[Oncofocus] Patient Test Report

Oncologica UK Ltd
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Surname		**Requesting clinician**	
Forename			
DOB		**Date requested**	
Gender			
Histology #		**Tumour %**	50
Primary site	Right Breast	**Tumour % (macrodissected)**	
Tumour subtype	Invasive Ductal Carcinoma		
Tissue type	Lymph Node metastasis		

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.

221 genes were targeted with 2530 unique amplicons covering oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors. Actionable genetic variants detected by Oncofocus are linked to 485 anti-cancer targeted therapies.

The following actionable variants were detected:

Variant Summary

Sample Cancer Type: Breast Cancer

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

Gene Variant	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials
ERBB2 amplification	◑ (12)	◑ (5)	● (6)	◑ (17)	● (91)
CCND1 amplification	✖	✖	✖	✖	● (2)
TP53 p.(K132N) c.396G>T	✖	✖	✖	✖	● (8)
ETV6-NTRK3 fusion	✖	✖	✖	✖	● (5)

EMA: European Medicine Agency, **US-FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **US-NCCN:** United States-National Comprehensive Cancer Network. Numbers in parentheses indicate the number of relevant therapies with evidence. Hotspot variants with >10% alternate allele reads, and in >10 unique reads are classified as 'detected' with an assay sensitivity and positive predictive value of 92%. Copy number variants; amplifications of a >5% confidence value of ≥4 after normalization and deletions of ≤1 are classified as present when the tumour% >50%. Gene Fusions are reported when occurring in >20 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.

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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Relevant Therapy Summary

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ERBB2 amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
trastuzumab	◑	◑	✖	✖	● (IV)
trastuzumab + capecitabine	◑	✖	✖	●	✖
trastuzumab + docetaxel	◑	✖	✖	●	✖
trastuzumab + paclitaxel	◑	✖	✖	●	✖
trastuzumab + aromatase inhibitor	◑	✖	✖	✖	✖
trastuzumab + carboplatin + docetaxel	◑	✖	✖	✖	✖
trastuzumab + cisplatin + fluorouracil	◑	✖	✖	✖	✖
ado-trastuzumab emtansine	●	●	●	●	● (IV)
lapatinib + capecitabine	●	●	✖	●	✖
pertuzumab + trastuzumab + docetaxel	●	●	✖	●	✖
lapatinib + trastuzumab	●	✖	●	●	● (II)
lapatinib + aromatase inhibitor	●	✖	✖	✖	✖
lapatinib + letrozole	✖	●	✖	✖	✖
pertuzumab + trastuzumab + chemotherapy	✖	✖	●	●	● (IV)
trastuzumab + chemotherapy	✖	✖	●	●	● (IV)
trastuzumab + hormone therapy + chemotherapy	✖	✖	●	●	● (III)
pertuzumab	✖	✖	●	✖	✖
hormone therapy	✖	✖	✖	●	✖
pertuzumab + trastuzumab + paclitaxel	✖	✖	✖	●	✖
trastuzumab + carboplatin + paclitaxel	✖	✖	✖	●	✖
trastuzumab + hormone therapy	✖	✖	✖	●	✖
trastuzumab + vinorelbine	✖	✖	✖	●	✖

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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	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
trastuzumab + chemotherapy (other)	✖	✖	✖	○	✖
trastuzumab + cisplatin + fluoropyrimidine	✖	✖	✖	○	✖
ado-trastuzumab emtansine, trastuzumab	✖	✖	✖	✖	● (IV)
pertuzumab + chemotherapy	✖	✖	✖	✖	● (IV)
aromatase inhibitor, tamoxifen	✖	✖	✖	✖	● (III)
lapatinib + chemotherapy, neratinib + chemotherapy	✖	✖	✖	✖	● (III)
lapatinib, lapatinib + trastuzumab, trastuzumab	✖	✖	✖	✖	● (III)
margetuximab + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + anastrozole, pertuzumab + trastuzumab + chemotherapy, pertuzumab + trastuzumab + exemestane, pertuzumab + trastuzumab + fulvestrant, pertuzumab + trastuzumab + letrozole, pertuzumab + trastuzumab + tamoxifen	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + chemotherapy + ferric carboxymaltose	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (III)
pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo	✖	✖	✖	✖	● (III)
trastuzumab + chemotherapy, trastuzumab + hormone therapy	✖	✖	✖	✖	● (III)
ado-trastuzumab emtansine, pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II/III)
abemaciclib	✖	✖	✖	✖	● (II)

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Relevant Therapy Summary (continued)

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ERBB2 amplification (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
ado-trastuzumab emtansine + lapatinib + chemotherapy, pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine + pertuzumab	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine + pertuzumab + chemotherapy	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine + pertuzumab, ganetespib, ganitumab + metformin hydrochloride, MK-2206, MK-2206 + trastuzumab, pembrolizumab + chemotherapy, pertuzumab + trastuzumab, talazoparib + chemotherapy, trastuzumab + chemotherapy, trastuzumab + trebananib, trebananib	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
ARRY-380 + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo	✖	✖	✖	✖	● (II)
bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
buparlisib + chemotherapy	✖	✖	✖	✖	● (II)
cabozantinib + trastuzumab	✖	✖	✖	✖	● (II)
everolimus + lapatinib	✖	✖	✖	✖	● (II)
everolimus + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
lapatinib + chemotherapy	✖	✖	✖	✖	● (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	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
lapatinib + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
lapatinib + trastuzumab + fulvestrant	✖	✖	✖	✖	● (II)
lapatinib + trastuzumab, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
nelipepimut-S + sargramostim + trastuzumab	✖	✖	✖	✖	● (II)
neratinib, neratinib + chemotherapy, neratinib + surgical intervention, neratinib + trastuzumab	✖	✖	✖	✖	● (II)
palbociclib + trastuzumab	✖	✖	✖	✖	● (II)
palbociclib + trastuzumab, palbociclib + trastuzumab + letrozole	✖	✖	✖	✖	● (II)
palbociclib, palbociclib + trastuzumab	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + fulvestrant + chemotherapy	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + hormone therapy + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + letrozole + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + letrozole	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab, pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
poziotinib	✖	✖	✖	✖	● (II)
trastuzumab + chemotherapy + metformin hydrochloride	✖	✖	✖	✖	● (II)
trastuzumab + chemotherapy + surgical intervention	✖	✖	✖	✖	● (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	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
trastuzumab + chemotherapy + zoledronic acid	✖	✖	✖	✖	● (II)
trastuzumab + enzalutamide	✖	✖	✖	✖	● (II)
trastuzumab + letrozole	✖	✖	✖	✖	● (II)
trastuzumab, trastuzumab + chemotherapy	✖	✖	✖	✖	● (II)
ado-trastuzumab emtansine + lapatinib + chemotherapy	✖	✖	✖	✖	● (I/II)
ado-trastuzumab emtansine + neratinib	✖	✖	✖	✖	● (I/II)
CART-HER-2	✖	✖	✖	✖	● (I/II)
copanlisib + trastuzumab	✖	✖	✖	✖	● (I/II)
durvalumab + ibrutinib	✖	✖	✖	✖	● (I/II)
everolimus + lapatinib + chemotherapy	✖	✖	✖	✖	● (I/II)
INXN-2001/1001	✖	✖	✖	✖	● (I/II)
masitinib + chemotherapy	✖	✖	✖	✖	● (I/II)
MCLA-128	✖	✖	✖	✖	● (I/II)
pembrolizumab + trastuzumab	✖	✖	✖	✖	● (I/II)
saracatinib + anastrozole	✖	✖	✖	✖	● (I/II)
selumetinib + vistusertib	✖	✖	✖	✖	● (I/II)
tamoxifen, taselisib + tamoxifen	✖	✖	✖	✖	● (I/II)
trastuzumab + natural killer cell treatment	✖	✖	✖	✖	● (I/II)
trastuzumab, trastuzumab + natural killer cell treatment	✖	✖	✖	✖	● (I/II)
varlitinib + chemotherapy	✖	✖	✖	✖	● (I/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	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
ado-trastuzumab emtansine + atezolizumab, ado-trastuzumab emtansine + atezolizumab + pertuzumab + trastuzumab + chemotherapy, atezolizumab + pertuzumab + trastuzumab, atezolizumab + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I)
ado-trastuzumab emtansine + palbociclib	✖	✖	✖	✖	● (I)
allitinib + chemotherapy	✖	✖	✖	✖	● (I)
alpelisib + LJM-716 + trastuzumab	✖	✖	✖	✖	● (I)
ARX-788	✖	✖	✖	✖	● (I)
buparlisib + lapatinib + chemotherapy, buparlisib + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I)
dacomitinib + gedatolisib	✖	✖	✖	✖	● (I)
durvalumab + trastuzumab	✖	✖	✖	✖	● (I)
everolimus + trastuzumab + letrozole	✖	✖	✖	✖	● (I)
FS-102	✖	✖	✖	✖	● (I)
KTN-3379, KTN-3379 + trastuzumab	✖	✖	✖	✖	● (I)
lapatinib + trastuzumab, pertuzumab, pertuzumab + trastuzumab, trastuzumab	✖	✖	✖	✖	● (I)
MEDI-4276	✖	✖	✖	✖	● (I)
MSC-2363318A	✖	✖	✖	✖	● (I)
neratinib + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I)
pirotinib	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)
pyrotinib + chemotherapy	✖	✖	✖	✖	● (I)

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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	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
RC-48	✖	✖	✖	✖	● (I)
SGN-LIV1A + trastuzumab	✖	✖	✖	✖	● (I)
SYD-985	✖	✖	✖	✖	● (I)

CCND1 amplification

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
palbociclib	✖	✖	✖	✖	● (II)
ribociclib	✖	✖	✖	✖	● (II)

TP53 p.(K132N) c.396G>T

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (II)
MK-1775 + olaparib	✖	✖	✖	✖	● (II)
olaparib + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab + hormone therapy + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + letrozole + chemotherapy + radiation therapy + surgical intervention	✖	✖	✖	✖	● (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

TP53 p.(K132N) c.396G>T (continued)

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
ixazomib + vorinostat	✖	✖	✖	✖	● (I)
MK-1775	✖	✖	✖	✖	● (I)
pembrolizumab + p53MVA	✖	✖	✖	✖	● (I)
SGT-53, SGT-53 + chemotherapy	✖	✖	✖	✖	● (I)

ETV6-NTRK3 fusion

Relevant Therapy	EMA	US-FDA	ESMO	US-NCCN	Global Clinical Trials*
entrectinib	✖	✖	✖	✖	● (II)
LOXO-101	✖	✖	✖	✖	● (II)
DS-6051b	✖	✖	✖	✖	● (I)
PLX-7486, PLX-7486 + chemotherapy	✖	✖	✖	✖	● (I)
sitravatinib	✖	✖	✖	✖	● (I)

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Current EMA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

EMA information is current as of 2016-10-03. For the most up-to-date information, search www.ema.europa.eu/ema.

ERBB2 amplification

◑ trastuzumab, trastuzumab + aromatase inhibitor, trastuzumab + capecitabine, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + docetaxel, trastuzumab + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2016-10-12 **Variant class:** ERBB2 amplification

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000278/WC500074922.pdf

◑ trastuzumab, trastuzumab + aromatase inhibitor, trastuzumab + capecitabine, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + docetaxel, trastuzumab + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2016-10-12 **Variant class:** ERBB2 overexpression

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000278/WC500074922.pdf

● ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2016-05-19 **Variant class:** ERBB2 amplification

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002389/WC500158593.pdf

● ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2016-05-19 **Variant class:** ERBB2 overexpression

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002389/WC500158593.pdf

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ERBB2 amplification (continued)

lapatinib + aromatase inhibitor

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 amplification

Other criteria: ER positive, PR positive

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

lapatinib + aromatase inhibitor

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

lapatinib + capecitabine

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 amplification

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

lapatinib + capecitabine

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 overexpression

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

lapatinib + trastuzumab

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 amplification

Other criteria: ER negative, PR negative

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

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ERBB2 amplification (continued)

lapatinib + trastuzumab

Cancer type: Breast Cancer **Label as of:** 2015-08-11 **Variant class:** ERBB2 overexpression

Other criteria: ER negative, PR negative

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000795/WC500044957.pdf

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2016-05-19 **Variant class:** ERBB2 amplification

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002547/WC500140980.pdf

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2016-05-19 **Variant class:** ERBB2 overexpression

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002547/WC500140980.pdf

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Current US-FDA Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-FDA information is current as of 2016-10-03. For the most up-to-date information, search www.fda.gov.

