January 5, 2017

Ocera Announces Successful Phase 1 Clinical Study of Orally-Administered OCR-002 in Patients with Cirrhosis

Data Support Feasibility of Oral OCR-002 as Maintenance Therapy for Patients with Hepatic Encephalopathy

Company Plans to Initiate Phase 2a in H1 2017 with New Optimized Tablet Formulation

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., Jan. 05, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced positive results from a Phase 1 clinical study of orally-administered OCR-002 (ornithine phenylacetate) in patients with cirrhosis. The Company is developing oral OCR-002 for chronic use to maintain remission of hepatic encephalopathy (HE), a neurocognitive disorder associated with serious liver disease.

"We are excited to report the findings showed favorable oral absorption and pharmacokinetics in the intended population," said Stan Bukofzer, M.D., Chief Medical Officer of Ocera. "This was the first study in which OCR-002 was delivered orally to patients with cirrhosis. We believe these data support our plan to study the administration of OCR-002 orally and chronically to patients with cirrhosis with the goal of keeping them stable in the outpatient setting."

In light of the insight gleaned from these results, Ocera plans to conduct a multi-dose Phase 2a study in cirrhotic patients using a tablet formulation to determine the steady-state PK and pharmacodynamics of OCR-002 over a range of doses. The Phase 1 study announced today used a liquid formulation. The Company expects to initiate the Phase 2a study in the first half of 2017.

Summary of Key Findings:

- OCR-002 was observed to be safe and well-tolerated across all treatment arms in the study.
- OCR-002 demonstrated absolute oral bioavailability of greater than 95% in the fasted state.
- Dosing under fed conditions delayed absorption slightly, lowered mean maximum concentration (Cmax) by 30-40% and reduced the absolute oral bioavailability to 75-80%. These data suggest the drug is potentially suitable to be taken conveniently at mealtime corresponding with when ammonia levels typically begin to rise in patients with HE.
- Plasma levels of the study drug and PAGN were similar when OCR-002 was dosed before and after the discontinuation of lactulose, a current standard of care for HE patients, indicating the study drug may be unaffected by its concomitant use. PAGN is the molecule formed from the combination of study drug with serum ammonia, and is excreted through the kidneys.
- Overall mean plasma exposure to study drug (AUC0-inf) was approximately 35-40% higher in Child-Pugh[1] C patients compared to Child-Pugh A patients, as expected given the greater impairment of liver function of Child-Pugh C patients. The Company believes that the higher plasma exposure is due to lower metabolism of the study drug by the severely impaired livers.

About the Phase 1 Orally-Available OCR-002 Study

The Phase 1 trial was an open-label, crossover study to determine the pharmacokinetics and the absolute oral bioavailability of OCR-002 in patients with varying degrees of cirrhosis. The study evaluated a single 5g dose of IV OCR-002, and single 5g doses of a liquid oral solution of OCR-002 administered across three treatment arms:

- Fasted while on lactulose
- Fed while on lactulose
- Fasted with discontinuation of lactose

About Hepatic Encephalopathy

Hepatic encephalopathy is a debilitating and progressive complication of liver cirrhosis or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation, and in its more severe form, stupor, coma and even death.

About Ocera

Ocera Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of OCR-002 (ornithine phenylacetate) in both intravenous and oral formulations. OCR-002 is an ammonia scavenger and has been granted orphan drug designation and Fast Track status by the U.S. Food and Drug Administration (FDA) for the treatment of hyperammonemia and resultant hepatic encephalopathy (HE) in patients with acute liver failure and acute-on-chronic liver disease.

Ocera's HE clinical development efforts also include a recently completed Phase 2b clinical trial, STOP-HE, which evaluated the safety and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized patients with elevated ammonia. Enrollment for the Phase 2b intravenous study was completed in December 2016, and the Company expects to publish top-line data of the STOP-HE study in the first quarter of 2017. For additional information, please see www.oceraine.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, without limitation, all statements related to the OCR-002 clinical development program, including but not limited to the potential benefits of OCR-002 to help patients with hepatic encephalopathy, the timing of clinical and enrollment milestones, and the timing of our clinical development plans and release of study data. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believe," "expected," "hope," "plan," "potential," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Ocera's current expectations. Forward-looking statements involve risks and uncertainties and Ocera's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including those risks and uncertainties discussed under the heading "Risk Factors" in Ocera's Annual Report on Form 10-K for the year ended December 31, 2015 and subsequent filings with the SEC. All information in this press release is as of the date of the release, and Ocera undertakes no duty to update this information unless required by law.

[1]Child-Pugh Scoring is a clinically relevant method of assessing the severity of liver impairment in patients with cirrhosis. A score, ranging from 5 (least severe) to 15 (most severe), is calculated by totaling the scores of five discrete variables: serum bilirubin, serum albumin, prothrombin time, ascites and encephalopathy. Scores of 5-6 are classified as Child-Pugh A (well compensated disease); scores of 10-15 are classified as Child-Pugh B (disease with significant functional compromise); and scores of 10-15 are classified as Child-Pugh C (decompensated liver disease).

Source: Ocera Therapeutics, Inc.

OCRX-G

Susan Sharpe
Ocera Therapeutics, Inc.
contact@oceraine.com
919-328-1109