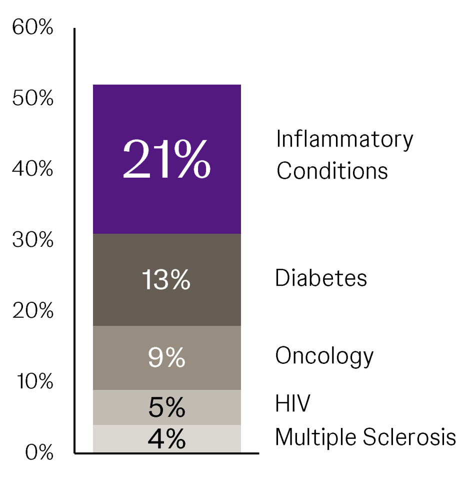
EVIDENCE SUMMARY: TREMFYA® (guselkumab) for moderately to severely active ulcerative colitis or Crohn's disease

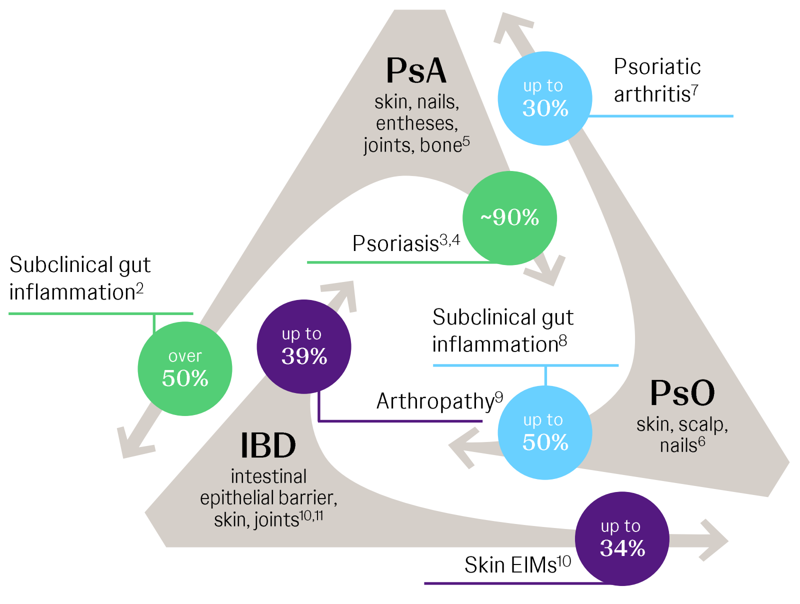
Inflammatory conditions have a significant impact on the patient and healthcare system

Immunologic therapies present the highest cost burden for commercial plans

Top 5 Therapy Classes for Commercial Plans, by Percent of Total PMPY Spending, 2020[1a]



Inflammatory conditions are complex and may present with extra-intestinal, extra-articular, and extra-cutaneous manifestations



United States prevalence[11]:

Site and presentation of inflammation[12,13]

UC:
Colon and the rectum, typically appears in a continuous pattern

CD:
Anywhere in the GI tract from the mouth to the anus, may appear in patches

TREMFYA® (guselkumab) is a fully human IL-23i indicated for the treatment of adults with[14b]:

- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis
- Moderately to severely active **ulcerative colitis**
- Moderately to severely active **Crohn's disease**

Pre-treatment evaluation and monitoring[c]

Induction — Week 0, 4, 8

Maintenance — Use the lowest effective recommended dosage to maintain therapeutic response — Week 12, 16, 20, 24

UC + CD
TREMFYA® (200 mg IV)
200 mg IV over at least an hour at Weeks 0, 4, and 8

CD only
TREMFYA® (400 mg SC)
400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8

Prefilled syringe (200 mg) or TREMFYA® pen (200 mg)
200 mg SC starting at Week 12, and q4w thereafter

OR

UC + CD
Prefilled syringe (100 mg), TREMFYA® pen (100 mg), or One-press injector (100 mg)
100 mg SC at Week 16, and q8w thereafter

TREMFYA® has demonstrated clinical efficacy in UC[14,15]

QUASAR clinical program

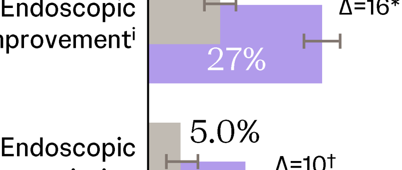
TREMFYA® was evaluated in multicenter, randomized, double-blind, placebo-controlled induction and maintenance studies in adult patients with moderately to severely active UC & prior response or intolerance to conventional or advanced therapy.[15d]

The induction study (N=701) randomized patients 3:2 to receive TREMFYA® 200 mg IV q4w or placebo IV.[14,15] The maintenance study (N=568) took TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[e] and rerandomized 1:1:1[f] to receive TREMFYA® 200 mg SC q4w, TREMFYA® 100 mg SC q8w, or placebo SC.[15]

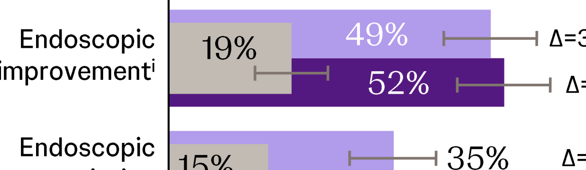
49% of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, or TOFA)

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC[14,15]

Primary endpoint at Week 12

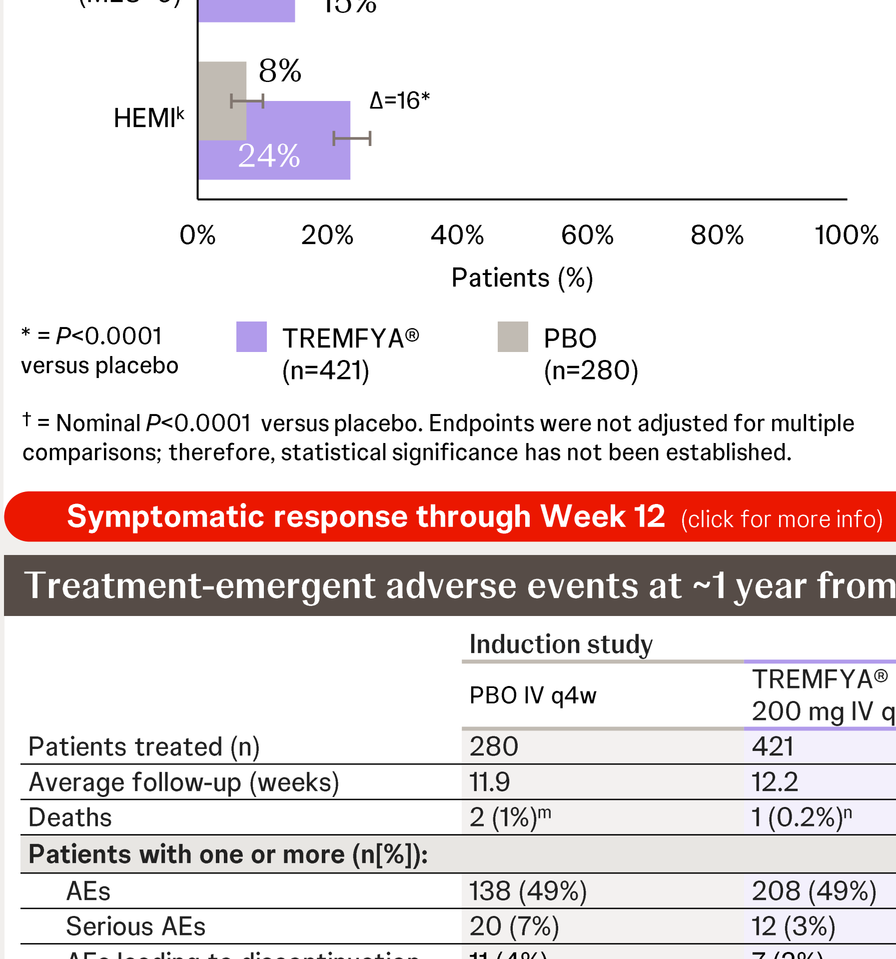


Primary endpoint at Week 44



99% (178/180) of patients in the combined TREMFYA® group who achieved clinical remission at Week 44 were **corticosteroid-free for ≥8 weeks**[15]

Select secondary endpoints at Week 12

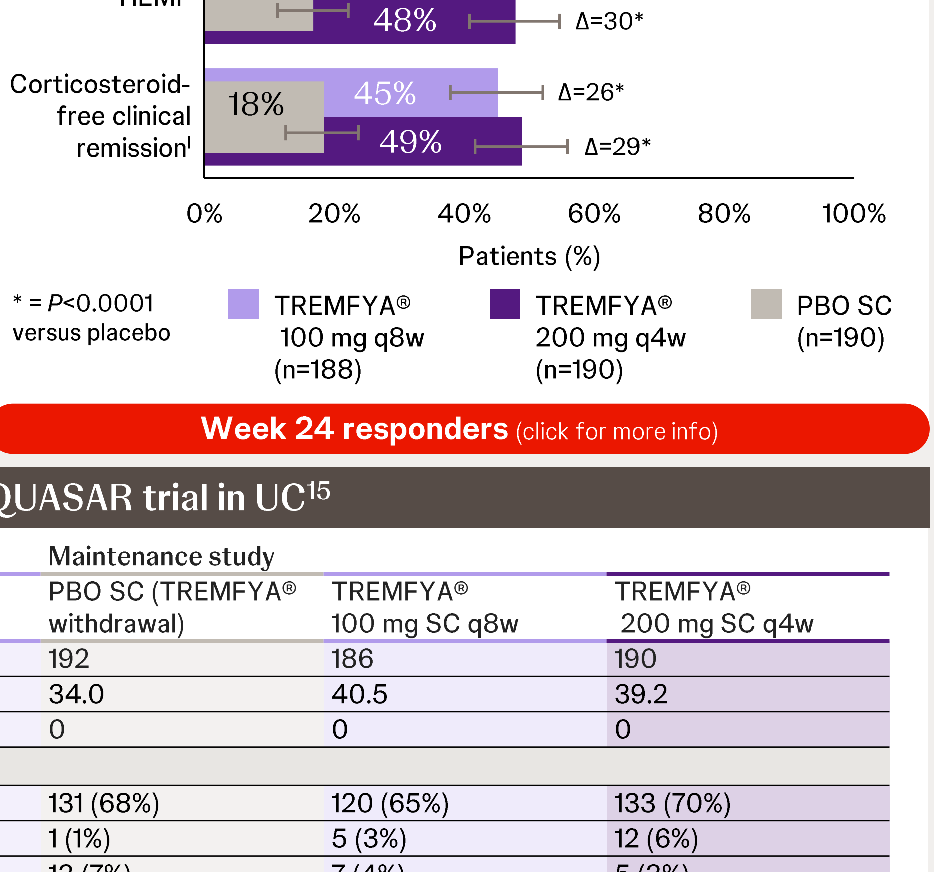


† = Nominal $P<0.0001$ versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Symptomatic response through Week 12 (click for more info)

Select secondary endpoints at Week 44

Over 1/3 of patients were in complete endoscopic remission (MES=0) at Week 44



Week 24 responders (click for more info)

Treatment-emergent adverse events at ~1 year from the QUASAR trial in UC[15]

	Induction study		Maintenance study		
	PBO IV q4w	TREMFYA® 200 mg IV q4w	PBO SC (TREMFYA® withdrawal)	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Patients treated (n)	280	421	192	186	190
Average follow-up (weeks)	11.9	12.2	34.0	40.5	39.2
Deaths	2 (1%)[m]	1 (0.2%)[n]	0	0	0
Patients with one or more (n[%]):					
AEs	138 (49%)	208 (49%)	131 (68%)	120 (65%)	133 (70%)
Serious AEs	20 (7%)	12 (3%)	1 (1%)	5 (3%)	12 (6%)
AEs leading to discontinuation	11 (4%)	7 (2%)	13 (7%)	7 (4%)	5 (3%)
Infections[16,17o]	43 (15%)	66 (16%)	63 (33%)	59 (32%)	59 (31%)
Serious Infections[o]	1 (0.4%)	3 (1%)	0	1 (1%)	2 (1%)

For additional safety information, please see TREMFYA® prescribing information here.

Guselkumab for CD

GALAXI clinical program[14,18]

Two identical 48-week, multicenter, randomized, double-blind, placebo- and biologic active-controlled, parallel-group, treat-through studies in adult patients with moderately to severely active CD, who had inadequate response, loss of response, or intolerance to oral CS, conventional IMMs, and/or biologic therapies (TNFi, VDZ).

~52% previously failed at least 1 biologic
N=1,021

Patients were randomized 2:2:2:1 to receive:

- **Induction:** TREMFYA® 200 mg IV or PBO IV at Weeks 0, 4, and 8; or STELARA® (ustekinumab) ~6 mg/kg IV at Week 0
- **Maintenance:** TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, STELARA® 90 mg SCq8w starting at Week 8, or PBO SC q4w starting at Week 12 in PBO induction responders
- Patients in the PBO group who met rescue criteria at Week 12 received an induction dose of STEMARA® ~6 mg/kg IV at Week 12 followed by a maintenance dose of STELARA® 90 mg SC q8w starting at Week 20

GRAVITI clinical program[14,19]

A 48-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, treat-through study in adult patients with moderately to severely active CD, who had inadequate response, loss of response, or intolerance to oral CS, conventional IMMs, and/or biologic therapies (TNFi, VDZ).

