September 8, 2025

Cocrystal Pharma Receives FDA IND Clearance for Challenge Study of Oral Broad-Spectrum Protease Inhibitor CDI-988, a Potential First Antiviral for Norovirus Prevention and Treatment

- *There are currently no approved vaccines or treatments for norovirus infection*
- *Cocrystal's CDI-988 is the first antiviral for the potential prevention and treatment of viral gastroenteritis caused by norovirus infections*
- *Phase 1b study is expected to start by year-end 2025*

BOTHELL, Wash., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces that the Company received a Study May Proceed Letter from the U.S. Food and Drug Administration (FDA) to conduct a Phase 1b challenge study evaluating CDI-988 for the prevention and treatment of norovirus infections. Cocrystal's oral broad-spectrum antiviral candidate CDI-988 represents a potential breakthrough for norovirus – the most common cause of acute viral gastroenteritis. The Phase 1b challenge study is planned to begin before year-end 2025.

CDI-988 is a novel pan-viral 3CL protease inhibitor developed for the treatment of norovirus and coronavirus infections. Preclinical data demonstrate that CDI-988 exhibits broad-spectrum antiviral activity by targeting a highly conserved region in the active site of the viral proteases. CDI-988 has shown effectiveness against major norovirus proteases including the prevalent GII.4 and GII.17. Data from the Phase 1 study showed oral CDI-988 to be well tolerated with a favorable safety profile. Currently, there are no approved vaccines or therapeutics for norovirus infections.

"The FDA's clearance of our CDI-988 study is an important milestone for Cocrystal and marks a significant step in advancing to the next stage of its clinical development. CDI-988 is the first novel, oral drug candidate for the prevention and treatment for norovirus infection and has demonstrated impressive data to date with broad antiviral activity," said Sam Lee, PhD, President and co-CEO of Cocrystal Pharma. "We look forward to the planned initiation of our Phase 1b challenge study and further determining the potential efficacy of CDI-988 in norovirus-infected patients."

About Norovirus

Norovirus infections affect millions globally, spreading rapidly through direct contact and contaminated food and surfaces. The virus is particularly problematic in confined environments such as cruise ships, hospitals, and military facilities. In the U.S., norovirus causes an estimated 21 million infections annually, including 109,000 hospitalizations, 465,000 emergency department visits and an estimated 900 deaths. Vulnerable populations,

including infants, elderly and those immuno-compromised, can face more severe and prolonged infections. Individuals can remain contagious for weeks after symptoms are resolved, complicating containment efforts.

Cocrystal Structure-Based Platform Technology
CDI-988 leverages Cocrystal's proprietary structure-based drug discovery platform, which provides three-dimensional visualization of inhibitor complexes at near-atomic resolution. This technology enables rapid identification of novel drug binding sites and accelerates the development of broad-spectrum antivirals for the treatment of acute and chronic viral diseases.

About Cocrystal Pharma, Inc.
Cocrystal Pharma, Inc. is a clinical-stage biotechnology company that addresses significant unmet needs by developing innovative antiviral treatments for challenging diseases including influenza, viral gastroenteritis, COVID, and hepatitis. Cocrystal employs unique structure-based technologies to create first- and best-in-class antiviral drugs.

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 plans to initiate a human Phase 1b challenge study for our norovirus 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, the risks and uncertainties arising from the ability of our clinical research organization to recruit volunteers for, and to otherwise proceed with the challenge study, our contract manufacturing organization's ability to produce the products needed for the study, geopolitical conflicts including those in Ukraine and Israel on our Company, our collaboration partners, and on the U.S., economy, including manufacturing and research delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions including any adverse impacts on our ability to obtain raw materials for and otherwise proceed with the study, and our ability to meet our liquidity needs. Further information on our risk factors is contained in our filings with the SEC, including the "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024. 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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