October 20, 2017

Ocera Presents Three Posters and an Oral Presentation on OCR-002 at the AASLD Liver Meeting®

REDWOOD CITY, Calif. and RESEARCH TRIANGLE PARK, N.C., Oct. 20, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced that clinical study findings of OCR-002 (ornithine phenylacetate) in development for the treatment and prevention of hepatic encephalopathy (HE) will be presented at The Liver Meeting® 2017, the 68th Annual Meeting of the American Association for the Study of Liver Disease (AASLD), October 20-24, 2017, at the Washington Convention Center in Washington, D.C. Select findings from each presentation are cited below.

Poster Presentations:

- ***Session:*** *Complications of Cirrhosis I*
- ***Session Date and Time:*** *October 20, 2017 from 8:00 AM to 5:30 PM ET*
- ***Location:*** *Hall D*

"STOP-HE: A Randomized, Double-blind, Placebo-controlled Study of OCR-002 in Patients with Hepatic Encephalopathy" - Publication Number: 502; Select findings include:

- The study demonstrated that OCR-002 reduced time to improvement in cirrhotic patients hospitalized with HE and elevated baseline ammonia, compared to placebo + standard of care (SOC) (p=0.034).
- The study confirmed the mechanism of action (MOA) of OCR-002 as an ammonia scavenger.
- Patients on OCR-002 normalized their ammonia faster than patients on placebo, which correlated with faster clinical improvement.
- The data support further study of OCR-002 as a new treatment option for patients hospitalized with overt HE.

"Geographic Differences for Patients Enrolled in STOP-HE: A Randomized, Phase 2 Study of OCR-002 for Hepatic Encephalopathy" - Publication Number: 499; Select findings include:

- In STOP-HE, differences were observed between patients enrolled in North America and Rest of World for baseline characteristics, severity of liver disease, use of concomitant medications and use of SOC treatments.
- Further study is needed to explore these differences more thoroughly.
- Geographic differences should be considered when designing clinical trials in patients with HE in order to avoid any bias.

"An Open-Label Crossover Study of the Pharmacokinetics of Ornithine Phenylacetate (OCR-002) after IV and Oral Doses in Subjects with Cirrhosis" - Publication Number: 501; Select findings include:

- Phenylacetate was rapidly absorbed and almost completely bioavailable (≥95%) from oral doses of OCR-002 in subjects with cirrhosis.
- Single oral and intravenous doses of 5g OCR-002 are well tolerated in cirrhotic subjects with Child Pugh A and C classification[1].
- The prolonged plasma half-life of PAA in cirrhotic subjects may allow reduced dosing frequency of oral OCR-002.
- Results of this study support the rationale for the development of an oral formulation of OCR-002 for reducing ammonia levels in cirrhotic patients.

Oral Presentation:

- ***Parallel 33:*** *Portal Hypertension: Risk Assessment and Treatment*
- ***Session Date and Time:*** *October 23, 2017 from 3:00 PM to 4:30 PM ET*
- ***Presentation Time:*** *3:30 PM to 3:45 PM ET*
- ***Location:*** *Room 207*

"OCR-002 (Ornithine Phenylacetate) is a Potent Ammonia Scavenger as Demonstrated in Phase 2b STOP-HE Study" - Publication Number: 219; Select findings include:

- Findings from STOP-HE confirm the MOA of OCR-002 as a potent ammonia scavenger.
- OCR-002 use in cirrhotic patients hospitalized with HE reduced plasma ammonia levels to a greater extent than placebo and SOC.
- OCR-002 reduced ammonia levels faster than placebo and SOC.
- OCR-002 led to faster clinical improvement than placebo and SOC.
- Results from this study will be used for study design for continued OCR-002 development.

"We are very pleased to have several presentations at AASLD highlighting the potential for OCR-002," said Linda Grais, M.D., CEO of Ocera. "We look forward to the data from our oral Phase 2a study later this year and to advancing the i.v. program following our upcoming meetings with the FDA."

"OCR-002 holds the promise for these acutely ill patients for which there is no direct ammonia scavenger approved by the FDA to treat them," said Professor Rajiv Jalan, M.B.B.S, M.D. Ph.D. "In a recent study conducted by my team evaluating cirrhotic patients with acute decompensation, we found that elevated ammonia left unchecked or allowed to rise is not only correlated with HE severity but is an independent predictor of mortality[2]."

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 (i.v.) 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 a recently completed Phase 2b clinical trial, STOP-HE, which evaluated the safety and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized patients with elevated ammonia. Ocera is preparing to meet with FDA later this year to review the i.v. program and discuss potential development paths forward.

Ocera is currently evaluating its oral tablet form of OCR-002 in a Phase 2a study in patients with cirrhosis as a chronic use option to maintain remission of HE. Results of this study are expected to be published by the end 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, 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).

[2] AASLD 2017 Publication Number 503 — "Ammonia is an important determinant of mortality in patients with acute deterioration of cirrhosis". Shalimar[2], Mohammed Sheikh[1], Rajeshwar Mookerjee[1], Banwari Agarwal[3], Rajiv Jalan[1]; [1]Institute of Liver and Digestive Health, University College London, London, United Kingdom; [2]Department of Gastroenterology, All India Institute of Medical Sciences, Delhi, India; [3]Intensive Care Department, Royal Free Hospital, London, United Kingdom.

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