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Cocrystal Pharma Receives UK MHRA Authorization to Initiate Its Phase 2a Influenza Human Challenge Trial with Oral PB2 Inhibitor CC-42344

BOTHELL, Wash., Oct. 31, 2023 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) (Cocrystal or the Company) announces receipt of authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) to initiate a Phase 2a human challenge trial with its broad-spectrum, oral PB2 inhibitor CC-42344 as a potential treatment for pandemic and seasonal influenza A. Cocrystal expects to begin treating influenza-infected subjects in this trial during the fourth quarter of 2023.

In late 2022 [Cocrystal reported highly favorable safety and tolerability results in the single-ascending and multiple-ascending dose portions of the healthy volunteer Phase 1 trial](#) conducted in Australia. The Phase 2a single-site, double-blind, placebo-controlled human challenge trial will evaluate the safety, viral and clinical measurements of orally administered CC-42344 in subjects infected with influenza A.

"We are pleased to have met the regulatory requirements of the MHRA to begin this Phase 2a human challenge trial in the UK," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "Influenza is a major global health threat that may become more challenging to treat due to emergence of highly pathogenic avian influenza viruses and resistance to approved influenza antivirals. The need for new therapeutic and prophylactic treatments is clear. Our encouraging Phase 1 data demonstrated that CC-42344 has a favorable safety profile and is well-tolerated. CC-42344 has the potential to be a best-in-class antiviral treatment for pandemic and seasonal influenza infections."

"We are closely working with a world leading clinical research organization that is experienced in testing infectious and respiratory disease antivirals using human challenge clinical trials," said James Martin, Cocrystal's CFO and Co-CEO. "Receiving authorization to move ahead with our Phase 2a trial is a major step in our quest to bring CC-42344 to market and make a meaningful contribution to improving health and reducing the cost of care."

About Seasonal Influenza

Each year there are approximately one billion cases of seasonal influenza worldwide, 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 CC-42344

CC-42344 was discovered using Cocrystal's proprietary structure-based drug discovery

platform technology and is a novel approach to treating pandemic and seasonal influenza A. *In vitro* data show that CC-42344 is highly active against drug-resistant influenza A strains with a high barrier to resistance, while also demonstrating favorable pharmacokinetic and safety profiles.

About Cocystal Pharma, Inc.

Cocystal 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. Cocystal employs unique structure-based technologies and Nobel Prize-winning expertise to create first- and best-in-class antiviral drugs. For further information about Cocystal, please visit www.cocystalpharma.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 initiation and characteristics of a Phase 2a study for CC-42344 and the potential efficacy and clinical benefits of such product candidate and the demand for such a product. 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 arising from manufacturing and research delays arising labor shortages and other factors, the ability of our Clinical Research Organization partner to recruit volunteers for, and to proceed with, the Phase 2a clinical study for CC-42344, general risks arising from conducting a clinical trial, receipt of regulatory approvals for future trials, regulatory changes, development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the governmental authorities, and potential mutations in a virus we are targeting which may result in variants that are resistant to a product candidate we may develop. 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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