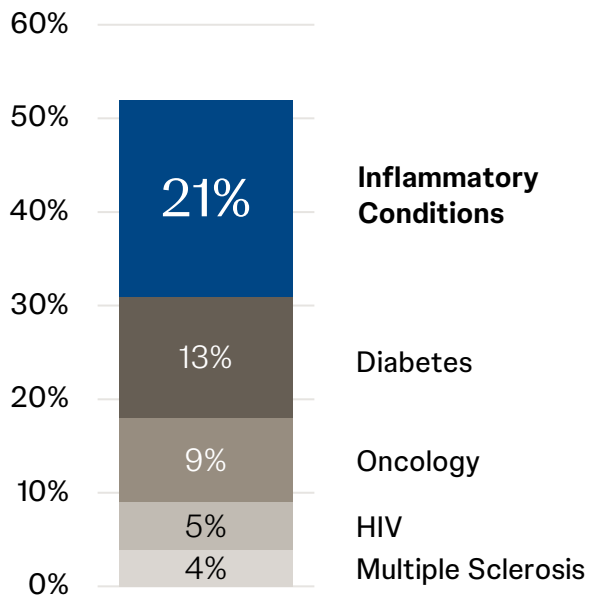
EVIDENCE & VALUE SUMMARY: TREMFYA® (guselkumab) for adult patients

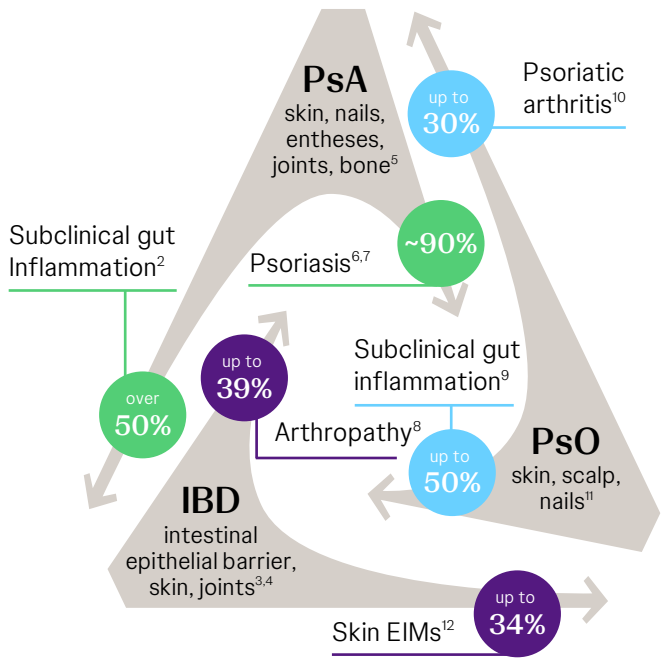
Inflammatory conditions have a significant impact on the patient and the United States healthcare system

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



These conditions impact many people in the United States

	Prevalence[a]	Moderate-to-severe disease	Biologic-treated
PsO	7,500,000[13]	20%[14]	51%[15]
PsA	2,250,000[10,13b]	80%[15]	62%[16]
CD	1,011,000[17]	58%[18]	44%[19]
UC	1,253,000[17]	40%[20]	16%[19]

Patients with PsO have a **4x** higher prevalence of IBD, with the highest risk in the population with both PsO and PsA[21]

Psoriatic diseases are complex with high unmet need and costs

In patients with PsO who develop PsA, skin manifestations may develop up to a decade before musculoskeletal, although musculoskeletal manifestations may occur at any time[10]

Radiologic damage in PsA is similar to that seen in patients with RA[10,22c]

Patients with PsO or PsA may also experience subclinical gut inflammation[2,9]

In a survey of patients with PsO and/or PsA[23]:

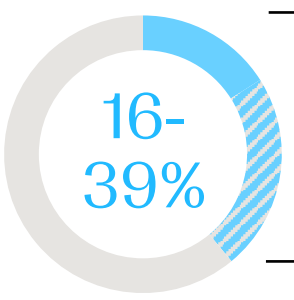
56%
experienced at least a moderate impact on quality of life

52%
screened positive for potential major depressive disorder

High economic burden[24-27]:

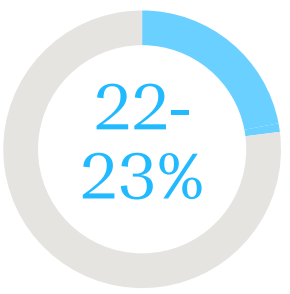
$9,591
PsO annual indirect cost due to total work productivity loss per patient

Among employed:



Experience work disability

Unemployed:



Inflammatory bowel diseases are complex with high unmet need and costs

UC: Colon and the rectum, typically appears in a continuous pattern[28]

CD: Anywhere in the GI tract from the mouth to the anus; may appear in patches[29]

Up to 40% of patients with CD have at least 1 EIM, and common EIMs include mucocutaneous, musculoskeletal, liver, eye, and urinary tract involvement.[3]

In a survey of patients with UC or CD[30d]:

agreed that symptoms impact most aspects of daily life

experienced anxiety, depression, and/or embarrassment because of IBD

High economic burden[31]:

UC direct and indirect costs in the United States:
$15.5 billion/year

CD direct and indirect costs in the United States:
$14.9 billion/year

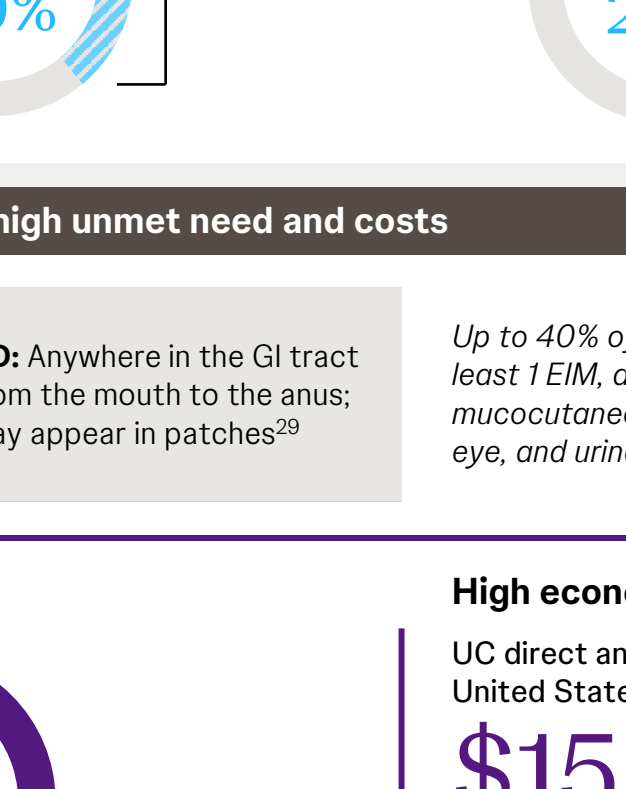
TREMFYA® is an IL-23i indicated for the treatment of adults with[32efg]:

PsO
Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

PsA
Active psoriatic arthritis

UC
Moderately to severely active ulcerative colitis

CD
Moderately to severely active Crohn's disease



Guselkumab is the only[h] fully human dual-acting, selective IL-23 inhibitor designed to neutralize inflammation at its cellular source[33-38]

Based on in vitro studies in inflammatory monocyte models. The clinical significance of these findings is unknown.

For additional information, please see TREMFYA® Prescribing Information here.

[a]In the United States. [b]Prevalence of patients with PsO who develop PsA. [c]Based on no difference in the radiographic severity of small joints between patient populations with RA and PsA. [d]Based on a survey of 302 adults with IBD in the United States via MyCrohnsandColitisTeam.com. [e]TREMFYA® dosing for adults with moderate to severe plaque PsO and active PsA: 100mg SC at Weeks 0 and 4, and q8w thereafter. For adults with moderately to severely active UC or 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. [f]**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. [g]TREMFYA® is also indicated for pediatric patients ≥6 years who weigh at least 40 kilograms with moderate to severe plaque PsO who are candidates for systemic therapy or photo therapy and pediatric patients ≥6 years who weigh at least 40 kilograms with active PsA. [h]"Only" Based on approved IL-23 inhibitors for active PsA or moderately to severely active UC as of September 2025.

CD, Crohn's disease, EIMs, extraintestinal manifestations; HIV, human immunodeficiency virus; IBD, inflammatory bowel disease, IL-23i, interleukin-23; IV, intravenous; PMPY, per member per year; PsA, psoriatic arthritis; PsO, psoriasis; q4w, every 4 weeks; q8w, every 8 weeks; RA, rheumatoid arthritis; SC, subcutaneous; UC, ulcerative colitis; US, United States.

1. Evernorth. Trend by plan type. Accessed October 28, 2024. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher JU. *J Rheumatol Suppl.* 2018;94;32-35. 3. Levine JS, et al. *Gastroenterol Hepatol (N Y).* 2011;7(4):235-241. 4. Matricon J, et al. *Self Nonself*. 2010;1(4):299-309. 5. Suzuki E, et al. *Autoimmun Rev.* 2014;13(4-5):496-502. 6. Ciocon DH, et al. *Br J Dermatol*. 2007;157(5):850-860. 7. Pennington SR, et al. *Front Med (Lausanne).* 2021;8:723944. 8. Arvikar SL, et al. *Curr Rev Musculoskelet Med.* 2011;4(3):123-131. 9. Sanchez IM, et al. *Curr Derm Rep.* 2018;7:59-74. 10. Mease P, et al. *J Am Acad Dermatol*. 2013;69(5):729-735. 11. Lowes MA, et al. *Annu Rev Immunol*. 2014;32:227-255. 12. Levine JS, et al. *Gastroenterol Hepatol (N Y)*. 2011;7(4):235-241. 13. Armstrong A, et al. *JAMA Dermatol.* 2021; 157(8): 1-7. 14. Menter A, et al. *J Am Acad Dermatol*. 2008;58(5):826-850. 15. Data on file. Janssen Biotech, Inc. 16. Kavanaugh A, et al. *Clinical Rheumatology*. 2018;37(8):2275-2280. 17. Lewis J, et al. *Gastroenterology*. 2023: 1-9. 18. Manceur A, et al. *J Med Econ.* 2020;23(10):1092-1101. 19. Yu H, et al. *Aliment Pharmacol Ther*. 2018;47(3);364-370. 2018. 20. Cohen R, et al. *J Med Econ*. 2015;18(6):447-456. 21. Eppinga H, et al. *Inflamm Bowel Dis.* 2017; 23(10):1783-1789. 22. Rahman P, et al. *J of Rheum*. 2001; 28(5):1041-1044. 23. Lebwohl M, et al. *Derm Ther*. 2022;12:61-78. 24. Villacorta R, et al. *Br J Dermatol*. 2020;183(3): 548–558. 25. Kaarela K, et al. *Scand J Rheumatol*. 1987;16:4036. 26. Zhu T, et al. *J Rheumatol*. 2010;37:121420. 27. Tillett W, et al. *Rheumatology (Oxford)*. 2012;51(2):275-283. 28. Ye Y, et al. *Inflamm Bowel Dis*. 2020;26(4):619-625. 29. 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. 30. Charabaty A, et al. *Crohn's and Colitis 360.* 2022;4:1-9. 31. Click B, et al. *Inflamm Bowel Dis.* 2020;26(8):1268-1275. 32. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 33. Wojtal K, et al. *PLoS One*. 2012;7(8):e43361. 34. Vos AC, et al. *Gastroenterology*. 2011;140(1):221-230. 35. Louis E, et al. *Aliment Pharmacol Ther*. 2004;19(5):511-519. 36. Abreu M, et al. DDW 2023. Oral Presentation #3856970. 37. Krueger J, et al. ISID 2023. Poster #1591. 38. Bsat M, et al. *Eur J Immunol*. 2020;50(11):1676-1690.

