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MacroGenics Presents Data from Phase 1 Study of MGD010 at Annual European Congress of Rheumatology (EULAR 2016)

Bispecific molecule based on DART® platform simultaneously targets B-cell antigens, CD32B and CD79B

MGD010 was well tolerated at all dose levels with no serious adverse effects

ROCKVILLE, Maryland, June 10, 2016 (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 the oral presentation of clinical data from its Phase 1 study of MGD010 at the Annual European Congress of Rheumatology (EULAR 2016) in London, England. Naimish Pandya, M.D., Senior Medical Director at MacroGenics, presented "Safety, Tolerability, and Functional Activity of MGD010, a DART® Molecule Targeting CD32B and CD79B, Following a Single Dose Administration in Healthy Volunteers."

The objectives of the study were to assess the safety, tolerability, pharmacokinetic and pharmacodynamic activity of MGD010 in healthy volunteers. MGD010, a Dual-Affinity Re-Targeting, or DART®, molecule, was designed to simultaneously target the B-cell surface proteins, CD32B and CD79B, and is being developed for the treatment of autoimmune disorders. CD32B is a checkpoint molecule expressed on B lymphocytes that, when co-ligated with CD79B, a component of the B-cell antigen receptor complex, delivers a co-inhibitory signal that dampens B-cell activation.

The Phase 1 study of MGD010 was a first-in-human, double-blind, placebo-controlled study in which a single dose of MGD010 was intravenously (IV) administered to 49 healthy subjects. Data from the study showed that MGD010 was well tolerated at all dose levels and no serious adverse effects were reported. None of the subjects participating in the study had premature discontinuations or infusion reactions, systemic hypersensitivity reactions or injection site reactions.

In addition, MGD010 demonstrated linear pharmacokinetics and dose-dependent selective binding to B lymphocytes without persistent B-cell depletion. The data also showed: (1) a dose-dependent downregulation of B-cell receptor-induced signaling together with down-modulation of B-cell receptor expression among circulating memory and naïve B cells, (2) a decrease in expression of the costimulatory CD40 molecule and (3) a decrease in circulating immunoglobulin M levels, each consistent with the targeted action of MGD010. These data support the continued research and development of MGD010 in patients with autoimmune and inflammatory disorders.

"MacroGenics is pleased with the positive and promising data from our Phase 1 study of MGD010, our first clinical DART molecule that specifically focuses on autoimmune disorders," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "MacroGenics continues to identify and evaluate new therapeutic candidates within our greater pipeline of immuno-oncology, autoimmune disorder and infectious disease programs, in order to better treat patients suffering from a range of diseases."

The presentation at the Annual European Congress of Rheumatology (EULAR 2016) is available for download from the Events & Presentations page on MacroGenics' website at http://ir.macrogenics.com/events.cfm.

About MGD010

MGD010 is a humanized DART molecule that simultaneously targets CD32B and CD79B. This product candidate is the first clinical autoimmune-focused DART program. In normal conditions, B cells utilize CD32B as one of the key negative regulators to ensure that tolerance to self is maintained and autoimmune disorders do not occur. MGD010 exploits this mechanism and triggers this inhibitory "immune checkpoint" loop for the inhibition of B-cell function, an approach that may be useful for the treatment of patients with autoimmune disorders. In pre-clinical studies, MGD010 was shown to modulate the function of human B cells without B-cell depletion in a variety of in vitro and in vivo models. MacroGenics believes this molecule can block those B cells that are activated to produce the pathogenic antibodies and promote the autoimmune process. As reported in earlier pre-clinical studies, MGD010 was shown to inhibit B lymphocytes from SLE (Systemic Lupus Erythematosus) patients in vitro; furthermore, MGD010 inhibits autoimmune responses in humanized mouse models.

Furthermore, in a non-human primate study, MGD010 has demonstrated a favorable safety profile and pharmacological effect on targeted B cells in the absence of B-cell depletion.

Under the terms of a 2014 collaboration, Takeda Pharmaceutical Company Limited has the option to obtain an exclusive worldwide license for MGD010 following review of a data package which will include the Phase 1 data presented today as well as additional clinical and preclinical data.

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. MacroGenics, the MacroGenics logo, and DART are trademarks or registered trademarks of MacroGenics, Inc.

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