Lilly and Dexcom team up on new program to help improve diabetes management

October 7, 2020

Companies will partner to promote Lyumjev, Lilly's new rapid-acting insulin, with Dexcom G6 Continuous Glucose Monitoring (CGM), highlighting the benefits of using each

INDIANAPOLIS and SAN DIEGO, Oct. 7, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and DexCom, Inc. (NASDAQ: DXCM) announced today a joint program for U.S. healthcare providers (HCPs) about Lilly's new rapid-acting mealtime insulin Lyumjev ™ (insulin lispro-aabc injection, 100 units/mL and 200 units/mL), now available in U.S. pharmacies, and Dexcom G6 CGM Systems. The program is designed to help clinicians use data to inform diabetes management, including giving visibility to the benefits of a new mealtime insulin.

HCPs treating type 1 and type 2 diabetes will be able to assess their patients' glucose levels and time in range with Dexcom G6 or Dexcom G6 Pro, either in blinded or unblinded mode, helping them quickly identify adult patients who struggle to manage their postprandial glucose (PPG) levels (glucose levels following meals) and who may benefit from a treatment like Lyumjev. As PPG is often overlooked as a significant contributor to A1C,[1] this partnership also aims to elevate PPG monitoring as an important component of diabetes treatment management.

"When it comes to treating diabetes, our partnership with Dexcom has the potential to be meaningful for HCPs who want to help their patients who may be struggling to manage their blood glucose levels after meals," said Adrienne Brown, vice president, U.S. Diabetes and Connected Care, Lilly. "Through this program, we can inspire confidence as clinicians and their patients evaluate new treatment options by showcasing how using these resources together can inform diabetes care."

Lilly and Dexcom will enhance HCP education by jointly sharing information about Lyumjev and the Dexcom G6 and G6 Pro through a variety of channels.

"We are thrilled to partner once again with a leader in diabetes care like Lilly," said Rick Doubleday, chief commercial officer at Dexcom. "Our goal is that the real-time data provided through Dexcom G6 and Dexcom G6 Pro will allow healthcare providers to help their patients with diabetes make more informed decisions, measure and evaluate their time in range, and have more visibility to the potential benefits of transitioning to a new mealtime insulin such as Lyumjev."

Those interested in learning more about Dexcom CGM or getting started on the Dexcom G6 should visit Dexcom.com. The Dexcom G6 is covered by 98 percent of private insurance in the U.S., by Medicare and by Medicaid in many states across the country. Dexcom also recently launched a patient assistance program available to current U.S. customers who lost their health insurance coverage due to the impacts of COVID-19.

Lyumjev is a novel formulation of insulin lispro, developed to speed the absorption of insulin into the bloodstream and reduce A1C levels in adults with diabetes. In clinical studies, Lyumjev provided superior reduction in blood sugar spikes compared with Humalog® (insulin lispro injection) when blood sugar was measured 1 and 2 hours after a meal. Lyumjev was approved by the FDA on June 15, 2020. HCPs can now prescribe Lyumjev, which is available for pharmacies nationwide to order. People who have commercial insurance can visit www.Lyumjev.com to access the Lyumjev Savings Card. For people without insurance coverage, Lyumjev is also included in the Lilly Insulin Value Program for $35 by calling the Lilly Diabetes Solution Center at (833) 808-1234. Operators at the Solution Center are available Monday through Friday from 8 a.m. to 8 p.m. (ET). Lilly is in discussions with insurance providers to make the new rapid-acting insulin available to as many people as possible.

People with diabetes and their HCPs who have questions about Lyumjev can visit www.Lyumjev.com or call The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979), Monday through Friday from 9 a.m. to 8 p.m. ET.

Terms, conditions, and limitations apply to Lilly savings cards and the Dexcom patient assistance program. See the companies' respective websites for additional details. The Lilly savings card is not available to those patients with government insurance such as Medicaid, Medicare, Medicare Part D, TRICARE®/CHAMPUS, Medigap, DoD, or any State Patient or Pharmaceutical Assistance Program. TRICARE® is a registered trademark of the Department of Defense (DoD), DHA.

