

Lilly to Introduce Lower-Priced Insulin

March 4, 2019

Authorized generic version of Humalog will be available in U.S. pharmacies at 50 percent lower list price

INDIANAPOLIS, March 4, 2019 /PRNewswire/ -- Reinforcing our commitment to lower out-of-pocket costs for people who need insulin, Eli Lilly and Company (NYSE: LLY) today announced we will introduce a lower-priced version of Humalog[®] (insulin lispro injection 100 units/mL) in the United States -- providing people with diabetes an insulin option that will have a list price 50 percent lower than the current Humalog list price.

"We've engaged in discussions about the price of insulin with many different stakeholders in America's health care system: people living with diabetes, caregivers, advocacy groups, health care professionals, payers, wholesalers, lawmakers, and leading health care scholars," said David A. Ricks, Lilly's chairman and chief executive officer. "Solutions that lower the cost of insulin at the pharmacy have been introduced in recent months, but more people need help. We're eager to bring forward a low-priced rapid-acting insulin.

"The significant rebates we pay on insulins do not directly benefit all patients. This needs to change," Ricks said. "There are numerous ideas, including the rebate reform proposal from HHS. For people with diabetes, a lower-priced insulin can serve as a bridge that addresses gaps in the system until a more sustainable model is achieved."

The lower-priced version will be called Insulin Lispro—the same molecule as Humalog—and will be available in vial and pen options. The list price of a single vial will be \$137.35. The list price of a five-pack of KwikPens will be \$265.20. Vials and pens of the lower-priced insulin have been manufactured, and Lilly will now work with supply chain partners to make them available in pharmacies as quickly as possible. It will be made available as an authorized generic through a Lilly subsidiary, ImClone Systems. Humalog will also remain available for people who want to continue accessing it through their current insurance plans. Introducing an alternative insulin option allows Lilly to provide a lower-priced insulin more quickly while providing payers time to renegotiate downstream contracts and adjust to new system economics.

"While this change is a step in the right direction, all of us in the health care community must do more to fix the problem of high out-of-pocket costs for Americans living with chronic conditions," Ricks said. "We hope our announcement is a catalyst for positive change across the U.S. health care system."

Lilly's Insulin Lispro is one of many initiatives the company has introduced to deliver lower out-of-pocket options to people living with diabetes. After exploring the logistics and feasibility of an authorized generic, Lilly began preparing manufacturing, labeling, and shipping plans last year for the possibility of Lilly's Insulin Lispro. People should call the Lilly Diabetes Solution Center at (833) 808-1234 to learn whether Lilly's Insulin Lispro, or another option, is the best financial choice for them.

The list price of Lilly's current Humalog presentations last increased in May of 2017.

Lilly Diabetes Solution Center, Other Actions Help Offset Costs

In addition to the introduction of Lilly's Insulin Lispro, we have taken several other steps to lower what people pay for insulin.

- In August 2018, we launched the Lilly Diabetes Solution Center. Staffed by health care professionals, the Solution Center provides significant savings on Lilly insulins in multiple ways, including point-of-sale savings, access to donated Lilly insulin at more than 150 contracted free clinics, and options for people who have immediate needs. More than 10,000 people each month are paying significantly less for their Lilly insulin through the Solution Center and other offerings. Anyone who uses Lilly insulin can call the Solution Center at (833) 808-1234 (9 am to 8 pm EST Monday through Friday) to see whether there is a lower-cost alternative available for them.
- In December 2016, Lilly introduced the first follow-on biologic basal insulin in the U.S., at a reduced price compared to branded competition. In the two years since that launch, the net price per prescription for the class of basal insulins in the U.S. has decreased by approximately 30 percent.
- Lilly also donates to charitable organizations that provide free medicine, including insulin, to patients meeting program eligibility requirements. In the last five years, Lilly has donated more than 5.4 million insulin vials and pens in the U.S.

The cost of insulin can vary dramatically depending on a person's insurance coverage. The vast majority of patients have flat co-pays and face lower out-of-pocket costs for insulin, so the price they pay at the pharmacy will not change. For people with high-deductible insurance plans, the uninsured, or people in the coverage gap of Medicare Part D, Lilly's Insulin Lispro is another option that can make insulin more affordable.

Indication for Humalog® (insulin lispro) and Insulin Lispro

Humalog and Insulin Lispro are man-made fast-acting insulin used to control high blood sugar in adults and children with diabetes mellitus.

Important Safety Information for Humalog® (insulin lispro) and Important Safety Information for Insulin Lispro

What is the most important information I should know about Humalog and Insulin Lispro?

