August 4, 2014

Type 2 diabetes: Jentadueto® (linagliptin and metformin hydrochloride) tablets label updated to include new data on blood glucose reductions in treatment-naive adults with high baseline A1C

- Combination of linagliptin and metformin significantly reduced blood glucose levels compared with linagliptin alone

RIDGEFIELD, Conn. and INDIANAPOLIS, Aug. 4, 2014 /PRNewswire/ -- The U.S. Prescribing Information for Jentadueto® (linagliptin and metformin hydrochloride) tablets now includes clinical trial data that showed linagliptin co-administered with metformin provided statistically significant decreases in blood glucose compared with linagliptin alone in treatment-naive* adults with type 2 diabetes and high baseline A1C levels (A1C of > /=8.5 to < /=12.0 percent). Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY) announced today that the data, based on results from a prospective 24-week phase IV clinical trial, have been added to the "Clinical Studies" section of the JENTADUETO U.S. Prescribing Information.

"We are extremely pleased with the addition to the JENTADUETO label. These data support the use of JENTADUETO as an initial type 2 diabetes treatment option in an important patient population - treatment-naive adults who have high baseline A1C levels," said Christophe Arbet-Engels, M.D., Ph.D., vice president, metabolic clinical development and medical affairs, BIPI. "In addition, these data reinforce the use of JENTADUETO, as an adjunct to diet and exercise, in helping adults with type 2 diabetes improve glycemic control."

The 24-week, randomized, double-blind study assessed the efficacy and safety of linagliptin (5 mg per day) in combination with metformin (1500 to 2000 mg per day; n=159) vs. linagliptin (5 mg per day; n=157) alone in treatment-naive adults with type 2 diabetes and high baseline A1C (A1C of > /=8.5 to < /=12.0 percent).

The primary endpoint of the trial — change from baseline in A1C after 24 weeks — demonstrated that initial therapy with the combination of linagliptin and metformin reduced A1C levels from baseline by 2.9 percent compared with 2.0 percent for linagliptin alone. There was a statistically significant mean difference in A1C between the combination and linagliptin alone of -0.84 percent. Key secondary findings showed fasting plasma glucose (FPG) levels were significantly decreased with the combination treatment compared with linagliptin alone (54 mg/dL vs. 35 mg/dL, mean difference -18 mg/dL) and that a greater percentage of patients achieved an A1C less than 7 percent with the combination of linagliptin and metformin (54 percent) compared with linagliptin alone (30 percent). The percentage of patients with investigator-defined hypoglycemic events was similar between treatment arms (linagliptin and metformin, 1.9 percent; linagliptin, 3.2 percent).

**note: Treatment-naive adults in this study were defined as adults with no antidiabetic therapy for 12 weeks prior to randomization.*

Please see full Prescribing Information for JENTADUETO, including Boxed Warning regarding the risk of lactic acidosis, and Medication Guide.

About Linagliptin

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 type 2 diabetes (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.

About Linagliptin/Metformin Hydrochloride

Linagliptin/metformin hydrochloride, which is marketed as Jentadueto® (linagliptin and metformin hydrochloride) tablets in the U.S., is a prescription medicine that contains two diabetes medicines, linagliptin and metformin. JENTADUETO can be used along with diet and exercise to improve glycemic control in adults with T2D when treatment with both linagliptin and metformin is appropriate. JENTADUETO should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JENTADUETO has not been studied in patients with a history of pancreatitis. The JENTADUETO label contains a Boxed Warning for the risk of lactic acidosis, a rare, but serious, complication that can occur due to metformin accumulation during treatment with JENTADUETO.

JENTADUETO was approved based on clinical trials that evaluated linagliptin and metformin as separate tablets. Bioequivalence of JENTADUETO was demonstrated with co-administered linagliptin and metformin tablets in healthy subjects.

What is JENTADUETO?
JENTADUETO is a prescription medicine that contains 2 diabetes medicines, linagliptin and metformin. JENTADUETO can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes when treatment with both linagliptin and metformin is appropriate.

JENTADUETO 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 JENTADUETO.

IMPORTANT SAFETY INFORMATION
What is the most important information I should know about JENTADUETO?

WARNING: RISK OF LACTIC ACIDOSIS

Serious side effects can happen in people taking JENTADUETO. Metformin, one of the medicines in JENTADUETO, can cause a rare but serious condition called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital.

Stop taking JENTADUETO and call your doctor right away if you feel very weak or tired, have unusual muscle pain, have trouble breathing, are very sleepy, have sudden nausea and vomiting or diarrhea, feel cold, especially in your arms or legs, feel dizzy or lightheaded, or have a slow or irregular heartbeat, as these could be symptoms of lactic acidosis.

