

Aravax Pty Ltd receives positive feedback on pre-IND filing for Phase 2 trial plans for PVX108 from U.S FDA.

30 September 2019, Melbourne, AUSTRALIA: Aravax, a clinical stage biotechnology company focused on developing the first therapy for peanut allergy which is designed to be safe, effective and convenient, has received positive feedback from the U.S Food and Drug Administration (FDA) in regard to its development plans for PVX108, a next generation, specific immunotherapy for the treatment of peanut allergy.

PVX108 is a next-generation, allergen-specific immunotherapy using peptides that represent critical fragments of peanut proteins to precisely target the T cells driving peanut allergy. Administered once per month, therapy is designed to precisely induce tolerance to peanut protein without the safety concerns constraining the use of the only registered therapy which uses natural extracts from peanuts.

The pre-IND meeting filing enabled Aravax management to present the results of nonclinical and clinical studies completed to date, its proposed Phase 2 clinical study design, and ask FDA questions about the PVX108 clinical development program ahead of filing an Investigational New Drug (IND). IND approval will enable Aravax to commence a Phase 2 clinical trials of PVX108 in the United States.

“We are extremely pleased with the feedback just received. FDA did not raise any concerns about the nonclinical studies presented, our completed Phase 1 trial results, or our proposed Phase 2 design. Furthermore, we received extremely useful advice about how to streamline our pharmaceutical development activities moving forwards. This provides great confidence in progressing the IND application and will send a positive signal to existing and incoming investors.” said Aravax CEO Pascal Hickey.

Earlier this year, Aravax presented the results of its randomized, double-blind, placebo-controlled Phase 1 trial (AVX-001) at the European Academy of Allergy and Clinical Immunology. The trial was conducted in 66 peanut-allergic adults at sites in Melbourne and Adelaide, Australia, and showed no evidence that PVX108 was associated with acute reactions, and no adverse events of clinical concern were observed. These data demonstrate that PVX108 has a highly favourable safety profile for treatment of peanut allergic patients, including those with severe allergy.

Aravax now intends to complete further nonclinical studies and file its IND application to progress Phase 2 trials in the U.S. and Australia.

- ENDS -

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.

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