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

LICENSE AGREEMENT WITH INTAS IN RESPECT OF HANSIZHUANG

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 of the Company is pleased to announce that on 27 October 2023, the Company entered into a license agreement (the "**License Agreement**") with Intas Pharmaceuticals Ltd. ("**Intas**"), pursuant to which, the Company agreed to grant to Intas an exclusive license in relation to HANSIZHUANG (serplulimab injection) (the "**Licensed Product**") in the Field (as defined below) in agreed Geographical Europe and India (the "**Territory**").

B. PRINCIPAL TERMS OF THE LICENSE AGREEMENT

License

The Company would grant to Intas:

(a) an exclusive, sublicensable license to commercialise the Licensed Product and to practice the relevant intellectual property rights and know-how for such commercialisation purposes in the Field in the Territory;

(b) a non-exclusive, sublicensable license to manufacture the Licensed Product in accordance with the applicable conditions stipulated in the License Agreement and the manufacturing and supply agreement to be entered into by the parties; and

(c) a license to develop and commercialise specific formulation of the Licensed Product (the "**Specific Formulation Developed by Intas**") pursuant to the terms under the License Agreement.

Field	(a) current indications and their corresponding formulations of the Licensed Product; and (b) any additional indications and formulations that the parties mutually agree to develop according to the License Agreement.
Territory	(a) Agreed Geographical Europe: 52 European countries including France, the United Kingdom, etc.; together with any additional member states added to the European Union ("**EU**") or European Economic Area during the term of the License Agreement (for the avoidance of doubt, and for the purpose of the License Agreement, any country that leaves or has left the EU or the European Economic Area shall be included in definition of Territory); and (b) India.
Payments and Royalties	Intas shall pay the Company: (a) upfront payments of no more than €42 million in total, amongst which, the first upfront payment of €26 million will be paid on the effective date of the License Agreement, and the second upfront payment of €16 million will be paid upon the European Medicines Agency issuing a positive opinion (Day 210 of the centralized procedure) for the Licensed Product to be used as a first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) (such upfront payment will be paid in full if the Licensed Product is approved by the European Medicines Agency before 31 July 2025, otherwise the payment will be reduced or cancelled depending on the duration of the delayed approval of marketing authorization); (b) regulatory milestone payments of no more than €43 million in total, which shall be reduced by €4.8 million if the approved price of the Licensed Product in any of the five EU countries (being France, Germany, Italy, Spain and the United kingdom) is lower than the agreed premium range; (c) commercial sales milestone payments of no more than €100 million in aggregate based on the annual net sales of the Licensed Product in the Territory for the first calendar year; (d) royalties at the rates ranging from 15% to 27% of the annual net profit of the Licensed Product (excluding the Specific Formulation Developed by Intas) in the Territory. For the Specific Formulation Developed by Intas, Intas shall pay to the Company royalties in an amount equal to 5% of the annual net sales.

Right of First Refusal	Intas has the right of first refusal to commercialise the additional competing antibody-drug conjugate or bispecific compound comprising the amino acid sequence of Serplulimab pursuant to the terms under the License Agreement.
Conversion of Exclusive License	During three (3) consecutive years following the launch of the Licensed Product in the Territory, if Intas achieves less than 60% of the agreed aggregated forecasts of purchase quantity in the Territory for its own reasons, the Company shall have the right to convert the exclusive license granted to Intas according to the License Agreement to a semi-exclusive license in those countries where the purchase quantity requirements are not meet, that is, the Company will have the right to out-license the relevant intellectual property rights and know-how of the Licensed Product to one additional third party.
Exclusive license of the Specific Formulation Developed by Intas to the Company granted by Intas	Intas grants the Company an exclusive license to commercialise the Specific Formulation Developed by Intas and to practice such intellectual property rights for such commercialisation purposes in China; Intas shall use commercially reasonable efforts to negotiate for the Company any other licenses from third parties required to commercialise the Specific Formulation Developed by Intas in China; the Company shall pay to Intas royalties in an amount equal to 5% of the annual net sales of such formulation in China commencing on the launch of the Specific Formulation Developed by Intas in China. Intas shall be responsible for manufacturing and supply of the Specific Formulation Developed by Intas pursuant to a separate supply agreement to be entered into by the parties.
Term	The License Agreement is effective from the date of execution (the "**Effective Date**") and, unless terminated according to the terms of the License Agreement, shall remain in effect on a country-by-country basis for an initial term of the latest of (a) ten (10) years after the date of the launch of the Licensed Product in such country; (b) the expiration of the last to expire regulatory exclusivity conferred by the applicable regulatory authority in such country for the Licensed Product, or (c) the expiry of the last valid claim of any patent of the Company that covers the Licensed Product on the market in the relevant country of the Territory (the "**Initial Term**"). Upon expiry of the Initial Term and upon expiry of each renewal, the License Agreement shall be automatically renewed for a renewal, unless either party notifies the other its intention not to renew the agreement at least six (6) months before the expiry of such term.

C. INFORMATION ABOUT THE 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 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 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). 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 sales promotion of HANSIZHUANG in mainland China is conducted by the Company's inhouse commercialisation team. As of the date of this announcement, the Company has entered into business cooperations with PT Kalbe Genexine Biologics and Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd. (上海復星醫藥產業發展有限公司) for commercialisation of HANSIZHUANG in Southeast Asia (10 countries), Middle East and North Africa (12 countries) and 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. 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$33.119 billion in 2022.

D. REASONS AND BENEFITS OF THE COLLABORATION

The Group has established a good cooperative relationship with Intas and its affiliates on the commercialisation of Trastuzumab for injection (trade name in mainland China: HANQUYOU; EU trade name: Zercepac®) in Europe, the United States of America, Canada and other regions. The collaboration with Intas on the commercialisation of the Licensed Product in Europe and India will help to further expand the overseas market of the Company's products, enhance the accessibility and recognition of the Company's products in the international market, thereby contributing to the continuous increase of the Company's income.

E. INFORMATION ABOUT INTAS

Intas, founded in 1976 and headquartered in Ahmedabad, India, is a pharmaceutical company engaged in the development, manufacturing, marketing, distribution and sale of generics, specialty generics, active pharmaceutical ingredients, biologic products, etc. worldwide. Intas and its subsidiaries collectively have more than 17,500 employees, sell products in more than 85 countries and have 16 manufacturing facilities worldwide.

To the best of the knowledge, information and belief of the Company having made all reasonable enquiries, Intas is not a connected person (as defined in the Listing Rules) of the Company.

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

Hong Kong, 27 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.