BioSpectrum the business of Bio & Health Sciences

Biocon, Mylan launch Ogivri in the US

03 December 2019 | News

This FDA-approved product, co-developed by Biocon Biologics and Mylan, was unanimously recommended by the FDA Oncologic Drugs Advisory Committee

Biocon Ltd. and Mylan N.V. have announced the U.S. launch of Ogivri™ (trastuzumab-dkst), a biosimilar to Herceptin® (trastuzumab). Ogivri is available in a 420mg multi-dose vial and a 150mg single-dose vial in order to provide patient dosing and treatment flexibility.

Ogivri was the first biosimilar trastuzumab approved by the U.S. Food and Drug Administration (FDA) and unanimously recommended by the FDA Oncologic Drugs Advisory Committee (ODAC). Ogivri is approved for all indications of Herceptin including for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). Trastuzumab and biosimilar trastuzumab products contain a Boxed Warning for cardiomyopathy, infusion reactions, pulmonary toxicity and embryo-fetal toxicity.

Two supplemental Biologics License Applications were recently approved by the FDA, expanding the manufacturing capability for Ogivri, as well as Mylan and Biocon's first U.S. biosimilar, Fulphila®, a biosimilar to Neulasta®. Mylan and Biocon Biologics have sufficient manufacturing capacity to fulfil demand in the U.S. and global markets for both products.

Dr Christiane Hamacher, CEO, Biocon Biologics, said: "The U.S. launch of Ogivri, the biosimilar trastuzumab co-developed by Biocon Biologics and Mylan, marks a significant milestone in our biosimilars journey. It is an important endorsement of our science, development and manufacturing capabilities in the area of monoclonal antibodies. The introduction of both 420mg multi-use vials and 150mg single-use vials of a high quality biosimilar trastuzumab with robust long-term efficacy and safety data will offer greater choice and value to patients, prescribers and payors in the U.S. As a global frontrunner in biosimilars, Biocon Biologics is committed to fulfil unmet patient needs by providing greater affordability for enhanced patient access. We aspire to serve 5 million patients through our biosimilars portfolio and cross a revenue milestone of US$ 1bn by FY22."

Mylan President Rajiv Malik commented: "As one of the largest suppliers of oncology medicines in the U.S., we are proud to offer Ogivri, biosimilar trastuzumab, in both the 420mg and 150mg strengths and help increase more affordable access to this important treatment option for breast and gastric cancer patients. With regulatory approval for our biosimilar trastuzumab in more than 80 countries worldwide, we are bringing vast global biosimilars experience to the U.S. and look forward to continuing our work with all stakeholders in the healthcare system to reduce costs, improve access and advance care. With Ogivri, Fulphila and our generic oncology portfolio, Mylan is uniquely positioned to provide a broad range of treatment options

for oncology patients.”

FDA approval of Ogivri was based on robust data demonstrating that Ogivri is highly similar to Herceptin and no clinically meaningful differences exist between the biosimilar product and Herceptin in terms of safety, purity and potency. Long-term results of the landmark HERITAGE study including overall survival data at 36 months were presented at this year’s American Society of Clinical Oncology (ASCO) Annual Meeting.

Dr. Hope S. Rugo, professor of medicine at the University of California, San Francisco, and lead author of the HERITAGE study commented: “Trastuzumab-dkst (Ogivri) has many firsts to its credit. It was one of the first biosimilar oncology products to get a unanimous approval vote at an ODAC meeting, and it was the first biosimilar study to be published in the Journal of the American Medical Association. In this context, the HERITAGE study had a unique trial design that not only evaluated objective response rate at week 24 as its primary endpoint but also assessed key endpoints including progression-free survival rate and overall survival at 36 months. The concordant efficacy data across all three endpoints conclusively demonstrated that Ogivri was similar to Herceptin, and patients without progression now continue on Ogivri as maintenance therapy. We are pleased that patients with HER2-positive cancers now have an additional treatment option backed by robust safety and efficacy data, including long-term 36-month data. The worldwide introduction of this agent has already improved access to trastuzumab.”