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)

VOLUNTARY ANNOUNCEMENT

OBTAINED THE BRAZILIAN GMP CERTIFICATES

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Company.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, 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 received two "Good Manufacturing Practices Certificates" (the "GMP **Certificates**") in relation to the certification of drug substance (DS) and drug product (DP) respectively issued by the Brazilian National Health Surveillance Agency (the "**ANVISA**"), pursuant to which the Company's biopharmaceutical production base in Xuhui District, Shanghai (Xuhui Facility) has successfully passed the GMP inspection by ANVISA for drug substance (DS) and drug product (DP) of HLX01 (rituximab injection) and HLX02 (trastuzumab for injection).

B. GMP CERTIFICATES

Company name:	Shanghai Henlius Biopharmaceutical Co., Ltd.
Address:	(Building D) Block 1, No. 1289 Yishan Road, Xuhui district, Shanghai
Certified product:	HLX01 (rituximab injection) and HLX02 (trastuzumab for injection)
Certification scope:	the drug substance (DS) and drug product (DP) production lines
Valid until:	16 October 2025
Certificate no.:	WCNE.TDHE.IKHW.QT1K.6MQA.MNLY.YQ9J.XYJ9.E0D5.SUTT; 4898622/22-4

C. ABOUT THE CERTIFIED PRODUCT AND ITS MARKET CONDITION

HLX01 (rituximab injection, trade name in mainland China: HANLIKANG) ("**HANLIKANG**"), a rituximab independently developed by the Company, was approved for commercialization in Mainland China (excluding Hong Kong, Macao and Taiwan regions, the same as below) by National Medical Products Administration ("**NMPA**") in February 2019. As of the date of this announcement, indications of HANLIKANG approved are: (1) Non-Hodgkin's lymphoma; (2) Chronic Lymphocytic Leukemia (CLL); and (3) Rheumatoid Arthritis (RA).

As of the date of this announcement, in addition to the Company's HLX01 (rituximab injection), the rituximab drugs that have been marketed globally include MabThera® of Roche Pharma, Truxima® of Teva Pharmaceutical and Ruxience® of Pfizer Inc.. According to the information provided by IQVIA MIDAS™ (IQVIA is a world-leading provider of professional medical and health information and strategic consultation), the global sales of trastuzumab in 2022 was approximately US$5.028 billion.

HLX02 (trastuzumab for injection, trade name in mainland China: HANQUYOU; European trade name: Zercepac®) is a monoclonal antibody biosimilar independently developed by the Company in accordance with the guidelines for biosimilar in the mainland China and the European Union (the "**EU**") with dual approvals in mainland China and the EU, for the adjuvant treatment of HER2-positive breast cancer and the treatment of HER2-positive breast cancer and gastric cancer. For mainland China, HANQUYOU (trastuzumab for injection) with the strength of 150mg/vial was approved by the NMPA for marketing in August 2020 and its supplemental new drug application (sNDA) for a new strength of 60mg/vial was also approved by the NMPA in August 2021. For oversea markets, Zercepac® (trastuzumab for injection) with the strength of 150mg/vial was approved by the European Commission ("**EC**") for marketing in the EU in July 2020 and its sNDA for strengths of 60mg/vial and 420mg/vial were also approved by the EC in 2021. The exclusive right to commercialize Zercepac® in geographical Europe was granted to Accord Healthcare Limited, a business partner of the Company. In addition to the aforementioned countries and regions, HLX02 (trastuzumab injection) was also approved for marketing in countries such as Australia, Cambodia, Singapore, Argentina etc. with the promotion of the Company's business partners.

As of the date of this announcement, in addition to the Company's HLX02 (trastuzumab injection), the trastuzumab drugs that have been marketed globally include Herceptin® of Roche Pharma, Kanjinti® of Amgen Inc. and Trazimera® of Pfizer Inc.. According to the information provided by IQVIA MIDAS™ (IQVIA is a world-leading provider of professional medical and health information and strategic consultation), the global sales of trastuzumab in 2022 was approximately US$3.958 billion.

D. IMPACT ON THE COMPANY AND RISK WARNING

ANVISA is a member of the Pharmaceutical Inspection Co-operation Scheme (the "**PIC/S**"). Obtaining the GMP Certificate from ANVISA marks that the drug substance (DS) and drug product (DP) production lines of HLX01 (rituximab injection) and HLX02 (trastuzumab for injection) meet the standards of PIC/S GMP. Notwithstanding, the launch of HLX01 (rituximab injection) and HLX02 (trastuzumab for injection) in Brazil remains subject to the approval of Marketing Authorization by the ANVISA.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 20 October 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang 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.

* *for identification purpose only*