[Oncofocus] Patient Test Report

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ONC17
Surname
Forename
DOB
Gender
Histology #
Primary site
Tumour subtype
Tissue Type

Requester
Contact details
Date requested

Tumour %
Tumour %
(macrodissected)

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.

237 genes were targeted using 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 635 anti-cancer targeted therapies.

A variant of unknown significance was identified in the BRCA2 gene: c.5213_5216delCTTA p.(Thr1738fs)
Although there is no published functional data on this particular variant, if it does cause BRCA2 aberration, then the therapies identified in this report would be indicated. Notably this BRCA2 aberration was detected at a high allele frequency raising the possibility that this is a germline mutation. However, the Oncofocus test is unable to distinguish somatic from germline mutations.

The table below details the further actionable variants detected in this sample:

Sample Cancer Type: Bladder Cancer

Variant Summary

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

Gene	Variant		Alt allele freq	EMA	FDA	ESMO	NCCN	Clinical Trials
ERBB2 amplification		(CN = 14.67)		○ (12)	○ (4)	○ (10)	○ (32)	● (10)
BRCA2	c.5213_5216delCTTA	p.(Thr1738fs)	50%	○ (1)	○ (1)	✖	○ (1)	● (11)
TP53	c.772G>T	p.(Glu258Ter)	45%	✖	✖	✖	✖	● (6)

EMA: European Medicine Agency, **FDA:** United States-Food and Drug Administration, **ESMO:** European Society for Medical Oncology, **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(PPV) of 92%. Copy number variants; amplifications of CN> 6 with the 5% confidence value of ≥4 after normalization and deletions with 95% CI ≤1 are classified as present when the tumour % >50% with a sensitivity of 80% and PPV 100%. Gene Fusions are reported when occurring in >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.

Disclaimer: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2017.11(006).

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Relevant Therapy Summary

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

ERBB2 amplification

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
ado-trastuzumab emtansine	○	○	○	○	● (II)
pertuzumab + trastuzumab + docetaxel	○	○	✖	○	✖
trastuzumab	○	○	✖	✖	✖
lapatinib + trastuzumab	○	✖	○	○	✖
trastuzumab + cisplatin + fluorouracil	○	✖	○	○	✖
lapatinib + capecitabine	○	✖	✖	○	✖
trastuzumab + capecitabine	○	✖	✖	○	✖
trastuzumab + docetaxel	○	✖	✖	○	✖
trastuzumab + paclitaxel	○	✖	✖	○	✖
lapatinib + aromatase inhibitor	○	✖	✖	✖	✖
trastuzumab + aromatase inhibitor	○	✖	✖	✖	✖
trastuzumab + carboplatin + docetaxel	○	✖	✖	✖	✖
neratinib	✖	○	✖	✖	✖
pertuzumab + trastuzumab + chemotherapy	✖	✖	○	○	✖
trastuzumab + capecitabine + cisplatin	✖	✖	○	○	✖
trastuzumab + chemotherapy	✖	✖	○	○	✖
trastuzumab + hormone therapy + chemotherapy	✖	✖	○	○	✖
trastuzumab + vinorelbine	✖	✖	○	○	✖
trastuzumab + taxane	✖	✖	○	✖	✖
trastuzumab containing regimen	✖	✖	○	✖	✖
hormone therapy	✖	✖	✖	○	✖
pertuzumab + trastuzumab + paclitaxel	✖	✖	✖	○	✖
trastuzumab + capecitabine + cisplatin + epirubicin	✖	✖	✖	○	✖

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

Referring pathology dept: Sapienza Universita di roma

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Relevant Therapy Summary (continued)

