Conatus Announces Top-line Results from ENCORE-NF Phase 2b Clinical Trial in NASH Fibrosis

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Shortfall on Primary Endpoint Shifts Focus for Emricasan to Ongoing NASH Cirrhosis Trials

SAN DIEGO, March 21, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced top-line results from the company's Phase 2b ENCORE-NF clinical trial in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) and liver fibrosis. The trial's primary endpoint was a ≥1 CRN fibrosis stage improvement with no worsening of steatohepatitis compared with placebo at week 72.

"Although emricasan did not have the desired effect in these earlier-stage NASH fibrosis patients, we believe its demonstrated biomarker activity across a broad spectrum of liver disease warrants continued evaluation in more advanced-stage NASH cirrhosis patients," said Steven J. Mento, Ph.D., President, Chief Executive Officer and co-founder of Conatus. "We look forward to seeing the additional data readouts expected over the coming months and reviewing the totality of these results with our collaborators at Novartis to determine the most appropriate path forward."

Consistent with safety results from 18 previously completed clinical trials, emricasan was generally well-tolerated in the ENCORE-NF clinical trial.

David T. Hagerty, M.D., Executive Vice President of Clinical Development at Conatus, said, "We are most grateful to the NASH fibrosis patients, principal investigators, clinical site staffs and the support teams who participated in the ENCORE-NF clinical trial."

About Emricasan
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. To date, emricasan has been studied in more than 950 patients in 19 completed clinical trials across a broad range of liver diseases. In NASH cirrhosis patients in multiple Phase 2 clinical trials, emricasan has demonstrated clinically meaningful reductions in severe portal hypertension, improvements in measures of liver function, and evidence of an anti-fibrotic treatment effect, as well as rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death, which play a role in the severity and progression of liver disease.

About ENCORE-NF
The randomized, double-blind ENCORE-NF Phase 2b clinical trial, initiated in the first quarter of 2016, enrolled and treated 318 patients with biopsy-confirmed NASH CRN fibrosis stages F1-F3 at baseline. Patients were randomized 1:1:1 to receive 5 mg of emricasan, 50 mg of emricasan, or placebo twice daily for 72 weeks. The trial was conducted at 87 U.S. and EU sites.

About Emricasan Clinical Development
ENCORE-NF is one of three randomized, double-blind, placebo-controlled Phase 2b clinical trials conducted by Conatus in collaboration with Novartis, 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) in approximately 210 patients with decompensated NASH cirrhosis, initiated in the second quarter of 2017, is advancing toward an event-driven analysis of clinical outcome results expected in mid-2019.
- ENCORE-PH (for Portal Hypertension) in 263 patients with NASH cirrhosis and severe portal hypertension, initiated in the fourth quarter of 2016, with top-line results after 24 weeks of treatment announced in the fourth quarter of 2018, is completing a six-month extension with liver function and clinical outcome results after 48 weeks of treatment expected in mid-2019.

Conatus and Novartis expect to evaluate the totality of data available from the ENCORE trials to determine the potential for further development of emricasan.

About Conatus Pharmaceuticals
Conatus is a biotechnology company focused on the development and commercialization of novel medicines to treat chronic diseases with significant unmet need. In collaboration with Novartis, Conatus is developing its lead in-licensed compound, emricasan, for the treatment of patients with NASH-driven chronic liver diseases. Conatus is independently developing its lead internally developed compound, CTS-2090, for the treatment of patients with chronic diseases involving inflammasome pathways. 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: a path forward for emricasan; and the timelines to announce results from the ENCORE clinical trials. 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: reported top-line results are based on preliminary analysis of key data and as a result, such top-line results may change following a more comprehensive review and may not accurately reflect the complete results of the clinical trial; Conatus' ability to successfully enroll patients in and complete its ongoing clinical trials; Novartis continuing development and commercialization of emricasan; the uncertainties inherent in the clinical drug development process, including, the potential for additional negative or confounding results for emricasan; Conatus' reliance on third parties to conduct its clinical trials, including the enrollment of patients, and manufacture its clinical drug supplies of emricasan; potential adverse side effects or other safety risks associated with emricasan that could delay or preclude its approval; results of future clinical trials of emricasan; and 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.

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