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Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company to Feature 30 Presentations on Type 1 and Type 2 Diabetes at the 72nd American Diabetes Association Scientific Sessions®

Alliance to feature research for their investigational novel basal insulin analog and investigational SGLT-2 inhibitor

RIDGEFIELD, Conn., and INDIANAPOLIS, June 5, 2012 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) are pleased to announce that less than two years after forming a strategic alliance aimed at bringing new treatments to patients with diabetes, the companies will present 30 abstracts across three compounds and three classes of medicine at the 72nd American Diabetes Association (ADA) Scientific Sessions® in Philadelphia, June 8-12.

Together, the Alliance will share data across a number of topics, including, but not limited to: efficacy and safety data in various populations of patients with diabetes, including patients on monotherapy and add-on therapy, and efficacy and safety data in comparison to another medication in the same class. This research, which demonstrates the Alliance's commitment to diabetes, includes:

- **Novel basal insulin:** For the first time, the Alliance will present pre-clinical, phase 1 and phase 2 data for their investigational novel basal insulin analog, LY2605541.
- **Empagliflozin:** 90-week safety and efficacy results for the investigational sodium glucose cotransporter-2 (SGLT-2) inhibitor empagliflozin as monotherapy or add-on to metformin will be presented as late-breaking data.
- **Linagliptin:** Results from two randomized phase 3 clinical trials and a post-hoc analysis for the dipeptidyl peptidase-4 (DPP-4) inhibitor linagliptin.
 - Linagliptin, which is marketed as Tradjenta® 5mg tablets in the U.S., is a once-daily tablet that is used along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine), and has not been studied in combination with insulin. Linagliptin is a DPP-4 inhibitor that does not require dose adjustments, regardless of declining renal function or hepatic impairment.

Novel Basal Insulin Analog (LY2605541) Data

Of the 10 abstracts to be presented for LY2605541, four are from two phase 2 studies in people with type 1 and type 2 diabetes. These presentations are as follows:

- **Saturday, June 9, 11:30 AM - 1:30 PM, General Poster Session**
 - Contrasting Weight Changes with LY2605541, a Novel Long-Acting Insulin, and Insulin Glargine Despite Similar Improved Glycemic Control in T1D and T2D (Lead Author: S. Jacober) [Poster No. 1023-P]
 - Better Glycemic Control and Weight Loss with the Novel Long-Acting Basal Insulin LY2605541 Compared with Insulin Glargine in Patients with Type 1 Diabetes (Lead Author: J. Rosenstock) [Poster No. 1026-P]
- **Monday, June 11, 4:30 - 6:30 PM, Oral Session: Insulin Analogs**
 - The Novel Long-Acting Insulin LY2605541 Is Superior to Insulin Glargine in Lowering Intra-Day Glucose Variability and Hypoglycemia Event Rate from Continuous Glucose Monitoring (CGM) in Patients with Type 2 Diabetes (Lead Author: R. Bergenstal) [Presentation 346-OR]
 - Reduced Nocturnal Hypoglycemia and Weight Loss with Novel Long-Acting Basal Insulin LY2605541 Compared with Insulin Glargine in Patients with Type 2 Diabetes (Lead Author: R. Bergenstal) [Presentation 347-OR]

Empagliflozin Data

Among the six abstracts for empagliflozin, late-breaking data evaluating its efficacy and safety as monotherapy or add-on to metformin will be presented. Details on this and additional empagliflozin presentations are as follows:

- **Saturday, June 9, 11:30 AM - 1:30 PM, General Poster Session**
 - The effect of hepatic impairment on the pharmacokinetics, safety and tolerability of empagliflozin, a potent sodium glucose cotransporter-2 inhibitor (Lead Author: S. Macha) [Poster No. 1067-P]
- **Sunday, June 10, 12:00 PM - 2:00 PM, Late-Breaker Poster Session**

