Prota Therapeutics Announces Publication in Allergy of Long-Term Peanut Allergy Study Confirming Clinical Remission as the Optimal Treatment Outcome

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Results affirm the advantages of Prota's remission peanut OIT treatments, which lead to significant and sustained benefits including substantially improved Health Related Quality of Life

- Study underscores the need to aim for remission as the optimal treatment outcome.
- Highlights significant long-term benefits provided by two high-dose peanut oral immunotherapy treatments that induce remission of allergy.

MELBOURNE, Australia, Aug. 14, 2024 /PRNewswire/ -- **Prota Therapeutics** Pty Ltd (Prota), an Australian clinical-stage biotechnology company focused on the development of novel oral immunotherapy treatments that induce remission of allergy, today announced publication in the journal ***Allergy*** of the first long-term study directly comparing remission and desensitization endpoints following food allergen oral immunotherapy (OIT). The Phase 2b follow-on study also reports 2-year post-treatment outcomes for Prota's remission-inducing high-dose peanut oral immunotherapies: PRT120, a standalone high-dose OIT, and PRT100, a probiotic OIT combination treatment, which were previously shown to induce remission of peanut allergy in 51% and 46% of treated patients, respectively.

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Groundbreaking Study Reveals Long-Term Benefits of Achieving Remission with Prota Therapeutics' Novel Peanut Allergy Treatments: The latest findings from the PPOIT-003LT study highlight the enduring benefits of Prota's high-dose remission-inducing oral immunotherapies, including substantially improved health related quality of life.

The **PPOIT-003LT study**, a continuation of the Phase 2b **PPOIT-003** randomized, multi-center trial, provides significant insights into the long-term outcomes of children who received one of two remission-inducing high-dose peanut oral immunotherapies: a Peanut Oral Immunotherapy on its own (OIT) or a combined Probiotic Peanut Oral Immunotherapy (PPOIT). The study directly compared the long-term benefits and risks associated with the different treatment outcomes -- remission, desensitization and allergy, and also reported long-term outcomes for OIT and PPOIT compared to placebo.

Findings validate remission as a preferred outcome to desensitization. Participants who achieved remission following treatment were able to stop treatment and safely consume peanuts freely. At two years after completing treatment, remission participants reported fewer peanut ingestion reactions, with no moderate or severe reactions, no rescue epinephrine injector use, and most importantly, significantly greater improvement in quality of life compared to participants who only achieved desensitization.

Participants who were only desensitized had difficulty maintaining their required daily peanut ingestion dose and continued to report severe reactions that required rescue epinephrine treatment. They did not experience any improvement in quality of life compared to the allergic group.

Findings also confirmed that both the high-dose OIT (PRT120) and the combination PPOIT (PRT100) treatments provide lasting benefits that persist or are improved upon during the 2-year period after stopping treatment. At 2-years after completing treatment with either PRT120 or PRT100, children experienced fewer reactions over time, and continued to enjoy significantly improved health related quality of life (HRQOL) compared to the placebo group.

Key Findings

- A standalone high-dose peanut oral immunotherapy (OIT) and a combination probiotic high-dose peanut oral immunotherapy (PPOIT) that induced remission of peanut allergy in 51% and 46% of treated patients, respectively, were shown to provide lasting benefits at 2-years after treatment, including significantly improved quality of life compared with placebo-treated patients.
- Participants with remission were half as likely to have an allergic reaction to peanut compared with desensitized patients (15.9% in the remission group, 36.8% in the desensitized group).
- In the 2nd-year after treatment, remission participants had no moderate or severe reactions and no rescue epinephrine use; whereas 24% of reactions in desensitized participants were moderate or severe, and 14.3% of desensitized participants required rescue epinephrine to treat reactions.
- Participants who achieved remission reported substantial and clinically meaningful improvement in health-related quality of life (HRQOL) compared with both desensitized participants and those who remained allergic; whereas participants who were only desensitized (without remission) showed no improvement in HRQOL compared with allergic participants.

Study Design

- **Participants:** 151 of the 176 (86%) eligible children aged 1-10 with confirmed peanut allergy who completed the Phase 2b PPOIT-003 randomized trial.
- **Study endpoints:** Comparison of long-term outcomes by clinical allergy status: remission, desensitization (without remission) and persistent allergy; comparison of long-term outcomes by treatment group: High-dose peanut oral immunotherapy (OIT), Probiotic Peanut Oral Immunotherapy (PPOIT), and placebo.
- **Outcomes Measured:** Peanut ingestion, reactions, and health-related quality of life (HRQOL) at 1-year and 2-years after treatment.

Summary

The follow-on study, PPOIT-003LT, showed two key findings:

- Remission is a demonstrably better outcome for patients than only being desensitized or remaining allergic. Remission participants reported fewer and milder allergic reactions to peanut (with no requirement for rescue epinephrine) compared to desensitized patients and, most importantly, experienced substantially better quality of life compared to both desensitized and allergic participants.
- The clinical benefits of both the high-dose OIT (Prota's lead product, PRT120) and PPOIT are sustained or even improved upon in the long-term, with continuing reductions in reactions to peanut over time, particularly for remission participants, and lasting quality of life improvements compared with placebo treatment.

Among benefits of achieving remission

- Freedom from ongoing treatment.
- Reduction in allergic reactions, and in severity of reactions.
- Substantial HRQOL improvements.
- Positive attitudes toward peanut consumption.
- Psychological benefits including reduced anxiety.

According to the study Principal Investigator, Paxton Loke, Ph.D., Research Clinician in the Allergy Immunology group at the Murdoch Children's Research Institute (MCRI), "Remission offers a more favorable long-term outcome in terms of reduced reactions and improved quality of life compared to desensitization without remission or persistent allergy. This study underscores the need to aim for remission as the optimal clinical outcome."

"The findings from the PPOIT-003LT study highlight the significant benefits of achieving remission through PRT120 treatment, a high-dose rapid escalation oral immunotherapy for peanut allergies," said Lead Investigator **Professor Mimi Tang**, Ph.D., Director of the Allergy Translation Centre and Head of Allergy Immunology at the Murdoch Children's Research Institute (MCRI), and CEO of Prota Therapeutics.

About Prota Therapeutics

Prota Therapeutics is an Australian proprietary limited late clinical-stage biotech company dedicated to advancing allergen oral immunotherapies for treating food allergies, particularly addressing the prevalent and potentially life-threatening issue of peanut allergy. **E**stablished in 2016 to develop and commercialize novel oral immunotherapy treatments, Prota holds an exclusive license to the proprietary food immunotherapy technology developed at the Murdoch Children's Research Institute (MCRI). For more information please visit: **https://protatherapeutics.com/**.

About Murdoch Children's Research Institute

Murdoch Children's Research Institute is the largest child health research institute in Australia committed to making discoveries and developing treatments to improve child and adolescent health in Australia and around the world. They are pioneering new treatments, trialling better vaccines and improving ways of diagnosing and helping sick babies, children and adolescents. It is one of the only research institutes in Australia to offer genetic testing to find answers for families of children with previously undiagnosed conditions.

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