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Trial begins for vaccine that builds gluten tolerance

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Singapore: ImmusanT, an early-stage biotechnology company based in Cambridge, Massachusetts, has initiated clinical trials to evaluate Nexvax2, the first therapeutic vaccine for patients with celiac disease. The trials are being held in New Zealand, Australia and the US.

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. Advancing the earlier Nexvax2 clinical trial, the new 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 being conducted in the US is to determine the safety, tolerability and pharmacokinetic profile of Nexvax2 in patients with celiac disease well controlled by a gluten-free diet. ImmusanT plans to enroll 30 adult subjects at approximately four trial sites. "We are kicking-off a robust clinical program that we hope demonstrates Nexvax2 dramatically reduces the body's immune response to dietary gluten so patients can resume a normal diet and return to good health," said Dr Patrick H. Griffin, chief medical officer of ImmusanT.

"There has been tremendous enthusiasm about Nexvax2 from patients and the medical community and this will provide terrific momentum for advancing our clinical program," said Leslie J Williams, president and CEO of ImmusanT.

BD (Becton, Dickinson and Company) is supplying novel intradermal injection solutions to ImmusanT to administer Nexvax2 in its clinical program. These solutions are based on BD's commercialized intradermal injection technology, BD Soluvia Microinjection System. BD has a longstanding history of developing and commercializing novel prefillable vaccine delivery systems. As compared with the traditional intradermal injection method, BD's intradermal injection technologies allow for a

clinician to use an injection technique that is perpendicular to the skin. This helps simplify the administration process while improving the success of intradermal injections.

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