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) HAS BEEN APPROVED FOR MARKETING IN INDONESIA FOR THE TREATMENT OF EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC)

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Company.

References are made to the announcements issued by the Company dated 12 September 2019, 30 September 2019 and 25 August 2023 in relation to (i) in September 2019, the Company reached an exclusive license agreement with PT Kalbe Genexine Biologics ("**KGbio**"), upon which KGbio is granted exclusive rights to develop and commercialize HANSIZHUANG (serplulimab injection) ("**HANSIZHUANG**") in certain indications and therapies in 10 ASEAN member countries; and (ii) in August 2023, the collaboration with KGbio has been further expanded to 12 Middle East and North African (MENA) countries, including Saudi Arabia, UAE, Egypt, Qatar, Jordan, Morocco, etc. for two indications of HANSIZHUANG including extensive-stage small cell lung cancer (ES-SCLC).

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, PT Kalbio Global Medika, the subsidiary of the Company's partner KGbio, has received the relevant registration certificates issued by Indonesia's National Agency for Drug and Food Control (Indonesian: Badan Pengawas Obat and Makanan, the BPOM) for the approval of the Company's self-developed anti-PD-1 mAb HANSIZHUANG under the trade name Zerpidio® in Indonesia for the treatment of extensive stage small cell lung cancer (ES-SCLC). This is the first time HANSIZHUANG has been approved for marketing in an overseas market, and it has thus become the first China anti-PD-1 mAb approved for marketing in Southeast Asia.

B. ABOUT HANSIZHUANG (SERPLULIMAB INJECTION)

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company and was approved for marketing in mainland China in March 2022. As of the date of this announcement, HANSIZHUANG has been approved for four indications in mainland China: (1) the treatment of adult patients with advanced unresectable or metastatic Microsatellite Instability-High ("**MSI-H**") solid tumours that have failed to respond to the standard therapy; (2) the first-line treatment of patients with unresectable locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) in combination with carboplatin and albumin-bound paclitaxel; (3) the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with carboplatin and etoposide; and (4) the first-line treatment of patients with PD-L1 positive unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) in combination with drugs containing fluorouracil and platinum. In March 2023, the marketing authorisation application (MAA) for HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) was validated by the European Medicines Agency (EMA); in December 2023, the new drug application (NDA) for HANSIZHUANG in combination with pemetrexed and carboplatin for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) has been accepted by the National Medical Products Administration ("**NMPA**"). HANSIZHUANG has been granted orphan-drug designations for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA) and the European Commission in April 2022 and December 2022, respectively. In December 2023, the Group received from Health and Youth Care Inspectorate (a health supervision agency in the Netherlands) the Certificates of GMP Compliance of a Manufacturer (the GMP Certificates), and the relevant production lines of HANSIZHUANG have met the GMP standards of the European Union. The Company is also 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 studies of HANSIZHUANG and its related combination therapies are as follows:

Product/Combination therapy	**Indications**	**Stage**
HANSIZHUANG	Unresectable or metastatic MSI-H solid tumours that have failed to respond to the standard therapy	In March 2022, approved by the NMPA for marketing

Product/Combination therapy	Indications	Stage
HANSIZHUANG + chemotherapy	Locally advanced or metastatic squamous non-small cell lung cancer	In October 2022, approved by the NMPA for marketing
	Extensive-stage small cell lung cancer	In January 2023, approved by the NMPA for marketing; the marketing authorisation application (MAA) in the European Union was validated in March 2023; in December 2023, approved for marketing in Indonesia; bridging study in the United States
	Locally advanced/recurrent or metastatic esophageal squamous cell carcinoma	In September 2023, approved by the NMPA for marketing
	Non-squamous non-small cell lung cancer	Phase 3 clinical trial in mainland China, which has met the primary study endpoints; the new drug application (NDA) in mainland China has been accepted in December 2023
	Neo-/adjuvant treatment of gastric cancer	Phase 3 clinical trial in mainland China
	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 European Union country (International multicentre trial)
HANSIZHUANG + HANBEITAI (bevacizumab injection)	Metastatic colorectal cancer	Phase 2/3 clinical trial in mainland China
HANSIZHUANG + HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection)	Head and neck squamous cell carcinoma, nasopharyngeal carcinoma, gastric cancer, esophageal squamous cell carcinoma, squamous non-small cell lung cancer	Phase 2 clinical trial in mainland China

Product/Combination therapy	Indications	Stage
HANSIZHUANG + HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection)	Metastatic colorectal cancer	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
HANSIZHUANG + HLX60 (recombinant humanised anti-GARP monoclonal antibody injection)	Advanced/metastatic solid tumours	Phase 1 clinical trial in Australia

C. MARKET CONDITION

As of the date of this announcement, in addition to HANSIZHUANG of the Company, monoclonal antibody drugs targeting PD-1 that have been marketed globally include Keytruda® of Merck & Co. Inc., Opdivo® of Bristol-Myers Squibb and Libtayo® of Regeneron Pharmaceuticals, Inc., etc. HANSIZHUANG has been approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) in China. In addition, there is no other monoclonal antibody drug targeting PD-1 approved for the treatment of such indication worldwide. Monoclonal antibody drugs targeting PD-L1 approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) worldwide include Imfinzi® of AstraZeneca Pharmaceuticals Co., Ltd., Adebrelimab® of Hengrui Pharmaceuticals and Tecentriq® of Roche Pharmaceuticals. 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$33.119 billion in 2022.

D. IMPACT ON THE COMPANY

This approval of HANSIZHUANG in Indonesia is the first time HANSIZHUANG has been successfully approved for marketing in an overseas market, and it has thus become the first China anti-PD-1 mAb successfully approved for marketing in Southeast Asia. Currently, the Company is joining hands with KGbio in more than 20 countries, and the approval is expected to bring HANSIZHUANG to more patients in Indonesia.

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

Hong Kong, 28 December 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.