

News Release

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ImmunogenX Receives Major Grant from the National Institutes of Health (NIH) to Conduct a Clinical Trial for Latiglutenase

The study will further advance an unmet therapeutic need for celiac disease

The NIH's National Institute of Allergy and Infectious Diseases (NIAID) has awarded a grant to ImmunogenX to conduct a Phase 2 trial for latiglutenase, an investigational drug for celiac disease (CD). The study will be conducted at multiple study centers including the Mayo Clinic (Rochester, MN) and Columbia University (New York, NY). The main focus will be symptom relief in CD patients who continue to exhibit high gluten-induced antibody levels (seropositive) despite strict adherence to a gluten-free diet (GFD). The primary outcome measure will be the FDA-reviewed and trial-tested Celiac Disease Symptom Diary[®] (CSDS[®]) patient-reported outcome (PRO) instrument for CD symptoms.

This NIH grant was awarded as part of the Small Business Innovation Research (SBIR) program and is notable for being a Fast-track application in which both the Phase I and II work is approved and at the highest funding level allowable due to an application addressing a critical topic area.

The Co-Principle Investigators on the project are Joseph A. Murray MD of the Mayo Clinic and Jack A. Syage PhD of ImmunogenX. These individuals have jointly conducted trials in the past and present for an ImmunogenX diagnostic technology for monitoring intestinal health (CypCel[™]) as well as for latiglutenase.

"We are very excited that NIAID recognizes the importance of this work by awarding a very competitive Fast-track grant. We hope to be a beacon for the positive use of public funds for society's benefit by conducting this therapeutic trial to address a critical unmet need for the management of celiac disease." remarks Jack Syage PhD, CEO of ImmunogenX.

Dr. Peter H.R. Green, MD of the Columbia University Celiac Disease Center adds, "So much is needed to relieve the pain and misery of celiac disease patients. We are gratified to be working with ImmunogenX to further develop this promising therapeutic candidate that is critically needed for these long-suffering patients."

About ImmunogenX

ImmunogenX[®] (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[™]) 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

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