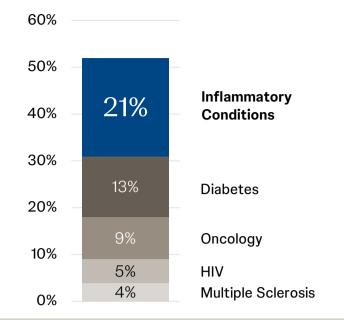
EVIDENCE & VALUE SUMMARY: TREMFYA® (guselkumab) for adult patients

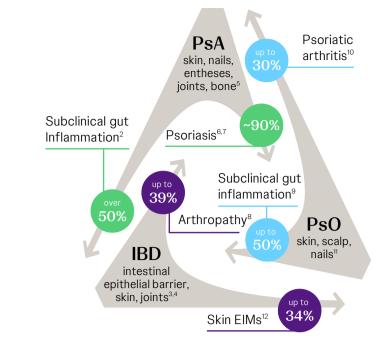
Inflammatory conditions have a significant impact on the patient and the United States healthcare system

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 extracutaneous manifestations



These conditions impact many people in the United States

	Prevalence ^a	Moderate-to-severe disease	Biologic-treated
PsO	7,500,00013	20%14	51% ¹⁵
PsA	2,250,000 ^{10,13b}	80%15	62%16
CD	1,011,00017	58% ¹⁸	44%19
UC	1,253,00017	40% ²⁰	16% ¹⁹

Patients with PsO have a 4Xhigher prevalence of IBD, with the highest risk in the population with both PsO and PsA²¹

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 time¹⁰



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 PsA²³:

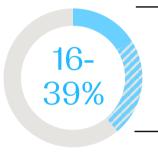
experienced at least a moderate impact on quality of life

screened positive for potential major depressive disorder

High economic burden²⁴⁻²⁷:

PsO annual indirect cost due to total work productivity loss per patient





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 pattern²⁸



CD: Anywhere in the GI tract from the mouth to the anus; may appear in patches²⁹

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 burden³¹:

UC direct and indirect costs in the United States:

\$15.5

CD direct and indirect costs in the **United States:**

\$14.9

TREMFYA® is an IL-23i indicated for the treatment of adults with^{32efg}:



Ps()

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





PsA
Active psoriatic arthritis



more info)



Moderately to severely active ulcerative colitis







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 source³³⁻³⁸

of these findings is unknown.

Based on in vitro studies in inflammatory monocyte models. The clinical significance

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

302 adults with IBD in the United States via MyCrohnsandColitisTeam.com. eTREMFYA® 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 LIC 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 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. 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. 9TREMFYA® 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.

aln the United States. Prevalence of patients with PsO who develop PsA. Based on no difference in the radiographic severity of small joints between patient populations with RA and PsA. Based on a survey of

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.

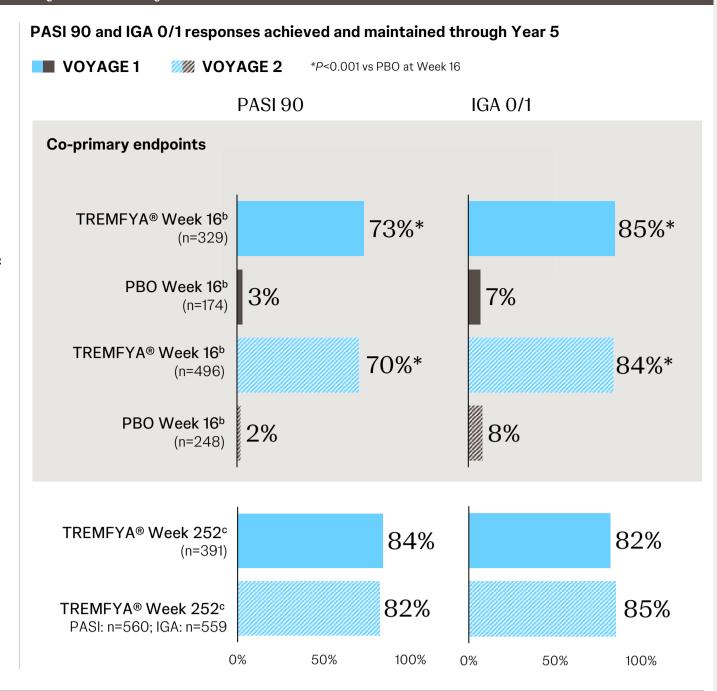
TREMFYA® (guselkumab) for adults with moderate to severe plaque psoriasis

TREMFYA® has established safety and efficacy in PsOa

Moderate to severe plaque PsO¹⁻⁵

VOYAGE 1 (N=837) and

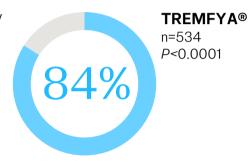
VOYAGE 2 (N=992) were phase 3, multicenter, double-blind, placebo-controlled, active comparator trials evaluating the efficacy and safety of TREMFYA® vs placebo in adult patients with moderate to severe plague PsO who were candidates for phototherapy and/or systemic therapy. Co-primary endpoints in both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

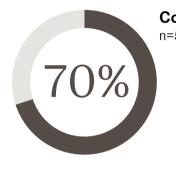


ECLIPSE (N=1048) was a phase 3, double blind, active comparator trial evaluating the efficacy and safety of TREMFYA® 100 mg versus Cosentyx® (secukinumab). The primary endpoint was PASI 90 at week 48 for noninferiority and then superiority tests.5d

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





Cosentyx® n=514

Selected safety profile^{1,6} Please refer to the full Prescribing Information for a complete listing of all adverse events for all indications,

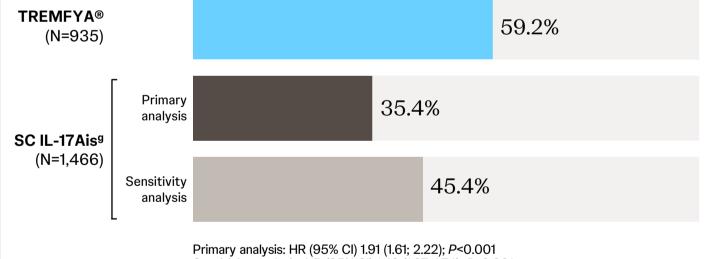
Safety data results are established through 5 years in moderate to severe plaque PsO

including other serious adverse events.

