FDA approves additional doses of Trulicity® (dulaglutide) for the treatment of type 2 diabetes

September 3, 2020

AWARD-11 showed 3.0 mg and 4.5 mg doses led to additional blood sugar control; as a secondary endpoint, both doses also led to weight loss

INDIANAPOLIS, Sept. 3, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) today approved two additional doses of Eli Lilly and Company's (NYSE: LLY) Trulicity® (dulaglutide). The approval expands the label of once-weekly Trulicity to include 3.0 mg and 4.5 mg doses based on data from AWARD-11. The phase 3 trial showed the additional doses led to further benefits in A1C and body weight reduction when compared to Trulicity 1.5 mg in people with type 2 diabetes.

"The FDA's decision to approve the additional doses of Trulicity is a positive step forward for people living with type 2 diabetes and their care teams," said Juan Pablo Frias, M.D., Medical Director and Principal Investigator, National Research Institute. "This progressive condition can require different treatment approaches over time, and findings from AWARD-11 showed the additional doses of Trulicity can lead to further A1C and weight reductions for people with type 2 diabetes whose current treatment may no longer be meeting their needs."

The AWARD-11 trial evaluated the safety and efficacy of additional doses of Trulicity (3.0 mg and 4.5 mg) compared to Trulicity 1.5 mg, using two different statistical approaches[i]. The efficacy estimand, which analyzes participants who remained on treatment throughout the trial, showed both doses led to significant reductions in A1C and weight:

- **4.5 mg** (A1C: -1.9 percent, weight: -10.4 pounds)
- **3.0 mg** (A1C: -1.7 percent; weight: -8.8 pounds)
- **1.5 mg** (A1C: -1.5 percent; weight: -6.8 pounds)

"People find the Trulicity pen simple and easy-to-use," said Leonard Glass, M.D., F.A.C.E, vice president of Medical Affairs, Lilly. "Now, with the 3.0 and 4.5 doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their condition progresses."

The additional doses of Trulicity will be available in United States pharmacies in late September.

Results from AWARD-11 are also under review by the European Medicines Agency's Committee for Medicinal Products for Human Use, with an opinion on whether to recommend approval by the European Commission expected this year.

About the AWARD-11 Study

The phase 3, randomized, double-blind, parallel arm study included 1,842 participants with type 2 diabetes and evaluated the efficacy and safety of two investigational doses of dulaglutide (3.0 mg and 4.5 mg) compared to Trulicity 1.5 mg. The primary objective of the study was to demonstrate that a once-weekly investigational dulaglutide dose (3.0 mg and/or 4.5 mg) was superior to the approved Trulicity 1.5 mg dose, as measured by A1C reduction from baseline, at 36 weeks in people with inadequately controlled type 2 diabetes on concomitant metformin therapy. The primary and secondary objectives could be met if one or both doses achieved statistical significance for the endpoints. Secondary and exploratory outcomes included change from baseline in mean body weight and fasting serum glucose (FSG), percentage of patients reaching an A1C goal of less than seven percent and occurrence of hypoglycemic episodes and pharmacokinetics at steady-state through 36 and 52 weeks. All participants started the study at a dose of Trulicity 0.75 mg once-weekly and then increased the dose in a step-wise approach at four week intervals to their final randomized maintenance dose of once-weekly 1.5 mg, 3.0 mg (via a 1.5 mg step) or 4.5 mg (via steps at 1.5 mg and 3.0 mg).

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 to improve blood sugar (glucose) and used 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.

- 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. Use Trulicity together with the diet and exercise that your doctor recommends.

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.

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

Low blood sugar (hypoglycemia). 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.

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?
- Do you take any other prescription medicines or over-the-counter drugs, vitamins or herbs?

Review the list below with your doctor. Trulicity may not be right for you if:

- You are pregnant or plan to become pregnant or breastfeeding or plan to breastfeed.
- You have type 1 diabetes.
- You have or have had an inflamed pancreas (pancreatitis).
- You have severe intestinal or stomach problems, such as slowed emptying or problems with digesting food.
- You are a child under 18 years old.

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) or go to **www.TRULICITY.com.**

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.

Please see full Prescribing Information, including Boxed Warning about possible thyroid tumors including thyroid cancer, and Medication Guide.

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About Diabetes

Approximately 34 million Americans[1] (just over 1 in 10) and an estimated 463 million adults worldwide[2] have diabetes. 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[1]. 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 and related conditions. We work to deliver breakthrough outcomes through innovative 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 lilly.com and lilly.com/newsroom. P-LLY

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about dulaglutide 3.0 mg and/or 4.5 mg as a potential treatment for people with type 2 diabetes 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 dulaglutide 3 mg and/or 4.5 mg 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.

[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services; 2020.

[2] International Diabetes Federation. IDF Diabetes Atlas, 9th edn. Brussels, Belgium: International Diabetes Federation, 2019. Available at: http://diabetesatlas.org.

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[i] The efficacy estimand was used to evaluate results in participants who stayed on treatment and did not start another diabetes medicine throughout the trial. The treatment-regimen estimand, conducted based on regulatory guidance, includes data from all participants through the end of the trial, which may include confounding effects of rescue medication or discontinuation from the study drug or the trial. In the treatment-regimen estimand, which was conducted based on regulatory guidance, each dose led to clinically meaningful A1C and body weight reductions but only the 4.5 mg dose showed superiority compared to Trulicity 1.5 mg.

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