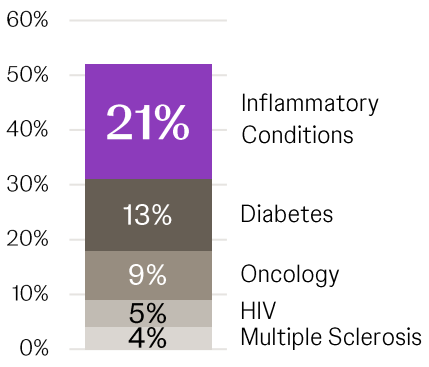
EVIDENCE & VALUE SUMMARY: TREMFYA® (guselkumab)

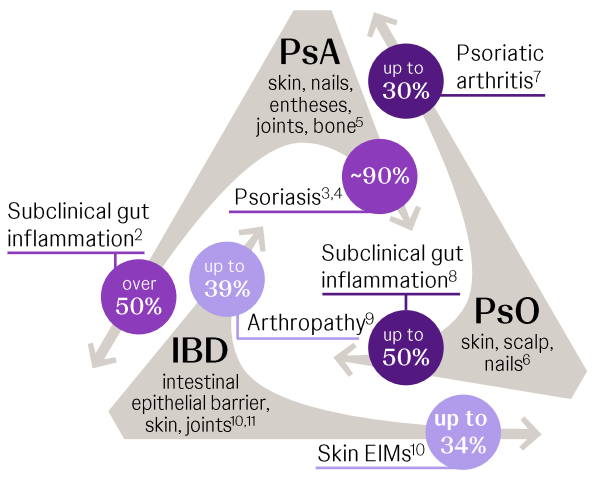
Inflammatory conditions have a significant impact on the patient and healthcare system

Immunologic therapies present the highest cost burden for commercial plans

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



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



Psoriatic diseases are complex with high unmet need and costs

In a Survey of Patients With PsO and/or PsA[12]:

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

52% screened positive for potential major depressive disorder

In a Survey of Patients With PsO and/or PsA[13-16]:

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

Among employed **16-39%** experience work disability

22-23% Unemployed

TREMFYA® is an IL-23i indicated for the treatment of adults with[17b]:

- Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis

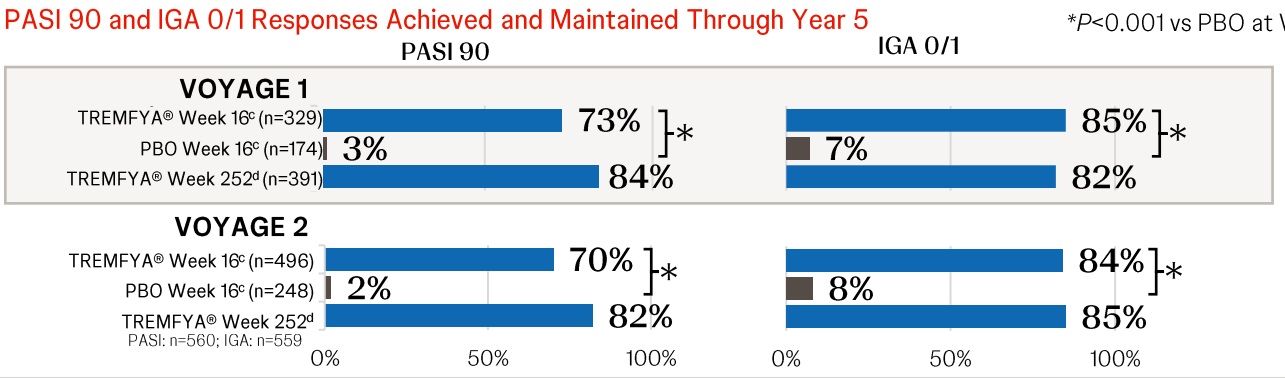
TREMFYA® has established safety and efficacy for adult patients with moderate to severe plaque PsO and active PsA

Moderate to Severe Plaque PsO[17-21]

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.[b]

PASI 90 and IGA 0/1 Responses Achieved and Maintained Through Year 5

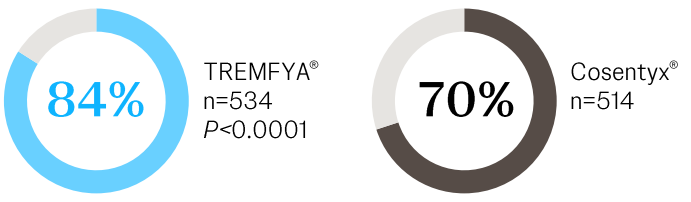
*$P<0.001$ vs PBO at Week 16



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.[21e]

