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Biocon and Mylan Announce Positive CHMP Opinion for Ogivri, Biosimilar Trastuzumab

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Ogivri is a biosimilar to Roche's Herceptin, which had brand sales of approximately $1.9 billion in Europe for the 12 months ending July 31, 2018



Biocon and Mylan announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Ogivri, a biosimilar to Roche's Herceptin (trastuzumab).

The positive CHMP opinion is based on data submitted as part of the Marketing Authorization Application which included similarity assessment in analytical testing, preclinical and clinical studies. Results demonstrated no clinically meaningful differences in quality, potency and safety; therefore, establishing biosimilarity to the reference product, Herceptin.

In addition, the Phase III clinical study (Heritage) demonstrated no clinically meaningful differences in terms of safety, efficacy and immunogenicity when compared to Herceptin in metastatic breast cancer patients, further reinforcing the highly similar nature of Ogivri. The CHMP positive opinion will now be considered by the European Commission. The decision on approval is expected by the end of 2018.

Ogivri is indicated for treatment of patients with HER2 positive early breast cancer (EBC), metastatic breast cancer (MBC) and metastatic gastric cancer (MGC). Under supervision of the relevant healthcare professional it can be prescribed as either monotherapy or in combination with other medicines dependent on the relevant diagnosis.

Dr Arun Chandavarkar, CEO and Joint Managing Director, Biocon said: "CHMP's positive opinion on Biocon and Mylan's biosimilar Trastuzumab is yet another endorsement of our ability to develop and manufacture complex biosimilars for the benefit of patients globally. This is the third molecule from our collaboration portfolio to receive positive opinion from the European CHMP. We shall continue to execute on our biosimilars strategy of expanding affordable access to high quality products targeting critical illnesses like cancer."

Mylan President Rajiv Malik commented: "Obtaining positive CHMP opinion for Ogivri is another significant achievement in Mylan's continued efforts to bring more affordable medicines to the market. The strong science and technology program

behind this product has been instrumental in achieving this milestone and moving us one step closer to providing patients with this alternative option. Mylan has a comprehensive and diverse biosimilars portfolio, and we are dedicated to bringing these complex medicines to market around the world."

Herceptin had brand sales of approximately $1.9 billion in Europe for the 12 months ending July 31, 2018, according to IQVIA. Ogivri was approved by the U.S. Food and Drug Administration (FDA) in 2017 and is the first FDA-approved biosimilar for Herceptin in the U.S. Additional regulatory approvals have been secured in 35 countries around the world.

Mylan and Biocon are exclusive partners on a broad portfolio of biosimilar and insulin products. Ogivri is one of 11 biologic and insulin 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.