January 6, 2022

Cocrystal Pharma Receives FDA Guidance to Advance Clinical Development of its COVID-19 Antiviral CDI-45205

Response to pre-IND briefing package supports pathway to initiating a Phase 1 clinical study in 2022

BOTHELL, Wash., Jan. 06, 2022 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") announces receipt of guidance from the U.S. Food and Drug Administration (FDA) for the further development of *CDI-45205*, Cocrystal's novel SARS-CoV-2 main protease inhibitor as a potential treatment for COVID-19 and its variants via intranasal/pulmonary delivery. The FDA's guidance was received in a written response to Cocrystal's pre-Investigational New Drug (IND) briefing package that was submitted in October 2021.

"The FDA's response contained extensive and valuable responses to a list of questions we proposed in our pre-IND briefing package, providing key insights on advancing the non-clinical and clinical development of *CDI-45205*," said Sam Lee, Ph.D., President and interim co-CEO of Cocrystal. "The FDA's guidance marks an important milestone in our continued development of *CDI-45205*. We now have a clearer pathway for our planned Phase 1 single-ascending-dose and multiple-ascending-dose study that we expect to initiate in 2022, as well as directives for designing a subsequent Phase 2 study."

The FDA's response covered topics including preclinical studies, manufacturing, pharmacology and toxicology, and clinical development plans for *CDI-45205* for Phase 1 and Phase 2 studies. In preparation for clinical development, Cocrystal intends to conduct *CDI-45205* formulation development, IND-enabling studies and virology assessments, as well as API drug manufacturing for use in preclinical and clinical studies.

CDI-45205 is one of three COVID-19 programs underway at Cocrystal. In the second COVID-19 program, the Company plans to begin a Phase 1 study also in 2022 with an orally administered main protease inhibitor. In the third COVID-19 program, Cocrystal is using its unique structure-based technology platform to discover replication inhibitors for oral administration.

"Our COVID-19 programs feature novel inhibitors that are specifically designed to block viral replication of SARS-CoV-2," said James Martin, Cocrystal's CFO and interim co-CEO. "Our inhibitors have shown antiviral activity against various SARS-CoV-2 variants to date, including the Alpha, Beta, Gamma and Delta variants, and now even the Omicron variant. CDI-45205 is not a quick-to-market repurposed drug. Because of its design, we remain highly confident in the broad-spectrum antiviral ability of our compound CDI-45205 in addressing SARS-CoV-2 and variants."

About CDI-45205
CDI-45205 is among a group of protease inhibitors obtained by Cocrystal 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 mice infected with MERS-CoV-2.

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), hepatitis C viruses 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 our plans to initiate two Phase 1 studies in 2022, our further development of CDI-45205 and using its platform to discover replication inhibitors, and the potential efficacy of antiviral inhibitors against existing and new variants of COVID-19. 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 arising from supply chain disruptions on our ability to obtain products including raw materials and test animals as well as similar problems with our vendors and our current CRO and future CROs and CMOs, the impact of the COVID-19 pandemic including new variants on the national and global economy, the cooperation of the FDA in accelerating development in our COVID-19 program, our collaboration partners' technology and software performing as expected, the results of future preclinical and clinical trials, general risks arising from clinical trials, receipt of regulatory approvals, 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.

Investor Contact:
LHA Investor Relations
Jody Cain
310-691-7100
jcain@lhai.com

###

Source: Cocrystal Pharma, Inc.