ActoBio Therapeutics™ Doses First Patient in Phase Ib/IIa Clinical Study of AG019 for the Treatment of Type 1 Diabetes

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A unique approach to induce immune tolerance using specifically targeted and designed ActoBiotics® Lactococcus lactis engineered to express therapeutic agents.

GHENT, Belgium, Oct. 29, 2018 /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, and Intrexon T1D Partners LLC, have announced that the first patient has been dosed in the Company's Phase Ib/IIa clinical trial for the treatment of early onset type 1 diabetes (T1D). ActoBiotics® AG019 is a therapeutic agent designed to induce immune tolerance in T1D, a disease with no approved disease-modifying treatment, which is currently managed through lifestyle modification and diet, combined with exogenous insulin.

Kevan Herold, MD, Professor of Immunobiology and of Medicine (Endocrinology) at Yale University commented, "ActoBio's AG019 shows real potential for stemming the progression of type 1 diabetes and, in combination with new methods of identifying at risk populations, may provide an exciting opportunity to prevent clinical onset. The successful outcome of clinical trials such as this one has the potential to reverse progression and entirely change the face of this disease." Professor Herold is also Executive Director of the Diabetes Center and Deputy Director of Translational Research at the Yale Center for Clinical Investigation and the US coordinating investigator for the AG019 study.

AG019 is formulated as an easy-to-take capsule consisting of engineered *Lactococcus lactis* specifically modified to deliver human proinsulin and the tolerance-enhancing cytokine human interleukin-10 to the mucosal lining of the gastro-intestinal tissues. The microbe-based platform offers several advantages over injectable biologics including a unique delivery method of a therapeutic agent capable of inducing oral immune tolerance to reverse T1D. In the Phase Ib portion of the study, patients will receive AG019 alone. In the Phase IIa portion, patients that receive treatment with AG019 will also receive a short initial course of teplizumab, an anti-CD3 monoclonal antibody. Pre-clinical studies in mice have demonstrated that AG019, in association with a short-term treatment with systemic anti-CD3 monoclonal antibody, successfully induced reversion to normal blood sugar levels in 60% of diabetic mice, and effectively reversed the disease in 89% of mice treated at early stage.

The Phase Ib/IIa study will be performed across a number of clinical sites specializing in the treatment of T1D in both the US and Belgium. Clinical trial results are expected at the beginning of 2020 and will provide data regarding the safety and efficacy of AG019 in humans.

"This trial is a critical next step in what we believe will be a very exciting journey in the development and assessment of a novel treatment option for early onset T1D. The progress our R&D team has made is significant. Pre-clinical studies indicating the effectiveness of our new class of microbe-based ActoBiotics® therapeutics give us confidence our approach will be a true game changer by providing safer and more efficacious treatments benefitting the patient's comfort and lifestyle," commented Pieter Rottiers, PhD, Chief Executive Officer of ActoBio Therapeutics™.

About Type 1 Diabetes
T1D is an autoimmune disease, which affects approximately 1.25 million Americans, of which 200,000 are under the age of 20. Without a cure, these numbers are predicted to grow to more than 5 million Americans in 2050. Recent estimates suggest T1D has a $14 billion annual economic impact, based on treatment cost and lost wages.[1]

About ActoBio Therapeutics, Inc.
ActoBio Therapeutics™ is pioneering a new class of microbe-based ActoBiotics® *Lactococcus lactis* biopharmaceuticals that enables expression and local delivery of disease-modifying therapeutics. The ActoBiotics® platform produces biologics through oral or topical administration with treatment applications across many diseases including oral, gastrointestinal, and autoimmune/allergic disorders. This approach is being developed to provide safer and more efficacious treatments than injectable biologicals. 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 LinkedIn.

About Intrexon T1D Partners
Intrexon T1D Partners is a private company organized to develop and commercialize products through the ActoBiotics® platform to treat type 1 diabetes. The company is a 50/50 joint venture between ActoBio Therapeutics™ and a select group of external investors.

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. Intrexon's integrated technology suite provides its partners across diverse markets with 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® and we invite you to discover more at www.dna.com or follow us on Twitter at @Intrexon, on Facebook, and LinkedIn.

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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.

For more information, contact:

Investor Contact:

Steven Harasym

Vice President, Investor Relations

investors@dna.com

Corporate Contact:

Marie Rossi, PhD

Vice President, Communications

Tel: +1 (301) 556-9850

publicrelations@dna.com

Local contact ActoBio Therapeutics – Ghent

Kristoff Baeten

PR & Communications

T +32 474 88 1212

abt.info@actobio.com

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[1] Juvenile Diabetes Research Foundation (www.JDRF.org)

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