Tremfya® (guselkumab)

Long-term data through Week 48 now available

VISIBLE results across all skin tones*

A first-of-its kind study to measure clearance objectively across all skin tones[1-4]*

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).

See pivotal trial data on pages 2 and 3

INDICATION

TREMFYA® is indicated for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

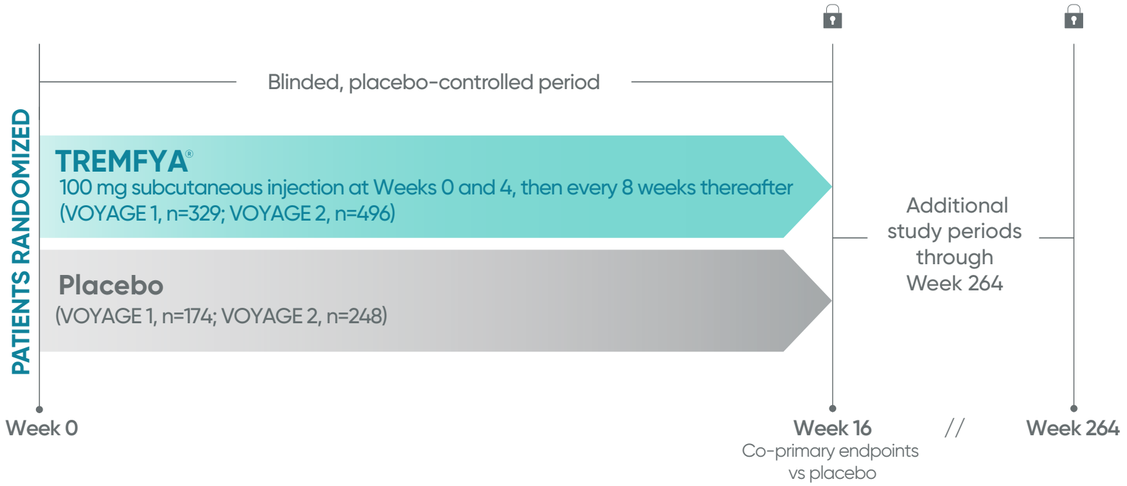
SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis before treating with TREMFYA®. Avoid use of live vaccines in patients treated with TREMFYA®. Please see related and other Important Safety Information on page 25.

VISIBLE™

VOYAGE 1 and VOYAGE 2—two pivotal, phase 3, multicenter, double-blind trials of TREMFYA®

VOYAGE 1 (n=837) and VOYAGE 2 (n=992)[5-9]



Abbreviated study design in graphic. Active-comparator arm is not shown.

In VOYAGE 1, patients continued TREMFYA® every 8 weeks through Week 48 and there was an active comparator-controlled period from Week 0 through Week 48. Patients initially randomized to active comparator entered a washout period after their final dose at Week 47 and entered open-label TREMFYA® from Week 52-252. VOYAGE 2 incorporated a randomized withdrawal and re-treatment from Week 28-72, followed by open-label TREMFYA® from Week 76-252.

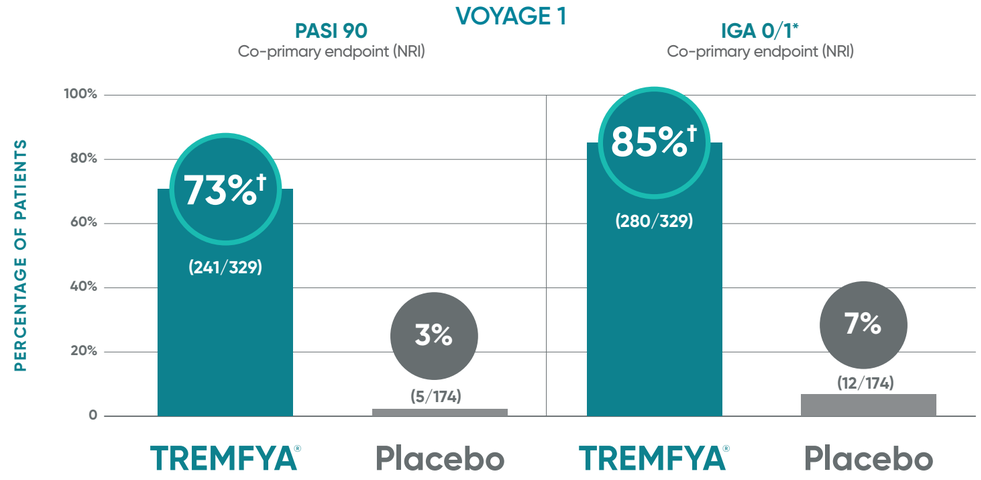
Patient eligibility[5-9]

- ≥18 years of age
- Moderate to severe plaque psoriasis (IGA score ≥3; PASI score ≥12; BSA involvement ≥10%) for ≥6 months
- Candidates for phototherapy and/or systemic treatment

Co-primary endpoints: PASI 90 and IGA 0/1 at Week 16.[6,7] ss-IGA was also evaluated at Week 16 (among ss-IGA ≥2 at baseline).

🔒=database lock.

VOYAGE 1 and VOYAGE 2 co-primary endpoints at Week 16[5-7]



In VOYAGE 2 at Week 16 (co-primary endpoints, NRI)[5,7]:
- 70% (347/496) of patients taking TREMFYA® achieved PASI 90 vs 2% (6/248) of patients taking placebo; *P*<0.001
- 84% (417/496) of patients taking TREMFYA® achieved IGA 0/1 vs 8% (21/248) of patients taking placebo; *P*<0.001

In VOYAGE 1 and VOYAGE 2 at Week 24 (major secondary endpoint, NRI)[5-7‡]:
- 53% (61/115) of patients in VOYAGE 1 and 48% (76/160) of patients in VOYAGE 2 achieved IGA 0

An improvement was seen in psoriasis involving the scalp in patients randomized to TREMFYA® compared to placebo at Week 16.[5]

In VOYAGE 1 at Week 48 (major secondary endpoints, NRI)[2,5,6‡]:
- 73% (84/115) of patients taking TREMFYA® achieved PASI 90
- 79% (91/115) of patients taking TREMFYA® achieved IGA 0/1
- 47% (54/115) of patients taking TREMFYA® achieved IGA 0

*IGA=Investigator's Global Assessment, IGA score of cleared (0) or minimal (1) using a 5-point scale of overall disease severity.
†*P*<0.001 vs placebo.
‡Results from **North American** sites only, which used a US-licensed active comparator. Active-comparator data not shown.

