SIMPONI® (golimumab)
SIMPONI - Use in Pediatric Patients with Ulcerative Colitis
(Pursuit 2 Study)

SUMMARY

- The company cannot recommend any practices, procedures, or usage that deviate from the approved labeling.
- PURSUIT 2 (NCT03596645) is a phase 3, randomized, open-label study to assess the efficacy and safety of SIMPONI in pediatric patients with moderately to severely active ulcerative colitis (UC).[1] Efficacy through induction week 6 and safety through week 54 are reported below.[2]

CLINICAL DATA

PHASE 3 STUDY IN PEDIATRIC ULCERATIVE COLITIS (PURSUIT 2)

Study Design

- Patients 2 to <18 years of age[2]
- Mayo score 6-12 (endoscopy subscore ≥2)[2]
- Patients with inadequate response or intolerance to conventional therapies or corticosteroid dependence[2]

Weight-Based Dosing Regimen

- Patients <45 kg[2]
  - SIMPONI SC 120 mg/m^2 at week 0 and 60 mg/m^2 at week 2
  - Then, 60 mg/m^2 every 4 weeks (q4w) from week 6-week 50
- Patients ≥45 kg[2]
  - SIMPONI SC 200 mg at week 0 and 100 mg at week 2
  - Then, 100 mg q4w from week 6-week 50

Primary Endpoint

- Clinical remission (Mayo score ≤2 with no individual score >1) at week 6[2]

Secondary Endpoints

- Clinical remission (Pediatric Ulcerative Colitis Activity Index [PUCAI])[2]
- Clinical response[2]
- Symptomatic remission[2]
- Endoscopic improvement[2]
- Maintenance of efficacy at week 54 among week 6 clinical remitters[2]

Results

- Sixty-nine patients were analyzed.[2]
  - Mean age: 13.4±3.3 years
  - Median Mayo score: 7
- For efficacy and safety results up to week 6 and 54, respectively, see Tables: Efficacy Up To Induction Week 6 and Treatment Emergent Adverse Events Up To Week 54.[2]

Efficacy Up To Induction Week 6[2]

Outcome, n (%)	SIMPONI (N=69)
Clinical remission[a] (Mayo score)	22 (31.9)
Clinical remission[b] (PUCAI)	23 (33.3)
Clinical response[c]	39 (56.5)
Symptomatic remission[d]	33 (47.8)
Endoscopic improvement[e]	28 (40.6)

Abbreviations: PUCAI, Pediatric Ulcerative Colitis Activity Index; SC, subcutaneous.
Note: In the adult population, clinical remission (per Mayo score) was achieved in 17.8% (45/253) of patients receiving SIMPONI. Patients received SIMPONI SC 200 mg → 100 mg.
[a]Clinical remission per Mayo score is defined as Mayo score ≤2 points with no individual subscore >1
[b]Clinical remission per the PUCAI is defined as PUCAI score <10
[c]Clinical response is defined as a decrease from baseline Mayo score ≥30% and ≥3 points with either a decrease from baseline in rectal bleeding subscore ≥1 or a rectal bleeding subscore of 0 or 1.
[d]Symptomatic remission is defined as Mayo stool frequency subscore of 0 or 1 and rectal bleeding subscore of 0.
[e]Endoscopic improvement is defined as an endoscopy subscore of 0 or 1.

- Of the patients who were in clinical remission at week 6 (according to Mayo criteria), 12/22 (54.5%) remained in clinical remission at week 54.
- Week 6 concentrations of golimumab were comparable to those observed in a reference adult UC population.

Treatment Emergent Adverse Events Up To Week 54[2]

	Induction Phase Week 0-6 N=69	Maintenance Phase Week 6-54 N=62
Average duration of follow-up (weeks)	6.3	40.0
Average exposure (number of administrations)	2.0	9.0
Patients with ≥1, n (%)[a,b]		
AEs	47 (68.1)	58 (93.5)
Serious AEs	10 (14.5)	21 (33.9)
AEs leading to death	0	0
AEs leading to discontinuation	6 (8.7)	9 (14.5)
Infections	17 (24.6)	9 (14.5)
Serious Infections	1 (1.4)	9 (14.5)
Malignant neoplasms	0	0
Injection-site reactions	2 (2.9)	3 (4.8)

Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; PUCAI, Pediatric Ulcerative Colitis Activity Index.
[a]AEs were coded using MedDRA version 26.1.
[b]Patients were only counted once for any given event, regardless of the number of times they experienced the event.

- No new safety signals were identified.

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, DERWENT® (and/or other

resources, including internal/external databases) was conducted on 22 April 2025.

REFERENCES

1. Janssen Research & Development, LLC. A study to assess the efficacy and safety of golimumab in pediatric participants with moderately to severely active ulcerative colitis (PURSUIT 2). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2025 May 2]. Available from: https://clinicaltrials.gov/study/NCT03596645 NLM Identifier: NCT03596645.

2. Turner D, Lomax K, Veereman G, et al. Efficacy, safety, and pharmacokinetics of golimumab in pediatric patients with moderately to severely active ulcerative colitis: results from the phase 3 open-label PURSUIT 2 study. Abstract presented at: Digestive Disease Week; May 3-6, 2025; San Diego, CA.