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European Commission grants Lilly and Boehringer Ingelheim's insulin glargine product marketing authorisation in Europe

-- First biosimilar insulin to receive regulatory approval in the EU

INDIANAPOLIS and INGELHEIM, Germany, Sept. 10, 2014 /PRNewswire/ -- The European Commission (EC) granted marketing authorisation for Eli Lilly and Company and Boehringer Ingelheim's insulin glargine product, indicated to treat diabetes in adults, adolescents and children aged 2 years and above. Lilly/Boehringer Ingelheim's insulin glargine product is the first insulin treatment approved through the European Medicines Agency's biosimilar pathway and the fourth diabetes product approved in the EU from the Lilly-Boehringer Ingelheim Alliance. It received a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) on June 26, 2014.

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"The marketing authorisation for this insulin glargine product in Europe is a significant achievement for the Lilly-Boehringer Ingelheim Alliance. We believe that insulin glargine will continue to be widely used for many years, and Lilly and Boehringer Ingelheim are committed to addressing the needs of people living with diabetes and providing support beyond the medicine," said Enrique Conterno, president, Lilly Diabetes.

The Alliance's insulin glargine product is a basal insulin with the same amino acid sequence as Lantus® (insulin glargine) and is intended to provide long-lasting blood sugar control between meals and at night.¹ Lilly/Boehringer Ingelheim's insulin glargine product will be available in a pre-filled pen and cartridges for a reusable pen.

"Basal insulin is an important mainstay of treatment for people with type 1 and type 2 diabetes, and we're pleased that Lilly/Boehringer Ingelheim's insulin glargine product will provide healthcare professionals and patients with another option to meet their insulin treatment needs, along with significant expertise and support from the Lilly-Boehringer Ingelheim Alliance," said Professor Klaus Dugi, Chief Medical Officer, Boehringer Ingelheim.

The marketing authorisation for the Alliance's insulin glargine product is based upon a comprehensive clinical data programme, which showed it has similar efficacy and safety compared to the currently marketed insulin glargine product in people with type 1 and type 2 diabetes. The application included results from pharmacokinetic and pharmacodynamic studies, as well as Phase III studies in patients with type 1 and type 2 diabetes.

While 'Abasria' is an approved name in Europe, it's not necessarily approved in other regions. Lilly and Boehringer Ingelheim are targeting a global trade name for the Alliance's insulin glargine product, which will be announced at a later date.

Lilly/Boehringer Ingelheim's insulin glargine product will be manufactured by Lilly, which has been manufacturing insulin since 1923. This history gives Lilly extensive expertise, insights and knowledge in the insulin space, enabling it to provide high quality medicines to diabetes patients worldwide.

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

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally with 142 affiliates and a total of more than 47,400 employees. The focus of the family-owned company, founded in 1885, is researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine.

Taking social responsibility is an important element of the corporate culture at Boehringer Ingelheim. This includes worldwide involvement in social projects, such as the initiative "Making More Health" and caring for the employees. Respect, equal opportunities and reconciling career and family form the foundation of the mutual cooperation. In everything it does, the company focuses on environmental protection and sustainability.

In 2013, Boehringer Ingelheim achieved net sales of about 14.1 billion euros. R&D expenditure corresponds to 19.5% of its net sales.

For more information please visit www.boehringer-ingelheim.com.

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, @LillyHealth on Twitter and <http://newsroom.lilly.com/social-channels>.

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

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