

# MacroGenics Presents Updated Data from Phase 1 Study of MGD010 at Annual European Congress of Rheumatology (EULAR 2017)

# Single dose administration of CD32B x CD79B bispecific DART® molecule delivers an immunomodulatory effect that counters B-cell function

ROCKVILLE, MD, June 17, 2017 (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 presentation of updated data from its Phase 1 study of MGD010 at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Madrid, Spain.

In a poster titled "Immunomodulatory Effects of MGD010, a DART® Molecule Targeting Human B-cell CD32B and CD79B," the Company highlighted the immunomodulatory impact of MGD010 on the response to hepatitis A vaccination (HAV), a model antigen challenge, in normal healthy subjects. These data demonstrate that by pharmacologically exploiting the activity of the checkpoint molecule CD32B in combination with the B-cell receptor (BCR) CD79B component, a single dose administration of MGD010 at either 3 or 10 mg/kg delivers an immunomodulatory effect that counters B-cell function.

In this portion of the Phase 1 study, 23 evaluable healthy subjects received 3 or 10 mg/kg MGD010 or placebo, followed by HAV immunization. There were no CTCAE grade 3 or higher adverse events related to MGD010. Consistent with prior observations, ex vivo flow cytometric analysis confirmed dose-dependent MGD010 binding to peripheral B cells without B-cell depletion, accompanied by decreased surface BCR and CD40 expression as well as a decrease in total serum IgM levels. Compared to the placebo group, reduced HAV seroconversion rates were observed in subjects treated with MGD010, with significantly lower HA-specific IgG levels.

"The updated data regarding HAV seroconversion further confirm that MGD010 can exert immunomodulatory activity in vivo consistent with its intended mechanism of action. Combined with its good safety profile, these results provide compelling rationale for further development of this therapeutic modality for autoimmune disorders," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics.

The poster is available for download from the Events & Presentations page on MacroGenics' website at <u>http://ir.macrogenics.com/events.cfm</u>.

## 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 the checkpoint receptor, 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 immune checkpoint loop for the inhibition of B-cell function, an approach that may be useful for the treatment of patients with autoimmune disorders.

MacroGenics reported initial data from a Phase 1 study of MGD010 at EULAR 2016. The initial portion of this study 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 the molecule 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.

The data from this study demonstrated that MGD010 was well tolerated as a single dose up to 10 mg/kg, with no evidence of peripheral B-cell activation or depletion. Moreover, MGD010 exhibited: (1) linear pharmacokinetics with properties similar to those of an antibody molecule, (2) dose-dependent B-cell occupancy (with saturation >1 mg/kg), (3) down-modulation of BCR expression among circulating memory and naïve B cells, (4) downregulation of BCR-induced signaling and diminished

propensity for ex-vivo BCR-induced B-cell activation, (5) a decrease in expression of the costimulatory CD40 molecule, and (6) a decrease in circulating immunoglobulin M levels.

#### 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.

### **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 "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 risks 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 only 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, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

###

CONTACTS: Jim Karrels, Senior Vice President, CFO MacroGenics, Inc. 1-301-251-5172, info@macrogenics.com

Karen Sharma, Senior Vice President MacDougall Biomedical Communications 1-781-235-3060, ksharma@macbiocom.com