Safety Results From	Adverse events		Serious adverse events		Infections		Serious infections	
VOYAGE Trials (PsO)	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]	O.1 [0.4]	0.2 [0.8]
Year 5, events/100 PYs of follow-up, n=1721e	149.4		5.0		60.6		0.9	

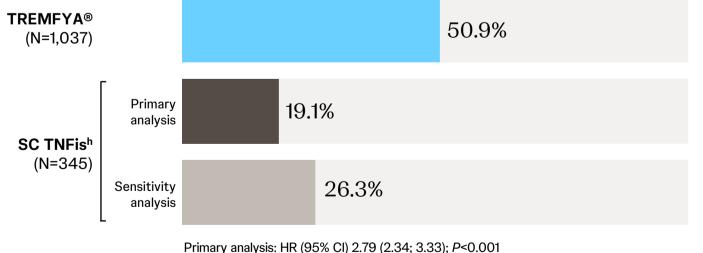
TREMFYA® has demonstrated significantly better treatment persistence versus comparators in plaque PsO^{7,8}

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



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

Sensitivity analysis: HR (95% CI) 1.49 (1.27; 1.74); P<0.001



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

Sensitivity analysis: HR (95% CI) 2.31 (1.92; 2.78); P<0.001

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,



SPECTREM: Adults who are bio-naïve with low BSA moderate plague PsO and special site involvement¹⁰



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

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failure rules. Includes patients who crossed over from placebo to receive GUS at Week 16. Intent-to-treat population. Plncludes all patients exposed to TREMFYA® in VOYAGE 1 and VOYAGE 2. 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. 9SC IL-17Ai agents included ixekizumab, secukinumab, and brodalumab. 9SC TNFi agents included adalimumab, certolizumab pegol, etanercept,

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, Hl. 8. Zhdanava M, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, Hl. 9. VISIBLE NCT05272150. 10. SPECTREM NCT06039189.

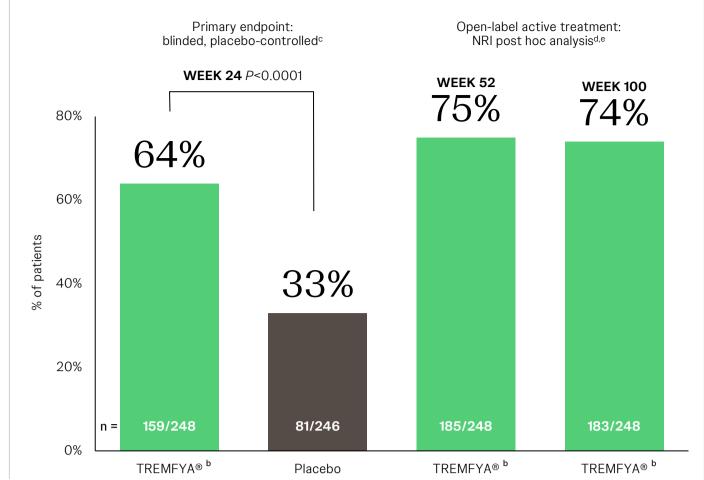
TREMFYA® (guselkumab) for adults with active psoriatic arthritis

TREMFYA® has established safety and efficacy in PsAa

Active PsA¹⁻³

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

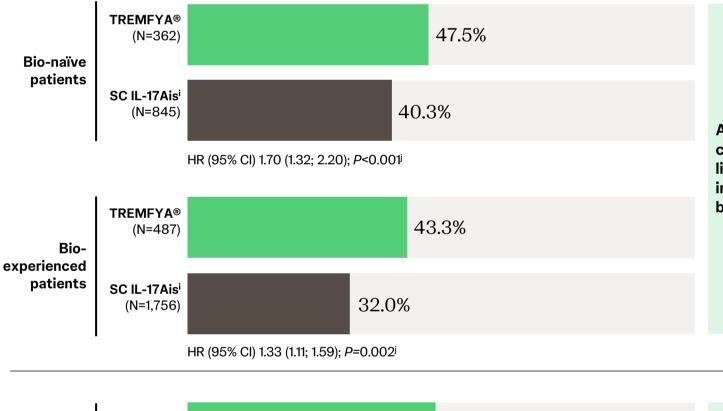
Safety data results are established through 2 years in active PsA

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.

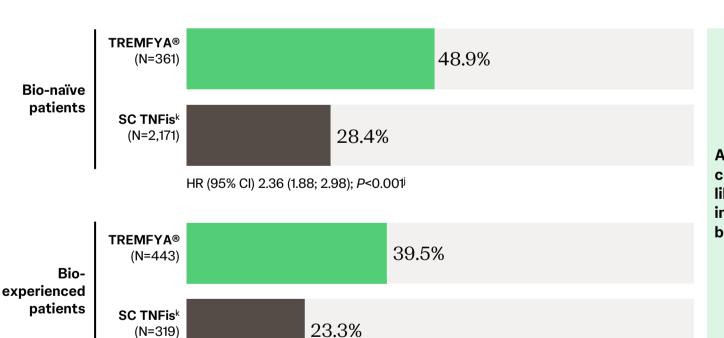
Adverse Serious Serious Infections infections events adverse events Safety Results From **DISCOVER Trials (PsA)** TREMFYA® Placebo TREMFYA® Placebo TREMFYA® Placebo TREMFYA® Placebo Week 24, 1.9 3.2 19.5 48.5 47.3 20.7 0.3 0.8 % [events/100 PYs of follow-up] [257.3] [220.0] [4.0] [9.3] [58.3] [58.5]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

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-17Aig or SC TNFi cohortsh



At 2 years, the TREMFYA cohort was ~1.7x more likely to remain persistent in both bio-naïve and bio-experienced cohorts⁶



At 2 years, the TREMFYA cohort was 2x more likely to remain persistent in both bio-naïve and bio-experienced cohorts⁷

HR (95% CI) 1.86 (1.46; 2.37); P<0.001

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 progression⁸



bio-naïve with active PsA axial disease⁹



SOLSTICE: Adults with active PsA and inadequate response or intolerance to a prior anti-TNF α^{10}

There is no guarantee that the investigational uses listed will be filed with and/or approved for marketing by the FDA.

The safety and efficacy of the investigational uses of this product have not been determined.

Return to first page r more information on ongoing t

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

from DISCOVER 1 are not shown. Patients with missing data were considered nonresponders. The same patients may not have responded at each time point. After Week 24, the study was open label with blinded dosing interval, which may have affected results. DISCOVER 2 only. 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. 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. L-17Ais included secukinumab and ixekizumab. Sensitivity analyses demonstrated similar trends. The FDA maintenance interval between administration; GUS, guselkumab; HR, hazard ratio; IL-17Ai, 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,

aTREMFYA® dosing in active PsA: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. Prespecified as-observed analysis from Week 24 to Week 100 from DISCOVER 2 and from Week 24 to Week 52

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, Hl. 7. Mease P, et al. Poster presented at: Maui Derm Hawaii 2025, January 20-24, 2025; Maui, Hl. 8. APEX NCT04882098. 9. STAR NCT04929210. 10. SOLSTICE NCT04936308.

