



Cosmo Announces Completion of Phase II Enrolment in Distal Ulcerative Colitis Program

Dublin, Ireland – May 18, 2026: Cosmo N.V. (SIX: COPN, XETRA: C43) ("Cosmo" or "the Company") today announced the completion of patient enrolment in its Phase II clinical trial (EUCT number: 2023-506917-23-00) evaluating its novel investigational therapy, Rifamycin enema, for the treatment of distal ulcerative colitis (UC) and ulcerative proctitis. A total of **77 patients** were enrolled at **24 clinical sites in Europe**, reflecting strong investigator engagement and efficient study execution.

Distal ulcerative colitis, and in particular ulcerative proctitis, remain clinically significant and underserved conditions, with both conditions affecting approximately 3.5 million patients worldwide. Current treatment options are often constrained by suboptimal topical efficacy or unnecessary systemic exposure, and the field has seen limited innovation in topical rectal therapies; particularly in the United States, where no new treatments have been approved for several years.

Cosmo's investigational therapy, rifamycin enema, is designed to address this gap. The product contains rifamycin sodium as the active ingredient and is formulated to transform into a bio-adhesive gel after administration. This allows targeted delivery of the active drug directly to the distal colon and rectum, where inflammation occurs.

This targeted delivery approach has the potential to represent a first in class advancement in the topical treatment of distal ulcerative colitis and ulcerative proctitis. By combining rifamycin's antibiotic and anti-inflammatory properties^{1,2,3} with precision delivery, mucosal adherence, and a neutral pH formulation, the therapy is designed to improve local efficacy and tolerability⁴.

The Phase II study is designed to evaluate the safety and efficacy of rifamycin enema in patients with distal ulcerative colitis and ulcerative proctitis. Topline results are expected in the fall of 2026.

Clinical Perspective

"Distal ulcerative colitis and ulcerative proctitis continue to represent a significant unmet medical need in daily clinical practice," said Professor Simon Travis, Professor of Clinical Gastroenterology, University of Oxford, and former President of the European Crohn's and Colitis Organization.

"Approximately 70% of patients with ulcerative colitis initially present with disease involving the rectum and distal colon, making this one of the most common forms of the disease encountered by

¹ Rosette C. et al. J Infectiology. 2019. 2(4): 18-24.

² Rosette C. et al. Drug Metab. Pharmacokinet. 2019. 34(3): 172-180.

³ Aiello C. et al. Microbiol. Res. 2025. 16, 44.

⁴ Mangano K. et al. Drug Deliv. Transl. Res. 2025. 15(9): 3296-3306.



gastroenterologists. Patients with proctitis are commonly excluded from Phase III programs of ulcerative colitis therapies and are therefore not specifically represented in the approved labels of those products. As a result, physicians continue to rely on treatment approaches that have seen little innovation for many years. Many patients experience persistent symptoms despite available therapies, underscoring the need for new treatments that directly target the site of inflammation."

Simon Travis added: *"A therapy designed for precise delivery to the distal colon, with mucosal adherence of the gel and a neutral pH, could represent a new treatment paradigm. Furthermore, a therapy such as topical rifamycin could locally address two of the known causes of UC: inflammation and an imbalance in gut bacteria. If confirmed in clinical trials, this approach has the potential to redefine how we manage patients with distal disease and proctitis in particular".*

Strategic Momentum and Execution

"This milestone reflects both strong execution and a clear strategic focus," said Giovanni Di Napoli, Chief Executive Officer of Cosmo. "We enrolled 77 patients across 24 sites on schedule, demonstrating strong investigator interest and the operational capabilities required to advance innovative therapies efficiently. Cosmo has a long-standing track record in gastroenterology and in developing targeted delivery technologies designed to act locally at the site of disease. This program builds directly on that expertise."

Giovanni Di Napoli added: *"We believe this program represents an attractive value creation opportunity for Cosmo. It addresses a large and underserved segment of the ulcerative colitis market with a differentiated, locally acting approach that has the potential to deliver meaningful clinical benefit while minimizing systemic exposure. With topline results expected in the fall of 2026, we are approaching an important value inflection point for this program and for Cosmo."*

About Distal Ulcerative Colitis and Ulcerative Proctitis

Distal ulcerative colitis is a form of ulcerative colitis affecting the descending colon, sigmoid colon, and rectum. Ulcerative proctitis is a form of ulcerative colitis affecting the rectum alone. Patients frequently experience persistent symptoms despite available therapies, underscoring the need for more effective and targeted treatment approaches.

About Cosmo

Cosmo is a life sciences company focused on MedTech AI, dermatology, gastrointestinal diseases, and contract development and manufacturing (CDMO). We design, develop, and manufacture advanced solutions that address critical medical needs and raise the standard of care. Our technologies are trusted by leading global pharmaceutical and MedTech companies and reach patients and healthcare providers around the world. Guided by our purpose – Building Health Confidence – our mission is to empower patients, healthcare professionals, and partners by innovating at the intersection of science and technology. Founded in 1997, Cosmo is headquartered in Dublin, Ireland, with offices in San Diego (USA), and in Lainate, Rome, and Catania (Italy). For more information, visit www.cosmohealthconfidence.com

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