December 11, 2017

Phase 1 Data for Flotetuzumab, MacroGenics' CD123 x CD3 DART® Molecule, Presented at 59th Annual ASH Meeting

- **Encouraging initial anti-leukemic activity with durable responses and acceptable tolerability observed in dose expansion cohort**
- **Data supports combination with MGA012 (anti-PD-1) to potentially enhance anti-leukemic effects**

Rockville, MD, Dec. 11, 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 ongoing Phase 1 study of flotetuzumab in an oral session at the 59th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, Georgia. John E. Godwin, M.D., Program Leader, Hematologic Malignancies at Earle A. Chiles Research Institute at Providence Cancer Center in Portland, Oregon presented "Preliminary Results of a Phase 1 Study of Flotetuzumab, a CD123 x CD3 Bispecific DART Protein, in Patients with Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome."

The ongoing Phase 1, first-in-human study of flotetuzumab was designed to determine safety, tolerability, maximum tolerated dose and initial anti-leukemic activity in patients with relapsed or refractory acute myeloid leukemia (AML) or intermediate-2/high risk myelodysplastic syndrome (MDS). To date, a total of 57 patients have been enrolled, including 11 AML patients in the dose expansion cohort.

Consistent with the dose escalation data that was previously presented at ESMO Congress 2017 in September, flotetuzumab has continued to demonstrate acceptable tolerability in patients treated to date in the dose expansion cohort. Infusion-related reaction and cytokine release syndrome (CRS) were the most common adverse events observed, with Grade 3 CRS occurring in 9 of 57 patients (15.8%). Implementation of a two-step, lead-in dose as well as early intervention with anti-cytokine therapy has helped to limit the severity and incidence of CRS.

As of the data cut-off date, of the eight evaluable patients in the dose expansion cohort who received a lead-in dose followed by 500 ng/kg/day of flotetuzumab via continuous IV infusion, six patients (75%) have evidence of anti-leukemic activity, with three of these patients experiencing an objective response. This included two patients who experienced CR/CRi and one patient who achieved MLF (morphologic leukemia-free state).

The duration of response for the eight patients who have achieved a MLF, CRi or CR in the dose escalation and dose expansion cohorts ranged from 1.0 to 5.8 months, with five of these responses still ongoing as of the November 30, 2017 data cut-off.

Further, in a translational data poster presentation, MacroGenics also described studies that support a rationale for using checkpoint blockade as an approach to potentially enhance the anti-leukemic activity of flotetuzumab. Among these findings, modulation of the PD-1/PD-L1 pathway was observed in patients treated with flotetuzumab, and the combination of flotetuzumab and PD-1/PD-L1 inhibitors was shown to synergistically enhance T-cell mediated cytotoxicity against AML cell lines in vitro.

"We continue to be encouraged by the tolerability and anti-leukemic activity of flotetuzumab as well as by the early data regarding the durability of responses observed in patients from our ongoing Phase 1 study of flotetuzumab," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "In addition, given the data-supported rationale for combining flotetuzumab with anti-PD-1, we intend to initiate a combination study with the anti-PD-1 mAb, MGA012, in the coming months, while we continue to enroll the AML and MDS dose expansion cohorts. We look forward to sharing additional flotetuzumab clinical data in 2018."

The presentation at the 59th Annual ASH meeting 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 at 13 clinical sites in the U.S. and Europe in a Phase 1 study designed to assess the safety, tolerability, maximum tolerated dose 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 exclusive 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.

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.

###

CONTACTS:

Jim Karrels, Senior Vice President, CFO
MacroGenics, Inc.
1-301-251-5172, info@macrogenics.com

Karen Sharma, Senior Vice President
MacDougall Biomedical Communications
1-781-235-3060, ksharma@macbiocom.com