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# Cocrystal Pharma Reports First Quarter 2019 Financial Results and Provides Corporate Update

*– Company is well positioned to achieve multiple corporate, clinical and research value-driving milestones in 2019 –*

BOTHELL, WA, May 10, 2019 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (NASDAQ: COCP), ("Cocrystal" or the "Company"), a clinical stage biotechnology company discovering and developing novel antiviral therapeutics, announced today its financial results for the quarter ended March 31, 2019 and provided a corporate update.

## Recent Corporate Highlights

- Signed exclusive license and collaboration agreement with Merck Sharp & Dohme Corp. ("Merck") to discover and develop certain proprietary influenza A/B antiviral agents and received a \$4 million upfront license fee;
- Closed a common stock-only private placement to three qualified, fundamental healthcare-focused institutional investors for gross proceeds of approximately \$4.2 million; and
- Reported encouraging safety and preliminary efficacy data for its U.S. Phase 2a study evaluating CC-31244 for the ultra-short treatment of hepatitis C virus (HCV) infected individuals. Eight of 12 subjects achieved the primary efficacy endpoint of sustained virologic response at 12 weeks after completion of treatment (SVR12).

"We continue to lay the foundation to successfully achieve key milestones over the course of 2019. Our recent collaboration with Merck and additional progress advancing our pipeline has provided the Company with continued confidence in the potential depth, breadth and utility of our platform technology. Additionally, we continue to be focused on advancing and expanding our hepatitis C clinical development program as well as driving forward our influenza program," commented Dr. Gary Wilcox, Chairman and Chief Executive Officer of Cocrystal.

## Clinical Programs Overview

### ***Pan-Genotypic Non-Nucleoside Inhibitor for the Ultra-short Treatment of Hepatitis C***

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.

#### *U.S. Phase 2a Study - University of Maryland*

The Company recently announced safety and preliminary efficacy data from its triple regimen, U.S. Phase 2a study evaluating CC-31244 and Epclusa (sofosbuvir/velpatasvir) for the ultra-short treatment of HCV infected individuals.

The U.S. Phase 2a study is an open-label study designed to evaluate the safety, tolerability, and preliminary efficacy of CC-31244 and Epclusa, an approved 12-week therapy for HCV developed by Gilead Sciences, Inc, 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. The treatment was well tolerated with no study discontinuations due to adverse events. Eight of 12 subjects achieved the primary efficacy endpoint of sustained virologic response at 12 weeks after completion of treatment (SVR12). SVR12 is defined as undetectable virus in blood 12 weeks after completion of treatment and is considered a virologic cure.

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

#### *Hong Kong Phase 2a Study*

The Humanity & Health Research Centre has received approval from the Hong Kong regulatory authorities to commence a second study in the HCV clinical development program, a Phase 2a investigator sponsored study in Hong Kong evaluating the safety, tolerability and preliminary efficacy of CC-31244 in combination with sofosbuvir and daclatsavir with or without a protease inhibitor, for the treatment of hepatitis C. The Humanity & Health Research Centre expects to commence the study in Q2 2019. The upcoming, Hong Kong Phase 2a open-label trial differs from the current Phase 2a trial Cocrystal is conducting by using a protease inhibitor as part of the combination regimen and having a shorter treatment duration.

#### *Expected Near-Term CC-31244 Clinical Program Milestones*

- Present full data of U.S. Phase 2a study at upcoming scientific conference.
- Commence Hong Kong Phase 2a study.
- Complete patient enrollment in Hong Kong Phase 2a study.
- Complete Hong Kong Phase 2a study and report top-line results.

### ***Influenza A/B Inhibitors and Influenza A***

#### *Influenza A/B Inhibitors*

The Company recently announced it entered into an exclusive license and collaboration agreement with Merck to discover and develop certain proprietary influenza A/B antiviral agents.

