



## Mylan and Biocon Receive Approvals from the European Commission and TGA Australia for Semglee™, Biosimilar Insulin Glargine

March 28, 2018

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, March 27, 2018 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL), one of the world's leading pharmaceutical companies, and Biocon Ltd. (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceutical company, today announced that their co-developed biosimilar insulin glargine Semglee™ has received marketing authorization approval from the European Commission (EC) following the positive recommendation by the Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency. Semglee™ 100 units/mL 3 mL prefilled disposable pen for people with diabetes, is the first biosimilar from Biocon and Mylan's joint portfolio to be approved in Europe.

Additionally, the Therapeutic Goods Administration (TGA), Australia has also approved biosimilar insulin glargine Semglee™ 100 IU/mL 3 mL prefilled pen for the people with diabetes in Australia.

**Mylan President Rajiv Malik** said, "We are excited to be able to bring Mylan and Biocon's biosimilar insulin glargine to Europe and Australia where millions of people are currently living with diabetes, and we are committed to continuing to bring high quality, more affordable biosimilar products to markets around the world. The investments that we have made to develop and manufacture a leading portfolio of complex products, including Semglee™, is one way that we are delivering on our commitment to expand access to high quality medicine."

**Dr. Arun Chandavarkar, CEO and Joint Managing Director, Biocon**, said, "The approval of Mylan and Biocon's biosimilar insulin glargine by the European Commission and TGA Australia are important milestones in our collaboration. It furthers our mission to provide a high quality, affordable insulin analog for people with diabetes globally. As a credible, global insulins player, we are committed to address the growing healthcare challenges associated with diabetes and have made significant investments in R&D and manufacturing to build scale and make our affordable insulins portfolio available in many markets."

The EC approval of Semglee™ applies to all European Union (EU) member states and the European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.

Diabetes is the fastest growing chronic condition in the world and the prevalence of this disease is increasing among all ages. In Europe the number of diabetics are expected to grow to 38 million by 2030\*\*, while in Australia it currently affects nearly two million\* people.

Mylan plans to launch Semglee™ in Australia later this year and expects to begin launching the product across various markets in Europe in the second half of 2018.

In addition to these approvals, marketing applications for Semglee™ have been submitted in Canada and the U.S., and are planned for key Emerging Markets.

Source: \*Diabetes Australia \*\*EU website

### About the Mylan and Biocon Collaboration

Biocon and Mylan are exclusive partners on a broad portfolio of biosimilars and insulin analogs. 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 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 more than 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. And we offer a leading portfolio of complex products, which includes 16 biosimilar and insulin analog products on the market or in development worldwide. These include 8 of the top 10 biologics in areas of oncology, immunology, endocrinology and ophthalmology.

Every member of our approximately 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.

### About Biocon

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 120 countries, it is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune. Biocon is among the Top 3 biosimilar insulins player globally in terms of volume share and has been committed to affordable diabetes management through its portfolio of recombinant human insulin and insulin analogs in India and several global markets. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of Novel Biologics, Biosimilars,

differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'. Some of its key brands are INSUGEN® (rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab), KRABEVA® ( Bevacizumab) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. The Company has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin. For more information log on [www.biocon.com](http://www.biocon.com) and follow-us on twitter: @bioconlimited

#### **Forward-Looking Statements: Mylan**

*This press release includes statements that constitute "forward-looking statements", including with regard to: Mylan plans to launch Semglee™ in Australia later this year and expects to begin launching the product across various markets in Europe in the second half of 2018; and that several submissions are planned for key emerging markets. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.*

#### **Forward-Looking Statements: Biocon**

*This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.*

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