Randomised, Multicentre, Open-label Phase II Trial Investigating Activity of Chemotherapy and Lapatinib and Trastuzumab in Patients With HER2-positive Metastatic Breast Cancer (MBC) Refractory to Anti HER2 Therapies

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: EudraCT Number: 2013-005044-29, GIM12-TYPHER

Population segments: Estrogen receptor positive, HER2 positive, Second line, Stage IV

Other inclusion criteria: ER positive

Phase: II

Therapy: lapatinib + trastuzumab + fulvestrant

Location: Italy

NCT02238509
A Randomised, Multicentre, Open-label Phase II Trial Investigating Activity of Chemotherapy and Lapatinib and Trastuzumab in Patients With HER2-positive Metastatic Breast Cancer (MBC) Refractory to Anti HER2 Therapies

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: EudraCT Number: 2013-005044-29, GIM12-TYPHER

Population segments: Estrogen receptor positive, HER2 positive, Second line, Stage IV

Phase: II

Therapies: lapatinib + trastuzumab, trastuzumab + chemotherapy

Location: Italy

NCT03321981
Phase II Study of MCLA-128-based Combinations in Metastatic Breast Cancer (MBC): MCLA-128/Trastuzumab/Chemotherapy in HER2-positive MBC and MCLA-128/Endocrine Therapy in Estrogen Receptor Positive and Low HER2 Expression MBC

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: EudraCT Number: 2017-002821-39, MCLA-128-CL02

Population segments: Estrogen receptor positive, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapies: MCLA-128 + trastuzumab, MCLA-128 + trastuzumab + chemotherapy

Locations: Belgium, France, United States

US States: KS, TN

US Contact: Dr. Ernesto Wasserman [130-253-8800; enquiries@merus.nl]

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ERBB2 amplification (continued)

NCT02673398
Phase II Study of Neratinib in Patients 60 and Older With HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 15342, NCI-2015-02282

Population segments: HER2 negative, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapy: neratinib

Location: United States

US State: CA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT03094052
An Open Label Study to Characterize the Incidence and Severity of Diarrhea in Patients With Early Stage HER2+ Breast Cancer Treated With Adjuvant Trastuzumab and Neratinib Followed by Neratinib Monotherapy, and Intensive Anti-diarrhea Prophylaxis

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 16-21133, 167514, NCI-2017-01443, UCSF CC#167514

Population segments: Adjuvant, Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Stage II, Stage III

Other inclusion criteria: Hormone receptor negative, Hormone receptor positive

Phase: II

Therapy: neratinib + trastuzumab + crofelemer + loperamide

Location: United States

US State: CA

US Contact: Chiara Wabl [415-353-7517; Chiara.Wabl@ucsf.edu]

NCT03289039
A Phase II Study of Neratinib With or Without Fulvestrant in HER2-Positive, ER-Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 17-318, NCI-2017-02356, washu

Population segments: Estrogen receptor positive, HER2 positive, Line of therapy N/A, Progesterone receptor positive, Stage IV

Other inclusion criteria: ER positive

Phase: II

Therapies: neratinib, neratinib + fulvestrant

Location: United States

US States: MA, ME, TX

US Contact: Dr. Heather A. Parsons [617-632-3800; HeatherA_Parsons@dfci.harvard.edu]

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ERBB2 amplification (continued)

NCT02448420
PATRICIA: A Phase II Clinical Trial of Combined Palbociclib and Trastuzumab, With or Without Letrozole, in Post-menopausal Patients With Previously-treated Locally Advanced or Metastatic HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: EudraCT Number: 2014-005006-38, PATRICIA, REec-2015-1446, SOLTI-1303, SOLTI-1303 PATRICIA

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 positive, Progesterone receptor positive, Stage III, Stage IV, Third line

Other inclusion criteria: ER negative, PR positive

Phase: II

Therapy: palbociclib + trastuzumab

Location: Spain

NCT02448420
PATRICIA: A Phase II Clinical Trial of Combined Palbociclib and Trastuzumab, With or Without Letrozole, in Post-menopausal Patients With Previously-treated Locally Advanced or Metastatic HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: EudraCT Number: 2014-005006-38, PATRICIA, REec-2015-1446, SOLTI-1303, SOLTI-1303 PATRICIA

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 positive, Progesterone receptor positive, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapies: palbociclib + trastuzumab, palbociclib + trastuzumab + letrozole

Location: Spain

NCT02774681
A Phase II Single Arm Study of Palbociclib in Patients With Metastatic HER2-Positive and Triple Negative Breast Cancer With Brain Metastasis

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: NCI-2016-00626, NU 15B08, STU00202582

Population segments: CNS mets, HER2 negative, HER2 positive, Second line, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapies: palbociclib, palbociclib + trastuzumab

Location: United States

US States: IL, TX

US Contact: Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

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ERBB2 amplification (continued)

NCT01042379
I-SPY 2 Trial (Investigation of Serial Studies to Predict Your Therapeutic Response With Imaging And moLecular Analysis 2)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 01042379, 097517, 2010-0145, 202755051910, 7518, ACRIN 6698 (Substudy), ACRIN-6698, Clinical Trial 17268, CRC 10016, I-SPY 2, I-SPY 2 TRIAL, I-SPY2 TRIAL, NCI-2014-00596, NCI-2015-00014, STU 052011-089, UPCC 16113

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Progesterone receptor positive, Stage II, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: II

Therapies: pembrolizumab + chemotherapy, pertuzumab + trastuzumab, SGN-LIV1A + chemotherapy, trastuzumab + chemotherapy

Location: United States

US States: AL, CA, CO, DC, FL, IL, MN, NY, OR, PA, WA

US Contact: Ruby Singhrao [415-353-4171; ruby.singhrao@ucsf.edu]

NCT03095352
A Randomized Phase II Study of Pembrolizumab, an Anti-PD (Programmed Cell Death)-1 Antibody, in Combination With Carboplatin Compared to Carboplatin Alone in Breast Cancer Patients With Chest Wall Disease

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 157521, 16-20911, CC#157521+167513, NCI-2018-00010, TBCRC 044, TBCRC 44

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Triple receptor negative

Phase: II

Therapies: pembrolizumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Location: United States

US States: CA, IN, TN

US Contact: Christina Chun [415-885-7820; christina.chun@ucsf.edu]

No NCT ID - see other identifier(s)
A Phase II Study Of Eribulin In Combination With Trastuzumab And Pertuzumab As First-Line Therapy For Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: SBCCSG-36, UMIN000021585

Population segments: First line, HER2 positive, Stage III, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A phase II study of eribulin in combination with pertuzumab and trastuzumab for advanced or recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer SONG-02

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: SONG-02, UMIN000014107

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
A phase II trial of pertuzumab and trastuzumab in combination with capecitabine in patients with metastatic breast cancer who received prior trastuzumab combination chemotherapy.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000012208

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
A Phase II Study of Pertuzumab +Trastuzumab+Capecitabine in Patients with Taxans and Trastuzumab Refractory for Advanced or Recurrent Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: SBCCSG-33, UMIN000012030

Population segments: HER2 positive, Second line, Stage I, Stage II, Stage III, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Phase II Trial of Pertuzumab plus Trastuzumab plus Docetaxel for HER2-Positive Metastatic Breast Cancer that Progressed During Prior Trastuzumab Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: CYBORG-002, UMIN000012452

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Phase II Trial of Pertuzumab And Trastuzumab In Combination With S-1 For Patients With HER2-Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifier: UMIN000024477

Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Japan

NCT03144947
Phase II, Open Label, Randomized, Biomarker Study of Immune-mediated Mechanism of Action of Neoadjuvant Subcutaneous (SC) Trastuzumab in Patients With Operable or Locally Advanced/Inflammatory HER2-positive Breast Cancer (ImmunHER)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: GOIRC-01-2016, IMMUN-HER

Population segments: Adjuvant, HER2 positive, Neoadjuvant, Stage II, Stage III

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: Italy

NCT02789657
BrUOG 308: Efficacy of Weekly Carboplatin and Paclitaxel With Trastuzumab and Pertuzumab (wPCbTP) and Switching to an Anthracycline-based Regimen (AC) in Non-responding Patients as Neoadjuvant Therapy in Clinical Stage I-III HER2-positive Breast Cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: BrUOG 308

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy + surgical intervention

Location: United States

US State: RI

US Contact: kayla rosati [401-863-3000; kayla_rosati@brown.edu]

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ERBB2 amplification (continued)

NCT03272477
A Prospective, Randomized, Multicenter, Open-label Comparison of Pre-surgical Combination of Trastuzumab and Pertuzumab With Concurrent Taxane Chemotherapy or Endocrine Therapy Given for Twelve Weeks With a Quality of Life Assessment of Trastuzumab, Pertuzumab in Combination With Standard (Neo)Adjuvant Treatment in Patients With Operable HER2+/HR+ Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: EudraCT Number: 2016-005157-21, PH002-TP-II, TP-II

Population segments: Adjuvant, Estrogen receptor positive, HER2 positive, Neoadjuvant, Progesterone receptor positive

Other inclusion criteria: Hormone receptor positive

Phase: II

Therapies: pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + hormone therapy

Location: Germany

NCT02659514
A Phase II Study of Poziotinib in Patients With HER2-Positive Metastatic Breast Cancer (MBC) Who Have Received Prior HER2 Regimens for MBC

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CTMS# 16-0003, NCI-2016-00645, SPI-POZ-201

Population segments: HER2 positive, Second line, Stage IV, Third line

Phase: II

Therapy: poziotinib

Location: United States

US States: CA, NY

US Contact: Dr. Medical Director [949-743-9267; spi-poz-201@sppirx.com]

No NCT ID - see other identifier(s)
Combination of Trastuzumab, Oxaliplatin, and Docetaxel as First-Line Treatment in HER2-positive Metastatic Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: ASL1205/001, EudraCT Number: 2006-000413-37, HOT trial, HOT-ASL 1205/001

Population segments: First line, HER2 positive, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Italy

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Neoadjuvant trastuzumab and nab-paclitaxel for HER2 positive breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000005210

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Prospective study of Eribulin plus Trastuzumab in patients with HER-2 positive metastatic breast cancer (KSCOG-BC06)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: KSCOG-BC06, UMIN000010761

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Prospective study of TS-1 / CPT-11 plus Trastuzumab in patients with HER-2 positive metastatic breast cancer (KSCOG-BC02)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: KSCOG-BC02, UMIN000008647

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Phase II Study of Liposomal Doxorubicin in Combination with Trastuzumab Plus Cyclophosphamide Followed by Docetaxel plus Trastuzumab as Primary Systemic Therapy for Patients with Locally Advanced Breast Cancer with Her2 Overexpression or Amplification.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: EudraCT Number: 2013-002684-25, MYETT, SICOG13 / 01

Population segments: HER2 positive, Neoadjuvant, Stage III

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Italy

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ERBB2 amplification (continued)

