

Press Release

## Health Canada Approves Biocon and Mylan's Ogivri™, the First Trastuzumab Biosimilar, for the Treatment of HER2-Positive Breast and Gastric Cancers

**BENGALURU, India and HERTFORDSHIRE, England/PITTSBURGH – May 22, 2019** –Biocon Ltd. and [Mylan N.V.](#) today announced that Health Canada has approved Mylan's Ogivri™ (trastuzumab), a biosimilar to Herceptin®<sup>1</sup> (trastuzumab) co-developed with Biocon, for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma).

Ogivri is the first trastuzumab biosimilar approved in Canada and the second biosimilar from Biocon and Mylan's joint portfolio approved in the market. Mylan plans to launch the product this quarter and anticipates potentially being the first company to offer a trastuzumab biosimilar in Canada.

**Dr [Christiane Hamacher](#), CEO, Biocon Biologics** said, *"We are pleased to enable access to Ogivri, a high quality biosimilar trastuzumab co-developed and manufactured by Biocon as an affordable treatment option for HER2- positive breast and gastric cancer patients in Canada. The Health Canada approval granted to Ogivri, will pave the way for its commercialization by our partner Mylan. Thousands of patients in Europe, India and key emerging markets are benefitting from our biosimilar trastuzumab. Biocon Biologics is committed to address unmet patient needs through its high quality, affordable biologics, globally."*

**Mylan's Chief Commercial Officer [Tony Mauro](#)** commented, *"As a global leader in the development of complex products, including biosimilar medicines, we're pleased to reach this approval milestone for Ogivri and the opportunity to bring this important treatment option to market for Canadian patients with HER2-positive breast and gastric cancers. We look forward to continuing our reimbursement discussions with the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that patients have access to Ogivri."*

Approval by Health Canada was based on robust data from structural and functional characterization using multiple orthogonal techniques, nonclinical studies and pharmacokinetic evaluation in healthy subjects and patients and a safety, efficacy and immunogenicity study in relevant patient populations, which compared Ogivri to Herceptin. The data demonstrated that Ogivri is highly similar to Herceptin with no clinically meaningful differences in terms of efficacy, safety, purity and potency.

Biocon and Mylan's trastuzumab biosimilar is currently approved in more than 65 countries around the world, including the U.S.

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<sup>1</sup> Herceptin® is a product of Hoffmann-La Roche Ltd.



### **About Biocon and Mylan Partnership**

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Our biosimilar to Herceptin 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 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 a fully-integrated, innovation-led global biopharmaceutical company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. The Company has developed and commercialized a range of Biosimilars (Monoclonal Antibodies, Pegfilgrastim, rh- Insulin and Insulin Glargine), Novel Biologics and differentiated Small Molecules in India and Key emerging markets. It has a large portfolio of biosimilars under global clinical development with three of these commercialized in the developed markets of EU, U.S. and Japan. It has promising novel assets in immunotherapy under development. Some of its key brands are INSUGEN® (rh-insulin), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab) and ALZUMAb™ (Itoлизumab). [www.biocon.com](http://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](http://Mylan.com). We routinely post information that may be important to investors on our website at [investor.mylan.com](http://investor.mylan.com).

### **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.

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

*This press release includes statements that constitute "forward-looking statements," including with regard to statements that: Mylan plans to launch the product this quarter and anticipates potentially being the first company to offer a trastuzumab biosimilar in Canada; and that we look forward to continuing our reimbursement discussions with the Canadian Agency for Drugs and Technologies in Health (CADTH) and Pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that patients have access to Ogivri. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; 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; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; 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.*

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