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Cocrystal Pharma Doses First Subjects in Clinical Study of CDI-988 For Pandemic Norovirus and Coronavirus

BOTHELL, Wash., Sept. 28, 2023 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company"), announces dosing of the first subjects in a Phase 1 clinical trial with its oral, first-in-class pan-norovirus and pan-coronavirus 3CL protease inhibitor CDI-988. This pan-viral protease inhibitor was discovered using the Company's proprietary structure-based drug discovery platform technology. The Phase 1 study will evaluate the safety, tolerability and pharmacokinetics of oral CDI-988 in single ascending doses (SAD) including food effect cohort, and multiple ascending doses (MAD) compared to placebo in healthy volunteers.

"CDI-988 is a breakthrough discovery of the first-in-class pan-coronavirus and pan-norovirus antiviral agent with potential efficacy in these two indications and we excited to take the first step in its clinical development. Our oral antiviral candidate has the potential to save patient lives and reduce the severity of norovirus and coronavirus infections now and in future pandemic outbreaks," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "We are looking forward to advancing CDI-988 to the next stage of norovirus and coronavirus clinical development upon completion of this Phase 1 study, setting up a transformational year ahead for Cocrystal."

Recent CDI-988 *in vitro* studies showed potent broad-spectrum antiviral activity against a panel of pandemic GII.4 norovirus proteases and a favorable pharmacokinetic property targeting the gastrointestinal tract. [GII.4 proteases have caused the majority of norovirus outbreaks worldwide since 2002](#) and represent an unmet medical need for an approved antiviral treatment and vaccine against noroviruses.

"We believe CDI-988 to be a gamechanger in providing an effective targeted, oral treatment for COVID-19 and its variants, as well as for noroviruses," added James Martin, Cocrystal's CFO and co-CEO. "There are no approved treatments or vaccines for norovirus, which has an [annual estimated societal cost of \\$60 billion](#). Driven by the anticipated emergence of new COVID-19 variants, the [global COVID-19 therapeutics market is estimated to exceed \\$16 billion by the end of 2031](#)."

"In keeping with our corporate mission, this Phase 1 study with CDI-988 is being run cost-efficiently under the favorable regulatory environment and government incentive programs offered by the Australian government," he added.

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, the elderly, 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. To date, no antiviral treatment or vaccine is approved for norovirus infections.

About CDI-988

CDI-988 was specifically designed and developed as a broad-spectrum antiviral inhibitor using Cocystal'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. Cocystal is approved to conduct a CDI-988 Phase 1 study in Australia by that country's Human Research Ethics Committee (HREC).

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) 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 as a product candidate for oral dual coronavirus-norovirus antiviral therapy and the potential efficacy and clinical benefits of, and 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 the Australian economy, manufacturing and research delays arising from labor shortages and other factors, and general risks arising from or involved in conducting a clinical study for CDI-988, including the results of such study. 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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