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Biocon announces approval for biosimilar Pertuzumab in Brazil through local partner Bionovis

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For the treatment of HER2-positive breast cancer across multiple disease stages



Biocon has announced that Brazil's regulatory authority, ANVISA, has approved Hertuzo® (pertuzumab), its biosimilar licensed to local partner Bionovis, for the treatment of HER2-positive breast cancer across multiple disease stages.

The approval builds on Biocon's landmark 10-year Productive Development Partnership (PDP) with Bionovis and Bahiafarma in Brazil, providing the consortium an opportunity to supply locally manufactured biosimilar pertuzumab to Brazil's public healthcare market.

The development follows the recent US FDA approval and European Commission marketing authorisation of Biocon's biosimilar pertuzumab, further strengthening its global oncology portfolio.

The availability of locally manufactured biosimilar pertuzumab has the potential to deliver cost savings to Brazil's public healthcare system while improving patient access to an important cancer therapy.

Hertuzo® is a biosimilar to the reference biological medicine Perjeta®. The approval was based on the totality of evidence from a comprehensive comparability assessment demonstrating biosimilarity to the reference product.

Hertuzo®, approved as a 420 mg concentrate for solution for infusion, is a biosimilar medicinal product and the active substance is Pertuzumab, a monoclonal antibody that binds with high affinity and specificity to the human epidermal growth factor receptor 2 (HER2), inhibiting the proliferation of tumour cells that overexpress HER2.