ERBB2 amplification

◑ trastuzumab

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2016-03-17 **Variant class:** ERBB2 amplification

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.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103792s5330lbl.pdf

◑ trastuzumab

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2016-03-17 **Variant class:** 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.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103792s5330lbl.pdf

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ERBB2 amplification (continued)

ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2016-07-25 **Variant class:** 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:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125427s096lbl.pdf

ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2016-07-25 **Variant class:** ERBB2 overexpression

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:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125427s096lbl.pdf

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.

ERBB2 amplification (continued)

lapatinib + capecitabine

Cancer type: Breast Cancer **Label as of:** 2015-03-31 **Variant class:** ERBB2 overexpression

Indications and usage:

TYKERB®, a kinase inhibitor, is 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:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022059s020lbl.pdf

lapatinib + letrozole

Cancer type: Breast Cancer **Label as of:** 2015-03-31 **Variant class:** ERBB2 overexpression

Other criteria: ER positive, PR positive

Indications and usage:

TYKERB®, a kinase inhibitor, is 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:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022059s020lbl.pdf

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.

ERBB2 amplification (continued)

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2016-03-22 **Variant class:** ERBB2 amplification

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 docetaxel 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. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival.

Limitations of Use:

- The safety of PERJETA® as part of a doxorubicin-containing regimen has not been established.
- The safety of PERJETA® administered for greater than 6 cycles for early breast cancer has not been established.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125409s109lbl.pdf

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2016-03-22 **Variant class:** 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 docetaxel 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. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival.

Limitations of Use:

- The safety of PERJETA® as part of a doxorubicin-containing regimen has not been established.
- The safety of PERJETA® administered for greater than 6 cycles for early breast cancer has not been established.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125409s109lbl.pdf

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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Current ESMO Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

ESMO information is current as of 2016-09-07. For the most up-to-date information, search www.esmo.org.

ERBB2 amplification

● trastuzumab + chemotherapy

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Primary breast cancer (Not specified)

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

Other criteria: ER positive

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Not specified

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

Other criteria: ER negative

ESMO Recommendation category: IV, B

Population segment (Line of therapy):
- Not specified

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

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.

ERBB2 amplification (continued)

ado-trastuzumab emtansine

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Progression after trastuzumab based therapy (Second-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2014) doi: 10.1093/annonc/mdu385 and The Breast 2014, doi: 10.1016/j.breast.2014.08.009.]

pertuzumab + trastuzumab + chemotherapy

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Previously untreated metastatic breast cancer (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2014) doi: 10.1093/annonc/mdu385 and The Breast 2014, doi: 10.1016/j.breast.2014.08.009.]

trastuzumab + chemotherapy

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Metastatic breast cancer previously treated in the adjuvant setting (First-line therapy)
- Metastatic breast cancer untreated with trastuzumab (First-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2014) doi: 10.1093/annonc/mdu385 and The Breast 2014, doi: 10.1016/j.breast.2014.08.009.]

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.

ERBB2 amplification (continued)

lapatinib + trastuzumab

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

ESMO Recommendation category: I, B

Population segment (Line of therapy):
- Progression on trastuzumab (Not specified)

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2014) doi: 10.1093/annonc/mdu385 and The Breast 2014, doi: 10.1016/j.breast.2014.08.009.]

pertuzumab

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

ESMO Recommendation category: II, C

Population segment (Line of therapy):
- Metastatic breast cancer previously untreated with pertuzumab (After first-line therapy)

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2014) doi: 10.1093/annonc/mdu385 and The Breast 2014, doi: 10.1016/j.breast.2014.08.009.]

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Current US-NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated

US-NCCN information is current as of 2016-09-07. 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

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

● trastuzumab + chemotherapy

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

Other criteria: ER negative and/or PR negative

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Tumors >1cm (Not specified)
- One or more > 2mm ipsilateral axillary lymph node metastases (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

● trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Node positive, Ductal, Lobular, Mixed, Metaplasic tumors greater than 1 mm to one or more ipsilateral axillary lymph node (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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)

ado-trastuzumab emtansine

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

hormone therapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN0) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

lapatinib + capecitabine

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

lapatinib + trastuzumab

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + chemotherapy

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

Other criteria: ER negative and PR negative, ER positive and/or PR positive

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Did not receive pertuzumab as part of neoadjuvant therapy (Neoadjuvant/adjuvant therapy)
- Disease progression after treatment with trastuzumab-based therapy without pertuzumab (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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pertuzumab + trastuzumab + paclitaxel

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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trastuzumab + capecitabine

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)
- Metastatic breast cancer previously treated with trastuzumab-based regimen (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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ERBB2 amplification (continued)

trastuzumab + carboplatin + paclitaxel

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + chemotherapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN1mi) (Not specified)
- Recurrent or stage IV, Endocrine refractory (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + chemotherapy

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

Other criteria: ER negative and/or PR negative

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or stage IV, Endocrine refractory (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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ERBB2 amplification (continued)

trastuzumab + docetaxel

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + hormone therapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors 0.6-1.0 cm (pT1, PT2, pT3 and pN1mi) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors 0.6-1.0 cm (pT1, PT2, pT3 and pN1mi) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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ERBB2 amplification (continued)

trastuzumab + paclitaxel

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Low-risk stage I disease (Neoadjuvant/adjuvant therapy)
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + vinorelbine

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

US-NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Metastatic breast cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

trastuzumab + hormone therapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN0) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

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)

● trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive and/or PR positive

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplasic tumors less than or equal to 0.5cm (pT1, PT2, pT3 and pN0) (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2016]

○ trastuzumab + cisplatin + fluoropyrimidine

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

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2016]

○ trastuzumab + cisplatin + fluoropyrimidine

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

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2016]

○ trastuzumab + cisplatin + fluoropyrimidine

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

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Locally advanced or metastatic gastric cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2016]

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)

trastuzumab + cisplatin + fluoropyrimidine

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

US-NCCN Recommendation category: 1

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2016]

trastuzumab + chemotherapy (other)

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2016]

trastuzumab + chemotherapy (other)

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2016]

trastuzumab + chemotherapy (other)

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Locally advanced or metastatic gastric cancer (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2016]

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.

ERBB2 amplification (continued)

trastuzumab + chemotherapy (other)

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

US-NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Locally advanced or metastatic adenocarcinoma (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2016]

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.

Current Global Clinical Trials Information

Global Clinical Trials information is current as of 2016-09-01. 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 identifiers: TrialTroveID-196620, UMIN000012210

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

Phase: IV

Therapy: pertuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
A Post-Marketing Clinical Study to Evaluate the Efficacy and Safety of Pertuzumab Combined with Trastuzumab and Docetaxel as First Line Treatment in HER2- Positive Inoperable or Recurrent Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: COMACHI, JapicCTI-132321, TrialTroveID-197276

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

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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 identifiers: TrialTroveID-198130, UMIN000012444

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

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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.

ERBB2 amplification (continued)

NCT02419742
An Indian Multicentric Open Label Prospective Phase IV Study to Evaluate Safety & Efficacy of Trastuzumab in HER2 Positive, and High Risk Node Negative Breast Cancer as Part of a Treatment Regimen Consisting of Doxorubicin, Cyclophosphamide, With Either Docetaxel or Paclitaxel (ACTH) or Docetaxel and Carboplatin (TCH)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: CTRI/2015/05/005789, ML28714, TrialTroveID-255808

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

Phase: IV

Therapy: trastuzumab + chemotherapy

Country: India

NCT02305641
Post-marketing surveillance of kadcyla in breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: ML29629, TrialTroveID-222026

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

Phase: IV

Therapy: ado-trastuzumab emtansine

Country: 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 identifiers: TrialTroveID-215196, UMIN000014750

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

Phase: IV

Therapies: ado-trastuzumab emtansine, trastuzumab

Country: Japan

No NCT ID - see other identifier(s)
Observational study of Pertuzumab,Trastuzumab and taxane combination therapy for patient with pretreated HER2-positive advanced or recurrent breast cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: TrialTroveID-206144, UMIN000013607

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

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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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ERBB2 amplification (continued)

NCT01777958
Noninterventional Study - Advanced HER2-positive Breast Cancer (Metastatic or Locally Recurrent, Inoperable): First-Line Treatment With PERJETA After Adjuvant Herceptin Therapy (HELENA)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: HELENA, ML28750, ML28750 HELENA, NIS HELENA ML28750, TrialTroveID-180579

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

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: Germany

NCT02445586
A Phase IV, Multicenter, Open-Label, Single Arm Study of Pertuzumab (In Combination With Trastuzumab and Docetaxel) In First Line Treatment of Indian Patients With HER2- Positive Advanced (Metastatic or Locally Recurrent) Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: CTRI/2015/05/005766, ML29282, TrialTroveID-257501

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

Phase: IV

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: India

No NCT ID - see other identifier(s)
Trastuzumab-Induced Early Cardiac Dysfunction Assessed by Speckle Tracking Echocardiography: Correlation with Chronic Inflammation and Oxidative Stress Markers

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifier: TrialTroveID-175802

Population segments: (N/A), HER2 positive, Line of therapy N/A

Phase: IV

Therapy: trastuzumab

Country: Italy

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.

ERBB2 amplification (continued)

NCT01808573
A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer Who Have Received Two or More Prior HER2 Directed Regimens in the Metastatic Setting

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 041304, 13-521, 13470, 1378GCC, 14-PPD-4, AAAM2506, AMC 2013-0450, CTMS# 15-2058, EudraCT Number: 2012-004492-38, NALA, NCI-2013-01418, NCRN526, NCRN526 NALA, PUMA NALA, PUMA-NER-1301, REec-2014-0746, TrialTroveID-182199, UKCRN ID: 14707

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

Phase: III

Therapies: lapatinib + chemotherapy, neratinib + chemotherapy

Countries: Argentina, Australia, Austria, Belgium, Brazil, Canada, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Republic of Korea, Russian Federation, Singapore, Spain, Sweden, Switzerland, Taiwan, United Kingdom, United States

US States: AZ, CA, CO, DC, FL, GA, HI, IL, IN, KY, MA, MD, MO, MS, NC, NE, NJ, NY, OH, PA, RI, TN, TX, VT, WV

US Contact: Puma Biotechnology Clinical Operations [424-248-6500; clinicaltrials@pumabiotechnology.com]

NCT01104571
Effect of Perioperative AntiHER-2 Therapy on Early Breast Cancer Study - Biological Phase (EPHOS-B)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: CCR3104, CRUK-08/002, EPHOS-B, EU-21029, EudraCT Number: 2008-005466-30, GSK-ICR-CTSU/2008/10017, ICR-CTSU/2008/10017, ISRCTN15004993, MREC-09/H1208/52, TrialTroveID-106372, UKCRN 5501, UM-CR-CTSU/2008/10017, UM-EPHOS-B

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

Other inclusion criteria: ER positive/negative

Phase: III

Therapies: lapatinib, lapatinib + trastuzumab, trastuzumab

Country: 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.

ERBB2 amplification (continued)

NCT02492711
A Phase III, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 157515, CP-MGAH22-04, EudraCT Number: 2015-000380-13, NCI-2016-00295, REec-2015-1816, S15-00845, SOPHIA, TrialTroveID-222276

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

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

Phase: III

Therapies: margetuximab + chemotherapy, trastuzumab + chemotherapy

Countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Portugal, Republic of Korea, Spain, United Kingdom, United States

US States: AL, AZ, CA, CO, DC, FL, GA, HI, IA, IL, IN, KY, LA, MA, MD, ME, MO, NH, NJ, NY, OH, OK, PA, TN, TX, UT, VA, WA

US Contact: Sutton Edlich [240-552-8082]

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 amplification

Other identifiers: CHEVENDO, D-V, Detect V, DV, EudraCT Number: 2014-002249-22, TrialTroveID-251026

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

Other inclusion criteria: ER positive, PR positive

Phase: III

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

Country: Germany

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.

