Innovate Biopharmaceuticals, Inc. Announces First Patient Dosed in the First Phase 3 Clinical Trial for Patients with Celiac Disease

August 13, 2019

CeD LA 3001 trial doses first patient in historic Phase 3 celiac disease trial

RALEIGH, N.C., Aug. 13, 2019 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (“Innovate”) (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today announced that it has dosed the first patient in its Phase 3 clinical trial, CeD LA 3001. This marks the first time any company has dosed a patient in a Phase 3 trial for celiac disease.

Larazotide acetate, or INN-202, is Innovate's leading drug candidate for the treatment of celiac disease. The drug is a tight junction regulator designed to help restore “leaky” or open junctions to a normal state. Celiac disease affects approximately 1% of the U.S. population, more than 3 million Americans, and is a high unmet need with no FDA approved treatments.

This Phase 3 study is a national, multicenter, double-blind, placebo-controlled, randomized, parallel-group trial that is expected to enroll approximately 600 patients. The study’s primary objective is to evaluate larazotide acetate as an adjunct therapy for patients with celiac disease who still experience symptoms despite being on a gluten-free diet. Larazotide is an oral therapy taken prior to meals, up to 3 times per day. Larazotide is not systemically absorbed and has a well-established safety profile.

Patrick Griffin, M.D., F.A.C.P., Innovate’s Chief Medical Officer said, "We are thrilled to announce the first patient dosed in our Phase 3 trial. We believe larazotide will have a meaningful impact on celiac patients and provide a therapy where none is approved. Progressing this trial is another step towards bringing a potentially groundbreaking therapy for celiac patients globally.”

Sandeep Laumas, M.D., CEO of Innovate, stated, “We are extremely pleased to start patient dosing in this pivotal Phase 3 trial for larazotide for celiac disease. This brings us closer in our mission of gaining approval for the first ever drug for celiac disease.”

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 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). Larazotide has been exposed to nearly 600 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 our operations and business strategy and the development of drug candidates. 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 Form 10-K for the year ended December 31, 2018, our Form 10-Q for the quarter ended June 30, 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.

Innovate Biopharmaceuticals, Inc.
Jennifer K. Zimmons, Ph.D.
Investor Relations
Tel: +1-917-214-3514
Email: jzimmons@innovatebiopharma.com
www.innovatebiopharma.com

Source: Innovate Biopharmaceuticals, Inc