Johnson&Johnson

US-SFM-6542 10/25

TREMFYA® (guselkumab) for adults with moderate to severe plaque psoriasis

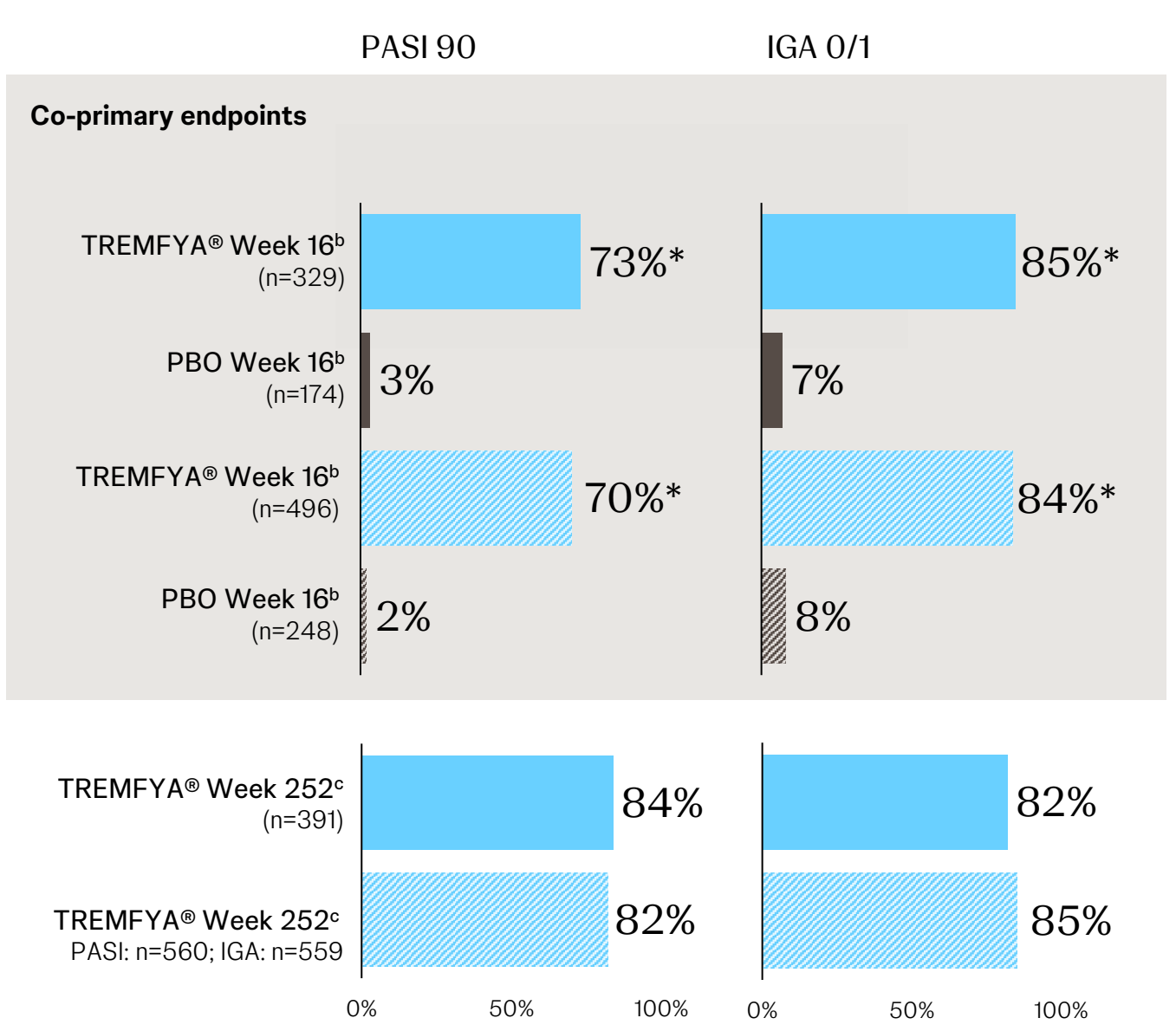
TREMFYA® has established safety and efficacy in PsO[a]

Moderate to severe plaque PsO[1-5]

VOYAGE 1 (N=837) and

VOYAGE 2 (N=992) were phase 3, multicenter, double-blind, placebo-controlled, active comparator trials evaluating the efficacy and safety of TREMFYA® vs placebo in adult patients with moderate to severe plaque PsO who were candidates for phototherapy and/or systemic therapy. Co-primary endpoints in both trials were PASI 90 and IGA 0/1 at Week 16.[a]

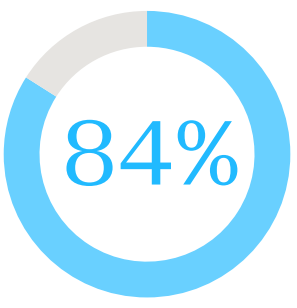
PASI 90 and IGA 0/1 responses achieved and maintained through Year 5



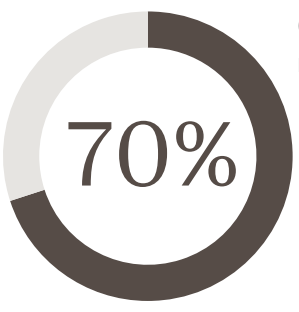
ECLIPSE (N=1048) was a phase 3, double blind, active comparator trial evaluating the efficacy and safety of TREMFYA® 100 mg versus Cosentyx® (secukinumab). The primary endpoint was PASI 90 at week 48 for noninferiority and then superiority tests.[5d]

The proportion of patients in the study who achieved PASI 90 response at Week 48 was greater in the TREMFYA® group than the comparator group

There were no new safety findings observed for either TREMFYA® or Cosentyx® in this study.[5]



TREMFYA®
n=534
P<0.0001



Cosentyx®
n=514

Safety data results are established through 5 years in moderate to severe plaque PsO

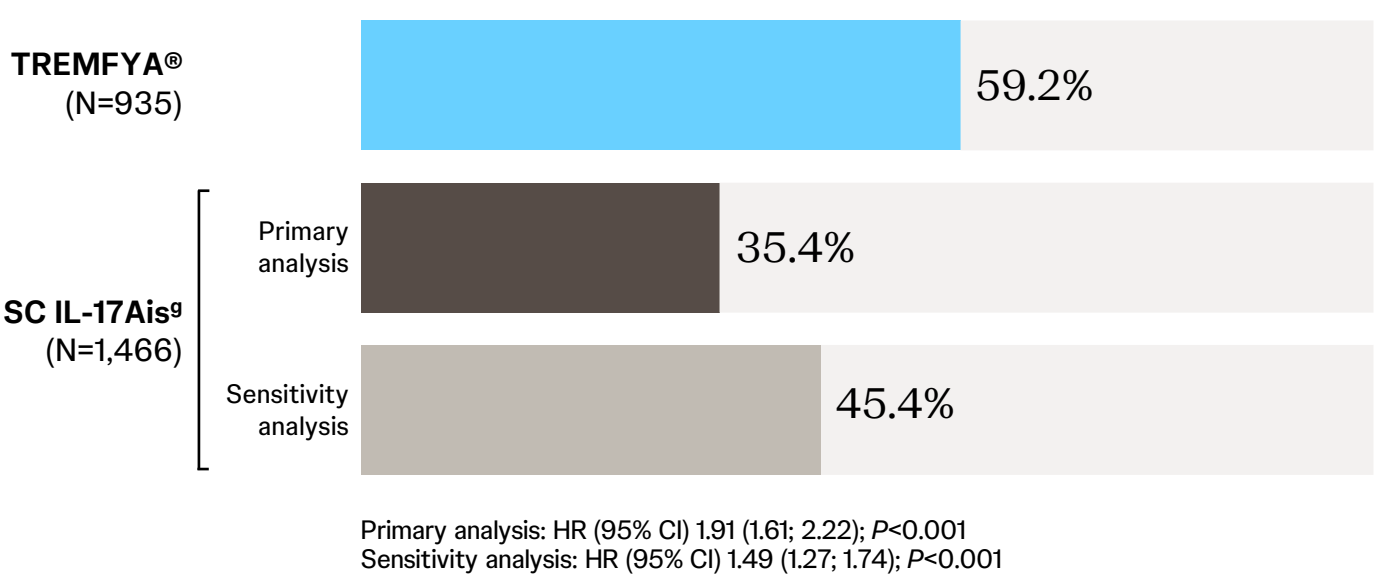
Selected safety profile[1,6]

Please refer to the full Prescribing Information for a complete listing of all adverse events for all indications, including other serious adverse events.

Safety Results From VOYAGE Trials (PsO)	Adverse events		Serious adverse events		Infections		Serious infections	
	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo
Week 16, % [events/100 PYs of follow-up] TREMFYA® n=823, placebo n=422	49.2 [330.1]	46.7 [316.9]	1.9 [6.3]	1.4 [4.7]	23.2 [97.9]	21.3 [86.4]	0.1 [0.4]	0.2 [0.8]
Year 5, events/100 PYs of follow-up, n=1721[e]	149.4	--	5.0	--	60.6	--	0.9	--

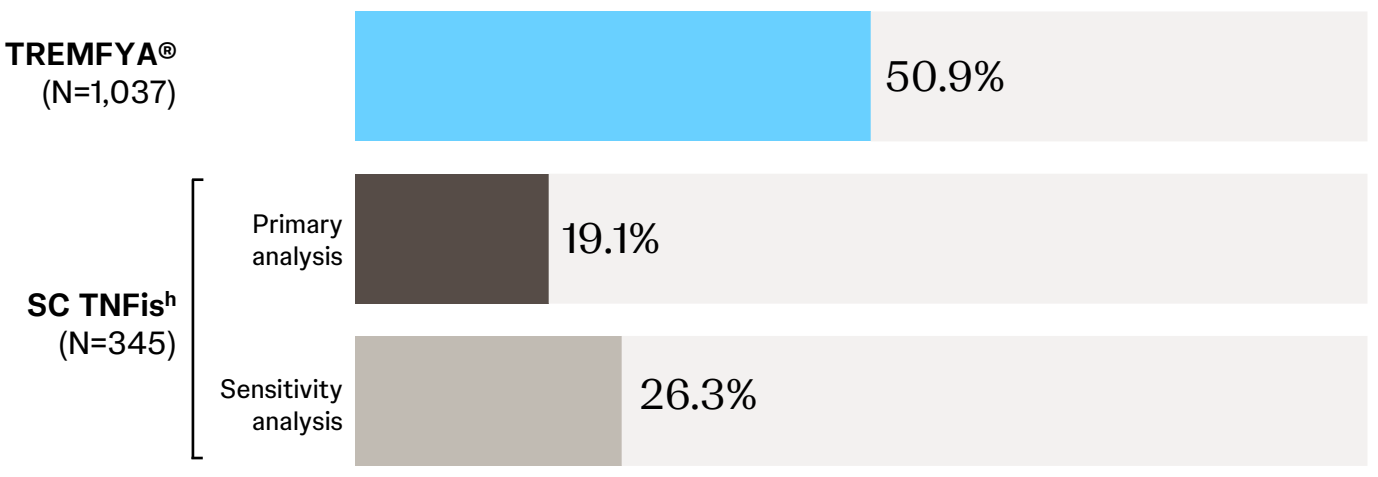
TREMFYA® has demonstrated significantly better treatment persistence versus comparators in plaque PsO[7,8]

Persistence while on US-labeled maintenance dose among the weighted GUS and SC IL-17Ai or SC TNFi cohorts[f]



Primary analysis: HR (95% CI) 1.91 (1.61; 2.22); *P*<0.001
Sensitivity analysis: HR (95% CI) 1.49 (1.27; 1.74); *P*<0.001

At 2 years, persistence for the TREMFYA® cohort was 1.5x greater than the IL-17Ai cohort
(primary analysis)



Primary analysis: HR (95% CI) 2.79 (2.34; 3.33); *P*<0.001
Sensitivity analysis: HR (95% CI) 2.31 (1.92; 2.78); *P*<0.001

At 2 years, persistence for the TREMFYA® cohort was 2.3x greater than the TNFi cohort
(primary analysis)

Limitations: Results may not be generalized to the uninsured, pts insured with plans other than commercial or self-insured plans, or those who do not continue treatment up to the maintenance phase. Prescription fills do not guarantee the medication was taken as prescribed. Results may be subject to residual confounding due to unmeasured confounders. Treatment effectiveness and reasons for discontinuation could not be assessed using claims data.

