



March 23, 2015

First-in-class type 2 diabetes treatment Glyxambi® (empagliflozin/linagliptin) tablets for adults now available in U.S. pharmacies

New dual inhibitor SGLT2/DPP-4 combination therapy offers improved glycemic control as an adjunct to diet and exercise

New GLYXAMBI savings program offered for eligible patients

RIDGEFIELD, Conn., and INDIANAPOLIS, March 23, 2015 /PRNewswire/ -- Glyxambi® (empagliflozin/linagliptin) tablets are now available by prescription in many leading chain and independent pharmacies across the U.S., including Walgreens and Rite Aid. GLYXAMBI, part of the Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY) Diabetes alliance portfolio, is the first and only dual inhibitor combination therapy approved in the U.S. to combine the mechanisms of action of a sodium glucose co-transporter-2 (SGLT2) inhibitor and a dipeptidyl peptidase-4 (DPP-4) inhibitor in a once-daily tablet.

GLYXAMBI is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) when both empagliflozin and linagliptin are appropriate treatments. GLYXAMBI is a once-daily tablet taken in the morning that combines 10 mg or 25 mg of empagliflozin, an SGLT2 inhibitor, with 5 mg of linagliptin, a DPP-4 inhibitor. GLYXAMBI is not for people with type 1 diabetes or for diabetic ketoacidosis (increased ketones in the blood or urine). If you have had pancreatitis (inflammation of the pancreas) it is not known if you have a higher chance of getting pancreatitis while taking GLYXAMBI.

"The rapid market availability of GLYXAMBI following its recent FDA approval in late January is a reflection of Boehringer Ingelheim and Lilly's commitment to bringing new treatment options to people with type 2 diabetes," said Kathleen Dowd, senior vice president, marketing, Boehringer Ingelheim Pharmaceuticals, Inc. "As the fourth diabetes medicine to emerge from our alliance pipeline in the U.S., we believe GLYXAMBI may help adults with type 2 diabetes lower their blood sugar and manage their diabetes."

A GLYXAMBI savings card program is available online and in many doctors' offices for patients who qualify. For terms and conditions and any questions regarding eligibility or benefits, visit GLYXAMBI.savings.com or call 1-855-GLYXAMBI (1-855-459-9262).

GLYXAMBI should not be taken if you have severe kidney problems, are on dialysis or if you are allergic to empagliflozin and linagliptin or any of the ingredients in GLYXAMBI. Symptoms of a serious allergic reaction to GLYXAMBI may include skin rash, itching, flaking or peeling; raised red patches on your skin (hives); difficulty swallowing or breathing; or swelling of your face, lips, tongue, and throat that may cause difficulty breathing or swallowing. If you have any of these symptoms, stop taking GLYXAMBI and call your doctor or go to the emergency room right away.

"As an add-on to metformin, GLYXAMBI was superior in reducing A1C when compared with either empagliflozin or linagliptin alone," said David Kendall, M.D., vice president, medical affairs, Lilly Diabetes. "The management of type 2 diabetes requires a personalized treatment plan, and GLYXAMBI provides patients and their physicians with a new option to help improve blood sugar control."

The U.S. Food and Drug Administration approval was based on a phase III clinical trial that evaluated the efficacy and safety of GLYXAMBI (10/5 mg and 25/5 mg) compared with the individual components of empagliflozin (10 mg or 25 mg) or linagliptin (5 mg) in adults with T2D who were also taking high-dose metformin (mean dose 1889 mg daily). The study, which randomized 686 adults with T2D and hemoglobin A1C (a measure of average blood glucose over the past two to three months) between 7.0 and 10.5 percent, examined the change from baseline in A1C at 24 weeks. The study demonstrated superior A1C reduction with GLYXAMBI compared with the individual components of empagliflozin or linagliptin. Starting from a mean baseline of approximately 8.0 percent, adults in this trial achieved a mean A1C of 6.9 and 6.7 percent with GLYXAMBI 10/5 mg and 25/5 mg, respectively, compared with a mean A1C of 7.3 and 7.4 percent for empagliflozin 10 mg and 25 mg, respectively, and 7.3 percent for linagliptin 5 mg.

Data recently published in *Diabetes Care* demonstrated that 58 percent and 62 percent of patients taking GLYXAMBI 10/5 mg or 25/5 mg, respectively, in addition to metformin achieved an A1C of less than 7 percent from a baseline A1C of approximately 8 percent, compared with 28 percent of patients taking empagliflozin 10 mg, 33 percent taking empagliflozin 25 mg and 36 percent taking linagliptin 5 mg.

Through 52 weeks, the safety profile of GLYXAMBI was demonstrated in a pooled analysis, and the most common adverse reactions were urinary tract infection (UTI) (12.5 percent and 11.4 percent for GLYXAMBI 10/5 mg and 25/5 mg, respectively; through 52 weeks, no patient discontinued GLYXAMBI due to UTIs), nasopharyngitis (5.9 percent and 6.6 percent for GLYXAMBI 10/5 mg and 25/5 mg, respectively) and upper respiratory tract infection (7.0 percent for GLYXAMBI 10/5 mg and 25/5 mg).

Serious side effects can happen to people taking GLYXAMBI, including inflammation of the pancreas (pancreatitis), which may be severe and lead to death. Before you start taking GLYXAMBI, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels. Stop taking GLYXAMBI 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 to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

What is GLYXAMBI?

