



## Boehringer Ingelheim and Lilly to Feature Type 2 Diabetes Research in Presentations at the 47th Annual Meeting of the European Association for the Study of Diabetes

### Long-term data to be presented for DPP-4 inhibitor, linagliptin

RIDGEFIELD, Conn. and INDIANAPOLIS, Sept. 7, 2011 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) will present the latest data from their diabetes portfolio at the 47th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Lisbon, Portugal, September 12-16. Study results evaluating the dipeptidyl peptidase-4 (DPP-4) inhibitor, linagliptin, as well as the investigational sodium-dependent glucose co-transporter-2 (SGLT-2) inhibitor, empagliflozin (BI-10773), will be featured among the seven presentations. Linagliptin 5 mg is marketed under the trade name Tradjenta™ (linagliptin) tablets in the U.S. and was approved by the U.S. Food and Drug Administration (FDA) in May 2011 to be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine). It has not been studied in combination with insulin.

A long-term study evaluating the efficacy and safety of linagliptin in patients with type 2 diabetes was selected by EASD as an oral presentation, taking place on Friday, September 16.

The presentations are as follows:

#### Linagliptin Data

Title	Format	Authors	Date/Time
<b>Preclinical</b> DPP-4 Inhibition - A New Approach for the Treatment of Uraemic Cardiomyopathy	Poster 824-P	L Chaykovska, K von Websky, S Heiden, J Rahnenfuhrer, T Klein, B Hocher	Date: Tues, Sept. 13 Time: 12:30-1:30 p.m.
<b>Phase III (52-week)</b> Long-term Efficacy and Safety of Linagliptin in Patients with Type 2 Diabetes and Severe Renal Impairment	Poster 821-P	J Newman, J McGill, S Patel, C Friedrich, C Sauce, H-J Woerle	Date: Tues, Sept. 13 Time: 12:30-1:30 p.m.
<b>Phase III (pooled analysis)</b> Linagliptin Improves Glycemic Control Independently of Diabetes Duration and Insulin Resistance in Patients with Type 2 Diabetes	Poster 832-P	S Patel, S-A Weber, A Emser, M von Eynatten, H-J Woerle	Date: Tues, Sept. 13 Time: 1:30-2:30 p.m.
<b>Phase II (12-week)</b> Efficacy and Safety of 5 mg Daily Dosing Regimens with Linagliptin in Patients with Type 2 Diabetes Inadequately Controlled on Metformin	Poster 831-P	E Rafeiro, S Ross, T Meinicke, R Toorawa, H-J Woerle	Date: Tues, Sept. 13 Time: 1:30-2:30 p.m.
<b>Preclinical</b> Effect of Linagliptin on Infarction Size and Cardiac Function in Rats After Myocardial Ischaemia Reperfusion	Poster 811-P	T Pfab, Y Sharkovska, M Alter, K von Websky, M Mark, T Klein, B Hocher	Date: Thurs, Sept. 15 Time: 1:30-2:30 p.m.
<b>Phase III (104 week)</b> Long-term Efficacy and Safety of the DPP-4 Inhibitor Linagliptin: Data from a Large Two-year Study in Patients with Type 2 Diabetes Mellitus	Oral Presentation 242-OP	A Schlosser, D Owens, M-R Taskinen, S Del Prato, R Gomis, S Patel, A Pivovarova, H-J Woerle	Date: Fri, Sept. 16 Time: 11:45 a.m.-12:00 p.m.

#### Empagliflozin Data

Title	Format	Authors	Date/Time
<b>Phase II (12 week)</b> ENCORE: Efficacy and Safety of BI-10773, a new Sodium Glucose Co-transporter-2 (SGLT-2) Inhibitor, in Type 2 Diabetes Patients Inadequately Controlled on Metformin	Oral Presentation 147-OP	L Seman, J Rosenstock, A Jelaska, S Pinnetti, S Hantel, H-J Woerle	Date: Thurs, Sept. 15 Time: 11:15-11:30 a.m.

\*All times in Western European Summer Time (WEST)

### Indication and Important Limitations of Use

TRADJENTA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

TRADJENTA has not been studied in combination with insulin.

## **Important Safety Information**

### **CONTRAINDICATIONS**

TRADJENTA is contraindicated in patients with a history of hypersensitivity reaction to linagliptin, such as urticaria, angioedema or bronchial hyperreactivity.

### **WARNINGS AND PRECAUTIONS**

#### **Use with Medications Known to Cause Hypoglycemia**

Insulin secretagogues (e.g., sulfonylurea) are known to cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with TRADJENTA.

#### **Macrovascular Outcomes**

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with TRADJENTA or any other antidiabetic drug.

### **ADVERSE REACTIONS**

Adverse reactions reported in  $\geq 5\%$  of patients treated with TRADJENTA and more commonly than in patients treated with placebo included nasopharyngitis.

Hypoglycemia was more commonly reported in patients treated with the combination of TRADJENTA and sulfonylurea compared with those treated with the combination of placebo and sulfonylurea. Pancreatitis was reported more often in patients randomized to linagliptin (1 per 538 person-years versus zero in 433 person-years for comparator).

### **DRUG INTERACTIONS**

The efficacy of TRADJENTA may be reduced when administered in combination with a strong P-glycoprotein or CYP3A4 inducer (e.g., rifampin). Therefore, use of alternative treatments is strongly recommended.

### **USE IN SPECIFIC POPULATIONS**

There are no adequate and well-controlled studies in pregnant women. Therefore, TRADJENTA should be used during pregnancy only if clearly needed. It is not known whether linagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRADJENTA is administered to a nursing woman. Safety and effectiveness of TRADJENTA in patients below the age of 18 have not been established.

To learn more about TRADJENTA and for full prescribing information visit: [www.TRADJENTA.com](http://www.TRADJENTA.com) 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

#### **About Diabetes**

Approximately 25.8 million Americans<sup>(1)</sup> and an estimated 220 million people<sup>(2)</sup> 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.<sup>(1)</sup> Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.<sup>(3)</sup>

#### **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-ingelheim.com](http://www.boehringer-ingelheim.com) or [www.lilly.com](http://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 145 affiliates and more than 42,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products 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 2010, Boehringer Ingelheim posted net sales of approximately \$16.7 billion (about 12.6 billion euro) while spending almost 24 percent of net sales in its largest business segment, Prescription Medicines, on research and development.

For more information, please visit <http://us.boehringer-ingelheim.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](http://www.lilly.com).

### **About Lilly Diabetes**

For more than 85 years, Lilly has been a worldwide leader in pioneering industry-leading solutions to support people living with and treating diabetes. Lilly introduced the world's first commercial insulin in 1923, and remains at the forefront of medical and delivery device innovation to manage diabetes. Lilly is also committed to providing solutions beyond therapy — practical tools, education, and support programs to help overcome barriers to success along the diabetes journey. At Lilly, the journeys of each person living with or treating diabetes inspire ours. For more information, visit [www.lillydiabetes.com](http://www.lillydiabetes.com).

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(1) Centers for Disease Control. National Diabetes Fact Sheet-2011. Available at: [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2011.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf). Accessed on: August 5, 2011.

(2) World Health Organization. Fact Sheet No. 312: What is Diabetes? Available at: <http://www.who.int/mediacentre/factsheets/fs312/en/>. Accessed on: August 5, 2011.

(3) International Diabetes Federation. Diabetes Atlas. 3rd edn. Brussels: International Diabetes Federation, 2006.

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