

April 3, 2018



Cocrystal Pharma Receives FDA Clearance to Initiate Phase 2a Clinical Study Evaluating CC-31244 for the Treatment of Hepatitis C Virus

– Company on track to commence patient enrollment and dosing in Q2 2018 –

– Topline data from Phase 2a study expected in Q4 2018 –

ATLANTA, GA and BOTHELL, WA, April 03, 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 that its Investigational New Drug (“IND”) application to the U.S. Food and Drug Administration (“FDA”) is now open and the Company is cleared to initiate its Phase 2a clinical study evaluating CC-31244 for the treatment of hepatitis C virus (“HCV”) infected individuals.

[Gary Wilcox, Vice Chairman and Interim Chief Executive Officer](#) of Cocrystal, commented, “The achievement of this regulatory milestone is a significant step forward in the advancement of our lead program, CC-31244. Based on the positive results from our Phase 1a/1b study, we believe that CC-31244 has the potential to change the treatment paradigm for patients living with HCV providing a shorter therapy with existing HCV combination therapies and a substantial and durable antiviral effect. We look forward to further evaluating the effect of CC-31244 and the commencement of this next phase of clinical development.”

[CC-31244](#), the Company’s lead product in development, is an investigational, oral, highly potent, broad-spectrum non-nucleoside inhibitor with high barrier to drug resistance designed and developed using the Company’s proprietary structure-based drug discovery technology. CC-31244 is active against all six HCV genotypes, with low level cytotoxicity in multiple cell types.

The Phase 2a study is an open-label study designed to evaluate the safety, tolerability and preliminary efficacy of CC-31244 with approved HCV drugs. Endpoints of the Phase 2a study include changes in HCV RNA viral load, adverse events and laboratory abnormalities. Cocrystal expects to commence its Phase 2a study of CC-31244 in the second quarter of 2018 and announce data in the fourth quarter of this year.

In August 2017, the Company [announced positive data from the Phase 1a/1b trial of CC-31244 for the treatment of chronic hepatitis C infection](#). This randomized, placebo-controlled, double-blind Phase 1a/1b study evaluated single and multiple ascending doses of CC-31244 for safety/tolerability, pharmacokinetics, and antiviral activity in healthy volunteers and

patients with HCV infection. 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 HCV genotype-1 infection received CC-31244 for 7 days (6, 400 mg daily; 6, 600 mg daily; 3, 200 mg twice daily). Eighteen subjects received placebo during the study.

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 HCV RNA viral load decline from baseline of 1000-fold by Day 4. Interestingly, the average viral load at 6 days after the last dose persisted in the range of 100-fold below baseline. HCV genotype 1b cell-based replicon assays using combinations of CC-31244 with other classes of HCV drugs showed additive and synergistic effects of CC-31244, providing important information for ultra-short therapy cocktail regimens.

About Hepatitis C

Hepatitis C is a viral infection of the liver that the World Health Organization estimates affects over 71 million people worldwide, including 3.5 million in the United States. The annual number of deaths due to hepatitis C is estimated at 350,000 globally or nearly 1,000 per day. Most patients develop chronic infections, which can lead to fibrosis (scarring), cirrhosis, liver failure, and liver cancer. The worldwide market for hepatitis C antiviral drugs was approximately \$12.6 billion in 2017.

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 a Phase 2a ready broad-spectrum novel non-nucleoside replication inhibitor of HCV. Phase 1b studies in HCV infected patients showed the largest reduction in viral load of any non-nucleoside inhibitor tested to date. The next step for CC-31244 is clinical trials as part of a cocktail for ultra-short therapy of 2 to 4 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 54% of the Company. Corporate investors include OPKO Health, Inc., Brace Pharma Capital, LLC and Teva Pharmaceuticals Industries, Ltd. For further information about Cocrystal, please visit www.cocrystalpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements including our expectations regarding the results from the Phase 2a study and our clinical results from our pipeline of other products. 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, the ability of the clinical research company conducting the Phase 2a study to recruit subjects and obtaining regulatory approval for our planned Phase 1 study. Further information on our risk factors is contained in our filings with the SEC, including our 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.

Investor Contact:

Jenene Thomas

Jenene Thomas Communications, LLC

(908) 938-1475

COCP@jtcir.com



Source: Cocrystal Pharma, Inc.