December 16, 2015

# FDA Approves Basaglar® (insulin glargine injection), a Long-Acting Insulin Treatment

## - BASAGLAR is the first FDA-approved follow-on insulin glargine treatment
## - BASAGLAR will be available in the U.S. starting on December 15, 2016

INDIANAPOLIS and RIDGEFIELD, Conn., Dec. 16, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) today announced that the U.S. Food and Drug Administration (FDA) granted approval for Basaglar® (insulin glargine injection) 100 units/mL. BASAGLAR is a long-acting insulin with an identical amino acid sequence to Lantus®, another U-100 insulin glargine. It is delivered via the prefilled BASAGLAR KwikPen®.

BASAGLAR is 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. 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.Â Â

"Lilly has a long history of developing and manufacturing insulin, having introduced the world's first commercial insulin more than 90 years ago," said David Kendall, MD, vice president, Global Medical Affairs, Lilly Diabetes. "BASAGLAR will be a welcome addition to our insulin and alliance portfolios, offering an option for people with diabetes who may need a long-acting insulin."

The BASAGLAR FDA approval is based, in part, upon an extensive clinical development program. The submission included results from 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.

The FDA approval follows BASAGLAR's tentative U.S. approval in August 2014, which was contingent upon patent litigation resolution. Per the settlement agreement with Sanofi, BASAGLAR will be available in the U.S. starting on December 15, 2016.

"The BASAGLAR FDA approval marks the first insulin therapy to be approved in the U.S. as part of our alliance with Lilly and broadens our portfolio of treatment options for people with type 1 and type 2 diabetes," said Paul Fonteyne, president and CEO, BIPI. "We remain committed to the care of people with diabetes and look forward to a successful U.S. launch of BASAGLAR."

This latest regulatory approval is the 11th for BASAGLAR worldwide, with launches taking place in several countries this year, including under the trade name Abasaglar® in Europe.

**BASAGLAR Indication**

BASAGLAR is a long-acting, man-made 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 for BASAGLAR®**

**What is the most important information I should know about BASAGLAR?**

- **Do not share your BASAGLAR KwikPen® 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.

**Who should not take BASAGLAR?**

- Do not use BASAGLAR if you are having an episode of low blood sugar (hypoglycemia) or have an allergy to any of the ingredients in BASAGLAR.
- It is not known if BASAGLAR is safe and effective in children less than six years of age with type 1 diabetes mellitus or in children with type 2 diabetes mellitus.

**What should I tell my healthcare provider before using BASAGLAR?**

**Before using BASAGLAR, tell your healthcare provider about all your medical conditions, including if you:**

- have liver or kidney problems.
- take any other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with BASAGLAR.
- are pregnant, planning to become pregnant, or are breastfeeding. BASAGLAR may harm your unborn or breastfeeding baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

**Before you start using BASAGLAR, talk with your healthcare provider about low blood sugar and how to manage it.**Â

**How should I use BASAGLAR?**

- Read the detailed **Instructions for Use** that come with your BASAGLAR KwikPen®.
- Use BASAGLAR exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much BASAGLAR to use and when to use it.
- Know the amount of BASAGLAR you use. Do not change the amount of BASAGLAR you use unless your healthcare provider tells you to.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- BASAGLAR may be used any time during the day, but BASAGLAR should be used at the same time each day.
- Only use BASAGLAR that is clear and colorless. If your BASAGLAR is cloudy or slightly colored, return it to your pharmacy for a replacement.
- BASAGLAR is injected under your skin (subcutaneously). Do not use BASAGLAR in an insulin pump or inject BASAGLAR in your vein (intravenously).
- Change (rotate) your injection sites within the area you chose for each dose. Do not use the exact spot for each injection.
- Do not mix BASAGLAR with any other type of insulin.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.
- While using BASAGLAR, do not drive or operate heavy machinery until you know how BASAGLAR affects you; and do not drink alcohol or use over-the-counter medicines that contain alcohol.

**Keep BASAGLAR and all medicines out of the reach of children.**

**What are the possible side effects of BASAGLAR?**

**BASAGLAR may cause serious side effects that can lead to death, including**:

- **Low blood sugar (hypoglycemia).** 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.
- **Severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs of allergic reaction:** a rash over your whole body, trouble breathing, a fast heartbeat, or sweating.
- **Low potassium level in your blood (hypokalemia).**
- **Heart failure**. Taking certain diabetes pills thiazolidinediones or "TZDs" with BASAGLAR may cause heart failure in some people, even in people who have never had heart failure or heart problems before. If you have already had

heart failure it may get worse if you take TZDs with BASAGLAR. Tell your healthcare provider if you have any new or worse symptoms of heart failure including shortness of breath, swelling of the ankles or feet, or sudden weight gain. Treatment with TZDs and BASAGLAR may need to be changed or stopped by your healthcare provider.

**Get emergency help if you have** trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, or confusion.

- **The most common side effects of BASAGLAR include** low blood sugar (hypoglycemia), allergic reactions, including reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy). **These are not all of the possible side effects.** Ask your healthcare provider for more information or for medical advice about side effects.

You may report side effects to the Food and Drug Administration (FDA). Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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For more information please click to access Full Prescribing Information and Patient Information.

Please see Instructions for Use included with your pen.

**About Diabetes**
Approximately 29 million Americans[1] and an estimated 415 million people worldwide[2] have type 1 or type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.[1] Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.[2]Â

**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. Depending on geographies, the companies either co-promote or separately promote the respective molecules each contributed to the alliance. 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 146 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 2014, Boehringer Ingelheim achieved net sales of about $16.96 billion dollars (13.3 billion euros). R&D expenditure corresponds to 19.9 percent of its net sales.

For more information please visit www.us.boehringer-ingelheim.com, 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. Â

**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.Â Â

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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® andÂ 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] Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2014*. Available at: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf. October 2014.

[2]Â International Diabetes Federation. *IDF Diabetes Atlas Executive Summary, 7th edn*. Brussels, Belgium: International Diabetes Federation, 2015. Available at: http://www.diabetesatlas.org/resources/2015-atlas.html.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/fda-approves-basaglar-insulin-glargine-injection-a-long-acting-insulin-treatment-300194249.html

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