Innovate Biopharma's Pediatric Ulcerative Colitis Drug Granted FDA Orphan Designation

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RALEIGH, N.C. (Globe Newswire Sept. 6, 2017) – Innovate Biopharmaceuticals Inc., a clinical stage biotechnology company focused on developing novel medicines for autoimmune and inflammatory disorders, announced today it has received U.S. Food and Drug Administration orphan drug designation for INN-108 as an oral therapy proposed for the treatment of pediatric ulcerative colitis.

About INN-108 :

INN-108 is a novel oral small molecule composed of two moieties, mesalamine/5-ASA, a currently approved agent for ulcerative colitis, and 4-aminophenylacetic acid (4-APAA), an immunomodulatory agent approved in Japan for rheumatoid arthritis. The two agents are covalently azo-bonded, thus only allowing their enzymatic separation in the colon. Innovate's preliminary data shows the combination could be a more efficacious drug than approved mesalamine/5-ASA treatments alone.

INN-108, which has successfully completed two Phase 1 clinical trials in the U.S. for mild to moderate ulcerative colitis in both healthy adult subjects and adults with ulcerative colitis, will enter a Phase 2 trial in 2018. A liquid oral formulation of INN-108 for ulcerative colitis is in development for greater convenience for pediatric use.

If INN-108 is approved, a seven-year period of market exclusivity for the indication is among the benefits of Orphan Drug status in the U.S.

About Ulcerative Colitis:

Ulcerative colitis is a chronic inflammatory bowel disease that mainly affects the large intestine, or colon. Symptoms typically include constant diarrhea mixed with blood, abdominal pain, increased bowel movements and in severe cases, weight loss and fatigue. Children can also develop unique complications related to growth, development, nutrition, pubertal maturation, bone mineral density accretion and psychological impacts.

Though the disease can present at any age, it often begins in teenagers and young adults. Various studies estimate that there are between 13,700 and 87,600 cases of pediatric ulcerative colitis in the United States, with most of those occurring in children aged 10 to 17.

About Innovate Biopharmaceuticals Inc.:

Innovate is a clinical stage biotechnology company focused on developing novel autoimmune/inflammation therapeutic drugs.

On July 3, 2017, Innovate announced that it has signed a definitive Merger Agreement with Monster Digital, Inc. (Nasdaq: MSDI), under which the shareholders of privately held Innovate Biopharmaceuticals Inc. will become the majority owners of Monster Digital Inc.

Innovate's lead drug candidate, larazotide acetate (INN-202), has successfully met its primary endpoint in an efficacy clinical trial for celiac disease. Larazotide successfully completed the End of Phase 2 Meeting with the FDA to prepare for expected Phase 3 clinical trials for larazotide in celiac disease in late 2017. In clinical studies in more than 800 patients, larazotide demonstrated a favorable safety profile comparable to placebo, due to what Innovate believes is its lack of systemic absorption from the small bowel. Larazotide has received Fast Track designation from the FDA.

Larazotide, an oral peptide formulated into a capsule, has a mechanism of action that decreases intestinal permeability and regulates tight junctions by reducing antigen trafficking across epithelial cells in the intestines. Innovate believes that larazotide is the only drug in the clinic with this mechanism of action of reducing intestinal permeability. Increased intestinal permeability, sometimes referred to as "leaky gut," has been widely recognized in the literature as a gateway to multiple autoimmune diseases, including celiac disease, irritable bowel syndrome (IBS), inflammatory bowel diseases (IBD, Crohn's and ulcerative colitis), type 1 diabetes mellitus (T1DM), nonalcoholic steatohepatitis (NASH), chronic kidney disease (CKD) and several others.

This press release contains forward-looking statements, including statements regarding the clinical development of our product candidates, which are subject to risks and uncertainties that could cause actual results to differ materially. Reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of our product development activities and clinical trials; the approval and commercialization of our product candidates; and risks of increased regulatory requirements, among others. These forward-looking statements speak only as of the date hereof. Innovate Biopharmaceuticals disclaims any obligation to update these forward-looking statements.

SOURCE: Innovate Biopharmaceuticals:

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