



NIH Awards Grant to ImmunogenX to Study Latiglutenase

Study will advance latiglutenase therapeutic and CypCel diagnostic

ImmunogenX announces that the National Institutes of Health (NIH) through the National Center for Complementary and Integrative Health (NCCIH) has awarded a grant to conduct a clinical study to advance the scientific basis for the company's therapeutic latiglutenase and its diagnostic CypCel™ technologies (Grant No. 1R33AT009637-01). This study entitled "Latiglutenase as a Treatment for Celiac Disease" will be conducted at the Mayo Clinic under Principal Investigators Dr. Joseph A. Murray (Mayo) and Dr. Jack A. Syage (ImmunogenX).

This two year placebo-controlled, double-blind and randomized study will monitor the effectiveness of latiglutenase to degrade gluten under a gluten challenge regimen. The biological signature (primary endpoint) will be villous height to crypt depth ratio (Vh:Cd) and this will be correlated to the clinical outcome measure for symptom change as measured by the Celiac Disease Symptom Diary (CDS[®]) patient-reported outcome (PRO) instrument. Patients will be further monitored by the CypCel™ diagnostic that uses a drug biomarker (simvastatin) to measure the state of villous health in the small intestine for patients before and immediately after the gluten challenge period and then again after a gluten-free run-out period.

As one reviewer remarked, "If successfully implemented, the study is highly significant with the potential to establish a much-needed treatment regimen for CD patients with dietary supplement plus gluten-free diet, and establish a novel diagnostic measurement of intestinal competence (CypCel)."

Dr. Joseph Murray, Principal Investigator states, "Evidence continues to mount for the efficacy of latiglutenase for both histologic protection and symptomatic improvement. This trial will strive to show both benefits in a single trial and further demonstrate the promising minimally-invasive CypCel diagnostic for monitoring changes in mucosal health due to gluten ingestion."

This study builds off of previously successful phase 2 trials for latiglutenase involving a gluten challenge (intended gluten ingestion) and real-world (unintended gluten ingestion) scenarios.

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 (formerly ALV003) 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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