Lilly to begin rollout of Tempo® Personalized Diabetes Management Platform

November 7, 2022

- *Centralized experience supports diabetes self-management through medication reminders, education resources and insulin dose logging*
- *Data shared through platform interface may help healthcare providers make data-driven decisions[±] about care for adults treated with select Lilly insulins*
- *Offers compatibility with the Dexcom® Continuous Glucose Monitoring Systems, [*,∞] the Tempo Blood Glucose Monitor (BGM) and other compatible BGMs, as well as wearable devices from Fitbit®, Garmin®, Google Fit® and the Apple Health app*

INDIANAPOLIS, Nov. 7, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will begin rollout of its first connected platform, the Tempo® Personalized Diabetes Management Platform, later this year in the U.S. The technology aims to help adults living with type 1 or type 2 diabetes and clinicians make informed, data-backed decisions to manage treatment with Lilly insulins.[±]

The platform consists of three key components – the Tempo Smart Button®; a compatible app, TempoSmart™; and a prefilled insulin pen, Tempo Pen® – which work together to deliver personalized guidance for adults with diabetes. The Smart Button was cleared by the U.S. Food and Drug Administration on September 16. The compatible app was developed in partnership with Welldoc® and is a private label iteration of the company's BlueStar®, a diabetes management app, customized to receive insulin dose-related data from the Tempo Smart Button.

Healthcare providers will have access to a clinician hub, Tempo Insights™, where they can access data shared by their patients through the app and track patients' progress.

"Lilly has over a century of knowledge of insulin and its complexities, and recognizes the emotional impact of managing diabetes[1,2]," said Kevin Cammack, Head of Connected Care, Lilly Diabetes. "Launching this platform is an opportunity for us to more broadly support those who rely on our insulins."

Here's how the platform works: The Tempo Smart Button is a reusable medical device that attaches to the top of a Tempo Pen — Lilly's prefilled, disposable insulin pens approved in 2019 and 2020. When paired via Bluetooth® wireless technology, the Smart Button is intended to detect, store and transfer insulin dose-related data to the compatible app. The app, TempoSmart, will record insulin dose information and facilitate data sharing between adults with diabetes and the healthcare providers who treat them.

Adults with diabetes can access insulin dose information and advanced features through TempoSmart, including:

- Medication reminders, personalized education resources and feedback on blood glucose levels.
- Integration with Dexcom Continuous Glucose Monitoring (CGM) Systems[∞] via secondary display,[*] as well as the Tempo Blood Glucose Monitor (BGM) and other compatible BGMs.
- Compatibility to sync data with wearable devices from Fitbit®, Garmin®, Google Fit® and the Apple Health app.

"Despite technological advancements, people continue to experience challenges with the complexities of insulin dosing,[3]" said Cammack. "Using the learnings from early adopters of Tempo, we look forward to continually innovating our technology to aid those who use Lilly insulins to manage their diabetes."

Lilly will conduct a phased rollout for the platform to select clinics starting later this year, followed by national availability targeted for 2023. The Tempo Pen is currently available for Lyumjev® (insulin lispro-aabc) injection, 100 units/mL, BASAGLAR® (insulin glargine) injection, 100 units/mL, and Humalog® (insulin lispro injection) 100 units/mL. Lilly continues to work with Welldoc to integrate additional features for TempoSmart in future software updates.

Outside of the U.S., Lilly received CE (Conformité Européenne or European Conformity) marking certification for the Tempo Smart Button on August 10 and plans to begin small-scale pilots in selected countries through partnerships with existing diabetes management ecosystems.

Lilly is committed to helping people access the medicines they need and will work with insurers, health systems and providers to help enable patient access to the Tempo Personalized Diabetes Management Platform. Lilly will be offering a savings card for the platform for people who qualify. For more information, connect with our Tempo Customer Support Service by calling 1-855-Lilly-Tempo. Text TEMPO to 85099 for alerts and updates on the Tempo platform.

