

Cocrystal Pharma Receives IRB Approval from Emory University School of Medicine for Phase 1b Human Challenge Study with CDI-988 for Prevention and Treatment of Norovirus

- *Subject enrollment expected to begin in Q1 2026*
- *CDI-988 is the first oral broad-spectrum antiviral drug candidate for potential prevention of norovirus outbreaks and treatment of acute viral gastroenteritis caused by norovirus infection*
- *There are no approved treatments or vaccines currently available for norovirus infection*

BOTHELL, Wash., Dec. 18, 2025 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company") announces the approval from the Institutional Review Board (IRB) at Emory University School of Medicine to initiate a Phase 1b human challenge study with CDI-988. This study aims to evaluate CDI-988 as both a preventive and treatment for norovirus infections. Initial screening of study subjects is currently underway, with enrollment expected to begin in the first quarter of 2026. The IRB approval from Emory University School of Medicine follows Cocrystal's prior regulatory milestones, including U.S. Food and Drug Administration (FDA) clearance of its investigational New Drug (IND) application.

CDI-988 is the first oral antiviral drug candidate developed for the prevention and treatment of norovirus acute gastroenteritis. It was specifically designed as a broad-spectrum inhibitor by targeting a highly conserved region of the viral 3CL protease of all noroviruses, including GII.4 and recently re-emerging GII.17.

The randomized, double-blind, placebo-controlled Phase 1b study will be conducted at Emory University and involve up to 40 healthy subjects ages 18-49. Participants will be screened and infected with the norovirus GII.2 (Snow Mountain Virus). The study's primary efficacy endpoint is to assess the reduction in incidence of clinical symptoms, while the secondary efficacy endpoint focuses on the reduction in viral shedding and disease severity. The study will also assess the safety and pharmacokinetic profile of CDI-988. Additional information is available on clinicaltrials.gov.

"This approval from the Emory IRB marks a significant milestone in advancing our Phase 1b norovirus challenge study," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "We are very excited about collaborating with the Emory team, given their exceptional expertise in norovirus and experience in human challenge studies."

“Cocrystal’s norovirus challenge study is a critical step in addressing the global burden of norovirus outbreaks, which account for an estimated 700 million cases each year worldwide. We are committed to delivering innovative medicine for norovirus outbreaks and chronic norovirus infection among immunocompromised patients,” added Dr. Lee.

“CDI-988 may revolutionize the management of the highly contagious norovirus, which is known for quickly spreading in hospitals, nursing homes, cruise ships, schools, disaster relief sites, military settings and other semi-closed environments,” said James Martin, CFO and co-CEO. “Used as a prophylaxis, oral CDI-988 could offer a potential solution and add a new layer of defense.”

CDI-988 was designed with Cocrystal’s proprietary structure-based drug discovery platform technology. In August 2025 Cocrystal announced favorable Phase 1 safety and tolerability data from all CDI-988 dose cohorts including the highest dose of 1200 mg. In September 2025 the Company received a Study May Proceed Letter from the FDA for the Phase 1b challenge study.

About Norovirus

Norovirus is a common and highly contagious virus that afflicts people of all ages and causes symptoms of acute gastroenteritis including nausea, vomiting, stomach pain and diarrhea, as well as fatigue, fever and dehydration. This debilitating illness [causes](#) an estimated 200,000 deaths worldwide each year, with a societal cost of approximately \$60 billion. In the U.S., norovirus is responsible for about 21 million cases of acute gastroenteritis annually, including 109,000 hospitalizations, 465,000 emergency department visits and nearly 900 deaths, with an estimated annual economic burden of [\\$10.6 billion](#).

Cocrystal Pharma’s Structure-Based Drug Discovery Platform Technology

Cocrystal’s proprietary structural biology, along with its expertise in enzymology and medicinal chemistry, enable its development of novel antiviral agents. The Company’s platform provides a three-dimensional structure of inhibitor complexes at near-atomic resolution, providing immediate insight to guide Structure Activity Relationships. This helps identify novel binding sites and enables a rapid turnaround of structural information through highly automated X-ray data processing and refinement. The goal of this technology is to facilitate the development of novel broad-spectrum antivirals for the treatment of acute, chronic and potentially pandemic viral diseases.

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), noroviruses and hepatitis C viruses. Cocrystal employs unique structure-based technologies 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 initiation of the

norovirus study in the first quarter of 2026 and the potential of CDI-988 for norovirus infections. 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 inflation, affordability, the possibility of a recession, the impact of future interest rate changes on the economy, tariffs and the resulting litigation, and geopolitical conflicts including those in Ukraine and Middle East on our Company, our collaboration partners, and on the U.S. and global economies, including manufacturing and research 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 the planned norovirus study or subsequent studies as well as similar problems with our vendors and our current and any future clinical research organizations (CROs) and contract manufacturing organizations (CMOs), 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, potential mutations in a virus we are targeting that may result in variants that are resistant to a product candidate we develop, the potential for the development of effective treatments by competitors which could reduce or eliminate a prospective future market share commercializing any product candidates we may develop in the future, and our ability to meet our future liquidity needs. 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, 2024 and the Prospectus dated September 25, 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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