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

NEW DRUG APPLICATION (NDA) FOR NEW INDICATION OF HANSIZHUANG (SERPLULIMAB INJECTION) IN COMBINATION WITH CHEMOTHERAPY FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH PD-L1 POSITIVE UNRESECTABLE LOCALLY ADVANCED/ RECURRENT OR METASTATIC ESOPHAGEAL SQUAMOUS CELL CARCINOMA (ESCC) HAS BEEN APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

A. INTRODUCTION

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

The board of directors (the "**Board**") of the Company is pleased to announce that, recently, the new drug application (NDA) for new indication of HANSIZHUANG (serplulimab injection) ("**HANSIZHUANG**"), an innovative anti-PD-1 monoclonal antibody independently developed by the Company, in combination with drugs containing fluorouracil and platinum for the first-line treatment of patients with PD-L1 positive unresectable locally advanced/ recurrent or metastatic esophageal squamous cell carcinoma (ESCC), has been approved by the National Medical Products Administration (the "**NMPA**"). This is the fourth indication for HANSIZHUANG approved for marketing in mainland China (excluding Hong Kong, Macau and Taiwan regions, same as below).

B. DETAILS OF THE DRUG AND THE APPROVAL

Common Name:	Serplulimab Injection
Trade Name:	HANSIZHUANG
Form:	Injection
Specification:	100mg(10ml)/vial
Registration Category:	Biological Product for Treatment Purpose
Drug Manufacturer:	Shanghai Henlius Biopharmaceutical Co., Ltd.* (上海復宏漢霖生物製藥有限公司, a wholly owned subsidiary of the Company)
Review Conclusions:	According to the Drug Administration Law of the People's Republic of China and relevant requirements, upon review, this drug satisfied the relevant requirements for drug registration and its new indication is approved: this drug in combination with drugs containing fluorouracil and platinum for the first-line treatment of patients with PD-L1 positive unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

C. 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) for 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. 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. In September 2022, the results of a phase 3 clinical study of HANSIZHUANG in combination with chemotherapy as first-line treatment for patients with extensive stage small cell lung cancer (ES-SCLC) were published online in The Journal of American Medical Association (JAMA, Impact Factor: 120.7), one of the top four medical journals in the world. In February 2023, the results of a phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for the first-line treatment of locally advanced/recurrent or metastatic esophageal squamous cell carcinoma were officially published in Nature Medicine (Impact Factor: 82.9), an international authoritative journal. In March 2023, the marketing authorization 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). 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.

The approval was primarily based on a randomized, double-blind, multicentre phase 3 clinical study. The results indicated that HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) could bring significant benefits in progression-free survival (PFS) and overall survival (OS) against chemotherapy (Cisplatin + 5-FU) in the treatment as a first-line treatment for patients with locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC), met the pre-defined primary endpoint criteria, and had good safety and tolerability.

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 has been 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
	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 and Australia (International multicentre trial)

Product/Combination therapy	Indications	Stage
HANSIZHUANG + HANBEITAI (bevacizumab injection)	Metastatic non-squamous non-small cell lung cancer	Phase 3 clinical trial in mainland China
	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
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

D. 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. Monoclonal antibody drugs targeting PD-1 approved for the treatment of esophageal squamous cell carcinoma (ESCC) worldwide include Keytruda® of Merck & Co. Inc., Opdivo® of Bristol-Myers Squibb and AiRuiKa® of Jiangsu Hengrui Pharmaceuticals Co., Ltd., 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.

E. IMPACT ON THE COMPANY

HANSIZHUANG (serplulimab injection) is the first innovative biological drugs that were independently developed by the Company and approved for marketing after the successful launch of HANLIKANG, HANQUYOU (European trade name: Zercepac®), HANDAYUAN and HANBEITAI. The indication of esophageal squamous cell carcinoma (ESCC) approved for marketing is the fourth indication for HANSIZHUANG successfully marketed in mainland China, which will further enhance the market competitiveness of HANSIZHUANG, and will also offer more treatment options to patients with esophageal squamous cell carcinoma (ESCC) in mainland China.

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

Hong Kong, 22 September 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang and Mr. Jun Zhu as the executive directors, 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*