Safety of Guselkumab in Patients Aged ≥60 Years With Immune-Mediated Inflammatory Diseases: A Pooled Analysis of Registrational Trials in UC, CD, PsA and PsO

Scan the QR code.

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

P1069

A.S. Faye,[1] S. Sebastian,[2] V. McCaffrey,[3] I. Bravatà,[4] M. Nazar,[5] D. Piscitelli,[6] S.D. Chakravarty,[6,7] S. Adsul,[6] J. Yee,[3] T. Baker,[3] B.E. Sands[8]

[1]Division of Gastroenterology, New York University, NY, USA; [2]Department of Gastroenterology, IBD Unit, Hull University Teaching Hospitals NHS Trust, Hull, UK; [3]Johnson & Johnson, UK; [4]Johnson & Johnson, Italy; [5]Johnson & Johnson, Poland; [6]Johnson & Johnson, USA; [7]Drexel University College of Medicine, Philadelphia, PA, USA; [8]Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, NY, USA.

Key Takeaways

- Among adults aged ≥60 years with CD, UC, PsO or PsA pooled from 14 RCTs, GUS demonstrated safety outcomes that were similar to or lower than those observed with PBO
  - ✓ Exposure-adjusted rates of TEAEs, SAEs, infections, MACEs, and VTEs were numerically lower with GUS compared to PBO across both the IBD and combined indications groups
  - ✓ No deaths or active tuberculosis cases were reported with GUS
  - ✓ Findings were generally consistent with those observed in the overall study population
- Overall, GUS showed a favourable safety profile in adults aged ≥60 years, aligned with its established safety profile

Background

Adults ≥60 years of age represent a growing demographic group worldwide, accounting for nearly one-third of individuals living with immune-mediated inflammatory diseases[1,2]

Guselkumab (GUS) is a fully human, dual-acting interleukin (IL)-23 inhibitor that selectively targets the p19 subunit and binds to CD64 on immune cells[3] and is approved for the treatment of Crohn's disease (CD), ulcerative colitis (UC), psoriasis (PsO) and psoriatic arthritis (PsA)[4]

Despite being at high risk for both disease- and treatment-related complications, the safety of advanced therapeutic options in older adults is poorly characterized[5]

Objectives

Evaluate the safety of GUS up to 1 year in patients aged ≥60 years pooled from 14 phase 2/3 randomized-controlled trials (RCTs)

Analysis Cohort

- Data were pooled from 14 phase 2/3 RCTs of GUS in PsA, PsO, UC, and CD
- Adults who received ≥1 dose of study treatment were included
- Non-biologic immunomodulators (including disease-modifying anti-rheumatic drugs) and corticosteroids were permitted in inflammatory bowel disease (IBD; UC and CD) and PsA RCTs, but not in PsO RCTs

RCT ID	RCT name	Indication
NCT03162796	DISCOVER-1	PsA
NCT03158285	DISCOVER-2	PsA
NCT02319759	PsA Phase 2	PsA
NCT02203032	NAVIGATE	PsO
NCT02207231	VOYAGE 1	PsO
NCT02207244	VOYAGE 2	PsO
NCT01483599	X-PLORE	PsO
NCT05528510	ASTRO	UC
NCT04033445	QUASAR	UC
NCT03662542	VEGA	UC
NCT03466411	GALAXI 1	CD
NCT03466411	GALAXI 2	CD
NCT03466411	GALAXI 3	CD
NCT05197049	GRAVITI	CD

Outcomes and Analyses

- Pooled safety data from RCTs were analysed through up to 1 year
- Patients were grouped by age: **≥60 years of age** and **overall population**
  - Age groups were further subdivided by indication: **Inflammatory bowel disease (IBD)** and **combined indications**
- Exposure-adjusted rates of treatment-emergent adverse events were reported per 100 patient-years (PY) with 95% confidence intervals (CI)

Results

Among patients with IBD aged ≥60 years, 238 received GUS and 98 received PBO, contributing 175.5 and 47.9 PY of follow-up, respectively, across up to 1 year in 14 RCTs

- In patients aged ≥60 years across combined indications, 618 received GUS and 212 received PBO, contributing 496.8 and 90.5 PY of follow-up, respectively, across up to 1 year
- Mean follow-up and treatment duration were comparable within treatment groups for patients aged ≥60 years compared to the overall population