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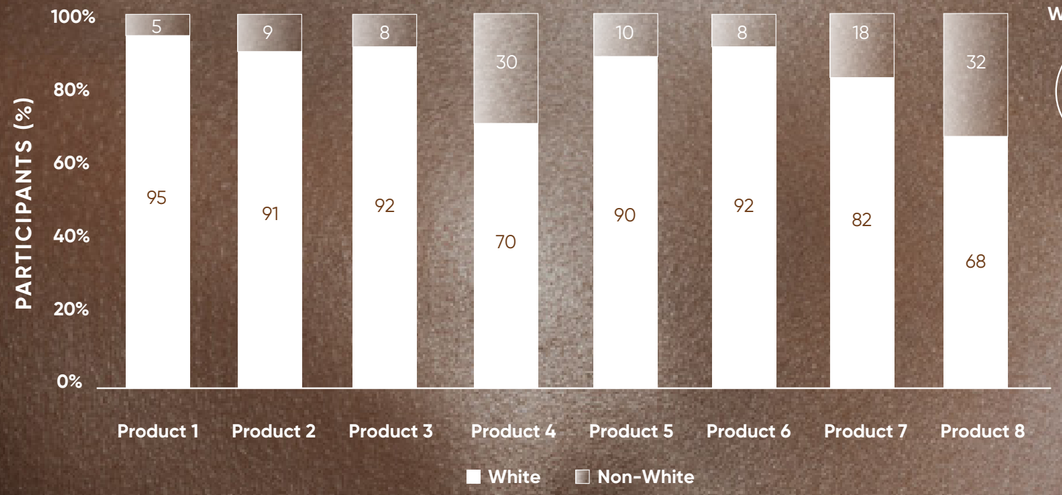
Tremfya® (guselkumab)

Minority representation has been less than ~30% in PsO biologic trials[10]

Participants in select industry-sponsored PsO biologic trials[10]



Disease prevalence of PsO in non-Hispanic White patients

78%[11]

Underrepresentation in clinical trials may help to explain challenges facing patients with skin of color.

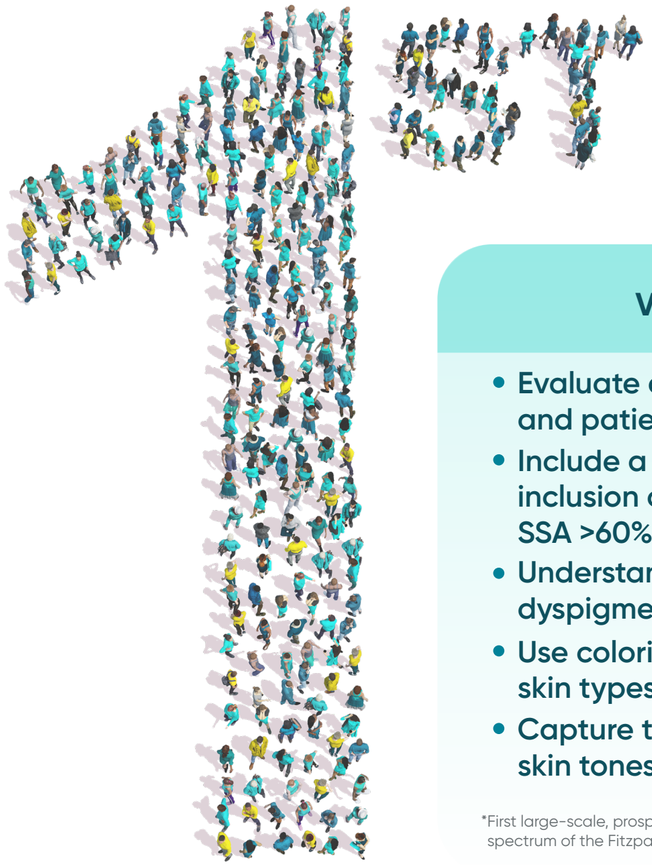
Factors that may impact patients with skin of color

Wait 3x
longer for final PsO diagnosis[12]

4x
more likely to require a biopsy to confirm PsO diagnosis[12]

Dark skin ranged from
4–19%
of images in dermatology textbooks[13–15]

Further investment in research and clinical study efforts will be key to closing these education gaps and may improve diagnosis and care.



IN MODERATE TO SEVERE PLAQUE PsO

First-of-its-kind study dedicated to patients across all skin tones[1,2]*

VISIBLE was designed to[1,2]:

- Evaluate efficacy and safety using clinical and patient-reported outcomes
- Include a dedicated scalp cohort with an inclusion criteria of SSA >30% (a mean baseline SSA >60% was observed)
- Understand post-inflammatory dyspigmentation and early diagnosis of PsA
- Use colorimetry devices to assess Fitzpatrick skin types
- Capture thousands of images across all skin tones

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis before treating with TREMFYA®. Avoid use of live vaccines in patients treated with TREMFYA®. Please see related and other Important Safety Information on page 25.

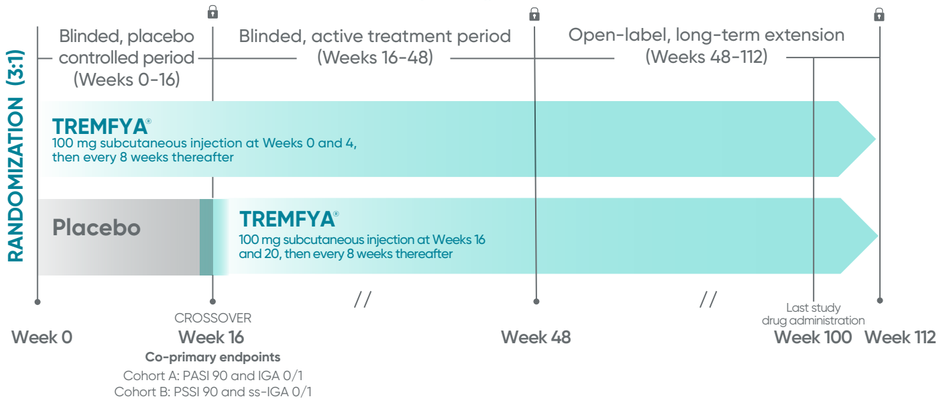
Tremfya® (guselkumab)

IN MODERATE TO SEVERE PLAQUE PsO

VISIBLE was uniquely designed for a diverse patient population[1-4]

VISIBLE is an ongoing phase 3b, multicenter, randomized, double-blind, placebo-controlled study

VISIBLE study design (n=211)



Selected inclusion criteria[1,2]

- ≥18 years of age
- Adults enrolled in VISIBLE self-identified as non-White
- Patients with all Fitzpatrick skin types I-VI* were eligible for enrollment in both cohorts (>50% of patients enrolled were Fitzpatrick skin type IV-VI)
- **Cohort A**: moderate to severe body plaque PsO (BSA ≥10%, PASI ≥12, and IGA ≥3)
- **Cohort B**: moderate to severe scalp PsO (SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 PsO plaque outside of scalp)
- Biologic-naïve and -experienced patients included

🔒=database lock.
*Fitzpatrick skin type was assessed by colorimetry.

