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EMA accepts First "China-Developed" Biosimilar - Henlius HLX02 MAA for Review

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HLX02 established 3 "Firsts" in China and globally- First China biosimilar to conduct a multi-centre, international Ph 3 clinical trial, First trastuzumab developed in China following NMPA technical guideline with NDA

Henlius

Henlius, a leading biotech company in China developing both biosimilar and innovative biologics, on 21 June 2019, announced that the European Medicines Agency (EMA) has officially accepted to review the Marketing Authorization Application (MAA) of its trastuzumab biosimilar HLX02. The European rights of this product have been out-licensed to its business partner Accord Healthcare. HLX02 is indicated for human epidermal growth factor receptor 2-positive (HER2+) early-stage breast cancer, HER2+ metastatic breast cancer, and untreated HER2+ metastatic gastric and gastroesophageal junction (GEJ) cancer.

The New Drug Application (NDA) of HLX02, a biosimilar of a classical targeted therapy for cancers, has been accepted for review by the National Medical Products Administration (NMPA) in China. The acceptance for review by the EMA demonstrates that the "China-developed" biosimilar has entered the global stage with the hope to benefit patients globally.

"We are very pleased to receive the EMA acceptance to review of our trastuzumab biosimilar HLX02 MAA submission," said Dr Scott Liu, co-Founder, President and CEO at Henlius. "It shows that our clinical, medical, regulatory affairs and quality system capabilities have been internationally recognized. We plan to work closely with EMA on this HLX02 MAA and hope to benefit HER2+ cancer patients globally with its high-quality and affordability."

The Phase 3 study aimed for head-to-head similarity evaluation in efficacy, safety and immunogenicity profiles between HLX02 and reference trastuzumab sourced from the European Union (EU) in 649 previously untreated patients with HER2+ metastatic breast cancer in mainland China, Ukraine, Poland and the Philippines. The Phase 1 study has successfully demonstrated the equivalence in pharmacokinetics and safety profiles between HLX02 and reference trastuzumab sourced from both EU and China.

Apart from the R&D and innovation efforts, Henlius is also actively creating new business models and expanding its global presence. The acceptance of the regulatory submission of trastuzumab biosimilar HLX02 MAA in Europe is another example of strong progress Henlius continues to make across the robust biosimilars portfolio. The acceptance of HLX02 MAA review marks a key milestone for the collaboration between Henlius and its partner Accord. In June 2018, Henlius signed the licensing and supply agreements with Accord. Under this partnership, Accord is exclusively authorized to commercialize HLX02 in 53 countries including UK, France, Germany, and Italy in Europe; 17 countries in Middle East-North Africa ("MENA") and certain countries in Commonwealth of Independent States ("CIS").

Henlius has strong capabilities in integrated innovation. Its first rituximab injection (HLX01) has been successfully launched in China. Currently, both HLX02 (trastuzumab biosimilar) and HLX03 (adalimumab biosimilar) NDAs are under NMPA review. Henlius has a robust R&D pipeline with IND/CTA filings for 13 products and two combination therapies in 23 indications.