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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

COMPLETION OF A CLINICAL STUDY OF HETEROLOGOUS BOOSTER IMMUNIZATION 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.

The Company is pleased to announce that a clinical study of heterologous booster immunization (the “**Study**”) of the SARS-CoV-2 mRNA vaccine (SYS6006) (the “**Product**”) developed by the Group was completed, with the expectations for safety and immunogenicity met.

The Study is a randomized, open-label and active-controlled clinical study to evaluate the immunogenicity and safety of a heterologous booster dose of a SARS-CoV-2 mRNA vaccine (SYS6006) or inactivated vaccine (study no.: SYS6006-IIT003) in population aged 18 years and above who have received SARS-CoV-2 vaccination. The objective is to evaluate the safety, tolerability and immunogenicity of SYS6006 in healthy population aged 18 years and above who have received 2 doses of inactivated SARS-CoV-2 vaccine or 3 doses of recombinant protein SARS-CoV-2 vaccine. The Study was divided into 5 groups: Group I consisted of those who received 1 dose of 20 μ g SYS6006 6 months after 2 previous doses of inactivated SARS-CoV-2 vaccine (87 cases), Group II consisted of those who received 1 dose of 30 μ g SYS6006 6 months after 2 previous doses of inactivated SARS-CoV-2 vaccine (83 cases), Group III consisted of those who received 1 dose of inactivated SARS-CoV-2 vaccine 6 months after 2 previous doses of inactivated SARS-CoV-2 vaccine (35 cases), Group A consisted of those who received 1 dose of 20 μ g SYS6006 6 months after 3 previous doses of recombinant protein SARS-CoV-2 vaccine (116 cases), Group B consisted of those who received 1 dose of 30 μ g SYS6006 6 months after 3 previous doses of recombinant protein SARS-CoV-2 vaccine (111 cases).

Study Results:

Safety: SYS6006 has a favourable safety profile with a low incidence of local and systemic adverse events (AE), except for a high incidence of pain at injection site. The adverse events were mainly Grade 1. No serious adverse events or adverse events of special interest was reported. The incidence and severity of adverse events were significantly lower than those reported in the literature for marketed mRNA vaccines, and similar to those of inactivated vaccines. In addition, the Study demonstrated that the incidence of adverse events of Grade 3 and above for booster immunization of SYS6006 was significantly lower following recombinant protein vaccination than following inactivated vaccination.

Immunogenicity: 14 days after booster immunization with 1 dose of SYS6006, the geometric mean titer (GMT) of total IgG antibodies in Groups I, II, A and B were 8,825 RU/mL, 9,191 RU/mL, 5,750 RU/mL and 5,212 RU/mL (with reference to WHO standard for quantification), respectively, and were 327, 340, 59 and 56 times of those before the booster immunization (27 RU/mL, 27 RU/mL, 97 RU/mL and 93 RU/mL), respectively; 21.6, 22.5, 14.1 and 12.7 times of those of the homologous booster of inactivated vaccine (409 RU/mL), respectively. Results of BA.2 live virus neutralizing antibodies in selected participants showed that the median tissue culture infectious dose (TCID₅₀) 14 days after booster immunization with SYS6006 following inactivated vaccination were 759 (20µg dose group) and 1,122 (30µg dose group), while the TCID₅₀ 14 days after booster immunization with SYS6006 following recombinant protein vaccination reached 2,454, which were 190, 281 and 614 times of those before the booster, respectively.

In conclusion, the results of this heterologous booster immunization study have showed that SYS6006 has favourable safety profile, superior immunogenicity and neutralising potency against Omicron BA.2 strain, as well as significant advantage as a booster dose against mutant strains.

Based on the positive clinical data obtained, the Group will endeavour to push forward the domestic and international multi-center clinical studies of the Product, 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