Innovate Biopharmaceuticals Announces Collaboration with Institut Gustave Roussy to Study Regulation of Intestinal Permeability and the Gut Microbiota using Larazotide in Immuno-oncology Checkpoint Inhibitor Failure Pre-Clinical Models

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Innovate reiterates the start of the first Phase 3 clinical trial in celiac disease in Q2 2019

RALEIGH, N.C., March 26, 2019 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases with its lead drug comprising a new class of medicines based on gut-restricted peptides which re-normalize the gut-epithelial barrier and the gut-liver axis, announced today it shall collaborate with Laurence Zitvogel, MD, PhD, Department of Immuno-Oncology, Institut Gustave Roussy, Villejuif, France, using larazotide acetate, Innovate's lead drug, which is entering the first ever Phase 3 trial for celiac disease in the second quarter of 2019.

Professor Zitvogel's work focuses on intestinal microbiome dysbiosis and its effects on responses to chemotherapy and checkpoint inhibitors suggesting a nexus between the gut and immune surveillance of cancers.[1,2] Her team and others have found that primary resistance to immune checkpoint inhibitors, such as CTLA-4 and PD-1 based immunotherapies, can be attributed to abnormal gut microbial composition.[3]

Intestinal permeability is compromised in numerous diseases where a disruption of the epithelial barrier that separates the lumen from the host's immune system may contribute to uncontrolled inflammation. Larazotide is a gut-restricted peptide which has been shown to re-normalize intestinal permeability in various inflammatory and metabolic preclinical models. Through this collaboration, Innovate and Pr. Zitvogel seek to understand how the therapeutic effect of immune checkpoint inhibitors such as antibodies to CTLA-4 and PD-1, is modulated by blocking translocation of bacterial antigens and toxins and certain metabolites from interacting with the host immune system in pre-clinical oncology models.

This emerging area of groundbreaking research looking at uncovering the role of the gut microbiome in the induction of cancer and response to immune checkpoint and chemotherapy, will be one of only four afternoon educational sessions to be held on Friday afternoon, March 29, 2019, titled "Modulating the Gut Microbiome to Treat Dysbiosis and Cancer" at the 2019 American Association for Cancer Research (AACR) Annual Meeting, at the Georgia World Congress Center in Atlanta, Georgia.

Sandeep Laumas, M.D., CEO of Innovate, stated, "We are pleased to work with Professor Zitvogel to understand how larazotide's re-normalization of intestinal permeability could affect the immune checkpoint therapeutic response in tumor models as well further help elucidate the complex interaction of the gut microbiome with the immune system in cancer."

Pr. Zitvogel, MD, PhD, Scientific Director of the Gustave Roussy Immuno-Oncology Program, said, "We need to deconvolute the delicate interactions between the intestinal epithelial cells, the microbiome and the immune system in the gut and their consequences on tumor immunosurveillance. I am excited to study how larazotide could normalize these interactions in advanced cancer patients to optimize their therapies."

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 and is preparing to launch the Phase 3 registration clinical trials for celiac disease in the second quarter 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.

About Gustave Roussy
Institut Gustave Roussy, leader in the fight against cancer in Europe, is a worldwide recognized comprehensive cancer centre dedicated to patient care and clinical research. It brings together 3,100 professionals whose missions are care, research and teaching.

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, 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 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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