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

TREMFYA® has demonstrated clinical efficacy in UC1,2

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}

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

- or placebo IV1,2

Maintenance: TREMFYA® Week 12 induction clinical responders and placebo crossover Week 24 responders^b (N=568) were rerandomized 1:1:1° to receive:

- TREMFYA® 200 mg SC q4w
- TREMFYA® 100 mg SC q8w
- Placebo SC²

of patients had prior inadequate response or intolerance to

advanced therapy (TNFis, VDZ, or TOFA)

ASTRO clinical program

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



 $\mathcal{A}\mathcal{A} \to \mathcal{A}$

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

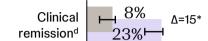
of patients had prior inadequate response or intolerance to advanced therapy (TNFis, VDZ, JAKi, or S1PRM)

$\mathsf{TREMFYA}^{ exttt{ iny }}$ demonstrated fast-acting and long-lasting clinical results in UC

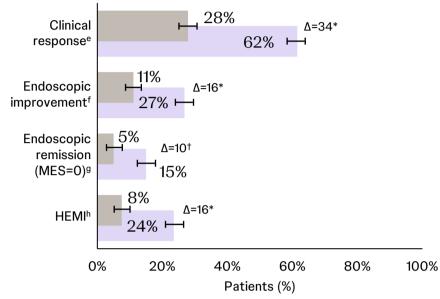
Data originated from separate pivotal trials for the biologic.

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

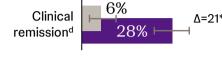


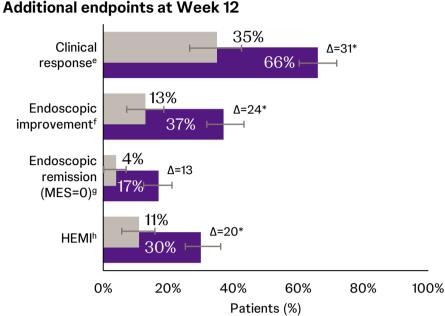
† = Nominal P<0.0001 versus placebo. Endpoints were not adjusted for multiple comparisons; therefore, statistical significance has not been established.

TREMFYA® (n=421)

ASTRO³⁻⁵

Primary endpoint at Week 12





PBO (n=139) TREMFYA® (n=279) Endoscopic remission at Week 12 was prespecified and not

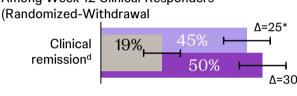
controlled for multiplicity. No statistical significance can be made. Symptomatic response through Week 12 (click for more info)

ASTRO⁵

QUASAR maintenance study^{1,2} Primary endpoint at Week 44

Among Week 12 Clinical Responders

* = P < 0.0001 versus placebo

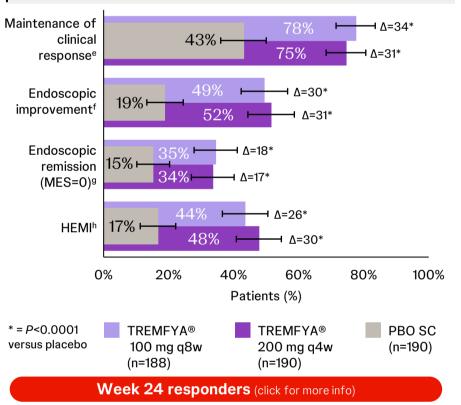


patients in the combined TREMFYA® group who achieved clinical were corticosteroidfree for ≥8 weeks2

99% (178/180) of

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



Treatment-emergent adverse events at ~1 year from

Prespecified exploratory endpoint at Week 48

* = P<0.0001 versus placebo

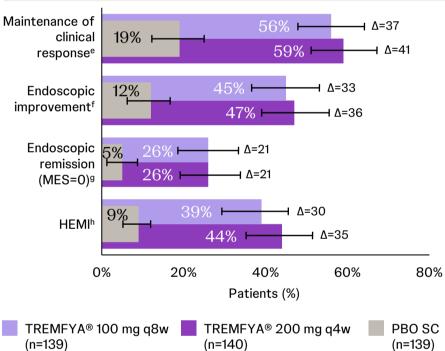
(Treat-through)

⊣ ∆=30 Clinical remissiond

Prespecified exploratory endpoints at Week 48 (Treat-through)

Over 1/4 of patients were in complete endoscopic remission

(MES=0) at Week 48



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

TREMFYA® PBO IV q4w 200 mg IV q4w 280 Patients treated (n) Average follow-up 11.9 12.2 (weeks) 2 (1%)i 1 (0.2%)^j Deaths Patients with one or more (n[%]): 208 (49%) **AEs** 138 (49%) 20 (7%) 12 (3%) Serious AEs AEs leading to 11 (4%) 7 (2%) discontinuation Infections^{6,7k} 43 (15%) 66 (16%) Serious Infectionsk 3 (1%) 1 (0.4%) Maintenance study (Week 44)² **TREMFYA® TREMFYA®** PBO SC (TREMFYA® 100 mg 200 mg SC q4w withdrawal) SC q8w Patients treated (n) 192 186 190 Average follow-up 34.0 40.5 39.2 (weeks) 0 0 0 Deaths Patients with one or more (n[%]): 120 (65%) 133 (70%) AEs 131 (68%) 5 (3%) 12 (6%) Serious AEs 1 (1%) AEs leading to 13 (7%) 7 (4%) 5 (3%) discontinuation Infections^{6,7k} 59 (32%) 63 (33%) 59 (31%) Serious Infectionsk 1 (1%) 2 (1%) For additional safety information, please see TREMFYA® prescribing information here.

the ASTRO trial in UC Through Week 12³

	PBO SCI		REMFY 00 mg	A® SC q4w
Patients treated (n)	139	2	279	
Average follow-up (weeks)	12.2	1	2.3	
Deaths	1 (0.7%) ^m	C)	
Patients with one or mor	e (n[%]):			
AEs	73 (52.5%)	1	10 (39.	4%)
Serious AEs	11 (7.9%)	7	(2.5%)
AEs leading to discontinuation	8 (5.8%)	3	3 (1.1%)	
Infections	28 (20.1%)	4	12 (15.1	%)
Serious Infections	0		2(0.7) ⁿ	
	Week 12 through to Wee		48 ⁵	
		TREMFYA 400 mg S0 q4w → 100	С	TREMFYA® 400 mg SC q4w → 200 mg

SC a8w PBO SCI SC q4w Patients treated (n) 136 138 140 Average follow-up 33.1 18.6 34.4 (weeks) 0 1 (0.7%)° 0 Deaths Patients with one or more (n[%]): 94 (68.1%) 95 (67.9%) **AEs** 61 (44.9%) Serious AEs 4 (2.9%) 7 (5.0%) 12 (8.8%) AEs leading to 8 (5.9%) 6 (4.3%) 2 (1.4%) discontinuation 40 (28.6%) 26 (19.1%) 43 (31.2%) Infections Serious Infections 2 (1.5%)p 2 (1.4%)9

request; no further use permitted. TREMFYA® is a trademark of Janssen Biotech, Inc.