ERBB2 amplification (continued)

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

Other identifiers: CHEVENDO, D-V, Detect V, DV, EudraCT Number: 2014-002249-22, TrialTroveID-251026

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

Other inclusion criteria: ER positive, PR positive

Phase: III

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

Country: Germany

NCT02402712
A Multicenter, Open-Label, Single-Arm Safety Study Of Herceptin SC In Combination With Perjeta And Docetaxel In Treatment Of Patients With HER2-Positive Advanced Breast Cancer (Metastatic Or Locally Recurrent)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: BO29159, CTBE2015000297, EudraCT Number: 2014-001458-40, MetaPHer, REec-2015-1454, TrialTroveID-253317, UKCRN ID: 18662

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

Phase: III

Therapy: pertuzumab + trastuzumab + chemotherapy

Countries: Belgium, Bulgaria, Canada, France, Germany, Hungary, Italy, Mexico, Poland, Portugal, Spain, United Kingdom

NCT02402712
A Multicenter, Open-Label, Single-Arm Safety Study Of Herceptin SC In Combination With Perjeta And Docetaxel In Treatment Of Patients With HER2-Positive Advanced Breast Cancer (Metastatic Or Locally Recurrent)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: BO29159, CTBE2015000297, EudraCT Number: 2014-001458-40, MetaPHer, REec-2015-1454, TrialTroveID-253317, UKCRN ID: 18662

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

Phase: III

Therapy: pertuzumab + trastuzumab + chemotherapy

Countries: Belgium, Bulgaria, Canada, France, Germany, Hungary, Italy, Mexico, Poland, Portugal, Spain, 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.

ERBB2 amplification (continued)

NCT02125344
A Randomized Phase III Trial Comparing Two Dose-dense, Dose-intensified Approaches (ETC and PM(Cb)) for Neoadjuvant Treatment of Patients With High-risk Early Breast Cancer (GeparOcto)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2014-000619-14, GBG 84, GBG84, GeparOcto, TrialTroveID-208065

Population segments: Anemia, Cancer-related, HER2 negative, HER2 positive, Iron deficiency, Neoadjuvant, Stage II, Stage III, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: III

Therapy: pertuzumab + trastuzumab + chemotherapy + ferric carboxymaltose

Country: 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 Locally Advanced and Metastatic Breast Cancer (Study of Perjeta Re-treatment for Clinical Outcomes) (PRECIOUS)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: JBCRG-M05, PRECIOUS, TrialTroveID-262555, UMIN000018202, UMIN000021514

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

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Country: Japan

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 Locally Advanced and Metastatic Breast Cancer (Study of Perjeta Re-treatment for Clinical Outcomes) (PRECIOUS)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: JBCRG-M05, PRECIOUS, TrialTroveID-262555, UMIN000018202, UMIN000021514

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

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Country: 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.

ERBB2 amplification (continued)

NCT02586025
A Randomized, Multicenter, Double-blind, Placebo-controlled, Phase III Study Evaluating Pertuzumab in Combination With Docetaxel and Trastuzumab as Neoadjuvant Therapy, and Pertuzumab in Combination With Trastuzumab as Adjuvant Therapy Following Surgery and Chemotherapy in Patients With Early-stage or Locally Advanced HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: CTR20150679, , TrialTroveID-266822, YO28762

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

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

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo

Countries: China, Republic of Korea, Taiwan, Thailand

NCT02586025
A Randomized, Multicenter, Double-blind, Placebo-controlled, Phase III Study Evaluating Pertuzumab in Combination With Docetaxel and Trastuzumab as Neoadjuvant Therapy, and Pertuzumab in Combination With Trastuzumab as Adjuvant Therapy Following Surgery and Chemotherapy in Patients With Early-stage or Locally Advanced HER2-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: CTR20150679, , TrialTroveID-266822, YO28762

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

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

Phase: III

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo

Countries: China, Republic of Korea, Taiwan, Thailand

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

Other identifiers: TMH Project-982, TrialTroveID-181718

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

Phase: III

Therapy: trastuzumab

Country: India

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)

NCT01875367
Clinical Trial to Evaluate Patient ´s Preference of Subcutaneous Trastuzumab (SC) Versus Intravenous (IV) Administration in Patients With HER2 Positive Advanced Breast Cancer (ABC) Who Have Received Intravenous Trastuzumab at Least 4 Months and Without Disease Progression

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: ChangHER-SC, EudraCT Number: 2012-004928-38, GEICAM/2012-07, TrialTroveID-188333

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

Phase: III

Therapy: trastuzumab

Country: Spain

NCT02040935
Homerus: A Local Open Label, Multicentre, Phase IIIb Study, Investigating Subcutaneous Trastuzumab Administered At Home With Single Injection Device In Patients With HER2-Positive Early Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2013-000829-31, HOMERUS, ML28878, NL44120.056.13, TrialTroveID-200740

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

Phase: III

Therapy: trastuzumab

Country: Netherlands

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 amplification

Other identifiers: SYSUCC-002, TrialTroveID-194434

Population segments: First line, HER2 positive, Stage IV

Other inclusion criteria: ER positive and/or PR positive

Phase: III

Therapies: trastuzumab + chemotherapy, trastuzumab + hormone therapy

Country: 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.

ERBB2 amplification (continued)

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

Other identifiers: SYSUCC-002, TrialTroveID-194434

Population segments: First line, HER2 positive, Stage IV

Other inclusion criteria: ER positive and/or PR positive

Phase: III

Therapies: trastuzumab + chemotherapy, trastuzumab + hormone therapy

Country: China

NCT00629278
SHORT-HER: Multicentric Randomised Phase III Trial of 2 Different Adjuvant Chemotherapy Regimens Plus 3 Vs 12 Months of Trastuzumab In Her2 Positive Breast Cancer Patients.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: AOUMODENA-SHORT-HER, EU-20825, EudraCT Number: 2007-004326-25, FARM62MC97, SHORT-HER, Short-HER, Shorther 2007-004326-25, TrialTroveID-085109

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

Other inclusion criteria: ER positive, PR positive

Phase: III

Therapy: trastuzumab + hormone therapy + chemotherapy

Country: Italy

NCT01702571
A Two-cohort, Open-label, Multicenter Study of Trastuzumab Emtansine (T-DM1) in HER2-positive Locally Advanced or Metastatic Breast Cancer Patients Who Have Received Prior Anti-HER2 and Chemotherapy-based Treatment.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: CTR20150630, EudraCT Number: 2012-001628-37, IRAS ID: 109645, KAMILLA, McG 1302, MO28231, NCRN463, NL42030.031.12, PER-130-12, RECF1930, TrialTroveID-175473, UKCRN: 12866

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

Phase: III

Therapy: ado-trastuzumab emtansine

Countries: China, Thailand

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)

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, TrialTroveID-159300, WSG-AM06

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

Phase: III

Therapies: aromatase inhibitor, tamoxifen

Country: Germany

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, TrialTroveID-243494

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

Phase: II/III

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

Country: Sweden

NCT02213744
A Randomized, Multicenter, Open Label Study of MM-302 Plus Trastuzumab vs. Chemotherapy of Physician`s Choice Plus Trastuzumab in Anthracycline Naive Patients With Locally Advanced/ Metastatic HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 107006, 14-533, 2014-0670, 250781, 6894, 9785-CL-1121, EudraCT Number: 2014-003159-73, HERMIONE, MM-302-02-02-03, OSU-15168, REec-2015-1599, S14-01346, TrialTroveID-250781, VICCBRE1480

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

Phase: II/III

Therapy: trastuzumab + chemotherapy

Countries: Austria, Belgium, Canada, France, Germany, Italy, Spain, United States

US States: AZ, CA, CO, CT, DC, FL, GA, IA, IL, IN, MA, MD, MI, MN, MO, NC, NJ, NY, OH, OR, PA, SC, TN, TX, UT, VA, WA

US Contact: Dr. Istvan Molnar [IMolnar@merrimack.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.

ERBB2 amplification (continued)

NCT02308020
A Phase II Study of Abemaciclib in Patients With Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 15-058, 15.1047, 15450, 18093, EudraCT Number: 2014-004010-28, I3Y-MC-JPBO, REec-2015-1963, Study JPBO, TrialTroveID-222182

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

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapy: abemaciclib

Countries: Australia, Austria, Belgium, Canada, France, Israel, Italy, New Zealand, Spain, United States

US States: CA, CO, DC, FL, GA, HI, KY, MA, MI, MO, NC, NM, NY, OR, PA, TN, TX

US Contact: Eli Lilly and Company [877-285-4559]

NCT02308020
A Phase II Study of Abemaciclib in Patients With Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 15-058, 15.1047, 15450, 18093, EudraCT Number: 2014-004010-28, I3Y-MC-JPBO, REec-2015-1963, Study JPBO, TrialTroveID-222182

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

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapy: abemaciclib

Countries: Australia, Austria, Belgium, Canada, France, Israel, Italy, New Zealand, Spain, United States

US States: CA, CO, DC, FL, GA, HI, KY, MA, MI, MO, NC, NM, NY, OR, PA, TN, TX

US Contact: Eli Lilly and Company [877-285-4559]

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.

ERBB2 amplification (continued)

NCT02414646
Adjuvant Ado-Trastuzumab Emtansine (T-DM1) for Older Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 15-019, NCI-2015-00468, RU011301I, TrialTroveID-255420

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

Other inclusion criteria: ER negative and PR negative

Phase: II

Therapy: ado-trastuzumab emtansine

Country: United States

US States: CA, IL, KS, MA, MI, MN, NC, NY, OH, VA

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

NCT02414646
Adjuvant Ado-Trastuzumab Emtansine (T-DM1) for Older Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 15-019, NCI-2015-00468, RU011301I, TrialTroveID-255420

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

Other inclusion criteria: ER negative and PR negative

Phase: II

Therapy: ado-trastuzumab emtansine

Country: United States

US States: CA, IL, KS, MA, MI, MN, NC, NY, OH, VA

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

NCT02073487
Randomized Open Label PhII Trial of Neoadjuvant Trastuzumab Emtansine (Te) in Combination w/Lapatinib (L) Followed by Abraxane (A) Compared w/ Trastuzumab Plus Pertuzumab Followed by Paclitaxel in Her 2 Neu Over-Expressed Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 1013-0164, TEAL, TrialTroveID-203714

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

Phase: II

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

Country: United States

US State: TX

US Contact: Houston Methodist Cancer Center [713-441-0629; ccresearch@houstonmethodist.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.

ERBB2 amplification (continued)

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

Other identifiers: 14-409, TrialTroveID-249435

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

Phase: II

Therapy: ado-trastuzumab emtansine + pertuzumab

Country: United States

US States: MA, TN

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

No NCT ID - see other identifier(s)
A randomized, multicenter, phase II trial comparing neo-adjuvant therapy using pertuzumab and trastuzumab emtansine based on the dual HER2 blockade in patients with operable HER2-positive primary breast cancer(Neo-peaks study)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: JBCRG-20, Neo-peaks study, TrialTroveID-214050, UMIN000014649

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

Phase: II

Therapy: ado-trastuzumab emtansine + pertuzumab + chemotherapy

Country: Japan

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 amplification

Other identifiers: 097517, 202755051910, 7518, ACRIN 6698 (Substudy), ACRIN-6698, CRC 10016, I-SPY 2 TRIAL, I-SPY2 TRIAL, NCI-2015-00014, STU 052011-089, TrialTroveID-120942, UPCC 16113

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

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

Phase: II

Therapies: ado-trastuzumab emtansine + pertuzumab, ganetespib, ganitumab + metformin hydrochloride, MK-2206, MK-2206 + trastuzumab, pembrolizumab + chemotherapy, pertuzumab + trastuzumab, talazoparib + chemotherapy, trastuzumab + chemotherapy, trastuzumab + trebananib, trebananib

Country: United States

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

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.

