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## **MacroGenics and Lilly Achieve Targeted Patient Enrollment in PROTÉGÉ, a Global Phase 2/3 Clinical Trial of Teplizumab in Type 1 Diabetes**

### **Phase 3 PROTÉGÉ ENCORE Clinical Trial Initiated**

**ROCKVILLE, MD and INDIANAPOLIS, June 16, 2009** – MacroGenics, Inc. and Eli Lilly and Company (NYSE:LLY) today announced that the PROTÉGÉ trial achieved its targeted patient enrollment. The trial is a pivotal Phase 2/3 clinical study evaluating teplizumab, an investigational compound under development for the treatment of individuals with recent-onset type 1 diabetes.

The PROTÉGÉ trial is a randomized, double-blind, multi-center, multi-national, 4-arm, controlled study designed to evaluate the safety and efficacy of teplizumab in individuals with recent-onset type 1 diabetes, aged 8 to 35, who are within 12 weeks of their diagnosis. More than 530 individuals are enrolled in the study across 14 countries, including the United States. The primary composite endpoint for PROTÉGÉ includes both the patient's total daily insulin usage and his/her HbA1c levels at 12 months. Secondary endpoints are evaluated at 24 months. Longer term safety and efficacy data from patients who complete the PROTÉGÉ trial are being collected in a separate Phase 3 study called the PROTÉGÉ Extension trial.

"The completion of enrollment of the PROTÉGÉ study is an important milestone for MacroGenics and for the type 1 diabetes research community," stated Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We appreciate the dedication of the patients, their caregivers and clinical investigators who helped advance this important late-stage clinical trial."

The companies also announced today that they have initiated the PROTÉGÉ ENCORE trial, another Phase 3 global study of teplizumab in individuals with recent-onset type 1 diabetes, designed to capture patient-reported outcome measures in addition to safety and efficacy data. Information about the PROTÉGÉ and PROTÉGÉ ENCORE trials is available at [www.protegediabetes.org](http://www.protegediabetes.org).

"For more than 85 years, Lilly has been a worldwide leader in pioneering industry-leading solutions to support people living with and treating diabetes," said Thomas F. Bumol Ph.D., Vice President, Biotechnology Research, Lilly Research Laboratories. "We have been pleased with MacroGenics' conduct of the PROTÉGÉ trial, and we are enthusiastic about the teplizumab clinical development program and expanding our efforts in the area of type 1 diabetes. Beyond diabetes, we also look forward to investigating teplizumab with MacroGenics to potentially treat other T-cell mediated autoimmune diseases."

### **About Teplizumab**

Teplizumab, an investigational compound under development for the treatment of individuals with recent-onset type 1 diabetes, is a humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas. Teplizumab binds to an epitope of the CD3-epsilon chain expressed on mature T cells and by doing so, may modulate the immunologic response that is a key component of the disease. If teplizumab is effective and has the ability to preserve or protect beta cells of the pancreas, patients may require less injected insulin and their blood glucose levels may be easier to control.

### **About Type 1 Diabetes**

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. The symptoms associated with type 1 diabetes can appear suddenly and leave a person dependent on injected insulin for life. The disease carries the constant threat of devastating complications such as heart and kidney disease, nerve damage and blindness. Although diagnosis most often occurs in childhood and adolescence, the disease can strike adults as well. Individuals with type 1 diabetes must test their blood sugar four or more times per day and take multiple insulin injections daily or continually infuse insulin through a pump. While trying to balance insulin doses with their food intake and daily activities, people with this form of diabetes must always be prepared for serious hypoglycemic (low blood sugar) and hyperglycemic (high blood sugar) reactions, both of which impact quality of life and can be life threatening. This balance is especially difficult to achieve in children and young adults who are very active physically.

## **About MacroGenics, Inc.**

MacroGenics is a private, venture-backed biotechnology company that focuses on the discovery, development and delivery to patients of novel biologics for autoimmune disorders, cancer and infectious diseases. Since its founding in 2000, the company has built a fully-integrated set of capabilities in monoclonal antibody product development. The company's product development efforts leverage three proprietary technology platforms: (1) cancer stem-like cells; (2) Dual Affinity Re-Targeting (DART), which allows the company to incorporate multiple specificities within a single molecule; and (3) Fc optimization, which enhances antibody-dependent effector functions. These powerful sets of capabilities and technology platforms have enabled MacroGenics to build a proprietary pipeline of innovative product candidates. The company's lead program, teplizumab, is an anti-CD3 antibody being developed for the treatment of autoimmune diseases. In October 2007, MacroGenics and Eli Lilly announced a global strategic alliance to develop and commercialize teplizumab as well as other potential next-generation anti-CD3 molecules. For more information about MacroGenics, please visit [www.macrogenics.com](http://www.macrogenics.com).

## **About Eli Lilly and Company**

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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. Information about Lilly is available at [www.lilly.com](http://www.lilly.com).

This press release contains forward-looking statements about the potential of the investigational compound teplizumab for the treatment of type 1 diabetes and reflects Lilly's current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the product will receive regulatory approval, or that the regulatory approval will be for the indication(s) anticipated by the company. There is also no guarantee that the product will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.