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Cocrystal Pharma Reports Highly Favorable Safety and Tolerability Results from a Phase 1 Study with its Oral Antiviral CC-42344 for the Treatment of Pandemic and Seasonal Influenza A

BOTHELL, Wash., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) announces highly favorable safety and tolerability results for its orally administered replication inhibitor CC-42344 in its Phase 1 study. CC-42344 is a broad-spectrum antiviral for the treatment of pandemic and seasonal influenza A with a novel mechanism of action. The randomized, double-controlled Phase 1 study was conducted in Australia to evaluate the safety, tolerability and pharmacokinetics (PK) of CC-42344 given orally at single doses up to 800 mg and daily doses up to 14 days in 56 healthy volunteers.

Approximately 50% of the participants who received a single dose of CC-42344 across all dose levels (100 to 800 mg) experienced adverse events, similar to the proportion of placebo subjects who also experienced adverse events. In the multiple-dose section of the study, the incidence of adverse events was 67% for both CC-42344 (50 to 200 mg) and placebo. The vast majority of adverse events were mild in severity. The most frequently reported adverse event was headache, which occurred at similar rates in CC-42344-treated and placebo-treated participants. There were no serious adverse events or drug discontinuation due to adverse events.

"We are encouraged by the highly favorable safety and tolerability results from this first-in-human study with CC-42344. These findings give us confidence to continue our clinical testing of this compound as a potential treatment for pandemic and seasonal influenza A," said Sam Lee, Ph.D., Cocrystal's President and co-interim CEO. "With these results our influenza A program has achieved a major milestone and we look forward to beginning a Phase 2a clinical study."

Cocrystal plans to apply to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct a Phase 2a human challenge study in early 2023. Subject to regulatory clearance, the study is expected to be initiated in the second half of 2023.

"On average about 8 percent of the U.S. population contracts influenza each season according to the Centers for Disease Control and Prevention. In addition to the health risk, influenza is responsible for approximately \$10.4 billion in direct costs for hospitalizations and outpatient visits in the U.S. annually. We are highly focused on advancing CC-42344 through the clinical process and toward making a meaningful contribution to improving health and reducing the cost of care," said James Martin, Cocrystal's CFO and interim Co-CEO.

About CC-42344

CC-42344 is an oral PB2 inhibitor discovered using Cocrystal's proprietary structure-based drug discovery platform technology. It is specifically designed to be effective against all significant pandemic and seasonal influenza A strains and to have a high barrier to resistance due to the way the virus' replication machinery is targeted. CC-42344 targets the influenza polymerase, an essential replication enzyme with several highly conserved regions common to multiple influenza strains. *In vitro* testing showed CC-42344's 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 PK and safety profiles.

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), 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. 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 potential of CC-42344 for the treatment of seasonal and pandemic influenza, and our expectations and plans to submit an application to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct a Phase 2a human challenge study in early 2023 and to initiate the Phase 2a study in the second half of 2023. 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, the risks and uncertainties arising from any future impact of COVID-19 (including long-term or pervasive effects of the virus), inflation, interest rate increases and the war in Ukraine on the U.K. and global economy and on our Company, including supply chain disruptions and our continued ability to proceed with our programs, including our influenza A program, the ability of the contract research organization to recruit patients into clinical trials, the results of future preclinical and clinical studies, and general risks arising from clinical trials. 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, 2021. 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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