QUASAR Jr: Guselkumab for pediatric participants with moderately to severely active UC8

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.

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

Return to first page

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

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. 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. dClinical 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. 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. Fendoscopic improvement: an endoscopy subscore of 0 or 1 with no friability. Endoscopic remission: an endoscopy subscore of 0. hHEMI: achieving a combination of histologic improvement and endoscopic improvement. Natural causes and cardiac arrest. Fatal acute myocardial infarction in a patient with preexisting cardiac risk factors. L'Defined as any AE coded to MedDRA organ class "Infections and infestations". Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. "Road traffic accident. Prilonidal disease and gastroenteritis. Intraventricular hemorrhage. Preumonia and COVID-19. 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

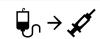
2025. Oral Presentation #OP800. 5. Data on File. Janssen Biotech, Inc. Horsham, PA. 6. Allegretti J, et al. Presented at DDW 2023. May 6-9, 2023. 7. Rubin D, et al. Presented at DDW 2024. May 18-21, 2024.

8. OUASAR Jr NCT06260163. US-SFM-6542 10/25 © Janssen Scientific Affairs, LLC. 2025. Provided in response to a medical information

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}



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).

GRAVITI clinical program^{1,3}



previously failed at least 1 biologic

N = 347

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 g8w starting at Week 20

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

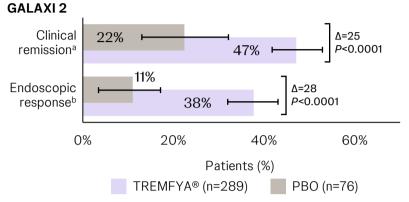
Both TREMFYA® IV and SC induction demonstrated clinical remission and endoscopic response at Week 12

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.

GALAXI²

Select secondary endpoints at Week 12

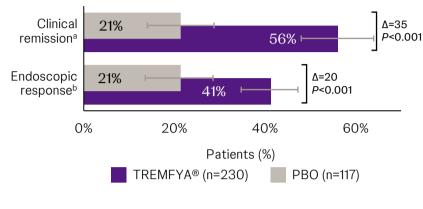


GALAXI 3 at Week 124: Clinical remission^t: TREMFYA® 47% (138/293) vs PBO 15% (11/72); P<0.0001

Endoscopic response^u: TREMFYA® 36% (106/293) vs PBO 14% (10/72); P<0.0001

GRAVITI3

Co-primary endpoints at Week 12 in GRAVITI³

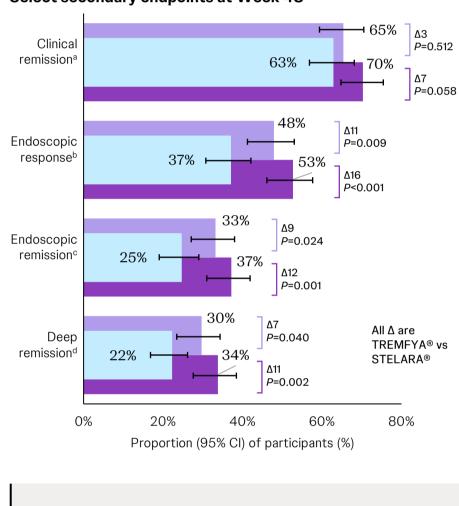


Clinical response through Week 12 (click for more info)

TREMFYA® demonstrated long-lasting clinical results in CD

GALAXI²

Select secondary endpoints at Week 48



~1/3 of patients were in deep remission at 1 year

Superiority vs STELARA® across all pooled endoscopic endpoints

- TREMFYA® 200 mg IV q4w → 100 mg SC q8w STELARA® ~6
- TREMFYA® 200 mg IV q4w → 200 mg SC q4w N=Pooled, 296

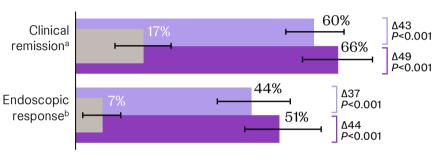
N=Pooled, 286

90 mg SC q8w N=Pooled, 291

mg/kg IV →

GRAVITI³

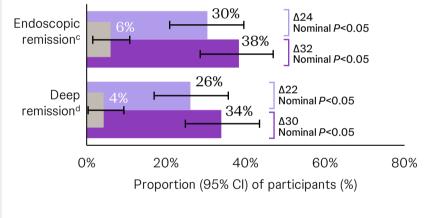
Additional multiplicity-controlled endpoints at Week 48



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

q4w → TREMFYA® 200 mg SC q4w N=115

TREMFYA® 400 mg SC

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} Pooled safety at Week 48 from GRAVITI^{3,4}

TREMFYA® TREMFYA® STELARA®

	PBO SC ^f	100 mg SC q8w	200 mg SC q4w	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%)

	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%)	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%)°
ı <u>here</u> .			

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

For additional safety information, please see TREMFYA® prescribing information

MACARONI 23: Guselkumab for pediatric



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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Johnson&Johnson

participants with CD5

For more information on ongoing trials, go to ClinicalTrials.gov. For additional information, please see TREMFYA® Prescribing Information here. aClinical remission: CDAI <150. bEndoscopic response: ≥50% improvement from baseline in SES-CD or SES-CD ≤2. cendoscopic remission: SES-CD ≤4 and a ≥2-point reduction from baseline and no subscore

greater than 1 in any individual component. dDeep remission: clinical remission AND endoscopic remission. 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. 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). Defined as any AE coded to MedDRA organ class "Infections and infestations". Liver abscess/bacterial infection and postop wound infection/vascular device infection. Anal abscess. JAcute sinusitis, abscess intestinal, intestinal fistula infection. Includes all PBO patients excluding data after a patient is rescued with TREMFYA®. Fatal gunshot wound (non-suicidal). An additional serious infection of anal abscess was reported in the PBO → TREMFYA® rescue group. "Bronchitis and appendicitis. "Gastroenteritis. AE, adverse effect; CD, Crohn's disease; Cl, 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.

doi:10.1053/j.gastro.2025.02.033. 4. Data on File. Janssen Biotech, Inc. Horsham, PA. 5. MACARONI 23 NCT05923073.

