Cocrystal Pharma Presents Positive Data from U.S. Phase 2a Study of CC-31244 Demonstrating Ability to Identify Patients More Likely to Respond to Ultrashort Treatment of HCV

- New data presented at the American Association for the Study of Liver Diseases (AASLD) 2019 Liver Meeting -

- Patients that achieved SVR had significantly higher frequencies of terminally differentiated effector memory CD8+ T cells compared with those who relapsed -

- Development of ultrashort treatment for hepatitis C virus (HCV) consists of CC-31244, an oral, potent, broad-spectrum NNI, as a part of combination therapy to include approved HCV DAAs (direct antiviral agents) -

BOTHELL, WA, Nov. 11, 2019 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (NASDAQ: COCP), (“Cocrystal” or the “Company”), a clinical stage biotechnology company discovering and developing novel antiviral therapeutics, presented at the AASLD 2019 Liver Meeting being held November 8-12, 2019 in Boston, MA, new data in a poster demonstrating positive data from its triple regimen, U.S. Phase 2a study evaluating CC-31244 and sofosbuvir/velpatasvir (Epclusa) for the ultrashort treatment of HCV infected individuals.

The poster titled, “Immune Cell Phenotypes Associated with Successful Response to 2 Weeks of a Novel Non-Nucleoside Inhibitor CDI-31244 Concurrent with 6 Weeks of Sofosbuvir/Velpatasvir in Subjects with Chronic Hepatitis C Genotype 1 Infection,” was presented by Joel Chua, MD, Assistant Professor of Medicine of the Institute of Human Virology at the University of Maryland School of Medicine and Principal Investigator of the U.S. Phase 2a trial, on Sunday November 10, 2019 and is available on the Company’s website here.

“We are pleased with the new data from the U.S. Phase 2a study that were presented this past weekend at the AASLD 2019 Liver Meeting. By investigating the association of specific immune cell biomarkers with sustained virologic response (SVR) or relapse in 12 treatment-native patients with chronic HCV genotype 1 infection without cirrhosis, we were able to successfully identify patients that are more likely to respond to our shorter treatment regimen,” commented Dr. Sam Lee, President of Cocrystal. “With the data demonstrated to date, we believe that CC-31244 has the potential to address the areas of unmet need that still exist in the HCV treatment landscape including the high cost which acts as a major
barrier for treatment. We are grateful to Dr. Chua and his team and look forward to advancing the development of CC-31244 and its potential to offer ultrashort duration HCV therapy."

Results from the Phase 2a study demonstrated that eight of 12 (67%) patients achieved primary endpoint of sustained virologic response (SVR) 12, which is considered a cure, using only 6 weeks of Epclusa’s therapy combined with only 2 weeks of CC-31244. Patients that achieved SVR had significantly higher frequencies of terminally differentiated effector memory CD8+ T cells compared with those who relapsed at both baseline and at end-of-6-week treatment. At the same time, the frequency of naïve CD8+ T cells was lower while the frequency of effector memory CD8+ T cells was higher in SVR patients; however, these differences were not statistically significant. NK cell cytotoxic phenotypes determined by measuring expression of TRAIL and CD107a also did not differ between SVR and relapse patients, unlike another study that evaluated a different regimen for 12 weeks.

CC-31244, an investigational, oral, broad-spectrum replication inhibitor or NNI, has a high barrier to drug resistance and is a highly potent, selective NNI that is active against all HCV genotypes (1-6) with low level cytotoxicity in multiple cell types. Epclusa is an approved 12-week therapy for HCV developed by Gilead Sciences, Inc. The U.S. Phase 2a study is an open-label study designed to evaluate the safety, tolerability, and preliminary efficacy of CC-31244 with Epclusa in 12 subjects with treatment-naïve HCV genotype 1. Subjects received oral 400 mg of CC-31244 and Epclusa for 2 weeks. Following this, the subjects continued Epclusa treatment alone for another 4 weeks. All subjects completed the 6-week treatment regimen.

In January 2019, Cocrystal announced safety and preliminary efficacy data from its triple regimen, U.S. Phase 2a study evaluating CC-31244. For additional information about the U.S. Phase 2a study of CC-31244 for the treatment of viral hepatitis C, please visit ClinicalTrials.gov and reference identifier NCT03501550.

About the AASLD 2019 Liver Meeting

AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. AASLD was founded in 1950 by a small group of leading liver specialists (including Hans Popper, Leon Schiff, Fred Hoffbauer, Cecil Watson, Jesse Bollman, and Sheila Sherlock, to name a few) to bring together those who had contributed to the field of hepatology.

The annual AASLD Liver Meeting has grown to an international society responsible for all aspects of hepatology, and our annual meeting, AASLD, has grown in attendance from 12 to more than 12,500 physicians, surgeons, researchers, and allied health professionals from around the world. For more information, please visit the conference website.

About CC-31244

CC-31244 is an investigational, oral, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI). It has been designed and developed using the Company's proprietary structure-based drug discovery technology to have a high barrier to drug resistance and to be a highly potent, selective NNI that is active against all HCV genotypes (1-6) with low level cytotoxicity in multiple cell types.
About Cocrystal Pharma, Inc.

Cocrystal Pharma, Inc. is a clinical stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of influenza viruses, hepatitis C viruses, and noroviruses. Cocrystal employs unique structure-based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs. The Company is developing CC-31244, an investigational, oral, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI). CC-31244 is currently being evaluated in a Phase 2a study for the treatment of hepatitis C as part of a cocktail for ultra-short therapy of 4 to 6 weeks. Cocrystal recently entered into an exclusive worldwide license and collaboration agreement with Merck & Co., Inc. to discover and develop certain proprietary influenza A/B antiviral agents. CC-42344, the Company’s molecule for the treatment of influenza A, is currently being evaluated in preclinical IND-enabling studies. In addition, the Company has a pipeline of promising early preclinical programs and continues to identify and develop non-nucleoside polymerase inhibitors for norovirus gastroenteritis using the Company’s proprietary structure-based drug design technology platform. For further information about Cocrystal, please visit www.cocrystalpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including our beliefs regarding the potential of CC-31244. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "could," "target," "potential," "is likely," "will," "expect" and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events. Some or all of the events anticipated by these forward-looking statements may not occur. Important factors that could cause actual results to differ from those in the forward-looking statements include, but are not limited to, risks arising general risks arising from clinical trials, and receipt of regulatory approvals. Further information on our risk factors is contained in our filings with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2018. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

Investor and Media Contact:
Jenene Thomas Communications, LLC
(833) 475-8247
COCP@jtcir.com
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Source: Cocrystal Pharma, Inc.