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Conatus Announces Completion of Enrollment in ENCORE-NF Phase 2b Clinical Trial of Emricasan in Patients with NASH Fibrosis

SAN DIEGO, Aug. 14, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced the completion of enrollment in ENCORE-NF, a randomized, double-blind, placebo-controlled, Phase 2b clinical trial evaluating emricasan, the company's first-in-class, orally-active pan-caspase inhibitor, in approximately 330 patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) and stage 1 to 3 fibrosis using the NASH Clinical Research Network (CRN) Histologic Scoring System. This trial is designed to evaluate the long-term safety and efficacy of emricasan in patients with NASH fibrosis as well as support the initial registration focus in liver cirrhosis.

"We are pleased to have completed enrollment in the ENCORE-NF clinical trial in this highly competitive NASH fibrosis field," said David T. Hagerty, M.D., Executive Vice President of Clinical Development at Conatus. "We would like to thank the patients and the investigators who are participating in the trial, and all the study teams who helped us reach this important milestone. Emricasan's ability to improve both liver fibrosis and liver inflammation has been demonstrated in preclinical models of NASH, and we look forward to helping advance this novel product candidate to address the substantial unmet medical needs of NASH fibrosis patients."

The ENCORE-NF clinical trial is being conducted at approximately 100 U.S. and EU clinical sites. Patients were randomized 1:1:1 to receive 5 mg of emricasan, 50 mg of emricasan, or placebo twice daily for 72 weeks. The primary endpoint is a biopsy-based improvement in fibrosis by at least one stage vs. placebo using NASH CRN without worsening of steatohepatitis. Secondary endpoints include resolution of steatohepatitis without worsening of fibrosis, nonalcoholic fatty liver disease (NAFLD) activity score (NAS) and its components (steatosis, lobular inflammation, and ballooning), collagen and fat content by biopsy, key serum biomarkers, and health-related quality of life, as well as safety and tolerability.

Emricasan Clinical Development

In collaboration with Novartis, Conatus is conducting four randomized, double-blind, placebo-controlled Phase 2b clinical trials designed to evaluate emricasan treatment in various patient populations, including three in the EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) series in patients with fibrosis or cirrhosis caused by NASH, and a fourth in POLT-HCV-SVR patients:

- 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), initiated in the fourth quarter of 2016, in approximately 240 patients with compensated or early decompensated NASH cirrhosis and severe portal hypertension, with top-line results expected in 2018 followed by an integrated 6-month treatment extension period for clinical outcomes;
- 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 2019; and
- POLT-HCV-SVR, initiated in the second quarter of 2014, in approximately 60 post-orthotopic liver transplant (POLT) recipients with liver fibrosis or cirrhosis post-transplant as a result of recurrent HCV infection who have successfully achieved a sustained viral response (SVR) following HCV antiviral therapy, with top-line results expected in the first half of 2018.

Results from the four ongoing emricasan clinical trials are expected to support the design of Phase 3 clinical efficacy and safety trials.

About Conatus Pharmaceuticals
Conatus is a biotechnology company focused on the development and commercialization 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, ENCORE-PH and POLT-HCV-SVR clinical trials; the ability of results from ongoing trials to support the design of Phase 3 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.

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