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;

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

TREMITYA® has demonstrated clinical efficacy in UC^Q

QUASAR clinical program

TREMEYAP was evaluated in multicenter. randomized, double-blind, placebe-controlled induction and maintenance studies in adult patients with moderately to severely active UC & prior response or intolerance to conventional or advanced therapy.24

49%

controlled, treat-through study of TREMEYA® in adults with moderately to severely active UC-8: rudoganto responso/intokranco to advirscod thorapy.^{3,6} Study design: The study (N=4/D), condensional patients this acceive TREMETO," 400 mg SC q-Ne for 12 weeks.

12 weeks followed by 100 mg SD qillur.^{3,6}

ASTRO clinical program

Amulticanter, randomizod, double-blind, PBO-

10 31

of pottents had prior inscirculate

tien 200 mg SD q/lw, 100 mg SD qfile, or placebo SD.^{3,4} Rescue criteria: Placebo non-respondero were avitiched to a reacter treatment of TREMEYA® 400 mg SC q4w for

of patients had prior tracinguate ivagoman of Intokuranca to ademiced therap (TMFb), VEIZ, JAKS, or STREET,

Induction: Patients (N=70t) were randomized 3:2 to receive:

TREMETO, 200 ing Night

or placeto NO Maintonance: TREMEYA* Wook 12 induction clinical responders and placelso cressover Week 24 responders* (N-550), were recondenized bit? to receive:

TREMETOR 2000 mg S0 of w. TREMETON 100 mg 50 qlav

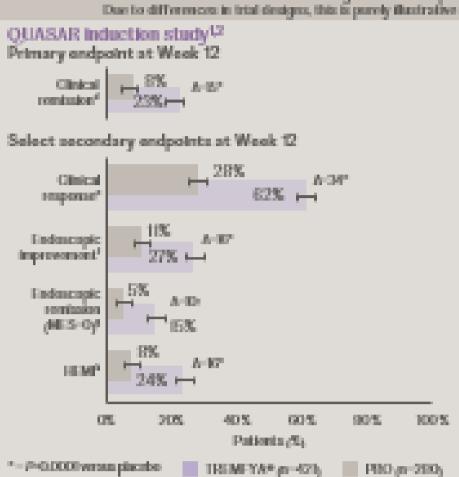
Pincelto 50³

CONTROL OF Intrigrance to anthrone conf. therapy/INFis, WING, or TOTAL

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

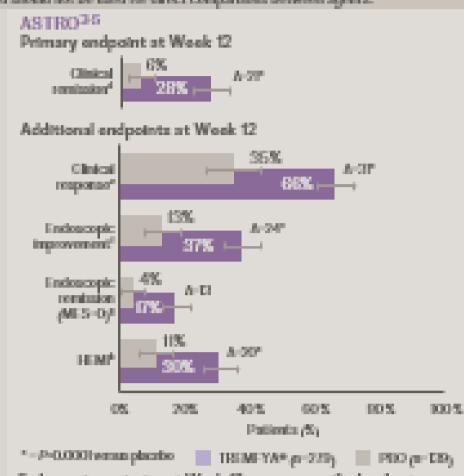
Data originated from argurate pivotal trials for the biologic.

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



Risminal P-0.0001 wersen placeba. Endpoints were not adjusted for multiple.

comparisons, therefore, statistical significance has not been established.



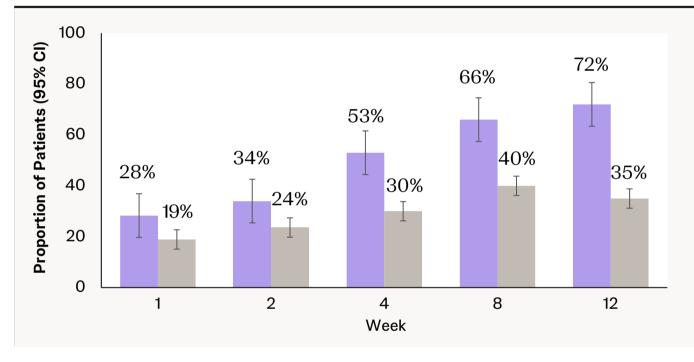
Endoscopic remission at Week 12 was prespectfied and not controlled for multiplicity. No statistical significance can be made.

Post hoc analysis: symptomatic response through Week 12 Separation from placebo in symptomatic response observed as early as Week 1



QUASAR: IV Induction¹

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.

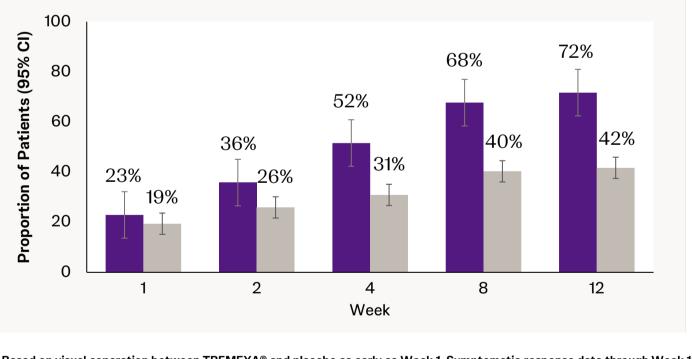
PBO

TREMFYA® 400 mg SC

TREMFYA® 200 mg IV

ASTRO: SC Induction²

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 (TREMEYAM withdrawal)	TREMEYA# 100 mg SG qftw	TREMEYAM 200 mg 5G q4w
Pationts treated ps	1902	100	190
Average follow-up (mooks)	24.0	40.5	39.2
Deatha	0	0	0
Patients with one or mo	ευ _τ α(X) ₂ -		
Alix	Tri (GERT)	DO(65%)	EEE_(70%)
Serious AEs	1(1%)	5 (CFS)	12 (9%)
All a leading to discontinuation	D(E)	7 (4%)	5 (2%)
infections ^{6,74}	631 (227E)	59 (37%)	50 (200)
Serious Infections ^b	0	1(85)	2 (1%)

		TREMEYAR	TREMEYAR
		400 mg 50	400 mg 50
		q4w → 100 mg	q4w → 2000 mg
	PBO SG ¹	SC qiller	SC offer
Pationis isosind ₍₁₉₎	136	T203	140
Average follow-up	19.6	34.4	22.1
prooks; Douths	0	1/0.7%/*	0
Patients with one or mo	wo.m(X) _p .ox	.,,	_
Mis	61,4439%	94(60.1%)	95(67.9%)
Serious AEx	17 (0.0%)	4,(2.9%)	7 (5.0%)
Alia leading to discontinuation	H (5.0%)	6(43%)	2 (14%)
Infections	26 (19.1%)	42 (21.2%)	40 (20.6%)
Serious Infections	2 (15%)*	0	2 (12(%))1



QUASAR An Guariburab for podatric participants with moderately to severely active UC^0 Fire surferly and officercy of the innertispolitimal asset of this precised home not be necleic regions.

