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

THE BIOLOGIC LICENSE APPLICATION (BLA) FOR PROPOSED BIOSIMILAR TO TRASTUZUMAB HLX02 FOR THE TREATMENT OF ADJUVANT BREAST CANCER, METASTATIC BREAST CANCER AND METASTATIC GASTRIC CANCER ACCEPTED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

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 development of the Company.

Reference is made to the announcement of the Company dated 4 January 2021 in relation to a license agreement entered into between the Company and Intas Pharmaceuticals Limited ("**Intas**"), Pursuant to which, the Company granted Intas and its affiliates an exclusive license to commercialize HLX02 (trastuzumab for injection) in the United States and Canada.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the United States Food and Drug Administration (FDA) has accepted the Biologic License Application (BLA) for HLX02 (trastuzumab for injection) with the strength of 150mg/vial for (1) adjuvant treatment of HER2 overexpressing breast cancer; (2) the treatment of HER2-overexpressing metastatic breast cancer; and (3) the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma submitted by Accord BioPharma Inc. (an affiliate of Intas).

B. BASIS FOR SUBMISSION

The submission is mainly based on the review of a series of study data of HLX02 (trastuzumab for injection), known as HANQUYOU in mainland China (excluding Hong Kong, Macau and Taiwan regions, same as below), versus its reference product (Herceptin®), including analytical similarity and clinical studies, etc.. These data prove that HLX02 (trastuzumab for injection) and reference product (Herceptin®) are highly similar in terms of quality, safety and efficacy.

C. ABOUT HLX02 (TRASTUZUMAB FOR INJECTION)

HLX02 (trastuzumab for injection, trade name in mainland China: HANQUYOU; EU trade name: Zercepac®; Australian trade names: Tuzucip®/Trastucip®) is a monoclonal antibody biosimilar independently developed by the Company in accordance with the guidelines for biosimilar in the mainland China and the European Union (the "**EU**") with dual approvals in mainland China and the EU, for the adjuvant treatment of HER2-positive breast cancer and the treatment of HER2-positive breast cancer and gastric cancer. For mainland China, HANQUYOU (trastuzumab for injection) with the strength of 150mg/vial was approved by the National Medical Products Administration (the "**NMPA**") for marketing in August 2020 and its supplemental new drug application (sNDA) for new strength of 60mg/vial was also approved by the NMPA in August 2021. For oversea markets, Zercepac® (trastuzumab for injection) with the strength of 150mg/vial was approved by the European Commission ("**EC**") for marketing in the EU in July 2020 and its sNDA for strengths of 60mg/vial and 420mg/vial were also approved by the EC in 2021. In July 2021, the Swissmedic approved the new drug application of Zercepac® (trastuzumab for injection) with the strength of 150mg/vial. The exclusive right to commercialize Zercepac® in Europe and in Switzerland was granted to Accord Healthcare Limited, a business partner of the Company. In July 2022, Tuzucip® and Trastucip® (trastuzumab for injection) with the strength of 150mg/vial was approved for marketing in Australia. The exclusive right to commercialize Tuzucip® and Trastucip® in Australia was granted to Cipla Limited, a business partner of the Company.

D. MARKET CONDITION

According to the information provided by IQVIA MIDAS™ (IQVIA is a world-leading provider of professional medical and health information and strategic consultation), the global sales of trastuzumab in 2021 and the first half of 2022 were approximately US$4.734 billion and US$2.074 billion, respectively.

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

Hong Kong, 14 February 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, 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.