PURPOSE and SAFETY SUMMARY

Important Facts About LYUMJEV™ (LOOM-jehv) and Humalog® (HU-ma-log)

- Lyumjev is also known as insulin lispro-aabc injection. Humalog is also known as insulin lispro injection.
- Lyumjev is a fast-acting insulin. Lyumjev is used to control high blood sugar in adults with diabetes. Humalog is a fast-acting insulin. Humalog is used to control high blood sugar in adults and children with diabetes. Lyumjev and Humalog are available only with a prescription.
- Lyumjev comes in two strengths: U-100 (100 units per milliliter) and U-200 (200 units per milliliter). The Lyumjev U-200 prefilled pen contains **2 times as much insulin** per 1 milliliter as standard (U-100) insulin. Humalog U-100 contains 100 units of insulin per milliliter. The dose window of the pen shows the number of insulin units to be delivered.
- It is not known if Lyumjev is safe and effective for children. It is not known if Humalog is safe and effective for children with type 2 diabetes or for children younger than 3 years of age with type 1 diabetes as there were no studies done with Humalog in these groups of children. If your doctor decides to give your child any insulin products, he or she may give you special instructions.

All Lyumjev and Humalog products contain insulin lispro.

Warnings

Do not take Lyumjev or Humalog if you have:

- symptoms of low blood sugar (hypoglycemia)
- an allergy to Lyumjev or Humalog or any of their ingredients.

Do not reuse needles or share your insulin injection supplies with other people. This includes your:

- prefilled pen for use by a single patient
- cartridges
- reusable pen that works with Lilly 3mL cartridges available for Humalog
- needles
- syringes

You or the other person can get a serious infection. This can happen even if you change the needle.

Do not change the type of insulin you take or your dose, unless your doctor tells you to. This could cause low or high blood sugar, which could be serious.

Do not use a syringe to remove Lyumjev or Humalog from your prefilled pen. This can cause you to take too much insulin. Taking too much insulin can lead to severe low blood sugar. This may result in seizures or death.

Lyumjev and Humalog may cause serious side effects. Some of these can lead to death. The possible serious side effects are:

- **Low blood sugar.** This can cause:

- dizziness or lightheadedness
- headache
- shakiness
- irritability
- sweating
- blurred vision
- fast heartbeat
- mood change
- confusion
- slurred speech
- anxiety
- hunger

If you are at risk of having severely low blood sugar, your doctor may prescribe a glucagon emergency kit. These are used when your blood sugar becomes too low and you are unable to take sugar by mouth. Glucagon helps your body release sugar into your bloodstream.

- **Severe allergic reaction.**
  Get emergency help right away if you have:

- a rash over your whole body
- sweating
- extreme drowsiness
- swelling of your face, tongue, or throat
- trouble breathing
- a faint feeling
- dizziness
- a fast heartbeat
- shortness of breath
- confusion

- **Low potassium in your blood.** This can lead to severe breathing problems, irregular heartbeat, and death.
- **Heart failure.** Taking diabetes pills called thiazolidinediones (thIE-uh-zOH-li-dEEn-dIE-OHns), or "TZDs," with Lyumjev or Humalog may cause heart failure in some people. This includes people who do not have any heart problems. If you have heart failure, it may get worse if you take TZDs with Lyumjev or Humalog. Tell your doctor if you have any new symptoms of heart failure, or if they get worse. Some symptoms of heart failure include: shortness of breath, swelling of ankles and feet, and sudden weight gain. Your doctor may need to change or stop treatment with TZDs and your insulin lispro product.
- **High blood sugar and ketoacidosis for Humalog insulin pump users.** You can have these serious problems when your insulin pump or infusion set stops working. They can also happen if your insulin is no longer effective. For these reasons, always keep extra insulin injection supplies with you.

Common side effects

The most common side effects of **Lyumjev and Humalog** are:

- low blood sugar
- reactions where you have injected insulin
- itching
- weight gain
- allergic reactions
- skin thickening or pits at the injection site
- rash

Other most common side effects with Humalog include swelling of your hands or feet.

These are not all of the possible side effects. 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

Talk with your doctor about low blood sugar and how to manage it. Also tell your doctor:

- about all of the medicines you take, including over-the-counter medicines, vitamins, and herbal supplements.
- about any other prescription medicines you take, especially ones called TZDs.
- about all of your medical conditions, including if you have heart failure or other heart, liver, or kidney problems.
- if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed.

How to take

Read the **Instructions for Use** that come with your **Lyumjev or Humalog**. Be sure to take your **Lyumjev or Humalog** and **check your blood sugar levels** exactly as your doctor tells you to. Your doctor may tell you to change your dose because of illness, increased stress, or changes in your weight, diet, or physical activity level. He or she may also tell you to change the amount or time of your dose because of other medicines or different types of insulin you take.

