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 TRIAL FOR RECOMBINANT ANTI-VEGF HUMANISED MONOCLONAL ANTIBODY OPHTHALMIC INJECTION HLX04-O FOR THE TREATMENT OF WET AGE-RELATED MACULAR DEGENERATION (wAMD) APPROVED IN AN EU COUNTRY (LATVIA)

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 announcement of the Company dated 15 October 2020 in relation to the Company's grant of the exclusive right of recombinant anti-VEGF humanised monoclonal antibody injection HLX04 ("**HLX04**") for ophthalmic treatment and/or therapy purposes worldwide to Essex Bio-Investment Limited ("**Essex Investment**") and Zhuhai Essex Bio-Pharmaceutical Company Limited* (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 (the "**Board**") of the Company is pleased to announce that, recently, the application for clinical trial for recombinant anti-VEGF humanised monoclonal antibody ophthalmic injection HLX04-O ("**HLX04-O**") for the treatment of wet age-related macular degeneration (wAMD) has been approved by the State Agency of Medicines of Latvia, which is the first approved clinical trial for HLX04-O in EU countries. We have successively submitted applications for clinical trial for HLX04-O in Hungary, Spain, Czech Republic and other EU countries, and are expected to receive approvals in the near future.

B. GLOBAL MULTICENTRE CLINICAL TRIAL FOR HLX04-O

The phase 3, global and multicentre clinical study of HLX04-O is intended to commence in the near future to further evaluate the efficacy and safety of HLX04-O for the treatment of wet age-related macular degeneration. According to the protocol of the clinical study, the study will be conducted in various countries/regions including mainland China, Australia, Russian Federation, Singapore, Spain and Poland.

C. INFORMATION ABOUT HLX04-O

HLX04-O is a new ophthalmic preparation product developed based on HLX04, a bevacizumab biosimilar independently developed by the Company, through optimizing the prescription, specifications and production processes of HLX04 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. By means of comparability studies, it shows that changes in production processes and prescriptions of the preparation have no adverse impact on the quality, safety and efficacy of the pharmaceutical preparation. The primary action mechanism of HLX04-O is to inhibit VEGF's binding to its receptor Flt-1 and KDR on endothelial cells to inhibit the activation of its tyrosine kinase signaling pathway, inhibit endothelial cell proliferation and reduce angiogenesis, thereby treating eye diseases associated with angiogenesis. In January and March 2021, HLX04-O for the treatment of wet age-related macular degeneration has been approved to commence the phase 3 clinical trial in Australia and the United States.

D. MARKET CONDITION

As of the date of this announcement, none of the bevacizumab products marketed globally has shown wet age-related macular degeneration (wAMD) indications. Large molecule drugs targeting wet age-related macular degeneration indications that have been marketed globally include Eylea® (Aflibercept), Lucentis® (Ranibizumab) and Langmu® (Conbercept). According to the latest statistics released by IQVIA MIDAS™, being the world's leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry, the worldwide sales of relevant drugs in 2020 were as follows: US$6,071 million for Eylea®; US$3,905 million for Lucentis®; and US$106 million for Langmu®.

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.
Qiyu CHEN
Chairman

Hong Kong, 20 April 2021

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the executive director, Mr. Qiyu Chen as the chairman and non-executive director, Mr. Yifang Wu, Ms. Xiaohui Guan, Dr. Aimin Hui 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.

* *for identification purpose only*