CanSino Biologics Inc.
康希諾生物股份公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock code: 6185)

INSIDE INFORMATION

RESEARCH FINDINGS OF PHASE I CLINICAL TRIAL FOR RECOMBINANT NOVEL CORONAVIRUS VACCINE (ADENOVIRUS TYPE 5 VECTOR)

This announcement is made by CanSino Biologics Inc. (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571, Laws of Hong Kong).

The Company is pleased to announce that, a research article titled "*Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial*" about findings of phase I clinical trial for the Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) (the "**Ad5-nCoV**") was published in *The Lancet* (the "**Research Article**"). For details of the Research Article, please refer to https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31208-3/fulltext.

A summary extracted from the Research Article is set below.

Background

A vaccine to protect against COVID-19 is urgently needed. We aimed to assess the safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 (Ad5) vectored COVID-19 vaccine expressing the spike glycoprotein of a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) strain.

Methods

We did a dose-escalation, single-centre, open-label, non-randomised, phase 1 trial of an Ad5 vectored COVID-19 vaccine in Wuhan, China. Healthy adults aged between 18 and 60 years were sequentially enrolled and allocated to one of three dose groups (5×10^{10}, 1×10^{11}, and 1.5×10^{11} viral particles) to receive an intramuscular injection of vaccine. The primary outcome was adverse events in the 7 days post-vaccination. Safety was assessed over 28 days post-vaccination. Specific antibodies were measured with ELISA, and the neutralising antibody responses induced by vaccination were detected with SARS-CoV-2 virus neutralisation and pseudovirus neutralisation tests. T-cell responses were assessed by enzyme-linked immunospot and flow-cytometry assays. This study is registered with ClinicalTrials.gov, NCT04313127.

Findings

Between March 16 and March 27, 2020, we screened 195 individuals for eligibility. Of them, 108 participants (51% male, 49% female; mean age 36.3 years) were recruited and received the low dose (n=36), middle dose (n=36), or high dose (n=36) of the vaccine. All enrolled participants were included in the analysis. At least one adverse reaction within the first 7 days after the vaccination was reported in 30 (83%) participants in the low dose group, 30 (83%) participants in the middle dose group, and 27 (75%) participants in the high dose group. The most common injection site adverse reaction was pain, which was reported in 58 (54%) vaccine recipients, and the most commonly reported systematic adverse reactions were fever (50 [46%]), fatigue (47 [44%]), headache (42 [39%]), and muscle pain (18 [17%]. Most adverse reactions that were reported in all dose groups were mild or moderate in severity. No serious adverse event was noted within 28 days post-vaccination. ELISA antibodies and neutralising antibodies increased significantly at day 14, and peaked 28 days post-vaccination. Specific T-cell response peaked at day 14 post-vaccination.

Interpretation

The Ad5 vectored COVID-19 vaccine is tolerable and immunogenic at 28 days post-vaccination. Humoral responses against SARS-CoV-2 peaked at day 28 post-vaccination in healthy adults, and rapid specific T-cell responses were noted from day 14 post-vaccination. Our findings suggest that the Ad5 vectored COVID-19 vaccine warrants further investigation.

Ad5-nCoV is jointly developed by the Company and Beijing Institute of Biotechnology, Academy of Military Medical Sciences. It is a genetic engineered vaccine candidate with the replication-defective adenovirus type 5 as the vector to express SARS-CoV-2 spike protein, which intends to be used to prevent the disease caused by the novel coronavirus COVID-19.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The safety and efficacy of Ad5-nCoV are subject to confirmation by clinical trials and we cannot guarantee that we will ultimately develop or market Ad5-nCoV successfully. Shareholders and potential investors are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board
CanSino Biologics Inc.
Xuefeng YU
Chairman

Hong Kong, May 25, 2020

As at the date of this announcement, the Board of Directors comprises Dr. Xuefeng YU, Dr. Shou Bai CHAO, Dr. Tao ZHU and Dr. Dongxu QIU as executive Directors, Mr. Qiang XU, Mr. Liang LIN, Ms. Nisa Bernice Wing-Yu LEUNG and Mr. Zhi XIAO as non-executive Directors, and Mr. Shiu Kwan Danny WAI, Ms. Zhu XIN, Mr. Shuifa GUI and Mr. Jianzhong LIU as independent non-executive Directors.