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4-Year Data Backs Prota, MCRI Peanut Immunotherapy

Prota says that four-year follow-up data of a 48-patient study of a probiotic and peanut immunotherapy treatment shows “long-lasting tolerance effects of treatment”.

Prota said that it licenced the technology from Melbourne’s Murdoch Children’s Research Institute at the Royal Children’s Hospital and last year received \$15 million in funding led by Oneventures (BD: Sep 29, 2016).

The company said that at the end of the 2013 trial, 20 of 24 children (83.3%) who received the probiotic and peanut immunotherapy were deemed tolerant to peanuts and four years later, 80 percent of the 20 children who had initially developed tolerance to peanut were still consuming peanut as part of their normal diet and 70 percent passed a further challenge test confirming long-term tolerance to peanut.

The study, entitled ‘Long-term clinical and immunological effects of probiotic and peanut oral immunotherapy after treatment cessation: 4-year follow-up of a randomised, double-blind, placebo-controlled trial’ was published in The Lancet, Child and Adolescent Health and is at: [http://thelancet.com/journals/lanchi/article/PIIS2352-4642\(17\)30041-X/fulltext](http://thelancet.com/journals/lanchi/article/PIIS2352-4642(17)30041-X/fulltext).

Prota said that the follow-up study data provided “the strongest evidence yet that a cure may be possible for peanut allergy and holds important implications for attacking the modern food allergy epidemic”.

The company said peanut allergy was the most common cause of anaphylaxis and one of the most common causes of death from food allergy.

Prota said that 48 children in the original randomized trial were given either a combination of the probiotic, *Lactobacillus rhamnosus*, together with peanut protein in increasing amounts, or a placebo, for 18 months to assess whether they would become tolerant to peanut.

Prota said that 19 children (79.2%) who received the combination probiotic peanut oral immunotherapy treatment were able to tolerate peanut at the end of the trial, compared to one child (4.2%) in the placebo group.

Prota chief scientific officer and lead researcher Prof Mimi Tang pioneered the treatment and said the study showed that the majority of treated children who tolerated peanut at the end of the original trial were still eating peanut essentially without reactions four years later.

“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,” Prof Tang said.

“Over half were consuming moderate to large amounts of peanut on a regular basis, others were only eating peanut infrequently,” Prof Tang said.

“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,” Prof Tang said.

Prota said that among the few that reported allergic reactions to peanut following intentional peanut intake since stopping treatment, none reported anaphylaxis.

Prota said the follow-up study was conducted by the MCRI with contributory funding from the MCRI and Australian Food Allergy Foundation.

Oneventures managing-partner Dr Paul Kelly said the Lancet publication “further validates the quality and rigor of Prof Tang’s work and its potential”.

Prota chief executive officer Dr Suzanne Lipe told Biotech Daily that an up-to 200-patient, multi-centre, phase II trial was underway in Australia with results expected in 2020, and an up-to 500-patient, pivotal, phase III, US regulatory-directed trial was being planned to start in 2019.

Prota is a private company.