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

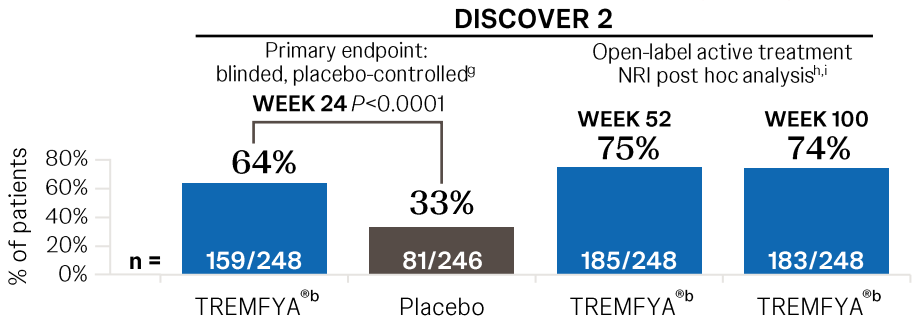
There were no new safety findings observed for either TREMFYA® or Cosentyx® in this study.[21]



Active PsA[17, 22-23]

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.[b]

Patients had Continuous Overall Improvement in Joint Response (ACR20) Rates Through 2 Years in DISCOVER 2[f]



DISCOVER 1

ACR20 response rates for TREMFYA® 100mg q8w vs placebo[17,24]:

- 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 5 years in moderate to severe plaque PsO and 2 years in active PsA

Selected Safety Profile[17, 22, 25]

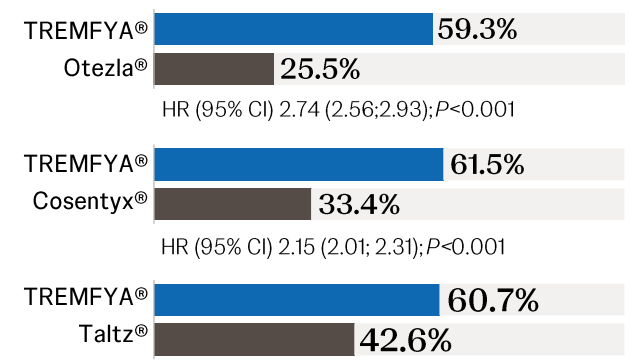
Safety Results from VOYAGE Trials (PsO) and DISCOVER Trials (PsA)

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

		Adverse Events		Serious Adverse Events		Infections		Serious Infections	
		TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo	TREMFYA®	Placebo
PsO	**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]
PsO	**Year 5,** events/100 PYs of follow-up, n=1721[j]	149.4	--	5.0	--	60.6	--	0.9	--
PsA	**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]
PsA	**Year 2,** events/100 PYs of follow-up, n=248[k]	158.0	--	6.1	--	40.5	--	2.2	--

TREMFYA® has demonstrated real-world persistence in PsO and PsA

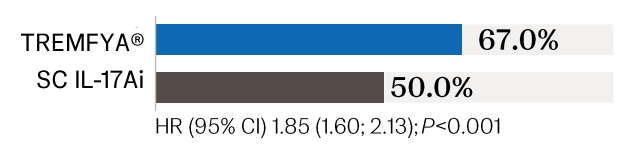
Kaplan-Meier persistence probability among patients with moderate to severe plaque PsO at 18 months[26-27l]



Among patients with PsO, TREMFYA® was **~3× more persistent** than Otezla® (apremilast) and **~2× more persistent** than Cosentyx® (secukinumab) and Taltz® (ixekizumab) at 18 months.

Based on a real-world study of IBM® MarketScan®-USA data in the United States.

Weighted Kaplan-Meier persistence probability among patients with active PsA at 12 months[28m,n]



Among patients with PsA, TREMFYA® was **~2× more persistent** than subcutaneous IL-17Ai inhibitors, including Cosentyx® and Taltz®.

Based on a real-world study of IQVIA® Health Plan Claims data in the United States.

Future considerations for TREMFYA®: select ongoing phase 3 and 4 trials

Plaque PsO

VISIBLE: Adults with skin of color, moderate-to-severe plaque PsO, and/or scalp PsO[29]
SPECTREM: Adults with bio-naïve, low BSA moderate plaque PsO and special site involvement[30]

Active PsA

APEX: Adults who are bio-naïve with active PsA and inhibiting radiographic progression[31]
STAR: Adults who are bio-naïve with active PsA axial disease[32]
SOLSTICE: Adults with active PsA and inadequate response or intolerance to a prior anti-TNFα[33]

Moderately to severely active IBD

GALAXI and GRAVITI: Adults with CD[34,35]
QUASAR and ASTRO: Adults with UC[36,37]

