

## News Release

Newport Beach, CA – July 2, 2020



# ImmunogenX and Mayo Clinic CeliacShield Trial for Latiglutenase Passes Safety and Efficacy Midterm Assessment

## Futility analysis for safety and efficacy supports continuation of trial

The Data and Safety Monitoring Board (DSMB) for the CeliacShield™ Trial (NCT03585478) convened June 17, 2020 and immediately approved the continuation of the trial for Latiglutenase, a therapeutic candidate for celiac disease (CD), being conducted at the Mayo Clinic (Rochester, MN). This midpoint futility analysis reviewed the primary histologic endpoint of villous height to crypt depth ratio (Vh:Cd) and adverse events (AE) in a gluten challenge placebo controlled double blind trial. This clinical trial is sponsored by the National Institutes of Health's (NIH) National Center for Complementary and Integrative Health (NCCIH).\* Besides the primary endpoint for Vh:Cd, other endpoints include: (i) histologic measure of intraepithelial lymphocytes (IEL), (ii) symptom response utilizing the celiac disease symptom diary (CSDS) to measure the severity of 6 gluten-induced symptoms, (iii) intestinal health as measured by the diagnostic monitoring tool CypCel and (iv) gluten content in urine for the placebo vs. latiglutenase arms during the gluten challenge period. Further information can be found at [celiacshield.com](http://celiacshield.com).

Principal Investigator, Joseph A. Murray MD of the Mayo Clinic, comments "The investigative team is happy to get the go ahead from the DSMB whose analysis of data thus far has found that the study merits continuation."

Jennifer A. Sealey Voyksner, PhD and CSO of ImmunogenX comments "Latiglutenase continues on its road to success as a best-in-class therapeutic candidate for treatment of celiac disease. These midpoint data support previous studies that showed that Latiglutenase may protect the mucosa to accidental gluten exposure and attenuate gluten-induced symptoms."

\* 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 (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 (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. 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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