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

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
trastuzumab + capecitabine + epirubicin + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + capecitabine + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + carboplatin + docetaxel + fluorouracil	✖	✖	✖	○	✖
trastuzumab + carboplatin + paclitaxel	✖	✖	✖	○	✖
trastuzumab + chemotherapy (other)	✖	✖	✖	○	✖
trastuzumab + cisplatin + docetaxel	✖	✖	✖	○	✖
trastuzumab + cisplatin + docetaxel + fluorouracil	✖	✖	✖	○	✖
trastuzumab + cisplatin + epirubicin + fluorouracil	✖	✖	✖	○	✖
trastuzumab + cisplatin + paclitaxel	✖	✖	✖	○	✖
trastuzumab + docetaxel + fluorouracil + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + epirubicin + fluorouracil + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + fluorouracil	✖	✖	✖	○	✖
trastuzumab + fluorouracil + irinotecan	✖	✖	✖	○	✖
trastuzumab + fluorouracil + oxaliplatin	✖	✖	✖	○	✖
trastuzumab + hormone therapy	✖	✖	✖	○	✖
trastuzumab + hormone therapy + chemoradiation therapy	✖	✖	✖	○	✖
ado-trastuzumab emtansine, ado-trastuzumab emtansine + pertuzumab	✖	✖	✖	✖	● (II)
afatinib	✖	✖	✖	✖	● (II)
lapatinib	✖	✖	✖	✖	● (II)
pertuzumab + trastuzumab	✖	✖	✖	✖	● (II)
CART-HER-2	✖	✖	✖	✖	● (I/II)
pirotinib	✖	✖	✖	✖	● (I/II)

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

Referring pathology dept: Sapienza Universita di roma

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Relevant Therapy Summary (continued)

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

ERBB2 amplification (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
neratinib + pertuzumab + trastuzumab + chemotherapy	✖	✖	✖	✖	● (I)
pyrotinib	✖	✖	✖	✖	● (I)
varlitinib + chemotherapy	✖	✖	✖	✖	● (I)

BRCA2 mutation

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
olaparib	○	✖	✖	✖	● (II)
rucaparib	✖	○	✖	○	✖
atezolizumab	✖	✖	✖	✖	● (II)
MK-1775	✖	✖	✖	✖	● (II)
MK-1775 + chemotherapy, veliparib + chemotherapy	✖	✖	✖	✖	● (II)
prexasertib	✖	✖	✖	✖	● (II)
VX-970, VX-970 + chemotherapy	✖	✖	✖	✖	● (I/II)
14C-rucaparib, rucaparib	✖	✖	✖	✖	● (I)
BGB-290 + BGB-A317	✖	✖	✖	✖	● (I)
durvalumab + olaparib	✖	✖	✖	✖	● (I)
PNT-737 + chemotherapy	✖	✖	✖	✖	● (I)
talazoparib + chemotherapy	✖	✖	✖	✖	● (I)

TP53 mutation

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
MK-1775 + olaparib	✖	✖	✖	✖	● (II)

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

Referring pathology dept: Sapienza Universita di roma

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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 mutation (continued)

Relevant Therapy	EMA	FDA	ESMO	NCCN	Clinical Trials*
VX-970, VX-970 + chemotherapy	✖	✖	✖	✖	● (I/II)
LY3143921	✖	✖	✖	✖	● (I)
pembrolizumab + p53MVA	✖	✖	✖	✖	● (I)
PNT-737 + chemotherapy	✖	✖	✖	✖	● (I)
SGT-53, SGT-53 + chemotherapy	✖	✖	✖	✖	● (I)

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

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Relevant Therapy Details

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 2017-09-25. For the most up-to-date information, search www.ema.europa.eu/ema.

ERBB2 amplification

○ ado-trastuzumab emtansine

Cancer type: Breast Cancer **Label as of:** 2017-07-27 **Variant class:** ERBB2 amplification

Reference:

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

○ lapatinib + aromatase inhibitor

Cancer type: Breast Cancer **Label as of:** 2017-08-29 **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 + capecitabine

Cancer type: Breast Cancer **Label as of:** 2017-08-29 **Variant class:** ERBB2 amplification

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:** 2017-08-29 **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)

pertuzumab + trastuzumab + docetaxel

Cancer type: Breast Cancer **Label as of:** 2017-08-22 **Variant class:** ERBB2 amplification

