Real-World Data Show Advantages in People Treated with Lilly's Once-Weekly Trulicity® (dulaglutide) Compared to Those Treated with Liraglutide and Exenatide QW

June 24, 2018

Data showing improved effectiveness, adherence and persistence to be presented at the ADA's 78th Scientific Sessions®

INDIANAPOLIS, June 24, 2018 /PRNewswire/ -- People with type 2 diabetes new to treatment with a glucagon-like peptide-1 (GLP-1) receptor agonist (RA) had better blood sugar control, were more likely to adhere to treatment and stayed on treatment longer with once-weekly Trulicity® (dulaglutide) compared to once-daily liraglutide and once-weekly exenatide QW according to real-world data.[1,2] These data are being presented at the American Diabetes Association's (ADA) 78th Scientific Sessions® in Orlando. Trulicity is Eli Lilly and Company's (NYSE: LLY) once-weekly, injectable GLP-1 RA approved to improve blood sugar (glucose) in adults with type 2 diabetes. Trulicity is available in 0.75 mg and 1.5 mg and should be used along with diet and exercise.

"We know that people with type 2 diabetes have significantly better glycemic control when they are able to take their medicines as prescribed, but recognize that there are ongoing challenges with ensuring people remain adherent to their treatment," said Qing Huang, PhD, associate director and principal investigator from HealthCore, Inc. "These real-world data show that people starting on once-weekly Trulicity are associated with a higher likelihood of adhering to their treatment regimen and having a lower A1C compared to two other GLP-1 RA options."

The retrospective observational study used U.S. claims data of people with type 2 diabetes newly prescribed Trulicity or either liraglutide or exenatide QW to compare how these treatments performed in a real-world setting.[1,2] People were matched against key characteristics such as age, gender, location and baseline A1C to ensure balance in comparing the groups. Trulicity consistently showed advantages across all measures, including A1C reductions, adherence (taking treatment as prescribed) and persistence (staying on treatment).[1,2]

After both six months and one year of treatment, Trulicity provided significantly better glycemic control than liraglutide (mean absolute reduction in A1C in percent)[1]:

- Six months: -1.10 percent (Trulicity), -0.86 percent (liraglutide)
- One year: -0.98 percent (Trulicity), -0.77 percent (liraglutide)

After six months and one year of treatment, Trulicity led to better glycemic control than exenatide QW (mean absolute reduction in A1C in percent)[1]:

- Six months: -1.15 percent (Trulicity), -0.92 percent (exenatide QW)
- One year: -1.00 percent (Trulicity), -0.77 percent (exenatide QW)

After one year, people taking Trulicity were significantly more likely to follow their treatment regimen and less likely to discontinue treatment than with liraglutide or exenatide QW. People taking Trulicity had significantly lower rates of discontinuing treatment than those taking liraglutide or exenatide QW.[2]

Trulicity vs. liraglutide

- Adherence: 51.2 percent (Trulicity), 38.2 percent (liraglutide)
- Persistence: 252.8 days (Trulicity), 218.2 days (liraglutide)
- Patients who discontinued treatment: 45.0 percent (Trulicity), 56.2 percent (liraglutide)

Trulicity vs. exenatide QW

- Adherence: 50.7 percent (Trulicity), 31.9 percent (exenatide QW)
- Persistence: 251.4 days (Trulicity), 192.5 days (exenatide QW)
- Patients who discontinued treatment: 45.1 percent (Trulicity), 65.6 percent (exenatide QW)

"Once-weekly Trulicity is designed to help people with type 2 diabetes achieve their A1C goals with a simple experience that may help ease the transition to an injectable treatment," said Laura Fernández Landó, MD, medical director, Lilly Diabetes. "These real-world results include one year Trulicity follow-up data and show Trulicity may make it easier for people new to GLP-1 RA treatment to stay on therapy."

About the Study

The retrospective real-world observational study used U.S. claims data from the HealthCore Integrated Research Database (HIRD®) between November 2014 and May 2016 to compare the glycemic effectiveness of Trulicity (1.5 mg and 0.75 mg) to liraglutide (1.8 mg and 0.6/1.2 mg) and exenatide QW in people with type 2 diabetes who were new to treatment (six months and one year). For the Trulicity vs. liraglutide comparisons, 41 percent and 59 percent took Trulicity 1.5 mg and 0.75 mg, respectively, and 56 percent and 44 percent took liraglutide 1.8 mg and 1.2 mg, respectively. The study also compared one year adherence and persistence among those treated with Trulicity, liraglutide and exenatide QW. Participants were 18 years or older and matched according to characteristics including baseline A1C, age, gender and location.

Indication and Limitations of Use for Trulicity®
Trulicity is a once-weekly injectable prescription medicine to improve blood sugar (glucose) in adults with type 2 diabetes mellitus. It should be used along with diet and exercise. Trulicity is not recommended as the first medication to treat diabetes. It has not been studied in people who have had inflammation of the pancreas (pancreatitis). Trulicity should not be used by people with type 1 diabetes, people with diabetic ketoacidosis, or people with a history of severe gastrointestinal (GI) disease. It is not a substitute for insulin. It has not been studied in children under 18 years of age.

