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 PHASE 1/2 CLINICAL STUDY OF RECOMBINANT ANTI-VEGF HUMANISED MONOCLONAL ANTIBODY INJECTION HLX04-O FOR THE TREATMENT OF WET AGE-RELATED MACULAR DEGENERATION (wAMD) HAS SHOWN ITS SAFETY AND TOLERABILITY AND DEMONSTRATED PRELIMINARY EFFICACY

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 announcements of the Company dated 15 October 2020 and 22 February 2023 in relation to the Company's grant of the exclusive right of HANBEITAI (bevacizumab injection) for ophthalmic treatment and/or therapy purposes worldwide to Essex Bio-Investment Limited ("**Essex Investment**") and Zhuhai Essex Bio-Pharmaceutical Company Limited* (珠海億勝生物製藥有限公司) (together with Essex Investment, the "**Essex**") and the agreement to co-develop the relevant product with Essex. The Company and Essex will bear 20% and 80% of the costs and expenses related to the relevant product development activities, respectively.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the phase 1/2 clinical study of recombinant anti-VEGF humanised monoclonal antibody injection HLX04-O ("**HLX04-O**") in patients with wet age-related macular degeneration (wAMD) has shown its safety and tolerability and demonstrated preliminary efficacy.

B. CLINICAL TRIAL DESIGN, PURPOSE AND CONCLUSION

This single-arm, open-label, multicentre, phase 1/2 study aimed to evaluate the safety and preliminary efficacy of HLX04-O via intravitreal injection ("**IVT**") in patients with active wet age-related macular degeneration. The study consisted of two parts. Part 1 was a safety run-in stage which enrolled 6 patients. Part 2 was a single-arm, open-label, multicentre, phase 2 study and 20 patients (including 6 patients from part 1) were enrolled in this part. All patients received HLX04-O IVT (1.25 mg/0.05 mL) every four weeks until death, withdrawal of informed consent, loss to follow-up, study termination by sponsor, or completion of one-year treatment. For part 1, the primary endpoint was safety event related to HLX04-O that occurred within four weeks after the first dose of HLX04-O; secondary endpoints were the systemic pharmacokinetic characteristics of HLX04-O after the first and fourth IVT

administration. For part 2, the primary endpoint was the mean change of letters from baseline in best corrected visual acuity (BCVA) at week 12; secondary endpoints included other efficacy measures, safety, immunogenicity, and systemic pharmacokinetic characteristics. The results showed that HLX04-O was safe and well tolerated in wet age-related macular degeneration patients, and preliminary efficacy was observed.

C. INFORMATION ABOUT HLX04-O

HLX04-O is a new ophthalmic preparation product developed based on HANBEITAI (bevacizumab injection) independently developed by the Company, through optimizing the prescription, specifications and production processes of HANBEITAI (bevacizumab injection) according to the requirements of ophthalmic drugs, without changing the active ingredients, and is intended to be used for the treatment of wet age-related macular degeneration. In November 2021, the first patient had been dosed in a phase 3 clinical study for HLX04-O for the treatment of wet age-related macular degeneration in mainland China. So far, the first patient has been dosed in an international multicentre phase 3 clinical study of HLX04-O in patients with wet age-related macular degeneration in an EU country (Latvia) and countries such as Australia and America successively.

D. MARKET CONDITION

As of the date of this announcement, none of the bevacizumab products marketed within the PRC has been approved for the treatment of wet age-related macular degeneration, and large molecule drugs targeting wet age-related macular degeneration indications that have been marketed within the PRC include Lucentis® (Ranibizumab), Langmu® (Conbercept) and Eylea® (Aflibercept). According to the statistics released by IQVIA CHPA (IQVIA is the world's leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales within the PRC of relevant drugs in 2022 were as follows: RMB1,347 million for Lucentis® (Ranibizumab); RMB1,116 million for Langmu® (Conbercept) and RMB644 million for Eylea® (Aflibercept).

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 HLX04-O. 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, 26 July 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 and Mr. Deyong Wen 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.

* *for identification purpose only*