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Jardiance® (empagliflozin) is the only diabetes medication to show a significant reduction in both cardiovascular risk and cardiovascular death in a dedicated outcome trial

- JARDIANCE achieved superiority for the primary CV endpoint and a significant reduction in CV death in people with T2D at high risk of CV events
- The results of the EMPA-REG OUTCOME® trial were published in NEJM and also presented at the 51st European Association for the Study of Diabetes Annual Meeting today

RIDGEFIELD, Conn., and INDIANAPOLIS, Sept. 17, 2015 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company's (NYSE: LLY) Jardiance® (empagliflozin) significantly reduced the risk of the combined endpoint of cardiovascular (CV) death, non-fatal heart attack or non-fatal stroke by 14 percent when added to standard of care in patients with type 2 diabetes (T2D) at high risk of CV events. There was a 38 percent reduction in CV death, with no significant difference in the risk of non-fatal heart attack or non-fatal stroke.

Experience the interactive Multimedia News Release here: http://www.multivu.com/players/English/7617351-bi-lilly-empa-reg-cv-results

In addition, treatment with JARDIANCE resulted in a lower risk of all-cause mortality (32 percent reduction) and hospitalization for heart failure (35 percent reduction).

"These results are both novel and exciting for the millions of people living with type 2 diabetes at risk for cardiovascular disease. Addressing the burden of cardiovascular events, including death, is at the core of diabetes care, and until now no single diabetes medication has been associated with a reduction in mortality," said lead investigator of the trial Bernard Zinman, M.D., Director, Diabetes Centre, Mount Sinai Hospital; Senior Scientist, Lunenfeld Tanenbaum Research Institute, and Professor of Medicine, University of Toronto, Canada. "In this study, empagliflozin was shown to prevent one out of three cardiovascular deaths."

Life expectancy of people with T2D at high CV risk is, on average, decreased by up to 12 years with approximately 50 percent of deaths in people with T2D caused by CV disease. The effect of JARDIANCE in this trial was observed on top of standard of care. This means the benefit was seen over and above other treatments patients were already receiving for diabetes and/or cardiovascular disease (such as blood pressure and cholesterol lowering-medications).

"The EMPA-REG OUTCOME trial results are encouraging for healthcare professionals and their patients," said Christopher P. Cannon, M.D., Cardiovascular Division, Brigham and Women's Hospital and Professor of Medicine, Harvard Medical School, who was not involved in the study. "Patients in the study were already being treated with medications that have been proven to reduce cardiovascular events. The observation that empagliflozin provided additional cardiovascular death reduction on top of these other medications is a very important finding."

The overall safety profile of JARDIANCE was consistent with previous trials. The incidence of diabetic ketoacidosis was at or below 0.1 percent and similar across all treatment groups.

These data were presented today at the 51st European Association for the Study of Diabetes Annual Meeting in Stockholm, Sweden, and simultaneously published in the *New England Journal of Medicine*.

"The Boehringer Ingelheim and Lilly Diabetes Alliance is very pleased to share the results of the EMPA-REG OUTCOME trial with the healthcare community," said Prof. Hans-Juergen Woerle, Global Vice President Medicine, Boehringer Ingelheim. "Cardiovascular disease is the number one cause of death in people with type 2 diabetes worldwide and reducing cardiovascular risk, including death, is an essential component of diabetes management."

About EMPA-REG OUTCOME
EMPA-REG OUTCOME was a long-term, multicenter, randomized, double-blind, placebo-controlled trial that involved more than 7,000 patients from 42 countries with type 2 diabetes at high risk for cardiovascular events. There were 772 primary outcome events in the EMPA-REG OUTCOME trial over a median observation period of 3.1 years.

The study was designed to assess the effect of JARDIANCE (10mg or 25mg once daily) added to standard of care compared with placebo added to standard of care. The primary endpoint was defined as time to first occurrence of either CV death, or non-fatal heart attack or non-fatal stroke. The study was designed to first test for non-inferiority and then for superiority.

Standard of care was comprised of glucose-lowering agents and cardiovascular drugs (including blood pressure and cholesterol-lowering medications).

Of the 7,020 treated patients, more than 97 percent completed the trial and vital status was available for more than 99 percent of these patients at study end. Analyses and results were independently validated and confirmed by the University of Freiburg, Germany, an internationally renowned academic center specializing in statistical analyses.

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 diagnosed adult diabetes cases in the U.S. 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 once-daily pill taken in the morning, used along with diet and exercise, to lower blood sugar (A1C) 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 the 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
  - Confusion
  - Sweating
  - Drowsiness
  - Irritability
  - Shaking or feeling jittery
  - Weakness
  - Hunger
  - Dizziness
  - Fast heart beat

- **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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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 Pharmaceuticals, Inc.
Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with 146 affiliates and more than 47,000 employees. Since its founding in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel treatments for human and veterinary medicine.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and families. Our employees create and engage in programs that strengthen our communities. To learn more about how we make more health for more people, visit our Corporate Social Responsibility Report.

In 2014, Boehringer Ingelheim achieved net sales of about $16.96 billion dollars (13.3 billion euros). R&D expenditure corresponds to 19.9 percent of its net sales.

For more information please visit www.us.boehringer-ingelheim.com, or follow us on Twitter @BoehringerUS.

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 or follow @LillyDiabetes.

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 (as that term is defined in the Private Securities Litigation Reform Act of 1995) about empagliflozin as a treatment for patients with type 2 diabetes along with diet and exercise and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that empagliflozin will receive additional regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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