VISIBLE™

> **Thanks to the thoughtful design of the VISIBLE trial, we now have clinical data and patient imagery that reflects our diverse patient populations.**
>
> -Andrew F. Alexis, MD, MPH, FAAD

VISIBLE focused on diverse patients across the Fitzpatrick scale[2]*

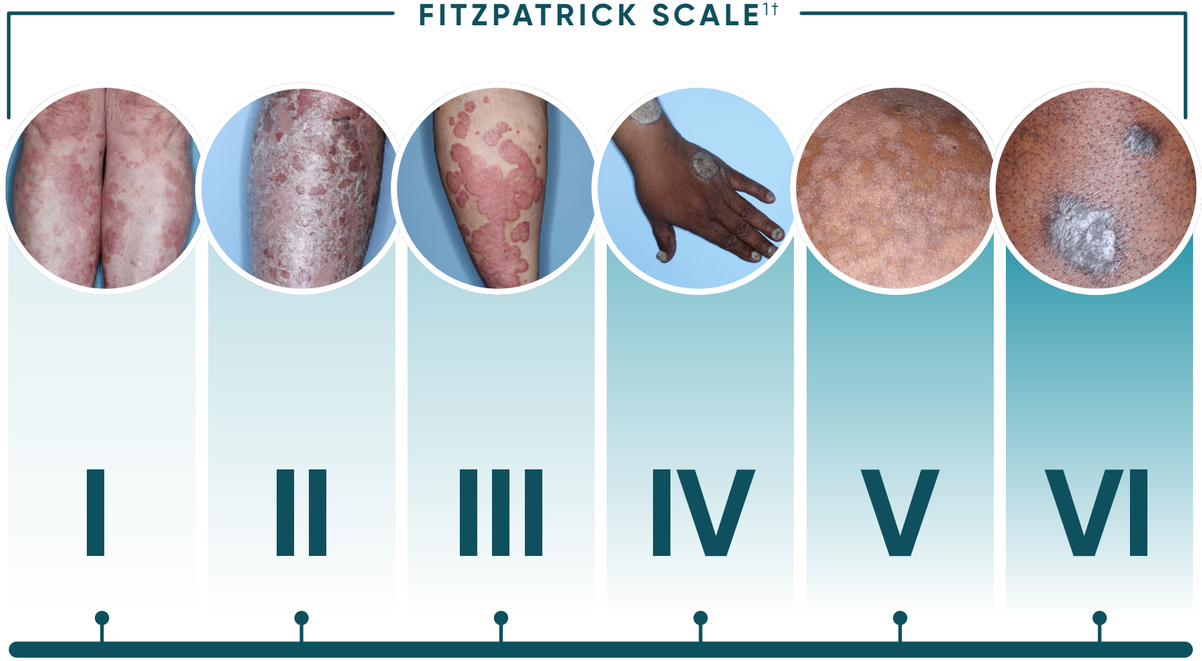
Self-identified racial and ethnicity categories and colorimeter determined FST (I-VI) in Cohort A and Cohort B (n=211)

	I	II	III	IV	V	VI
African-American/Black (n=23)						
African Indian or Alaska Native (n=1)						
Asian (n=63)						
East Asian (n=14)						
Filipino (n=7)						
South Asian (n=22)						
Southeast Asian (n=20)						
Non-White Hispanic/Latino (n=94)						
Central American (n=9)						
Cuban (n=13)						
Mexican (n=50)						
Puerto Rican (n=5)						
South American (n=15)						
Middle Eastern (n=13)						
Native Hawaiian or Pacific Islander (n=1)						
Multiracial (n=12)						
Other (n=4)						

FST=Fitzpatrick skin type.

*Fitzpatrick skin type was assessed by colorimetry.

We are striving to build the largest library of PsO patient images across all skin tones*



Baseline patient photos from the VISIBLE study.

Images are Janssen-owned from blinded trial: NCT05272150.

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Fitzpatrick skin type was assessed by colorimetry.

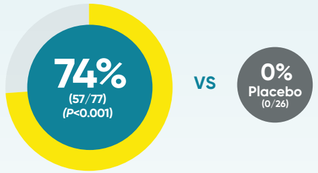
Cohort A

IN MODERATE TO SEVERE PLAQUE PsO

Skin clearance across all skin tones* at Weeks 16 and 48[2,3]

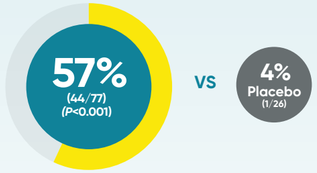
IGA 0/1 and PASI 90 at Weeks 16 and 48 (NRI)

IGA 0/1 at Week 16†



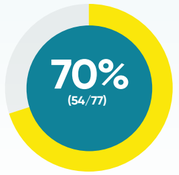
Co-primary endpoint

PASI 90 at Week 16†



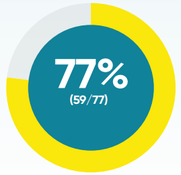
Co-primary endpoint

IGA 0/1 at Week 48‡



Other prespecified endpoint

PASI 90 at Week 48‡



Other prespecified endpoint

Week 48 data were prespecified and not multiplicity controlled. The same patients may not have responded at each time point.

See VISIBLE study design on page 7

NRI=nonresponder imputation.

