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Henlius, Accord receive EMA approval for Zercepac®, trastuzumab biosimilar

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Zercepac (HLX02) potentially treat HER2-positive early-stage breast cancer, HER2-positive metastatic breast cancer and untreated HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction.

Shanghai Henlius Biotech, Inc. announced that Marketing Authorization Application ('**MAA**") for HLX02 (trastuzumab for injection, EU trade name: Zercepac®) submitted by Accord Healthcare S.L.U., a wholly-owned subsidiary of the Company's business partner Accord Healthcare Limited, has recently been approved by the European Commission ('**EC**"). HLX02 is potentially for the treatment of HER2-positive early-stage breast cancer, HER2-positive metastatic breast cancer and untreated HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction. Upon being approved, centralized marketing authorization in respect of HLX02 is granted in all EU Member States as well as in Iceland, Liechtenstein and Norway (each a European Economic Area (EEA) country).

The approval of EC is mainly based on the review of a series of study data of HLX02, including analytical characterization studies, preclinical studies and clinical studies. The results confirmed the biosimilarity of Zercepac®(HLX02), demonstrating comparable efficacy and safety to the reference product, Herceptin®.

In April 2020, Shanghai Henlius Biopharmaceutical Co., Ltd. a wholly-owned subsidiary of the Company, received two Certificates of GMP Compliance of a Manufacturer from Poland's Chief Pharmaceutical Inspector. The Company's drug substance (DS) line and drug product (DP) line for HLX02 trastuzumab biosimilar at Xuhui District, Shanghai has successfully passed the Good Manufacturing Practice (GMP) on-site inspection by the EU. In May 2020, the MAA of HLX02 submitted by Accord Healthcare S.L.U. has adopted a positive opinion and recommended approval for MAA from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

Zercepac® (HLX02) is a monoclonal antibody biosimilar independently developed by the Company in accordance with the guiding principles on biosimilar in the PRC and EU, for the treatment of HER2-positive early-stage breast cancer, HER2-positive metastatic breast cancer and untreated HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction. In April 2019, the NDA of HLX02 was accepted by the National Medical Products Administration ("**NMPA**") and has been assigned to the priority review and approval list by the NMPA.

As of the date of this announcement, the trastuzumab available in the EU and Iceland, Liechtenstein and Norway (each an EEA country) include Herceptin® of Roche, Herzuma® of Celltrion, Ontruzant® of Samsung Bioepis, etc. According to the information provided by IQVIA MIDAS™ (IQVIA is a world-leading provider of professional medical and health information and strategic consultation), in 2019, the sales of trastuzumab in the EU and Iceland, Liechtenstein and Norway (each an EEA country) were approximately USD1.368 billion.