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BASAGLAR® (insulin glargine injection 100 units/mL), A Long-Acting Basal Insulin, Is Now Available in U.S.

- BASAGLAR, a follow-on insulin to Lantus, is accompanied by resources designed to help address barriers of beginning insulin treatment

INDIANAPOLIS and RIDGEFIELD, Conn., Dec. 15, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim Pharmaceuticals, Inc. announced today that BASAGLAR® (insulin glargine injection 100 units/mL) is available by prescription in the U.S. BASAGLAR is a follow-on insulin to Lantus®. It is a long-acting insulin with an amino acid sequence identical to Lantus, another U-100 insulin glargine.

In December 2015, the U.S. Food and Drug Administration (FDA) approved BASAGLAR as a long-acting insulin used to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes. BASAGLAR should not be used to treat diabetic ketoacidosis. BASAGLAR should not be used during episodes of low blood sugar (hypoglycemia) or in people with an allergy to insulin glargine or any of the ingredients in BASAGLAR.

"Lilly and Boehringer Ingelheim are proud to bring another proven effective diabetes treatment choice to people who may need a long-acting insulin to help control their blood sugar," said David Kendall, M.D., vice president, Global Medical Affairs, Lilly Diabetes. "We know that starting insulin can be a challenging experience for some people with type 2 diabetes. As part of our continuing commitment to the diabetes community, we are expanding our educational resources."

With resources designed to be simple, BASAGLAR goes beyond just insulin by offering helpful support for people beginning insulin. These bilingual resources include an app for smartphones and tablets to provide an interactive experience that helps patients relax and guides them through injection using their BASAGLAR KwikPen®, injection demo kits (available through HCPs), and access to educational videos. Do NOT reuse needles or share insulin pens, even if the needle has been changed.

"In my practice, I regularly see people with type 2 diabetes who feel completely overwhelmed or nervous when they learn they need to begin insulin treatment," said Eugene Wright, M.D., consulting associate, Medicine and Community and Family Medicine, Southern Regional AHEC. "These feelings are understandable because many people with type 2 diabetes face fear and anxiety about injections, a sense of failure about the progression of their condition, or concern over fitting insulin into daily life. For many who need insulin, I believe that reassurance and education are key, and I think they will appreciate the additional resources that help address some of these barriers as they begin treatment with BASAGLAR."

BASAGLAR will be available by prescription from retail and mail order pharmacies across the U.S. As the top three pharmacy benefit managers have selected BASAGLAR for their formularies, it is expected to be widely covered by commercial insurance plans. In addition, Lilly and Boehringer Ingelheim will offer a BASAGLAR savings card for eligible people.

For more information about BASAGLAR, the support resources, or eligibility details for the savings card, please visit www.BASAGLAR.com.

About BASAGLAR

In December 2015, BASAGLAR was the first insulin product approved through an abbreviated approval pathway under the Federal Food, Drug, and Cosmetic Act. The extensive clinical development program for BASAGLAR included pharmacokinetic and pharmacodynamic studies, as well as Phase III studies in people with type 1 and type 2 diabetes comparing the safety and efficacy of BASAGLAR to U.S.-and non-U.S.-approved Lantus.

BASAGLAR Indication

BASAGLAR is a long-acting insulin indicated to control high blood sugar in adults and children with type 1 diabetes and adults with type 2 diabetes.

BASAGLAR should not be used to treat diabetic ketoacidosis.

Important Safety Information

Do not take BASAGLAR® (insulin glargine injection) during episodes of low blood sugar or if you are allergic to insulin glargine or any of the ingredients in BASAGLAR.

Do NOT reuse needles or share insulin pens, even if the needle has been changed.

Before starting BASAGLAR, tell your doctor about all your medical conditions, including if you have liver or kidney problems, if you are pregnant or planning to become pregnant, or if you are breastfeeding or planning to breastfeed.

BASAGLAR should be taken once a day at the same time every day. Test your blood sugar levels while using insulin. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

The most common side effect of insulin, including BASAGLAR, is low blood sugar (hypoglycemia), which may be serious and life threatening. Signs and symptoms may include dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood change, or hunger.

Do NOT dilute or mix BASAGLAR with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. BASAGLAR must only be used if the solution is clear and colorless with no particles visible. Always make sure you have the correct insulin before each injection.

BASAGLAR may cause serious side effects that can lead to death, such as severe allergic reactions. **Get emergency help** if you have:

- | A rash over your whole body
- | Trouble breathing
- | A fast heartbeat
- | Sweating
- | Swelling of your face, tongue, or throat
- | Shortness of breath
- | Extreme drowsiness, dizziness, or confusion

Heart failure can occur if you are taking insulin together with medicines called TZDs (thiazolidinediones), even if you have never had heart failure or other heart problems. If you already have heart failure, it may get worse while you take TZDs with BASAGLAR. Your treatment with TZDs and BASAGLAR may need to be changed or stopped by your doctor if you have new or worsening heart failure. Tell your doctor if you have any new or worsening symptoms of heart failure, including:

- | Shortness of breath
- | Swelling of your ankles or feet
- | Sudden weight gain

Tell your doctor about all the medications you take, including over-the-counter medicines, vitamins, and herbal supplements.

While using BASAGLAR, do not drive or operate heavy machinery until you know how BASAGLAR affects you. Do not drink alcohol or use other medicines that contain alcohol.

Other possible side effects may include swelling, weight gain, low potassium, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions. **These are not all the possible side effects.** Call your doctor 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.

The BASAGLAR KwikPen is a disposable, prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instructions for Use that accompanies the pen. BASAGLAR is available by prescription only.

Please see [Prescribing Information](#) and [Patient Information](#) provided.

Please see Instructions for Use that come with the pen.

About Diabetes

Approximately 29 million Americans and an estimated 415 million people worldwide have diabetes, and nearly 28 percent of Americans with diabetes — totaling 8 million people — are undiagnosed.^{1,2} In the U.S., approximately 12 percent of those aged 20 and older have diabetes.² Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diagnosed adult diabetes cases in the U.S.² Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. The alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs. Find out more about the alliance at www.boehringer-ingelheim.com or www.lilly.com.

About Boehringer Ingelheim

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with 145 affiliates and more than 47,000 employees. Since its founding in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel treatments for human and veterinary medicine.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and families. Our employees create and engage in programs that strengthen our communities. To learn more about how we make more health for more people, visit our [Corporate Social Responsibility Report](#).

In 2015, Boehringer Ingelheim achieved net sales of about \$15.8 billion dollars (14.8 billion euros). R&D expenditure corresponds to 20.3 percent of its net sales.

For more information, please visit <https://www.boehringer-ingelheim.us/>, or follow us on Twitter @BoehringerUS.

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.

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 www.lilly.com and newsroom.lilly.com/social-channels.

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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 BASAGLAR (insulin glargine injection) as a treatment for adults and children with type 1 diabetes and adults 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 BASAGLAR 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.

BASAGLAR[®], Abasaglar[®] and KwikPen[®] are registered trademarks of Eli Lilly and Company.

Lantus[®] is a registered trademark of sanofi-aventis U.S. LLC.

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¹ International Diabetes Federation. IDF Diabetes Atlas. 7th ed. Brussels, Belgium: International Diabetes Federation; 2015. Available at: <http://www.diabetesatlas.org/resources/2015-atlas.html>. Accessed on September 8, 2016.

² Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014. Available at: <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>. Accessed on September 8, 2016.



To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/basaglar-insulin-glargine-injection-100-unitsml-a-long-acting-basal-insulin-is-now-available-in-us-300378865.html>

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