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
‡Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

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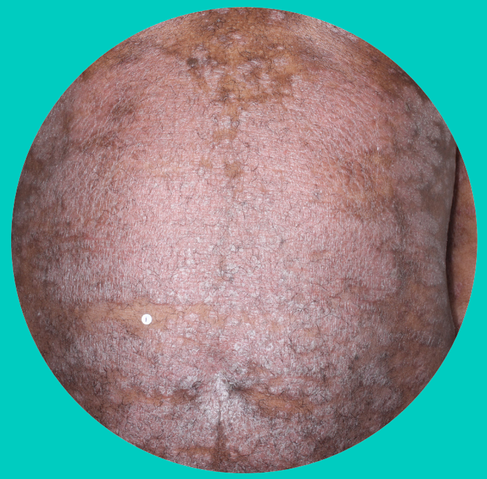
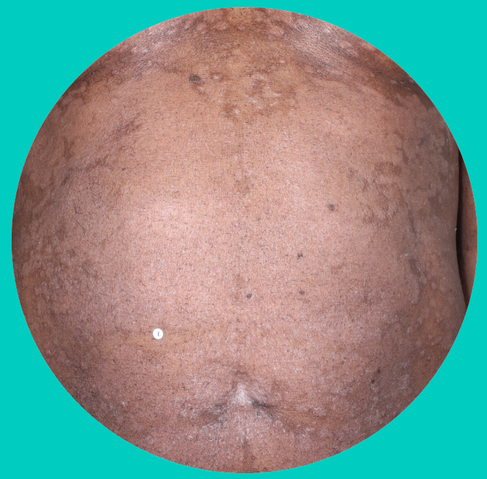
Tremfya® (guselkumab)

WEEK 0



PASI=45.1

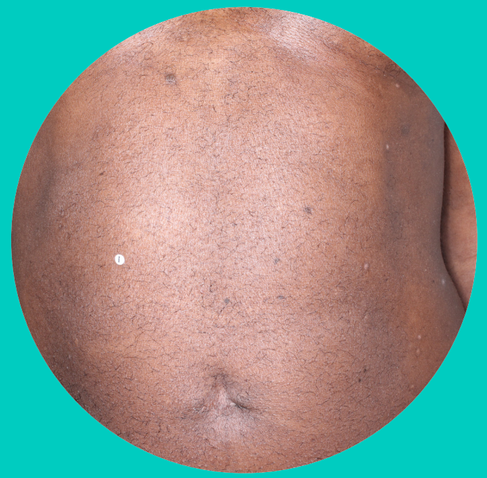
WEEK 4



PASI=21.6

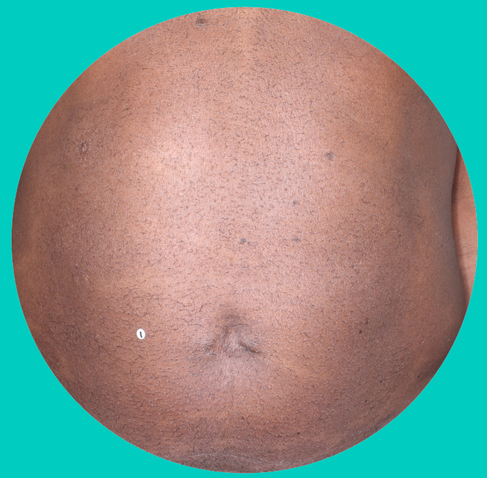
Fitzpatrick VI

WEEK 16



PASI=9.6
(79% PASI improvement)

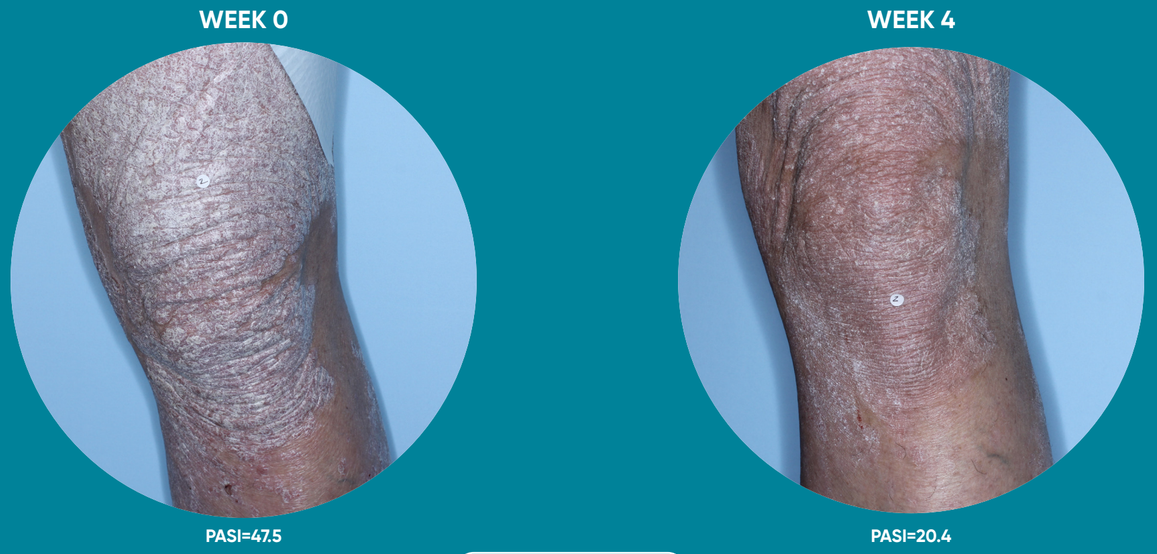
WEEK 48



PASI=3.3
(93% PASI improvement)

Actual patient from the VISIBLE study. Individual results may vary.

Images are Janssen-owned from blinded trial: NCT05272150.

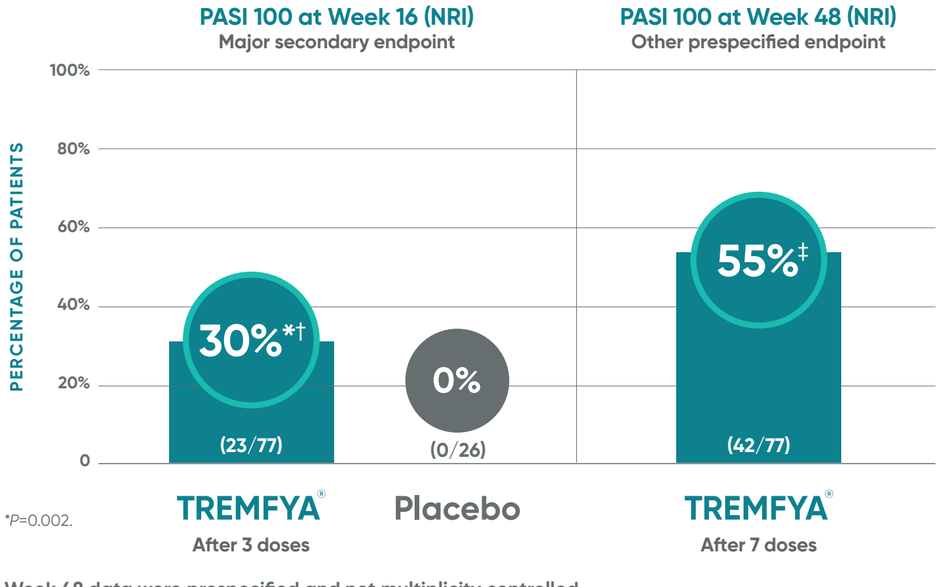


Actual patient from the VISIBLE study. Individual results may vary.

