ImmusanT Data Shows Up-dosing Substantially Increases Nexvax2® Dose Levels That Are Safe and Tolerable, Further Supports Phase 2 Studies

-- Stepwise up-dosing enables administration at higher dose levels --

-- Adverse events and symptom levels similar to placebo --

CAMBRIDGE, Mass. – November 28, 2017 – ImmusanT, Inc., a clinical-stage company developing Nexvax2®, a therapeutic vaccine designed to protect patients with celiac disease against exposure to gluten, and ultimately restore immune intolerance in celiac disease, today announced the publication of data demonstrating Nexvax2 to be both safe and tolerable at substantially higher dose levels when preceded by stepwise up-dosing from low starting doses. The manuscript, titled "Epitope-Specific Immunotherapy Targeting CD4-Positive T Cells in Celiac Disease: Safety, Pharmacokinetics, and Effects on Intestinal Histology and Plasma Cytokines with Escalating Dose Regimens of Nexvax2 in a Randomized, Double-Blind, Placebo-Controlled Phase 1 Study" was published online in *EBioMedicine,* an Open Access Elsevier journal supported by Cell Press and *The Lancet*.

"This study demonstrates that gradually increasing the dose from a low, well-tolerated starting dose enables Nexvax2 to be safe and tolerable without dose-limiting adverse events at a level of 900 µg, six times the maximum tolerated dose with fixed dose schedules," said Robert Anderson, MBChB, Ph.D., Chief Scientific Officer of ImmusanT. "This is significant because dose strength is thought to determine the efficacy of peptide-based immunotherapy, and up-dosing now allows us to test efficacy of Nexvax2 at levels that have the potential to be more effective in patients inadvertently exposed to gluten while they do their best to maintain a gluten-free diet. These results support the potential use of Nexvax2 as a maintenance treatment for those living with celiac disease, and further support the advancement of Nexvax2 into phase 2 clinical trials."

The results of this study met both primary and secondary endpoints, including no excess of adverse events and no increasing plasma cytokine levels after dosing. Self-reported gastrointestinal symptom scores were similar for treatment with Nexvax2 and placebo. The study findings provide clinical evidence supporting the interpretation that T-cell responsiveness to antigenic components of gluten in celiac disease is reduced by recent exposure to the same antigen. An important finding of the study was that regular administration of Nexvax2 over nine weeks including four weeks at the maintenance dose level of 900 µg had no damaging effect on the small intestine. Celiac disease patients homozygous for HLA-DQ2.5, a group that had been prone to first dose adverse events in previous trials of Nexvax2, were assessed in a separate cohort and had an adverse event profile after high maintenance doses of Nexvax2 preceded by up-dosing similar to placebo.

"Approximately 90% of celiac disease patients carry the human leukocyte antigen-DQ2.5 (HLA-DQ2.5) immune recognition gene, and at present the only solution for all those living on celiac disease is a gluten-free diet," said A. James M. Daveson, Faculty of Medicine at the University of Queensland and first author of the study. "This study marks the first clinical evidence of up-dosing in reducing adverse effects and in enabling higher maintenance dose levels in a T-cell mediated autoimmune disease. Dose optimization is a critical aspect of successful therapeutic development programs. The present study advances understanding of Nexvax2, which has the potential to provide a long-sought treatment option for celiac disease."

“The significance of these results go beyond a safety and dosing study,” said Leslie J. Williams, Chief Executive Officer of ImmusanT. “All outcome measures point to Nexvax2 not only being safe but active and tolerated without cytokine release at levels measurable in blood. We look forward to applying these insights to both our celiac disease program and other therapeutic programs going forward.”

To access the article, visit the Publications page of the ImmusanT website.

About Celiac Disease
Celiac disease is an acquired, T cell-mediated autoimmune gastrointestinal disease triggered by the ingestion of gluten from wheat, rye and barley. About 90% of individuals affected by celiac disease carry the human leukocyte antigen-DQ2.5 (HLA-DQ2.5) immune recognition gene which facilitates the immune response to peptide fragments of gluten. A gluten-free diet is the only current management for this disease. The global prevalence of celiac disease is approximately 1%. General awareness of celiac disease is increasing as serological testing becomes more widespread in medical practice, but presently over 80% of cases go unrecognized in the United States. When a person with celiac disease consumes gluten, the individual’s immune system responds by triggering T cells to fight the offending proteins, damaging the small intestine and inhibiting the absorption of important nutrients into the body. Undiagnosed, celiac disease can contribute to poor educational performance and failure to thrive in children. Untreated disease in adults is associated with osteoporosis and increased risk of fractures, anemia, reduced fertility, problems during pregnancy and birth, short stature, dental enamel hypoplasia, dermatitis, recurrent stomatitis and cancer. With no available drug therapy, the only option is a strict and lifelong elimination of gluten from the diet. Compliance is often challenging, and the majority of people continue to have residual damage to their small intestine in spite of adherence to a gluten-free diet.

About Nexvax2®
Nexvax2® is the only therapeutic approach for celiac disease in clinical development today that targets the fundamental cause of the disease; the loss of immune tolerance to gluten. Nexvax2® is a therapeutic vaccine that reprograms the T-cells responsible for the symptoms of celiac disease to stop triggering a pro-inflammatory response. Nexvax2 intends to protect patients with celiac disease against inadvertent exposure to gluten.

About ImmusanT, Inc.
ImmusanT is a privately held biotechnology company focused on protecting patients with celiac disease against the effects of gluten. By harnessing new discoveries in immunology, ImmusanT aims to improve diagnosis and medical management of celiac disease by protecting against the effects of gluten exposure while patients maintain a gluten-free diet. The company is developing Nexvax2®, a therapeutic vaccine for celiac disease, and diagnostic and monitoring tools to improve celiac disease management. ImmusanT’s targeted immunotherapy discovery platform can be applied to a variety of autoimmune diseases. To learn more about ImmusanT, visit www.ImmusanT.com, or follow ImmusanT on Twitter.

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