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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

BIOLOGICS LICENSE APPLICATION (BLA) FOR HANBEITAI (BEVACIZUMAB INJECTION) HAS BEEN ACCEPTED 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 (the “**Board**”) of the Company is pleased to announce that, recently, the biologics license application (the “**BLA**”) for HANBEITAI (bevacizumab injection) (“**HANBEITAI**”) independently developed by the Company has been accepted by the United States Food and Drug Administration (“**FDA**”) for the following proposed indications: (1) metastatic colorectal cancer; (2) unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment; (3) recurrent glioblastoma in adults; (4) metastatic renal cell carcinoma, in combination with interferon alfa; (5) epithelial ovarian, fallopian tube cancer or primary peritoneal cancer; and (6) persistent, recurrent or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

B. BACKGROUND AND BASIS FOR SUBMISSION

Per the guidance for industry issued by FDA, “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product”, the BLA submitted to the FDA is mainly based on data generated by HANBEITAI versus its reference drug, including analytical similarity studies, PK similarity study, etc. These data demonstrate high similarity and no clinically meaningful differences between HANBEITAI and its reference drug.

C. ABOUT HANBEITAI

HANBEITAI is a bevacizumab (recombinant anti-VEGF humanized monoclonal antibody injection) independently developed by the Company and was approved for commercialisation in Chinese Mainland (excluding Hong Kong, Macau and Taiwan regions of China, the same as below) in November 2021. As of the date of this announcement, HANBEITAI has been approved for indications in Chinese Mainland: (1) metastatic colorectal cancer; (2) advanced, metastatic or recurrent non-small cell lung cancer; (3) recurrent glioblastoma; (4) hepatocellular carcinoma; (5) epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; and (6) cervical cancer.

D. MARKET CONDITION

According to the latest data from IQVIA MIDAS™ (provided by IQVIA, which is a global provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the sales value of bevacizumab products worldwide for the year of 2024 was approximately US\$5.25 billion.

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

Hong Kong, 13 January 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.