Images are Janssen-owned from blinded trial: NCT05272150.

IN MODERATE TO SEVERE PLAQUE PsO

Complete skin clearance rates after 3 doses and after 7 doses[2,3]



*P=0.002.

Week 48 data were prespecified and not multiplicity controlled.
The same patients may not have responded at each time point.

NRI=nonresponder imputation.

†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
‡Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

See VISIBLE study design on page 7

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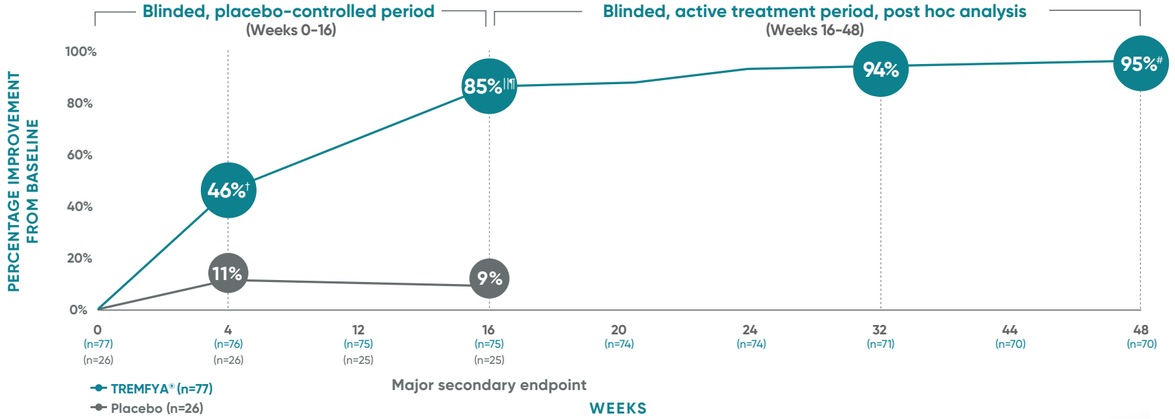
Tremfya® (guselkumab)

IN MODERATE TO SEVERE PLAQUE PsO

Mean PASI improvement from baseline[2]

Mean PASI improvement from baseline at Week 16 and Week 48*‡§



Weeks 16 to 48 are a post hoc analysis; therefore, statistical significance has not been established. The same patients may not have responded at each time point.

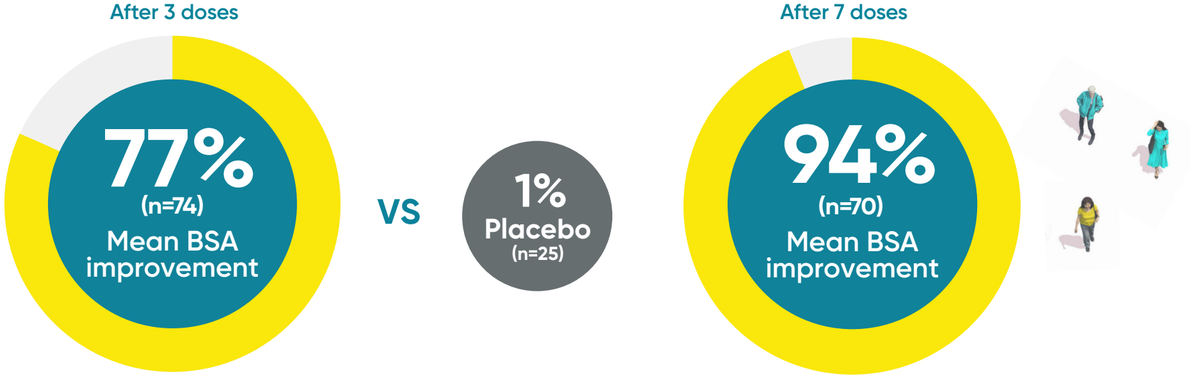
*Mean PASI improvement is an assessment of the average percentage improvement from baseline in psoriatic signs of redness, thickness, scale, and body surface area of involvement.
†**Efficacy measures at Week 4 were prespecified and were not multiplicity controlled. Therefore, *P* values are nominal and no statistical comparisons can be made.**
‡Patients received 100 mg subcutaneous TREMFYA® at Week 0, Week 4, and every 8 weeks thereafter.
§When participants discontinued study agent due to lack of efficacy, worsening of PsO or use of a prohibited PsO treatment, zero change from baseline was assigned from that point onward. Missing data were not imputed.
‖Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
¶*P*<0.001 vs. placebo. *P*-values were based on the mixed-effect model for repeated measures (MMRM).
#Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

See VISIBLE study design on page 7

IN MODERATE TO SEVERE PLAQUE PsO

Mean BSA improvement from baseline[2]

Mean BSA improvement from baseline at Week 16 and Week 48*†



Week 16‡‖
Major secondary endpoint

Week 48§
Other prespecified endpoint

Week 48 data were prespecified and not multiplicity controlled. The same patients may not have responded at each time point.

BSA=body surface area.

*Mean BSA improvement is an assessment of the average percentage improvement from baseline in BSA of involvement.
†When participants discontinued study agent due to lack of efficacy, worsening of PsO or use of a prohibited PsO treatment, zero change from baseline was assigned from that point onward. Missing data were not imputed.
‡Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
§Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.
‖*P*<0.001 vs. placebo. *P*-values were based on the mixed-effect model for repeated measures (MMRM).

