VERDICT Clinical Trial Factsheet

Determination of the Optimal Treatment Target in Ulcerative Colitis

TRIAL STATUS
Active, Not Recruiting

PHASE:
1 2 3 **4**

CLASS
Gut-selective immunosuppressive biologic[1]

Learn more at clinicaltrials.gov

Dosage & Administration[2]

Population[2]
Patients with moderately to severely active ulcerative colitis

Study Design[2]
✔ Multicenter ✔ Prospective ✔ Randomized

Primary Outcome Measures[2]

Select Secondary Outcome Measures[2]

References

1. Takeda Pharmaceuticals. Entyvio® (vedolizumab) SmPC. Swissmedic: June 2024 [Accessed January 2026]. Available from: https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=63285
2. Determination of the Optimal Treatment Target in Ulcerative Colitis (VERDICT). Clinicaltrials.gov identifier: NCT04259138. Updated: January 2026. Accessed: January 2026. https://clinicaltrials.gov/study/NCT04259138
3. Jairath V, et al. *BMJ Open Gastroenterol.* 2024;11 :e001218

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VV-MEDMAT-132536 | January 2026

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Dosage & Administration[2]

- **Biological: Treatment Algorithm A**
  - Participants who are treatment-naïve at screening will follow treatment algorithm A. Participants, upon entry into the study, will require standard first-line therapy. Either oral 5-ASA and/or immunosuppressive (with optional oral corticosteroid in combination) will be initiated.
  - Participants will be assessed to determine if remission target is achieved at weeks 16, 32 and 48. If the participant has achieved their treatment target, they will continue that line of therapy. If the participant has not achieved their treatment target, treatment and/or dose escalation will be administered according to the algorithm.
- **Biological: Treatment Algorithm B**
  - Participants who are taking non-biologic UC therapies at screening will follow treatment algorithm B.
  - Participants will change to intravenous vedolizumab therapy.
  - Participants will be assessed to determine if remission target is achieved at weeks 16, 32 and 48. If the participant has achieved their treatment target, they will continue that line of therapy. If the participant has not achieved their treatment target, treatment and/or dose escalation will be administered according to the algorithm.
- **Biological: Treatment Algorithm C**
  - Participants who are taking anti-TNF, tofacitinib or ustekinumab therapy at screening will follow treatment algorithm C.
  - Participants will change to intravenous vedolizumab therapy.
  - Participants will be assessed to determine if remission target is achieved at weeks 16, 32 and 48. If the participant has achieved their treatment target, they will continue that line of therapy. If the participant has not achieved their treatment target, treatment and/or dose escalation will be administered according to the algorithm.

5-ASA, 5-aminosalicylate; **TNF**, tumor necrosis factor; **UC**, ulcerative colitis

Population[2]

Patients with moderately to severely active ulcerative colitis

Actual enrollment
672 participants

Select Inclusion criteria[2]

- Diagnosis of UC confirmed by clinical, endoscopic, and histological evidence prior to screening as per standard criteria
- Moderately to severely active UC with a Mayo rectal bleeding subscore ≥1 and a Mayo endoscopic subscore (MES) ≥2, with minimum disease extent of 15 cm and objective evidence of inflammation that can be visualized using central endoscopic imaging system

Select Exclusion criteria[2]

- Subjects who have historically failed (i.e., had an inadequate response with, lost response to, or were intolerant to) 2 or more compounds or classes of advanced therapeutic options (biologics or small molecules; e.g., anti-TNFs, ustekinumab, or tofacitinib) for the treatment of their UC
- Current or previous treatment with vedolizumab, etrolizumab, or natalizumab
- Topical therapy (corticosteroid or 5-aminosalicylate [5-ASA]) use within 2 weeks prior to screening endoscopy
- Change to oral corticosteroid dosing within 2 weeks prior to randomization
- Known diagnosis of CD, indeterminate colitis, ischemic colitis, radiation colitis, diverticular disease associated with colitis, or microscopic colitis
- Short gut syndrome
- Positive stool culture for or active Clostridioides difficile infection (as demonstrated by positive toxin and/or antigen)

This is not a complete list of Inclusion and Exclusion Criteria. Before making any decision regarding trial enrollment, please consult the complete list at: https://clinicaltrials.gov/study/NCT04259138

5-ASA, 5-aminosalicylate; **CD**, Crohn's disease; **MES**, Mayo endoscopic subscore; **TNF**, tumor necrosis factor; **UC**, ulcerative colitis

Study Design[2]

✔ Multicenter ✔ Prospective ✔ Randomized

A Phase 4, multicenter, prospective, randomized trial to determine whether using a treatment target of corticosteroid-free symptomatic plus endoscopic plus histological remission is superior to a treatment target of just corticosteroid-free symptomatic remission in relation to UC-associated complications (NCT04259138)[1,2]

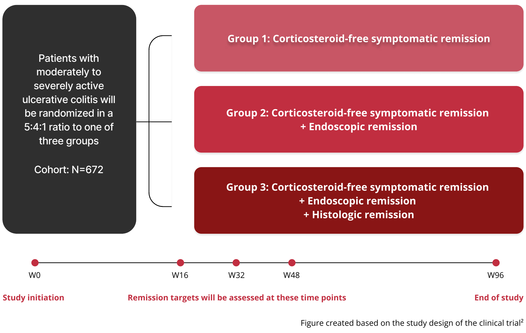

Figure created based on the study design of the clinical trial[2]

UC, ulcerative colitis; **W**, week

Primary Outcome Measures[2]

Primary efficacy objective: To determine whether a treatment target of corticosteroid-free symptomatic+endoscopic+histologic remission is superior to a treatment target of corticosteroid-free symptomatic remission alone, with regard to the primary efficacy outcome within up to 80 weeks of follow-up after target achievement[2,3]

Primary efficacy outcome: Time from treatment target achievement to a UC-related complication among patients who achieved their assigned treatment target[2,3]

UC, ulcerative colitis

Select Secondary Outcome Measures[2]

- Difference in time to a UC-related complication compared between treatment target groups 1 and 2[2]
- Difference in time to a UC-related complication compared between treatment target groups 2 and 3[2]
- Difference in time to a UC-related complication compared between treatment target groups (fast responder sub-group)[2]

UC, ulcerative colitis

References

1. Takeda Pharmaceuticals. Entyvio® (vedolizumab) SmPC. Swissmedic: June 2024 [Accessed January 2026]. Available from: https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=63285
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