

## News Release

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# The National Institutes of Health (NIH) Award Another Major Grant to ImmunogenX to Conduct a Clinical Trial for Latiglutenase

## The study addresses patients with genetically-linked type 1 diabetes and celiac disease

The NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has awarded a grant to ImmunogenX to conduct a Phase 2 clinical trial using latiglutenase, an investigational drug for celiac disease (CD). The study will be conducted at the Stanford University School of Medicine in the Department of Pediatrics, which has strong type 1 diabetes (T1D) and celiac disease (CD) programs. T1D and CD are genetically-linked autoimmune diseases accounting for a high prevalence of CD in T1D patients. The burden on individuals diagnosed with both diseases is enormous given the divergent dietary restrictions of maintaining tight blood sugar control while on a gluten-free diet (GFD).

This NIH grant was awarded under the Small Business Innovation Research (SBIR) program. This "Fast-track" project incorporates both Phase I and Phase II work and was approved at the highest allowable funding level; the result of addressing a critical topic area. The Co-Principle Investigators on the project are David M. Maahs MD, PhD of Stanford and Jack A. Syage PhD of ImmunogenX. The main focus will be symptom relief in T1D+CD patients who continue to exhibit high gluten-induced antibody levels (seropositive) despite strict adherence to a GFD. The primary outcome measure will be the FDA-reviewed and trial-tested Celiac Disease Symptom Diary<sup>®</sup> (CDS<sup>D</sup>) patient-reported outcome (PRO) instrument for CD symptoms.

"This NIDDK grant addresses the burden of combined T1D and CD diagnoses and the demonstrated potential for latiglutenase to provide much needed relief for these patients who face insurmountable dietary challenges in managing their diseases. We are gratified by the trust NIH places on ImmunogenX's clinical program for latiglutenase as evidenced by the awarding of multiple grants." states Jack Syage PhD, CEO of ImmunogenX.

Dr. David M. Maahs, MD of Stanford University adds, "Latiglutenase has demonstrated great promise as a therapy to reduce the burden of celiac disease, which afflicts 5-10% of people with type 1 diabetes, and the challenge of a gluten free diet. We are gratified to be working with ImmunogenX to further develop this promising therapeutic candidate that is critically needed for these patients who struggle with this dual diagnosis."

### About ImmunogenX

ImmunogenX<sup>®</sup> (a subsidiary of Immunogenics LLC) is a clinical-stage biotherapeutics company founded in 2013 and is supported by a team of world-renowned clinicians, scientists and advisors in celiac disease research. The company is developing Latiglutenase for celiac disease therapy. ImmunogenX is also developing a minimally-invasive diagnostic tool for celiac disease management (CypCel<sup>™</sup>) based on a clinically relevant metabolic marker compound that can assess the state of recovery of a celiac patient adhering to a gluten-free diet or other treatment. For food safety, ImmunogenX is pioneering advanced mass spectrometry methods to identify and measure physiologically relevant gluten peptide sequences found in wheat, barley, and rye.

[www.immunogenx.com](http://www.immunogenx.com)

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