ERBB2 amplification (continued)

NCT01853748
A Randomized Phase II Study of Trastuzumab Emtansine (T-DM1) vs. Paclitaxel in Combination With Trastuzumab for Stage I HER2-Positive Breast Cancer (ATEMPT Trial)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 00048638, 13-048, 137522, 14-221, 2013-0957, ATEMPT Trial, DFCI 13-048, ML28160, NCI-2013-01818, TBCRC 033, TrialTroveID-186443

Population segments: Adjuvant, HER2 positive, Stage I

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

Phase: II

Therapies: ado-trastuzumab emtansine, trastuzumab + chemotherapy

Country: United States

US States: AL, CA, CT, DC, FL, ID, IL, IN, MA, MD, ME, MI, MN, MO, NC, NH, NJ, NY, OH, PA, TN, TX, WA

US Contact: Dr. Sara Tolaney [617-632-2335; stolaney@partners.org]

NCT01853748
A Randomized Phase II Study of Trastuzumab Emtansine (T-DM1) vs. Paclitaxel in Combination With Trastuzumab for Stage I HER2-Positive Breast Cancer (ATEMPT Trial)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 00048638, 13-048, 137522, 14-221, 2013-0957, ATEMPT Trial, DFCI 13-048, ML28160, NCI-2013-01818, TBCRC 033, TrialTroveID-186443

Population segments: Adjuvant, HER2 positive, Stage I

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

Phase: II

Therapies: ado-trastuzumab emtansine, trastuzumab + chemotherapy

Country: United States

US States: AL, CA, CT, DC, FL, ID, IL, IN, MA, MD, ME, MI, MN, MO, NC, NH, NJ, NY, OH, PA, TN, TX, WA

US Contact: Dr. Sara Tolaney [617-632-2335; stolaney@partners.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.

ERBB2 amplification (continued)

NCT02614794
Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: HER2CLIMB, , ONT-380-206, TrialTroveID-258510

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

Phase: II

Therapies: ARRY-380 + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo

Countries: Canada, United States

US States: AL, CO, CT, FL, GA, IL, MA, MI, NC, NE, NJ, NY, OR, PA, TN, TX, WA, WI

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

NCT02614794
Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: HER2CLIMB, , ONT-380-206, TrialTroveID-258510

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

Phase: II

Therapies: ARRY-380 + trastuzumab + chemotherapy, trastuzumab + chemotherapy + placebo

Countries: Canada, United States

US States: AL, CO, CT, FL, GA, IL, MA, MI, NC, NE, NJ, NY, OR, PA, TN, TX, WA, WI

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

NCT01690325
Molecular Imaging for Response Assessment of Bevacizumab + Docetaxel as Neoadjuvant Chemotherapy in Primary Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2009-013331-37, GALADON, TrialTroveID-154138, WSG-AM05

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

Phase: II

Therapies: bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Country: Germany

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)

NCT02000882
Phase II Multicenter Single-arm Study of BKM120 Plus Capecitabine for Breast Cancer Patients With Brain Metastases

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 11025, CBKM120ZUS39T, Novartis CBKM120ZUS39T, TrialTroveID-198421, USO 11025

Population segments: CNS mets, HER2 negative, HER2 positive, Second line or greater/ Refractory/Relapsed, Stage IV, Triple receptor negative

Phase: II

Therapy: buparlisib + chemotherapy

Country: United States

US State: TX

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

NCT02000882
Phase II Multicenter Single-arm Study of BKM120 Plus Capecitabine for Breast Cancer Patients With Brain Metastases

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 11025, CBKM120ZUS39T, Novartis CBKM120ZUS39T, TrialTroveID-198421, USO 11025

Population segments: CNS mets, HER2 negative, HER2 positive, Second line or greater/ Refractory/Relapsed, Stage IV, Triple receptor negative

Phase: II

Therapy: buparlisib + chemotherapy

Country: United States

US State: TX

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

NCT02260531
A Phase II Study of Cabozantinib Alone or in Combination With Trastuzumab in Breast Cancer Patients With Brain Metastases

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 14-359, NCI-2014-02365, TrialTroveID-218514

Population segments: CNS mets, HER2 negative, HER2 positive, Second line or greater/ Refractory/Relapsed, Stage IV, Triple receptor negative

Phase: II

Therapy: cabozantinib + trastuzumab

Country: United States

US State: MA

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.

ERBB2 amplification (continued)

NCT01283789
Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 12418, 2010-IIT-Novartis-RAD-001, HSC 12418, NCI-2016-00027,, TrialTroveID-141401

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

Phase: II

Therapy: everolimus + lapatinib

Country: United States

US State: KS

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

NCT01283789
Phase II Trial of Lapatinib and RAD-001 for HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 12418, 2010-IIT-Novartis-RAD-001, HSC 12418, NCI-2016-00027,, TrialTroveID-141401

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

Phase: II

Therapy: everolimus + lapatinib

Country: United States

US State: KS

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

NCT01305941
A Phase II Study Evaluating The Efficacy And Tolerability Of Everolimus (RAD001) In Combination With Trastuzumab And Vinorelbine In The Treatment Of Progressive HER2-Positive Breast Cancer Brain Metastases

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 11-0242, LCCC 1025, LCCC1025, TrialTroveID-143197, VICCBRE1304

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

Phase: II

Therapy: everolimus + trastuzumab + chemotherapy

Country: United States

US States: AL, NC, TN

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)

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

Other identifiers: NCCCTS-11-583, TrialTroveID-177908

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

Phase: II

Therapy: lapatinib + chemotherapy

Country: Republic of Korea

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 overexpression

Other identifiers: NCCCTS-11-583, TrialTroveID-177908

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

Phase: II

Therapy: lapatinib + chemotherapy

Country: Republic of Korea

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

Other identifiers: 20140570, KROG1103, NCI-2012-01977, RTOG 1119, RTOG-1119, TrialTroveID-169961

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

Phase: II

Therapy: lapatinib + radiation therapy

Countries: Canada, Republic of Korea, United States

US States: AL, AZ, CT, FL, GA, IA, ID, IL, IN, KS, LA, MI, MN, MO, MS, NJ, NY, OH, PA, VA, WI, WV

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)

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 amplification

Other identifiers: 20140570, KROG1103, NCI-2012-01977, RTOG 1119, RTOG-1119, TrialTroveID-169961

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

Phase: II

Therapy: lapatinib + radiation therapy

Countries: Canada, Republic of Korea, United States

US States: AL, AZ, CT, FL, GA, IA, ID, IL, IN, KS, LA, MI, MN, MO, MS, NJ, NY, OH, PA, VA, WI, WV

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

NCT01873833
Phase II Trial of Metronomic Capecitabine and Cyclophosphamide With Lapatinib and Ttrastuzumab in Patients With HER2 Positive Metastatic Breast Cancer Who Have Progressed on a Previous Trastuzumab-Based Regimen

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 1B-12-10, NCI-2013-01086, TrialTroveID-188235

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

Phase: II

Therapy: lapatinib + trastuzumab + chemotherapy

Country: United States

US State: CA

US Contact: USC Norris Comprehensive Cancer Center Recruiting - Kristy A. Watkins [323-865-0452; Kristy.Watkins@med.usc.edu]

NCT01891357
A Multicenter Site, Open Label, Phase II Trial to Validate Predictive Markers for the Response Evaluation of a Combined Chemo-immunotherapy in Patients With HER2-positive Early Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2012-003679-21, Neo-PREDICT-HER2, TrialTroveID-189633, WSG-AM07, WSG-AM07 (Neo-PREDICT-HER2)

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

Phase: II

Therapy: lapatinib + trastuzumab + chemotherapy

Country: Germany

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.

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

Other identifiers: EudraCT Number: 2013-005044-29, GIM12-TYPHER, TrialTroveID-216708

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

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapy: lapatinib + trastuzumab + fulvestrant

Country: Italy

NCT02213042
An Open-Label, Phase II, Study to Evaluate Biomarkers Associated with Response to Subsequent Therapies in Subjects with HER2-Positive Metastatic Breast Cancer Receiving Treatment with Trastuzumab in Combination with Lapatinib or Chemotherapy (EGF117165)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 117165, DB in 3L MBC, EGF117165, EudraCT Number: 2014-001220-30, REec-2014-1065, TrialTroveID-214435

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

Phase: II

Therapies: lapatinib + trastuzumab, trastuzumab + chemotherapy

Countries: Argentina, Austria, Brazil, Hong Kong, Italy, Mexico, Peru, Philippines, Russian Federation, Spain, Thailand, United States

US States: MA, TX

US Contact: Novartis Pharmaceuticals [888-669-6682]

NCT02213042
An Open-Label, Phase II, Study to Evaluate Biomarkers Associated with Response to Subsequent Therapies in Subjects with HER2-Positive Metastatic Breast Cancer Receiving Treatment with Trastuzumab in Combination with Lapatinib or Chemotherapy (EGF117165)

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 117165, DB in 3L MBC, EGF117165, EudraCT Number: 2014-001220-30, REec-2014-1065, TrialTroveID-214435

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

Phase: II

Therapies: lapatinib + trastuzumab, trastuzumab + chemotherapy

Countries: Argentina, Austria, Brazil, Hong Kong, Italy, Mexico, Peru, Philippines, Russian Federation, Spain, Thailand, United States

US States: MA, TX

US Contact: Novartis Pharmaceuticals [888-669-6682]

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)

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

Other identifiers: EudraCT Number: 2013-005044-29, GIM12-TYPHER, TrialTroveID-216708

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

Phase: II

Therapies: lapatinib + trastuzumab, trastuzumab + chemotherapy

Country: Italy

NCT02297698
Phase II Trial of Combination Immunotherapy with Nelipepimut-S + GM-CSF (NeuVax) and Trastuzumab in High-risk HER2+ Breast Cancer Patients

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 2014-0443, TrialTroveID-207925

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

Phase: II

Therapy: nelipepimut-S + sargramostim + trastuzumab

Country: United States

US States: CA, CO, DC, FL, IL, IN, MD, NM, NY, TX, VA, WA, WI

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

NCT01494662
A Phase II Trial of HKI-272 (Neratinib) for Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer and Brain Metastases

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 11-344, TBCRC 022, TrialTroveID-158829, UMCC 2012.034

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

Phase: II

Therapies: neratinib, neratinib + chemotherapy, neratinib + surgical intervention, neratinib + trastuzumab

Country: United States

US States: CA, DC, MA, MD, MI, NC, PA, TX

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.

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 amplification

Other identifiers: EudraCT Number: 2014-005006-38, PATRICIA, REec-2015-1446, SOLTI-1303, TrialTroveID-256931

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

Other inclusion criteria: ER negative, PR positive

Phase: II

Therapy: palbociclib + trastuzumab

Country: 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

Other identifiers: EudraCT Number: 2014-005006-38, PATRICIA, REec-2015-1446, SOLTI-1303, TrialTroveID-256931

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

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapies: palbociclib + trastuzumab, palbociclib + trastuzumab + letrozole

Country: 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, TrialTroveID-279079

Population segments: CNS mets, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Stage IV, Triple receptor negative

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapies: palbociclib, palbociclib + trastuzumab

Country: United States

US State: IL

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

ERBB2 amplification (continued)

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, TrialTroveID-275562, UMIN000021585

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: Japan

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, TrialTroveID-209955, UMIN000014107

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
A Study of Eribulin in Combination with Trastuzumab and Pertuzumab for Advanced or Recurrent Human Epidermal Growth Factor Receptor 2 (HER2)-positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: JBCRG-M03, TrialTroveID-196752, UMIN000012232

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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 identifiers: TrialTroveID-196596, UMIN000012208

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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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ERBB2 amplification (continued)

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

Other identifiers: SBCCSG-33, TrialTroveID-195194, UMIN000012030

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: 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, TrialTroveID-198231, UMIN000012452

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: Japan

NCT01730833
Phase II Prospective Open Label Single Arm Study of Pertuzumab, Trastuzumab, and Nab-Paclitaxel in Patients With HER-2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 12147, NCI-2012-02371, TrialTroveID-177942

Population segments: First line, HER2 positive, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: CA

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)

NCT01855828
Single Arm, Neoadjuvant, Phase II Trial of Pertuzumab and Trastuzumab Administered Concomitantly With Weekly Paclitaxel and FEC for Clinical Stage I-II HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 1305012136, ML28772, NCI-2015-02018, TrialTroveID-186539

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: CT

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

NCT01855828
Single Arm, Neoadjuvant, Phase II Trial of Pertuzumab and Trastuzumab Administered Concomitantly With Weekly Paclitaxel and FEC for Clinical Stage I-II HER2-Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 1305012136, ML28772, NCI-2015-02018, TrialTroveID-186539

