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

APPLICATION FOR CLINICAL TRIALS OF HLX78 (LASOFOXIFENE) WAS APPROVED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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.

The board of directors (the "**Board**") of the Company is pleased to announce that, recently, HLX78 (lasofoxifene) ("**HLX78**") was approved by the National Medical Products Administration to commence in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below): (1) a phase 1 clinical trial of HLX78 in Chinese healthy subjects; and (2) an international multi-center phase 3 clinical trial and the indication is HLX78 in combination with Abemaciclib for the treatment of pre – and postmenopausal women and men who have previously received aromatase inhibitor (AI) combined with a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor and have locally advanced or metastatic estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2)— breast cancer with an estrogen receptor 1 (ESR1) mutation. The Company proposes to commence relevant clinical trials in mainland China when the conditions are fulfilled.

B. ABOUT HLX78

HLX78 is an oral selective estrogen receptor modulator (SERM) licensed by the Company from Sermonix Pharmaceuticals, Inc. intended for the treatment of ER+/HER2 – breast cancer with ESR1 mutation, and the Company has its exclusive rights in China (including Hong Kong, Macau and Taiwan regions). Currently, an international multi-center phase 3 clinical trial (one of the above approved studies) of the product is being commenced in the United States, Europe, Canada and other regions. At an earlier stage, in two phase 2 clinal trials of lasofoxifene in breast cancer patients harboring ESR1 mutation, lasofoxifene has demonstrated positive clinical efficacy as a monotherapy or in combination with CDK4/6 inhibitor.

C. MARKET CONDITION

HLX78 is an oral SERM (selective estrogen receptor modulator) targeting breast cancer patients with ESR1 mutation. As at the date of this announcement, there is not any oral SERM approved for the treatment of ESR1 mutated breast cancer worldwide. And worldwide only Elacestrant, an oral SERD (selective estrogen receptor degrader), was approved for the treatment of ESR1 mutated breast cancer by the United States Food and Drug Administration in January 2023. According to IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales of Elacestrant was US$140 million in the year of 2023 in global market.

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 commercialisation of HLX78. 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, 14 May 2024

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.