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Henlius biosimilar HLX02 gets NDA acceptance from NMPA

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HLX02 is a biosimilar developed by Henlius with independent intellectual property for the treatment of HER2 positive metastatic breastcancer (BC) and metastatic gastric cancer (GC)



Shanghai Henlius Biotech, Inc., subsidiary of Shanghai Fosun Pharmaceutical Group Co. has recently received a New Drug Application (NDA) acceptance from the National Medical Products Administration (NMPA) for its biosimilar HLX02, a trastuzumab for injection.

HLX02 is the first trastuzumab conducted multi-center, global phase 3 clinical trial with head–to-head comparison, and also the third product of Henlius which received NDA acceptance following on HLX01 (Rituximab Injection) and HLX03 (Adalimumab Injection).

Clinical Studies with Rigorous Design and Solid Data

HLX02 is a biosimilar developed by Henlius with independent intellectual property for the treatment of HER2 positive metastatic breastcancer (BC) and metastatic gastric cancer (GC). In July 2015 and January 2016, HLX02 was approved by the CFDA (now China NMPA) for IND in patients with BC and GC successively. A phase 1 clinical trial of HLX02 was demonstrated pharmacokinetics equivalence with trastuzumab (German sourced) and trastuzumab (China sourced) and similar safety and immunogenicity profiles in healthy Chinese males. The result showed similarity between HLX02 and the two original trastuzumab from different sources.

In order to benefit more patients with unmet medical needs, Henlius conducted a head-to-head comparison studies of HLX02 worldwide align with regional and global regulatory requirements, making HLX02 the first domestic biosimilar conducted global multi-center phase 3 clinical studies. Recently, the clinical studies have finished enrollment in mainland China, Ukraine, Poland and the Philippines.

Henlius also established global partnership to help HLX02 explore overseas markets. In December 2017, Henlius and Jacobson Group established a licensing framework agreement. Under this agreement, Jacobson Medical will be granted an exclusive rights to develop and market HLX02 in HongKong and Macau, and a right of first negotiation for certain countries within the Association of Southeast Nations (“ASEAN”). In June 2018, Henlius has executed license and supply agreements with Accord. Under this partnership,Accord is exclusively authorized to commercialize HLX02 in 53 countries including UK, France, Germany, Spain, Italy in Geographical Europe, 17 countries in Middle East-North Africa (“MENA”) and certain

countries in Common wealth of Independent States (“CIS”).

Furthermore, Henlius and Cipla Ltd.(“Cipla”), a leading global pharmaceutical company in India, have executed license and supply agreements, whereby Cipla has obtained exclusive authorization for developing and commercializing HLX02 in select emerging markets in Asia Pacific and Latin America.

"We are very pleased to receive the NMPA acceptance of HLX02 NDA,” Dr. Scott Liu, the co-Founder, President and CEO at Henlius said, “with the successful NDA approval of HLX01, Henlius plans to further expand our footprints to more countries around the world leveraging the Company’s advantage of global integrated innovation. Looking forward, Henlius will continue to bring high-quality, antibody-based therapeutics in compliance with international standards to be the most trusted and admired biotech company.”