



## ActoBio Therapeutics™ Receives IND Green Light for New Antigen-Specific Immunotherapy Study Aimed at Improving Celiac Patients' Tolerance of Gluten

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- Celiac Disease is an underserved market with no approved pharmacological therapies -

- Food-microbe based therapeutic candidate AG017 is designed to address the underlying cause of disease -

Ghent, Belgium, Aug. 19, 2019 /PRNewswire/ -- [ActoBio Therapeutics, Inc.](#), a wholly owned subsidiary of Intrexon Corporation (NASDAQ: XON) and innovative clinical-stage biotechnology company focused on a new class of microbe-based therapeutic agents, announced that the U.S. Food and Drug Administration (FDA) has given its permission to an Investigational New Drug (IND) application for AG017, an innovative orally-delivered therapeutic candidate for the treatment of celiac disease. ActoBio Therapeutics™ plans to enroll celiac disease patients in the Phase Ib/IIa study in the U.S. and Europe later this year.

ActoBio Therapeutics™ is dedicated to developing and commercializing the next generation of oral antigen-specific immunotherapy utilizing its proprietary delivery vehicle. ActoBiotics® programs are very well suited to address unmet needs in a wide range of autoimmune and allergic diseases through induction of antigen-specific immune tolerance that can prevent, retard or reverse the disease. ActoBiotics® AG017 for the treatment of celiac disease will be the second antigen-specific investigational immunotherapy candidate in clinical development following ActoBiotics® AG019, which is currently in a Phase Ib/IIa clinical study for the treatment of type 1 diabetes. Both programs will help further advance the Company's strategy to develop antigen-specific immunotherapies toward other autoimmune indications.

ActoBio Therapeutics™ is developing oral ActoBiotics® AG017 capsules based on the safe food-grade bacterium *Lactococcus lactis* which is specifically engineered to express a gliadin peptide in combination with an immunomodulating cytokine. ActoBiotics® AG017 is an antigen-specific investigational immunotherapy candidate with the potential to reverse gluten sensitivity. Over 90% of patients with celiac disease have an HLA-DQ2.5 genotype, and the target population for the clinical trial is patients within this group whose celiac disease is well controlled on a gluten-free diet.

Celiac disease is a chronic intestinal inflammatory disorder estimated to affect 1 in 100 people worldwide and is caused by an autoimmune reaction triggered by ingestion of dietary gluten proteins. The subsequent intestinal damage leads to malabsorption of some nutrients, along with diarrhea, bloating, weight loss, fatigue and anemia, as well as serious complications in some individuals<sup>1</sup>. There is currently no FDA-approved drug for celiac disease, with the only available treatment being life-long adherence to a strict gluten free diet, which is increasingly believed to be insufficient for many sufferers.

"Celiac disease has a significant physical, emotional and practical impact on patients and their families. AG017 is a unique candidate for treating the disease, which may allow patients to relax their dietary restrictions. Therefore, we are excited to be involved in the first clinical trial with this potential treatment and look forward to exploring the promise of AG017 in addressing unmet patient needs," commented Professor Knut Lundin, one of the leading investigators for clinical studies in celiac disease and former consultant for ActoBio Therapeutics™, professor of medicine and head of clinical education at the University of Oslo and senior consultant in gastroenterology at Oslo University Hospital.

Pieter Rottiers, PhD, chief executive officer of ActoBio Therapeutics™ stated, "We are delighted to be moving forward and entering clinical trials with our ActoBiotics® AG017 for celiac disease. We have demonstrated that this product is safe and efficacious in animal studies. Our approach with AG017 is to target the underlying cause of celiac disease, and this next stage of the program will allow us to evaluate how our preclinical results will translate in patients."

<sup>1</sup> Mayo Clinic. Celiac Disease: Symptoms and Causes. Accessed August 2019 via the [Mayo Clinic website](#).

### About Celiac Disease

Celiac disease is an autoimmune disorder, which induces an immune response to dietary gluten in genetically susceptible individuals, causing inflammation and damage to the small intestine. Around 1 in 100 people worldwide are estimated to suffer from this disorder, with many being undiagnosed and therefore at a higher risk of developing serious complications such as anemia, osteoporosis, neurological and autoimmune disorders<sup>1</sup>.

### About ActoBio Therapeutics, Inc.

ActoBio Therapeutics™ is pioneering a new class of microbe-based ActoBiotic® *Lactococcus lactis* biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics. The ActoBiotics® platform produces biologics that through oral or topical administration are being investigated as possible treatments for many diseases including oral, gastrointestinal and autoimmune/allergic disorders. This approach is being developed to provide treatments that are an alternative to injectable biologics. ActoBio Therapeutics™ has a strong R&D pipeline with the latest stage candidate in Phase IIb and an extensive portfolio of candidates ready for clinical development across a number of potential indications. For further information and updates please visit us at [www.actobio.com](#) or follow us on Twitter at [@ActobioT](#) and [LinkedIn](#).

### About Intrexon Corporation

Intrexon Corporation (NASDAQ: XON) is Powering the Bioindustrial Revolution with Better DNA™ to create biologically-based products that improve

the quality of life and the health of the planet through two operating units – Intrexon Health and Intrexon Bioengineering. Intrexon Health is focused on addressing unmet medical needs through a diverse spectrum of therapeutic modalities, including gene and cell therapies, microbial bioproduction, and regenerative medicine. Intrexon Bioengineering seeks to address global challenges across food, agriculture, environmental, energy, and industrial fields by advancing biologically engineered solutions to improve sustainability and efficiency. Our integrated technology suite provides industrial-scale design and development of complex biological systems delivering unprecedented control, quality, function, and performance of living cells. We call our synthetic biology approach Better DNA<sup>®</sup>, and we invite you to discover more at [www.dna.com](http://www.dna.com) or follow us on Twitter at [@Intrexon](https://twitter.com/Intrexon), on [Facebook](https://www.facebook.com/Intrexon), and [LinkedIn](https://www.linkedin.com/company/intrexon).

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**Safe Harbor Statement**

Some of the statements made in this press release are forward-looking statements. These forward-looking statements are based upon our current expectations and projections about future events and generally relate to our plans, objectives and expectations for the development of our business. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this press release.

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