ImmusanT Presents Data from Multiple Studies Supporting Continued Development of Nexvax2®

-- Increased Cytokine Levels After Gluten in Celiac Disease Provide Potential Basis for Novel Diagnostic --

-- Biomarkers to Potentially be Used as Clinical Indicators for Assessing Disease Activity Identified --

CAMBRIDGE, Mass. – Sept. 11, 2017 – ImmusanT, Inc., a clinical-stage company developing Nexvax2®, a therapeutic vaccine intended to protect against the effects of gluten exposure while maintaining a gluten-free diet in HLA-DQ2.5+ patients with celiac disease, today announced it has presented data demonstrating the immunologic basis for the early clinical effects of gluten in celiac disease. The results were presented in two poster presentations and summarized in an invited oral presentation at the International Celiac Disease Symposium (ICDS), which occurred September 8-10, 2017 in New Delhi, India.

"The data we presented at ICDS show that early cytokine changes in blood following gluten ingestion could provide the basis for a new diagnostic for celiac disease in patients on a gluten free diet with an uncertain diagnosis," said Robert Anderson, MBChB, Ph.D., Chief Scientific Officer of ImmusanT. "Additionally, the data show that early changes in circulating cytokines after a single gluten exposure could also provide a clinical indicator for assessing disease activity. These insights, along with the demonstrated potential to differentiate between celiac disease and non-celiac gluten sensitivity (NCGS) through the assessment of IL-2, support the continued development and potential of targeted immunotherapies such as Nexvax2®."

Dr. Anderson addressed these and other insights in the company's oral presentation entitled "Immunotherapy for celiac disease".

The first poster presentation, "An acute cytokine signature elicited by a bolus gluten challenge identifies patients following a gluten-free diet (GFD) with celiac disease (CeD) from those without", detailed results from two separate studies that characterized for the first time changes in circulating levels of cytokines caused by gluten in celiac disease. Elevations in circulating cytokines were specific to celiac disease volunteers who consumed gluten. Cytokines were increased from as early as 2 hours and up to 8 hours after eating gluten. The most prominently increased and earliest cytokine to increase after gluten in celiac disease was interleukin (IL)-2, a cytokine released by activated T cells. The findings position gluten-reactive T cells in the frontline of the immune response, causing early clinical manifestations experienced by celiac disease patients when they eat food containing gluten. This is an important advance and further supports the potential clinical impact of agents such as Nexvax2® that selectively modify gluten-reactive T cells.

Data from the second poster presentation, "Increase in plasma interleukin (IL)-2, IL-8, and IL-10 from 2 to 6 hours on oral gluten challenge differentiates between celiac disease (CeD) and non-celiac gluten sensitivity (NCGS) in patients on gluten-free diet (GFD)", found that patients diagnosed with celiac disease had highly significant elevations in plasma IL-2 and IL-8 after consuming a standardized gluten food challenge, while those with NCGS did not. The study further highlighted that immune activation caused by gluten involves early T-cell activation in celiac disease, but this is absent in patients with NCGS.

"These studies are significant because those with celiac disease often adopt a gluten-free diet prior to proper evaluation, which complicates the interpretation of current diagnostic tests," said Leslie Williams, President and Chief Executive Officer of ImmusanT. "We have demonstrated an ability to identify celiac patients from the non-celiac gluten sensitive population. With approximately 80% of people living with celiac disease undiagnosed and no current treatment available, these data demonstrate the potential for a simple, highly sensitive and specific diagnostic tool to improve patient health."

About Celiac Disease

Celiac disease is a T cell-mediated autoimmune gastrointestinal disease triggered by the ingestion of gluten from wheat, rye and barley predominantly in individuals who carry the human leukocyte antigen-DQ2.5 (*HLA-DQ2.5*) immune recognition gene. A gluten-free diet is the only current management for this disease. The community prevalence of celiac disease is approximately 1% in the U.S., but over 80% of cases go unrecognized. 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 is a major contributor 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, that is the loss of immune tolerance to gluten. Nexvax2® is a combination of three proprietary peptides that is delivered by injection as a therapeutic vaccine and reprograms the T-cells that respond to gluten antigens in celiac disease patients so that they stop triggering a pro-inflammatory response. By increasing the threshold for clinical reactivity to natural exposure to gluten, Nexvax2® is intended to protect patients with celiac disease against inadvertent exposure to gluten and ultimately restore immunological and clinical tolerance 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. Founded in 2010, ImmusanT is backed by Vatera Healthcare Partners. More information may be found at www.ImmusanT.com, or follow ImmusanT on Twitter.

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