- Safety and efficacy of empagliflozin as monotherapy or add-on to metformin in a 78-week open-label extension study in patients with type 2 diabetes (Lead Author: HJ Woerle) [Poster No. 49-LB]

Linagliptin Data

A total of 14 clinical and preclinical abstracts regarding linagliptin will be presented at the meeting. Details of select presentations are as follows:

- **Saturday, June 9, 11:30 AM - 1:30 PM, General Poster Session**

- Efficacy and safety of linagliptin as add-on therapy to basal insulin in patients with type 2 diabetes (Lead Author: H. Yki-Jarvinen) [Poster No. 999-P]
- Efficacy and safety of linagliptin in elderly patients (≥70 Years) with type 2 diabetes (Lead Author: A. Barnett) [Poster No. 1017-P]
- Linagliptin is more effective than glimepiride at achieving a composite outcome of A1C target with no hypoglycemia and no weight gain over 2 years in mildly hyperglycemic type 2 diabetes patients on metformin (Lead Author: B. Gallwitz) [Poster No. 1044-P]

What are TRADJENTA tablets?

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).

It is not known if TRADJENTA is safe and effective when used with insulin.

Important Safety Information

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 are rash, raised red patches on your skin (hives), swelling of your face, lips, 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 right away.

What should I tell my doctor before taking TRADJENTA?

Tell your doctor if you take other medicines that can lower your blood sugar, such as a sulfonylurea or insulin.

TRADJENTA may cause serious side effects, including low blood sugar (hypoglycemia). 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 medicine or insulin may need to be lowered while you take TRADJENTA.

Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, or feeling jittery.

Also tell your doctor if you take rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

Tell your doctor if you are pregnant or planning to become pregnant or are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

What are the possible side effects of TRADJENTA?

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

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 safety information, please see Patient Information and full Prescribing Information.

To learn more about TRADJENTA visit: www.TRADJENTA.com. For full prescribing information visit: <http://bidocs.boehringer-ingenelheim.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.

About Diabetes

Approximately 25.8 million Americans⁽¹⁾ and an estimated 366 million people⁽²⁾ worldwide have type 1 and type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.⁽¹⁾ Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.⁽³⁾

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in the field of diabetes that centers on four pipeline compounds representing several of the largest treatment classes. This alliance leverages the companies' strengths as two of the world's leading pharmaceutical companies, combining Boehringer Ingelheim's solid track record of research-driven innovation and Lilly's innovative research, experience, and pioneering history in diabetes. 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-ingenelheim.com or www.lilly.com.

About Boehringer Ingelheim Pharmaceuticals, Inc.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 44,000 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.

As a central element of its culture, Boehringer Ingelheim pledges to act socially responsible. 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 2011, Boehringer Ingelheim achieved net sales of about \$17.1 billion (13.2 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 23.5% of its net sales.

For more information, please visit <http://us.boehringer-ingenelheim.com> and follow us on Twitter at <http://twitter.com/boehringerus>.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, IN, Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.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 work to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and our continued commitment to providing real solutions — from medicines to support programs and more — to make lives better. For more information, visit www.lillydiabetes.com.

This press release contains forward-looking statements about TRADJENTA tablets for the treatment of type 2 diabetes and two investigational compounds, empagliflozin and novel basal insulin LY2605541*, which are currently in development for the treatment of 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, that empagliflozin and novel basal insulin LY2605541* will receive required regulatory approvals, or that TRADJENTA will 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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REFERENCES

1. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. 2011.
2. International Diabetes Federation. Diabetes Atlas, 5th Edition: Fact Sheet. 2011.
3. International Diabetes Federation. Diabetes Atlas, 5th Edition: What is Diabetes? <http://www.idf.org/diabetesatlas/5e/what-is-diabetes>. Accessed on: February 22, 2012.

*Novel basal insulin LY2605541 and empagliflozin are investigational compounds. Their safety and efficacy have not yet been fully established.

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

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