



New Data Shows Previously Allergic Children Still Able to Tolerate Peanut Four Years after Treatment with a Novel Immunotherapy Licensed by Prota Therapeutics

- ***Publication from MCRI of four year follow up data from a study evaluating a novel oral immunotherapy to treat peanut allergy - The Lancet, Child and Adolescent Health.***
- ***At the end of the original trial in 2013, 82% of children who received the probiotic and peanut immunotherapy (PPOIT) were deemed tolerant to peanuts***
- ***Four years later, the majority of children who had initially developed tolerance to peanut are still consuming peanut as part of their normal diet (80%) and passed a further challenge test confirming long-term tolerance to peanut (70%)***

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MELBOURNE, Australia--(BUSINESS WIRE)--Allergy immunotherapy company Prota Therapeutics Pty Ltd (Prota) is pleased to announce results from a follow up study of the probiotic and peanut immunotherapy (PPOIT) treatment which it has licensed from the Murdoch Childrens Research Institute (MCRI), demonstrating long-lasting tolerance effects of treatment more than four years after the original study ended.

Prota believes that this follow up study data provides the strongest evidence yet that a cure may be possible for peanut allergy and holds important implications for attacking the modern food allergy epidemic. Peanut allergy is the commonest cause of anaphylaxis, a life-threatening allergic reaction, and one of the commonest causes of death from food allergy.

Chief Scientific Officer and lead researcher Professor Mimi Tang, who pioneered the PPOIT treatment, followed children four years after they completed the initial trial. Children in the original PPOIT randomised trial were given either a combination of the probiotic, *Lactobacillus rhamnosus*, together with peanut protein in increasing amounts, or a placebo (56 children in total, randomized equally), for 18 months, to assess whether children would become tolerant to peanut.

Outstandingly, more than 80 per cent of children who received the combination probiotic peanut oral immunotherapy treatment were able to tolerate peanut at the end of the trial, compared to less than four percent in the placebo group. Children who developed tolerance to peanut in the first trial were instructed to introduce peanut as part of their normal diet after the study ended; whereas children who remained peanut allergic were advised to continue peanut avoidance according to current care.

The latest follow up study investigated whether the benefits of the oral treatment were maintained four years later.

Prof Tang said this study showed that the majority of PPOIT-treated children who tolerated peanut at the end of the original trial were still eating peanut essentially without reactions four years later.

“Of the PPOIT-treated participants who achieved short term tolerance at the end of the original trial, 80% were still eating peanut without symptoms and 70% had long-lasting challenge-proven tolerance four years after stopping treatment,” Prof Tang said.

“These children had been eating peanut freely in their diet without having to follow any particular program of peanut intake in the years after treatment was completed. Over half were consuming moderate to large amounts of peanut on a regular basis, others were only eating peanut infrequently. The importance of this finding is that these children were able to eat peanut like children who don’t have peanut allergy and still maintain their tolerant state, protected against reactions to peanut.”

The majority (83%) of participants treated with PPOIT in the original trial reported no allergic reactions to either intentional or accidental peanut ingestion in the four years post treatment. Of critical importance, amongst the few that reported allergic reactions to peanut following intentional peanut intake since stopping treatment, none reported anaphylaxis.

This follow up study was conducted by the MCRI with contributory funding from the MCRI and Australian Food Allergy Foundation. In September 2016, Prota Therapeutics, was set up with seed capital from the MCRI and subsequently received Series A funding commitment of \$15 million dollars from Australian venture capital firm, OneVentures, with funds leveraged by the Australian Federal Government’s Biomedical Translation Fund. Prota will accelerate development of an approved product to make this vital treatment available globally to people with peanut allergy.

Dr Paul Kelly, Managing Partner of OneVentures said “OneVentures is proud to invest in the translation of Professor Tang’s ground-breaking work into a commercial product for the treatment of peanut allergy in the first instance and then potentially other food allergies. This publication in the Lancet Child and Adolescent Health further validates the quality and rigor of Professor Tang’s work and its potential.”

Dr Suzanne Lipe, CEO of Prota Therapeutics, said the results of the investigation, demonstrating such a high proportion of subjects still continuing to be tolerant four years later, was extremely promising and if confirmed in a larger Phase III study, would represent a paradigm shift in the way peanut allergy is managed.

“Rather than using therapy that protects against accidental ingestion, Prota’s products aim to provide sustained long-term effects and the ability to include peanut in the diet. For the first time, we could have products on the market that provide meaningful and long-lasting treatment benefits, which allow sufferers to eat peanut products without thinking about it, as part of a regular diet just like unaffected people.”

“The MCRI and Prota’s success will be a major achievement on a global scale and making this vital treatment available is what drives the team to accelerate the development program through the FDA approval process.”

“It also suggests the exciting possibility that tolerance is a realistic target for other food allergy treatments, opening a potential pipeline of products for the company.”

Background:

The prevalence of food allergy has risen dramatically in recent decades. While allergies to egg, milk, wheat and soy generally resolve during childhood, nut and seafood allergies often persist throughout life.

How does it work?

By introducing the probiotic, *Lactobacillus rhamnosus*, in conjunction with peanut protein, our researchers believe they have been able to modify the allergic response to peanut so the immune system produces protective responses, rather than a harmful response, to the peanut protein!

Food Allergy Facts:

- Food allergy affects about 250 million people worldwide

- Food allergies have increased 350 per cent over the past 20 years
- Peanut allergy has increased at the greatest rate
- More than 10 per cent of Australian infants have food allergy, including 3 per cent with peanut allergy
- Peanut allergy is one of the most common causes of death due to food-induced anaphylaxis

About Prota Therapeutics

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

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. A global growth focus drives investment selection with portfolio companies addressing multi-billion dollar problems from breakthroughs in healthcare (e.g. needle free vaccine delivery) through to the transformation of online education (e.g. next generation courseware and personalised learning) and the connected world (IoT, SaaS and virtual reality).

Read more about OneVentures at www.one-ventures.com

About MCRI

Read more about MCRI at <https://www.mcri.edu.au>

Available for interview:

Professor Mimi Tang – lead author of the study who can discuss the research results and what it means for Australian parents of children with peanut allergies.

Dr Suzanne Lipe – CEO of Prota Therapeutics Pty Ltd, who can discuss the company plans for developing and commercializing the peanut allergy product.

Contacts

WE Buchan

Scott Newstead, +61 3 8866 1218

snewstead@buchanwe.com.au

or

Prota Therapeutics Pty Ltd

Dr Suzanne Lipe

suzanne.lipe@protatherapeutics.com

or

MCRI

Inga Feitsma, +61 3 9936 6336

inga.feitsma@mcri.edu.au