BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

NMPA approves China's first trastuzumab biosimilar

18 August 2020 | News

Henlius Biotech recently announced that the trastuzumab biosimilar HLX02, developed and manufactured by Henlius independently.

Shanghai-based Henlius Biotech, Inc. (HK) recently announced that the trastuzumab biosimilar HLX02, developed and manufactured by Henlius independently, has been approved by the National Medical Products Administration (NMPA). On 27th July, HLX02 (EU brand name Zercepac®) has also been approved by the European Commission (EC), making HLX02 the first China-developed mAb biosimilar to be approved both in China and in the EU.

The common name of HLX02 is trastuzumab injection and it is indicated for the treatment of HER2-positive early breast cancer, HER2-positive metastatic breast cancer and HER2-positive metastatic gastric cancer. Trastuzumab has been included in China's National Reimbursement Drug List (NRDL) in 2017. During the development process of HLX02 , Henlius strictly followed the NMPA and European Medicines Agency (EMA) biosimilar guidelines and has taken multiple head-to-head comparisons between HLX02 and the reference trastuzumab. Results from analytical studies, preclinical studies, a Phase 1 clinical study and a global multi-center Phase 3 clinical study showed that HLX02 is highly similar to the reference trastuzumab in terms of quality, safety and efficacy.

Henlius has implemented the concept of QbD (quality by design) in process development for HLX02 and has adopted single-use technology for its manufacturing, leading to a decreased risk of contamination and increased production efficiency. The manufacturing site of HLX02 and its quality management system have passed multiple on-site inspections and audits by NMPA, EMA, EU Qualified Persons (QP) and international business partners of Henlius, and have obtained China and EU GMP certificates.