

MacroGenics Announces Presentation of Pre-clinical Data on new DART(r) Candidate MGD011 at 56th Annual Meeting of the American Society of Hematology

Results Support Initiation of Clinical Development of MGD011 in Hematological Malignancies

Rockville, MD, Dec. 6, 2014 (GLOBE NEWSWIRE) -- December 6, 2014 -- 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 preclinical data for MGD011, a humanized CD19 x CD3 Dual-Affinity Re-Targeting (DART®) protein, at the 56th Annual Meeting of the American Society of Hematology (ASH), taking place in San Francisco, CA. These data demonstrate potent T-cell mediated anti-tumor activity in preclinical models.

Liqin Liu, Ph.D., Senior Scientist at MacroGenics, presented a poster titled: MGD011, Humanized CD19 x CD3 DART® Protein with Enhanced Pharmacokinetic Properties, Demonstrates Potent T-Cell Mediated Anti-Tumor Activity in Preclinical Models and Durable B-Cell Depletion in Cynomolgus Monkeys Following Once-a-Week Dosing.

"CD19-targeted therapies have generated a great deal of excitement and based on our pre-clinical data, we believe that MGD011 has strong potential in the treatment of patients with certain types of hematological malignancies," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We are enthusiastic about the initiation of clinical development in 2015."

Pre-Clinical Study Results with MGD011

The pre-clinical studies investigated the ability of MGD011 to mediate anti-tumor activity. These studies demonstrated potent anti-tumor activity in vitro and in mouse leukemia/lymphoma tumor models, with high complete response rates and no evidence of relapse over the study duration. MGD011, whose components cross-react with the corresponding cynomolgus monkey antigens, displayed prolonged pharmacokinetic properties in this species, consistent with that of a monoclonal antibody. Treatment with MGD011 induced durable, marked decrease in circulating B lymphocytes and profound B-cell depletion in lymphoid organs in cynomolgus monkeys following once-a-week dosing. MGD011 was well tolerated at doses up to 100 mcg/kg, the highest dose tested, with modest elevations in serum cytokines but no adverse findings. The results of these preclinical studies provide a strong rationale for the clinical development of MGD011 as a molecule for the treatment of B-cell malignancies.

About MGD011

MGD011, a humanized CD19 x CD3 bispecific DART protein, is being developed for the treatment of B-cell hematological malignancies. CD19, a lymphocyte-specific marker expressed from early B-lymphocyte development through mature memory B cells, is highly represented in B-cell malignancies. This makes it attractive for targeted interventions. MGD011 is designed to redirect T cells, via their CD3 component, to eliminate CD19-expressing cells found in many hematological malignancies. MGD011 has been engineered to address half-life challenges posed by other programs targeting CD19 and CD3. This product candidate has an Fc domain, which allows for extended pharmacokinetic properties and convenient dosing at a once-a-week or longer interval. In addition, MGD011 and the Company's other DART molecules that redirect T cells against cancer targets are manufactured using a conventional antibody platform without the complexity of having to genetically modify T cells from individual patients as required by approaches such as chimeric antigen receptor (CAR) T-cells.

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. 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 future expectations and plans and prospects 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, including those discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2014 and the subsequent Quarterly Reports on Form 10-Q. 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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