



Technovalia, Sypharma and BioNet announce the establishment of Genetis, the first Australian Vaccine Development and Manufacturing Hub for mRNA, DNA and recombinant vaccines.

Establishment of the first end-to-end Australian capability for product development and commercial scale production of mRNA, DNA and recombinant vaccines

By bringing together the technology, product development, GMP manufacturing, clinical and regulatory expertise of key consortium partners Technovalia, Sypharma and BioNet, Genetis will provide a unique Australian-based vaccine contract and product development manufacturing hub for Australian and offshore research organisations seeking access to quality capability and TGA approved products.

The founding partners have been sharing common interest and commitment in the fight against the COVID-19 pandemic through the rapid development, production and/or evaluation of several COVID vaccines. BioNet has established a strong DNA and mRNA manufacturing platform and produced vaccine candidates in clinical development stage. Technovalia has initiated the first needle-free DNA COVID vaccine trial in Australia, and Sypharma has been involved in the fill-finish and manufacture of several COVID vaccine candidates.

The agreement, in the form of a Memorandum of Understanding (MoU), formalises the mutual interaction and strengthens the existing relationship between BioNet, Sypharma and Technovalia at the strategic and operational levels. Genetis will operate as an independent Vaccine Hub offering Contract Development Manufacturing Services and Product Development Expertise for mRNA, DNA and recombinant vaccines. It is the first of its kind and it will accelerate vaccine development and manufacturing through a comprehensive ecosystem in Victoria and Australia.

Genetis will be operational in July 2022 for formulation, end of line packaging and fill-finish. Drug Substance and Drug Product GMP manufacturing capability is scheduled for 2023 and large-scale commercial capability for 2024.

Mr. Laurent Dapremont, Chief Executive Officer of Technovalia said *“We are very pleased to see the crystallisation of a project which started 18 months ago with the assembly of a unique consortium of partners bringing the key assets, expertise and commitment to establish a comprehensive solution to the development and production of innovative vaccines in Australia. We are convinced that Genetis will contribute significantly to strengthen Australian’ sovereignty for essential medicines and add significant value to the rich Australian research ecosystem.”*

Dr. Pham Hong Thai, Chief Executive Officer of BioNet, said: *“Genetis is the first example of how deep collaborative efforts between local and international partners can create value. By leveraging existing Sypharma’s assets, TGA-*

certified facilities and CMO expertise, we can rapidly transfer BioNet's nucleic acid vaccine manufacturing platform, enable and scale up both fill and finish, and drug substance manufacturing capacity in Australia. Combined to BioNet's and Technovalia's expertise in product development, Genetis will offer a unique value to Australian researchers and partners".

Mr. Ganesh Varnakulasingham, Chief Executive Officer of Sypharma, said: *"We are very excited by the launch of Genetis. Based on its expertise in recombinant vaccine development and manufacturing, BioNet has developed and optimised in a record time a nucleic acid manufacturing platform (mRNA and DNA) which can significantly help in the fight against the current pandemic, and against future threats. The Genetis business model allows to rapidly deploy this technology in Australia offering a unique inclusive value proposition to all stakeholders."*

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 collaborating with the Vax4COVID alliance on the COVALIA trial, a phase 1 study of Covid-19 vaccine candidate, COVIGEN, in healthy participants using the PharmaJet® needle-free devices. Technovalia is also 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 biotech company that focuses on bio-innovation and the development of genetically designed vaccines against re-emerging and pandemic diseases. BioNet's vision is to establish strong partnering networks to share vaccine expertise and enable access to life-saving vaccines anywhere in the world. Over the years, the company has built global research collaborations, product development and manufacturing alliances leading to the supply of billions of doses of vaccines worldwide.

BioNet is the world's only manufacturer of recombinant pertussis-only aP_{gen} vaccine (Pertagen®) and a recombinant TdaP_{gen} vaccine (Boostagen®), containing a genetically inactivated pertussis toxin (PT_{gen}). BioNet has been developing genetic vaccines against SARS-CoV-2 and its variant strains using nucleic acid technology platforms. Covigen is a COVID-19 DNA vaccine being evaluated in human trials in Australia. BioNet also jointly developed the manufacturing process of Chulacov-19 mRNA vaccine for clinical use. Most recently, BioNet was awarded a global innovative project in partnership with CEPI (Coalition for Epidemic Preparedness Innovations), IVI (International Vaccine Institute) and several universities, to rapidly advance the development of a pan coronavirus multiple mRNA vaccine against several types of coronaviruses.

BioNet's main operations are situated in Bangkok, Thailand and Lyon, France.

www.bionet-asia.com

About Sypharma

Sypharma is an Australian speciality contract manufacturing group which was founded in 2005. Sypharma specialises in contract manufacturing products for early clinical to Phase I, II, and III clinical trials, and have a range of multipurpose cleanrooms for the manufacture of injectable pharmaceutical products, and medical devices. Equipped with modern, comprehensive and specialised manufacturing equipment services, Sypharma's expertise and experience are available to clients seeking the manufacture and packaging of therapeutic goods, veterinary products and consumer items. Licenses include accreditation from the TGA, ISO13485 and USFDA. Sypharma manufactures products from R&D through to commercial volumes for both large and small volume parenterals. In addition to contract manufacturing development services, Sypharma collaborates with local and international partners to innovate and develop new technologies required to produce modern medicines, as evidenced by Sypharma's involvement in the contract manufacture of 7 COVID19 vaccine and/or treatments in the past 24 months.

<https://www.sypharma.com.au>

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