COVALIA study update: Interim Safety Results from needle-free SARS-CoV2 DNA vaccine phase 1 trial

- **First needle-free SARS-CoV2 DNA vaccine tested in Australia is well tolerated**
- **No safety concerns were observed**
- **Ongoing study enrolment for booster dose**

Melbourne 17 January 2022 –Technovalia, an Australian biotech vaccine developer today announced the interim safety results of the ongoing phase 1 clinical trial evaluating COVIGEN, a DNA Covid-19 vaccine candidate, in healthy participants using the PharmaJet® Needle-free Devices.

Interim safety data showed that Covigen is well tolerated and no safety concerns were observed. Full safety data are expected by February 2022. The phase 1 trial involved 27 participants to assess the safety and immunogenicity of two COVIGEN doses given to healthy volunteers who had not yet had a COVID-19 vaccine. The trial is ongoing, now recruiting in three states across Australia (NSW, SA, and WA) for the evaluation of COVIGEN as a booster on volunteers having received two doses of the available vaccines in Australia. Participants are being recruited by Scientia Clinical Research (Sydney), the Telethon Kids Institute (Perth) and the Women's and Children's Hospital (Adelaide).

About the trial

This phase 1, multi-centre, double-blind, dose-ranging, randomized, placebo-controlled trial is assessing 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. The study will also assess COVIGEN as a booster dose on healthy subjects fully vaccinated with the available Covid vaccines.

Lead Principal Investigator, **A/Prof Nicholas Wood**, The University of Sydney Children's Hospital Westmead Clinical School says: "*Analysis of safety data from the first sentinel groups of volunteers enrolled in the COVALIA study show no safety concerns, and that the tolerability profile is comparable or lesser to that of mRNA COVID-19 vaccines. Amid the pandemic, it is now also important to assess the safety and immunogenicity of one dose of Covigen as a booster in already fully vaccinated volunteers.*"

Mr. Laurent Dapremont, Chief Executive Officer of Technovalia said "*We are pleased with these positive interim safety results from the ongoing COVALIA study which reinforce the existing pre-clinical data available. COVIGEN is the first plasmid-DNA vaccine to be tested in Australia and it is encouraging to observe no safety concern in the participants. We believe both mRNA and DNA vaccines will play an important role to combat the spread of Covid.*"

Dr. Pham Hong Thai, Chief Executive Officer of BioNet, said: "*We are happy to see these initial positive results for COVIGEN, our first COVID genetic vaccine. These results will help bringing forward our development programs in Australia and elsewhere. BioNet has developed and optimised in a record time a nucleic acid manufacturing platform (DNA and mRNA) which can significantly help in the fight against the pandemic, and against future threats.*"

Mr. Chris Cappello, President and CEO, PharmaJet commented: "*We welcome this positive news and are proud to be part of the Covigen vaccine development with Technovalia, BioNet and their Australian partners. These results are consistent*

with data from other DNA vaccines administered using the PharmaJet Needle-free Injection Systems, including those with from the first approved plasmid-based DNA vaccine for COVID-19."

About COVID-19

COVID-19 is a pandemic disease caused by SARS-COV-2 coronavirus. Currently, there have been more than 318 million confirmed cases worldwide of COVID-19, including 5.5 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 14th of January 2022, a total of 1,195,158 cases and 2,522 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

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-CoV-2 and its variant strains using DNA and mRNA technology platforms. COVIGEN is a COVID-19 DNA vaccine being evaluated in human trials in Australia. BioNet has also been manufacturing clinical lots of COVID-19 mRNA vaccine in collaboration with US, EU and Thai academic/biotech partners.
www.bionet-asia.com

About PharmaJet

PharmaJet's mission is to improve people's lives through needle-free technology. PharmaJet Needle-free Systems provide increased vaccine effectiveness, a preferred patient and caregiver experience, and a proven path to commercialization. They are also safe, fast, and easy-to-use. 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 partnerships across the globe.
www.pharmajet.com

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