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ImmusanT Reports Positive Results from Nexvax2 Phase 1 Study in Celiac Disease

Data Featured in Poster of Distinction and Symposia on Advances in Celiac Disease at Digestive Disease Week

CHICAGO, Illinois, May 9, 2011 – ImmusanT, Inc., a biotechnology company developing an immunotherapeutic vaccine, companion diagnostic and monitoring tool for celiac disease, reported positive results from a Phase 1 study evaluating the safety, tolerability and bioactivity of Nexvax2® in patients with celiac disease. ImmusanT Chief Scientific and Medical Officer Dr. Bob Anderson presented results from the Nexvax2 Phase 1 study and led a symposium and session discussions about celiac disease at Digestive Disease Week in Chicago.

The randomized, placebo controlled, double-blind Phase 1 study evaluated weekly intradermal injections of Nexvax2 compared to placebo in patients with celiac disease on a strict gluten-free diet. The therapeutic vaccine combines three proprietary peptides that elicit an immune response in patients with celiac disease who carry the immune recognition gene HLA-DQ2. In the three week study, the safety and tolerability profile of Nexvax2 were similar to placebo. Gastrointestinal symptoms were more common at the highest dose, confirming the selection of the toxic peptides that can eventually induce tolerance. Symptoms and mobilization of gluten-specific T-cells observed after administration of Nexvax2 were similar to those triggered by acute oral gluten exposure in HLA-DQ2 patients on a gluten-free diet. This suggests these same peptides may be used in an in-vitro diagnostic for HLA-DQ2 celiac disease.

“The Nexvax2 immunotherapy is designed to desensitize celiac disease patients to the toxic effects of gluten. In our Phase 1 study, Nexvax2 was safe and well tolerated, and importantly we saw a Nexvax2-specific T-cell response that confirms the desired bioactivity in HLA-DQ2 genotype patients,” said Dr. Anderson. “As we continue the clinical development of Nexvax2, which we expect to advance to a Phase 2a trial within the next ten months, we hope to demonstrate a dramatic reduction of the body’s rejection of dietary gluten so patients can resume a normal diet and return to good health,” Dr. Anderson continued. In addition to his role at ImmusanT, Dr. Anderson is a gastroenterologist and highly respected expert in immunology

and clinical management of celiac disease at the Department of Gastroenterology at Melbourne Health and Professor at The Walter and Eliza Hall Institute of Medical Research.

View Dr. Anderson's summary of DDW Poster #SU1235, presented Sunday, May 8th, on the DDWMeeting YouTube Channel.

Dr. Anderson and collaborating researchers also presented at DDW results from the first population study that supports the use of a combination of HLA-DQ genetic and serology tests to determine the prevalence of celiac disease. Whereas a single screening serology test followed by biopsy (per medical guidelines) can be expensive by creating many unnecessary gastroscopies, the problem is overcome by including additional serology and HLA-DQ genotyping tests. The study also concluded that the cost per diagnosis can be reduced by up to 50% by introducing HLA-DQ genotyping to reduce gastroscopies, which also makes this a cost-effective and efficient diagnostic method appropriate for the primary care setting.

ImmusanT is collaborating with INOVA Diagnostics to develop improved serologic tests for celiac disease. In addition, ImmusanT is developing its own functional T-cell diagnostic, designed to be used both as a standalone test as well as a monitoring test for the therapeutic.

About Celiac Disease
Celiac disease is an inherited autoimmune disorder that affects the digestive process of the small intestine. When a person with celiac disease consumes gluten, a protein found in wheat, rye and barley, 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. With no available drug therapy, the only option for the approximately 1% of the global population that has celiac disease is to eliminate gluten from the diet. Compliance is often challenging and nearly half the people on the strict elimination diet still have residual damage to their small intestine.

Undiagnosed, celiac disease is a major contributor to poor educational performance and failure to thrive in children. Untreated disease in adults is associated with increased risk of fractures and osteoporosis, problems during pregnancy and birth, short stature, dental enamel hypoplasia, dermatitis, recurrent stomatitis and cancer.

About ImmusanT, Inc.
ImmusanT is a privately-held biotechnology company focused on restoring tolerance to gluten in celiac disease by harnessing new discoveries in immunology that improve diagnosis and treatment and return patients to a normal diet, good health and improved quality of life. The company's Nexvax2® therapeutic vaccine for celiac disease is preparing to advance to Phase 2a clinical trials. ImmusanT is simultaneously developing a companion diagnostic and monitoring tool to improve celiac disease management. Its targeted immunotherapy discovery platform may have additional applications for a variety of epitope-specific autoimmune diseases. More information can be found at www.ImmusanT.com.

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