There is the generation that the investigational cost third will be filled with credit approved for martisting by the FDA Return to first page

For more information on ongoing trials, go to <u>Clinicafficials.gov</u>. For additional information, please see TREMEYA® Prescribing information <u>her</u>e.

Manhestirly in several parties IC defined as instation baseline condition Magazines of 10 in 8 with a Magazinetical parties or a Land a Magazinetic advance of 2 based on certain eview. Wherein resource requesters at Work 25, are the planets recomposites at Work 12 also went on to recoive TRANTA 2021 mg W glue for 12 works and were in all third requires to TRANTA at Work 24. Policets. From a please 2's manhemized, disable billed, planelse controlled, including nicely after the manufactured a chiral exposure to TECM YES according to the phase 3 matrices accordingly. \$2 min. contaction Magnetical Response automates of Cort Landows International Internation, a Magnetic State of State of Digital Andrew State of S have industrian baseline in the modified Mayor source; compareed foliand frequency, restal blending, and entire any enthroused Mayor source at these the physician's girlind accessored filey (NSX and a 2 paints, with of the surface from hander in the croid blending subscure or according subscure of Star L. Tadioscopic improvements an entire copy subscure of Star Swith on Haldity Windowsopic remissions accentisingly solution of S. \$4.00 unlikely a condition of historiagic improvement and endocogin improvement. Make all courses and conduct access it Fatal analy represented inflantian in a patient anti-preestiming number side fundament. Defined as any Affirmation Med SAA organisation, Indications and indicatations. Anothering address a state of patient in research with TREMETARS. When it is all for amident. Whetelid disease and partner testis. Astronomicals former large. Processes and COVID-10. Was soon of appreciation.

All, where of Peri, H.M., historesia complement and recognitive contraction of the process of the Period Complement of th infantiols; TW / term recents being UC, absentive rolling M.C., vehilorands; W.C., west Cl., W.E., west SE. 1.110 MFAM (Prescribing Information), James of States, No. Horshop, Ph. 2. Public D, et al. Lauret. 2003 (Oxford Str. 3. Preprint Street L., et al. 1933) 2003. Oxfore contains. 2010. A Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street Lauret MANN

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

TREMFYA* has demonstrated clinical efficacy in UC^Q

QUASAR clinical program

TREMETOR 200 ing N g/w

TREMETOR 2000 mg S0 of w. TREMPTOP 100 mg 50 qliw

or placebo M^{1,2}

Pincelto 50³



TREMEYAP was evaluated in multicenter. randomized, double-blind, placebe-controlled induction and maintenance studies in adult patients with moderately to severely active UC & prior response or intolerance to conventional or advanced therapy.24

Maintenance: TREMEYA* Week 12 induction clinical.

(N-550), were recondenized bit? to receive:

responders and placelso cressover Week 24 responders*

Inclucition: Patients yN=70ty were randomized 3:2 to receive:

49%

of pottents had prior inadequate foregoing or Intrigrance to anthropic code therapy/IMHs. WINT, or TOTAL

ASTRO clinical program

12 weeks followed by 100 mg SD qillur.^{3,6}

Amulticantar, randomized, double-blind, PBOcontrolled, treat-through study of TREMEYA® in adults with moderately to severely active UC-8: rudoquite responso/intolerance to advirscod



20 30

Study design: The study (N=410), condensional patients tt1 to receive TREMEYS? 400 mg SC q4w for 12 weeks. tien 200 mg SD q/lw, 100 mg SD qfile, or placebo SD.^{3,4}

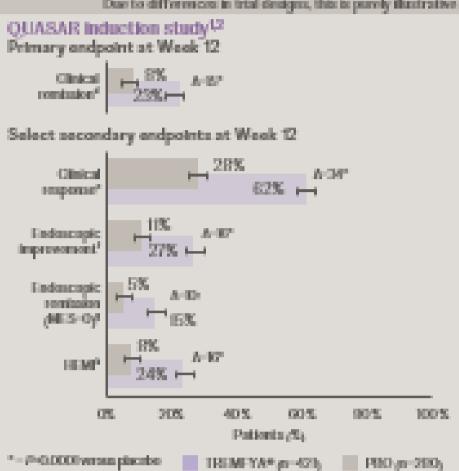
Rinaciae criteria: Placebo non-emponders were switched to a reacter treatment of TREMEYA® 400 mg SC q4w for

of patients had prior tradequate. CONTRACTOR OF Intokuranca to automosed therap (TMFbs, VDZ, JAVO) or STREET,

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

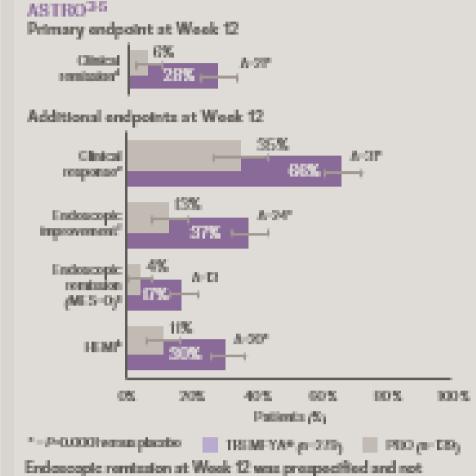


Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.



Nominal P-0.0001 versus piacaba. Endpoints were not adjusted for multiple

comparisons, therefore, statistical significance has not been established.



controlled for multiplicity. No statistical significance can be made.

QUASAR: Clinical response at Week 12 or Week 24

Cumulative clinical response

TREMFYA® 200 mg IV → TREMFYA® 200 mg SC^c

TREMFYA® 200 mg IV

Clinical response at Week 12¹

Δ=34%

P<0.0001a

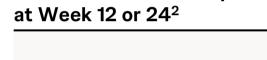
Proportion (95% CI) of patients (%)

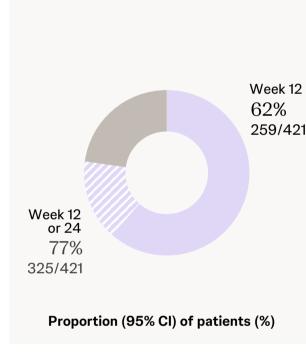
28%

78/280

Clinical response at Week 242 Among Week 12 clinical nonresponders

to TREMFYA® IV induction who received additional TREMFYA® SC treatment^b 55% 66/120 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.

