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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

EUROPEAN COMMISSION (EC) APPROVED TWO NEW INDICATIONS FOR SERPLULIMAB INJECTION (TRADE NAME IN CHINESE MAINLAND: HANSIZHUANG; TRADE NAME IN THE EUROPEAN UNION: HETRONIFLY®)

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 European Commission (“**EC**”) has approved two new indications for serplulimab injection (Trade name in Chinese Mainland: HANSIZHUANG; Trade name in the European Union: HETRONIFLY®) (“**Serplulimab**”) independently developed by the Company. The newly approved indications are as follows: (1) Serplulimab in combination with fluoropyrimidine- and platinum-based chemotherapy indicated for the first-line treatment of adult patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) with PD-L1 expression of CPS \geq 5, and (2) Serplulimab in combination with carboplatin and pemetrexed indicated for the first-line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung carcinoma (nsNSCLC) without EGFR, or ALK/ROS1 mutations who are ineligible for local therapy with curative intent (the “**Two New Indications**”). This indicates that the Two New Indications of Serplulimab has been approved in all EU Member States as well as in Iceland, Liechtenstein and Norway (each a European Economic Area (EEA) country).

B. BASIS FOR APPROVAL BY THE EUROPEAN COMMISSION (EC)

The approval by the EC is primarily based on two randomized, double-blind, multi-center phase 3 clinical studies. The results of the studies showed that: (1) Serplulimab in combination with chemotherapy (Cisplatin and 5-Fluorouracil) showed significant benefits compared with chemotherapy (Cisplatin and 5-Fluorouracil) in the treatment of previously untreated locally advanced or metastatic esophageal squamous cell carcinoma (ESCC), reaching the pre-specified primary endpoint criteria, and demonstrated good safety and tolerability; (2) Serplulimab in combination with chemotherapy (Carboplatin-Pemetrexed) showed significant benefits compared with chemotherapy (Carboplatin-Pemetrexed) in

the treatment of previously untreated advanced non-squamous non-small cell lung cancer (nsNSCLC), reaching the pre-specified primary endpoint criteria, and demonstrated good safety and tolerability. In December 2023, the Group received several Good Manufacturing Practice (GMP) certificates issued by the Health and Youth Care Inspectorate of the Netherlands, indicating that the relevant production lines for Serplulimab are in compliance with the EU GMP standards. In addition, in March 2026, Serplulimab received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending the approval of the Two New Indications.

C. ABOUT SERPLULIMAB

Serplulimab 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 treatment 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), and was approved for marketing in the EU for the indication of the combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). Meanwhile, Serplulimab was also approved for marketing in the 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 October 2023, the Company entered into a license agreement with Intas Pharmaceuticals Ltd. (“Intas”), pursuant to which the Company agreed to grant an exclusive license to Intas to commercialise Serplulimab in agreed European regions and India.

In addition, the Company is in the process of advancing a number of clinical trials of Serplulimab and related combination therapies globally, covering a wide range of indications such as lung cancer, head and neck squamous cell carcinoma, colorectal cancer and gastric cancer. As of the date of this announcement, the latest development progress of Serplulimab and its related combination therapies is as follows:

Product/ Combination therapy	Indications	Latest progress
Serplulimab + chemotherapy	Extensive-stage small cell lung cancer	Bridging study in the United States Bridging study in Japan
	Neo-/adjuvant treatment for gastric cancer	Phase 3 clinical trial in Chinese Mainland has met the primary endpoint Being granted the Breakthrough Therapy Designation, New Drug Application (NDA) has been accepted and has been granted the procedure for priority review in Chinese Mainland
	Limited-stage small cell lung cancer (Serplulimab in combination with chemotherapy and concurrent radiotherapy)	Phase 3 clinical trial in Chinese Mainland, the United States, Australia and EU countries (international multi-centre trial)

Product/ Combination therapy	Indications	Latest progress
Serplulimab + Bevacizumab + chemotherapy	Metastatic colorectal cancer	Phase 2/3 clinical trial in Chinese Mainland, Japan and Indonesia (international multi-centre trial)
Serplulimab + HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection)	Squamous non-small cell lung cancer and other solid tumours	Phase 2 clinical trial in Chinese Mainland
HLX43 (an antibody-drug conjugate targeting PD-L1) + Serplulimab	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 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

The marketing approval of the Two New Indications for Serplulimab in the European Union represents further recognition of Serplulimab from the international mainstream markets, which will enhance the influence of its products in the international market, and benefit more global patients.

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

Hong Kong, 10 May 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.