

News Release

Newport Beach, CA – February 13, 2020



Enrollment Begins for Latiglutenase (IMGX003) Phase 2b Trial for Treatment of Celiac Disease

Trial focuses on symptom endpoints for seropositive patients

ImmunogenX is pleased to announce that patient enrollment has begun for a Phase 2b clinical trial (NCT04243551, named “Solutions for Celiac”™). This trial is funded by the National Institutes of Health’s (NIH) National Institute of Allergy and Infectious Diseases (NIAID) as a grant to ImmunogenX. The multi-center trial includes Columbia University in New York, NY, Mayo Clinic in Rochester, MN, and private practice sites located in the US. This trial will test the safety and efficacy of the company’s lead therapeutic candidate, Latiglutenase (IMGX003). The mechanism of action of IMGX003 is based on breaking down gluten in the stomach. Thus, treatment with IMGX003 will result in reduction of gluten-induced symptoms and improvement of quality of life in celiac disease (CD) patients. The goal of this trial is to further validate the results obtained from a previous Phase 2b trial (NCT01917630, named Celiaction®) that showed statistically and clinically significant improvement in symptom severity, frequency and quality of life in CD patients who remained persistently seropositive to gluten-induced antibodies (Syage et al. Dig. Dis. & Sci. 2017 and Syage et al. GastroHep 2019). Further information can be found on solutionsforceliac.com.

Co-Investigator Peter H.R. Green MD of Columbia University Celiac Disease Center remarks about this latest trial, “We are very pleased to have the opportunity to participate on a critical real-world trial focusing on the most vulnerable CD patients. The indication of symptom relief is at the root of their acute suffering when inadvertently exposed to gluten.”

Matthew A. Dickason MBA, COO and Lead on ImmunogenX’s clinical programs comments, “This trial is the culmination of an enormous effort on the part of our team and we are excited about the prospects for success based on the positive outcomes from the previous Celiaction™ trial. We fully expect this trial to lead to an end-of-Phase 2 meeting with FDA enroute to a final Phase 3 trial to make this therapy commercially available to the benefit of long-suffering CD 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 (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

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