Press Release

Biocon and Mylan's Biosimilar Trastuzumab Receives Approval from ANVISA, Brazil Through Their Partner Libbs

Bengaluru, India, Hertfordshire, England/Pittsburgh, USA, and Sao Paulo, Brazil, December 29, 2017 - Biosimilar Trastuzumab, co-developed by Biocon Ltd. (BSE code: 532523, NSE: BIOCON) and Mylan N.V. (NASDAQ, TASE: MYL), has been approved by ANVISA, the Brazilian regulatory agency, through their partner Libbs Farmaceutica (Libbs), a leading Brazilian pharmaceutical company.

Co-developed by Biocon and Mylan, this is the first biosimilar Trastuzumab to be approved in Brazil and is indicated for the treatment of overexpressing HER2-positive metastatic breast cancer, HER2-positive early stage breast cancer and HER2-positive advanced gastric cancer. Libbs will commercialize the product in Brazil under the brand name Zedora, which will provide affordable access to a cutting-edge biologics therapy for patients in Brazil.

Dr Arun Chandavarkar, CEO and Joint Managing Director, Biocon, **said:** *"This marks the first approval for a biosimilar Trastuzumab by Brazil's ANVISA and demonstrates our commitment to provide access to high-quality and affordable biologics to patients across the globe. Cancer patients in India and some emerging markets have benefited with our Trastuzumab and the approval in Brazil will enable affordable access to this critical biologic therapy for the treatment of HER2-positive breast and gastric cancers in the country. We are committed to make global impact with our affordable antibodies against cancer."*

Mylan CEO Heather Bresch commented: *"The number of women diagnosed with breast cancer in Brazil is increasing. Sadly, many of the women with HER2-positive metastatic breast cancer in Brazil do not have access to Trastuzumab through the country's public health system. The approval of Zedora, Brazil's first Trastuzumab biosimilar, is an important step in our efforts to increase access to this critical product for patients with certain breast and gastric cancers and reduce the overall financial burden for health systems around the world*."

Alcebíades de Mendonça Athayde Júnior, Libbs CEO, said: *"The approval of Zedora will allow us to bring this first-of-its-kind biosimilar Trastuzumab to breast and gastric cancer patients in Brazil. Biosimilar Trastuzumab, co-developed by Biocon and Mylan, can help expand cancer-patient access to more affordable treatment and contribute to significant savings to Brazil's healthcare system. Zedora will strengthen our current product portfolio as a new generation targeted therapy that can benefit cancer patients immensely."*

Biocon and Mylan are responsible for the development of biosimilar Trastuzumab. While currently the trastuzumab will be manufactured by Biocon and supplied to Libbs for commercialization in Brazil; over a period of time the technology will be transferred to Libbs and the public partner Butantan through a Productive Development Partnership (PDP). Libbs have already built the biotechnological site to manufacture Zedora for the Brazilian market.

This is a significant approval as it sets the stage for the entry of our biosimilar Trastuzumab into Brazil, which is among the top three emerging markets globally for Trastuzumab. The pharmaceutical market in Brazil is predicted to grow to US$30 billion in 2021 from US$26 billion in 2016. (Source:GlobalData)

Breast cancer is the leading cause of cancer death in women in Brazil, where new cases are estimated to be over 57,000 annually, with an estimated incidence of 56 cases per 100,000 women. It is the second-most common type of cancer that affects women in Brazil, after non-melanoma skin cancer*. Trastuzumab is now included on the WHO list of essential medicines.

Earlier this month, Biocon and Mylan marked a major milestone with the U.S. Food and Drug Administration approval of their biosimilar Trastuzumab. Biocon and Mylan's biosimilar Trastuzumab is also under review by regulatory authorities in Australia, Canada, Europe and several additional markets. It is already approved in several other countries around the world, including India, where it is providing increased access to this more affordable biologic for cancer patients.

**Source: Instituto Nacional de Câncer José Alencar Gomes Da Silva. Estimativa 2014: incidência de câncer no Brasil. Rio de Janeiro, 2014.*

About Biocon and Mylan Partnership

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar Trastuzumab is one of the six biologic products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the product in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon has co-exclusive commercialization rights with Mylan for the product in the rest of the world.

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™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin. 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 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 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.

About Libbs

Libbs is a 100% Brazilian pharmaceutical company which has been in the market for 59 years and employs around 2500 people. Currently, it is on the 8th position in the ranking of pharmaceutical companies in the Brazilian national retail market. The company invests 10% of its revenue in R&D and innovation. It now has around 90 brands in the market in 200 different presentations distributed across several specialties, including gynecology, central nervous system, cardiology, oncology and dermatology. Libbs' biotechnology unit, called Biotec, was launched in 2016 and is responsible for the production of monoclonal antibodies. With a total production capacity of 400kg of biopharmaceutical products per year, Biotec applies the single-use system, a technology based on bioreactors with disposable bags. For more information, please visit http://www.libbs.com.br

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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.

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to: providing affordable access to cutting-edge biologics therapy for patients in Brazil who are otherwise not able to afford expensive originator products; the approval of Zedora, Brazil's first trastuzumab biosimilar, being an important step in our efforts to increase access to this critical product for patients with certain breast and gastric cancers and reduce the overall financial burden for health systems around the world; and the pharmaceutical market in Brazil being predicted to grow to U.S. $30 billion in 2021 from U.S. $26 billion in 2016. 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: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other 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.