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Type 2 diabetes: findings presented from retrospective analysis of pooled data examining linagliptin in African-American adults

RIDGEFIELD, Conn. and INDIANAPOLIS, May 15, 2014 /PRNewswire/ -- Data from a retrospective pooled analysis of eight phase III trials (two 18-week and six 24-week) of linagliptin 5 mg once-daily, showed reductions from baseline A1c at 18 (eight trials) and 24 (six trials) weeks compared to placebo in African-American adults with type 2 diabetes (T2D), Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) announced. Additionally, similar proportions of patients in the linagliptin and placebo groups experienced adverse events, including the incidence of investigator-reported hypoglycemia. These data were presented at the American Association of Clinical Endocrinologists (AACE) 23rd Annual Scientific & Clinical Congress in Las Vegas.[1]

"African-Americans have an increased risk of developing type 2 diabetes and are less likely to achieve glycemic targets due to genetic and environmental factors, yet they are underrepresented in clinical trials," said Christophe Arbet-Engels, M.D., Ph.D., vice president, metabolic clinical development and medical affairs, Boehringer Ingelheim Pharmaceuticals, Inc. "The findings from this retrospective pooled data analysis help support the efficacy and safety profile of linagliptin as a treatment option for African-American adults with type 2 diabetes. We are proud to contribute to the clinical knowledge about oral glucose-lowering drugs specifically in the African-American population."

According to the Centers for Disease Control and Prevention (CDC), African-Americans, along with other minority groups, are at a higher risk for T2D than the rest of the population.[2]

About the Retrospective Pooled Analysis
The retrospective pooled analysis from eight randomized, placebo-controlled phase III trials included 336 adults with T2D from North and South America who self-reported their race as African-American. Of the participants, 173 received linagliptin 5 mg and 163 received placebo once-daily, either as monotherapy or add-on to various glucose-lowering regimens, for 18 weeks (two trials) or 24 weeks (six trials). The primary efficacy endpoint was change in A1c from baseline to 18 weeks or 24 weeks. Mean baseline A1c levels were 8.53 percent in the linagliptin group and 8.61 percent in the placebo group. Safety was assessed according to incidence and intensity of adverse events (AEs), including the incidence and intensity of hypoglycemia.

Key findings from the retrospective pooled analysis:

- Placebo-adjusted mean change (95 percent CI) in hemoglobin A1c levels (a measure of average blood glucose) from baseline of -0.69 percent (-0.92, -0.46) at week 18 (eight trials) and −0.64 percent (−0.90, −0.39) at week 24 (six trials).
- Similar proportions of patients in the linagliptin and placebo groups experienced AEs (65.3 percent and 68.1 percent, respectively) with a lower percentage of patients experiencing drug-related AEs in the linagliptin group compared with placebo (9.2 percent and 13.5 percent, respectively).
- Incidence of hypoglycemia was similar across groups (12.1 percent on linagliptin, 11.7 percent on placebo).

Linagliptin, which is marketed as Tradjenta® (linagliptin) tablets in the U.S., is a once-daily, 5-mg tablet used along with diet and exercise to improve glycemic control in adults with T2D. TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. TRADJENTA has not been studied in patients with a history of pancreatitis.

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).

If you have had inflammation of the pancreas (pancreatitis) in the past, it is not known if you have a higher chance of getting pancreatitis while you take TRADJENTA.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TRADJENTA?
Serious side effects can happen to people taking TRADJENTA, including inflammation of the pancreas (pancreatitis), which may be severe and lead to death. Before you start taking TRADJENTA, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels.

Stop taking TRADJENTA and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

Who should not take TRADJENTA?
Do not take TRADJENTA if you are allergic to TRADJENTA or any of the ingredients in TRADJENTA.

Symptoms of a serious allergic reaction to TRADJENTA may include rash, itching, flaking or peeling; raised red patches on your skin (hives); swelling of your face, lips, tongue 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 using TRADJENTA?
Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

Especially 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.
- rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®)^, an antibiotic that is used to treat tuberculosis.

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

What are the possible side effects of TRADJENTA?
The most common side effects of TRADJENTA include stuffy or runny nose, sore throat, cough and diarrhea.

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 Medication Guide and full Prescribing Information.

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To learn more about TRADJENTA visit: www.TRADJENTA.com. For full Prescribing Information and Medication Guide visit: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Tradjenta/Tradjenta.pdf

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

About Diabetes
Approximately 24.4 million Americans and an estimated 382 million people worldwide have type 1 or type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 85 to 95 percent of all diabetes cases. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.[3]

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. The alliance leverages the strengths of two of the world's leading pharmaceutical companies. 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 Pharmaceuticals, Inc.
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 142 affiliates and more than 47,400 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.

Social responsibility is a central element of Boehringer Ingelheim's culture. 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 2013, Boehringer Ingelheim achieved net sales of about $18.7 billion (14.1 billion euro). R&D expenditure in the Prescription Medicines business corresponds to 19.5% of its net sales.

For more information please visit http://www.us.boehringer-ingelheim.com

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels.

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 are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a broad and growing product portfolio and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com.

This press release contains forward-looking statements about TRADJENTA 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 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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1. Thrasher J et al. Efficacy and Safety of TRADJENTA in Black/African American Patients with Type 2 Diabetes (T2D): Pooled Analysis From 8 Randomized, Placebo-controlled Phase 3 Trials. Presented at the American Association of Clinical Endocrinologists (AACE) 23rd Annual Scientific & Clinical Congress. May 15-19. Las Vegas, Nevada.
2. Centers for Disease Control and Prevention. Groups Especially Affected by Diabetes. http://www.cdc.gov/diabetes/consumer/groups.htm. Accessed on May 1, 2014.
3. International Diabetes Federation. Diabetes Atlas, 6th Edition. 2013.

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