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First Patient Enrolled in New Cardiovascular and Renal Outcomes Trial for TRADJENTA® (linagliptin) Tablets in Type 2 Diabetes

Boehringer Ingelheim and Lilly initiate post-marketing trial with a planned enrollment of more than 8,000 adults with type 2 diabetes in 24 countries

RIDGEFIELD, Conn. and INDIANAPOLIS, July 31, 2013 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY) today announced enrollment of the first patient into a cardiovascular (CV) and renal outcomes trial for linagliptin (TRADJENTA) tablets. The CARMELINA[1] (**CA**rdiovascular Safety & **R**enal **M**icrovascular outcom**E** study with **LINA**gliptin, 5 mg once daily in patients with type 2 diabetes mellitus at high vascular risk) trial will investigate the effect of the once-daily dipeptidyl peptidase-4 (DPP-4) inhibitor linagliptin on cardiovascular and renal outcomes in adults with type 2 diabetes (T2D) at risk of major macro- and microvascular events.

"Diabetes is a major risk factor for cardiovascular disease, as well as a leading cause of chronic renal failure," said Dr. Julio Rosenstock, director of the Dallas Diabetes and Endocrine Center at Medical City in Dallas and principal investigator of the study. "CARMELINA will investigate both cardiovascular and renal outcomes with a DPP-4 inhibitor."

The CARMELINA study will look to enroll more than 8,000 adults with T2D in 24 countries at more than 500 sites around the world.[1] The CV endpoint will be time to the first occurrence of either CV death (including fatal stroke and fatal myocardial infarction [MI, also known as a heart attack]); non-fatal MI; non-fatal stroke; or hospitalization for unstable angina pectoris (unpredictable chest pain produced when the heart is not getting enough blood). The renal, or kidney, outcome is measured as time to first occurrence of renal death, sustained end-stage renal disease or sustained decrease of > /=50% in estimated glomerular filtration rate (eGFR, a measure of kidney function that estimates the amount of blood the kidneys are filtering each minute).[1] Completion of the study is expected in 2018.

"Boehringer Ingelheim and Lilly are committed to patient safety, and we are pleased the first patient has been enrolled in the CARMELINA trial," said Christophe Arbet-Engels, MD, PhD, vice president, metabolic-clinical development and medical affairs, Boehringer Ingelheim Pharmaceuticals, Inc. "Clinical trials like CARMELINA provide physicians with information they need to better understand the safety and efficacy of linagliptin, so that they can appropriately treat people with uncontrolled T2D."

About CARMELINA
CARMELINA is a long-term study investigating the efficacy and safety of linagliptin 5 mg once daily versus placebo on cardiovascular and renal microvascular outcomes in people with T2D who are at high risk of major macro- and microvascular events. Adults with T2D and previous CV complications and albuminuria, which is too much protein in the urine (*urine albumin-to-creatinine ratio* [UACR] > /= 30 mg/g), and/or evidence of renal microvascular-related end-organ damage (eGFR 15- < 45 with any UACR or eGFR > /= 45-75 with an UACR > 200 mg/g) will be randomized into the study.

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. 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). TRADJENTA has not been studied in patients with a history of pancreatitis and it is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using TRADJENTA. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with TRADJENTA or any other antihyperglycemic drug.

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 linagliptin 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 U.S. 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 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[2] and an estimated 371 million people worldwide[3] 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.[2] Diabetes is a chronic condition that occurs when the body does not properly produce or use the hormone insulin.[4] Diabetes was estimated to cost the U.S. $245 billion in 2012.[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.

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 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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