See VISIBLE study design on page 7

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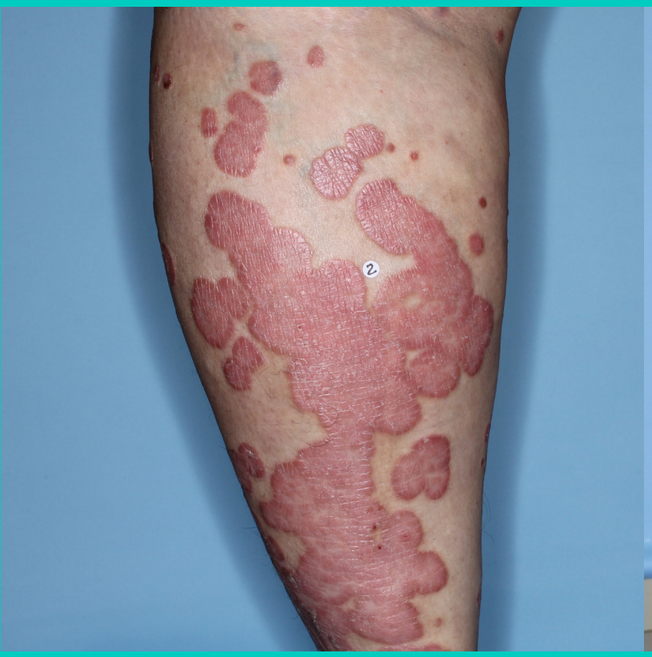
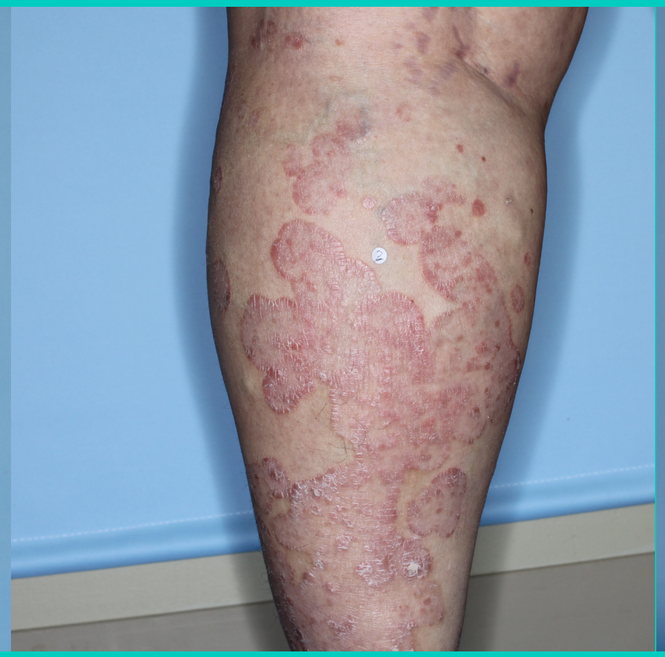
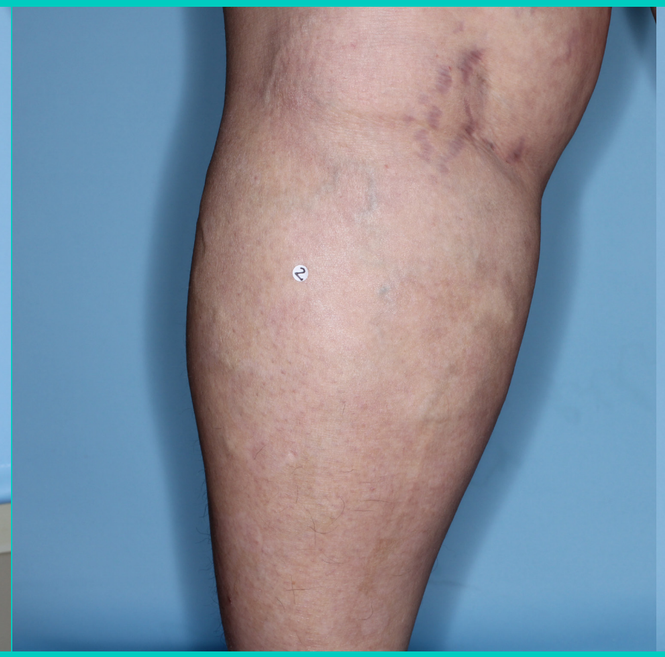
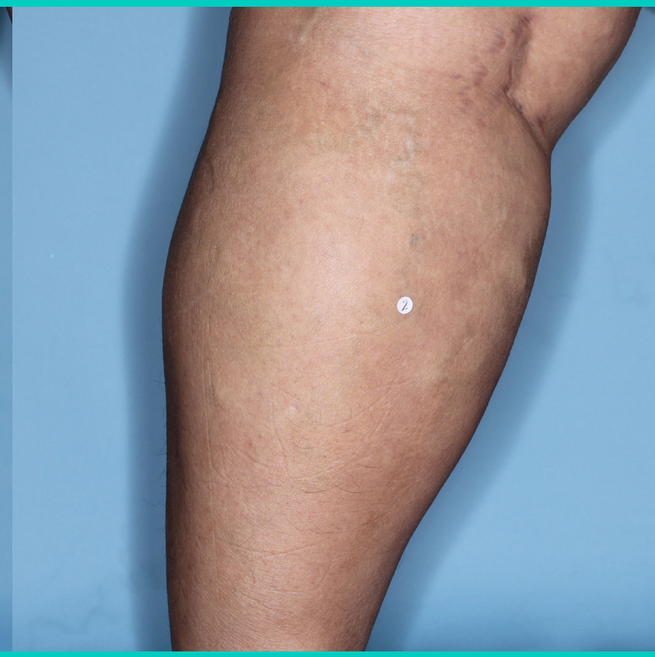
Tremfya® (guselkumab)

Fitzpatrick III

WEEK 0	WEEK 4	WEEK 16	WEEK 48
			
PASI=20.6	**PASI=14.4**	**PASI=2.9 (86% PASI improvement)**	**PASI=1.1 (95% PASI improvement)**

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VISIBLE Cohort A co-primary endpoints at Week 16 (NRI)[2,3*†]:

- PASI 90: TREMFYA® 57% (44/77) vs placebo 4% (1/26) (*P*<0.001)
- IGA 0/1: TREMFYA® 74% (57/77) vs placebo 0% (0/26) (*P*<0.001)

Actual patient from the VISIBLE study. Individual results may vary.
Images are Janssen-owned from blinded trial: NCT05272150.
*Nonresponder imputation (NRI) methods were used for analysis.
†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.

