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Cocrystal Pharma Reports Phase 1 Results with Oral, Broad-Acting Antiviral Drug CDI-988 for Prophylaxis and Treatment of Norovirus, Coronaviruses and Other Viral Infections

- *Data show favorable safety and tolerability with dosing up to 800 mg for 10 days*
- *Plans to initiate human challenge study in 2025 in norovirus-infected subjects*

BOTHELL, Wash., Jan. 08, 2025 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company") announces favorable safety and tolerability results at dosing up to 800 mg per day for 10 consecutive days from the multiple-ascending dose (MAD) portion of the ongoing Phase 1 study with its oral protease inhibitor CDI-988, the first pan-viral drug candidate in development as an orally administered treatment of norovirus and coronavirus infections. The Company also announces that an additional cohort with a higher dose of 1,200 mg and a shorter treatment duration of five consecutive days will be conducted to further assess CDI-988's safety, tolerability and pharmacokinetics.

"Norovirus outbreaks are surging across the U.S. as well as on cruise ships with nearly 900 passengers sickened from gastrointestinal disease in December alone," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "There are currently no approved antivirals or vaccines for norovirus and the ability to curtail outbreaks is limited, making norovirus infection a significant unmet need. We are pleased to report positive Phase 1 results with these data demonstrating that CDI-988 had a favorable safety profile and was well-tolerated, supporting further clinical advancement of this potentially first effective norovirus antiviral."

"CDI-988 is our first pan-viral protease inhibitor with the potential to be used for prophylaxis and treatment for norovirus and coronavirus infections. We look forward to making a significant impact on norovirus outbreaks with this development candidate," he added. "We expect to begin enrollment in the Phase 1 study higher-dose cohort in the current quarter and to initiate a human challenge study in norovirus-infected subjects later in 2025."

CDI-988 is a potent, oral, broad-spectrum antiviral inhibitor of a highly conserved region in the active site of noroviruses, coronaviruses and other 3CL viral proteases. It was specifically designed and developed using Cocrystal's proprietary structure-based drug discovery platform technology. CDI-988 has shown pan-viral activity against multiple norovirus strains, including the genogroup II, genotype 4 (GII.4) [viruses that cause severe vomiting, diarrhea and stomach pain](#).

About Noroviruses

Human noroviruses are highly contagious, constantly evolving, extremely stable in the environment and associated with debilitating illness. Outbreaks occur most commonly in semi-closed communities such as nursing homes, hospitals, cruise ships, schools, disaster relief sites and military settings. 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.

According to the [Centers for Disease Control and Prevention](#) (CDC), an estimated 685 million cases and an estimated 200,000 deaths are attributed to norovirus each year worldwide, with an estimated societal cost of approximately \$60 billion. 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. The estimated annual burden of noroviruses to the U.S. is \$10.6 billion, according to the [National Institutes of Health \(NIH\)](#).

Structure-Based Platform Technology

Cocrystal's proprietary structural biology, along with its expertise in enzymology and medicinal chemistry, enable its development of novel antiviral agents. The Company's platform provides a three-dimensional structure of inhibitor complexes at near-atomic resolution, providing immediate insight to guide Structure Activity Relationships. This helps to identify novel binding sites and allows for a rapid turnaround of structural information through highly automated X-ray data processing and refinement. The goal of this technology is to facilitate the development of best-in-class antiviral therapies that have fast onset of action and/or shortened treatment time, are safe, well tolerated and easy to administer, are effective against all viral subtypes that cause disease and have a high barrier to viral resistance.

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 Cocrystal's plans to initiate a human challenge study in 2025 and the expansion of the current ongoing clinical trial with a higher dosage during the current quarter. 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 such studies 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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