MacroGenics Announces Margetuximab Granted Orphan Drug Designation in the U.S. for Gastric Cancer

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Rockville, MD, June 05, 2020 (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 U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to margetuximab, an investigational, Fc-engineered monoclonal antibody targeting HER2 for the treatment of gastric and gastroesophageal junction cancer.

Margetuximab is currently being evaluated in the Phase 2/3 MAHOGANY clinical trial in combination with checkpoint inhibition, 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 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.

“We are pleased that the FDA has granted orphan status to margetuximab,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We believe that our immune-enhancing antibody targeting HER2 has the potential to improve upon the clinical activity of existing standard of care for patients with gastric or gastroesophageal cancer.”

The FDA grants ODD to medicines intended for the treatment, diagnosis or prevention of rare diseases of disorders that affect fewer than 200,000 people in the U.S. The designation provides certain incentives, which may include seven years of marketing exclusivity for the orphan indication, certain federal grants, tax credits and waiver of certain FDA fees.

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. According to the American Cancer Society, approximately 27,600 new cases of gastric cancer will be diagnosed in the U.S in 2020 and more than 11,000 people will die from the disease. 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 Fc-engineered, 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 to enhance the engagement of the immune system through MacroGenics’ Fc Optimization technology. A Biologics License Application (BLA) for margetuximab for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy is under review by the FDA, with a Prescription Drug User Fee Act (PDUFA) goal date of December 18, 2020. Margetuximab is also being evaluated in combination with checkpoint blockade. The Phase 2/3 MAHOGANY trial for the treatment of patients with HER2-positive gastroesophageal cancer is ongoing (NCT04082364). For more information please visit www.clinicaltrials.gov.

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 the timing and steps required in the regulatory review process, expectations for regulatory approvals, the impact of competitive products, our ability to enter into agreements with strategic partners and other matters that could affect the availability or commercial potential of the Company's product candidates, business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises such as the novel coronavirus (referred to as COVID-19), 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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