Shanghai Henlius Biotech, Inc.
上海復宏漢霖生物技術股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 2696)

INSIDE INFORMATION ANNOUNCEMENT MARKETING AUTHORIZATION APPLICATION (MAA) FOR HLX02 (TRASTUZUMAB FOR INJECTION, EU TRADE NAME: ZERCEPAC®) BEING APPROVED BY THE EUROPEAN COMMISSION (EC)

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited ("**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571, Laws of Hong Kong).

The board of directors of the Company (the "**Board**") is pleased to announce that Marketing Authorization Application ("**MAA**") for HLX02 (trastuzumab for injection, EU trade name: Zercepac®) ("**HLX02**") submitted by Accord Healthcare S.L.U., a wholly-owned subsidiary of the Company's business partner Accord Healthcare Limited ("**Accord**"), 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, a 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).

B. BASIS FOR THE APPROVAL

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. These data prove that HLX02 and reference listed drug (Herceptin®) are highly similar in terms of quality, safety and efficacy.

In April 2020, Shanghai Henlius Biopharmaceutical Co., Ltd. (上海復宏漢霖生物製藥有限公司), 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 have 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. was 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).

C. ABOUT HLX02

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.

WARNING STATEMENT REQUIRED BY RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: We may not be able to ultimately commercialise HLX02 successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Qiyu CHEN
Chairman

Hong Kong, 29 July 2020

As at the date of this announcement, the board of directors of the Company comprises Dr. Scott Shi-Kau Liu as the executive director, Mr. Qiyu Chen as the chairman and non-executive director, Mr. Yifang Wu, Ms. Xiaohui Guan, Dr. Aimin Hui and Mr. Zihou Yan as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.