University of Sydney receives approval to start COVALIA, a Phase 1 Clinical Trial of COVIGEN, a New COVID-19 Vaccine Candidate in Australia

First needle-free DNA-based COVID-19 candidate vaccine to be tested in Australia in a Phase 1 trial in healthy subjects aged 18 to 75 years old

- The Lead Investigator, A/Prof Nicholas Wood at the University of Sydney Children's Hospital Westmead Clinical School received human research ethics approval for a phase 1 trial in healthy subjects aged 18 to 75 years old.
- Patient screening and enrolment to commence in April 2021.
- Ethics approval process represents first independent review of COVIGEN pre-clinical safety and efficacy data.

Melbourne – 22 March 2021 - The University of Sydney, Technovalia and Vax4COVID today announced that Human Research Ethics Committee (HREC) approved the phase 1 trial of COVID-19 vaccine COVIGEN in Australia, in healthy participants aged between 18 and 75 years old.

The vaccine will be tested in three states across Australia (NSW, SA, and WA) through Vax4COVID, an alliance of Australian vaccine clinical trial centres. The phase 1 trial involves 150 participants to assess the safety and immunogenicity in healthy volunteers. Screening and enrolments of participants are expected to commence in April.

About the COVALIA trial

The phase 1, multi-centre, double-blind, dose-ranging, randomised, placebo-controlled trial will assess the safety, reactogenicity and immunogenicity of different doses of COVIGEN given to healthy subjects aged 18 to 75 years old. As a phase 1 trial, the key goal is to examine the safety of two doses of COVIGEN, given one month apart. If the trial is successful, then a phase 2 trial will be undertaken in a larger number of participants.

The Lead Investigator, **A/Prof Nicholas Wood**, at the University of Sydney Children's Hospital Westmead Clinical School says: "*We are excited to start enrolment along with our colleagues in Perth and Adelaide, and to undertake the first needle-free COVID vaccine trial in Australia. The start of the COVALIA study is a significant milestone for all involved in this one-of-a-kind partnership between Australian institutions, the industry and the Australian government via the The Medical Research Future Fund (MRFF).*"

Mr. Laurent Dapremont, Chief Executive Officer of Technovalia said: *"We are very pleased that the COVALIA trial received the green light to start recruiting in the coming weeks. This is the result of a global partnership which started in 2020 with the COVIGEN project. We believe nucleic acid vaccines will play an important role to combat the pandemic, especially with the emergence of new SARS-CoV-2 variants, and we are looking forward to working with all our partners to bring and produce in Australia this COVID-19 DNA-based vaccine."*

About COVID-19

COVID-19 is a pandemic disease caused by SARS-COV-2 coronavirus. Currently, there have been more than 120 million confirmed cases worldwide of COVID-19, including 2.7 million deaths reported to the World Health Organization (WHO). COVID-19 can spread from person to person through close contact, contact with droplets and touching surfaces from an infected person. COVID-19 was first confirmed in Australia in late January 2020. As of the 22nd of March 2021, a total of 29,192 cases and 909 deaths have been reported in Australia.

About Technovalia

Melbourne-based Technovalia is a privately-owned Australian biotech company dedicated to the research and development of innovative vaccines and diagnostics. In partnership with several academic organisations and international companies, Technovalia is investing in the development of new technology platforms that have the potential to significantly improve protection against several infectious diseases by producing safer, more stable, and more cost-effective vaccines and diagnostics.
www.technovalia.com

About Vax4COVID

Led by the Doherty Institute of Infection and Immunity, Vax4COVID is an alliance of experienced Australian vaccine clinical trial centres formed to facilitate the conduct of trials of SARS-CoV-2 vaccine candidates. This expertise focuses on rapid planning, recruitment, ethics and GMO approvals, and execution of SARS-CoV-2 vaccine trials in healthy individuals and/or at-risk populations. This multistate, multicentre alliance brings together investigators and clinical trial centres with extensive experience and expertise in industry-sponsored vaccine clinical trials, including clinical trials of pandemic viral vaccines.
www.vaxforcovid.org

For further information, please contact:
Ms Michelle Tat
Marketing Communications
E-mail: info@technovalia.com
www.technovalia.com