Conatus Pharmaceuticals Reports First Quarter 2019 Financial Results and Program Updates

May 2, 2019

SAN DIEGO, May 02, 2019 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (Nasdaq:CNAT) today announced financial results for the first quarter ended March 31, 2019, and provided updates on its development programs.

Program Updates
The company is currently conducting two double-blind, placebo-controlled Phase 2b clinical trials in collaboration with Novartis – the EmricasaN, a Caspase inhibitOR, for Evaluation (ENCORE) trials, designed to evaluate emricasan, a first-in-class pan-caspase inhibitor, in patients with liver cirrhosis caused by nonalcoholic steatohepatitis (NASH).

- The ENCORE-LF (for Liver Function) clinical trial, initiated in the second quarter of 2017, has enrolled approximately 210 patients with stable decompensated NASH cirrhosis. The primary endpoint is event-free survival, which is a composite of all-cause mortality, new decompensation events, or ≥4 points progression in Model for End-stage Liver Disease (MELD) score. Enrollment was completed in the first quarter of 2019. Top-line results triggered by reaching a prespecified number of events are expected in mid-2019.

- The ENCORE-PH (for Portal Hypertension) clinical trial, initiated in the fourth quarter of 2016, enrolled 263 patients with compensated or early decompensated NASH cirrhosis and severe portal hypertension. The trial's primary endpoint was change in mean hepatic venous pressure gradient (HVPG) from baseline to Week 24 in any of three emricasan dosing groups compared with placebo. Top-line results were reported in December 2018 showing HVPG trends consistently favoring emricasan compared with placebo in the overall population but not meeting the primary endpoint. The greatest improvement was observed in patients with a baseline HVPG of 16 mmHg or higher.

  Week 24 results from the ENCORE-PH clinical trial were detailed in a late-breaker oral presentation at The International Liver Congress™ 2019, the Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria, on April 13, 2019. The associated abstract was also selected by EASL for inclusion in the "Best of ILC" summary slide deck highlighting the most noteworthy contributions to the scientific program at this year's meeting. A copy of the presentation is available in the Investors section of the Conatus website at www.conatuspharma.com.

  Patients had the option to continue on their assigned doses of treatment or placebo in a double-blind 24-week extension period. Results following the extension period are expected in mid-2019 and will include longer term safety, liver function and clinical outcomes, but there will be no additional HVPG measurements.

During the first quarter of 2019, the company announced top-line results from a third double-blind, placebo-controlled Phase 2b clinical trial, the ENCORE-NF (for NASH Fibrosis) clinical trial in patients with biopsy-confirmed 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. The trial did not meet the primary endpoint.

The company announced in March 2019 the selection of its first internally developed product candidate, CTS-2090, an orally active inhibitor of caspase 1. Caspase 1 occupies a uniquely central position in the NLRP3 inflammasome pathway and blocks activation of the potent inflammatory cytokine IL-1β. Blocking IL-1β is a clinically validated approach to treating inflammatory diseases, with several injectable biologic products using that mechanism of action already on the market. CTS-2090 is currently in preclinical development and IND-enabling studies, with an initial clinical trial planned to begin by the first half of 2020. The company plans to pursue rare autoinflammatory diseases as initial clinical targets for CTS-2090.

Financial Results
The net loss was $4.7 million for the first quarter of 2019 compared with a net loss of $5.0 million for the first quarter of 2018.

Total revenues were $7.0 million for the first quarter of 2019 compared with $9.7 million for the first quarter of 2018. Total revenues consisted of collaboration revenues related to the Novartis agreement. The decrease in total revenues was primarily due to lower emricasan-related research and development expenses resulting in corresponding lower revenues related to the Novartis agreement.

Research and development expenses were $9.4 million for the first quarter of 2019 compared with $12.1 million for the first quarter of 2018. The decrease in research and development expenses was primarily due to lower spending related to the ENCORE-PH clinical trial and manufacturing activities, partially offset by higher spending related to the ENCORE-LF clinical trial.

General and administrative expenses were $2.6 million for the first quarter of 2019 compared with $2.7 million for the first quarter of 2018.

Cash, cash equivalents and marketable securities were $33.8 million at March 31, 2019, compared with $40.7 million at December 31, 2018, and a projected year-end 2019 balance, without including any potential milestone payments under the Novartis collaboration, of between $10 million and $15 million.

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: the timelines to announce results from the ENCORE clinical trials; the plan and timeline to begin an initial clinical trial of CTS-2090; the initial clinical targets for CTS-2090; and the projected year-end cash balance. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continues" 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: Conatus' ability to successfully complete its ongoing and planned clinical trials; Novartis continuing development and commercialization of emricasan; Conatus' reliance on third parties to conduct its clinical trials, including the enrollment of patients, and manufacture its supplies of emricasan and CTS-2090; 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; Conatus' ability to obtain additional financing in order to co-commercialize emricasan or develop CTS-2090 or other compounds; 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.

Conatus Pharmaceuticals Inc.
Selected Condensed Financial Information
(In thousands, except per share data)
(Unaudited)

Statements of Operations	**Three Months Ended March 31,**	
	2019	**2018**
Revenues:		
Collaboration revenue	$ 7,024	$ 9,737
Operating expenses:		
Research and development	9,383	12,081
General and administrative	2,591	2,713
Total operating expenses	11,974	14,794
Loss from operations	(4,950)	(5,057)
Other income/expense	203	39
Net loss	$ (4,747)	$ (5,018)
Net loss per share, basic and diluted	$ (0.14)	$ (0.17)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	33,165	30,048

Balance Sheets	**March 31, 2019**	**December 31, 2018**
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 33,833	$ 40,692
Collaboration receivables	3,860	3,677
Prepaid and other current assets	2,633	3,057
Total current assets	40,326	47,426
Property and equipment, net	145	154
Other assets	1,707	1,223
Total assets	$ 42,178	$ 48,803

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other current liabilities	$ 8,625	$ 8,446
Current portion of deferred revenue	8,150	10,075
Total current liabilities	16,775	18,521
Deferred revenue, less current portion	1,576	2,815
Other long-term liabilities	229	68
Stockholders' equity	23,598	27,399
Total liabilities and stockholders' equity	$ 42,178	$ 48,803

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