MacroGenics Announces Submission of Margetuximab Biologics License Application to U.S. FDA

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ROCKVILLE, MD, Dec. 19, 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 Company has submitted a Biologics License Application (BLA) for margetuximab, an investigational, Fc-engineered, monoclonal antibody that targets HER2. The margetuximab BLA is for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy. The submission is based on the safety and efficacy results of the pivotal phase 3 SOPHIA study, which were first presented at the 2019 American Society of Clinical Oncology annual meeting, with updated data recently presented at the 2019 San Antonio Breast Cancer Symposium.

"As the Company's first BLA submission, this is a key milestone for MacroGenics. We are grateful to the patients who participated in this study, as well as their families, and all involved in developing margetuximab," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "With this submission, we look forward to working with the Agency to bring margetuximab to appropriate patients. We believe the positive clinical trial results in SOPHIA demonstrate margetuximab's potential as a treatment option for patients living with this devastating disease."

About the SOPHIA Study

The SOPHIA study (NCT02492711) is a randomized, open-label Phase 3 clinical trial evaluating margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer, who have previously been treated with anti-HER2-targeted therapies. All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine, or T-DM1.

The study enrolled 536 patients who were randomized 1:1 to receive either margetuximab (n=266) given intravenously at 15 mg/kg every three weeks or trastuzumab (n=270) given intravenously at 6 mg/kg (or 8 mg/kg for loading dose) every three weeks in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine) given at the standard dose. Intent-to-treat PFS analysis occurred after 265 PFS events, and the first and second interim OS analyses occurred after 158 and 270 OS events, respectively. Final OS analysis is planned after 385 events and is expected to occur in the second half of 2020.

Primary endpoints are sequentially-assessed PFS, determined by centrally-blinded radiological review, and OS. Key secondary endpoints are PFS by investigator assessment and ORR. Tertiary endpoints include ORR by investigator assessment and safety. PFS and ORR were assessed according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1). Effect of CD16A (FcγRIIIa) 158 genotype on margetuximab activity is a pre-specified exploratory endpoint.

About Margetuximab

Margetuximab is an investigational monoclonal antibody that targets the HER2 oncoprotein. Margetuximab was designed to provide HER2 blockade and has similar HER2 binding and antiproliferative effects as trastuzumab. In addition, the Fc region of margetuximab has been engineered to enhance the engagement of the immune system. Margetuximab is also being evaluated in combination with anti-PD-1 therapy for the potential treatment of patients with HER2-positive gastric or gastroesophageal junction cancer. MacroGenics has initiated the Phase 2/3 MAHOGANY study (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. For more information, please see the Company's website at www.macrogenics.com. MacroGenics and the MacroGenics logo 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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