Reference:

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

trastuzumab + aromatase inhibitor

Cancer type: Breast Cancer **Label as of:** 2017-04-19 **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/000278/WC500074922.pdf

trastuzumab, trastuzumab + capecitabine, trastuzumab + carboplatin + docetaxel, trastuzumab + cisplatin + fluorouracil, trastuzumab + docetaxel, trastuzumab + paclitaxel

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2017-04-19 **Variant class:** ERBB2 amplification

Reference:

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

BRCA2 mutation

olaparib

Cancer type: Ovarian Cancer **Label as of:** 2017-06-14 **Variant class:** BRCA mutation

Reference:

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003726/WC500180151.pdf

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Current FDA Information

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

FDA information is current as of 2017-09-25. For the most up-to-date information, search www.fda.gov.

ERBB2 amplification

○ 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

○ neratinib

Cancer type: Breast Cancer **Label as of:** 2017-07-17 **Variant class:** ERBB2 amplification

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

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

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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

trastuzumab

Cancer type: Breast Cancer, Esophageal Cancer, Gastric Cancer **Label as of:** 2017-04-27 **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.

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

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103792s5337lbl.pdf

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BRCA2 mutation

rucaparib

Cancer type: Ovarian Cancer **Label as of:** 2016-12-19 **Variant class:** BRCA mutation

Indications and usage:

RUBRACA™ is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA™.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Reference:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209115s000lbl.pdf

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Current ESMO Information

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

ESMO information is current as of 2017-09-01. For the most up-to-date information, search www.esmo.org.

ERBB2 amplification

○ trastuzumab + capecitabine + cisplatin

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Not specified

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

○ 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 + cisplatin + fluorouracil

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

ESMO Recommendation category: I, A

Population segment (Line of therapy):
- Not specified

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

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ERBB2 amplification (continued)

trastuzumab + 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 containing regimen

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

ESMO Recommendation category: II, B

Population segment (Line of therapy):
- Not Specified

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

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.]

ado-trastuzumab emtansine

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

ESMO Recommendation category: 1, A

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

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + chemotherapy

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

ESMO Recommendation category: 1, A

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

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

trastuzumab + chemotherapy

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

ESMO Recommendation category: 1, 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 (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

trastuzumab + taxane

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

ESMO Recommendation category: 1, A

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

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

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ERBB2 amplification (continued)

trastuzumab + vinorelbine

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

ESMO Recommendation category: 1, A

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

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

lapatinib + trastuzumab

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

ESMO Recommendation category: 1, B

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

Reference: ESMO Clinical Practice Guidelines - ESO-ESMO Advanced Breast Cancer [Ann Oncol (2016) doi: 10.1093/annonc/mdw544 and The Breast 2016, doi: dx.doi.org/10.1016/j.breast.2016.10.001.]

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Current NCCN Information

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

NCCN information is current as of 2017-09-01. 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

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

NCCN Recommendation category: 1

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

○ trastuzumab + capecitabine + cisplatin

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

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

○ trastuzumab + capecitabine + cisplatin

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

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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ERBB2 amplification (continued)

trastuzumab + chemotherapy

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

Other criteria: ER negative, PR negative

NCCN Recommendation category: 1

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + cisplatin + fluorouracil

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

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

trastuzumab + cisplatin + fluorouracil

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

NCCN Recommendation category: 1

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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ERBB2 amplification (continued)

trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 1

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

ado-trastuzumab emtansine

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or metastatic Invasive Breast Cancer; Only if not suitable for preferred treatment (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

hormone therapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic histology; Node metastasis ≤2 mm axillary; Tumor ≤0.5 cm including microinvasive; pN1mi (Not specified)
- Ductal, Lobular, Mixed, Metaplastic histology; Node metastasis ≤2 mm axillary; Tumor 06.-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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ERBB2 amplification (continued)

lapatinib + capecitabine

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or metastatic Invasive Breast Cancer; trastuzumab-exposed (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

lapatinib + trastuzumab

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or metastatic Invasive Breast Cancer; trastuzumab-exposed; Without cytotoxic therapy (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

pertuzumab + trastuzumab + chemotherapy

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- 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 2.2017]

