

Cocrystal Pharma to Extend Phase 2a Influenza Challenge Study with Oral PB2 inhibitor CC-42344

- *Data support favorable safety and tolerability profile with no serious adverse events (SAEs) or study-related drug discontinuations*
- *Enrollment to be extended due to low influenza infection among challenged participants; virology results are uninterpretable*

BOTHELL, Wash., Dec. 31, 2024 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) (“Cocrystal” or the “Company”) announces plans to extend enrollment in the Phase 2a human challenge study with its investigational, broad-spectrum, oral influenza PB2 inhibitor CC-42344 due to unexpectedly low influenza infection among study participants who were challenged with a H3N2 viral strain. This randomized, double-blind, placebo-controlled Phase 2a study is evaluating the safety, tolerability, pharmacokinetics (PK), antiviral activity and clinical measurements of CC-42344 at a single site in the United Kingdom.

CC-42344 is a drug candidate in development as an oral treatment for pandemic avian and seasonal influenza A infections. In December 2023, [Cocrystal Pharma announced enrollment of the first patient in this study](#) and in May 2024, the [Company announced full enrollment](#) of 78 subjects.

“While CC-42344 showed a favorable safety and tolerability profile, we’re disappointed by the low infectivity rate of the challenge influenza strain used in this study. The establishment of robust influenza infection in healthy, uninfected study subjects is critical to determine clinical endpoints for evaluating antiviral molecules. The low infectivity obtained in this study hindered antiviral data analysis,” said Sam Lee, Ph.D., Cocrystal’s President and co-CEO.

“We remain optimistic about CC-42344 due to its unique mechanism of action with a high barrier to developing resistance, which could render it a best-in-class antiviral treatment for pandemic and seasonal influenza infections. We are also encouraged by CC-42344’s favorable safety and tolerability profile from the Phase 2a study to date, with no SAEs and no drug-related discontinuations by study participants.

“We are working with the clinical research organization to prepare a protocol amendment for approval by the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) in order to extend enrollment in this study, and to ensure necessary infection rates among enrolled study subjects,” he added.

About CC-42344

CC-42344 is a new class of antiviral treatment designed to effectively block an essential step

in the viral replication and transcription of pandemic and seasonal influenza A and was discovered using the Company's proprietary structure-based drug discovery platform technology. CC-42344 showed excellent *in vitro* antiviral activity against pandemic and seasonal influenza A strains, as well as strains that are resistant to Tamiflu[®] and Xofluza[®]. In late 2022, Cocystal reported [favorable safety and tolerability results](#) from a Phase 1 study in healthy subjects conducted in Australia. The Company initiated the Phase 2a human challenge study in December 2024 following authorization from the MHRA. In June 2024, the Company reported *in vitro* studies demonstrating that CC-42344 inhibited the activity of the PB2 protein in the new highly pathogenic avian influenza A (H5N1) PB2 protein recently identified in humans.

About Influenza A

Influenza is a major global health threat that may become more challenging to treat due to the emergence of highly pathogenic avian influenza viruses and resistance to approved influenza antivirals. [Each year there are approximately 1 billion cases of seasonal influenza worldwide, 3-5 million severe illnesses and up to 650,000 deaths. On average, about 8% of the U.S. population contracts influenza each season. In addition to the health risk, influenza is responsible for an estimated \\$11.2 billion in direct and indirect costs in the U.S. annually.](#)

Structure-Based Platform Technology

Cocystal's proprietary structural biology, along with its expertise in enzymology and medicinal chemistry, enable its development of novel antiviral agents. The Company's platform provides a three-dimensional structure of inhibitor complexes at near-atomic resolution, providing immediate insight to guide Structure Activity Relationships. This helps to identify novel binding sites and allows for a rapid turnaround of structural information through highly automated X-ray data processing and refinement. The goal of this technology is to facilitate the development of best-in-class antiviral therapies that have fast onset of action and/or shortened treatment time, are safe, well tolerated and easy to administer, are effective against all viral subtypes that cause disease and have a high barrier to viral resistance.

About Cocystal Pharma, Inc.

Cocystal Pharma, Inc. is a clinical-stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication process of influenza viruses, coronaviruses (including SARS-CoV-2), noroviruses and hepatitis C viruses. Cocystal employs unique structure-based technologies and Nobel Prize-winning expertise to create first- and best-in-class antiviral drugs. For further information about Cocystal, please visit www.cocystalpharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the extension of enrollments, regulatory approval and achieving the necessary infection rate. 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 relating to our ability to obtain regulatory authority for and proceed with clinical trials including the recruiting of volunteers for such studies by our clinical research organizations and vendors, the results of such studies, our collaboration partners' technology and software performing as expected, general risks arising from clinical studies, receipt of regulatory approvals, regulatory changes, and potential development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government, and potential mutations in a virus we are targeting that may result in variants that are resistant to a product candidate we develop. 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, 2023. 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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