Actavis Receives FDA Approval for VIBERZI (eluxadoline) for the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D) in Adults

- First in class treatment for IBS-D treats hallmark symptoms of IBS-D; 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, May 27, 2015 /PRNewswire/ -- Actavis plc (NYSE: ACT) announced today that VIBERZI™ (eluxadoline) was approved by the Food and Drug Administration (FDA) as a twice-daily, oral treatment for adults suffering from irritable bowel syndrome with diarrhea (IBS-D). VIBERZI (eluxadoline) has mixed opioid receptor activity, it is a mu receptor agonist, a delta receptor antagonist, and a kappa receptor agonist.

"The FDA's approval of VIBERZI is the first step to providing physicians with a new, evidence-based, treatment option for their adult patients with IBS-D," said David Nicholson, Executive Vice President, Actavis Global Brands R&D. "At Actavis, we are dedicated to providing new treatment options, and the development of new agents that help address the most bothersome symptoms of IBS-D. We are very pleased to be working with the FDA to advance this IBS-D treatment and we eagerly await DEA scheduling determination later this year."

IBS-D is a multifactorial disorder marked by recurrent abdominal pain or discomfort and altered bowel function that affects as many as 15 million adult Americans, impacting about twice as many women as men. There are few treatment options available for IBS-D, particularly options that relieve both the diarrhea and abdominal pain associated with IBS-D.

"The unpredictable symptoms experienced by patients with IBS-D can have a significant impact on everyday life," said William D. Chey, MD, Nostrant Professor of Gastroenterology at the University of Michigan Health System. "It's exciting when physicians are able to add an additional treatment option like VIBERZI to their toolbox for patients with IBS-D."

The FDA has recommended that VIBERZI be classified as a controlled substance. This recommendation has been submitted to the U.S. Drug
Enforcement Administration (DEA). Once VIBERZI receives final scheduling designation, the updated label will be available. Pending final scheduling designation, product launch is anticipated in Q1 2016.

About VIBERZI

VIBERZI is an orally active compound indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in men and women. VIBERZI (eluxadoline) has mixed opioid receptor activity, it is a mu receptor agonist, a delta receptor antagonist, and a kappa receptor agonist.

Efficacy was established in two Phase III clinical studies, demonstrating significant superiority over placebo on the composite endpoint of simultaneous improvement in both abdominal pain and diarrhea at both 75 mg and 100 mg twice daily doses. The primary efficacy responder endpoint was evaluated over the duration of double-blind, placebo-controlled treatment. Response rates were compared based on patients who met the daily composite response criteria (improvement in both abdominal pain and stool consistency on the same day) for at least 50% of the days from weeks 1 to 12 (FDA endpoint) and weeks 1 to 26 (European Medicines Agency endpoint).

The most common adverse events in the two Phase III clinical trials were constipation (7% and 8% for eluxadoline 75 mg and 100 mg; 2% for placebo) and nausea (8% and 7% for eluxadoline 75 mg and 100 mg; 5% for placebo). Rates of severe constipation were less than 1% in patients receiving 75 mg and 100 mg eluxadoline. Rates of discontinuation due to constipation were low for both eluxadoline and placebo (≤2%) and similar rates of constipation occurred between the active and placebo arms beyond 3 months of treatment. A total of 2,426 subjects were enrolled across the two studies.

For more information including full prescribing information about VIBERZI at [http://www.actavis.com/Actavis...](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.

About Actavis
Actavis plc (NYSE: ACT), headquartered in Dublin, Ireland, is a unique, global pharmaceutical company and a leader in a new industry model—Growth Pharma. Actavis is focused on developing, manufacturing and commercializing innovative branded pharmaceuticals, high-quality generic and over-the-counter medicines and biologic products for patients around the world.

Actavis markets a portfolio of best-in-class products that provide valuable treatments for the central nervous system, eye care, medical aesthetics, gastroenterology, women's health, urology, cardiovascular and anti-infective therapeutic categories, and operates the world's third-largest global generics business, providing patients around the globe with increased access to affordable, high-quality medicines. Actavis is an industry leader in research and development, with one of the broadest development pipelines in the pharmaceutical industry and a leading position in the submission of generic product applications globally.

With commercial operations in approximately 100 countries, Actavis is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives.

Actavis intends to adopt a new global name – Allergan – pending shareholder approval in 2015.

For more information, visit Actavis' website at www.actavis.com.

Actavis Cautionary Statement Regarding Forward-Looking Statements

Statements contained in this communication that refer to Actavis' estimated or anticipated future results, including estimated synergies, or other non-historical facts are forward-looking statements that reflect Actavis' current perspective of existing trends and information as of the date of this communication. Actual results may differ materially from Actavis' current expectations depending upon a number of factors affecting Actavis' business. These factors include, among others, the timing and success of product launches; the difficulty of predicting the timing or outcome of product development efforts and regulatory agency approvals or actions, if any; market acceptance of and continued demand for Actavis' products; difficulties or delays in manufacturing; and such other risks and uncertainties detailed in Actavis' periodic public filings with the Securities and Exchange Commission, including but not limited
to Actavis plc's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 and from time to time in Actavis' other investor communications. Except as expressly required by law, Actavis disclaims any intent or obligation to update or revise these forward-looking statements.


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