

Reports Positive Results In Phase 2 IBS-c Study

WALTHAM, Mass.--(BUSINESS WIRE)--Dynogen Pharmaceuticals, Inc. today reported positive results of its randomized, double-blind, placebo-controlled, parallel group Phase 2 trial of DDP733 in patients with irritable bowel syndrome with constipation (IBS-c). DDP733 achieved an overall clinical response rate of 54% in patients receiving a dose of 1.4 mg t.i.d. compared to a 15% clinical response rate for patients receiving placebo. This was a statistically significant difference in a clinical endpoint which has been accepted by the FDA as a registration endpoint for this indication. The drug was well tolerated in this study. Detailed results will be submitted for disclosure in a peer-reviewed journal or at a future medical conference.

DDP733 is an oral, partial agonist of the serotonin type 3 receptor (5-HT₃). This DDP733 Phase 2 trial enrolled 91 men and women with IBS-c as determined by the Rome II criteria at multiple centers in Canada. The clinical response rate was assessed using the Overall Subject Global Assessment (OSGA) of relief of IBS, an accepted measure for efficacy in IBS clinical trials. Additionally, a pharmacodynamic assessment of gastrointestinal transit time was included in the study, but the assay did not perform reliably and no conclusions could be drawn.

"We are extremely pleased to see such positive clinical results in this Phase 2 study," said Lee R. Brettman, M.D., Chief Executive Officer at Dynogen. "There is currently only one approved treatment for IBS-c, a chronic disease that afflicts approximately 9 million adults in the U.S., and is the second most common cause for sick leave behind the common cold. The strong clinical activity and good safety profile clearly differentiate this product candidate from the only marketed drug and other late-stage products in development for IBS-c."

"We demonstrated statistical significance, a robust response rate and clear separation from placebo on an endpoint that has been used as the basis for regulatory approval," commented Dr. Suhail Nurbhai, MRCP, Vice President of Clinical Development at Dynogen. "We plan to initiate a Phase 2b study this year to build on these impressive results."

DDP733 was well tolerated with no unexpected drug-related adverse events. Drug-related adverse events were mainly mild to moderate and transient, and required no intervention. DDP733 has been evaluated in more than 350 subjects to date.

About DDP733

DDP733 is an oral, partial agonist of the serotonin type 3 receptor (5-HT₃). Serotonin is a neurotransmitter that is known to be involved in the control of the gastrointestinal (GI) system. Preclinical studies of DDP733 established the compound's prokinetic properties (the ability to promote the motility of the GI tract). Dynogen's preclinical studies have also shown that DDP733 is minimally absorbed by the cells lining the gastrointestinal tract and, as a result, more of the product candidate remains available at the desired local site of action. Previous clinical studies of the compound have demonstrated favorable safety and pharmacokinetic profiles. Dynogen is also studying DDP733 in a Phase 1b clinical trial as a treatment for nocturnal gastroesophageal reflux disease, and expects to complete enrollment of that trial in the first half of 2007.

About Irritable Bowel Syndrome (IBS)

Irritable bowel syndrome is a chronic condition that is believed to be caused by the dysfunction of the muscles and/or nerves of the organs of the GI tract. Patients with IBS experience abdominal pain, discomfort and bloating accompanied by altered bowel habit that can include either diarrhea, constipation or both. IBS has prevalence of up to 12% of the general population, and females account for 80% of the patient population with severe cases.

It is the most common disease diagnosed by gastroenterologists and one of the most common disorders seen by primary care physicians.

About Dynogen Pharmaceuticals, Inc.

Dynogen is a clinical-stage company developing a portfolio of treatments for gastrointestinal and genitourinary disorders. The Company is focused on large and untapped markets in disease areas that severely impair a patient's quality of life, such as irritable bowel syndrome, gastroesophageal reflux disease and overactive bladder. The Company leverages its development expertise to identify promising clinical compounds and rapidly advance them towards registration. Dynogen currently has multiple double-blind, placebo-controlled Phase 2 studies underway. www.dynogen.com

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