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

SERPLULIMAB INJECTION (CHINESE TRADE NAME: HANSIZHUANG) RECEIVED POSITIVE OPINION FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OF THE EUROPEAN MEDICINES AGENCY (EMA)

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Company.

Reference is made to the announcement of the Company dated 23 March 2023 in relation to that the marketing authorisation application ("**MAA**") for serplulimab injection (Chinese trade name: HANSIZHUANG) ("**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**"). In October 2023, the Company entered into a license agreement with Intas Pharmaceuticals Ltd. ("**Intas**"), pursuant to which, the Company agreed to grant to Intas an exclusive license to commercialise HANSIZHUANG in agreed Geographical Europe and India.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, HANSIZHUANG received a positive opinion from the Committee for Medicinal Products for Human Use ("**CHMP**") of the EMA, recommending the approval of HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). The opinion from CHMP will be submitted to the European Commission ("**EC**"), then the EC will issue a final review decision based on such opinion within the next two to three months. Once approved by the EC, a centralized marketing authorisation in respect of HANSIZHUANG will be valid in all EU Member States as well as European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

B. BASIS FOR THE OPINION

The positive opinion from CHMP is primarily based on a randomized, double-blinded, international multi-center Phase 3 clinical study. The results indicated that HANSIZHUANG in combination with chemotherapy (carboplatin-etoposide) could bring more significant benefits compared to chemotherapy (carboplatin-etoposide) in the treatment of previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC), which met the standard of the primary endpoint as determined with a favorable safety and tolerability. In December 2023, the Group received several GMP Certificates from Health and Youth Care Inspectorate (a health supervision agency in the Netherlands), indicating that production lines related to HANSIZHUANG have met the GMP standards of the EU.

C. ABOUT SERPLULIMAB INJECTION (CHINESE TRADE NAME: HANSIZHUANG)

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company and was approved for marketing in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below) 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. 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.

As of the date of this announcement, the latest progress of HANSIZHUANG and its related combination therapies are as follows:

Product/Combination therapy	**Indications**	**Latest progress**
HANSIZHUANG	Unresectable or metastatic MSI-H solid tumours that have failed to respond to the standard therapy	In March 2022, approved by the National Medical Products Administration ("**NMPA**") for marketing

Product/Combination therapy	Indications	Latest progress
HANSIZHUANG + chemotherapy	Locally advanced or metastatic squamous non-small cell lung cancer	In October 2022, approved by the NMPA for marketing
	Extensive-stage small cell lung cancer	In January 2023, approved by the NMPA for marketing; In March 2023, MAA in the EU was validated by the EMA; Approved for marketing in Indonesia, Cambodia and Thailand; Bridging study in the United States
	Locally advanced/recurrent or metastatic esophageal squamous cell carcinoma	In September 2023, approved by the NMPA for marketing
	Non-squamous non-small cell lung cancer	Phase 3 clinical trial in mainland China, which has met the primary study endpoints; In December 2023, the new drug application (NDA) in mainland China has been accepted by the NMPA
	Neo-/adjuvant treatment of gastric cancer	Phase 3 clinical trial in mainland China
	Limited-stage small cell lung cancer (HANSIZHUANG in combination with chemotherapy and concurrent radiotherapy)	Phase 3 clinical trial in mainland China, the United States, Australia and EU country (International multicentre trial)
HANSIZHUANG + bevacizumab + chemotherapy	Metastatic colorectal cancer	Phase 2/3 clinical trial in mainland China
HANSIZHUANG + HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection)	Head and neck squamous cell carcinoma, nasopharyngeal carcinoma, gastric cancer, esophageal squamous cell carcinoma, squamous non-small cell lung cancer	Phase 2 clinical trial in mainland China

Product/Combination therapy	Indications	Latest progress
HANSIZHUANG + HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) + chemotherapy	Non-small cell lung cancer	Phase 2 clinical trial in mainland China
HLX208 (BRAF V600E inhibitor)+ HANSIZHUANG	Non-small cell lung cancer	Phase 2 clinical trial in mainland China
HLX53 (anti-TIGIT Fc fusion protein) + HANSIZHUANG + HANBEITAI (bevacizumab injection)	Locally advanced or metastatic hepatocellular carcinoma	Phase 2 clinical trial in mainland China

D. MARKET CONDITION

As of the date of this announcement, in addition to HANSIZHUANG of the Company, other monoclonal antibody drugs targeting PD-1 that have been marketed globally include Keytruda® of Merck & Co. Inc., Opdivo® of Bristol-Myers Squibb and Libtayo® of Regeneron Pharmaceuticals, Inc., etc., other monoclonal antibody drugs targeting PD-1 approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) worldwide include TEVIMBRA® of BeiGene, Ltd. and TUOYI® of Shanghai Junshi Biosciences Co., Ltd.. According to the statistics released by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the worldwide sales of the monoclonal antibody drugs targeting PD-1 amounted to approximately US$39.749 billion in 2023.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 20 September 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, Dr. 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.