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INNOVIMMUNE TO PRESENT SUPERIOR PRECLINICAL THERAPEUTIC EFFICACY RESULTS IN RHEUMATOID ARTHRITIS OF ITS INV-17 ROR GAMMA T INHIBITOR PROGRAM AT THE 2014 AMERICAN COLLEGE OF RHEUMATOLOGY ANNUAL MEETING

2nd Preclinical Autoimmune Disease Proof of Concept Established for INV-17

New York City (November 5, 2014) --Specialty drug discovery company, Innovimmune Biotherapeutics Holding, LLC will present data demonstrating successful treatment of rheumatoid arthritis [RA] in a murine collagen-induced arthritis [CIA] model with its proprietary oral small molecule Retinoic acid receptor-related Orphan Receptor gamma t [ROR γ t] modulators from their INV-17 portfolio. The results will be presented at the 2014 American College of Rheumatology Annual Meeting in Boston on November 16, 2014 and the abstract available online (<http://www.acrannualmeeting.org/abstracts/>).

In the CIA study, an INV-17 ROR γ t modulator lead compound was administered orally for 28 days in a therapeutic regimen following RA disease induction. The data demonstrate that mice treated with INV-17 achieved statistically significant reduction in cumulative arthritis score ($p < 0.001$) as the primary study end-point, in contrast to a vehicle (placebo) group. Significant improvement in clinical disease scores in the INV-17 group began on day 13 ($p = 0.04$), with maximal therapeutic effects observed on day 16 ($p = 0.0007$) through day 26 ($p = 0.0003$) and through the end of the study ($p = 0.01$).

“This is a remarkable finding in that a novel therapeutic approach targeting pathogenic T helper 17 [T_H17] cells through ROR γ t modulation provides superior preclinical treatment efficacy in RA. These results, which demonstrate successful RA disease amelioration in the absence of toxicity, may provide a novel oral disease-modifying antirheumatic drug [DMARD] treatment strategy with an oral INV-17 drug for RA and other T_H17-mediated autoimmune diseases,” said Ellen M. Ginzler, M.D., M.P.H.; Distinguished Teaching Professor of Medicine and Chief, Division of Rheumatology, SUNY Downstate Medical Center.



ROR γ t is the master regulator of human T_H17 cells that play a critical role in the pathogenesis of several autoimmune diseases. The selection of an oral INV-17 clinical candidate compound is being fast-tracked concurrently for potential therapeutic applications in multiple ROR γ t-regulated autoimmune diseases with significant unmet medical needs.

“These findings of the successful preclinical therapeutic utility of INV-17 in RA, together with prior efficacy data announced for the successful disease prevention in a murine model of multiple sclerosis (13 *J Neurol Sci.* Gaweco et al), further strengthen our parallel IND-enabling development and regulatory strategies for multiple autoimmune disease indications of prioritized clinical lead compounds of the INV-17 portfolio. We believe our best-in-class ROR γ t inhibitors will provide significant treatment advance in several autoimmune diseases, and are strongly encouraged having achieved the second preclinical Proof of Concept for INV-17 in RA,” said Anderson Gaweco, M.D., Ph.D., CEO of Innovimmune.

ABOUT INNOVIMMUNE

Innovimmune Biotherapeutics Holding, LLC is a New York City-based specialty drug discovery and exploratory development biotechnology company leading the development of novel first-in-class and best-in-class proprietary oral small molecule New Molecular Entity immunomodulatory drugs for the treatment of autoimmune and immunoinflammatory diseases.

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