Lilly's AWARD-PEDS trial investigating use of Trulicity® (dulaglutide) in youth and adolescents with type 2 diabetes showed superiority in A1C reduction vs placebo

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AWARD-PEDS results presented at ADA's 82nd Scientific Sessions® and simultaneously published in the New England Journal of Medicine demonstrate A1C reductions of up to 1.5% for Trulicity compared to placebo in this underserved population

INDIANAPOLIS, June 4, 2022 /PRNewswire/ -- In the phase 3 AWARD-PEDS clinical trial from Eli Lilly and Company (NYSE: LLY), Trulicity® (dulaglutide) (at 0.75 mg and 1.5 mg doses) led to superior A1C reductions at 26 weeks versus placebo in youth and adolescents (ages 10 to 17 years old) with type 2 diabetes inadequately controlled with diet and exercise, with or without metformin and/or basal insulin. The study, presented in a poster at the American Diabetes Association's® (ADA) 82nd Scientific Sessions and simultaneously published in the *New England Journal of Medicine*, met all of its primary and secondary glycemic control objectives: percent of patients achieving A1C of <7%, fasting plasma glucose (FPG) change from baseline and mean change in A1C in the individual dose groups. Significant reductions in both A1C and fasting glucose were observed through week 26 compared to placebo. Among patients treated with Trulicity (pooled data), 51.5% reached an A1C of <7% based on treatment regimen estimand.[1]

"The incidence of type 2 diabetes among youth and adolescents is on the rise, particularly among minority populations, and the disease can be even more progressive and difficult to treat than in adults," said Silva Arslanian, M.D., scientific director and principal investigator, UPMC Children's Hospital of Pittsburgh. "Youth and adolescents achieved superior A1C reductions on both doses of Trulicity in AWARD-PEDS compared to participants randomized to the placebo group. These results are especially encouraging as they speak to the potential of Trulicity for this patient population."

The AWARD-PEDS trial (n=154) evaluated the efficacy and safety of once-weekly Trulicity 0.75 mg and 1.5 mg compared to placebo in youth and adolescents with type 2 diabetes inadequately controlled with diet and exercise, with or without metformin and/or basal insulin. Study participants included 55% identifying as Hispanic/Latino and 15% as Black/African American, with a mean age of 14.5 years and a mean body mass index (BMI) of 34.1 kg/m^2. The mean duration of diabetes was 2.0 years, mean A1C was 8.1%, and mean weight was 90.5 kg. The primary objective was to demonstrate superiority of Trulicity (pooled dose groups) versus placebo for change from baseline in A1C at 26 weeks. The study achieved this primary objective, and both doses of Trulicity (0.75 mg and 1.5 mg) achieved superior and statistically significant A1C reductions from baseline compared to placebo and also achieved significant results for key secondary endpoints of glycemic control at 26 weeks. For the efficacy estimand, results showed:[1]

- Adjusted (least squares mean) A1C reduction compared to placebo: -1.0% (p=0.002, Trulicity 0.75 mg), -1.5% (p<0.001, Trulicity 1.5 mg), -1.3% (p<0.001, Trulicity pooled doses). Patients assigned to placebo had an adjusted (least squares mean) A1C increase from baseline of +0.5%.
- Percent of participants achieving A1C <7%: 60.0% (p<0.001, Trulicity 0.75 mg), 53.2% (p<0.001, Trulicity 1.5 mg), 56.5% (p<0.001, Trulicity pooled doses), 18.4% (placebo).
- Adjusted (least squares mean) fasting glucose reduction compared to placebo: -25.9 mg/dL (p=0.021, Trulicity 0.75 mg), -45.1 mg/dL (p<0.001, Trulicity 1.5 mg), -35.5 mg/dL (p<0.001, Trulicity pooled doses). Patients assigned to placebo had an adjusted (least squares mean) fasting glucose increase from baseline of +17.3 mg/dL.
- Rescue therapy administration compared to placebo: 2.9% (Trulicity), 17.6% (placebo).
- Adjusted (least squares mean) change in BMI: -0.2 kg/m^2 (Trulicity 0.75 mg), -0.1 kg/m^2 (Trulicity 1.5 mg), -0.1 kg/m^2 (Trulicity pooled doses), 0.0 kg/m^2 (placebo). Trulicity did not have significant effect versus placebo on BMI through 26 weeks.

The treatment-regimen estimand results showed:

- Adjusted (least squares mean) A1C reduction compared to placebo: -1.2% (p<0.001, Trulicity 0.75 mg), -1.5% (p<0.001, Trulicity 1.5 mg), -1.4% (p<0.001, Trulicity pooled doses). Patients assigned to placebo had an adjusted (least squares mean) A1C increase from baseline of +0.6%.
- Percent of participants achieving A1C <7%: 54.9% (p<0.001, Trulicity 0.75 mg), 48.1% (p<0.001, Trulicity 1.5 mg), 51.5% (p<0.001, Trulicity pooled doses), 13.7% (placebo).
- Adjusted (least squares mean) fasting glucose reduction compared to placebo: -29.9 mg/dL (p=0.005, Trulicity 0.75 mg), -42.0 mg/dL (p<0.001, Trulicity 1.5 mg), -35.9 mg/dL (p<0.001, Trulicity pooled doses). Patients assigned to placebo had an adjusted (least squares mean) fasting glucose increase from baseline of +17.1 mg/dL.

The treatment-regimen estimand included all the data from the intention-to-treat population regardless of antihyperglycemic rescue status.