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: CT

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

NCT02252887
Phase II Study of Gemcitabine, Trastuzumab, and Pertuzumab in the Treatment of Metastatic HER2-Positive Breast Cancer After Prior Trastuzumab/ Pertuzumab- or Pertuzumab-Based Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 14-124, NCI-2015-00078, TrialTroveID-217944

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US States: CT, NJ, NY

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)

NCT02252887
Phase II Study of Gemcitabine, Trastuzumab, and Pertuzumab in the Treatment of Metastatic HER2-Positive Breast Cancer After Prior Trastuzumab/Pertuzumab- or Pertuzumab-Based Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 14-124, NCI-2015-00078, TrialTroveID-217944

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US States: CT, NJ, NY

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

No NCT ID - see other identifier(s)
Multicenter Phase II tiral of Combination Therapy Using Abraxane and Trastuzumab +/-Pertuzumab For HER2-Positive Locally Advanced or Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTroveID-158358, UMIN000006838

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

Phase: II

Therapies: pertuzumab + trastuzumab + chemotherapy, trastuzumab + chemotherapy

Country: Japan

NCT02345772
Neoadjuvant Hormonal Therapy Combined With Chemoimmunotherapy (Taxotere, Trastuzumab and Pertuzumab) in Patients With HER2-positive and ER-Positive Breast Cancer (NeoHTTP Study)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: NeoHTTP, TrialTroveID-251024, WIRB 20140462

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

Phase: II

Therapy: pertuzumab + trastuzumab + fulvestrant + chemotherapy

Country: United States

US State: AZ

US Contact: Research Nurse Coordinator [623-207-3000; Westerntrials@ctca-hope.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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ERBB2 amplification (continued)

NCT02411344
PERtuzumab-trastuzumab Plus lEetrozoLe In Endocrine Sensitive Breast Cancer: a Phase II neoAdjuvant Study

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: AS.T.R.O.BC01-13, AS.TRO BC01-13, EudraCT Number: 2013-002662-40, PER-ELISA, TrialTroveID-255149

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

Other inclusion criteria: ER positive and/or PR positive

Phase: II

Therapy: pertuzumab + trastuzumab + letrozole

Country: Italy

NCT02659514
A Phase 2 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 amplification

Other identifiers: NCI-2016-00645, SPI-POZ-201, TrialTroveID-253276

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

Phase: II

Therapy: poziotinib

Country: United States

US States: CA, NY

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

No NCT ID - see other identifier(s)
Phase II Study of Neoadjuvant Chemotherapy with Docetaxel, Carboplatin, and Trastuzumab for Operable Her2-positive Breast Cancer Patients.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: KBC-SG 1201, TrialTroveID-196870, UMIN000012256

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

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ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Safety study of q3w S-1 in combination with q3w trastuzumab for HER2 positive metastatic breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTroveID-189282, UMIN000011049

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
Phase II study of neoadjuvant chemotherapy with the nab Paclitaxel And Trastuzumab followed by FEC for the HER2-positive resectable primary breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTroveID-171392, UMIN000008465

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
Multicenter phase II trial of neoadjuvant chemotherapy with trastuzumab, docetaxel, and carboplatin for HER2-positive operable breast cancer: KBOG-1204 trial

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: KBOG-1204, TrialTroveID-183134, UMIN000010227

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
The safety and efficacy trial of nab-paclitaxel and trastuzumab as neoadjuvant chemotherapy for HER2-positive breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTrove-ID200533, UMIN000012798

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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.

ERBB2 amplification (continued)

No NCT ID - see other identifier(s)
Phase II Study Of Neoadjuvant Nab-paclitaxel And Trastuzumab For ER Negative And HER2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTroveID-268560, UMIN000019616

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

Other inclusion criteria: ER negative

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
A feasibility study of sequential Anthracycline-based regimen and Nab-Paclitaxel / Trastuzumab followed by Trastuzumab as postoperative adjuvant chemotherapy for Her 2 positive breast cancer (SBCCSG-22)

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: SBCCSG-22, TrialTroveID-164135, UMIN000006085

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

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 identifiers: TrialTroveID-152411, UMIN000005210

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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, TrialTroveID-186732, UMIN000010761

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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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ERBB2 amplification (continued)

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, TrialTroveID-110436

Population segments: First line, HER2 positive, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Italy

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, TrialTroveID-172496, UMIN000008647

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

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

Other identifiers: BJ307-Neo02, TrialTroveID-262283

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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 amplification

Other identifiers: OMC BC-04, TrialTroveID-267504

Population segments: (N/A), HER2 positive, Neoadjuvant

Other inclusion criteria: ER negative

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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.

ERBB2 amplification (continued)

NCT02488564
Clinical and Traslational Phase II Study of Liposomal Doxorubicin plus Docetaxel and Trastuzumab with Metformin as Primary Systemic Therapy for Operable and Locally Advanced Recombinant Human ErbB-2 HER2 Positive Breast Cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2014-002602-20, IRST174.09, met-HEReMYTA, TrialTroveID-253444

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

Phase: II

Therapy: trastuzumab + chemotherapy + metformin hydrochloride

Country: Italy

No NCT ID - see other identifier(s)
Ki67 index guided selection of preoperative chemotherapy for HER2 positive breast cancer - a randomized phase II trial.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: TrialTroveID-160851, UMIN000007074

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

Phase: II

Therapy: trastuzumab + chemotherapy + surgical intervention

Country: Japan

NCT02091960
A Phase II, Multicenter, Open-label Study to Assess the Efficacy and Safety of Enzalutamide with Trastuzumab in Subjects with HER2+ AR+ Metastatic or Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 1B-14-4, 9785-CL-1121, BRE -240, CTBE2015000280, DFCI:14-288, EudraCT Number: 2013-000093-29, ICORG 13-11, IND: 113,339, NCI-2014-01012, REec-2014-1010, TrialTroveID-205159, VICCBRE1430

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

Other inclusion criteria: AR expression, ER negative, PR negative

Phase: II

Therapy: trastuzumab + enzalutamide

Countries: Belgium, Canada, Italy, Spain, United Kingdom, United States

US States: CA, CO, FL, IL, IN, MA, MO, OH, PA, TN, TX

US Contact: Astellas Pharma Global Development [800-888-7704 ext 5473; clintrials.info@us.astellas.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.

ERBB2 amplification (continued)

NCT02091960
A Phase II, Multicenter, Open-label Study to Assess the Efficacy and Safety of Enzalutamide with Trastuzumab in Subjects with HER2+ AR+ Metastatic or Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 1B-14-4, 9785-CL-1121, BRE -240, CTBE2015000280, DFCI:14-288, EudraCT Number: 2013-000093-29, ICORG 13-11, IND: 113,339, NCI-2014-01012, REec-2014-1010, TrialTroveID-205159, VICCBRE1430

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

Other inclusion criteria: AR expression, ER negative, PR negative

Phase: II

Therapy: trastuzumab + enzalutamide

Countries: Belgium, Canada, Italy, Spain, United Kingdom, United States

US States: CA, CO, FL, IL, IN, MA, MO, OH, PA, TN, TX

US Contact: Astellas Pharma Global Development [800-888-7704 ext 5473; clintrials.info@us.astellas.com]

No NCT ID - see other identifier(s)
Phase II study of preoperative treatment of inflammatory breast cancer with bevacizumab in combination with weekly carboplatin and paclitaxel + or - trastuzumab and metronomic cyclophosphamide and endocrine therapy.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2009-016453-17, IEO S504/509, IEURONC_II_2009_008, TrialTroveID-141210

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

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

Phase: II

Therapies: bevacizumab + chemotherapy, bevacizumab + trastuzumab + chemotherapy

Country: Italy

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, TrialTroveID-210420, UMIN000014189

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

Phase: II

Therapy: lapatinib + trastuzumab

Country: 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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ERBB2 amplification (continued)

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, TrialTroveID-120590, UPCC 03909, UPCC03909

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

Phase: II

Therapy: palbociclib + trastuzumab

Country: United States

US State: PA

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

NCT01796197
Phase II Trial of Paclitaxel Combined With Trastuzumab and Pertuzumab as Pre-Operative Therapy for Inflammatory Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 12-497, TrialTroveID-182381

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: MA

US Contact: Dr. Beth Overmoyer [617-632-4056; bovermoyer@partners.org]

NCT01959490
Next Generation Sequencing to Evaluate Breast Cancer Subtypes and Genomic Predictors of Response to Therapy in the Preoperative Setting for Stage II-III Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: CASE 14112, CASE 14112-04-13-14C, CASE14112, NCI-2013-01422, TrialTroveID-195323

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: OH

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.

ERBB2 amplification (continued)

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, TrialTroveID-257064, UCI 14-67

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

Phase: II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: CA

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

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant classes: ERBB2 positive & TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482

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

Phase: II

Therapies: pertuzumab + trastuzumab + hormone therapy + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + letrozole + chemotherapy + radiation therapy + surgical intervention

Country: Norway

NCT01817452
A Prospective, Randomized Multicenter, Open-label Comparison of Preoperative Combination of Trastuzumab and Pertuzumab With or Without Concurrent Taxane Chemotherapy Given for Twelve Weeks in Patients With Operable HER2+/HR- Breast Cancer Within the ADAPT Protocol

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: ADAPT HER2+/HR-, EudraCT Number: 2011-001462-17, TrialTroveID-181371, WSG-AM06 / ADAPT HER2+/HR-

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

Phase: II

Therapies: pertuzumab + trastuzumab, pertuzumab + trastuzumab + chemotherapy

Country: Germany

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)

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 identifiers: TrialTroveID-195469, UMIN000012047

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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, TrialTroveID-123950

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

Other inclusion criteria: ER negative, PR negative

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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, TrialTroveID-121640

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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, TrialTroveID-164392, UMIN000006547

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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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ERBB2 amplification (continued)

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 identifiers: TrialTroveID-208244, UMIN000013886

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
Combination therapy of Eribulin with Trastuzumab for HER2 positive metastatic breast cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: SBP04, TrialTroveID-204331, UMIN000009296

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
Pegylated Liposomal Doxorubicin Hydrochloride and Trastuzumab in the First Line Treatment of Metastatic HER2 Positive Breast Carcinoma in Elderly Women

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2606 B, EudraCT Number: 2006-007089-12, GOIM 2606 B, TrialTroveID-069322

Population segments: First line, HER2 positive, Stage IV

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Italy

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, TrialTroveID-188836, UMIN000011020

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: 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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ERBB2 amplification (continued)

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 identifiers: TrialTroveID-199983, UMIN000007113

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

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 identifiers: TrialTroveID-195448, UMIN000012048

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Japan

NCT00618657
A Phase II Study of Breast Cancer Treatment Using Weekly Carboplatin +Nab-paclitaxel, Plus Trastuzumab (HER2+) or Bevacizumab (HER2-) in the Neoadjuvant Setting

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 2007-6084, 20990234, HS#2007-6084, NCI-2010-00155, TrialTroveID-084377, UCI 07-61, UCI-07-61

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: United States

US State: CA

US Contact: Dr. Rita S. Mehta [877-827-8839; UCstudy@uci.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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ERBB2 amplification (continued)

NCT01387295
Intra-hepatic Chemotherapy With Oxaliplatin Every Second Week in Combination With Systemic Capecitabine in Patient With Non-resectable Liver Metastases From Breast Cancer A Phase II Trial in Patients With Limited Extrahepatic Disease

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2009-014821-17, MA 0918, TrialTroveID-149256

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Denmark

NCT01387373
Intra-hepatic Chemotherapy with Oxaliplatin Every Second Week in Combination with Systemic Capecitabine in Patient with Non-resectable Liver Metastases from Breast Cancer. A Phase II Trial

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2009-014863-37, MA 0919, TrialTroveID-149349

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: Denmark

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, NCI-2012-01372, TrialTroveID-179329

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: United States

US State: NE

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.