46% previously failed at least 1 biologic
N=347

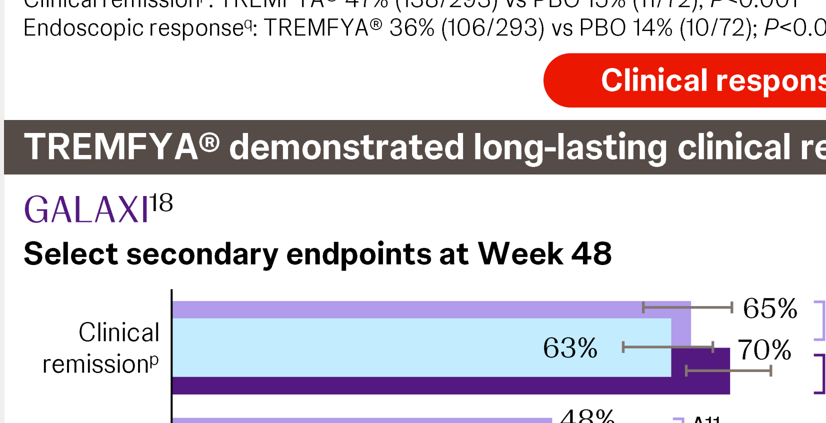
Patients were randomized 1:1:1 to receive:

- **Induction:** TREMFYA® 400 mg SC q4w or PBO SC q4w at Weeks 0, 4, and 8
- **Maintenance:** TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, or continued on PBO SC q4w (PBO induction responders)
- Patients in the PBO group who met rescue criteria at Week 16 received an induction dose of TREMFYA® 400 mg SC q4w starting at Week 16 followed by a maintenance dose of TRMFYA® 100 mg SC q8w starting at Week 32

Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

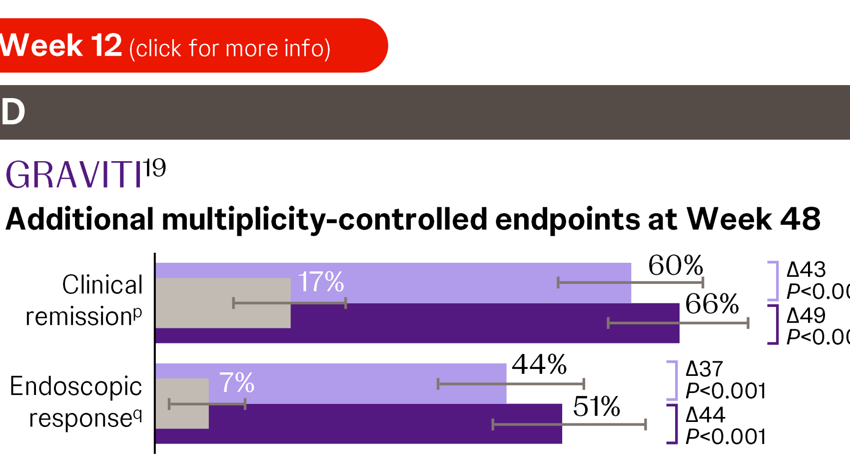
Data originated from separate pivotal trials for the biologic.
Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

GALAXI[18]
Select secondary endpoints at Week 12
GALAXI 2



GALAXI 3 at Week 12[16]:
Clinical remission[p]: TREMFYA® 47% (138/293) vs PBO 15% (11/72); $P<0.001$
Endoscopic response[q]: TREMFYA® 36% (106/293) vs PBO 14% (10/72); $P<0.001$

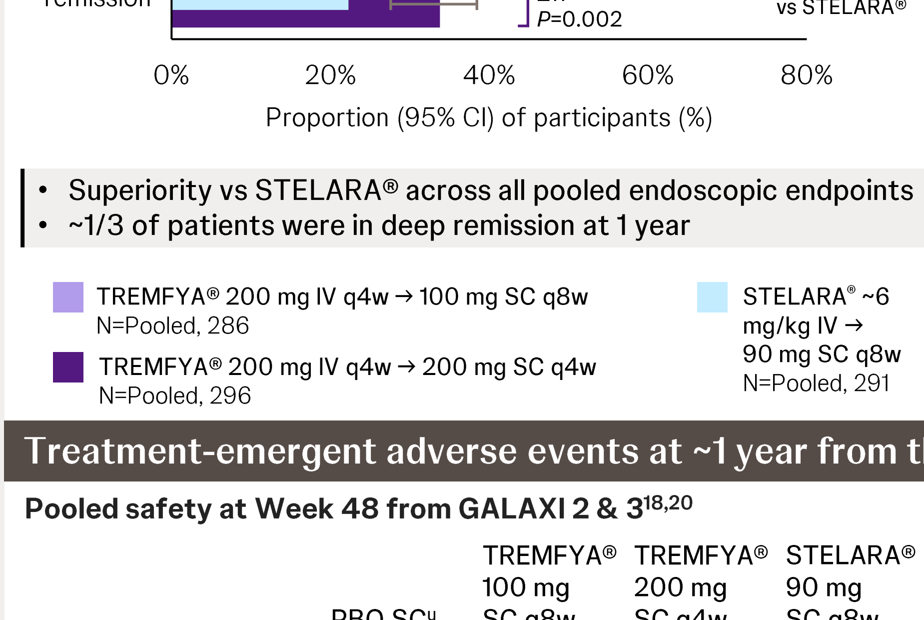
GRAVITI[19]
Co-primary endpoints at Week 12



Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

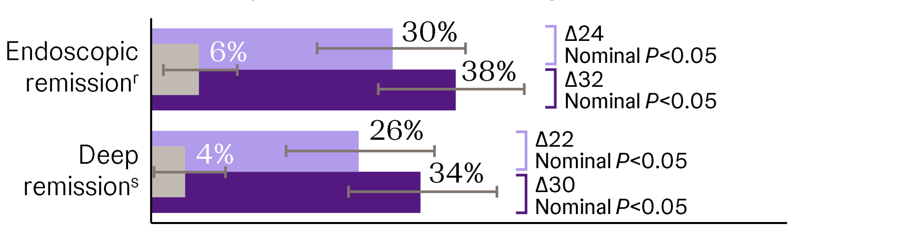
GALAXI[18]
Select secondary endpoints at Week 48



- Superiority vs STELARA® across all pooled endoscopic endpoints
- ~1/3 of patients were in deep remission at 1 year

TREMFYA® 200 mg IV q4w → 100 mg SC q8w, N=Pooled, 286
TREMFYA® 200 mg IV q4w → 200 mg SC q4w, N=Pooled, 296
STELARA® ~6 mg/kg IV → 90 mg SC q8w, N=Pooled, 291

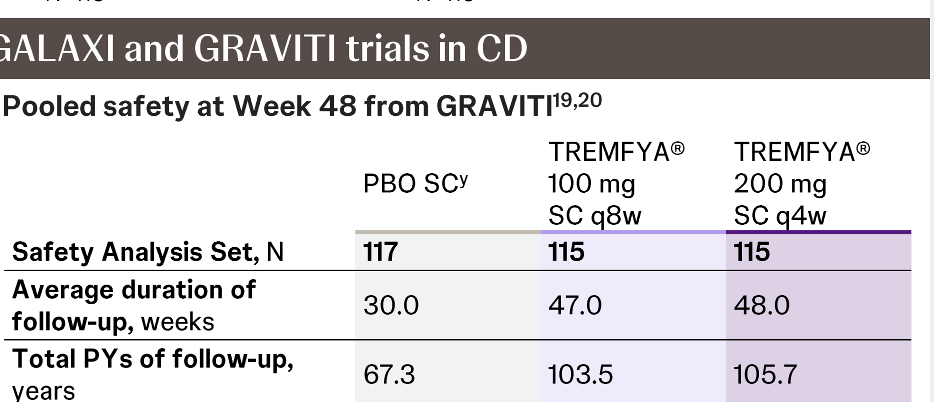
GRAVITI[19]
Additional multiplicity-controlled endpoints at Week 48



97% (67/69) and 99% (75/76) of patients treated with TREMFYA® (guselkumab) 400 mg → 100 mg and TREMFYA® 400 mg → 200 mg, respectively, who achieved clinical remission at Week 48 were CS-free for ≥90 days (post-hoc analysis)[20t]

Other endpoints at Week 48

Endoscopic remission and deep remission at Week 48 were prespecified but not controlled for multiplicity. No statistical or clinical significance can be made.



TREMFYA® 400 mg SC q4w → TREMFYA® 100 mg SC q8w, N=115
TREMFYA® 400 mg SC q4w → TREMFYA® 200 mg SC q4w, N=115
Placebo SC, N=117

Treatment-emergent adverse events at ~1 year from the GALAXI and GRAVITI trials in CD

Pooled safety at Week 48 from GALAXI 2 & 3[18,20]

	PBO SC[u]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w	STELARA® 90 mg SC q8w
All-Treated Safety Analysis Set, N	**153**	**296**	**299**	**300**
Average Duration of Follow-up, weeks	21.8	46.2	46.7	45.5
Total PYs of Follow-up	64.0	261.8	267.3	261.4
Deaths	0	0	0	0
Patients with 1 or more:				
AEs, n (%)	82 (53.6%)	225 (76.0%)	233 (77.9%)	236 (78.7%)
Events/100 PYs of follow-up	499.7	327.3	353.5	340.5
SAEs, n (%)	16 (10.5)	32 (10.8)	21 (7.0)	35 (11.7)
Events/100 PYs of follow-up	32.8	14.9	9.7	18.4
AEs leading to discontinuation, n (%)	13 (8.5%)	21 (7.1%)	19 (6.4%)	22 (7.3%)
Events/100 PYs of follow-up	20.3	8.4	7.5	8.8
Infections[o], n (%)	39 (25.5%)	127 (42.9%)	147 (49.2%)	126 (42.0%)
Events/100 PYs of follow-up	87.5	77.9	88.3	77.7
Serious infections[o], n (%)	2 (1.3%)[v]	1 (0.3%)[w]	3 (1.0%)[x]	12 (4.0%)

Pooled safety at Week 48 from GRAVITI[19,20]

	PBO SC[y]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Safety Analysis Set, N	**117**	**115**	**115**
Average duration of follow-up, weeks	30.0	47.0	48.0
Total PYs of follow-up, years	67.3	103.5	105.7
Deaths, n (%)	0	1 (0.9%)[z]	0
Patients with 1 or more:			
AEs, n (%)	77 (65.8%)	95 (82.6%)	92 (80.0%)
Events/100 PYs of follow-up	413.0	307.2	327.2
SAEs, n (%)	16 (13.7%)	15 (13.0%)	9 (7.8%)
Events/100 PYs follow-up	37.1	15.5	13.2
AEs leading to discontinuation, n (%)	10 (8.5%)	4 (3.5%)	3 (2.6%)
Events/100 PYs of follow-up	14.9	6.8	2.8
Infections, n (%)	36 (30.8%)	56 (48.7%)	47 (40.9%)
Events/100 PYs of follow-up	81.7	91.8	70.0
Serious infections[aa], n (%)	0	2 (1.7%)[ab]	1 (0.9%)[ac]

For additional safety information, please see TREMFYA® prescribing information here.

Future considerations for TREMFYA®: Select ongoing phase 3 trials in IBD

ASTRO: Guselkumab SC induction and maintenance for adults with moderately to severely active UC[21]

QUASAR Jr: Guselkumab for pediatric participants with moderately to severely active UC[22]

MACARONI 23: Guselkumab for pediatric participants with CD[23]

The safety and efficacy of the investigational uses of this product have not been determined. There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA.

For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® prescribing information here.

[a]In the United States. [b]TREMFYA® dosing for moderate to severe plaque PsO and active PsA: 100mg SC at weeks 0 and 4, and q8w thereafter. For moderately to severely active UC, induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. For moderately to severely active CD: IV induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8 OR 400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. [c]**Pretreatment Evaluations**: Prior to initiating treatment with TREMFYA®, evaluate patients for tuberculosis (TB) infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines. **Monitoring**: Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. For the treatment of CD or UC, monitor liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. TREMFYA® is intended for use under the guidance and supervision of a healthcare professional. TREMFYA® may be administered by a healthcare professional, or a patient/caregiver may inject after proper training in subcutaneous injection technique. [d]Moderately to severely active UC defined as induction baseline modified Mayo score of 5 to 9 with a Mayo rectal bleeding subscore ≥ 1 and a Mayo endoscopic subscore ≥ 2 based on central review. [e]Placebo crossover responders at Week 24 are the placebo nonresponders at Week 12 who went on to receive TREMFYA 200 mg IV q4w for 12 weeks and were in clinical response to TREMFYA at Week 24. [f]Patients from a phase 2b randomized, double-blind, placebo-controlled, induction dose-finding study who demonstrated a clinical response to TREMFYA® were also randomized into the phase 3 maintenance study. [g]Clinical remission: Mayo stool frequency subscore of 0 or 1, and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability. [h]Clinical response: decrease from induction baseline in the modified Mayo score (3-component [stool frequency, rectal bleeding, and endoscopy subscores] Mayo score without the physician's global assessment) by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1. [i]Endoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. [j]Endoscopic remission: an endoscopy subscore of 0. [k]HEMI: achieving a combination of histologic improvement and endoscopic improvement. [l]CS-free clinical remission: clinical remission without any use of corticosteroids for ≥8 weeks prior to assessment. [m]Natural causes and cardiac arrest. [n]Fatal acute myocardial infarction in a patient with pre-existing cardiac risk factors. [o]Defined as any AE coded to MedDRA organ class "Infections and infestations". [p]Clinical remission: CDAI <150. [q]Endoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. [r]Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore greater than 1 in any individual component. [s]Deep remission: clinical remission AND endoscopic remission. [t]CS-free is defined as patients in clinical remission at Week 48 and not receiving CS for ≥90 days prior. Denominator is patients in clinical remission at Week 48. [u]Events attributed to patients randomized to PBO, except where a patient is randomized to PBO and cross over to STELARA® (only events that occur while patients are on PBO are included). [v]Liver abscess/bacterial infection and postop wound infection/vascular device infection. [w]Anal abscess. [x]Acute sinusitis, abscess intestinal, intestinal fistula infection. [y]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [z]Fatal gunshot wound (non-suicidal). [aa]An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. [ab]Bronchitis and appendicitis. [ac]Gastroenteritis

AE, adverse effect; CD, Crohn's disease; CDAI, Clinical Disease Activity Index; CI, confidence interval; EIM, extraintestinal manifestation; GAL, GALAXI; HEMI, histo-endoscopic mucosal improvement; HIV, human immunodeficiency virus; IBD, irritable bowel disease; IL-23i, interleukin-23i; IV, intravenous; LTE, long-term extension; MedDRA, Medical Dictionary for Regulatory Activities; MES, modified endoscopic subscore; PBO, placebo; PMPY, per-member, per-year; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient years; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious adverse effect; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; TOFA, tofacitinib; TNF, tumor necrosis factor; UC, ulcerative colitis; ULN, upper limit of normal; UST, ustekinumab; VDZ, vedolizumab; W12, week 12; W48, week 48.

1. Evernorth. Trend by plan type. Accessed July 6, 2023. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher J, et al. *J Rheum Suppl.* 2018;94:32-35. 3. Pennington SR, et al. *Front Med (Lausanne).* 2021;8:723944. 4. Ciocon D, Kimball A. *Br J Dermatol.* 2007;157(5):850-860. 5. Suzuki E, et al. *Autoimmunity Rev.* 2014;13:496-502. 6. Lowes M, et al. *Annu Rev Immunol.* 2014;32:227-255. 7. Mease P, et al. J Am Acad Dermatol. 2013;69(5):729-735. 8. Sanchez I, et al. Curr Dermatol Rep. 2018;7(1):59-74. 9. Arvikar S, et al. Curr Rev Musculoskel Med. 2011;4(3):123-131. 10. Levine J, et al. *Gastroenterol Hepatol.* 2011;7:235-241. 11. Lewis J, et al. *Gastroenterology.* 2023: 1-9. 12. Ye Y, et al. *Inflamm Bowel Dis.* 2020;26(4):619-625. 13. The Crohn's & Colitis Foundation of America. The facts about inflammatory bowel diseases. Updated November 2014. Accessed February 20, 2024. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. 14. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 15. Rubin D, et al. *Lancet.* 2025;405:33-49. 16. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 17. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 18. Panaccione R, et al. DDW 2024. May 18-21, 2024. 19. Hart A, et al. *Gastroenterology.* 2025; doi:10.1053/j.gastro.2025.02.033. 20. Data on File. Janssen Biotech, Inc. Horsham, PA. 21. ASTRO NCT05528510. 22. QUASAR Jr NCT06260163. 23. MACARONI 23 NCT05923073.

