Innovate Biopharmaceuticals Enters into a Collaboration with Massachusetts General Hospital and Announces Capital Update for the Celiac Disease Clinical Program and its NASH Development Strategy on December 17, 2018

December 4, 2018

-- *Announces collaboration in high unmet need Alcoholic Liver Diseases (ALD), including severe alcoholic hepatitis, with novel gut-specific, clinical-stage asset, larazotide acetate*

-- Investor update on capital plan for the celiac disease clinical program and NASH development strategy scheduled for December 17, 2018

RALEIGH, N.C., Dec. 04, 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 scheduled an investor update on December 17, 2018 regarding its capital plan for the celiac disease clinical program and NASH development strategy.

In addition, the company has launched a collaboration with Jay Luther, MD, & Raymond T. Chung, MD at the Gastroenterology Unit at Massachusetts General Hospital. Drs. Luther and Chung, faculty members at Harvard Medical School, have published in the area of liver diseases and other gastrointestinal disorders. Dr. Luther, a clinical and research member at Massachusetts General Hospital's Crohn's and Colitis Center and Liver Center, and Dr. Chung, Associate Professor and Director of Hepatology, have research interests that include developing novel therapeutics for liver diseases.

Building on previous research[1] that showed a type of permeability known as "leaky gut" may cause microbial translocation of toxic products into the circulation, Innovate is expanding its work in liver disease and announcing a collaboration with MGH in order to elucidate ethanol-induced toxin uptake and sequalae in an ALD model where data is expected to be presented at an upcoming conference in 2019. The work being conducted is a pre-cursor to potential discussions with the FDA regarding the blunting of toxins in high unmet need forms of alcoholic liver disease, including acute-on-chronic forms, such as alcoholic hepatitis, that have been shown to lead to hospitalizations (1% of hospital admissions in 2010)[2] and high mortality rates (20–30% at 1 month and 40–70% at 6 months).[3]

Through this collaboration, MGH and Innovate seek to understand how certain toxins, which are normally contained within the luminal compartment of the intestine, are breaching the gut vascular barrier via ethanol-induced disruption and infiltrating the systemic circulation causing liver disease via an inflammatory loop of the gut-liver axis. This work could elucidate the interplay of this mechanism in a variety of liver diseases including nonalcoholic and alcoholic forms of liver pathology. Innovate expects that this research will inform its understanding of how agents, like larazotide, may prevent this "leaky" barrier from worsening and provide a potential advantage in treating a variety of liver diseases. The mechanistic basis of larazotide's action on renormalizing the gut vascular barrier in certain forms of ALD, such as acute on chronic forms such as severe alcoholic steatohepatitis (ASH), could lend to studying this agent via a Subpart H[4] approval process, where as a condition of approval, Innovate would study the agent in confirmatory clinical trials.

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

Christopher Prior, Ph.D., CEO of Innovate, stated, "We are pleased to be collaborating with Dr. Luther and Massachusetts General Hospital to research the effects of larazotide on liver diseases, as we believe larazotide can help patients by blocking a variety of intestinal toxins from entering the circulation and triggering debilitating inflammatory 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
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 MM deaths in 2016 due to cirrhosis and chronic liver disease, of which more than one quarter were related to alcoholic liver diseases.[5] 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.[6]

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.

Forward Looking Statements
This press release includes forward-looking statements including, but not limited to, statements related to the development of drug candidates, our plans to raise capital, 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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