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Cocrystal Pharma Submits Pre-Investigational New Drug Briefing Package to the FDA for Clinical Development Guidance of CDI-45205 for COVID-19 Treatment

FDA's response is expected to provide greater clarity and guidance on designing Phase 1 and Phase 2 clinical trials for CDI-45205

BOTHELL, Wash., Nov. 01, 2021 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces the submission of a pre-Investigational New Drug (IND) briefing package to the U.S. Food and Drug Administration (FDA) for its broad-spectrum protease inhibitor CDI-45205 for the treatment of patients with COVID-19.

"The pre-IND submission is a critical step to obtain the FDA's guidance on preclinical studies, manufacturing, toxicology, and clinical development plans for CDI-45205. We look forward to our communication with the FDA and advancing toward Phase 1 and Phase 2 clinical trials to address the unmet needs of patients and to contribute to global efforts to end this pandemic," said Sam Lee, Ph.D., Cocrystal's co-interim CEO and President.

"As with all of our antiviral candidates, we are exploring multiple routes of administration including oral, inhalation, and injection," added Dr. Lee. "We anticipate that CDI-45205 is best suited for intranasal/pulmonary administration based on its novel mechanism of action and pharmacokinetic profile, with this route having the advantage of direct delivery to the respiratory system, a primary infection site for SARS-CoV-2. We are also advancing preclinical studies with our novel oral COVID-19 protease inhibitors developed using our proprietary structure-based drug discovery technology, and are very excited about potential multiple treatment options for COVID-19."

"A number of drugs are being developed as COVID-19 treatments that were originally designed for other indications. These repurposed drugs or drug candidates are a good start for humanity, but likely not the best-in-class solution that will end the pandemic," said James Martin, Cocrystal's co-interim CEO and CFO. "Our drug candidates are specifically designed to target the viral replication enzymes and protease, which we believe makes it possible to develop effective treatments for COVID-19 and its variants."

About CDI-45205

CDI-45205 is among a group of protease inhibitors obtained under an exclusive license agreement with Kansas State University Research Foundation (KSURF) in 2020. CDI-45205

and several analogs showed potent *in vitro* activity against the SARS-CoV-2 Delta (India/B.1.617.2), Gamma (Brazil/P.1), Alpha (United Kingdom/B.1.1.7) and Beta (South African/B.1.351) variants, surpassing the activity observed with the original Wuhan strain. CDI-45205 has also shown good bioavailability in mouse and rat pharmacokinetic studies via intraperitoneal injection, and no cytotoxicity against a variety of human cell lines. Preclinical research demonstrated a strong synergistic effect with the FDA-approved COVID-19 medicine remdesivir. Additionally, a proof-of-concept animal study demonstrated that daily injection of CDI-45205 exhibited favorable *in vivo* efficacy in MERS-CoV-2 infected mice.

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 coronaviruses (including SARS-CoV-2), influenza viruses, hepatitis C virus and noroviruses. 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 FDA's response to our recent submission for CDI-45205, the ability to develop and efficacy of potential treatments against COVID-19 and advance our product candidates into clinical trials, and our strategy with respect to clinical development. 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 impact of the COVID-19 pandemic on the national and global economy, on our collaboration partners, CROs, CMOs, and on our Company, including manufacturing and research delays arising from raw material and test animal shortages and other supply chain disruptions, potential delays related to the FDA's review of our submissions, receipt of regulatory approvals, the results of any future clinical trials, general risks arising from clinical trials, regulatory changes, and development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government. 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, 2020. 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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