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**Ocera Therapeutics, Inc. Completes Enrollment in *FHAST*<sup>1</sup>, a Pivotal Phase 3  
Clinical Trial in Fistulizing Crohn's Disease**

San Diego, CA, October 8, 2007 – Ocera Therapeutics, Inc., a privately-held biopharmaceutical company focused on the development and commercialization of proprietary compounds to treat gastrointestinal and liver diseases announced today that it has completed the patient enrollment of its Phase 3 study in fistulizing Crohn's disease. This pivotal, double-blind, placebo controlled study, *FHAST*<sup>1</sup> (Fistula Healing with AST-120), has been designed to determine the efficacy and safety of oral AST-120 in 240 patients with Crohn's disease suffering from perianal fistulas. Initial data from the trial will be available in the first quarter of 2008.

"We are very pleased to have completed the enrollment in our *FHAST*<sup>1</sup> pivotal trial evaluating AST-120 in a timely manner," stated Laurent Fischer, M.D., President and CEO of Ocera Therapeutics. "We would like to thank our investigators and patients in North America, Europe and Israel for their participation in the study."

Data from a double blind, placebo controlled Japanese study of AST-120 in fistulizing Crohn's disease sponsored by Kureha and presented at the Digestive Disease Week in May 2006 demonstrated that AST-120 significantly reduces draining fistulas compared to placebo.

"Up to one third of patients with Crohn's disease suffer from draining perianal fistulas, a chronic and debilitating condition that significantly affects their quality of life," said Professor Stephen Hanauer, M.D., Director of the Section of Gastroenterology and Nutrition at the University of Chicago and the Principal Investigator in the study. "Despite effective treatments, there is an unmet need for new and well-tolerated oral agents for patients with mild to moderate Crohn's disease who suffer from fistulas."

"We were pleased to participate in this Phase 3 trial evaluating the efficacy and safety of AST-120, a new oral treatment option, in fistulizing Crohn's disease," added Professor Simon Travis, M.D., Clinical Director of Gastroenterology and Endoscopy at John Radcliffe Hospital, Oxford and the lead investigator in Europe.

Ocera also recently announced the initiation of Phase 2 trials with AST-120 in Irritable Bowel Syndrome and Hepatic Encephalopathy. AST-120 is an oral agent known to adsorb bile acids, toxins and mediators of inflammation from the gastrointestinal tract with the potential to address multiple gastrointestinal diseases. Ocera in-licensed AST-120 from Kureha Corporation based in Tokyo, Japan. AST-120 is not absorbed in the gut and is

marketed in Japan and Korea for chronic kidney disease, where it has been used in more than 200,000 patients.

### **About FFAST<sup>1</sup>**

Fistula Healing With **AST-120** is a double-blind, placebo controlled pivotal Phase 3 trial evaluating the efficacy and safety of AST-120 for eight weeks in 240 patients. The primary efficacy endpoint of the study is the number of patients with at least a 50 percent reduction in the number of draining fistulas at both week four and week eight compared to the baseline. Secondary endpoints include changes in Crohn's Disease Activity Index (CDAI) and Perianal Disease Activity Index (PDAI), two markers of disease severity and quality of life. Ocera expects initial data to be released in the first quarter of 2008. Patients treated in the FFAST<sup>1</sup> study who respond to therapy are followed up for six months. In addition, patients who did not respond to the initial regimen have the opportunity to switch to the alternate treatment, ensuring that patients randomized to placebo who fail therapy can have access to AST-120.

For information on Ocera Therapeutics sponsored clinical trials, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Key word: **AST-120**.

### **About Crohn's Disease**

Crohn's disease is a chronic disorder that causes inflammation of the digestive tract that most commonly affects the small intestine and/or the colon. Some patients may develop tears in the lining of the intestine, which may cause pain and bleeding. Inflammation may also cause a fistula to develop. A fistula, a consequence of the inflammatory process, is a tunnel that leads from one loop of intestine to another, or that connects the intestine to the bladder, vagina, or skin. Fistulas occur most commonly around the anal area (perianal fistulas). More information on Crohn's disease can be found on the Crohn's and Colitis Foundation of America's website at [www.cffa.org](http://www.cffa.org).

### **About Ocera Therapeutics, Inc.**

Ocera Therapeutics, Inc. is a privately-held biopharmaceutical company focused on the licensing, development and commercialization of proprietary compounds to treat a broad range of gastrointestinal and liver diseases. Ocera Therapeutics is based in San Diego and is pursuing the development of AST-120 in Crohn's disease and other gastrointestinal and liver diseases including Pouchitis, Hepatic Encephalopathy, Irritable Bowel Syndrome and Proton Pump Inhibitor-resistant Gastroesophageal Reflux Disease. Ocera Therapeutics has raised \$26.5 million dollars in venture financing from Domain Associates, Sofinnova Ventures and Thomas, McNerney & Partners. Additional information on the Company can be found at [www.oceratherapeutics.com](http://www.oceratherapeutics.com).

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