

Henlius & Accord Healthcare receives EMA approval for Zercepac®

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Zercepac® is the first monoclonal antibody (mAb), and the third biosimilar, launched by Accord in Europe and is the first mAb developed by Henlius to be approved in the EU.



The European Commission (EC) has approved Shanghai-based Henlius Biotech, Inc. and Accord Healthcare Limited (Accord)'s Zercepac®, biosimilar trastuzumab, for the treatment of certain patients with HER2-positive early breast cancer, HER2-positive metastatic breast cancer, and previously untreated HER2-positive metastatic gastric cancer.

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Dr Scott Liu, co-founder, and CEO of Henlius, said, "Henlius' mission is to improve patients' lives by providing them with quality and affordable protein therapeutics through technical innovation and operational excellence. The approval of Zercepac® in the EU is a significant milestone in our global strategy. This achievement announces that our capability in the development and manufacturing of biologics has reached international standards. In the future, Henlius will provide more high-quality biologics as new treatment options to benefit patients worldwide."