VISIBLE Cohort A other prespecified endpoints at Week 48 (NRI)[2*‡]:

- PASI 90: TREMFYA® 77% (59/77)
- IGA 0/1: TREMFYA® 70% (54/77)

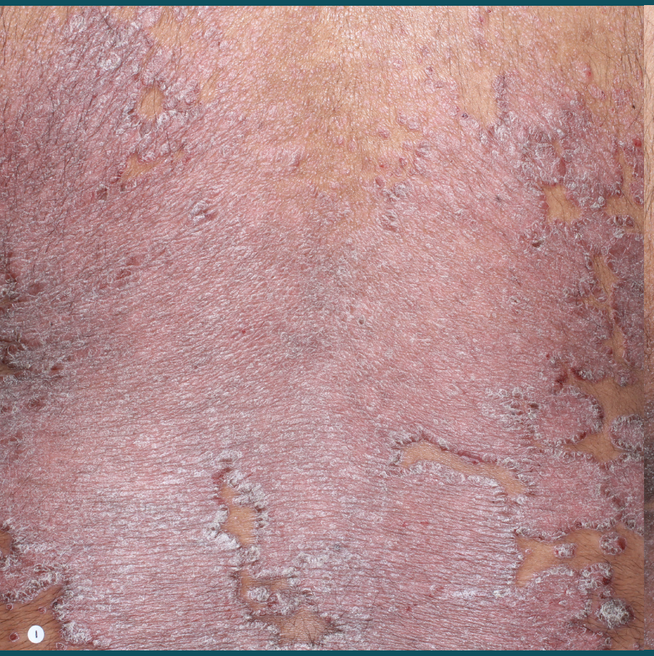
Week 48 data were prespecified and not multiplicity controlled. The same patients may not have responded at each time point.

‡Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

Fitzpatrick IV

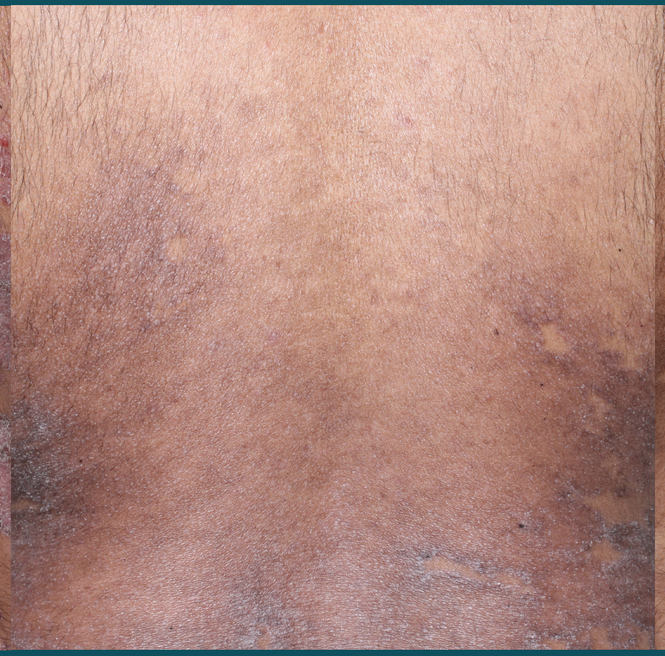
Tremfya® (guselkumab)

WEEK 0



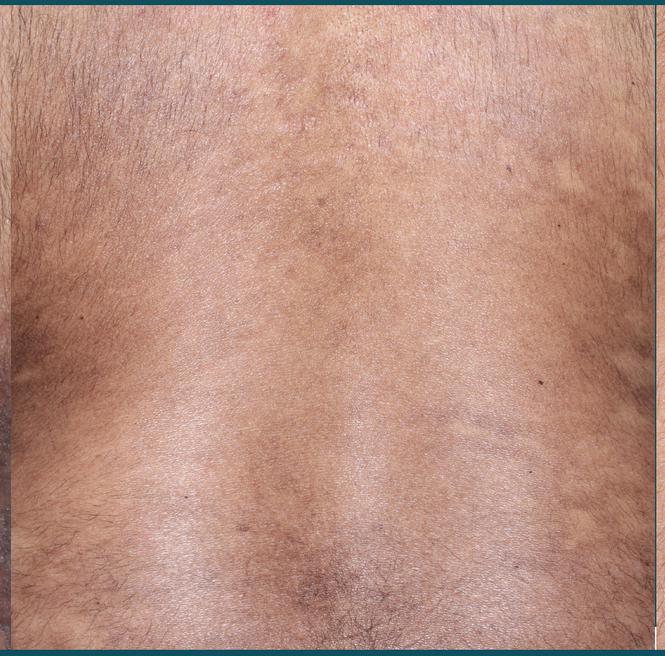
PASI=41.5

WEEK 4



PASI=23.6

WEEK 16



PASI=1.6
(96% PASI improvement)

VISIBLE Cohort A co-primary endpoints at Week 16 (NRI)[2,3*†]:

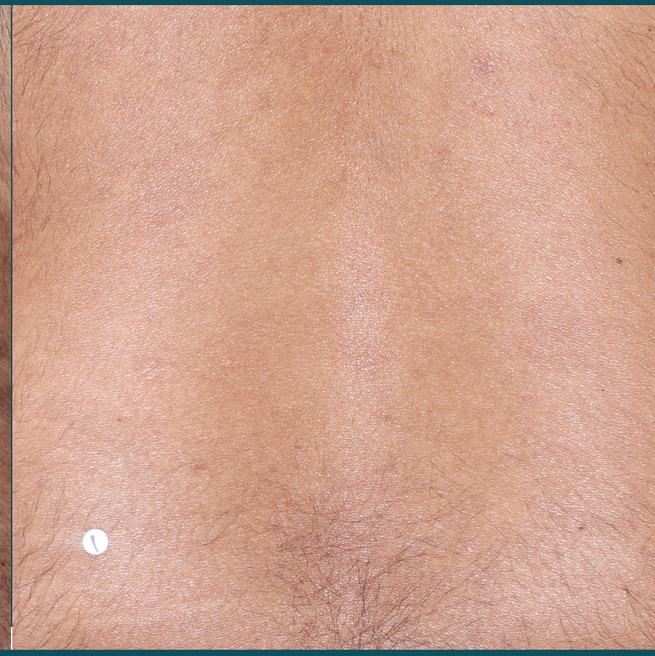
- PASI 90: TREMFYA® 57% (44/77) vs placebo 4% (1/26) (*P*<0.001)
- IGA 0/1: TREMFYA® 74% (57/77) vs placebo 0% (0/26) (*P*<0.001)

VISIBLE Cohort A major secondary endpoint at Week 16 (NRI)[2,3*†]:

- PASI 100: TREMFYA® 30% (23/77) vs placebo 0% (0/26) (*P*=0.002)

Actual patient from the VISIBLE study. Individual results may vary.
Images are Janssen-owned from blinded trial: NCT05272150.
*Nonresponder imputation (NRI) methods were used for analysis.
†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.

