

ImmunogenX initiates Ph2 trial for its lead therapeutic and diagnostic candidates Latiglutenate and CypCel

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Both technologies address unmet needs for patients with celiac disease



ImmunogenX has announced the initiation of a Phase 2 clinical trial (named Celiac Shield), sponsored by the National Institutes of Health's (NIH) National Center for Complementary and Integrative Health (NCCIH), to be conducted at the Mayo Clinic in Rochester, MN. The trial will test the safety and efficacy of the company's lead therapeutic candidate Latiglutenate for the protection of intestinal health and the reduction of symptoms in the presence of a 6 week gluten challenge treatment period. Key endpoints include: (i) intestinal health measured by villous height to crypt depth ratio (Vh:Cd) from a biopsy at the beginning and end of the treatment period, (ii) symptom response utilizing a daily diary measuring the severity of 6 gluten-induced symptoms, and (iii) intestinal health as measured by the diagnostic method CypCel, which uses simvastatin as a biomarker for villous degradation. Urine samples will also be collected periodically to measure gluten content for the placebo vs. latiglutenate arms during the gluten challenge period. This work builds off of positive results reported for Latiglutenate (Syage et al. Dig. Dis. & Sci. 2017) and for CypCel (Moron, Am J Gastroenterol 2013).

The Co-Principal Investigators on the project are Joseph A. Murray MD of the Mayo Clinic and Jack A. Syage PhD of ImmunogenX. These investigators have worked together on a previous trial that focused on the CypCel diagnostic for disease management.

"This trial represents an exciting opportunity to test our therapeutic drug Latiglutenate alongside our diagnostic disease management tool CypCel. Though these are independent developments, and not companions, the opportunity to run a controlled gluten-challenge trial allows us to test both candidates simultaneously," states Jack Syage PhD, CEO of ImmunogenX. "We are extremely grateful to the NIH for recognizing the importance of this work and for providing essential funding for celiac disease research."

Immunogen, 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 Latiglutenate for celiac disease therapy. ImmunogenX is also developing a minimally-invasive diagnostic tool for celiac disease management 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.