NCT02510781
A Study on Neoadjuvant Therapy for Her-2 Positive Breast Cancer and the Prognosis Detecting Circulating Tumor Cells

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: BJ307-Neo02

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: Hormone receptor status

Phase: II

Therapy: trastuzumab + chemotherapy

Location: China

NCT02598310
Phase II Study of Neoadjuvant Nab-paclitaxel (PTX) and Trastuzumab for ER Negative and HER2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: OMC BC-04, OMC-BC04, UMIN000019616

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II

Other inclusion criteria: ER negative

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

NCT02614794
Phase II Randomized, Double-Blinded, Controlled Study of Tucatinib vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma (HER2CLIMB)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 16-092, 16-195, 1603017423, 16195, 1654GCC, 2016-0054, C-266, CTMS# 16-0014, EudraCT Number: 2015-002801-12, F17038, HER2CLIMB, IRAS ID:220300, NCI-2016-00402, ONT-380-206, RWF_ONT-380-206, TRIO ONT-380-206, UW16005, VICCBRE1642

Population segments: CNS mets, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapies: trastuzumab + chemotherapy + placebo, trastuzumab + Tucatinib + chemotherapy

Locations: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Israel, Italy, Portugal, Spain, United Kingdom, United States

US States: AL, AZ, CA, CO, CT, DC, FL, GA, IL, IN, KS, LA, MA, MD, MI, MN, MO, NC, NE, NH, NJ, NY, OH, OR, PA, SC, TN, TX, VA, WA, WI

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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ERBB2 amplification (continued)

NCT03571633
A Multicenter, Randomized, Open-label, Phase II Trial Aiming to Evaluate the Impact of Pegfilgrastim on Trastuzumab Anti-tumor Effect and ADCC in Operable HER2 Positive Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: BREASTIMMU02, ET17-057, EudraCT Number: 2017-002069-22

Population segments: Adjuvant, HER2 positive, Neoadjuvant, Stage 0, Stage I, Stage II

Phase: II

Therapies: trastuzumab + chemotherapy, trastuzumab + chemotherapy + pegfilgrastim

Location: France

NCT02214004
A Phase II Trial of Preoperative HER2 Targeting and Endocrine Therapy in Postmenopausal Women With HER2 and HR Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: HERAKLES, ML28601

Population segments: Estrogen receptor positive, HER2 positive, Neoadjuvant, Progesterone receptor positive, Stage I, Stage II, Stage III

Other inclusion criteria: ER positive

Phase: II

Therapy: trastuzumab + letrozole

Location: Republic of Korea

NCT00781612
An Open-Label, Multicenter Extension Study of Trastuzumab Emtansine Administered as a Single Agent or in Combination With Other Anti-Cancer Therapies in Patients Previously Enrolled in a Genentech and/or F. Hoffmann-La Roche Ltd-Sponsored Trastuzumab Emtansine Study

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 09-0114, 09-096, 2014-CT0213, BO25430, BRE 155 IST, EudraCT Number: 2010-021067-32, IRAS ID: 77750, JapicCTI-163168, NCI-2009-01154, PER-075-11, PHRR150810-001060, TDM4529g, TDM4529g / BO25430, UW10039

Population segments: First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapies: ado-trastuzumab emtansine, ado-trastuzumab emtansine + chemotherapy, ado-trastuzumab emtansine + pertuzumab, ado-trastuzumab emtansine + pertuzumab + chemotherapy

Locations: France, Italy, Russian Federation

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Reinduction with lapatinib followed by retreatment with trastuzumab-based therapy after disease progression multi-HER2 targeted therapies in HER2-positive metastatic breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: Recover HER2, UMIN000014189

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: lapatinib + trastuzumab

Location: Japan

No NCT ID - see other identifier(s)
A Randomized Parallel Open-Label Controlled Multicenter Phase II Trial of Selatinib ditosilate Combined with Capecitabine in the Treating Patients with Advanced HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: CTR20161036, QLSLTN-202

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapies: lapatinib, selatinib ditosilate + chemotherapy

Location: China

NCT01037790
Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: NCI-2009-01467, Study 1006, UPCC 03909, UPCC03909

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Metastatic, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: RB1 positive

Phase: II

Therapy: palbociclib + trastuzumab

Location: United States

US State: PA

US Contact: Dr. Peter O. Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

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ERBB2 amplification (continued)

NCT02907918
A Phase II Neoadjuvant Study of Palbociclib in Combination With Letrozole and Trastuzumab as Neoadjuvant Treatment of Stage II-III ER+ HER2+ Breast Cancer (PALTAN)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 201610019, NCI-2016-01516, PALTAN

Population segments: Estrogen receptor positive, HER2 positive, Neoadjuvant, Stage II, Stage III

Other inclusion criteria: ER positive

Phase: II

Therapies: palbociclib + trastuzumab + hormone therapy, palbociclib + trastuzumab + letrozole

Location: United States

US State: MO

US Contact: Dr. Foluso O. Ademuyiwa [314-454-8313; bisiademuyiwa@wustl.edu]

NCT02436993
A Phase II Study of Breast Cancer Treatment Using Weekly Carboplatin + Paclitaxel With Pertuzumab + Trastuzumab (HER2+) or Bevacizumab (HER2-) in the Neoadjuvant Setting

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2015-1888, UCI 14-67

Population segments: HER2 negative, HER2 positive, Neoadjuvant, Stage I

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Location: United States

US State: CA

US Contact: UC Irvine Health Chao Family Comprehensive Cancer Center [877-827-8839; UCstudy@uci.edu]

NCT03161353
Chemotherapy-free Trastuzumab and Pertuzumab in HER2-positive (Human Epidermal Receptor) Breast Cancer: FDG-PET Response-adapted Strategy. The PHERGain Study

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2016-002676-27, MedOPP096, MedOPP096-MO39229, PHERGain

Population segments: Adjuvant, HER2 positive, Maintenance/Consolidation, Neoadjuvant, Stage I, Stage II, Stage III

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: II

Therapies: pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + letrozole, pertuzumab + trastuzumab + tamoxifen

Locations: Belgium, France, Germany, Italy, Spain, United Kingdom

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Pilot study of low-dose Nab-paclitaxel as adjuvant chemotherapy in patients with breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000012047

Population segments: (N/A), Adjuvant, HER2 negative, HER2 positive

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Phase II Study of Epirubicin, Cisplatin and 5 - Fluorouracil Continuous Infusion (ECF) Followed by Weekly Paclitaxel in Combination with Metronomic Cyclophosphamide + or - Trastuzumab as Preoperative Treatment in Locally Advanced Breast Carcinoma ER and PgR Negative

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2009-012048-18, IEO S479/209, S479/209

Population segments: HER2 negative, HER2 positive, Neoadjuvant, Stage III

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Italy

No NCT ID - see other identifier(s)
A Phase II Study of Metronomic Oral Chemotherapy with Cyclophosphamide plus Capecitabine in combination with Herceptin to treat HER2 positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2905, EudraCT Number: 2009-017083-16, GOIM2905

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Stage III, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Italy

No NCT ID - see other identifier(s)
Phase II study of q3w nab-paclitaxel in combination with q3w trastuzumab for HER2 positive metastatic breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: Nature study, UMIN000006547

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Phase II study of the combination of Eribulin and Trastuzumab Evaluating Efficacy and Safety in Patients with advanced/recurrent HER2-positive breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: SBCCSG-31, UMIN000011020

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Evaluation of efficacy and safety of combination therapy with trastuzumab and eribulin for HER2-positive inoperableness or metastatic breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000007113

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
Activity of trastuzumab based chemotherapy in metastatic breast patients with HER2-negative primary tumor but HER2 positive circulating tumor cells (CareMore-Trastuzumab)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: Caremore-Trastuzumab, EudraCT Number: 2014-004432-18

Population segments: HER2 negative, HER2 positive, Line of therapy N/A, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Netherlands

No NCT ID - see other identifier(s)
A Phase II study of neoadjuvant epirubicin/cyclophosphamide (EC) followed by weekly nanoparticle albumin-bound paclitaxel with trastuzumab for HER2-positive breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000013886

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Phase II Study of low-dose Nab-paclitaxel for Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000012048

Population segments: HER2 negative, HER2 positive, Line of therapy N/A, Stage III, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Location: Japan

NCT01750073
A Phase II Study Of Neoadjuvant Chemotherapy With And Without Trastuzumab In Patients With Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 264-12, 264-12-FB, NCI-2012-01372

Population segments: Adjuvant, Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Progesterone receptor positive, Stage I, Stage II, Stage III, Triple receptor negative

Phase: II

Therapy: trastuzumab + chemotherapy

Location: United States

US State: NE

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02654119
A Phase II Study of Adjuvant Therapy Using a Regimen of Cyclophosphamide, Paclitaxel With Trastuzumab in Stage I-II HER2/Neu Positive Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 318-15, NCI-2015-01879

Population segments: Adjuvant, First line, HER2 positive, Stage I, Stage II

Phase: II

Therapy: trastuzumab + chemotherapy

Location: United States

US State: NE

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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ERBB2 amplification (continued)

NCT03140553
TCH (Docetaxel/Carboplatin/ Trastuzumab) Versus EC -TH(Epirubicin/ Cyclophosphamide Followed by Docetaxe/Trastuzumab) as Neoadjuvant Treatment for HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: 20170308

Population segments: HER2 positive, Neoadjuvant, Stage II, Stage III

Phase: II

Therapy: trastuzumab + chemotherapy

Location: China

No NCT ID - see other identifier(s)
A Phase II Neoadjuvant Trial of Concurrent Trastuzumab, Paclitaxel and Endocrine Therapy in Women with HER2-Positive and Hormone Receptor-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: HERPLET, UMIN000009108

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapy: trastuzumab + hormone therapy + chemotherapy

Location: Japan

No NCT ID - see other identifier(s)
A phase II neoadjuvant trial of concurrent trastuzumab and aromatase inhibitor in postmenopausal women with HER2-positive and hormone receptor-positive breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000007353

Population segments: HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapy: trastuzumab + letrozole

Location: Japan

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ERBB2 amplification (continued)

NCT03179904
Phase II Trial to Evaluate the Efficacy of the FASN Inhibitor, TVB-2640, in Combination With Paclitaxel and Trastuzumab in Patients With HER2+ Metastatic Breast Cancer Resistant to Trastuzumab and Taxane-Based Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: MC1633, NCI-2017-00944

Population segments: First line, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapy: trastuzumab + TVB-2640 + chemotherapy

Location: United States

US States: AZ, FL, MN

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

No NCT ID - see other identifier(s)
A Phase II Single Arm Trial To Assess The Efficacy Of ASLAN001 Plus Capecitabine In Previously Irradiated, Progressing Central Nervous System (CNS) Metastases For HER2 Positive Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: ASLAN001/006