Database: IQVIA PharMetrics® Plus Database. Study periods: 01/01/2016-12/31/2023

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

VISIBLE: Adults with skin of color, moderate-to-severe plaque PsO, and/or scalp PsO[9]

SPECTREM: Adults who are bio-naïve with low BSA moderate plaque PsO and special site involvement[10]

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

[a]TREMFYA® dosing for moderate to severe plaque PsO: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. [b]Nonresponder imputation. [c]Data from an open-label extension. Treatment failure rules. Includes patients who crossed over from placebo to receive GUS at Week 16. [d]Intent-to-treat population. [e]Includes all patients exposed to TREMFYA® in VOYAGE 1 and VOYAGE 2. [f]Study objective: **Compare real-world persistence among patients with PsO switching to treatment with US labeled dosing for TREMFYA® versus SC IL-17Ais or SC TNFis. Summay of select methods:** Overlap propensity score weights were used to balance baseline characteristics between the GUS and SC IL-17Ai or SC TNFi cohorts; balance was assessed using standardized differences. Persistence was defined as no gaps in treatment supply >120 days for GUS and infliximab (2x the 8-week dosing interval) or >60 days for adalimumab, certolizumab pegol, etanercept, ixekizumab, secukinumab, and brodalumab (2x the typical dispensing interval of 4 weeks; brodalumab: 2x the typical dispensing interval of 2 doses for 4 weeks). A sensitivity analysis was conducted using a gap >120 days for all agents; the last day of index agent supply before the gap defined the discontinuation date. [g]SC IL-17Ai agents included ixekizumab, secukinumab, and brodalumab. [h]SC TNFi agents included adalimumab, certolizumab pegol, etanercept, and infliximab.

BSA, body surface area; CI, confidence interval; GUS, guselkumab; HR, hazard ratio; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsO, psoriasis; PYs, patient-years; q8w, every 8 weeks.

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. VOYAGE 1 NCT02207231. 3. VOYAGE 2 NCT02207244. 4. Reich K, et al. *Br J Dermatol*. 2021; 1087-1088. 5. Reich K, et al. *Lancet*. 2019;394(10201):831-839. 6. Data on file. Janssen Biotech, Inc. 7. Zhdanava M, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, HI. 8. Zhdanava M, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, HI. 9. VISIBLE NCT05272150. 10. SPECTREM NCT06039189.

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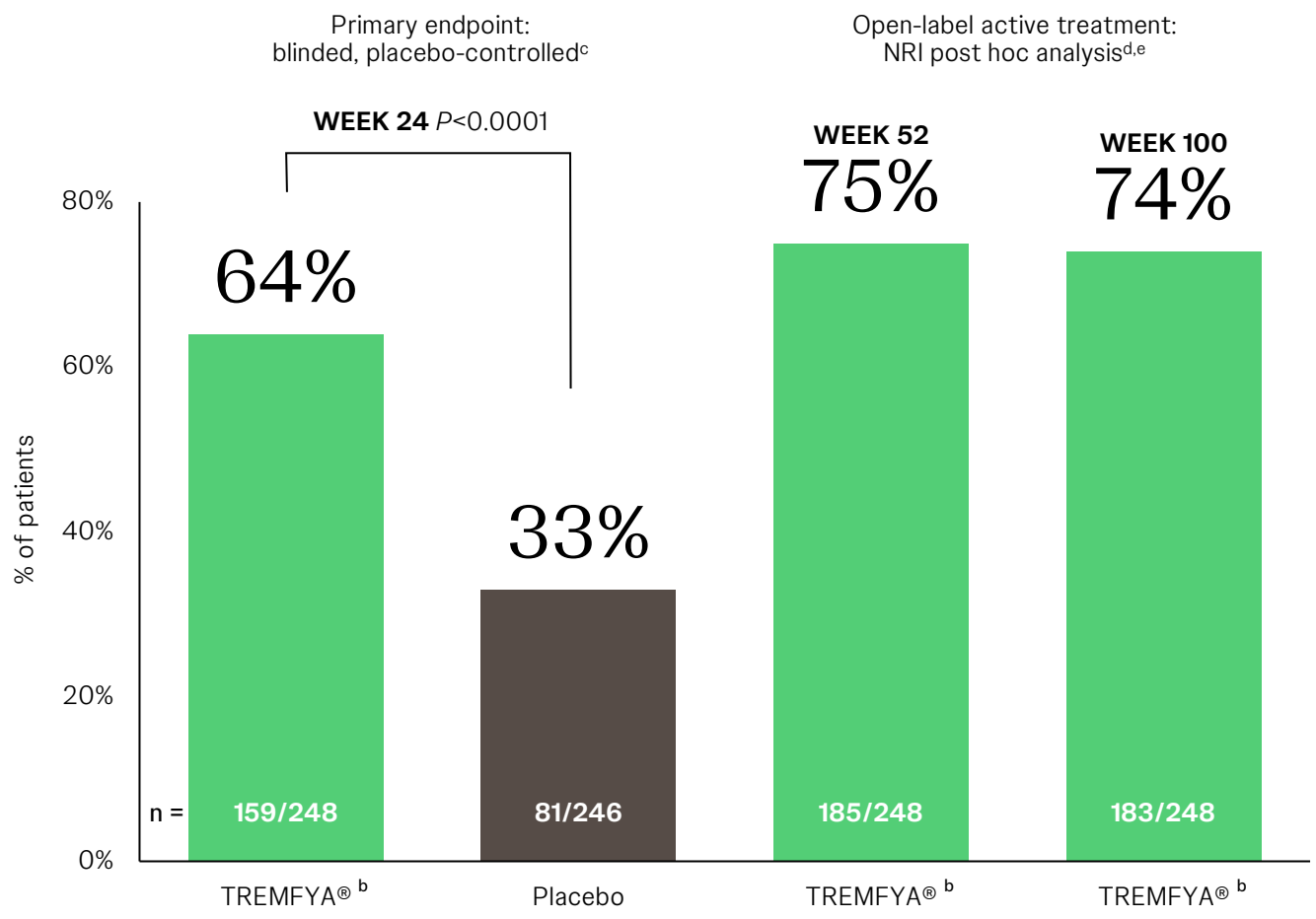
TREMFYA® (guselkumab) for adults with active psoriatic arthritis

TREMFYA® has established safety and efficacy in PsA[a]

Active PsA[1-3]

DISCOVER 1 (N=381; bio-naïve population [69%] and bio-experienced population: ≤2 TNFα inhibitors [31%]) and **DISCOVER 2** (N=739; bio-naïve population) were phase 3, multicenter, double-blind, placebo-controlled trials evaluating the efficacy and safety of TREMFYA® vs placebo in adult patients with active PsA despite standard therapies. The primary endpoint in both trials was ACR20 at Week 24.[a]

Patients had continuous overall improvement in joint response (ACR20) rates through 2 years in DISCOVER 2[b]



DISCOVER 1
ACR20 response rates for TREMFYA® 100 mg q8w vs placebo[1,4]:

At 24 weeks:
52% (66/127) vs 22% (28/126); *P*<0.0001

At 52 weeks:
60% (76/127) of patients receiving GUS q8w

Safety data results are established through 2 years in active PsA

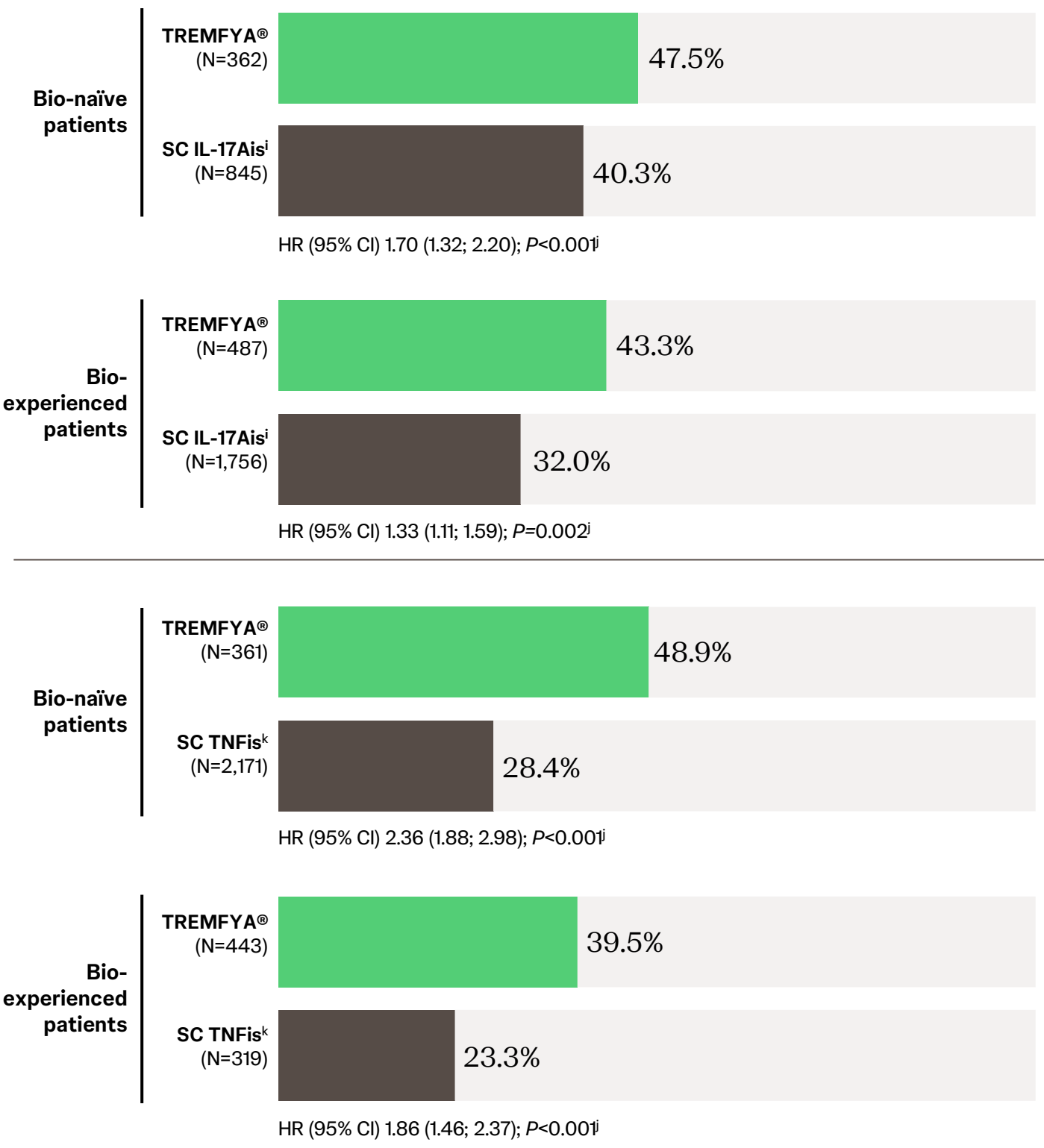
Selected safety profile[1-2,5]

Please refer to the full Prescribing Information for a complete listing of all adverse events for all indications, including other serious adverse events.

Safety Results From DISCOVER Trials (PsA)	Adverse events		Serious adverse events		Infections		Serious infections	
	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo
Week 24, % [events/100 PYs of follow-up] TREMFYA® n=375, placebo n=372	48.5 [257.3]	47.3 [220.0]	1.9 [4.0]	3.2 [9.3]	19.5 [58.3]	20.7 [58.5]	0.3 [0.6]	0.8 [4.1]
Year 2, events/100 PYs of follow-up, n=248[f]	158.0	--	6.1	--	40.5	--	2.2	--

TREMFYA® has demonstrated significantly better treatment persistence versus comparators in active PsA[6,7]

Persistence while on US-labeled maintenance dose among the weighted GUS and SC IL-17Ai[g] or SC TNFi cohorts[h]



At 2 years, the TREMFYA cohort was ~1.7x more likely to remain persistent in both bio-naïve and bio-experienced cohorts[6]

At 2 years, the TREMFYA cohort was 2x more likely to remain persistent in both bio-naïve and bio-experienced cohorts[7]

Limitations: Results may not be generalized to the uninsured, pts insured with plans other than commercial or self-insured plans, or those who do not continue treatment up to the maintenance phase. Prescription fills do not guarantee the medication was taken as prescribed. Results may be subject to residual confounding due to unmeasured confounders. Treatment effectiveness and reasons for discontinuation could not be assessed using claims data.

Database: IQVIA PharMetrics® Plus Database. Study periods: 07/14/2020-12/31/2022

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

APEX: Adults who are bio-naïve with active PsA and inhibiting radiographic progression[8]

STAR: Adults who are bio-naïve with active PsA axial disease[9]

SOLSTICE: Adults with active PsA and inadequate response or intolerance to a prior anti-TNFα[10]

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.

