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

SAN DIEGO, June 26, 2017 (GLOBE NEWSWIRE) -- Conatus Pharmaceuticals Inc. (NASDAQ:CNAT) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug 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 FDA's Orphan Drug Designation program is intended to encourage the development of drugs and biologics that may provide benefit to patients suffering from rare diseases or conditions.

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.

"The FDA's Orphan Drug Designation of IDN-7314 for the treatment of PSC highlights the need for novel therapies for this patient population," said Conatus Co-Founder, President and Chief Executive Officer, Steven J. Mento, Ph.D. "There are no curative or disease-modifying treatments for PSC itself. Continued progression over time ultimately leads to liver transplant or liver failure. For Conatus, the Orphan Drug Designation provides a potential opportunity to address an important unmet medical need and expand the company's drug development pipeline beyond emricasan. We will continue to evaluate this opportunity along with others as we advance toward announcement of our initial pipeline plans later in 2017."

About FDA Orphan Drug Designation
The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing a treatment drug. Orphan Drug Designation confers special incentives to the drug developer, including tax credits on the clinical development costs, prescription drug user fee waivers and a possible seven-year period of marketing exclusivity in the U.S. for the drug if it subsequently receives the first FDA approval for the disease or condition for which it has such designation.

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 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, 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: IDN-7314 as a potential treatment for PSC; plans to announce pipeline development opportunities in 2017; 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.

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