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Biocon, Mylan launch Ogivri in Australia

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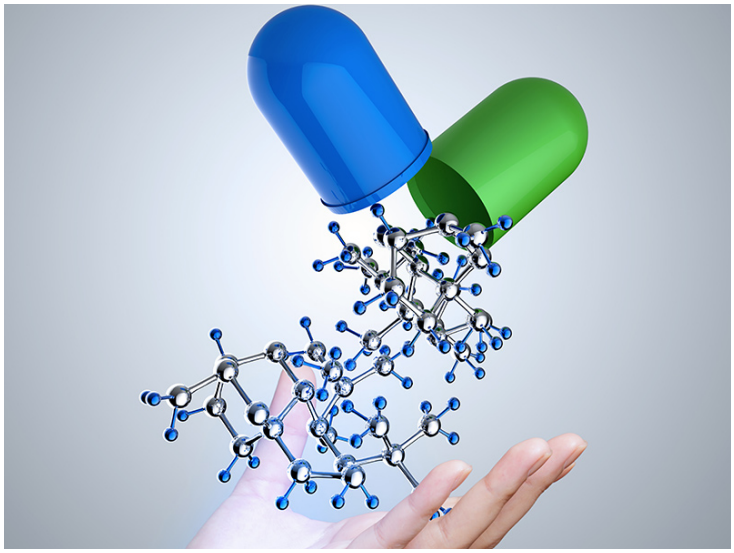

Biocon Ltd. and Mylan N.V. have announced the launch in Australia of Ogivri™ (trastuzumab), a biosimilar to Herceptin®[1] (trastuzumab), for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma).

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.