March 8, 2017

Ocera to Announce Additional Encouraging Results from its Phase 2b STOP-HE Study of IV OCR-002 in Patients with Hepatic Encephalopathy

IV OCR-002 statistically significantly normalized ammonia faster than standard of care

Ammonia reduction statistically significantly correlated with clinical improvement in HE symptoms

Ocera plans to meet with FDA in Q3 2017 to inform development paths forward for IV OCR-002

Company presentation scheduled for today, March 8, 2017 at 11:20 AM ET

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., March 08, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), a clinical stage biopharmaceutical company focused on acute and chronic orphan liver diseases, today announced it will report additional encouraging results from its Phase 2b STOP-HE study of intravenous (IV) OCR-002 in hospitalized patients with Hepatic Encephalopathy (HE) at the Cowen and Company 37th Annual Healthcare Conference at 11:20 AM Eastern Time today.

"Further analysis of the data from our STOP-HE trial confirms that OCR-002 rapidly and safely lowered ammonia and, importantly, the ammonia reduction correlated statistically with clinical improvement," said Linda Grais, M.D., Chief Executive Officer of Ocera. "With greater confidence, we believe the most relevant efficacy considerations likely include earlier timing of drug administration, measuring efficacy sooner after drug administration, and administering the appropriate and tolerable dose regimen of OCR-002. We look forward to discussing these data as well as Phase 3 development with FDA later this year."

"We are very encouraged by the additional study data indicating IV OCR-002 provided clinical benefit over placebo in other parameters as well, such as the Physician Overall Evaluation, Model for End-Stage Liver Disease (MELD) scores, and in renal function as measured by the change from baseline in Blood Urea Nitrogen (BUN) levels," said Stan Bukofzer, M.D., Chief Medical Officer of Ocera.

Initial STOP-HE results reported in January 2017 included:

- OCR-002 demonstrated a highly statistically significant reduction in ammonia levels over placebo, p=0.028;
- Higher doses (15g, 20g) showed strong evidence of benefit across multiple endpoints;
- Clinical improvement dose trend observed; responder rate increased as dose increased and was superior to placebo at all doses; and
- OCR-002 was safe and well-tolerated; higher doses had a lower percentage of deaths and life threatening adverse events compared to placebo

Additional results to be presented today include:

- Ammonia reduction correlates with clinical improvement, p=0.0006;
- Dose proportional response and pharmacokinetic data indicate some patients were under-dosed;
- Earlier timing of drug administration and efficacy assessment is important:
  - Patients who improve within 48 hours are discharged earlier than patients who do not improve within 48 hours;
  - Patients on OCR-002 are more likely to respond within 48 hours compared to placebo, p=0.026;
- Pre-defined measures of improvement were statistically significant: ammonia reduction, p=0.017 and Physician overall evaluation, p= 0.026;
- OCR-002 demonstrated improvement in the Model for End-Stage Liver Disease (MELD) scores, p=0.051; and
- OCR-002 showed improvement in renal function as measured by the change from baseline in Blood Urea Nitrogen (BUN) levels, p=0.04

A live webcast of the presentation will be available in the "Investors" section of Ocera's website, www.ocerainc.com. A replay of the presentation will be available for 60 days following the conference for those unable to listen live.

STOP-HE Study Design

STOP-HE was 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 231 hospitalized patients with liver cirrhosis and elevated serum ammonia (hyperammonemia). Either OCR-002 or placebo was administered to patients intravenously as a continuous infusion for up to five days along with standard of care. The OCR-002 arm was dosed with 10, 15 or 20 grams over 24 hours based on the patient's degree of liver impairment and modeling of OCR-002 metabolism, in addition to safety considerations in this high-risk patient population.

About Hepatic Encephalopathy

Hepatic encephalopathy (HE) is a debilitating and progressive complication of liver cirrhosis or liver failure, marked by increasing ammonia levels, mental changes including confusion, impaired motor skills, disorientation, and in its more severe form, stupor, coma and even death. HE is categorized as either covert or overt depending on the degree of neurocognitive impairment, with overt HE (OHE) typically precipitating the need for hospitalization. Patients frequently cycle from remission to recurrence following an initial overt episode. The number of OHE episodes appears to be directly linked to persistent neurological impairment and seems to be cumulative; thus the need to manage HE patients is vital. It is estimated that HE-related hospitalization costs exceed $7 billion[1] annually in the U.S. alone.

[1] Clinical Gastroenterology and Hepatology 2012; 10:1034-1041

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.

Ocera's HE clinical development efforts also include a recently completed Phase 1 clinical trial of an oral formulation of OCR-002 in patients with cirrhosis as a potential chronic use option to maintain remission of HE. The Company expects to initiate a multi-dose Phase 2a study of oral OCR-002, also in cirrhotic patients, 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 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 planned meeting with the FDA, our ability to identify a development path forward for OCR-002, whether any future studies of OCR-002 we may conduct will demonstrate similar results to our Phase 2b study, the timing of our planned Phase 2a study of the oral formulation of OCR-002 in cirrhotic patients, 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, as well as 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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