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

[a]TREMFYA® dosing in active PsA: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. [b]Prespecified as-observed analysis from Week 24 to Week 100 from DISCOVER 2 and from Week 24 to Week 52 from DISCOVER 1 are not shown. [c]Patients with missing data were considered nonresponders. [d]The same patients may not have responded at each time point. [e]After Week 24, the study was open label with blinded dosing interval, which may have affected results. [f]DISCOVER 2 only. [g]GUS vs SC IL-17Ai cohorts compared using weighted Cox proportional hazard models. Primary analysis was conducted based on 2x the FDA maintenance interval between administration per label after induction. Sensitivity analyses were conducted based on 1x the FDA maintenance interval between administration per label after induction as well as a fixed discontinuation gap of 112 days. [h]GUS vs SC TNFi cohorts compared using weighted Cox proportional hazard models further adjusted for csDMARD and tsDMAD use in bio-naïve cohort only. Primary analysis was conducted based on 2x the FDA maintenance interval between administration per label after induction. Sensitivity analyses were conducted based on 1x the FDA maintenance interval between administration per label after induction as well as a fixed discontinuation gap of 112 days. [i]IL-17Ais included secukinumab and ixekizumab. [j]Sensitivity analyses demonstrated similar trends. [k]TNFis included adalimumab, etanercept, certolizumab pegol, and SC golimumab.

ACR, American College of Rheumatology; bDMARD, biologic disease modifying anti-rheumatic drug; CI, confidence interval; FDA, Food and Drug Administration; GUS, guselkumab; HR, hazard ratio; IL-17Ai, interleukin-17A inhibitor; NRI, nonresponder imputation; PsA, psoriatic arthritis; PYs, patient-years; q8w, every 8 weeks; SC, subcutaneous; TNFα, tumor necrosis factor alpha; TNFi, tumor necrosis factor inhibitor.

1. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. McInnes I, et al. *Arthritis Rheumatol*. 2022;74(3):475-485. 3. Mease P, et al. *Lancet*. 2020; 395:1126-1136. 4. Ritchlin C, et al. *RMD Open*. 2021;7(1):e001457. 5. Data on file. Janssen Biotech, Inc. 6. Mease P, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, HI. 7. Mease P, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, HI. 8. APEX NCT04882098. 9. STAR NCT04929210. 10. SOLSTICE NCT04936308.

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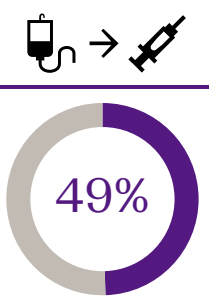
TREMFYA® (guselkumab) for adults with moderately to severely active ulcerative colitis

TREMFYA® has demonstrated clinical efficacy in UC[1,2]

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.[2a]



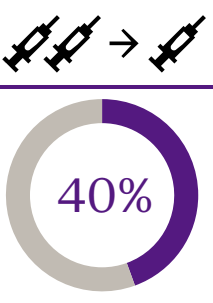
of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, or TOFA)

Induction: Patients (N=701) were randomized 3:2 to receive:
- TREMFYA® 200 mg IV q4w
- or placebo IV[1,2]

Maintenance: TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[b] (N=568) were rerandomized 1:1:1[c] to receive:
- TREMFYA® 200 mg SC q4w
- TREMFYA® 100 mg SC q8w
- Placebo SC[2]

ASTRO clinical program

A multicenter, randomized, double-blind, PBO-controlled, treat-through study of TREMFYA® in adults with moderately to severely active UC & inadequate response/intolerance to advanced therapy.[3,4]



of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, JAKi, or S1PRM)

Study design: The study (N=418) randomized patients 1:1:1 to receive TREMFYA® 400 mg SC q4w for 12 weeks then 200 mg SC q4w, 100 mg SC q8w, or placebo SC.[3,4]

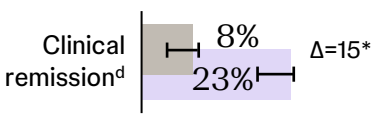
Rescue criteria: Placebo non-responders were switched to a rescue treatment of TREMFYA® 400 mg SC q4w for 12 weeks followed by 100 mg SC q8w.[3,4]

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC

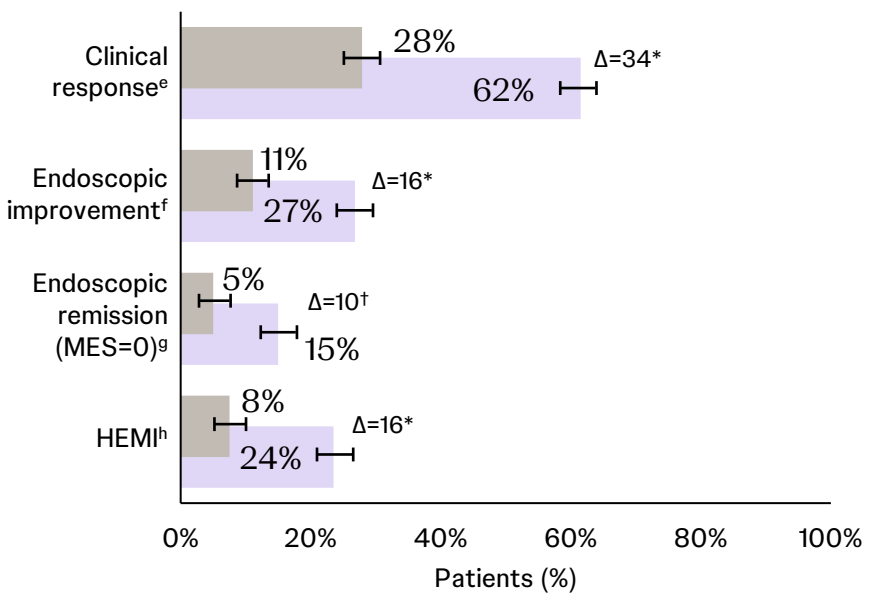
Data originated from separate pivotal trials for the biologic.
Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

QUASAR induction study[1,2]

Primary endpoint at Week 12



Select secondary endpoints at Week 12

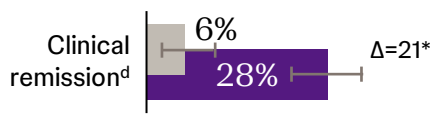


* = *P*<0.0001 versus placebo TREMFYA® (n=421) PBO (n=280)

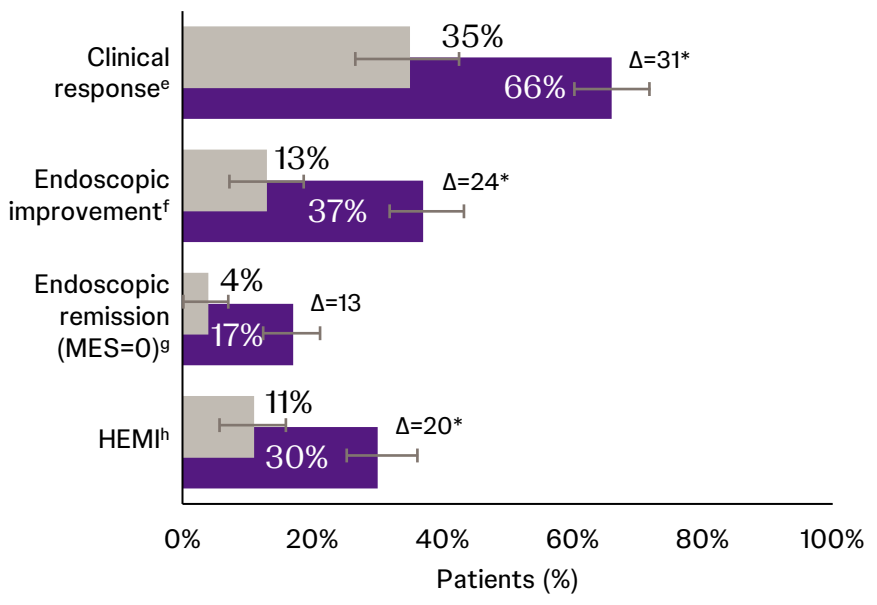
† = Nominal *P*<0.0001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

ASTRO[3-5]

Primary endpoint at Week 12



Additional endpoints at Week 12



* = *P*<0.0001 versus placebo TREMFYA® (n=279) PBO (n=139)

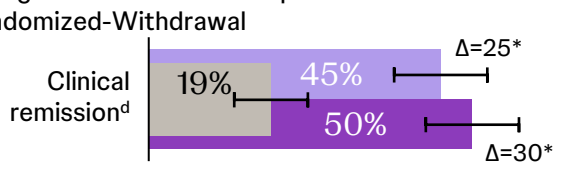
Endoscopic remission at Week 12 was prespecified and not controlled for multiplicity. No statistical significance can be made.

Symptomatic response through Week 12 (click for more info)

QUASAR maintenance study[1,2]

Primary endpoint at Week 44

Among Week 12 Clinical Responders (Randomized-Withdrawal)

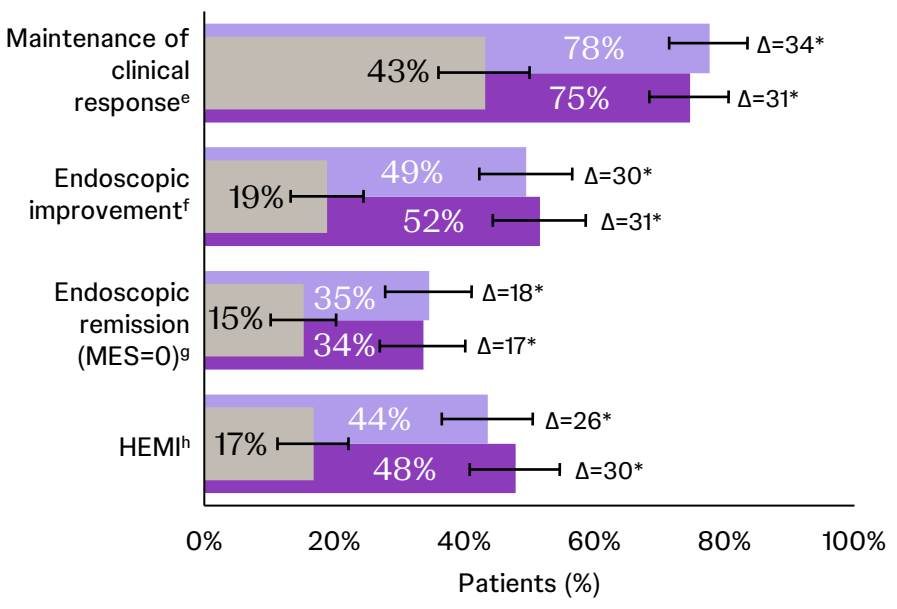


99% (178/180) of patients in the combined TREMFYA® group who achieved clinical remission at Week 44 were **corticosteroid-free for ≥8 weeks**[2]

Select secondary endpoints at Week 44

Among Week 12 Clinical Responders (Randomized-Withdrawal)

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)

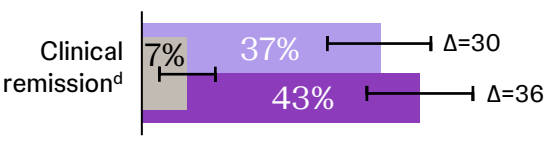
PBO SC (n=190)

Week 24 responders (click for more info)

ASTRO[5]

Prespecified exploratory endpoint at Week 48

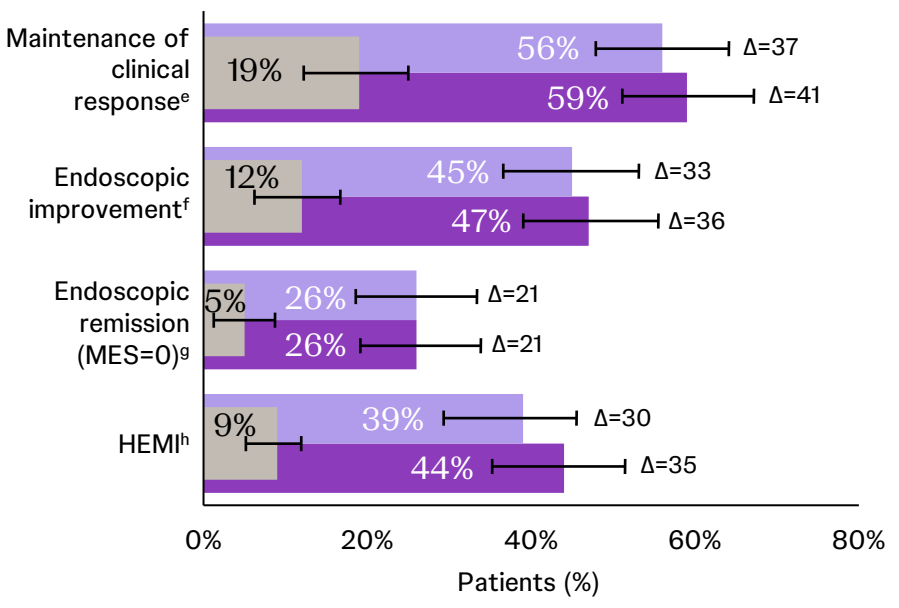
(Treat-through)



Prespecified exploratory endpoints at Week 48

(Treat-through)

Over 1/4 of patients were in complete endoscopic remission (MES=0) at Week 48



TREMFYA® 100 mg q8w (n=139)

TREMFYA® 200 mg q4w (n=140)

PBO SC (n=139)

Endpoints at Week 48 were prespecified and not controlled for multiplicity. No statistical significance can be made.

