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MacroGenics Announces Margetuximab (MGAH22) Phase 1 Data Presentation at ASCO; Initiates Phase 2 Clinical Study to Evaluate Activity of Margetuximab in Patients with Metastatic Breast Cancer

ROCKVILLE, Maryland - May 21, 2013/PRNewswire/ - MacroGenics, Inc. today announced that an abstract titled, "Phase 1 study of margetuximab (MGAH22), an Fc-modified chimeric monoclonal antibody (MAb), in patients with advanced solid tumors expressing the HER2 oncoprotein," will be presented at the 2013 Annual Meeting of the American Society of Clinical Oncology during the Developmental Therapeutics - Immunotherapy Oral Abstract Session on Monday, June 3 at 4:15 - 4:30 PM. The presentation will describe the results of a first-in-human study of MacroGenics' next-generation anti-HER2 monoclonal antibody, margetuximab, which is being developed to treat HER2-expressing tumors.

MacroGenics has optimized the Fc region of margetuximab to increase cancer cell killing via Antibody-Dependent Cell-mediated Cytotoxicity (ADCC). Margetuximab also has shown improved control of tumor growth in human tumor xenograft models in mice as compared to that of anti-HER2 antibodies with a wild type Fc region. A development goal for margetuximab is to enable the treatment of a broader population of patients than those eligible for treatment with current HER2-targeted therapies.

MacroGenics also announced that the first patient has received study drug in a Phase 2 clinical study evaluating margetuximab in patients with metastatic breast cancer. This study is designed to evaluate the activity of margetuximab in up to 41 patients with metastatic breast cancer whose tumors express a moderate level of the oncoprotein, HER2, represented by a 2+ score by immunohistochemistry. These tumors must also lack evidence of HER2 gene amplification as determined by FISH testing. The trial is being conducted at six sites across the United States. For more information on the clinical trial, please see www.clinicaltrials.gov.

"To date, the results of our Phase 1 study are very encouraging and thus provide justification for advancing margetuximab into Phase 2 development," stated Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "While HER2 has proven to be an important target for several approved anti-cancer therapies, many patients are inadequately treated with existing therapies. Our next study will explore whether margetuximab can improve clinical outcomes in a sub-population of breast cancer patients, particularly those with low HER2 expression. Additional studies with margetuximab in patients with HER-2 expressing tumors other than breast cancer are anticipated."

About Breast Cancer and Margetuximab

The HER2 oncoprotein is over-expressed and plays an important role in tumorigenesis, tumor aggressiveness, and outcome in breast cancer and other solid tumors. HER2 has proven to be an excellent target for cancer therapeutics, given the success of currently marketed HER2-directed therapies.

According to the National Cancer Institute, over 230,000 women in the U.S. are diagnosed with breast cancer annually. Of these women, only about 20% have tumors that are HER2 positive (IHC 3+, or HER2 gene-amplified). One development goal for margetuximab is to target a similarly large group of patients whose tumors exhibit HER2 expression that is less than 3+ and lack evidence of HER2 gene amplification and for whom current anti-HER2 therapies are not indicated. Another goal for margetuximab is to determine if the Fc modifications will improve clinical outcomes in patients with tumors that are currently treated with other HER2 therapies, which would be consistent with results seen in laboratory models.

About MacroGenics, Inc.

MacroGenics is a leader in the discovery and development of innovative medicines that utilize its next-generation antibody-based technologies. The company is advancing a pipeline of product candidates to treat patients with cancer and other serious, complex diseases. MacroGenics' products and platforms have attracted multiple partnerships with leading pharmaceutical companies around the globe. www.macrogenics.com

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enroll patients in, planned clinical trials. The Company assumes no obligation to update any forward-looking statements as a result of new information, future events or developments, except as required by law.