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ERBB2 amplification (continued)

pertuzumab + trastuzumab + paclitaxel

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

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

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + capecitabine

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or metastatic Invasive Breast Cancer (Not specified)
- Recurrent or metastatic Invasive Breast Cancer; trastuzumab-exposed (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + carboplatin + paclitaxel

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

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

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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ERBB2 amplification (continued)

trastuzumab + chemotherapy

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

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic, Tubular, Mucinous histology; Node metastasis ≤2 mm axillary; Tumor ≤0.5 cm including microinvasive pN1mi or Tumor 06.-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + chemotherapy (other)

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

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

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Recurrent or metastatic Invasive Breast Cancer; trastuzumab-exposed (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + docetaxel

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

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

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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ERBB2 amplification (continued)

trastuzumab + hormone therapy + chemoradiation therapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic histology; Node metastasis ≤2 mm axillary; Tumor ≤0.5 cm including microinvasive; pN1mi (Not specified)
- Ductal, Lobular, Mixed, Metaplastic histology; Node metastasis ≤2 mm axillary; Tumor 06.-1.0 cm (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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trastuzumab + paclitaxel

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

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

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

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ERBB2 amplification (continued)

trastuzumab + vinorelbine

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

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

NCCN Recommendation category: 2A

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

hormone therapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2B

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

trastuzumab + capecitabine

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

trastuzumab + capecitabine

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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ERBB2 amplification (continued)

○ trastuzumab + capecitabine + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

○ trastuzumab + capecitabine + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

○ trastuzumab + carboplatin + docetaxel + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

○ trastuzumab + carboplatin + docetaxel + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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ERBB2 amplification (continued)

trastuzumab + carboplatin + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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trastuzumab + carboplatin + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + chemotherapy

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

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Ductal, Lobular, Mixed, Metaplastic, Tubular, Mucinous histology; Tumor ≤0.5 cm including microinvasive; pN0 (Not specified)

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

---

trastuzumab + cisplatin + docetaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

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ERBB2 amplification (continued)

trastuzumab + cisplatin + docetaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + cisplatin + docetaxel + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

---

trastuzumab + cisplatin + docetaxel + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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trastuzumab + cisplatin + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
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ERBB2 amplification (continued)

trastuzumab + cisplatin + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + docetaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

---

trastuzumab + docetaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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trastuzumab + docetaxel + fluorouracil + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

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ERBB2 amplification (continued)

trastuzumab + docetaxel + fluorouracil + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

---

trastuzumab + fluorouracil

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

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trastuzumab + fluorouracil + irinotecan

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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ERBB2 amplification (continued)

trastuzumab + fluorouracil + irinotecan

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + fluorouracil + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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trastuzumab + fluorouracil + oxaliplatin

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + hormone therapy

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

Other criteria: ER positive, PR positive

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 2.2017]

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ERBB2 amplification (continued)

○ trastuzumab + hormone therapy + chemotherapy

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

Other criteria: ER positive, PR positive

NCCN Recommendation category: 2B

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

○ trastuzumab + paclitaxel

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

Other criteria: ER negative, PR negative

NCCN Recommendation category: 2B

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

Reference: NCCN Guidelines® - NCCN-Breast Cancer [Version 2.2017]

○ trastuzumab + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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ERBB2 amplification (continued)

trastuzumab + paclitaxel

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

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- Unresectable locally advanced, recurrent, or metastatic Adenocarcinoma, local therapy not indicated (First-line therapy)

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + capecitabine + cisplatin + epirubicin

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

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

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

---

trastuzumab + capecitabine + cisplatin + epirubicin

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

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

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

---

trastuzumab + capecitabine + epirubicin + oxaliplatin

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

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

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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Email: info@oncologica.com

