



Australian peanut therapy developer Aravax reveals positive Phase I trial results at world-leading allergy conference

Melbourne biotech to take its revolutionary peanut allergy treatment to Phase II clinical trials

February 25, 2019, Melbourne, Australia – Aravax, a clinical stage biotechnology company focused on developing the next generation of peanut allergy immunotherapy with advantages in safety and practicality, has presented its clinical trial results at one of the world’s most prominent allergy conferences today.

Melbourne-based Aravax today announced positive results from the Phase I trial of its peanut allergy therapy, at the 2019 American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting in San Francisco. The trial data showed that Aravax’s therapy has a highly favorable safety profile, even in patients with severe peanut allergies.

“Peanut allergy is the most common cause of food allergy-related deaths in children, and there is an urgent need for safe, effective and convenient therapies that address the underlying cause of this potentially fatal disease,” said Pascal Hickey, CEO of Aravax.

Almost two in every hundred Australians suffer from peanut allergy, and currently there is no therapy to reduce the severity of allergic reactions that can occur following accidental consumption. Despite patients attempting to follow a peanut-free diet, every year around 40% of peanut allergic individuals will suffer a serious adverse event from inadvertent exposure, including anaphylaxis which can lead to death.

Traditionally, allergy specialists have treated patients using repeat doses of the allergy-causing substance. Similar approaches are being developed to treat peanut allergy, but the use of therapies containing whole peanut protein carries a high risk of severe reactions and requires daily dosing for lengthy periods.

As part of Aravax’s Phase I trials carried out over the past 18 months at CMAX Clinical Research in Adelaide and Nucleus Network in Melbourne, Aravax evaluated the safety and tolerability of its product known as PVX108 through single and repeated administration across a range of doses.

The Phase I results are significant as compared with other immunotherapeutic approaches to peanut allergy, Aravax’s product does not contain the parts of peanut protein that cause severe allergic reactions, and its once-a-month dosing regimen is a far simpler solution than taking medication every day.

“We believe that this therapy has important potential to improve the lives of millions of people with peanut allergies. The results from our Phase I clinical trial demonstrate that our peptide-based immunotherapy approach has a positive safety profile, so now we are working with the clinical community to design a Phase II study of PVX108, which will be conducted in Australia and the United States,” Dr Hickey said.

Aravax’s technology is underpinned by more than a decade of research led by Professor Robyn O’Hehir and her team at Alfred Health and Monash University, which has been supported by the Australian Food Allergy Foundation, the Alfred Hospital Trust, and the National Health and Medical

Research Council. In 2015, Aravax secured over \$4.85 million in investment from the Medical Research Commercialisation Fund (MRCF) to develop the technology through to initial clinical trials.

Professor Robyn O’Hehir, Professor and Head of Department of Respiratory Medicine, Allergy and Clinical Immunology, Central Clinical School, Monash University and Chief Medical Advisor to Aravax also discussed the data during an AAAAI press conference over the weekend.

“Although early-stage, these results suggest that a peptide-based approach to peanut allergy immunotherapy could offer significant safety advantages over other approaches in later stages of development,” said Professor O’Hehir. “This is a significant breakthrough in the search for a safe therapy for peanut allergy, and builds on prior work showing that PVX108 targets the peanut-specific T cells that are believed to be the underlying cause of disease.”

Aravax’s Phase I results, “*Safety and Tolerability of a Novel Peptide-Based Immunotherapy for Peanut Allergy*” will be presented at the AAAAI Annual Conference at 9:45 a.m. PST on Monday, February 25th.

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Aravax & MRCF

Andrew Hamilton: +61420 447 669 or ah@manacomcommunications.com

Annabelle Dick: +6427 819 7011 ad@manacomcommunications.com

Phase I clinical trial results

The Phase 1 study comprised two phases, the first of which assessed single, ascending doses [0.05 nmol – 150 nmol] of PVX108 and enrolled eight cohorts of six subjects each. Subjects of each cohort were randomized to receive PVX108 or the placebo. Cohorts were enrolled one at a time, starting with a single injection. The dose escalated for each successive cohort, with the eighth cohort receiving the highest dose. In the second phase, 18 additional subjects were randomized to receive six injections of 150 nmol over a 16-week period. Key findings from the study include:

- There were no serious adverse reactions in patients receiving PVX108.
- Adverse events considered possibly or probably related to treatment were graded mild or moderate, with the majority being transient, mild injection site reactions. None of the adverse events was deemed of clinical concern by the study Safety Review Committee.
- There was no relationship between dose level and frequency or severity of adverse events.

In a separate study utilizing blood samples donated by peanut-allergy sufferers, in vitro assays also confirmed a lack of basophil reactivity to PVX108.

About Aravax

Aravax is a clinical stage biotechnology company focused on developing the first safe and rapidly effective treatment for peanut allergy. The treatment uses highly targeted technology that can reset the immune system to tolerate peanut without evoking allergic reactions during treatment.

Aravax's technology is underpinned by over a decade of research led by Professor Robyn O'Hehir and her team at Alfred Health and Monash University, which has been supported by the Australian Food Allergy Foundation, the Alfred Hospital Trust, and the National Health and Medical Research Council of Australia.

The novel technology uses carefully selected fragments of peanut proteins to switch off allergic reactions. The product does not contain whole protein allergens which are known to cause life-threatening anaphylactic reactions. Aravax's PVX108 therefore has the potential to break the paradigm of allergen immunotherapy by targeting the underlying cause of disease without exposing patients to the risk of acute reactions to treatment.

Aravax is headquartered in Melbourne, Australia.

For more information visit: www.aravax.com.au

About Brandon Capital Partners and the Medical Research Commercialisation Fund

Brandon Capital Partners is a venture capital firm that manages the Medical Research Commercialisation Fund (MRCF), Australia and New Zealand's largest life science investment fund, with AU\$505 million under management.

The MRCF is a unique collaboration between major Australian superannuation funds, the Australian and New Zealand governments, Australian state governments and more than 50 leading medical research institutes and research hospitals. The MRCF supports the development and commercialisation of early-stage biomedical discoveries originating from member research organisations, providing both capital and expertise to guide the successful development of new therapies.

The MRCF has supported more than 34 start-up companies to date, 28 of which were founded by the MRCF. Brandon Capital's funds have invested in some of the most promising life sciences companies, including; Aravax, Global Kinetics Corporation, PolyActiva, Osprey Medical and Vaxxas.

For more information visit: www.mrcf.com.au