- Do not share your Humalog or Insulin Lispro KwikPen or syringe with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
- Do not change the insulin you use without talking to your healthcare provider. Changes may make you more likely to experience low or high blood sugar. Changes should be made cautiously under the supervision of your healthcare provider.
- Test your blood sugar levels as your healthcare provider instructs.
- Your insulin dose may need to change because of illness, stress, other medicines you take, change in diet, or change in physical activity or exercise.
- When used in a pump, do not mix or dilute Humalog or Insulin Lispro with any other insulin or liquid.

Who should not take Humalog or Insulin Lispro?

 Do not take Humalog or Insulin Lispro if your blood sugar is too low (hypoglycemia) or if you are allergic to Humalog or Insulin Lispro or any of the ingredients in Humalog or Insulin Lispro.

Before using Humalog or Insulin Lispro, what should I tell my healthcare providers?

- About all of your medical conditions, including liver, kidney, or heart failure or other heart problems.
- If you are pregnant, planning to become pregnant, or are breastfeeding.
- About all the medicines you take, including prescription (especially ones commonly called TZDs [thiazolidinediones]) and nonprescription medicines, vitamins, and herbal supplements.

How should I use Humalog or Insulin Lispro?

- Humalog and Insulin Lispro are rapid-acting insulins. Take Humalog or Insulin Lispro within fifteen minutes before eating or right after eating a meal.
- Always make sure you receive the correct type of Humalog or Insulin Lispro from the pharmacy.
- Do not use Humalog or Insulin Lispro if it is cloudy, colored, or has solid particles or clumps in it.
- Inject Humalog or Insulin Lispro under your skin (subcutaneously). Never inject into a vein or muscle. Change (rotate) your injection site with each dose. Make sure you inject the correct insulin and dose.
- Do not re-use needles. Always use a new needle for each injection. Re-use of needles can cause you to receive the wrong dose of Humalog or Insulin Lispro and result in infection.
- Do not drive or operate heavy machinery until you know how Humalog or Insulin Lispro affects you. Do not use alcohol while using Humalog or Insulin Lispro.

What are the possible side effects of Humalog or Insulin Lispro?

- Severe low blood sugar can cause unconsciousness (passing out), seizures, and death. Low blood sugar is the most
 common side effect. There are many causes of low blood sugar, including taking too much Humalog or Insulin Lispro. It is
 important to treat it quickly. You can treat mild to moderate low blood sugar by drinking or eating a quick source of sugar
 right away. Symptoms may be different for each person. Be sure to talk to your healthcare provider about low blood sugar
 symptoms and treatment.
- Severe life-threatening allergic reactions (whole-body reactions) can happen. Get medical help right away if you develop a rash over your whole body, have trouble breathing, have a fast heartbeat, or are sweating.
- Humalog or Insulin Lispro can cause life-threatening low potassium in your blood (hypokalemia), which can cause severe breathing problems, irregular heartbeat, and death.
- Serious side effects can include swelling of your hands and feet and heart failure when taking certain pills called
 thiazolidinediones or "TZDs" with Humalog or Insulin Lispro. This may occur in some people even if they have not had
 heart problems before. Tell your healthcare provider if you have shortness of breath, swelling of your ankles or feet, or
 sudden weight gain, which may be symptoms of heart failure. Your healthcare provider may need to adjust or stop your
 treatment with TZDs or Humalog or Insulin Lispro.
- Failure of your insulin pump or infusion set or degradation of the insulin in the pump can cause hyperglycemia and ketoacidosis. Always carry an alternate form of insulin administration in case of pump failure.
- The most common side effects of Humalog or Insulin Lispro include low blood sugar, allergic reactions, including reactions at your injection site, skin thickening or pits at the injection site (lipodystrophy), itching, and rash. These are not all of the possible side effects. Ask your healthcare provider for more information or for medical advice about side effects.

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

Humalog and Insulin Lispro are available by prescription only.

For additional information, talk to your healthcare providers and please click to access Humalog <u>Full Prescribing Information</u> and <u>Patient Prescribing Information</u>.

For additional information, talk to your healthcare providers and click to access Insulin Lispro Full Prescribing Information and Patient Prescribing Information.

Please see Instructions for Use included with Humalog and Insulin Lispro products.

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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 and collaboration, a broad and growing product portfolio, and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com or follow us on Twitter: @LillyDiabetes and on Facebook: LillyDiabetesUS.

About Eli Lilly and Company

Lilly is a global healthcare 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 www.lilly.com/newsroom/social-channels. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Insulin Lispro and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are risks and uncertainties related to the commercialization and regulation of Insulin Lispro and authorized generics. Among other things, there can be no guarantee that future clinical study results or individual patient experiences will be consistent with results to date. 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.

Humalog® is a registered trademark of Eli Lilly and Company.

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