May 30, 2015

MacroGenics Presents Updated Data from Phase 1 Study of Margetuximab at ASCO Annual Meeting 2015

Data Show Signs of Clinical Activity for Margetuximab in HER2-Expressing Tumors

ROCKVILLE, Md., May 30, 2015 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (Nasdaq:MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases, announced that updated results of the Phase 1 study of margetuximab were reported during a poster session today at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO). Howard A. Burris III, M.D., FACP, Chief Medical Officer of Sarah Cannon Research Institute, and first author presented "Updated findings of a first-in-human, phase 1 study of margetuximab, an Fc-optimized chimeric monoclonal antibody, in patients with HER2-positive advanced solid tumors," during the Breast Cancer HER2/ER poster session. The primary objective of the study was to evaluate safety of margetuximab using two dosing regimens. Margetuximab was found to be well-tolerated at all doses.

Study Results

This open-label, multi-dose, single-arm, multi-center Phase 1, dose-escalation study was conducted in 60 patients with HER2-positive (2+ or 3+ by immunohistochemistry, or IHC) neoplasms, including 23 with breast cancer, and was aimed at defining the toxicity profile, maximum tolerated dose, pharmacokinetics, immunogenicity and potential anti-tumor activity of margetuximab (MGAH22).

Margetuximab was administered by IV infusion once per week for 4 weeks in the following dose escalation cohorts: 0.1, 0.3, 1.0, 3.0, and 6.0 mg/kg; and once every 3 weeks in the following dose escalation cohorts: 10.0, 15.0, and 18.0 mg/kg. Study results showed that margetuximab was well-tolerated at all explored doses, including the highest dose tested. Infusion reactions were generally mild overall and were well controlled with pre-medication.

The most common adverse events (AEs) were Grade 1-2 constitutional symptoms and infusion-related reactions. No cardiac dysfunction was observed. Monotherapy anti-tumor activity was observed across several tumor types, including patients with gastric, colorectal and head and neck cancer as well as patients with breast cancer who had received extensive prior therapy and progressed on prior HER2-directed therapy. Tumor reductions were observed in 13 of 19 evaluable patients with breast cancer, including 4 of 19 patients with confirmed partial responses. In this population, a median progression-free survival (PFS) of approximately 5.5 months was observed.

MacroGenics will commence SOPHIA, a pivotal Phase 3 study in approximately 530 patients, in the third quarter of 2015. This study is planned to evaluate margetuximab plus chemotherapy against trastuzumab plus chemotherapy in third-line metastatic breast cancer patients with HER2 expression at the 3+ level by IHC or 2+ level by IHC with gene amplification. MacroGenics projects that it will take approximately three years to complete this study.

Dr. Burris commented, "Our team was pleased to find that margetuximab was well tolerated by patients in this study and showed promising activity in patients who have limited treatment options. The updated Phase 1 study results show the potential for margetuximab in the treatment of HER2-expressing tumors, and I look forward to the start of the Phase 3 SOPHIA breast cancer study."

The poster is available for download from the Events & Presentations page on MacroGenics' website at http://ir.macrogenics.com/events.cfm. In addition, a poster discussion session will take place at ASCO on Saturday, May 30, 2015, from 1:15 - 2:30pm (CT) at N Hall B1.

About Margetuximab

Margetuximab is an antibody that targets HER2-expressing tumors, including certain types of breast and gastroesophageal cancers. Human epidermal growth factor receptor 2, or HER2, is critical for the growth of many types of tumors. Using its Fc-optimization platform, the Company has engineered the Fc-region of margetuximab to increase margetuximab's ability to kill

tumor cells through an Fc-dependent mechanism, including antibody dependent cell-mediated cytotoxicity, or ADCC. In addition to its anticipated Phase 3 SOPHIA study in metastatic breast cancer, the Company also plans to commence an exploratory Phase 1/2 study in the fourth quarter of 2015 combining margetuximab with another immuno-oncology therapeutic in patients with gastroesophageal cancer.

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases. The company generates its pipeline of product candidates from its proprietary suite of next-generation antibody-based technology platforms. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see the Company's website at www.macrogenics.com. MacroGenics is a registered trademark of MacroGenics, Inc.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other risk factors described in the Company's filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

CONTACT: Jim Karrels, Senior Vice President, CFO

MacroGenics, Inc.

1-301-251-5172, info@macrogenics.com

Karen Sharma, Vice President

MacDougall Biomedical Communications

1-781-235-3060, ksharma@macbiocom.com

Source: MacroGenics, Inc.