The overall safety profile of Trulicity in the AWARD-PEDS trial was consistent with its known safety profile in adults with type 2 diabetes. Gastrointestinal side effects, including nausea, vomiting and diarrhea, were among the most commonly reported adverse events and comparable to that observed in adults.[1] For those treated with Trulicity (0.75 mg and 1.5 mg pooled data), gastrointestinal side effects occurred more frequently compared to placebo and included diarrhea (18.4% vs 13.7%), nausea (14.6% vs 7.8%) and vomiting (15.5% vs 3.9%) over the 26-week period.

Adverse events leading to treatment discontinuation through week 26 for Trulicity groups were 2.9% vs 0% in placebo group. No statistically significant differences in the incidence of hypoglycemia were observed between dulaglutide and placebo groups for any hypoglycemia category.

"Type 2 diabetes in youth is challenging to manage, with few approved treatment options," said Mike Mason, president, Lilly Diabetes. "In the U.S., minority populations have among the highest prevalence of youth-onset type 2 diabetes in the world and, given this, we made an intentional effort to recruit and enroll populations commonly under-represented in clinical trials. The unmet need for effective yet convenient treatments for youth with type 2 diabetes is substantial and we look forward to sharing these results with regulatory authorities as we pursue a potential new indication for Trulicity."

About the AWARD-PEDS Clinical Trial
AWARD-PEDS was a randomized, placebo-controlled trial comparing the efficacy and safety of once-weekly Trulicity 0.75 mg and 1.5 mg to placebo in youth and adolescents (ages 10 to 17 years old) with type 2 diabetes inadequately controlled with diet and exercise, with or without metformin and/or basal insulin. The trial randomized 154 participants to receive either Trulicity 0.75 mg, 1.5 mg or placebo. The primary objective was to demonstrate that Trulicity (pooled 0.75 mg and 1.5 mg dose groups) is superior to placebo in A1C reduction from baseline to 26 weeks. The treatment regimen estimand included the intention-to-treat population regardless of rescue status or treatment adherence. The efficacy estimand included data from the intention-to-treat population up to the point that rescue therapy was initiated. Key secondary efficacy measures also assessed at 26 weeks were the percentage of participants achieving A1C <7% from baseline, change in fasting blood glucose, and change in BMI. The proportion of patients needing rescue therapy for hyperglycemia was also assessed.

PURPOSE AND SAFETY SUMMARY WITH WARNINGS

Important Facts About Trulicity® (Trū-li-si-tee). It is also known as dulaglutide.

- Trulicity is a prescription medicine for adults with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors.
- It is not known if TRULICITY can be used in people who have had inflammation of the pancreas (pancreatitis). TRULICITY is not for use in people with type 1 diabetes and is not recommended for use in people with severe stomach or intestinal problems. It is not known if TRULICITY is safe and effective for use in children. TRULICITY should not be used in children under 18 years of age.
- Trulicity is given through an injection (needle). You take it once a week by injecting it under the skin of your stomach, thigh, or upper arm.

Warnings
Trulicity may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, trouble swallowing, hoarseness, or shortness of breath. If you have a symptom, tell your doctor.

- Do not use Trulicity if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Trulicity if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Trulicity if you are allergic to dulaglutide or other ingredients in Trulicity.

Ask your doctor how to recognize the serious side effects below and what to do if you think you have one:
Inflamed pancreas (pancreatitis). Stop using Trulicity and call your healthcare provider right away if you have severe pain in your stomach area (abdomen), with or without vomiting, that will not go away. You may feel the pain from your abdomen to your back.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use TRULICITY with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin.

Signs and symptoms of low blood sugar may include dizziness or light-headedness, confusion or drowsiness, headache, blurred vision, slurred speech, fast heartbeat, sweating, hunger, shakiness, feeling jittery, weakness, anxiety, irritability, or mood changes.

Serious allergic reactions. Stop using Trulicity and get medical help right away if you have any symptoms of a serious allergic reaction which may include swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting, or feeling dizzy, or very rapid heartbeat.

Acute kidney injury. 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.

Changes in vision. Tell your healthcare provider if you have changes in your eyesight (vision) during treatment with Trulicity.

Common side effects
The most common side effects of Trulicity include nausea, diarrhea, vomiting, abdominal pain and decreased appetite, indigestion, and fatigue.

These are not all the possible side effects of Trulicity.

Tell your doctor if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before using

- **Your healthcare provider should show you how to use Trulicity before you use it for the first time.**
- **Before you use Trulicity, talk to your doctor about low blood sugar and how to manage it.**

Review these questions with your doctor:

- Do you have other medical conditions, including problems with your pancreas, kidneys, liver, or stomach, or have a history of diabetic retinopathy (vision problems related to diabetes)?
- Do you take other diabetes medicines, such as insulin or sulfonylureas?
- Are you pregnant or plan to become pregnant or breastfeeding or plan to breastfeed?
- Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbs?

How to take

- Read the Instructions for Use that come with Trulicity.
- Use Trulicity exactly as your doctor says.
- Do not share your Trulicity pen, syringe, or needles with another person.
- Do not give Trulicity to other people.
- If you take too much Trulicity, call your healthcare provider or seek medical advice promptly.

Learn more
For more information, call 1-844-TRU-INFO (1-844-878-4636).

This summary provides basic information about Trulicity but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Trulicity and how to take it. Your doctor is the best person to help you decide if Trulicity is right for you.

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About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. P-LLY

Cautionary Statement Regarding Forward-Looking Statements
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 for people with type 2 diabetes and other conditions and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that Trulicity will receive additional regulatory approvals, or that Trulicity will be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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.

[1] Arslanian SA, et al. Dulaglutide in Youth with Type 2 Diabetes (T2D): Results of the AWARD-PEDS Randomized, Placebo-Controlled Trial. Abstract 5-LB. Presented at the American Diabetes Association's® (ADA) 82nd Scientific Sessions®; June 3–7, 2022.

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