^aAdjusted 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). 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. 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.

i realment-emergent adverse events at –1 year from the QUASAR trial in UC

62%

259/421

Induction study (Week 12) THE RESERVE 200 mg/V q-fw PROW y/w Patients treated my 2590 Average follow-up 12.2 prooks, 2 (25) 1/0.252/Departmen Patients with one or more $n(X)_p$ 200 (40%) All in 1281 (499%) $200 \pm 120 \pm$ 12 (21%) Serious Alia. Alia leading to $\equiv_{\xi}48\eta$ $T_i(22k_i)$ discontinuation Infections^{CN} 40 (65%) Serious infections³ 1/0.4%) Maintenance study (Week 4-4) TREMEYA# THE RESIDENCE PRO 50 (TREMEYAM 100 mg 200 mg SD q4w withdrawnly SGI qilbar Patients treated psy INC. III O 190 Average follow-up 24.0 400.55 200.2 wooks, σ. 0 Depaths Patients with one or more $\mu(X)$ THE PERSON. DOMESTA. EEE (POSS) Sertious AFa: D (OK) $1/m_0$ is green Alia leading to $m_0 m_0$ 7 (4%) $s_i c s_j$ discontinuation infections 57% 509 (327%) GCI (CEPE) 50 (200) Serious Infections? 1/88g2(15)For additional safety information, please use TREMEYA® preacribing re considerations for TREMFYA#: Select ongoi

the ASTRO trial in UC Through Wook: 12³

i realment-emergent adverse events at -1 year from

	PBO SCI		1183MF3 4000 mg	yye g SG q-fw
Patients treated ps	139		200	
Average follow-up (wooks)	17.2		10.23	
Doutha	1/0.7%/*		0	
Patients with one or mo				
AEs Serious AEs	73 (57.5%) 11 (19%)		T (2.22	2.4%) E)
All's leading to discontinuation	= (5.07%)		3 (LB	
Infections Serious Infections	20 (20.HS) 0		47 (E) 2(0.1)	TE ₀
	Week 12 through	gh to We	elk edil ^k	
		1185MF 400 mg q4w →	50 00 mg	THEMFYA* 400 mg 50 q4w → 200 mg
	PBO SG ¹	SC qilte	_	SC q-tw
Pationis treated pay	136	T202		140
Average follow-up prooksy	18.6	34.4		33.1
Douths	0	1(0.7%)		0
Patients with one or mo	ro _z n(X) ₂		_	NOT THE REAL
Alia Nobel III	61/4026	94 (98.)		95 (67.9%)
Sorious AEs AEs loading to	17 (0.0%)	4,0.9%	_	7 (5.0%)
discontinuation	H (5.0%)	6(4.35)	1	2 (14%)
Infections	26 (89.8%)	42,(213	59	40,/20.0%
Serious Infections	2 (15%)*	0	_	2 (D4E)*
on <u>her</u> p.				
course 12 desiration les 11M2				

QUASAR Jr. Granikumab for podatric participants with moderately to sewerely active UC Fire surferly and officercy of the innertispolitimal asset of this precised home not be necleic regions.

There is the generation that the investigational cost third will be filled with credit approved for martisting by the FDA Return to first page

For more information on ongoing trials, go to <u>Clinicafficials.gov</u>. For additional information, please see TREMEYA® Prescribing information <u>her</u>e.

Manhestirly in several parties IC defined as instation baseline condition Magazines of 10 in 8 with a Magazinetical parties or a Land a Magazinetic advance of 2 based on certain eview. Wherein

resource requesters at Work 25, are the planets recomposites at Work 12 also went on to recoive TRANTA 2021 mg W glue for 12 works and were in all third requires to TRANTA at Work 24. Policets. From a please 2's manhemized, disable billed, planelse controlled, including nicely after the manufactured a chiral exposure to TECM YES according to the phase 3 matrices accordingly. \$2 min. contaction Magnetical Response automates of Cort Landows International Internation, a Magnetic State of State of Digital Andrew State of S have industrian baseline in the modified Mayor source; compareed foliand frequency, restal blending, and entire any enthroused Mayor source at these the physician's girlind accessored filey (NSX and a 2 paints, with of the surface from hander in the croid blending subscure or according subscure of Star L. Tadioscopic improvements an entire copy subscure of Star Swith on Haldity Windowsopic remissions accentisingly solution of S. \$4.00 unlikely a condition of historiagic improvement and endocogin improvement. Make all courses and conduct access it Fatal analy represented inflantian in a patient anti-preestiming number side fundament. Defined as any Affirmation Med SAA organisation, Indications and indicatations. Anothering address a state of patient in research with TREMETARS. When it is all for amidest. Whetelid library and partner testis. Astronomicals formerlage. Processes and COVID-10. Was soon of appreciatio. All, where of Peri, H.M., historesia complement and recognitive contraction of the process of the Period Complement of th

infantiols; TW / term recents being UC, absentive rolling M.C., vehilorands; W.C., west Cl., W.E., west SE. 1.110 MFAM (Prescribing Information), James of States, No. Horshop, Ph. 2. Public D, et al. Lauret. 2003 (Oxford Str. 3. Preprint Street L., et al. 1933) 2003. Oxfore contains. 2010. A Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street L., et al. 1933) 2003. Oxford Street Lauret MANNE CO. 1930 (Oxford Street Lauret MANN

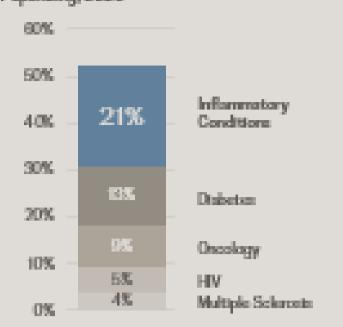
2026. Orall Presentation JOSP ICO. S. Fishin on File January States, Jun. Humbars, Fil. E. Allegeriti J., et al. Presentation ICOM 2023. Hup E-9, 2023. S. Fishin D, et al. Presented at ICOM 2024. May St. 73, 2024. IL QUADALAS METROPOLICA.

