

## COVALIA study update: first healthy volunteers dosed in needle-free SARS-CoV2 DNA vaccine phase 1 trial

### First needle-free SARS-CoV2 DNA vaccine to be tested in Australia in a phase 1 trial in healthy subjects aged 18 to 75 years old

**Melbourne – 30<sup>th</sup> June 2021** – Australian biotech company Technovalia is pleased to announce that the first volunteers have been enrolled and dosed in the COVALIA trial, a phase 1 study of Covid-19 vaccine candidate, COVIGEN, in healthy participants using the PharmaJet<sup>®</sup> needle-free devices. 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.

The phase 1 trial involves 150 participants to assess the safety and immunogenicity in healthy volunteers. Participants are being recruited by Scientia Clinical Research (Sydney), the Telethon Kids Institute (Perth) and the Women's and Children's Hospital (Adelaide). Preclinical studies confirmed the safety and immunogenicity of COVIGEN. If successful, a phase 2 trial will include a larger number of participants.

#### About the trial

This phase 1, multi-centre, double-blind, 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. Full study details can be found at ANZCTR under trial ID NCT04742842.

Lead Principal Investigator, **A/Prof Nicholas Wood**, The University of Sydney Children's Hospital Westmead Clinical School says: *"We are very excited to start enrolment along with our colleagues in Perth and Adelaide, and to undertake the first needle-free COVID vaccine trial in Australia."*

**Mr. Laurent Dapremont**, Chief Executive Officer of Technovalia says *"We are very pleased to report that the first volunteers have been enrolled and dosed in this important study. COVIGEN is the first plasmid-DNA vaccine to be tested in Australia. We believe nucleic acid vaccines will play an important role to combat the pandemic, especially with the emergence of new variants and the focus on country self-reliance for the manufacturing of essential medicines."*

**Dr. Pham Hong Thai**, Chief Executive Officer of BioNet, said: *"The COVALIA study is the result of a strong collaborative effort with our partners in Australia. The COVIGEN vaccine has been developed with a technology which can be easily transferable for local production as it only requires Biosafety Level (BSL)-1 manufacturing capabilities. The technology is also very suitable for the rapid development of new variant vaccines."*

**Mr. Chris Cappello**, President and CEO, PharmaJet commented: *"We are pleased to be collaborating with Technovalia, BioNet and their partners as they move into human clinical trials. Our Needle-free Systems provide the platform to get vaccines directly into cells to help maximize target gene expression in the body. Our findings from multiple clinical studies with other DNA vaccines have resulted in improved effectiveness from using our devices."*

### About COVID-19

COVID-19 is a pandemic disease caused by SARS-COV-2 coronavirus. Currently, there have been more than 180 million confirmed cases worldwide of COVID-19, including 3.9 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 30<sup>th</sup> of June 2021, a total of 30,528 cases and 910 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. Technovalia 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 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 been developing genetic vaccines against SARS-CoV2 and its variant strains using DNA and mRNA technology platforms. COVIGEN is a COVID-19 DNA vaccine being evaluated in human trials in Australia.

[www.bionet-asia.com](http://www.bionet-asia.com)

### About PharmaJet

The PharmaJet Needle-free Systems are safe, fast, and easy-to-use. They eliminate needlestick injuries, needle reuse and cross contamination, and help reduce sharps waste disposal. The Stratis® System has U.S. FDA 510(k) marketing clearance, CE Mark, and WHO PQS certification to deliver vaccines intramuscularly. The Tropis® System has CE Mark and WHO PQS certification for intradermal injections; it is being used in multiple COVID-19 DNA vaccine development programs in partnership with Zydus Cadila, BioNet/Technovalia, GeneOne Life Science, and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), among others.

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

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