Innovate Biopharmaceuticals Enters into an Agreement with Amarex Clinical Research for Data Management and Biostatistics for Phase 3 Celiac Disease Trial

August 23, 2018

RALEIGH, N.C., Aug. 23, 2018 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today announced it signed an agreement with Amarex Clinical Research to provide data management and biostatistics for its planned Phase 3 celiac disease trial. Pursuant to the agreement, Amarex will provide Innovate with electronic data capture solutions and associated services for data management and biostatistics.

June Almenoff, M.D., Ph.D., F.A.C.P, CMO and COO of Innovate said, “With their strong expertise in biostatistics and data management, I am pleased to be working with Amarex to support our Phase 3 trial. Our clinical team has been impressed with Amarex’s capabilities, and we look forward to a productive working relationship.”

Kazem Kazempour, Ph.D., Amarex’s President and Chief Executive Officer, said, “We are excited to support Innovate in the development of its novel therapeutic, which has the potential to help so many patients suffering from celiac disease. We look forward to working closely with Innovate’s experienced team to advance the clinical development of larazotide for this underserved population.”

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 in 2017 and is preparing to begin Phase 3 registration clinical trials for celiac disease, targeted to commence later in 2018. 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 Amarex Clinical Research LLC:
Amarex is a global contract research organization providing clinical trial services to pharmaceutical companies and has expertise in product development plan creation, product safety and efficacy testing, and applications to the FDA for marketing approval of new or improved medical products.

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 potential for Innovate’s drug development pipeline candidates in treating the diseases and conditions for which they are being developed, Innovate’s start of clinical trials for celiac disease, NASH, Crohn’s disease, and ulcerative colitis, and Innovate’s ability to develop future collaborations. 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 Quarterly Report on Form 10-Q filed with the SEC on August 14, 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.

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