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

HLX208 (BRAF V600E INHIBITOR) FOR THE TREATMENT OF ADULT LANGERHANS CELL HISTIOCYTOSIS (LCH) AND ERDHEIM-CHESTER DISEASE (ECD) WITH BRAF V600E MUTATION HAS BEEN OFFICIALLY GRANTED THE BREAKTHROUGH THERAPY DESIGNATION BY THE CENTER FOR DRUG EVALUATION OF 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 of the Company (the "**Board**") is pleased to announce that, recently, HLX208 (BRAF V600E inhibitor) (the "**HLX208**") for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation has been officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (the "**CDE**") of the National Medical Products Administration (the "**NMPA**"). According to the relative measures of the Administration of Drug Registration (《藥品註冊管理辦法》) and the Announcement of the NMPA on the Release of Three Documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈＜突破性治療藥物審評工作程序(試行)＞等三個文件的公告》(2020年第82號)), drugs granted the Breakthrough Therapy Designation are prioritized by the CDE in communications and guidance to promote the drug development progress.

B. ABOUT HLX208

HLX208 is a small-molecule inhibitor targeting the human BRAF protein V600E mutation, licensed by the Company from Suzhou NeuPharma Co., Ltd.* (蘇州潤新生物科技有限公司) in May 2021. It has exhibited excellent drug efficacy and safety in pre-clinical research. The BRAF protein is an important upstream regulator of MAPK/ERK signaling pathway, and its V600E mutation can induce constitutive activity of BRAF protein. It is a potential drug target for a variety of tumors including colorectal cancer, thyroid cancer, melanoma, lung cancer, brain cancer, and certain rare diseases including adult Langerhans Cell Histiocytosis (LCH) and Erdheim Chester disease (ECD). In January 2022, application for phase 1b/2 clinical trial of HLX208 monotherapy or in combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In the same month, the first patient has been dosed in the phase 2 clinical trial of HLX208 for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in mainland China (excluding Hong Kong, Macau and Taiwan regions, same as below). In November 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG and its combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In February 2023, the first patient has been dosed in a phase 1b/2 clinical trial of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG for the treatment of non-small cell lung cancer (NSCLC) in mainland China.

C. MARKET CONDITION

As at the date of this announcement, the BRAF mutation-targeting drugs that have been marketed in mainland China include Zobovolt® of Roche Pharma (Schweiz) Ltd. and Tefila® of Novartis AG. There are no BRAF mutant-targeted drugs that have been approved in mainland China for the treatment of BRAF V600E-mutated adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD). According to the information provided by IQVIA CHAP (being the world's leading provider of professional information and strategic consulting services in the healthcare industry; IQVIA CHPA data represents the drug sales market of hospitals with more than 100 beds in mainland China. The actual sales of different drugs may differ from IQVIA CHPA data to varying degrees due to their different sales distribution channels), the sales of BRAF mutant-targeted drugs in mainland China in 2022 was approximately RMB126 million.

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 HLX208. 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, 6 April 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.