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 APPROVED 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 applications of HANDAYUAN (adalimumab injection) ("**HANDAYUAN**") which is independently developed by the Company for the four new indications of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease and pediatric Crohn's disease (the "**New Indications**") have been approved by the National Medical Products Administration (the **"NMPA**").

B. BASIC INFORMATION ABOUT THE APPROVAL OF THE NEW INDICATIONS

Common Name:	Adalimumab injection
Trade Name:	HANDAYUAN
Dosage Form:	Injection
Specification:	40 mg (0.8 ml)/vial
Registration Category:	Biological Product for Treatment Purpose
Drug Manufacturer:	Shanghai Henlius Biopharmaceutical Co., Ltd.* (上海復宏漢霖生物製藥有限公司, a wholly owned subsidiary of the Company)
Review Conclusions:	According to the Drug Administration Law of the People's Republic of China and relevant requirements, upon review, the drug satisfied the relevant requirements for drug registration and the supplemental new drug applications of inclusion of four new indications of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease and pediatric Crohn's disease are approved.

C. ABOUT HANDAYUAN (ADALIMUMAB INJECTION)

HANDAYUAN (adalimumab injection) is a biosimilar of adalimumab independently developed by the Company, was approved by the NMPA in mainland China (excluding Hong Kong, Macau and Taiwan regions, the same as below) in December 2020. As of the date of this announcement, HANDAYUAN has been approved for eight indications in mainland China: (1) rheumatoid arthritis; (2) ankylosing spondylitis; (3) plaque psoriasis; (4) uveitis; (5) polyarticular juvenile idiopathic arthritis; (6) pediatric plaque psoriasis; (7) Crohn's disease; and (8) pediatric Crohn's disease.

D. 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 Sandoz, 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 2023 was approximately RMB948 million and US$41.334 billion, respectively.

E. IMPACT ON THE COMPANY

The approval of the New Indications will further expand the therapeutic area of HANDAYUAN to the gastroenterology and pediatrics and provide more treatment options for patients with the relevant indications in mainland China.

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

Hong Kong, 22 May 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.