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Ocera Therapeutics Announces Presentation of Data Showing OCR-002 Prevented Progression of Fibrosis in Preclinical Model of Non-alcoholic Fatty Liver Disease (NAFLD)

Supports potential for OCR-002 in the treatment of NAFLD/NASH

Data to be presented at The International Liver Congress™ 2017 of the European Association for the Study of the Liver (EASL)

PALO ALTO, Calif. and RESEARCH TRIANGLE PARK, N.C., April 12, 2017 (GLOBE NEWSWIRE) -- Ocera Therapeutics, Inc. (NASDAQ:OCRX), a clinical stage biopharmaceutical company focused on acute and chronic orphan liver diseases, today announced that data from an investigator-sponsored preclinical study of Ocera's validated ammonia scavenger, ornithine phenylacetate (OCR-002), will be presented in a poster session at The International Liver Congress™ of the European Association for the Study of the Liver (EASL 2017) in Amsterdam, The Netherlands, on Thursday, April 20, 2017.

The study investigated the effect of OCR-002 in a NAFLD rat model in which animals were fed a High Fat and High Cholesterol (HFHC) diet for up to 16 weeks. Compared to normal rats, NAFLD rats showed a significant increase in ammonia ($p<0.05$), as well as increased blood levels of cholesterol, ALT and AST. The NAFLD rats treated with OCR-002 showed significant reduction in the progression of fibrosis compared to untreated NAFLD rats. Moreover, OCR-002 substantially reduced:

- Liver / Body weight ratio
- Hepatic lipid content, and
- Hepatic collagen

In prior clinical trials, OCR-002 has been demonstrated to work in humans by conjugating its phenylacetate moiety with glutamine (which contains ammonia) to form phenylacetylglutamine (PAGN), which is then excreted through the kidneys. In some animal models, phenylacetate also combined with glycine to form phenylacetylglycine (PAG), also excreted in the urine. In the OCR-002 treated NAFLD rats, high levels of PAGN and PAG were observed, indicating the mechanism of action of OCR-002.

"We are again excited to see evidence of OCR-002's ability to target ammonia in hyperammonemia-related indications that in turn drives clinical improvement," said Stan Bukofzer, M.D., Ocera's Chief Medical Officer. "In our recently completed STOP-HE Phase 2b study in patients hospitalized with acute hepatic encephalopathy (HE), OCR-002 demonstrated a highly statistically significant correlation between rapid reduction of the neurotoxin ammonia, and improvement in the neurocognitive symptoms of HE ($p=0.0006$). The preclinical study to be presented at EASL demonstrated the impact of OCR-002 in a NAFLD model and its corresponding ability to significantly reduce the progression of fibrosis, adding to our belief that OCR-002 may have broad potential to treat ammonia-driven complications."

Professor Rajiv Jalan, M.B.B.S, M.D. Ph.D., whose group performed the research at UCL said, "The data provide further proof that ammonia is more than just a neurotoxin and establishes ammonia as a therapeutic target for the prevention of progression of non-alcoholic fatty liver disease. As OCR-002 is already in advanced stages of clinical development, these data can readily be translated into real benefits for patients with appropriate clinical trials."

The poster abstract can be accessed by poster number Thu-389 via the congress website at: https://events.easl.eu/EventProgramme/ILC2017/POSTER.aspx.

About NAFLD/NASH

Non-alcoholic fatty liver disease (NAFLD) comprises a wide spectrum of liver disease ranging from hepatic steatosis (i.e., the accumulation of fat in the liver) to non-alcoholic steatohepatitis (NASH) (i.e., liver inflammation and fibrosis) to advanced fibrosis and cirrhosis, resulting in increased mortality.

NAFLD is associated with a reduction in gene expression and activity of the urea cycle enzyme ornithine transcarbamylase (OTC). OTC reduction leads to hyperammonemia and the activation of hepatic stellate cells (HSCs), key cells involved in the development of hepatic fibrosis and its progression.

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 OCR-002 IV and Oral Formulations

OCR-002 is in development by Ocera in both an intravenous (IV) formulation as a potential treatment for hospitalized patients with acute HE, and in an oral formulation to potentially provide step-down therapy and as a chronic use option to maintain remission of HE in patients with cirrhosis. The Company expects to meet with the Food and Drug Administration (FDA) in the third quarter of 2017 to discuss the recently completed Phase 2b study (STOP-HE) findings of IV OCR-002 and its potential paths forward. In addition, Ocera plans to initiate enrollment in a Phase 2a multi-dose study of oral OCR-002 in cirrhotic patients this quarter with data expected by the end of 2017.

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. 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 potential benefits of OCR-002 to help patients with NAFLD/NASH, the timing of clinical and enrollment milestones, including the timing of Ocera's planned FDA meeting, the timing of initiation of Ocera's Phase 2a trial of oral OCR-002 and the timing of release of study data. 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, 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.

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