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ImmusanT starts trials of celiac disease vaccine, Nexvax2

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ImmusanT Initiates Clinical Trials of Nexvax2 Therapeutic Vaccine



Singapore:Ã?Â ImmusanT initiated clinical trials in New Zealand, Australia and the US to evaluate Nexvax2, the first therapeutic vaccine for patients with celiac disease.

Nexvax2 is designed to re-establish patients' tolerance to the toxic effects of gluten, a protein in wheat, barley and rye, and allow them to return to a normal diet. There are currently no approved medicines available for people with celiac disease, who must manage their condition by eliminating gluten-containing foods from their diet.

The Nexvax2 clinical trial program underway in Australia and New Zealand is a randomized, double-blind, placebo-controlled phase Ib study evaluating multiple ascending doses of Nexvax2 for the induction of gluten tolerance in patients on a gluten-free diet. ImmusanT expects to enroll 84 subjects at approximately four study sites in the two countries in order to evaluate safety, tolerability and pharmacokinetics, and to select doses for investigation in subsequent studies.

The second study, a randomized, double-blind, placebo-controlled phase I trial is being conducted in the US to determine the safety, tolerability and pharmacokinetic profile of Nexvax2 in patients with celiac disease. ImmusanT plans to enroll 30 adult subjects at approximately four trial sites.

In ImmusanT's international trials, patients will have a confirmed diagnosis of celiac disease and carry the immune recognition gene HLA-DQ2. Up to 90 percent of individuals with celiac disease have this gene. Furthermore, prospective patients will be screened using the company's companion diagnostic technology to identify suitable candidates for the therapeutic vaccine. ImmusanT will use this novel blood test to measure gluten-reactive T cells in celiac disease as a potential marker for immune modulation with Nexvax2.

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