



ImmunogenX Donates Patient Reported Outcome Instruments to the Foundation for Celiac Disease Outcome Measures

Industry and academic researchers to be given access to a celiac disease dedicated patient reported outcome (PRO) tool set for use in clinical trials

ImmunogenX[®], a biopharmaceutical company focused on the diagnosis and treatment of celiac disease, today announced that it has licensed its PRO tool set to the Foundation for Celiac Disease Outcome Measures, Inc., a non-profit charitable corporation headed by Drs. Daniel C. Adelman, Ciarán P. Kelly and Daniel A. Leffler. The principal PRO instrument is the Celiac Disease Symptom Diary[®] (CDSD[®]) among a group of four other PRO and quality-of-life tools. These instruments were developed by Alvine Pharmaceuticals, Inc and ICON PLC (formerly Oxford Outcomes) in compliance with FDA guidances and the primary tools have been rigorously tested in large clinical studies of patients with celiac disease; Dr. Adelman oversaw the development of the PRO instruments while serving as Chief Medical Officer at Alvine. The assets of Alvine Pharmaceuticals including the PRO tool set and Latiglutenase (formerly ALV003 and renamed IMGX003), a potential celiac disease therapy in clinical development, were acquired by ImmunogenX in February 2016.

“As a company dedicated to bettering the lives of patients with celiac disease, ImmunogenX is pleased to make this exceptional PRO tool set available to the community of celiac disease researchers under the management of the Foundation for Celiac Disease Outcomes Measures,” said Dr. Jack A. Syage, CEO of ImmunogenX.

Dr. Adelman added “We are grateful to ImmunogenX for generously providing the PRO tool set to our foundation in order to share these resources with any interested and qualified researchers for use in the development of therapies for patients with celiac disease. We believe that it is in the best interests of celiac disease clinical researchers to have access to a single set of rigorously developed PRO instruments to measure symptom severity and frequency in patients participating in clinical studies. These research tools will greatly facilitate the prospects of bringing new therapies for celiac disease through clinical trials.”

“The Foundation for Celiac Disease Outcomes Measures is delighted to be able to offer these high quality and extensively tested PRO tools to the Celiac research community” said Dr. Kelly. “This generous action by ImmunogenX fills a vital need for clinical research and development in celiac disease and will facilitate and substantially accelerate advances in the field.”

About ImmunogenX

ImmunogenX (a subsidiary of Immunogenics LLC) is a clinical-stage company founded in 2013 and is supported by a team of world-renowned clinicians, scientists and advisors in celiac disease research. The company recently acquired Latiglutenase for celiac disease therapy, which is currently in Phase 2 clinical trials. ImmunogenX is also developing a diagnostic tool for celiac disease management based on a clinically successful metabolic marker compound that can measure the state of recovery of a celiac patient undergoing 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 and has developed the first multiplexed analytical method to detect and quantify trace levels of gluten and other allergens in food and consumer products.

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About the Foundation for Celiac Disease Outcome Measures, Inc.

The Foundation for Celiac Disease Outcome Measures is a 501(c)3 corporation registered in the Commonwealth of Massachusetts. The instruments available for licensure include: the Celiac Disease Symptom Diary[®] (CSDS[®]), the Impact of Celiac Disease Symptom Questionnaire[®] (ICDSQ[®]), the Impact of the Gluten-Free Diet Questionnaire[®] (IGFDQ[®]), a pediatric PRO and a pediatric observer reported outcome (ObsRO) tool. These patient-reported outcome and quality-of-life instruments are available for per-protocol licensure to qualified researchers conducting clinical studies involving patients with celiac disease.

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