BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

EMA accepts marketing authorization applications for Mylan and Biocon's proposed biosimilars

01 December 2017 | News

European Medicines Agency (EMA) has accepted for review Mylan's Marketing Authorization Applications for proposed biosimilar trastuzumab and proposed biosimilar pegfilgrastim

India's biopharmaceutical giant Biocon, today announced that the European Medicines Agency (EMA) has accepted for review Mylan's Marketing Authorization Applications (MAA) for proposed biosimilar trastuzumab and proposed biosimilar pegfilgrastim.

Trastuzumab is used to treat certain HER2-positive breast and gastric cancers. Pegfilgrastim is used to reduce the duration of neutropenia (low count of neutrophils, a type of white blood cells) and the incidence of fever associated with neutropenia in adult patients treated with chemotherapy in certain types of cancer.

EMA acceptance of the submissions follows an earlier withdrawal of both applications in response to an audit conducted by the European inspecting authority of Biocon's drug product facility. Biocon has completed the Corrective and Preventive Actions (CAPAs) outlined as a result of the audit observations. The CAPAs will be confirmed during reinspection, which will be completed as part of the regulatory review process.

Good Manufacturing Practice (GMP) compliance certificates for Biocon's two drug substance manufacturing facilities in Bangalore have been issued previously. Approval of these sites is key in the development and approval process as drug substance manufacture is core to the production of the actual biologic product in GMP compliance.

Mylan President Rajiv Malik commented: "We are extremely pleased with the acceptance of our MAAs. Having gone through initial reviews of the applications and after completing the CAPAs from the EMA audit, we are even more confident with the strength of our MAAs. Additionally, the Voluntary Action Indicated (VAI) designation we received from FDA gives us further confidence in the readiness of the manufacturing site. We now look forward to moving ahead with the rest of the regulatory review process in Europe and to bringing these important treatment options to cancer patients.

“These developments also demonstrate Mylan’s commitment to our partnership with Biocon, the strength of the collaboration’s scientific and manufacturing capabilities, and our relentless approach to increasing access to and affordability of important treatment options in Europe and around the world through the introduction of biosimilars.”

Dr Arun Chandavarkar, CEO & Joint Managing Director, Biocon said: “EMA’s acceptance for review of the Marketing Authorization Applications (MAAs) for our proposed biosimilars of trastuzumab and pegfilgrastim is indeed a welcome development. These applications were resubmitted upon completion of the Corrective and Preventive Actions (CAPAs), including the modifications of our aseptic drug product facility. We expect these CAPAs to be verified during inspection as part of the review process. We continue to work closely with our partner Mylan in engaging with EMA to provide these high quality, affordable therapy options for cancer patients in Europe.”