ImmusanT Announces First Patient Dosed in Phase 2 Trial of Therapeutic Vaccine for Celiac Disease

CAMBRIDGE, Mass. – September 27, 2018 – ImmusanT, Inc., a clinical stage company that is leveraging its Epitope-Specific Immuno-Therapy™ (ESIT™) platform to translate and deliver first-in-class peptide-based immune therapies to patients living with autoimmune diseases, today announced that the first patient has been dosed in its Phase 2 RESET CeD trial for the treatment of celiac disease. The trial will evaluate the safety and efficacy of Nexvax2®, the company's lead investigational therapeutic vaccine in celiac disease patients who carry the immune recognition genes for HLA-DQ2.5, a subset that accounts for approximately 90% of those living with the disease.

"The initiation of our Nexvax2 Phase 2 trial is significant for patients who suffer from celiac disease, a condition affecting approximately 1% of the global population," said Leslie Williams, Chief Executive Officer of ImmusanT. "This trial is designed to demonstrate protection against inadvertent exposure to gluten, but the ultimate goal is to develop Nexvax2 as a treatment that will allow patients to return to an unrestricted diet. We look forward to taking the next step to collect the clinical evidence to move Nexvax2 towards approval."

This Phase 2 study will build upon previous Phase 1 results that have shown Nexvax2 to be safe and tolerable at its highest dose levels following stepwise up-dosing. By further testing Nexvax2 at therapeutically-relevant dose levels, the company believes the findings will be significant in advancing the understanding of the potential impact of peptide-based immunotherapies.

"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 Ken Truitt, M.D., Chief Medical Officer of ImmusanT. "Avoiding gluten is burdensome and not entirely effective; even the most diligent patients incur inadvertent exposure. Through this study we anticipate making new insights that will further our ability to demonstrate specific suppression of the immune response to gluten epitopes and associated effects of celiac disease."

RESET CeD intends to enroll approximately 150 patients across the United States, Australia and New Zealand. For more information about RESET CeD, including inclusion and exclusion criteria, please visit www.clinicaltrials.gov (Identifier: NCT03644069).

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 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 (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

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