Conatus Pharmaceuticals Announces Publications Expanding on Previously Reported Results from Completed Phase 2 NAFLD-NASH, Portal Hypertension and Liver Cirrhosis Clinical Trials

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SAN DIEGO, Jan. 28, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced publications expanding on previously reported results from three of the company's completed Phase 2 clinical trials.

- Mitchell Schiffman, M.D., is the lead author on a new publication[1] in *Alimentary Pharmacology and Therapeutics* detailing results from the double-blind, placebo-controlled Phase 2 NAFLD/NASH clinical trial. This trial enrolled 38 patients with nonalcoholic fatty liver disease (NAFLD), including the subset of NAFLD patients with nonalcoholic steatohepatitis (NASH). Patients were randomized 1:1 to receive either 25 mg of emricasan or placebo orally twice daily for 28 days. Top-line results from the NAFLD/NASH clinical trial were released in March 2015 and presented at The International Liver Congress™, the annual meeting of the European Association for the Study of the Liver (EASL), in April 2015[2].

- Guadalupe Garcia-Tsao, M.D., is the lead author on a new publication[3] in *Hepatology* detailing results from the exploratory, open-label Phase 2 Portal Hypertension clinical trial. This trial enrolled 23 patients with portal hypertension and compensated liver cirrhosis that was predominantly due to NASH or hepatitis C virus (HCV), including patients with active HCV infection and patients who had a sustained viral response to antiviral therapy. Patients received 25 mg of emricasan orally twice daily for 28 days. Top-line results from the Portal Hypertension clinical trial were released in September 2015 and presented at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in November 2015[4].

- Catherine Frenette, M.D., is the lead author on a new publication[5] in *Clinical Gastroenterology and Hepatology* detailing results from the Phase 2 Liver Cirrhosis trial. This trial enrolled 86 patients with liver cirrhosis, mild to moderate liver impairment and a Model for End-stage Liver Disease (MELD) score of 11 to 18 during the screening period. In the first phase of the trial, patients were randomized 1:1 to receive 25 mg of emricasan or placebo orally twice daily for 28 days. Top-line results from the first stage were released in January 2016 and presented at the EASL annual meeting in April 2016. In the open-label second stage, patients who completed the first stage of the trial, either on treatment or placebo, received emricasan for up to an additional three months. Top-line results from the second stage were released in May 2016 and presented at the AASLD annual meeting in November 2016[6].

"The results from this series of Phase 2 clinical trials led to the design of the three Phase 2b ENCORE clinical trials for NASH patients with liver fibrosis or cirrhosis," said David T. Hagerty, M.D., Executive Vice President of Clinical Development at Conatus. "We believe the aggregate data from the ENCORE trials will support discussions regarding the further development of emricasan."

Emricasan Clinical Development

In collaboration with Novartis, Conatus is conducting three randomized, double-blind, placebo-controlled Phase 2b clinical trials, the EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) trials, designed to evaluate emricasan in patients with fibrosis or cirrhosis caused by NASH:

- ENCORE-NF (for NASH Fibrosis), initiated in the first quarter of 2016, in approximately 330 patients with NASH fibrosis, with top-line results expected in the first half of 2019;

- ENCORE-PH (for Portal Hypertension), for which top-line results were announced in December 2018, has an ongoing six-month extension with 48-week liver function and clinical outcome results expected in mid-2019; and

- ENCORE-LF (for Liver Function), initiated in the second quarter of 2017, in approximately 210 patients with decompensated NASH cirrhosis, with top-line results expected in mid-2019.

About Conatus Pharmaceuticals
Conatus is a biotechnology company focused on the development of novel medicines to treat liver disease. In collaboration with Novartis, Conatus is developing its lead compound, emricasan, for the treatment of patients with chronic liver disease. For additional information, please visit www.conatuspharma.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding: the potential for the aggregate data from the ENCORE trials to support discussions regarding the further development of emricasan; the timeline for results from the ENCORE trials; and caspase inhibitors' potential to interrupt the progression of a variety of diseases. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates,"

“believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including: the potential that further analysis of the data described herein or additional data may yield different results; results of future clinical trials of emricasan; the potential for competing products to limit the clinical trial enrollment opportunities for emricasan in certain indications; the uncertainty of the U.S. Food and Drug Administration’s and other regulatory agencies’ approval processes and other regulatory requirements; and those risks described in the company’s prior press releases and in the periodic reports it files with the Securities and Exchange Commission. The events and circumstances reflected in the company’s forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

[1] Schiffman M *et al*. Randomised clinical trial: emricasan versus placebo significantly decreases ALT and caspase activation in subjects with non-alcoholic fatty liver disease. *Aliment Pharmacol Ther*. 2019;49:64-73. DOI: 10.1111/apt.15030.

[2] Shiffman M *et al*. A placebo-controlled, multicenter, double-blind, randomised trial of emricasan (IDN-6556) in subjects with non-alcoholic fatty liver disease (NAFLD) and raised transaminases. Poster presented at EASL April 2015. Poster #LP37.

[3] Garcia-Tsao G *et al*. Emricasan (IDN-6556) Lowers Portal Pressure in Patients with Compensated Cirrhosis and Severe Portal Hypertension. *Hepatol*. 2018. DOI: 10.1002/hep.30199.

[4] Garcia-Tsao G *et al*. Emricasan (IDN-6556) administered orally for 28 days lowers portal pressure in patients with compensated cirrhosis and severe portal hypertension. Late-breaking oral presentation at AASLD November 2015. Presentation #LB6.

[5] Frenette, CT *et al*. Emricasan Improves Liver Function in Patients With Cirrhosis and High Model for End-stage Liver Disease Scores Compared With Placebo. *Clin Gastroenterol Hepatol*. 2018. DOI: 10.1016/j.cgh.2018.06.012.

[6] Frenette C *et al*. Emricasan (IDN-6556) orally for three months in patients with cirrhosis and MELD scores 11-18 improves clinical parameters of cirrhosis in patients with baseline MELD score ≥15. Late breaker oral presentation at EASL April 2016. Presentation #LBO5.

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