Before injecting your Lyumjev or Humalog

You can inject your insulin dose yourself, or you can have a trained caregiver inject it for you. Make sure you or your caregiver:

- Check the insulin label before each injection. This will help you make sure that you are taking the correct insulin.
- Use a new needle for each injection. You can get a serious infection or the wrong dose of insulin if you re-use needles.
- Change (rotate) where you inject your insulin with each dose. This can reduce your chance of getting pits, lumps, or thickened skin where you inject your insulin. **Do not** inject your insulin into the exact same spot or where the skin has pits or lumps. **Avoid** injecting into thickened, tender, bruised, scaly, hard, scarred, or damaged skin.

When you are ready to inject

- Inject Lyumjev under your skin at the beginning of a meal or within 20 minutes after you start eating a meal.
- Inject Humalog under your skin within 15 minutes before or right after you eat a meal.

Staying safe while taking your Lyumjev or Humalog

To stay safe while taking your insulin, be sure to **never** inject Lyumjev U-200 in your vein, muscle, or with an insulin pump. Also be sure **not to**:

- mix Lyumjev with other insulins
- drive or use heavy machinery until you know how your Lyumjev or Humalog affects you.
- drink alcohol or use other medicines that contain alcohol when taking your Lyumjev or Humalog.

Learn more

For more information, call 1-800-545-5979 or go to www.Lyumjev.com or www.humalog.com

This summary provides basic information about Lyumjev and Humalog. It does not include all information known about these medicines. 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 health care provider about your insulin lispro product and how to take it. Your doctor is the best person to help you decide if these medicines are right for you.

Please see Lyumjev Full Prescribing Information including Patient Prescribing Information

Please see Humalog Full Prescribing Information including Patient Prescribing Information

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

UR HI CON BS 15JUN2020

About Diabetes

Approximately 34 million Americans[2] (just over 1 in 10) and an estimated 463 million adults worldwide[3] 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 Dexcom CGM

The Dexcom G6 provides data-driven insights that are designed to allow people with diabetes to improve their insulin therapy and condition management. Dexcom G6 capabilities include continuous glucose readings, the elimination of routine fingersticks,* proactive and predictive alerts and alarms, remote glucose monitoring† and more. The G6 Pro is also the first and only single use, professional CGM available in blinded and unblinded mode that allows healthcare providers to view data about a patient's glucose patterns over a single 10-day period. Through Dexcom CLARITY – a diabetes management application offered for both patients and physicians – HCPs can access data remotely, regardless of whether their patients are using the personal or professional version of G6.

About DexCom Inc.

DexCom, Inc. empowers people to take control of diabetes through innovative continuous glucose monitoring (CGM) products. Headquartered in San

Diego, California, Dexcom has emerged as a leader of diabetes care technology. By listening to the needs of patients, caregivers, and clinicians, Dexcom simplifies and improves diabetes management around the world.

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 health care leader that unites caring with discovery to create medicines that 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

*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.

†Separate Follow app required.

© 2020 Dexcom, Inc. Dexcom, Dexcom G6 and Dexcom Follow are registered trademarks of Dexcom, Inc. in the U.S., and may be registered in other countries. All rights reserved.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Lyumjev™ (insulin lispro-aabc injection) as a treatment to improve glycemic control in adults with type 1 and type 2 diabetes, and a joint program between Eli Lilly and Company and DexCom, Inc. designed to help U.S. healthcare providers use data to inform diabetes management and reflects Lilly's current beliefs. However, as with any pharmaceutical product or medical device, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there is no guarantee that Lyumjev will be commercially successful or 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.

PP-UR-US-0211 10/2020 ©Lilly USA, LLC 2020. All rights reserved.

References

1. Hershon, K., Hirsh, B., and Odugbesan, O. Importance of Postprandial Glucose in Relation to A1C and Cardiovascular Disease. *Clinical Diabetes*. 2019; 37 (3): 250-269. Available at: https://clinical.diabetesjournals.org/content/37/3/250.article-info
2. 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.
3. International Diabetes Federation. IDF Diabetes Atlas, 9th edn. Brussels, Belgium: International Diabetes Federation, 2019. Available at: http://diabetesatlas.org.

Refer to:Maggie Pfeiffer; monson_maggie@lilly.com; +1 (317) 650-5939 (Lilly Media)
Kevin Hern; hern_kevin_r@lilly.com; +1 (317) 277-1838 (Lilly Investors)
James McIntosh; james.mcintosh@dexcom.com; +1 (619) 884-2118 (Dexcom Media)
Steve Pacelli; spacelli@dexcom.com; +1 (858) 200-0255 (Dexcom Investors)

View original content to download multimedia:http://www.prnewswire.com/news-releases/lilly-and-dexcom-team-up-on-new-program-to-help-improve-diabetes-management-301147221.html

SOURCE Eli Lilly and Company