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

ORPHAN-DRUG DESIGNATION IN RESPECT OF HANSIZHUANG (SERPLULIMAB INJECTION) FOR THE TREATMENT OF SMALL CELL LUNG CANCER (SCLC) GRANTED BY THE EUROPEAN COMMISSION (EC)

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 update of the Company.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, Henlius Europe GmbH, a controlling subsidiary of the Company, received a letter from the European Commission (EC) in relation to HANSIZHUANG (serplulimab injection) (the "**HANSIZHUANG**") independently developed by the Company, which has been granted orphan-drug designation for the treatment of small cell lung cancer (SCLC) by the European Commission (EC). The qualification was granted by the European Commission (EC) in accordance with the positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

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 two 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; and (2) the first-line treatment of patients with unresectable locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) in combination with carboplatin and albumin-bound paclitaxel. In addition, the new drug applications for another two indications of HANSIZHUANG have been accepted by the National Medical Products Administration (the "**NMPA**"): in April 2022, the new drug application (NDA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of previously untreated patients with extensive stage small cell lung cancer (ES-SCLC) was accepted by the NMPA; in August 2022, the new drug application (NDA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of patients with locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) was accepted by the 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. In September 2022, the results of a phase 3 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 of 157.3), one of the top four medical journals in the world. HANSIZHUANG is planned to be used for the treatment of a variety of solid tumours, and in addition to the indications of the MSI-H solid tumours and squamous non-small cell lung cancer (sqNSCLC) which have been approved for marketing, HANSIZHUANG is being undergone clinical studies in 11 combination therapies with it as the core in various countries and regions around the world.

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
	Previously untreated extensive-stage small cell lung cancer	Phase 3 clinical trial (International multicentre trial) in mainland China, Türkiye and other countries and regions, which has met the primary study endpoint, bridging study in the United States, and in April 2022, the new drug application (NDA) has been accepted in mainland China
	Locally advanced/metastatic esophageal squamous cell carcinoma	Phase 3 clinical trial in mainland China, which has met the primary study endpoints, and in August 2022, the new drug application (NDA) has been accepted in mainland China
	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 (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
	Advanced hepatocellular carcinoma	Phase 2 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)	Recurrent or metastatic squamous cell carcinoma of the head and neck	Phase 2 clinical trial in mainland China
	Locally advanced/recurrent or distant metastatic squamous non-small cell lung cancer	Phase 2 clinical trial in mainland China
HANSIZHUANG + HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection)	Advanced/metastatic solid tumours	Phase 1 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. There is no monoclonal antibody drug targeting PD-1 approved for the treatment of small cell lung cancer (SCLC) worldwide. Monoclonal antibody drugs targeting PD-L1 approved for the treatment of small cell lung cancer (SCLC) worldwide include Imfinzi® of AstraZeneca Pharmaceuticals Co., Ltd. and Tecentriq® of Roche Pharmaceuticals. According to the statistics released by IQVIA MIDASTM (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$28.08 billion and US$15.99 billion in 2021 and the first half of 2022, respectively.

D. THE IMPACT OF THE DESIGNATION ON THE COMPANY AND THE RISK WARNING

The orphan-drug designation granted by the European Commission (EC) will be beneficial for HANSIZHUANG (serplulimab injection) to enjoy certain policy supports in the subsequent R&D, registration and commercialisation in the treatment of small cell lung cancer (SCLC) in the European Union, including but not limited to (1) protocol assistance for clinical studies; (2) access to the centralised authorisation procedure; (3) ten years of market exclusivity after the drug is approved for marketing; and (4) fee reductions for regulatory activities.

The grant of European Union orphan-drug designation is based on the European Commission regulation No. 141/2000. According to the relevant regulations, if the product that has been granted the designation is determined to no longer meet the criteria for orphan-drug designation before obtaining the marketing license, the orphan-drug registration shall be removed.

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

Hong Kong, 15 December 2022

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. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Mr. Zihou Yan 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.