



## Updated Clinical Data from Combination of Margetuximab and Pembrolizumab in Gastric Cancer Presented at 2019 ASCO Gastrointestinal Cancers Symposium

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- 32.7% Objective response rate in HER2+ IHC 3+ second-line gastric cancer patients
- Well tolerated in dose escalation and expansion cohorts

**ROCKVILLE, MD, January 17, 2019 (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, today announced presentation of updated data from its Phase 2 clinical trial of margetuximab plus pembrolizumab for patients with advanced HER2+ gastric carcinoma in a poster session at the 2019 ASCO Gastrointestinal Cancers Symposium in San Francisco, California. The poster was titled "Antitumor Activity of Margetuximab plus Pembrolizumab in Patients with Advanced HER2+ (IHC3+) Gastric Carcinoma."

This Phase 2 open-label, dose escalation study evaluates margetuximab, an Fc-optimized anti-HER2 monoclonal antibody, in combination with pembrolizumab, an anti-PD-1 antibody, an investigational regimen that is designed to coordinately engage innate and adaptive immunity for the treatment of patients with gastroesophageal cancer. The trial seeks to characterize the safety, tolerability, maximum tolerated dose, and antitumor activity of this combination. Enrolled patients had relapsed or refractory advanced HER2+ gastric or gastroesophageal junction cancer with disease progression after or resistance to treatment with trastuzumab plus chemotherapy. The 25 patients in the most recently enrolled expansion cohort had HER2+ gastric carcinoma that was 3+ by immunohistochemistry (IHC). Patients in the study were enrolled irrespective of PD-L1 expression status.

Acceptable tolerability was observed in the safety population of 95 patients, 92 of whom were treated at the recommended Phase 2 dose of 15 mg/kg for margetuximab and 200mg for pembrolizumab, both on an every three week schedule of administration. Grade 3 or higher treatment-related adverse events (TRAE) occurred in 17.9% of patients, the most common of which was infusion-related reaction (3.2%).

As of the January 8, 2019 data cut-off date for the current update of this ongoing study, objective responses were observed in 18/55 HER2+ (IHC 3+) response-evaluable gastric cancer patients, including 14 confirmed and 4 unconfirmed. The Objective Response Rate (ORR) for this population was 32.7%, with a Disease Control Rate (or DCR, which includes partial responses and stable disease) of 69.1%. Median Progression-Free Survival (PFS) was 4.7 months. In the subset of these patients who were also PD-L1 positive, objective responses were observed in 12/23 (52.2%) patients, with a DCR of 82.6% and PFS of 4.14 months. As of the data cut-off date, the study was ongoing with 13 patients remaining on therapy. The median Overall Survival (OS) in either of these groups was not reached at the time of data cut-off.

"We continue to be very encouraged by the tolerability and antitumor activity of margetuximab with an anti-PD-1 mAb, an investigational, chemotherapy-free approach that is designed to coordinately engage innate and adaptive immunity for treatment of patients with advanced HER2+ gastric cancer," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Later this quarter, we plan to discuss proposed development plans for testing margetuximab in combination with an anti-PD-1 agent with the U.S. FDA. We also intend to discuss plans with ex-U.S. regulatory agencies in collaboration with our partner in the Greater China region, Zai Lab, later this year."

The poster presented at the 2019 ASCO Gastrointestinal Cancers Symposium is available for download from the Events & Presentations page on MacroGenics' website at <http://ir.macrogenics.com/events.cfm>.

### About Margetuximab

Margetuximab is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastric, gastroesophageal, bladder and other forms of solid tumor cancers, making it a key marker for biologic therapy. The Phase 2 study of margetuximab in gastric cancer incorporates pembrolizumab, which is provided by Merck & Co., under a previously announced arrangement. MacroGenics is also studying margetuximab as a potential treatment for metastatic breast cancer in a Phase 3 study called SOPHIA, which has been fully enrolled and for which topline PFS results will be disclosed in the first quarter of 2019.

### 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. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. 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](http://www.macrogenics.com). MacroGenics, the MacroGenics logo and DART are trademarks or registered trademarks of MacroGenics, Inc.

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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 "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk of delays or failure in reaching an agreement with the FDA regarding the release of a clinical hold, 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 risks 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 only 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, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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