ERBB2 amplification (continued)

trastuzumab + capecitabine + epirubicin + oxaliplatin

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

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

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

trastuzumab + cisplatin + epirubicin + fluorouracil

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

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

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

trastuzumab + cisplatin + epirubicin + fluorouracil

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

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

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

trastuzumab + epirubicin + fluorouracil + oxaliplatin

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

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

Reference: NCCN Guidelines® - NCCN-Esophageal and Esophagogastric Junction Cancers [Version 2.2017]

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 + epirubicin + fluorouracil + oxaliplatin

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

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

Reference: NCCN Guidelines® - NCCN-Gastric Cancer [Version 3.2017]

BRCA2 mutation

rucaparib

Cancer type: Ovarian Cancer **Variant class:** BRCA mutation

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- Advanced Ovarian Cancer who have received 2 or more lines of chemotherapy; Platinum-resistance disease (Recurrence therapy)

Reference: NCCN Guidelines® - NCCN-Ovarian Cancer [Version 3.2017]

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 Clinical Trials Information

Clinical Trials information is current as of 2017-09-01. 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'.

BRCA2 mutation + TP53 mutation

NCT02797977
A Phase 1 Trial of Oral SRA737 (a Chk1 Inhibitor) Given in Combination With Gemcitabine Plus Cisplatin or Gemcitabine Alone in Subjects With Advanced Cancer

Cancer type: Bladder Cancer

Variant classes: BRCA2 & TP53 mutation

Other identifiers: 198606, 30498, CRUKD/16/005, PNT737-02, SRA737-02

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

Phase: I

Therapy: PNT-737 + chemotherapy

Location: United Kingdom

ERBB2 amplification

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

Cancer type: Bladder Cancer

Variant class: ERBB2 amplification

Other identifier: 15-335

Population segments: First line, Stage III, Stage IV

Phase: II

Therapy: ado-trastuzumab emtansine

Location: United States

US State: NY

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

NCT02780687
LUX-Bladder 1: Phase II Open Label Single Arm Exploratory Trial of Oral Afatinib Monotherapy Following Platinum Failure for Patients With Advanced/Metastatic Urothelial Tract Carcinoma With Genetic Alterations in ERBB Receptors.

Cancer type: Bladder Cancer

Variant class: ERBB2 amplification

Other identifiers: 1200.261, EudraCT Number: 2015-005427-10, REec-2016-2295

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

Phase: II

Therapy: afatinib

Locations: 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.

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ERBB2 amplification (continued)

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-C1, EAY131-C2, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-J, EAY131-L, EAY131-M, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-W, EAY131-X, EAY131-Y, EAY131-Z1A, EAY131-Z1B, EAY131-Z1C, EAY131-Z1D, EAY131-Z1E, EAY131-Z1F, EAY131-Z1G, EAY131-Z1H, EAY131-Z1I, EAY131-Z1J, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH

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

Phase: II

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

Locations: Puerto Rico, United States

US States: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

US Contact: Fox Chase Cancer Center [888-369-2427]

NCT02029001
A Two-period, Multicenter, Randomized, Open-label, Phase II Study Evaluating the Clinical Benefit of a Maintenance Treatment Targeting Tumor Molecular Alterations in Patients With Progressive Locally-advanced or Metastatic Solid Tumors MOST: My own specific treatment

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: ET12-081, EudraCT number: 2012-004510-34, MOST, ProfiLER

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

Phase: II

Therapy: lapatinib

Location: France

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ERBB2 amplification (continued)

NCT02091141

My Pathway: An Open-Label Phase IIa Study Evaluating Trastuzumab/ Pertuzumab, Erlotinib, Vemurafenib/ Cobimetinib, Vismodegib, Alectinib, and Atezolizumab in Patients Who Have Advanced Solid Tumors With Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: 1403013519, 2014-0459, AAAN9701, J1480, ML28897, ML28897/PRO 02, ML28897PRO/02, My Pathway, MyPathway, NCI-2014-01811

