



Innovate Biopharmaceuticals Announces the Start of the First Phase 3 Clinical Trial in Celiac Disease

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Launch of the first ever phase 3 trial in the history of celiac disease

RALEIGH, N.C., June 10, 2019 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, announced the start of the first phase 3 clinical trial in celiac disease. Innovate expects to provide further updates as screening and enrollment proceed over the next few months.

Innovate's Chief Medical Officer, Dr. Patrick H. Griffin, stated, "We are proud to start the first ever phase 3 clinical trial to address a large unmet need for celiac patient suffering from continued symptoms in spite of being on a gluten-free diet." Innovate's Chairman and CEO, Dr. Sandeep Laumas, added, "This is a landmark event in the history of celiac disease for the first ever phase 3 trial to get underway as well as a key pivotal moment for Innovate. We are especially thankful to our partners, physicians and our investors whose support of Innovate's management has led to this outcome."

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 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 Quarterly Report on Form 10-Q filed with the SEC on May 10, 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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Source: Innovate Biopharmaceuticals, Inc