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Ocera Therapeutics Presents Data On AST-120 In Patients With Hepatic Encephalopathy At The European Association For The Study Of Liver Disease

Main Category: Liver Disease / Hepatitis
Also Included In: Clinical Trials / Drug Trials; Pharma Industry / Biotech Industry
Article Date: 29 Apr 2009 - 1:00 PST

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Ocera Therapeutics, Inc., a privately held biopharmaceutical company, announced that data from its phase 2 study of AST-120 for the treatment of patients with low-grade hepatic encephalopathy was presented April 25th at the 44th Annual Meeting of the European Association for the Study of Liver Disease (EASL) in Copenhagen. The study showed that AST-120 was better tolerated than lactulose, the standard of care in this population, with similar overall efficacy. An improvement on neurocognitive measures was also seen with AST-120. Based on these positive data, Ocera has initiated and dosed their first patient in the ASTUTE study, a phase 2b study of AST-120 in patients with mild hepatic encephalopathy (MHE).

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The phase 2a study randomly assigned 47 patients with West Haven Scale (WHS) Grade 1-2 hepatic encephalopathy to 4 weeks of treatment with either AST-120 2g sachets (A) QID or lactulose (L) titrated to bowel movements. Forty-one patients were evaluable (n=21 A, 20 L) and 6 were excluded (n=3 L: non-compliance, n=3 A: other causes). Treatment response by WHS at Week 4 was similar between treatment groups (38.1% vs. 35.0%, A vs. L). AST-120 also produced an improvement in neurocognitive measures. A statistically significant reduction in pruritus, a secondary endpoint of the trial, was seen with AST-120 compared to lactulose. Adverse events related to diarrhea ($p = 0.04$) and flatulence ($p = 0.02$) were significantly less in patients treated with AST-120.

The improvement seen in neurocognitive measures is consistent with reports that neuropsychometric testing is required to truly measure deficits and detect changes in neurocognitive functioning in the MHE patient population.

"Patients with mild hepatic encephalopathy often don't comply with lactulose therapy because of the side effects," said Paul Pockros, M.D., division head of gastroenterology and hepatology at Scripps Clinic and the principal investigator of the study. "A safe, easily tolerated alternative such as AST-120 would be of great benefit in the management of these patients."

The ASTUTE Trial ("AST-120 Use for the Treatment of Hepatic Encephalopathy") is a Phase 2 multi-site, randomized, double-blind, placebo-controlled 8-week study in up to 150 patients with MHE. Patients will be evaluated on neurocognitive improvement at the end of the study, defined as the change in the global summary score of the RBANS or Repeatable Battery for the Assessment of Neuropsychological Status.

"The ASTUTE trial will use a battery of neuropsychometric tests to assess the efficacy of AST-120 in an MHE population," said Scott Harris, M.D., Ocera's chief medical officer, "Up to 60 percent of patients with cirrhosis have MHE and impaired neurocognitive function, a condition for which no drugs are approved."

About AST-120

AST-120 is a novel microspherical carbon adsorbent with a selective adsorption profile for a variety of unwanted substances in the digestive tract. These substances may be responsible for a number of conditions, including Hepatic Encephalopathy (HE), Irritable Bowel Syndrome (IBS), and pouchitis. They include ammonia, indoles (serotonin, octopamine), histamine, secondary bile acids,

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advanced glycation endproducts (AGE), and certain bacterial toxins. Ocera licensed the compound from the Kureha Corporation (Japan) in 2005.

About Ocera Therapeutics, Inc.

Ocera Therapeutics, based in San Diego, California, USA, is a privately held biopharmaceutical company focused on the development and commercialization of proprietary compounds to treat acute and chronic liver diseases and a broad range of gastrointestinal disorders. In addition to AST-120, Ocera is developing OCR-002 in hepatic encephalopathy due to complications of cirrhosis and acute liver failure. Ocera has raised $62.5 million dollars in venture financing from Domain Associates, Sofinnova Ventures, Thomas, McNerney & Partners, Montagu Newhall and InterWest Partners.

Source: Ocera Therapeutics, Inc

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