

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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
SUPPLEMENTAL APPLICATIONS FOR NEW INDICATIONS OF
HLX01 漢利康 (RITUXIMAB INJECTION) BEING ACCEPTED
BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION**

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 (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 the “Acceptance Notice” (Acceptance Number: CYSB2000106 Guo, CYSB2000107 Guo) of the supplemental applications for new indications of HLX01 漢利康 (rituximab injection) from the National Medical Products Administration (“**NMPA**”). The supplemental applications for two new indications of HLX01 漢利康 (rituximab injection) have been submitted.

B. BACKGROUND OF AND BASIS FOR SUBMISSION

HLX01 漢利康 (rituximab injection), being the first domestic mAb biosimilar independently developed by the Company, was approved for commercialisation in Mainland China (excluding Hong Kong, Macao and Taiwan regions, similarly hereinafter) on 22 February 2019. The indications approved are: (1) relapsed or refractory follicular central lymphoma; (2) previously-untreated CD20-positive stage III-IV follicular non-Hodgkin lymphoma; (3) CD20-positive diffuse large B cell non-Hodgkin lymphoma (DLBCL). In December 2019, the original rituximab MabThera® was approved for two new indications in Mainland China, that is, the monotherapy maintenance therapy after complete or partial response under MabThera® in combination with chemotherapy for patients with initially-treated follicular lymphoma, and fludarabine and cyclophosphamide (FC) combination therapy for patients with previously-untreated or relapsed/refractory chronic lymphocytic leukaemia (CLL).

According to the Technical Guidelines for R&D and Evaluation of Biosimilars (Trial) (《生物類似藥研發與評價技術指導原則(試行)》), when clinical similarities are proved in comparative trials, the indications of biosimilars may be expanded to include other indications of reference drugs. The expanded indications shall be those with same pathological mechanisms and/or receptors and the same action mechanisms and targets. In comparative trials, appropriate indications shall be selected and adequate evaluation shall be made on the safety and immunogenicity of the expanded indications. HLX01 漢利康 (rituximab injection) is a MabThera® biosimilar, and its indication may be reasonably expanded to monotherapy maintenance therapy after complete or partial response under rituximab in combination with chemotherapy for patients with initially-treated follicular lymphoma, and fludarabine and cyclophosphamide (FC) combination therapy for patients with previously-untreated or relapsed/refractory chronic lymphocytic leukaemia (CLL).

C. SIGNIFICANCE OF SUBMISSION

If the supplemental applications for new indications of HLX01 漢利康 (rituximab injection) are successfully approved by the NMPA, it will provide more medication options for domestic patients with follicular lymphoma and CLL.

D. MARKET CONDITION

As of the date of this announcement, the rituximab injections commercially available in Mainland China include MabThera® developed by Shanghai Roche Pharmaceuticals Ltd. and 漢利康 developed by Shanghai Henlius Biopharmaceutical Co., Ltd.* (上海復宏漢霖生物製藥有限公司). According to information provided by IQVIA CHPA (a world-leading provider of professional medical and health information and strategic consultation), the sales of rituximab injections amounted to approximately RMB2.505 billion in Mainland China in 2019.

E. RISK NOTICE

Given the uncertainties of drugs in supplementary application process and in market competitions in the future, 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, 19 May 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.

* for identification purpose only