September 10, 2017

Phase 1 Data for Flotetuzumab, MacroGenics' CD123 x CD3 DART® Molecule, Presented at ESMO Congress 2017

- *Acceptable tolerability observed in first-in-human study*
- *Encouraging initial anti-leukemic activity observed in relapsed/refractory AML patients*

ROCKVILLE, MD, Sept. 10, 2017 (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, today announced the presentation of clinical data from its Phase 1 study of flotetuzumab in an oral session at the European Society for Medical Oncology Annual Congress, ESMO 2017, in Madrid, Spain. Norbert Vey, M.D., Team Leader Translational Medicine — Hematology at Institut Paoli-Calmettes, Marseille, France, presented "Interim Results from a Phase 1 First-in-Human study of flotetuzumab, a CD123 x CD3 bispecific DART molecule, in AML/MDS."

The ongoing Phase 1, first-in-human, dose-escalation study was designed to determine safety, tolerability, maximum tolerated dose and initial anti-leukemic activity of flotetuzumab in patients with relapsed or refractory acute myeloid leukemia (AML) or intermediate-2/high risk myelodysplastic syndrome (MDS).

Flotetuzumab demonstrated acceptable tolerability in the dose escalation portion of the study. Infusion-related reaction and cytokine release syndrome (CRS) were the most common adverse events observed, with Grade 3 CRS occurring in 6 of 47 patients (12.8%). A two-step, lead-in dose as well as early intervention with anti-cytokine therapy was implemented to limit the severity and incidence of CRS.

Encouraging initial anti-leukemic activity has been observed in patients treated at the threshold flotetuzumab dose of 500ng/kg/day or greater. As of the data cut-off date, of the 14 response-evaluable patients treated at this dose, eight (57%) patients had anti-leukemic activity, with six (43%) of these patients experiencing an objective response. This included four (28%) patients who experienced CR/CRi, with one patient who experienced a molecular CR. In the majority of patients who responded, anti-leukemic activity was observed after a single cycle of therapy.

"MacroGenics is pleased with the encouraging data from this ongoing Phase 1 study of flotetuzumab, our first clinical DART molecule focused on T-cell redirected killing," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Enrollment of the AML and MDS dose-expansion cohorts at the selected dose and schedule are well under way and we expect to present updated clinical data at an additional scientific conference later this year."

The presentation at ESMO Congress 2017 is available for download from the Events & Presentations page on MacroGenics' website at http://ir.macrogenics.com/events.cfm.

About Flotetuzumab

Flotetuzumab (also known as MGD006 and S80880) is a clinical-stage molecule that recognizes both CD123 and CD3. CD123, the Interleukin-3 receptor alpha chain, has been reported to be over-expressed on cancer cells in a wide range of hematological malignancies, including AML and MDS. The primary mechanism of action of flotetuzumab is believed to be its ability to redirect T lymphocytes to kill CD123-expressing cells. To achieve this, the DART molecule combines a portion of an antibody recognizing CD3, an activating molecule expressed by T cells, with an arm that recognizes CD123 on the target cancer cells.

Flotetuzumab is currently being evaluated in the U.S. and Europe in a Phase 1 dose-escalation study designed to assess the safety, tolerability, and initial anti-leukemic activity of the molecule in patients with relapsed/refractory AML or intermediate-2/high risk MDS. MacroGenics retains full development and commercialization rights to flotetuzumab in the U.S., Canada, Mexico, Japan, South Korea and India. Servier participates in the development of flotetuzumab and has rights to this molecule in all other countries. The U.S. Food and Drug Administration has granted orphan drug designation to flotetuzumab for the treatment of AML.

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 primarily 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. MacroGenics, the MacroGenics logo, and DART are trademarks or registered trademarks of MacroGenics, Inc.

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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 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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