Exposure and Follow-up Metrics by Age Group and Indication[a]	Patients aged ≥60 years				Overall population			
	IBD[b]		Combined indications[b,c]		IBD[b]		Combined indications[b,c]	
	GUS[d] (N=238)	PBO[e] (N=98)	GUS[d] (N=618)	PBO[e] (N=212)	GUS[d] (N=2057)	PBO[e] (N=886)	GUS[d] (N=5048)	PBO[e] (N=1771)
Mean follow-up, weeks[f]	38.5	25.5	41.9	22.3	41.4	25.0	42.9	22.3
Mean treatment, weeks	31.1	22.4	32.8	19.2	33.8	21.6	33.5	19.1
Total PY of follow-up	175.5	47.9	496.8	90.5	1630.1	424.3	4152.8	758.3

*[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). [c]Includes: IBD (CD and UC), PsO and PsA. UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). PsO: CNTO1959PSO3001, CNTO1959PSO3002, CNTO1959PSO3003 and CNTO1959PSO2001 (to Week 52). PsA: CNTO1959PSA3001 (to Week 60), CNTO1959PSA3002 (to Week 52), CNTO1959PSA2001 (to Week 56). [d]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [e]UC: Data to first GUS dose (PBO) or ≥12 weeks after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. [f]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. **AE**=adverse event, **IBD**=inflammatory bowel disease, **PBO**=placebo, **SCS**=summary of clinical safety.*

Among patients aged ≥60 years, exposure-adjusted rates of TEAEs, SAEs, and infections were numerically lower with GUS than with PBO across both the IBD and combined indications groups

- No deaths were reported with GUS in either the IBD or combined indications groups among patients aged ≥60 years
- Similar findings were observed in the overall population

TEAEs by Age Group and Indication[a]	Patients aged ≥60 years				Overall population			
	IBD[b]		Combined indications[b,c]		IBD[b]		Combined indications[b,c]	
	GUS[d] (N=238)	PBO[e] (N=98)	GUS[d] (N=618)	PBO[e] (N=212)	GUS[d] (N=2057)	PBO[e] (N=886)	GUS[d] (N=5048)	PBO[e] (N=1771)
Patients with AEs, N(%)	164 (68.9)	63 (64.3)	418 (67.6)	125 (59.0)	1502 (73.0)	558 (63.0)	3349 (66.3)	973 (54.9)
TEAE/100 PY (95% CI)[f]								
Any TEAE[g]	93.5 (79.7, 108.9)	131.5 (101.0, 168.2)	84.1 (76.3, 92.6)	138.1 (115.0, 164.6)	92.1 (87.5, 96.9)	131.5 (120.8, 142.9)	80.6 (77.9, 83.4)	128.3 (120.4, 136.6)
SAE	11.4 (7.0, 17.6)	23.0 (11.5, 41.1)	9.3 (6.8, 12.4)	16.6 (9.3, 27.3)	8.8 (7.5, 10.4)	17.9 (14.1, 22.4)	6.5 (5.8, 7.3)	12.7 (10.3, 15.5)
Infection	39.9 (31.1, 50.4)	56.4 (37.1, 82.0)	42.3 (36.7, 48.4)	55.3 (41.0, 72.8)	47.5 (44.2, 51.0)	53.0 (46.3, 60.4)	44.7 (42.7, 46.8)	53.0 (48.0, 58.5)
Serious infection	2.3 (0.6, 5.8)	2.1 (0.1, 11.6)	1.8 (0.8, 3.4)	1.1 (0.0, 6.2)	1.8 (1.2, 2.6)	1.7 (0.7, 3.4)	1.4 (1.0, 1.8)	1.2 (0.5, 2.3)
Death	0.0	4.2 (0.5, 15.1)	0.0	2.2 (0.3, 8.0)	0.1 (<0.1, 0.4)	0.5 (0.1, 1.7)	0.1 (0.0, 0.2)	0.5 (0.1, 1.4)

