Innovate Biopharmaceuticals Strengthens Clinical Development with the Addition of Patrick H. Griffin, M.D., F.A.C.P.

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RALEIGH, N.C., Nov. 26, 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 that Patrick H. Griffin, M.D., F.A.C.P. has joined as the acting head of clinical development. Dr. Griffin will assume the clinical development responsibilities previously held by June Almenoff, M.D., Ph.D., Innovate's former Chief Medical Officer, who remains a consultant to Innovate. Dr. Griffin has several decades of clinical development experience in gastroenterology, autoimmune and metabolic diseases. His expertise in gastroenterology was instrumental during his tenure at ImmunsanT, Inc. where he focused on celiac disease, and subsequently at Synergy Pharmaceuticals, Inc. where he was responsible for multiple phase 3 clinical trials for Trulance® (plecanatide).

Since May 2013, Dr. Griffin has served as the Chief Medical Officer of Synergy Pharmaceuticals, Inc. managing the late-stage development of Trulance® (plecanatide). While at Synergy Pharmaceuticals, Dr. Griffin oversaw multiple phase 3 clinical trials that supported Trulance's approval in two indications: irritable bowel syndrome with constipation (IBS-C), and chronic idiopathic constipation (CIC). From January 2010 to February 2012, Dr. Griffin was the first Chief Medical Officer and Senior Vice President Development at ImmusanT, Inc., a biotechnology company developing immune therapies for autoimmune diseases including celiac disease and Type-1 diabetes. Prior to joining ImmusanT, Dr. Griffin held positions of increasing responsibility at Forest Laboratories and subsequently at Sanofi-Aventis. While at Sanofi-Aventis as the Head of External Innovation for the immuno-inflammation therapeutic strategy unit, Dr. Griffin focused on therapeutic approaches to autoimmunity through immune system modulation. Dr. Griffin is a board-certified physician in both internal medicine and gastroenterology, and is a Fellow of the American College of Physicians. Dr. Griffin received his medical degree from Columbia University, completing a residency in internal medicine at Presbyterian Hospital in New York, and a fellowship in gastroenterology at Brigham and Women's Hospital in Boston. Following his residency and fellowship, Dr. Griffin joined the medical faculty of Columbia College of Physicians and Surgeons, where he held a number of academic, clinical research, teaching and management positions, as well as a solo private practice in New York.

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 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 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. 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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