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 AND SUPPLY AGREEMENT WITH ORGANON FOR HLX11 (ANTI-HER2 DOMAIN II HUMANISED MONOCLONAL ANTIBODY INJECTION) AND HLX14 (RECOMBINANT ANTI-RANKL HUMAN MONOCLONAL ANTIBODY INJECTION)

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 13 June 2022, the Company entered into a license and supply agreement (the "**License and Supply Agreement**") with Organon LLC ("**Organon**"), pursuant to which the Company agreed to grant Organon and its affiliates a license to commercialize HLX11 (anti-HER2 domain II humanised monoclonal antibody injection) ("**HLX11**") and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) ("**HLX14**", together with HLX11, the "**Licensed Products**") in the Field globally except for mainland China, Hong Kong, Macau and Taiwan regions (the "**Territory**").

B. PRINCIPAL TERMS OF THE LICENSE AND SUPPLY AGREEMENT

License the Company has agreed to grant Organon and its affiliates a license under the licensed patents, licensed know-how and product IP to:

(a) use and reference the dossier of the Licensed Products solely for obtaining marketing approvals of the Licensed Products in the Field in the Territory;

(b) commercialize the Licensed Products in the Field in the Territory;

(c) manufacture and have manufactured the Licensed Products solely for the purpose of commercialize Licensed Products in the Field in the Territory;

(d) regulatory develop Licensed Products in the Field in the Territory; and

(e) maintain, obtain, and update marketing approvals and other regulatory permits in the Field in the Territory as necessary.

Territory worldwide territories excluding mainland China, Hong Kong, Macau and Taiwan regions.

Field the treatment of the indications for each biosimilar product approved in marketing approvals on a Licensed Product-by-Licensed Product and country-by-county basis.

Payment Organon shall pay the Company:

(a) an upfront fee of US$70 million in connection with the execution of the License and Supply Agreement, consisting of a non-refundable payment amount of US$40 million with respect to HLX11 and a payment amount of US$30 million with respect to HLX14;

(b) development and regulatory milestone payments of not more than US$103 million in aggregate based on achievements of each development and regulatory milestones of each Licensed Products; and

(c) commercial sales milestone payments of not more than US$365 million in aggregate based on achievements of each commercial sales milestones of each Licensed Products.

Subject to the terms of the License and Supply Agreement, Organon has rights to terminate the cooperation relating to HLX14 at any time prior to the parties agreeing that the phase 3 study of HLX14 has been successful. If Organon exercises such rights, the Company shall fully refund the upfront fee and development milestone payments relating to HLX14 received prior to such termination, unless the last patient dosing in a phase 3 clinical trial of HLX14 is achieved before the agreed deadline in which case half of the HLX14 upfront fee (US$15 million) shall become non-refundable.

In addition to the upfront fees for HLX11 and HLX14, Organon shall pay the Company a refundable amount of US$3 million (the "**Option Payment**") as an upfront fee for the option to license the commercialization rights to HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection, a biosimilar of ipilimumab independently being developed by the Company) ("**HLX13**") in the Territory. The Option Payment will be fully refundable if Organon declines to exercise the option or if the parties fail to enter into an agreement with respect to the license of HLX13 within a specified time frame.

In addition, Organon and its affiliates shall also purchase the Licensed Products for the Territory exclusively from the Company and pay the supply prices to the Company. Subject to the License and Supply Agreement, if Organon wishes to manufacture the Licensed Products by itself or its licensee manufacturers, Organon shall not be required to pay the supply prices for the Licensed Products manufactured by itself or its licensee manufacturers, but shall pay a royalty to the Company for such Licensed Products at an agreed rate.

Term the License and Supply Agreement is effective from the date of its execution, and remain in effect until Organon decide to terminate it on a Licensed Product-by-Licensed Product and country-by-country basis with a prior written notice, or the parties decide to terminate the agreement earlier pursuant to the License and Supply Agreement.

C. INFORMATION ABOUT THE LICENSED PRODUCTS

HLX11 (anti-HER2 domain II humanised monoclonal antibody injection) is a biosimilar of pertuzumab independently developed by the Company, the reference product is Perjeta®, which is intended for the treatment of metastatic breast cancer and early breast cancer. In April 2022, the first patient has been dosed in a phase 3 clinical trial of HLX11 in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below). As of the date of this announcement, the pertuzumab injection product available worldwide is Perjeta® of Roche. 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 global sales of pertuzumab injection product in 2021 was US$3.896 billion.

HLX14 (recombinant anti-RANKL human monoclonal antibody injection) is a biosimilar of Denosumab independently developed by the Company, the reference products are Prolia® and Xgeva®, which is intended for the treatment of postmenopausal osteoporosis in women with high fracture risks and the scope of what has been approved for its reference products. The first patient has been dosed in a phase 1 clinical trial of HLX14 in mainland China in November 2020, phase 3 clinical trial of HLX14 will be commenced soon. As of the date of this announcement, the denosumab injection products available worldwide includes Prolia® and Xgeva® of Amgen Inc., PRALIA® of Daiichi Sankyo Company Limited and Rozel® of Intas Pharmaceuticals Ltd., etc.. According to the statistics released by IQVIA MIDAS™, the global sales of denosumab injection products in 2021 was US$5.849 billion.

D. REASONS AND BENEFITS OF ENTERING INTO THE LICENSE AND SUPPLY AGREEMENT

The entering into of the License and Supply Agreement with Organon will further promote the overseas market expansion of the Company's products, strengthen the accessibility and acceptance of the Company's products in global markets and contribute to the continuous increase in the Company's revenue.

E. INFORMATION ABOUT ORGANON

Organon is a wholly-owned subsidiary of Organon & Co., a global healthcare company with a focus on improving the health of women throughout their lives. Organon & Co. has a portfolio of more than 60 medicines and products across a range of therapeutic areas. Led by the women's health portfolio coupled with an expanding biosimilars business and stable franchise of established medicines, Organon & Co.'s products produce strong cash flows that will support investments in innovation and future growth opportunities. In addition, Organon & Co. is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

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

WARNING STATEMENT WITH REFERENCE TO THE REQUIREMENTS UNDER RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: The Company cannot guarantee the successful development and commercialization of Licensed Products. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

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

Hong Kong, 13 June 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, Dr. Aimin Hui 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.