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European Medicines Agency approves Biocon Biologics' new mAbs facility in India

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Receives renewal of GMP certifications for India and Malaysia sites

Biocon Biologics Ltd (BBL), a global, fully integrated biosimilars company and a subsidiary of Biocon Ltd, has received approval from the European Medicines Agency (EMA) to manufacture biosimilar Bevacizumab at its new, world-class, multi-product monoclonal antibodies (mAbs) drug substance facility at Bengaluru.

This approval will provide significant additional capacity to address patients' needs across markets in Europe. The facility has previously been approved to manufacture biosimilar Trastuzumab in September 2022.

The company has also announced that EMA has renewed its Good Manufacturing Practice (GMP) Certificates of Compliance for its biosimilars manufacturing facility at Bengaluru and its insulin facility in Malaysia following routine GMP inspections. These certificates were issued by the Health Products Regulatory Authority (HPRA), Ireland, on behalf of EMA.