



Mylan and Biocon Launch First Trastuzumab Biosimilar, Ogivri™, in Australia

1 August 2019, Bengaluru, India

Biocon Ltd. and **Mylan N.V.** today announced the launch in Australia of Ogivri™ (trastuzumab), a biosimilar to Herceptin®¹ (trastuzumab), for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma).

Ogivri is the first trastuzumab biosimilar approved and launched in Australia and available on the Pharmaceutical Benefits Scheme (PBS).

Biosimilars generate savings that help manage the growing costs of Australia's health care system, particularly the PBS. They enable greater patients access to necessary treatments and free up funding for the listing of the latest treatments.

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.

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 exposure to more than 20 biosimilar medicines have been recorded^{2,3,4,5}.

TGA approval of Ogivri was based on robust data that demonstrated that Ogivri is highly similar to Herceptin with no clinically meaningful differences in efficacy, safety, purity and potency. One of the comparative studies, the HERITAGE study - published in the Journal of the American Medical Association (Rugo H. et al, JAMA, 2017; 317;1:37-47) - involved 500 patients with HER2 positive metastatic breast cancer from 95 participating sites around the world. It found patient response to the two treatments to be equivalent in terms of reduction in tumour size at 24 weeks and overall survival at 48 weeks.

Dr Christiane Hamacher, CEO, Biocon Biologics said, *"We are extremely excited to enable access to Ogivri, in Australia, a high quality biosimilar trastuzumab, co-developed and manufactured by Biocon. Thousands of patients in Europe, India, and key emerging markets are benefitting from our biosimilar trastuzumab. Commercialisation of Ogivri by Mylan, in Australia, extends the global footprint of our biosimilar trastuzumab. We remain committed to transforming healthcare globally, by addressing patient needs through our high quality, affordable biologics."*

Mylan Australia Country Manager, Sylvain Vigneault commented, *"As a global leader in the development of complex products, including biosimilar medicines, we're pleased to launch our first biosimilar in Australia. Biosimilars increase timely and affordable patient access to the latest treatments and help deliver a sustainable PBS. Mylan's investment in biosimilars is an exciting evolution in how we can treat Australian patients. We are delighted that Ogivri enables Mylan, with our partner Biocon, to bring this treatment option to Australian patients with HER2-positive breast and gastric cancers."*

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



About the 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 11 biologic products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialisation 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 commercialisation rights for the product 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 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.

About Biocon Ltd:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is a fully-integrated, innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune diseases. 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™ (Itolizumab). www.biocon.com Follow-us on Twitter: @bioconlimited

¹ Herceptin® is a product of Hoffmann-La Roche Ltd.

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: an 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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