



ImmusanT Reports Data on Novel Celiac Disease Diagnostic Approach

- Data Presented in Oral Presentation at Digestive Disease Week 2017 -

CAMBRIDGE, Mass. – May 8, 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 the presentation of data demonstrating a novel method of identifying patients on a gluten-free diet with celiac disease. The study, conducted in collaboration with researchers from the Walter and Eliza Hall Institute, was presented in an oral presentation at Digestive Disease Week (DDW) 2017 in Chicago, Illinois.

Celiac disease (CeD) is an immune-mediated gastrointestinal disease caused by dietary gluten predominantly in individuals who carry the human leukocyte antigen-DQ2.5 (*HLA-DQ2.5*) immune recognition gene, and shares key pathogenic and genetic features with organ-specific autoimmune diseases. Currently, there is no pharmaceutical treatment for celiac disease and the only method of management is to maintain a gluten-free diet (GFD). GFD is often adopted before evaluation for CeD, which renders current tests for CeD inaccurate and creates diagnostic and management uncertainty. Patients on a GFD who seek a diagnosis of CeD often refuse or cannot tolerate a gluten challenge for the duration typically needed for accurate results of tests for serological and histological markers of CeD. Because of this, a faster and more tolerable diagnostic is needed to identify patients on a gluten-free diet with celiac disease.

“In this study, we have identified a distinct cytokine signature present in the serum of subjects with celiac disease 4 hours after the ingestion of gluten, suggesting that the measurement of serum cytokines following a single gluten challenge may allow for the identification of patients on a gluten-free diet with celiac disease,” said Dr. Bob Anderson, Chief Scientific Officer of ImmusanT. “We are hopeful that with additional studies, this could ultimately provide an improved alternative to current methods of testing for the diagnosis of celiac disease, which are cumbersome and often not well tolerated by the patient.”

“Celiac disease is estimated to affect approximately 1% of the United States population, but over 80% of cases remain undiagnosed, as methods of diagnosis are invasive and inconvenient for patients,” said Leslie Williams, President and Chief Executive Officer of ImmusanT. “The study presented today provides rationale for continued development of this novel diagnostic method as we aim to provide a more sensitive, rapid and tolerable alternative to current tests for patients suffering from celiac disease.”

In an oral presentation titled “Serum IL-2 and IL-8 are elevated within 4h after gluten ingestion in celiac disease (CeD) patients on glutenfree diet (GFD) – potential to resolve indeterminate diagnoses for patients on GFD,” Dr. Anderson presented data from a randomized, double-blind, placebo-controlled food challenge study that enrolled volunteers with HLA-DQ2.5+ celiac disease who were compliant with a gluten-free diet. In the study, 21 volunteers received either vital wheat gluten flour or a matched gluten-free flour drink over the course of 10 minutes. Serum chemokines and cytokines were measured 30 minutes prior to food challenge, then at four, six, and 24 hours after the challenge. Vital signs and patient-reported outcomes (CeD PRO) were recorded hourly.

Results of the study demonstrated that, at 4 hours following food challenge, serum levels of the cytokine IL-8 were significantly higher after exposure to gluten than placebo (median fold change from baseline: gluten: 2.4 vs. placebo: 1.1, $p=0.012$). Serum levels of IL-2 were also significantly increased at 4 hours,

confirming T-cell activation in response to gluten exposure (median fold change from baseline: gluten: 19.5 vs. placebo: 0.7, p=0.0001).

About Celiac Disease

Celiac disease is a T cell-mediated autoimmune disease triggered by the ingestion of gluten from wheat, rye and barley in genetically susceptible individuals. 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 Digestive Disease Week

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 6-9, 2017, at McCormick Place, Chicago, IL. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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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