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Publication in PLOS Pathogens Shows the Potential of DART® Molecules for HIV Reservoir Elimination Strategy

- *Second paper published demonstrating DART molecule potential against HIV*
- *Data support HIV research contract recently awarded to MacroGenics by NIAID*

ROCKVILLE, Md., Nov. 05, 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, announced a publication today in *PLOS Pathogens* in collaboration with investigators at Gilead Sciences. This study provides proof-of-concept preclinical data on bi-specific Dual-Affinity Re-Targeting, or DART, molecules designed to reduce the HIV reservoir in subjects treated with continuous antiretroviral therapy. The publication of this paper follows another recent paper published in the *Journal of Clinical Investigation* featuring the utility of the DART technology in eliminating latent HIV infection.

MGD014 is a bispecific, Fc-bearing DART molecule that targets HIV-infected cells and CD3-expressing T cells, and is being developed by MacroGenics under a contract awarded in September 2015 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. MGD014 is the first DART molecule targeting an infectious agent that is planned for clinical testing. The work under the contract will build on both recently published preclinical studies demonstrating that DART molecules targeting the HIV envelope (Env) protein and T cells, via their CD3 component, are able to redirect the immune system's T cells to kill HIV-infected cells. DART molecules could be used independently or become a key part of a "shock-and-kill" strategy in conjunction with HIV latency reversing agents currently under development.

Today's paper in *PLOS Pathogens* reports that engineered molecules recruiting killer T cells to target HIV-infected cells expressing Env protein can induce killing of the HIV-infected cells. Working on the "kill" step, the team of researchers at MacroGenics and Gilead Sciences designed and evaluated DART molecules derived from broadly reactive anti-Env antibodies. These DART molecules were reactive against cells infected with diverse HIV isolates and were capable of reducing the level of HIV expression ex vivo in blood cells isolated from HIV-infected participants on suppressive antiretroviral therapy.

The paper published earlier this week in the *Journal of Clinical Investigation,* which first appeared online in September, also demonstrated the potential of DART molecules as part of a "shock-and-kill" strategy against HIV. Two DART molecules developed at MacroGenics in collaboration with Duke University School of Medicine and the University of North Carolina at Chapel Hill (UNC) showed the ability to redirect T cells to kill cells infected by HIV isolates derived from subjects on continuous antiretroviral therapy, and to induce the killing of HIV-infected cells obtained from subjects following ex vivo induction of virus expression with a latency reversing agent.

The initial phase of the work under the NIAID contract is to advance a first DART molecule (MGD014) through Investigational New Drug (IND) application submission. Pre-clinical IND-enabling studies will include collaborations with investigators at Duke and UNC. NIAID may also exercise options to advance MGD014 into Phase 1/2 clinical trials as well as develop and test a second DART molecule. A third clinical trial would evaluate one of the DART molecules in combination with a latency reversing agent.

"This is a great opportunity for MacroGenics to expand our DART platform for therapeutics applications beyond oncology and autoimmune disorders and into infectious diseases," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We are encouraged by our proof-of-concept studies that show HIV DART molecules could act as potent immunotherapeutic agents with the potential to be part of a 'shock-and-kill' strategy against HIV."

The development of a DART molecule targeting HIV is funded in part by NIAID under contract no. HHSN272201500032C.

Background on Dual-Affinity Re-Targeting (DART) Platform

MacroGenics' DART platform enables the targeting of multiple antigens or cells by using a single molecule with an antibody-like structure. The Company has created over 100 DART molecules which have been configured for 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 attractive manufacturability. Five DART molecules are currently being evaluated in Phase 1 clinical studies.

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 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 "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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