UNDER EMBARGO UNTIL 00:01 (AEDT) 8th March 2023

Aravax initiates Phase 2 peanut allergy clinical trials in Australia

8 March 2023, Melbourne, Australia: Aravax, a clinical stage biotechnology company developing next generation immunotherapies which are safe, convenient, and precisely targeted, today announces it has initiated the first clinical trial sites in Australia for AVX-201 in Australia, a Phase 2 trial of PVX108 for the treatment of peanut allergy.

Aravax received the green light for its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) in 2022. Clinical trial AVX-201 will be led in Australia by regional principle investigator Associate Professor Kirsten Perrett, Population Allergy Group Leader at the Murdoch Children's Research Institute. Associate Professor Perrett is also a Paediatric Allergist and Vaccinologist and Director of the National Allergy Centre of Excellence (NACE).

Allergy clinical trial centres across Victoria, South Australia, New South Wales and Western Australia now invite children and adolescents aged four to 17 years with peanut allergy to take part in the phase 2 study. Researchers aim to evaluate the efficacy of the novel therapy PVX108.

Aravax's PVX108 is a highly differentiated specific medicine developed using the company's platform technology. It does not contain peanut proteins, which put patients at risk of serious side effects. It is designed to precisely retrain the immune system to tolerate peanut allergens, and requires monthly, rather than daily dosing.

"We're excited to start Phase 2 trials of PVX108 in Australia. Using peanut food challenges before and after treatment, this trial will evaluate the efficacy of PVX108 when given as monthly doses over 12 months," says Dr Pascal Hickey, CEO, Aravax.

In Phase 1 trials, researchers observed PVX108 produced changes in the immune response to peanut protein, which continued to develop once dosing had completed. "In this Phase 2 trial we will investigate whether those early immunological changes translate to the development of sustained tolerance to peanuts," continues Dr Hickey.

Associate Professor Perrett says, the prevalence of food allergy, particularly peanut allergies, among infants and children is concerning. "A Murdoch Children's-led study found one in 10 infants in Australia are diagnosed with a food allergy, while almost three per cent of children are allergic to peanuts. Determining whether there is a successful peanut allergy therapy could have a global impact and transform the lives of many people."

In Australia, more than five million people live with allergic disease, and the country is considered the allergy capital of the world, according to the NACE.

Most allergic reactions to peanuts are mild like swelling of the lips or hives, but severe reactions can present very suddenly without warning. The risk of experiencing a life-threatening reaction without warning has a great impact on the lives of those with peanut allergies, and for parents and caregivers of children with the allergy.

Aravax is initiating Phase 2 trials of PVX108 in Australia following on from $20m investment as part of its series B funding round, led by Australian life science investors, Brandon Capital and Tenmile.

More information and details on how to apply to partake in the clinical trial can be found on the on the NACE and Aravax websites.

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About Aravax

Aravax is a clinical stage biotechnology company focused on revolutionising the treatment of food allergies with next-generation specific immunotherapies which are safe, effective and convenient. Aravax applies proprietary technology and know-how to design highly targeted pharmacotherapies, which reset the immune system to tolerate a specific allergen without evoking allergic reactions during treatment. The lead product, PVX108, is being developed for the treatment of peanut allergy. Aravax is headquartered in Melbourne, Australia, and was founded in 2015 with venture capital from Brandon Capital and technology from Alfred Health and Monash University.

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

About Aravax's Phase 2 trial

AVX-201 is a double blind randomised Phase 2 study in adolescents and children with peanut allergy. The aims of the trial are to evaluate the efficacy and safety of PVX108 when administered intradermally in monthly doses over a 12 month period. The trial will be conducted under an US FDA IND at sites in Australia and in the United States. Australian sites will initiate recruitment in early 2023.

For more information visit:
https://clinicaltrials.gov/ct2/show/NCT05621317?term=aravax&draw=2&rank=1