June 24, 2019

Conatus Announces Results from ENCORE-LF and ENCORE-PH Phase 2b Clinical Trials in NASH Cirrhosis

SAN DIEGO, June 24, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced that top-line results from the company's ENCORE-LF clinical trial of emricasan did not meet its primary endpoint and the company is discontinuing further treatment of patients enrolled in the ENCORE-LF clinical trial. Also, results from the 24-week extension in the company's ENCORE-PH clinical trial of emricasan were consistent with results from the initial 24-week treatment period and did not meet predefined objectives. Conatus will continue to work with its partner Novartis on ensuring that all remaining obligations related to the emricasan program are fulfilled.

The randomized, double-blind ENCORE-LF Phase 2b clinical trial, initiated in the second quarter of 2017, enrolled 217 patients with decompensated NASH 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 trial was conducted at 73 U.S. sites. The trial's primary endpoint was event-free survival, which was defined as a composite of all-cause mortality, new decompensation events, or ≥4 points progression in Model for End-stage Liver Disease (MELD) score. The primary analysis was conducted after reaching an overall target number of events and showed no statistically significant differences in event rates between the treatment and placebo arms and no clear trends indicating a potential treatment effect.

The randomized, double-blind ENCORE-PH Phase 2b clinical trial, initiated in the fourth quarter of 2016, enrolled 263 NASH patients with compensated or early decompensated liver cirrhosis and severe portal hypertension confirmed by hepatic venous pressure gradient (HVPG) of ≥12 mmHg at baseline. Patients were randomized 1:1:1:1 to receive 5 mg of emricasan, 25 mg of emricasan, 50 mg of emricasan, or placebo twice daily for 24 weeks. The trial was conducted at 75 U.S. and EU sites. As announced in December 2018, the trial failed to meet its primary endpoint – change in mean hepatic venous pressure gradient (HVPG) from baseline to Week 24 in any of three emricasan dosing groups compared with placebo. Patients enrolled in the ENCORE-PH clinical trial were allowed to continue treatment or placebo in a 24-week extension period to evaluate longer term safety, liver function and clinical outcomes. Results following the extension period were consistent with Week 24 results, showing no statistically significant differences between treatment and placebo arms and no clear trends indicating a potential treatment effect.

Consistent with safety results from 19 previously completed clinical trials, emricasan was generally well-tolerated in both the ENCORE-LF and ENCORE-PH clinical trials.

"We designed the ENCORE program to give emricasan an opportunity to achieve its potential through a series of clinical trials tailored to specific patient populations encompassing a broad range of chronic liver disease," said Steven J. Mento, Ph.D., President, Chief Executive Officer and co-founder of Conatus. "We are disappointed that

emricasan failed to meet the expectations established in prior preclinical and clinical studies, but confident that the ENCORE trials provided a fair evaluation of emricasan's lack of efficacy in these patient populations."

David T. Hagerty, M.D., Executive Vice President of Clinical Development at Conatus, said, "We offer sincere thanks to the patients, principal investigators, collaborators, service providers and investors who enabled the development of emricasan. We offer hope that the scientific and clinical communities will build on the knowledge gained from these efforts in their continued pursuit of new treatment alternatives for chronic liver disease."

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 remaining obligations related to the emricasan program. 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; 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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Source: Conatus Pharmaceuticals Inc.