You have a higher chance of getting lactic acidosis with JENTADUETO if you have kidney problems, liver problems, congestive heart failure that requires medicines, drink alcohol very often, or drink a lot of alcohol in short-term "binge" drinking, get dehydrated (lose a large amount of body fluids), have certain x-ray tests with dyes or contrast agents that are injected into your body, have surgery, have a heart attack, severe infection, or stroke, and are 80 years of age or older and have not had your kidneys tested.

Inflammation of the pancreas (pancreatitis) is another serious side effect that can happen to people taking JENTADUETO. Pancreatitis may be severe and lead to death. Before you start taking JENTADUETO tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels.

Stop taking JENTADUETO 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 JENTADUETO?
Do not take JENTADUETO if you:

- have kidney problems.
- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).
- are allergic to linagliptin, metformin or any of the ingredients in JENTADUETO. Symptoms of an allergic reaction may include rash, itching, flaking or peeling; raised red patches on your skin (hives); and 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 JENTADUETO and call your doctor or go to the emergency room right away.

What should I tell my doctor before using JENTADUETO?
Before you take JENTADUETO, tell your doctor if you:

- have or have had inflammation of your pancreas (pancreatitis).
- have kidney problems.
- are going to get an injection of dye or contrast agents for an x-ray procedure. JENTADUETO will need to be stopped for a short time. Talk to your doctor about when you should stop JENTADUETO and when you should start JENTADUETO again.
- have liver problems.
- have heart problems, including congestive heart failure.
- drink alcohol very often, or drink a lot of alcohol in short-term "binge" drinking.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if JENTADUETO will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if JENTADUETO passes into your breast milk.
- are older than 80 years; you should not take JENTADUETO unless your kidneys have been checked and they are

normal.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. JENTADUETO may affect the way other medicines work, and other medicines may affect how JENTADUETO works. Especially tell your doctor if you take

- other medicines that can lower your blood sugar. If you take JENTADUETO 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 JENTADUETO.
- rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®)^, an antibiotic that is used to treat tuberculosis.

What are the possible side effects of JENTADUETO?
JENTADUETO may cause serious side effects, including

- Lactic acidosis (a build-up of lactic acid in the blood).
- Inflammation of the pancreas (pancreatitis).
- Low blood sugar (hypoglycemia), especially if you take JENTADUETO with another medicine that can cause low blood sugar. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.
- Allergic (hypersensitivity) reactions can happen after your first dose or up to 3 months after starting JENTADUETO. Symptoms may include swelling of your face, lips, throat, and other areas on your skin; difficulty with swallowing or breathing; raised, red areas on your skin (hives); skin rash, itching, flaking, or peeling.

The most common side effects of JENTADUETO include stuffy or runny nose, sore throat, and diarrhea.

These are not all the possible side effects of JENTADUETO. For more information, ask your doctor or pharmacist. **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.**

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Click here for full Prescribing Information, including Boxed Warning regarding the risk of lactic acidosis, and Medication Guide.

To learn more about JENTADUETO visit: www.JENTADUETO.com. For full Prescribing Information, including Boxed Warning regarding the risk of lactic acidosis, and Medication Guide visit: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Jentadueto/Jentadueto.pdf.

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

What is TRADJENTA?
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 or go to the emergency room right away.

What should I tell my doctor before using TRADJENTA?
Tell your doctor about all your medical conditions, including if you have or have had inflammation of your pancreas (pancreatitis).

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. 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.
- 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?
TRADJENTA may cause serious side effects, including

- Inflammation of the pancreas (pancreatitis).
- Low blood sugar (hypoglycemia), especially if you take TRADJENTA with another medicine that can cause low blood sugar. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.
- Allergic (hypersensitivity) reactions can happen after your first dose or up to 3 months after starting TRADJENTA. Symptoms may include swelling of your face, lips, throat, and other areas on your skin; difficulty with swallowing or breathing; raised, red areas on your skin (hives); skin rash, itching, flaking, or peeling.

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

These are not all the possible side effects of TRADJENTA. For more information, ask your doctor or pharmacist. **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.**

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Click here for full Prescribing Information, including Medication Guide.

To learn more about TRADJENTA visit: www.TRADJENTA.com. For full prescribing information, including medication guide 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.

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About Diabetes
Approximately 29 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.

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 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.

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.

This press release contains forward-looking statements about linagliptin and linagliptin+metformin hydrochloride 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 commercialisation. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that linagliptin will prove to 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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SOURCE Eli Lilly and Company; Boehringer Ingelheim Pharmaceuticals, Inc.