Trial record **1 of 1** for: sophia AND Margetuximab

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Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of HER2+ Metastatic Breast Cancer (SOPHIA)

This study is currently recruiting participants.

See **Contacts and Locations**

Verified September 2017 *by MacroGenics*

Sponsor:
MacroGenics

Information provided by (Responsible Party):
MacroGenics

ClinicalTrials.gov Identifier:
NCT02492711

First received: July 6, 2015
Last updated: September 13, 2017
Last verified: September 2017
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer

How to Read a Study Record

Purpose

The purpose of this study is to determine whether patients treated with **margetuximab** plus chemotherapy have longer progression free survival and overall survival than patients treated with trastuzumab plus chemotherapy.

Condition	Intervention	Phase
HER-2 Positive Breast Cancer Metastatic Neoplasm	Biological: **Margetuximab** Biological: Trastuzumab Drug: Capecitabine Drug: Eribulin Drug: Gemcitabine Drug: Vinorelbine	Phase 3

Access to an investigational treatment associated with this study is available outside the clinical trial. More info ...

Study Type:	Interventional
Study Design:	Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment
Official Title:	A Phase 3, 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

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

Drug Information available for: Trastuzumab

U.S. FDA Resources

Further study details as provided by MacroGenics:

Primary Outcome Measures:

- Progression-free survival (PFS) as determined by independent radiological review.
  [Time Frame: Approximately 41 months after the first subject is randomized; anticipated evaluation Dec 2018]
- Overall survival (OS) defined as the number of days from randomization to the date of death (from any cause). [Time Frame: Approximately 15 months after the last subject is randomized; anticipated evaluation Mar 2020]

  Overall survival of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with advanced HER2+ breast cancer.

Secondary Outcome Measures:

- To evaluate progression-free survival (PFS), as assessed by study investigators.
  [Time Frame: PFS will be evaluated approximately 41 months after the first subject is randomized.]
- To evaluate the objective response rate (ORR) as determined by independent radiological review.
  [Time Frame: ORR will be evaluated approximately 41 months after the first subject is randomized.]

Estimated Enrollment:	530
Study Start Date:	July 2015
Estimated Study Completion Date:	March 2021

Estimated Primary Completion Date: March 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **Margetuximab** plus chemotherapy **Margetuximab** 15 mg/kg every 21 days plus Capecitabine 1000 mg/m2 BID for 14 days in a 21-day cycle or Eribulin 1.4 mg/m2 Day 1 and 8 of a 21-day cycle or Gemcitabine 1000 mg/m2 Day 1 and 8 of a 21-day cycle or Vinorelbine 25-30 mg/m2 Day 1 and 8 of a 21-day cycle	Biological: **Margetuximab** 15 mg/kg via IV (intravenous) infusion over 120 minutes on day 1 of each 21 day cycle, until progression or unacceptable toxicity develops. Drug: Capecitabine 1000 mg/m2 BID for 14 days in a 21-day cycle Other Name: Xeloda® Drug: Eribulin 1.4 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Halaven® Drug: Gemcitabine 1000 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Gemzar ® Drug: Vinorelbine 25-30 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Navelbine®
Active Comparator: Trastuzumab plus chemotherapy Trastuzumab 8 mg/kg loading dose then 6 mg/kg every 21 days plus Capecitabine 1000 mg/m2 BID for 14 days in a 21-day cycle or Eribulin 1.4 mg/m2 Day 1 and 8 of a 21-day cycle or Gemcitabine 1000 mg/m2 Day 1 and 8 of a 21-day cycle or Vinorelbine 25-30 mg/m2 Day 1 and 8 of a 21-day cycle	Biological: Trastuzumab 8 mg/kg via IV (intravenous) infusion for the first dose and 6 mg/kg for all subsequent doses via IV infusion over 30-90 minutes on day 1 of each 21 day cycle, until progression or unacceptable toxicity develops. Other Name: Herceptin® Drug: Capecitabine 1000 mg/m2 BID for 14 days in a 21-day cycle Other Name: Xeloda® Drug: Eribulin 1.4 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Halaven® Drug: Gemcitabine 1000 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Gemzar ®