Important Safety Information for Trulicity®

Tell your healthcare provider if you get a lump or swelling in your neck, have hoarseness, trouble swallowing, or shortness of breath while taking Trulicity. These may be symptoms of thyroid cancer. In studies with rats or mice, Trulicity and medicines that work like Trulicity caused thyroid tumors, including thyroid cancer. It is not known if Trulicity will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Do not take Trulicity if you or any of your family members have ever had MTC or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Do not take Trulicity if you have had an allergic reaction to dulaglutide or any of the other ingredients in Trulicity.

Trulicity should not be used in children under 18 years of age.

Trulicity may cause serious side effects, including:

Inflammation of your pancreas (pancreatitis). If you have pain in your stomach area (abdomen) that is severe and will not go away, stop taking Trulicity and call your healthcare provider right away. The pain may happen with or without vomiting. It may be felt going from your abdomen through to your back.

- **Low blood sugar (hypoglycemia).** If you are using another medicine that can cause low blood sugar (such as insulin or a sulfonylurea) while taking Trulicity, your risk for getting low blood sugar (hypoglycemia) may be higher. Signs and symptoms of low blood sugar may include dizziness, blurred vision, anxiety, irritability, mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery. Talk to your healthcare provider about low blood sugar and how to manage it.
- **Serious allergic reactions.** Stop taking Trulicity and get medical help right away if you have symptoms of a serious allergic reaction including: swelling of your face, lips, tongue or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.
- **Kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration). This may cause kidney problems to get worse.
- **Severe stomach problems.** Trulicity may cause stomach problems, which could be severe.

Tell your healthcare provider if you:

- have or have had problems with your pancreas, kidneys, or liver.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have any other medical conditions.
- are pregnant or plan to become pregnant, or if you become pregnant while taking Trulicity. It is not known if Trulicity will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Trulicity passes into your breast milk. You should not use Trulicity while breastfeeding without first talking to your healthcare provider.
- are taking other medicines including prescription and over-the-counter medicines, vitamins, and herbal supplements. Trulicity may affect the way some medicines work and some medicines may affect the way Trulicity works.
- are taking other medicines to treat diabetes, including insulin or sulfonylureas.

If you take too much Trulicity, call your healthcare provider or go to the nearest emergency room right away.

The most common side effects with Trulicity may include: nausea, diarrhea, vomiting, abdominal pain and decreased appetite. Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of Trulicity. Call your doctor for medical advice about side effects.

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

Please click to access Prescribing Information, including Boxed Warning about possible thyroid tumors including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

DG CON ISI 24AUG2017

About Diabetes
Approximately 30 million Americans[3] and an estimated 425 million adults worldwide have diabetes.[4] Type 2 diabetes is the most common type internationally, accounting for an estimated 90 to 95 percent of all diabetes cases in the United States alone.[3] Diabetes is a chronic disease that occurs when the body does not properly produce or use the hormone insulin.

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, collaboration and quality manufacturing we strive to make life better for people affected by diabetes. We offer a wide range of therapies and a continued determination to provide real solutions—from medicines and technologies to support programs and more. For the latest updates, visithttp://www.lillydiabetes.com/or follow us on Twitter: @LillyDiabetes and Facebook: LillyDiabetesUS.

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 www.lilly.com/newsroom/social-channels.

P-LLY

Trulicity® is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Trulicity as a treatment of type 2 diabetes, along with diet and exercise, and Lilly's current beliefs. 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 study findings to date, that Trulicity will receive additional regulatory approvals or that Trulicity will prove to be commercially successful. 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.

©LillyUSA, LLC 2018. All rights reserved.

References:

1. Mody R, Huang Q, Yu M, et. al. Comparative Glycemic Effectiveness of Dulaglutide vs. Liraglutide and Exenatide QW in a US Real-World Setting. Abstract 1071-P. Presented at 78th American Diabetes Association Scientific Sessions; June 22-26, Orlando, FL.
2. Mody R, Huang Q, Yu M, et. al. Dulaglutide has Higher Adherence and Persistence than Liraglutide and Exenatide QW: 1-year Follow-up from US Real-World Data. Abstract 1264-P. Presented at 78th American Diabetes Association Scientific Sessions; June 22-26, Orlando, FL.
3. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Available at: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. November 2017.
4. International Diabetes Federation. IDF Diabetes Atlas, 8th edn, 2017. Available at: http://www.diabetesatlas.org/. November 2017.

Refer to: Dani Barnhizer: dbarnhizer@lilly.com: 317-607-6119

View original content with multimedia:http://www.prnewswire.com/news-releases/real-world-data-show-advantages-in-people-treated-with-lillys-once-weekly-trulicity-dulaglutide-compared-to-those-treated-with-liraglutide-and-exenatide-qw-300671061.html

SOURCE Eli Lilly and Company