US-SFM-6481 04/25

Johnson&Johnson

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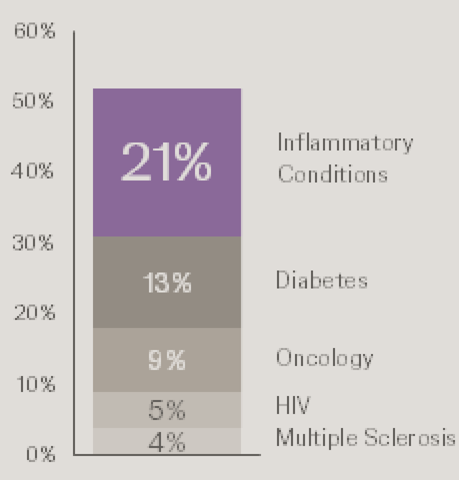

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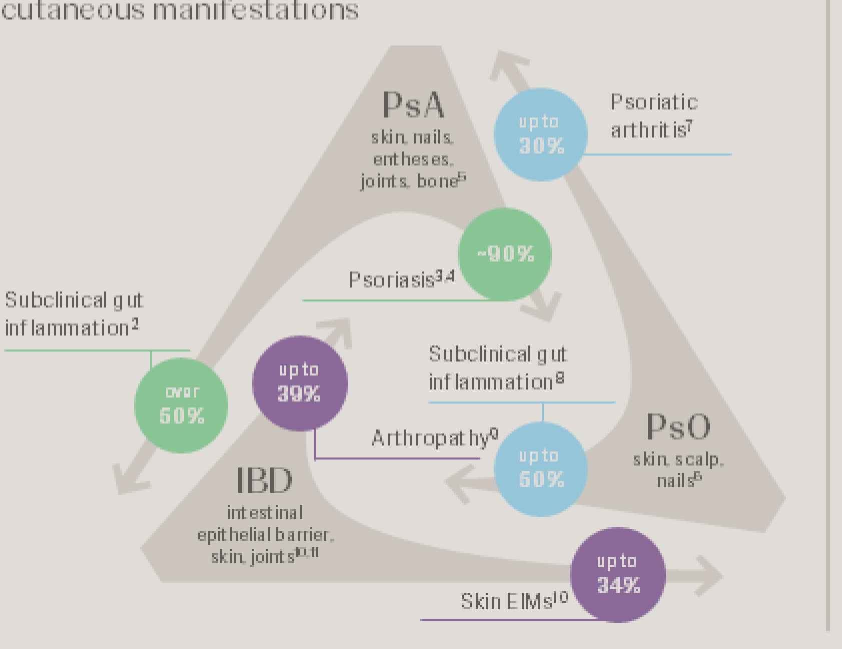

United States prevalence[11]:

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UC: Colon and the rectum, typically appears in a continuous pattern

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- Active psoriatic arthritis
- Moderately to severely active **ulcerative colitis**
- Moderately to severely active **Crohn's disease**

Pre-treatment evaluation and monitoring[c]

Induction | Maintenance — Use the lowest effective recommended dosage to maintain therapeutic response

Week 0, 4, 8, 12, 16, 20, 24

UC + CD: **TREMFYA® (200 mg IV)** 200 mg IV over at least an hour at Weeks 0, 4, and 8

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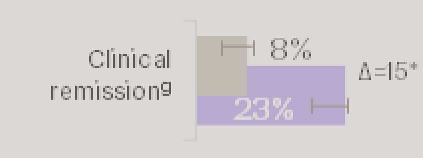
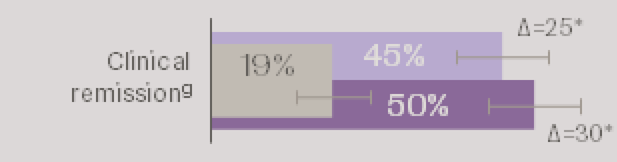


Primary endpoint at Week 44



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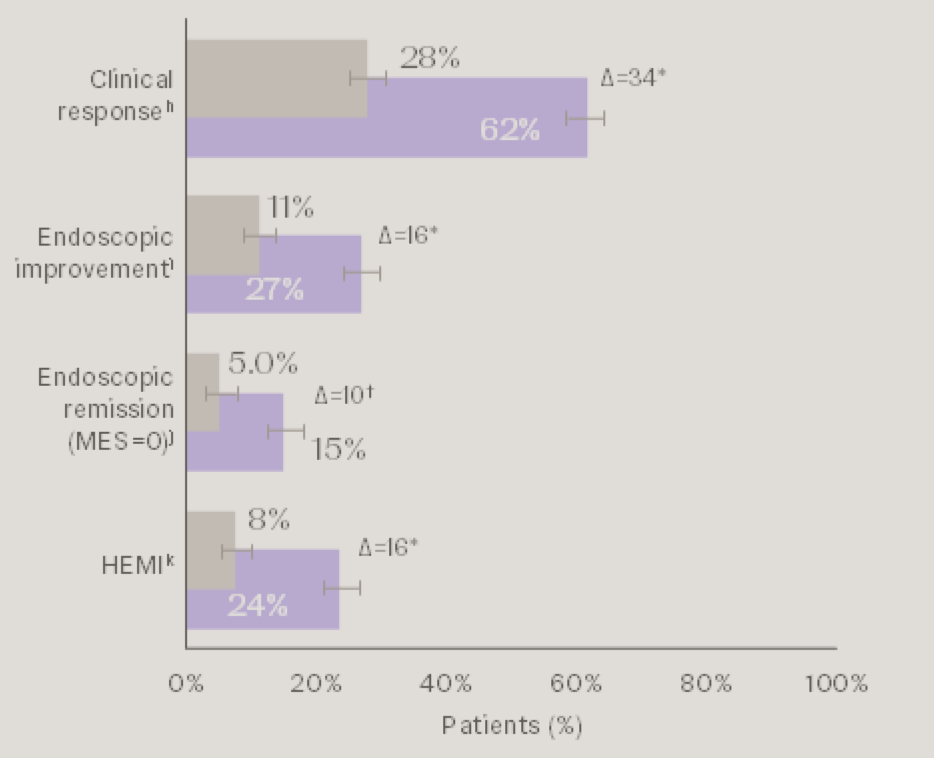
Select secondary endpoints at Week 12

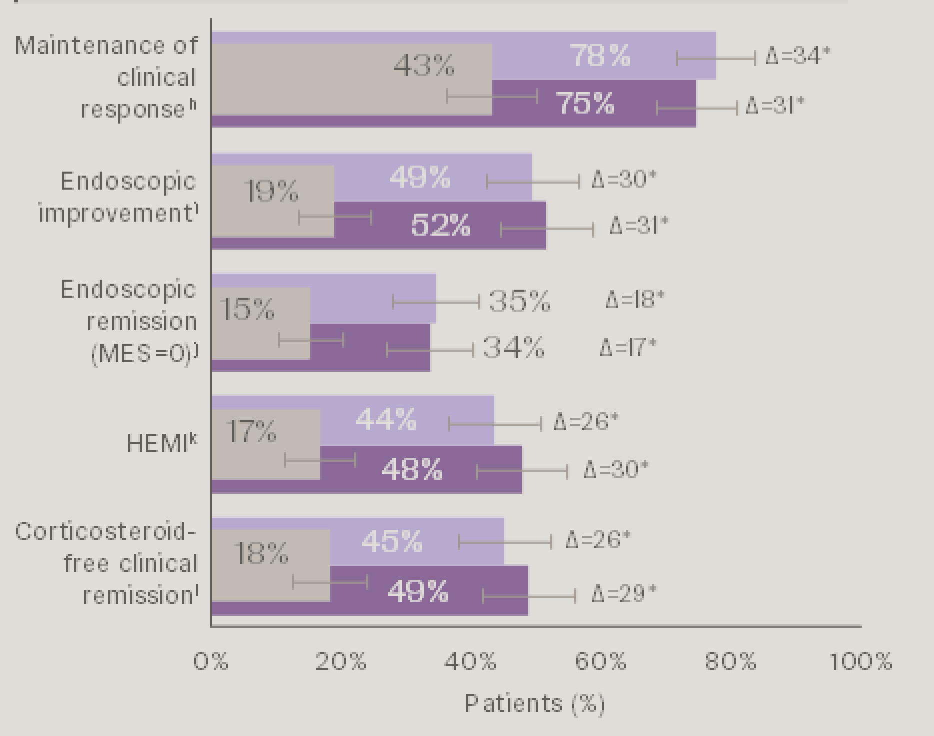


* = $P<0.0001$ versus placebo; TREMFYA® (n=421); PBO (n=280)

† = Nominal $P<0.0001$ versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Select secondary endpoints at Week 44

Over 1/3 of patients were in complete endoscopic remission (MES=0) at Week 44



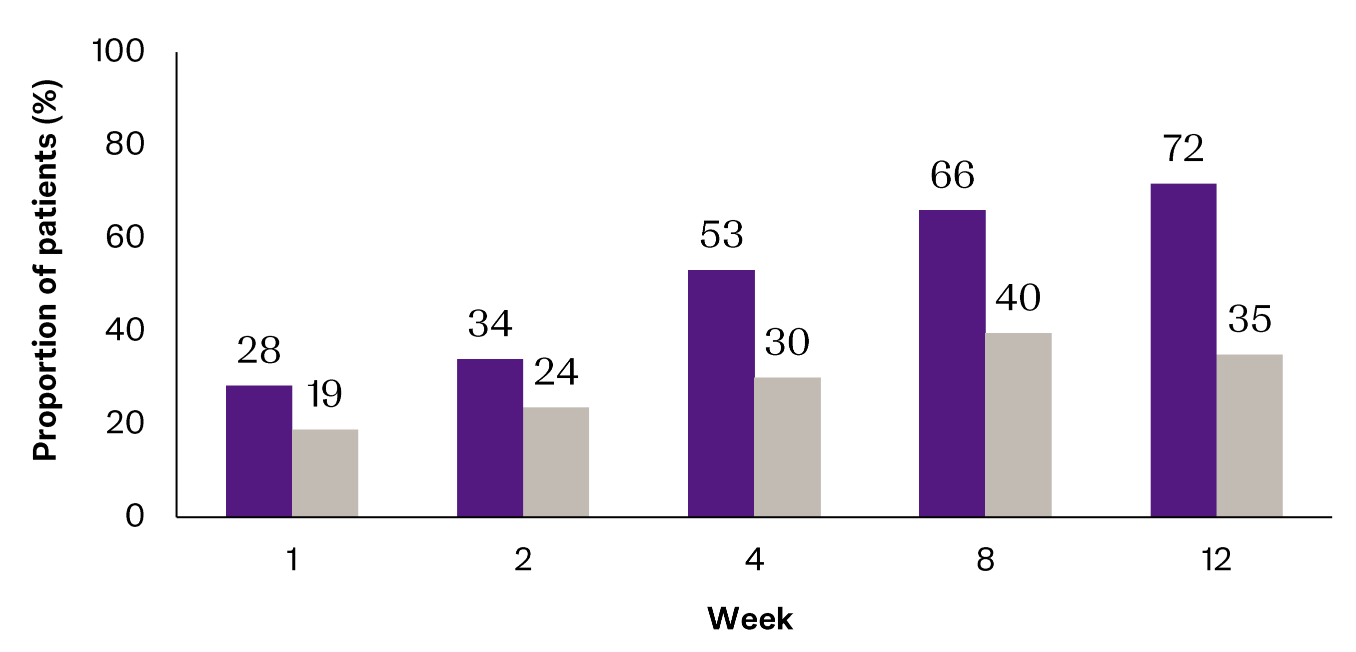
* = $P<0.0001$ versus placebo; TREMFYA® 100 mg q8w (n=188); TREMFYA® 200 mg q4w (n=190); PBO SC (n=190)

Symptomatic response through Week 12 (click for more info) | **Week 24 responders** (click for more info)

Treatment-emergent adverse events at ~1 year from the QUASAR trial in UC[15]

Post hoc analysis: symptomatic response through Week 12

Separation from placebo in symptomatic response observed as early as Week 1*



Symptomatic remission was significantly greater with TREMFYA® vs placebo at the first study visit (Week 4, 23% vs 13%, $P<0.001$) and at Week 12 (50% vs 21%, $P<0.0001$)

Based on visual separation between TREMFYA® and placebo as early as Week 1. Symptomatic response data through Week 12 were *post hoc* analyses and not adjusted for multiplicity. No statistical or clinical significance can be made.

IV, intravenous; PBO, placebo.

Rubin D, et al. *Lancet*. 2025;405:33-49.

