



Innovate Biopharmaceuticals Announces Acceptance of Three Abstracts Focusing on the Molecular Biology and Pharmacology of Larazotide for the 2019 Digestive Disease Week Conference

February 25, 2019

Highlighting the Protective Effect in Alcoholic Steatohepatitis (ASH) models and Molecular Mechanism of Action of Larazotide Acetate via the Myosin Light Chain Kinase

RALEIGH, N.C., Feb. 25, 2019 (GLOBE NEWSWIRE) -- [Innovate Biopharmaceuticals, Inc.](http://www.innovatebiopharm.com) (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced that three abstracts were accepted for poster presentations during the 2019 Digestive Disease Week (DDW) conference to be held May 18-21, 2019, in San Diego, CA. These abstracts, separately authored with Massachusetts General Hospital (MGH), Harvard Medical School and North Carolina State University (NC State), showcase larazotide acetate's ability to reduce permeability in an alcohol induced "leaky gut" model and further elucidate its molecular mechanism of action of renormalizing tight junctions.

Digestive disease characterized by an increase in intestinal permeability, including celiac disease and inflammatory bowel diseases are associated with inflammation that triggers opening of interepithelial tight junctions via the 'master regulator' of tight junctions: myosin light chain kinase (MLCK).¹ Gluten that triggers celiac disease has recently been shown to increase intestinal permeability via activation of MLCK.² Innovate's new research recently accepted for presentation at Digestive Disease Week in San Diego, May 2019 shows that larazotide inhibits MLCK in human Caco-2 cells, thereby revealing a central molecular mechanism for larazotide to reduce intestinal permeability.

Title: *Larazotide acetate prevents and rescues from ethanol-induced permeability changes in an in vitro model system*

Date/Time: Saturday, May 18, 2019, from 12:00pm – 2:00pm PDT

Poster Session Title: Alcoholic Liver Diseases – Clinical & Experimental

Title: *Larazotide protects the intestinal tight junction barrier during anoxia/reoxygenation injury via inhibition of myosin light chain kinase*

Date/Time: May 19, 2019, from 12:00pm – 2:00pm PDT

Poster Session Title: Epithelial Junctions and Barrier Function

Title: *Establishment and characterization of a leaky porcine jejunal cell line grown as a 2-dimensional monolayer using crypt culture media and their response to the tight junction agent larazotide acetate*

Date/Time: May 19, 2019, from 12:00pm – 2:00pm PDT

Poster Session Title: Cell Biology, Biochem and Integrative Physiology

Dr. Luther commented, "We are excited to continue working with Innovate." Dr. Luther further added, "By working with Innovate and larazotide, we hope to advance our understanding of liver diseases which ultimately could lead to better outcomes for patients."

"Previously we demonstrated the broad range of antigens that are prevented from crossing the intestinal wall following treatment with larazotide, and this new data continues to add to the characterization of this unique peptide's novel mechanism of action and potential minimizing the trafficking of antigens through leaky gut," remarked Anthony Blikslager, DVM, PhD, DACVS, AGAF, Professor of Equine Surgery and Gastroenterology at NC State University's College of Veterinary Medicine.

Sandeep Laumas, M.D., Executive Chairman & CEO of Innovate, said, "We are delighted by the work conducted at NC State elucidating the molecular mechanism by which larazotide restores structural integrity of the intestinal barrier with the potential to restrict entry into the circulation of immunogens that trigger inflammatory disease." Dr Laumas, further commented, "The work conducted at MGH is very exciting, demonstrating how larazotide may protect intestinal epithelia from an insult of alcohol which could lead to a potential treatment for alcoholic steatohepatitis. These findings enhance our understanding of the underlying molecular biology and pharmacology of larazotide acetate and its broad application to treat a variety of diseases."

About larazotide acetate for celiac disease

In celiac disease, larazotide is the only drug which has successfully met its primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Innovate completed the End of Phase 2 Meeting with the FDA and is preparing to launch the Phase 3 registration clinical trials for celiac disease in the first half of 2019. Nearly 600 subjects have been exposed to larazotide in clinical trials, and a safety profile comparable to placebo has been demonstrated. Larazotide has received Fast Track designation from the FDA for celiac disease.

About Alcoholic Liver Diseases (ALD) and Alcoholic Steatohepatitis (ASH)

Alcoholic liver disease (ALD) comprises a spectrum of conditions arising from excessive alcohol intake, from reversible fatty liver to acute alcoholic hepatitis, chronic fibrosis and cirrhosis and hepatocellular cancer (HCC). ALD, including progression from alcoholic fatty liver to alcoholic steatohepatitis (ASH) is characterized by hepatic inflammation which could lead to a chronic form leading to cirrhosis and in some cases hepatocellular carcinoma. In addition, severe ASH (with or without cirrhosis) can lead to alcoholic hepatitis, which is an acute clinical presentation of ALD that is associated with liver failure and high mortality. The Global Burden of Disease (GBD) project estimated there were more than 1.2 million deaths in 2016 due to cirrhosis and chronic liver disease, of which more than one quarter were related to alcoholic liver diseases.³ Patients with severe ASH may develop the acute clinical entity of alcoholic hepatitis, a disease characterized by jaundice and liver failure. Of the patients who survive alcoholic hepatitis, 70% will develop cirrhosis. By contrast, 40% of patients with alcoholic liver cirrhosis may also develop alcoholic hepatitis (acute-on-chronic disease), with very high mortality rates.⁴

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, ASH, 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.

Forward Looking Statements

This press release includes forward-looking statements including, but not limited to, statements related to the development of drug candidates, our operations and 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, including, without limitation, to fund our current and future preclinical studies and clinical trials; the success, timing and cost of our drug development program and our ongoing or future preclinical studies and clinical trials, including, without limitation, the possibility of unfavorable new clinical and preclinical data and additional analyses of existing data, as well as the risks that prior clinical and preclinical results may not be replicated; 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 Quarterly Report on Form 10-Q filed with the SEC on November 13, 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.

SOURCE: Innovate Biopharmaceuticals, Inc.

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