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Lilly and Boehringer Ingelheim Present Health Outcomes Data for Investigational Novel Basal Insulin Analogue

BERLIN, Oct. 2, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim today announced patient-reported health outcomes data from a Phase II study of their investigational novel basal insulin analogue, LY2605541, in patients with type 2 diabetes. Study results showed that in addition to clinical results showing a statistically significant 48 percent baseline adjusted reduction in nocturnal hypoglycaemia compared with insulin glargine [0.25 vs. 0.39 events/ 30 days/patient, after adjusting for baseline hypoglycaemia events (p=0.020)][1], patients treated with LY2605541* reported a statistically significant reduction in the anxiety and fear associated with experiencing a hypoglycaemic event based upon the Adult Low Blood Sugar Survey (ALBSS).[2] These data will be presented at the 48th European Association for the Study of Diabetes (EASD) Annual Meeting in Berlin, Germany.

Hypoglycaemia data were collected during a Phase II clinical study comparing LY2605541 with insulin glargine in patients with type 2 diabetes. In addition to the reduction in nocturnal hypoglycaemia in LY2605541-treated patients, results showed the treatments had similar overall rates of hypoglycaemia (p=0.08, not statistically significant).[1]

The study used a validated patient-experience questionnaire called the Adult Low Blood Sugar Survey (ALBSS)[3] to measure patients' fear of mild-to-moderate hypoglycaemia and associated behaviors during the previous four weeks. Hypoglycaemia was defined as low blood glucose levels that were less than or equal to 70 mg/dL. The ALBSS measures the worry or fear associated with the impact of the patients' experience with a hypoglycaemic event and subsequent behaviors that are associated with avoiding future events based upon a previous experience.

The results of this study found:

- Patients treated with LY2605541 had a lower average score on the fear subscale of the ALBSS at week 12 than those treated with insulin glargine (6.6 vs. 10.0; p=0.022).[2]
- LY2605541 and insulin glargine had similar effects on patient behavior at week 12 (p=NS).[2] Examples of change in subsequent behaviors associated with avoiding future hypoglycaemic events included eating large snacks, keeping blood sugar levels higher in social situations, staying at home more than liked and limiting exercise/physical activity.
- LY2605541-treated patients had lower average total scores on the ALBSS compared with glargine-treated patients (13.0 vs. 16.5 in the glargine group; p=0.026).[2]

"As we continue development of our investigational novel basal insulin, we wanted to understand both the impact of the fear of hypoglycaemia and the impact of hypoglycaemic events and the emotional toll for the person with diabetes," said David Kendall, M.D., distinguished medical fellow, Lilly Diabetes. "We look forward to further studying LY2605541 in a large Phase III program to better understand the clinical impact of these patient-reported health outcomes results."

About the Phase II Study[1]

The Phase II, randomized, open-label, parallel study evaluated LY2605541 in lowering self-monitored fasting blood glucose levels compared to insulin glargine in adults with type 2 diabetes. Patients were converted to morning insulin administration during a four-week lead-in period and were randomized 2:1 to morning administration of LY2605541 (195 patients) or glargine (93 patients) for a total of 12 weeks.

The primary endpoint of the study showed that LY2605541 and glargine had similar effects on lowering average daily self-monitored fasting (before breakfast) glucose levels (p=0 .433) and HbA1c (p=0.279) over 12 weeks.

Following treatment with LY2605541, blood tests on liver function (as measured by mean ALT and AST levels) statistically significantly increased from baseline and were higher than with insulin glargine. The mean levels of both liver enzymes remained within the normal range during the study for glargine and LY2605541-treated patients.

In the Phase II type 2 diabetes study, triglyceride levels in patients treated with LY2605541 were not significantly different from

baseline (163 mg/dL to 172 mg/dL), but statistically higher compared to insulin glargine (160 mg/dL vs. 147 mg/dL). There was no significant difference in LDL-C or HDL-C in patients treated with LY2605541 from baseline or compared with insulin glargine.

Patients also completed the Adult Low Blood Sugar Survey (ALBSS), a 33-item questionnaire divided into two subscales that independently assess patients' behaviors related to preventing hypoglycaemia and its effects, as well as patients' fear (worry) about consequences of a hypoglycemic episode. This was a prospective measure in the Phase II type 2 diabetes study for LY2605541.* For each item, patients reported how often the item was true using a 5-point Likert scale (0, never to 4, almost always). Patients completed the ALBSS at baseline, week 6 and week 12 of the study. The ALBSS yields an individual score for the behavior and fear subscales as well as a total score.[2]

About Diabetes

An estimated 366 million people[4] worldwide have type 1 and type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases. Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[5]

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in the field of diabetes that centers on four pipeline compounds representing several of the largest treatment classes. This alliance leverages the companies' strengths as two of the world's leading pharmaceutical companies, combining Boehringer Ingelheim's solid track record of research-driven innovation and Lilly's innovative research, experience, and pioneering history in diabetes. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs. Find out more about the alliance at www.boehringer-ingelheim.com or www.lilly.com.

About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 44,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine.

As a central element of its culture, Boehringer Ingelheim pledges to act socially responsible. Involvement in social projects, caring for employees and their families, and providing equal opportunities for all employees form the foundation of the global operations. Mutual cooperation and respect, as well as environmental protection and sustainability are intrinsic factors in all of Boehringer Ingelheim's endeavours.

In 2011, Boehringer Ingelheim achieved net sales of about 13.2 billion euro. R&D expenditure in the business area Prescription Medicines corresponds to 23.5% of its net sales.

For more information please visit www.boehringer-ingelheim.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, IN, 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.

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we work to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and our continued commitment to providing real solutions — from medicines to support programs and more — to make lives better.

For more information, visit www.lillydiabetes.com.

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This press release contains forward-looking statements that are based on Lilly's current expectations for LY2605541(novel

basal insulin), but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantee that novel basal insulin will receive the necessary clinical and manufacturing regulatory approvals or that it will prove to be commercially successful. In addition, there can be no guarantee that the companies will realize the financial and commercial results anticipated from this collaboration. Other risk factors that may affect Lilly's results can be found in the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. The companies undertake no duty to update forward-looking statements.

**LY2605541 is an investigational agent. Its efficacy and safety have not been finally established.*

REFERENCES

1. Bergenstal RM, Rosenstock J, Arakaki RF, Prince MJ, Qu Y, Sinha VP, Howey DC, Jacober SJ. Weight loss and lower nocturnal hypoglycaemia with novel long-acting basal insulin LY2605541 versus insulin glargine in patients with type 2 diabetes. EASD: 48th Annual Meeting; Berlin, Germany; 2012.

2. Curtis, B, Shi, C. Novel long-acting basal insulin analogue LY2605541 significantly reduces nocturnal hypoglycaemia and fear of hypoglycaemia compared to insulin glargine in patients with type 2 diabetes mellitus. Abstract #954. Presented at the 48th European Society for the Study of Diabetes (EASD) Annual Meeting. 1-5 October 2012, Berlin, Germany.

3. Cox DJ, Irvine A, Gonder-Frederick L, Nowacek G, Butterfield J. Fear of hypoglycemia: quantification, validation, and utilization. Diabetes Care 1987, 10:617-621.

4. International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2011.

5. International Diabetes Federation. Diabetes Atlas, 5th Edition: What is Diabetes? http://www.idf.org/diabetesatlas/5e/what-is-diabetes. Accessed on: August 2, 2012.

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