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

THE FIRST SUBJECT HAS BEEN DOSED IN A PHASE 1 CLINICAL STUDY IN HEALTHY SUBJECTS OF HLX6018 (RECOMBINANT ANTI-GARP/TGF-β1 HUMANISED MONOCLONAL ANTIBODY INJECTION) IN MAINLAND CHINA

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 first subject has been dosed in a phase 1 clinical study in healthy subjects of HLX6018 (recombinant anti-GARP/TGF-β1 humanised monoclonal antibody injection) ("**HLX6018**") in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This randomised, double-blind, placebo-controlled, single-dose, dose-escalation phase 1 study aims to evaluate the safety, tolerability, pharmacokinetic characteristics, and immunogenicity of HLX6018 in healthy volunteers. Eligible subjects will be given different doses (0.25 mg/kg, 1.0 mg/kg, 4.0 mg/kg, 12 mg/kg, 25 mg/kg, 50 mg/kg, 70 mg/kg) of HLX6018 or placebo via intravenously infusion. The proposed male to female ratio in each dose group is close to 1:1. After all subjects in each dose group complete dosing and a 21-day safety observation period, the Safety Review Committee (the "**SRC**") will assess safety and decide whether to initiate the next dose group. After reaching the pre-planned maximum dose (70 mg/kg), the SRC will decide whether to explore higher dose levels. The primary endpoint of this study is safety evaluation, including the number and incidence of adverse events and serious adverse events, vital signs, physical examination, laboratory tests and 12-lead electrocardiogram; secondary endpoints include pharmacokinetic parameters and immunogenicity.

C. ABOUT HLX6018

HLX6018 is an innovative anti-GARP/TGF-β1 complex monoclonal antibody independently developed by the Company, which is intended to be used for the treatment of fibrosis-related diseases. Glycoprotein A Repetitions Predominant ("**GARP**") is a Type I transmembrane cell surface docking receptor for latent transforming growth factor-β1 ("**TGF-β1**"). The complex formed by GARP binding with latent TGF-β1 triggers structural changes by binding with integrins or cleavage by thrombin, releasing mature TGF-β1. HLX6018 can inhibit the release of mature TGF-β1 by specifically binding to the GARP/TGF-β1 complex, subsequently suppressing the TGF-β1-mediated activation, proliferation, and extracellular matrix secretion of fibroblasts to achieve the purpose of treating fibrosis-related diseases. Non-clinical studies have shown that HLX6018 has significant anti-pulmonary fibrosis and renal fibrosis effects and has a favorable safety profile. In March 2024, application for clinical trial of HLX6018 for the treatment of idiopathic pulmonary fibrosis was approved by the National Medical Products Administration.

D. MARKET CONDITION

As at the date of this announcement, no monoclonal antibody targeting GARP/TGF-β1 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 HLX6018. 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, 23 April 2024

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. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang 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.