

May 1, 2024



Enrollment Completed in Phase 2a Study with Cocrystal Pharma's Oral Antiviral Candidate CC-42344 for Pandemic and Seasonal Influenza

BOTHELL, Wash., May 01, 2024 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces completion of enrollment of 78 subjects who were infected with influenza A in a randomized, double-blind, placebo-controlled Phase 2a human challenge clinical study evaluating the safety, tolerability, antiviral and clinical measurements of its novel, broad-spectrum, oral PB2 inhibitor 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.

"There is an urgent need for new influenza antivirals targeting highly pathogenic avian pandemic and seasonal influenza strains. It's gratifying to report the timely completion of enrollment in this important study, keeping us on track to announce topline results later this year. This human challenge study was conducted in the United Kingdom and was designed to evaluate a favorable safety profile, virological effects, and an improvement in clinical symptom for CC-42344 as a potential oral treatment for avian pandemic and seasonal influenza A," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "We are pleased to advance our robust pipeline with achievement of this important clinical development milestone as we continue to build our leadership in influenza therapeutics."

In March 2024 Cocrystal announced receipt of positive Pre-Investigational New Drug (Pre-IND) feedback from the FDA providing guidance and clarification on critical steps including designing a proposed Phase 2b study protocol for CC-42344 as a potential oral treatment for pandemic and seasonal influenza A.

Cocrystal also plans to begin a Phase 1 study in Australia with an inhaled formulation of CC-42344 as a potential influenza A treatment and post-exposure prophylaxis. Recent preclinical data showed that inhaled CC-42344 exhibited highly effective delivery into the lung, superior lung exposure, efficacy in influenza-infected human lung epithelia and a favorable safety profile.

CC-42344 Influenza A PB2 Inhibitor

In December 2023, Cocrystal announced the achievement of first-patient-in for the Phase 2a human challenge clinical trial with CC-42344, an investigational new oral antiviral inhibitor for the treatment of pandemic and seasonal influenza A. The randomized, double-blind, placebo-controlled study was designed to evaluate the safety, tolerability, viral and clinical measurements of influenza A infection in subjects dosed with oral CC-42344 treatment. The

study enrolled 78 healthy subjects.

In late 2022 Cocrystal reported [favorable safety and tolerability results](#) in the single-ascending and multiple-ascending dose portions of the healthy volunteer Phase 1 trial conducted in Australia. Preclinical data showed that CC-42344 is highly active against seasonal and pandemic influenza A strains.

About Seasonal Influenza

Each year there are approximately 1 billion cases of seasonal influenza worldwide, with 3-5 million severe illnesses and up to 650,000 deaths, according to the World Health Organization. [On average about 8% of the U.S. population contracts influenza each season](#) In addition to the health risk, [influenza is responsible for approximately \\$10.4 billion in direct costs for hospitalizations and outpatient visits for adults in the U.S. annually.](#)

About Cocrystal Pharma, Inc.

Cocrystal 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. Cocrystal employs unique structure-based technologies and Nobel Prize-winning expertise to create first- and best-in-class antiviral drugs. For further information about Cocrystal, please visit www.cocrystalpharma.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 expected timing and results of the Phase 2a trial for CC-42344 for the oral treatment of influenza A in 2024, an anticipated Phase 2b trial for oral treatment of influenza A following the Phase 2a trial, plans to begin a Phase 1 study in Australia for an inhaled formulation of CC-42344 as a potential influenza A treatment and prophylaxis, and the potential efficacy and clinical benefits of, and market for, such product candidates. 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 proceed with the studies including recruiting volunteers and procuring materials for such studies by our clinical research organizations and vendors, the results of such studies and our ability to obtain FDA approval to initiate the Phase 2b study. 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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Source: Cocrystal Pharma, Inc.