ImmusanT Secures Fast-Track Designation for Lead Therapeutic Vaccine Candidate Nexvax2 for Patients with Celiac Disease (CeD)

Nexvax2 Has Been Designed to Potentially Restore Immune Tolerance to Gluten in Patients with CeD

CAMBRIDGE, Mass. – January 2, 2019 – 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, announced today the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the company's lead therapeutic candidate, Nexvax2, being developed to protect celiac disease (CeD) patients who carry the HLA-DQ2.5 immune recognition genes, from inadvertent gluten exposure. Patients with the HLA-DQ2.5 genes account for more than 90% of the CeD population. A global Phase 2 study assessing Nexvax2 is currently recruiting patients.

The FDA grants fast track status to certain investigational drugs to expedite the development and/or review process for therapeutic candidates with the potential to fulfill unmet needs of patients with serious or life-threatening conditions.

"We view the fast track designation for our lead candidate, Nexvax2, as a testament to the significant need for bringing therapeutic solutions to patients with celiac disease as quickly as possible," said Leslie Williams, chief executive officer for ImmusanT. "Currently, there are no disease-modifying therapies for this condition, and the only solution for patients is strict adherence to a lifelong, gluten-free diet. Our hope is that by helping restore immune tolerance towards gluten, Nexvax2 will improve quality of life and prevent the serious complications of chronic gluten exposure in celiac disease patients. The development of Nexvax2 aligns with our strategic vision of transforming how patients with autoimmune diseases are treated."

Nexvax2 consists of a proprietary combination of three, short peptides that represent the gluten-derived immune-activating epitopes in HLA-DQ2.5+ patients. Administered as a subcutaneous injection, Nexvax2 has completed multiple Phase 1b clinical trials, which yielded data supporting safety and tolerability as well as proof-of-mechanism and effectiveness.

"Celiac disease is a life-changing condition that causes significant health problems due to cumulative damage from chronic and repetitive bouts of gluten-triggered inflammation. In earlier Phase 1 studies assessing Nexvax2, a relationship between dosing schedule, pharmacokinetics and systemic biomarkers as a pharmacodynamic readout in ESIT was demonstrated for the first time," said Ken Truitt, M.D., chief medical officer for ImmusanT. "Using a novel panel of celiac disease-associated immunological markers, identified in early clinical studies, we can follow both acute symptoms and the underlying inflammatory response following gluten exposure. This helps monitor Nexvax2's effectiveness in altering the disease process. We have high hopes that immunomodulation with Nexvax2 can help the majority of

celiac patients live without fear of inadvertent gluten exposure and associated health problems."

ImmusanT's Phase 2 RESET trial is a randomized, double-blind, placebo-controlled study in HLA-DQ2.5+ adults with CeD to assess the effect of Nexvax2 on symptoms after masked gluten food challenge. The trial intends to enroll approximately 150 patients across the U.S., Australia and New Zealand.

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 (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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