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

Phase: II

Therapy: pertuzumab + trastuzumab

Location: United States

US States: AR, AZ, CA, CO, FL, GA, IL, MD, MN, MO, NC, ND, NY, OH, OK, OR, PA, SD, TN, TX, VA, WA, WI

US Contact: Hoffmann-La Roche, Study Director [888-662-6728; global.rochegenentechtrials@roche.com]

NCT02693535

Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: NCI-2017-00510, Pro00014171, TAPUR

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: United States

US States: AZ, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, UT, WA

US Contact: Pam Mangat [pam.mangat@asco.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)

NCT02925234
A Dutch National Study on behalf of the Center for Personalized Cancer Treatment (CPCT) to Facilitate Patient Access to Commercially Available, Targeted Anti-cancer Drugs to determine the Potential Efficacy in Treatment of Advanced Cancers with a Known Molecular Profile

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: DRUP, EudraCT Number: 2015-004398-33, M15DRU, NL54757.031.16

Population segments: Aggressive, Diffuse large B-cell lymphoma (DLBCL), First line, Follicular lymphoma (FL), Indolent, Mantle cell lymphoma (MCL), Other subtype, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: pertuzumab + trastuzumab

Location: Netherlands

NCT01935843
Clinical Study of Chimeric HER-2 Antigen Receptor-modified T Cells in Chemotherapy Refractory HER-2 Advanced Solid Tumors.

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 positive

Other identifier: CHN-PLAGH-BT-009

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

Phase: I/II

Therapy: CART-HER-2

Location: China

NCT02442414
A Phase 1 Study of KBP-5209 in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: ERBB aberration

Other identifiers: 2014-0891, 5209-CPK-1001, NCI-2015-00881

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

Phase: I/II

Therapy: pirotinib

Location: United States

US States: IN, TX, UT

US Contact: Matthew S. Hunt [608-332-8641; Matthew.hunt2@covance.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)

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 identifier: 149517

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

Phase: I

Therapy: neratinib + pertuzumab + trastuzumab + chemotherapy

Location: 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

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

Phase: I

Therapy: pirotinib

Location: China

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

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 amplification

Other identifiers: NCI-2017-00491, SHRUS 1001

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

Phase: I

Therapy: pyrotinib

Location: United States

US States: MA, 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.

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ERBB2 amplification (continued)

NCT02435927
Phase I Study to Evaluate the Safety and Tolerability of ASLAN001 in Combination with Oxaliplatin and Capecitabine or Oxaliplatin and 5-FU with Leucovorin

Cancer type: Unspecified Solid Tumor

Variant class: ERBB2 aberration

Other identifier: ASLAN001-002SG

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

Exclusion criteria variant class: EGFR T790M mutation

Phase: I

Therapy: varlitinib + chemotherapy

Location: Singapore

BRCA2 mutation

NCT02546661
An Open-Label, Randomised, Multi-Drug, Biomarker-Directed, Multi-Centre, Multi-arm Phase Ib Study in Patients With Muscle Invasive Bladder Cancer (MIBC) Who Have Progressed on Prior Treatment (BISCAY).

Cancer type: Bladder Cancer

Variant class: BRCA2 aberration

Other identifiers: 16-1579, AAAQ4008, AZ-D2615C00001-GU118, BISCAY, D2615C00001, EudraCT Number: 2015-002228-25, GU 118, IRAS ID: 184374, J1604, NCI-2016-01122

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

Phase: I

Therapy: durvalumab + olaparib

Locations: Canada, France, Spain, United Kingdom, United States

US States: MD, NY, TN, WI

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.

