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MacroGenics' MGD006 Granted Orphan Drug Status for AML by FDA

ROCKVILLE, MD, Jan. 05, 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 that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to MGD006 (also known as S80880), a DART® molecule that recognizes both CD123 and CD3, for the investigational treatment of acute myeloid leukemia (AML).

MGD006 is currently being evaluated in the U.S. and Europe in a Phase 1 dose-escalation study designed to assess the safety and tolerability of the molecule in patients with relapsed/refractory AML or myelodysplastic syndrome (MDS). MacroGenics retains full development and commercialization rights to MGD006 in the U.S., Canada, Mexico, Japan, South Korea and India. Servier participates in the development and has rights to MGD006 in all other countries.

The FDA orphan drug designation provides certain incentives for medications intended for the treatment, diagnosis or prevention of rare diseases. At present, these incentives include seven years of marketing exclusivity for the orphan indication, certain federal grants, tax credits and waiver of certain FDA fees.

"The FDA's decision to grant orphan drug designation for MGD006 in AML is an important regulatory milestone for MacroGenics as we continue to develop this bispecific DART molecule in this difficult-to-treat disease," said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. "We believe MGD006 has the potential to be a significant advancement in the treatment of AML, and are pleased that the FDA has recognized the potential of MGD006 to benefit patients in need. We expect to select a dose this year to advance MGD006 into its next phase of clinical development."

About MGD006

MGD006 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 MGD006 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.

In December 2016, MacroGenics presented initial clinical experience from the ongoing Phase 1 study of MGD006. Dosing schema and supportive care regimens have been refined to enable therapeutic goals and decrease the effects of cytokine induction by MGD006, an anticipated event resulting from the engagement and activation of T lymphocytes. In addition, the Company continues to characterize the pharmacokinetic properties and clinical activity of MGD006 in AML patients.

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. 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 "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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