- **Induction**: TREMFYA® 200 mg IV or PBO IV at Weeks 0, 4, and 8; or STELARA® (ustekinumab) ~6 mg/kg IV at Week 0
- **Maintenance**: TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, STELARA® 90 mg SC q8w starting at Week 8, or PBO SC q4w starting at Week 12 in PBO induction responders
- Patients in the PBO group who met rescue criteria at Week 12 received an induction dose of STEMARA® ~6 mg/kg IV at Week 12 followed by a maintenance dose of STELARA® 90 mg SC q8w starting at Week 20

- **Induction**: TREMFYA® 400 mg SC q4w or PBO SC q4w at Weeks 0, 4, and 8
- **Maintenance**: TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, or continued on PBO SC q4w (PBO induction responders)
- Patients in the PBO group who met rescue criteria at Week 16 received an induction dose of TREMFYA® 400 mg SC q4w starting at Week 16 followed by a maintenance dose of TRMFYA® 100 mg SC q8w starting at Week 32

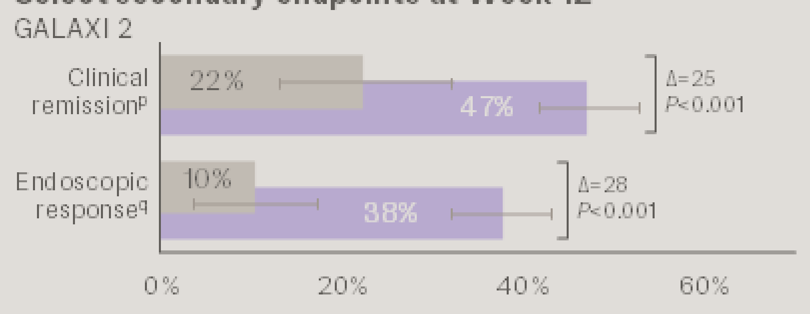
Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

Data originated from separate pivotal trials for the biologic.
Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

GALAXI[18]

Select secondary endpoints at Week 12

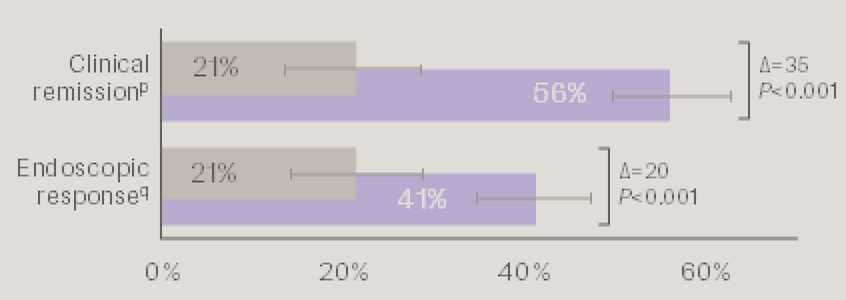
GALAXI 2



GALAXI 3 at Week 12[16]:
Clinical remission[p]: TREMFYA® 47% (138/293) vs PBO 15% (11/72); $P<0.001$
Endoscopic response[q]: TREMFYA® 36% (106/293) vs PBO 14% (10/72); $P<0.001$

GRAVITI[19]

Co-primary endpoints at Week 12

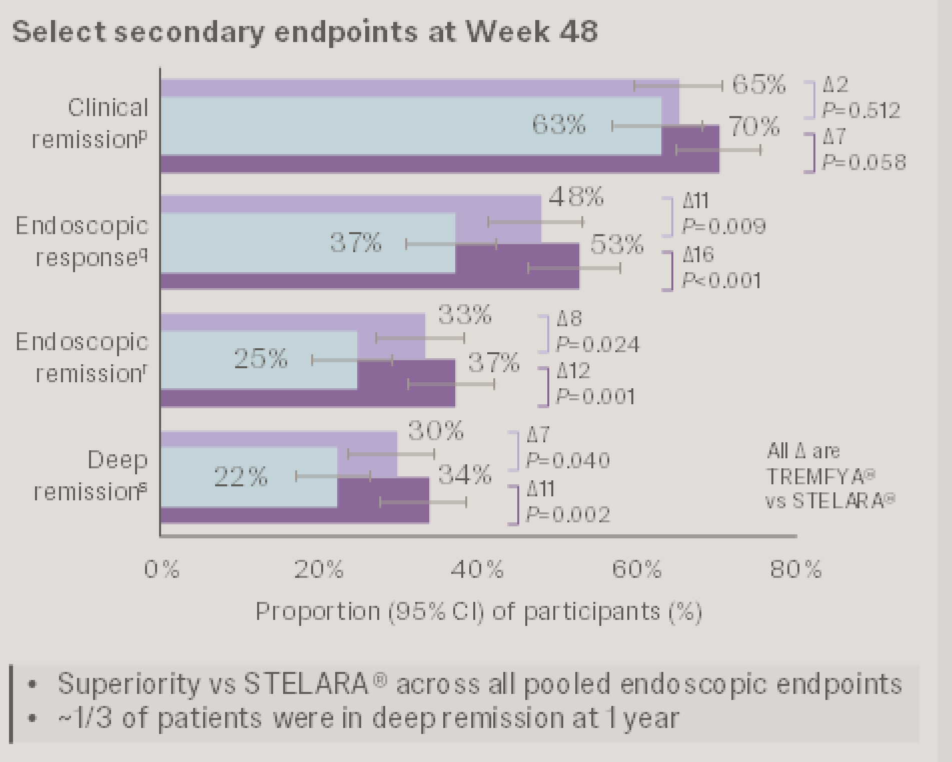


Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

GALAXI[18]

Select secondary endpoints at Week 48

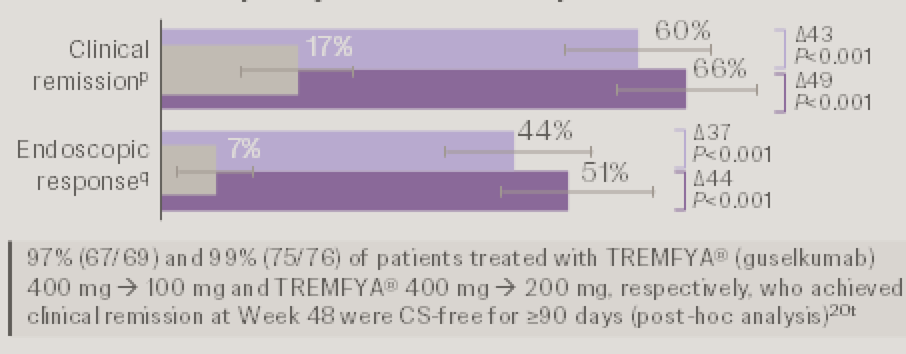


- Superiority vs STELARA® across all pooled endoscopic endpoints
- ~1/3 of patients were in deep remission at 1 year

TREMFYA® 200 mg IV q4w → 100 mg SC q8w N=Pooled, 286; TREMFYA® 200 mg IV q4w → 200 mg SC q4w N=Pooled, 296; STELARA® ~6 mg/kg IV → 90 mg SC q8w N=Pooled, 291

GRAVITI[19]

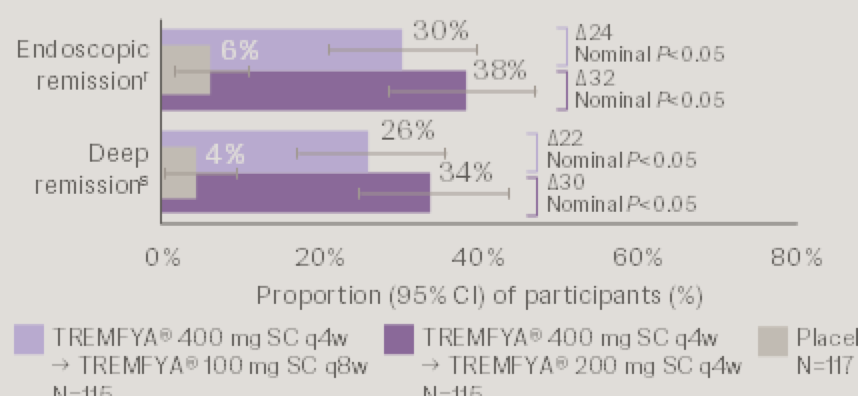
Additional multiplicity-controlled endpoints at Week 48



97% (67/69) and 99% (75/76) of patients treated with TREMFYA® (guselkumab) 400 mg → 100 mg and TREMFYA® 400 mg → 200 mg, respectively, who achieved clinical remission at Week 48 were CS-free for ≥90 days (post-hoc analysis)[20t]

Other endpoints at Week 48

Endoscopic remission and deep remission at Week 48 were prespecified but not controlled for multiplicity. No statistical or clinical significance can be made.



TREMFYA® 400 mg SC q4w → TREMFYA® 100 mg SC q8w N=115; TREMFYA® 400 mg SC q4w → TREMFYA® 200 mg SC q4w N=115; Placebo SC N=117

Treatment-emergent adverse events at ~1 year from the GALAXI and GRAVITI trials in CD

Pooled safety at Week 48 from GALAXI 2 & 3[18,20]

	PBO SC[u]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w	STELARA® 90 mg SC q8w
All-Treated Safety Analysis Set, N	153	296	299	300
Average Duration of Follow-up, weeks	21.8	46.2	46.7	45.5
Total PYs of Follow-up	64.0	261.8	267.3	261.4
Deaths	0	0	0	0
Patients with 1 or more:				
AEs, n (%)	82 (53.6%)	225 (76.0%)	233 (77.9%)	236 (78.7%)
Events/100 PYs of follow-up	499.7	327.3	353.5	340.5
SAEs, n (%)	16 (10.5)	32 (10.8)	21 (7.0)	35 (11.7)
Events/100 PYs of follow-up	32.8	14.9	9.7	18.4
AEs leading to discontinuation, n (%)	13 (8.5%)	21 (7.1%)	19 (6.4%)	22 (7.3%)
Events/100 PYs of follow-up	20.3	8.4	7.5	8.8
Infections[o], n (%)	39 (25.5%)	127 (42.9%)	147 (49.2%)	126 (42.0%)
Events/100 PYs of follow-up	87.5	77.9	88.3	77.7
Serious infections[o], n (%)	2 (1.3%)[v]	1 (0.3%)[w]	3 (1.0%)[x]	12 (4.0%)

Pooled safety at Week 48 from GRAVITI[19,20]

	PBO SC[y]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Safety Analysis Set, N	117	115	115
Average duration of follow-up, weeks	30.0	47.0	48.0
Total PYs of follow-up, years	67.3	103.5	105.7
Deaths, n (%)	0	1 (0.9%)[z]	0
Patients with 1 or more:			
AEs, n (%)	77 (65.8%)	95 (82.6%)	92 (80.0%)
Events/100 PYs of follow-up	413.0	307.2	327.2
SAEs, n (%)	16 (13.7%)	15 (13.0%)	9 (7.8%)
Events/100 PYs follow-up	37.1	15.5	13.2
AEs leading to discontinuation, n (%)	10 (8.5%)	4 (3.5%)	3 (2.6%)
Events/100 PYs of follow-up	14.9	6.8	2.8
Infections, n (%)	36 (30.8%)	56 (48.7%)	47 (40.9%)
Events/100 PYs of follow-up	81.7	91.8	70.0
Serious infections[aa], n (%)	0	2 (1.7%)[ab]	1 (0.9%)[ac]

For additional safety information, please see TREMFYA® prescribing information here.

Future considerations for TREMFYA®: Select ongoing phase 3 trials in IBD

- **ASTRO:** Guselkumab SC induction and maintenance for adults with moderately to severely active UC[21]
- **QUASAR Jr:** Guselkumab for pediatric participants with moderately to severely active UC[22]
- **MACARONI 23:** Guselkumab for pediatric participants with CD[23]

The safety and efficacy of the investigational uses of this product have not been determined. There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA.

For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® prescribing information here.

[a]In the United States. [b]TREMFYA® dosing for moderate to severe plaque PsO and active PsA: 100mg SC at weeks 0 and 4, and q8w thereafter. For moderately to severely active UC, induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. For moderately to severely active CD: IV induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8 OR 400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. [c]**Pretreatment Evaluations**: Prior to initiating treatment with TREMFYA®, evaluate patients for tuberculosis (TB) infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines. **Monitoring:** Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. For the treatment of CD or UC, monitor liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. TREMFYA® is intended for use under the guidance and supervision of a healthcare professional. TREMFYA® may be administered by a healthcare professional, or a patient/caregiver may inject after proper training in subcutaneous injection technique. [d]Moderately to severely active UC defined as induction baseline modified Mayo score of 5 to 9 with a Mayo rectal bleeding subscore ≥ 1 and a Mayo endoscopic subscore ≥ 2 based on central review. [e]Placebo crossover responders at Week 24 are the placebo nonresponders at Week 12 who went on to receive TREMFYA 200 mg IV q4w for 12 weeks and were in clinical response to TREMFYA at Week 24. [f]Patients from a phase 2b randomized, double-blind, placebo-controlled, induction dose-finding study who demonstrated a clinical response to TREMFYA® were also randomized into the phase 3 maintenance study. [g]Clinical remission: Mayo stool frequency subscore of 0 or 1, and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability. [h]Clinical response: decrease from induction baseline in the modified Mayo score (3-component [stool frequency, rectal bleeding, and endoscopy subscores] Mayo score without the physician's global assessment) by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1. [i]Endoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. [j]Endoscopic remission: an endoscopy subscore of 0. [k]HEMI: achieving a combination of histologic improvement and endoscopic improvement. [l]CS-free clinical remission: clinical remission without any use of corticosteroids for ≥8 weeks prior to assessment. [m]Natural causes and cardiac arrest. [n]Fatal acute myocardial infarction in a patient with pre-existing cardiac risk factors. [o]Defined as any AE coded to MedDRA organ class "Infections and infestations". [p]Clinical remission: CDAI <150. [q]Endoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. [r]Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore greater than 1 in any individual component. [s]Deep remission: clinical remission AND endoscopic remission. [t]CS-free is defined as patients in clinical remission at Week 48 and not receiving CS for ≥90 days prior. Denominator is patients in clinical remission at Week 48. [u]Events attributed to patients randomized to PBO, except where a patient is randomized to PBO and cross over to STELARA® (only events that occur while patients are on PBO are included). [v]Liver abscess/bacterial infection and postop wound infection/vascular device infection. [w]Anal abscess. [x]Acute sinusitis, abscess intestinal, intestinal fistula infection. [y]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [z]Fatal gunshot wound (non-suicidal). [aa]An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. [ab]Bronchitis and appendicitis. [ac]Gastroenteritis

AE, adverse effect; CD, Crohn's disease; CDAI, Clinical Disease Activity Index; CI, confidence interval; EIM, extraintestinal manifestation; GAL, GALAXI; HEMI, histo-endoscopic mucosal improvement; HIV, human immunodeficiency virus; IBD, irritable bowel disease; IL-23i, interleukin-23i; IV, intravenous; LTE, long-term extension; MedDRA, Medical Dictionary for Regulatory Activities; MES, modified endoscopic subscore; PBO, placebo; PMPY, per-member, per-year; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient years; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious adverse effect; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; TOFA, tofacitinib; TNF, tumor necrosis factor; UC, ulcerative colitis; ULN, upper limit of normal; UST, ustekinumab; VDZ, vedolizumab; W12, week 12; W48, week 48.

1. Evernorth. Trend by plan type. Accessed July 6, 2023. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher J, et al. *J Rheum Suppl*. 2018;94:32-35. 3. Pennington SR, et al. *Front Med (Lausanne)*. 2021;8:723944. 4. Ciocon D, Kimball A. *Br J Dermatol*. 2007;157(5):850-860. 5. Suzuki E, et al. *Autoimmunity Rev*. 2014;13:496-502. 6. Lowes M, et al. *Annu Rev Immunol*. 2014;32:227-255. 7. Mease P, et al. J Am Acad Dermatol. 2013;69(5):729-735. 8. Sanchez I, et al. Curr Dermatol Rep. 2018;7(1):59-74. 9. Arvikar S, et al. Curr Rev Musculoskel Med. 2011;4(3):123-131. 10. Levine J, et al. *Gastroenterol Hepatol*. 2011;7:235-241. 11. Lewis J, et al. *Gastroenterology*. 2023:1-9. 12. Ye Y, et al. *Inflamm Bowel Dis*. 2020;26(4):619-625. 13. The Crohn's & Colitis Foundation of America. The facts about inflammatory bowel diseases. Updated November 2014. Accessed February 20, 2024. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. 14. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 15. Rubin D, et al. *Lancet*. 2025;405:33-49. 16. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 17. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 18. Panaccione R, et al. DDW 2024. May 18-21, 2024. 19. Hart A, et al. *Gastroenterology*. 2025; doi:10.1053/j.gastro.2025.02.033. 20. Data on File. Janssen Biotech, Inc. Horsham, PA. 21. ASTRO NCT05528510. 22. QUASAR Jr NCT06260163. 23. MACARONI 23 NCT05923073.