Population segments: (N/A), CNS mets, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: II

Therapy: varlitinib + chemotherapy

Location: Singapore

NCT03384914
A Multicenter Phase II Study of Vaccines to Prevent Recurrence in Patients With HER-2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: MCC-19117

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage I, Stage II, Stage III

Phase: II

Therapy: WOKVAC + dendritic cell vaccine

Location: United States

US State: FL

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT03202316
A Phase II Study of Triple Combination of Atezolizumab + Cobimetinib + Eribulin (ACE) in Patients With Recurrent/ Metastatic Inflammatory Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 status

Other identifiers: 2016-0890, NCI-2017-01601

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: Hormone receptor status

Phase: II

Therapy: atezolizumab + cobimetinib + chemotherapy

Location: United States

US State: TX

US Contact: Dr. Bora Lim [713-792-2817; blim@mdanderson.org]

NCT02705859
Phase Ib/II Clinical Trial of Copanlisib in Combination With Trastuzumab in Pretreated Recurrent or Metastatic HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: EudraCT Number: 2015-003687-36, ICORG 15-02, ICORG1502, Panther

Population segments: Fourth line or greater, HER2 positive, Second line, Stage III, Stage IV

Phase: I/II

Therapy: copanlisib + trastuzumab

Location: Ireland

NCT03379428
Phase I/II Trial of Ibrutinib Plus Trastuzumab in HER2-amplified Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 14-05914-059, 14059

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: I/II

Therapies: ibrutinib + trastuzumab, trastuzumab

Location: United States

US State: TX

US Contact: Elaine B. de [281-863-6710; elaine.deguzman@mckesson.com]

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ERBB2 amplification (continued)

NCT03112590
A Phase I-II Study of Interferon-gamma Plus Weekly Paclitaxel, Trastuzumab and Pertuzumab in Patients With HER-2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: MCC-18936, NCI-2017-00923

Population segments: First line, HER2 positive, Second line, Stage 0, Stage I, Stage II, Stage III, Stage IV

Phase: I/II

Therapy: interferon gamma + pertuzumab + trastuzumab + chemotherapy

Location: United States

US State: FL

US Contact: Dawn Goodridge [813-745-1807; dawn.goodridge@moffitt.org]

No NCT ID - see other identifier(s)
Phase I/II Study Eribulin Mesylate and Lapatinib for Metastatic in Patients With Human Epidermal Growth Factor receptor 2-Positive Breast Cancer Previously Treated With an Anthracycline, Taxane and Trastuzumab.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000011671

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I/II

Therapy: lapatinib + chemotherapy

Location: Japan

NCT03052634
Phase Ib/II Study of RC48-ADC in HER2-Positive in Advanced Breast Cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 003 CANCER, CTR20161035

Population segments: Estrogen receptor positive, First line, Fourth line or greater, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Phase: I/II

Therapies: lapatinib + chemotherapy, RC-48

Location: China

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ERBB2 amplification (continued)

NCT02912949
A Phase I/II Study of MCLA-128, a Full Length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients With Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2014-003277-42, MCLA-128-CL01, NL51045.031.14

Population segments: Adenocarcinoma, ALK, EGFR, Estrogen receptor positive, Fourth line or greater, HER2 positive, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Third line

Phase: I/II

Therapy: MCLA-128

Locations: France, Italy, Netherlands, Spain

NCT03377387
Phase Ib/II Study of Capecitabine 7/7 Schedule With Neratinib in Patients With Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 17-585, NCI-2017-02448

Population segments: HER2 positive, Second line, Stage IV

Phase: I/II

Therapy: neratinib + chemotherapy

Location: United States

US States: NJ, NY

US Contact: Dr. Chau Dang [914-367-7181; dangc@mskcc.org]

NCT03101748
A Phase 1b Study of Neratinib, Pertuzumab and Trastuzumab With Taxol (3HT) in Primary Metastatic and Locally Advanced Breast Cancer, and Phase II Study of 3HT Followed by AC in HER2 + Primary IBC, and Neratinib With Taxol (NT) Followed by AC in HR+ /HER2- Primary IBC

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 2016-0537, NCI-2017-00813

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Stage III, Stage IV

Phase: I/II

Therapy: neratinib + pertuzumab + trastuzumab + chemotherapy

Location: United States

US State: TX

US Contact: Dr. Bora Lim [713-792-2817; blim@mdanderson.org]

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ERBB2 amplification (continued)

NCT03304080
A Multicenter, Phase I/II Trial of Anastrozole, Palbociclib, Trastuzumab and Pertuzumab in HeR-positive, Her2-positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 17-0919, GCO 17-0919, NCI-2018-00678

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Stage IV

Other inclusion criteria: ER positive, PR positive

Phase: I/II

Therapy: palbociclib + pertuzumab + trastuzumab + anastrozole

Location: United States

US State: NY

US Contact: Dr. Amy Tiersten [212-824-8591; amy.tiersten@mssm.edu]

NCT03054363
Phase IB/II Open-label Single Arm Study to Evaluate Safety and Efficacy of Tucatinib in Combination With Palbociclib and Letrozole in Subjects With Hormone Receptor Positive and HER2-positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 16-1661, 16-1661.cc, NCI-2017-01776, TULiP

Population segments: Estrogen receptor positive, First line, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV

Other inclusion criteria: ER positive, PR positive

Phase: I/II

Therapy: palbociclib + Tucatinib + letrozole

Location: United States

US States: AZ, CO, NM, NY, TX

US Contact: Tiffany Colvin [720-848-0664; tiffany.colvin@ucdenver.edu]

NCT02066532
Phase I/II Trial of Ruxolitinib in Combination With Trastuzumab in Metastatic HER2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifier: AAAM1906

Population segments: Fourth line or greater, HER2 positive, Stage IV

Phase: I/II

Therapy: ruxolitinib + trastuzumab

Location: United States

US State: NY

US Contact: Dr. Kevin Kalinsky [212-305-1945; KK2693@cumc.columbia.edu]

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ERBB2 amplification (continued)

NCT03410927
A Phase I/II, Open Label, Multicenter Study to Investigate the Safety, Pharmacokinetics, and Efficacy of TAS0728, an Oral Covalent Binding Inhibitor of HER2, in Subjects With Advanced Solid Tumors With HER2 or HER3 Abnormalities

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 18116, 2017-0994, EudraCT Number: 2017-004415-39, NCI-2018-00211, REFMAL 555, TO-TAS0728-101

Population segments: Adenocarcinoma, Fourth line or greater, HER2 positive, Large Cell, Second line, Stage III, Stage IV, Third line

Phase: I/II

Therapy: TAS0728

Locations: United Kingdom, United States

US States: NY, TN, TX

US Contact: Dr. Mark Kirshbaum [609-750-5300; MKirschbaum@taihooncology.com]

No NCT ID - see other identifier(s)
Phase I/II study of Chemotherapy with Nab-paclitaxel, Carboplatin and Trastuzumab in HER2-positive Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: UMIN000007600

Population segments: HER2 positive, Line of therapy N/A, Stage III

Phase: I/II

Therapy: trastuzumab + chemotherapy

Location: Japan

NCT02030561
Phase I/II Study of Expanded, Activated Autologous Natural Killer Cell Infusions With Trastuzumab for Patients With HER2+ Breast and Gastric Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 2013/00566, MC01/21/13

Population segments: Fourth line or greater, HER2 positive, Stage IV, Third line

Phase: I/II

Therapy: trastuzumab + natural killer cell treatment

Location: Singapore

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ERBB2 amplification (continued)

NCT02396108
Phase Ib Dose-confirmation Study of ASLAN001 Combined With Weekly Paclitaxel and Carboplatin in Advanced Solid Tumours, Followed by an Open-label Phase II Study in Patients With Stage I-III HER2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 2014/01282, ASLAN001-004

Population segments: Fourth line or greater, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III

Phase: I/II

Therapy: varlitinib + chemotherapy

Location: Singapore

NCT02236000
A Phase Ib/II Dose-Escalation Study Evaluating the Combination of Trastuzumab Emtansine (T-DM1) With Neratinib in Women With Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: FB-10, NCI-2015-00275, NFI1114, NSABP FB-10

Population segments: Estrogen receptor positive, HER2 positive, Progesterone receptor positive, Second line, Stage IV

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: I/II

Therapy: ado-trastuzumab emtansine + neratinib

Location: United States

US States: FL, IL, OH, OK, PA, RI, WV

US Contact: Diana Gosik [412-339-5333; diana.gosik@nsabp.org]

NCT03190967
Phase I/II Study of T-DM1 Alone Versus T-DM1 and Metronomic Temozolomide in Secondary Prevention of HER2-Positive Breast Cancer Brain Metastases Following Stereotactic Radiosurgery

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 17-C-0115, 170115, NCI-17-C-0115, NCI-2017-01113

Population segments: Adjuvant, CNS mets, HER2 positive, Stage IV

Phase: I/II

Therapies: ado-trastuzumab emtansine, ado-trastuzumab emtansine + chemotherapy

Location: United States

US State: MD

US Contact: Nicole D. Houston [240-760-6127; houstonnd@mail.nih.gov]

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ERBB2 amplification (continued)

NCT02499328
A Phase Ib/II, Open-Label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumor Activity of MEDI4736 in Combination With AZD9150 or AZD5069 in Patients With Advanced Solid Malignancies and Subsequently Comparing AZD9150 and AZD5069 Both as Monotherapy and in Combination With MEDI4736 as Second Line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2015-0353, 20160938, D5660C00004, EudraCT Number: 2015-002525-19, IRAS ID: 189899, NCI-2015-01342, REec-2016-2093, REFMAL 406, RM 406, SCORES, UCI-16-50, UW15083

Population segments: Estrogen receptor positive, HER2 positive, Hormone refractory, Second line, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: I/II

Therapy: AZD-5069 + durvalumab

Locations: Belgium, Germany, Italy, Spain, United Kingdom, United States

US States: AL, CA, CO, FL, IN, MA, MI, MT, NJ, OH, TX, VA, WA

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

NCT01935843
Clinical Study of Chimeric HER-2 Antigen Receptor-modified T Cells in Chemotherapy Refractory HER-2 Advanced Solid Tumors.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: CHN-PLAGH-BT-009

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I/II

Therapy: CART-HER-2

Location: China

No identifiers available
Safety and Tolerability of Lapatinib in Combination with Vinorelbine (N) and Capecitabine (C) as Second Line Treatment in Patients with Her2 Positive Metastatic Breast Cancer (MBC)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV

Phase: I/II

Therapy: lapatinib + chemotherapy

Location: Italy

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
A Prospective, Multicentre, Open-label, Randomized, Uncontrolled, Phase 1/2 Study to Evaluate Efficacy and Safety of Masitinib in Combination With Gemcitabine or Carboplatin or Capecitabine in Patients With a Metastatic or Locally Advanced Breast Cancer (All Hormonal Status Tumor Except Triple Negative Tumor) and Who Relapsed After a First Line Chemotherapy.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: AB10005, EudraCT Number: 2010-022646-24, REec-2015-1494

