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 SERPLULIMAB INJECTION (RECOMBINANT HUMANISED ANTI-PD-1 MONOCLONAL ANTIBODY INJECTION, ORIGINAL PROJECT CODE: HLX10) HAS BEEN GRANTED PRIORITY REVIEW BY THE CENTER FOR DRUG EVALUATION OF 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 (the "**Board**") of the Company is pleased to announce that, today, Serplulimab injection (recombinant humanised anti-PD-1 monoclonal antibody injection, original project code: HLX10) ("**Serplulimab Injection**") independently developed by the Company has been officially granted priority review by the Centre for Drug Evaluation of the National Medical Products Administration ("**NMPA**").

B. DRUG OVERVIEW

Drug name: Serplulimab Injection

Dosage form: Injection

Specification: 100mg(10ml)/vial

Stage of submission: Production

Applicant: Shanghai Henlius Biopharmaceuticals Co., Ltd. (上海復宏漢霖生物製藥有限公司, a wholly-owned subsidiary of the Company)

Acceptance No.: CXSS2101000 Guo

Reasons for priority review: Upon review, the application is in compliance with relevant requirements under the Administration Measures for Drug Registration and the Announcement of NMPA on the Three Documents Including the Procedures on Evaluation of Drugs for Breakthrough Therapy (Trial) (No. 82[2020]), and it is agreed to be granted priority review according to the prioritized examination scope "(5) Drugs that are eligible for conditional approval".

C. ABOUT SERPLULIMAB INJECTION

Serplulimab Injection is an innovative anti-PD-1 monoclonal antibody independently developed by the Company for the treatment of solid tumours and chronic hepatitis B, which is currently being undergone clinical studies in a number of monotherapy and combination therapies worldwide. In March 2021, the critical phase 2 clinical study of Serplulimab Injection for the treatment of unresectable or metastatic microsatellite instability-high solid tumours that fail to respond to the standard therapy met the primary study endpoint. The results of this clinical study demonstrated the good effectiveness and safety of Serplulimab Injection in this indication. In April 2021, the new drug application (NDA) of Serplulimab Injection for the treatment of unresectable or metastatic microsatellite instability-high solid tumours that fail to respond to the standard therapy was accepted by the Centre for Drug Evaluation of the NMPA.

As of the date of this announcement, the studies of Serplulimab Injection and its related combination therapies are as follows:

	Indications	**Stage**
Serplulimab Injection	Unresectable or metastatic microsatellite instability-high (MSI-H) solid tumours that fail to respond to the standard therapy	Phase 2 clinical trial in mainland China (the primary study endpoint was met), and the new drug application (NDA) was accepted
	Solid tumours	Phase 1 clinical trial in Taiwan region
	Solid tumours	Clinical trial approval obtained in the USA
	Chronic hepatitis B	Phase 2 clinical trial in Taiwan region

	Indications	Stage
Serplulimab Injection+chemotherapy	Locally advanced/metastatic esophageal squamous cell carcinoma	Phase 3 clinical trial in mainland China
	Locally advanced or metastatic squamous non-small cell lung cancer	Phase 3 clinical trial in the countries and regions such as mainland China and Turkey (International multi-centre trial)
	Untreated extensive-stage small cell lung cancer	Phase 3 clinical trial in the countries and regions such as mainland China and Turkey (International multi-centre trial)
	Gastric cancer	Phase 3 clinical trial in mainland China (International multi-centre trial)
Serplulimab Injection+bevacizumab injection (a recombinant humanised anti-VEGF monoclonal antibody injection, original project code: HLX04)	Advanced solid tumours	Phase 1 clinical trial in mainland China
	Advanced hepatocellular carcinoma	Phase 2 clinical trial in mainland China
	Metastatic non-squamous non-small cell lung cancer	Phase 3 clinical trial in mainland China
	Metastatic colorectal cancer	Phase 2/3 clinical trial in mainland China
Serplulimab Injection+HLX07 (a recombinant humanised anti-EGFR monoclonal antibody injection)	Recurrent or metastatic head and neck squamous cell carcinoma	Phase 2 clinical trial in mainland China

D. MARKET CONDITION

As of the date of this announcement, monoclonal antibody drugs targeting PD-1 that have been marketed globally include Keytruda® of Merck & Co. Inc., Opdivo® of Bristol-Myers Squibb and AiRuiKa® of Suzhou Shengdiya Biopharmaceuticals Co., Ltd. (a wholly-owned subsidiary of Jiangsu Hengrui Medicine Co., Ltd.). To date, no similar product has been approved for this type of indication (unresectable or metastatic microsatellite instability-high solid tumours that fail to respond to the standard therapy) in the PRC. According to the statistics released by IQVIA MIDAS™ (IQVIA is the world's leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), the worldwide sales of the monoclonal antibody drugs targeting PD-1 in 2020 was approximately US$23.075 billion.

WARNING STATEMENT REQUIRED BY 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 commercialisation of Serplulimab Injection. 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.
Qiyu CHEN
Chairman

Hong Kong, 28 April 2021

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the executive director, Mr. Qiyu Chen as the chairman and non-executive director, Mr. Yifang Wu, Ms. Xiaohui Guan, Dr. Aimin Hui and Mr. Zihou Yan 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.