June 19, 2014

MacroGenics Initiates Phase 1 Study of MGD006 for the Treatment of Acute Myeloid Leukemia

MGD006 Represents the First DART(R) Molecule to Enter the Clinic

ROCKVILLE, Md., June 19, 2014 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (Nasdaq:MGNX), a clinical-stage biopharmaceutical company focused on discovering and identifying innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune disease, today announced that a first patient received drug in a Phase 1 study of MGD006 in relapsed or refractory acute myeloid leukemia (AML). MGD006 is a humanized, Dual-Affinity Re-Targeting (DART®) bi-specific antibody-based molecule that binds to both CD123 and CD3, antigens expressed on leukemic cells and T lymphocytes, respectively. This study marks the first clinical trial of a DART product candidate.

"We are very enthusiastic about the initiation of this study in which we will explore MGD006's ability to redirect T cells against CD123-positive leukemic blasts in patients with relapsed or refractory AML," said John Di Persio, M.D., Ph.D., lead investigator and Chief, Division of Oncology, Washington University School of Medicine in St. Louis. "We hope to gain an understanding of the safety, tolerability and activity of MGD006 in this study."

"The initiation of this Phase 1 study marks a significant milestone as the first of our portfolio of DART molecules, MGD006, enters the clinic," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "MGD006 has demonstrated great promise as a T cell-re-directed cancer immunotherapy in pre-clinical studies. We will see whether these studies translate into clinical trial results indicative of clinical improvement for patients with AML, a disease for which standard therapies have advanced little in the last thirty years."

MacroGenics has development and commercialization rights to MGD006 in the U.S., Canada, Mexico, Japan, South Korea and India; MacroGenics' partner, Servier, has rights to MGD006 in all other countries.

About the Study

The Phase 1 dose-escalation study is designed to assess the safety and tolerability of MGD006 in patients with relapsed or refractory AML. The study will enroll up to 58 patients across multiple sites in the U.S. The study has been initiated at Washington University School of Medicine in St. Louis with John Di Persio, M.D., Ph.D. serving as the lead investigator. In addition to the primary safety endpoint, secondary endpoints of pharmacokinetics and activity will be evaluated, as will a number of translational endpoints examining the immunobiology of MGD006.

About MGD006

MGD006 is a humanized DART molecule that recognizes both CD123 and CD3. The molecule was designed to redirect T cells via their CD3 component to kill CD123-expressing cells, as shown pre-clinically. CD123, the Interleukin-3 receptor alpha chain, has been reported to be overexpressed on malignant cells in a wide range of hematological malignancies including AML and myelodysplastic syndrome (MDS). AML and MDS are thought to arise in and be perpetuated by a small population of leukemic stem cells (LSCs) that generally resist conventional chemotherapeutic agents. LSCs are characterized by high levels of CD123 expression that is low or absent in the corresponding hematopoietic progenitors and stem cell populations in normal human bone marrow.

About the DART Platform

MacroGenics' DART platform enables the targeting of multiple antigens or cells by using a single molecule with dual antibody-like binding regions. The Company has created over 100 DART molecules, which have been designed for evaluation in the potential treatment of cancer, autoimmune disorders and infectious disease. These DARTs can be tailored for either short or prolonged pharmacokinetics and have demonstrated good stability and manufacturability. The Company expects to advance multiple additional DART molecules into clinical development in 2014 and 2015 and beyond.

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 and autoimmune diseases. The Company generates its pipeline of product candidates from its proprietary suite of next-generation antibody technology platforms, which it believes improve the performance of monoclonal antibodies and antibody-derived molecules. The Company creates both differentiated molecules that are directed to novel cancer targets, as well as "bio-betters," which are drugs designed to improve upon marketed medicines. The combination of MacroGenics' technology platforms and antibody engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. www.macrogenics.com

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.

CONTACT: Jim Karrels, 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.