[±] ***Warning:*** *The Tempo Personalized Diabetes Management Platform is intended to help support the management of your diabetes. You must continue to independently manage your blood glucose values and your prescribed regimen with support from your healthcare practitioner.*

**Secondary display is available with 3-hour delay in the TempoSmart App.*

[∞] ***Warning:*** *Do not make dosing decisions based on CGM data from the TempoSmart App. Follow instructions on your CGM system.*

Tempo Smart Button Intended Use
The Smart Button is intended to detect, store, and transfer insulin dose-related data from a Tempo Pen to a compatible application (App). The Smart Button is indicated for single-patient use by patients 18 years or older who are diagnosed with type 1 or type 2 diabetes mellitus, using prefilled insulin Tempo Pens, and using a compatible App.

Important Safety Information for Tempo Personalized Diabetes Management Platform
DO NOT start over, skip, or repeat your injection when using the Tempo Personalized Diabetes Management Platform if you are not sure you took your insulin or if you are not sure your insulin dosing information is correct. Instead, monitor your blood glucose and consult your Healthcare Provider. Call 911 if you are experiencing a medical emergency. Ensure you work with your Healthcare Provider on a backup diabetes management plan if your Tempo Smart Button or TempoSmart App stops working. Having a backup plan and supplies can help avoid severe low and high glucose. Keep the Tempo Smart Button away from children. For product and safety information, including Warnings and Cautions, read the Tempo Smart Button Instructions for Use, TempoSmart App User Guides and Tempo Welcome Kit and Tempo Refill Kit Instructions.

INDICATION AND SAFETY SUMMARY
Lyumjev® (LOOM-jehv) and Humalog® (HU-ma-log)

- Lyumjev is a fast-acting insulin used to control high blood sugar in adults and children with diabetes. Humalog is a fast-acting insulin. Humalog is used to control high blood sugar in adults and children with diabetes.
- Lyumjev comes in two strengths: U-100 (100 units per milliliter) and U-200 (200 units per milliliter). Lyumjev U-200 contains **2 times as much insulin** in 1 milliliter as Lyumjev U-100. 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 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 insulin lispro-aabc, Humalog, or any of the ingredients in Lyumjev or Humalog.

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	• sweating	• confusion
• headache	• blurred vision	• slurred speech
• shakiness	• fast heartbeat	• anxiety
• irritability	• mood change	• 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.

- **Low potassium in your blood.** This can lead to severe breathing problems, irregular heartbeat, and death.
- **Severe allergic reaction.**
  Get emergency help right away if you have:

• a rash over your whole body	• trouble breathing	• a fast heartbeat
• sweating	• a faint feeling	• shortness of breath
• extreme drowsiness	• dizziness	• confusion

• swelling of your face, tongue, or throat

- **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.

- **Sudden onset of high blood sugar and high amounts of ketones in your blood or urine.** You can have these serious side effects when your insulin pump or infusion set is not working the right way, if there are handling errors, or if your insulin is no longer effective. For these reasons, you may not get the right amount of insulin, so always keep extra insulin and injection supplies with you.

Common side effects

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

• low blood sugar
• reactions or pain at the injection or infusion site with insulin pump use
• itching
• weight gain
• allergic reactions
• skin thickening or pits at the injection or infusion 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 reuse 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.
- Monitor injection and infusion sites closely when initiating therapy with Lyumjev in children. Contact a healthcare provider if persistent injection or infusion site reactions occur.

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 or liquids
- 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

Lyumjev and Humalog are prescription medicines. 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 healthcare 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.

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Please see Lyumjev Full Prescribing Information including Patient Prescribing Information
Please see Humalog Full Prescribing Information including Patient Prescribing Information

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INDICATION AND SAFETY SUMMARY

BASAGLAR® (bāz-a-glar) is a long-acting insulin used to control high blood sugar in:

- adults with type 1 or type 2 diabetes
- children with type 1 diabetes

It is not known if BASAGLAR is safe and effective in children with type 2 diabetes or in children younger than 6 years with type 1 diabetes. There were no studies done with BASAGLAR in these groups of children. If your doctor decides to give your child BASAGLAR, he or she may give you special instructions.

BASAGLAR is not used to treat diabetic ketoacidosis.

