



Innovate Biopharmaceuticals Enters into an R&D Collaboration on Larazotide's Corrective Effect on the Dysfunctional Intestinal Barrier and the Dysfunctional Microbiome in various Diseases with the University of Maryland School of Medicine

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RALEIGH, N.C., June 28, 2018 (GLOBE NEWSWIRE) -- [Innovate Biopharmaceuticals Inc.](#) (Nasdaq:INNT), a clinical stage biotechnology company focused on developing novel medicines for autoimmune and inflammatory diseases, announced today it has agreed to collaborate with Professor O. Colin Stine, Ph.D., at the University of Maryland School of Medicine, whose research is focused on the study of molecular mechanism of bacterial invasion of the intestinal barrier and disruption of the microbiota in several infectious diseases.

Dr. Stine commented, "Larazotide is the only known molecule in late stage clinical trials that decreases intestinal permeability. Permeability of the intestinal barrier and its modulation by the microbiota are fundamental processes underlying several diseases such as Environmental Enteric Dysfunction, known as EED, and autoimmune/inflammatory diseases including celiac disease, non-alcoholic steatohepatitis and inflammatory bowel diseases. Recently, the microbiota and its impact on converting PD1/PDL1 therapy unresponsive tumors sensitive to immunotherapy is opening another key gateway to study the role of the dysfunctional intestinal barrier and its correction by larazotide."

Chris Prior, Ph.D., CEO of Innovate, stated, "Professor Stine's research has demonstrated that correcting the dysfunctional intestinal barrier and the dysfunctional microbiome can have a beneficial effect in various diseases. The increased recognition of the barrier and microbiome dysfunction as causative elements in diseases ranging from EED to autoimmune to metabolic and oncology. We believe intestinal barrier function compromised by dysbiosis can be restored by larazotide and this mechanism of action has the potential to provide tremendous clinical benefit."

Dr. Stine has [published extensively](#) on the molecular mechanisms bacteria use in intestinal diseases of children, especially in developing countries. He led a major study that compared the bacteria in children with and without diarrhea. Dr. Stine further added, "The mechanisms responsible for maintenance and restoration of the intestinal barrier should be the same whether the inflammation manifests as diarrhea and/or stunting in children from low-income countries or in adults suffering from intestinal ischemia/reperfusion injuries, inflammatory bowel diseases and celiac disease. Larazotide could play a significant role in this restoration process."

About University of Maryland, Department of Epidemiology and Public Health

Celebrating its 210th Anniversary, the [University of Maryland School Of Medicine](#) is the first public medical school in the United States and continues accelerating innovation and discovery in medicine today. The [Department of Epidemiology and Public Health](#) trains public health experts; conducts population-based, clinical, and translational research; and investigates the causes and consequences of diseases. It translates the results of interdisciplinary studies into clinical practice and community-based interventions to prevent disease and improve public health. For the past seven years, the Department of Epidemiology and Public Health has been ranked in the top five nationally in Public Health and Preventive Medicine among public Schools of Medicine.

About Innovate Biopharmaceuticals, Inc.(Nasdaq:INNT):

Innovate is a clinical stage biotechnology company focused on developing novel therapeutics for immuno-inflammatory diseases. Innovate's lead drug candidate, larazotide acetate, has a mechanism of action that renormalizes the dysfunctional intestinal barrier by decreasing intestinal permeability and reducing antigen trafficking, such as gliadin fragments in celiac disease, and bacterial toxins and immunogenic antigens in non-alcoholic steatohepatitis (NASH). In several diseases, including celiac disease, NASH, Crohn's disease, ulcerative colitis, irritable bowel syndrome (IBS), type 1 diabetes mellitus (T1DM), chronic kidney disease (CKD), the intestinal barrier is dysfunctional with increased permeability.

In celiac disease, larazotide is the only drug which has successfully met the primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Innovate successfully completed the End of Phase 2 Meeting with the FDA in 2017 and is preparing to begin Phase 3 registration clinical trials for celiac disease later in 2018. In clinical trials testing of more than 800 patients, larazotide demonstrated a favorable safety profile comparable to placebo for long-term chronic administration. Larazotide has received Fast Track designation from the FDA for celiac disease.

Forward Looking Statements

This press release includes forward-looking statements including, but not limited to, statements related to our operations, the potential of the products we are developing and our business strategy. The forward-looking statements contained in this press release are based on management's current expectations and are subject to substantial risks, uncertainty and changes in circumstances. Actual results may differ materially from those expressed by these expectations due to risks and uncertainties, including, among others, those related to our ability to obtain additional capital on favorable terms to us, or at all, the success, timing and cost of our drug development program and our ongoing or future clinical trials, the lengthy and unpredictable nature of the drug approval process, and our ability to commercialize our product candidates if approved. These risks and uncertainties include, but may not be limited to, those described in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 14, 2018, our Quarterly Report on Form 10-Q filed with the SEC on May 15, 2018, and our subsequent filings with the SEC. Forward-looking statements speak only as of the date of this press release, and we undertake no obligation to review or update any forward-looking statement except as may be required by applicable law.

SOURCE: Innovate Biopharmaceuticals, Inc.

Contact:

Kendyle Woodard

Tel: +1 (919) 275 – 1933

investor.relations@innovatebiopharma.com

www.innovatebiopharma.com

 Primary Logo

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