



Innovate Biopharmaceuticals Announces Acceptance of Two Abstracts for the Digestive Disease Week 2018 Conference

May 9, 2018

Highlighting the Dose Response and Mechanism of Action of Larazotide Acetate

- *In large animals, larazotide replicated its mechanism of action by renormalizing the dysfunctional intestinal barrier*
- *In spite of damage from severe insults, from ischemia to NSAID damage, larazotide was able to recover the damaged intestinal barrier and decrease permeability*

RALEIGH, N.C., May 09, 2018 (GLOBE NEWSWIRE) -- [Innovate Biopharmaceuticals, Inc.](#) (Nasdaq:INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced that two abstracts were accepted for poster presentations during the 2018 Digestive Disease Week (DDW) conference being held June 2-5, 2018 in Washington, DC. These abstracts, jointly authored with NC State University, showcase larazotide acetate's ability to stimulate the recovery of ischemic-injured intestinal tissue by regulating tight junctions.

Date/Time: Saturday, June 2 from 12:00pm – 2:00pm ET

[Title: Larazotide Stimulates Recovery of Ischemic-Injured Intestine in a Dose-Dependent Manner Associated with Restoration of Tight Junctions](#)

Session Number: 5050

Presentation Number: Sa 1183

Room: Hall C

Date/Time: Sunday, June 3 from 12:00pm – 2:00pm ET

[Title: Larazotide Stimulates Recovery of Ischemic-Injured Intestine in The Presence of the Non-Steroidal Anti-Inflammatory Drug \(NSAID\) Indomethacin Related to Recovery of Tight Junctions](#)

Session Number: 6285

Presentation Number: Su 2039

Room: Hall C

Christopher Prior, Ph.D., CEO of Innovate, said, "It is remarkable that larazotide acetate has been shown to restore structural integrity of an intestinal wall following such a severe ischemic insult and is yet another demonstration of how this oral peptide has the potential to reduce permeability of the gut. We believe this broad mechanism offers great promise at preventing undesirable antigens in the lumen of the intestine from entering the body and triggering inflammation leading to tissue damage and dysfunction of critical organs. We are excited to explore this mode of action in the treatment of celiac disease, our lead program, and in liver diseases such as NASH."

"I have not seen a compound work so effectively in this model. We demonstrated a narrow range low dose response that would approximate active dose levels in humans. We are continuing to demonstrate the broad range of antigens that are prevented from crossing the intestinal wall following treatment with larazotide," remarked Anthony Blikslager, DVM, PhD, DACVS, AGAF, Professor of Equine Surgery and Gastroenterology at NC State University's College of Veterinary Medicine.

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

Innovate is a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and 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 nonalcoholic 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 for larazotide to begin Phase 3 registration clinical trials for celiac disease later in 2018. Larazotide has been exposed to more than 500 subjects in clinical trials demonstrating 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 the potential for Innovate's drug development pipeline candidates in treating the diseases and conditions for which they are being developed, Innovate's start of clinical trials for celiac disease, NASH, Crohn's disease, and ulcerative colitis, and Innovate's ability to develop future collaborations. 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, and in any 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.

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