



## **ImmusanT Initiates Phase 2 Enrollment for its Lead Therapeutic Vaccine Candidate in Patients With Celiac Disease in Australia and New Zealand**

***Nexvax2® Currently the Only Disease-Modifying Therapeutic in Clinical Development for Patients with Celiac Disease***

**CAMBRIDGE, Mass. – October 30, 2018** – [ImmusanT, Inc.](#), a clinical stage company leveraging its Epitope-Specific Immuno-Therapy™ (ESIT™) platform to deliver first-in-class peptide-based immunomodulatory vaccine therapies to patients with autoimmune diseases, initiated enrollment in Australia and New Zealand for its Phase 2 RESET CeD study assessing the safety, tolerability and efficacy of its lead therapeutic candidate, Nexvax2®, in patients with celiac disease who carry the immune recognition genes for HLA-DQ2.5. The latter accounts for approximately 90% of the celiac patient population, and Nexvax2 is designed to protect these patients from the effects of gluten exposure.

The randomized, double-blind, placebo-controlled Phase 2 study of Nexvax2 is currently the only disease-modifying therapeutic candidate in clinical development for patients with celiac disease. Administered subcutaneously, Nexvax2 is intended to reprogram T cells that trigger an inflammatory response to gluten, thereby suppressing inflammation in patients with celiac disease.

“Initial early development of Nexvax2 took place in Australia and New Zealand, and we are thrilled to be expanding our recently launched Phase 2 trial to patients from regions that have been with us from the beginning,” said Leslie Williams, chief executive officer of ImmusanT. “Inadvertent gluten exposures can cause significant and long-term negative impacts on patient health. At ImmusanT, we are deeply committed to advancing Nexvax2 to protect celiac patients from the effects of inevitable gluten exposure.”

In prior Phase 1 studies, Nexvax2 was shown to be safe and well-tolerated when administered at its highest dose levels. By advancing into Phase 2 clinical trials, ImmusanT aims to confirm clinical efficacy of Nexvax2, and broaden the company’s understanding of the potential impact of peptide-based immunotherapies, further enhancing its proprietary ESIT platform.

The Australian trial will be conducted at sites in Melbourne, Perth, Adelaide and Brisbane, in addition to sites in New Zealand and the U.S.

“This trial is important in establishing clinical proof-of-concept for a treatment that would provide benefit beyond that of the gluten-free diet,” said Jason Tye-Din, MBBS, Ph.D., principal investigator at the Royal Melbourne Hospital and head of celiac research at the Walter and Eliza Hall Institute of Medical Research in Melbourne, Australia. “The gluten-free diet is the only

current treatment for celiac disease, but it is onerous, complex and not always effective. Even the most diligent patients can suffer the adverse effects of accidental exposure. This study will test if Nexvax2 can specifically target the immune response to gluten in people with celiac disease and modify associated symptoms.”

Michael Bell, president of Coeliac Australia, stated, “Our members and many thousands of Australians with celiac disease have been looking forward to the announcement of the Phase 2 trial. Many have been following the development of Nexvax2 for more than a decade and are hopeful the results will take us one step closer to an effective treatment for celiac disease.”

RESET CeD intends to enroll approximately 150 patients across the U.S., Australia and New Zealand. For more information about RESET CeD, including inclusion and exclusion criteria, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT03644069). In Australia, trials will start in Melbourne and then roll out in Perth, Adelaide, Brisbane, Mackay and the Sunshine Coast.

Along with Nexvax2, ImmusanT is developing vaccines for other HLA-associated autoimmune diseases, including type 1 diabetes.

### **About the RESET CeD Trial**

RESET CeD is a Phase 2, randomized, double-blind, placebo-controlled clinical study of Nexvax2®, in adult subjects with confirmed celiac disease who have been following a gluten free diet for at least 12 consecutive months prior to screening. This study will evaluate the efficacy of Nexvax2 administered subcutaneously. The study plan consists of 3 periods: a screening period of 6 weeks, an approximately 16 week treatment period, and a 4 week post-treatment observational follow-up. Further information on the trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT03644069).

### **About Celiac Disease**

Celiac disease is a T-cell-mediated, chronic inflammatory disease of the intestine caused by an auto-immune-like reaction to dietary gluten proteins in genetically susceptible individuals. When a person with celiac disease consumes gluten proteins in wheat, rye and barley, the individual’s immune system responds inappropriately by triggering T-cells specific for select epitopes (peptides) to fight the offending proteins (antigens), causing immune activation and acute digestive symptoms. Ultimately, this reaction to ongoing gluten exposure causes chronic inflammation of the small intestine and compromises its ability to absorb nutrients into the body.

Celiac disease is becoming increasingly prevalent, and it is estimated that the disease currently affects 2 to 3 million Americans and an estimated 1% of the global population. With rapidly increasing numbers of patients being diagnosed with the disease, there is a growing need for improved treatments. The only intervention currently available is a strict, lifelong gluten-free diet (GFD). While GFD reduces intestinal inflammation, even minute amounts of gluten can still

trigger an immune reaction with symptoms that can be more pronounced than before GFD was adopted. GFD also imposes a significant burden, negatively affects quality of life and can be difficult to follow since even minute amounts can trigger an immune reaction.

### **About Nexvax2®**

Nexvax2® is the most advanced therapeutic approach for celiac disease in clinical development today that targets the fundamental cause of the disease. Nexvax2 is an epitope-specific immuno-therapy, a class of therapeutic vaccine, that reprograms the T cells responsible for celiac disease to stop triggering a pro-inflammatory response. Nexvax2 is composed of peptides that include the epitopes most commonly recognized by T cells responsible for celiac disease. Nexvax2 intends to protect patients with celiac disease against inadvertent exposure to gluten.

### **About ImmusanT, Inc.**

At ImmusanT, we are developing a new class of therapeutic vaccines to change the lives of people living with autoimmune diseases. Our Epitope-Specific Immuno-Therapy™ (ESIT™) platform provides a precision medicine approach to restoring immune tolerance across a range of diseases, including celiac disease and type 1 diabetes. Our lead program, Nexvax2®, is in clinical development with the goal of protecting celiac disease patients against the debilitating effects of gluten. [www.ImmusanT.com](http://www.ImmusanT.com)

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