MacroGenics Presents Tebotelimab Data in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma at the 2020 ASH Annual Meeting

December 7, 2020

- ***53.8% ORR in relapsed/refractory DLBCL patients***
- ?***Preliminary duration of response of up to 168 days observed, with six of seven ongoing responses as of cut-off date*** ?

ROCKVILLE, MD, Dec. 07, 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 updated results from a dose expansion study of tebotelimab, an investigational, bispecific PD-1 × LAG-3 DART® molecule, in patients with diffuse large B-cell lymphoma (DLBCL). The data were presented at the 62nd Annual Meeting of the American Society of Hematology (ASH) taking place December 5-8, 2020.

LAG-3 has been shown to be highly expressed in DLBCL and has emerged as a therapeutic target of interest in this population, while PD-1-targeted therapy has yielded modest efficacy. There remains significant unmet need for patients with relapsed/refractory (R/R) DLBCL.

In one of the tebotelimab monotherapy dose expansion cohorts, 20 DLBCL patients were enrolled, half of whom were CAR T cell therapy experienced. As of the October 23, 2020 data cut-off, there were 13 response-evaluable patients.

A preliminary objective response rate (ORR) of 53.8% (7 of 13 patients) was observed, including responses in five of seven CAR T cell-naïve patients and in two of six CAR T cell experienced patients, the latter of whom both had complete responses. A preliminary duration of response of up to 168 days was observed, with six of seven ongoing responses as of the cut-off date. In the study, baseline LAG-3 expression appeared to associate with clinical response, with additional analyses ongoing.

Tebotelimab was generally well-tolerated among heavily pre-treated R/R DLBCL patients, with manageable infusion-related reactions and no evidence of tumor lysis syndrome. The most common TRAE was pyrexia, which occurred in three (15%) patients. A single Grade 3 TRAE of anemia was observed.

“Although early, the preliminary ORR observed in relapsed/refractory DLBCL patients treated with tebotelimab is promising,“ said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. “Beyond our continued enrollment of patients in the combination study of tebotelimab in solid tumors, we look forward to presenting data from the full cohort of the 20 enrolled DLBCL patients, as well as potentially defining a future registration path for this DART molecule.”

About Diffuse Large B-Cell Lymphoma

DLBCL is the most common histologic subtype of non-Hodgkin lymphoma (NHL) accounting for approximately 25 percent of NHL cases globally. According to published research, the incidence in the U.S. and England is approximately 7 cases per 100,000 persons per year, with a median age at presentation of 64 years. DLBCL represents a heterogeneous group of tumors consisting of large, transformed B cells with prominent nucleoli and basophilic cytoplasm, a diffuse growth pattern, and a high proliferation fraction. While DLBCL is curable in approximately half of cases with current therapy, particularly those who achieve a complete remission with first-line treatment, significant unmet medical need remains for patients with relapsed or refractory disease.

About Tebotelimab

Tebotelimab (previously known as MGD013) is an investigational, first-in-class bispecific, tetravalent DART molecule targeting PD-1 and LAG-3. Tebotelimab has been engineered to concomitantly or independently bind to PD-1 and LAG-3 and disrupt these non-redundant inhibitory pathways to further restore exhausted T-cell function. Tebotelimab is being evaluated in a Phase 1 dose expansion study as monotherapy in several tumor types, including both solid tumors and hematological malignancies, and in combination with margetuximab, an investigational Fc-engineered monoclonal antibody targeting HER-2, in three cohorts of patients with advanced HER2-positive cancers (NCT03219268). Tebotelimab will also be evaluated in combination with margetuximab and chemotherapy as part of the ongoing Phase 2/3 MAHOGANY study in patients with HER2-positive gastric or gastroesophageal junction cancer (NCT04082364). MacroGenics’ regional partner in Greater China, Zai Lab, participates in the MAHOGANY study and is also evaluating tebotelimab independently in Phase 1 combination studies with niraparib, a PARP inhibitor, and brivanib, a dual target tyrosine kinase inhibitor of the VEGF and FGF receptors, for the study of advanced gastric cancer and hepatocellular carcinoma, respectively.

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, 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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