BioSpectrum the business of Bio & Health Sciences ASIA EDITION

USFDA accepts Actavis' ANDA filing

September 4, 2014 | Regulatory | By BioSpectrum Bureau



Singapore: "The NDA filing of Eluxadoline marks an important step forward for this potential first-in-class treatment, which demonstrates our commitment to helping patients suffering from this debilitating condition," said Mr Paul Covington, MD, senior vice president, clinical operations and development, Furiex Pharmaceuticals, a subsidiary of Actavis.

"We are pleased that the FDA has granted Eluxadoline a priority review, setting the stage for us to bring this potential new treatment option to patients promptly," he added.

The NDA submission for Eluxadoline is based on the results of two Phase III clinical studies that met their primary endpoints.

The 12-week efficacy portion of the studies demonstrated significant superiority over placebo in the composite endpoint of the simultaneous improvement in both pain and diarrhea at both 75mg and 100mg doses.

Eluxadoline was well-tolerated and the adverse events (reported in greater than 5 percent of Eluxadoline-treated patients and at an incidence greater than placebo) consisted of constipation [7.4 percent (75 mg) and 8.6 percent (100 mg) vs 2.5 percent placebo], nausea [8.1 percent (75mg) and 7.5 percent (100mg) vs 5.1 percent placebo] and abdominal pain [4.1 percent (75mg) and 5.0 percent (100mg) vs 2.7 percent placebo]. The studies consisted of approximately 2,500 patients.

Pursuant to pre-NDA discussions with FDA, Actavis is planning to submit an amendment to the NDA with additional data from a study that was ongoing at the time of submission. As a result, it is expected that this will extend the Prescription Drug User Fee Act (PDUFA) date by three months. The company expects the PDUFA date in Q2 2015.

"There continues to be an unmet need for treatments to manage the chronic symptoms experienced by patients with IBS-D. If approved, Eluxadoline could be a promising option for patients who continue to suffer from these symptoms," said Mr Anthony Lembo, MD, attending physician, Beth Israel Deaconess Medical Center and associate professor of Medicine, Harvard Medical School.