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

OBTAINED EU GMP CERTIFICATES

A. INTRODUCTION

This announcement is made by Shanghai Henlius Biotech, Inc. (the "**Company**") pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Chapter 571, Laws of Hong Kong).

Reference is made to the announcement of the Company dated 27 October 2023 in relation to the Company having granted to Intas Pharmaceuticals Ltd. an exclusive license to commercialise HANSIZHUANG (Serplulimab Injection) ("**HANSIZHUANG**") in agreed Geographical Europe and India.

The board of directors (the "**Board**") of the Company is pleased to announce that, recently, Shanghai Henlius Biopharmaceutical Co., Ltd.* ("**Henlius Biopharmaceutical**") and Shanghai Henlius Biologics Co., Ltd.* ("**Henlius Biologics**"), wholly-owned subsidiaries of the Company, 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**"), pursuant to which the drug substance (DS) south line and drug product (DP) no. 2 line, etc. of HANSIZHUANG have passed the GMP certification. According to the GMP mutual recognition system among European Union ("**EU**") member states, the passing of GMP certification indicates that the production lines of HANSIZHUANG have met the GMP standards of the EU. At the same time, the original GMP Certificates of the EU for the relevant production lines of HANQUYOU (trastuzumab for injection, European brand name: Zercepac®) have been renewed upon expiry.

B. RELEVANT DETAILS OF THE EU GMP CERTIFICATES

(i) The GMP Certificates obtained by Henlius Biopharmaceutical

Name of enterprise:	Shanghai Henlius Biopharmaceutical Co., Ltd.*
Address:	(Building D) Block 1, No. 1289 Yishan Road, Xuhui District, Shanghai; Building No.1, No. 182, Wenjun Road, Songjiang District, Shanghai (the address of the warehouse involved in this certification)
Certified products:	Serplulimab injection, trastuzumab for injection
Scope of certification:	Drug substance (DS) south line, drug product (DP) no. 1 line, drug product (DP) no. 2 line, and warehouse, etc.
Term:	3 years commencing from the inspection date (14 August 2023)
Certificate numbers:	NL/H 23/2049709, NL/H 23/2049709A1, NL/H 23/2049709C

(ii) The GMP Certificate obtained by Henlius Biologics

Name of enterprise:	Shanghai Henlius Biologics Co., Ltd.*
Address:	Building No.1, No. 182, Wenjun Road, Songjiang District, Shanghai
Certified product:	Serplulimab injection
Scope of certification:	MCB/WCB storage and secondary packaging line
Term:	3 years commencing from the inspection date (14 August 2023)
Certificate number:	NL/H 23/2049709B

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 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 ("**EC**") in April 2022 and December 2022, respectively. 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
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 authorization application (MAA) in the European Union was validated in March 2023; 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 EU country (International multicentre trial)
HANSIZHUANG + HANBEITAI (bevacizumab injection)	Metastatic colorectal cancer	Phase 2/3 clinical trial in mainland China

Product/Combination therapy	Indications	Stage
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
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

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. 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 AND RISK WARNING

This is the first time that the relevant production lines of HANSIZHUANG have passed the GMP certification of an EU member state. According to the GMP mutual recognition system among EU member states, the passing of GMP certification of the Netherlands indicates that the above-mentioned production lines have met the GMP standards of the EU, laying a solid foundation for the Group to further expand the overseas market of HANSIZHUANG. So far, the relevant production lines of HANSIZHUANG have obtained GMP certifications in China, EU and Indonesia. After obtaining the GMP Certificates, the marketing of HANSIZHUANG in EU is still subject to the approval for the marketing authorisation application (MAA) by EU.

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

Hong Kong, 22 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.

* *For identification purpose only*