VARSITY Clinical Trial Factsheet

Moderately to severely active ulcerative colitis

VARSITY Study

Vedolizumab[1] vs. adalimumab[2]

Study design: a phase 3b, randomized, double-blind, double-dummy, active-controlled superiority trial[3]

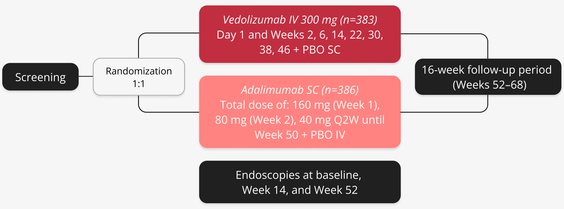


Figure based on data from Sands BE, et al. *N Engl J Med* 2019;381:1215-26

PRIMARY ENDPOINT

- Clinical remission at Week 52 (defined as a total score ≤2 on the Mayo scale and no subscore >1 on any of the four components)[3]

SECONDARY ENDPOINTS

- Endoscopic improvement (defined as a subscore of 0 or 1 on the Mayo endoscopic component)[3]
- Corticosteroid-free clinical remission at Week 52 in patients receiving corticosteroids at baseline[3]

EXPLORATORY ENDPOINTS

- Clinical remission at both Week 14 and Week 52[3]
- Improvement in subscores on the patient-reported components of the Mayo scale (stool frequency and rectal bleeding)[3]
- Improvement of QoL (defined as an increase of ≥16 points in the IBDQ score)[3]
- Histologic remission (defined as a Geboes score <2.0)[3]

KEY INCLUSION CRITERIA

- ✓ 18 to 85 years of age[3]
- ✓ Moderately to severely active UC[3]
- ✓ Colonic involvement of at least 15cm[3]
- ✓ Confirmed diagnosis of UC at least 3 months prior to screening[3]

KEY EXCLUSION CRITERIA

- ✗ Evidence of abdominal abscess or toxic megacolon[3]
- ✗ Extensive colonic resection, subtotal or total colectomy[3]
- ✗ Evidence of an active infection[3]
- ✗ Previously administered with vedolizumab or adalimumab[3]
- ✗ Unstable or uncontrolled cardiovascular disorder[3]

CD, Crohn's disease; **IBDQ**, inflammatory bowel disease questionnaire; **IV**, intravenous; **PBO**, placebo; **Q2W**, every 2 weeks; **QoL**, quality of life; **RHI**, Robarts Histopathology Index; **SC** subcutaneous; **TNFα**, tumor necrosis factor alpha; **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
2. AbbVie. Humira® (adalimumab) – SmPC. Swissmedic: January 2025 [Accessed January 2026]. Available from: https://swissmedicinfo.ch/showText.aspx?textType=FI&lang=DE&authNr=56221
3. Sands BE, et al. N Engl J Med. 2019;381:1215–26 (supplementary appendix).

PRIMARY ENDPOINT

- Vedolizumab was superior to adalimumab in achieving clinical remission at Week 52[1]
- Patients who had not previously received TNFα inhibitor therapy saw greater clinical remission at Week 52 compared with patients who had received previous TNFα inhibitor therapy across both vedolizumab and adalimumab groups[1]

Clinical remission at Week 52[1,2]

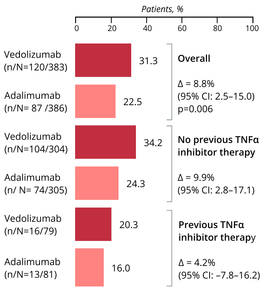
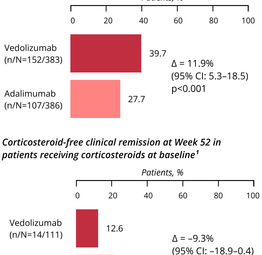


Figure adapted from Sands BE, et al. *N Engl J Med.* 2019;381:1215–26 (Figure 1A).

