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

FIRST PATIENT HAS BEEN DOSED IN A PHASE 2 CLINICAL TRIAL OF HLX26 (A RECOMBINANT ANTI-LAG-3 HUMANIZED MONOCLONAL ANTIBODY INJECTION) IN COMBINATION WITH HANSIZHUANG (SERPLULIMAB INJECTION) FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER (mCRC) PATIENTS WHO HAVE RECEIVED THIRD-LINE TREATMENT IN MAINLAND CHINA

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 2 clinical trial of HLX26 (a recombinant anti-LAG-3 humanized monoclonal antibody injection) ("**HLX26**") independently developed by the Company in combination with HANSIZHUANG (serplulimab injection) ("**HANSIZHUANG**") for the treatment of metastatic colorectal cancer (mCRC) patients who have received third-line treatment in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below).

B. CLINICAL TRIAL DESIGN AND PURPOSE

This two-stage, phase 2 clinical study aims to evaluate the efficacy, safety, and tolerability of HLX26 in combination with HANSIZHUANG in metastatic colorectal cancer (mCRC) patients who have received third-line treatment. Stage 1 is a dose-escalation study following "3+3" design. Eligible subjects will be given different doses of HLX26 (500, 800, and 1,600 mg) and fixed-dose HANSIZHUANG (300 mg) intravenously every 3 weeks. The primary endpoints are the dose-limiting toxicity (DLT) and maximum tolerated dose (MTD). Secondary endpoints include pharmacokinetic parameters, immunogenicity, safety, and preliminary efficacy. Stage 2 is a dose-expansion study. The primary endpoint of this stage is the objective response rate (ORR) assessed by investigator per RECIST v1.1. The secondary endpoints include other efficacy endpoints, such as progression-free survival (PFS), disease control rate (DCR), duration of response (DOR), and overall survival (OS), as well as safety, immunogenicity, and pharmacokinetic characteristics.

C. ABOUT HLX26 AND HANSIZHUANG

HLX26 is an innovative humanized monoclonal antibody targeting Lymphocyte-activation gene 3 ("**LAG-3**") extracellular domains independently developed by the Company, which is projected to be used for the treatment of solid tumours and lymphomas. In October 2021, the first subject has been dosed in the phase 1 clinical trial of HLX26 for the treatment of solid tumours and lymphomas in mainland China. HLX26 blocks the interaction between LAG-3 and its ligand to block the LAG-3-mediated signaling pathway of inhibiting T-cell function, and shows tumour inhibiting effect through blocking immune escape in the tumour microenvironment in combination with HANSIZHUANG. Pre-clinical pharmacodynamics studies both in vivo and in vitro have proved that the combination of HLX26 and HANSIZHUANG has a synergistic effect on restoring the killing function of T cells, showing more significant anti-tumour activity. In August 2022, the first patient has been dosed in the phase 1 clinical trial of HLX26 in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours in mainland China. In May 2023, application for phase 2 clinical trial of HLX26 in combination with HANSIZHUANG and chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC) was approved by the National Medical Products Administration (the "**NMPA**").

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company and was approved for marketing in mainland China in March 2022. As of the date of this announcement, HANSIZHUANG has been approved for three indications in mainland China: (1) the treatment of adult patients with advanced unresectable or metastatic Microsatellite Instability-High ("**MSI-H**") solid tumours that have failed to respond to the standard therapy; (2) the first-line treatment of patients with unresectable locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) in combination with carboplatin and albumin-bound paclitaxel; and (3) the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with carboplatin and etoposide. In August 2022, the new drug application (NDA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of patients with locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) was accepted by the NMPA. In March 2023, HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) has been validated by the European Medicines Agency (EMA). HANSIZHUANG is planned to be used for the treatment of a variety of solid tumours, and in addition to the indications of the MSI-H solid tumours, squamous non-small cell lung cancer (sqNSCLC) and extensive-stage small cell lung cancer (ES-SCLC) which have been approved for marketing, HANSIZHUANG is being undergone clinical studies in 11 combination therapies with it as the core in various countries and regions around the world.

D. MARKET CONDITION

As at the date of this announcement, no marketing approval by the NMPA has been obtained for similar combination therapy in mainland China. A drug combination targeting LAG-3 and targeting PD-1 that has been marketed globally is OPDUALAG™ of Bristol-Myers Squibb, which was approved by the U.S. Food and Drug Administration in March 2022. According to the statistics released by IQVIA MIDAS™ (provided by IQVIA, a world-leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the global sales of product targeting LAG-3 in combination with targeting PD-1 in 2022 was approximately US$231 million.

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 HLX26. 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, 15 June 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Mr. Zihou Yan as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.