

June 28, 2018



# Cocrystal Pharma Commences Enrollment and Initiates Patient Dosing in Phase 2a Study Evaluating CC-31244 for the Treatment of HCV

*- Topline results from Phase 2a study expected to be announced before year end -*

ATLANTA, GA and BOTHELL, WA, June 28, 2018 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (NASDAQ: COCP), ("Cocrystal" or the "Company"), a clinical stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of hepatitis viruses, influenza viruses and noroviruses, announced today the commencement of enrollment and initiation of patient dosing in its Phase 2a clinical study evaluating CC-31244 for the treatment of hepatitis C virus (HCV)-infected individuals.

Gary Wilcox, Vice Chairman and Chief Executive Officer of Cocrystal, commented, "We are pleased to advance the clinical development of our lead program, CC-31244 with the commencement of enrollment and patient dosing in our Phase 2a study. The start of this study represents an exciting clinical milestone, and we look forward to announcing topline results before the end of this year. Importantly, our team is diligently focused on the successful completion of this Phase 2a study and we believe the results will be integral in guiding our next phase of development for our hepatitis C program."

The Phase 2a open-label study is designed to evaluate the safety, tolerability and preliminary efficacy of CC-31244 with an approved HCV drug. Dr. Joel Chua, Institute of Human Virology, University of Maryland Baltimore, will serve as the Principal Investigator of the study. Enrolled subjects will self-administer orally 400 mg of CC-31244 and a fixed dose combination of sofosbuvir and velpatasvir for 14 days. After 14 days the subjects will continue the treatment for another 4 weeks on the fixed dose combination of sofosbuvir and velpatasvir. Subjects will be followed up until 24 weeks after the last dose of sofosbuvir and velpatasvir to determine if they have achieved sustained virologic response (SVR). Primary and secondary efficacy endpoints are SVR at 12 weeks post-treatment (SVR12) and at 24 weeks post-treatment (SVR24), respectively.

Dr. Chua commented, "The need for treatment options with ultra-short duration for individuals chronically infected with hepatitis C remains a significant unmet need. We are encouraged by the results that CC-31244 has demonstrated to date, and I believe it has shown not only great potential, but also tremendous promise in meeting the need for safe and rapid treatment options."

The Company previously reported positive data from the Phase 1a/1b trial of CC-31244 for the treatment of chronic hepatitis C infection. The Phase 1a/1b study was a randomized,

placebo-controlled, double-blind trial designed to evaluate single and multiple ascending doses of CC-31244 for safety/tolerability, pharmacokinetics, and antiviral activity in hepatitis C infected patients. In Phase 1a, 30 healthy volunteers received single doses (20-400 mg) of CC-31244, and 12 healthy volunteers received repeated doses of CC-31244 (either 200 or 400 mg) for 7 days. In Phase 1b, 15 patients with hepatitis C genotype 1 infection received CC-31244 for 7 days (6, 400 mg daily; 6, 600 mg daily; 3, 200 mg twice daily).

As reported, there were no dose-limiting adverse events, study discontinuations due to adverse events, or serious adverse events. Viral load data showed that CC-31244 administered once daily (400 mg or 600 mg) or twice daily (200 mg) for 7 days had a substantial and durable antiviral effect, with an average hepatitis C RNA viral load decline from baseline of 1000-fold by Day 4. Interestingly, the mean viral load at 6 days after the last dose persisted in the range of 100-fold below baseline. Hepatitis C genotype 1b cell-based replicon assays using combinations of CC-31244 with other classes of hepatitis C drugs showed additive and synergistic effects of CC-31244, providing important information for ultra-short therapy cocktail regimens.

For additional information about the Phase 2a study of CC-31244 for the treatment of viral hepatitis C, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference identifier NCT03501550.

### **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 Hepatitis C Virus**

Hepatitis C virus (HCV) is a viral infection of the liver that causes both acute and chronic infection, and according to the World Health Organization in 2017, affects an estimated 71 million people worldwide, including 3.5 million in the United States. Chronic HCV infection can lead to fibrosis (scarring), cirrhosis, liver failure, and liver cancer. Approximately 399,000 people die each year from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma.

### **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 hepatitis viruses, influenza viruses, and noroviruses. Cocrystal employs unique structure-based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs. CC-31244 is in a Phase 2a trial. It is a broad-spectrum novel non-nucleoside replication inhibitor of the hepatitis C virus. Phase 1b studies in HCV-infected patients showed the largest reduction in viral load of any non-nucleoside inhibitor tested to date. CC-31244 is now in clinical trials as part of a cocktail for ultra-short therapy of 2 to 6 weeks. The lead candidate for influenza has advanced to IND-enabling studies. It is effective in animal models against both the pandemic and seasonal strains of influenza. In addition, the Company has a pipeline of promising early preclinical programs. Two private investors own approximately 48% of the Company. Corporate investors include OPKO Health, Inc., Brace

Pharma Capital, LLC and Teva Pharmaceuticals Industries, Ltd. For further information about Cocrysal, please visit [www.cocrystalpharma.com](http://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 expectations regarding the manner of conducting and future progress of the Phase 2a study, and our future success. 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 the availability of products manufactured by third parties and the ability of the clinical research organization conducting the Phase 2a study to recruit subjects. Further information on our risk factors is contained in our filings with the SEC, including the Prospectus Supplement dated April 30, 2018, and our Annual Report on Form 10-K for the year ended December 31, 2017. 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.

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Source: Cocrystal Pharma, Inc.