



September 17, 2013

Diabetes Alliance to Feature 17 Presentations for Linagliptin and Investigational Compound Empagliflozin[^] During the 49th Annual Meeting of the European Association for the Study of Diabetes (EASD)

Presentations at EASD to include safety and efficacy data for the Diabetes Alliance compounds

RIDGEFIELD, Conn. and INDIANAPOLIS, Sept. 17, 2013 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (Lilly; NYSE: LLY) today announced they will feature five oral and 12 poster presentations for linagliptin and the investigational compound empagliflozin[^] at the 49th Annual Meeting of the European Association for the Study of Diabetes (EASD), which will take place in Barcelona from September 23 — 27.

Empagliflozin Data

A total of eight clinical abstracts for the investigational agent empagliflozin will be presented. Empagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitor being investigated for the reduction of blood glucose levels in adults with type 2 diabetes (T2D). The emerging SGLT2 inhibitor class removes excess glucose through the urine by blocking glucose re-absorption by the kidney.

[^]*Empagliflozin is an investigational compound. Its safety and efficacy have not been established.*

Details of clinical presentations for empagliflozin are as follows:¹

Tuesday, September 24, 12:30—1:30 CET, General Poster Session

- Empagliflozin as Add-on to Basal Insulin for 78 Weeks Improves Glycemic Control and Weight Loss in Insulin-Treated Type 2 Diabetes (T2DM) (Presenting Author: J. Rosenstock) [Poster No. 931]
- Safety and Efficacy of Empagliflozin Monotherapy in a 52-Week Study in Japanese Patients with Type 2 Diabetes Mellitus (Presenting Author: H. J. Woerle) [Poster No. 930]
- Metabolic Response to Sodium Glucose Transporter 2 (SGLT2) Inhibition with Empagliflozin in Patients with Type 2 Diabetes (T2D) (Presenting Author: E. Ferrannini) [Poster No. 932]

Tuesday, September 24, 1:45—2:45 CET, General Poster Session

- Empagliflozin Improves Blood Pressure in Patients with Type 2 Diabetes (T2DM) and Hypertension (Presenting Author: I. Tikkanen) [Poster No. 942]
- Empagliflozin Improved Glycemic Parameters and Cardiovascular Risk Factors in Patients with Type 2 Diabetes (T2DM): Pooled Data from Four Pivotal Phase III Trials (Presenting Author: T. Hach) [Poster No. 943]
- Design of the Empagliflozin Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus (Presenting Author: S. E. Inzucchi) [Poster No. 944]

Wednesday, September 25, 12:30—1:30 CET, General Poster Session

- Empagliflozin in Patients with Type 2 Diabetes Mellitus (T2DM) and Stage 3A, 3B and 4 Chronic Kidney Disease (CKD) (Presenting Author: A. Mithal) [Poster No. 952]

Thursday, September 26, 3:00 — 4:30 CET, Oral Presentation

- The Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor Empagliflozin Improves Glycemic Control in Patients with Type 1 Diabetes: A Single-Arm Clinical Trial (Presenting Author: B. A. Perkins) [Oral Presentation No. 31]

Linagliptin Data

A total of nine clinical and pre-clinical abstracts for linagliptin will also be presented. Linagliptin is an inhibitor of the enzyme, dipeptidyl peptidase-4 (DPP-4), which breaks down the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) that are involved with regulating blood sugar.²

Details of all presentations for linagliptin are as follows:¹

Wednesday, September 25, 10:45 — 12:15 CET, Oral Presentation

- Baseline Characteristics of Participants Enrolled in the Cardiovascular Outcome Study of Linagliptin Versus Glimepiride in Early Type 2 Diabetes (CAROLINA) (Presenting Author: J. Rosenstock) [Oral Presentation No. 73]

Wednesday, September 25, 12:30 — 1:30 CET, General Poster Sessions

- Efficacy and Safety of Linagliptin as Add-On Therapy to Basal Insulin and Metformin in Patients with Type 2 Diabetes (Presenting Author: S. Duran-Garcia) [Poster No. 892]

