September 26, 2013

Data Presented at 49th EASD Annual Meeting Show Treatment with Lilly's Investigational Dulaglutide Resulted in Improved Patient-Reported Health Outcomes

Improvements in several indicators of diabetes management, including perceptions about hyperglycaemia and weight, observed for investigational GLP-1 receptor agonist

BARCELONA, Spain, Sept. 26, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive patient-reported health outcomes from a Phase III clinical trial of dulaglutide, an investigational, long-acting glucagon-like peptide 1 (GLP-1) receptor agonist being studied as a once-weekly treatment for type 2 diabetes. These results will be presented at the 49th European Association for the Study of Diabetes (EASD) Annual Meeting in Barcelona, Spain.

In addition to reductions in HbA1c (hemoglobin A1c) levels and weight at 26 and 52 weeks with dulaglutide 1.5 mg,[1] dulaglutide-treated patients reported significant, positive improvements compared to baseline across several patient-reported indicators of diabetes management, measured using validated questionnaires, including:

- satisfaction with treatment and rates of perceived hyperglycaemia as measured by the Diabetes Treatment Satisfaction Questionnaire (DTSQ);
- weight-related self-perception (Impact of Weight on Self-Perception (IW-SP) and Ability to Perform Physical Activities of Daily Living Questionnaires (APPADL)); and
- perceived current health status (EuroQoL 5-Dimension Questionnaire (EQ-5D)).[2]

"Patients' perception of how diabetes treatment may affect their lives is an important consideration when choosing a medication. We are pleased that in this study, patients treated with dulaglutide reported improvements in several patient-reported outcome measures," said Gwen Krivi, Ph.D., vice president, Lilly Diabetes product development. "These results, coupled with dulaglutide's positive clinical data, suggest that, if approved, our investigational once-weekly GLP-1 may be an attractive treatment option for patients with type 2 diabetes."

The patient-reported outcomes from the AWARD-1 trial showed that treatment satisfaction, as measured by the DTSQ, was significantly higher with dulaglutide compared to baseline, and was significantly greater compared to placebo and exenatide twice-daily at 26 weeks. Significant improvements were also seen compared to baseline and exenatide twice-daily at 52 weeks.[2]

Clinical results from the AWARD-1 trial showed that treatment with dulaglutide 1.5 mg led to improvements in HbA1c levels and weight reductions.[1] Dulaglutide-treated patients also demonstrated significant improvements compared to baseline and exenatide twice-daily in perceived hyperglycaemia scores (using DTSQ) at 26 and 52 weeks.[2]

Patients in the study noted significant improvements in weight-related self-perception (IW-SP) compared to baseline at 26 weeks, which persisted through one year of treatment. These improvements were not significantly different between all treatment groups.[2] There were no significant differences in the ability to perform physical activities of daily living (APPADL) between dulaglutide-treated patients compared to baseline, placebo or exenatide-treated patients.[2]

Treatment with dulaglutide, as well as with exenatide twice-daily, led to significant improvements in perceptions of current health status (EQ-5D) compared to baseline at 26 weeks; these improvements with dulaglutide 1.5 mg as well as exenatide twice-daily were also significant compared to placebo. Significant improvements were also seen compared to baseline at one year, with no significant differences between dulaglutide and exenatide twice-daily.

In the clinical trial, gastrointestinal-related symptoms, including nausea, vomiting and diarrhoea, were the most common adverse events reported for dulaglutide and were mostly mild to moderate and transient.

Dulaglutide is one of several diabetes molecules in Lilly's late-stage pipeline. The company has a number of potential new medicines in clinical development for the treatment of diabetes and its related conditions. Lilly expects to submit dulaglutide to regulatory authorities in 2013.

About the Study[1,2]
AWARD-1 was a randomised, 52-week, placebo-controlled comparison of the effects of dulaglutide and exenatide twice-daily on glycaemic control in patients with type 2 diabetes on metformin and pioglitazone. The primary objective of the study, conducted in 978 patients, was to evaluate whether dulaglutide 1.5 mg, dosed once-weekly, was superior to placebo in reducing HbA1c from baseline at 26 weeks.

To evaluate health outcomes, patients were administered questionnaires at baseline and again prior to follow-up visits at 26 and 52 weeks. Treatment satisfaction[*], as well as perceived hyperglycaemia and hypoglycaemia, were measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ); impact of weight was measured using the Impact of Weight on Self-Perception Questionnaire (IW-SP) and the Ability to Perform Physical Activities of Daily Living Questionnaire (APPADL); and perceived current health status was measured using the EuroQoL 5-Dimension Questionnaire (EQ-5D).

About Diabetes
Approximately 25.8 million Americans[3] and an estimated 371 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]

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.

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. P-LLY

This press release contains forward-looking statements about dulaglutide that are based on Lilly's current expectations. Actual results could differ materially from these expectations. There are significant risks and uncertainties in the process of drug development and commercialization. There can be no guarantee that future study results and patient experience will be consistent with the study findings to date. There can also be no guarantee that dulaglutide will be submitted to regulatory authorities in 2013, that it will receive the necessary clinical and manufacturing regulatory approvals, or that it will prove to be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, the company undertakes no duty to update forward-looking statements.

[*]Treatment satisfaction refers to an individual's subjective appraisal of their experience of treatment (both process and outcomes), including ease of use, side effects and efficacy.[6]

References

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Refer to: Candace Johnson, +1-317-755-9143, johnson_candace_a@lilly.com

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