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 HLX316 FOR INJECTION (B7-H3-TARGETING SIALIDASE FC FUSION PROTEIN) 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 HLX316 for injection (B7-H3-targeting sialidase Fc fusion protein) ("**HLX316**") in patients with advanced/metastatic solid tumours in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This is an open-label, first-in-human phase 1 clinical study to evaluate the safety, tolerability, pharmacokinetic profiles, and preliminary efficacy of HLX316 in patients with advanced/metastatic solid tumours. The study consists of two stages: phase 1a dose escalation and backfill stage, and phase 1b dose expansion stage. Phase 1a includes five dose levels ranging from 1.0 mg/kg to 30.0 mg/kg, with once-weekly administration. The 1.0 mg/kg cohort adopts an accelerated titration design, while the remaining four dose cohorts follow a "3+3" dose escalation design. Dose backfill may be conducted at selected dose levels following safety evaluation. The dose level(s) for phase 1b expansion will be determined based on the safety and preliminary efficacy data from phase 1a, with a dosing regimen consistent with the corresponding cohort(s) in phase 1a. The primary objectives of this study are to evaluate the safety and tolerability of HLX316 in patients with advanced/metastatic solid tumours, to determine its maximum tolerated dose ("**MTD**") and recommended phase 2 dose ("**RP2D**"), and to preliminarily evaluate its anti-tumour efficacy. The primary endpoints include the incidence of dose-limiting toxicities (DLT), the MTD and RP2D of HLX316, and the objective response rate (ORR) assessed by the investigator.

C. ABOUT HLX316

HLX316 is a sialidase Fc fusion protein created by fusing the Company's proprietary heavy-chain-only antibody variable domain (VHH) targeting B7-H3 with a sialidase bifunctional fusion protein licensed from Palleon Pharmaceuticals Inc. in May 2024, which is intended for the treatment of advanced/metastatic solid tumours. HLX316 is a novel, first-in-class, B7-H3-targeting sialidase heterodimer composed of: (1) an engineered human sialidase Neu2 (with increased stability and manufacturability compared to wild-type Neu2) fused to a human IgG1 Fc region; and (2) a heavy chain-only antibody variable region (VHH) that specifically binds to human B7-H3, fused to a human IgG1 Fc region. HLX316 targets tumours expressing B7-H3 and exerts immune checkpoint blockade by enzymatic cleavage of immunosuppressive sialylated glycans and enhancing anti-tumour immune responses without triggering systemic immune activation. Pre-clinical studies have shown that HLX316 exhibits potent antigen-directed desialylation effects on tumour cells in vitro, tumour growth inhibition in humanised mouse models, and potential therapeutic benefit for advanced solid tumours. In March 2026, the investigational new drug (IND) application for the phase 1 clinical trial of HLX316 in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA).

D. MARKET CONDITION

As at the date of this announcement, no B7-H3-targeting sialidase Fc fusion protein 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 HLX316. 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, 22 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.