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

	Induction study (Week 12)[2]	
	PBO IV q4w	TREMFYA® 200 mg IV q4w
Patients treated (n)	280	421
Average follow-up (weeks)	11.9	12.2
Deaths	2 (1%)[i]	1 (0.2%)[j]
Patients with one or more (n[%]):		
AEs	138 (49%)	208 (49%)
Serious AEs	20 (7%)	12 (3%)
AEs leading to discontinuation	11 (4%)	7 (2%)
Infections[6,7k]	43 (15%)	66 (16%)
Serious Infections[k]	1 (0.4%)	3 (1%)

	Maintenance study (Week 44)[2]		
	PBO SC (TREMFYA® withdrawal)	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Patients treated (n)	192	186	190
Average follow-up (weeks)	34.0	40.5	39.2
Deaths	0	0	0
Patients with one or more (n[%]):			
AEs	131 (68%)	120 (65%)	133 (70%)
Serious AEs	1 (1%)	5 (3%)	12 (6%)
AEs leading to discontinuation	13 (7%)	7 (4%)	5 (3%)
Infections[6,7k]	63 (33%)	59 (32%)	59 (31%)
Serious Infections[k]	0	1 (1%)	2 (1%)

Treatment-emergent adverse events at ~1 year from the ASTRO trial in UC

	Through Week 12[3]	
	PBO SC[l]	TREMFYA® 400 mg SC q4w
Patients treated (n)	139	279
Average follow-up (weeks)	12.2	12.3
Deaths	1 (0.7%)[m]	0
Patients with one or more (n[%]):		
AEs	73 (52.5%)	110 (39.4%)
Serious AEs	11 (7.9%)	7 (2.5%)
AEs leading to discontinuation	8 (5.8%)	3 (1.1%)
Infections	28 (20.1%)	42 (15.1%)
Serious Infections	0	2(0.7)[n]

	Week 12 through to Week 48[5]		
	PBO SC[l]	TREMFYA® 400 mg SC q4w → 100 mg SC q8w	TREMFYA® 400 mg SC q4w → 200 mg SC q4w
Patients treated (n)	136	138	140
Average follow-up (weeks)	18.6	34.4	33.1
Deaths	0	1 (0.7%)[o]	0
Patients with one or more (n[%]):			
AEs	61 (44.9%)	94 (68.1%)	95 (67.9%)
Serious AEs	12 (8.8%)	4 (2.9%)	7 (5.0%)
AEs leading to discontinuation	8 (5.9%)	6 (4.3%)	2 (1.4%)
Infections	26 (19.1%)	43 (31.2%)	40 (28.6%)
Serious Infections	2 (1.5%)[p]	0	2 (1.4%)[q]

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

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

QUASAR Jr: Guselkumab for pediatric participants with moderately to severely active UC[8]

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.

Return to first page

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

[a]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. [b]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. [c]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. [d]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. [e]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. [f]Endoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. [g]Endoscopic remission: an endoscopy subscore of 0. [h]HEMI: achieving a combination of histologic improvement and endoscopic improvement. [i]Natural causes and cardiac arrest. [j]Fatal acute myocardial infarction in a patient with pre-existing cardiac risk factors. [k]Defined as any AE coded to MedDRA organ class "Infections and infestations". [l]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [m]Road traffic accident. [n]Pilonidal disease and gastroenteritis. [o]Intraventricular hemorrhage. [p]Pneumonia and COVID-19. [q]Two cases of appendicitis.

AE, adverse effect; HEMI, histo-endoscopic mucosal improvement; IV, intravenous; MES, modified endoscopic subscore; PBO, placebo; q4w, every 4 weeks; q8w, every 8 weeks; SC, subcutaneous; TOFA, tofacitinib; TNF, tumor necrosis factor; UC, ulcerative colitis; VDZ, vedolizumab; W12, week 12; W48, week 48.

1. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 2. Rubin D, et al. Lancet. 2025;405:33-49. 3. Peyrin-Biroulet L, et al. ECCO 2025. Oral Presentation #OP10. 4. Long M, et al. DDW 2025. Oral Presentation #OP800. 5. Data on File. Janssen Biotech, Inc. Horsham, PA. 6. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 7. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 8. QUASAR Jr NCT06260163.

US-SFM-6542 10/25

Johnson&Johnson

TREMFYA® (guselkumab) for adults with moderately to severely active Crohn's disease

TREMFYA® has demonstrated clinical efficacy in CD[1,2,3]

GALAXI clinical program[1,2]

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).

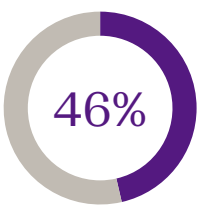
previously failed at least 1 biologic
N=1,021

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; or PBO IV 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, 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 STELARA® ~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[1,3]

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).



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 TREMFYA® 100 mg SC q8w starting at Week 32

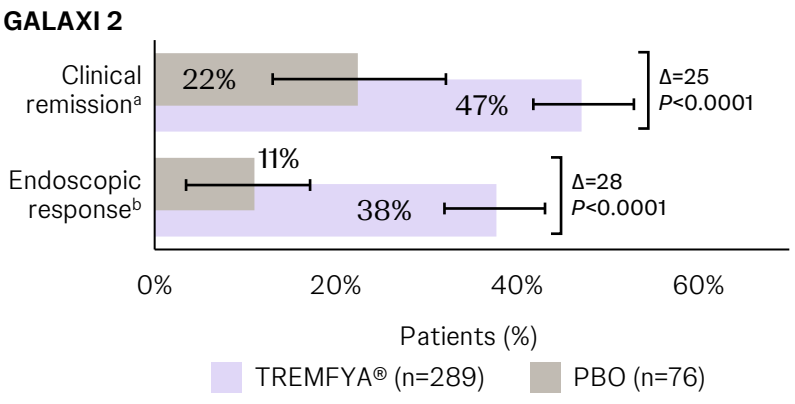
Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

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[2]

Select secondary endpoints at Week 12

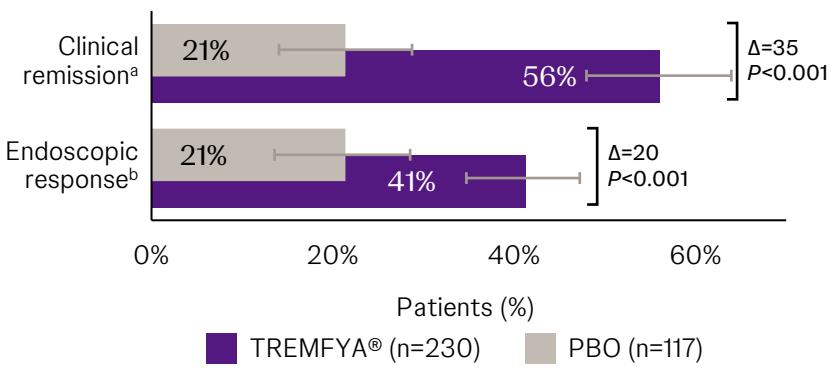
GALAXI 2



GALAXI 3 at Week 12[4]:
Clinical remission[t]: TREMFYA® 47% (138/293) vs PBO 15% (11/72); *P*<0.0001
Endoscopic response[u]: TREMFYA® 36% (106/293) vs PBO 14% (10/72); *P*<0.0001

GRAVITI[3]

Co-primary endpoints at Week 12 in GRAVITI[3]

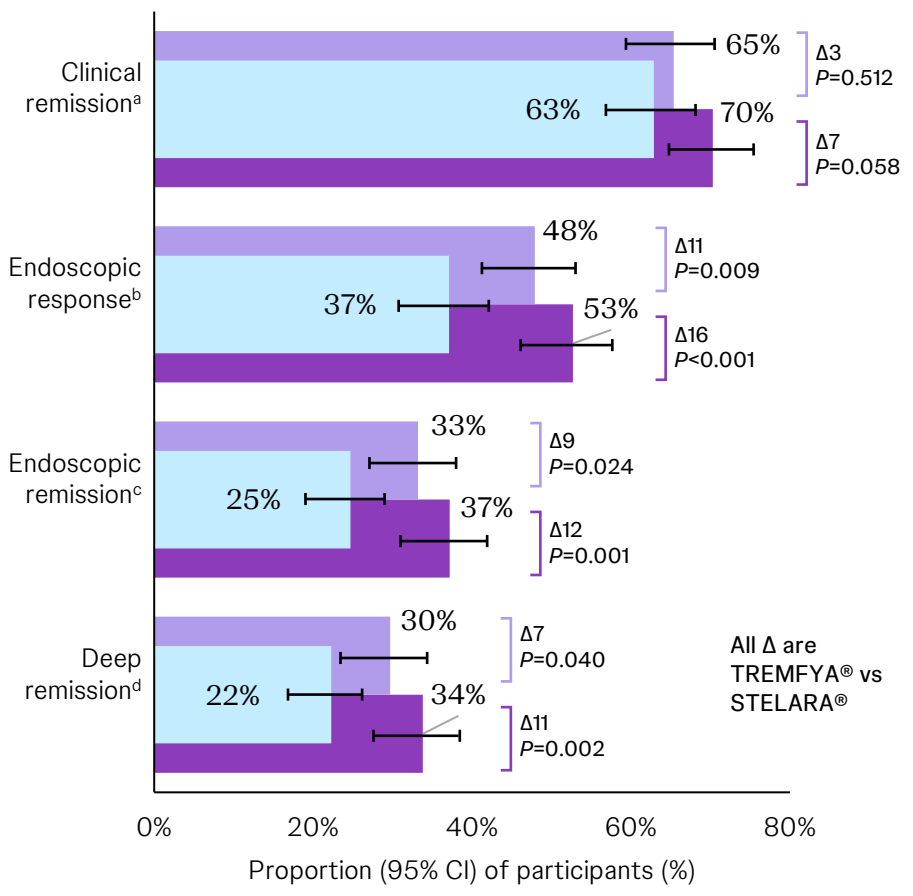


Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

GALAXI[2]

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

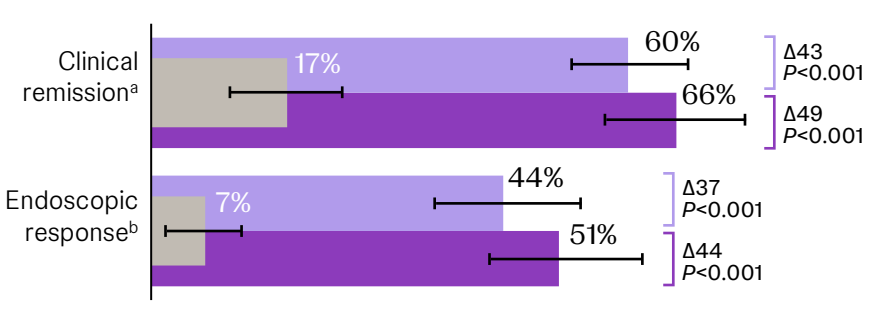
TREMFYA® 200 mg IV q4w → 100 mg SC q8w
N=Pooled, 286

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[3]

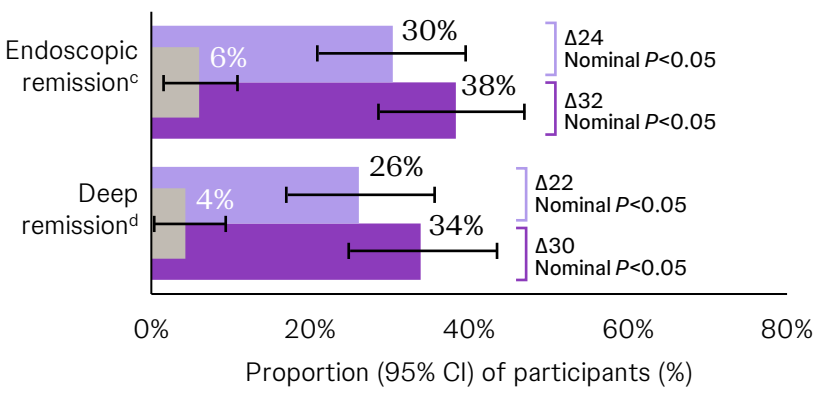
Additional multiplicity-controlled endpoints at Week 48



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)[4e]

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[2,4]

	PBO SC[f]	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[g], 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[g], n (%)	2 (1.3%)[h]	1 (0.3%)[i]	3 (1.0%)[j]	12 (4.0%)

Pooled safety at Week 48 from GRAVITI[3,4]

	PBO SC[k]	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%)[l]	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[m], n (%)	0	2 (1.7%)[n]	1 (0.9%)[o]

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

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

MACARONI 23: Guselkumab for pediatric participants with CD[5]

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.