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

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

[a]In the United States. [b]TREMFYA® Dosing: 100 mg administered subcutaneously at Week 0, 4, and q8w thereafter. [c]Nonresponder imputation. [d]Data from an open-label extension. Treatment failure rules. Includes patients who crossed over from placebo to receive GUS at Week 16. [e]Intent-to-treat population. [f]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. [g]Patients with missing data were considered nonresponders. [h]The same patients may not have responded at each time point. [i]After Week 24, the study was open label with blinded dosing interval, which may have affected results. [j]Includes all patients exposed to TREMFYA® in VOYAGE 1 and VOYAGE 2. [k]DISCOVER 2 only. [l]Results may not be generalized to the uninsured or patients with noncommercial insurance. Prescription fills do not account for whether medication was taken. Results may be subject to residual confounding. [m]Results may not be generalized to the uninsured or patients with noncommercial insurance. Data do not ensure treatments are taken as prescribed. Claims data do not provide treatment effectiveness or reasons for discontinuation. Days of supply in pharmacy claims data can be inaccurate due to coverage restrictions. Imputation is a valid approach that is often utilized in claims-based analyses but may lead to misclassifications. [n]Primary analysis was conducted based on 2x the FDA maintenance interval between administration per label after induction. TREMFYA® versus SC IL-17Ai compared using weighted Cox proportional hazard models.

ACR, American College of Rheumatology; BSA, body surface area; CD, Crohn's Disease; CI, confidence interval; EIM, extraintestinal manifestations; FDA, Food and Drug Administration; GUS, guselkumab; HIV, human immunodeficiency virus; HR, hazard ratio; IBD, inflammatory bowel disease; IGA, investigator global assessment; IL-23i, interleukin-23 inhibitor; MetS, metabolic syndrome; NRI, non responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; PMPY, per-member-per-year; PsA, psoriatic arthritis; PsO, psoriasis; PYs, patient-years; q8w, every 8 weeks; SC, subcutaneous; SC IL-17Ai, subcutaneous interleukin-17A inhibitor; UC, ulcerative colitis.

1. Evernorth. Trend by plan type. Accessed July 6, 2023. https://www.evernorth.com/drug-trend-report/trend-by-plan-type. 2. Scher J, et al. *J Rheum Suppl.* 2018;94:32-35. 3. Pennington SR, et al. *Front Med (Lausanne).* 2021;8:723944. 4. Ciocon D, Kimball A. *Br J Dermatol.* 2007;157(5):850-860. 5. Suzuki E, et al. *Autoimmunity Rev.* 2014;13:496-502. 6. Lowes M, et al. *Annu Rev Immunol.* 2014;32:227-255. 7. Mease P, et al. *J Am Acad Dermatol.* 2013;69(5):729-735. 8. Sanchez I, et al. *Curr Dermatol Rep.* 2018;7(1):59-74. 9. Arvikar S, et al. *Curr Rev Musculoskel Med.* 2011;4(3):123-131. 10. Levine J, et al. *Gastroenterol Hepatol.* 2011;7:235-241. 11. Matricon J, et al. *Self/NonSelf.* 2010;1:299-309. 12. Lebwohl M, et al. *Derm Ther.* 2022; 12:61-78. 13. Villacorta R, et al. *Br J Dermatol.* 2020; 183(3): 548–558. 14. Kaarela K, et al. *Scand J Rheumatol* 1987;16:4036. 15. Zhu T, et al. *J Rheumatol.* 2010; 37:121420. 16. Tillett W, et al. *Rheumatology* (Oxford). 2012;51(2):275-283. 17. TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 18. VOYAGE 1 NCT02207231. 19. VOYAGE 2 NCT02207244. 20. Reich K, et al. *Br J Dermatol.* 2021; 1087-1088. 21. Reich K, et al. *Lancet.* 2019;394(10201):831-839. 22. McInnes I, et al. *Arthritis Rheumatol.* 2022;74(3):475-485. 23. Mease P, et al. *Lancet.* 2020; 395:1126-1136. 24. Ritchlin C, et al. *RMD Open.* 2021;7(1):e001457. 25. Data on file. Janssen Biotech, Inc. 26. Fitzgerald T, et al. Poster presented at: 2022 Fall Clinical Dermatology Conference, October 20-23 2022, Las Vegas, NV. 27. Zhdanava M, et al. Poster presented at: 2022 Fall Clinical Dermatology Conference, October 20-23, 2022, Las Vegas, NV. 28. Walsh J, et al. Poster Presented at: 2023 Congress of Clinical Rheumatology West, September 7-10, 2023, San Diego, CA. 29. VISIBLE NCT05272150. 30. SPECTREM NCT06039189. 31. APEX NCT04882098. 32. STAR NCT04929210. 33. SOLSTICE NCT04936308. 34. GALAXI NCT03466411. 35. GRAVITI NCT05197049. 36. QUASAR NCT04033445. 37. ASTRO NCT05528510.

Johnson&Johnson

US-SFM-6123 04/24