

MEDIA RELEASE

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**Prota/MCRI completes enrolment of Phase 2b multicentre clinical trial of probiotic oral immunotherapy for the treatment of peanut allergy (PPOIT-003)**

- **200 patients have been enrolled and commenced on treatment**
- **The multicentre study is being conducted in Melbourne, Adelaide and Perth**
- **Treatment will continue through 2019 with top line results expected in the first quarter of 2020**
- **The randomised, blind study is designed to compare PPOIT (probiotic and peanut oral immunotherapy) with both Peanut OIT (peanut oral immunotherapy without probiotic) and placebo**

Melbourne, Australia: Pioneering allergy immunotherapy company Prota Therapeutics Pty Ltd (Prota) is pleased to announce full enrolment to the multicentre Phase 2b clinical trial investigating the effectiveness of its Probiotic and Peanut Oral Immunotherapy (PPOIT) treatment licensed from the Murdoch Children's Research Institute (MCRI).

The PPOIT-003 clinical study has been designed to provide evidence of a longer lasting tolerance to peanut in a larger number of patients and to compare probiotic and peanut oral immunotherapy (PPOIT) with peanut oral immunotherapy (OIT) alone, to assess the added effect of the probiotic. Recruitment of participants for the study has been completed ahead of schedule, with enrolment at clinical sites in Melbourne, Adelaide and Perth.

Prota CEO, Dr Suzanne Lipe, said of the update: "This is a tremendous milestone in the advancement of PPOIT and another step towards the further validation necessary for commercialisation. The rate of enrolment demonstrates both the demand and necessity for a treatment for peanut allergies, but also other food allergies more generally."

Previously published in the peer reviewed journal, the Journal of Allergy and Clinical Immunology, children in the PPOIT randomised trial were given a combination of the probiotic, *Lactobacillus rhamnosus*, together with peanut protein in increasing amounts, or a placebo for an 18 month treatment period. Impressively, 82 per cent of children who received PPOIT treatment could tolerate peanut at the end of the trial when tested, compared to three percent in the placebo group (or 74 per cent with PPOIT compared to three percent with placebo by intent-to-treat analysis). After the study ended, children who developed tolerance to peanut were instructed to introduce peanut as part of their normal diet; whereas children who remained peanut allergic or had only achieved desensitisation were advised to continue peanut avoidance according to current care.

Chief Scientific Officer and lead researcher Professor Mimi Tang, who pioneered the PPOIT treatment, re-evaluated the children four years after they completed the initial trial, to assess long

term tolerance. Results published in The Lancet Child and Adolescent Health showed that the benefits of the probiotic peanut oral immunotherapy treatment were maintained four years later in the majority of those treated. “Of those PPOIT-treated participants who were tolerant to peanut at the end of the original trial (and who participated in the follow up study), 80% were still eating peanut and 70% had long-lasting challenge-proven tolerance four years after stopping treatment.”

Unlike many other peanut allergy treatments in development, this therapy allows children with peanut allergy to actively incorporate peanut and peanut products in their regular diet if they wish and does not require ongoing regular treatment to maintain protection. The treatment continues to attract the attention of global biopharmaceutical companies, with findings suggesting that tolerance could be a realistic target for treatment of peanut allergy. The possibility that this treatment approach can be applied to treat other food allergies provides additional potential product opportunities for Prota.

Prota Therapeutics has been funded since establishment by OneVentures Funds II and III. “Continuity of funding through the clinical trial process has been critical to ensuring Prota maintains momentum in bringing this life-saving solution to market”, said Dr Graeme Wald, Principal at OneVentures and Chairman of the Prota Board.

Peanut allergy is the most common cause of anaphylaxis, a life-threatening allergic reaction, and a leading cause of death from food allergy.

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**About PPOIT (Probiotic and Peanut Oral Immunotherapy)**

Probiotic and Peanut Oral Immunotherapy is a potential innovative treatment for peanut allergies. Developed at the Murdoch Children’s Research Institute by a team led by Professor Mimi Tang, the treatment has been licenced to Prota Therapeutics for further study and commercialisation. The treatment to be developed by Prota Therapeutics is a proprietary combination of a Lactobacillus rhamnosus probiotic strain specifically formulated and manufactured in collaboration with Chr. Hansen, together with a formulated peanut product oral immunotherapy.

**About Prota Therapeutics**

Prota Therapeutics is a private Australian company developing immunotherapy-based treatments for food allergy. The company's lead product based on innovative research licensed from the Murdoch Children's Research Institute, is under development as a treatment for the most common cause of life-threatening anaphylaxis, peanut allergy.

The new treatment for peanut allergy is rapidly progressing through clinical development and commercialization through its partnerships and the support of investors, led by Sydney based venture capital firm OneVentures, supported by the Australian Government's Biomedical Translation Fund initiative.

### **About OneVentures**

OneVentures is an Australian venture capital firm with \$320M under management launching its first fund in 2010. OneVentures utilises its strengths in business building to accelerate portfolio company performance. OneVentures has three main funds, two of which are actively investing. The OneVentures Innovation and Growth Fund II and OneVentures Healthcare Fund III, have approximately \$200M in available capital for technology and healthcare businesses. The OneVentures Healthcare Fund III launched in December 2016. The \$170M fund is licenced under the Australian Government's Biomedical Translation Fund (BTF) program and is actively seeking investments in Australian domiciled companies commercialising medical devices and drugs in clinical development and diagnostics.

Read more about OneVentures at [www.one-ventures.com](http://www.one-ventures.com)

### **About MCRI**

The Murdoch Children's Research Institute (MCRI) is the largest child health research institute in Australia and is one of the top five worldwide. MCRI is renowned as a world leader in paediatric research including allergy, infectious diseases, immune disorders, genetics, cancer, stem cell technology and population health. The Institute is co-located with campus partners The Royal Children's Hospital and the University of Melbourne. This unique position allows MCRI to translate discoveries in laboratory, clinical and public health research into real benefits to help children around Australia and the world live healthier, happier lives.

The MCRI commenced the study (PPOIT-003) as sponsor, following a significant research grant from the NHMRC.

Read more about MCRI at [www.mcri.edu.au](http://www.mcri.edu.au)