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: I/II

Therapy: masitinib + chemotherapy

Locations: France, Spain

NCT02843126
A Phase I/II Study to Evaluate Safety and Efficacy of Trastuzumab Plus Natural Killer(NK) Immunotherapy To Recurrent Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage I, Stage II

Phase: I/II

Therapies: trastuzumab, trastuzumab + natural killer cell treatment

Location: China

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers

Cancer type: Breast Cancer

Variant class: ERBB2 aberration

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, UKCRN ID:18725

Population segments: Adenocarcinoma, EGFR, FGFR, HER2 negative, KRAS, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

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ERBB2 amplification (continued)

NCT01730118
A Phase I Study of an Adenoviral Transduced Autologous Dendritic Cell Vaccine Expressing Human HER2/Neu ECTM in Adults withTumors With 1-3+ HER2/Neu Expression

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 1207-1179, 13-C-0016, 130016, NCI-13-C-0016, US-1179

Population segments: Estrogen receptor positive, First line, Fourth line or greater, HER2 positive, Second line, Stage III, Stage IV, Third line

Phase: I

Therapy: AdHER-2

Location: United States

US State: MD

US Contact: Lee C. England [301-451-0492; lee.england@nih.gov]

NCT02390427
Phase Ib Dose-escalation Trial of Taselisib (GDC-0032) in Combination With Anti-HER2 Therapies in Participants With Advanced HER2+ Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 15-024, BRE 269, DFCI 15-024, ML29407, NCI-2015-00627

Population segments: Estrogen receptor positive, HER2 positive, Stage III, Stage IV, Third line

Phase: I

Therapies: ado-trastuzumab emtansine + pertuzumab + taselisib, ado-trastuzumab emtansine + taselisib, pertuzumab + taselisib + trastuzumab, pertuzumab + taselisib + trastuzumab + chemotherapy

Location: United States

US States: MA, TN

US Contact: Dr. Ian Krop [617-632-2335; IKROP@PARTNERS.ORG]

NCT03429101
A Phase Ib Study of Poziotinib in Combination With T-DM1 in Women With Advanced or Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: SPI-POZ-101

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: ado-trastuzumab emtansine + poziotinib

Location: United States

US State: CA

US Contact: Dr. Nawazish Khan [949-743-9325; spi-poz-101@sppirx.com]

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ERBB2 amplification (continued)

NCT03364348
A Phase IB Dose Escalation Trial of Human Anti-4-1BB Agonistic Antibody PF-05082566 in Combination With Adotrastuzumab-Emtansine or Trastuzumab in Patients With HER2-Positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: BRS0070, NCI-2016-01881, NCI-2016-01881

Population segments: First line, HER2 positive, Second line, Stage III, Stage IV, Third line

Phase: I

Therapies: ado-trastuzumab emtansine + utomilumab, trastuzumab + utomilumab

Location: United States

US State: CA

US Contact: Oshra Sedan [650-723-0628; osedan@stanford.edu]

No NCT ID - see other identifier(s)
To Explore Safety, Tolerability, Efficacy and Pharmacokinetics Of AST-1306 Combined With Capecitabine In Patients With Recurrent HER2-Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: ALS1004AST1306, CTR20150568

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: allitinib + chemotherapy

Location: China

No NCT ID - see other identifier(s)
A Single-Center, Open, Dose-Expansion Phase Ia Clinical Study Evaluates the Safety, Tolerability, and Pharmacokinetic Characteristics of ARX788 Monotherapy for HER2-positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CTR20171162, ZMC-ARX788-111

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: ARX-788

Location: China

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ERBB2 amplification (continued)

NCT02512237
A Phase 1, Multicenter, Open-label, Multiple Dose-escalation Study of ARX788, Intravenously Administered as a Single Agent in Subjects With Advanced Cancers With HER2 Expression

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CT782, U1111-1173-5221, ZMC-ARX788-101

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: ARX-788

Locations: Australia, New Zealand

NCT03255070
A Phase I, Multicenter, Open-label, Multiple Dose-escalation Study of ARX788, Intravenously Administered as a Single Agent in Subjects With Advanced Cancers With HER2 Expression

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: ARX788-1711, NCI-2018-00274

Population segments: HER2 positive, Second line, Stage IV

Phase: I

Therapy: ARX-788

Locations: Australia, United States

US State: MO

US Contact: Dr. Yong Jiang Hei [858-875-2400; yong.hei@ambrx.com]

No NCT ID - see other identifier(s)
A Phase I, Open, Single-center Dose Escalation To Evaluate Safety, Tolerability and Pharmacokinetic Characteristics of BAT8001 Injection In Patients With HER2 Positive Solid Tumors.

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: BAT-8001-001-CR, CTR20170072

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: BAT-8001

Location: China

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT03062007
Open-label Study of Safety, Tolerability and Pharmacokinetics of Multiple Doses of BI-CON-02 in Patients With HER2-positive Metastatic Breast Cancer, Previously Treated With Trastuzumab

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifier: ONC-BICON02-01

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: BI-CON-02

Location: Russian Federation

NCT02152943
Combination Treatment With Everolimus, Letrozole and Trastuzumab in Hormone Receptor and HER2/Neu-positive Patients With Advanced Metastatic Breast Cancer and Other Solid Tumors: Evaluating Synergy and Overcoming Resistance

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 2014-0119, NCI-2014-01615

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 positive, Maintenance/Consolidation, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive, PR positive

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Location: United States

US State: TX

US Contact: Dr. Filip Janku [713-563-1930]

NCT02476539
An Ascending Single and Multiple Dose Study of the Pharmacokinetics, Safety and Tolerability of the Irreversible Epidermal Growth Factor Receptor Inhibitor Hemay022 in Patients With HER2-Positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: CTR20150326, Hemay022-002

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: Hemay022

Location: China

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT03308201
Study Evaluating Hemay022 in Combination With Exemestane In Subjects With ER Positive and HER2 Positive Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: CTR20170726, HM022BC1C01

Population segments: Estrogen receptor positive, HER2 positive, Second line, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: I

Therapy: Hemay022 + exemestane

Location: China

NCT03620201
A Pilot Single Arm Open Label Trial Evaluating M7824 (Anti-PD-L1/TGF-Beta TRAP) in a Window Setting in Patients With Stage II-III HER2/Neu Positive (HER2+) Breast Cancer (BC)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 2017-0502, NCI-2018-01184

Population segments: HER2 positive, Line of therapy N/A, Stage II, Stage III

Phase: I

Therapy: M-7824 + chemotherapy

Location: United States

US State: TX

US Contact: Dr. Jennifer Litton [713-792-2817; jlitton@mdanderson.org]

NCT03084926
A Phase I, First-in-human, Single-arm, Multi-center, Open-label, Repeated-Dose, Dose Escalation Study to Assess Safety, Tolerability and Pharmacokinetics of MP0274 in Patients With Advanced HER2-positive Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 2017-00921, EudraCT Number: 2016-004712-36, IRAS ID: 222863, MP0274-CP101, SNCTP000002338

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: MP-0274

Locations: Germany, Switzerland, United Kingdom

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT03197389
Effect of Pembrolizumab (Keytruda) on Biomarkers Related to Intratumoral Immunity, Proliferation and Apoptosis in Early ER/PR Negative Breast Cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifier: MK 3475-318

Population segments: HER2 negative, HER2 positive, Neoadjuvant, Stage 0, Stage I, Stage II, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: I

Therapy: pembrolizumab

Location: Belgium

NCT02390427
Phase Ib Dose-escalation Trial of Taselisib (GDC-0032) in Combination With Anti-HER2 Therapies in Participants With Advanced HER2+ Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: 15-024, BRE 269, DFCI 15-024, ML29407, NCI-2015-00627

Population segments: Estrogen receptor positive, HER2 positive, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive, PR positive

Phase: I

Therapy: pertuzumab + taselisib + trastuzumab + fulvestrant

Location: United States

US States: MA, TN

US Contact: Dr. Ian Krop [617-632-2335; IKROP@PARTNERS.ORG]

NCT03135171
A Phase I Multi-Center Trial of Trastuzumab and Pertuzumab in Combination With Tocilizumab in Subjects With Metastatic HER2 Positive Breast Cancer Resistant to Trastuzumab

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: HUM00125505, NCI-2017-02497, UMCC 2017.002

Population segments: HER2 positive, Second line, Stage IV

Phase: I

Therapies: pertuzumab + tocilizumab + trastuzumab, tocilizumab + trastuzumab

Location: United States

US State: MI

US Contact: Dr. Monika Burness [800-865-1125; mburness@umich.edu]

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ERBB2 amplification (continued)

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients With HER2-positive Solid Tumors Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: NCI-2017-00491, SHRUS 1001

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: pyrotinib

Location: United States

US States: FL, MA, MI, MO, NY, TN

US Contact: Dr. Ewa Matczak [609-423-2155 ext 215; ewa.matczak@hengruitherapeutics.com]

No NCT ID - see other identifier(s)
Feasibility study of a short Trastuzumab infusion in patients with breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifier: UMIN000018294

Population segments: First line, HER2 positive, Stage I, Stage II, Stage III

Phase: I

Therapy: trastuzumab

Location: Japan

NCT02571530
Phase 1 Trial of Super-selective Intra-arterial Cerebral Infusion of Trastuzumab After Blood-Brain Barrier Disruption for the Treatment of Cerebral Metastases of HER2/Neu Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifier: 15-312

Population segments: CNS mets, HER2 positive, Second line, Stage IV

Phase: I

Therapy: trastuzumab

Location: United States

US State: NY

US Contact: Dr. John Boockvar [212-434-3900]

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ERBB2 amplification (continued)

NCT02892123
Phase I Trial of ZW25 in Patients With Locally Advanced (Unresectable) and/or Metastatic HER2-expressing Cancers

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 2016-0532, NCI-2017-01210, ZWI-ZW25-101

Population segments: Fourth line or greater, HER2 positive, Stage III, Stage IV

Phase: I

Therapy: ZW-25

Locations: Canada, United States

US States: CA, CO, IL, TN, TX, WA

US Contact: Dr. Linda Lai [206-260-2078; linda.lai@zymeworks.com]

NCT02057133
A Phase Ib Study of Abemaciclib in Combination With Therapies for Patients With Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 14-070, 14-085, 15252, AAAM7756, BRE 239 IST, I3Y-MC-JPBH, JPBH, NCI-2014-01032, USO 13122, VICCBRE1411

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Third line

Phase: I

Therapies: abemaciclib + pertuzumab + trastuzumab + hormone therapy + loperamide, abemaciclib + pertuzumab + trastuzumab + loperamide

