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ImmusanT Announces Completion of Phase 1b Clinical Trial of Nexvax2® for the Treatment of Celiac Disease

-- Phase 2 dose regimen identified --

CAMBRIDGE, Mass. – Feb. 22, 2017 – ImmusanT, Inc., a clinical-stage company developing Nexvax2®, a therapeutic vaccine intended to protect against the effects of gluten exposure in *HLA-DQ2.5*+ patients with celiac disease, today announced the completion of a Phase 1b clinical trial evaluating the safety and tolerability of Nexvax2 in celiac disease. The trial met its objectives and identified a Phase 2 dose regimen.

Celiac disease 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. Approximately 90% of celiac disease patients carry the *HLA-DQ2.5* gene. Currently, there is no pharmaceutical treatment for celiac disease and the only method of management is to maintain a gluten-free diet (GFD). Effective implementation of a GFD is onerous and often impractical. Persistent intestinal injury and frequent digestive symptoms in many patients are evidence of ongoing gluten exposure. ImmusanT is developing Nexvax2, an epitope-specific immuno-therapy (ESIT) that consists of three immunodominant peptides, designed to protect against gluten exposure.

The study was a randomized, double-blind, placebo-controlled, dose titration trial to evaluate the safety and tolerability of gradual dose escalation before increased maintenance doses of Nexvax2 in patients with celiac disease. The study enrolled 38 patients with celiac disease who were stratified by *HLA-DQ2.5* genotype and randomly assigned to one of three cohorts. All cohorts were then randomized to escalating doses of intradermally-administered Nexvax2 or placebo followed by maintenance doses higher than those previously tested for a period of 46 or 60 days. Results of this clinical trial support a dosing regimen for a planned Phase 2 clinical trial of Nexvax2 in patients with celiac disease.

Earlier clinical trial results, presented at Digestive Disease Week in May 2016, demonstrated that the first fixed dose administration of Nexvax2 resulted in transient immune activation and symptoms similar to those associated with gluten ingestion in patients with celiac disease. Later doses in a fixed dose regimen were well tolerated and resulted in immune unresponsiveness to the gluten epitopes in Nexvax2.

Nexvax2 is the most advanced of a novel class of epitope-specific immunotherapy (ESIT) drugs and, to date, it has been tested in over 150 patients in four clinical studies. ESIT utilizes short soluble peptides encompassing dominant epitopes recognized by CD4+ T cells implicated in autoimmune pathologies. The results of this Phase 1b clinical trial of Nexvax2 provide important insights into the optimization of dosing and immune monitoring for this new class of drug.

“We are very pleased with the completion of our Phase 1b clinical trial testing Nexvax2 in patients with *HLA-DQ2.5*+ celiac disease,” said Leslie Williams, President and Chief Executive Officer of ImmusanT. “This study has informed the design of our planned Phase 2 clinical trial for Nexvax2 in patients with celiac disease. Nexvax2 has the potential to protect against the effects of gluten exposure in patients with celiac disease and improve their quality of life.”

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. 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.

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.

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 aim to improve diagnosis and treatment and return patients to a normal diet, good health and improved quality of life. The company is developing Nexvax2®, a therapeutic vaccine for celiac disease, and a companion diagnostic and monitoring tool to improve celiac disease management. ImmusanT's targeted immunotherapy discovery platform can be applied to a variety of epitope-specific 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.

ImmusanT Contact:
Leslie Williams
President and CEO
(617) 299-8399 Ext. 201
Leslie@ImmusanT.com

Media Contact:
Casey R. Doucette, Ph.D.
MacDougall Biomedical Communications
(781) 235-3060
cdoucette@macbiocom.com

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