June 1, 2017

Boehringer Ingelheim and Lilly Diabetes Alliance to Present 33 Abstracts at the American Diabetes Association's 77th Scientific Sessions®

- Clinical and pre-clinical data will showcase breadth of treatment options

RIDGEFIELD, Conn. and INDIANAPOLIS, June 1, 2017 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) will present 33 abstracts highlighting the companies' wide range of diabetes treatment options at the 77th American Diabetes Association's (ADA) Scientific Sessions® in San Diego, June 9-13.

With compounds representing several of the largest diabetes treatment classes, Boehringer Ingelheim and Lilly will feature posters, abstracts and oral presentations for their range of products, including Jardiance® (empagliflozin) tablets, Tradjenta® (linagliptin) tablets and Basaglar® (insulin glargine injection) 100 units/mL.

"Since diabetes requires a personalized treatment regimen best suited to each individual, it is important that we understand how different treatment options can help people with diabetes manage their condition," said Thomas Seck, M.D., vice president, Clinical Development and Medical Affairs, Primary Care, Boehringer Ingelheim Pharmaceuticals, Inc. "With our broad portfolio of treatment options, we, along with Lilly, are looking forward to showcasing our research efforts and sharing new data at this year's ADA Scientific Sessions."

Highlighted presentations and posters include the following:

JARDIANCE Data
JARDIANCE is approved by the U.S. Food and Drug Administration to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. JARDIANCE is also approved as an adjunct to diet and exercise to improve glycemic control, or blood glucose levels, in adults with type 2 diabetes.

A special session at ADA titled "What More Can We Learn from EMPA-REG?" will review new analyses from the landmark EMPA-REG OUTCOME® trial on Saturday, June 10 from 12:30-1:30 p.m. PDT/3:30-4:30 p.m. EDT. EMPA-REG OUTCOME was a long-term, multicenter, randomized, double-blind, placebo-controlled trial which investigated the effects of JARDIANCE compared with placebo when added to standard of care type 2 diabetes and cardiovascular medicines in adults with type 2 diabetes and established cardiovascular disease.

The session will include the following abstracts:

- Empagliflozin (EMPA) Reduces Heart Failure Irrespective of Control of Blood Pressure (BP), Low Density Lipoprotein Cholesterol (LDL-C), and HbA1c (Presenting author: Fitchett, D.) [1172-P]
- Empagliflozin reduces mortality in analyses adjusted for control of blood pressure (BP), low density lipoprotein cholesterol (LDL-C) and HbA1c over time (Presenting author: Zinman, B.) [1173-P]
- Reduction in cardiovascular (CV) death with empagliflozin is consistent across categories of baseline HbA1c and change in HbA1c: results from EMPA-REG OUTCOME (Presenting author: Inzucchi, S.E.) [1174-P]
- Empagliflozin and progression of kidney disease in patients at high renal risk: slope analyses from EMPA-REG OUTCOME (Presenting author: Wanner, C.) [1175-P]
- Empagliflozin and incidence of acute kidney injury: pooled safety analysis in > 12,000 individuals (Presenting author: Wheeler, D.) [1176-P]
- Effect of the SGLT-2 inhibitor EMPA on vascular function and central hemodynamics in patients with type 2 diabetes (Presenting author: Schmieder, R.) [1177-P]

TRADJENTA Data
TRADJENTA is approved to lower blood sugar in adults with type 2 diabetes along with diet and exercise. A poster presentation will focus on the CARMELINA (CArdiovascular Safety & Renal Microvascular outcomE study with LINAgliptin) trial, which is investigating the impact of treatment with TRADJENTA versus placebo on top of standard of care on cardiovascular and renal outcomes.

Sunday, June 11, 12:00-1:00 p.m. PDT/3:00-4:00 p.m. EDT (general poster session)

- CARMELINA® Trial Baseline Characteristics: A Cardiovascular and Renal Microvascular Outcome Trial with Linagliptin in Patients with Type 2 Diabetes at High Vascular Risk (Presenting author: Rosenstock, J.) [1284-P]

BASAGLAR Data
BASAGLAR is a long-acting insulin used to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes. BASAGLAR is not for treating diabetic ketoacidosis. The following BASAGLAR data will be included in a moderated poster discussion titled "Insulins with a 'Twist'" on Sunday, June 11 from 12:00-1:00 p.m. PDT/3:00-4:00 p.m. EDT.

