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EMA Grants Conatus Orphan Drug Designation for IDN-7314 for the Treatment of PSC

SAN DIEGO, Oct. 18, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (NASDAQ:CNAT) today announced that the European Medicines Agency (EMA) has granted orphan designation to Conatus' drug candidate IDN-7314 for the treatment of primary sclerosing cholangitis (PSC), a disease affecting bile ducts in the liver which can lead to cirrhosis and liver failure. The EMA's orphan designation program is intended to encourage the development of medicines that may provide benefit to patients suffering from rare life-threatening or chronically debilitating conditions. IDN-7314 was granted Orphan Drug Designation for the treatment of PSC by the U.S. Food and Drug Administration in June 2017.

IDN-7314 is an orally active pan-caspase protease inhibitor designed to reduce the activity of enzymes that mediate inflammation and cell death (or apoptosis), which has demonstrated reduction of relevant biomarkers in two preclinical models of PSC. One nonclinical model, the Mdr2$^{-/-}$ (knockout) mouse model is considered the current benchmark nonclinical model of PSC. A new preclinical model, second mitochondria-derived activator of caspases (SMAC)-mimetic induced PSC in mice, has recently been reported that reproduces much of the phenotype of human PSC. IDN-7314 significantly improved biochemical indices of hepatic and biliary damage in these murine models of PSC, and these results suggest the involvement of caspases in the progression of PSC.

"As we advance in the evaluation of opportunities to expand our pipeline beyond emricasan, adding orphan designation in Europe to the recent orphan drug designation in the United States enhances the potential attractiveness of developing IDN-7314 for the treatment of PSC," said Conatus Co-Founder, President and Chief Executive Officer, Steven J. Mento, Ph.D. "We continue to evaluate a number of potential internal and external opportunities with a goal of announcing our initial pipeline expansion plans later in 2017."

About EMA Orphan Drug Designation
The EMA orphan drug designation is granted only to medicines being developed for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition with a prevalence in the European Union (EU) not more than five in 10,000. EMA orphan drug designation benefits include protocol assistance, access to the EU centralized authorization procedure, reduced EU regulatory filing fees and ten years of market exclusivity. Conatus would be eligible for additional incentives available to small and medium-sized enterprises (SMEs), including administrative and procedural assistance with the European regulatory process.

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: IDN-7314 as a potential treatment for PSC; plans to announce pipeline development opportunities in 2017; 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: the risk that the preclinical results may not be predictive of future clinical results; Conatus' ability to utilize the EMA orphan designation; 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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