



## **Lilly Announces Positive Phase II Data on Investigational Medicine for Patients with Type 2 Diabetes**

NEW ORLEANS, June 6, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today new, positive Phase II study results of LY2189265, its investigational glucagon-like peptide 1 (GLP-1) analog administered subcutaneously once-weekly for the treatment of type 2 diabetes. These data will be presented as part of the American Diabetes Association's (ADA) 69th Annual Scientific Sessions.

In the Phase II study, known as GBCJ, LY2189265 was significantly superior to placebo in reducing key measures of glycemic control, including fasting serum glucose and hemoglobin A1C (HbA1C). In this study, LY2189265 showed an insulinotropic (stimulating the secretion of insulin) effect, suggesting it produced the desired outcome in participants. In Study GBCJ, LY2189265 was generally well-tolerated.

"We are excited about these data and the hope they could provide to the millions of diabetes patients who are struggling to maintain tight control of their blood glucose," said Pawel Fludzinski, Ph.D., global development leader for the GLP-1Fc team. "Evaluating the results of this study is an important step forward towards potentially bringing this innovative treatment to patients."

### About Study GBCJ

In a 16-week, Phase II study of LY2189265, 262 patients with type 2 diabetes who were suboptimally controlled on at least two oral diabetes medicines were randomized to one of four arms: 1.0 mg of LY2189265 for 16 weeks; 0.5 mg of LY2189265 for four weeks followed by 1.0 mg for 12 weeks; and 1.0 mg of LY2189265 for four weeks followed by 2.0 mg for 12 weeks or placebo. The primary endpoint was glycemic control, as measured by change from baseline in HbA1C; additional endpoints evaluated included changes in fasting serum glucose, solid mixed meal glucose excursion and body weight.

For all doses in this study, statistically significant reductions in all metabolic measures were observed. Both 1 mg and 2 mg doses of LY2189265 were significantly different from placebo, but no significant differences between the doses were seen. LY2189265 was generally well-tolerated. The incidence of hypoglycemic episodes was not significantly different between the placebo and the treatment groups. The most frequently observed treatment-related adverse events were nausea, diarrhea and abdominal distension. One patient was diagnosed with clinical pancreatitis, following the eleventh dose of LY2189265. The patient remained in the study for observation and has fully recovered.

"Given our more than 80 years of experience in pioneering diabetes treatments, we are encouraged by these data," noted Steve Paul, M.D., executive vice president, science and technology, and president of Lilly Research Laboratories. "In this study, LY2189265 was administered once weekly and demonstrated significant glucose-lowering activity and reduced body weight, supporting its potential to become a new treatment option for the millions of people with type 2 diabetes."

### About LY2189265

LY2189265, a once-weekly injection, is a novel-engineered fusion protein, consisting of a dipeptidyl peptidase-IV (DDP-IV) protected GLP-1 analog linked to a fragment of immunoglobulin G4 that is believed to increase the duration of its pharmacological effect. Based on this study presented at this year's ADA meeting, LY2189265 is believed to reduce blood sugar in patients with type 2 diabetes by enhancing glucose-dependent insulin secretion from the pancreas.

### Diabetes: A Global Epidemic

Researchers say new diabetes treatments are needed because the disease is growing globally at epidemic proportions. Currently, about 24 million Americans have diabetes(1), with 90-95 percent of those suffering from type 2 diabetes(2). It is estimated that nearly 60 percent of the people with diabetes are not achieving treatment goals for controlling blood sugar(3), putting them at serious risk for debilitating or potentially fatal complications including heart disease, stroke, nerve damage, lower limb amputation, vision loss and kidney disease(4).

### 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.

This press release contains forward-looking statements about the potential of the investigational compound LY2189265 for the treatment of type 2 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.

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(1) American Diabetes Association. "Diabetes Statistics." Available at: <http://www.diabetes.org/diabetes-statistics.jsp> Accessed May 13, 2009.

(2) Centers for Disease Control and Prevention. "National Diabetes Fact Sheet 2007." Available at [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2007.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf) Accessed May 13, 2009

(3) Saydah SH, Fradkin J and Cowie CC. "Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes." JAMA: 291(3), January 21, 2004

(4) Centers for Disease Control and Prevention. "National Diabetes Fact Sheet 2007." Available at [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2007.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf) Accessed May 13, 2009

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