Wednesday, September 25, 3:00 — 4:30 CET, Oral Presentation

- Cardiovascular (CV) Safety of Linagliptin in Patients with Type 2 Diabetes (T2D): A Pooled Comprehensive Analysis of Prospectively Adjudicated CV Events in Phase 3 Studies (Presenting Author: O. E. Johansen) [Oral Presentation No. 112]
- Linagliptin and The Angiotensin II Receptor Blocker Telmisartan Show Comparable Efficacy but Different Renoprotective Pathways in Rats with 5/6 Nephrectomy (Presenting Author: B. Hocher) [Oral Presentation No. 143]

Thursday, September 26, 10:45 — 12:15 CET, Oral Presentation

- Insights into the Mechanism of Action of Linagliptin in Reducing Ischaemic Brain Damage Following Stroke in Diabetic and Non-Diabetic Mice (Presenting Author: V. Darsalia) [Oral Presentation No. 152]

Thursday, September 26, 12:30 — 1:30 CET, General Poster Session

- Renal Safety and Outcomes with Linagliptin: Meta-Analysis of Individual Data for 5466 Patients with Type 2 Diabetes (Presenting Author: M. von Eynatten) [Poster No. 913]
- Linagliptin Versus Placebo Followed by Glimepiride in Type 2 Diabetes Patients with Moderate to Severe Renal Impairment (Presenting Author: P-H. Groop) [Poster No. 914]

Thursday, September 26, 1:45 — 2:45 CET, General Poster Session

- Safety and Tolerability of Linagliptin in 7400 Patients with Type 2 Diabetes: A Pooled Comprehensive Analysis of Prospective Safety Reporting in Placebo-Controlled Studies (Presenting Author: M. Lehrke) [Poster No. 986]
- Renal Safety of Linagliptin in Elderly Patients with Type 2 Diabetes: Analysis of Pooled Patient Data From 7 Phase 3 Clinical Trials (Presenting Author: A. H. Barnett) [Poster No. 926]

Linagliptin, which is marketed as TRADJENTA[®] (linagliptin) tablets in the U.S., is a once-daily 5-mg tablet 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). TRADJENTA has not been studied in patients with a history of pancreatitis, and it is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using TRADJENTA.

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).

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 symptoms of a serious allergic reaction, stop taking TRADJENTA and call your doctor right away.

What should I tell my doctor before using TRADJENTA?

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, 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 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.
- rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®)*, an antibiotic that is used to treat tuberculosis.

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?

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

You are encouraged to report negative side effects of prescription drugs to the U.S. FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more safety information, please see [Medication Guide and full Prescribing Information](#).

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*The brands listed are trademarks of their respective owners and are not trademarks of Boehringer Ingelheim Pharmaceuticals, Inc. The makers of these brands are not affiliated with and do not endorse Boehringer Ingelheim Pharmaceuticals, Inc., or its products.

To learn more about TRADJENTA visit: www.TRADJENTA.com. For full Prescribing Information and Medication Guide visit: <http://bidocs.boehringer-ingelheim.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 Americans⁶ and an estimated 371 million people worldwide have type 1 or type 2 diabetes.³ Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.⁴ Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.⁵ Diabetes was estimated to cost the U.S. \$245 billion in 2012⁷.

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 three compounds representing several of the largest diabetes 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-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 140 affiliates and more than 46,000 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.

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 2012, Boehringer Ingelheim achieved net sales of about \$19.1 billion (14.7 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 22.5% of its net sales.

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

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 a continued commitment to providing real solutions—from medicines to support programs and more—to make lives better.

For more information, visit www.lillydiabetes.com.

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This press release contains forward looking statements about empagliflozin, an investigational compound being studied for the treatment of type 2 diabetes, and linagliptin, a DPP-4 inhibitor approved 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 linagliptin will be commercially successful, or that empagliflozin will receive regulatory approvals or prove to be commercially successful or that empagliflozin will receive regulatory approvals or 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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