US-SFM-6481 04/25

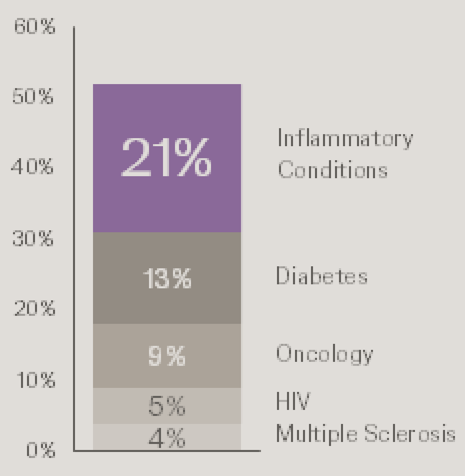
Johnson&Johnson

EVIDENCE SUMMARY: TREMFYA® (guselkumab) for moderately to severely active ulcerative colitis or Crohn's disease

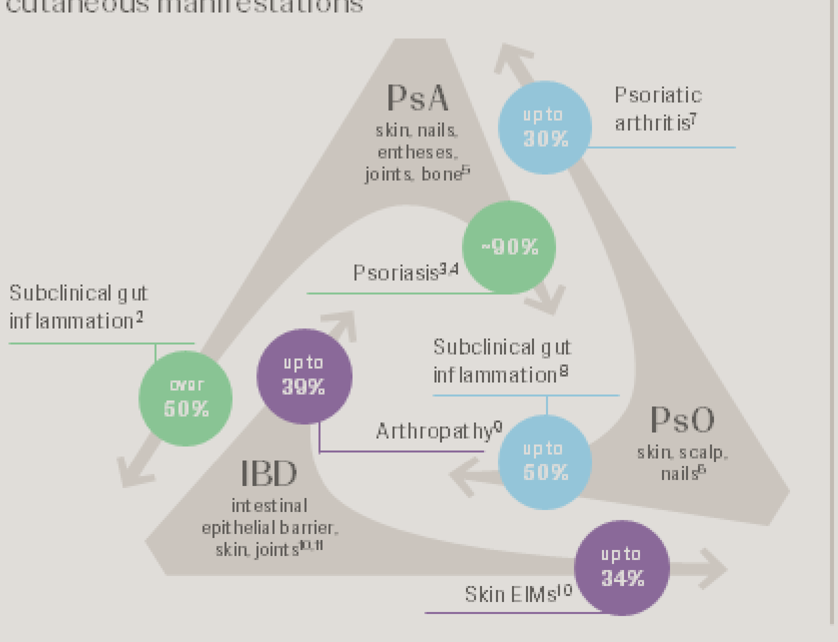
Inflammatory conditions have a significant impact on the patient and healthcare system

Immunologic therapies present the highest cost burden for commercial plans

Top 5 Therapy Classes for Commercial Plans, by Percent of Total PMPY Spending, 2020[1a]



Inflammatory conditions are complex and may present with extra-intestinal, extra-articular, and extra-cutaneous manifestations



United States prevalence[11]:

Site and presentation of inflammation[12,13]

UC: Colon and the rectum, typically appears in a continuous pattern

CD: Anywhere in the GI tract from the mouth to the anus, may appear in patches

TREMFYA® (guselkumab) is a fully human IL-23i indicated for the treatment of adults with[14b]:

- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis
- Moderately to severely active **ulcerative colitis**
- Moderately to severely active **Crohn's disease**

Pre-treatment evaluation and monitoring[c]

Induction | Maintenance — Use the lowest effective recommended dosage to maintain therapeutic response

Week 0, 4, 8 | 12, 16, 20, 24

UC + CD: **TREMFYA® (200 mg IV)** 200 mg IV over at least an hour at Weeks 0, 4, and 8

CD only: **TREMFYA® (400 mg SC)** 400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8

Prefilled syringe (200 mg) or TREMFYA® pen (200 mg) 200 mg SC starting at Week 12, and q4w thereafter

OR

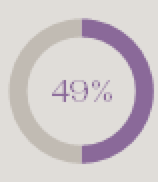
UC + CD: **Prefilled syringe (100 mg), TREMFYA® pen (100 mg), or One-press injector (100 mg)** 100 mg SC at Week 16, and q8w thereafter

TREMFYA® has demonstrated clinical efficacy in UC[14,15]

QUASAR clinical program

TREMFYA® was evaluated in multicenter, randomized, double-blind, placebo-controlled induction and maintenance studies in adult patients with moderately to severely active UC & prior response or intolerance to conventional or advanced therapy.[15d]

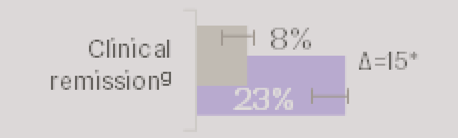
The induction study (N=701) randomized patients 3:2 to receive TREMFYA® 200 mg IV q4w or placebo IV.[14,15] The maintenance study (N=568) took TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[e] and rerandomized 1:1:1[f] to receive TREMFYA® 200 mg SC q4w, TREMFYA® 100 mg SC q8w, or placebo SC.[15]



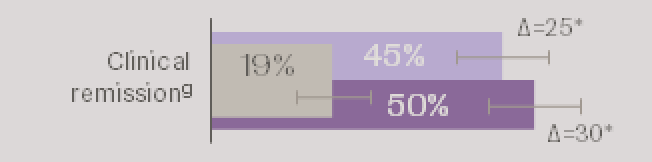
of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, or TOFA)

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC[14,15]

Primary endpoint at Week 12

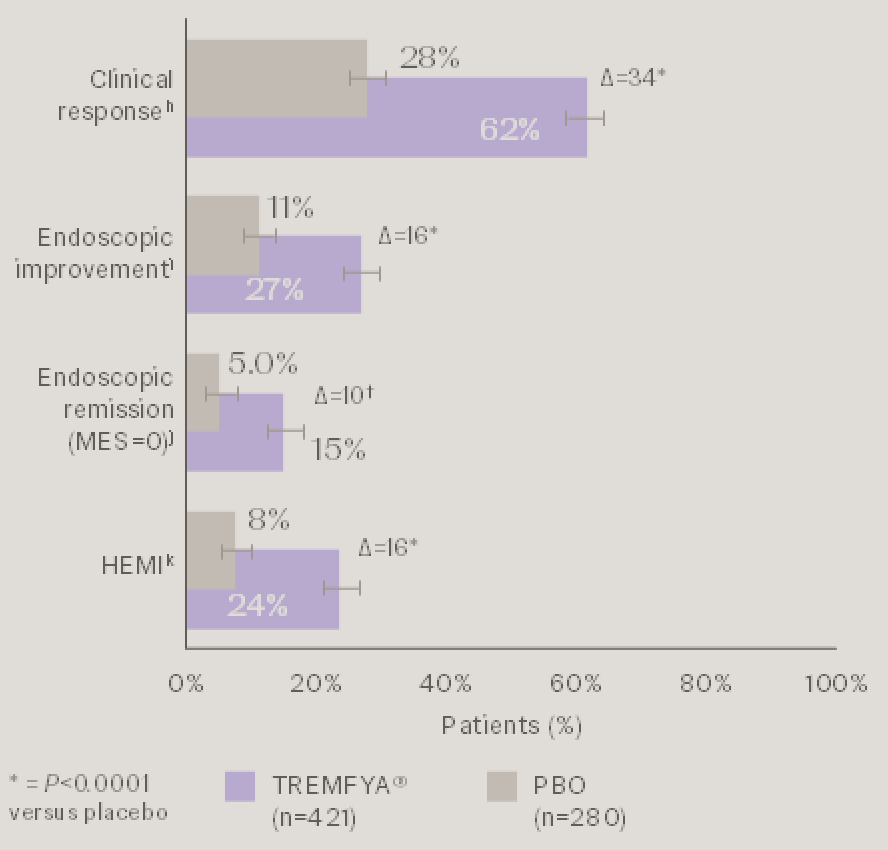


Primary endpoint at Week 44



99% (178/180) of patients in the combined TREMFYA® group who achieved clinical remission at Week 44 were **corticosteroid-free for ≥8 weeks**[15]

Select secondary endpoints at Week 12

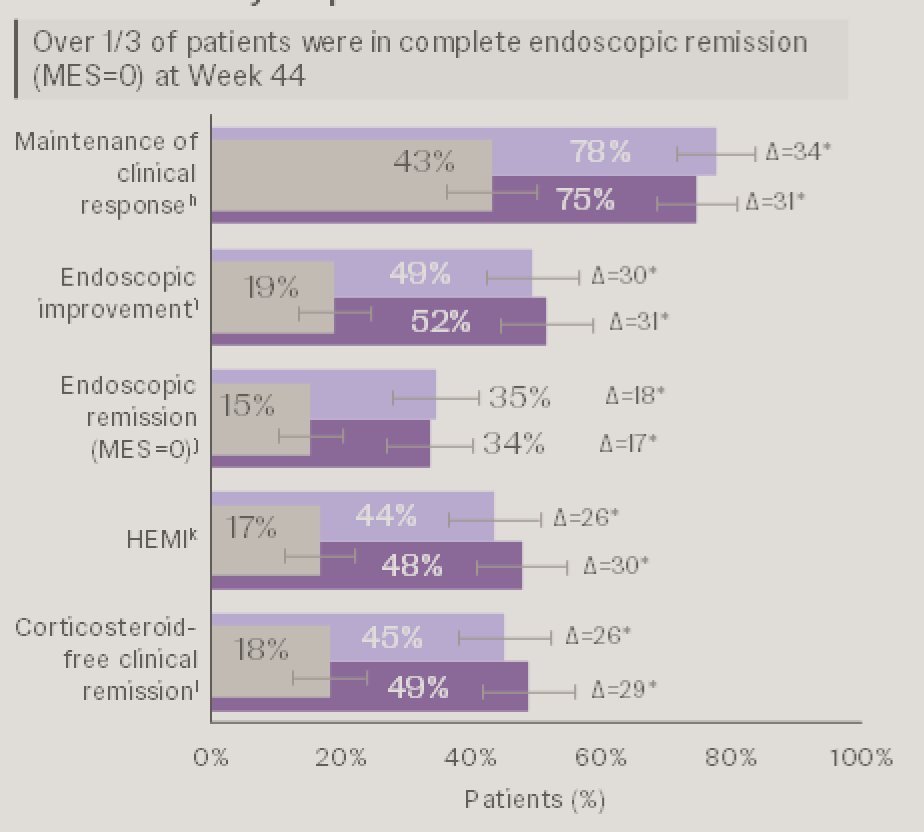


† = Nominal P<0.0001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Symptomatic response through Week 12 (click for more info)

Select secondary endpoints at Week 44

Over 1/3 of patients were in complete endoscopic remission (MES=0) at Week 44



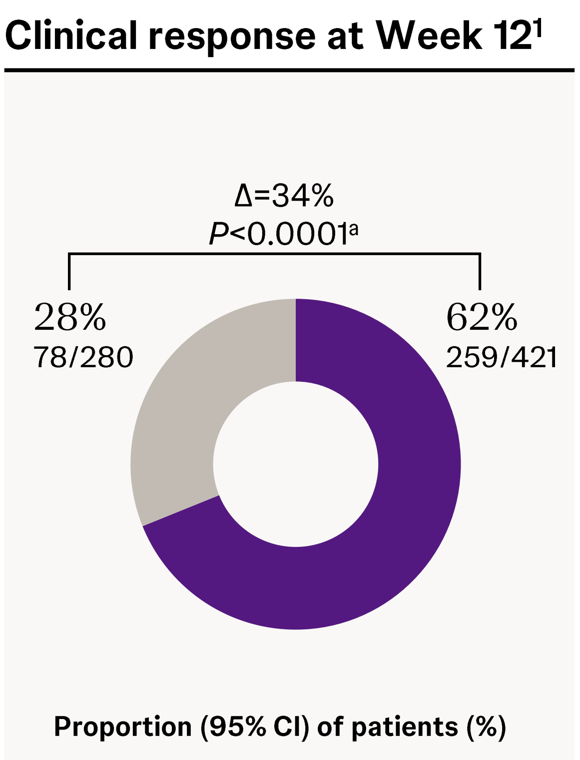
Week 24 responders (click for more info)

Treatment-emergent adverse events at ~1 year from the QUASAR trial in UC[15]

Clinical response at Week 12 or Week 24

Placebo IV | TREMFYA® 200 mg IV | TREMFYA® 200 mg IV → TREMFYA® 200 mg SC[c]

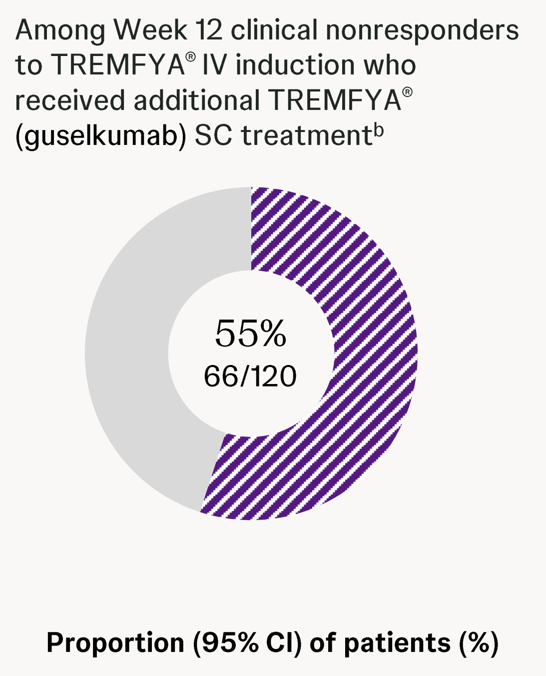
Clinical response at Week 12[1]



Proportion (95% CI) of patients (%)

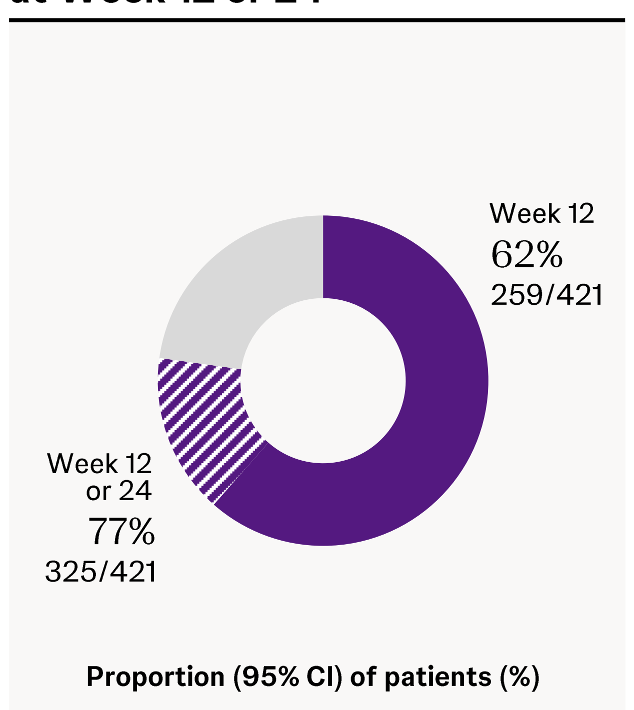
Clinical response at Week 24[2]

Among Week 12 clinical nonresponders to TREMFYA® IV induction who received additional TREMFYA® (guselkumab) SC treatment[b]



Proportion (95% CI) of patients (%)

Cumulative clinical response at Week 12 or 24[2]



Proportion (95% CI) of patients (%)

Clinical response: A decrease from baseline in the modified Mayo score by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.

