



## **ImmunogenX Completes CypCel Trial for Celiac Disease**

### **Further validation of minimally-invasive monitor of celiac villous intestinal health**

ImmunogenX and the Mayo Clinic are pleased to announce the completion of a longitudinal study to further evaluate a disease management tool for monitoring the intestinal health of recovering celiac disease patients. The method, which we call CypCel™ is based on a drug biomarker simvastatin, a cholesterol reducing medication, that has the unusual property of being highly metabolized in the small intestine by the enzyme CYP3A4, which is expressed on the villi. The patient ingests a simvastatin tablet and then provides a blood sample at two later time points. The concentration of the simvastatin in the blood samples is directly related to the villous health of the patient; in patients with healthy villi a high rate of metabolism leads to reduced concentration of simvastatin in the blood samples whereas in patients with damaged villi, the converse is true. Simvastatin levels measured in individuals at periodic intervals therefore can monitor progressive changes that are indicative of whether a treatment, such as a gluten-free diet, is effective.

The Mayo study was conducted on newly diagnosed and long-term healed celiac disease patients as well as non-celiac healthy control subjects. The results showed a trend toward systematic improvement in villous health in newly diagnosed patients adhering to a gluten-free diet whereas the other cohort groups representing healthy villi showed negligible further improvement as expected. These results are consistent with a previous published study (Moron, Am J Gastroenterol 2013). This work was selected for an oral presentation at the revered Tampere Celiac Disease Symposium 2018 held in Tampere, Finland from September 13-15, 2018.

“We are very excited to be developing this new diagnostic method, which serves as an alternative to an expensive and invasive biopsy” states Dr. Jennifer Sealey Voyksner, CSO of ImmunogenX. She further adds “This method also makes use of a novel mass spectrometry analysis developed in our laboratories.”

Dr. Joseph Murray of the Mayo Clinic and the principal investigator of this project remarks “There is a great need to develop a routine diagnostic to monitor changes in the histology of celiac patients. We were pleased to lead on this study and look forward to further development and bringing this diagnostic into clinical practice.”

### **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 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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