

Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 4-15-2016.

Submission # 10

This submission was received on 4-01-2016 which was after the deadline. Therefore, this submission will not be reviewed for oral testimony presentation.

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Friday, April 01, 2016 3:52 PM
To: 'Kant_Christopher'
Cc: 'Kassel_Eric'; 'McGarr_Seau'; Gennrich, Jane - Medicaid
Subject: RE: Request To Present Public Testimony - April 15 - Within the GI Motility Category - Allergan

As this article was published in January and you failed to meet our time line guidelines, we cannot make an exception to review this information for testimony.

Tami Eide, Pharm.D., BCPS

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From: Kant_Christopher [<mailto:Christopher.Kant@Allergan.com>]
Sent: Friday, April 01, 2016 3:00 PM
To: Eide, Tamara J. - Medicaid
Cc: Kassel_Eric; McGarr_Seau
Subject: Request To Present Public Testimony - April 15 - Within the GI Motility Category - Allergan

Dear Dr. Eide:

We respectfully request your consideration; and that of your P & T committee members, to receive and review the attached summary document; announcing the publication of two successful IBS-D, Phase III clinical trials, appearing in the January 21, 2016 issue of The New England Journal of Medicine (Lembo AJ et al, 374:3, 242-253).

Just yesterday, I learned from a colleague, that we had regrettably overlooked this submittal within the timing outlined in the Idaho Public Testimony Guidelines. We would sincerely appreciate your consideration in providing an exception; and, are hopeful we can publically present on April 15.

Content within the first two pages of the attachment, aligns with and addresses important sections of the "Scientific information provided by pharmaceutical manufacturers or their representatives" section of you P&T guidance document; providing new and rigorous clinical information in a therapeutic space with significant unmet need.

Thank you very much in advance for your consideration.

Sincerely,

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VIBERZI™ (eluxadoline) Phase III Trial Results Published in The New England Journal of Medicine

- VIBERZI has been approved for use in the United States in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D)
- VIBERZI demonstrated effective and sustained relief of abdominal pain and diarrhea
- IBS-D can be debilitating, affecting up to 15 million Americans, and there are limited therapeutic options for managing the chronic symptoms

DUBLIN, Jan. 21, 2016 /PRNewswire/ -- 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 $\geq 30\%$ 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.

About VIBERZI

VIBERZI (eluxadoline) is a twice daily, oral medication indicated for use in adults suffering from irritable bowel syndrome with diarrhea (IBS-D).

VIBERZI (pronounced vye-BER-zee) is an orally active compound indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in men and women that acts locally in the gut.

IMPORTANT SAFETY INFORMATION FOR VIBERZI

Contraindications

VIBERZI is contraindicated for patients with:

- Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction; a history of pancreatitis; structural diseases of the pancreas.
- Alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages per day.
- Severe hepatic impairment.
- A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Sphincter of Oddi Spasm:

- There is a potential for increased risk of sphincter of Oddi spasm, resulting in pancreatitis or hepatic enzyme elevation associated with acute abdominal pain (eg, biliary-type pain) with VIBERZI. These events were reported in less than 1% of patients receiving VIBERZI in clinical trials.
- Patients without a gallbladder are at increased risk. Consider alternative therapies before using VIBERZI in patients without a gallbladder and evaluate the benefits and risks of VIBERZI in these patients.
- Inform patients without a gallbladder that they may be at increased risk for symptoms of sphincter of Oddi spasm, such as elevated liver transaminases associated with abdominal pain or pancreatitis, especially during the first few weeks of treatment. Instruct patients to stop VIBERZI and seek medical attention if they experience symptoms of sphincter of Oddi spasm.

Pancreatitis:

- There is a potential for increased risk of pancreatitis not associated with sphincter of Oddi spasm; such events were reported in less than 1% of patients receiving VIBERZI in clinical trials, and the majority were

associated with excessive alcohol intake. All pancreatic events resolved upon discontinuation of VIBERZI.

- Instruct patients to avoid chronic or acute excessive alcohol use while taking VIBERZI. Monitor for new or worsening abdominal pain that may radiate to the back or shoulder, with or without nausea and vomiting, associated with elevations of pancreatic enzymes. Instruct patients to stop VIBERZI and seek medical attention if they experience symptoms suggestive of pancreatitis.

Adverse Reactions

- The most commonly reported adverse reactions (incidence >5% and greater than placebo) were constipation, nausea, and abdominal pain.

Please also see full Prescribing Information for VIBERZI.

For more information including full prescribing information about VIBERZI at <http://www.actavis.com/Actavis...>

About IBS-D

Irritable bowel syndrome with diarrhea (IBS-D) is a functional bowel disorder characterized by chronic abdominal pain and frequent diarrhea, which affects approximately 15 million patients in the U.S. Although the exact cause of IBS-D is not known, symptoms are thought to result from a disturbance in the way the gastrointestinal tract and nervous system interact.

IBS-D can be debilitating and there are limited therapeutic options for managing the chronic symptoms. IBS-D is associated with economic burden in direct medical costs and indirect social costs such as absenteeism and lost productivity, along with decreased quality of life.