Under the terms of the agreement, Merck will fund all research and development for the program, including clinical development, and will be responsible for worldwide

commercialization of any products derived from the collaboration. Cocrystal was paid a \$4 million upfront license fee and is eligible to receive payments related to designated development, regulatory and sales milestones with the potential to earn up to \$156 million, plus undisclosed royalties on product sales.

### *Influenza A*

Cocrystal is developing novel, broad spectrum influenza antivirals that are specifically designed to be effective against all significant A strains of the influenza virus and to have a high barrier to resistance due to the way they target the virus's replication machinery. Cocrystal's uniquely developed molecules target the influenza polymerase, an essential replication enzyme with several highly essential regions common to influenza strains, including pandemic strains.

CC-42344, the Company's lead molecule, binds to a highly conserved PB2 site of influenza polymerase complex and exhibits a novel mechanism of action which inhibits replication. CC-42344 has shown excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu® resistant strains, and shows a favorable pharmacokinetic and safety profile. CC-42344 is currently being evaluated in preclinical IND-enabling studies for the treatment of influenza.

Further, the Company has identified molecules which have activity against both Strain A and Strain B. Several of these have potencies approaching single digit nanomolar. The Company is considering oral, intravenous and inhaled routes of delivery.

### *Expected Near-Term CC-42344 Clinical Program Milestones*

- Complete preclinical IND-enabling studies.
- File a regulatory submission.
  
- Initiate Phase 1 study evaluating CC-42344 for the treatment of influenza.

### **Summary of Financial Results for Q1 2019**

As of March 31, 2019, Cocrystal had approximately \$8,571,000 cash on hand. Based on management's current projections, the Company expects to have sufficient cash to fund operations into the first quarter of 2020. The Company has approximately \$8,500,000 cash on hand as of the date of this press release.

For the quarter ended March 31, 2019, the Company had revenues of approximately \$5,078,000 compared to no revenue in the first quarter of 2018. Revenues all came from the Merck Collaboration Agreement and consisted of the \$4,000,000 license fee, and reimbursement of expenses for services provided by the Company.

For the quarter ended March 31, 2018, the Company reported net income of approximately \$2,971,000 compared to a net loss of approximately \$1,553,000 for the same period in 2018. The overall income increase of \$4,524,000 is primarily due to revenue resulting from the Company's recently executed collaboration agreement with Merck.

Total research and development expenses were approximately \$878,000 for the three months ended March 31, 2019, compared with \$877,000 for the three months ended March

31, 2018. General and administrative expenses were \$1,323,000 for the three months ended March 31, 2019, compared with \$1,190,000 for the three months ended March 31, 2018.

### **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 Phase 2a studies for the treatment of hepatitis C as part of a cocktail for ultra-short therapy. Cocrystal recently entered into an exclusive worldwide license and collaboration agreement with Merck Sharp & Dohme Corp. 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](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 anticipated advancements under our Merck collaboration agreement, achievement of the expected near-term operational, preclinical, clinical and research milestones, including the expected progress and results of the University of Maryland and Hong Kong Phase 2a studies, expected reductions in research and development expenses in 2019 resulting from our collaborations and our liquidity. 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. These forward-looking statements are based on Cocrystal's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks arising from our reliance on Merck's continuing the collaboration agreement, the results from preclinical and clinical studies, the availability of products manufactured by third parties, the research organizations' ability to recruit subjects, receipt of regulatory approvals, general risks arising from clinical trials, unanticipated litigation and other expenses and factors that affect the capital markets in general and early stage biotechnology companies. See also the Risk Factors described in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2018. The Company has based these forward-looking statements on its current expectations and assumptions about future events. While management considers these expectations and assumptions to be reasonable, they are inherently subject to significant business, economic, competitive, regulatory, and other risks, contingencies, and uncertainties, most of which are difficult to predict and many of which are beyond the Company's control. The Company does not assume any obligations to update any of these forward-looking statements.

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Source: Cocrystal Pharma, Inc.