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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 A PHASE 1 CLINICAL STUDY OF HLX37 (RECOMBINANT HUMANISED ANTI-PD-L1 AND ANTI-VEGF BISPECIFIC ANTIBODY) IN PATIENTS WITH ADVANCED/METASTATIC SOLID TUMOURS 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 a phase 1 clinical study of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody) (“**HLX37**”) independently developed by the Company in patients with advanced/metastatic solid tumours in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is an open-label, first-in-human phase 1 clinical trial evaluating the safety, tolerability, pharmacokinetic (PK) profiles, and preliminary efficacy of HLX37 in subjects with advanced/metastatic solid tumours. The study consists of two phases: phase 1a dose escalation (comprising monotherapy and combination therapy) and phase 1b dose expansion. The phase 1a monotherapy arm is conducted in subjects with advanced solid tumors, evaluating 6 dose levels ranging from 1.0 mg/kg to 45.0 mg/kg every three weeks; the combination therapy arm will explore different doses of HLX37 in combination with pemetrexed or albumin-bound paclitaxel/paclitaxel and carboplatin in subjects with advanced non-small cell lung cancer. The dosing regimen and tumour types for phase 1b will be determined based on the results of phase 1a. The primary endpoints of this study aim to evaluate the incidence of dose-limiting toxicity (DLT) to determine the maximum tolerated dose (MTD) and the recommended Phase 2 dose (RP2D) for both monotherapy and combination therapy. Secondary endpoints of this study include safety indicators such as adverse events, PK parameters, and immunogenicity, as well as efficacy indicators including objective response rate (ORR), progression-free survival (PFS), and overall survival (OS), alongside the exploration of potential predictive biomarkers.

C. ABOUT HLX37

HLX37 is a recombinant humanised bispecific antibody targeting PD-L1 and VEGF independently developed by the company, intended for the treatment of advanced/metastatic solid tumours. HLX37 can act on two different targets simultaneously, and its mechanism of action combines two therapeutic pathways: (1) blocking PD-1/PD-L1 signal pathway: by blocking the binding of PD-L1 on the surface of tumour cells and PD-1 on the surface of T cells, tumour immunosuppression effect is lifted, thereby restoring the ability of T cells to kill tumours; (2) blocking the angiogenesis pathway: by inhibiting the binding of VEGF to its receptor, reducing tumor angiogenesis, thereby limiting tumor growth and metastasis. This dual-target design may produce synergistic antitumor effects and potentially reduce the risk of drug resistance. By specifically binding to PD-L1 on tumour cells, HLX37 achieves enrichment of bispecific molecules within the tumour, resulting in greater efficacy than the combination of anti-PD-L1 monoclonal antibody and anti-VEGF monoclonal antibody. Pre-clinical studies have shown that HLX37 can inhibit tumour growth and has showed favorable safety. In November 2025, the investigational new drug (IND) application for the phase 1 clinical trial of HLX37 in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA).

D. MARKET CONDITION

According to the statistics released by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales volume of bispecific antibody targeting PD-1/PD-L1 and VEGF worldwide for the year of 2024 was approximately USD0.92 million (the first product worldwide was approved in May 2024).

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 HLX37. 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, 29 December 2025

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.