Margetuximab Demonstrated Single Agent Activity in a Phase 1 Study

- Margetuximab was evaluated in a dose escalation and expansion study in patients with HER2+ tumors
- Margetuximab was well tolerated with mild to moderate infusion-related reaction or cytokine release syndrome (e.g., fatigue, nausea, vomiting, diarrhea, and elevated liver enzymes)
- Single agent activity was observed in patients with breast or gastric cancer
- Safety and activity profile of margetuximab was deemed acceptable to proceed with randomized study in patients with HER2+ MBC

Related Adverse Events: All That Occurred ≥10% of All Patients

- Infusion-related reaction
- Fatigue
- Nausea
- Pyrexia
- Vomiting
- Blood Amlyase Increased
- Chills
- Cytokine Release Syndrome
- Diarrhea
- Lymphocyte Count Decreased
- Lymphopenia

Percent (%) 0 20 40 60 80 100

Preferred Term

Data as of 01 Oct 2015

Study Design

- Phase 3, randomized, open-label, comparator-controlled study comparing margetuximab to trastuzumab, each in combination with chemotherapy
- Patients randomized 1:1 to receive either margetuximab or trastuzumab in combination with chemotherapy of the investigator's choice to be chosen from capecitabine, erubulin, gemcitabine, or vinorelbine
- N = 530 patients based on hazard ratio for OS of 0.75 with power of 80%
- Randomization stratified by number of metastatic sites (≤2, >2), number of lines of therapy in metastatic setting (≤2, >2), and choice of chemotherapy
- Independent radiologic review to determine PFS and ORR

Entry Criteria

- Histologically proven metastatic or locally-advanced/ refractory HER2+ breast cancer based on most recently available tumor biopsy collected from the patient. Tumors may be estrogen receptor (ER)/progesterone receptor (PR) positive or negative
- Prior treatment with pertuzumab, trastuzumab, and ado-trastuzumab emtansine in neoadjuvant, adjuvant, or metastatic setting
- Prior radiotherapy, hormonal therapies, and other anti-HER2 therapies are allowed
- Prior treatment for at least one, and no more than three, lines of therapy in the metastatic setting. Patients must have progressed on or following, most recent line of therapy
- Resolution of all chemotherapy or radiation-related toxicities to ≤ Grade 1
- Acceptable laboratory parameters
- Negative pregnancy test and effective contraception

Key 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 prior allogeneic bone marrow, stem-cell, or solid organ transplantation
- History of clinically significant cardiovascular disease
- History of 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

Study Status

- Ongoing; 16 Countries, 192 Sites

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References


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