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 EUROPEAN COMMISSION (EC) HAS APPROVED A NEW INDICATION FOR SERPLULIMAB INJECTION (TRADE NAME IN CHINESE MAINLAND: HANSIZHUANG; TRADE NAME IN THE EUROPEAN UNION: HETRONIFLY®), IN COMBINATION WITH CHEMOTHERAPY INDICATED FOR THE FIRST-LINE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC SQUAMOUS NON-SMALL CELL LUNG CARCINOMA (sqNSCLC)

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 a new indication for serplulimab injection (Trade name in Chinese Mainland: HANSIZHUANG; Trade name in the European Union: HETRONIFLY®) independently developed by the Company ("**Serplulimab**"): Serplulimab in combination with carboplatin and nab-paclitaxel indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma (sqNSCLC) (the "**New Indication**"). This indicates that the New Indication 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 one randomised, double-blind, international, multi-centre phase 3 clinical study. The results of the study showed that Serplulimab in combination with carboplatin and nab-paclitaxel showed significant benefits in the first-line treatment of unresectable, locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC), reaching the pre-specified primary endpoint, 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 May 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 New Indication.

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 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, and the EU for its approved 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). 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 and its European subsidiary Accord Healthcare 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 and colorectal 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
	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)
Serplulimab + Bevacizumab + chemotherapy	Metastatic colorectal cancer	Phase 2/3 clinical trial in Chinese Mainland, Japan and Indonesia (international multi-centre trial)

Product/Combination therapy	Indications	Latest progress
HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) + Serplulimab + chemotherapy	Squamous non-small cell lung cancer	Phase 2/3 clinical trial in Chinese Mainland (international multi-centre trial)
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 approval of Serplulimab for the new indication for marketing in the European Union represents further recognition of the product by major international markets, and will also enhance the international influence of the Company's products, benefiting more patients worldwide.

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

Hong Kong, 25 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.