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## **New study results show Tradjenta® (linagliptin) reduces blood sugar in adults with type 2 diabetes at risk for kidney impairment**

- Renal safety profile was consistent with that demonstrated in previous trials**
- Results from the MARLINA-T2D™ trial will be presented at the American Diabetes Association 76th Scientific Sessions®**

RIDGEFIELD, Conn. and INDIANAPOLIS, June 11, 2016 /PRNewswire/ -- Results from the MARLINA-T2D™ trial demonstrated that Tradjenta® (linagliptin), which is marketed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY), reduced blood sugar in adults with type 2 diabetes (T2D) who are at risk for kidney impairment, with a renal safety profile similar to that seen in other trials. The findings will be presented tomorrow at the American Diabetes Association 76th Scientific Sessions® in New Orleans.

"Up to half of people with type 2 diabetes experience long-term problems with kidney function," said Professor Per-Henrik Groop, professor of nephrology, and chief physician at the division of nephrology, Helsinki University Central Hospital, Helsinki, Finland and principal investigator of the MARLINA-T2D trial. "Diabetes treatment options are generally limited for this group. These results support the use of TRADJENTA, with just one dose for all patients, including those with type 2 diabetes who have early signs of kidney disease."

In people who have diabetes, high levels of blood glucose can damage the kidneys' filters. Over time, the damage can increase risk for developing kidney impairment. One of the first signs of damaged kidneys and early stage kidney disease is leakage of the protein albumin out of the kidneys into the urine — a condition known as albuminuria that indicates risk for further worsening of kidney function.

MARLINA-T2D examined the safety and efficacy of TRADJENTA versus placebo in 360 patients with T2D and albuminuria (defined as urinary albumin-to-creatinine ratio (UACR) 30-3000 mg/g creatinine). At 24 weeks, TRADJENTA was associated with a significant 0.6 percent reduction in A1C (a measure of average blood glucose over the past two to three months) versus placebo. Change in albuminuria, as measured by UACR, was non-significant with TRADJENTA versus placebo. TRADJENTA was well tolerated in the trial, with a renal safety profile consistent with that of previous clinical trials.

"The treatment of type 2 diabetes is rarely a simple matter—people with this condition are often dealing with a multitude of complications, including problems with their kidneys," said Professor Hans-Juergen Woerle, global vice president medicine, Boehringer Ingelheim. "The MARLINA-T2D trial results further support the use of TRADJENTA as a once-daily therapy that does not require dose adjustment regardless of renal function."

### **About Diabetes**

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 either does not properly produce, or use, the hormone insulin.

### **What is TRADJENTA?**

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 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 over-the-counter 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.

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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.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

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

## **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](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.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with 145 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 2015, Boehringer Ingelheim achieved net sales of about \$15.8 billion dollars (14.8 billion euros). R&D expenditure corresponds to 20.3 percent of its net sales.

For more information please visit [www.us.boehringer-ingelheim.com](http://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](http://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/](http://www.lilly.com/) and [newsroom.lilly.com/social-channels](http://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 TRADJENTA 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 TRADJENTA 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.*

Tradjenta® is a registered trademark of Boehringer Ingelheim

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/new-study-results-show-tradjenta-linagliptin-reduces-blood-sugar-in-adults-with-type-2-diabetes-at-risk-for-kidney-impairment-300283291.html>

SOURCE Eli Lilly and Company; Boehringer Ingelheim

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