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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

THE FIRST PATIENT HAS BEEN DOSED IN AN INTERNATIONAL MULTICENTER PHASE 2/3 CLINICAL STUDY COMPARING PIMURTAMAB HLX07 (RECOMBINANT ANTI-EGFR HUMANIZED MONOCLONAL ANTIBODY INJECTION) IN COMBINATION WITH HANSIZHUANG (SERPLULIMAB INJECTION) AND CHEMOTHERAPY VERSUS PLACEBO IN COMBINATION WITH HANSIZHUANG (SERPLULIMAB INJECTION) OR PEMBROLIZUMAB AND CHEMOTHERAPY FOR THE FIRST-LINE TREATMENT OF ADVANCED SQUAMOUS NON-SMALL CELL LUNG CANCER (SQNSCLC) IN CHINESE MAINLAND

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 patient has been dosed in an international, multicenter, phase 2/3 clinical study comparing pimurutamab HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) (“**HLX07**”) in combination with HANSIZHUANG (serplulimab injection) (“**HANSIZHUANG**”) and chemotherapy versus placebo in combination with HANSIZHUANG (serplulimab injection) or pembrolizumab and chemotherapy for the first-line treatment of advanced squamous non-small cell lung cancer (sqNSCLC) in Chinese Mainland (excluding Hong Kong, Macao and Taiwan regions of China, same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a randomized, double-blind, multicenter, parallel-controlled phase 2/3 clinical study designed to evaluate HLX07 in combination with HANSIZHUANG and chemotherapy versus placebo in combination with HANSIZHUANG or pembrolizumab and chemotherapy as first-line treatment in patients with advanced squamous non-small cell lung cancer (sqNSCLC). The study consists of two parts. Part I is a phase 2 study, in which participants will be randomized in a 1:1:1 ratio to one of the three groups: Group A: HLX07 1,000mg in combination with serplulimab and chemotherapy; Group B: HLX07 600mg in combination with serplulimab and chemotherapy; and Group C: placebo in combination with serplulimab and chemotherapy. Treatment will be administered once every 3 weeks (Q3W) for a total of 4 cycles, followed by maintenance therapy with the corresponding dose of HLX07 or placebo in combination with HANSIZHUANG. The primary endpoints of Part I are progression-free survival (PFS) and objective response rate (ORR), as assessed by Blinded Independent Central Review (BICR). Part II is a phase 3 study, for which the dose of HLX07 will be determined based on the results of Part I. Eligible participants will be randomized in a 1:1 ratio to one of two groups. Experimental group: HLX07 in combination with HANSIZHUANG and chemotherapy, administered Q3W for 4 cycles, followed by maintenance therapy with HLX07 in combination with serplulimab. Control group: placebo in combination with pembrolizumab and chemotherapy, administered Q3W for 4 cycles, followed by maintenance therapy with placebo in combination with pembrolizumab. The primary endpoints of Part II are PFS assessed by BICR, and overall survival (OS). The primary objective of this study is to evaluate the efficacy of HLX07 in combination with HANSIZHUANG and chemotherapy versus placebo in combination with HANSIZHUANG or pembrolizumab and chemotherapy as first-line treatment in patients with advanced sqNSCLC. Secondary objectives include evaluating the safety, pharmacokinetic (PK) characteristics, and immunogenicity of HLX07 in combination with HANSIZHUANG and chemotherapy, as well as evaluating the relationship between EGFR and PD-L1 expression in tumor tissues and efficacy.

C. ABOUT HLX07 AND HANSIZHUANG

HLX07 is an innovative biologic drug targeting EGFR independently developed by the Company, which is projected to be used for the treatment of advanced solid tumours. In February 2023, the results of the phase 1b/2 clinical study of HLX07 in combination with chemotherapy for the treatment of advanced solid tumours showed that HLX07 was safe and well tolerated. At present, several phase 2 clinical studies on HLX07 have been commenced in Chinese Mainland, primarily including the phase 2 clinical trial of HLX07 for the monotherapy of advanced cutaneous squamous cell carcinoma (CSCC) and other solid tumours, as well as the phase 2 clinical trial of HANSIZHUANG in combination with HLX07 for the treatment of advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) and other solid tumours.

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company, which was approved for marketing in Chinese Mainland for indications including the combination with chemotherapy for the first-line treatment of squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsNSCLC). In December 2025, the New Drug Application (NDA) for HANSIZHUANG in combination with chemotherapy for neo-/adjuvant treatment for gastric cancer has been accepted by the National Medical Products Administration (NMPA), and has been granted the procedure for priority review. Meanwhile, HANSIZHUANG was approved for marketing in European Union, United Kingdom, Indonesia, Cambodia, Thailand, Malaysia, Singapore, India and other countries/regions respectively, and has been granted Orphan-drug Designation by drug administrations in the United States, Switzerland, South Korea and other countries/regions, respectively. In addition, the Company is in the process of advancing a number of clinical studies of HANSIZHUANG and related combination therapies globally, covering a wide range of indications such as lung cancer, head and neck squamous cell carcinoma, colorectal cancer and gastric cancer.

In March 2026, the investigational new drug application for HLX07 in combination with HANSIZHUANG and chemotherapy for the treatment of advanced squamous non-small cell lung cancer (sqNSCLC) was approved by the NMPA. In April 2026, the phase 2/3 clinical trial of HLX07 in combination with HANSIZHUANG and chemotherapy for the treatment of advanced squamous non-small cell lung cancer (sqNSCLC), has been approved to commence in Australia.

D. MARKET CONDITION

As of the date of this announcement, no similar combination 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 commercialisation of HLX07. 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, 26 May 2026

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and non-executive director, Dr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.