

ImmunogenX and Mayo Clinic Successfully Complete the CeliacShield Trial

A significant advance for latiglutenase and CypCel™ in the treatment and management of celiac disease

ImmunogenX is happy to announce the successful completion of the CeliacShield™ trial (NCT03585478). This gluten-challenge trial measured several outcomes including histology, symptoms, serology, and gluten in urine. The trial also incorporated our CypCel diagnostic technology as a monitor of small intestinal villous health utilizing the drug biomarker simvastatin as measured in blood samples. Histologic protection was assessed by measuring changes in villous height to crypt death ratio ($\Delta Vh:Cd$) and intraepithelial lymphocytes (ΔIEL) before and after a 6-week, 2g per day gluten challenge period. The attenuation of $\Delta Vh:Cd$ and ΔIEL for the active (1200-mg latiglutenase) group relative to placebo was 82% and 60% with p-values of 0.0758 and 0.0181 (ANCOVA), respectively. Measurements of gluten immunogenic peptides in urine showed reduction of gluten of 77% for latiglutenase vs. placebo with $p = 0.0009$ (unpaired, 2-tailed t-test). Symptom attenuation was 93% (abdominal pain), 53% (bloating) and 99% (tiredness) with a 3 x 2-week trend-line significance of $p = 0.0142$, 0.0298 and 0.0018 (unpaired, 2-tailed t-test), respectively. Serology measurements for TTG-IgA, DGP-IgG and DGP-IgG all showed worsening for placebo and improvement for latiglutenase groups relative to baseline.

Matthew Dickason, MBA, Lead Project Manager, comments “We are very pleased with the outcome of the CeliacShield trial, particularly given the disruptions caused by COVID-19. The Mayo and ImmunogenX team creatively persevered despite these challenging conditions to bring this trial to a successful conclusion.”

Mayo Clinic Principal Investigator, Joseph A. Murray, MD, states “Latiglutenase is proving to be a leading therapeutic candidate for celiac disease patients as an adjunct to a gluten-free diet. We are very encouraged by these results and the potential for success in subsequent trials. We are especially grateful for the dedicated participants who hung in there despite the pandemic.”

This clinical trial was sponsored by the National Institutes of Health’s (NIH) National Center for Complementary and Integrative Health (NCCIH).^{*} Further information can be found at celiacshield.com.

^{*} The content of this news release is solely the responsibility of ImmunogenX and does not necessarily represent the official views of the National Institutes of Health.

About ImmunogenX

ImmunogenX, Inc. 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 (IMGX003) 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. www.immunogenx.com

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