

April 2, 2026



Cocrystal Pharma Receives FDA Fast Track Designation for CDI-988 for Norovirus Infection Treatment and Preventive

- *FDA Fast Track designation supports accelerated development and expedites regulatory review*
- *Norovirus is responsible for an estimated 685 million global cases each year and approximately \$60 billion in worldwide economic impact*

BOTHELL, Wash., April 02, 2026 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company") announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its oral, direct-acting protease inhibitor, CDI-988, the first oral antiviral candidate being developed for treatment and prophylaxis of norovirus infection.

FDA Fast Track designation aims to facilitate the development and accelerate the review process for drugs that treat serious conditions and address unmet medical needs. The designation enables early and frequent communication with the FDA throughout the development process, allows for rolling review of a New Drug Application (NDA), and may qualify a product for Priority Review at the time of NDA submission.

CDI-988 was designed and developed as an inhibitor of a highly conserved region of noroviruses, coronaviruses, and other 3CL viral proteases. A Phase 1b norovirus challenge study is underway at Emory University School of Medicine to evaluate CDI-988 to both prevent and treat norovirus infection.

"We are pleased that the FDA has granted Fast Track designation for CDI-988, marking a significant milestone for Cocrystal and a critical step toward helping patients with norovirus," said Sam Lee, Ph.D., President and co-CEO of Cocrystal Pharma. "Norovirus infections are highly contagious and can cause acute gastroenteritis, resulting in nausea, vomiting, stomach pain, diarrhea, fatigue, fever and dehydration. While most people recover within a few days, immunocompromised individuals can experience chronic, long-term norovirus infections that can persist for weeks to years. Based on compelling data generated to date, we believe that CDI-988 has the potential to both prevent and treat norovirus infection.

"This designation further validates using our unique structure-based drug discovery technology to design pan-viral antivirals that are effective new treatment options," added Dr. Lee. "We look forward to more frequent interactions with the FDA with the goal of delivering the first therapeutic and preventive medicine to treat norovirus infections."

About Norovirus

Norovirus is a leading cause of acute gastroenteritis, responsible for an [estimated 685 million global cases each year and approximately \\$60 billion in worldwide economic impact. In the United States alone, the virus is associated with 21 million infections annually, resulting in around 109,000 hospitalizations, 465,000 emergency department visits, and 900 deaths.](#) The estimated annual economic burden in the [U.S. exceeds \\$10.6 billion.](#) In developing nations, norovirus contributes to [up to 1.1 million hospitalizations and 218,000 pediatric deaths each year.](#)

Cocrystal's ongoing Phase 1b randomized, double-blind, placebo-controlled challenge study ([NCT07198139](#)) at Emory University School of Medicine will evaluate CDI-988 in up to 40 healthy adults. The primary endpoint is a reduction in the incidence of clinical symptoms, with secondary endpoints assessing viral shedding, disease severity, safety, and pharmacokinetics.

About Cocrystal Pharma's Structure-Based Drug Discovery Platform

Cocrystal is leveraging its structure-based drug discovery platform technology to design next-generation antiviral candidates that precisely target viral replication mechanisms. By binding to highly conserved regions of viral enzymes, the Company's compounds aim to maintain potency against mutating strains while minimizing off-target effects, offering potentially safer, broad-spectrum antiviral solutions. This approach streamlines candidate identification and optimization, enabling more rapid progression of promising therapies with robust resistance and safety profiles.

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 noroviruses, influenza viruses, coronaviruses (including SARS-CoV-2), and rhinoviruses. Cocrystal employs unique structure-based technologies and Nobel Prize-winning expertise to create viable 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 for more frequent interactions with the FDA and our goals with respect to our norovirus 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, the risks and uncertainties arising from delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions including any adverse impacts on our ability to obtain raw materials for and otherwise proceed with studies as well as similar problems with our vendors and our current and any future clinical research organization (CROs) and contract manufacturing organizations, the progress and results of the studies including any adverse findings or delays, the ability of us and our CROs to recruit volunteers for, and to otherwise proceed

with, clinical studies, our and our collaboration partners' technology and software performing as expected, financial difficulties experienced by certain partners, the results of any current and future preclinical and clinical studies, general risks arising from clinical studies, receipt of regulatory approvals, regulatory changes and any adverse developments which may arise therefrom, and general economic adverse effects from the ongoing conflict with Iran. Further information on our risk factors is contained in our filings with the SEC, including the "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2025. 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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Source: Cocrystal Pharma, Inc.