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

2023 EXCLUSIVE LICENSE AGREEMENT WITH KGBIO FOR HANSIZHUANG AND AMENDMENT TO 2019 EXCLUSIVE LICENSE AGREEMENT

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 under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

References are made to the announcements issued by the Company dated 12 September 2019 and 30 September 2019 in relation to the entering into an exclusive license agreement (the "**2019 Exclusive License Agreement**") with PT Kalbe Genexine Biologics (the "**KGbio**"), pursuant to which the Company agreed to grant to KGbio an exclusive license to develop and commercialise HANSIZHUANG (serplulimab injection) (the "**Licensed Product**") in the agreed Southeast Asia countries (the "**Existing Territory**").

The board of directors of the Company is pleased to announce that on 25 August 2023, the Company and KGbio entered into (i) an exclusive license agreement (the "**2023 Exclusive License Agreement**"), pursuant to which the Company agreed to grant to KGbio an exclusive license to commercialise the Licensed Product in the Field (as defined below) within the agreed Middle East and North African countries (the"**New Territory**"); and (ii) an amendment to the 2019 Exclusive License Agreement (the "**Amendment to 2019 Exclusive License Agreement**") to amend the term in relation to the commercial sales milestone payments.

B. PRINCIPAL TERMS OF THE 2023 EXCLUSIVE LICENSE AGREEMENT

License Grant

The Company will grant to KGbio:

(a) An exclusive license to use and reference the dossier, the relative Know-How, patents, and product IP for the purpose of filing marketing approval applications and obtaining and maintaining marketing approvals for the Licensed Product in the Field in the New Territory; and

(b) A sublicensable and exclusive license to commercialise the Licensed Product in the Field in the New Territory.

Field

the treatment for extensive-stage small cell lung cancer (ES-SCLC) and a second indication (if any) as agreed by parties through separate agreements.

New Territory

the agreed Middle East and North African countries including Bahrain, Egypt, Jordan, Kuwait, Oman, Palestine, Qatar, Saudi Arabia, the United Arab Emirates, Morocco, Algeria, Tunisia, but excluding Turkey and Israel.

Payments and Royalties

KGbio shall pay the Company:

(a) an upfront fee of US$7 million in connection with the execution of the 2023 Exclusive License Agreement, within 60 calendar days upon receipt of request for payment from the Company;

(b) regulatory milestone payments of not more than US$8 million in aggregate based on achievements of each regulatory milestone of the Licensed Product in the New Territory;

(c) commercial sales milestone payments under the 2019 Exclusive License Agreement (as amended by the Amendment to 2019 Exclusive License Agreement) and 2023 Exclusive License Agreement of not more than US$650 million in aggregate based on each achievement of level of cumulative net sales of Licensed Product in the Existing Territory and the New Territory; and

(d) royalties of 15% to 20% of the cumulative net sales, based on the level of the cumulative net sales of Licensed Product in the New Territory.

Term	the 2023 Exclusive License Agreement is effective from the date of its execution and shall remain in effect for 10 years from the first launch of the Licensed Product in the New Territory, and shall be automatically renewed every five years for a period of five years, unless it is terminated earlier in accordance with the agreed circumstances.

C. PRINCIPAL TERMS OF THE AMENDMENT TO 2019 EXCLUSIVE LICENSE AGREEMENT

Pursuant to the 2019 Exclusive License Agreement, after commercialisation of Licensed Product, KGbio shall pay to the Company commercial sales milestone payments of not exceeding US$650 million depending on the achievement of level of cumulative net sales of Licensed Product in the Existing Territory. Under the Amendment to 2019 Exclusive License Agreement, the parties agreed to amend the term in relation to the commercial sales milestone payments so that each achievement of commercial sales milestone under the 2019 Exclusive License Agreement shall also include the cumulative net sales of Licensed Product in the New Territory under the 2023 Exclusive License Agreement, details of which has been set out in "B. PRINCIPAL TERMS OF THE 2023 EXCLUSIVE LICENSE AGREEMENT" above. After such amendment, the term in relation to the commercial sales milestone payments as stated in the 2019 Exclusive License Agreement (as amended by the Amendment to 2019 Exclusive License Agreement) and the 2023 Exclusive License Agreement are one and the same.

Save as disclosed above, other terms and conditions of the 2019 Exclusive License Agreement remain unchanged.

D. INFORMATION ABOUT LICENSED PRODUCT

HANSIZHUANG (serplulimab injection) 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 regions, the same as below) in March 2022. As of the date of this announcement, HANSIZHUANG has been approved for three 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; and (3) the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with carboplatin and etoposide. 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 National Medical Products Administration. In March 2023, 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). HANSIZHUANG is planned to be used for the treatment of a variety of solid tumours, and in addition to the indications 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. The sales promotion of HANSIZHUANG in mainland China is conducted by the Company's inhouse commercialisation team. As of the date of this announcement, besides KGbio, the Company has entered into business cooperations with Shanghai Fosun Pharmaceutical Industrial Development Company Limited* (上海復星醫藥產業發展有限公司) for commercialisation of HANSIZHUANG in the United States.

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 mainland 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., Tecentriq® of Roche Pharmaceuticals and Adebrelimab® of Hengrui Pharmaceuticals. According to the latest 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$33.103 billion in 2022.

E. REASONS AND BENEFITS OF THE COLLABORATION WITH KGBIO

The Company has established a good cooperative relationship with KGbio for the commercialisation of the Licensed Product in the Southeast Asia regions. The collaboration with KGbio on the commercialisation of the Licensed Product in the Middle East and North African regions will help further promote the overseas market expansion of the Licensed Product, strengthen the accessibility and international recognition of the Company's products.

F. INFORMATION ABOUT KGBIO

KGbio is a biotechnology company established in 2016, its business model revolves around in-licensing novel biologics and select biosimilars in oncology and high-specialty therapeutic areas (typically pre-IND or early clinical stage), with the objective to out-license them in target geographies after finishing clinical development as well as regulatory and reimbursement approvals. PT Kalbe Farma Tbk. ("**Kalbe Farma**"), the controlling shareholder of KGbio, was established in 1966. Kalbe Farma's shares have been listed on the Indonesia Stock Exchange (IDX: KLBF) since 1991 and Kalbe Farma is one of the largest listed companies in the field of medication and with strong drug sales network and channels in Southeast Asia.

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

Hong Kong, 25 August 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. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan and Mr. Deyong Wen 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 purposes only.*