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Enrollment Completed in Phase 1 Influenza A Study with Cocrystal Pharma's Oral Antiviral Candidate CC-42344

BOTHELL, Wash., Oct. 26, 2022 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) announces the completion of enrollment in a Phase 1 healthy volunteer study to assess the safety, tolerability and pharmacokinetics (PK) of its orally administered, novel, broad-spectrum antiviral candidate CC-42344 for the treatment of pandemic and seasonal influenza A. CC-42344 represents a new class of antiviral treatment designed to block an essential step in the viral replication and transcription of pandemic and seasonal influenza A.

In March 2022 enrollment was initiated in the randomized, double-blind, placebo-controlled Phase 1 study, which is being conducted in Australia. In July 2022 the company announced PK results from the single-ascending-dose portion of the study, which support once-daily dosing. Enrollment is now complete with the highest dose of the multiple-ascending-dose portion of the study.

To continue advancing the development of CC-42344, Cocrystal engaged a U.K.-based clinical research organization in August 2022 to conduct a human challenge Phase 2a study evaluating the antiviral activity safety and PK of CC-42344 in subjects infected with influenza A. This study will expose healthy volunteers to the virus in a controlled setting, which will significantly shorten the timeline for generating results.

"Completing enrollment in our Phase 1 study keeps us on track to announce topline results this year," said Sam Lee, Ph.D., Cocrystal's President and co-interim CEO. "Results from this study will be incorporated into a regulatory submission to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct the human challenge Phase 2a study. Pending approval by the Agency, we expect initiation of the Phase 2a study in the second half of 2023."

About CC-42344 and Influenza

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 essential 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.

According to a June 2022 report by Precision Reports, the global influenza therapeutics

market is projected to reach \$9.5 billion by 2027, up from \$6.6 billion in 2020 and growing at a 4.8% CAGR between 2021 and 2027.

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.

Cocrystal Pharma 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 completion and submission of our Phase 1 results to the United Kingdom Medicines and Healthcare Products Regulatory Agency, our collaboration with a U.K.-based clinical research organization to conduct a Phase 2a clinical trial and the characteristics and anticipated resulting shortened timeline for the study including the anticipated initiation of the study in the second half of 2023, the potential design and efficacy of CC-42344, and the demand for products designed to treat influenza and opportunities presented thereby. 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 availability of federal government funding and budgetary issues that may arise, the risks and uncertainties arising from any future impact of the Russian invasion of Ukraine, and/or inflation and interest rate increases on the global economy, the U.K. and on our Company and collaboration partners, including supply chain disruptions and our continued ability to proceed with our programs such as obtaining the requisite regulatory approvals including from the United Kingdom Medicines and Healthcare Products Regulatory Agency, the ability of the CRO to recruit patients into clinical trials, and the results of the studies for CC-42344. 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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