Return to first page

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

[a]Clinical remission: CDAI <150. [b]Endoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. [c]Endoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore greater than 1 in any individual component. [d]Deep remission: clinical remission AND endoscopic remission. [e]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. [f]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). [g]Defined as any AE coded to MedDRA organ class "Infections and infestations". [h]Liver abscess/bacterial infection and postop wound infection/vascular device infection. [i]Anal abscess. [j]Acute sinusitis, abscess intestinal, intestinal fistula infection. [k]Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. [l]Fatal gunshot wound (non-suicidal). [m]An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. [n]Bronchitis and appendicitis. [o]Gastroenteritis.

AE, adverse effect; CD, Crohn's disease; CI, confidence interval; CS, corticosteroid-free; IMM, immunomodulators; IV, intravenous; PBO, placebo; PY, patient year; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious adverse event; SC, subcutaneous; TNF, tumor necrosis factor; VDZ, vedolizumab.

1. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 2. Panaccione R, et al. Lancet. 2025; https://doi.org/10.1016/S0140-6736(25)00681-6. 3. Hart A, et al. Gastroenterology. 2025; doi:10.1053/j.gastro.2025.02.033. 4. Data on File. Janssen Biotech, Inc. Horsham, PA. 5. MACARONI 23 NCT05923073.

US-SFM-6542 10/25

Johnson&Johnson

TREMFYA® (guselkumab) for adults with moderately to severely active ulcerative colitis

TREMFYA® has demonstrated clinical efficacy in UC[1,2]

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.

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

Induction: Patients (N=701) were randomized 3:2 to receive:
- TREMFYA® 200 mg IV q4w
- or placebo IV

Maintenance: TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders (N=568) were rerandomized 1:1:1 to receive:
- TREMFYA® 200 mg SC q4w
- TREMFYA® 100 mg SC q8w
- Placebo SC

ASTRO clinical program

A multicenter, randomized, double-blind, PBO-controlled, treat-through study of TREMFYA® in adults with moderately to severely active UC & inadequate response/intolerance to advanced therapy.

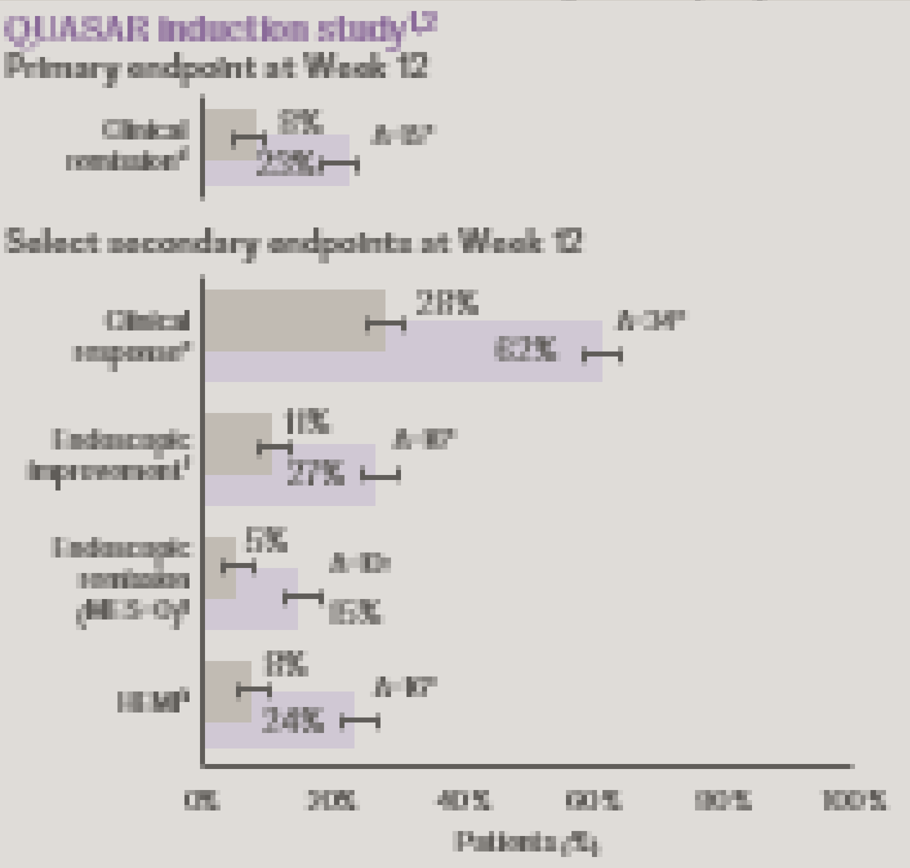
40% of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, JAKi, or S1PRM)

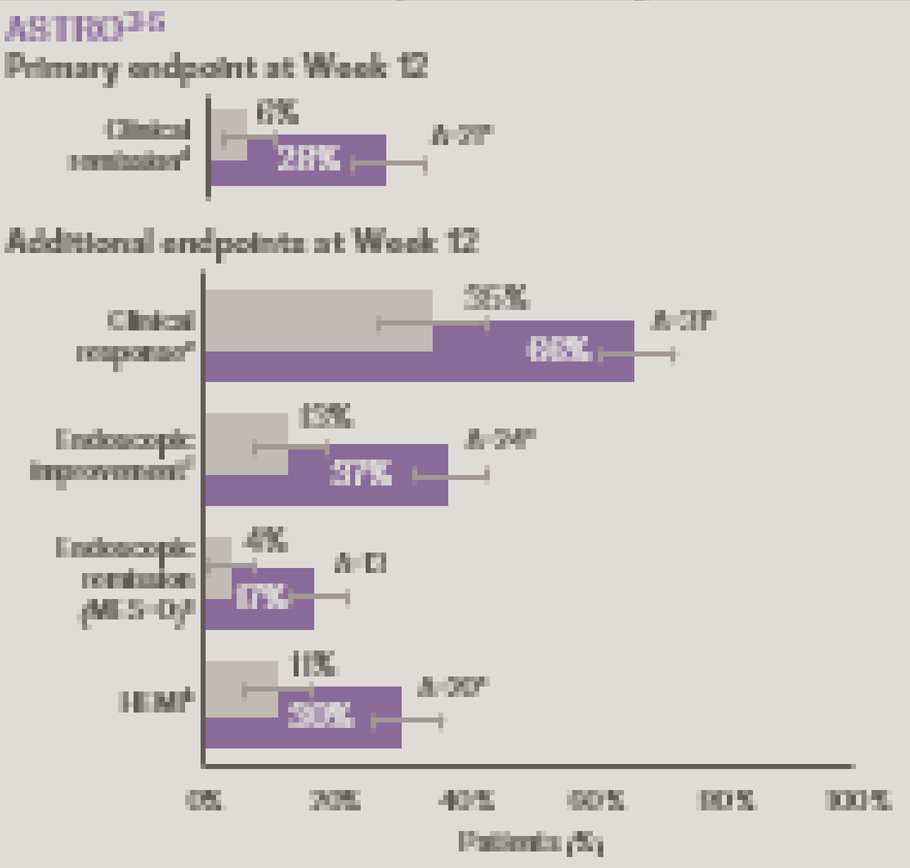
Study design: The study (N=418) randomized patients 1:1:1 to receive TREMFYA® 400 mg SC q4w for 12 weeks then 200 mg SC q4w, 100 mg SC q8w, or placebo SC.

Rescue criteria: Placebo non-responders were switched to a rescue treatment of TREMFYA® 400 mg SC q4w for 12 weeks followed by 100 mg SC q8w.

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC

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.





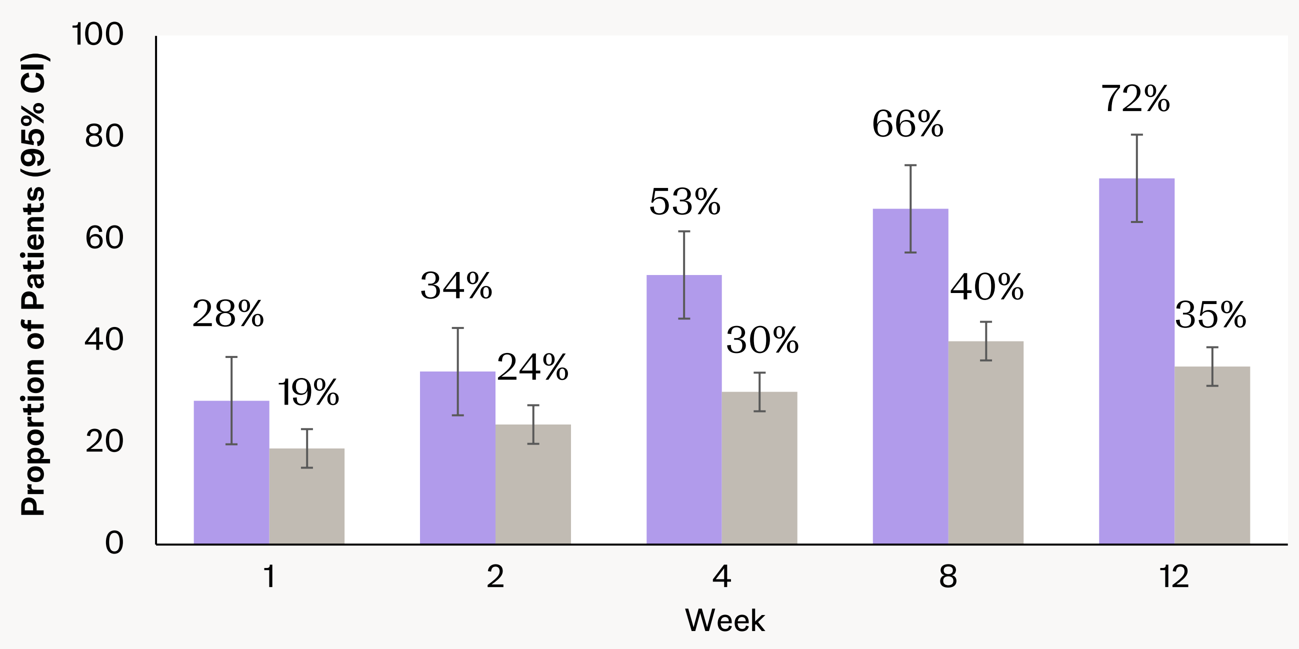
Endoscopic remission at Week 12 was prespecified and not controlled for multiplicity. No statistical significance can be made.

Post hoc analysis: symptomatic response through Week 12

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

QUASAR: IV Induction[1]

Post Hoc



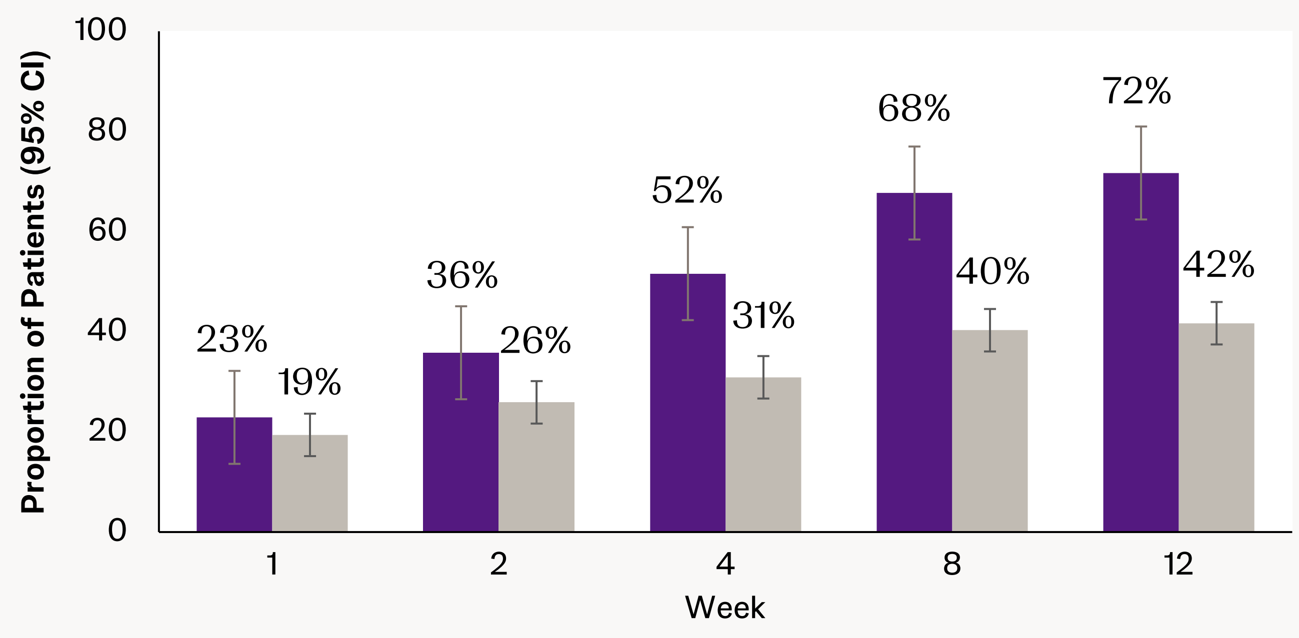
Data originated from separate pivotal trials for the biologic.

Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

- PBO
- TREMFYA® 400 mg SC
- TREMFYA® 200 mg IV

ASTRO: SC Induction[2]

Post Hoc



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; SC, subcutaneous.

1. Rubin DT, et al. *Lancet*. 2025;405(10472):33-49. 2. Data on file. Janssen Biotech, Inc.

	PBO SC (TREMFYA® withdrawal)	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Patients treated (n)	192	186	190
Average follow-up (weeks)	24.0	40.5	39.2
Deaths	0	0	0
Patients with one or more, n(%):			
AEs	131 (68%)	120 (65%)	133 (70%)
Serious AEs	1 (1%)	5 (3%)	12 (6%)
AEs leading to discontinuation	13 (7%)	7 (4%)	5 (3%)
Infections	63 (33%)	59 (32%)	59 (31%)
Serious infections	0	1 (1%)	2 (1%)

	PBO SC	TREMFYA® 400 mg SC q4w → 100 mg SC q8w	TREMFYA® 400 mg SC q4w → 200 mg SC q4w
Patients treated (n)	136	138	140
Average follow-up (weeks)	18.6	34.4	33.1
Deaths	0	1 (0.7%)*	0
Patients with one or more, n(%):			
AEs	61 (44.9%)	94 (68.1%)	95 (67.9%)
Serious AEs	12 (8.8%)	4 (2.9%)	7 (5.0%)
AEs leading to discontinuation	9 (6.6%)	6 (4.3%)	2 (1.4%)
Infections	26 (19.1%)	43 (31.2%)	40 (28.6%)
Serious infections	2 (1.5%)	0	2 (1.4%)

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

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

QUASAR Jr. Guselkumab for pediatric participants with moderately to severely active UC

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.

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

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TREMFYA® (guselkumab) for adults with moderately to severely active ulcerative colitis

TREMFYA® has demonstrated clinical efficacy in UC[1,2]

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.[2a]

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

Induction: Patients (N=701) were randomized 3:2 to receive:
- TREMFYA® 200 mg IV q4w
- or placebo IV[2]

Maintenance: TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders[b] (N=568) were randomized 1:1:1[c] to receive:
- TREMFYA® 200 mg SC q4w
- TREMFYA® 100 mg SC q8w
- Placebo SC[2]

ASTRO clinical program

A multicenter, randomized, double-blind, PBO-controlled, treat-through study of TREMFYA® in adults with moderately to severely active UC & inadequate response/intolerance to advanced therapy.[3,4]

of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, JAKi, or S1PRM)

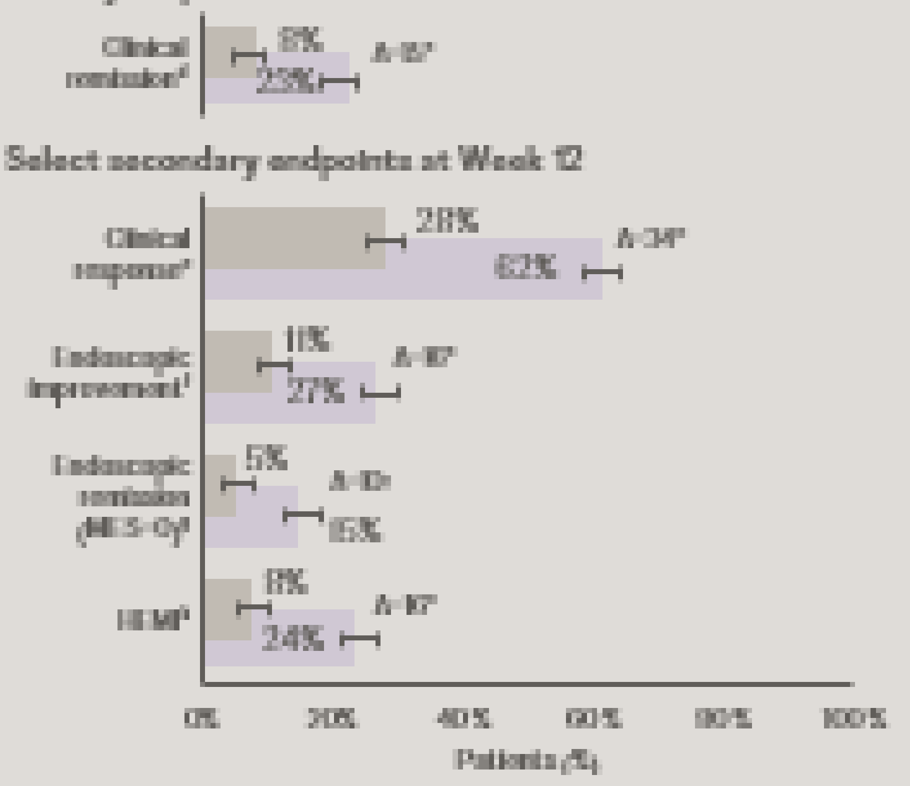
Study design: The study (N=418) randomized patients 1:1:1 to receive TREMFYA® 400 mg SC q4w for 12 weeks then 200 mg SC q4w, 100 mg SC q8w, or placebo SC.[3,4]

Rescue criteria: Placebo non-responders were switched to a rescue treatment of TREMFYA® 400 mg SC q4w for 12 weeks followed by 100 mg SC q8w.[3,4]

TREMFYA® demonstrated fast-acting and long-lasting clinical results in UC

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.

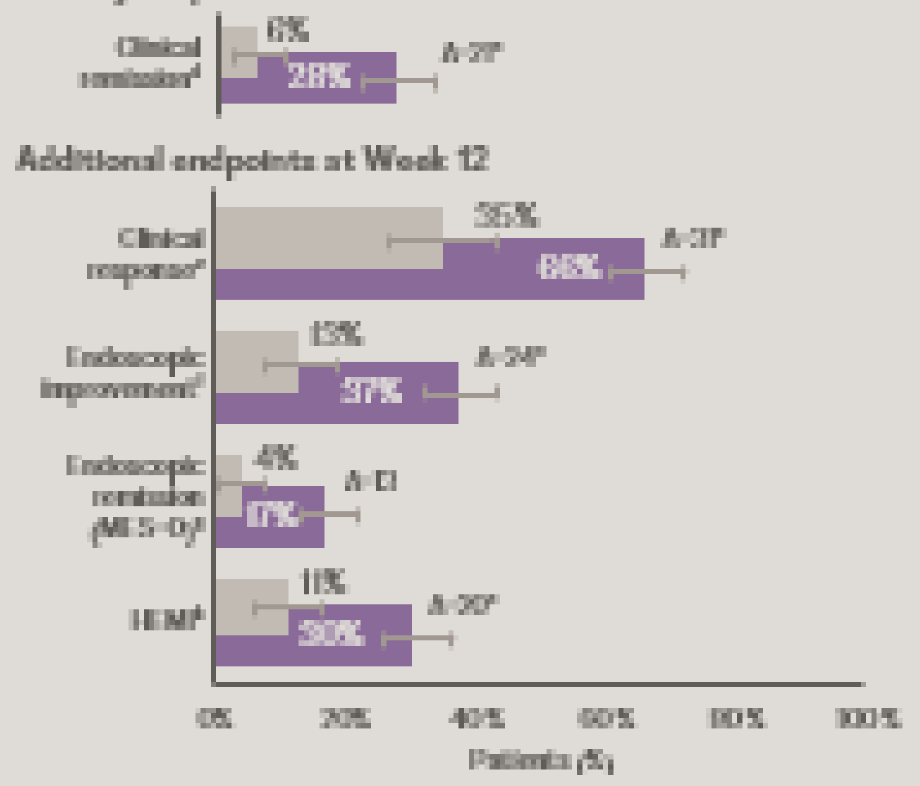
QUASAR induction study[1,2]



* = 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.

ASTRO[3-5]



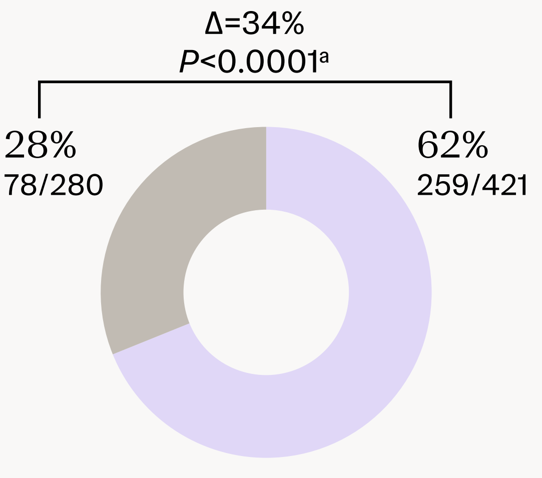
* = P<0.0001 versus placebo; TREMFYA® (n=279); PBO (n=139)

Endoscopic remission at Week 12 was prespecified and not controlled for multiplicity. No statistical significance can be made.

QUASAR: Clinical response at Week 12 or Week 24

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

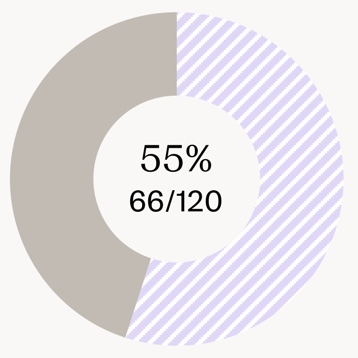
Clinical response at Week 12[1]



Proportion (95% CI) of patients (%)

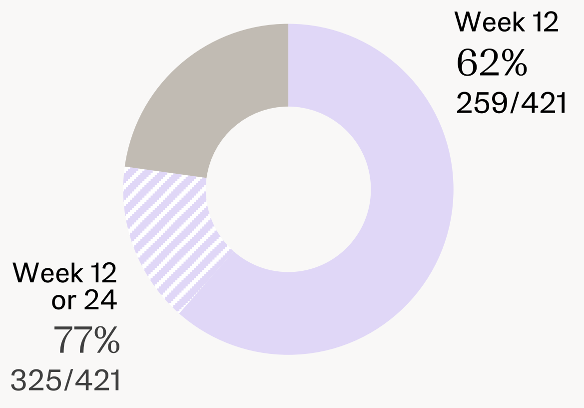
Clinical response at Week 24[2]

Among Week 12 clinical nonresponders to TREMFYA® IV induction who received additional TREMFYA® 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.

