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Ocera Initiates Phase 2a Study with Oral OCR-002 in Patients with Cirrhosis

Results Expected by Year-End 2017

REDWOOD CITY, Calif. and RESEARCH TRIANGLE PARK, N.C., June 01, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced the dosing of the first patients in Part Two of a Phase1/Phase 2a clinical trial of oral OCR-002 (ornithine phenylacetate). Oral OCR-002 is a validated ammonia scavenger in development for use as a step-down therapy and for chronic use to maintain remission of hepatic encephalopathy (HE), a neurocognitive disorder associated with serious liver disease.

The Phase 2a portion of the trial is an open-label, multiple-dose, randomized, 3-period crossover study. It is designed to evaluate the steady-state pharmacokinetics and pharmacodynamics of three times daily administration of three daily dose regimens, 6, 12 and 21 grams, of OCR-002 tablets in 18 patients with Child-Pugh[1] B cirrhosis. We expect to complete the trial and report top-line results by the end of 2017.

"Advancing oral OCR-002 into Phase 2a marks another significant milestone in the progression of our pipeline and programs for orphan and other serious liver diseases," said Linda Grais, Chief Executive Officer of Ocera.

"Patients with cirrhosis continue to have significant breakthrough episodes of HE, even with current standard of care for HE prevention. We are developing an oral formulation to address this need. Our initial focus will be as a step-down therapy for patients following hospitalization for an acute episode of overt HE, in order to prevent re-hospitalization and relapse of HE."

About the Part1/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 Child-Pugh[1] A and C 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 under various fasted and fed conditions.

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 showed a beneficial food effect.
- A well-characterized pharmacokinetic profile was established.

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 in patients with acute liver failure and acute-on-chronic liver disease. For additional information, please see www.oceraинc.com.

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 (IV) OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized patients with elevated ammonia. The Company is preparing to meet with the FDA later this year to review the IV OCR-002 program and discuss potential development paths forward. 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 our study results, our ability to identify a development path forward for IV OCR-002, and the timing and nature of our future clinical development plans. 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 the risk that we may need to conduct one or more additional studies in light of the fact our Phase 2b trial did not meet its clinical endpoints, including related cost and timing issues associated with future studies, if any, our ability to raise sufficient capital or consummate other strategic transactions to enable the continued development of OCR-002, and 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, 2016 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).

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