



## ImmusanT Presents Clinical Data Supporting Improved Dosing Strategy for Nexvax2® and Explaining Early Gluten-Related Clinical Effects in Celiac Disease

*- Gradual dose escalation allows high maintenance doses -*

*- Ingestion of gluten correlated with rapid T cell activation, suggesting symptoms are triggered by T cells -*

**CAMBRIDGE, Mass. – October 31, 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 the presentation of data from two studies. The first demonstrated the safety and tolerability and immunological and intestinal effects of Nexvax2® following initial step-wise escalating doses and maintenance doses higher than the previously determined maximum tolerated dose (MTD) for fixed dose schedules. The second study elucidates the mechanism explaining the early onset of symptoms experienced by celiac disease (CeD) patients after gluten intake. Both presentations were delivered Monday, October 30 at United European Gastroenterology (UEG) Week.

“Results presented today suggest that gradual up dosing to a higher maintenance dose is well tolerated and will be an effective regimen for our Phase 2 trials. This regimen overcomes the first dose effect that was seen in earlier studies without escalation. The first dose effect seen in earlier studies included dose-dependent gastrointestinal symptoms and immune activation, reflected by increased plasma cytokines with onset from two to four hours after the first dose,” said Dr. Bob Anderson, Chief Scientific Officer of ImmusanT. “These new results suggest that higher maintenance doses are well-tolerated when preceded by gradual dose escalation, potentially leading to improved patient outcomes.”

In the first presentation, entitled “**Safety and tolerability, immunological and intestinal effects, and pharmacokinetics (PK) of dose titration preceding maintenance doses of Nexvax2® in HLA-DQ2.5+ celiac disease (CeD)**,” Nexvax2 was studied for safety and tolerability, immunological and intestinal effects, and pharmacokinetics (PK) of dose titration preceding maintenance doses. Nexvax2 was administered at a 150-microgram dose, preceded by four escalating doses starting at three micrograms, and subsequent dose levels up to 900 µg. Results demonstrated that the adverse event profile and changes in plasma cytokines were similar to placebo, and Nexvax2 was shown to have systemic, dose-dependent bioavailability. In addition, intestinal histology was not adversely affected, and showed trends towards improvement after the high maintenance dose schedule. These data show that a gradual dose escalation of Nexvax2 allows higher maintenance doses—an important finding for future clinical trials.

The second study was entitled “**Gluten ingestion and intradermal injection of peptides that activate gluten-specific CD4+ T cells elicit a cytokine signature dominated by interleukin-2 in celiac disease**”. This study explains that immune activation triggered by T cells causes the early onset of symptoms experienced by patients with celiac disease after they consume gluten. These new mechanistic insights give added support to targeting gluten-specific T cells with therapeutics such as ImmusanT’s Nexvax2 to protect against symptoms accompanying gluten exposure.

“These data not only show a good pharmacokinetic and safety profile for repeated dosing of Nexvax2, but also answer the longstanding question of why there is such a fast clinical response to gluten ingestion in CeD patients,” said Leslie Williams, President and Chief Executive Officer of ImmusanT. “Such results

support the therapeutic potential of Nexvax2 and encourage us to continue developing Nexvax2 as a potential treatment for celiac disease, for which there are no approved medicines available today.”

### **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](http://www.immusant.com), or follow [ImmusanT](#) on Twitter.

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