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

SERPLULIMAB INJECTION PASSED GMP COMPLIANCE INSPECTION BY THE INDONESIAN FOOD AND DRUG AUTHORITY

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.

References are made to the announcements issued by the Company dated 12 September 2019 and 30 September 2019 in relation to an exclusive license agreement entered into between the Company and PT Kalbe Genexine Biologics (the "**KGbio**"), pursuant to which the Company agreed to grant to KGbio an exclusive license to develop and commercialise Serplulimab Injection (trade name in mainland China: HANSIZHUANG) ("**HANSIZHUANG**") in 10 Southeast Asia countries including Indonesia, Singapore, Malaysia, etc.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, PT Kalbio Global Medika, a subsidiary of KGbio, the Company's business partner, has received the close-out letter of GMP inspection issued by the Indonesian Food and Drug Authority (the "**BPOM**"), pursuant to which the Company's biopharmaceutical production base in Xuhui District, Shanghai (Xuhui Facility) has successfully passed the GMP compliance inspection for drug substance (DS) and drug product (DP) of HANSIZHUANG by the BPOM.

B. OVERVIEW OF ON-SITE INSPECTION OF PHARMACEUTICAL PRODUCTION BASE

Name of enterprise:	Shanghai Henlius Biopharmaceuticals Co., Ltd.
Address of production base:	(Building D) Block 1, No. 1289 Yishan Road, Xuhui district, Shanghai
Product subject to inspection:	Serplulimab Injection
Scope of inspection:	drug substance (DS) south line, drug product (DP) no. 2 line, and the relevant laboratory and warehouse, etc.
Conclusion of inspection:	compliance with Good Manufacturing Practice for Medicinal Products

C. ABOUT HANSIZHUANG

HANSIZHUANG is an innovative anti-PD-1 monoclonal antibody independently developed by the Company and was approved for marketing in mainland China (excluding Hong Kong, Macau and Taiwan, the same as below) 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) of HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) has been validated by the European Medicines Agency (EMA). 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, in addition to HANSIZHUANG of the Company, the 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. According to the statistics released by IQVIA MIDAS™ (IQVIA is the world's leading 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$33.103 billion in 2022.

D. IMPACT ON THE COMPANY AND RISK WARNING

BPOM is a member of the Pharmaceutical Inspection Co-operation Scheme (the "**PIC/S**"). The passing of the GMP compliance inspection of BPOM marks that the drug substance (DS) and drug product (DP) production lines of HANSIZHUANG have met the standards of PIC/S GMP, laying a foundation for further expansion of the overseas market of HANSIZHUANG. The launch of HANSIZHUANG in Indonesia remains subject to Marketing Authorisation approval by the BPOM.

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

Hong Kong, 11 October 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.