



Innovate Biopharmaceuticals Enters into a Collaboration on Larazotide's Effect on Improving the Microbiome of Children with EED with the University of Virginia School of Medicine

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RALEIGH, N.C., July 31, 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 James P. Nataro, MD, PhD, MBA, the Benjamin Armistead Shepherd Professor and Chair, Director of Children's Services, UVA Children's Hospital of the University of Virginia School of Medicine, whose research is focused on the study of enteric bacteria and their roles in health and disease.

Dr. Nataro commented, "I am excited by this collaboration. Abnormalities of intestinal permeability underlie a host of human diseases such as environmental enteric dysfunction, known as EED. EED is a disorder that afflicts millions of children around the world, leading to growth faltering, cognitive delay and impaired resistance to infection."

Dr. Nataro has [published extensively on](#) intestinal infection and gut health among children in the U.S. and around the world. Dr. Nataro's lab is funded by the National Institutes of Health (NIH) and independent foundations. His current work on larazotide is funded by the [Bill and Melinda Gates Foundation](#).

Christopher Prior, Ph.D., CEO of Innovate, stated, "Larazotide is the only known molecule in late stage clinical trials that specifically restores intestinal barrier function. We are pleased to be collaborating with Dr. Nataro, and the University of Virginia School of Medicine to research the effects of larazotide on EED. We believe that EED is an unmet need with no current treatment and a serious health concern for millions of children globally."

About EED

Environmental enteric dysfunction is a common malady afflicting millions of children who live in impoverished circumstances around the world. EED is characterized by intestinal inflammation and abnormal permeability, and results in growth faltering and malnutrition. Although the precise cause of EED remains elusive, gut bacteria are thought to play a role in its pathogenesis.

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

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