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 COLOMBIAN GMP CERTIFICATION

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.

Reference is made to the announcement of the Company dated 5 December 2019 in relation to the Company having granted to Farma De Colombia S.A.S an exclusive license to commercialise Rituximab injection (trade name in mainland China: HANLIKANG) ("**HANLIKANG**") in Colombia, Peru, Ecuador and Venezuela.

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 the resolution of the Colombian National Food and Drug Surveillance Institute (the "**INVIMA**") to grant it the Certification of Good Manufacturing Practices of Biological Products (the "**GMP Certification**"), pursuant to which the Company's biopharmaceutical production base in Xuhui District, Shanghai (Xuhui Facility) has successfully passed the GMP inspection by the INVIMA for drug substance (DS) and drug product (DP) of HANLIKANG.

B. RELEVANT DETAILS OF THE GMP CERTIFICATION

Company name:	Shanghai Henlius Biopharmaceutical Co., Ltd.
Address:	(Building D) Block 1, No. 1289 Yishan Road, Xuhui district, Shanghai
Certified product:	Rituximab injection
Scope of certification:	North and south line for drug substance (DS); line 1 and line 2 for drug product (DP)
Valid period:	3 years commencing from 16 November 2023

C. ABOUT THE CERTIFIED PRODUCT AND ITS MARKET CONDITION

HANLIKANG, a rituximab independently developed by the Company, was approved for commercialisation in Mainland China (excluding Hong Kong, Macao and Taiwan regions) 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 HANLIKANG, 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 rituximab in 2022 was approximately US$5.028 billion.

D. IMPACT ON THE COMPANY AND RISK WARNING

Obtaining the Colombian GMP Certification laid a foundation for the Company to further expand the South American market of HANLIKANG. The launch of HANLIKANG in Colombia remains subject to Marketing Authorisation approval by the INVIMA.

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

Hong Kong, 28 November 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*