Location: United States

US States: AR, CA, MA, MN, NC, NY, OK, OR, PA, TN, TX

US Contact: Eli Lilly and Company [877-285-4559]

NCT01976169
Phase IB Study of PD-0332991 in Combination with T-DM1 in the Treatment of Patients with Advanced HER2 (Human Epidermal Growth Factor Receptor 2)-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 8843, Mod13_STU 042013-042, Mod9_STU 042013-042, NCI-2014-00821, SCCC 05113, STU 042013-042

Population segments: HER2 positive, Second line, Stage III, Stage IV

Other inclusion criteria: CDKN2A underexpression, RB1 positive

Phase: I

Therapy: ado-trastuzumab emtansine + palbociclib

Location: United States

US State: TX

US Contact: Dr. Barbara Haley [214-648-4180; barbara.haley@utsouthwestern.edu]

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ERBB2 amplification (continued)

NCT03032107
A Phase Ib Study Of Pembrolizumab In Combination With Trastuzumab-DM1 In Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 16-492, DFCI 16-492, NCI-2017-00402

Population segments: HER2 positive, Second line, Stage IV

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: I

Therapy: ado-trastuzumab emtansine + pembrolizumab

Location: United States

US State: MA

US Contact: Dr. Sara Tolaney [617-632-2335; stolaney@partners.org]

NCT03650348
A Phase Ib, Open-Label, Dose Escalation Study of PRS-343 in Combination With Atezolizumab in Patients With HER2-Positive Advanced or Metastatic Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: PRS-343-PCS_08_18

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: atezolizumab + PRS-343

Location: United States

US State: TX

US Contact: Dr. Ingmar Bruns [857-246-8998; bruns@pieris.com]

NCT01920061
A Phase Ib Open-label Three-arm Multi-center Study To Assess The Safety And Tolerability Of Pf-05212384 (pi3k/Mtor Inhibitor) In Combination With Other Anti-tumor Agents

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 101938, 13-382, 133229, B2151002, EudraCT Number: 2013-001390-24, NCI-2013-01814, P1TB21502, Pro00027912

Population segments: EGFR, First line, HER2 negative, HER2 positive, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: dacomitinib + gedatolisib

Locations: Italy, Spain, United Kingdom, United States

US States: AL, CA, MA, MI, SC

US Contact: Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov_Inquiries@pfizer.com]

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ERBB2 amplification (continued)

NCT03004534
A Presurgical Tissue-Acquisition Study to Evaluate Molecular Alterations in Human Breast Cancer Tissue Following Short-Term Exposure to the Androgen Receptor Antagonist ODM-201

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2016-004151-79, HC6-24-c 201058, TRIO030

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

Phase: I

Therapy: darolutamide

Locations: Canada, Germany, United States

US States: CA, FL

US Contact: Dr. Dennis Slamon [310-825-5193; dslamon@mednet.ucla.edu]

NCT03319459
FATE-NK100 as Monotherapy and in Combination With Monoclonal Antibody in Subjects With Advanced Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: DIMENSION, NK-101

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: FATE-NK100 + trastuzumab

Location: United States

US State: MN

US Contact: Sara Weymer [858-875-1800; clinical@fatetherapeutics.com]

No NCT ID - see other identifier(s)
Phase I trial of S-1 plus Lapatinib in patients with HER-2 positive metastatic breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: UMIN000004921

Population segments: HER2 positive, Line of therapy N/A, Stage IV

Phase: I

Therapy: lapatinib + chemotherapy

Location: Japan

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ERBB2 amplification (continued)

NCT02872025
Testing the Ability of Pembrolizumab to Alter the Tumor Immune MicroEnvironment (TIME) of High Risk DCIS

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 16-19401, 16704, NCI-2017-01320

Population segments: HER2 positive, Neoadjuvant, Stage 0

Other inclusion criteria: Hormone receptor negative

Phase: I

Therapy: pembrolizumab

Location: United States

US State: CA

US Contact: Katherine Forster [415-885-7691; katherine.forster@ucsf.edu]

NCT03284723
A Phase 1 Dose Escalation Study Evaluating The Safety And Tolerability Of Pf-06804103 In Patients With Human Epidermal Growth Factor Receptor 2 (her2) Positive Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: C0541001, EudraCT Number: 2017-002538-22, NCI-2017-02036

Population segments: (N/A), First line, HER2 positive, Second line or greater/Refractory/Relapsed

Phase: I

Therapy: PF-06804103

Location: United States

US States: CA, TX

US Contact: Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov_Inquiries@pfizer.com]

NCT03330561
A Phase I, Open-Label, Dose Escalation Study of PRS-343 in Patients With HER2-Positive Advanced or Metastatic Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: PRS-343-PCS_04_16

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV

Phase: I

Therapy: PRS-343

Location: United States

US States: NY, TN, TX

US Contact: Dr. Ingmar Bruns [857-246-8998; bruns@pieris.com]

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ERBB2 amplification (continued)

NCT02627274
An Open-Label, Multicenter, Dose-Escalation, Phase Ia/Ib Study to Evaluate Safety, Pharmacokinetics, and Therapeutic Activity of RO6874281, an Immunocytokine Consisting of Interleukin 2 Variant (IL-2v) Targeting Fibroblast Activation Protein-a (FAP), as a Single Agent (Part A) or in Combination With Trastuzumab or Cetuximab (Part B or C)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 1612074879, BP29842, EudraCT Number: 2015-002251-97, FAP/BP29842, IRAS ID 213487, NCI-2016-01441, REC Reference 16/LO/2078, REec-2016-2017, RG7461

Population segments: HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: RG-7461 + trastuzumab

Locations: Denmark, France, Italy, Netherlands, Spain, United Kingdom, United States

US States: AZ, CA, CO, NY

US Contact: Reference Study ID Number: BP29842 [888-662-6728; global-roche-genentech-trials@gene.com]

NCT01969643
A Phase I, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients With Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 1311013056, 14-013, 14-306, 16104, 18862, 20131069, BRE 225 IST, NCI-2013-02245, SGNLVA-001, UW 13038

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Stage III, Stage IV, Third line, Triple receptor negative

Phase: I

Therapy: SGN-LIV1A + trastuzumab

Location: United States

US States: AL, AZ, CA, CO, CT, FL, GA, IL, IN, LA, MA, MD, MI, MN, MO, NC, NM, NV, NY, OH, OR, TN, TX, WA, WV

US Contact: Seattle Genetics Trial Information Support [866-333-7436; clinicaltrials@seagen.com]

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ERBB2 amplification (continued)

NCT02965885
A Phase IA/IB Study Evaluating TAS-116 in Patients With Advanced Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 10058010, EudraCT Number: 2015-005328-24, NCI-2017-01001, TAS-116-101

Population segments: EGFR, HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: TAS-116

Locations: Italy, United Kingdom, United States

US States: OH, SC, VA

US Contact: Dr. Elizabeth Calleja [609-285-5280; ECalleja@taihooncology.com]

NCT02562378
Phase I Multicenter Clinical Trial Evaluating the Combination of Trastuzumab Emtansine (T-DM1) and Non-pegylated Liposomal Doxorubicin in HER2-positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: Medopp038, THELMA

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: trastuzumab + chemotherapy

Locations: France, Spain

NCT02675829
A Phase II Trial of Ado-Trastuzumab Emtansine for Patients With HER2 Amplified or Mutant Cancers

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 15-335, NCI-2016-00262

Population segments: First line, Fourth line or greater, Second line, Stage III, Stage IV, Third line

Phase: II

Therapy: ado-trastuzumab emtansine

Location: United States

US State: NY

US Contact: Dr. Bob Li [646-888-4201]

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ERBB2 amplification (continued)

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER

Population segments: Maintenance/Consolidation, Second line, Stage III, Stage IV

Phase: II

Therapy: lapatinib

Location: France

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-C1, EAY131-C2, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-J, EAY131-L, EAY131-M, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-W, EAY131-X, EAY131-Y, EAY131-Z1A, EAY131-Z1B, EAY131-Z1C, EAY131-Z1D, EAY131-Z1E, EAY131-Z1F, EAY131-Z1G, EAY131-Z1H, EAY131-Z1I, EAY131-Z1J, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH

Population segments: (N/A), Aggressive, Classical, Fourth line or greater, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line, Stage III, Stage IV, Third line

Phase: II

Therapy: pertuzumab + trastuzumab

Locations: Puerto Rico, United States

US States: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: NCI-2017-00510, Pro00014171, TAPUR

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: United States

US States: AL, AZ, CA, FL, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, TX, UT, VA, WA

US Contact: Pam Mangat [pam.mangat@asco.org]

NCT02925234
A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification or ERBB2 overexpression

Other identifiers: DRUP, EudraCT Number: 2015-004398-33, M15DRU, NL54757.031.16

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), First line, Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Netherlands

NCT03297606
Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifiers: CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Canada

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ERBB2 amplification (continued)

NCT03065387
Phase I Study of the Pan-ERBB Inhibitor Neratinib Given in Combination With Everolimus, Palbociclib or Trametinib in Advanced Cancer Subjects With EGFR Mutation/Amplification, HER2 Mutation/ Amplification or HER3/4 Mutation

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 2016-0430, NCI-2018-01218

Population segments: HER2 negative, HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapies: everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib

Location: United States

US State: TX

US Contact: Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

NCT02829372
A Phase 1, First-in-man, Multicenter, Open-label, Dose-escalation Study of Single-agent GBR 1302 in Subjects With HER2 Positive Cancers

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 overexpression

Other identifiers: EudraCT Number: 2015-002926-38, GBR 1302-101, NCI-2017-02411

Population segments: (N/A), HER2 positive, Line of therapy N/A

Phase: I

Therapy: GBR 1302

Locations: Germany, United States

US States: KS, MI, TX, UT

US Contact: Phumla Adesanya [201-684-8000; clinicaltrialsdisclosuredesk@glenmarkpharma.com]

No NCT ID - see other identifier(s)
Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 overexpression or ERBB2 amplification

Other identifiers: 5209-CPK-1002, CTR20150792

Population segments: EGFR, HER2 positive, Second line or greater/Refractory/ Relapsed, Stage III, Stage IV

Phase: I

Therapy: pirotinib

Location: China

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 amplification (continued)

NCT02881138
Safety, Tolerability, Open Label, Pharmacokinetics Ascending Dose Clinical Study Of RC48 In Patients With HER2-Positive Malignant in Advanced Malignant Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 overexpression

Other identifiers: C001 CANCER, CTR20150876

Population segments: Estrogen receptor positive, First line, Fourth line or greater, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Phase: I

Therapy: RC-48

Location: China

NCT02881190
A Tolerance, Safety and Pharmacokinetic Ascending Dose Phase I Study of RC48-ADC Administered Intravenously to Subjects With HER2-Positive Malignant in Advanced Malignant Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 overexpression

