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 SUPPLEMENTAL APPLICATIONS OF HANDAYUAN (ADALIMUMAB INJECTION) FOR THE NEW INDICATIONS HAVE BEEN ACCEPTED BY THE 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, the supplemental new drug applications of HANDAYUAN (adalimumab injection) ("**HANDAYUAN**") which is independently developed by the Company for the new indications of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease and pediatric Crohn's disease have been accepted by the National Medical Products Administration (the "**NMPA**").

B. BACKGROUND OF AND BASIS FOR SUBMISSION

HANDAYUAN (adalimumab injection) is a biosimilar of adalimumab independently developed by the Company, which was approved by the NMPA for marketing in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below) in December 2020. As of the date of this announcement, the indications of HANDAYUAN approved in mainland China are: (1) rheumatoid arthritis; (2) ankylosing spondylitis; (3) plaque psoriasis; and (4) uveitis.

The applications add the indications of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease and pediatric Crohn's disease, of which the originator adalimumab has been approved in mainland China. The extrapolation of these indications is mainly based on: (1) the proven similarity conclusion between HANDAYUAN and the original drug; (2) the same or similar mechanisms of action between the extrapolated indications and the indication in clinical comparative study; and (3) the selection of sensitive

population and appropriate indication for key clinical trials, with substantial safety and immunogenicity data. The extrapolation of these indications is in compliance with the requirements of the Technical Guidelines for R&D and Evaluation of Biosimilars (Trial) (《生物類似藥研發與評價技術指導原則(試行)》), Clinical Trial Guidelines for Adalimumab Injection Biosimilars (《阿達木單抗注射液生物類似藥臨床試驗指導原則》), the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) and other regulations and policies in China for extrapolation of indication.

C. MARKET CONDITION

As at the date of this announcement, in addition to the Company's HANDAYUAN, the adalimumab marketed in mainland China include Humira® of AbbVie, Anjianning® of Hisun Biopharmaceutical Co., Ltd. and QLETLI® of Bio-Thera Solutions, Ltd., etc. The adalimumab marketed globally include Humira® of AbbVie, Amgevita® of Amgen and Hyrimoz® of Novartis, etc. According to the information of IQVIA CHPA and IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales volume of adalimumab in mainland China and worldwide for the year of 2022 was approximately RMB797 million and US$38.008 billion, respectively.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 29 February 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, Mr. 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.