	Drug: Vinorelbine 25-30 mg/m2 on days 1 and 8 of a 21-day cycle Other Name: Navelbine®

Detailed Description:
An evaluation of efficacy, as measured by progression-free survival (PFS) assessed by independent review and overall survival (OS), of margetuximab plus chemotherapy compared with trastuzumab plus chemotherapy in patients with advanced HER2+ breast cancer who have received at least 2 prior lines of anti-HER2 directed therapy in the metastatic setting, or in case of having received (neo) adjuvant pertuzumab, at least 1 prior line of anti-HER2 directed therapy in the metastatic setting, and who have received at least one, and no more than three, lines of therapy overall in the metastatic setting.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically-proven metastatic or locally-advanced relapsed/refractory HER2+ breast cancer based on the most recently available tumor biopsy collected from the patient. Tumors may be estrogen receptor (ER)/progesterone receptor (PgR) positive or negative.
- Have received at least 2 prior lines of anti-HER2 directed therapy in the metastatic setting, or in case of having received (neo)adjuvant pertuzumab, at least 1 prior line of anti-HER2 directed therapy in the metastatic setting. In either case, patients must have received prior treatment with pertuzumab, in the (neo)adjuvant or metastatic setting. Prior radiotherapy, hormonal therapies, and other anti-HER2 therapies are allowed.
- Prior treatment with at least one, and no more than three, lines of therapy overall in the metastatic setting. Patients must have progressed on or following, the most recent line of therapy.
- Resolution of all chemotherapy or radiation-related toxicities to ≤ Grade 1
- Life expectancy ≥ 12 weeks
- Acceptable laboratory parameters
- Women of childbearing potential must have negative pregnancy test performed within 14 days of randomization and on the first day of treatment. All subjects must agree to use an effective form of contraception for the duration of study treatment and for 7 months after the last dose of study drug.

Exclusion Criteria:

- Known, untreated brain metastasis. Patients with signs or symptoms of brain metastasis must have a CT or MRI performed within 4 weeks prior to randomization to specifically exclude the presence of radiographically-detected brain metastases
- History of uncontrolled seizures within 6 months of randomization
- History of prior allogeneic bone marrow, stem-cell, or solid organ transplantation

- History of clinically significant cardiovascular disease
- Clinically-significant pulmonary compromise, including a requirement for supplemental oxygen use to maintain adequate oxygenation
- Any condition that would be a contraindication to receiving trastuzumab as described in the approved local label or a condition that would prevent treatment with the physician's choice of chemotherapy

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02492711

Contacts

Contact: Sutton Edlich (240) 552-8082

Show 197 Study Locations

Sponsors and Collaborators

MacroGenics

Investigators

Study Director: Edwin Rock, MD PhD MacroGenics

More Information

Responsible Party:	MacroGenics
ClinicalTrials.gov Identifier:	NCT02492711 History of Changes
Other Study ID Numbers:	CP-MGAH22-04
Study First Received:	July 6, 2015
Last Updated:	September 13, 2017

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

Additional relevant MeSH terms:

Breast Neoplasms	Antimetabolites, Antineoplastic
Neoplasm Metastasis	Antimetabolites
Neoplasms by Site	Molecular Mechanisms of Pharmacological Action
Neoplasms	
Breast Diseases	Antineoplastic Agents
Skin Diseases	Antiviral Agents
Neoplastic Processes	Anti-Infective Agents
Pathologic Processes	Enzyme Inhibitors

Gemcitabine	Immunosuppressive Agents
Capecitabine	Immunologic Factors
Vinorelbine	Physiological Effects of Drugs
Trastuzumab	Antineoplastic Agents, Phytogenic

ClinicalTrials.gov processed this record on September 19, 2017