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 PHASE 1 CLINICAL TRIAL OF ACE2-FC RECEPTOR FUSION PROTEIN HLX71(FOR THE TREATMENT OF NOVEL CORONAVIRUS PNEUMONIA)DEMONSTRATING GOOD SAFETY AND TOLERABILITY

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, ACE2-Fc receptor fusion protein HLX71 ("**HLX71**"), independently developed by the Company has completed the Phase 1 clinical study, which demonstrated good safety and tolerability in a Phase 1 clinical study conducted in healthy adult subjects.

B. CLINICAL TRIAL DESIGN, PURPOSE AND CONCLUSION

This is a randomised, double-blind, placebo-controlled, dose-escalation phase 1 study. Eight healthy adult subjects were enrolled in each of the four treatment groups (1 mg/kg, 3 mg/kg, 10 mg/kg and 15 mg/kg) and were randomized in each treatment group at a 3:1 ratio, with 6 subjects receiving HLX71 and 2 subjects receiving placebo. The primary objective of this study was to assess the dose-limiting toxicity (DLT), safety, and tolerability of HLX71. The secondary objectives included the evaluation of immunogenicity, pharmacodynamics, and pharmacokinetics of HLX71.

No DLTs were reported, and no new safety signals were observed during the study. The results demonstrated that HLX71 was safe and well tolerated in healthy adult subjects.

C. ABOUT HLX71

HLX71 is a recombinant human Angiotensin converting enzyme 2 (hACE2) fusion protein with IgG1 Fc at the C-terminal, which is independently developed by the Company. It is intended to be used in the treatment of novel coronavirus pneumonia (COVID-19). The mechanism of its action is that HLX71 can competitively bind to spike protein on the surface of SARS-CoV-2, thus inhibiting the binding of virus to Angiotensin converting enzyme 2 (ACE2) on the surface of host cells, and ultimately achieve the effect of inhibiting virus infection. According to the results of pre-clinical pharmacological study, pharmacokinetic study and safety evaluation, HLX71 could significantly inhibit the infection of SARS-CoV-2 virus with high safety level, which could be used in subsequent human clinical trials. In November 2020, the investigational new drug application (IND) of HLX71 for the treatment of novel coronavirus pneumonia (COVID-19) was approved by the U.S. Food and Drug Administration (FDA).

D. MARKET CONDITION

As at the date of this announcement, no ACE2-Fc receptor fusion protein drug for novel coronavirus pneumonia (COVID-19) has been approved for marketing globally.

WARNING STATEMENT WITH REFERENCE TO THE REQUIREMENTS UNDER 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 commercialization of HLX71. 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.
Wenjie Zhang
Chairman

Hong Kong, 14 March 2022

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. Qiyu Chen, 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.