Other identifiers: C002 CANCER, CTR20150822

Population segments: First line, HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapy: RC-48

Location: China

NCT02892123
Phase I Trial of ZW25 in Patients With Locally Advanced (Unresectable) and/or Metastatic HER2-expressing Cancers

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 2016-0532, NCI-2017-01210, ZWI-ZW25-101

Population segments: Fourth line or greater, HER2 positive, Stage III, Stage IV

Phase: I

Therapy: ZW-25

Locations: Canada, United States

US States: CA, CO, IL, TN, TX, WA

US Contact: Dr. Linda Lai [206-260-2078; linda.lai@zymeworks.com]

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ERBB2 amplification (continued)

NCT03448042
A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of BTRC4017A Administered Intravenously in Patients With Locally Advanced or Metastatic HER2-Expressing Cancers

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 positive

Other identifier: GO40311

Population segments: HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: BTRC-4017A

Location: United States

US State: TN

US Contact: Reference Study ID Number: GO40311 [888-662-6728; global-roche-genentech-trials@gene.com]

NCT02435927
Phase I Study to Evaluate the Safety and Tolerability of ASLAN001 in Combination with Oxaliplatin and Capecitabine or Oxaliplatin and 5-FU with Leucovorin

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifier: ASLAN001-002SG

Population segments: Second line, Stage IV

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

ERBB2 p.(S310F) c.929C>T

NCT02673398
Phase II Study of Neratinib in Patients 60 and Older With HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 S310F mutation

Other identifiers: 15342, NCI-2015-02282

Population segments: HER2 negative, HER2 positive, Second line, Stage III, Stage IV

Phase: II

Therapy: neratinib

Location: United States

US State: CA

US Contact: Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

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ERBB2 p.(S310F) c.929C>T (continued)

No NCT ID - see other identifier(s)
An open label, single arm, single agent, phase II trial of neratinib, an irreversible ERBB2 inhibitor, in metastatic ERBB2 mutant, HER2 negative breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: EORTC-1304-BCG - Anabela, EudraCT Number: 2013-004713-40, PUMA-NER-1202

Population segments: HER2 negative, Line of therapy N/A, Stage IV

Phase: II

Therapy: neratinib

Location: Belgium

NCT03182634

A Multiple Parallel Cohort, Multi-centre Phase IIa Trial Aiming to Provide Proof of Principle Efficacy for Designated Targeted Therapies in Patients With Advanced Breast Cancer Where the Targetable Mutation is Identified Through ctDNA plasma-based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) trial

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 31608, EudraCT Number: 2015-003735-36, ICR-CTSU/2015/10056, IRAS 187103, ISRCTN16945804, plasmaMATCH

Population segments: Estrogen receptor positive, First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER negative

Phase: II

Therapy: neratinib

Location: United Kingdom

NCT03182634

A Multiple Parallel Cohort, Multi-centre Phase IIa Trial Aiming to Provide Proof of Principle Efficacy for Designated Targeted Therapies in Patients With Advanced Breast Cancer Where the Targetable Mutation is Identified Through ctDNA plasma-based Molecular profiling of Advanced breast cancer to inform Therapeutic Choices (plasmaMATCH) trial

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 31608, EudraCT Number: 2015-003735-36, ICR-CTSU/2015/10056, IRAS 187103, ISRCTN16945804, plasmaMATCH

Population segments: Estrogen receptor positive, First line, HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Other inclusion criteria: ER positive

Phase: II

Therapy: neratinib + fulvestrant

Location: United Kingdom

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ERBB2 p.(S310F) c.929C>T (continued)

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

Other inclusion criteria: ERBB2 negative, ER positive, PR positive

Phase: II

Therapies: neratinib + fulvestrant, neratinib + trastuzumab + fulvestrant

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

NCT01953926
An Open-Label, Phase II Study Of Neratinib In Patients With Solid Tumors With Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) Mutations Or EGFR Gene Amplification

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 13-140, 13-615, 2013-0904, CTA733, EudraCT Number: 2013-002872-42, IRAS ID: 171670, NCI-2014-00495, PUMA-NER-5201, REec-2014-0843, SUMMIT, SUMMIT basket

Population segments: EGFR, Estrogen receptor positive, First line, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: Hormone receptor negative

Phase: II

Therapy: neratinib + trastuzumab

Locations: Australia, Belgium, Denmark, France, Israel, Italy, Republic of Korea, Spain, United States

US States: CA, FL, IL, LA, MA, MO, NY, PA, TN, TX, WI

US Contact: Puma Biotechnology Clinical Operations Senior Director [424-248-6500; ClinicalTrials@pumabiotechnology.com]

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ERBB2 p.(S310F) c.929C>T (continued)

NCT01953926
An Open-Label, Phase II Study Of Neratinib In Patients With Solid Tumors With Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) Mutations Or EGFR Gene Amplification

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 13-140, 13-615, 2013-0904, CTA733, EudraCT Number: 2013-002872-42, IRAS ID: 171670, NCI-2014-00495, PUMA-NER-5201, REec-2014-0843, SUMMIT, SUMMIT basket

Population segments: EGFR, Estrogen receptor positive, First line, Fourth line or greater, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage IV, Third line, Triple receptor negative

Other inclusion criteria: Hormone receptor positive

Phase: II

Therapy: neratinib + trastuzumab + fulvestrant

Locations: Australia, Belgium, Denmark, France, Israel, Italy, Republic of Korea, Spain, United States

US States: CA, FL, IL, LA, MA, MO, NY, PA, TN, TX, WI

US Contact: Puma Biotechnology Clinical Operations Senior Director [424-248-6500; ClinicalTrials@pumabiotechnology.com]

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

Other inclusion criteria: ERBB2 negative

Phase: II

Therapies: neratinib, neratinib + trastuzumab

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

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ERBB2 p.(S310F) c.929C>T (continued)

NCT01670877
A Phase II Study of Neratinib Alone and in Combination With Fulvestrant in Metastatic HER2 Non-amplified But HER2 Mutant Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 12-X244, 13-195, 13041901, 1B-13-1, 201209135, DFCI: 13-237, MutHER, NCI-2012-01513, UAB1326, WASHU 201209135

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, Second line, Stage IV, Third line

Other inclusion criteria: ERBB2 negative, ER negative

Phase: II

Therapies: neratinib, neratinib + trastuzumab

Location: United States

US States: AL, CA, FL, IL, MA, MN, MO, NC, SD, TX

US Contact: Dr. Cynthia Ma [314-362-9383; cynthiaxma@wustl.edu]

NCT03202316
A Phase II Study of Triple Combination of Atezolizumab + Cobimetinib + Eribulin (ACE) in Patients With Recurrent/ Metastatic Inflammatory Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 status

Other identifiers: 2016-0890, NCI-2017-01601

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: Hormone receptor status

Phase: II

Therapy: atezolizumab + cobimetinib + chemotherapy

Location: United States

US State: TX

US Contact: Dr. Bora Lim [713-792-2817; blim@mdanderson.org]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ERBB2 p.(S310F) c.929C>T (continued)

NCT03410927
A Phase I/II, Open Label, Multicenter Study to Investigate the Safety, Pharmacokinetics, and Efficacy of TAS0728, an Oral Covalent Binding Inhibitor of HER2, in Subjects With Advanced Solid Tumors With HER2 or HER3 Abnormalities

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 18116, 2017-0994, EudraCT Number: 2017-004415-39, NCI-2018-00211, REFMAL 555, TO-TAS0728-101

Population segments: Adenocarcinoma, Fourth line or greater, HER2 positive, Large Cell, Second line, Stage III, Stage IV, Third line

Phase: I/II

Therapy: TAS0728

Locations: United Kingdom, United States

US States: NY, TN, TX

US Contact: Dr. Mark Kirshbaum [609-750-5300; MKirschbaum@taihooncology.com]

NCT02583542
A Phase Ib/IIa Study of AZD2014 in Combination With Selumetinib in Patients With Advanced Cancers

Cancer type: Breast Cancer

Variant class: ERBB2 aberration

Other identifiers: 009896QM, EudraCT Number: 2014-002613-31, IRAS ID 172356, Torcmek, UKCRN ID:18725

Population segments: Adenocarcinoma, EGFR, FGFR, HER2 negative, KRAS, Large Cell, Second line, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Location: United Kingdom

NCT02152943
Combination Treatment With Everolimus, Letrozole and Trastuzumab in Hormone Receptor and HER2/Neu-positive Patients With Advanced Metastatic Breast Cancer and Other Solid Tumors: Evaluating Synergy and Overcoming Resistance

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: 2014-0119, NCI-2014-01615

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 positive, Maintenance/Consolidation, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line

Other inclusion criteria: ER positive, PR positive

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Location: United States

US State: TX

US Contact: Dr. Filip Janku [713-563-1930]

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ERBB2 p.(S310F) c.929C>T (continued)

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients With HER2-positive Solid Tumors Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 mutation

Other identifiers: NCI-2017-00491, SHRUS 1001

Population segments: HER2 positive, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: pyrotinib

Location: United States

US States: FL, MA, MI, MO, NY, TN

US Contact: Dr. Ewa Matczak [609-423-2155 ext 215; ewa.matczak@hengruitherapeutics.com]

NCT03004534
A Presurgical Tissue-Acquisition Study to Evaluate Molecular Alterations in Human Breast Cancer Tissue Following Short-Term Exposure to the Androgen Receptor Antagonist ODM-201

Cancer type: Breast Cancer

Variant class: ERBB2 status

Other identifiers: EudraCT Number: 2016-004151-79, HC6-24-c 201058, TRIO030

Population segments: Estrogen receptor positive, HER2 negative, HER2 positive, Neoadjuvant, Stage I, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ER negative, ER positive, PR negative, PR positive

Phase: I

Therapy: darolutamide

Locations: Canada, Germany, United States

US States: CA, FL

US Contact: Dr. Dennis Slamon [310-825-5193; dslamon@mednet.ucla.edu]

No NCT ID - see other identifier(s)
Precision 2: an open explorative phase II, open label study of afatinib in the treatment of advanced cancer carrying an EGFR, a HER2 or a HER3 mutation.

