

# MacroGenics Preclinical Research on MGD006 DART(R) Molecule Published in Science Translational Medicine

- MGD006 Enables T Cells to Recognize and Kill Leukemia Cells
  - Research Paved the Way for Human Clinical Trials

ROCKVILLE, Md., May 27, 2015 (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 publication of a nonclinical research paper on MGD006 in *Science Translational Medicine*. MGD006 is a humanized, Dual-Affinity Re-Targeting (DART®) molecule that recognizes both CD123 and CD3. CD123, the Interleukin-3 receptor alpha chain, is expressed on malignant cells, including leukemic stem cells (LSC), in acute myeloid leukemia (AML) and other hematological diseases. The primary mechanism of action of MGD006 is its ability to redirect T lymphocytes to kill CD123-expressing cells. To achieve this, the DART combines a portion of an antibody recognizing CD3, an activating molecule expressed by T cells, with an arm that recognizes CD123 on the target cells. The recently published research shows anticancer activity in vitro and in mouse models together with favorable pharmacodynamic and safety profile in nonhuman primates.

The prognosis of patients with AML remains poor overall despite existing therapy, and substantial unmet need exists for these individuals. AML patients may benefit from targeted immunotherapy approaches. The paper titled "A CD3xCD123 bispecific DART for redirecting host T cells to myelogenous leukemia: Preclinical activity and safety in nonhuman primates," describes how MacroGenics' scientists engineered the MGD006 DART and demonstrated in vitro that the molecule can arm T cells from AML patients to reduce blast counts and is effective in eliminating AML cells implanted in mice. Furthermore, MGD006 administered to cynomolgus monkeys demonstrated potent pharmacodynamic activity in the form of near complete elimination of circulating CD123-positive cells at doses that were safe and well tolerated.

"This research paved the way for our initiation of a Phase 1 clinical study of MGD006 in 2014," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "This was a significant milestone for our DART platform and I am pleased to say that the study is progressing well. MGD006 has demonstrated great promise as a T-cell re-directed cancer immunotherapy in preclinical studies. We are hopeful that these studies will translate into clinical trial results indicative of clinical improvement for patients with AML, myelodysplastic syndrome and several other forms of leukemia and lymphoma."

# About the Phase 1 Study of MGD006

MacroGenics continues to enroll patients in the dose escalation portion of a Phase 1 study of MGD006 for the treatment of AML. The Phase 1 dose-escalation study is designed to assess the safety and tolerability of MGD006 in patients with relapsed or refractory AML. In addition to the primary safety endpoint, secondary endpoints of pharmacokinetics and pharmacodynamic activity will be evaluated, as will a number of biomarkers examining the immunobiology of MGD006. The Phase 1 study was initiated at Washington University School of Medicine in St. Louis. In addition, Emory University and Providence Portland Medical Center are now recruiting patients and a fourth site is expected to commence patient recruitment in June.

# **About MGD006**

MGD006 is a humanized DART molecule that can simultaneously bind CD123 and CD3. CD123 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 LSCs that generally resist conventional chemotherapeutic agents. LSCs are characterized by comparably high levels of CD123 expression in contrast to the limited or absent CD123 expression in the corresponding hematopoietic stem cell population in normal human bone marrow.

MacroGenics has retained 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 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 DART molecules can be tailored for either short or prolonged pharmacokinetics and have demonstrated good stability and manufacturability. MacroGenics and its partners expect to have a total of five DART molecules in clinical development by the end of 2015.

## 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 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 <a href="www.macrogenics.com">www.macrogenics.com</a>. MacroGenics and DART are 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 "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.

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