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

APPLICATION FOR THE CLINICAL TRIAL OF HLX53 (ANTI-TIGIT FC FUSION PROTEIN) IN COMBINATION WITH HANSIZHUANG (SERPLULIMAB INJECTION) AND HANBEITAI (BEVACIZUMAB INJECTION) FOR THE FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC HEPATOCELLULAR CARCINOMA WAS APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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, application for the clinical trial of HLX53 (anti-TIGIT Fc fusion protein) ("**HLX53**") in combination with HANSIZHUANG (serplulimab injection) ("**HANSIZHUANG**") and HANBEITAI (bevacizumab injection) ("**HANBEITAI**") for the first-line treatment of locally advanced or metastatic hepatocellular carcinoma (HCC) was approved by the National Medical Products Administration (the "**NMPA**"). The Company proposes to commence the phase 2 clinical trial of such therapy in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below) when clinical trial conditions are fulfilled.

B. ABOUT HLX53, HANSIZHUANG AND HANBEITAI

HLX53 is an innovative anti T cell immunoreceptor with immunoglobulin and ITIM domains ("**TIGIT**") Fc fusion protein independently developed by the Company, which is intended to be used for the treatment of advanced solid tumours or lymphomas and is in phase 1 clinical trial in mainland China. TIGIT is an inhibitory receptor, which is mainly expressed on natural killer ("**NK**") cells, activated CD8+ T and CD4+ T cells, and T regulatory cells (Treg). TIGIT binds to the ligand CD155 (also called Poliovirus receptor, "**PVR**") mainly expressed on antigen-presenting cells (APC) or the surface of tumour cells, thereby downregulating cell functions of T cells and NK cells. Studies have shown that HLX53 can specifically bind to human TIGIT and block the binding of TIGIT/PVR to cut off the downstream negative signals and reactivate the immune response effect of T cells to tumours.

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 four 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; (3) the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with carboplatin and etoposide; and (4) the first-line treatment of patients with PD-L1 positive unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) in combination with drugs containing fluorouracil and platinum. In addition, the new drug application (NDA) for the fifth indication for HANSIZHUANG for the first-line treatment of non-squamous non-small cell lung cancer (nsNSCLC) has also been accepted by the NMPA. In the international market, HANSIZHUANG has been approved by the Indonesian Food and Drug Authority (BPOM) for the treatment of extensive-stage small cell lung cancer (ES-SCLC), becoming the first domestic anti-PD-1 monoclonal antibody approved for marketing in Southeast Asia. The marketing authorisation application (MAA) of HANSIZHUANG in the European Union has also been validated by the European Medicines Agency (EMA), and the bridging study in the United States is progressing steadily. The Company is also in the process of advancing a number of clinical studies of HANSIZHUANG and related combination therapies globally, covering a wide range of indications such as lung cancer, esophageal carcinoma, head and neck squamous cell carcinoma, colorectal cancer and gastric cancer.

HANBEITAI is a bevacizumab (recombinant anti-VEGF humanized monoclonal antibody injection) independently developed by the Company in accordance with the guiding principle on biosimilar in China and was approved for commercialisation in mainland China in November 2021. As of the date of this announcement, HANBEITAI has been approved for five indications in mainland China: (1) metastatic colorectal cancer; (2) advanced, metastatic or recurrent non-small cell lung cancer; (3) recurrent glioblastoma; (4) epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; and (5) cervical cancer.

In view of the good efficacy of anti-PD-1/PD-L1 antibody combined with anti-VEGF antibody in the first-line treatment of patients with advanced hepatocellular carcinoma and the synergistic effect of TIGIT and PD-1/PD-L1 signaling pathway, the combination of the three products for the first-line treatment of advanced hepatocellular carcinoma is worth further exploration.

C. MARKET CONDITION

As of the date of this announcement, no similar combination therapy 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 HLX53. 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, 17 April 2024

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. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang 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.