



Innovate Biopharmaceuticals' Dose Response Data for Larazotide Acetate Demonstrating Its Unique Mechanism of Action and Applications in Diseases Caused by Increased Intestinal Permeability

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RALEIGH, NC (Globe Newswire December 28, 2017) – [Innovate Biopharmaceuticals Inc.](#) ("Innovate"), a clinical stage biotechnology company focused on developing novel medicines for autoimmune and inflammatory disorders, announced today it has submitted an abstract for presentation at the [Digestive Disease Week \(DDW\) conference](#) in Washington D.C., June 2-5, 2018, entitled "Larazotide stimulates recovery of ischemic-injured intestine in a dose-dependent manner associated with restoration of tight junctions."

[Dr. Anthony Blikslager](#), professor of gastroenterology at North Carolina State University, who conducted the experiments, said, "Our recent work has revealed the likely mechanisms for an optimal dose for larazotide, which has also been noted in recent clinical trials. These mechanisms include the production of inhibitory peptides cleaved from the parent compound at high larazotide doses. Nonetheless, larazotide induces a remarkably robust recovery response in severely injured tissues at its optimal dose."

The data reveal a narrow dose response for larazotide with the higher doses showing inhibition. Further studies have identified specific breakdown fragments of larazotide that can act as antagonists causing inhibition as the larazotide dose increases and the fragments accumulate. Innovate believes these data explain the clinical findings that significant efficacy is achieved in a narrow low dose range while inhibition occurs above a higher dose threshold.

Dr. Blikslager is [widely published](#) on studying mechanisms responsible for maintenance and restoration of the intestinal barrier, with the ultimate objective of pharmacologically restoring the mucosal barrier in patients suffering from diseases associated with increased intestinal permeability. Restoring the intestinal barrier would be significant for patients suffering from diseases such as intestinal ischemia/reperfusion injury, inflammatory bowel diseases, and gastric ulcer disease due to the potential medical complications associated with these diseases.

About Innovate Biopharmaceuticals, Inc.:

Innovate is a clinical stage biotechnology company focused on developing novel medicines for autoimmune and inflammatory disorders.

On July 3, 2017, Innovate announced that it had signed a definitive [Merger Agreement with Monster Digital, Inc. \(Nasdaq: MSDI\)](#), under which the shareholders of privately-held Innovate Biopharmaceuticals, Inc. will become the majority owners of Monster Digital, Inc.

Innovate's lead drug candidate, [larazotide acetate \(INN-202\)](#), has successfully met its primary endpoint in an efficacy clinical trial for celiac disease. Larazotide successfully completed the End of Phase 2 Meeting with the FDA to prepare for expected Phase 3 clinical trials for larazotide in celiac disease in 2018. In clinical studies in more than 800 patients, larazotide demonstrated a favorable safety profile comparable to placebo, due to what Innovate believes is its lack of systemic absorption from the small bowel. Larazotide has received Fast Track designation from the FDA.

Larazotide, an oral peptide formulated into a capsule, has a mechanism of action which decreases intestinal permeability and regulates tight junctions by reducing antigen trafficking across epithelial cells in the intestines. Innovate believes that larazotide is the only drug in the clinic with this mechanism of action of reducing intestinal permeability. Increased intestinal permeability, sometimes referred to as "leaky gut," has been widely recognized in the literature as a gateway to multiple autoimmune diseases, including celiac disease, irritable bowel syndrome (IBS), inflammatory bowel diseases (IBD, Crohn's and ulcerative colitis), type 1 diabetes mellitus (T1DM), nonalcoholic steatohepatitis (NASH), chronic kidney disease (CKD) and several others.

This press release contains forward-looking statements, including statements regarding the clinical development of our product candidates, which are subject to risks and uncertainties that could cause actual results to differ materially. Reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of our product development activities and clinical trials; the approval and commercialization of our product candidates; the timing of data submission, and risks of increased regulatory requirements, amongst others. These forward-looking statements speak only as of the date hereof. Innovate Biopharmaceuticals disclaims any obligation to update these forward-looking statements.

SOURCE: Innovate Biopharmaceuticals:

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