Cancer type: Unspecified Cancer

Variant class: ERBB2 mutation

Other identifiers: 1200.264, EudraCT Number: 2016-003411-34, Precision 2

Population segments: HER2 positive, Line of therapy N/A, Stage III, Stage IV

Phase: II

Therapy: afatinib

Location: Belgium

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ERBB2 p.(S310F) c.929C>T (continued)

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER

Population segments: Maintenance/Consolidation, Second line, Stage III, Stage IV

Phase: II

Therapy: lapatinib

Location: France

NCT02925234
A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: DRUP, EudraCT Number: 2015-004398-33, M15DRU, NL54757.031.16

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), First line, Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Other subtype, Second line, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Netherlands

NCT03297606
Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifiers: CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Canada

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ERBB2 p.(S310F) c.929C>T (continued)

NCT03065387
Phase I Study of the Pan-ERBB Inhibitor Neratinib Given in Combination With Everolimus, Palbociclib or Trametinib in Advanced Cancer Subjects With EGFR Mutation/Amplification, HER2 Mutation/ Amplification or HER3/4 Mutation

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 2016-0430, NCI-2018-01218

Population segments: HER2 negative, HER2 positive, Second line, Stage III, Stage IV

Phase: I

Therapies: everolimus + neratinib, neratinib + palbociclib, neratinib + trametinib

Location: United States

US State: TX

US Contact: Dr. Sarina Piha-Paul [713-563-1930; spihapau@mdanderson.org]

No NCT ID - see other identifier(s)
Phase I Clinical Study With Advanced Solid Tumors KBP-5209 Treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 mutation

Other identifiers: 5209-CPK-1002, CTR20150792

Population segments: EGFR, HER2 positive, Second line or greater/Refractory/ Relapsed, Stage III, Stage IV

Phase: I

Therapy: pirotinib

Location: China

NCT02435927
Phase I Study to Evaluate the Safety and Tolerability of ASLAN001 in Combination with Oxaliplatin and Capecitabine or Oxaliplatin and 5-FU with Leucovorin

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifier: ASLAN001-002SG

Population segments: Second line, Stage IV

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ATR p.(E560*) c.1678G>T

NCT03344965
A Phase II Study of Olaparib Monotherapy in Metastatic Breast Cancer Patients With Germline or Somatic Mutations in DNA Repair Genes (Olaparib Expanded)

Cancer type: Breast Cancer

Variant class: ATR mutation

Other identifiers: 17-428, NCI-2018-00778

Population segments: Estrogen receptor positive, Progesterone receptor positive, Second line, Stage IV

Phase: II

Therapy: olaparib

Location: United States

US State: MA

US Contact: Dr. Nadine Tung [617-667-1962; ntung@bidmc.harvard.edu]

NCT02401347
A Phase II Clinical Trial of the PARP Inhibitor Talazoparib in BRCA1 and BRCA2 Wild-Type Patients With (i) Advanced Triple-Negative Breast Cancer and Homologous Recombination Deficiency, and (ii) Advanced HER2-Negative Breast Cancer or Other Solid Tumors With Either a Mutation in Homologous Recombination Pathway Genes Talazoparib Beyond BRCA (TBB) Trial

Cancer type: Breast Cancer

Variant class: ATR mutation

Other identifiers: BRS0050, NCI-2015-00036, TBB

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 negative

Phase: II

Therapy: talazoparib

Location: United States

US State: CA

US Contact: Pei Jen Chang [650-725-0866; peijenc@stanford.edu]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ATR p.(E560*) c.1678G>T (continued)

NCT03330405
A Phase Ib/II Study To Evaluate Safety And Anti Tumor Activity Of Avelumab In Combination With The Poly(Adenosine Diphosphate [Adp]-Ribose) Polymerase (Parp) Inhibitor Talazoparib In Patients With Locally Advanced Or Metastatic Solid Tumors

Cancer type: Breast Cancer

Variant class: DNA repair pathway

Other identifiers: 17-687, 2017-0524, 34807, B9991025, EudraCT Number: 2017-001509-33, JAVELIN PARP MEDLEY, NCI-2017-02385, s17-01353

Population segments: Estrogen receptor positive, HER2 negative, Hormone refractory, Progesterone receptor positive, Second line, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: Hormone receptor positive

Phase: I/II

Therapy: avelumab + talazoparib

Locations: Australia, Russian Federation, United States

US States: AR, MA, NY, OH, TX

US Contact: Pfizer CT.gov Call Center [800-718-1021; ClinicalTrials.gov_Inquiries@pfizer.com]

NCT03188965
An Open-label, First-in-human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Patients With Advanced Solid Tumors and Lymphomas

Cancer type: Breast Cancer

Variant class: DNA repair pathway

Other identifiers: 18594, 2017-0186, BAY1895344/18594, EudraCT Number: 2016-004484-39, IRAS ID-218516, NCI-2018-00206, Trial ID: 16754

Population segments: Adenocarcinoma, Aggressive, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Mantle cell lymphoma (MCL), Second line, Squamous Cell, Stage III, Stage IV

Other inclusion criteria: ERBB2 negative, ER negative, PR negative

Phase: I/II

Therapy: BAY-1895344

Locations: Canada, Singapore, Switzerland, United Kingdom, United States

US State: TX

US Contact: Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ATR p.(E560*) c.1678G>T (continued)

NCT03188965
An Open-label, First-in-human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Patients With Advanced Solid Tumors and Lymphomas

Cancer type: Breast Cancer

Variant class: DNA repair pathway

Other identifiers: 18594, 2017-0186, BAY1895344/18594, EudraCT Number: 2016-004484-39, IRAS ID-218516, NCI-2018-00206, Trial ID: 16754

Population segments: Adenocarcinoma, Aggressive, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Mantle cell lymphoma (MCL), Second line, Squamous Cell, Stage III, Stage IV

Other inclusion criteria: ERBB2 negative, ER positive, PR positive

Phase: I/II

Therapy: BAY-1895344

Locations: Canada, Singapore, Switzerland, United Kingdom, United States

US State: TX

US Contact: Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

No NCT ID - see other identifier(s)
Single Arm, Open label, Signal Seeking, Phase IIa Trial Of The Activity Of Olaparib In Combination With Durvalumab In Patients With Tumours With Homologous Recombination Repair Defects

Cancer type: Unspecified Solid Tumor

Variant class: ATR mutation

Other identifiers: ACTRN12617001000392, MoST Addendum 3, U1111-1182-6652

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: durvalumab + olaparib

Location: Australia

NCT03207347
A Phase II Trial of the PARP Inhibitor, Niraparib, in BAP1 and Other DNA Damage Response (DDR) Pathway Deficient Neoplasms (UF-STO-ETI-001)

Cancer type: Unspecified Cancer

Variant class: ATR mutation

Other identifier: UF-STO-ETI-001

Population segments: (N/A), Second line

Phase: II

Therapy: niraparib

Location: United States

US State: FL

US Contact: Ashton Monismith [352-265-0680 ext 87657; amonismith@ufl.edu]

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ATR p.(E560*) c.1678G>T (continued)

NCT02873975
A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: ATR mutation

Other identifiers: 16-281, I4D-MC-E006, NCI-2016-01564

Population segments: Second line, Stage III, Stage IV

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shapiro@dfci.harvard.edu]

NCT02286687
Phase II Study of the PARP Inhibitor BMN 673 (Talazoparib Tosylate) in Advanced Cancer Patients With Somatic Alterations in BRCA1/2, Mutations/Deletions in PTEN or PTEN Loss, a Homologous Recombination Defect, Mutations/ Deletions in Other BRCA Pathway Genes and Germline Mutation in BRCA1/2 (Not Breast or Ovarian Cancer)

Cancer type: Unspecified Cancer

Variant class: ATR mutation

Other identifiers: 2013-0961, NCI-2014-02494

Population segments: Fourth line or greater, Stage III, Stage IV

Phase: II

Therapy: talazoparib

Location: United States

US State: TX

US Contact: Dr. Sarina Piha-Paul [713-563-1930]

No NCT ID - see other identifier(s)
An Open-Label Study of the Safety, Tolerability, and Pharmacokinetic/ Pharmacodynamic Profile of VX-970 as a Single Agent in Combination with Carboplatin in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: DNA repair mutation

Other identifiers: EudraCT Number: 2013-005100-34, VX13-970-002

Population segments: (N/A), Adenocarcinoma, HER2 negative, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapies: VX-970, VX-970 + chemotherapy

Location: United Kingdom

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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ATR p.(E560*) c.1678G>T (continued)

NCT03188965
An Open-label, First-in-human, Dose-escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose and / or Recommended Phase II Dose of the ATR Inhibitor BAY1895344 in Patients With Advanced Solid Tumors and Lymphomas

Cancer type: Unspecified Solid Tumor

Variant class: DNA repair pathway

Other identifiers: 18594, 2017-0186, BAY1895344/18594, EudraCT Number: 2016-004484-39, IRAS ID-218516, NCI-2018-00206, Trial ID: 16754

Population segments: Adenocarcinoma, Aggressive, Diffuse large B-cell lymphoma (DLBCL), Hormone refractory, Indolent, Mantle cell lymphoma (MCL), Second line, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapy: BAY-1895344

Locations: Canada, Singapore, Switzerland, United Kingdom, United States

US State: TX

US Contact: Bayer Clinical Trials Contact [888-842-2937; clinical-trials-contact@bayer.com]

NCT03061188
Phase I/Ib Study of Nivolumab and Veliparib in Patients With Advanced Solid Tumors and Lymphoma With and Without Alterations in Selected DNA Repair Genes

Cancer type: Unspecified Solid Tumor

Variant class: ATR mutation

Other identifiers: NCI-2016-02018, NU 16MH03, NU 16MH03 23786, STU00204250

Population segments: Aggressive, Classical, Cutaneous T-cell lymphoma (CTCL), Diffuse large B-cell lymphoma (DLBCL), Mantle cell lymphoma (MCL), Nodular lymphocyte-predominant, Other subtype, Peripheral T-cell lymphoma (PTCL), Second line, Stage IV

Phase: I

Therapy: nivolumab + veliparib

Location: United States

US State: IL

US Contact: Study Coordinator [312-695-1301; cancertrials@northwestern.edu]

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FGF19 amplification

NCT02052778
Phase I/II Study of TAS-120 in Patients With Advanced Solid Tumors Harboring FGF/FGFR Aberrations

Cancer type: Breast Cancer

Variant class: FGF19 amplification

Other identifiers: 121062, 14-135, 17-23, 17084, 2014-0069, CSET 2107, CT680, EudraCT Number: 2013-004810-16, IND Number 121062, IRAS ID 143913, IRAS ID 143913, MC# 17-23, NCI-2014-01148, NL 20171130, NL64142.056.17, P 47317, REFMAL 340, TPU-TAS-120-101, UW18036

Population segments: FGFR, Second line, Stage III, Stage IV

Phase: I/II

Therapy: TAS-120

Locations: Australia, France, Hong Kong, Spain, United Kingdom, United States

US States: AZ, CA, FL, MA, MN, NM, NY, PA, SC, TX, WA

US Contact: Dr. Jerry Huang [jhuang@taihooncology.com]

NCT02393248
A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies

Cancer type: Breast Cancer

Variant class: FGF aberration

Other identifiers: 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

Population segments: (N/A), FGFR, Second line, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapies: INCB-54828, INCB-54828 + chemotherapy, INCB-54828 + pembrolizumab, INCB-54828 + trastuzumab

