



Developing an immunotherapy to replace gluten-free diet for celiac disease sufferers

Overview: Celiac Disease

For most people, eating foods with wheat, rye or barley is natural and normal and critical to their diet. Gluten is a protein and a common component of all of those grains. During digestion, gluten is broken down and absorbed by cells that line the small intestine, providing nutrients to the body.

For people who have celiac disease, something goes wrong with the cells of the immune system. Rather than viewing gluten as a nutrient, the cells see it as an invader – a threat to the body that must be fought off, like a disease-causing virus or bacteria.

T cells – the body’s disease-fighting soldiers – are stimulated to combat the gluten. They recruit other immune cells and secrete special chemicals that modify and destroy the gluten. In the process, they damage the lining of the small intestine, reducing the body’s ability to absorb nutrients and causing symptoms such as digestive pain, constipation, diarrhea and fatigue.

The only way to treat celiac disease is to eliminate all gluten from the diet for life. This can be very difficult, because gluten is hidden in many foods.

Nexvax2 Offers Hope to Patients with Celiac Disease

ImmusanT is a biotech company developing a new, experimental celiac disease therapy. Most people with celiac disease have a gene called HLA-DQ2, which makes them a good candidate for Nexvax2®.

Nexvax2 is the only disease-modifying treatment in development today. It is delivered intradermally as a therapeutic vaccine and reprograms the T cells so they stop responding defensively when gluten is present. Without T cells continuing to cause injury to the small intestine, it returns to a healthy state and patients can resume a healthy diet. Booster shots of Nexvax2 would offer periodic reinforcements of the treatment. Nexvax2 is the only therapeutic currently in development that would enable patients to return to a normal diet.

“A treatment that would allow the small intestine to recover and let patients return to a normal diet would be life-changing.”

– Dr. Robert Anderson,
Chief Scientific Officer, ImmusanT

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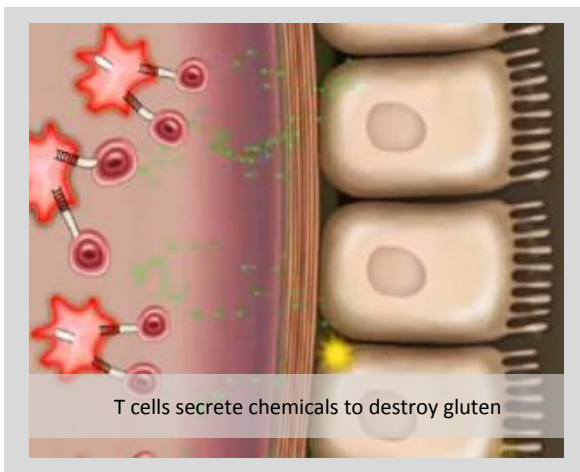
Nexvax2 in Clinical Trials

Nexvax2 is composed of three synthetic peptides that are responsible for the immune response in 80-90% of celiac disease cases. These gluten-derived peptides are recognized by T cells and they stimulate an immune response. The discovery of these peptides marked a turning point in the development of a therapeutic vaccine designed to induce tolerance to gluten.

In a first-in-man, Phase I clinical trial conducted in Australia, the safety and tolerability of Nexvax2 were similar to placebo. The positive results warranted further clinical development.

A Phase Ib clinical trial is currently underway in Australia and New Zealand to determine the safety, tolerability and pharmacokinetic profile of Nexvax2 in patients with the HLA-DQ2 gene whose celiac disease is well controlled by a gluten-free diet.

A second Phase Ib trial is now enrolling in the United States to determine the safety, tolerability and pharmacokinetic profile of Nexvax2 in HLA-DQ2 patients with celiac disease well controlled by a gluten-free diet. For more information on the clinical trials, visit <http://www.immusant.com/clinical-trial/>.




About ImmusanT

ImmusanT is a Cambridge, Massachusetts-based 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. More information can be found at www.ImmusanT.com.

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