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
SHANGHAI HENLIUS ISSUES LATEST CLINICAL STUDY DATA ON HLX04 (RECOMBINANT HUMANISED ANTI-VEGF MONOCLONAL ANTIBODY INJECTION) IN 23RD ANNUAL MEETING OF CSCO

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**" or "**Shanghai Henlius**") 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 the Company has recently issued the latest clinical study data on HLX04 (recombinant humanised anti-VEGF monoclonal antibody injection) ("**HLX04**") through oral reporting in the 23rd Annual Meeting of Chinese Society of Clinical Oncology (CSCO).

HLX04, A Bevacizumab Biosimilar, Versus Reference Bevacizumab in Combination with XELOX or mFOLFOX6 as First-line Treatment for Metastatic Colorectal Cancer (mCRC): A Phase 3 study

(A) Study design

HLX04-mCRC03 is a multicentre, randomised, double-blind, parallel-controlled Phase 3 study (NCT03511963) aimed to compare the efficacy, safety and immunogenicity of HLX04 to reference bevacizumab in combination with chemotherapy (XELOX or mFOLFOX6) as first-line treatment in patients with metastatic colorectal cancer (mCRC). Enrolled patients were randomised (1:1) to receive either HLX04 or reference bevacizumab intravenously (7.5mg/kg every 3 weeks when combined with XELOX or 5mg/kg every 2 weeks when combined with mFOLFOX6). The primary endpoint was progression-free survival rate at week 36 ($PFSR_{36wk}$).

(B) Results

1) Efficacy

a) Primary endpoint

675 patients were enrolled (HLX04, N=338; Reference bevacizumab, N=337). Per FAS, $PFSR_{36wk}$ was 46.4% in HLX04 group and 50.7% in reference bevacizumab group. The group difference was -4.2% (90% CI: -10.6%, 2.1%), which fell entirely in the pre-defined equivalence margins (-11%, 15%), demonstrating equivalent efficacy between HLX04 and reference bevacizumab.

b) Secondary endpoints

There was no statistically significant difference ($p > 0.05$) between the treatment groups in secondary endpoints, including overall survival (OS), progression-free survival (PFS), objective response rate (ORR), time to response (TTR) and duration of response (DoR).

2) Safety and immunogenicity

The safety and immunogenicity profiles were similar between HLX04 and reference bevacizumab.

(C) Conclusion

The results of the Phase 3 study demonstrated the equivalence in efficacy between HLX04 and reference bevacizumab with similar safety and immunogenicity profiles as first-line treatment for mCRC patients. HLX04 will provide an alternative treatment option for cancer patients as a potential biosimilar candidate.

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, 20 September 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.