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New Phase 3 data for Tradjenta® (linagliptin) tablets in black or African American patients with type 2 diabetes showed significant improvement in blood sugar

First published trial of a dipeptidyl peptidase-4 (DPP-4) inhibitor specifically conducted in black or African American patients with type 2 diabetes

RIDGEFIELD, Conn. and INDIANAPOLIS, May 24, 2012 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) today announced Phase 3 study results for linagliptin 5 mg once-daily, which showed significant hemoglobin A1c (HbA1c or A1C) reduction of 0.88 percent compared to 0.24 percent in the placebo group (p=0.0002) at 24 weeks in black or African American adult patients with type 2 diabetes whose blood sugar was not adequately controlled.[1] Linagliptin is marketed as Tradjenta® 5mg once-daily tablets in the U.S., and is the first and only member of the dipeptidyl peptidase-4 (DPP-4) inhibitor class to be approved at one dosage strength. The data were presented at the American Association of Clinical Endocrinologists (AACE) 21st annual Scientific and Clinical Congress.

TRADJENTA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. TRADJENTA is a DPP-4 inhibitor that does not require dose adjustments regardless of declining renal function or hepatic impairment.[2] TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine). It has not been studied in combination with insulin.

In the U.S., African Americans and other ethnic minorities are significantly underrepresented in clinical trials.[3] This is the first published trial of a DPP-4 inhibitor specifically conducted in black or African American adult patients with type 2 diabetes.

"These findings support the efficacy and safety profile of linagliptin as a treatment option for African American adult patients with type 2 diabetes," said lead investigator James Thrasher, MD, FACE, Arkansas Diabetes and Endocrinology Center. "As there may be differences in response to treatment among ethnic groups, an important finding of this trial is that the results are consistent with the A1C reduction seen in the linagliptin pivotal trials, which included a small sample of African American patients."

African American adults are disproportionately affected by diagnosed diabetes. In the U.S., the risk of diabetes is 77 percent greater for non-Hispanic black adults, when compared to non-Hispanic white adults, [4] with an estimated 18.7 percent (4.9 million) of all non-Hispanic black adults living with the disease.[4]

In the 24-week study, 226 patients were randomized (106 to linagliptin, and 120 to placebo)[1], and received at least one dose of the study drug in order to be included in the safety analyses.[1] Patients who had a measurement of A1C at baseline (linagliptin 8.63 percent +/-0.11; placebo 8.70 percent +/-0.11) and at least one measurement post-baseline (200) were included in the analyses of efficacy.[1] A1C was measured every six weeks during the study and the difference between the groups was significantly different by six weeks and remained so throughout the study.[1]

The number of patients experiencing adverse events was similar for the linagliptin and placebo groups.[1] The most common adverse events reported in this trial were hyperglycemia (high blood sugar levels [linagliptin 2.8 percent; placebo 9.2 percent]) and nasopharyngitis (inflammation of the nose or pharynx [linagliptin 3.8 percent; placebo 5 percent]).[1] Hypoglycemia occurred in three patients in the linagliptin group and one patient in the placebo group, and none of the events required external assistance.[1]

"These data are important because we know that African Americans are significantly more likely to have diabetes than non-Hispanic Whites," said John Smith, MD, PhD, senior vice president for clinical development and medical affairs, Boehringer Ingelheim Pharmaceuticals, Inc. "This study suggests that linagliptin provides black or African American adult patients with another option to improve control of their blood sugar, and it also reaffirms Boehringer Ingelheim and Lilly Diabetes' shared commitment to address the needs of the millions of Americans living with type 2 diabetes."

A secondary endpoint of the study looked at the proportion of patients with an A1C value of less than 7.0 percent,[1] a target level recommended by the American Diabetes Association.[5] Although the study was designed to recruit patients with an A1C of at least 7.5 percent at screening[1], a few patients were below 7.0 percent at the baseline measurement, and these patients were excluded from this analysis.[1] All other patients with a baseline and at least one on-treatment measurement were

included.[1] At week 24, patients in the linagliptin group were significantly more likely to meet this target (28.0 percent versus 8.7 percent, p=0.001).[1]

Patients in the linagliptin group were also significantly more likely to see an A1C reduction of at least half a percent at week 24, with more than half the patients (55.3 percent) in the linagliptin group having a reduction of 0.5 percent or more, compared with 28.3 percent in the placebo group (p < 0.0001).[1]

To learn more about linagliptin and for full prescribing information visit: www.TRADJENTA.com, or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.

What are TRADJENTA 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).

It is not known if TRADJENTA is safe and effective when used with insulin.

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 medicine 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 breast-feeding or plan to breast-feed.

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.

To learn more about TRADJENTA visit: www.TRADJENTA.com. For full prescribing information visit: http://bidocs.boehringer-

ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&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 Americans[4] and an estimated 366 million people worldwide[6] 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.[4] Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[7]

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 endeavors.

In 2011, Boehringer Ingelheim achieved net sales of about $17.1 billion (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 http://us.boehringer-ingelheim.com and follow us on Twitter at http://twitter.com/boehringerus .

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.

This press release contains forward-looking statements about TRADJENTA *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* TRADJENTA *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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[6] International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2011.

[7] International Diabetes Federation. Diabetes Atlas, 5th Edition: What is Diabetes? http://www.idf.org/diabetesatlas/5e/what-is-diabetes. Accessed on: April 17, 2012.

SOURCE Eli Lilly and Company