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## CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

*(Incorporated in Hong Kong with limited liability)*

(Stock code: 1093)

### VOLUNTARY ANNOUNCEMENT

#### UPDATE ON THE CLINICAL STUDY PROGRESS OF SARS-CoV-2 mRNA VACCINE (SYS6006)

This announcement is made by the board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis.

SYS6006 (the “**Product**”) is the Group’s self-developed mRNA vaccine against the SARS-CoV-2 mutant strains, with 6 clinical studies initiated. An update on the study progress is provided below.

**1. Safety and preliminary immunogenicity of SYS6006 in healthy population aged 18 to 59 years in a randomized, blinded, placebo-controlled and dose-escalation Phase I clinical study (study no.: SYS6006-001)**

The study is designed to evaluate the safety, tolerability, immunogenicity and immune persistence of SYS6006 in healthy population aged 18 to 59 years. The primary endpoint is the adverse events from the first dose through 30 days after the second dose, while the secondary endpoint is the immunogenicity after vaccination as well as long-term safety. The study started enrollment on 27 April 2022 at Shulan (Hangzhou) Hospital, Zhejiang Province, and currently the safety observation as well as immunogenicity evaluation have been completed for all subjects 30 days after the second dose of vaccination. The results have demonstrated that SYS6006 has a good safety profile with mainly Grade 1 adverse events and no serious adverse events or adverse events of special interest occurred, which demonstrated significant advantages in safety profile compared to those reported in the literature of similar products. The immunogenicity results showed that SYS6006 has a relatively strong neutralizing potency and cross-neutralization against various strains (WT, Delta, BA.2, BA.5).

**2. Safety and preliminary immunogenicity of SYS6006 in healthy population aged 60 years or above in a randomized, blinded, placebo-controlled and dose-escalation Phase I clinical study (study no.: SYS6006-002)**

The study is designed to evaluate the safety, tolerability, immunogenicity and immune persistence of SYS6006 in healthy population aged 60 years or above. The primary endpoint is the adverse events from the first dose through 30 days after the second dose, while the secondary endpoint is the immunogenicity after vaccination as well as long-term safety. The study started enrollment on 1 June 2022 at Shulan (Hangzhou) Hospital, Zhejiang Province and Sir Run Run Hospital of Nanjing Medical University. Currently, the enrollments as well as the second dose of vaccination have been completed for all subjects. Results demonstrated a good safety profile.

**3. Immunogenicity and safety of SYS6006 in healthy population aged 18 years or above in a randomized, blinded and placebo-controlled Phase II clinical study (study no: SYS6006-003)**

The study is designed to evaluate the immunogenicity, immune persistence and safety of SYS6006 in healthy population aged 18 years or above. The primary endpoint is the immunogenicity as well as the adverse events from the first dose through 30 days after the second dose, while the secondary endpoint is the immune persistence after vaccination as well as long-term safety. The study started enrollment on 28 June 2022 at Hebei Provincial Centre for Disease Control and Prevention. Currently, the enrollments as well as the second dose of vaccination have been completed for all subjects in the 18-59 years old subgroup. Results demonstrated a good safety profile, which were similar to the Phase I results.

**4. Immunogenicity and safety of heterologous booster of SYS6006 or inactivated vaccine in population aged 18 years or above who have received SARS-CoV-2 vaccination in a randomized, open-label and active-controlled clinical study (study no.: SYS6006-IIT003)**

The study is designed to evaluate the safety, tolerability and immunogenicity of SYS6006 in healthy population aged 18 years or above who have received two doses of inactivated SARS-CoV-2 vaccine or three doses of recombinant protein SARS-CoV-2 vaccine. The study has been completed and results demonstrate that SYS6006 has a good safety profile, superior immunogenicity and neutralizing potency against dominant strain Omicron BA.2, and has a significant advantage as a heterologous booster dose against mutant strains (information of the study results have been published in the Company's announcement (title: Completion of a Clinical Study of Heterologous Booster Immunization of SARS-CoV-2 mRNA Vaccine (SYS6006)) dated 23 August 2022).

**5. Safety and immunogenicity of heterologous booster of SYS6006 in population aged 18 years or above who have received inactivated SARS-CoV-2 vaccination in a single-center, open-label clinical study (study no.: SYS6006-007)**

The study has passed the ethical review at Zhongnan Hospital of Wuhan University and obtained the administrative license from Human Genetic Resources Management Office of Ministry of Science and Technology of the PRC, and has started enrollment on 19 August 2022 at Zhongnan Hospital of Wuhan University.

**6. Evaluate the safety and efficacy of heterologous or homologous booster of different technology routes of SARS-CoV-2 vaccination in a prospective, multi-center, randomized, controlled, open-label and blinded clinical study**

The study, organized by the Scientific Research Task Force on Vaccine Development of the Joint Prevention and Control Mechanism of the State Council, is currently underway.

In addition, the Group is also actively expediting the initiation of the Phase III clinical study of SYS6006 overseas and in Hong Kong.

The Group will endeavor to push forward the domestic and international multi-center clinical studies of the Product as well as its commercialization, and strive to launch the Product as soon as possible to contribute towards the efforts in tackling the COVID-19 pandemic.

By order of the Board  
**CSPC Pharmaceutical Group Limited**  
**Cai Dongchen**  
*Chairman*

Hong Kong, 23 August 2022

*As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.*