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# **Cocrystal Announces Positive Data from the Successful Completion of Phase 1a/1b Trial of the Non-Nucleoside Polymerase Inhibitor CC-31244 for the Treatment of Chronic Hepatitis C Infection**

ATLANTA, GA and BOTHELL, WA -- (Marketwired) -- 08/15/17 -- Cocrystal Pharma, Inc. (OTCQB: COCP), a clinical stage biopharmaceutical company focused on developing innovative antiviral therapeutics, today announced the successful completion and positive data from the Phase 1a/1b study for its lead broad spectrum compound, CC-31244, in healthy volunteers and in hepatitis C virus (HCV)-infected individuals. CC-31244 is a broad-spectrum, potent NS5B non-nucleoside inhibitor (NNI) of HCV replication with a high barrier to resistance.

This randomized, placebo-controlled, double-blind Phase 1a/1b study was designed to evaluate single and multiple ascending doses of CC-31244 for safety/tolerability, pharmacokinetics, and antiviral activity in HCV-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 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.

There were no dose-limiting adverse events, study discontinuations due to adverse events, or serious adverse events reported. 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 3 log orders by Day 4. Interestingly, the average viral load at 6 days after the last dose persisted in the range of 1.7-2.0 log orders 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 regimen.

"The successful completion of the Phase 1a/1b study represents a significant milestone for the Company. Given the absence of dose-limiting adverse effects in both healthy and HCV-infected subjects, and the significant antiviral effect observed in conjunction with the sustained antiviral activity post treatment, we are eager to advance CC-31244 into Phase 2 development in combination with other direct acting antivirals," said Gary L. Wilcox, Ph.D., Interim Chief Executive Officer of the Company.

"The human pharmacokinetic and safety data were consistent with the excellent nonclinical safety data, and the sustained antiviral effect up to 6 days following treatment supports the

preclinical data that indicates significant accumulation of CC-31244 in the liver, which is also the site of infection. The antiviral data provide a strong scientific rationale to support the notion that CC-31244 is a potential best-in-class NNI, which could be used as an important component in an all-oral, ultra-short HCV combination therapy," added Sam Lee, Ph.D., President and co-inventor of this drug.

### ***Summary of Key Findings:***

- There were no dose-limiting adverse events, study discontinuations due to adverse events, or serious adverse events reported with CC-31244.
- CC-31244 monotherapy for 7 days established an excellent proof-of-concept for the anti-HCV activity of CC-31244 resulting in a mean viral load reduction of 3 log orders.
- The slow rebound post treatment is a unique feature of CC-31244 resulting in a lingering antiviral effect of up to 2 log orders after 6 days post last dose.

### ***About CC-31244***

CC-31244 is an investigational, oral, potent, broad-spectrum NNI with high barrier to drug resistance designed and developed using the Company's proprietary structure-based drug discovery technology. The molecule interacts with the NS5B RNA polymerase of all major HCV genotypes.

### ***About Hepatitis C***

Hepatitis C is a viral infection of the liver that according to The World Health Organization in 2013 affects over 150 million people worldwide of whom only about 1% have been cured to date. 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 \$12 billion in 2015.

### ***About Cocystal Pharma***

Cocystal is a pharmaceutical company seeking to discover and develop novel antiviral therapeutics as treatments for serious and/or chronic viral diseases. Cocystal employs unique structure based technologies and Nobel Prize winning expertise to create first- and best-in-class antiviral drugs. These technologies, including our nucleoside chemistry expertise, are designed to efficiently deliver small molecule therapeutics that are safe, effective and convenient to administer. The company has identified promising, preclinical stage antiviral compounds for unmet medical needs including hepatitis, influenza and norovirus infections. Cocystal has previously received strategic investments from Teva Pharmaceuticals, OPKO Health (NASDAQ: OPK), Brace Pharma Capital, LLC, and The Frost Group. For further information about Cocystal, please refer to [www.cocystalpharma.com](http://www.cocystalpharma.com).

### ***Forward Looking Statements***

To the extent that statements contained in this press release are not descriptions of historical facts regarding Cocystal, they are forward-looking statements reflecting the current beliefs and expectations of management including statements regarding development plans for treatments related to hepatitis C, influenza and norovirus. Forward-looking statements in this release involve substantial risks and uncertainties that could cause future results to differ significantly from what is expressed or implied by the forward-looking statements. For a description of the risks and uncertainties that could cause actual results to

differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see filings Cocrystal has made with the Securities and Exchange Commission including its Form 10-K filed on March 31, 2017.

*Contact Information:*

Cocrystal Pharma, Inc.

Gary Wilcox

[gwilcox@cocrystalpharma.com](mailto:gwilcox@cocrystalpharma.com)

or

James Martin

[jmartin@cocrystalphama.com](mailto:jmartin@cocrystalphama.com)

Source: Cocrystal Pharma, Inc.