



## **Lilly and MacroGenics Announce Licensing and Collaboration Agreement**

### **Lilly to Acquire Phase III Molecule Teplizumab for the Treatment of Type 1 Diabetes Companies to Collaborate on the Development of Autoimmune Disease Treatments**

ROCKVILLE, Md., and INDIANAPOLIS, Oct 18, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) and MacroGenics, Inc. today announced that the two companies have entered into a global strategic alliance to develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody, as well as other potential next generation anti-CD3 molecules for use in the treatment of autoimmune diseases. As part of the deal, Lilly will acquire the exclusive rights to the molecule. Teplizumab is currently being studied in the PROTEGE trial, a global pivotal Phase II/III clinical trial for individuals with recent-onset type 1 diabetes. MacroGenics will continue to oversee the PROTEGE trial.

Under the terms of the agreement, MacroGenics will receive an initial payment of \$41 million, as well as \$3 million in other committed funds. MacroGenics may also receive up to \$200 million in potential development milestones for the type 1 diabetes indication. If teplizumab is successfully commercialized, MacroGenics may receive up to \$250 million in potential sales milestones and would receive escalating royalties on sales commensurate with the current stage of development of the product. In addition, MacroGenics would have the option to co-promote teplizumab for certain indications in the U.S. Lilly may make an equity investment in MacroGenics of up to \$10 million in the company's next private financing round or initial public offering. Lilly may also decide to pursue several additional indications for teplizumab or other next generation anti-CD3 molecules developed with MacroGenics. If Lilly pursues each one of those indications and they all ultimately gain approval, additional milestone payments to MacroGenics could exceed \$600 million. Other terms of the deal were not disclosed.

The transaction is expected to become effective in the fourth quarter of 2007, contingent upon clearance under the Hart-Scott-Rodino Anti-Trust Improvements Act, if required. At closing, Lilly would expect a charge to earnings for acquired in-process research and development. The amount of the charge has not yet been determined, but is estimated to be \$0.03 per share. The impact to Lilly's fourth quarter and full-year 2007 earnings per share guidance is included in the 2007 Financial Guidance section of Lilly's third quarter financial results press release that was issued today.

"This agreement will expand Lilly's pipeline of late stage molecules and will strengthen one of our core therapeutic areas," said David Moller, M.D., Lilly, vice president of endocrine and cardiovascular research and clinical investigation. "We remain committed to maintaining our leadership role in diabetes care, including an expanded presence in the area of type 1 diabetes. We will continue to seek out innovative molecules to add to our diabetes portfolio in order to best respond to the growing health crisis posed by diabetes worldwide."

"Teplizumab is a significant addition to our growing portfolio of biotechnology-derived medicines, which are a key strategy for Lilly," said Thomas Bumol, Ph.D., Lilly, vice president, biotechnology discovery research, and president, Applied Molecular Evolution. "Immune tolerance represents a novel therapeutic approach to the treatment of autoimmune disease, and we are excited to be partnering with MacroGenics to clinically evaluate this mechanism in type 1 diabetes."

"We are delighted to enter into this deal with Lilly, an established leader in diabetes care, to develop teplizumab in multiple T-cell-mediated autoimmune diseases and to advance the molecule toward regulatory submission for recent-onset type 1 diabetes," stated Dr. Scott Koenig, president and CEO of MacroGenics. "We also look forward to working with Lilly to develop next generation CD3 product candidates to potentially treat a variety of autoimmune diseases, such as psoriasis and rheumatoid arthritis."

#### **About Teplizumab**

Teplizumab, also called MGA031, is a humanized, non-Fc receptor binding, anti-CD3 monoclonal antibody. Teplizumab binds to an epitope of the CD3- epsilon chain expressed on mature T lymphocytes and, by doing so, may modulate the pathological immunologic responses underlying multiple autoimmune diseases. Specifically, teplizumab may inhibit unwanted effector T cells and enhances beneficial regulatory T cell functions, thus promoting immune tolerance.

#### **About the PROTEGE Trial**

The PROTEGE trial, a global, pivotal Phase II/III clinical trial study, is evaluating the safety and efficacy of three teplizumab

dosing regimens administered at the start of the study and again at six months in individuals with recent-onset type 1 diabetes ages 8 to 35 who are up to 12 weeks from their diagnosis.

Type 1 diabetes is an autoimmune disease in which the body's immune system attacks and destroys the insulin-producing beta cells of the pancreas. Researchers believe teplizumab may control the T lymphocytes that mediate destruction of the insulin-producing beta cells of the islets of the pancreas. In doing so, they believe teplizumab may have the ability to preserve and protect the remaining beta cells of the pancreas.

Additional information regarding the PROTEGE trial is available online at [www.protegediabetes.org](http://www.protegediabetes.org).

#### About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at [www.lilly.com](http://www.lilly.com).

#### About MacroGenics, Inc.

Founded in 2000, MacroGenics is a private, venture-backed biotechnology company headquartered in Rockville, Maryland that focuses on the development, manufacture, and commercialization of immunotherapeutics for autoimmune disorders, cancer and infectious diseases. The company's proprietary Fc engineering technology offers ways of improving antibody function, such as enhancing the antibody's ability to eliminate cancer cells, cells that contribute to autoimmune disorders, or those infected with certain pathogens. The company is developing first-in-class product candidates from its autoimmunity, oncology and infectious disease portfolios. For more information about MacroGenics, please visit [www.macrogenics.com](http://www.macrogenics.com).

This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, the completion of clinical trials, the FDA and other foreign review processes and other governmental regulation, Lilly and MacroGenics' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in Lilly's most recent filings with the Securities and Exchange Commission. Lilly undertakes no duty to update forward looking statements.

C: LLY

SOURCE Eli Lilly and Company

Copyright (C) 2007 PR Newswire. All rights reserved

News Provided by COMTEX