



November 7, 2015

Data from MacroGenics' Ongoing Phase 1 Study of Enoblituzumab (MGA271) Presented at 30th Annual SITC Meeting 2015

- **Anti-B7-H3 antibody is well-tolerated**
- **Single-agent, anti-tumor activity observed across several tumor types**
- **Initial evidence of T-cell immunomodulatory role**

ROCKVILLE, Md., Nov. 07, 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 interim results of an ongoing Phase 1 dose-escalation study of enoblituzumab (MGA271) were presented in the late-breaking abstract session today at the 2015 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD. Dr. John Powderly II of the Carolina BioOncology Institute, Huntersville, NC, presented "Interim Results of an Ongoing Phase 1, Dose Escalation Study of MGA271 (Fc-optimized Humanized Anti-B7-H3 Monoclonal Antibody) in Patients with Refractory B7-H3-Expressing Neoplasms or Neoplasms Whose Vasculature Expresses B7-H3."

This study is being conducted to evaluate the safety of enoblituzumab in patients with advanced cancer that expresses B7-H3 in the tumor and/or tumor-associated vasculature. Additional study objectives are to define the toxicity profile, maximum tolerated dose, pharmacokinetics, immunogenicity and potential anti-tumor activity of enoblituzumab in patients with refractory cancer that expresses B7-H3.

Enoblituzumab has been well tolerated at all dose levels tested in the Phase 1 study (up to 15 mg/kg), with Grade 3/Grade 4 drug-related adverse events (AEs) in only 4% of patients, no severe immune-related adverse events, and no drug-related treatment discontinuations. The most common AEs have been infusion-related reactions and fatigue. Mild-moderate infusion reactions have been readily managed with conventional supportive care, including administration of corticosteroids and a decreased infusion rate.

In this ongoing Phase 1 dose-escalation study of enoblituzumab, monotherapy anti-tumor activity was observed across several tumor types, including patients with prostate and bladder cancer as well as melanoma. Overall, this patient population had been heavily pre-treated (median number of prior therapies = 3), and in the patients with melanoma, all had been treated previously with one or more checkpoint inhibitors (anti-CTLA-4, anti-PD-1 and/or anti-PD-L1 antibodies).

In addition to the presentation of initial safety and activity data, Dr. Powderly presented findings demonstrating increases in T-cell repertoire (TCR) clonality in the peripheral blood of tumor patients following treatment with enoblituzumab, demonstrating that enoblituzumab can modulate T cells in these patients. Collectively, these findings support the ongoing evaluation of enoblituzumab as monotherapy and in combination with other immuno-oncology agents, including pembrolizumab and ipilimumab.

"We are encouraged by the initial single-agent activity of enoblituzumab, including tumor regression in heavily pre-treated patients across several tumor types," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "The ongoing Phase 1 study also shows that enoblituzumab has been well tolerated in patients, suggesting that this anti-B7-H3 antibody also may be readily combinable with other immuno-oncology agents such as checkpoint inhibitors."

MacroGenics plans to present additional clinical data in 2016, as it continues to enroll patients in additional monotherapy expansion cohorts and recently commenced two combination studies of enoblituzumab with either ipilimumab or pembrolizumab.

Dr. Powderly's slide presentation at SITC is available for download from the Events & Presentations page on MacroGenics' website at <http://ir.macrogenics.com/events.cfm>.

Background on Enoblituzumab (MGA271)

Enoblituzumab is a humanized, Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules that are involved in immune regulation. B7-H3 is over-expressed by a wide variety of solid tumor cells as well as cancer stem

cells and tumor-associated vasculature. Enoblituzumab is currently undergoing Phase 1 testing both as monotherapy and in combination with checkpoint inhibitors across patients with a wide range of solid tumors. MacroGenics retains worldwide development and commercialization rights to its franchise of B7-H3 directed programs, including enoblituzumab and MGD009, a bi-specific Dual-Affinity Re-Targeting (DART®) molecule targeting B7-H3 and CD3.

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. DART, 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 "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.

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.

News Provided by Acquire Media