Saturday, June 10, 11:30 a.m.-12:30 p.m. PDT/2:30-3:30 p.m. EDT (general poster session)

- Efficacy and Safety Between Insulin Glargine Products (LY2963016 and Lantus®) in Patients with T2DM: the ELEMENT 5 Study (Presenting author: Pollom, R.K.) [963-P]

A complete list of abstracts to be presented or published at the 77th ADA Scientific Sessions can be found here.

About the EMPA-REG OUTCOME Trial (NCT01131676)
EMPA-REG OUTCOME was a long-term, multicenter, randomized, double-blind, placebo-controlled trial of more than 7,000 patients, from 42 countries, with type 2 diabetes and established cardiovascular disease.

The study assessed the effect of JARDIANCE (10 mg or 25 mg once daily) added to standard of care compared with placebo added to standard of care. Standard of care was comprised of glucose-lowering agents and cardiovascular drugs (including for blood pressure and cholesterol). The primary endpoint was defined as time to first occurrence of cardiovascular death, non-fatal heart attack or non-fatal stroke.

About Diabetes and Cardiovascular Disease
Approximately 29 million Americans and an estimated 415 million people worldwide have 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. Type 2 diabetes 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 does not properly produce or use the hormone insulin.

Due to the complications associated with diabetes, such as high blood sugar, high blood pressure and obesity, cardiovascular disease is a major complication and the leading cause of death associated with diabetes. People with diabetes are two to four times more likely to develop cardiovascular disease than people without diabetes. Approximately 50 percent of deaths in people with type 2 diabetes worldwide and 68 percent of deaths in people with type 2 diabetes in the U.S. are caused by cardiovascular disease. In the U.S., health care costs for managing cardiovascular conditions in patients with diabetes totaled more than $23 billion in 2012.

Having diabetes can shorten a person's lifespan by as much as six years compared with someone without diabetes.* And having both diabetes and a history of heart attack or stroke can shorten a person's lifespan by as much as 12 years compared with someone without these conditions.**

* Based on having a history of diabetes at age 60.
** Based on having a history of diabetes and heart attack or stroke at age 60.

About Educational Initiatives
Given the critical connection between diabetes and cardiovascular disease, Boehringer Ingelheim and Eli Lilly and Company are committed to providing a wide range of diabetes therapies along with programs and support to raise awareness, understanding and action toward reducing the impact of cardiovascular disease in people with type 2 diabetes.

What is JARDIANCE? (www.jardiance.com)
JARDIANCE is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

JARDIANCE is also used to reduce the risk of cardiovascular death in adults with type 2 diabetes who have known cardiovascular disease.

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.

- **Ketoacidosis (increased ketones in your blood or urine).** Ketoacidosis is a serious condition and may need to be treated in the hospital. Ketoacidosis may lead to death. Ketoacidosis occurs in people with type 1 diabetes and can also occur in people with type 2 diabetes taking JARDIANCE, even if blood sugar is less than 250 mg/dL. **Stop taking JARDIANCE and call your doctor right away if you get any of the following symptoms,** and if possible, check for ketones in your urine:
  - nausea
  - vomiting
  - stomach-area (abdominal) pain
  - tiredness
  - trouble breathing

- **Serious urinary tract infections.** Serious urinary tract infections can occur in people taking JARDIANCE and may lead to hospitalization. Tell your doctor if you have symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often or right away, pain in the lower part of your stomach or pelvis, or blood in the urine. Sometimes people also may have a fever, back pain, nausea or vomiting.

- **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
- are going to have surgery
- are eating less due to illness, surgery, or a change in your diet
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas
- drink alcohol very often, or drink a lot of alcohol in the short term ("binge" drinking)
- 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 heartbeat
  - Sweating
  - Shaking or feeling jittery

- **Kidney Problems.** Sudden kidney injury has happened in people taking JARDIANCE. Talk to your doctor right away if you reduce the amount you eat or drink, or if you lose liquids; for example, from vomiting, diarrhea, or being in the sun too long.

- **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 and Patient Information.

JAR CONS ISI 1.11.17

What is TRADJENTA? (www.tradjenta.com)
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 of these symptoms, 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.

