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Ocera Therapeutics Announces Late-Breaker Abstract Accepted for Presentation at the AASLD Liver Meeting 2016

-- Encouraging Data from NIH-Sponsored Study of OCR-002 in the Treatment of Patients with Acute Liver Failure --

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., Oct. 24, 2016 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced that clinical data from STOP-ALF, a Phase 2a clinical trial to evaluate the **S**afety and **T**olerability of **O**rnithine **P**henylacetate (OCR-002) in patients with **A**cute **L**iver **F**ailure, will be presented in the late-breaking poster session at The Liver Meeting® 2016, the 67th Annual Meeting of the American Association for the Study of Liver Disease (AASLD), being held on November 11-15, 2016, in Boston, Massachusetts.

Key findings of this safety study reflected in the abstract include the following:

- No drug-related serious adverse events observed; all doses well-tolerated
- Therapeutic serum levels of phenylacetate (PAA) were achieved at infusion rates of OCR-002 20g/24h
- Therapeutic PAA levels appeared to result in considerable ammonia excretion in urine as phenylacetylglutamine (PAGN), the end product by which PAA clears the neurotoxin ammonia, even in patients with non-oliguric renal failure

"Hyperammonemia can lead to cerebral edema, and remains a significant cause of morbidity and mortality in patients with acute liver failure," commented William M. Lee, M.D., principal investigator of the study. "We are very excited by the results of this safety trial and hope further studies can be conducted to examine the potential for OCR-002 to help clear the high ammonia levels, and improve the outcome of these patients."

"We are very pleased this important study has been completed," said Stan Bukofzer, M.D., Chief Medical Officer of Ocera. "In light of the safety profile and tolerability of OCR-002 in this very ill patient population, we believe it could have potential in the management of Acute Liver Failure."

Additional details including the presentation abstract can be found on the AASLD website by clicking this link.

About STOP-ALF

The Phase 2a study was a multi-center, open-label study, conducted in two cohorts of patients diagnosed with acute liver failure. Patients were treated pursuant to one of four escalating dosing regimens of intravenously-administered OCR-002, an ammonia scavenger, which were advanced only after safety and certain pharmacokinetic data were reviewed. Cohort 1 was comprised of affected patients with minimal renal dysfunction (defined as serum creatinine ≤ 1.5 mg/dL and mean arterial pressure of > 65 mm Hg). Cohort 2 included affected patients with compromised renal function (defined as serum creatinine > 1.5 mg/dL and < 10 mg/dL with mean arterial pressure of > 65 mm Hg). Dose levels within the four regimens ranged from approximately 3.33 g/24h to 20 g/24h for up to 5 treatment days. 36 of 47 patients enrolled are considered evaluable having completed at least 72 hours of treatment. The study, ClinicalTrials.gov: NCT00518440, was conducted by the Acute Liver Failure Study Group, grant number U-01-58369, an NIH-sponsored network of university tertiary care liver transplant sites, with support and supply of study medication from Ocera.

About Acute Liver Failure (ALF)

Acute liver failure is a rare syndrome with a significant mortality rate affecting an estimated 2,000 previously healthy individuals annually in the U.S. ALF is a rapid deterioration of liver function, often due to acetaminophen and idiosyncratic drug reactions, resulting in the liver's inability to clear the circulating toxin Ammonia, which can lead to cerebral edema, intracranial hypertension, brainstem herniation and 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 include an ongoing Phase 2b clinical trial, STOP-HE, which is evaluating the safety and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized patients with elevated ammonia. The Company expects to complete enrollment in the STOP-HE trial in the fourth quarter of 2016 with top-line data to be published soon thereafter.

Concurrent with STOP-HE, Ocera is evaluating orally-available OCR-002 in a Phase 1 study in patients with cirrhosis as a chronic use option to maintain remission of HE. Results of part one of this study are expected to be published by the end of 2016 with part two expected to commence in the first half 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 clinical development of OCR-002, including but not limited to the potential benefits of OCR-002 to help patients with acute liver failure or hepatic encephalopathy, the timing of clinical and enrollment milestones, and the timing of completion of enrollment and availability 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.

The content of this announcement is the sole responsibility of the authors and does not necessarily represent the official views or imply endorsement of the NIH.

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