January 30, 2017

Ocera Announces Top-line Results for Phase 2b Study in Hepatic Encephalopathy

Primary and Secondary Endpoints Showed Trend and Dose-Related Clinical Benefit Although Not Statistically Significant

Ammonia Scavenger OCR-002 Demonstrated Statistically Significant Reduction in Ammonia Levels

OCR-002 Was Safe and Well-Tolerated

Management to Host Conference Call and Webcast Today at 8:30 a.m. ET

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., Jan. 30, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced top-line results from its exploratory STOP-HE Phase 2b **St**udy evaluating the efficacy, safety and tolerability of intravenously-administered **O**rnithine **P**henylacetate (OCR-002) in hospitalized patients with **H**epatic **E**ncephalopathy (HE). Although not statistically significant, OCR-002 demonstrated a 17-hour reduction over placebo (47 *versus* 64 hours, respectively) for the primary endpoint, which was time to improvement in HE symptoms, p=0.129, hazard ratio 1.25. In addition, OCR-002 demonstrated a 15-hour reduction over placebo (87 *versus* 102 hours, respectively) for the secondary endpoint, which was median time to complete response in HE symptoms, p=0.361, hazard ratio 1.16. Consistent with its mechanism of action, OCR-002 exhibited a statistically significant reduction over placebo for the study's pre-specified exploratory endpoint which was time to achieve normal plasma ammonia levels, p=0.028, hazard ratio 1.69.

"This is a key milestone for Ocera: the results confirmed that OCR-002 rapidly and safely lowered ammonia and showed a dose-related clinical benefit," said Linda Grais, M.D., Chief Executive Officer of Ocera. "The patients at the higher doses (15 and 20 grams) had faster clinical improvement and greater complete response rates compared to the patients on the lowest dose (10 grams) and those on placebo. These findings will be integral in determining dose levels for future studies. We want to thank the patients and their families, caregivers and investigators for their support and participation in STOP-HE."

"Initial analysis shows that a higher percentage of patients respond as the dose of OCR-002 increases, notwithstanding that the clinical endpoints did not reach statistical significance," said Stan Bukofzer, M.D., Chief Medical Officer of Ocera. "This dose-response direction was also observed for the highly statistically significant ammonia reduction. Moreover, the safety profile shows no safety signal for OCR-002 compared to placebo. At the highest drug doses, there were favorable differences compared to placebo in the frequency of deaths and serious life threatening safety events. We expect further exploratory analyses will provide additional clarity for our goal of advancing intravenous OCR-002 into Phase 3 development."

Robert S. Rahimi, M.D., MSCR, Transplant Hepatologist at Baylor Scott and White Health Care System and a lead investigator of the STOP-HE study, commented, "OCR-002 showed important benefit over the standard of care (a decades-old laxative) which could allow for a significant shift in the treatment paradigm. I'm equally excited about Ocera's companion tablet form of the drug in development for chronic use. I believe OCR-002 could be a game changer in the management of HE," added Dr. Rahimi.

Summary of Other Key Findings:

	OCR-002 (Doses)					
Plasma Ammonia µmol/L	**≤10g**	**15g**	**20g**	**Total**	**Placebo**	**p-value^**
Median Change from Baseline to 3 hours post end-of-infusion	-19.3	-28.4	-38.9	-30.8	-11.8	0.017
Median Change from Baseline in Time Normalized AUC	-15.5	-24.2	-28.8	-22.8	-4.4	<0.001

- Clinical response at 3 hours post end-of-infusion (responder analysis): OCR-002 64%, placebo 55%, p=0.149
- Median time to hospital discharge: no statistically significant difference

- OCR-002 was observed to be safe and well-tolerated at all dose levels evaluated
- Fewer deaths occurred in the OCR-002 arm (11) *versus* placebo (15)

^Comparison of placebo and total OCR-002 based on Van Elteren test
Time to event analysis based on log-rank test; all tests two-tailed

Ocera plans to submit the detailed results from this Phase 2b study for presentation at a future scientific conference or in a journal publication.

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 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. The condition 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

Conference Call and Webcast Details

The Ocera management team will host a conference call and webcast today, Monday, January 30, 2017, at 8:30 a.m. Eastern Time, to discuss the top-line Phase 2b STOP-HE results and future development plans for OCR-002 in hepatic encephalopathy. The conference call can be accessed by dialing 877-312-5502 toll-free in the U.S., and 253-237-1131 for participants outside the U.S. The conference ID number is 55441119. A live webcast of the conference call, along with reference slides, will also be available online from the investor relations events page of the Company's website at www.oceraInc.com.

A replay of the event will be available approximately one hour after completion and will be archived on the Company's website for approximately 90 days following the event.

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 1 clinical trial 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, also in cirrhotic patients, in the first half of 2017. For additional information, please see www.oceraInc.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 release of additional clinical data 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, 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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