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

	Induction study (Week 12)[2]	
	PBO IV q4w	TREMFYA® 200 mg IV q4w
Patients treated (n)	280	421
Average follow-up (weeks)	11.9	12.2
Deaths	2 (1%)†	1 (0.2%)†
Patients with one or more, n (%):		
AEs	138 (49%)	208 (49%)
Serious AEs	20 (7%)	12 (3%)
AEs leading to discontinuation	11 (4%)	7 (2%)
Infections[‡,7]	43 (15%)	66 (16%)
Serious infections[‡]	1 (0.4%)	3 (1%)

	Maintenance study (Week 44)[2]		
	PBO SC (TREMFYA® withdrawal)	TREMFYA® 100 mg SC q8w	TREMFYA® 200 mg SC q4w
Patients treated (n)	192	186	190
Average follow-up (weeks)	34.0	40.5	39.2
Deaths	0	0	0
Patients with one or more, n (%):			
AEs	129 (68%)	120 (65%)	133 (70%)
Serious AEs	1 (1%)	5 (3%)	12 (6%)
AEs leading to discontinuation	13 (7%)	7 (4%)	5 (3%)
Infections[‡,7]	63 (33%)	59 (32%)	58 (31%)
Serious infections[‡]	0	1 (1%)	2 (1%)

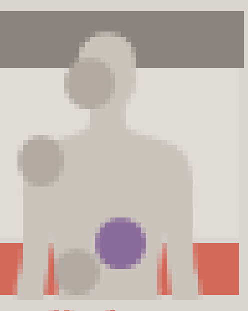
Treatment-emergent adverse events at ~1 year from the ASTRO trial in UC

	Through Week 12[3]	
	PBO SC[‖]	TREMFYA® 400 mg SC q4w
Patients treated (n)	139	279
Average follow-up (weeks)	12.2	12.3
Deaths	1 (0.7%)*	0
Patients with one or more, n (%):		
AEs	73 (52.5%)	110 (39.4%)
Serious AEs	11 (7.9%)	7 (2.5%)
AEs leading to discontinuation	8 (5.8%)	3 (1.1%)
Infections	28 (20.1%)	42 (15.1%)
Serious infections	0	2 (0.7)*

	Week 12 through to Week 48[6]		
	PBO SC[‖]	TREMFYA® 400 mg SC q4w → 100 mg SC q8w	TREMFYA® 400 mg SC q4w → 200 mg SC q4w
Patients treated (n)	136	138	140
Average follow-up (weeks)	18.6	34.4	33.1
Deaths	0	1 (0.7%)*	0
Patients with one or more, n (%):			
AEs	61 (44.9%)	94 (68.1%)	95 (67.9%)
Serious AEs	12 (8.8%)	4 (2.9%)	7 (5.0%)
AEs leading to discontinuation	8 (5.9%)	6 (4.3%)	2 (1.4%)
Infections	26 (19.1%)	43 (31.2%)	40 (28.6%)
Serious infections	2 (1.5%)*	0	2 (1.4%)*

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

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



QUASAR Jr. Guselkumab for pediatric participants with moderately to severely active UC[8]

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.

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

[a]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. [illegible]

[illegible]

1. TREMFYA® [Prescribing Information]. Janssen Biotech, Inc. Horsham, PA. 2. Rubin D, et al. Lancet. 2025;405:33-49. 3. Peyrin-Biroulet L, et al. ECCO 2025. Oral Presentation OP10. 4. Long M, et al. DDW 2025. Oral Presentation. 5. Data on File. Janssen Biotech, Inc. Horsham, PA. 6. Allegretti J, et al. Presented at DDW 2025. May 3-6, 2025. 7. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024. 8. QUASAR Jr. NCT05923073.

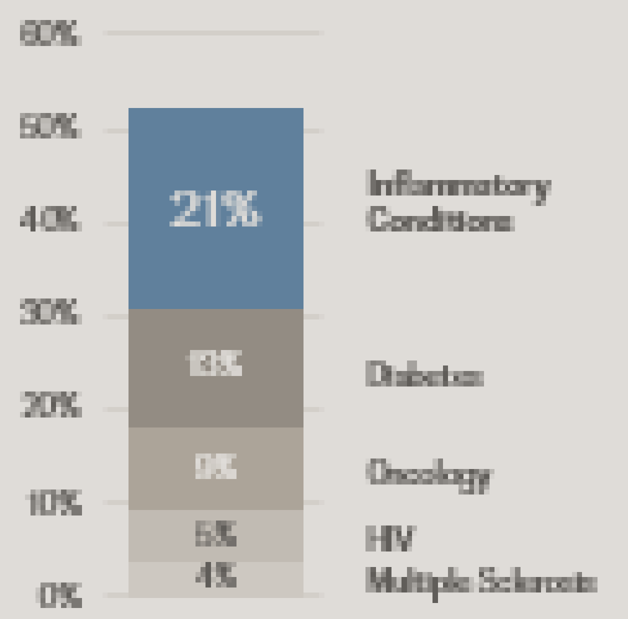
Johnson&Johnson

EVIDENCE & VALUE SUMMARY: TREMFYA® (guselkumab) for adult patients

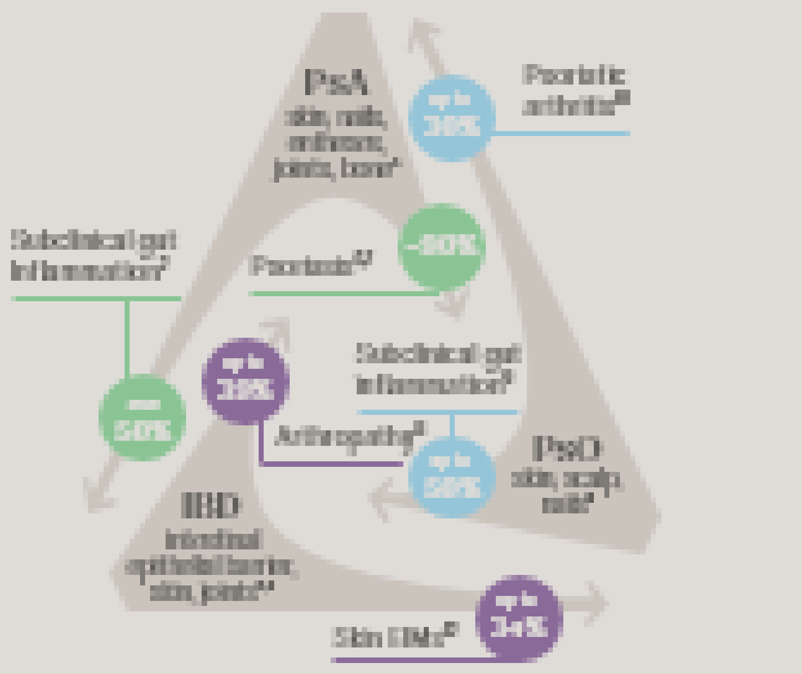
Inflammatory conditions have a significant impact on the patient and the United States healthcare system

Immunologic therapies present the highest cost burden for commercial plans

Top 5 therapy classes for commercial plans, by percent of total PMPY spending, 2020[a]



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



These conditions impact many people in the United States

	Prevalence[a]	Moderate-to-severe disease	Biologic-treated
PsO	7,500,000[13]	20%[14]	5.6%[15]
PsA	2,250,000[10,13b]	80%[15]	62%[16]
CD	1,011,000[17]	58%[18]	44%[19]
UC	1,253,000[17]	40%[20]	16%[19]

Patients with PsO have a **4x** higher prevalence of IBD, with the highest risk in the population with both PsO and PsA[21]

Psoriatic diseases are complex with high unmet need and costs

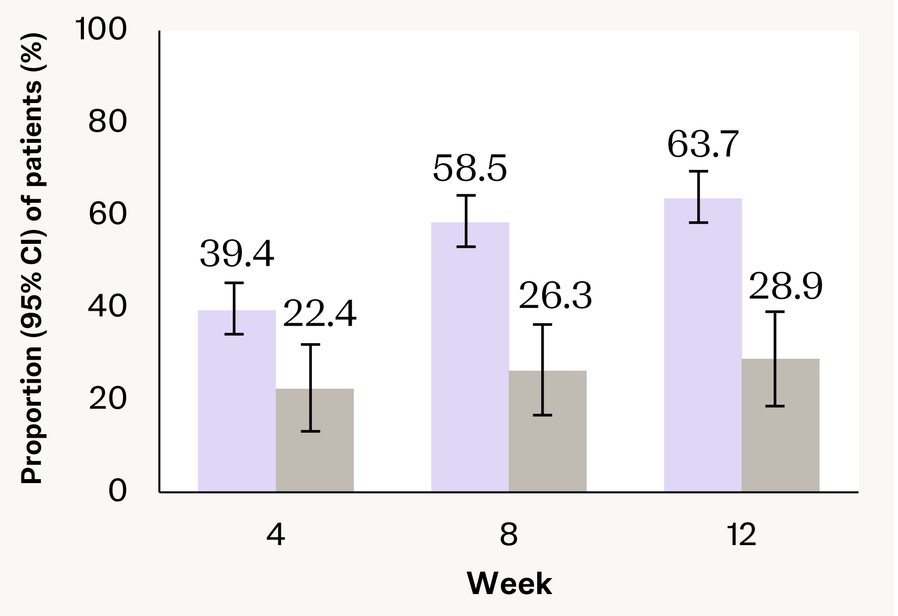
In patients with PsO who develop PsA,

Radiologic damage in

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.

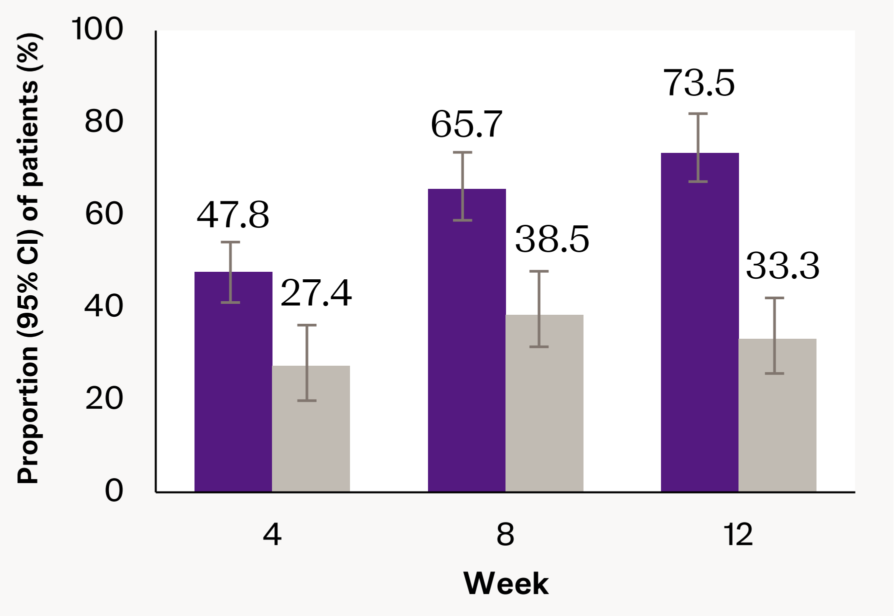
IV introduction: GALAXI 2 clinical response[1]



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.

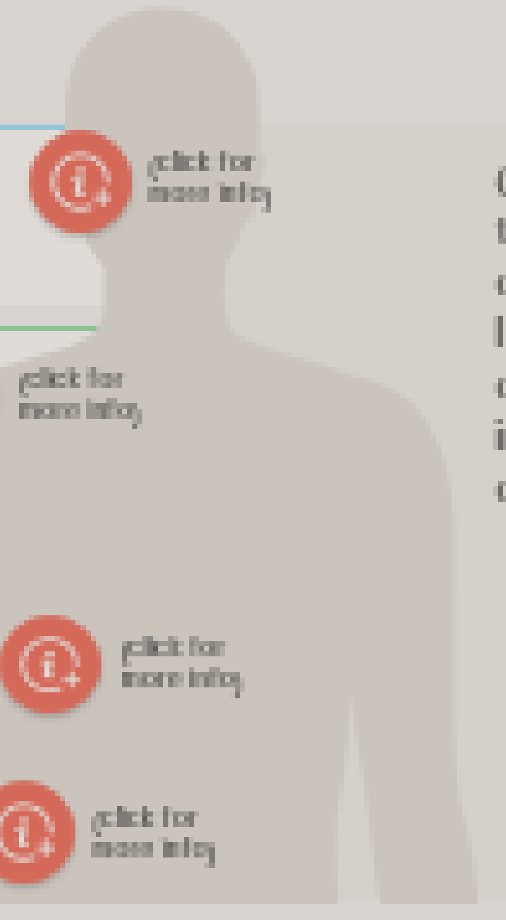
1. Panaccione R, et al. DDW 2024. Oral Presentation #1057b. 2. Hart A, et al. *Gastroenterology*. 2025; doi:10.1053/j.gastro.2025.02.033.

agreed that symptoms impact most aspects of daily life

experienced anxiety, depression, and/or embarrassment because of IBD

CD direct and indirect costs in the United States: **$14.9** billion/year

TREMFYA® is an IL-23i indicated for the treatment of adults with[22a-g]:



PsO Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

PsA Active psoriatic arthritis

UC Moderately to severely active ulcerative colitis

CD Moderately to severely active Crohn's disease

Guselkumab is the only[h] fully human dual-acting, selective IL-23 inhibitor designed to neutralize inflammation at its cellular source[33-38]

For additional information, please see TREMFYA® Prescribing Information here.

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