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ImmusanT Reports Nexvax2 Phase 1 Data in Patients with Celiac Disease

- Data Presented at Digestive Disease Week 2016 -

CAMBRIDGE, Mass. – May 24, 2016 – 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 results of two Phase 1 studies of Nexvax2[®] in patients with celiac disease. The studies were presented in an oral presentation and two poster presentations at Digestive Disease Week (DDW) 2016 in San Diego, California.

Celiac disease is an immune-mediated gastrointestinal disease caused by dietary gluten predominantly in individuals who carry the *HLA-DQ2.5* immune recognition gene, and shares key pathogenic and genetic features with organ-specific autoimmune (AI) diseases. ImmusanT is developing Nexvax2[®], an epitope-specific immuno-therapy (ESIT) that consists of an injectable formulation of 3 peptides with epitopes recognized by gluten-reactive CD4+ T cells to target and render these cells unresponsive to gluten.

One poster, titled “A Single Intradermal (ID) Injection of Nexvax2[®], a Peptide Composition with Dominant Epitopes for Gluten-Reactive CD4+ T Cells, Activates T Cells and Triggers Acute Gastrointestinal Symptoms in HLA-DQ2.5+ People with Celiac Disease (CeD),” included data from two Phase 1b clinical trials investigating the safety, tolerability, pharmacokinetics, and mechanism of action of Nexvax2 in 82 HLA-DQ2.5+ subjects with celiac disease on a gluten-free diet. In these studies, subjects received intradermal administration of Nexvax2 or placebo, and cytokine and chemokine serum levels were evaluated six hours post-dose. The results demonstrated that Nexvax2 peptides were detectable in plasma shortly after administration until up to four hours post-dose and confirmed T-cell engagement within 2 hours of administration. This suggests that gluten-specific memory CD4+ T cells were activated by Nexvax2 and could be related to the clinical effects observed following gluten ingestion in patients with celiac disease.

A second poster, titled “Nexvax2[®], a Peptide-Based Antigen-Specific Immunotherapy, Administered Intradermally Three-Times Over 15-Days attenuates Responsiveness to Immuno-Dominant Gluten Peptides in HLA-DQ2.5+ People with Celiac Disease (CeD),” reported the results of a Phase 1 clinical trial evaluating a dosing strategy for Nexvax2 in 77 HLA-DQ2.5+ subjects with celiac disease. The double-blind, crossover, placebo-controlled study evaluated the safety, tolerability, pharmacokinetics and biologic effects of Nexvax2, administered intra-dermally once per week for a three-week period. Data demonstrated that, when compared to placebo, three weekly doses of Nexvax2 modulated pro-inflammatory cytokine release following a 3-day gluten challenge. However, the three doses of Nexvax2 were insufficient to induce systemic unresponsiveness to the gluten challenge. These observations suggest that Nexvax2 may be more effective with longer or more intensive dosing schedules, and this hypothesis is being tested in ongoing studies.

In an oral presentation titled “Efficacy, Safety, Tolerability, and Immunological Effects of Nexvax2[®], a Peptide-Based Therapeutic Vaccine, Administered by Intra-Dermal (ID) Injection Twice-Weekly for 8-Weeks in HLA-DQ2.5+ Celiac Disease (CeD),” Dr. Bob Anderson, Chief Scientific Officer of ImmusanT, presented data from a double-blind, crossover, placebo-controlled study in which 59 subjects were randomized to receive 16 doses of either Nexvax2 or placebo, administered twice weekly for 8 weeks, and were subsequently evaluated for T-cell response to a 3-day gluten challenge. T-cell activation after the first dose of Nexvax2 was observed, as evidenced by elevated plasma cytokine levels demonstrating a distinct signature. Following a final dose on day 53, both the Nexvax2 and placebo-treated patients

showed plasma cytokines and GI symptoms that were similar, suggesting the induction of antigenic non-responsiveness to Nexvax2 administration. A post-treatment gluten challenge showed that a majority of patients treated with Nexvax2 failed to reproduce the elevated T-cell responses observed after the 1st dose. In addition, patients who had received Nexvax2 had a higher completion rate of the gluten challenge compared to placebo-treated patients. Dr. Anderson commented, “the results of this study demonstrate for the first time that an antigen-specific immunotherapy using peptides can induce antigen-specific unresponsiveness to dominant epitopes for gluten-reactive CD4+ T cells.”

“We are encouraged by the Phase 1 study results presented at DDW, which demonstrate that Nexvax2 appears to be well tolerated. In addition, these data begin to elucidate the proposed mechanism of action for Nexvax2 in HLA-DQ2.5+ patients with celiac disease,” said Leslie Williams, President and Chief Executive Officer of ImmusanT. “Each study supports the therapeutic potential of our lead program and builds the rationale for the continued development of Nexvax2 as a treatment for celiac disease, for which there are currently no approved medicines available. We look forward to the initiation of a Phase 2 study of Nexvax2 using a personalized approach to development in patients with celiac disease.”

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% percent in the U.S., but over 80 percent 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 the people continue to have residual damage to their small intestine in spite of adherence to 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.

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