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about GLYXAMBI?

Serious side effects can happen to people taking GLYXAMBI, including:

- **Inflammation of the pancreas** (pancreatitis), which may be severe and lead to death. Before you start taking GLYXAMBI, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels.

Stop taking GLYXAMBI 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 to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

- **Dehydration.** GLYXAMBI can cause some people to have dehydration (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, light-headed, or weak, especially when you stand up. You may be at higher risk of dehydration if you have low blood pressure, take medicines to lower your blood pressure, including water pills (diuretics), are on a low salt diet, have kidney problems, or are 65 years of age or older.
- **Vaginal yeast infection.** Women who take GLYXAMBI may get vaginal yeast infections. Talk to your doctor if you experience vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), and/or vaginal itching.
- **Yeast infection of the penis.** Men who take GLYXAMBI may get a yeast infection of the skin around the penis, especially uncircumcised males and those with chronic infections. Talk to your doctor if you experience redness, itching or swelling of the penis, rash of the penis, foul smelling discharge from the penis, and/or pain in the skin around penis.

Who should not take GLYXAMBI?

Do not take GLYXAMBI if you have severe kidney problems or are on dialysis.

Do not take GLYXAMBI if you are allergic to empagliflozin and linagliptin or any of the ingredients in GLYXAMBI.

Symptoms of a serious allergic reaction to GLYXAMBI may include skin rash, itching, flaking or peeling; raised red patches on your skin (hives); difficulty swallowing or breathing; or swelling of your face, lips, tongue, and throat that may cause difficulty breathing or swallowing. If you have any of these symptoms, stop taking GLYXAMBI and call your doctor or go to the emergency room right away.

What should I tell my doctor before using GLYXAMBI?

Tell your doctor if you:

- have kidney problems. Your doctor may do blood tests to check your kidneys before and during your treatment with GLYXAMBI
- have liver problems

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of infection of the vagina or penis
- have a history of urinary tract infections or problems with urination
- have any other medical condition
- are pregnant or plan to become pregnant. It is unknown if GLYXAMBI will harm your unborn baby. Tell your doctor right away if you become pregnant during treatment with GLYXAMBI
- are breastfeeding, or planning to breastfeed. It is unknown if GLYXAMBI passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GLYXAMBI may affect the way other medicines work, and other medicines may affect how GLYXAMBI works.

Especially tell your doctor if you take:

- insulin or other medicines that can lower your blood sugar
- diuretics (water pills)
- rifampin (Rifadin[®], Rimactane[®], Rifater[®], Rifamate[®])*, an antibiotic that is used to treat tuberculosis

*These trademarks are owned by third parties not affiliated with GLYXAMBI.

What are the possible side effects of GLYXAMBI?

GLYXAMBI may cause serious side effects, including:

- **Low blood sugar (hypoglycemia)**, if you take GLYXAMBI with another medicine that can cause low blood sugar such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.
- **Urinary tract infections** are a common side effect of GLYXAMBI but can sometimes be serious. Symptoms may include burning feeling when passing urine, urine that looks cloudy, and/or pain in the pelvis or back.
- **Allergic (hypersensitivity) reactions** can happen after your first dose or up to 3 months after starting GLYXAMBI. 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); and/or skin rash, itching, flaking, or peeling. If you have any of these symptoms, stop taking GLYXAMBI and call your doctor or go to the emergency room right away.
- **Kidney problems**, especially in people 75 years and older and people who already have kidney problems
- **Increased fats in your blood (cholesterol).**

The most common side effects of GLYXAMBI include urinary tract infections, stuffy or runny nose and sore throat, and upper respiratory tract infections.

These are not all the possible side effects of GLYXAMBI. 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.

GLX CONS ISI 1.30.15

Visit GLYXAMBI.com for full [Prescribing Information, including Medication Guide](#).

About Diabetes

Approximately 29 million Americans and an estimated 387 million people worldwide have type 1 or type 2 diabetes, and nearly 28 percent of Americans with diabetes—totaling 8 million people—are undiagnosed. In the U.S., approximately 12 percent of those aged 20 and older have diabetes. T2D is the most common type, accounting for an estimated 90 to 95 percent of all adults diagnosed with diabetes in the U.S. 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. This 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

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 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 newsroom.lilly.com/social-channels.

This press release contains forward looking statements about GLYXAMBI for the treatment of type 2 diabetes along with diet and exercise. 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 GLYXAMBI will be commercially successful, or that it will receive additional regulatory approvals. 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.

Glyxambi® is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc.

P-LLY
GLX646304PR

CONTACT:

Emily Baier Geary
Public Relations
Boehringer Ingelheim Pharmaceuticals, Inc.
Email: emily.geary@boehringer-ingelheim.com
Phone: (203) 791-5997

Molly McCully
Communications Manager
Lilly Diabetes
Email: mccully_molly@lilly.com
Phone: (317) 478-5423

Lilly



Boehringer
Ingelheim

Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

Logo - <http://photos.prnewswire.com/prnh/20110825/DE57898LOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/first-in-class-type-2-diabetes-treatment-glyxambi-empagliflozinlinagliptin-tablets-for-adults-now-available-in-us-pharmacies-300054038.html>

SOURCE Eli Lilly and Company; Boehringer Ingelheim

News Provided by Acquire Media