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Biocon gets US FDA approval for Pebrilzoâ?¢ Injection, biosimilar to PerjetaÂ®, expanding oncology portfolio

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An important step toward broadening treatment option for patients with HER2-positive breast cancer in the United States



Biocon has announced that the US Food and Drug Administration (FDA) has approved Pebrilzo™ (pertuzumab-qcay), a biosimilar of the reference product Perjeta® (pertuzumab). PEBRILZO is a monoclonal antibody used to treat HER2-positive breast cancer by blocking HER2 receptors on cancer cells. The FDA approval further strengthens Biocon's oncology portfolio.

In September, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had given a positive opinion recommending the granting of a marketing authorisation for Biocon's Pertuzumab biosimilar as 420 mg/14 mL concentrate solution for infusion, under the brand name Pebrilzo®, for the treatment of HER2â??positive breast cancer across multiple disease stages in Europe.

Biocon also announced a global settlement and license agreement with Genentech securing the earliest licensed launch date for PEBRILZO in the United States in Q3 of calendar year 2028.

Biocon's oncology strategy combines an established portfolio with continued development across additional treatment approaches. PEBRILZO will join its robust portfolio of oncology therapies, which includes Ogivri® (trastuzumab-dkst), Jobevne® (bevacizumab-nwgd), Fulphila® (pegfilgrastim-jmdb), and Aukelso® (denosumab-kyqq). Building on this foundation, Biocon's growing oncology pipeline includes proposed biosimilars to trastuzumab/hyaluronidase, nivolumab and pembrolizumab, spanning HER2-directed therapy and immuno-oncology.