August 8, 2022

Cocrystal Pharma Engages CRO to Conduct Phase 2a Human Challenge Influenza A Clinical Trial with Novel, Broad-Spectrum Antiviral Candidate CC-42344

BOTHELL, Wash., Aug. 08, 2022 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces it has engaged hVIVO, a subsidiary of London-based Open Orphan plc (AIM: ORPH), a rapidly growing specialist contract research organization (CRO), to conduct a Phase 2a clinical trial with the Company's novel, broad-spectrum, orally administered antiviral candidate *CC-42344*. This candidate represents a new class of investigational medicine designed to directly inhibit replication of the virus for the treatment of pandemic and seasonal influenza A.

"We are highly encouraged by the Phase 1 healthy volunteer trial results received so far and are committed to rapidly advancing this program into a human challenge Phase 2a trial in influenza A-infected subjects," said Sam Lee, Ph.D., Cocrystal's President and co-interim CEO. "The fact that influenza virus is constantly mutating against existing influenza antiviral drugs elevates an urgent need for effective antiviral therapeutics. *CC-42344* is a broad-spectrum oral PB2 inhibitor that is highly active against drug-resistant influenza A strains. Further clinical development of *CC-42344* offers an opportunity to address the need. Open Orphan is a world leader in conducting human challenge clinical trials with antiviral drug candidates, making it an ideal partner for conducting our Phase 2a trial."

The single-center, double-blind, placebo-controlled Phase 2a human challenge trial is designed to evaluate safety, viral and clinical measures of orally administered *CC-42344* to subjects challenged with influenza A. The trial is expected to be initiated in the second half of 2023, pending approval from the United Kingdom Medicines and Healthcare Products Regulatory Agency. This study will be conducted at hVIVO's state-of-the-art facility in the United Kingdom.

Yamin "Mo" Khan, Open Orphan CEO, said, "We are pleased to be working with Cocrystal to evaluate its promising antiviral drug candidate for influenza A. A human challenge trial is an excellent option for Cocrystal, as it can rapidly provide efficacy data at a lower cost than traditional field trials."

Cocrystal is conducting a Phase 1 study with *CC-42344* in healthy subjects in Australia. The Company recently announced pharmacokinetic (PK) data supporting once-daily dosing from the single-ascending dose portion of this study. Enrollment in the multiple-ascending dose portion of the Phase 1 trial is ongoing, with full trial results expected in 2022.

About CC-42344 and Influenza
CC-42344 is an oral PB2 inhibitor that blocks an essential step of viral replication.*CC-42344* was 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, including pandemic 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 pharmacokinetic and safety profiles.

The global influenza therapeutics market is projected to reach $9.5 billion by 2027, from $6.6 billion in 2020, growing at a 4.8% CAGR between 2021 and 2027, according to a report published by Precision Reports in June 2022.

About hVIVO and Open Orphan plc
hVIVO, a subsidiary of Open Orphan plc, is a rapidly growing specialist contract research organization (CRO) and the world leader in testing infectious and respiratory disease vaccines and antivirals using human challenge clinical trials, providing end-to-end early clinical development services for its broad and longstanding client base of biopharma companies.

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 our collaboration with hVIVO to conduct a Phase 2a clinical trial for CC-42344 and the anticipated timeline for the study, 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 COVID-19 pandemic including in Australia, the Russian invasion of Ukraine, and/or inflation and Federal Reserve interest rate increases in response thereto on the global economy and on our Company, 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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