ERBB2 amplification (continued)

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, TrialTroveID-271400

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

Phase: II

Therapy: trastuzumab + chemotherapy

Country: United States

US State: NE

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

NCT01472146
Phase II Clinical Trial of Neoadjuvant Treatment With Zolendronic Acid Plus Anthracycline and Taxane in Locally Advanced Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 154/10 - Zo-NANTAX, TrialTroveID-156985, Zo-neo2011, ZoNantax

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

Phase: II

Therapy: trastuzumab + chemotherapy + zoledronic acid

Country: Brazil

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, TrialTroveID-175990, UMIN000009108

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

Other inclusion criteria: ER positive and/or PR positive

Phase: II

Therapy: trastuzumab + hormone therapy + chemotherapy

Country: 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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ERBB2 amplification (continued)

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 identifiers: TrialTroveID-162796, UMIN000007353

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

Other inclusion criteria: ER positive and/or PR positive

Phase: II

Therapy: trastuzumab + letrozole

Country: Japan

No NCT ID - see other identifier(s)
Early Cardiac Changes During Anthracycline and/or Trastuzumab Therapy in Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: ACTRN12611000153910, TrialTroveID-144193, U1111-1119-2755

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

Phase: II

Therapies: trastuzumab, trastuzumab + chemotherapy

Country: Australia

NCT02073916
Phase Ib trial of trastuzumab emtansine in combination with lapatinib plus abraxane in metastatic Her 2 neu over-expressed breast cancer patients

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 0813-0139, STELA, TrialTroveID-203684

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

Phase: I/II

Therapy: ado-trastuzumab emtansine + lapatinib + chemotherapy

Country: United States

US State: TX

US Contact: Houston Methodist Cancer Center [713-441-0629; ccresearch@houstonmethodist.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 amplification (continued)

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 amplification

Other identifiers: EudraCT Number: 2015-003687-36, ICORG 15-02, ICORG1502, Panther, TrialTroveID-272101

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

Phase: I/II

Therapy: copanlisib + trastuzumab

Country: Ireland

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

Other identifiers: EudraCT Number: 2015-003687-36, ICORG 15-02, ICORG1502, Panther, TrialTroveID-272101

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

Phase: I/II

Therapy: copanlisib + trastuzumab

Country: Ireland

NCT01783756
Phase Ib/II Single-arm Trial Evaluating the Combination of Lapatinib, Everolimus and Capecitabine for the Treatment of Patients With HER2-positive Metastatic Breast Cancer With CNS Progression After Trastuzumab

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: NCI-2013-00082, TrialTroveID-181550, TRIO-US B09

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

Phase: I/II

Therapy: everolimus + lapatinib + chemotherapy

Country: United States

US State: CA

US Contact: Sara A. Hurvitz [888-798-0719; shurvitz@mednet.ucla.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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ERBB2 amplification (continued)

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 identifiers: TrialTroveID-193369, UMIN000011671

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

Phase: I/II

Therapy: lapatinib + chemotherapy

Country: Japan

No NCT ID - see other identifier(s)
An Open-label, Multi-center, Dose-escalation, Safety and Tolerability Phase I/II Study of MCLA-128 for the Treatment of Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: EudraCT Number: 2014-003277-42, MCLA-128-CL01, NL51045.031.14, TrialTroveID-250381

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

Phase: I/II

Therapy: MCLA-128

Countries: Netherlands, Spain

NCT02129556
A Phase Ib/II Trial Evaluating the Efficacy of MK-3475 and Trastuzumab in Patients With Trastuzumab-resistant, HER2-positive Metastatic Breast Cancers

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: BIG 4-13, EudraCT Number: 2013-004770-10, IBCSG 45-13, IBCSG 45-13 PANACEA, IBCSG 45-13/BIG 4-13, PANACEA, TrialTroveID-208268

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

Phase: I/II

Therapy: pembrolizumab + trastuzumab

Countries: Australia, Austria, Belgium, France, Italy

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)

NCT02139358
Phase I/IIa Trial of Gemcitabine Plus Trastuzumab and Pertuzumab in Previously Treated Metastatic HER2+ Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 17656, MCC-17656, ML28939, TrialTroveID-208961

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

Phase: I/II

Therapy: pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: FL

US Contact: Deanna Hogue [813-745-8304; deanna.hogue@moffitt.org]

NCT01216176
A Phase I Pharmacokinetic and Randomized Phase II Trial of Neoadjuvant Treatment With Anastrozole Plus AZD0530 in Postmenopausal Patients With Hormone Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 20080325, SCCC 2008002, TrialTroveID-102299, UMIAMI-20080325

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

Other inclusion criteria: ER positive and/or PR positive

Phase: I/II

Therapy: saracatinib + anastrozole

Country: United States

US State: FL

US Contact: University of Miami Sylvester Comprehensive Cancer Center [866-574-5124; sylvester@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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ERBB2 amplification (continued)

NCT01216176
A Phase I Pharmacokinetic and Randomized Phase II Trial of Neoadjuvant Treatment With Anastrozole Plus AZD0530 in Postmenopausal Patients With Hormone Receptor Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 20080325, SCCC 2008002, TrialTroveID-102299, UMIAMI-20080325

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

Other inclusion criteria: ER positive and/or PR positive

Phase: I/II

Therapy: saracatinib + anastrozole

Country: United States

US State: FL

US Contact: University of Miami Sylvester Comprehensive Cancer Center [866-574-5124; sylvester@emergingmed.com]

NCT01373710
Phase I-II Study of Safety and Efficacy of Intrathecal Trastuzumab Administration in Metastatic HER2 Positive Breast Cancer Patients Developing Carcinomatous Meningitis

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 09/501/M, Eudract Number: 2009-017218-63, HIT, RECF1519, TrialTroveID-148279

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

Phase: I/II

Therapy: trastuzumab

Country: France

NCT01373710
Phase I-II Study of Safety and Efficacy of Intrathecal Trastuzumab Administration in Metastatic HER2 Positive Breast Cancer Patients Developing Carcinomatous Meningitis

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 09/501/M, Eudract Number: 2009-017218-63, HIT, RECF1519, TrialTroveID-148279

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

Phase: I/II

Therapy: trastuzumab

Country: France

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)

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

Other identifiers: TrialTroveID-165503, UMIN000007600

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

Phase: I/II

Therapy: trastuzumab + chemotherapy

Country: 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

Other identifiers: 2013/00566, MC01/21/13, TrialTroveID-200369

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

Phase: I/II

Therapy: trastuzumab + natural killer cell treatment

Country: Singapore

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 amplification

Other identifiers: 2013/00566, MC01/21/13, TrialTroveID-200369

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

Phase: I/II

Therapy: trastuzumab + natural killer cell treatment

Country: Singapore

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 overexpression

Other identifiers: 2014/01282, ASLAN001-004, TrialTroveID-254309

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

Phase: I/II

Therapy: varlitinib + chemotherapy

Country: 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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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

Other identifiers: 2014/01282, ASLAN001-004, TrialTroveID-254309

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

Phase: I/II

Therapy: varlitinib + chemotherapy

Country: 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, NFI1114, NSABP FB-10, TrialTroveID-216534

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

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

Phase: I/II

Therapy: ado-trastuzumab emtansine + neratinib

Country: United States

US States: FL, OH, PA, RI, WV

US Contact: Diana Gosik [800-270-3165; diana.gosik@nsabp.org]

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 identifiers: CHN-PLAGH-BT-009, TrialTroveID-193409

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

Phase: I/II

Therapy: CART-HER-2

Country: 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)

NCT02547961
Chimeric Antigen Receptor-Modified T Cells for HER-2 Positive Recurrent and Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: Breast Cancer CAR-T 001, TrialTroveID-264477

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

Phase: I/II

Therapy: CART-HER-2

Country: China

NCT02713984
A Clinical Research of CAR T Cells Targeting HER2 Positive Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: TMMU-BTC-005, TrialTroveID-275196

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

Phase: I/II

Therapy: CART-HER-2

Country: China

NCT02403271
A Multi-Center Study of the Bruton`s Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination With MEDI4736, in Subjects With Relapsed or Refractory Solid Tumors.

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 00061881, 2015-0076, PCYC-1135-CA, TrialTroveID-220168

Population segments: Adenocarcinoma, HER2 negative, HER2 positive, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: durvalumab + ibrutinib

Country: United States

US States: AL, AZ, CA, FL, IL, NC, NJ, TN, TX

US Contact: Darlene Ebeling [408-990-7366; debeling@pcyc.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.

ERBB2 amplification (continued)

NCT02423902
A Single-arm, Open-label Study of Ad-RTS-hIL-12 + Veledimex Following First- or Second-Line Standard Treatment in Subjects With Locally Advanced or Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 15-024, ATI001-203, TrialTroveID-252970

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

Phase: I/II

Therapy: INXN-2001/1001

Country: United States

US State: NY

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

No NCT ID - see other identifier(s)
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

Other identifier: TrialTroveID-136450

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

Phase: I/II

Therapy: lapatinib + chemotherapy

Country: Italy

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, TrialTroveID-203366

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

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

Phase: I/II

Therapy: masitinib + chemotherapy

Countries: France, Spain

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.

ERBB2 amplification (continued)

NCT02285179
Phase I/prospective randomized phase II trial Of the Safety and Efficacy of tamoxifen in combination with the Isoform selective Pi3K inhibitor GDC-0032 compared with tamoxifen alONe in hormone receptor positive, HER2 negative, metastatic breast cancer patients with prior exposure to endocrine treatment (POSEIDON trial)

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2013-003947-51, IRAS ID: 139349, M14POS, NL49184.031.14, POSEIDON trial, REec-2016-2238, TrialTroveID-220300, UKCRN ID: 18165

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

Other inclusion criteria: ER positive and/or PR positive

Phase: I/II

Therapies: tamoxifen, taselisib + tamoxifen

Countries: Netherlands, Spain, United Kingdom

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

Other identifier: TrialTroveID-283109

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

Phase: I/II

Therapies: trastuzumab, trastuzumab + natural killer cell treatment

Country: 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, TrialTroveID-265019, UKCRN ID:18725

Population segments: EGFR, FGFR, HER2 negative, HER2 positive, KRAS, Second line or greater/Refractory/Relapsed, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapy: selumetinib + vistusertib

Country: 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.

ERBB2 amplification (continued)

NCT01816035
Thrombokinetic Studies of Ado-trastuzumab Emtansine

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 7900, NCI-2013-00552, TrialTroveID-183712

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

Phase: I

Therapy: ado-trastuzumab emtansine

Country: United States

US State: WA

US Contact: Vijayakrishna Gadi [206-288-2222]

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, TrialTroveID-267371

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

Phase: I

Therapy: allitinib + chemotherapy

Country: China

NCT02167854
A Phase I, Open-Label Study Evaluating the Safety and Tolerability of LJM716, BYL719 and Trastuzumab in Patients With Metastatic HER2+ Breast Cancer.

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 14-057, TrialTroveID-211253

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

Other inclusion criteria: PIK3CA wild type

Phase: I

Therapy: alpelisib + LJM-716 + trastuzumab

Country: United States

US State: NY

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)

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

Other identifiers: TrialTroveID-262338, ZMC-ARX788-101

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

Phase: I

Therapy: ARX-788

Countries: Australia, New Zealand

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 amplification

Other identifiers: TrialTroveID-262338, ZMC-ARX788-101

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

Phase: I

Therapy: ARX-788

Countries: Australia, New Zealand

NCT01300962
LCCC 1024: A Four Part, Phase I Dose-Escalation Study of the Combinations of Concurrent BKM120 and Capecitabine, or Concurrent BYL719 and Capecitabine, or Concurrent BKM120 and Capecitabine and Trastuzumab, or Concurrent BKM120 and Capecitabine and Lapatinib in Patients With Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 00030313, 11-0060, LCCC 1024, LCCC1024, NCI-2013-00951, TrialTroveID-142831

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

Phase: I

Therapies: buparlisib + lapatinib + chemotherapy, buparlisib + trastuzumab + chemotherapy

Country: United States

US State: NC

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)

NCT01300962
LCCC 1024: A Four Part, Phase I Dose-Escalation Study of the Combinations of Concurrent BKM120 and Capecitabine, or Concurrent BYL719 and Capecitabine, or Concurrent BKM120 and Capecitabine and Trastuzumab, or Concurrent BKM120 and Capecitabine and Lapatinib in Patients With Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 00030313, 11-0060, LCCC 1024, LCCC1024, NCI-2013-00951, TrialTroveID-142831

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

Phase: I

Therapies: buparlisib + lapatinib + chemotherapy, buparlisib + trastuzumab + chemotherapy

Country: United States

US State: NC

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

NCT02286219
Phase 1, Multiple Ascending Dose Study of Anti-HER2 FCAB FS102 in HER2 Positive Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: 2014-1221, 20142312, CA014-001, FS10214100, NCI-2015-00318, TrialTroveID-220332

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

Phase: I

Therapy: FS-102

Country: United States

US States: DC, TN, TX, WA

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

NCT01875666
Defining the HER2 Positive (+) Breast Cancer Kinome Response to Trastuzumab, Pertuzumab, Combination Trastuzumab +Pertuzumab, or Combination Trastuzumab + Lapatinib

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: 13-401, CLAP016AUS33T, LAP200136, LCCC 1214, LCCC1214, ML28342, TrialTroveID-188436

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

Phase: I

Therapies: lapatinib + trastuzumab, pertuzumab, pertuzumab + trastuzumab, trastuzumab

Country: United States

US States: AL, IN, MA, NC, TX

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.

