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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 NIVOLUMAB BIOSIMILAR HLX18 (RECOMBINANT ANTI-PD-1 HUMANIZED MONOCLONAL ANTIBODY INJECTION) FOR THE TREATMENT OF MULTIPLE SOLID TUMORS WAS 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 nivolumab biosimilar HLX18 (recombinant anti-PD-1 humanized monoclonal antibody injection) (“**HLX18**”) independently developed by the Company for the treatment of multiple solid tumors was 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 HLX18

HLX18 is a nivolumab biosimilar independently developed by the Company, and its potential indications include the indications of the original drug approved such as melanoma, non-small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, gastric cancer, gastroesophageal junction cancer or esophageal adenocarcinoma, esophageal cancer, colorectal cancer and hepatocellular carcinoma etc. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumor cells and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Nivolumab is a human immunoglobulin G4 (IgG4) monoclonal antibody (HuMAb) that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the antitumor immune response.

C. MARKET CONDITION

According to the statistics released by IQVIA MIDAS™ (IQVIA is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales volume of nivolumab worldwide for the year of 2024 was approximately USD11.103 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 HLX18. 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, 19 December 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. 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.