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

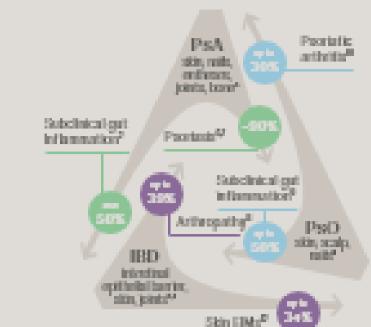
inflammatory conditions have a significant impact on the patient and the United States healthcare system.

immunologic therapies present the highest cost burden for commercial plans

Top 5 therapy classes for commercial plans, by percent of total PMPY spending, 202014



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



These conditions impact many people in the United States

	Prevalence*	Moderate-to-severe disease	Biologic-treated
PsO	7,500,000	20% ^H	58%
PsA	2,250,000 ^{R(Eb}	80%E	62% ⁸⁵
CD	1,011,000/17	58% ^{III}	44% ¹⁰
UC:	1,253,000	40%20	16% 89

Patients with PaO have a 4xhigher prevalence of IBD, with the highest risk in the population with both PaO and PaA21

Psoriatic diseases are complex with high unmet need and costs

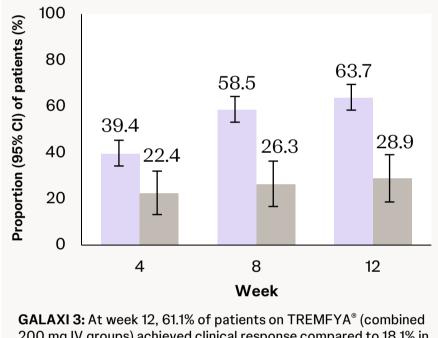
In partients with PsD who develop PsA,

Radiologic damage in

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

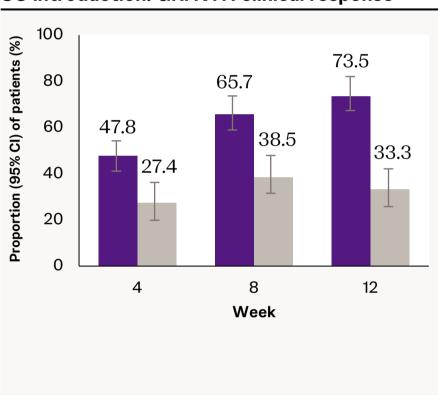
Data originated from separate pivotal trials for the biologic. Due to differences in trial designs, this is purely illustrative and should not be used for direct comparisons between agents.

IV introduction: GALAXI 2 clinical response¹



200 mg IV groups) achieved clinical response compared to 18.1% in the placebo group¹

Placebo (N=76) TREMFYA® 200 mg IV q4w (N=289) SC introduction: GRAVITI clinical response²



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

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.

most sepects of daily life

agreed that symptoms impact



experienced anxiety, depression,

CD direct and indirect coats in the United States:

Guselkumab is

IL-23 inhibitor

the onlyh fully human

dual-acting, selective

designed to neutralize

explicacidels. The obsteal signific of these findings bonds

inflammation at its

cellular source³³⁻³⁸

TREMFYA® is an IL-23I indicated for the treatment of adults with $^{22al}9$.



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





Active popriatic arthritis





Moderately to severely active elementive colities







Moderately to severely active Croke's disease



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

300 minits with BCD in the Obtained Distinct on MyConference Collision was APPEND AND desired for malaboration to severe plangua PAC and antice Path SECong SC at Weeks Coard 4, and after Weeks O. A. and D. entiriorance ECO on SC at Week III and after the order OF 200 on III and after the continue the language to contain the specific requires. Protectioned Evaluations Prior in Infliciting is entraced with TELMCYSP, contact a patients for informations/TEL infraction, obtain few exceptors and inflicities levels, and complete of age appropriate constructions according to our ent inconstruction guideless. Monitoring Monitor potents for algorithms of sortion TE during and of the treatment with TEEM TAX For the treatment of CCC in CCC, most or less express and littration banks for at least 10 works of treatment, and periodically the molecular countries patient examplement. THE NP NAV is intended for one make the gathern and represent of a feed flower professional. THESP NAV encycles substitutes of by a feed flower professional, or a partiest for region may bejon it for proper training in automateurs as injection technique. WHESP NAV in also indicated for products patients of yours also weight it beat. 40 blog was able confer to severe pluque PGC who are carefulness for systemic through or plants the upg and profesion patients of yours. who weigh at least 4.0 tilegeness with active Po.A. PCHy* Based on approved 1. 22 tribitions for active Police moderately to severely active SC as at Engineelee 2020.

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1. Forevar B. Torod by plantings. Assessment Database 26, 2024. https://www.evenurith.com/drag forest report firmed by plantings. 2. Salam 43. J Houseachi Tappi. 2020;04, 22-21. 3. Lexico 43., et al. Continued Continued Special N 15 2015 (Sp. 2015 241, 4 Matrice of print in 2015 Special 2015 Sp. 2015 2003/05/05/05/05 (ID. 7. Persington 20, et al. Part Most Engagemy). 2023/05/2044. E. Archer 21., et al. Care For Manustrated Most 2013/05/2014. E. Navador 88, et al. Care Form Says. 2013/05/14. E. AREA December 2020, (ESQS) 1-7. In Marrier A, et al. J. Am Anna December 2020, (ESQS) 2020, To Date on Sile. Assesses Biotech, Inc. 10. Enterough A, et al. Chital Managemental, pp. 2020, 2020, 12. Leafur J., et al. Conference Supplier Sept. 1-6. M. Harrow A, et al. J. Markhous. 2023 (2018) 600-160. M. Vall, et al. Allerent Pharmacol Day. 2018; (2) (2018) 700-200. Sept. 20. Colore S, et al. J. Markhous. 70% (10%) 517 416. 71. Equippe H, et al. influence flower/tim. 2013; 20(2) 1100 5100. 71. Enhanced?, et al. J. of Moran. 2023; 20(3) 504 504 5.71. Laborati 16, et al. Dono Thre. 2022 (2013) 11. 24. William tal.i., et al Re-Afterward 2000/EGQ 1681-1681-26. Exercises, et al Joseph Missessind 1983/EACH 20. 76: Test J. Missessind 2000/ACH 20. 77. Mint W. et al. (Researchings/Stefans). 2002/ACH 20. 77. 28. Ye Y, et al. Inflorm Board Dr. 2019;20;618-619. 28. The Code's B Colds Foundation of America. The Social Inflormationy Second Absonute. Updated Recorder 2019. Accompand February 20, 2024. https://www.contention.com/documents/action.com/doc SECREPARTMENT OF STREET AND A complete production of the state of the This Louise E., et al. Allowed Pharmonol Pharmon