ERBB2 amplification (continued)

NCT02576548
A Phase I Multicenter, Open-label, Dose-escalation, and Dose-expansion Study to Evaluate the Safety, Pharmacokinetics, Immunogencity, and Antitumor Activity of MEDI4276 in Subjects With Select HER2-expressing Advanced Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: D5760C00001, NCI-2016-00412, TrialTroveID-266157

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

Phase: I

Therapy: MEDI-4276

Country: United States

US States: CA, FL, IN, NC, TN

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

NCT02576548
A Phase I Multicenter, Open-label, Dose-escalation, and Dose-expansion Study to Evaluate the Safety, Pharmacokinetics, Immunogencity, and Antitumor Activity of MEDI4276 in Subjects With Select HER2-expressing Advanced Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: D5760C00001, NCI-2016-00412, TrialTroveID-266157

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

Phase: I

Therapy: MEDI-4276

Country: United States

US States: CA, FL, IN, NC, TN

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.com]

NCT02598427
Phase I Dose Escalation Trial of Intrathecal Pertuzumab and Trastuzumab in Patients With New Untreated Asymptomatic or Low Symptomatic Brain Metastasis

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: NCI-2016-00827, Pro00061309, TrialTroveID-267500

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

Phase: I

Therapy: pertuzumab + trastuzumab

Country: United States

US State: NC

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)

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: SHRUS 1001, TrialTroveID-261429

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

Phase: I

Therapy: pyrotinib

Country: United States

US State: TX

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

NCT02500199
A Two-part Phase I, Open Label, Dose Escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Pyrotinib in Patients Whose Disease Progressed on Prior HER2 Targeted Therapy

Cancer type: Breast Cancer

Variant class: ERBB2 amplification

Other identifiers: SHRUS 1001, TrialTroveID-261429

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

Phase: I

Therapy: pyrotinib

Country: United States

US State: TX

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

NCT02277717
A Two Part First-in-human Phase I Study (With Expanded Cohorts) With the Antibody-drug Conjugate SYD985 to Evaluate the Safety, Pharmacokinetics and Efficacy in Patients With Locally Advanced or Metastatic Solid Tumors

Cancer type: Breast Cancer

Variant class: ERBB2 overexpression

Other identifiers: EudraCT Number: 2014-001798-15, IRAS ID 159824, MOMULT05, NL50221.091.14, SYD985.001, TrialTroveID-201742

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

Phase: I

Therapy: SYD-985

Countries: Belgium, Netherlands, 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)

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 identifiers: TrialTroveID-262799, UMIN000018294

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

Phase: I

Therapy: trastuzumab

Country: Japan

NCT02605915
A Phase Ib, Open-Label, Two-Arm Study Evaluating The Safety And Pharmacokinetics of Atezolizumab (Anti-Pd-L1 Antibody) in Combination With Trastuzumab Emtansine or With Trastuzumab And Pertuzumab in Patients With Her2 Positive Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: EudraCT Number: 2015-002113-29, GO29831, NCI-2015-02225, SCRI-GO29831-BRE261, TrialTroveID-268036

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

Phase: I

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

Country: United States

US States: AL, MD, MI, NC, OH, PA, TN, TX, WI

US Contact: Hoffmann-La Roche Clinical Trials - Reference Study ID Number: GO29831 [888-662-6728; global.rochegenentechtrials@roche.com]

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, NCI-2014-00821, SCCC 05113, STU 042013-042, TrialTroveID-196691

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

Phase: I

Therapy: ado-trastuzumab emtansine + palbociclib

Country: United States

US State: TX

US Contact: Dr. Arthur Frankel [214-648-4180; Arthur.Frankel@UTSouthwestern.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.

ERBB2 amplification (continued)

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, TrialTroveID-191835

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

Countries: Canada, Italy, Spain, United Kingdom, United States

US States: CA, MA, MI, PA, SC

US Contact: Pfizer CT.gov Call Center [800-718-1021]

NCT02649686
A Phase Ib Pharmacodynamic Study of Durvalumab (MEDI4736) in Patients With HER-2 Positive Metastatic Breast Cancer (MBC) Receiving Trastuzumab

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: I229, NCIC CTG: IND.229, TrialTroveID-271035

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

Phase: I

Therapy: durvalumab + trastuzumab

Country: Canada

NCT02014909
Part I and Part II A Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of KTN3379 in Adult Subjects With Advanced Tumors Alone or With Chemotherapy

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: KTN3379-CL-001, NCI-2013-02452, TrialTroveID-199352

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

Phase: I

Therapies: KTN-3379, KTN-3379 + trastuzumab

Country: United States

US State: PA

US Contact: Lisa Kamen [203-907-0958; lisa.kamen@kolltan.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.

ERBB2 amplification (continued)

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 identifiers: TrialTroveID-152867, UMIN000004921

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

Phase: I

Therapy: lapatinib + chemotherapy

Country: Japan

NCT02361112
A Phase I Study of Pyrotinib In Combination with Capecitabine In Patients With HER2 Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: BLTN-Ic, TrialTroveID-252048

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

Phase: I

Therapy: pyrotinib + chemotherapy

Country: China

NCT01969643
A Phase I, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients With LIV-1-Positive Metastatic Breast Cancer

Cancer type: Breast Cancer

Variant class: ERBB2 positive

Other identifiers: 1311013056, 14-013, 14-306, 20131069, BRE 225 IST, NCI-2013-02245, SGNLVA-001, TrialTroveID-185934, UW 13038

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

Phase: I

Therapy: SGN-LIV1A + trastuzumab

Country: United States

US States: AL, CA, CT, IN, MA, MI, MN, NY, TN, WA

US Contact: Seattle Genetics [866-333-7436; clinicaltrials@seagen.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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ERBB2 amplification (continued)

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, TrialTroveID-265364

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

Phase: I

Therapy: trastuzumab + chemotherapy

Country: Spain

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH, TrialTroveID-258747

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

Phase: II

Therapy: ado-trastuzumab emtansine

Country: 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, WA, WI, WV, WY

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

NCT02675829
A Phase II Trial of Ado-Trastuzumab Emtansine for Patients With HER2 Amplified or Mutant Cancers

Cancer type: Unspecified Cancer

Variant class: ERBB2 amplification

Other identifiers: 15-335, TrialTroveID-256389

Population segments: First line, Stage III, Stage IV

Phase: II

Therapy: ado-trastuzumab emtansine

Country: United States

US State: NY

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)

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, TrialTroveID-200294

Population segments: Maintenance/Consolidation, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: lapatinib

Country: France

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: Pro00014171, TAPUR, TrialTroveID-273941

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: pertuzumab + trastuzumab

Country: United States

US States: MI, NC

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

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: Unspecified Solid Tumor

Variant class: ERBB2 overexpression

Other identifiers: 2014-0119, NCI-2014-01615, TrialTroveID-210119

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

Other inclusion criteria: ER positive and/or PR positive

Phase: I

Therapy: everolimus + trastuzumab + letrozole

Country: United States

US State: TX

US Contact: Dr. Filip Janku [713-563-1930]

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)

NCT02593708
Phase I Study to Evaluate the Safety of Neratinib in Combination With Paclitaxel, Trastuzumab and Pertuzumab in Women and Men With Advanced or Metastatic HER2+ Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 149517, TrialTroveID-267207

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

Phase: I

Therapy: neratinib + pertuzumab + trastuzumab + chemotherapy

Country: United States

US State: CA

US Contact: Michelle Melisko [415-353-7070; Michelle.Melisko@ucsf.edu]

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 amplification

Other identifiers: 5209-CPK-1002, CTR20150792, TrialTroveID-269399

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

Phase: I

Therapy: pirotinib

Country: China

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, TrialTroveID-271028

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

Phase: I

Therapy: RC-48

Country: China

NCT02881190
A Tolerance, Safety and Pharmacokinetic Ascending Dose Phase I Study of RC48-ADC Administered Subcutaneously 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, TrialTroveID-270499

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

Phase: I

Therapy: RC-48

Country: 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.

ERBB2 amplification (continued)

NCT01971515
A Phase I, First-in-Human, Dose Escalation Trial of MSC2363318A, a Dual p70S6K/Akt Inhibitor, in Subjects With Advanced Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifiers: 2013-0525, CHRMS 14-081, EMR100018-001, NCI-2013-02370, TrialTroveID-196334

Population segments: Aggressive, Classical, EGFR, HER2 positive, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MSC-2363318A

Country: United States

US States: CA, MI, TX, VT

US Contact: US Medical Information [888-275-7376]

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 identifiers: ASLAN001-002SG, TrialTroveID-254374

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Country: 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.

CCND1 amplification

NCT02187783
Modular Phase II Study to Link Targeted Therapy to Patients with Pathway Activated Tumors: Module 8 - LEE011 for Patients with CDK4/6 Pathway Activated Tumors

Cancer type: Breast Cancer

Variant class: CCND1 amplification

Other identifiers: 051501, 2014-0689, CLEE011XUS03, NCI-2014-02068, SIGNATURE, TrialTroveID-212878

Population segments: Adenocarcinoma, Aggressive, Classical, Cutaneous T-cell lymphoma (CTCL), Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), HER2 negative, Indolent, Lymphoblastic lymphoma (LBL), N/A, Nodular lymphocyte-predominant, Other subtype, Peripheral T-cell lymphoma (PTCL), Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Triple receptor negative, Waldenstrom`s macroglobulinemia (WM)

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: II

Therapy: ribociclib

Country: United States

US State: TX

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

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, TrialTroveID-120590, UPCC 03909, UPCC03909

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

Phase: II

Therapy: palbociclib

Country: United States

US State: PA

US Contact: 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.

CCND1 amplification (continued)

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: CCND1 amplification

Other identifiers: CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-X, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH, TrialTroveID-258747

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

Other inclusion criteria: RB1 expression

Phase: II

Therapy: palbociclib

Country: 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, WA, WI, WV, WY

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

TP53 p.(K132N) c.396G>T

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant classes: ERBB2 positive & TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482

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

Phase: II

Therapies: pertuzumab + trastuzumab + hormone therapy + chemotherapy + radiation therapy + surgical intervention, pertuzumab + trastuzumab + letrozole + chemotherapy + radiation therapy + surgical intervention

Country: Norway

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.

TP53 p.(K132N) c.396G>T (continued)

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482

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

Other inclusion criteria: ER positive, PR positive

Phase: II

Therapies: hormone therapy + chemotherapy + radiation therapy + surgical intervention, letrozole + chemotherapy + radiation therapy + surgical intervention

Country: Norway

NCT02624973
Personalized Treatment of High-risk Mammary Cancer - the PETREMAC Trial

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 2015/8463, 912008, EudraCT Number: 2015-002816-34, PETREMAC, TrialTroveID-269482

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

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: II

Therapy: olaparib + chemotherapy + radiation therapy + surgical intervention

Country: Norway

NCT02432963
A Phase I Study of a p53MVA Vaccine in Combination With Pembrolizumab

Cancer type: Breast Cancer

Variant class: TP53 mutation

Other identifiers: 116634, 122284, 122771, 124524, 15002, NCI-2015-00653, TrialTroveID-256830

Population segments: HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative, Unresectable

Other inclusion criteria: ERBB2 wild type, ER negative, PR negative

Phase: I

Therapy: pembrolizumab + p53MVA

Country: United States

US State: CA

US Contact: Vincent Chung [800-826-4673]

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.

