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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

HANSIZHUANG (SERPLULIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY FOR NEO-/ADJUVANT TREATMENT FOR GASTRIC CANCER HAS BEEN OFFICIALLY GRANTED THE BREAKTHROUGH THERAPY DESIGNATION BY THE CENTER FOR DRUG EVALUATION OF 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, the HANSIZHUANG (serplulimab injection) independently developed by the Company (“**HANSIZHUANG**”) in combination with chemotherapy for neo-/adjuvant treatment for gastric cancer has been officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration (NMPA).

B. 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
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

C. MARKET CONDITION

As at the date of this announcement, no monoclonal antibody drug targeting PD-1 has been approved globally for the neo-/adjuvant treatment for gastric cancer. 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\$45.704 billion in 2024.

D. THE IMPACT OF THE GRANT ON THE COMPANY

According to the relative measures of the Administration of Drug Registration (《藥品註冊管理辦法》) and the Announcement of the NMPA on the Release of Three Documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》(2020年第82號)), the scope of Breakthrough Therapy Designation procedure applied to, during clinical trials period, innovative drugs or improved new drugs that are intended for prevention or treatment of severe diseases that are life-threatening or significantly impact the quality of life, for which there is no existing treatment or for where sufficient evidence indicates advantages of that therapy over available treatment options. Drugs granted the Breakthrough Therapy Designation are prioritized by the CDE in communications and guidance to promote the drug development progress. Drug granted the Breakthrough Therapy Designation may be eligible for apply for conditional approval and priority review, under conditions that meet the relevant criteria, when submitting its new drug application. This granting of Breakthrough Therapy Designation represents the high recognition of the efficacy of HANSIZHUANG in combination with chemotherapy for neo-/adjuvant treatment for gastric cancer, and it is expected to accelerate its regulatory review and market approval process.

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

Hong Kong, 20 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.