



## **Technovalia partners with the Vax4COVID Alliance and BioNet to start a Phase 1 Human Vaccine Trial in Australia with COVIGEN, a COVID-19 gene-based vaccine**

**First SARS-CoV2 DNA vaccine to be tested in Australia in a phase 1/1b trial in healthy subjects aged 18 to 75 years old**

**Melbourne 20<sup>th</sup> September 2020** - Technovalia and Vax4COVID are announcing the commencement of an extended Phase 1 Human Trial in Australia evaluating COVIGEN, a COVID-19 gene-based vaccine manufactured by BioNet.

Under the Australian Medical Research Future Fund (MRFF) Coronavirus Research Response (2020 COVID-19 Vaccine Candidate Research Grant) lead investigator, A/Prof Nicholas Wood (University of Sydney, Australia) will evaluate the COVIGEN vaccine candidate for the first time in humans.

Since March 2020, Australian biotech company Technovalia and its international vaccine partner BioNet have been actively developing gene-based COVID-19 vaccine candidates. Preclinical studies confirmed the safety and immunogenicity of COVIGEN. With the support of the Australian Government through the Medical Research Future Fund (MRFF), A/Prof Wood and Vax4Covid will lead the further clinical development of this recombinant vaccine against COVID-19 in Australia.

COVIGEN is a needle-free DNA-based vaccine. There are several candidate DNA vaccines against COVID-19 in development of which few of them are tested in clinical trials in the US, Japan and South Korea. As of 21st September 2020, COVIGEN will be the 5th DNA vaccine to enter trial worldwide and the first one in Australia. This clinical trial will include adults and elderly, who are at highest risk for severe COVID-19 disease. The vaccine will be tested in three states across Australia (NSW, SA, and WA) through Vax4COVID, an alliance of Australian vaccine clinical trial centres, formed to facilitate the conduct of clinical trials of SARS-CoV-2 vaccine candidates in Australia. Recruitment will start in Q4 2020.

Through this network of key experts and partners, this collaborative approach will accelerate the development and access to this promising COVID-19 candidate vaccine in Australia. Technovalia and BioNet have the expertise and experience required to bring a vaccine to licensure, and the capacity for large-scale production of COVIGEN vaccines in Australia. Technovalia is collaborating with Queensland-based LuinaBio, one of Australia's most experienced manufacturing organization on the technology transfer of the vaccine production to Australia for Australians.

Technovalia and BioNet have a long-standing collaboration and commitment to bring innovative vaccines in Australia such as a new generation recombinant vaccine against whooping cough, a re-emerging respiratory disease affecting mainly newborns in Australia. A phase 2/3 trial evaluating Pertagen, a recombinant pertussis-only vaccine started in Perth in July 2020.

### **About the trial**

This phase 1/1b, multi-centre, observer-blinded, dose-ranging, randomized, 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 it is a phase 1 trial the key goal is to examine the safety of 2 doses of COVIGEN, given 1 month apart. If the trial is successful then a phase 2 trial will be undertaken in a larger number of participants.

Lead Principal Investigator, **A/Prof Nicholas Wood**, The University of Sydney Children's Hospital Westmead Clinical School says: *"this phase 1 trial will be the first DNA based COVID vaccine trial in Australia. It is an excellent partnership with Australian academics and industry supported by MRFF funding. If the trial proves the vaccine to be safe then larger phase 2 trials are planned."*

**Mr. Laurent Dapremont**, Chief Executive Officer of Technovalia says *"we are very pleased and proud to be able to contribute to the development of an effective solution to the crisis we have been living for many months. This is a unique collaborative effort with outstanding partners and clinicians, and most importantly, plans are being put in place with BioNet and LuinaBio to rapidly bring a safe and effective vaccine against Covid-19 which can be produced in Australia."*

**Dr. Pham Hong Thai**, Chief Executive Officer of BioNet-Asia, said: *"We are glad to continue our collaboration with Technovalia as this is the second vaccine to be evaluated in Australia, first Pertagen® and now COVIGEN, two recombinant vaccines against highly contagious respiratory diseases, respectively pertussis (whooping cough) and COVID-19. We are also delighted to join A/Prof. Wood and his colleagues from Vax4COVID in the fight against the COVID-19 pandemic in Australia."*

### About COVID-19

COVID-19 is a new infectious disease caused by the most recently discovered coronavirus known as SARS-CoV-2 virus. This virus and disease were unknown before the outbreak began in December 2019 in Wuhan City in China. Currently, more than 29 million people worldwide have been diagnosed COVID-19. COVID-19 can spread from person to person through close contact, contact with droplets and touching surfaces from an infected person. There is currently no vaccine available to prevent the spread of the coronavirus. COVID-19 was first confirmed in Australia in late January 2020. As of 18th September 2020, a total of 26,813 cases have been reported with many cases reported in VIC, NSW and QLD.

<https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert>

### 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. Technovalia is developing a Chikungunya in collaboration with Monash University, VIC, and is working with The Telethon Kids Institute, WA, to test BioNet's recombinant acellular pertussis-only vaccine Pertagen® in PertaPrime, a phase II-III randomised controlled trial in Australia.

[www.technovalia.com](http://www.technovalia.com)

### About BioNet

BioNet is a French-Thai fully-integrated Biotech company focusing on the discovery, manufacturing and supply of innovative life-saving vaccines. BioNet is the world's only manufacturer of recombinant pertussis-only vaccine (Pertagen®, aP vaccine) and a recombinant Tdap vaccine (Boostagen®), containing a genetically-inactivated pertussis toxin (PTgen). BioNet has built several strategic alliances fostering vaccine self-reliance leading to the supply of billions of doses of vaccines. The company has many ongoing collaborative projects on the development of recombinant and nucleic acid vaccines. BioNet and Pasteur Institute (Paris) are developing a DNA vaccine against Dengue and Zika diseases. Leveraging on its expertise in recombinant DNA technology, BioNet produced clinical lots of SARS-Cov-2 gene-based vaccine (COVIGEN), to be evaluated in human trials within 2020.

[www.bionet-asia.com](http://www.bionet-asia.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 Phase II 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, including healthcare workers and older adults, with the capacity to pre-recruit cohorts of interested individuals. 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](http://www.vaxforcovid.org)

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