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Cocrystal Pharma Receives Pre-IND Responses from the FDA on Oral CC-42344 for Treating Influenza A

Feedback provides greater clarity on regulatory requirements for planned Phase 2b trial

BOTHELL, Wash., March 19, 2024 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces it has received Pre-Investigational New Drug (Pre-IND) feedback from the U.S. Food and Drug Administration (FDA) regarding CC-42344 as a potential oral treatment for pandemic and seasonal influenza A. A Pre-IND review provides the opportunity to obtain FDA guidance and clarification on critical steps such as the proposed clinical trial design, as well as clinical drug manufacturing and nonclinical studies deemed necessary before filing the trial design. The feedback was provided in a written response to a Pre-IND package and questions submitted by the Company in January 2024.

"We value the FDA guidance as we prepare to file the IND for our Phase 2b trial and open enrollment of patients in the U.S.," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "This is an important milestone that provides greater clarity on the regulatory requirements and our planned oral CC-42344 clinical program."

A Phase 2a challenge study of oral CC-42344 is underway in the United Kingdom to evaluate safety, and viral and clinical measures in healthy volunteers who are infected with the influenza A virus. The Company expects to report topline results from this study in the second half of this year.

In addition, preparations are underway to begin a Phase 1 study in Australia with the Company's inhaled formulation of CC-42344 as a potential influenza A treatment and prophylaxis for those exposed to the virus. 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

CC-42344 is a novel, broad-spectrum, investigational antiviral candidate for the treatment of pandemic and seasonal influenza A. CC-42344 inhibits the first step in the viral replication process of influenza A by binding to a highly conserved PB2 site of the polymerase complex that is essential to replication. *In vitro* testing with CC-42344 showed excellent antiviral activity against influenza A strains, including pandemic and seasonal strains, as well as against strains resistant to Tamiflu® and Xofluza®, while also demonstrating favorable pharmacokinetic and safety profiles. In addition, oral CC-42344 demonstrated favorable safety and tolerability results in a Phase 1 study in Australia. This antiviral candidate was discovered using the Company's proprietary structure-based drug discovery platform technology.

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 results of the Phase 2a trial for CC-42344 for the oral treatment of influenza A in the second half of 2024, efforts in preparation for an anticipated Phase 2b trial for oral treatment of influenza A following the Phase 2a trial, efforts 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, 2022. 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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