SECONDARY ENDPOINTS

- At Week 52, endoscopic improvement was observed in a higher percentage of patients receiving vedolizumab versus adalimumab[1]
- There was no statistically significant difference between vedolizumab and adalimumab for corticosteroid-free remission at Week 52[1]

***Endoscopic improvement at Week 52 in the overall population*[1]**



***Corticosteroid-free clinical remission at Week 52 in patients receiving corticosteroids at baseline*[1]**

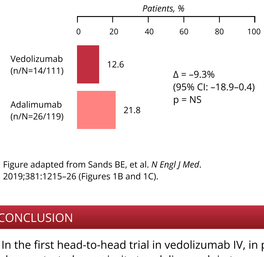
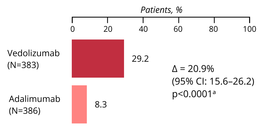


Figure adapted from Sands BE, et al. *N Engl J Med.* 2019;381:1215–26 (Figures 1B and 1C).

EXPLORATORY ENDPOINTS

- 18.3% of patients who received vedolizumab achieved durable remission* compared with 11.9% of patients in the adalimumab group (difference 6.3%; 95% CI: 1.3–11.3)[1]
- 58.2% of the patients in the vedolizumab group had a subscore of 0 or 1 on the stool frequency component of the Mayo scale at Week 52, versus 44.8% in the adalimumab group (difference 13.3%; 95% CI: 6.4–20.3)[1]
- 65.8% of patients treated with vedolizumab achieved a rectal bleeding subscore of ≤1 at Week 52, compared with 54.7% of those in the adalimumab group (difference 11.1%; 95% CI: 4.2–17.9)[2]
- QoL improved from baseline to Week 52 (increase of ≥16 points in the IBDQ score) in 52.0% of patients in the vedolizumab group and 42.2% in the adalimumab group (difference 9.7%; 95% CI: 2.7–16.7)[1]
- Histologic remission at Week 52 favored vedolizumab as measured by Geboes score and RHI score[3]

***Histologic remission with a Geboes score <2*[3]**



***Histologic remission with a RHI score ≤2*[3]**

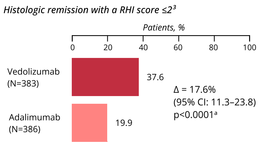


Figure adapted from Peyrin-Biroulet L, et al. *Gastroenterology.* 2021;161(4):1156-1167.e3 (Figures 1B and 3B).[a] Nominal p value.

- Histologic remission was indicated by a Geboes score <2 or by an RHI score ≤2. Patients with missing data were considered not to have had a response[3]

TOLERABILITY

- 69.2% in the adalimumab group and 62.7% in the vedolizumab group experienced adverse events[1]
- Serious adverse events occurred in 11% of patients in the vedolizumab group and 13.7% in the adalimumab group[1]
- Exposure-adjusted incidence rates of infections and serious infections were numerically lower in the vedolizumab group compared to the adalimumab group[1]

CONCLUSION

- In the first head-to-head trial in vedolizumab IV, in patients with moderately to severely active UC, vedolizumab demonstrated superiority to adalimumab in terms of clinical remission and endoscopic improvement, but not corticosteroid-free clinical remission.[1] The results for the outcomes of histologic remission were consistent with the findings for clinical remission and endoscopic improvement.[1]

*Patients who were in clinical remission at Week 14 and Week 52 were considered as having achieved durable clinical remission.

The Δ symbol refers to the difference between the vedolizumab and adalimumab groups (with the exact 95% CI).

CI, confidence interval; **IBDQ**, inflammatory bowel disease questionnaire; **IV,** intravenous; **QoL**, quality of life; **RHI**, Robarts Histopathology Index; **TNFα**, tumor necrosis factor alpha; **UC**, ulcerative colitis; **NS**, not significant.

References

1. Sands BE, et al. *N Engl J Med*. 2019;381:1215–26
2. Sands BE, et al. *N Engl J Med*. 2019;381:1215–26 (supplementary appendix)
3. Peyrin-Biroulet L, et al. *Gastroenterology*. 2021;161:1156–67.e3

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