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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

FIRST PATIENT HAS BEEN DOSED IN AN INTERNATIONAL MULTICENTER PHASE 1 CLINICAL STUDY OF IPILIMUMAB BIOSIMILAR HLX13 (RECOMBINANT ANTI-CTLA-4 FULLY HUMAN MONOCLONAL ANTIBODY INJECTION) AS A FIRST-LINE TREATMENT FOR PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA (HCC) 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 an international multicenter phase 1 clinical study of Ipilimumab biosimilar HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) ("**HLX13**") independently developed by the Company as a first-line treatment for patients with unresectable hepatocellular carcinoma (HCC) in mainland China.

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is an international multicenter, randomized, double-blind, parallel-controlled phase 1 clinical study to evaluate the similarity in pharmacokinetic (PK) profiles, safety, efficacy, and immunogenicity between HLX13 and its reference product YERVOY® (US-sourced), each in combination with OPDIVO® (EU-sourced, generic name: nivolumab), in patients with previously untreated, unresectable advanced hepatocellular carcinoma (HCC). Eligible subjects will be randomly assigned to two groups at a 1:1 ratio. Subjects will receive HLX13 or YERVOY® in combination with OPDIVO® once every 3 weeks for the first 4 cycles, followed by OPDIVO® monotherapy administered every 4 weeks as maintenance treatment. The primary endpoints are area under the serum concentration-time curve from time 0 to 21 days (AUC0-21d) after the 1st dose and the area under the serum concentration-time curve within a dosing interval at steady-state (AUCss) after the 4th dose. Secondary endpoints include other PK parameters, efficacy assessments, safety and immunogenicity.

C. ABOUT HLX13

HLX13 is a biosimilar of Ipilimumab independently developed by the Company, and is intended for the indications of the reference drug such as melanoma, renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal squamous cell carcinoma, etc. Ipilimumab is a fully human, anti-CTLA-4 (cytotoxic T-lymphocytes associated antigen 4, also known as CD152), IgG1 monoclonal antibody with κ light chain. By blocking the binding between CTLA-4 and the ligands, Ipilimumab can elevate the immune response and in turn achieve the goal of killing tumors. In June 2023, application for the clinical trial of HLX13 for the treatment of hepatocellular carcinoma (HCC) was approved by the National Medical Products Administration. In November 2023, application for clinical trial of HLX13 for the treatment of melanoma, renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal squamous cell carcinoma was approved by the National Medical Products Administration. In September 2025, the investigational new drug application (IND) for the phase 1 clinical trial of HLX13 as a first-line treatment for patients with unresectable hepatocellular carcinoma (HCC) was approved by the United States Food and Drug Administration (FDA). In April 2025, the Company entered into a license agreement with Sandoz AG, pursuant to which, the Company granted an exclusive license to Sandoz AG to commercialize HLX13 within the United States, agreed European countries, Japan, Australia and Canada.

D. MARKET CONDITION

According to the information of IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the worldwide sales of Ipilimumab in 2024 was approximately US$2.873 billion.

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 HLX13. 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, 25 November 2025

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.