*[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). [c]Includes: IBD (CD and UC), PsO and PsA. UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). PsO: CNTO1959PSO3001, CNTO1959PSO3002, CNTO1959PSO3003 and CNTO1959PSO2001 (to Week 52). PsA: CNTO1959PSA3001 (to Week 60), CNTO1959PSA3002 (to Week 52), CNTO1959PSA2001 (to Week 56). [d]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [e]UC: Data to first GUS dose (PBO) or ≥12 weeks after last induction (re-randomised to PBO), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. [f]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [g]Confidence interval based on an exact method assuming that the observed number of subjects follows a Poisson distribution. **SAE**=serious adverse event, **TEAE**=treatment-emergent adverse event.*

Among patients aged ≥60 years, exposure-adjusted rates of opportunistic infections, MACEs, and VTEs were numerically lower with GUS than with PBO across both the IBD and combined indication groups

- Among patients aged ≥60 years, exposure-adjusted malignancy rates (including non-melanoma skin cancer) were comparable between GUS and PBO in the IBD group, with broadly overlapping 95% CIs in the combined indications group indicating similar rates
- No cases of active tuberculosis were reported with GUS in either the IBD or combined indications groups among patients aged ≥60 years
- Similar findings were observed in the overall population

Targeted TEAEs by Age Group and Indication[a]	Patients aged ≥60 years				Overall population			
	IBD[b]		Combined indications[b,c]		IBD[b]		Combined indications[b,c]	
	GUS[d] (N=238)	PBO[e] (N=98)	GUS[d] (N=618)	PBO[e] (N=212)	GUS[d] (N=2057)	PBO[e] (N=886)	GUS[d] (N=5048)	PBO[e] (N=1771)
TEAE/100 PY (95% CI)[f]								
Active tuberculosis[g]	0.0	0.0	0.0	0.0	0.1 (0.0, 0.3)	0.0 (0.0, 0.7)	0.0 (0.0, 0.1)	0.0 (0.0, 0.4)
Malignancy[h,i]	4.6 (2.0, 9.0)	4.2 (0.5, 15.1)	4.0 (2.5, 6.2)	2.2 (0.3, 8.0)	0.7 (0.4, 1.3)	0.9 (0.3, 2.4)	0.7 (0.5, 1.0)	0.7 (0.2, 1.5)
Opportunistic infection[j]	1.1 (0.1, 4.1)	2.1 (0.1, 11.6)	0.6 (0.1, 1.8)	1.1 (<0.1, 6.2)	0.3 (0.1, 0.6)	0.7 (0.2, 2.1)	0.1 (0.1, 0.3)	0.4 (0.1, 1.2)
MACE[k]	1.1 0.1, 4.1)	4.2 (0.5, 15.1)	1.2 (0.4, 2.6)	2.2 (0.3, 8.0)	0.3 (0.1, 0.7)	0.5 (0.1, 1.7)	0.4 (0.2, 0.6)	0.4 (0.1, 1.2)
VTE[l]	0.6 (<0.1, 3.2)	2.1 (0.1, 11.6)	0.4 (0.1, 1.5)	1.1 (<0.1, 6.2)	0.4 (0.2, 0.9)	0.0 (0.0, 0.7)	0.3 (0.2, 0.6)	0.0 (0.0, 0.4)

*[a]Safety events reported throughout the reporting period to approximately one year; SCS all treated. [b]UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). [c]Includes: IBD (CD and UC), PsO and PsA. UC: CNTO1959UCO3001 (to Week 20, 32 or 44 depending on entry or treatment status); CNTO1959UCO2002 (to Week 38, monotherapy arm only). CD: CNTO1959CRD3001 GALAXI 1, GALAXI 2 and GALAXI 3 and CNTO1959CRD3004 GRAVITI (to Week 48). PsO: CNTO1959PSO3001, CNTO1959PSO3002, CNTO1959PSO3003 and CNTO1959PSO2001 (to Week 52). PsA: CNTO1959PSA3001 (to Week 60), CNTO1959PSA3002 (to Week 52), CNTO1959PSA2001 (to Week 56). [d]UC: All GUS data and up to 12 weeks post-induction for PBO in Maintenance Study. CD, PsO, PsA: Data from first GUS dose for early escape/crossover. [e]UC: Data to first GUS dose (PBO) or ≥12 weeks after last induction (re-randomised to placebo), until dose adjustment. CD, PsO, PsA: Data to early escape/rescue/crossover. [f]Cumulative treatment duration for each study agent was calculated as the time from first to last dose across all relevant periods. [g]Active tuberculosis events are identified by the MedDRA HLT of 'Tuberculous infections' excluding the preferred term of 'Latent tuberculosis'. [h]Malignancies are defined as the narrow terms in the MedDRA SMQ of 'Malignant Tumours'. [i]The majority of malignancies reported in patients aged ≥60 years were non-melanoma skin cancers, primarily basal cell carcinoma and squamous cell carcinoma. [j]Opportunistic infections are defined as the narrow terms in the MedDRA SMQ of 'Opportunistic Infections'. [k]MACE were identified by clinical review. [l]VTE terms are based on customised MedDRA query. **HLT**=high level terms, **MACE**=major adverse cardiovascular event, **SMQ**=standardized MedDRA queries, **VTE**=venous thromboembolism.*

