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Cocrystal Pharma Selects Novel Oral Protease Inhibitor CDI-988 as Norovirus Lead

First dual coronavirus-norovirus oral antiviral is scheduled for Phase 1 in healthy volunteers

In vitro studies show broad-spectrum activity against noroviruses including GII.4 pandemic strains

No approved treatments or vaccines for norovirus infection

BOTHELL, Wash., Aug. 08, 2023 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company"), a clinical-stage biopharmaceutical company dedicated to developing novel small molecule antiviral therapeutics, announces the selection of its novel, oral, broad-spectrum 3CL protease inhibitor CDI-988 as a potential oral therapy for norovirus. The randomized, double-blind, placebo-controlled Phase 1 study of CDI-988 is approved by Australia Human Research Ethics Committees (HREC). The study is designed to assess the safety, tolerability and pharmacokinetics of CDI-988.

With no approved treatments or vaccines, norovirus represents a significant unmet medical need. It is a highly contagious infection and is the most common cause of acute gastroenteritis, accounting for [nearly one in five cases](#). 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 \$60 billion. About 200 million cases are reported among children under five years of age, leading to an estimated 50,000 child deaths every year. Among 30 known genotypes of human norovirus, [nearly 60% of outbreaks are attributable to genogroup II, genotype 4 \(GI.4\)](#) strains, which have caused periodic human pandemics since 1996.

CDI-988 was specifically designed and developed as a broad-spectrum antiviral inhibitor using Cocrystal's proprietary structure-based drug discovery platform technology. It targets a highly conserved region in the active site of coronaviruses, noroviruses and other 3CL viral proteases. Cocrystal previously selected CDI-988 to investigate as an oral treatment for COVID-19 and is approved to conduct a Phase 1 study in Australia, following approval by that country's Human Research Ethics Committee (HREC). In recent preclinical *in vitro* studies, CDI-988 showed potent broad-spectrum antiviral activity against a panel of pandemic GII.4 norovirus proteases and a favorable pharmacokinetic property targeting the gastrointestinal tract.

"In preclinical testing CDI-988 showed significant activity against seven different pandemic strains of norovirus, and we are enthusiastic about developing this compound as a dual broad-spectrum antiviral inhibitor," said Sam Lee, PhD, Cocrystal President and co-CEO. "CDI-988 further validates our proprietary structure-based drug-discovery platform

technology and contributes to our robust product pipeline. Our approach is to develop an effective targeted oral treatment for acute and chronic gastroenteritis caused by norovirus, as well as for potential use in addressing future pandemic norovirus outbreaks.”

“Given the recent increase in norovirus cases and the lack of approved treatments or vaccines, we continue to see a significant opportunity for our broad-spectrum antiviral CDI-988,” said James Martin, Cocystal CFO and co-CEO. “There has been a sharp rise in norovirus outbreaks worldwide since 1996 with the emergence of the GII.4 strain. [Already in 2023, 13 outbreaks on cruise ships have been reported](#), the largest number of such infections in a decade.”

About Norovirus

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 and people with immunodeficiency. In the United States 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 CDC. The National Institutes of Health](#) (NIH) estimates the annual burden to the U.S. at \$10.6 billion. Outbreaks occur most commonly in semi-closed communities such as nursing homes, hospitals, cruise ships, schools, disaster relief sites and military settings.

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 and noroviruses) and hepatitis C viruses. 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 1 study for CDI-988 and the potential efficacy and clinical benefits of 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, regulatory approval to commence the planned trial, risks relating to the Australian economy, 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 1 clinical study for CDI-988, and general risks arising from conducting a clinical trial. 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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