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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)

INSIDE INFORMATION ANNOUNCEMENT

NEW DRUG APPLICATION (NDA) FOR NEW INDICATION OF HANSIZHUANG (SERPLULIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY FOR NEO-/ADJUVANT TREATMENT FOR GASTRIC CANCER HAS BEEN APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the “**Company**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors of the Company (the “**Board**”) is pleased to announce that, recently, the new drug application (NDA) for new indication of HANSIZHUANG (serplulimab injection) (“**HANSIZHUANG**”), an innovative anti-PD-1 monoclonal antibody independently developed by the Company, in combination with Oxaliplatin and S-1 for neoadjuvant treatment of resectable gastric cancer with tumour PD-L1 expression CPS ≥ 5 , followed by adjuvant monotherapy after surgery, has been approved by the National Medical Products Administration (NMPA).

The approval was primarily based on a randomized, double-blind, multi-center phase 3 clinical study. The study results demonstrated that neoadjuvant HANSIZHUANG plus chemotherapy followed by adjuvant HANSIZHUANG monotherapy significantly improved the event-free survival (EFS) of the patients compared with neoadjuvant placebo plus chemotherapy followed by adjuvant chemotherapy and that this improvement met the pre-defined efficacy criteria. In addition, this regimen showed better safety and tolerability compared with full-course chemotherapy.

B. DETAILS OF THE DRUG AND THE APPROVAL

Common Name:	Serplulimab Injection
Trade Name:	HANSIZHUANG
Form:	Injection
Specification:	100mg (10ml)/vial

Registration Category: Biological Product for Treatment Purpose
Drug Manufacturer: Shanghai Henlius Biopharmaceutical Co., Ltd.* (上海復宏漢霖生物製藥有限公司, a wholly owned subsidiary of the Company)
Review Conclusions: According to the Drug Administration Law of the People's Republic of China and relevant requirements, upon review, this drug satisfied the relevant requirements for drug registration and its new indication is approved: this drug in combination with Oxaliplatin and S-1 for neoadjuvant treatment of resectable gastric cancer with tumour PD-L1 expression CPS $\geq$ 5, followed by adjuvant monotherapy of this drug after surgery.

C. ABOUT HANSIZHUANG

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company, which was approved for marketing in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, same as below) for indications including the combination with chemotherapy for the first-line treatments of squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsNSCLC) as well as the combination with chemotherapy for neo-/adjuvant treatment for gastric cancer. Meanwhile, HANSIZHUANG was also 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, 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, head and neck squamous cell carcinoma and colorectal cancer. As of the date of this announcement, the latest progress of HANSIZHUANG and the relevant combination therapies is 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
	Limited-stage small cell lung cancer (HANSIZHUANG in combination with chemotherapy and concurrent radiotherapy)	Phase 3 clinical trial in Chinese Mainland, the United States, Australia and EU countries (International multi-center trial)

Product/Combination therapy	Indications	Latest progress
HANSIZHUANG + bevacizumab + chemotherapy	Metastatic colorectal cancer	Phase 2/3 clinical trial in Chinese Mainland, Japan and Indonesia (International multi-center trial)
HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) + HANSIZHUANG + chemotherapy	Squamous non-small cell lung cancer	Phase 2/3 clinical trial in Chinese Mainland (International multi-center trial)
HLX43 (an antibody-drug conjugate targeting PD-L1) + HANSIZHUANG	Solid tumours	Phase 1b/2 clinical trial in Chinese Mainland

D. MARKET CONDITION

According to the data provided by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services for the pharmaceutical and healthcare industry), the sales value of monoclonal antibody drugs targeting PD-1 worldwide for the year of 2025 was approximately US\$50.871 billion.

E. IMPACT ON THE COMPANY

It is the first treatment regimen using immune monotherapy to replace adjuvant chemotherapy after surgery in the perioperative period for gastric cancer approved worldwide. This will further enhance the market competitiveness of HANSIZHUANG, and will also offer more treatment options to patients with gastric cancer in Chinese Mainland.

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

Hong Kong, 9 June 2026

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.

* for identification purposes only