Locations: Denmark, United States

US States: AL, DC, FL, MI, MO, NC, NJ, OH, SC, TX

US Contact: Incyte Call Center [855-463-3463]

NCT03144661
A Phase I, Open-Label, Dose-Escalation and Expansion, Safety and Tolerability Study of INCB062079 in Subjects With Advanced Hepatocellular Carcinoma and Other Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: FGF19 aberration

Other identifiers: 18-006, INCB 62079-101, INCB62079-101, NCI-2017-02493, UMCC 2017.041

Population segments: Second line, Stage III, Stage IV

Phase: I/II

Therapy: INCB-62079

Locations: Belgium, United States

US States: AL, AZ, IN, MI, NY

US Contact: Incyte Corporation Call Center (US) [855-463-3463; medinfo@incyte.com]

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FGF19 amplification (continued)

NCT03235570
A Phase I, Open-Label, Dose-Escalation, Dose-Expansion, Safety and Tolerability Study of INCB054828 in Japanese Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: FGF aberration

Other identifier: INCB 54828-102

Population segments: Line of therapy N/A, Stage III, Stage IV

Phase: I

Therapy: INCB-54828

Location: Japan

NCT02275910
A Phase I Study of E7090 in Subjects With Solid Tumor

Cancer type: Unspecified Solid Tumor

Variant class: FGF pathway

Other identifiers: E7090-J081-101, JapicCTI-142740

Population segments: Fourth line or greater, Stage III, Stage IV

Phase: I

Therapy: E-7090

Location: Japan

TP53 p.(G112fs) c.335delG

NCT03566485
BRE 17107: A Phase Ib/II Trial of Atezolizumab (an Anti-PD-L1 Monoclonal Antibody) With Cobimetinib (a MEK1/2 Inhibitor) or Idasanutlin (an MDM2 Antagonist) in Metastatic ER+ Breast Cancer.

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: BRE 17107, NCI-2018-01159, VICC BRE 17107

Population segments: Estrogen receptor positive, HER2 negative, Stage IV, Third line

Other inclusion criteria: ERBB2 negative, ER positive, PR positive

Phase: I/II

Therapy: atezolizumab + cobimetinib

Location: United States

US State: TN

US Contact: Clinical Trials Information Program [800-811-8480; cip@vanderbilt.edu]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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TP53 p.(G112fs) c.335delG (continued)

NCT03096054
A Cancer Research UK (CR-UK) Phase I Trial of LY3143921 a Cdc7 Inhibitor in Adult Patients With Advanced Solid Tumours

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: CPMS ID 35213, CRUKD/17/004, EudraCT Number: 2016-001245-80, IRAS ID 216105, MREC No. 17/NI/0005

Population segments: HER2 negative, Line of therapy N/A, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Other inclusion criteria: ERBB2 negative, ER negative, PR negative

Phase: I

Therapy: LY3143921

Location: United Kingdom

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD6738 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1508016363, 16-314, NCI-2016-00922, OLAPCO, VICCMD1672

Population segments: First line, Second line, Stage IV

Phase: II

Therapy: adavosertib + olaparib

Location: United States

US States: CT, MA, OH, TN

US Contact: Manuel Avedissian [203-737-3669; manuel.avedissian@yale.edu]

No NCT ID - see other identifier(s)
An Open-Label Study of the Safety, Tolerability, and Pharmacokinetic/ Pharmacodynamic Profile of VX-970 as a Single Agent in Combination with Carboplatin in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: EudraCT Number: 2013-005100-34, VX13-970-002

Population segments: (N/A), Adenocarcinoma, HER2 negative, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapies: VX-970, VX-970 + chemotherapy

Location: United Kingdom

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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FGF3 amplification

NCT02393248
A Phase I/II, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies

Cancer type: Breast Cancer

Variant class: FGF aberration

Other identifiers: 00061567, 2014-1099, 201503012, EudraCT Number: 2016-002831-14, INCB 54828-101, INCB54828-101, MC# 15-03, NCI-2015-00611, OSU-15241

Population segments: (N/A), FGFR, Second line, Squamous Cell, Stage III, Stage IV

Phase: I/II

Therapies: INCB-54828, INCB-54828 + chemotherapy, INCB-54828 + pembrolizumab, INCB-54828 + trastuzumab

Locations: Denmark, United States

US States: AL, DC, FL, MI, MO, NC, NJ, OH, SC, TX

US Contact: Incyte Call Center [855-463-3463]

NCT02052778
Phase I/II Study of TAS-120 in Patients With Advanced Solid Tumors Harboring FGF/FGFR Aberrations

Cancer type: Breast Cancer

Variant class: FGF aberration

Other identifiers: 121062, 14-135, 17-23, 17084, 2014-0069, CSET 2107, CT680, EudraCT Number: 2013-004810-16, IND Number 121062, IRAS ID 143913, IRAS ID 143913, MC# 17-23, NCI-2014-01148, NL 20171130, NL64142.056.17, P 47317, REFMAL 340, TPU-TAS-120-101, UW18036

Population segments: FGFR, Second line, Stage III, Stage IV

Phase: I/II

Therapy: TAS-120

Locations: Australia, France, Hong Kong, Spain, United Kingdom, United States

US States: AZ, CA, FL, MA, MN, NM, NY, PA, SC, TX, WA

US Contact: Dr. Jerry Huang [jhuang@taihooncology.com]

NCT03235570
A Phase I, Open-Label, Dose-Escalation, Dose-Expansion, Safety and Tolerability Study of INCB054828 in Japanese Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: FGF aberration

Other identifier: INCB 54828-102

Population segments: Line of therapy N/A, Stage III, Stage IV

Phase: I

Therapy: INCB-54828

Location: Japan

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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FGF3 amplification (continued)

NCT02275910
A Phase I Study of E7090 in Subjects With Solid Tumor

Cancer type: Unspecified Solid Tumor

Variant class: FGF pathway

Other identifiers: E7090-J081-101, JapicCTI-142740

Population segments: Fourth line or greater, Stage III, Stage IV

Phase: I

Therapy: E-7090

Location: Japan

CCND1 amplification

NCT03310879
A Phase II Study of the CDK4/6 Inhibitor Abemaciclib in Patients With Solid Tumors Harboring Genetic Alterations in Genes Encoding D-type Cyclins or Amplification of CDK4 or CDK6

Cancer type: Unspecified Solid Tumor

Variant class: CCND1 amplification

Other identifiers: 17-343, NCI-2017-02359

Population segments: First line, Stage III, Stage IV

Phase: II

Therapy: abemaciclib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; geoffrey_shapiro@dfci.harvard.edu]

NCT01037790
Phase II Trial of the Cyclin-Dependent Kinase Inhibitor PD 0332991 in Patients With Cancer

Cancer type: Unspecified Solid Tumor

Variant class: CCND1 amplification

Other identifiers: NCI-2009-01467, Study 1006, UPCC 03909, UPCC03909

Population segments: Estrogen receptor positive, Fourth line or greater, HER2 negative, HER2 positive, Metastatic, Progesterone receptor positive, Second line, Stage III, Stage IV, Third line, Triple receptor negative

Phase: II

Therapy: palbociclib

Location: United States

US State: PA

US Contact: Dr. Peter O. Dwyer [855-216-0098; PennCancerTrials@emergingmed.com]

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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CCND1 amplification (continued)

NCT02896335
A Phase II Study of Palbociclib in Progressive Brain Metastases Harboring Alterations in the CDK Pathway

Cancer type: Unspecified Solid Tumor

Variant class: CCND1 amplification

Other identifiers: 16-254, NCI-2016-02025

Population segments: CNS mets, Second line, Stage IV

Phase: II

Therapy: palbociclib

Location: United States

US State: MA

US Contact: Dr. Priscilla Brastianos [617-724-8770; PBRASTIANOS@mgh.harvard.edu]

NCT03297606
Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial

Cancer type: Unspecified Solid Tumor

Variant class: CCND1 aberration

Other identifiers: CA209-9DL, CAPTUR, ESR-17-12831, ML39800, PM1, WI233446

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), First line, Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line, Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: palbociclib

Location: Canada

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

ERBB2 amplification

Variant Class	Evidence Items
ERBB aberration	0
↳ ERBB2 status	3
↳ ERBB2 aberration	6
↳ ERBB2 positive	73
↳ ERBB2 amplification	152
ERBB aberration	0
↳ ERBB2 status	3
↳ ERBB2 aberration	6
↳ ERBB2 positive	73
↳ ERBB2 overexpression	189

ERBB2 p.(S310F) c.929C>T

Variant Class	Evidence Items
ERBB aberration	0
↳ ERBB2 status	3
↳ ERBB2 aberration	6
↳ ERBB2 mutation status	0
↳ ERBB2 mutation	17
↳ ERBB2 activating mutation	0
↳ ERBB2 S310F mutation	1

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

ATR p.(E560*) c.1678G>T

Variant Class	Evidence Items
DNA repair pathway	4
↳ DNA repair mutation	1
↳ ATR mutation	7
↳ ATR deleterious mutation	0
Fanconi anemia pathway	0
↳ ATR mutation	7
↳ ATR deleterious mutation	0

FGF19 amplification

Variant Class	Evidence Items
FGF pathway	2
↳ FGF aberration	5
↳ FGF19 aberration	1
↳ FGF19 amplification	1

TP53 p.(G112fs) c.335delG

Variant Class	Evidence Items
TP53 aberration	0
↳ TP53 mutation	4
↳ TP53 deleterious mutation	0

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

FGF3 amplification

Variant Class	Evidence Items
FGF pathway	2
↳ FGF aberration	5

CCND1 amplification

Variant Class	Evidence Items
G1/S cell cycle pathway	0
↳ CCND1 aberration	1
↳ CCND1 amplification	3

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Allele Frequency	Transcript	Variant Effect	Gene Class	Variant Class
ATR	p.(E560*)	c.1678G>T	.	48.37%	NM_001184.3	nonsense	Loss of Function	Deleterious
TP53	p.(G112fs)	c.335delG	.	44.20%	NM_000546.5	frameshift Deletion	Loss of Function	Deleterious
ERBB2	p.(S310F)	c.929C>T	COSM48358	75.14%	NM_004448.3	missense	Gain of Function	Hotspot

Copy Number Variations

Gene	Locus	Copy Number
CCND1	chr11:69455971	7.29
FGF19	chr11:69513953	8.06
FGF3	chr11:69624975	7.35
ERBB2	chr17:37868167	19.95

Other mutations, copy number variations, or fusions that were detected but not classified by the Oncofocus Test as actionable by a known therapeutic targeted agent are not listed in the results section of this report.

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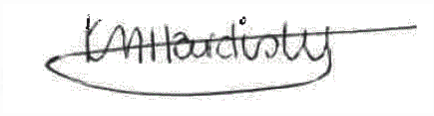
Report Authorised by

Signed



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