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Conatus Announces Exercise of License Option for Global Development and Commercialization of Emricasan Following Notice of Initiation of Phase 2b ENCORE-LF Clinical Trial in NASH Cirrhosis

SAN DIEGO, May 04, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced that Novartis has exercised its option to an exclusive license for the global development and commercialization of emricasan, the company's first-in-class, orally-active pan-caspase inhibitor, under terms of the Option, Collaboration and License Agreement signed in December 2016. Subject to usual and customary conditions, including required anti-trust approvals, the license will become effective upon Conatus' receipt of a $7 million option exercise payment, expected in mid-2017. The option exercise by Novartis followed notification by Conatus of the initiation of the Phase 2b ENCORE-LF (for Liver Function) randomized, double-blind, placebo-controlled clinical trial evaluating emricasan in patients with decompensated liver cirrhosis caused by nonalcoholic steatohepatitis (NASH).

With the $50 million upfront payment received in December 2016, the $15 million received in exchange for a convertible promissory note issued to Novartis in February 2017, the anticipated $7 million option exercise payment, and Novartis sharing 50% of the costs of Conatus' four ongoing Phase 2b emricasan clinical trials after the license becomes effective, the company believes that current financial resources are sufficient to maintain operations and ongoing clinical development activities through the end of 2019. In addition, with the Novartis commitment to fund Phase 3 single agent emricasan development and all combination drug development activities, the company believes the resources are in place to complete emricasan development both as a single agent for NASH cirrhosis, and as a single agent or part of a combination drug therapy for NASH fibrosis.

Conatus is eligible to receive significant payments if certain clinical development, regulatory and commercial milestones are met, as well as tiered double digit royalties on emricasan single agent sales and tiered single to double digit royalties on sales of combination drug products containing emricasan. Conatus has the option to co-commercialize emricasan in the United States, including combination drug therapies, on a cost-sharing and revenue-sharing basis in lieu of U.S. royalties and with reduced ex-U.S. royalties.

"We are excited that Novartis has demonstrated its commitment to our collaboration with the timely exercise of its license option following the initiation of the ENCORE-LF clinical trial," said Conatus co-founder, President and Chief Executive Officer Steven J. Mento, Ph.D. "We believe this collaboration provides emricasan with its best opportunity to advance through the remaining development process toward making this novel treatment available to patients. We remain focused on the timely completion of our emricasan Phase 2b clinical development program, with expected data readouts beginning in the first half of 2018, and on rolling out independent pipeline development opportunities later in 2017 to build additional long-term value for our shareholders."

ENCORE-LF Clinical Trial

The ENCORE-LF clinical trial is expected to be conducted at approximately 90 clinical sites, and is designed to evaluate dosing, efficacy and safety of emricasan in approximately 210 patients with decompensated NASH cirrhosis. Patients will be 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 for each treatment group compared with the placebo group. For the purposes of the trial, events are defined as all-cause mortality, new decompensation events, or a progression of ≥4 points in the Model for End-stage Liver Disease (MELD) score. Key secondary endpoints include safety and tolerability, MELD and Child-Pugh scores, liver transplantation rates, liver metabolic function using the BreathID® Methacetin Breath Test, and health-related quality of life.

"With the initiation of ENCORE-LF, we believe emricasan is the only treatment candidate being evaluated in clinical trials in patients with both compensated and decompensated NASH cirrhosis," added Dr. Mento, "reflecting emricasan's demonstrated ability to improve both portal hypertension and liver function. With additional clinical trials in patients with NASH fibrosis and in liver transplant recipients with residual fibrosis and cirrhosis after clearance of their hepatitis C virus infections, we are exploring emricasan's broad potential in multiple segments of chronic liver disease with significant unmet medical need, using clinically relevant endpoints in four defined patient populations, any or all of which we believe could define potential pathways to registration."

Conatus is conducting three ongoing EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) clinical trials designed to

evaluate emricasan treatment in various NASH patient populations:

- ENCORE-LF, in decompensated NASH cirrhosis, with top-line results expected in 2019;
- ENCORE-NF (for NASH Fibrosis), a randomized, double-blind, placebo-controlled Phase 2b clinical trial, initiated in the first quarter of 2016, evaluating potential improvements in fibrosis and steatohepatitis in approximately 330 patients with NASH fibrosis. Based on anticipated completion of enrollment, top-line results after 18 months of twice-daily treatment with emricasan or placebo are now expected in the first half of 2019; and
- ENCORE-PH (for Portal Hypertension), a randomized, double-blind, placebo-controlled Phase 2b clinical trial, initiated in the fourth quarter of 2016, evaluating dosing, efficacy and safety of emricasan in approximately 240 patients with compensated or early decompensated NASH cirrhosis and severe portal hypertension. Conatus has amended the ENCORE-PH clinical trial protocol to integrate a six-month treatment extension period for clinical outcomes, rather than conduct a separate extension trial. Top-line results for the primary endpoint after the first six months of twice-daily treatment with emricasan or placebo are expected in 2018.

The company is conducting a fourth ongoing clinical trial in hepatitis C virus (HCV) patients:

- POLT-HCV-SVR, a randomized, double-blind, placebo-controlled Phase 2b clinical trial, initiated in the second quarter of 2014, evaluating potential improvements in fibrosis 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. Top-line results after two years of twice-daily treatment with emricasan or placebo are 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. Conatus is developing its lead compound, emricasan, for the treatment of patients with chronic liver disease. Emricasan is designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Conatus believes that by reducing the activity of these enzymes, emricasan has the potential to interrupt the disease progression across the spectrum of 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 option exercise payment being received by Conatus and the license becoming effective in mid-2017; the sufficiency of current financial resources and anticipated payments and expense reimbursements to maintain operations and ongoing clinical development activities through the end of 2019; the opportunity for the Novartis collaboration to make treatments available to patients; the details of and the timelines to announce results from the ENCORE-LF, ENCORE-NF, ENCORE-PH and POLT-HCV-SVR clinical trials; plans to announce pipeline development opportunities in 2017 and the ability of such opportunities to generate long-term value for shareholders; emricasan being the only candidate being evaluated for compensated and decompensated NASH cirrhosis patients; the ability of any of the four defined patient populations in the Phase 2b clinical trials to define pathways to registration; the possibility that results from ongoing trials will support the design of Phase 3 clinical trials; and emricasan's potential to interrupt the disease progression across the spectrum of liver disease. 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