MacroGenics and Lilly Announce Pivotal Clinical Trial of Teplizumab Did Not Meet Primary Efficacy Endpoint

ROCKVILLE, Md. and INDIANAPOLIS, Oct 20, 2010 /PRNewswire via COMTEX News Network/ -- MacroGenics, Inc. and Eli Lilly and Company (NYSE: LLY) today announced that the Protege Data Monitoring Committee (DMC), composed of independent experts in the fields of diabetes and biostatistics, has completed a planned analysis of one-year safety and efficacy data of the Protege Phase 3 clinical trial of teplizumab, an investigational biologic under development for the treatment of individuals with recent-onset type 1 diabetes.

The DMC concluded that the primary efficacy endpoint of the study, a composite of a patient's total daily insulin usage and HbA1c level at 12 months, was not met. The DMC, noting that all administration of experimental drug had been completed, commented that appropriate safety monitoring is warranted. No unanticipated safety issues were identified in the DMC's review.

"We will comply with the DMC's recommendations," said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer, MacroGenics. "We remain committed to discovering and developing novel biologics for the treatment of autoimmune disorders like type 1 diabetes."

Following careful evaluation of the DMC's recommendations for Protege, based on the lack of efficacy, the companies have decided to suspend further enrollment and dosing of patients in two other ongoing clinical trials of teplizumab in type 1 diabetes: the Protege Encore Trial, a second Phase 3 trial of the same design as Protege, and the SUBCUE trial, a Phase 1b trial that is exploring the subcutaneous administration in patients with type 1 diabetes.

"The failure to meet the primary endpoint is obviously disappointing for the millions of people who live with and treat type 1 diabetes," said Gwen Krivi, Vice President, Product Development, Lilly Diabetes. "Lilly and MacroGenics will be considering all options for teplizumab in type 1 diabetes as well as the impact of the DMC's recommendations on other potential indications."

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. Insulin is a hormone that is needed to convert sugar (glucose), starches and other food into energy needed for daily life. People with type 1 diabetes must take multiple injections of insulin daily or continually infuse insulin through a pump to manage their blood glucose levels.

Type 1 diabetes, previously known as juvenile diabetes, usually strikes in childhood, adolescence, or young adulthood, but lasts for a lifetime. Of the nearly 24 million Americans who have diabetes, as many as 3 million may have type 1.(i)

About Teplizumab

Teplizumab, also called MGA031 and hOKT31 (Ala-Ala), is a humanized, 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 enhance beneficial regulatory T cell functions, thus promoting immune tolerance.

About MacroGenics

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) 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. For more information about MacroGenics, please visit www.macrogenics.com**.**

About Lilly

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. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about teplizumab and reflects Lilly's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that this compound will prove safe and effective for any anticipated indication or achieve commercial success. 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.

P-LLY

(i) Type 1 Diabetes, 2004; *KRC Research for JDRF, Jan. 2005* - http://www.jdrf.org

(Logo: http://photos.prnewswire.com/prnh/20101020/DE85906LOGO)

(Logo: http://www.newscom.com/cgi-bin/prnh/20101020/DE85906LOGO)

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

(Logo: http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company