TP53 p.(K132N) c.396G>T (continued)

NCT02576444
A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) Alone and in Combination With AZD1775, AZD5363, or AZD2014 in Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1508016363, OLAPCO, TrialTroveID-266161

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

Phase: II

Therapy: MK-1775 + olaparib

Country: United States

US State: CT

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

NCT02042989
A Phase I Study of MLN9708 and Vorinostat to Target Autophagy in Patients With Advanced p53 Mutant Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 2013-0511, NCI-2014-01091, TrialTroveID-201319

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

Phase: I

Therapy: ixazomib + vorinostat

Country: United States

US State: TX

US Contact: Dr. Siqing Fu [713-563-1930]

NCT02610075
A Phase Ib Study to Determine the Maximum Tolerated Dose (MTD) of AZD1775 Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumours.

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: D6015C00003, REFMAL 398, TrialTroveID- 268385

Population segments: Liver mets, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: MK-1775

Country: United States

US States: CO, TN

US Contact: AstraZeneca Clinical Study Information Center [877-240-9479; information.center@astrazeneca.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.

TP53 p.(K132N) c.396G>T (continued)

NCT02354547
A Phase I Study of SGT-53, a TfRscFv-Liposome-p53 Complex, in Children with Refractory or Recurrent Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: 1405-1316, SGT53-01-2, TrialTroveID-251586

Population segments: (N/A), Second line or greater/Refractory/Relapsed

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Country: United States

US State: TX

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

ETV6-NTRK3 fusion

NCT02568267
An Open-Label, Multicenter, Global Phase II Basket Study of Entrectinib for the Treatment of Patients With Locally Advanced or Metastatic Solid Tumors That Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements (STARTRK-2) Studies of Tumor Alterations Responsive to Targeting Receptor Kinases (STARCK-2)

Cancer type: Unspecified Solid Tumor

Variant class: NTRK3 fusion

Other identifiers: EudraCT Number: 2015-003385-84, IRAS ID: 196539, NCI-2015-01848, RXDX-101-02, STARTRK-2, TrialTroveID-265482

Population segments: Anaplastic, Peripheral T-cell lymphoma (PTCL), Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: II

Therapy: entrectinib

Countries: Australia, Belgium, France, Italy, Republic of Korea, Singapore, Taiwan, United Kingdom, United States

US States: AL, AZ, CA, CO, DC, FL, GA, HI, IL, IN, MA, MI, MN, MO, NH, NY, OH, OK, OR, PA, TX, UT, VA, WA, WI

US Contact: Ignyta Inc. [844-782-7875; STARTRKtrials@ignyta.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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ETV6-NTRK3 fusion (continued)

NCT02576431
A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects With NTRK Fusion-Positive Tumors

Cancer type: Unspecified Solid Tumor

Variant class: NTRK3 fusion

Other identifiers: 15-183, 2015-0728, EudraCT Number: 2015-003582-28, LOXO-TRK-15002, NAVIGATE, NCI-2015-01947, REec-2016-2301, TrialTroveID-263088, VICCMD15110

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

Phase: II

Therapy: LOXO-101

Countries: Denmark, Ireland, Republic of Korea, Singapore, Spain, United States

US States: CA, DC, FL, NC, NH, NY, OH, PA, TN, TX, VA, WA, WV

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

NCT02097810
A Phase I/IIa, Multicenter, Open-Label Study of Oral Entrectinib (RXDX-101) in Adult Patients with Locally Advanced or Metastatic Cancer Confirmed to be Positive for NTRK1, NTRK2, NTRK3, ROS1, or ALK Molecular Alterations

Cancer type: Unspecified Solid Tumor

Variant class: NTRK3 aberration

Other identifiers: 14-131, 14-271, 2014-0512, EudraCT Number: 2014-001326-15, REec-2014-1210, RXDX-101-01, STARTRK-1, TrialTroveID-203930, UCI 14-01, UCI-14-01

Population segments: Adenocarcinoma, ALK, Large Cell, Locally advanced, Metastatic, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I/II

Therapy: entrectinib

Countries: Republic of Korea, Spain, United States

US States: CA, CO, DC, FL, MA, NY, TN, TX

US Contact: Ignyta, Inc. [858-255-5959]

NCT02279433
A Phase I, Two-Part, Multi-Center, Non Randomized, Open-Label, Multiple Dose First-In-Human Study of DS-6051b, An Oral ROS1 And NTRK Inhibitor, in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: NTRK3 fusion

Other identifiers: DS6051-A-U101, NCI-2015-01963, TrialTroveID-219871, UCI 14-39, UCI-14-39

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

Phase: I

Therapy: DS-6051b

Country: United States

US States: AZ, CA, MA, TX

US Contact: Aaron Logue [513-579-9911; A.Logue@Medpace.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.

ETV6-NTRK3 fusion (continued)

NCT02675491
Phase I Study of DS-6051b in Japanese Subjects With Advanced Solid Malignant Tumors Harboring Either a ROS1 or NTRK Fusion Gene

Cancer type: Unspecified Solid Tumor

Variant class: NTRK fusion

Other identifiers: DS6051-A-J102, JapicCTI-153111, TrialTroveID-272673

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

Phase: I

Therapy: DS-6051b

Country: Japan

NCT02122913
A Phase I Study of the Oral TRK Inhibitor LOXO-101 in Adult Patients With Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: NTRK3 aberration

Other identifiers: 2014-1056, LOXO-TRK-14001, TrialTroveID-207712

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

Phase: I

Therapy: LOXO-101

Country: United States

US States: CO, MA, OH, OR, PA, TN, TX

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

NCT01804530
A Phase I Study to Assess Safety, Pharmacokinetics, and Pharmacodynamics of PLX7486 as a Single Agent and in Combination With Gemcitabine and Nab-Paclitaxel in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: NTRK fusion

Other identifiers: 101937, MUSC 101937, PLX119-01, TrialTroveID-182876

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

Phase: I

Therapies: PLX-7486, PLX-7486 + chemotherapy

Country: United States

US States: AZ, CA, MA, MD, SC

US Contact: Theresa Cho [510-647-4000; tcho@plexxikon.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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ETV6-NTRK3 fusion (continued)

NCT02219711
A Phase I/Ib Study of MGCD516 in Patients With Advanced Solid Tumor Malignancies

Cancer type: Unspecified Solid Tumor

Variant class: NTRK fusion

Other identifiers: 516-001, 76853, AAAO0006, NCI-2014-01866, TrialTroveID-197300

Population segments: Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase: I

Therapy: sitravatinib

Country: United States

US States: AL, CA, MA, MI, MO, NM, NY, SC, TN, TX, UT, WA, WI

US Contact: Mirati Therapeutics Study Locator Services [844-356-0895; miratistudylocator@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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Appendix: 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
ERBB2 aberration	3
↳ ERBB2 positive	62
↳ ERBB2 overexpression	50
ERBB2 aberration	3
↳ ERBB2 positive	62
↳ ERBB2 amplification	131

CCND1 amplification

Variant Class	Evidence Items
G1/S cell cycle pathway	0
↳ CCND1 amplification	3

TP53 p.(K132N) c.396G>T

Variant Class	Evidence Items
TP53 mutation	9

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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Appendix: 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.

ETV6-NTRK3 fusion

Variant Class	Evidence Items
NTRK aberration	0
↳ NTRK fusion	3
↳ NTRK3 fusion	3
↳ NTRK3 aberration	2
↳ NTRK3 positive	0
↳ NTRK3 fusion	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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Appendix: Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
TP53	p.(K132N)	c.396G>T	COSM10991	chr17:7578534	14.47%	NM_000546.5	missense

Gene Fusions (RNA)

Genes	Variant ID	Locus	Counts
ETV6-NTRK3	ETV6-NTRK3.E5N15.COSF571	chr12:12022903 - chr15:88483984	26

Copy Number Variations

Gene	Locus	Copy Number
CCND1	chr11:69456941	5.22
ERBB2	chr17:37845133	23.28

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.

TERMS AND CONDITIONS

The following paragraph on Liability is an extract from the Oncologica Tests' Terms and Conditions. The extract is to draw your attention to particular terms applicable to you but nothing set out here is intended to supersede or override our Terms and Conditions, which can be found on our website at www.oncologica.com under the title Oncologica Tests' Terms and Conditions. Please read these Oncologica Test Terms and Conditions carefully before you submit an order for the Oncologica Tests, as you will be bound by these Terms and Conditions, once a contract comes into existence as per paragraph 2 of the Oncologica Test's Terms and Conditions.

6. Liability

6.1 Oncologica operates in compliance with international ISO15189:2012 standards and is regulated by UKAS. The Oncologica Tests have not been cleared or approved by the United States Food and Drug Administration; however, such clearance or approval is not required.

6.2 The Patient agrees that the Oncologica Test Report is intended for clinical use and interpretation by a physician who is experienced and skilled in the use and interpretation of clinical test data. The Oncologica Test Report is based on the Sample submitted by the Patient. The Oncologica Test Report should not be considered or its contents applied to any other patient or any other sample. Oncologica does not update an Oncologica Test Report once it has been sent.

6.3 Information compiled in the Oncologica Test Report includes is from publicly available as well as proprietary sources. By updating the source database, Oncologica makes every effort to provide the most accurate and up-to-date information. However, Oncologica does not warrant or represent that the information in the Oncologica Test Report is accurate, timely or complete.

6.4 The Oncologica Test Report contains drug and clinical trial information. However, Oncologica does not warrant or represent that any drug or clinical trial identified by the Oncologica Test will guarantee a therapeutic response for a particular Patient. The drugs listed in an Oncologica Test Report are ranked on clinical evidence as to the predicted efficacy or appropriateness for the Patient. The Patient shall ensure that its physician shall evaluate and interpret the Oncologica Test Report, along with all other available clinical information about the Patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, nor solely on the information contained in the Oncologica Test Report.

6.5 Subject to paragraph **6.10**, Oncologica shall have no liability for any use made of the information provided in the Oncologica Test Report, including but not limited to any report prepared by Oncologica summarising the results of the Oncologica Tests, any advice supplied by Oncologica, any decisions taken, or for any costs incurred by Patient and/or the Patient's physician and/or the Agent in consequence of such use, advice or decisions. The Oncologica Test and/or the Oncologica Test Report is not a substitute for the Patient's physician's professional judgment. The use of the information provided in the Oncologica Test Report is provided as a tool for the ordering physician's use in determining the appropriate treatment for the Patient. The decision as to what course of treatment and the appropriate use of the information provided by the Oncologica Test Report is solely that of the Patient's physician.

6.6 Oncologica does not warrant or represent or guarantee that the Oncologica Tests will identify an actionable genetic alteration that is linked to anti-cancer targeted therapies. Although the Oncologica Tests are comprehensive, in a proportion of Patients, the Oncologica Test result may not identify any actionable mutations for a patient's cancer. In the event that no actionable alteration in the Sample is identified by the Oncologica Test, then the Patient is still under full obligation to pay the Charges and no refund is available to the Patient and/or Agent.

6.7 The Oncologica Test identifies genomic actionable alterations found in the submitted Sample that are linked to anti-cancer targeted agents. Also note that this test only examines tumour, and not normal tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

6.8 Subject to Clause **6.8**, Oncologica shall not be liable to the Patient whether in contract, tort (including negligence and breach of statutory duty), or otherwise for any:

(a) Error or defect in the Oncologica Test Report as a result of any inaccurate or incomplete information supplied by the Patient;

(b) Loss of data or materials, including the Sample and/or the Report and including any loss arising as a result of the acts or omissions of a courier;

(c) Indirect or consequential loss arising whether or not advised of the possibility of the same.

6.9 Subject to the provisions of this Clause 6, Oncologica' s total liability to the Patient in respect of all losses arising under or in connection with the Contract, whether in contract, tort (including negligence and breach of statutory duty), or otherwise, shall in no circumstances exceed the Charges paid for the Test that is the subject of the claim.

6.10 Nothing in the Contract limits or excludes the liability of Oncologica for breach of its obligations under section 12 of the Sale of Goods Act 1979 and/or section 2 of the Supply of Goods and Services Act 1982; death or personal injury resulting from negligence; or fraud or fraudulent misrepresentation.

6.11 If the Patient is a consumer (and not a business), the Patient expressly acknowledges and agrees that the Test is supplied to the Patient's specification and therefore there is no right to cancel the Test following acceptance under Clause 2.2. If the Patient is a consumer, then notwithstanding any other provisions of the Contract, none of the Patient's consumer statutory rights are affected.


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