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Conatus Announces Completion of Enrollment in ENCORE-LF Phase 2b Clinical Trial of Emricasan in Patients with Decompensated NASH Cirrhosis

SAN DIEGO, Feb. 12, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced the completion of enrollment in ENCORE-LF, a Phase 2b clinical trial evaluating emricasan, the company's first-in-class, orally-active pan-caspase inhibitor.

"With screening in the ENCORE-LF clinical trial complete, we remain on track for clinical events as announced last quarter, with top-line results expected in mid-2019," said David T. Hagerty, M.D., Executive Vice President of Clinical Development at Conatus. "We sincerely appreciate the participation of these advanced liver disease patients and their contributions to the development of emricasan to address a serious and largely unmet medical need."

The ENCORE-LF clinical trial is designed to evaluate safety, dosing and efficacy of emricasan in patients with decompensated NASH cirrhosis as an integral part of the company's initial registration strategy. The double-blind, placebo-controlled, trial is being conducted at approximately 90 U.S. clinical sites in approximately 210 patients with nonalcoholic steatohepatitis (NASH) who have stable decompensated liver cirrhosis. Patients were randomized 1:1:1 to receive 5 mg of emricasan, 25 mg of emricasan, or placebo twice daily for at least 48 weeks. The primary endpoint is event-free survival, which is a composite of all-cause mortality, new decompensation events, or Model for End-stage Liver Disease (MELD) score progression ≥4 points. Analysis of the primary endpoint will be triggered upon reaching a prespecified target number of events. An additional analysis is planned after all patients have completed at least 48 weeks of dosing.

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-LF (for Liver Function) with top-line results expected in mid-2019 as described above;
- ENCORE-NF (for NASH Fibrosis) with top-line results after 72 weeks of treatment for approximately 330 patients with NASH fibrosis expected in the first half of 2019; and
- ENCORE-PH (for Portal Hypertension) with top-line results after 24 weeks of treatment for 263 patients with NASH cirrhosis and severe portal hypertension announced in the

fourth quarter of 2018, and results after 48 weeks of treatment for patients opting to continue 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. Emricasan is a first-in-class, orally active pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Conatus believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases. 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 details of and the timelines to announce results from the ENCORE-LF, ENCORE-NF and ENCORE-PH clinical 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 those risks described in Conatus’ prior press releases and in the periodic reports it files with the Securities and Exchange Commission. The events and circumstances reflected in Conatus’ 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, Conatus 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.

CONTACT: Alan Engbring
Conatus Pharmaceuticals Inc.
(858) 376-2637
aengbring@conatuspharma.com

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