GPN *vaccines* pty ltd

Gamma-PN™ – a "Serotype-Independent" (Universal) Pneumococcal Vaccine

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COMPANY DETAILS

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Australian Biologics (Regulatory)

Further Information

Further information about GPN Vaccines may be obtained by e-mailing Prof Tim Hirst at tim@ gpnvaccines.com or calling him on +61 420 942 824.

The Opportunity

GPN Vaccines Pty Ltd was established in September 2017 with a world-class Board of Directors and Scientific & Advisory Board members to develop and commercialise a new broad spectrum vaccine against *Streptococcus pneumoniae* (the pneumococcus) - the world's foremost bacterial pathogen. *S. pneumoniae* causes pneumonia, bacteraemia, meningitis and otitis media and each year is responsible for 1-2 million deaths worldwide, killing more children than AIDS, malaria and tuberculosis combined. A pneumococcal polysaccharide-protein conjugate vaccine (Prevnar®) sold by Pfizer, has become a "blockbuster" with annual sales now exceeding US$6.3 billion[1]. However despite its success Prevnar-13 (the most advanced version of Prevnar®) has major shortcomings in terms of cost, restricted serotype coverage (protecting against just 13 of the 97 known serotypes of *S. pneumoniae*), and an increasing prevalence of disease caused by pneumococcal serotypes against which Prevnar-13 provides no protection whatsoever. The Centers for Disease Control (CDC) in the USA has reported that 75%-80% of cases of invasive pneumococcal disease are now caused by serotypes not present in Prevnar-13[2]. Thus, there is an unmet need and a global market for a vaccine capable of protecting against all pneumococci, regardless of strain serotype.

Experts directly involved in developing Prevnar®, and who are members of GPN Vaccines' Scientific & Advisory Board, believe polysaccharide-protein conjugates have reached their upper limit and that creation of Prevnar-14, -15, or -16 to expand serotype coverage will not satisfy the FDA's requirement for non-inferiority of new vaccines. Thus, a radically different approach is needed to create a pneumococcal vaccine capable of protecting against all pneumococci, regardless of strain serotype.

The Company

GPN Vaccines broad-spectrum pneumococcal vaccine was acquired from Gamma Vaccines Pty Ltd. It is being developed in conjunction with world-leading pneumococcal researchers at the University of Adelaide (UoA) in South Australia.

The technology is a proprietary engineered strain of *S. pneumoniae* that lacks capsular polysaccharide, is avirulent and is safe to handle. When cultured and then inactivated with high-energy photons ("gamma-rays"), a whole cell gamma-irradiated pneumococcal vaccine is produced, called "Gamma-PN™", that overcomes the key shortcomings of Prevnar-13.

Intellectual Property

IP rights to Gamma-PN™ are 100% owned by GPN Vaccines Pty Ltd following assignment of PCT Patent Application (AU2016/050231) entitled "Streptococcal Vaccine" filed on 26-Mar-2016 from Gamma Vaccines. In February 2017 IP Australia issued a "clean" International Preliminary Report on Patentability (IPRP) accepting all claims as novel, inventive and industrially applicable; thereby guaranteeing patent issuance in Australia and facilitating its prosecution worldwide, with National Phase applications now filed in AU, BR, CA, CN, EU, ID, IN, JP, KR, MY, SG, US and ZA.

Non-Dilutive Grant Awards

On 11-Oct-2017 the NHMRC - Australia's peak medical research agency - awarded a $1M grant to GPN Vaccines/UoA towards further development of Gamma-PN™ and on 17-Dec-2017 the South Australia Government awarded a $300,000 commercialisation grant to GPN Vaccines.

The Technology

Gamma-PN™ is a whole bacterial cell vaccine capable of inducing broad-spectrum T- and B-cell immunity to cross-reactive protein antigens of the pneumococcus. This is sufficient to provide protection against different pathogenic pneumococcal strains irrespective of strain serotype. The vaccine is produced by exposing the vaccine strain to high energy photons (gamma-rays) to create the inactivated whole cell vaccine. A scanning electron micrograph of Gamma-PN™ is shown in Fig 1.

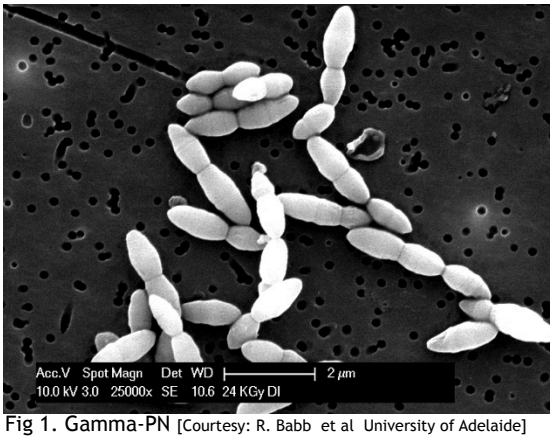

Fig 1. Gamma-PN [Courtesy: R. Babb et al University of Adelaide]

Promising pre-clinical studies[3] have demonstrated that intranasal vaccination with Gamma-PN™ protects experimental animals against lethal pneumococcal sepsis caused by *S. pneumoniae* strain D39 (serotype 2) or by strain P9 (serotype 6A) (Fig 2 & 3). In addition, Gamma-PN™ reduced bacterial loads in the lungs and the nasopharynx and protected animals that were challenged with *S. pneumoniae* strain EF3030 (serotype 19F). This represents a breakthrough in the development of a serotype independent pneumococcal vaccine.

