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Biocon & Mylan's biosimilar gets Brazilian approval

29 December 2017 | News

Libbs Farmaceutica will commercialize the product in Brazil under the brand name Zedora.

The biosimilar trastuzumab has been approved by ANVISA, the Brazilian regulatory agency. Co-developed by Biocon and Mylan, this is the first biosimilar trastuzumab to be approved in Brazil and is indicated for the treatment of overexpressing HER2-positive metastatic breast cancer, HER2-positive early stage breast cancer and HER2-positive advanced gastric cancer.

A leading Brazilian pharmaceutical company, Libbs Farmaceutica will commercialize the product in Brazil under the brand name Zedora, which will provide affordable access to a cutting-edge biologics therapy for patients in Brazil.

Biocon and Mylan are responsible for the development of biosimilar trastuzumab. While currently the trastuzumab will be manufactured by Biocon and supplied to Libbs for commercialization in Brazil; over a period of time the technology will be transferred to Libbs and the public partner Butantan through a Productive Development Partnership (PDP). Libbs have already built the biotechnological site to manufacture Zedora for the Brazilian market.

Biocon and Mylan's biosimilar trastuzumab is also under review by regulatory authorities in Australia, Canada, Europe and several additional markets. It is already approved in several other countries around the world, including India, where it is providing increased access to this more affordable biologic for cancer patients.