SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Mecru Clinical Research Unit
Empowering The Community Towards Health Care Solutions

# SINOVAC, CHINA AND PARTNER NUMOLUX, SOUTH AFRICA LAUNCHING PAEDIATRIC COVID-19 VACCINE TRIAL (THE PEDCORONAVAC STUDY) AT SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Numolux Group (Pty) Ltd of Pretoria is the authorized representative in South Africa of SINOVAC Life Sciences Co., Ltd., a subsidiary of the SINOVAC Biotech Ltd. ("SINOVAC") of Beijing, China. SINOVAC and Numolux announced that they are ready with its partners to launch a Phase III pediatric COVID-19 vaccine study on 10 September with the first child to be vaccinated at the MeCRU Clinical Research Unit, based at the Sefako Makgatho Health Sciences University (SMU), South Africa.

The study is a Multi-center, Randomized, Double-blind, Placebo-controlled Phase Ⅲ Clinical Trial to Evaluate the Efficacy, Immunogenicity and Safety of SINOVAC Inactivated COVID-19 Vaccine (CoronaVac®) in children and adolescents aged 6 months to 17 years. The primary objective of the study is to evaluate the efficacy of two doses of CoronaVac® against confirmed symptomatic COVID-19 cases in children and adolescents aged 6 months to 17 years. Efficacy will also be evaluated against hospitalization and severe COVID-19 cases.

The study worldwide will enroll 14 000 children and adolescents in various pediatric age group cohorts across 5 countries (South Africa, Chile, Philippines, Malaysia and Kenya). Numolux has partnered with 7 clinical research sites across South Africa to enroll 2000 participants from 6 months to 17 years.

Participants in the trial will receive 2 doses of CoronaVac® or placebo 28 days apart. Efficacy assessments to include the surveillance for COVID-19 like symptoms and the laboratory confirmation of SARS-CoV-2 infection by RT-PCR. Any confirmed COVID-19 case will be followed by the investigators until resolution. Whole viral genome sequencing to detect mutations or variants of concern among all the confirmed COVID-19 cases during the trial will be done. Interim analysis will be done when 47 COVID-19 cases have been reported. Safety will be evaluated in terms of solicited local and systemic adverse events during 7 days following vaccination and of unsolicited adverse events during 28 days post-vaccination. Occurrence and relationship of serious adverse events will be monitored from first dose to 12 months after the last dose. Humoral immune response across a subset of all pediatric age group cohorts will be evaluated and cell mediated immune response in a subset of vaccinated participants in Chile will be investigated.

In South Africa, the trial has received South African Health Products Regulatory Authority (SAHPRA), Pharma Ethics and SMUREC approval and is listed on the South African Clinical Trial Registry (Identification number DOH-27-082021-6331).

This study has public health importance globally because a vaccine that prevents COVID-19 disease and transmission in pediatrics would be a crucial tool to assist in curbing the pandemic. Although children and adolescents have a milder form of the disease than adults, they remain susceptible to infection and severe manifestations across all ages.

SINOVAC is committed to the research and development of a safe and effective vaccine that protects people of all ages and comorbidities against COVID-19.

**About Sinovac COVID19 Vaccine: CoronaVac®**

CoronaVac® is an inactivated SARS-COV-2 vaccine manufactured by SINOVAC Life Sciences Co., Ltd., a subsidiary of the SINOVAC Biotech Ltd., a leading provider of biopharmaceutical products in China.

CoronaVac® received validation from the western science establishment in May 2020 when Science Journal published results of the pre-clinical studies, and in Nov 2020 Lancet published the Phase I/II study results of CoronaVac® in adults followed by a paper in Lancet in July 2021 of the Phase Ⅲ study in conducted in Turkey showing high efficacy (83.5%) against symptomatic PCR confirmed cases with good safety and tolerability, a real-world study from Chile published in the NEJM 02 Sep. 2021 showing 65.9% efficacy of the vaccine in preventing COVID-19 infection in adults and 87.5% in preventing hospitalizations, 90.3% (95% CI, 89.1 to 91.4) for the prevention of ICU admission, and 86.3% (95% CI, 84.5 to 87.9) for the prevention of Covid-19–related death. The Phase I/II study in children has been conducted in China and the results have been published in the Lancet, 28 June 2021.

CoronaVac® is currently approved for emergency use or marketing use with condition in adults in nearly 50 countries worldwide, as well as WHO, and approved for emergency use in children in China on 28 May 2021. CoronaVac® also received EUA/Section 21 approval from SAHPRA on 01 July 2021.

**About the Numolux Group (Pty) Ltd**

The Numolux group, based in Pretoria, South Africa have been providing advanced and sustainable health solutions to both the public and private sector, locally and internationally, since 2017. Numolux, together with its alliance partners, identifies latent needs with solutions for Hospital Infrastructure, Health Mobile Units, Adaptive Diagnostic Devices, Military Medical Equipment, Rapid Tests, Pharma Products and Vaccines. The CEO of the Numolux Group, Mr Hilton Klein, made the following statement and I quote “The children of Africa are the future of Africa and something must be done to protect the future of Africa against the deadliest pandemic the world has ever seen. Numolux Group has joined Sinovac in the fight against this deadly monster to ensure that the children of Africa have access to a safe and effective children’s vaccine to protect them against COVID-19. Numolux has declared war against this deadly virus and we will do everything in our power to ensure we protect the future of the African children.”

Partners of Numolux Group of companies include Ardent Consulting, providing scientific and technical expertise, and Numolux-Curanto Pharma assisting with regulatory applications. Numolux is the authorized representative of Sinovac Life Sciences in South Africa.

**MEDIA**

The official launch of the trial , and vaccination of the first participant will take place on: Date: Friday, 10 September 2021

**Time:** 9am - 11am; MEDIA BRIEFING at 11h30

**Venue:** MeCRU Research Unit at the Sefako Makgatho Health Sciences University. Tshwane Gauteng

Any media interested in attending the event, please inform us:

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