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Ocera Completes Enrollment of STOP-HE, a Phase 2b Study of OCR-002 in Hospitalized Patients with Hepatic Encephalopathy

Top-line Data Expected in First Quarter 2017

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., Dec. 07, 2016 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced it has completed enrollment in its Phase 2b STOP-HE **St**udy evaluating the efficacy, safety and tolerability of **O**rnithine **P**henylacetate (OCR-002) in hospitalized patients with **H**epatic **E**ncephalopathy (STOP-HE).

"This is a critical milestone for the Company," said Linda Grais, M.D., Chief Executive Officer of Ocera. "Hepatic encephalopathy (HE) is a serious and costly condition, causing increasing numbers of hospitalizations every year. The current standard of care is limited, and we believe that physicians are eager for more effective therapeutic options to help patients improve faster and return to their normal mental status."

"We anticipate that STOP-HE will deliver a rich source of global data from approximately 230 patients that should provide a greater understanding about the disease and its response to treatment, and inform the further development path of OCR-002," said Stan Bukofzer, M.D., Chief Medical Officer of Ocera. "We believe OCR-002 could become a first-line and foundational therapy for treating hospitalized patients with HE and expect to report top-line data in the first quarter of 2017."

STOP-HE Study Design

STOP-HE is a placebo-controlled, randomized, double-blind clinical trial designed to evaluate the safety, pharmacokinetics and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized cirrhotic patients with elevated ammonia. Either OCR-002 or placebo was administered to patients intravenously for up to five days along with standard of care. The OCR-002 arm was dosed with 20, 15, or 10 grams over 24 hours based on the patient's degree of liver impairment in order to normalize drug exposure. The primary efficacy endpoint is time to meaningful clinical improvement in HE symptoms as analyzed using a 0.05 level 2-sided log-rank test of equality of time to event curves with 80% power.

About Hepatic Encephalopathy (HE)

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 clinical development program also includes evaluation of orally-available OCR-002 in an ongoing 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.oceraинc.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, the timing of our clinical development plans and release of study data and the quality and quantity of data generated from our STOP-HE trial. 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.

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