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ASIA EDITION

Henlius and Organon Secure EC Approval for First Pertuzumab Biosimilar in Europe

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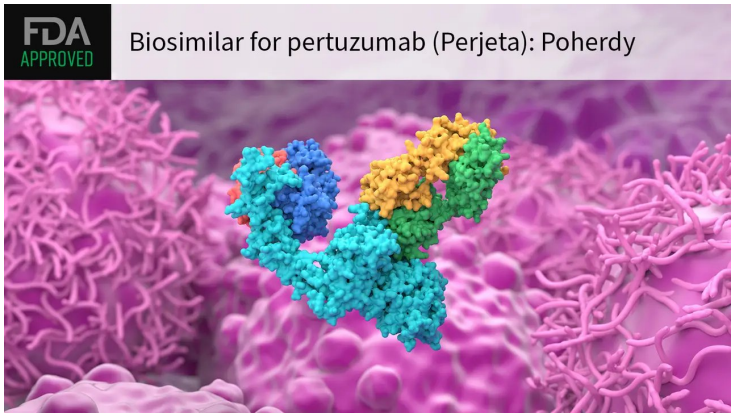
POHERDY becomes the first and only approved biosimilar to Perjeta in Europe, expanding treatment access for eligible HER2-positive breast cancer patients.



Shanghai Henlius Biotech and Organon have received European Commission marketing authorisation for POHERDY, a pertuzumab biosimilar for intravenous use.

The approval makes POHERDY the first and only approved biosimilar to Perjeta in Europe, marking a significant regulatory and commercial milestone in the HER2-positive breast cancer treatment landscape. For European healthcare systems, the development adds a new biosimilar option in an area where treatment access, biologics affordability and long-term oncology care sustainability remain important priorities.

POHERDY is authorised for all indications of the reference product in Europe. It is indicated in combination with trastuzumab and docetaxel for adults with HER2-positive metastatic or locally recurrent unresectable breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. It is also indicated with trastuzumab and chemotherapy as neoadjuvant treatment for adults with HER2-positive locally advanced, inflammatory or early-stage breast cancer at high risk of recurrence, and as adjuvant treatment for adults with HER2-positive early breast cancer at high risk of recurrence.

The approval was based on a comprehensive data package, including structural and functional analytical data, clinical pharmacokinetic data and comparative clinical studies. The evidence demonstrated that POHERDY is highly similar to the reference product based on totality of evidence across analytical, pharmacokinetic, efficacy, safety and immunogenicity parameters.

The milestone builds on Henlius and Organon's 2022 license and supply agreement, under which Organon received exclusive global commercialisation rights to several Henlius biosimilars, including POHERDY, outside China. The collaboration combines Henlius' biosimilar development and manufacturing capabilities with Organon's commercial footprint across global markets.

For Henlius, the EC approval strengthens its global biosimilar track record, with the company reporting regulatory approvals for 10 products across more than 60 countries and regions as of early 2026. For Organon, POHERDY expands its biosimilars portfolio and supports its focus on women’s health and access to essential medicines.