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

FIRST PATIENT IN MAINLAND CHINA HAS BEEN DOSED IN AN INTERNATIONAL MULTI-CENTER PHASE 3 CLINICAL STUDY OF THE COMBINATION OF HLX78 (LASOFOXIFENE) AND ABEMACICLIB COMPARED TO THE COMBINATION OF FULVESTRANT AND ABEMACICLIB FOR THE TREATMENT OF LOCALLY ADVANCED OR METASTATIC BREAST CANCER

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 of the Company (the "**Board**") is pleased to announce that, recently, the first patient in mainland China (excluding Hong Kong, Macau and Taiwan regions, same as below) has been dosed in an international multi-center phase 3 clinical trial ("**ELAINE-3**") of the combination of HLX78 (lasofoxifene) ("**HLX78**") and abemaciclib to the combination of fulvestrant and abemaciclib for the treatment of pre- and postmenopausal women and men with locally advanced or metastatic estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) breast cancer who have disease progression on an aromatase inhibitor (AI) in combination with either palbociclib or ribociclib as their first hormonal treatment for metastatic disease and who have an estrogen receptor 1 (ESR1) mutation. Currently, ELAINE-3 is being conducted globally by Sermonix Pharmaceuticals, Inc. ("**Sermonix**"), and the first patient has been dosed in January 2024. ELAINE-3 is being commenced recruiting in the United States, Europe, Canada and other regions.

B. CLINICAL TRIAL DESIGN AND PURPOSE

This is a phase 3, open label, controlled, randomized, multicenter study comparing the efficacy, safety, and tolerability of the combination of lasofoxifene and abemaciclib with that of fulvestrant and abemaciclib for the treatment of men and pre- and postmenopausal women with locally advanced or metastatic ER+/HER2- breast cancer who have disease progression on an aromatase inhibitor in combination with either palbociclib or ribociclib as their first hormonal treatment for metastatic disease and who have an ESR1 mutation. Eligible participants will be randomized at 1:1 to receive lasofoxifene (5 mg/day, oral administration) combined with abemaciclib or fulvestrant combined with abemaciclib. The primary objective of this study is to evaluate the progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as determined by blinded independent central review (BICR) of each treatment arm, the secondary objectives are to evaluate objective response rate (ORR), overall survival (OS), clinical benefit rate (CBR), duration of response (DoR), time to response (TTR), time to cytotoxic chemotherapy, quality of life, and safety, etc.

C. ABOUT HLX78

HLX78 is an oral selective estrogen receptor modulator (SERM) licensed by the Company from Sermonix in January 2024, which is intended for the treatment of ER+/HER2- breast cancer with an ESR1 mutation, and the Company has its exclusive rights to develop and commercialize it in China (including Hong Kong, Macau and Taiwan regions, same as below). In June 2024, the Company and Sermonix signed a supplementary agreement to expand the scope of license to all of Asia. The Company shall be solely responsible for all aspects of the development of ELAINE-3 in China, other than that, the Company and Sermonix will collaborate on co-development of lasofoxifene in Japan. Lasofoxifene belongs to the class of drugs known as estrogen agonist/antagonists, and these molecules have been described to exert both tissue and gene selective ER activity. Following receptor binding, the resultant conformational change, receptor dimerization, and interaction with co-regulators results in SERM-specific transcription of target genes. In November 2024, the first patient has been dosed in a phase 1 clinical study to evaluate the safety, tolerability and pharmacokinetic characteristics of HLX78 in healthy Chinese adult women in mainland China.

D. 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 no 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 approximately 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 commercialization 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, 24 December 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, Dr. 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.