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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

THE PHASE 3 CLINICAL STUDY OF HANSIZHUANG (SERPLULIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY FOR NEO-/ADJUVANT TREATMENT FOR GASTRIC CANCER MET PRIMARY ENDPOINT

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 phase 3 clinical study comparing HANSIZHUANG (serplulimab injection) independently developed by the Company ("**HANSIZHUANG**") or placebo in combination with chemotherapy (SOX) for neo-/adjuvant treatment for gastric cancer, met the primary endpoint of event-free survival (EFS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee ("**IDMC**"), supporting an early new drug application submission.

B. INTERIM ANALYSIS CONCLUSION OF THE STUDY

The study is a randomized, double-blind, multi-center phase 3 clinical study among patients with early-stage gastric cancer, aiming to compare the efficacy and safety of HANSIZHUANG or placebo in combination with chemotherapy as a neo-/adjuvant treatment for patients with early-stage gastric cancer. Based on the results of pre-defined interim analysis conducted by IDMC, HANSIZHUANG in combination with chemotherapy showed a significant improvement in event-free survival (EFS) against placebo in combination with chemotherapy, which met the pre-defined efficacy criteria. The pathological complete response (pCR) rate was more than three times that of the control group, and the risk of recurrence in patients was significantly reduced. At the same time, the safety profile was good, and no new safety signal was observed.

C. ABOUT HANSIZHUANG

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company, which was approved for marketing in mainland China (excluding Hong Kong, Macau and Taiwan regions of China, same as below) for indications including the combination with chemotherapy for the first-line treatment of squamous non-small cell lung cancer (sq-NSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsq-NSCLC). Meanwhile, HANSIZHUANG was approved for marketing in European Union, United Kingdom, Indonesia, Cambodia, Thailand, Malaysia, Singapore, India and other countries/regions respectively, and has been granted Orphan-drug Designation by drug administrations in the United States, European Union, Switzerland, South Korea and other countries/regions, respectively.

In addition, the Company is 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 the related combination therapies are as follows:

Product/Combination therapy	**Indications**	**Latest progress**
HANSIZHUANG + chemotherapy	Extensive-stage small cell lung cancer	Bridging study in the United States Bridging study in Japan
	Neo-/adjuvant treatment of gastric cancer	Phase 3 clinical trial in mainland China has met the primary endpoint
	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 countries (International multicentre trial)
HANSIZHUANG + bevacizumab + chemotherapy	Metastatic colorectal cancer	Phase 2/3 clinical trial in mainland China, Japan, and Indonesia (International multicentre trial)
HANSIZHUANG + HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection)	Squamous non-small cell lung cancer and other solid tumours	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

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$45.550 billion in 2024.

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

Hong Kong, 9 October 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.