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BRCA2 mutation (continued)

NCT02465060
Molecular Analysis for Therapy Choice (MATCH)

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: 15-7002, CTSU/EAY131, EAY131, EAY131-A, EAY131-B, EAY131-C1, EAY131-C2, EAY131-E, EAY131-F, EAY131-G, EAY131-H, EAY131-I, EAY131-J, EAY131-L, EAY131-M, EAY131-MATCH, EAY131-N, EAY131-P, EAY131-Q, EAY131-R, EAY131-S1, EAY131-S2, EAY131-T, EAY131-U, EAY131-V, EAY131-W, EAY131-X, EAY131-Y, EAY131-Z1A, EAY131-Z1B, EAY131-Z1C, EAY131-Z1D, EAY131-Z1E, EAY131-Z1F, EAY131-Z1G, EAY131-Z1H, EAY131-Z1I, EAY131-Z1J, ECOGEAY131-M, MATCH, NCI-2015-00054, NCI-MATCH

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

Phase: II

Therapy: MK-1775

Locations: Puerto Rico, United States

US States: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

US Contact: Fox Chase Cancer Center [888-369-2427]

NCT02693535
Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: NCI-2017-00510, Pro00014171, TAPUR

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), Indolent, Lymphoblastic lymphoma (LBL), Mantle cell lymphoma (MCL), Other subtype, Second line or greater/Refractory/Relapsed, Small lymphocytic lymphoma (SLL), Stage III, Stage IV, Waldenstrom`s macroglobulinemia (WM)

Phase: II

Therapy: olaparib

Location: United States

US States: AZ, GA, IL, MI, NC, ND, NE, OK, OR, PA, SD, UT, WA

US Contact: Pam Mangat [pam.mangat@asco.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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BRCA2 mutation (continued)

NCT02873975
A Phase II Study of the CHK1 Inhibitor LY2606368 in Patients With Advanced Solid Tumors Exhibiting Replicative Stress or Homologous Recombination Repair Deficiency

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: 16-281, I4D-MC-E006, NCI-2016-01564

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

Phase: II

Therapy: prexasertib

Location: United States

US State: MA

US Contact: Dr. Geoffrey Shapiro [617-632-4942; Geoffrey_Shapiro@dfci.harvard.edu]

NCT02091141
My Pathway: An Open-Label Phase IIa Study Evaluating Trastuzumab/ Pertuzumab, Erlotinib, Vemurafenib/ Cobimetinib, Vismodegib, Alectinib, and Atezolizumab in Patients Who Have Advanced Solid Tumors With Mutations or Gene Expression Abnormalities Predictive of Response to One of These Agents

Cancer type: Unspecified Solid Tumor

Variant class: DNA repair pathway

Other identifiers: 1403013519, 2014-0459, AAAN9701, J1480, ML28897, ML28897/PRO 02, ML28897PRO/02, My Pathway, MyPathway, NCI-2014-01811

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

Phase: II

Therapy: atezolizumab

Location: United States

US States: AR, AZ, CA, CO, FL, GA, IL, MD, MN, MO, NC, ND, NY, OH, OK, OR, PA, SD, TN, TX, VA, WA, WI

US Contact: Hoffmann-La Roche, Study Director [888-662-6728; global.rochegenentechtrials@roche.com]

NCT01827384
Molecular Profiling-Based Assignment of Cancer Therapy for Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: DNA repair pathway

Other identifiers: 13-C-0105, 130105, 9149, M-PACT, MPACT, NCI-13-C-0105, NCI-2013-01588, NCI-MPACT, P121047

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

Phase: II

Therapies: MK-1775 + chemotherapy, veliparib + chemotherapy

Location: United States

US States: CO, KY, MD, MO, NJ, PA, TX

US Contact: National Institutes of Health Clinical Center [888-624-1937]

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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BRCA2 mutation (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 Cancer

Variant class: DNA repair pathway

Other identifiers: 1508016363, 16-314, NCI-2016-00922, OLAPCO

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

Phase: II

Therapy: olaparib

Location: United States

US States: CT, MA, TN

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

No NCT ID - see other identifier(s)
An Open-Label Study of the Safety, Tolerability, and Pharmacokinetic/ Pharmacodynamic Profile of VX-970 as a Single Agent in Combination with Carboplatin in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: DNA repair mutation

Other identifiers: EudraCT Number: 2013-005100-34, VX13-970-002

Population segments: (N/A), Adenocarcinoma, HER2 negative, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapies: VX-970, VX-970 + chemotherapy

