



May 6, 2013

Retrospective analysis of linagliptin data in sub-populations with type 2 diabetes presented at AACE 22nd Annual Scientific & Clinical Congress

Retrospective pooled analyses evaluated linagliptin treatment in American Hispanic/Latino people with type 2 diabetes, as well as in people living with type 2 diabetes for at least 10 years

RIDGEFIELD, Conn. and INDIANAPOLIS, May 6, 2013 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) today announced results from two new pooled analyses of phase III data with the dipeptidyl peptidase-4 (DPP-4) inhibitor linagliptin, presented at the American Association of Clinical Endocrinologists (AACE) 22nd Annual Scientific & Clinical Congress.

In one retrospective pooled analysis, data were included from Hispanic/Latino adults with type 2 diabetes (T2D), a population that is disproportionately affected by T2D.¹ Data pooled from six phase III studies showed that treatment with linagliptin reduced glucose levels (HbA_{1c}) versus placebo in this patient population.

In a second retrospective analysis, data were pooled from two phase III studies that included people with long-standing T2D (> / =10 years). The analysis showed reductions in HbA_{1c} from baseline with linagliptin versus placebo.

"Response to treatment can vary between sub-populations of adults with type 2 diabetes," said Christophe Arbet-Engels, MD, PhD, vice president, clinical development and medical affairs metabolic, Boehringer Ingelheim Pharmaceuticals, Inc. "Those with long-standing type 2 diabetes or of Hispanic/Latino origin are often difficult to treat or under-treated."

About Poster No. 1118 - Sub-population of Hispanic/Latino Adults with T2D

The findings from the first presentation were derived from six randomized, double-blind, placebo-controlled phase III studies of linagliptin 5 mg/d given as monotherapy or in addition to common glucose-lowering therapies.¹ Of the six studies included in the analysis, two were 18 weeks in duration and four were 24 weeks in duration.¹ A total of 731 American Hispanic/Latino patients (467 who received linagliptin and 264 who received placebo) were included in the full analysis set (FAS), which was comprised of all randomized patients treated with at least one dose of the study drug, and who had their HbA_{1c} measured at baseline and at least once during the treatment period.¹ The primary efficacy endpoint was change in HbA_{1c} from baseline to 18 or 24 weeks.¹ Baseline HbA_{1c} levels were 8.25% in the linagliptin group and 8.23% in the placebo group.¹

Key findings of the retrospective analysis for the linagliptin treatment group included¹:

- 0.58% reduction in HbA_{1c} compared to placebo after 24 weeks of treatment (95% confidence interval [CI]-0.74, -0.42; p < 0.0001)
- 14.6% reported drug-related AEs vs. 18.4% for placebo

About Poster No. 1119 - Sub-population of Adults with Long-standing T2D

For the second retrospective analysis, researchers pooled data from two phase III studies of 202 patients with a reported T2D duration of ≥10 years, who received either linagliptin 5 mg/d (n=122) or placebo (n=80).² The average exposure to both treatments was 169 days.² A total of 192 patients (117 linagliptin and 75 placebo) were included in the FAS.² The primary endpoint was change in HbA_{1c} from baseline to 24 weeks.² Baseline HbA_{1c} levels were 8.07% in the linagliptin group and 8.45% in the placebo group.²

Key findings of the retrospective analysis for the linagliptin treatment group included²:

- 0.66% reduction in HbA_{1c} compared to placebo after 24 weeks of treatment (CI: -0.95, -0.38; p < 0.0001)
- 21.3% reported treatment-related AEs vs. 16.3% in the placebo arm

Linagliptin, which is marketed as Tradjenta® (linagliptin) tablets in the U.S., is a once-daily 5mg tablet used along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine). Linagliptin is a DPP-4 inhibitor that does not require dose adjustments, regardless of declining renal function or hepatic impairment.

What are TRADJENTA (linagliptin) tablets?

TRADJENTA is a prescription medicine that is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

TRADJENTA is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

Important Safety Information

Who should not take TRADJENTA?

Do not take TRADJENTA if you are allergic to linagliptin or any of the ingredients in TRADJENTA. Symptoms of a serious allergic reaction to TRADJENTA are rash, raised red patches on your skin (hives), swelling of your face, lips, and throat that may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking TRADJENTA and call your doctor right away.

What should I tell my doctor before taking TRADJENTA?

Tell your doctor if you take other medicines that can lower your blood sugar, such as a sulfonylurea or insulin.

TRADJENTA may cause serious side effects, including low blood sugar (hypoglycemia). If you take TRADJENTA with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered while you take TRADJENTA.

Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.

Also tell your doctor if you take rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

Tell your doctor if you are pregnant or planning to become pregnant or are breastfeeding or plan to breastfeed.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

What are the possible side effects of TRADJENTA?

The most common side effects of TRADJENTA include stuffy or runny nose and sore throat.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more safety information, please see [Patient Information and full Prescribing Information](#).

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To learn more about TRADJENTA visit: www.TRADJENTA.com. For full prescribing information visit: <http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renentn&folderPath=/Prescribing+Information/PIs/Tradjenta/Tradjenta.pdf> or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.

Please report any unexpected effects or product problems to the Boehringer Ingelheim Drug Information Unit by calling 1-800-542-6257.

About Diabetes

Approximately 25.8 million Americans³ and an estimated 371 million people worldwide⁴ have type 1 or type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.³ Diabetes is a chronic

condition 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 three compounds representing several of the largest diabetes 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

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation (Ridgefield, CT) and a member of the Boehringer Ingelheim group of companies.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 140 affiliates and more than 46,000 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 has a demonstrated commitment to corporate social responsibility. 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 endeavors.

In 2012, Boehringer Ingelheim achieved net sales of about \$19.1 billion (14.7 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 22.5% of its net sales.

For more information please visit www.us.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 a 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 about linagliptin tablets for the treatment of type 2 diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that linagliptin will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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References

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