

# MacroGenics and Takeda Enter Strategic Alliance to Develop DART for Treatment of Autoimmune Disorders

- Option-based collaboration around MGD010 product candidate
- Incorporates MacroGenics' proprietary DART technology for bi-specific targeting of CD32B and CD79B
- MacroGenics has option to co-promote in the United States
- MacroGenics may participate in funding late-stage development in exchange for North American profit share

ROCKVILLE, Md. and OSAKA, Japan, May 27, 2014 (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 and autoimmune diseases, and Takeda Pharmaceutical Company Limited jointly announced today that they have entered into an option agreement for the development and commercialization of MGD010. This product candidate incorporates MacroGenics' proprietary platform for Dual-Affinity Re-Targeting (DART®) to simultaneously engage CD32B and CD79B, which are two B-cell surface proteins. MGD010 is currently in pre-clinical development for the treatment of autoimmune diseases.

"We are very pleased to be collaborating with MacroGenics, given the company's expertise in exploring ways to harness the power of the immune system to treat complex, difficult diseases, including autoimmune disorders. We believe bi-specific antibodies are an important new frontier in medicine that may unlock additional therapeutic options for patients in the future," said Tetsuyuki Maruyama, Ph.D., General Manager of the Pharmaceutical Research Division at Takeda. "We look forward to building a long-term strategic collaboration with MacroGenics."



Under the terms of the agreement, MacroGenics will receive an upfront payment of \$15 million and Takeda receives an option to obtain an exclusive worldwide license for MGD010 following the completion of a pre-defined Phase 1a study. MacroGenics will lead all product development activities until that time. If Takeda exercises its option, it will assume responsibility for future development and pay MacroGenics an option exercise fee which, when combined with the upfront payment and an early development milestone, will total \$33 million. Assuming successful development and commercialization of MGD010, MacroGenics could receive up to an additional \$468.5 million in clinical, regulatory and commercialization milestone payments. If commercialized, MacroGenics would receive double-digit royalties on any global net sales and has the option to co-promote MGD010 with Takeda in the United States. Finally, MacroGenics may elect to fund a portion of Phase 3 clinical development in exchange for a North American profit share.

"We are delighted to enter into this collaboration with Takeda. This partnership represents our fifth DART collaboration and MGD010 represents the first autoimmune DART program planned for clinical development," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "As a leading global pharmaceutical company, Takeda brings extraordinary expertise in the autoimmune area with significant capabilities in developing and delivering novel medicines to patients. This collaboration will enable us to further broaden and accelerate our pipeline of innovative DART-based product candidates."

#### **About MGD010**

Currently approved B-cell-targeted therapies either cause depletion of B cells, thus limiting their applicability due to the potential for infections, or exhibit a delayed onset of action and limited efficacy across patient populations. To address these limitations, MacroGenics is developing MGD010, a humanized DART compound that simultaneously targets CD32B and CD79B.

In pre-clinical studies, MGD010 modulates the function of human B cells without B cell depletion. In normal conditions, B cells utilize CD32B as one of the key negative regulators to ensure that tolerance to self is maintained and autoimmune disease does not occur. MGD010 exploits this mechanism and triggers this inhibitory "immune checkpoint" loop. MacroGenics believes this molecule preferentially blocks those B cells that are activated to produce the pathogenic antibodies that promote the

autoimmune process. Studies in SLE (Systemic Lupus Erythematosus) patient B cells and humanized mouse models have demonstrated that MGD010 can block B cell activation in the absence of B cell depletion. To advance this program to the clinic, MacroGenics completed studies in a non-human primate model with MGD010 demonstrating a favorable safety profile and pharmacological effects on targeted B cells.

### **Background on DART Platform**

MacroGenics' Dual-Affinity Re-Targeting (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-based molecules, or DARTs, which have been configured for the potential treatment of cancer, autoimmune disorders and infectious disease. These DARTs can be tailored for either short or prolonged pharmacokinetics and have demonstrated good stability and attractive manufacturability. The Company has completed in vitro and in vivo proof of concept pre-clinical studies with multiple candidates and expects to advance its first two DARTs into clinical development in 2014.

#### 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 and autoimmune diseases. The Company generates its pipeline of product candidates from its proprietary suite of next-generation antibody technology platforms, which it believes improve the performance of monoclonal antibodies and antibody-derived molecules. The Company creates both differentiated molecules that are directed to novel cancer targets, as well as "bio-betters," which are drugs designed to improve upon marketed medicines. The combination of MacroGenics' technology platforms and antibody engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. <a href="https://www.MacroGenics.com">www.MacroGenics.com</a>

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

Any statements in this press release about future expectations, plans and prospects for MacroGenics, 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," "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 most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and any 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. MacroGenics 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.

## **About Takeda Pharmaceutical Company Limited**

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, <a href="www.Takeda.com">www.Takeda.com</a>.

#### **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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