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 INVESTIGATIONAL NEW DRUG APPLICATION OF HLX316 FOR INJECTION (B7-H3-TARGETING SIALIDASE FC FUSION PROTEIN) FOR THE TREATMENT OF PATIENTS WITH ADVANCED/METASTATIC SOLID TUMOURS APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

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 investigational new drug (IND) application for the phase 1 clinical trial of HLX316 for injection (B7-H3-targeting sialidase Fc fusion protein) ("**HLX316**") in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA).

B. 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. ("**Palleon**") 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 tumors expressing B7-H3 and exerts immune checkpoint blockade by enzymatic cleavage of immunosuppressive sialylated glycans and enhancing anti-tumor immune responses without triggering systemic immune activation. Pre-clinical studies have shown that HLX316 exhibits potent antigen-directed desialylation effects on tumor cells in vitro, tumor growth inhibition in humanized mouse models, and potential therapeutic benefit for advanced solid tumors.

C. 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 commercialization 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, 9 March 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.