[a]Adjusted treatment difference (95% CI) based on Cochran-Mantel-Haenszel method (adjusted for stratification factors: biologic and/or JAK-inhibitor failure status and concomitant use of corticosteroids at baseline). [b]Patients who had a prohibited change in UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 12 were considered not to have achieved the specified endpoints. [c]Patients received TREMFYA® 200 mg IV at weeks 0, 4, 8 and then TREMFYA® 200 mg SC at weeks 12, 16, and 20.

AE, adverse event; CI, confidence interval; IV, intravenous; JAK, Janus kinase; SC, subcutaneous; UC, ulcerative colitis.

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. Rubin D, et al. Lancet. Suppl. 2025;.405:S1-S92.

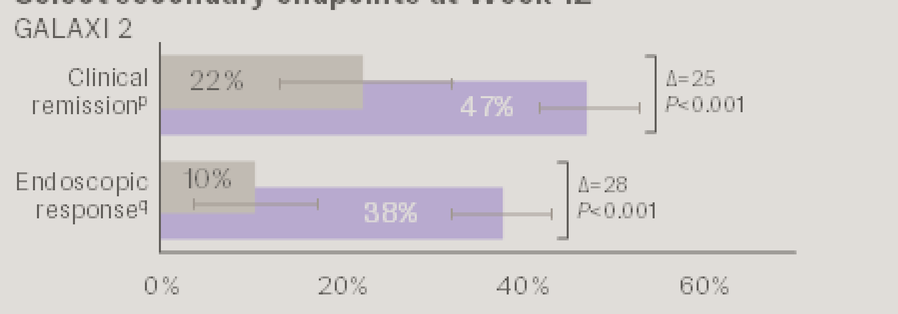
Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

Data originated from separate pivotal trials for the biologic.
Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

GALAXI[18]

Select secondary endpoints at Week 12

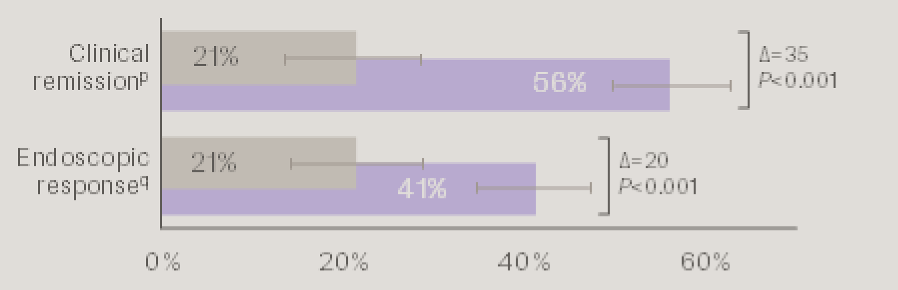
GALAXI 2



GALAXI 3 at Week 12[16]:
Clinical remission[p]: TREMFYA® 47% (138/293) vs PBO 15% (11/72); P<0.001
Endoscopic response[q]: TREMFYA® 36% (106/293) vs PBO 14% (10/72); P<0.001

GRAVITI[19]

Co-primary endpoints at Week 12

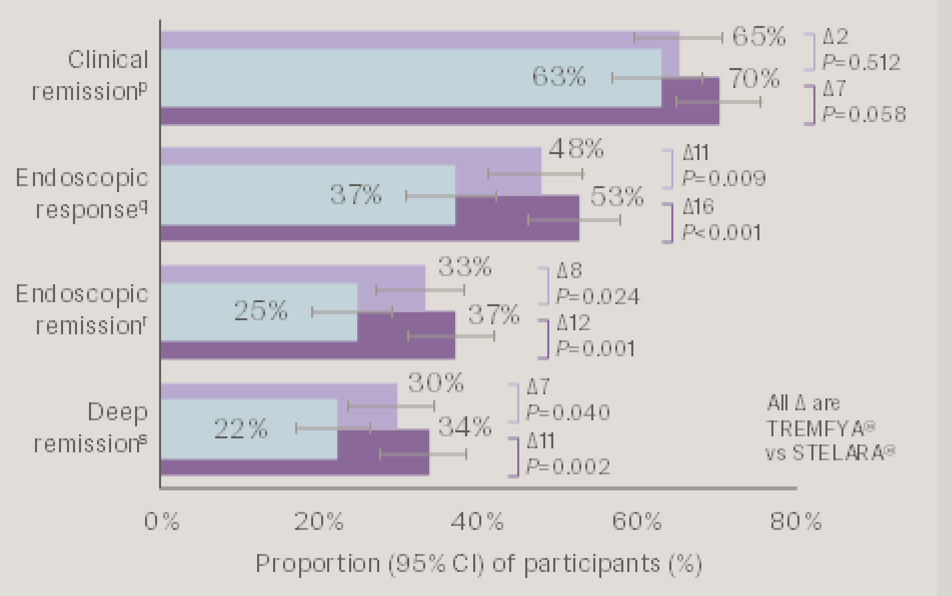


Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

GALAXI[18]

Select secondary endpoints at Week 48

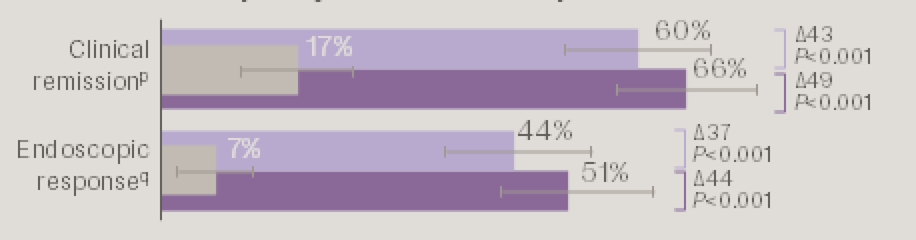


- Superiority vs STELARA® across all pooled endoscopic endpoints
- ~1/3 of patients were in deep remission at 1 year

TREMFYA® 200 mg IV q4w → 100 mg SC q8w N=Pooled, 286
TREMFYA® 200 mg IV q4w → 200 mg SC q4w N=Pooled, 296
STELARA® ~6 mg/kg IV → 90 mg SC q8w N=Pooled, 291

GRAVITI[19]

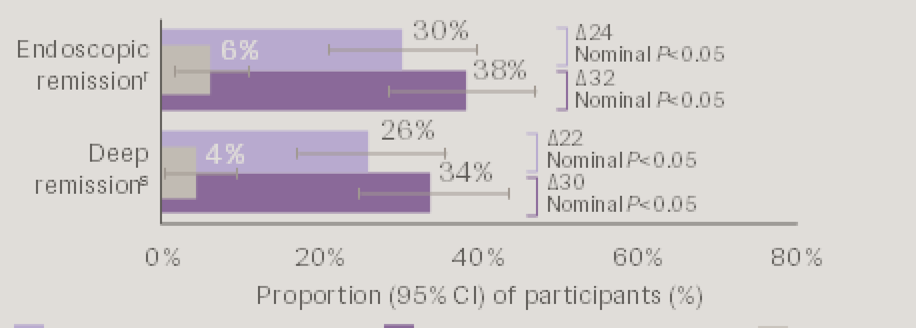
Additional multiplicity-controlled endpoints at Week 48



97% (67/69) and 99% (75/76) of patients treated with TREMFYA® (guselkumab) 400 mg → 100 mg and TREMFYA® 400 mg → 200 mg, respectively, who achieved clinical remission at Week 48 were CS-free for ≥90 days (post-hoc analysis)[20t]

Other endpoints at Week 48

Endoscopic remission and deep remission at Week 48 were prespecified but not controlled for multiplicity. No statistical or clinical significance can be made.



TREMFYA® 400 mg SC q4w → TREMFYA® 100 mg SC q8w N=115
TREMFYA® 400 mg SC q4w → TREMFYA® 200 mg SC q4w N=115
Placebo SC N=117

Treatment-emergent adverse events at ~1 year from the GALAXI and GRAVITI trials in CD

Pooled safety at Week 48 from GALAXI 2 & 3[18,20]

	PBO SC[u]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w	STELARA® 90 mg SC q8w
All-Treated Safety Analysis Set, N	153	296	299	300
Average Duration of Follow-up, weeks	21.8	46.2	46.7	45.5
Total PYs of Follow-up	64.0	261.8	267.3	261.4
Deaths	0	0	0	0
Patients with 1 or more:				
AEs, n (%)	82 (53.6%)	225 (76.0%)	233 (77.9%)	236 (78.7%)
Events/100 PYs of follow-up	499.7	327.3	353.5	340.5
SAEs, n (%)	16 (10.5)	32 (10.8)	21 (7.0)	35 (11.7)
Events/100 PYs of follow-up	32.8	14.9	9.7	18.4
AEs leading to discontinuation, n (%)	13 (8.5%)	21 (7.1%)	19 (6.4%)	22 (7.3%)
Events/100 PYs of follow-up	20.3	8.4	7.5	8.8
Infections[o], n (%)	39 (25.5%)	127 (42.9%)	147 (49.2%)	126 (42.0%)
Events/100 PYs of follow-up	87.5	77.9	88.3	77.7
Serious infections[o], n (%)	2 (1.3%)[v]	1 (0.3%)[w]	3 (1.0%)[x]	12 (4.0%)

Pooled safety at Week 48 from GRAVITI[19,20]

	PBO SC[y]	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Safety Analysis Set, N	117	115	115
Average duration of follow-up, weeks	30.0	47.0	48.0
Total PYs of follow-up, years	67.3	103.5	105.7
Deaths, n (%)	0	1 (0.9%)[z]	0
Patients with 1 or more:			
AEs, n (%)	77 (65.8%)	95 (82.6%)	92 (80.0%)
Events/100 PYs of follow-up	413.0	307.2	327.2
SAEs, n (%)	16 (13.7%)	15 (13.0%)	9 (7.8%)
Events/100 PYs follow-up	37.1	15.5	13.2
AEs leading to discontinuation, n (%)	10 (8.5%)	4 (3.5%)	3 (2.6%)
Events/100 PYs of follow-up	14.9	6.8	2.8
Infections, n (%)	36 (30.8%)	56 (48.7%)	47 (40.9%)
Events/100 PYs of follow-up	81.7	91.8	70.0
Serious infections[aa], n (%)	0	2 (1.7%)[ab]	1 (0.9%)[ac]

For additional safety information, please see TREMFYA® prescribing information here.

Future considerations for TREMFYA®: Select ongoing phase 3 trials in IBD

ASTRO: Guselkumab SC induction and maintenance for adults with moderately to severely active UC[21]

QUASAR Jr: Guselkumab for pediatric participants with moderately to severely active UC[22]

MACARONI 23: Guselkumab for pediatric participants with CD[23]

The safety and efficacy of the investigational uses of this product have not been determined. There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA.

For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® prescribing information here.

[a]In the United States. [b]TREMFYA® dosing for moderate to severe plaque PsO and active PsA: 100mg SC at weeks 0 and 4, and q8w thereafter. For moderately to severely active UC, induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. For moderately to severely active CD: IV induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8 OR 400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. [c]**Pretreatment Evaluations**: Prior to initiating treatment with TREMFYA®, evaluate patients for tuberculosis (TB) infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines. **Monitoring:** Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. For the treatment of CD or UC, monitor liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. TREMFYA® is intended for use under the guidance and supervision of a healthcare professional. TREMFYA® may be administered by a healthcare professional, or a patient/caregiver may inject after proper training in subcutaneous injection technique. [d]Moderately to severely active UC defined as induction baseline modified Mayo score of 5 to 9 with a Mayo rectal bleeding subscore ≥1 and a Mayo endoscopic subscore ≥ 2 based on central review. [e]Placebo crossover responders at Week 24 are the placebo nonresponders at Week 12 who went on to receive TREMFYA 200 mg IV q4w for 12 weeks and were in clinical response to TREMFYA at Week 24. [f]Patients from a phase 2b randomized, double-blind, placebo-controlled, induction dose-finding study who demonstrated a clinical response to TREMFYA® were also randomized into the phase 3 maintenance study. [g]Clinical remission: Mayo stool frequency subscore of 0 or 1, and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability. [h]Clinical response: decrease from induction baseline in the modified Mayo score (3-component [stool frequency, rectal bleeding, and endoscopy subscores] Mayo score without the physician's global assessment) by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1. [i]Endoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. [j]Endoscopic remission: an endoscopy subscore of 0. [k]HEMI: achieving a combination of histologic improvement and endoscopic improvement. [l]CS-free clinical remission: clinical remission without any use of corticosteroids for ≥8 weeks prior to assessment. [m]Natural causes and cardiac arrest. [n]Fatal acute myocardial infarction in a patient with pre-existing cardiac risk factors. [o]Defined as any AE coded to MedDRA organ class "Infections and infestations". [p]Clinical remission: CDAI <150. [q]Endoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. [r]Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore greater than 1 in any individual component. [s]Deep remission: clinical remission AND endoscopic remission. [t]CS-free is defined as patients in clinical remission at Week 48 and not receiving CS for ≥90 days prior. Denominator is patients in clinical remission at Week 48. [u]Events attributed to patients randomized to PBO, except where a patient is randomized to PBO and cross over to STELARA® (only events that occur while patients are on PBO are included). [v]Liver abscess/bacterial infection and postop wound infection/vascular device infection. [w]Anal abscess. [x]Acute sinusitis, abscess intestinal, intestinal fistula infection. [y]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [z]Fatal gunshot wound (non-suicidal). [aa]An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. [ab]Bronchitis and appendicitis. [ac]Gastroenteritis

AE, adverse effect; CD, Crohn's disease; CDAI, Clinical Disease Activity Index; CI, confidence interval; EIM, extraintestinal manifestation; GAL, GALAXI; HEMI, histo-endoscopic mucosal improvement; HIV, human immunodeficiency virus; IBD, irritable bowel disease; IL-23i, interleukin-23i; IV, intravenous; LTE, long-term extension; MedDRA, Medical Dictionary for Regulatory Activities; MES, modified endoscopic subscore; PBO, placebo; PMPY, per-member, per-year; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient years; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious adverse effect; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; TOFA, tofacitinib; TNF, tumor necrosis factor; UC, ulcerative colitis; ULN, upper limit of normal; UST, ustekinumab; VDZ, vedolizumab; W12, week 12; W48, week 48.

