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Biocon Biosimilar Trastuzumab receives approvals in EU

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The European Commission has granted Marketing Authorization for Ogivri to Biocon's partner Mylan.



Ogivri, a biosimilar Trastuzumab jointly developed by Biocon and Mylan, has been approved in the EU. The European Commission has granted Marketing Authorization for Ogivri to Biocon’s partner Mylan.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP} previously issued a positive opinion recommending approval of Ogivri as a biosimilar to Roche's Herceptin (Trastuzumab) on October 18,2018.

Ogivri is indicated for the 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.