September 26, 2024

Cocrystal Pharma Advances Oral Pan-Viral Protease Inhibitor CDI-988 into Phase 1 Multiple-Ascending Dose Cohorts

BOTHELL, Wash., Sept. 26, 2024 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces dosing of the first subjects in the multiple-ascending dose (MAD) portion of the Phase 1 study with CDI-988, its potent, broad-spectrum, oral pan-viral protease inhibitor. Topline study results are expected in late 2024 or early 2025. CDI-988 was specifically designed and developed using Cocrystal's proprietary structure-based drug discovery platform technology and is being developed as the first-in-class pan-viral antiviral for the treatment of viral gastroenteritis and COVID-19 caused by noroviruses and coronaviruses, respectively.

"We are delighted to advance the clinical evaluation of CDI-988, a novel direct-acting antiviral (DAA) targeting the viral proteases of noroviruses and coronaviruses," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "Multiple-ascending dose results will further evaluate safety and tolerability of this potentially groundbreaking antiviral therapeutic."

This randomized, double-blind Phase 1 study, which is being conducted at a single center in Australia, is evaluating the safety, tolerability and pharmacokinetics of orally administered CDI-988 compared with placebo in healthy adults. In July 2024 Cocrystal reported favorable safety and tolerability results from study participants in the single-ascending dose (SAD) portion of the trial. All SAD participants completed the study with no reported serious adverse events or severe treatment-emergent adverse events. No clinically significant observations were noted in laboratory assessments, physical exams or electrocardiograms.

About Noroviruses

Human noroviruses are highly contagious, constantly evolving, extremely stable in the environment and associated with debilitating illness. Symptoms include vomiting and diarrhea, with or without nausea and abdominal cramps. Norovirus infection can be much more severe and prolonged in specific risk groups including infants, children, the elderly and people with immunodeficiency. In the U.S. alone, noroviruses are responsible for an estimated 21 million cases of acute gastroenteritis annually, including 109,000 hospitalizations, 465,000 emergency department visits and nearly 900 deaths, according to the Centers for Disease Control and Prevention (CDC). The estimated annual burden of noroviruses to the U.S. at $10.6 billion, according to the National Institutes of Health (NIH). Outbreaks occur most commonly in semi-closed communities such as nursing homes, hospitals, cruise ships, schools, disaster relief sites and military settings. To date, no antiviral treatment or vaccine is approved for norovirus infections.

Coronaviruses Including SARS-CoV-2 and its Variants

Coronaviruses (CoV) are a family of viruses that historically have been associated with a wide range of symptoms, ranging from no symptoms at all to more severe disease that includes pneumonia, acute respiratory distress syndrome (ARDS), kidney failure and death. By targeting the viral replication enzymes and protease, Cocrystal believes it is possible to develop an effective treatment for all coronaviruses, including SARS-CoV-2 (which causes COVID-19) and its variants, ARDS and Middle East Respiratory Syndrome (MERS). The ability of an asymptomatic individual to transmit infection heightened the public health challenge of COVID-19.

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), noroviruses, and hepatitis C viruses. 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 efficacy of CDI-988 against coronaviruses and noroviruses, the expected timing of topline results of the MAD portion of the CDI-988 study, and the potential market for such product candidate. 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, risks relating to our ability to obtain regulatory authority for and proceed with clinical trials including the recruiting of volunteers for the MAD cohorts of the CDI-988 Phase 1 study by our clinical research organizations and vendors, the results of such studies, our collaboration partners' technology and software performing as expected, general risks arising from clinical studies, receipt of regulatory approvals, regulatory changes, and potential development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government, and potential mutations in a virus we are targeting that may result in variants that are resistant to a product candidate we 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, 2023. 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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Source: Cocrystal Pharma, Inc.