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 HLX97 (KAT6A/B SMALL MOLECULE INHIBITOR) 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 HLX97 (KAT6A/B small molecule inhibitor) ("**HLX97**") independently developed by the Company 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 study is a multicenter, open-label phase 1 clinical trial designed to evaluate the safety, tolerability, pharmacokinetic ("**PK**") characteristics, and preliminary antitumor activity of HLX97 in patients with advanced or metastatic solid tumours. The study consists of two parts: Part 1 is the dose-escalation phase, which includes monotherapy dose escalation (Part 1A) and combination therapy dose escalation (Part 1B); Part 2 is the dose-expansion phase. Part 1A, the monotherapy dose-escalation phase, will be conducted in patients with advanced/metastatic solid tumours and will include five dose levels ranging from 1.0 mg to 15.0 mg. HLX97 will be administered orally from Day 1 to Day 28 of each cycle, once a day, for 4 weeks each cycle. Part 1B, the combination therapy dose-escalation phase, will explore 2 to 3 dose levels of HLX97 in combination with fulvestrant in patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer. Part 2 will be conducted in patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer: two groups receiving different doses of HLX97 in combination with fulvestrant, and one group receiving fulvestrant monotherapy. The primary endpoints of Part 1 are to evaluate the incidence of dose-limiting toxicities (DLT) and to determine the maximum tolerated dose (MTD) of HLX97 as monotherapy and in combination with fulvestrant. The primary endpoints of Part

2 are the objective response rate (ORR) and progression-free survival (PFS) as assessed by the investigator according to RECIST version 1.1, as well as the recommended Phase 2 dose (RP2D) of HLX97 in combination with fulvestrant. Secondary endpoints include the safety of HLX97 as monotherapy and in combination, PK parameters, additional efficacy endpoints (such as duration of response (DOR), disease control rate (DCR), and overall survival (OS)), and exploratory pharmacodynamic and predictive biomarker analyses.

C. ABOUT HLX97

HLX97 is a small molecule inhibitor of lysine acetyltransferase 6A/B (KAT6A/B) independently developed by the Company, intended for the treatment of advanced/metastatic solid tumours. KAT6A and its paralog KAT6B, as histone lysine acetyltransferases, can participate in the acetylation of lysine residues on histone H3 along with other chromatin-associated proteins, thereby playing a carcinogenic role in various tumour types. In breast cancer, the amplification/overexpression of the KAT6A gene has been confirmed to be closely associated with the development of endocrine therapy resistance. Therefore, inhibiting KAT6 is expected to overcome endocrine therapy resistance. Non-clinical studies have shown that HLX97 can inhibit the activity of KAT6A/B, demonstrating good anti-tumour effects and safety. In March 2026, the investigational new drug (IND) application for the phase 1 clinical trial of HLX97 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 KAT6A/B small molecule inhibitor 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 HLX97. 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, 13 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.