ImmusanT Initiates Clinical Trials of Nexvax2 Therapeutic Vaccine for Celiac Disease

CAMBRIDGE, Mass., September 4, 2012 – ImmusanT announced today that it has initiated clinical trials in New Zealand, Australia and the U.S. to evaluate Nexvax2®, the first therapeutic vaccine for patients with celiac disease. Nexvax2 is designed to re-establish patients' tolerance to the toxic effects of gluten, a protein in wheat, barley and rye, and allow them to return to a normal diet. There are currently no approved medicines available for people with celiac disease, who must manage their condition by eliminating gluten-containing foods from their diet.

Advancing the earlier Nexvax2 clinical trial, the new program underway in Australia and New Zealand is a randomized, double-blind, placebo-controlled Phase 1b study evaluating multiple ascending doses of Nexvax2 for the induction of gluten tolerance in patients on a gluten-free diet. ImmusanT expects to enroll 84 subjects at approximately four study sites in the two countries in order to evaluate safety, tolerability and pharmacokinetics, and to select doses for investigation in subsequent studies.

The second study, a randomized, double-blind, placebo-controlled Phase 1 trial being conducted in the U.S. is to determine the safety, tolerability and pharmacokinetic profile of Nexvax2 in patients with celiac disease well controlled by a gluten-free diet. ImmusanT plans to enroll 30 adult subjects at approximately four trial sites.

"We are kicking-off a robust clinical program that we hope demonstrates Nexvax2 dramatically reduces the body's immune response to dietary gluten so patients can resume a normal diet and return to good health," said Patrick H. Griffin, M.D., Chief Medical Officer of ImmusanT. "Our clinical development program will allow us to further examine the role of antigen-specific T cells in celiac disease activation and in the re-establishment of tolerance to gluten."

"There has been tremendous enthusiasm about Nexvax2 from patients and the medical community and this will provide terrific momentum for advancing our clinical program," said Leslie J. Williams, President and CEO of ImmusanT.

BD (Becton, Dickinson and Company) is supplying novel intradermal injection solutions to ImmusanT to administer Nexvax2 in its clinical program. These solutions are based on BD's commercialized intradermal injection technology, BD Soluvia™ Microinjection System. BD has a longstanding history of developing and commercializing novel prefillable vaccine delivery systems. As compared with the traditional intradermal injection method, BD's intradermal injection technologies allow for a clinician to use an injection technique that is perpendicular to the skin. This helps simplify the administration process while improving the success of intradermal injections.

In ImmusanT's international trials, patients will have a confirmed diagnosis of celiac disease and carry the immune recognition gene HLA-DQ2. Up to 90 percent of individuals with celiac

disease have this gene. Furthermore, prospective patients will be screened using the company's companion diagnostic technology to identify suitable candidates for the therapeutic vaccine. ImmusanT will use this novel blood test to measure gluten-reactive T cells in celiac disease as a potential marker for immune modulation with Nexvax2.

About Nexvax2®

Nexvax2 is a therapeutic vaccine that combines three proprietary peptides that elicit an immune response in patients with celiac disease who carry the immune recognition gene HLA-DQ2. In an approach similar to treatments for allergies to cats and dust mites, Nexvax2 is designed to reprogram gluten-specific T cells triggered by the patient's immune response to the protein. The goal is for Nexvax2 to restore celiac patients' immune tolerance to gluten, reduce inflammation in the nutrient-absorbing villi that line the small intestine, return the intestine to a healthy state, and allow patients to eat a normal diet.

About Celiac Disease

Celiac disease is an inherited autoimmune disorder that affects the digestive process of the small intestine. When a person with celiac disease consumes gluten, a protein found in wheat, rye and barley, 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 for the approximately 1 percent of the global population that has celiac disease is to eliminate gluten from the diet. Compliance is often challenging and nearly half the people on the strict elimination diet still have residual damage to their small intestine.

Undiagnosed, celiac disease is a major contributor to poor educational performance and failure to thrive in children. Untreated disease in adults is associated with increased risk of fractures and osteoporosis, 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 can be found at www.ImmusanT.com.

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