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 IN AN EU COUNTRY HAS BEEN DOSED IN AN INTERNATIONAL MULTICENTRE PHASE 3 CLINICAL STUDY OF HANSIZHUANG (SERPLULIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY AND CONCURRENT RADIOTHERAPY FOR THE TREATMENT OF LIMITED-STAGE SMALL CELL LUNG CANCER

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 in an EU country (Latvia) has been dosed in an international multicentre phase 3 clinical study comparing HANSIZHUANG (serplulimab injection) independently developed by the Company ("**HANSIZHUANG**") or placebo in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) patients.

B. CLINICAL TRIAL DESIGN AND PURPOSE

This randomised, double-blind, international multicentre, phase 3 clinical study aims to compare the efficacy and safety of HANSIZHUANG or placebo in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy in patients with limited-stage small cell lung cancer (LS-SCLC). Eligible patients will be randomised into two groups at a ratio of 1:1. The primary objective of this study is to evaluate the antitumour activity of HANSIZHUANG plus chemotherapy and concurrent radiotherapy in limited-stage small cell lung cancer (LS-SCLC) patients. The primary endpoint of this study is overall survival (OS). The secondary endpoints include progression-free survival (PFS), objective response rate (ORR), and duration of response (DOR) assessed by investigators per RECIST 1.1, as well as safety and immunogenicity.

C. ABOUT 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. HANSIZHUANG has been granted orphan-drug designations for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA) and the European Commission (EC) in April 2022 and December 2022, respectively. In September 2022, the results of a phase 3 clinical study of HANSIZHUANG in combination with chemotherapy as first-line treatment for patients with extensive-stage small cell lung cancer (ES-SCLC) were published online in The Journal of American Medical Association (JAMA, impact factor of 120.7), one of the top four medical journals in the world. In February 2023, the results of a phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for the first-line treatment of locally advanced/recurrent or metastatic esophageal squamous cell carcinoma were officially published in Nature Medicine (Impact Factor: 82.9), an international authoritative journal. In March 2023, the marketing authorization application (MAA) for HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) was validated by the European Medicines Agency (EMA). 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 studies of HANSIZHUANG and its related combination therapies are as follows:

Product/Combination therapy	**Indications**	**Stage**
HANSIZHUANG	Unresectable or metastatic MSI-H solid tumours that have failed to respond to the standard therapy	In March 2022, approved by the NMPA for marketing

Product/Combination therapy	Indications	Stage
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; the marketing authorization application (MAA) in the European Union was validated in March 2023; bridging study in the United States
	Locally advanced/recurrent or metastatic esophageal squamous cell carcinoma	In September 2023, approved by the NMPA for marketing
	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 + HANBEITAI (bevacizumab injection)	Metastatic non-squamous non-small cell lung cancer	Phase 3 clinical trial in mainland China
	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
HANSIZHUANG + HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection)	Metastatic colorectal cancer	Phase 2 clinical trial in mainland China

Product/Combination therapy	Indications	Stage
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
HANSIZHUANG + HLX60 (recombinant humanised anti-GARP monoclonal antibody injection)	Advanced/metastatic solid tumours	Phase 1 clinical trial in Australia

D. MARKET CONDITION

As of the date of this announcement, in addition to HANSIZHUANG of the Company, 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. There is no monoclonal antibody drug targeting PD-1 or PD-L1 approved for the treatment of limited-stage small cell lung cancer (LS-SCLC) worldwide. According to the latest statistics released by IQVIA MIDAS™ (IQVIA is the world's leading 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$33.103 billion in 2022.

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

Hong Kong, 25 October 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. 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.