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Cocrystal Pharma Receives Australian Regulatory Clearance to Initiate Phase 1 Study of CC-42344 for the Treatment of Pandemic and Seasonal Influenza

BOTHELL, Wash., Oct. 06, 2021 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company"), a clinical-stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of coronaviruses, influenza, hepatitis C viruses and noroviruses, announces receipt of clearance from an Australian Human Research Ethics Committee (HREC) to initiate a Phase 1 trial with its orally administered PB2 inhibitor CC-42344 for the treatment of pandemic and seasonal influenza A.

The Phase 1 randomized, double-blind, placebo-controlled study is expected to enroll 56 healthy volunteers at a single site in Australia. The study is designed to assess the safety, tolerability and pharmacokinetics of CC-42344.

CC-42344 binds to a highly conserved PB2 site of influenza polymerase complex and exhibits a novel mechanism of action that inhibits viral replication. In preclinical testing, CC-42344 demonstrated excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu® and Xofluza®-resistant strains, as well as favorable pharmacokinetic and drug-resistance profiles.

"The need for a novel, broad-spectrum, oral antiviral for pandemic and seasonal influenza A is clear as current approved influenza treatments are partially effective and are prone to viral resistance," said Sam Lee, Ph.D., Cocrystal's President and co-interim CEO. "We discovered CC-43244 using our proprietary structure-based drug discovery platform technologies. CC-43244 is specifically designed to be effective against pandemic and seasonal influenza A strains and emerging avian influenza viruses."

"Our decision to conduct the Phase 1 trial in Australia was due to favorable regulatory policies and a clinical trial environment that aligns with our strategy for rapid, cost-efficient and high-quality clinical development," added James Martin, Cocrystal's CFO and co-interim CEO. "We are delighted to begin our first clinical study with CC-42344 as a treatment for this major global health concern."

The World Health Organization (WHO) estimate there are approximately 1 billion cases of influenza annually worldwide, resulting in 3 million to 5 million cases of severe illness and 290,000 to 650,000 deaths. The Center for Disease Control (CDC) estimates that since 2010 influenza has resulted in 9 million to 45 million illnesses in the U.S. annually, resulting in 140,000 to 810,000 hospitalizations and 12,000 to 61,000 deaths.

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 coronaviruses (including SARS-CoV-2), influenza viruses, hepatitis C virus 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 conducting the Phase 1 study of CC-42344 in Australia and our strategy with respect to clinical development. 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 the impact of the COVID-19 pandemic on the national and global economy, on our collaboration partners, CROs, CMOs, and on our Company, including raw material and test animal shortages and other supply chain disruptions, the ability of our CROs to recruit volunteers for, and to proceed with, clinical trials, possible delays resulting from the lockdowns in Australia, potential delays related to the manufacturing of the drug for the study, the results of clinical trials, general risks arising from clinical trials, receipt of regulatory approvals, regulatory changes, and development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government. 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, 2020. 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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