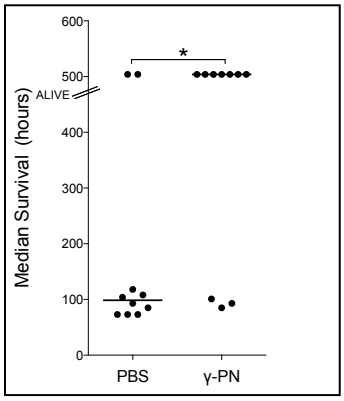

Fig. 2. Survival time of mice after IN vaccination with γ-PN and challenge with *S. pneumoniae* D39 (serotype 2). PBS control. * $P < 0.05$.

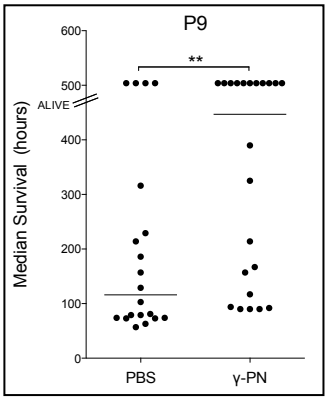

Fig. 3. Survival time of mice after IN vaccination with γ-PN and challenge with *S. pneumoniae* P9 (serotype 6A). PBS control. ** $P < 0.01$.

The development of Gamma-PN™ was supported by the Commonwealth Government of Australia via an ARC Linkage Grant awarded to the University of Adelaide, with Gamma Vaccines Pty Ltd as the Industrial Sponsor.

[1]www.statista.com/statistics/314566/leading-global-vaccine-products-by-revenue;[2]www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html;
[3]Babb et al (2016) *Clinical Science*. 130:697-710.

Board of Directors

Tim HIRST, DPhil, MAICD (Chairman & CEO)

Tim is the Chairman & CEO of GPN Vaccines. He has extensive expertise in the life sciences, executive management and venture capital investment. He was CEO of ANU Connect Ventures - a pre-seed VC fund, the Deputy Vice Chancellor for Research & Innovation at The University of Sydney and Professor & Head of Microbiology at the University of Bristol, UK. He is an active angel investor working with investment groups throughout Australia and US to assist early stage companies to raise capital and develop their innovative technologies. Tim is also Chairman of Gamma Vaccines Pty Ltd and an Honorary Professor at the University of Adelaide.

Mohammed ALSHARIFI, BVetMed, BSc, PhD (Director)

Mohammed is a director of GPN Vaccines as well as a Senior Lecturer in Virology & Immunology at The University of Adelaide and Chief Scientific Officer of Gamma Vaccines Pty Ltd. Mohammed brings a wealth of experience in the use of gamma-irradiation to inactivate viral and bacterial pathogens and he was a Chief Investigator on the ARC Linkage grant that led to the development of the Gamma-PN vaccine program.

Martin GÖTTING, (Director)

Martin is a director of GPN Vaccines as well as the General Manager of Capricorn Consilium GmbH (Ltd.) - a Vienna–based consulting and interim management company. Martin has extensive experience in the vaccine pharma-industry with over 20 years at Behringwerke AG/Chiron Vaccines International, including as Global Head of Production and Sales Logistics and as Director Commercial Operations. He was also VP Marketing, Sales & Supply at Intercell AG (today Valneva), a company focused on the development of modern prophylactic and therapeutic vaccines against infectious diseases.

Barry PALTE, BBusSc, FIA (Director)

Barry is a director of GPN Vaccines as well as the Deputy Chairman and co-founder of BlueMount Capital, an investment banking and strategic business development group with multiple offices in Australia and China. He is also the global co-Chairman of the International Association of Investment Bankers. Barry has extensive experience in commercialising technologies in Australia, US, UK & China and has served as the start-up CEO of a globally successful high technology company. His prior corporate career included Head of M&A and Strategic Development at Australia's largest Bank, CBA.

James PATON, PhD (Director)

James Paton is a director of GPN Vaccines as well as Professor of Microbiology and the Director of the Research Centre for Infectious Diseases at University of Adelaide. He is Australia's preeminent authority on the pathogenesis of *S. pneumoniae* and was recently named South Australian Scientist of the Year (2017). James is an NHMRC Snr. Principle Research Fellow and he directs an internationally acclaimed team of researchers at the University of Adelaide. He has published over 360 research papers and in the last 8 years has raised over $36M in grants to support his research activities. James was the lead Chief Investigator on the ARC Linkage grant that led to the development of the Gamma-PN vaccine.

Scientific & Advisory Board

Jim Ackland (ex CSL, regulatory affairs expert); **Steve Cole** (ex VP Abbott Laboratories, specialist in BD in Asia); **Justin Davies** (Head of Radiation Services, ANSTO); **Adam Finn** (Prof. of Paediatrics, University of Bristol, specialist in clinical trials of pneumococcal vaccines); **Bruce Forrest** (ex VP of Pfizer, responsible for clinical development and evaluation of Prevnar®); **Matthew Frank** (entrepreneur and ex Snr Director Corporate Development at Genenetch); **Jack Love** (ex Pfizer, responsible for achieving FDA-regulatory approval of Prevnar®); **Steve Nagler** (Director of MedPro); **Jean Petre** (ex Head of Human Vaccines, GSK); and **Paul Rolan** (Prof of Pharmacology & Director of Innovation, University of Adelaide).