



PureTech Founded Entity Vedanta Biosciences Announces Phase 2 Study of VE202 in Ulcerative Colitis Did Not Meet Primary Endpoint

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VE202 was well tolerated, with no reports of treatment-related serious adverse events

Additional analyses from COLLECTiVE202 to be shared in upcoming scientific forums

Vedanta to focus resources on ongoing Phase 3 RESTORATiVE303 registrational study of VE303 in recurrent Clostridioides difficile infection

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) (" PureTech "), noted that its Founded Entity, Vedanta Biosciences , ("Vedanta") a late clinical-stage biopharmaceutical company developing microbiome-based oral therapies for gastrointestinal diseases, today announced that its candidate VE202 did not meet the primary endpoint in the Phase 2 COLLECTiVE202 study for the treatment of patients with mild-to-moderate ulcerative colitis (UC).

Vedanta remains focused on advancing its lead program, VE303, for the prevention of recurrent *Clostridioides difficile* infection (CDI). Ulcerative colitis and CDI are distinct diseases with different underlying biology, and VE202 and VE303 have different bacterial compositions and mechanisms of action. VE303 has demonstrated positive Phase 2 results, reducing CDI recurrence risk by more than 30% compared with placebo, and is currently being evaluated in the global, registrational Phase 3 RESTORATiVE303 study. The program has received both Fast Track and Orphan Drug designations from the FDA and, if approved, is positioned to become the first live biotherapeutic product for any indication. Vedanta is also advancing VE707, designed to prevent infections caused by multidrug-resistant organisms, with an IND submission planned for 2026.

Over the course of 2025, PureTech's ownership stake in Vedanta has been diluted to 4.2% on a fully diluted basis.

The full text of the announcement from Vedanta is as follows:

Vedanta Biosciences Announces Phase 2 Study of VE202 in Ulcerative Colitis Did Not Meet Primary Endpoint

VE202 was well tolerated, with no reports of treatment-related serious adverse events

Additional analyses from COLLECTIVE202 to be shared in upcoming scientific forums

*Vedanta to focus resources on ongoing Phase 3 RESTORATIVE303 registrational study of VE303 in recurrent *Clostridioides difficile* infection*

CAMBRIDGE, Mass. , August 13, 2025 - [Vedanta Biosciences](#) , a late clinical-stage biopharmaceutical company developing microbiome-based oral therapies for gastrointestinal diseases, today announced that its candidate VE202 did not meet the primary endpoint of endoscopic response in the Phase 2 COLLECTIVE202 study for the treatment of patients with mild-to-moderate ulcerative colitis (UC).

"We are very disappointed that our study did not meet its efficacy endpoints, and our greatest regret is that people living with inflammatory bowel disease will not, for now, have the opportunity to benefit from a new treatment option," said Bernat Olle, Ph.D., Chief Executive Officer of Vedanta Biosciences . "The gut microbiome is a well-recognized driver of IBD, yet remains a facet of the disease untouched by current treatments. As a field, we have not yet succeeded in making a meaningful impact for people with IBD through microbiome-based approaches, but every study moves us closer to that goal. We are committed to sharing further analyses of this study at upcoming scientific meetings to help chart new paths forward.

"Our priority at Vedanta remains the successful execution of our ongoing global pivotal study of VE303 for the prevention of recurrent *C. difficile* infection, with the goal of potentially delivering the first approved Live Biotherapeutic Product in any indication - and, in doing so, addressing a serious health condition with a significant unmet medical need," concluded Dr. Olle.

In the randomized, placebo-controlled COLLECTIVE202 study, endoscopic and clinical responses were assessed using standardized criteria, and the observed response rates in the VE202 group were not statistically different from those in the placebo group. VE202 was generally safe and well tolerated - most adverse events were mild or moderate in intensity, with no reports of treatment-related serious adverse events. Analyses of bacterial colonization, histological findings, and immune responses are ongoing and will be shared in future scientific forums.

Vedanta remains focused on advancing its other pipeline programs:

1. **VE303:** Vedanta is currently enrolling patients into RESTORATIVE303, a registrational Phase 3 study of VE303 for the prevention of recurrent *C. difficile* infection (rCDI) at over 200 sites in 24 countries. The Phase 3 program is supported by results from a positive Phase 2 study, in which VE303 demonstrated potentially best-in-disease efficacy with a 30.5% absolute risk reduction compared with placebo and greater than 80% reduction in the odds of a CDI recurrence.
2. **VE707:** Vedanta is also advancing VE707 to prevent infections by multidrug-resistant organisms that

affect a wide range of vulnerable populations in areas such as oncology, urology, transplantation, and critical care, with IND submission planned for 1H 2026.

About the COLLECTiVE202 Study

COLLECTiVE202 is a double-blind, placebo-controlled, randomized clinical trial conducted at sites in the United States, Europe, and Australia. The study enrolled 114 patients, between the ages of 18 and 75 years, with mild-to-moderate ulcerative colitis who had not been exposed to any biologic or advanced oral therapies. Either VE202 (N=57) or placebo (N=57) was added to a patient's stable background ulcerative colitis therapy. The primary endpoints were safety and Week 8 endoscopic response (defined as a reduction of at least 1 point on the Mayo endoscopic subscore). Secondary endpoints included clinical response and remission, endoscopic improvement and remission, as well as histological assessments and measures of colonization, quality-of-life and inflammatory biomarkers. For more information on COLLECTiVE202 (NCT05370885), visit clinicaltrials.gov.

About Vedanta Biosciences

[Vedanta Biosciences](#) is a clinical-stage biopharmaceutical company developing microbiome-based oral medicines for the treatment of gastrointestinal diseases. The company's lead asset is a potential first-in-class therapy, VE303, currently in a global Phase 3 registrational trial for prevention of recurrent *C. difficile* infection. Vedanta leverages its proprietary industry-leading product engine to develop therapeutic drug candidates based on defined bacterial consortia. The product engine is supported by broad foundational intellectual property and spans the development lifecycle from discovery to commercialization. It includes one of the largest libraries of bacteria isolated from the human microbiome, vast clinical datasets, proprietary capabilities in consortium design, and end-to-end CGMP manufacturing capabilities at commercial launch scale.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep portfolio through its experienced research and development team and its extensive network of scientists, clinicians, and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 29 therapeutics and therapeutic candidates, including three that have been approved by the U.S. Food and Drug Administration. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration-enabling studies. All of the underlying programs and platforms that resulted in this portfolio of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points.

For more information, visit www.puretechhealth.com or connect with us on X (formerly Twitter) @puretechh.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are or may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation those related to Vedanta's development plans, the applicability of the platform, potential benefits to patients, and Vedanta's and our future prospects, developments and strategies. The forward-looking

statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2024, filed with the SEC and in our other regulatory filings. These forward-looking statements are based on assumptions regarding the present and future business strategies of the Company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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