Innovate Biopharmaceuticals Shows Larazotide is the First Drug, with its Novel Mechanism of Action of Re-normalizing the Intestinal Barrier, to Demonstrate Improvements in validated NASH Biomarkers and Endpoints in synergy with obeticholic acid, an FXR ag

April 29, 2019

Continued execution toward start of the first phase 3 celiac disease clinical trial in the current quarter with key sites for trial launch selected and active recruitment efforts underway

NASH Data Presentation at Analyst Meeting at Digestive Disease Week (DDW) conference on May 20, 2019 in San Diego

RALEIGH, N.C., April 29, 2019 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced today that larazotide acetate, a new class of medicine based on gut-restricted peptides which re-normalize the intestinal epithelial barrier and gut-liver axis, is the first drug with this novel mechanism to shown improvements in validated NASH biomarkers and endpoints. Key topline findings from a biopsy-proven translational mouse model of NASH (the AMLN-diet Gubra NASH mouse model) will be presented at an Analyst Meeting at the Digestive Disease Week (DDW) conference on May 20, 2019 in San Diego as well submitted to The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD) in fall, 2019.

Recent Achievements
Clinical

- Active patient recruitment efforts underway
- Selected more than 100 clinical research sites to participate in our registration trial: CeD-LA-3001 Study: *A Phase 3, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Larazotide for Relief of Persistent Symptoms in Patients with Celiac Disease on a Gluten Free Diet.*

R&D

- Immuno-oncology: started academic collaboration with Institut Gustave Roussy to study regulation of intestinal permeability and the gut microbiota using larazotide in immuno-oncology checkpoint inhibitor failure preclinical models

Upcoming Milestones

- Start of patient screening and randomization for the first phase 3 celiac disease trial
- NASH data presentation at Analyst Meeting at Digestive Disease Week (DDW) conference on May 20, 2019 in San Diego
- Further updates on NASH pathway for clinical development
- Continuation of pre-clinical studies for alcoholic steatohepatitis (ASH)
- Initiation of additional scientific and clinical collaborations

NASH Pre-clinical Data Highlights
In a 12 week preclinical study of larazotide acetate combined with obeticholic acid (OCA), data demonstrated statistically significant reductions in plasma total cholesterol ($p<0.001$), absolute ($p<0.05$) and relative liver weights ($p<0.01$), relative ($p<0.001$) and total liver cholesterol ($p<0.001$), and relative ($p<0.01$) and absolute liver triglycerides ($p<0.001$), when compared to vehicle control animals that did not receive any larazotide or OCA. The non-alcoholic fatty liver disease activity score (NAS score), the clinical measure of NASH activity, improved in the majority of animals treated with the combination of larazotide/OCA when compared to vehicle ($p<0.001$). Histological steatosis scores trended positively, and lobular inflammation was statistically significantly improved ($p<0.01$) in the larazotide/OCA group when compared to vehicle control animals.

Dr. Stephen Harrison, Medical Director of Pinnacle Clinical Research in San Antonio, Texas, an expert in clinical trials for NASH said, “These preclinical data, demonstrating a synergistic effect of larazotide, which targets intestinal permeability, when combined with obeticholic acid, a well characterized farnesoid X receptor (FXR) agonist’. Dr Harrison added, “the data mandates a clinical study to understand this novel mechanism’s effect in patients. There is a high unmet need for NASH and agents which may improve existing modalities via novel mechanisms would greatly benefit patients.”

Sandeep Laumas, M.D., CEO of Innovate, said, “The first quarter of 2019 was focused on continued preparation for the first celiac disease phase 3 clinical trial. Larazotide’s positive effect in a pre-clinical model has, for the first time shown, a novel mechanism for treatment of NASH in combination with other drugs. We are very excited with this data along with previous preclinical studies (AASLD 2018 abstracts) could seek to move to a proof-of concept clinical trial after receipt of additional financing. The unique mechanism of larazotide has consistently proven itself in a series of models for multiple diseases. We are also awaiting data from the immuno-oncology microbiome study which is studying larazotide’s effect on converting checkpoint inhibitor / PD-1 non-responders to responders via modulation of gut permeability and the microbiome.”

2019 First Quarter Financial Results
As previously disclosed, as of March 31, 2019, Innovate had estimated unaudited cash and cash equivalents of $11.5 million, compared to $5.7 million at December 31, 2018. This is a preliminary unaudited estimate of the cash and cash equivalents of the Company as of March 31, 2019.

Webcast
As previously announced, Innovate plans to host a conference call at 8:00 am ET today, April 29, 2019, to discuss certain of its financial results for the first quarter ended March 31, 2019, and to provide operational updates. Please visit the Investor section of Innovate's website for further details on accessing the webcast.

A live and archived audio webcast of the conference call will be available on the Events and Presentations page of Innovate's corporate website at www.innovatebiopharma.com.

About NAFLD/NASH:
Nonalcoholic steatohepatitis (NASH) is a severe disease of the liver caused by inflammation and a buildup of fat in the organ. In the United States, NASH affects up to approximately 2-5% of the population. An additional 10-30% of Americans have fat in their livers, but no inflammation or liver damage, a condition called NAFLD or "fatty liver." The underlying cause of NASH is unclear, but it most often occurs in persons who are middle-aged and overweight or obese. It has been shown that chronic liver diseases, including NAFLD/NASH, may cause perturbations in the epithelial lining of the gut, and disrupt barrier integrity, causing a normal intestine to become more permeable. This "leaky gut" could cause passage of unwanted toxins and antigenic components to "cross-talk" to the liver via the blood circulation causing inflammation and damage to hepatocytes. This gut-liver axis is an emerging area of research in chronic liver diseases, such as NAFLD/NASH.

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 operations and business strategy, capital raising, our expected financial results, and corporate updates. 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, including, without limitation, raising additional funds for our Phase 3 registration trial for INN-202, and 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. These risks and uncertainties include, but may not be limited to, those described in our Annual Report on Form 10-K filed with the SEC on March 18, 2019, 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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