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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 RECEIPT OF EUROPEAN UNION GMP CERTIFICATES

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 (the “**Board**”) of the Company is pleased to announce that, 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, has recently received two “Certificates of GMP Compliance of a Manufacturer” (the “**GMP Certificates**”) respectively in relation to the certification of drug substance (DS) and drug product (DP), which are issued by Chief Pharmaceutical Inspector, a health regulatory body in Poland. The Company’s biopharmaceutical manufacturing facility in Xuhui, Shanghai, (the “**Xuhui Facility**”) has successfully passed the GMP inspection by the European Union (“**EU**”) in respect of HLX02 (trastuzumab for injection) drug substance (DS) and drug product (DP).

B. GMP CERTIFICATES

Set out below is the summary of the DS GMP Certificate for the Xuhui Facility:

Company name:	Shanghai Henlius Biopharmaceutical Co., Ltd.
Address:	Block D, 1289 Yishan Road, Xuhui District, Shanghai
Certified product:	HLX02 (trastuzumab for injection) (lyophilized powder) (150mg/bottle)
Certification scope:	Drug substance (DS) south line, cell bank preparation, storage and management
Valid period:	3 years from 9 December 2019
Certificate no.:	IWSC.405.12.2020.ABU.1 WTC/0606_01_02/70

Set out below is the summary of the DP GMP Certificate for the Xuhui Facility:

Company name:	Shanghai Henlius Biopharmaceutical Co., Ltd.
Address:	Block D, 1289 Yishan Road, Xuhui District, Shanghai
Certified product:	HLX02 (trastuzumab for injection) (lyophilized powder) (150mg/bottle)
Certification scope:	Lyophilized drug product line (DP)
Valid period:	3 years from 9 December 2019
Certificate no.:	IWSF.405.36.2020.KK.1 WTC/0606_01_01/68

* for identification purpose only

C. DESCRIPTION OF THE CERTIFIED PRODUCT AND ITS MARKET CONDITION

HLX02 (trastuzumab for injection) is a biosimilar monoclonal antibody independently developed by the Company based on the European Union guideline on biosimilar biological medicinal products, which is intended to be used for the treatment of HER2-positive early breast cancer, HER2-positive metastatic breast cancer and HER2-positive metastatic gastric cancer indications. In April 2019, the New Drug Application (NDA) of HLX02 (trastuzumab for injection) was accepted by the National Medical Products Administration, and was subsequently granted the priority review status. In June 2019, the Marketing Authorisation Application (MAA) in relation to HLX02 (trastuzumab for injection) submitted by the Company's business partner Accord Healthcare Limited was accepted by European Medicines Agency (EMA).

As at the date of this announcement, the trastuzumab sold worldwide mainly included Herceptin® of Roche, Kanjinti® of Amgen/Allergan, and Herzuma® of Celtrion, etc. According to the information of IQVIA MIDAS™ (IQVIA is a leading provider of professional medical and health information and strategic consultation), the global sales of trastuzumab in 2019 was approximately US\$6.143 billion.

D. IMPACT ON THE COMPANY AND RISK NOTICE

According to the GMP mutual recognition system of EU member states, the receipt of the GMP Certificates from Chief Pharmaceutical Inspector, a health regulatory body in Poland, indicates that the Company's Xuhui Facility has met the GMP standards of the EU. The launch of HLX02 (trastuzumab for injection) in the European Union remains subject to EU Marketing Authorisation Application (MAA) approval after the receipt of the GMP Certificates. In addition, set out below is the warning statement required by Rule 18A.05 of the Rule Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: **The Company cannot guarantee the successful development and commercialisation of HLX02. 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, 23 April 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.