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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

FIRST PATIENT HAS BEEN DOSED IN THE PHASE 2 CLINICAL STUDY OF HLX79 INJECTION (HUMAN SIALIDASE FUSION PROTEIN) IN COMBINATION WITH HANLIKANG (RITUXIMAB INJECTION) FOR THE TREATMENT OF ACTIVE GLOMERULONEPHRITIS IN MAINLAND CHINA

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 first patient has been dosed in a phase 2 clinical study of HLX79 injection (human sialidase fusion protein) ("**HLX79**") in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis in Mainland China (excluding Hong Kong, Macau and Taiwan regions of China, same as below).

B. CLINICAL TRIAL DESIGN AND OBJECTIVES

This study is a double-blind, randomized, controlled, multicenter, Phase II study to evaluate the efficacy, safety, and tolerability of HLX79 in combination with HANLIKANG compared with placebo in patients with active glomerulonephritis (lupus nephritis (LN) and membranous nephropathy (MN)). The study includes two parts. Part I of the study is the dose escalation period. Eligible subjects will receive HLX79 (10 mg/kg, 20 mg/kg, or 30 mg/kg) combined with HANLIKANG or HANLIKANG placebo (375 mg/m^2) once a week. The primary objective is to evaluate the safety and tolerability of HLX79 in combination with

HANLIKANG and placebo in combination with HANLIKANG for active glomerulonephritis. Part II of the study is the preliminary efficacy exploration period. Eligible subjects will receive HLX79 (high dose/low dose) combined with HANLIKANG (375 mg/m²), HLX79 placebo combined with HANLIKANG, or HLX79 placebo combined with HANLIKANG placebo once a week at a ratio of 2:2:1:1. The primary objective in part II is to evaluate the clinical efficacy of HLX79 in combination with HANLIKANG, placebo in combination with HANLIKANG, as well as placebo alone, in subjects with active glomerulonephritis on the basis of standard treatment. The secondary objectives include other clinical efficacy, safety, tolerability, pharmacokinetic (PK) characteristics, and immunogenicity. The exploratory objective is to evaluate the dynamic changes of potential biomarkers.

C. ABOUT HLX79 AND HANLIKANG

HLX79 is a sialidase fusion protein created through gene fusion of a human sialidase enzyme with a human monoclonal antibody, licensed in by the Company from Palleon Pharmaceuticals Inc. ("**Palleon**"). According to the licensing agreement, the Company and Palleon will develop HLX79 worldwide according to the joint global development plan, and the Company has exclusive rights to HLX79 in China (including Hong Kong, Macau and Taiwan regions). HLX79 removes the immunosuppressive terminal sialic acid of sialoglycans on the surface of pathogenic immune cells, enhancing B lymphocyte depletion and reducing profibrotic M2-like macrophages in the context of autoimmune diseases to help restore immune balance. In March 2025, the application for the phase 2 clinical trial of HLX79 in combination with HANLIKANG for the treatment of active glomerulonephritis was approved by the National Medical Products Administration (NMPA).

HANLIKANG, a rituximab independently developed by the Company, was approved for commercialization in Mainland China by the National Medical Products Administration (NMPA) in February 2019. As of the date of this announcement, indications of HANLIKANG approved in Mainland China are Non-Hodgkin's lymphoma (NHL); Chronic Lymphocytic Leukemia (CLL); and Rheumatoid Arthritis (RA). In addition, HANLIKANG has been approved for marketing in Peru, Nicaragua and Bolivia for the treatment of Non-Hodgkin's lymphoma (NHL); Chronic Lymphocytic Leukemia (CLL); Rheumatoid Arthritis (RA); Granulomatosis with polyangiitis (GPA); Microscopic Polyangiitis (MPA) and Pemphigus vulgaris (PV).

Results of pre-clinical studies indicate that HLX79 is capable of enhancing the depletion of B lymphocytes by HANLIKANG. It is expected that the combination of HANLIKANG and HLX79 will benefit the patients with glomerulonephritis.

D. MARKET CONDITION

As at the date of this announcement, no similar combination has been approved for marketing globally.

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 HLX79. 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, 6 August 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. 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.