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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)

VOLUNTARY ANNOUNCEMENT

BEVACIZUMAB INJECTION (RECOMBINANT ANTI-VEGF HUMANIZED MONOCLONAL ANTIBODY INJECTION, ORIGINAL PROJECT CODE: HLX04) PASSED GMP COMPLIANCE ON-SITE INSPECTION

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, recently, Shanghai Henlius Biopharmaceuticals 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 “Notification of the Results of the On-site Inspection of Pharmaceutical Production Base” issued by Shanghai Medical Products Administration, pursuant to which the biopharmaceutical production base of the Company in Xuhui district, Shanghai (the “**Xuhui Base**”) successfully passed the on-site inspection conducted by Shanghai Medical Products Administration at drug substance (“**DS**”) south line and drug product (“**DP**”) no.1 line for the production of bevacizumab injection (recombinant anti-VEGF humanized monoclonal antibody injection, original project code: HLX04) (“**Bevacizumab Injection**”).

B. OVERVIEW OF ON-SITE INSPECTION OF PHARMACEUTICAL PRODUCTION BASE

Name of enterprise	: Shanghai Henlius Biopharmaceuticals Co., Ltd.
Address of production base	: Whole building of (Building D) Block 1, No. 1289 Yishan Road, Xuhui district, Shanghai
Product subject to inspection	: Bevacizumab Injection
Scope of inspection	: DS south line and DP no.1 line
Conclusion of inspection	: Requirements under “Good Manufacturing Practice for Pharmaceutical Products” are passed

C. ABOUT BEVACIZUMAB INJECTION

Bevacizumab Injection is a monoclonal anti-VEGF biosimilar independently developed by the Company, which is planned to use for treatment of metastatic colorectal cancer and non-squamous non-small cell lung cancer indications. In August 2020, the phase 3 clinical study of the Bevacizumab Injection for the treatment of metastatic colorectal cancer has completed and the trial has met the pre-defined primary endpoint. The result of the trial showed that the efficacy of Bevacizumab Injection for first-line treatment of metastatic colorectal cancer is equivalent to that of reference bevacizumab (the “**Original Drug**”), and its safety, tolerability and immunogenicity are similar to the Original Drug. In September 2020, the new drug application (“**NDA**”) for Bevacizumab Injection has been accepted by the Center for Drug Evaluation of the National Medical Products Administration for the treatment of metastatic colorectal cancer and advanced, metastatic or recurrent non-small cell lung cancer.

As of the date of this announcement, the bevacizumab commercially available in mainland China (excluding Hong Kong, Macao and Taiwan regions, the same below) include Avastin® of Roche, Ankeda (安可達®) of Qilu Pharmaceutical Co., Ltd., and BYVASDA® of Innovent Biologics (Suzhou), Inc. According to the information provided by IQVIA CHAP (IQVIA is the world’s leading provider of professional information and strategic consulting services for the healthcare industry), the sales of bevacizumab in mainland China amounted to approximately RMB2,884 million and approximately RMB3,625 million in 2019 and 2020, respectively.

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 develop and ultimately commercialize Bevacizumab Injection 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, 27 April 2021

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang 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.