ImmusanT Blood Test Differentiates Celiac from Non-Celiac Patients Through Cytokine Levels

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

-- Interleukin-2 (IL-2) Further Identified as Clinical Indicator for Celiac Disease --

CAMBRIDGE, Mass. – November 1, 2017 – ImmusanT, Inc., a clinical-stage company developing Nexvax2®, a therapeutic vaccine being investigated to protect against the effects of gluten in HLA-DQ2.5+ patients with celiac disease, today announced data from its collaboration with Norwegian researchers demonstrating an ability to differentiate celiac disease (CeD) and non-celiac gluten-sensitive (NCGS) patients based on cytokine levels. The data, which were presented by Professor Knut Lundin, University of Oslo, at United European Gastroenterology (UEG) Week, support the company's novel approach to developing a diagnostic and further the company's understanding of the immunological underpinnings of CeD.

"These findings are important because many patients maintaining a gluten-free diet have not had a diagnostic workup, and cannot tolerate ingesting gluten for the duration necessary to be properly tested for celiac disease," said Robert Anderson, MBChB, Ph.D., Chief Scientific Officer of ImmusanT. "By identifying the disease through plasma or blood test, which this data suggests is possible, patients would only be required to consume gluten on one occasion and would still achieve accurate results."

The 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)" detailed results from a study done in collaboration with the University of Oslo that characterized changes in circulating levels of cytokines caused by gluten in CeD and NCGS patients. Specifically, the study evaluated IL-2, IL-8 and IL-10 in plasma after gluten ingestion in CeD and NCGS subjects on GFD using highly sensitive assays. Gluten induced mucosal changes in 5 of 19 treated CeD patients and mobilized T cells in 12 of 15 evaluated patients, while no signs of symptomatic response were seen in "gluten-sensitive" patients. Elevations in IL-2, IL-8 and IL-10 were significantly increased in CeD compared to NCGS, with IL-2 being the most sensitive.

The medical need for proper identification of CeD is clear, as an estimated 80% of patients are undiagnosed and the only intervention available today, a GFD, is burdensome but necessary for CeD. For people who do not have CeD, gluten may not be the cause of their symptoms and a gluten-free diet is unlikely to be a healthy long-term solution. Patients often adopt a GFD before being evaluated for CeD, which renders the current tests inaccurate. Along with more accurate diagnoses for those living with CeD, a new blood test could help address the emerging medical problem of inaccurate self-diagnosis, in which those who do not have CeD employ a GFD without medical consultation.

"These results support our approach to developing a simple blood test for diagnosing celiac disease without the discomfort and inconvenience of current testing methods. This would be the first biomarker for measuring systemic T-cell immunity to gluten," said Leslie Williams, Chief Executive Officer of ImmusanT. "These are encouraging results which will be evaluated further in larger clinical studies."

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 global prevalence of celiac disease is approximately 1%, 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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