



August 1, 2014

FDA approves Jardiance® (empagliflozin) tablets for adults with type 2 diabetes

Third product from the BI-Lilly Diabetes alliance to be approved by FDA

RIDGEFIELD, Conn., and INDIANAPOLIS, Aug. 1, 2014 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY) today announced the U.S. Food and Drug Administration (FDA) approved Jardiance® (empagliflozin) tablets as an adjunct to diet and exercise to improve glycemic control, or blood glucose levels, in adults with type 2 diabetes (T2D). JARDIANCE is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

JARDIANCE, a once-daily, 10 mg or 25 mg tablet, is a sodium glucose co-transporter-2 (SGLT2) inhibitor. JARDIANCE works by blocking the reabsorption of glucose in the kidney, increasing glucose excretion and lowering blood glucose levels in adults with T2D who have elevated blood glucose levels.

Patients should not take JARDIANCE if they have severe kidney problems or are on dialysis, or if they are allergic to empagliflozin or any ingredient in JARDIANCE. JARDIANCE can cause some people to have dehydration (the loss of body water and salt), which may lead to a drop in blood pressure, and may cause patients to feel dizzy or faint.

"Many adults with type 2 diabetes still have difficulty controlling their blood sugar levels even with treatment. There is a critical need for new treatment options to help these patients," said Christophe Arbet-Engels, M.D., Ph.D., vice president, metabolic-clinical development and medical affairs, BIPI. "JARDIANCE is a new option that has been shown in clinical trials to reduce blood sugar levels. Although not approved for weight loss, modest weight loss was also observed in these clinical trials."

The FDA approval is based on results from a large clinical program comprised of more than 10 multinational clinical trials and more than 13,000 adults with T2D. Phase III studies showed JARDIANCE significantly reduced hemoglobin A1C (a measure of average blood glucose over the past two to three months) and fasting blood sugar after 24 weeks as a stand-alone treatment or in combination with a range of background treatments, including metformin, sulfonylureas, insulin and pioglitazone. Although JARDIANCE is not approved for lowering weight or blood pressure, modest reductions in both weight and systolic blood pressure were observed in clinical trials.

The most common adverse reactions associated with JARDIANCE were urinary tract infections and vaginal yeast infections. Hypoglycemia was more commonly reported in patients treated with the combination of JARDIANCE and sulfonylurea or insulin.

"Today's FDA approval of JARDIANCE provides an exciting new option in the treatment of adults with type 2 diabetes and demonstrates our commitment to these patients, as it marks the third diabetes medicine to emerge from our alliance pipeline," said Enrique Conterno, president, Lilly Diabetes.

About Diabetes

Approximately 29 million Americans and an estimated 382 million people worldwide have type 1 or type 2 diabetes. T2D 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.

What is JARDIANCE?

JARDIANCE is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

JARDIANCE is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

IMPORTANT SAFETY INFORMATION

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

JARDIANCE can cause serious side effects, including:

- **Dehydration.** **JARDIANCE** 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 a 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
- are 65 years of age or older.

- **Vaginal yeast infection.** Women who take JARDIANCE 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 JARDIANCE 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 JARDIANCE?

- **Do not take** JARDIANCE if you are allergic to empagliflozin or any of the ingredients in JARDIANCE.

Symptoms of serious allergic reactions to JARDIANCE may include:

- skin rash
- raised red patches on your skin (hives)
- swelling of the face, lips, tongue, and throat that may cause difficulty breathing or swallowing.

If you have any of these symptoms, stop taking JARDIANCE and contact your doctor or go to the nearest emergency room right away.

- **Do not take** JARDIANCE if you have severe kidney problems or are on dialysis.

What should I tell my doctor before using JARDIANCE?

Tell your doctor if you:

- have kidney problems. Your doctor may do blood tests to check your kidneys before and during your treatment with JARDIANCE
- have liver problems
- have a history of urinary tract infections or problems with urination
- have any other medical conditions
- are pregnant or planning to become pregnant. It is unknown if JARDIANCE will harm your unborn baby
- are breastfeeding, or plan to breastfeed. It is unknown if JARDIANCE 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. Especially tell your doctor if you take water pills (diuretics) or medicines that can lower your blood sugar such as insulin.

What are other possible side effects of JARDIANCE?

- **Low blood sugar** (hypoglycemia): if you take JARDIANCE with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of low blood sugar is higher. The dose of your sulfonylurea or insulin may need to be lowered. Symptoms of low blood sugar may include:
 - Headache
 - Drowsiness
 - Weakness
 - Dizziness
 - Confusion
 - Irritability

- Hunger
- Fast heart beat
- Sweating
- Shaking or feeling jittery
- **Kidney Problems**, especially in people 75 years of age or older and people who already have kidney problems
- **Urinary Tract Infection**: symptoms may include burning feeling when passing urine, pain in the pelvis or back, or urine that looks cloudy
- **Increased fats in your blood (cholesterol).**

The most common side effects of JARDIANCE include urinary tract infections, and yeast infections in females.

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 information, please see full Prescribing Information, including Patient Information.

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For full Prescribing Information and Patient Information, visit:

<http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renentnt&folderPath=/Prescribing+Information/PIs/Jardiance/jardiance.pdf>

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 JARDIANCE 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 JARDIANCE 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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