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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

NEW DRUG APPLICATION (NDA) FOR RECOMBINANT ANTI-VEGF HUMANISED MONOCLONAL ANTIBODY INJECTION HLX04-O HAS BEEN ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)

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 HLX04-O (a recombinant humanized anti-VEGF monoclonal antibody ophthalmic injection independently developed by the Company, original project code: HLX04) ("**HLX04-O**") for ophthalmic treatment and/or therapy purposes worldwide to Essex Bio-Investment Limited and Zhuhai Essex Bio-Pharmaceutical Company Limited* (珠海億勝生物製藥有限公司) (together, "**Essex**") and the agreement to co-develop the relevant product with Essex.

The board of directors of the Company (the "**Board**") is pleased to announce that, recently, the New Drug Application (NDA) for HLX04-O for the treatment of wet age-related macular degeneration (wAMD) has been accepted by the Center for Drug Evaluation of the National Medical Products Administration (NMPA).

B. BACKGROUND OF AND BASIS FOR SUBMISSION

The first New Drug Application (NDA) for HLX04-O is primarily supported by a multi-centre, randomized, double-blind, active-controlled, non-inferiority phase 3 clinical study comparing intravitreal injections (IVT) of HLX04-O versus ranibizumab in Chinese patients with wet age-related macular degeneration (wAMD). The study met its primary endpoint, demonstrating non-inferiority of HLX04-O to ranibizumab in the mean change from baseline in best-corrected visual acuity (BCVA) at week 48. HLX04-O exhibited a favorable safety profile, with no new safety signals identified.

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 (wAMD). In July 2023, the phase 1/2 clinical study of HLX04-O in patients with wet age-related macular degeneration (wAMD) has shown its safety and tolerability and demonstrated preliminary efficacy. In April 2025, the phase 3 clinical study of HLX04-O in Chinese patients with wet age-related macular degeneration (wAMD) met its primary endpoint. In addition, an international multi-center phase 3 clinical study of HLX04-O in patients with wet age-related macular degeneration (wAMD) is ongoing successively in several European countries, Australia, America, and mainland China (excluding Hong Kong, Macau, and Taiwan regions of the PRC, the same as below).

D. MARKET CONDITION

As of the date of this announcement, none of the bevacizumab products marketed in mainland China has been approved for the treatment of wet age-related macular degeneration (wAMD). According to the statistics released by IQVIA CHPA (IQVIA is the world's provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales of drugs approved in mainland China for the treatment of wet age-related macular degeneration (wAMD) in 2024 were approximately RMB4.90 billion.

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, 13 August 2025

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and non-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.

* *for identification purpose only*