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
RESULTS OF A PHASE 3 CLINICAL STUDY OF HLX04 (RECOMBINANT HUMANISED ANTI-VEGF MONOCLONAL ANTIBODY INJECTION)

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, the Company has completed phase 3 clinical study in respect of HLX04 (recombinant humanised anti-VEGF monoclonal antibody injection, a bevacizumab biosimilar) ("**HLX04**") for the treatment of metastatic colorectal cancer (mCRC) (the "**Study**"), and the trial has met the pre-defined primary endpoint.

B. CLINICAL TRIAL DESIGN, PURPOSE AND CONCLUSION

This is a randomised, double-blind, multicentre, parallel-controlled Phase 3 study aimed to compare the efficacy, safety and immunogenicity of HLX04 to reference bevacizumab (hereinafter referred to as the "**reference bevacizumab**") in combination with chemotherapy (XELOX or mFOLFOX6) as first-line treatment in patients with metastatic colorectal cancer. The primary objective of the Study was to demonstrate the equivalent efficacy of HLX04 to reference bevacizumab, and the primary endpoint was progression free survival rate at 36 week ($PFSR_{36w}$). Secondary objectives include other efficacy evaluations of HLX04 compared to reference bevacizumab, and evaluations of the safety, tolerability and immunogenicity of HLX04 compared to reference bevacizumab.

The Study has met its primary and secondary objectives, demonstrating the equivalent efficacy of HLX04 to reference bevacizumab as first-line treatment for metastatic colorectal cancer. The safety, tolerability, and immunogenicity of HLX04 were similar to those of reference bevacizumab.

C. ABOUT HLX04

HLX04 is a monoclonal antibody biosimilar (bevacizumab biosimilar) developed by the Company independently. Currently, the Company is preparing to submit a new drug application (NDA) to the National Medical Products Administration of the PRC for the application of HLX04 for the treatment of metastatic colorectal cancer, and non-squamous, non-small cell lung cancer. At the same time, the Company is also actively carrying out the combination therapy study of HLX04 in combine with HLX10, the Company's innovative monoclonal antibody product (recombinant humanised anti-PD-1 monoclonal antibody injection), and the indications cover advanced solid tumor (phase 1 clinical trial), metastatic non-squamous, non-small cell lung cancer (phase 3 clinical trial) and advanced hepatocellular carcinoma (phase 2 clinical trial).

D. MARKET CONDITION OF BEVACIZUMAB

As at the date of this announcement, the bevacizumab commercially available in mainland China (excluding Hong Kong, Macao and Taiwan, 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 CHPA (IQVIA is a world-leading provider of professional medical and health information and strategic consultation), the sales of bevacizumab amounted to approximately RMB2.883 billion in mainland China in 2019.

WARNING STATEMENT REQUIRED BY RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: The Company cannot guarantee the successful development and commercialisation of HLX04. 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, 12 August, 2020

As at the date of this announcement, the Board 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.