Material is distributed for scientific purposes on Johnson & Johnson J&J Medical Connect, and is not for promotional use

PRESENTED AT: The 21st Congress of ECCO; February 20, 2026; Stockholm, Sweden. **REFERENCES: 1.** Su QY. *Front Public Health.* 2025; 13: 1527680. **2.** Caron B. *J Crohns Colitis.* 2024; 18: ii3-15. **3.** Sachen K. *Front Immunol.* 2025; 1532852. **4.** Tremfya (guselkumab) [package insert]. https://www.ema.europa.eu/en/documents/overview/tremfya-epar-medicine-overview_en.pdf. Accessed October 2025. **5.** Zazzara MB. *Eur Geriatr Med.* 2021; 12: 463-73. **ACKNOWLEDGEMENTS:** Medical writing support was provided by JSS Medical Research, Inc, under the direction of the authors in accordance with Good Publication Practice guidelines (Ann Intern Med. 2022;175:1298-1304). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: ASF:** Consulting honoraria: AbbVie, Eli Lilly, and Takeda. **SS:** ECCO governing board member. **VM, IB, MN, SN, DP, SDC, SA, JY, TB:** Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. **BES**: Honoraria for consulting: Aclaris Therapeutics, Adaxion Therapeutics, Adiso Therapeutics, Agomab Therapeutics, Alfasigma, Alimentiv, Amgen, AnaptysBio, AstraZeneca, Attovia Therapeutics, Biolojic Design, BiomeBank, Biora Therapeutics, Boehringer-Ingelheim, Caldera Therapeutics, Cellarity, Cytoki Pharma, Disc Medicine, Eli Lilly & Company, Ensho Therapeutics, Enthera, Enveda Biosciences, Equilium, Evommune, Ferring, Fzata, Galapagos, Genentech (Roche), Genesis Therapeutics, Gilead Sciences, GlaxoSmithKline, Globalport, Ignite Biomedical, Imedex, Imhotex, Immunitas Therapeutics, Immunyx Pharma, Kallyope, Kyowa Kirin, LifeMine Therapeutics, Merck & Co., Merck Sharp & Dohme, Microba, Microbiotica, Mirador Therapeutics, Mitsubishi Tanabe Pharma, Mobius Care, Morphic Therapeutic, MRM Health, Nexus Therapeutics, Nimbus Discovery, Novartis, Numab Therapeutics, Odyssey Therapeutics, ONO Pharmaceutical, OSE Immunotherapeutics, Palisade Bio, Pioneering Medicines Explorations, Prometheus Biosciences, Protagonist Therapeutics, Q32 Bio, Quotient Therapeutics, Rasayana Therapeutics, Recludix Pharma, Reistone Biopharma, Sanofi, Slate Bio, Sorriso Pharmaceuticals, Spyre Therapeutics, Synlogic, Target RWE, Televant, Teva, Thetis Pharmaceuticals, TR1X, Trex Bio, Union Therapeutics, VectivBio, Vedanta Biosciences, Vividion Therapeutics and Xencor. Honoraria for consulting, speaking and other support: AbbVie, Abivax, Bristol Myers Squibb, Celltrion, Eli Lilly & Company, Genentech (Roche), Johnson &Johnson, Merck & Company, Pfizer, Takeda, and Teva; Honoraria for consulting, stock and stock options: Ventyx Biosciences; and stock from Doximity.