

Press Release

Biocon and Mylan Launch First Insulin Glargine Biosimilar, Semglee®, in Australia

October 3, 2019, Bengaluru, India

Biocon Ltd and **Mylan N.V.** today announced the launch of Semglee® (insulin glargine solution for injection 100 IU/mL in a 3mL pre-filled pen), the first insulin glargine biosimilar in Australia available on the Pharmaceutical Benefits Scheme (PBS).

Insulin glargine is a long-acting basal insulin analogue, given once daily to help control the blood sugar levels of those with diabetes. It is indicated for the treatment of type 1 diabetes mellitus in adults, adolescents and children aged six years and above and type 2 diabetes mellitus in adults. Diabetes is recognised as the world's fastest growing chronic condition and is the biggest challenge confronting Australia's health system. Almost two million Australians have diabetes, with 280 Australian developing diabetes every day – one person every five minutes. The total annual cost impact of diabetes in Australia is estimated at \$14.6 billion.¹

More affordable treatment options for healthcare providers and their patients, such as biosimilars, generate savings that help manage the growing costs of Australia's health care system, particularly the PBS.

The Government recognises the importance of driving biosimilar uptake to create a competitive and sustainable biosimilars market. In 2015, the Government committed to the Biosimilar Awareness Initiative and in 2018 increased its commitment by supporting the Generic and Biosimilar Medicines Association through a \$5 million grant to undertake activities that further promote the appropriate prescribing, dispensing and use of biosimilar medicines.

Dr Christiane Hamacher, CEO, Biocon Biologics said, *"We are extremely excited to enable affordable access to Semglee, a high quality biosimilar Insulin Glargine, co-developed and manufactured by Biocon Biologics, to people with diabetes in Australia. We are committed to use our science, scale and expertise to shift the access paradigm for patients in need of insulins across the globe. As a leading global insulins player, Biocon has been addressing the needs of patients with diabetes for over 15 years and we are confident that availability of Semglee through the Pharmaceutical Benefits Scheme will expand patient access to this therapy in Australia and will reduce the cost burden for PBS. Today, patients in Europe, India and key emerging markets are already benefiting from our biosimilar Insulin Glargine."*

Mylan Australia Country Manager, Sylvain Vigneault commented, *"The launch of Semglee further demonstrates Mylan's ongoing commitment to increase access to biosimilars for patients. Biosimilars mark a new era in treatment. They enable more patients to be treated, deliver significant savings to the PBS and help provide sustainability to the healthcare system overall."*



“We are delighted that Semglee enables Mylan to strengthen and support its global diabetes and metabolism portfolio of approximately 400 products.”

Biosimilars have been used safely and effectively in Europe, USA, Australia and many other countries. Since 2006, in the EU alone, over 700 million patient days of clinical experience to more than 20 biosimilar medicines have been recorded^{2,3,4,5}.

TGA approval of Semglee, co-developed by Biocon and Mylan, was based on robust data that demonstrated that Semglee is highly similar to the reference insulin glargine, with no clinically meaningful differences in efficacy, safety, purity and potency.

Mylan and Biocon's insulin glargine biosimilar is currently approved in more than 40 countries around the world.

About Biocon and Mylan Partnership

Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. Insulin glargine is one of the three insulin analogs being co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for insulin glargine in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon has exclusive rights for Japan and a few emerging markets, and co-exclusive commercialization rights with Mylan in the rest of the world.

About Biocon Limited:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune.

Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated ‘pure play’ biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. Biocon is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. In multiple countries like Mexico and Malaysia, nearly all insulin-requiring diabetics take Biocon’s insulins. The Company has a large portfolio of biosimilars under global clinical development with three of these commercialized in at least one of the developed markets of EU, U.S. and Japan.

Biocon Limited has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as generic formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. www.biocon.com Follow-us on Twitter: @bioconlimited



About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

Mylan in Australia is one of the leading suppliers by volume of prescription medicines to the PBS. Mylan has one of Australia's largest medicine manufacturing sites, based at Carole Park, Queensland. More than 3 billion doses of oral solid dose medicine were produced last year for the Australian and export markets. Mylan's Australian-made medicine can be found in more than 40 countries around the world.

¹ Diabetes Australia website (<https://www.diabetesaustralia.com.au/diabetes-in-australia>) Accessed 23 September 2019

² Cohen H, Beydoun D, Chien D et al. Adv Ther 2016;33(12):2160-2172.

³ Ward M. Literature Review of International Biosimilar Medicines: Update June – September 2016. Accessed from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-literature-review>. Accessed 6 March 2019

⁴ Ward M. Literature Review of International Biosimilar Medicines: Update December 2017 – February 2018. Updated: 24 April 2018. Accessed from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-literature-review>. Accessed 6 March 2019

⁵ Van den Hoven A. Biosimilar medicines clinical use: a n experience based -EU perspective. Available at <https://www.medicinesforeurope.com/docs/20170713%20-%20Biosimilar%20Medicines%20Group,%20EU%20experience-AVH-US%20FDA%20Adcom.pdf>. Accessed 6 March 2019

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