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ActoBio Therapeutics progresses to Phase Ib/IIa for AG019

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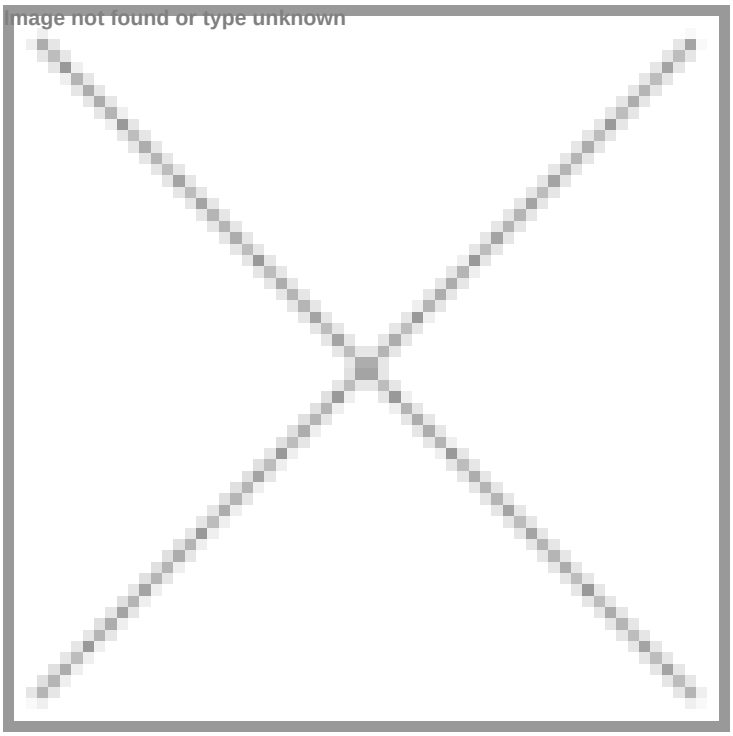

ActoBio Therapeutics, a wholly owned subsidiary of Intrexon Corporation and innovative clinical-stage biotechnology company focused on a new class of microbe-based therapeutic agents, has announced that it will progress to the next stage of the Phase Ib/IIa clinical trial for investigational drug AG019 for the treatment of early-onset type 1 diabetes (T1D). This follows a scheduled review by the independent Data and Safety Monitoring Board, which supported moving forward with the study. Therefore, the Company may now initiate enrollment of the next two patient cohorts of the study: AG019 dosing in patients 12-17 years of age and combination dosing of AG019 plus teplizumab (PRV-031) in adults.

ActoBiotics AG019 is an investigational drug designed to induce oral immune tolerance to reverse T1D, a disease with no approved disease-modifying treatment that is currently managed through lifestyle modification and diet combined with exogenous insulin. AG019 is formulated as an oral 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. In the next stage of the study, AG019 will be utilized in combination with PRV-031, a Phase III anti-CD3 monoclonal antibody in development for the interception and prevention of clinical T1D, pursuant to a collaboration with Provention Bio. Inc., (NASDAQ: PRVB), a clinical-stage biopharmaceutical company.

The Phase IIa study will evaluate AG019 administered for 8 weeks in combination with PRV-031 for the first 12 days as compared to placebo. Pre-clinical studies of AG019, in association with a short-term treatment with a systemic anti-CD3 monoclonal antibody, induced reversion to normal blood sugar levels in 60% of diabetic mice and reversed the disease in 89% of mice treated at early stage of the disease. The results of the current trial are expected in 2020 and will provide initial data regarding the safety and efficacy of AG019 in humans.

"PRV-031 immunotherapy has shown remarkable promise as a single agent for the interception and prevention of type 1 diabetes," commented Ashleigh Palmer, Provention Bio's Co-Founder and Chief Executive Officer. "Combination strategies offer potential opportunities to improve outcomes for early onset type 1 diabetes. We share ActoBio's commitment to investigating new disease-modifying therapeutic options for type 1 diabetes patients and their families, and we look forward to learning more about the combination of PRV-031 plus AG019 as this study advances."

Pieter Rottiers, PhD, Chief Executive Officer of ActoBio Therapeutics stated, "We are excited to start the AG019 trial in the 12- to 17-year-old patient cohort, since T1D onset occurs most frequently in adolescents. We are also looking forward to collaborating with Provention Bio in this next stage of testing in patients. We have high hopes that the combination of AG019 and PRV-031 will prove safe and well-tolerated, to allow us to then move on to study efficacy as we aim to make a difference to T1D patients' lives. We believe that AG019, alone or in combination with teplizumab, offers potential as a new therapeutic option to address this high unmet need."

ActoBio Therapeutics is pioneering a new class of microbe-based ActoBiotics *Lactococcus lactis* biopharmaceuticals that enable expression and local delivery of disease-modifying therapeutics. The ActoBiotics platform produces biologics following oral or topical administration with possible treatment applications across many diseases including oral, gastrointestinal and autoimmune/allergic disorders. 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.