



September 12, 2016

## **Takeda and MacroGenics Announce the Conclusion of their MGD010 License and Option Agreement**

### **MacroGenics regains worldwide rights to DART molecule for autoimmune disorders**

Rockville, MD, Sept. 12, 2016 (GLOBE NEWSWIRE) -- and Osaka, Japan, Sept. 12, 2016 -- 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, and Takeda Pharmaceutical Company Limited (TSE: 4502) today announced the conclusion of their License and Option Agreement for MGD010. MacroGenics has regained the worldwide rights to MGD010, a bispecific molecule targeting CD32B and CD79B. Takeda's decision comes earlier than the predefined expiration of its option exercise period and follows Takeda's recently announced therapeutic area re-prioritization. Takeda's decision was not based on the ongoing Phase 1 study with MGD010. MacroGenics plans to continue to advance the development of this product candidate based on the positive study results reported to date.

"We presented promising interim data from our ongoing Phase 1 study of MGD010 in an oral presentation at the Annual European Congress of Rheumatology (EULAR 2016) in London this past June," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We view Takeda's early decision to not exercise its option as an opportunity for MacroGenics. This enables us to further develop MGD010 on our own or explore future strategic partnering opportunities with this program."

"We have enjoyed collaborating with MacroGenics on this development project," said Takeda's Emiliangelo Ratti, Global Head Central Nervous System Therapeutic Area Unit. "While our re-prioritization on key therapeutic areas has resulted in a change of direction for Takeda's role in this program, we look forward to MacroGenics' continued progress with MGD010 as a potential new therapy for patients suffering from B-cell mediated autoimmune and inflammatory disorders."

In May 2014, MacroGenics entered into an agreement with Takeda regarding MGD010. Under the terms of that agreement, Takeda received an option to obtain an exclusive worldwide license for MGD010 following the delivery of a data package, including data from a completed, pre-defined Phase 1 study. Takeda has given formal notification it does not intend to exercise this option, allowing MacroGenics to control worldwide development and commercialization rights to MGD010. To date, MacroGenics has led all MGD010 product development activities. Takeda and MacroGenics are also parties to a separate research collaboration that was entered into in September 2014.

### **About MGD010**

MGD010 is a humanized DART molecule that simultaneously targets CD32B and CD79B. 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. 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.

Interim data from a first-in-human, double-blind, placebo-controlled Phase 1 study in which a single dose of MGD010 is intravenously (IV) administered to healthy subjects were presented at EULAR 2016. Initial data from the first 49 subjects showed that MGD010 was well tolerated at all dose levels and no serious adverse effects were reported. 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. MacroGenics is currently completing the enrollment of an additional 24 healthy subjects

in a final segment of the Phase 1 study, in which subjects will be assessed for immune modulation by MGD010 following Hepatitis A vaccination.

## **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](http://www.macrogenics.com). MacroGenics, the MacroGenics logo, and DART are trademarks or registered trademarks of MacroGenics, Inc.

## **MacroGenics' Cautionary Note on Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for MacroGenics, including statements about MacroGenics' strategy, future operations, clinical development of its therapeutic candidates, milestone or opt-in payments from MacroGenics' collaborators, MacroGenics' anticipated milestones and future expectations and plans and prospects for MacroGenics 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 MacroGenics' product candidates and other risks described in MacroGenics' filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent MacroGenics' views only as of the date hereof. MacroGenics anticipates that subsequent events and developments will cause MacroGenics' views to change. However, while MacroGenics may elect to update these forward-looking statements at some point in the future, it 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 MacroGenics' views as of any date subsequent to the date hereof.

## **About Takeda**

Takeda Pharmaceutical Company Limited is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and central nervous system therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as our presence in Emerging Markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit <http://www.takeda.com/news>.

## **Takeda's Forward-Looking Statements**

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or

product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither MacroGenics nor Takeda undertake any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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