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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 1B/2 CLINICAL STUDY OF HLX701 (RECOMBINANT HUMAN SIRP α -IgG4 Fc FUSION PROTEIN INJECTION) IN COMBINATION WITH CETUXIMAB AND CHEMOTHERAPY FOR THE TREATMENT OF ADVANCED COLORECTAL CANCER 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 1b/2 clinical study of HLX701 (recombinant human SIRP α -IgG4 Fc fusion protein injection) (“**HLX701**”) in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer in Chinese Mainland (excluding China Hong Kong, Macau and Taiwan regions).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a phase 1b/2 clinical study comparing HLX701 in combination with cetuximab and chemotherapy (FOLFOX/FOLFIRI) versus placebo in combination with cetuximab and chemotherapy (FOLFOX/FOLFIRI) in patients with recurrent, unresectable, or metastatic RAS/BRAF wild-type colorectal cancer who previously received chemotherapy. This study consists of three stages: In Stage 1 (safety run-in stage), it adopts 3+3 dose-escalation approach, with a total of 4 dose levels ranging from 5 mg/kg to 18mg/kg. Subjects will be treated with HLX701 in combination with cetuximab and chemotherapy (FOLFOX/FOLFIRI) at different dose levels, with intravenous administration once per week. In Stage 2, it has a total of 3 dose groups ranging from 8 mg/kg to 18 mg/kg, administered once weekly by intravenous infusion, aiming to evaluate the clinical efficacy and safety of HLX701 in combination with cetuximab and chemotherapy (FOLFOX/FOLFIRI) at different dose levels. Stage 3 is a randomized, double-blind and multi-center study comparing the efficacy and safety of HLX701 or placebo in combination with cetuximab and chemotherapy. The primary endpoint for Stage 1 is the proportion of dose-limiting toxicities (DLTs), while secondary endpoints include safety indicators such as adverse events, efficacy indicators such as objective response rate (ORR) and disease control rate (DCR), pharmacokinetic (PK)

parameters, and immunogenicity. The primary endpoints for Stage 2 are determination of the recommended Phase II dose (RP2D) and the ORR and progression-free survival (PFS) as assessed by Blinded Independent Central Review (BICR). The primary endpoints for Stage 3 are the ORR and PFS as assessed by BICR. The secondary endpoints for Stage 2 and Stage 3 include safety indicators such as adverse events, overall survival (OS), efficacy endpoints (e.g., ORR and PFS assessed by investigators), PK parameters, and immunogenicity, as well as the exploration of association between biomarkers and efficacy.

C. ABOUT HLX701

HLX701 is a SIRP α -Fc fusion protein licensed in by the Company from FBD Biologics Limited, which is intended for the treatment of various advanced stage solid tumours and several phase 1/2 clinical trials are being conducted worldwide. According to the licensing arrangement, the Company obtained an exclusive right to develop, manufacture and commercialise HLX701 in China (excluding Taiwan region of China) and designated countries in Southeast Asia as well as Middle East and North Africa. HLX701 is a fusion of the engineered immunoglobulin variable (IgV) domain of human SIRP α with the crystallizable fragment (Fc) region of human Immunoglobulin G4 (IgG4). By binding to CD47 on tumour cells, HLX701 effectively blocks the inhibitory CD47-mediated anti phagocytic signaling to promote macrophage phagocytosis of tumour cells and enhance anti tumour activity. Preclinical studies have demonstrated that HLX701 in combination with chemotherapy drugs, immune checkpoint inhibitors, epidermal growth factor receptor inhibitors, anti-angiogenesis drugs and other targeted drugs exhibit synergistic efficacy, hinting that its combination with standard treatment may synergistically enhance innate and adaptive immune responses. In January 2026, the investigational new drug (IND) application for the phase 1b/2 clinical trial of HLX701 in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer was approved by the National Medical Products Administration (NMPA).

D. MARKET CONDITION

As at the date of this announcement, no SIRP α -Fc fusion protein targeting CD47 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 HLX701. 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 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.