Celiac Disease

Celiac disease is defined by gluten-dependent, chronic inflammation and damage to the small intestine associated with circulating autoantibodies in genetically susceptible individuals. The underlying cause is a T-cell mediated immune reaction that usually develops in infancy or early childhood to a group of related proteins from wheat, barley and rye, collectively called gluten.

The body’s response to gluten in celiac disease is a potent, but self-defeating attempt by the immune system to eradicate innocuous dietary gluten, as if it is a dangerous bacteria or virus. Celiac disease is self-perpetuating as long as gluten continues to be consumed, and can cause digestive symptoms, nutritional deficiencies that sometimes result in anemia and osteoporosis, as well as a diverse range of complications in other parts of the body that can be severe and sometimes life-threatening.

Genetic testing indicates the vast majority of individuals diagnosed with celiac disease carry the two genes that code for the immune recognition protein named HLA-DQ2.5, the remaining 10% of patients have genes for the closely related HLA-DQ2.2 or HLA-DQ8. These immune recognition proteins selectively bind and present peptide fragments from partially digested gluten to T cells, facilitating the immune reaction causing celiac disease.

Currently, diagnosis of celiac disease involves a blood test for the detection of specific antibodies, followed by a gastroscopy and collection of biopsies from the small intestine that are examined for inflammatory damage typical of untreated celiac disease. Unfortunately, these methods are invasive and inconvenient, but also unreliable when gluten has been removed from the diet for an extended period of time, as antibody levels and intestinal damage tend to normalize without exposure to gluten.

With rapidly increasing numbers of patients diagnosed with celiac disease, there is a growing need for improved, less intrusive treatments and diagnostics. The only therapeutic approach available today is a strict, lifelong gluten-free diet, which is burdensome and often does not fully resolve symptoms or intestinal pathology.
ImmusanT’s proprietary discovery platform has mapped the parts of nutritional gluten proteins that cause undesired immune activation in patients with celiac disease according to their genetic background.

Nexvax2® is a combination of three proprietary peptides that elicit an immune response in patients with celiac disease (CeD) who carry the immune recognition gene, HLA-DQ2.5, which accounts for the condition in 80% to 90% of patients. Nexvax2® is delivered intradermally as a therapeutic vaccine and reprograms the T-cells that respond to gluten antigens in CeD patients so that they stop responding defensively by triggering a pro-inflammatory response. As a result, by preventing T-cells from continuing to cause inflammation in the small intestine, the injured tissue heals and patients would be able to resume an unrestricted diet and enjoy improved health. Booster shots of Nexvax2® would offer periodic reinforcements of the treatment to establish a prolonged tolerance to gluten.

ImmusanT has recently completed two Phase 1b safety, tolerability, and pharmacodynamics clinical trials, which provided unprecedented data supporting proof-of-mechanism and effectiveness. Specifically, Nexvax2® was found to engage antigen-specific target cells, and a distinct immunological signature was discovered. After repeated dosing, patients who received Nexvax2® were able to complete gluten challenge in contrast to placebo.

Nexvax2® is the only disease-modifying therapeutic approach for celiac disease in clinical development today that has the potential to enable patients to return to a normal diet, good health, and improved quality of life.

About ImmusanT

ImmusanT is a clinical development-stage biotechnology company focused on an innovative disease-modifying approach to induce immune tolerance in autoimmune diseases. Using our proprietary discovery platform for targeted (epiotope-specific) immunotherapy, ImmusanT has developed a therapy and personalized diagnostics for celiac disease and is expanding to other autoimmune diseases including Type 1 diabetes.