Vedolizumab

Key Milestone Studies*

2013

GEMINI 1 [1]

Aim:
To evaluate the efficacy and safety of VDZ in patients with moderately to severely active UC who failed conventional therapy

Conclusion:
VDZ was more effective than placebo as an induction and maintenance therapy in UC

GEMINI 2 [2]

Aim:
To evaluate the efficacy and safety of VDZ, in the induction and maintenance phase, in patients with moderately to severely active CD who failed conventional therapy

Conclusion:
VDZ-treated patients were more likely to achieve remission at Week 6 and maintain remission at Week 52 vs placebo; AEs were more common with VDZ vs placebo

2015

GEMINI 3 [4]

Aim:
To assess efficacy, safety, and tolerability of VDZ induction therapy in patients with moderately to severely active CD, focusing on patients with previous TNFα antagonist failure

Conclusion:
In patients who had prior anti-TNFα treatment failure compared with placebo, VDZ was similarly effective in inducing clinical remission at Week 6

VDZ IV was authorized for patients with moderately to severely active UC or CD with inadequate response, or loss of response to conventional therapy, or a TNFα antagonist in Switzerland in February 2015 [3]

2016

VICTORY [5†]

Aim:
This real-world study, initiated in 2014, assessed the effectiveness and safety of VDZ in patients with moderately to severely active CD

Conclusion:
Data on clinical remission, mucosal healing, and deep remission further confirmed the efficacy of VDZ in a real-world setting for CD

2019

VARSITY [6]

Aim:
To directly compare the efficacy and safety of VDZ IV and ADA SC[7] in patients with moderately to severely active UC

Conclusion:
The first H2H study demonstrated that VDZ IV was superior to ADA SC in achieving clinical remission and endoscopic improvement, but not in CS-free clinical remission

VERSIFY [8]

Aim:
To evaluate the efficacy of VDZ on endoscopic remission and response in patients with moderately to severely active CD

Conclusion:
Endoscopic remission was greater in patients naïve to anti-TNFα agents than patients with anti-TNFα failure at Weeks 26 and 52, demonstrating the efficacy of VDZ to induce and sustain endoscopic improvement in patients with CD

LOVE-CD [9†]

Aim:
To evaluate the ability of VDZ to induce histologic and endoscopic remission in patients with moderately to severely active CD

Conclusion:
VDZ treatment induced histologic and endoscopic remission in patients with CD after Weeks 26 and 52, respectively, and improved endoscopic outcomes were associated with higher VDZ serum concentrations

2020

VISIBLE 1 [10]

Aim:
To evaluate VDZ SC as a maintenance treatment in patients with moderately to severely active UC

Conclusion:
VDZ SC was an effective maintenance therapy compared with placebo, with a favorable tolerability profile, demonstrating that either VDZ SC or IV can be administered without loss of efficacy or additional safety concerns

GEMINI LTS [11]

Aim:
To evaluate the long-term safety of VDZ in patients with moderately to severely active UC and CD across 8 years

Conclusion:
The tolerability profile of VDZ remained favorable with no new safety concerns compared with placebo, further supporting the long-term use of VDZ in patients with either UC or CD

VDZ SC was authorized for the maintenance of patients with moderately to severely active UC or CD in Switzerland in 2020 [3]

2021

EVOLVE [12†]

Aim:
To compare clinical effectiveness and safety of VDZ in biologic-naïve patients with moderately to severely active UC and CD

Conclusion:
In a RW setting, 1L biologic-naïve patients treated with VDZ and anti-TNFα yielded similar clinical effectiveness; however, VDZ demonstrated a more favorable tolerability profile, suggesting VDZ may have a more favorable benefit-risk profile as a 1L biologic treatment

2022

VISIBLE 2 [13]

Aim:
To evaluate a VDZ SC formulation as maintenance treatment in adults with moderately to severely active CD

Conclusion:
VDZ SC is an effective maintenance therapy, with a more favorable tolerability profile compared with placebo (no new safety signals except for ISRs) in patients who responded to two infusions of VDZ IV therapy, supporting VDZ SC as an additional option for patients who require maintenance therapy

2023

EARNEST [14]

Aim:
To evaluate the efficacy of VDZ in the treatment of chronic pouchitis

Conclusion:
VDZ treatment was more effective than placebo in inducing remission in patients who had chronic pouchitis after undergoing IPAA for UC

VDZ was authorized for patients with moderately to severely active chronic pouchitis in Switzerland in 2023 [3]

VERDICT (ONGOING) [15]

Aim:
To determine whether endoscopic and histologic remission are superior treatment targets to symptomatic remission in moderately to severely active UC (NCT04259138)

*Studies were ordered based on the full issue primary publication date.
†VICTORY, LOVE-CD, and EVOLVE are real-world studies.

Abbreviations

1L, first-line; **ADA**, adalimumab; **AE**, adverse event; **CD**, Crohn's disease; **CS**, corticosteroid; **EMA**, European Medicine's Agency; **H2H**, head-to-head; **IPAA**, ileal-pouch anal anastomosis; **ISR**, injection-site reaction; **IV**, intravenous; **LTS**, long-term safety; **RW**, real-world; **SC**, subcutaneous; **SmPC**, Summary of Product Characteristics; **TNFα**, tumor necrosis factor alpha; **UC**, ulcerative colitis; **VDZ**, vedolizumab.

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VV-MEDMAT-131715 | January 2026