Jiangsu Recbio Technology Co., Ltd.
江蘇瑞科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: 2179)

VOLUNTARY ANNOUNCEMENT

POSITIVE RESULTS IN THE INTERIM ANALYSIS OF THE CLINICAL TRIAL OF THE COMPANY'S NOVEL ADJUVANTED RECOMBINANT SHINGLES VACCINE REC610 IN THE PHILIPPINES

This announcement is made by Jiangsu Recbio Technology Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on voluntary basis. References are made to the Company's voluntary announcements dated February 13, 2023 and July 26, 2023 in relation to the subject enrollment and clinical trial progress of the clinical trial of the Company's novel adjuvanted recombinant shingles vaccine, REC610 ("**REC610**") in the Philippines and the acceptance of clinical trial application for REC610 in China.

The board of directors of the Company (the "**Board**") is pleased to announce that the novel adjuvanted recombinant shingles vaccine REC610 independently developed by the Company has recently achieved positive results in the interim analysis of first-in-human ("**FIH**") clinical trial in the Philippines.

Previously, the Company conducted a GSK Shingrix® active-controlled FIH clinical trial of REC610 in the Philippines. The Interim Analysis (IA) results showed that REC610 demonstrated overall favorable safety and tolerability profile in healthy participants aged 40 and above after two doses of the vaccination. REC610 induced strong gE-specific humoral and cellular immune responses, which were evident after the first vaccination and reached the peak at 30 days after the second vaccination. The humoral and cellular immune responses were comparable between REC610 and Shingrix® group, and the immune response level in REC610 group was numerically higher than that in Shingrix® group.

1) **Safety:** REC610 had good safety profile with the two-dose vaccination regimen. No SAE, AESI or TEAE leading to early discontinuation was reported. The incidences of vaccination related TEAEs, solicited local and systemic TEAEs, unsolicited TEAEs were comparable between REC610 group and Shingrix® group. Majority of vaccination related TEAE were Grade 1 or Grade 2, and all recovered in 1-3 days post vaccination. The common (≥5%) solicited TEAEs in REC610 group included injection site pain, injection site swelling, pyrexia, headache, and myalgia.

2) **Immunogenicity:** REC610 induced strong gE-specific humoral and cellular immune responses, which were evident after the first vaccination and reached the peak at 30 days after the second vaccination. The humoral and cellular immune responses were comparable between REC610 and Shingrix® group, and the immune response level in REC610 group was numerically higher than that in Shingrix® group. REC610 induced favorable humoral and cellular immune responses in both elderly and adult groups.

   Both REC610 and Shingrix® groups induced high levels of gE-specific antibodies at 60 days after the first dose vaccination, and 30 days after the second dose vaccination. The GMT, GMI and SCR of gE-specific antibodies were comparable in REC610 group and Shingrix® group, especially, the GMT and GMI of gE-specific antibodies were numerically higher in REC610 group than those in Shingrix® group. Both REC610 and Shingrix® groups induced strong cellular immune response at 60 days after the first dose vaccination, and 30 days after the second vaccination. Tested by the internationally recognized ICS method, the frequencies and CMI response rates of CD4+ T cells secreting at least one or two of gE-specific cytokines were comparable in REC610 group and Shingrix® group, and the cellular immune response level was numerically higher in REC610 group than that in Shingrix® group.

Shingles is a common viral infectious disease. According to statistics, about 6 million new cases of shingles occur each year in China, and the incidence of shingles has gradually become younger in recent years. According to global research data on shingles vaccines that have been marketed, as compared to attenuated live vaccines, novel adjuvanted recombinant shingles vaccines can provide stronger cellular immune and protective efficacy. REC610 is equipped with a novel adjuvant BFA01 independently developed by the Company, which can promote the production of high levels of VZV glycoprotein E (gE)-specific CD4+ T cells and antibody. REC610 is intended to prevent shingles in adults aged 40 and above. According to statistics, China's population aged 40 and above is approximately 700 million. Only GlaxoSmithKline's Shingrix®, the new adjuvant recombinant vaccine, is on the market in China, and there is a strong demand for import substitution.

REC610 received a drug clinical trial approval notice (notice number: 2023LP02151) issued by the National Medical Products Administration in October 2023, and is approved for use as a preventive 3.3 biological product in its Phase I and Phase III clinical trials being carried out in China. The Company will adopt a randomized, double-blind, parallel controlled phase I clinical trial in 180 healthy adult subjects aged 40 and above in Mainland China in near term to evaluate the safety, tolerability and immunogenicity of REC610.

Shareholders and potential investors should note that the Group may not develop or market REC610 successfully and should exercise caution when dealing in the securities of the Company.

By order of the Board
Jiangsu Recbio Technology Co., Ltd.
Dr. Liu Yong
Chairman

Jiangsu Province, the PRC, December 29, 2023

As at the date of this announcement, the Board comprises Dr. Liu Yong as the chairman of the Board and an executive Director, Dr. Chen Jianping, Mr. Li Bu and Ms. Chen Qingqing as executive Directors, Dr. Hong Kunxue, Dr. Zhou Hongbin, Mr. Zhang Jiaxin and Mr. Hu Houwei as non-executive Directors, and Mr. Liang Guodong, Dr. Xia Lijun, Professor Gao Feng and Professor Yuen Ming Fai as independent non-executive Directors.