# 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 II 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 *"Immunogenicity and safety of a recombinant adenovirus type-5-vectored COVID-19 vaccine in healthy adults aged 18 years or older: a randomised, double-blind, placebo-controlled, phase 2 trial"* about findings of phase II 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)31605-6/fulltext.

A summary extracted from the Research Article is set below.

***Background***

*This is the first randomised controlled trial for assessment of the immunogenicity and safety of a candidate non-replicating adenovirus type-5 (Ad5)-vectored COVID-19 vaccine, aiming to determine an appropriate dose of the candidate vaccine for an efficacy study.*

## Methods

*This randomised, double-blind, placebo-controlled, phase 2 trial of the Ad5-vectored COVID-19 vaccine was done in a single centre in Wuhan, China. Healthy adults aged 18 years or older, who were HIV-negative and previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection-free, were eligible to participate and were randomly assigned to receive the vaccine at a dose of $1\times10^{11}$ viral particles per mL or $5\times10^{10}$ viral particles per mL, or placebo. Investigators allocated participants at a ratio of 2:1:1 to receive a single injection intramuscularly in the arm. The randomisation list (block size 4) was generated by an independent statistician. Participants, investigators, and staff undertaking laboratory analyses were masked to group allocation. The primary endpoints for immunogenicity were the geometric mean titres (GMTs) of specific ELISA antibody responses to the receptor binding domain (RBD) and neutralising antibody responses at day 28. The primary endpoint for safety evaluation was the incidence of adverse reactions within 14 days. All recruited participants who received at least one dose were included in the primary and safety analyses. This study is registered with ClinicalTrials.gov, NCT04341389.*

## Findings

*603 volunteers were recruited and screened for eligibility between April 11 and 16, 2020. 508 eligible participants (50% male; mean age 39·7 years, SD 12·5) consented to participate in the trial and were randomly assigned to receive the vaccine ($1\times10^{11}$ viral particles n=253; $5\times10^{10}$ viral particles n=129) or placebo (n=126). In the $1\times10^{11}$ and $5\times10^{10}$ viral particles dose groups, the RBD-specific ELISA antibodies peaked at 656·5 (95% CI 575·2–749·2) and 571·0 (467·6–697·3), with seroconversion rates at 96% (95% CI 93–98) and 97% (92–99), respectively, at day 28. Both doses of the vaccine induced significant neutralising antibody responses to live SARS-CoV-2, with GMTs of 19·5 (95% CI 16·8–22·7) and 18·3 (14·4–23·3) in participants receiving $1\times10^{11}$ and $5\times10^{10}$ viral particles, respectively. Specific interferon γ enzyme-linked immunospot assay responses post vaccination were observed in 227 (90%, 95% CI 85–93) of 253 and 113 (88%, 81–92) of 129 participants in the $1\times10^{11}$ and $5\times10^{10}$ viral particles dose groups, respectively. Solicited adverse reactions were reported by 183 (72%) of 253 and 96 (74%) of 129 participants in the $1\times10^{11}$ and $5\times10^{10}$ viral particles dose groups, respectively. Severe adverse reactions were reported by 24 (9%) participants in the $1\times10^{11}$ viral particles dose group and one (1%) participant in the $5\times10^{10}$ viral particles dose group. No serious adverse reactions were documented.*

## Interpretation

*The Ad5-vectored COVID-19 vaccine at $5\times10^{10}$ viral particles is safe, and induced significant immune responses in the majority of recipients after a single immunisation.*

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, July 21, 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.*