Location: United Kingdom

NCT02986100
An Open-Label, Non-Randomized, Phase I Study to Assess the Absorption, Metabolism, and Excretion Following a Single Oral Dose of [14C]-Rucaparib in Patients With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: CO-338-045, EudraCT Number: 2015-004394-32

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

Phase: I

Therapies: 14C-rucaparib, rucaparib

Location: Hungary

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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BRCA2 mutation (continued)

NCT02317874
A Phase I Study of BMN 673 in Combination with Carboplatin and Paclitaxel in Patients with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: BRCA2 mutation

Other identifiers: 051513, 9782, NCI 9782, NCI-2014-02474, NCI9782

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

Phase: I

Therapy: talazoparib + chemotherapy

Location: United States

US States: NJ, WI

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

NCT02660034
A Phase 1b, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics and Antitumor Activity of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Combination With the PARP Inhibitor BGB-290 in Subjects With Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: HRR pathway

Other identifiers: BGB-A317/BGB-290_Study_001, CT783

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

Phase: I

Therapy: BGB-290 + BGB-A317

Location: Australia

TP53 mutation

NCT03096054
A Cancer Research UK (CR-UK) Phase I Trial of LY3143921 a Cdc7 Inhibitor in Adult Patients With Advanced Solid Tumours

Cancer type: Bladder Cancer

Variant class: TP53 mutation

Other identifier: CRUKD/17/004

Population segments: HER2 negative, Line of therapy N/A, Squamous Cell, Stage III, Stage IV, Triple receptor negative

Phase: I

Therapy: LY3143921

Location: United Kingdom

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

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TP53 mutation (continued)

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

Cancer type: Bladder Cancer

Variant class: TP53 mutation

Other identifiers: 116634, 122284, 122771, 124524, 15002, 17012, NCI-2015-00653

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

Phase: I

Therapy: pembrolizumab + p53MVA

Location: United States

US State: CA

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

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, 16-314, NCI-2016-00922, OLAPCO

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

Phase: II

Therapy: MK-1775 + olaparib

Location: United States

US States: CT, MA, TN

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

No NCT ID - see other identifier(s)
An Open-Label Study of the Safety, Tolerability, and Pharmacokinetic/ Pharmacodynamic Profile of VX-970 as a Single Agent in Combination with Carboplatin in Subjects with Advanced Solid Tumors

Cancer type: Unspecified Solid Tumor

Variant class: TP53 mutation

Other identifiers: EudraCT Number: 2013-005100-34, VX13-970-002

Population segments: (N/A), Adenocarcinoma, HER2 negative, Second line or greater/ Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase: I/II

Therapies: VX-970, VX-970 + chemotherapy

Location: United Kingdom

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

Disclaimer: The data presented here is a result of the curation of published data sources, but may not be exhaustive. The data version is 2017.11(006).

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TP53 mutation (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

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

Phase: I

Therapies: SGT-53, SGT-53 + chemotherapy

Location: United States

US State: 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.

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Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

ERBB2 amplification

Variant Class	Evidence Items
ERBB aberration	1
↳ ERBB2 status	0
↳ ERBB2 aberration	1
↳ ERBB2 positive	7
↳ ERBB2 amplification	88

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Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

BRCA2 mutation

Variant Class	Evidence Items
DNA repair pathway	3
↳ DNA repair mutation	1
↳ BRCA mutation	3
↳ BRCA2 mutation	7
↳ BRCA2 aberration	1
↳ BRCA2 mutation	7
HRR pathway	1
↳ BRCA2 aberration	1
↳ BRCA2 mutation	7
↳ HRR mutation	0
↳ BRCA mutation	3
↳ BRCA2 mutation	7
Fanconi anemia pathway	0
↳ FANC mutation	0
↳ BRCA2 mutation	7
↳ BRCA2 aberration	1
↳ BRCA2 mutation	7
↳ BRCA mutation	3
↳ BRCA2 mutation	7

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

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Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

TP53 mutation

Variant Class	Evidence Items
TP53 mutation	7

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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