1. Evernorth. Trend by plan type. Accessed July 6, 2023. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher J, et al. *J Rheum Suppl.* 2018;94:32-35. 3. Pennington SR, et al. *Front Med (Lausanne).* 2021;8:723944. 4. Ciocon D, Kimball A. *Br J Dermatol.* 2007;157(5):850-860. 5. Suzuki E, et al. *Autoimmunity Rev.* 2014;13:496-502. 6. Lowes M, et al. *Annu Rev Immunol.* 2014;32:227-255. 7. Mease P, et al. J Am Acad Dermatol. 2013;69(5):729-735. 8. Sanchez I, et al. Curr Dermatol Rep. 2018;7(1):59-74. 9. Arvikar S, et al. Curr Rev Musculoskel Med. 2011;4(3):123-131. 10. Levine J, et al. *Gastroenterol Hepatol.* 2011;7:235-241. 11. Lewis J, et al. *Gastroenterology.* 2023:1-9. 12. Ye Y, et al. *Inflamm Bowel Dis.* 2020;26(4):619-625. 13. The Crohn's & Colitis Foundation of America. The facts about inflammatory bowel diseases. Updated November 2014. Accessed February 20, 2024. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. 14. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 15. Rubin D, et al. *Lancet.* 2025;405:33-49. 16. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 17. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 18. Panaccione R, et al. DDW 2024. May 18-21, 2024. 19. Hart A, et al. *Gastroenterology.* 2025; doi:10.1053/j.gastro.2025.02.033. 20. Data on File. Janssen Biotech, Inc. Horsham, PA. 21. ASTRO NCT05528510. 22. QUASAR Jr NCT06260163. 23. MACARONI 23 NCT05923073.

US-SFM-64810 4/25

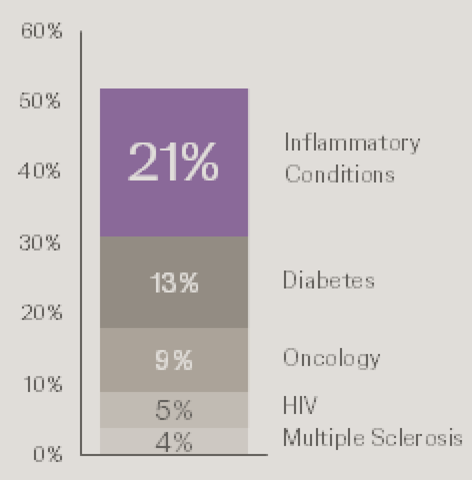
Johnson&Johnson

EVIDENCE SUMMARY: TREMFYA® (guselkumab) for moderately to severely active ulcerative colitis or Crohn's disease

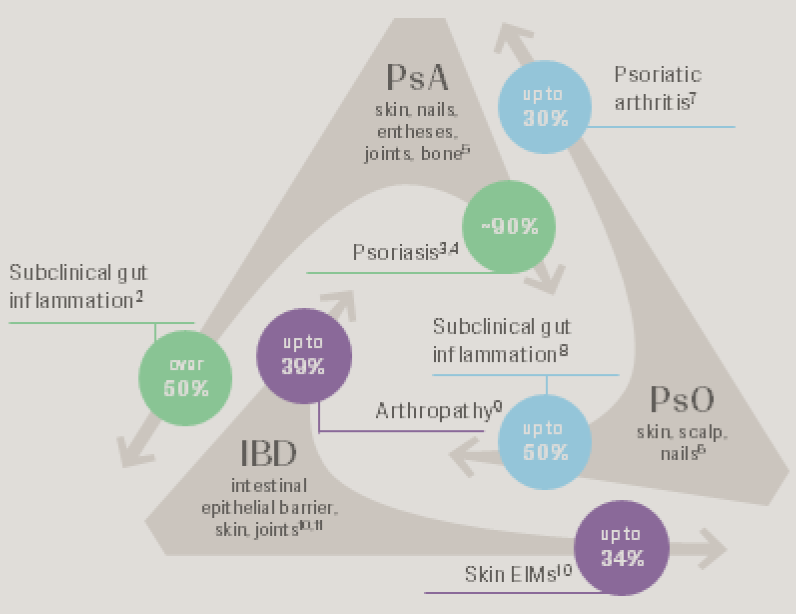
Inflammatory conditions have a significant impact on the patient and healthcare system

Immunologic therapies present the highest cost burden for commercial plans

Top 5 Therapy Classes for Commercial Plans, by Percent of Total PMPY Spending, 2020[1a]



Inflammatory conditions are complex and may present with extra-intestinal, extra-articular, and extra-cutaneous manifestations



United States prevalence[11]:

- UC: 1,253,000 cases
- CD: 1,011,000 cases

Site and presentation of inflammation[12,13]

UC: Colon and the rectum, typically appears in a continuous pattern

CD: Anywhere in the GI tract from the mouth to the anus, may appear in patches

TREMFYA® (guselkumab) is a fully human IL-23i indicated for the treatment of adults with[14b]:

- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis
- Moderately to severely active **ulcerative colitis**
- Moderately to severely active **Crohn's disease**

Pre-treatment evaluation and monitoring[c]

Induction — Week 0, 4, 8

Maintenance — Use the lowest effective recommended dosage to maintain therapeutic response — Week 12, 16, 20, 24

UC + CD

TREMFYA® (200 mg IV)
200 mg IV over at least an hour at Weeks 0, 4, and 8

CD only

TREMFYA® (400 mg SC)
400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8

Prefilled syringe (200 mg) or TREMFYA® pen (200 mg)
200 mg SC starting at Week 12, and q4w thereafter

UC + CD

OR

Prefilled syringe (100 mg), TREMFYA® pen (100 mg), or One-press injector (100 mg)
100 mg SC at Week 16, and q8w thereafter

TREMFYA® has demonstrated clinical efficacy in UC[14,15]

QUASAR clinical program

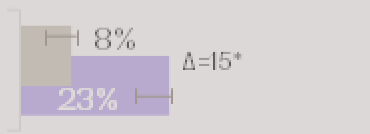
TREMFYA® was evaluated in multicenter, randomized, double-blind, placebo-controlled induction and maintenance studies in adult patients with moderately to severely active UC & prior response or intolerance to conventional or advanced therapy.[15d]

The induction study (N=701) randomized patients 3:2 to receive TREMFYA® 200 mg IV q4w or placebo IV.[14,15] The maintenance study (N=568) took TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[e] and rerandomized 1:1:1[f] to receive TREMFYA® 200 mg SC q4w, TREMFYA® 100 mg SC q8w, or placebo SC.[15]

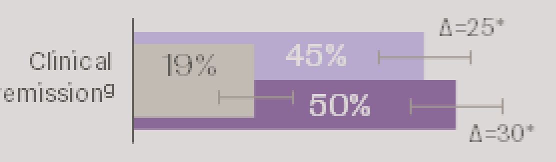
49% of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, or TOFA)

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC[14,15]

Primary endpoint at Week 12

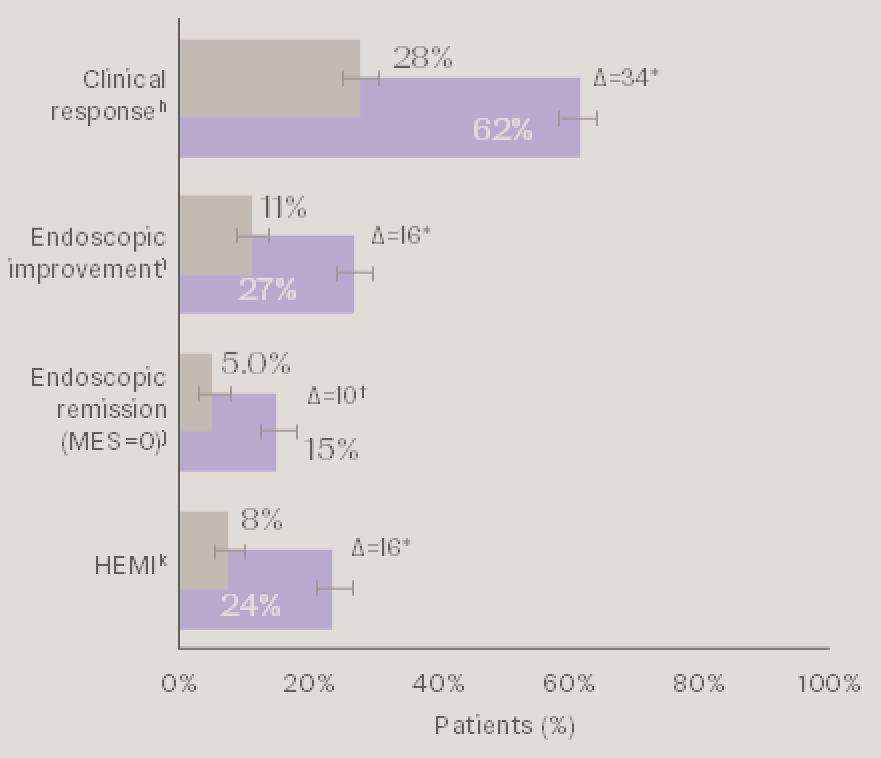


Primary endpoint at Week 44



99% (178/180) of patients in the combined TREMFYA® group who achieved clinical remission at Week 44 were **corticosteroid-free for ≥8 weeks**[15]

Select secondary endpoints at Week 12



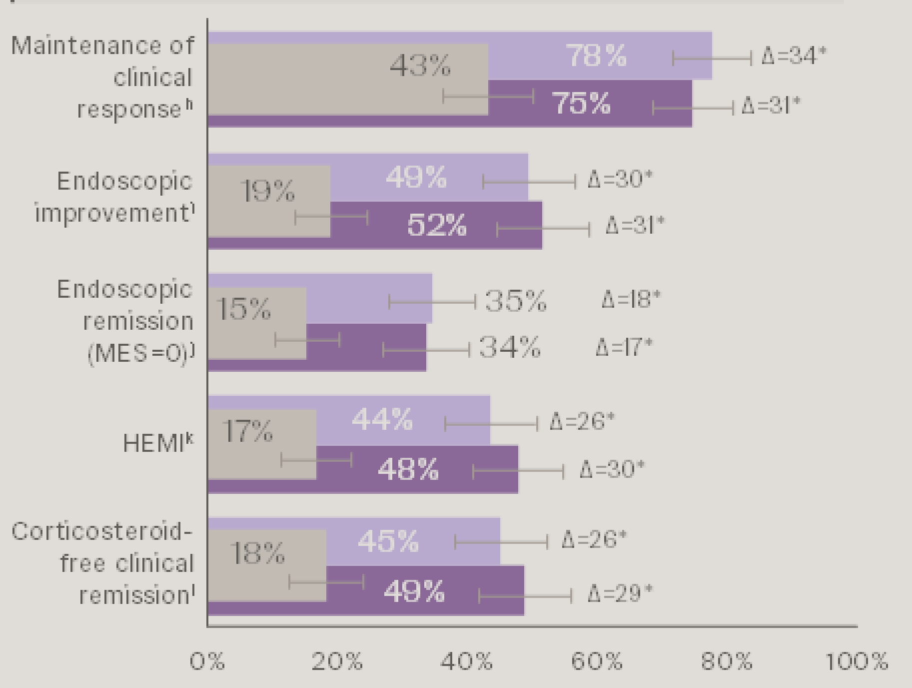
* = P<0.0001 versus placebo; TREMFYA® (n=421); PBO (n=280)

† = Nominal P<0.0001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

Symptomatic response through Week 12 (click for more info)

Select secondary endpoints at Week 44

Over 1/3 of patients were in complete endoscopic remission (MES=0) at Week 44



* = P<0.0001 versus placebo; TREMFYA® 100 mg q8w (n=188); TREMFYA® 200 mg q4w (n=190); PBO SC (n=190)

Week 24 responders (click for more info)

Treatment-emergent adverse events at ~1 year from the QUASAR trial in UC[15]

	Induction study		Maintenance study		
	PBO IV q4w	TREMFYA® 200 mg IV q4w	PBO SC (TREMFYA® withdrawal)	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Patients treated (n)	280	421	192	186	190
Average follow-up (weeks)	11.9	12.2	34.0	40.5	39.2
Deaths	2 (1%)[m]	1 (0.2%)[n]	0	0	0
Patients with one or more (n[%]):					
AEs	138 (49%)	208 (49%)	131 (68%)	120 (65%)	133 (70%)
Serious AEs	20 (7%)	12 (3%)	1 (1%)	5 (3%)	12 (6%)
AEs leading to discontinuation	11 (4%)	7 (2%)	13 (7%)	7 (4%)	5 (3%)
Infections[16,17o]	43 (15%)	66 (16%)	63 (33%)	59 (32%)	59 (31%)
Serious Infections[o]	1 (0.4%)	3 (1%)	0	1 (1%)	2 (1%)

For additional safety information, please see TREMFYA® prescribing information here.

Guselkumab for CD

GALAXI clinical program[14,18]

Two identical 48-week, multicenter, randomized, double-blind, placebo- and biologic active-controlled, parallel-group, treat-through studies in adult patients with moderately to severely active CD, who had inadequate response, loss of response, or intolerance to oral CS, conventional IMMs, and/or biologic therapies (TNFi, VDZ).

~52% previously failed at least 1 biologic, **N=1,021**

Patients were randomized 2:2:2:1 to receive:

- **Induction**: TREMFYA® 200 mg IV or PBO IV at Weeks 0, 4, and 8; or STELARA® (ustekinumab) ~6 mg/kg IV at Week 0
- **Maintenance**: TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, STELARA® 90 mg SC q8w starting at Week 8, or PBO SC q4w starting at Week 12 in PBO induction responders
- Patients in the PBO group who met rescue criteria at Week 12 received an induction dose of STEMARA® ~6 mg/kg IV at Week 12 followed by a maintenance dose of STELARA® 90 mg SC q8w starting at Week 20

GRAVITI clinical program[14,19]

A 48-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, treat-through study in adult patients with moderately to severely active CD, who had inadequate response, loss of response, or intolerance to oral CS, conventional IMMs, and/or biologic therapies (TNFi, VDZ).

