MacroGenics Announces Initiation of Phase 2/3 MAHOGANY Study of Margetuximab in Gastric or Gastroesophageal Junction Cancer

ROCKVILLE, MD, October 25, 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 that the first patient has been dosed in the Phase 2/3 MAHOGANY clinical trial of margetuximab, an investigational, Fc-optimized monoclonal antibody targeting HER2, in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with HER2-positive gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.

“The MAHOGANY study for patients with gastric or gastroesophageal junction cancer is designed to support registration of margetuximab and is a part of our strategy to advance margetuximab in HER2-positive cancers,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “The combination of margetuximab and a checkpoint inhibitor could potentially provide a chemotherapy-free option as a first-line treatment for patients whose tumors are positive for both HER2 and PD-L1 or be used with chemotherapy in a broader HER2-positive population to improve the clinical activity of existing standard of care.”

The MAHOGANY Study Design

MAHOGANY (NCT04082364) is a Phase 2/3 clinical trial in two modules designed to evaluate margetuximab in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with advanced or metastatic HER2-positive GEJ/GC.

Module A is designed as a single arm study to test margetuximab plus MGA012 (also known as INCMGA00012), an investigational anti PD-1 monoclonal antibody, in patients with HER2-positive and PD-L1-positive tumors. The primary outcome measure for efficacy is objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST).

Module B is designed as a randomized trial to test margetuximab plus a checkpoint inhibitor in combination with chemotherapy compared to standard of care therapy of trastuzumab with chemotherapy in patients with HER2-positive tumors irrespective of PD-L1 expression. Patients randomized to one of two experimental arms containing a checkpoint inhibitor will receive either MGA012 or MGD013, an investigational DART® molecule targeting PD-1 and LAG-3. The primary outcome measure for efficacy is overall survival (OS).

The Phase 2/3 clinical trial is planned to be conducted at clinical sites globally, in collaboration with Zai Lab, the company’s regional partner in Greater China. For additional information about the MAHOGANY study, please visit https://clinicaltrials.gov/ct2/show/NCT04082364.

The MAHOGANY study is based on results from an ongoing Phase 2 study of margetuximab plus pembrolizumab, an anti-PD-1 monoclonal antibody, for patients with advanced HER2-positive GC or GEJ cancer who have previously been treated with chemotherapy and trastuzumab in the metastatic setting. Data were presented at the European Society for Medical Oncology (ESMO) Annual Congress in September 2019.

About Gastric and Gastroesophageal Junction Cancer

Cancer of the stomach (gastric cancer) or the gastroesophageal junction (where the esophagus joins the stomach) is collectively known as gastroesophageal adenocarcinoma and is the fifth most common tumor type worldwide. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of 5-20%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2-positive.

About Margetuximab

Margetuximab is an investigational monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Margetuximab was designed to provide HER2 blockade and has similar HER2 binding and antiproliferative effects as trastuzumab. In addition, margetuximab has been engineered with MacroGenics' Fc Optimization technology to enhance the engagement of the immune system and affect killing of cancer cells through antibody dependent cellular cytotoxicity (ADCC). Beyond gastric and GEJ cancer, margetuximab is also being evaluated in combination with chemotherapy in the Phase 3 SOPHIA study for the treatment of patients with metastatic HER2-positive breast cancer who have previously been treated with anti-HER2-targeted therapies.

About MGA012

MGA012 is an investigational, humanized, proprietary anti-PD-1 monoclonal antibody being developed for use as monotherapy as well as in combination with other potential cancer therapeutics. MGA012 was licensed to Incyte Corporation in 2017 under an exclusive global collaboration and license agreement. MacroGenics retains the right to develop its pipeline molecules with MGA012. Incyte is pursuing development of MGA012 monotherapy in three potentially registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer. Incyte and MacroGenics are each conducting multiple studies of MGA012 in combination with other agents.

About MGD013

MGD013 is an investigational, first-in-class bispecific DART molecule designed to provide co-blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies.

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. MacroGenics, the MacroGenics logo and DART are trademarks or registered trademarks 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 "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 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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