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

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.
- Joint pain. Some people who take medicines called DPP-4 inhibitors like TRADJENTA, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- Skin Reaction. Some people who take medicines called DPP-4 inhibitors like TRADJENTA, may develop a skin reaction called bullous pemphigoid which can be serious and may need to be treated in a hospital. Tell your doctor right away if you develop blisters.

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.**

TJ CONS lSI 9JAN2017

For more safety information, please see Prescribing Information and Medication Guide.

About BASAGLAR (www.basaglar.com)
In December 2015, BASAGLAR was the first insulin product approved through an abbreviated approval pathway under the Federal Food, Drug, and Cosmetic Act. The extensive clinical development program for BASAGLAR included pharmacokinetic and pharmacodynamic studies, as well as Phase III studies in people with type 1 and type 2 diabetes comparing the safety and efficacy of BASAGLAR to U.S.-and non-U.S.-approved Lantus®.

BASAGLAR Indication
BASAGLAR is a long-acting insulin used to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes.

BASAGLAR is not for treating diabetic ketoacidosis.

Important Safety Information

Do not take BASAGLAR® (insulin glargine injection) during episodes of low blood sugar or if you are allergic to insulin glargine or any of the ingredients in BASAGLAR.

Do NOT reuse needles or share insulin pens, even if the needle has been changed.

Before starting BASAGLAR, tell your doctor about all your medical conditions, including if you have liver or kidney problems, if you are pregnant or planning to become pregnant, or if you are breastfeeding or planning to breastfeed.

BASAGLAR should be taken once a day at the same time every day. Test your blood sugar levels while using insulin. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

The most common side effect of insulin, including BASAGLAR, is low blood sugar (hypoglycemia), which may be serious and life threatening. Signs and symptoms may include dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood change, or hunger.

Do NOT dilute or mix BASAGLAR with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. BASAGLAR must only be used if the solution is clear and colorless with no particles visible. Always make sure you have the correct insulin before each injection.

BASAGLAR may cause serious side effects that can lead to death, such as severe allergic reactions. **Get emergency help** if you have:

- A rash over your whole body
- Trouble breathing
- A fast heartbeat
- Sweating
- Swelling of your face, tongue, or throat
- Shortness of breath
- Extreme drowsiness, dizziness, or confusion

Heart failure can occur if you are taking insulin together with medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure, it may get worse while you take TZDs with BASAGLAR. Your treatment with TZDs and BASAGLAR may need to be changed or stopped by your doctor if you have new or worsening heart failure. Tell your doctor if you have any new or worsening symptoms of heart failure, including:

- Shortness of breath
- Swelling of your ankles or feet
- Sudden weight gain

Tell your doctor about all the medications you take, including over-the-counter medicines, vitamins, and herbal supplements.

While using BASAGLAR, do not drive or operate heavy machinery until you know how BASAGLAR affects you. Do not drink alcohol or use other medicines that contain alcohol.

Other possible side effects may include swelling, weight gain, low potassium, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions. **These are not all the possible side effects.** Call your doctor for medical advice about side effects.

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.

The BASAGLAR KwikPen is a disposable, prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instructions for Use that accompanies the pen. BASAGLAR is available by prescription only.

BV DTC ISI 24JUN2016

Please see Prescribing Information and Patient Information provided.

Please see Instructions for Use that come with the pen.

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.

Boehringer Ingelheim
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 top 20 pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with approximately 50,000 employees. Since its founding in 1885, the company has remained family-owned and today creates value through innovation for three business areas including human pharmaceuticals, animal health and biopharmaceutical contract manufacturing.

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

In 2016, Boehringer Ingelheim achieved net sales of about $17.6 billion (15.9 billion euros). R&D expenditure corresponds to 19.6 percent of its net sales.

For more information please visit www.boehringer-ingelheim.us, 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.

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 JARDIANCE, TRADJENTA and BASAGLAR, 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 JARDIANCE, TRADJENTA and BASAGLAR 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.

P-LLY

PC-03957

CONTACT:

Jen Forsyth
Director, Public Relations
Boehringer Ingelheim Pharmaceuticals, Inc.
Email: jennifer.forsyth@boehringer-ingelheim.com
Phone: (203) 791-5889

Dani Barnhizer
Communications Manager
Lilly Diabetes
Email: dbarnhizer@lilly.com
Phone: (317) 607-6119