



January 29, 2018

Mylan and Biocon Receive Positive CHMP Opinion for Semglee™, Biosimilar Insulin Glargine

First biosimilar from Mylan and Biocon's joint portfolio recommended for approval in the European Union (EU)

HERTFORDSHIRE, England and PITTSBURGH and BENGALURU, India, Jan. 29, 2018 /PRNewswire/ -- [Mylan N.V.](#) (NASDAQ, TASE: MYL) and Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Semglee™, insulin glargine, a long-acting insulin analog used in the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

The CHMP positive opinion will be considered by the European Commission. The European Commission decision on the approval is expected in April.

Mylan President Rajiv Malik commented, "We are pleased with CHMP's decision to recommend approval of Mylan and Biocon's biosimilar insulin glargine. With approximately 60 million people living with diabetes in the European Region and prevalence on the rise, we have an important role to play to help increase access to high-quality, more affordable treatment options for patients. Mylan is a global leader in the development and manufacturing of complex products, and we are proud of our regulatory, clinical and scientific capabilities that have allowed us to reach this important milestone."

Arun Chandavarkar, CEO and Joint Managing Director, Biocon said, "CHMP's decision to recommend approval of Biocon and Mylan's biosimilar insulin glargine brings us a step closer to offer high quality, affordable options for people with diabetes in the EU. This is an outcome of our commitment to be a credible, global insulins player on the back of significant investments together with our partner Mylan in global scale manufacturing and R&D after having previously obtained approvals for our insulin glargine in Japan and key emerging markets."

Data submitted as part of the Marketing Authorization Application included analytical similarity data, metabolic assays, euglycemic clamp data in type 1 diabetes patients for demonstration of similar PD and PK response, as well as robust clinical endpoint studies in patients with Type 1 and Type 2 Diabetes comparing Semglee with the reference product, insulin glargine to demonstrate similar safety, efficacy and immunogenicity up to 52 weeks.

In addition to the European submission, marketing applications for Semglee have been submitted in Australia, Canada, and the U.S. and are planned for key Emerging Markets.

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. 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. 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™ (Itoлизumab), 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.

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to: approval of Semglee; that the European Commission decision on the approval is expected in April; and that we have an important role to play to help increase access to high-quality, more affordable treatment options for patients. 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 forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. The statements - written and oral - that we periodically make contain forward looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify such statements by using words such as 'anticipates', 'estimates', 'expects', 'projects', 'intends', 'plans', 'believes' and words of similar substance in connection with any discussion of future performance. The market data & rankings used, are based on several published reports and internal company assessment. We cannot guarantee that these forward- looking statements will be realized, although we believe we have been prudent in our assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should bear this in mind. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.



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