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# Allergan announces publication of VIBERZI Phase III trial results in The New England Journal of Medicine

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Allergan plc (NYSE: AGN) announced today the publication of the positive results of the Phase III trials of VIBERZI™ C IV (eluxadoline) for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in the January 21 issue of *The New England Journal of Medicine* (NEJM). The trial results are from two Phase III randomized, multi-center, multi-national, double-blind, placebo-controlled trials (Studies 1 and 2). IBS-D is a functional bowel disorder commonly characterized by chronic abdominal pain and frequent diarrhea, which affects approximately 15 million patients in the U.S.

"These significant Phase III results highlight the efficacy of VIBERZI, demonstrating an exciting new treatment option that provides improvements for two of the most common symptoms of IBS-D, which patients have struggled to address," said David Nicholson, President & Executive Vice President of Global R&D at Allergan. "With so many Americans forced to deal with limited treatment options, VIBERZI is an effective first-in-line therapy that is positioned to address a major unmet need."

In these trials, significantly more patients treated with VIBERZI experienced improvements in diarrhea and abdominal pain, as compared with placebo. Efficacy was defined as simultaneous reductions in the daily worst abdominal pain score by >30% as compared to the baseline weekly average and a reduction in the Bristol Stool Scale (BSS) to <5, on at least 50% of the days within a 12-week treatment interval. These trial results demonstrated sustained and effective relief of both symptoms.

A total of 1280 patients in Study 1 and 1145 patients in Study 2 received treatment with VIBERZI 75 mg, VIBERZI 100 mg or placebo twice daily. Overall, the patients were a mean age of 45 years (ranging from 18 to 80 years with 10% at least 65 years of age or older), 66% female, 86% white, 11% black, and 27% Hispanic.

Study 1 and Study 2 included identical 26-week double-blind, placebo-controlled treatment periods. Study 1 continued double-blinded for an additional 26 weeks for long-term safety (total of 52 weeks of treatment). Study 2 included a 4-week single-blinded, placebo-withdrawal period upon completion of the 26-week treatment period. During the double-blind treatment phase and the single-blinded placebo withdrawal phase, patients were allowed to take loperamide rescue medication for the acute treatment of uncontrolled diarrhea, but were not allowed to take any other antidiarrheal, antispasmodic agent or rifaximin for their diarrhea. Additionally, patients were allowed to take aspirin-containing medications or nonsteroidal anti-inflammatory drugs, but no narcotic or opioid containing agents.

Based on efficacy of VIBERZI 75 mg and 100 mg at 12 weeks of treatment, VIBERZI was approved by the Food and Drug Administration (FDA) as a twice-daily, oral treatment indicated for use in adults suffering from IBS-D. VIBERZI has mixed opioid receptor activity – it is a mu receptor agonist, a delta receptor antagonist, and a kappa receptor agonist that acts locally in the gut.

Source:
Allergan plc