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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

THE INVESTIGATIONAL NEW DRUG APPLICATION FOR THE PHASE 1 CLINICAL TRIAL OF CETUXIMAB INJECTION BIOSIMILAR HLX05-N (RECOMBINANT ANTI-EGFR CHIMERIC HUMAN-MONOCLONAL ANTIBODY INJECTION) FOR METASTATIC COLORECTAL CANCER (mCRC) APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

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 investigational new drug application (IND) for the phase 1 clinical trial of HLX05-N (recombinant anti-EGFR chimeric human-murine monoclonal antibody injection) (“**HLX05-N**”) for metastatic colorectal cancer (mCRC), a cetuximab injection biosimilar independently developed by the company, has been approved by the United States Food and Drug Administration (FDA). The Company proposes to commence relevant clinical trial in the United States, when the conditions are met.

B. ABOUT HLX05-N

HLX05-N is a cetuximab injection biosimilar independently developed by the Company, intended for the treatment of colorectal cancer and head and neck squamous cell carcinoma. Epidermal Growth Factor Receptor (EGFR) is a transmembrane glycoprotein expressed in both normal epithelial tissues and various tumor tissues, including colorectal cancer and head and neck cancer. Cetuximab specifically binds to EGFR in both normal and tumor cells, competitively inhibiting the binding of ligands such as EGF. This binding blocks receptor phosphorylation and the activation of associated kinases, thereby inhibiting cell growth, inducing apoptosis, and reducing the production of matrix metalloproteinases and vascular endothelial growth factor. While EGFR activates wild-type RAS proteins through signal transduction, it is ineffective against RAS-mutant cells. Furthermore, cetuximab exerts anti-tumor effects on certain tumors through antibody-dependent cellular cytotoxicity (ADCC). Pharmaceutical and non-clinical comparative studies have demonstrated that HLX05-N is

similar to the reference cetuximab injection. In April 2026, the investigational new drug application (IND) for the phase 1 clinical trial of HLX05-N for metastatic colorectal cancer (mCRC) was approved by the National Medical Products Administration (NMPA).

C. MARKET CONDITION

According to IQVIA MIDAS™ (IQVIA is a global professional information and strategic consulting service provider for the pharmaceutical and healthcare industry), the sales revenues of cetuximab injection biosimilar globally amounted to approximately USD1,658 million in 2025.

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 HLX05-N. 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, 10 May 2026

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. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.