Warnings - Do not take BASAGLAR if you have:

- symptoms of low blood sugar (hypoglycemia)
- an allergy to BASAGLAR or any of its ingredients

Do not reuse needles or share your BASAGLAR prefilled pen with other people. You or the other person can get a serious infection. This can happen even if you change the needle.

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

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

- **Low blood sugar.** This can lead to:

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

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

• a rash over your whole body	• trouble breathing	• a fast heartbeat
• swelling of your face, tongue, or throat	• sweating	• shortness of breath
• extreme drowsiness, dizziness, or 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/ (TZDs) with BASAGLAR 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 BASAGLAR. Tell your doctor if you have any new symptoms of heart failure, or if they get worse. These are: shortness of breath, swelling of the ankles or feet, and sudden weight gain. Your doctor may need to change or stop treatment with TZDs and BASAGLAR.

Common side effects

The most common side effects of BASAGLAR are:

• low blood sugar	• allergic reactions
• minor reactions where you have injected BASAGLAR	• changes in fat tissue where you have injected BASAGLAR
• itching	• rash
• swelling	• weight gain

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. 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 have heart failure, it may get worse while you take TZDs with BASAGLAR.
❑ if you are pregnant, breastfeeding, or plan to become pregnant. It is not known if BASAGLAR may harm your unborn or breastfeeding baby.

How to take

The BASAGLAR prefilled pen is a disposable insulin delivery device for use by a single patient to inject BASAGLAR. Read the **Instructions for Use** that come with your BASAGLAR prefilled pen. These instructions provide details on how to prepare and inject a dose of BASAGLAR, and how to throw away used BASAGLAR prefilled pens and needles.

Be sure to **check your blood sugar levels** and use BASAGLAR 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 level of physical activity or exercise. He or she may also tell you to change your dose because of other medicines you take.

Before injecting your BASAGLAR
You can inject BASAGLAR yourself, or you can have a trained caregiver inject it for you. Make sure you or your caregiver:

- Check your insulin label each time you give your injection. This will help you make sure that you are using 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.

When you are ready to inject

- Take BASAGLAR once a day, at the same time each day.
- Change (rotate) where you inject your insulin with each dose. This can help 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.

Staying safe while taking your BASAGLAR
To stay safe while taking BASAGLAR, be sure you **only** use BASAGLAR that is clear and colorless and does not have any particles.

Be sure you **do not:**

- mix BASAGLAR with any other type of insulin or solution.
- drive or use heavy machinery until you know how BASAGLAR affects you.
- drink alcohol or use other medicines that contain alcohol when taking BASAGLAR.

Learn more
BASAGLAR is a prescription medicine. For more information, call 1-800-545-5979 or go to **BASAGLAR.com**.

This summary provides basic information about BASAGLAR 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 health care provider about BASAGLAR and how to take it. Your doctor is the best person to help you decide if BASAGLAR is right for you.

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Please see BASAGLAR Full Prescribing Information including Patient Prescribing Information

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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

About Welldoc

Welldoc® is revolutionizing chronic disease management to help transform lives. BlueStar®, an FDA-cleared digital health solution, guides individuals through the complicated journey of living with diabetes by enabling them to self-manage their conditions and enhancing connections to their healthcare

team. Welldoc streamlines the relationships between payers, employers and healthcare systems resources, with the goal of improving population health and reducing the costs of chronic diseases. For more information on Welldoc, including BlueStar indications of use, visit www.welldoc.com. TempoSmart does not include the prescription features of BlueStar Rx. For full labeling information, visit www.welldoc.com.

Lilly 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 Lilly and Welldoc's collaboration and licensing agreement, including commercialization strategies, and reflects Lilly's current beliefs and expectations. However, as with any such undertaking, there are substantial risks and uncertainties in the process of commercializing pharmaceutical products and medical devices. Among other things, there is no guarantee that Lilly will realize the expected benefits from the collaboration and license agreement, that Lilly's connected insulin solutions will be commercially successful, that Lilly will meet the anticipated timelines described in this release, or that Lilly will execute its strategy as expected. 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.

References

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