46% previously failed at least 1 biologic, **N=347**

Patients were randomized 1:1:1 to receive:

- **Induction**: TREMFYA® 400 mg SC q4w or PBO SC q4w at Weeks 0, 4, and 8
- **Maintenance**: TREMFYA® 200 mg SC q4w starting at Week 12, TREMFYA® 100 mg SC q8w starting at Week 16, or continued on PBO SC q4w (PBO induction responders)
- Patients in the PBO group who met rescue criteria at Week 16 received an induction dose of TREMFYA® 400 mg SC q4w starting at Week 16 followed by a maintenance dose of TRMFYA® 100 mg SC q8w starting at Week 32

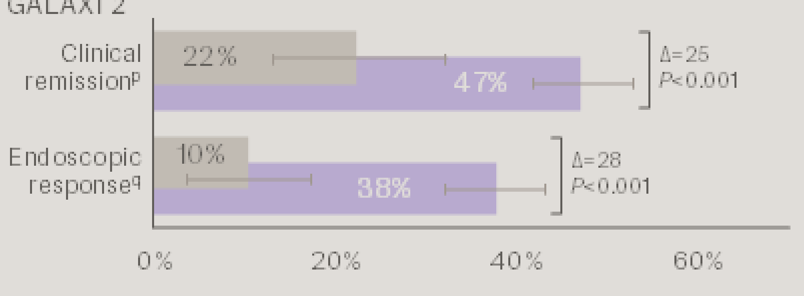
Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

Data originated from separate pivotal trials for the biologic.
Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

GALAXI[18]

Select secondary endpoints at Week 12

GALAXI 2

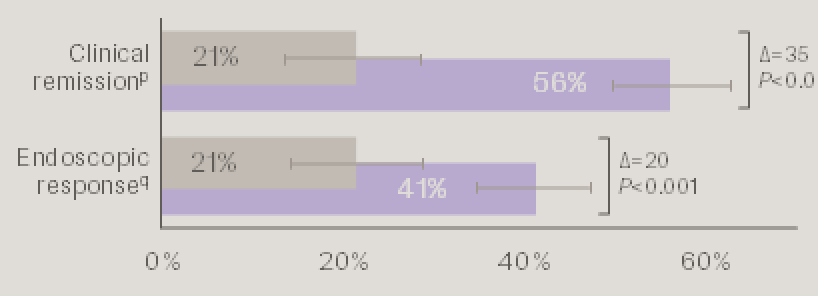


TREMFYA® (n=289); PBO (n=76)

GALAXI 3 at Week 12[16]:
Clinical remission[p]: TREMFYA® 47% (138/293) vs PBO 15% (11/72); P<0.001
Endoscopic response[q]: TREMFYA® 36% (106/293) vs PBO 14% (10/72); P<0.001

GRAVITI[19]

Co-primary endpoints at Week 12



TREMFYA® (n=230); PBO (n=117)

Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

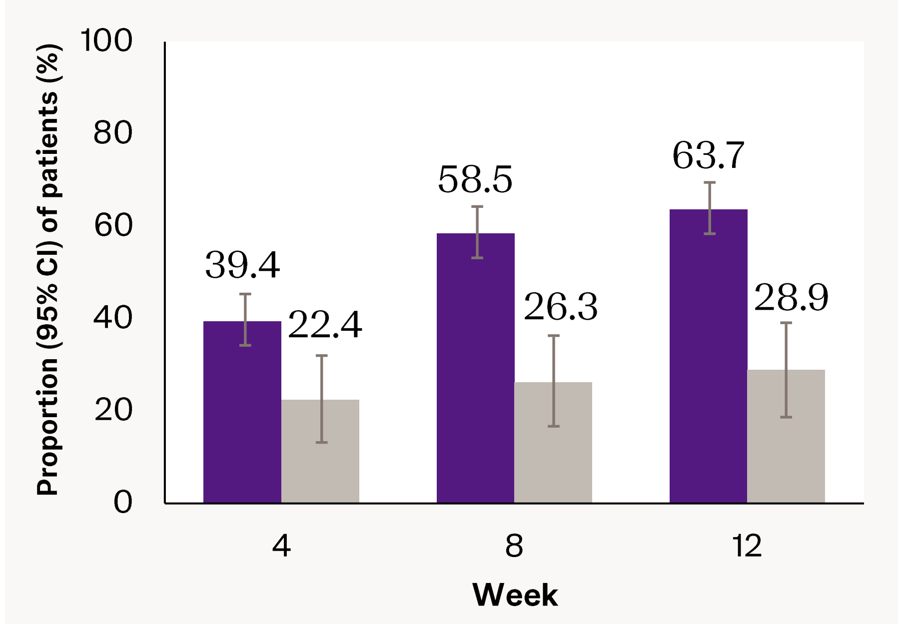
GALAXI[18]

GRAVITI[19]

Both TREMFYA® SC and IV induction separated from placebo in clinical response as early as Week 4

Data originated from separate pivotal trials for the biologic. Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

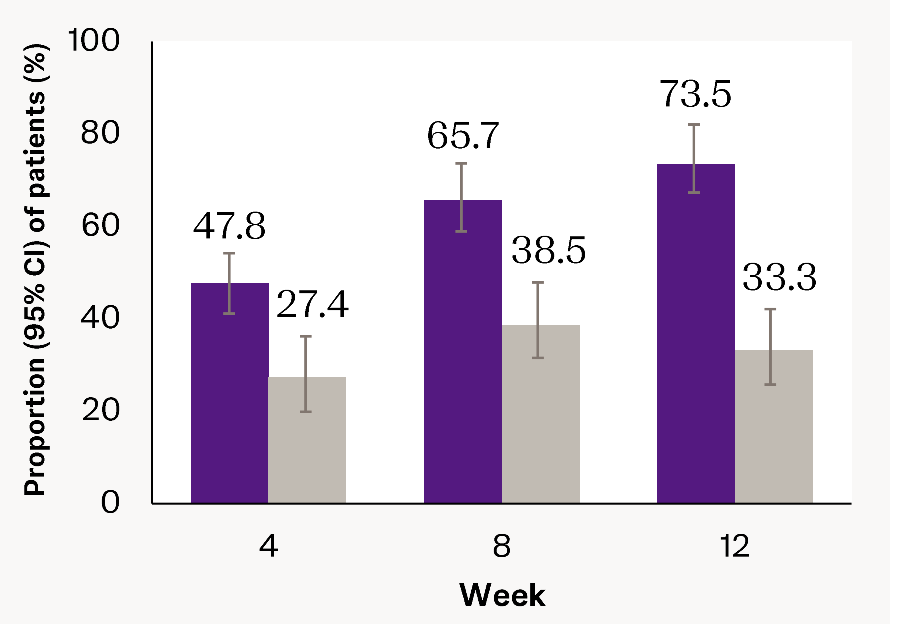
IV introduction: GALAXI 2 clinical response[1]



GALAXI 3: At week 12, 61.1% of patients on TREMFYA® (combined 200 mg IV groups) achieved clinical response compared to 18.1% in the placebo group[1]

Placebo (N=76); TREMFYA® 200 mg IV q4w (N=289)

SC introduction: GRAVITI clinical response[2]



Placebo (N=117); TREMFYA® 400 mg SC q4w (N=230)

Clinical response at **Weeks 8 and 12 for GALAXI and at Weeks 4 and 8 for GRAVITI** were prespecified but not adjusted for multiplicity. Clinical response at **Week 4 for GALAXI** was adjusted for multiplicity (with nominal P-value). No statistical or clinical significance can be made. **Clinical response:** ≥100-point reduction from baseline in CDAI score or CDAI score <150

CDAI, Crohn's disease activity index; CI, confidence interval; IV, intravenous; q4w, every 4 weeks; SC, subcutaneous.

1. Panaccione R, et al. DDW 2024. Oral Presentation #1057b. 2. Hart A, et al. *Gastroenterology*. 2025; doi:10.1053/j.gastro.2025.02.033.

SAEs, n (%)	16 (10.5)	32 (10.8)	21 (7.0)	35 (11.7)
Events/100 PYs of follow-up	32.8	14.9	9.7	18.4
AEs leading to discontinuation, n (%)	13 (8.5%)	21 (7.1%)	19 (6.4%)	22 (7.3%)
Events/100 PYs of follow-up	20.3	8.4	7.5	8.8
Infections[o], n (%)	39 (25.5%)	127 (42.9%)	147 (49.2%)	126 (42.0%)
Events/100 PYs of follow-up	87.5	77.9	88.3	77.7
Serious infections[o], n (%)	2 (1.3%)[v]	1 (0.3%)[w]	3 (1.0%)[x]	12 (4.0%)

SAEs, n (%)	16 (13.7%)	15 (13.0%)	9 (7.8%)
Events/100 PYs follow-up	37.1	15.5	13.2
AEs leading to discontinuation, n (%)	10 (8.5%)	4 (3.5%)	3 (2.6%)
Events/100 PYs of follow-up	14.9	6.8	2.8
Infections, n (%)	36 (30.8%)	56 (48.7%)	47 (40.9%)
Events/100 PYs of follow-up	81.7	91.8	70.0
Serious infections[aa], n (%)	0	2 (1.7%)[ab]	1 (0.9%)[ac]

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Future considerations for TREMFYA®: Select ongoing phase 3 trials in IBD

- **ASTRO:** Guselkumab SC induction and maintenance for adults with moderately to severely active UC[21]
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- **MACARONI 23:** Guselkumab for pediatric participants with CD[23]

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[a]In the United States. [b]TREMFYA® dosing for moderate to severe plaque PsO and active PsA: 100mg SC at weeks 0 and 4, and q8w thereafter. For moderately to severely active UC, induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. For moderately to severely active CD: IV induction: 200 mg IV over at least 1 hour at Weeks 0, 4, and 8 OR 400 mg SC given as two consecutive injections of 200 mg each at Weeks 0, 4, and 8; maintenance: 100 mg SC at Week 16 and q8w thereafter OR 200 mg SC at Week 12 and q4w thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. [c]**Pretreatment Evaluations**: Prior to initiating treatment with TREMFYA®, evaluate patients for tuberculosis (TB) infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines. **Monitoring**: Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. For the treatment of CD or UC, monitor liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. TREMFYA® is intended for use under the guidance and supervision of a healthcare professional. TREMFYA® may be administered by a healthcare professional, or a patient/caregiver may inject after proper training in subcutaneous injection technique. [d]Moderately to severely active UC defined as induction baseline modified Mayo score of 5 to 9 with a Mayo rectal bleeding subscore ≥ 1 and a Mayo endoscopic subscore ≥ 2 based on central review. [e]Placebo crossover responders at Week 24 are the placebo nonresponders at Week 12 who went on to receive TREMFYA 200 mg IV q4w for 12 weeks and were in clinical response to TREMFYA at Week 24. [f]Patients from a phase 2b randomized, double-blind, placebo-controlled, induction dose-finding study who demonstrated a clinical response to TREMFYA® were also randomized into the phase 3 maintenance study. [g]Clinical remission: Mayo stool frequency subscore of 0 or 1, and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability. [h]Clinical response: decrease from induction baseline in the modified Mayo score (3-component [stool frequency, rectal bleeding, and endoscopy subscores] Mayo score without the physician's global assessment) by ≥30% and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1. [i]Endoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. [j]Endoscopic remission: an endoscopy subscore of 0. [k]HEMI: achieving a combination of histologic improvement and endoscopic improvement. [l]CS-free clinical remission: clinical remission without any use of corticosteroids for ≥8 weeks prior to assessment. [m]Natural causes and cardiac arrest. [n]Fatal acute myocardial infarction in a patient with pre-existing cardiac risk factors. [o]Defined as any AE coded to MedDRA organ class "Infections and infestations". [p]Clinical remission: CDAI <150. [q]Endoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. [r]Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore greater than 1 in any individual component. [s]Deep remission: clinical remission AND endoscopic remission. [t]CS-free is defined as patients in clinical remission at Week 48 and not receiving CS for ≥90 days prior. Denominator is patients in clinical remission at Week 48. [u]Events attributed to patients randomized to PBO, except where a patient is randomized to PBO and cross over to STELARA® (only events that occur while patients are on PBO are included). [v]Liver abscess/bacterial infection and postop wound infection/vascular device infection. [w]Anal abscess. [x]Acute sinusitis, abscess intestinal, intestinal fistula infection. [y]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [z]Fatal gunshot wound (non-suicidal). [aa]An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. [ab]Bronchitis and appendicitis. [ac]Gastroenteritis

AE, adverse effect; CD, Crohn's disease; CDAI, Clinical Disease Activity Index; CI, confidence interval; EIM, extraintestinal manifestation; GAL, GALAXI; HEMI, histo-endoscopic mucosal improvement; HIV, human immunodeficiency virus; IBD, irritable bowel disease; IL-23i, interleukin-23i; IV, intravenous; LTE, long-term extension; MedDRA, Medical Dictionary for Regulatory Activities; MES, modified endoscopic subscore; PBO, placebo; PMPY, per-member, per-year; PsA, psoriatic arthritis; PsO, psoriasis; PY, patient years; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious adverse effect; SC, subcutaneous; SES-CD, Simple Endoscopic Score for Crohn's Disease; TOFA, tofacitinib; TNF, tumor necrosis factor; UC, ulcerative colitis; ULN, upper limit of normal; UST, ustekinumab; VDZ, vedolizumab; W12, week 12; W48, week 48.

1. Evernorth. Trend by plan type. Accessed July 6, 2023. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher J, et al. *J Rheum Suppl*. 2018;94:32-35. 3. Pennington SR, et al. *Front Med (Lausanne)*. 2021;8:723944. 4. Ciocon D, Kimball A. *Br J Dermatol*. 2007;157(5):850-860. 5. Suzuki E, et al. *Autoimmunity Rev*. 2014;13:496-502. 6. Lowes M, et al. *Annu Rev Immunol*. 2014;32:227-255. 7. Mease P, et al. J Am Acad Dermatol. 2013;69(5):729-735. 8. Sanchez I, et al. Curr Dermatol Rep. 2018;7(1):59-74. 9. Arvikar S, et al. Curr Rev Musculoskel Med. 2011;4(3):123-131. 10. Levine J, et al. *Gastroenterol Hepatol*. 2011;7:235-241. 11. Lewis J, et al. *Gastroenterology*. 2023;1-9. 12. Ye Y, et al. *Inflamm Bowel Dis*. 2020;26(4):619-625. 13. The Crohn's & Colitis Foundation of America. The facts about inflammatory bowel diseases. Updated November 2014. Accessed February 20, 2024. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. 14. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 15. Rubin D, et al. *Lancet*. 2025;405:33-49. 16. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 17. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 18. Panaccione R, et al. DDW 2024. May 18-21, 2024. 19. Hart A, et al. *Gastroenterology*. 2025; doi:10.1053/j.gastro.2025.02.033. 20. Data on File. Janssen Biotech, Inc. Horsham, PA. 21. ASTRO NCT05528510. 22. QUASAR Jr NCT06260163. 23. MACARONI 23 NCT05923073.

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