WEEK 48



PASI=0
(100% PASI improvement)

VISIBLE Cohort A other prespecified endpoints at Week 48 (NRI)[2*‡]:

- PASI 90: TREMFYA® 77% (59/77)
- IGA 0/1: TREMFYA® 70% (54/77)

VISIBLE Cohort A other prespecified endpoint at Week 48 (NRI)[2*‡]:

- PASI 100: TREMFYA® 55% (42/77)

Week 48 data were prespecified and not multiplicity controlled. The same patients may not have responded at each time point.
‡Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

SELECTED IMPORTANT SAFETY INFORMATION
TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis before treating with TREMFYA®. Avoid use of live vaccines in patients treated with TREMFYA® Please see related and other Important Safety Information on page 25.

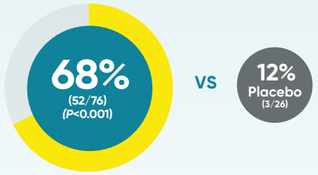
Cohort B

IN MODERATE TO SEVERE PLAQUE PsO

Scalp clearance across all skin tones* at Weeks 16 and 48

ss-IGA 0/1 and PSSI 90 at Weeks 16 and 48 (NRI)

ss-IGA 0/1 at Week 16†

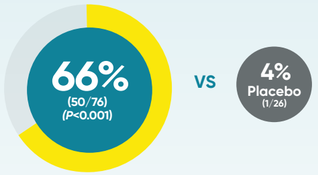


VS

12%
Placebo
(3/26)

Co-primary endpoint

PSSI 90 at Week 16†

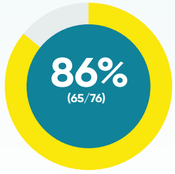


VS

4%
Placebo
(1/26)

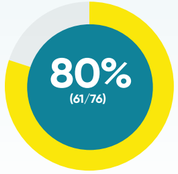
Co-primary endpoint

ss-IGA 0/1 at Week 48‡



Other prespecified endpoint

PSSI 90 at Week 48‡



Other prespecified endpoint

Week 48 data were prespecified and not multiplicity controlled.
The same patients may not have responded at each time point.

See VISIBLE study design on page 7

NRI=nonresponder imputation.

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
‡Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

SELECTED IMPORTANT SAFETY INFORMATION

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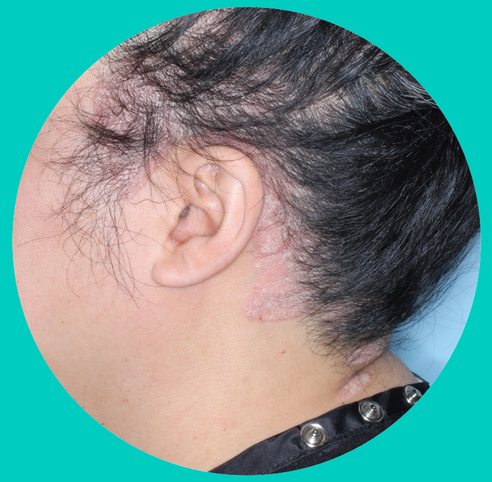
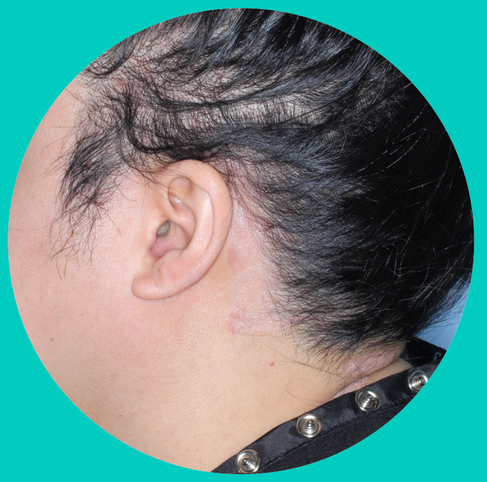
Tremfya® (guselkumab)

WEEK 0



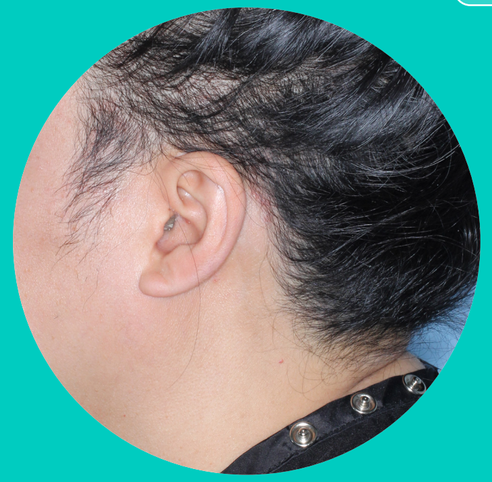
PSSI=60

WEEK 4



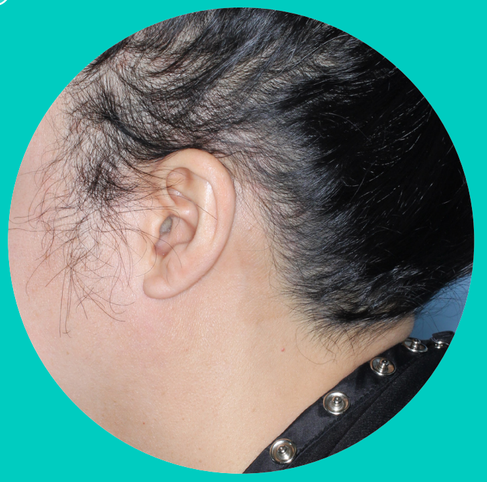
Fitzpatrick III

WEEK 16



PSSI=6
(90% PSSI improvement)

WEEK 48



PSSI=1
(98% PSSI improvement)

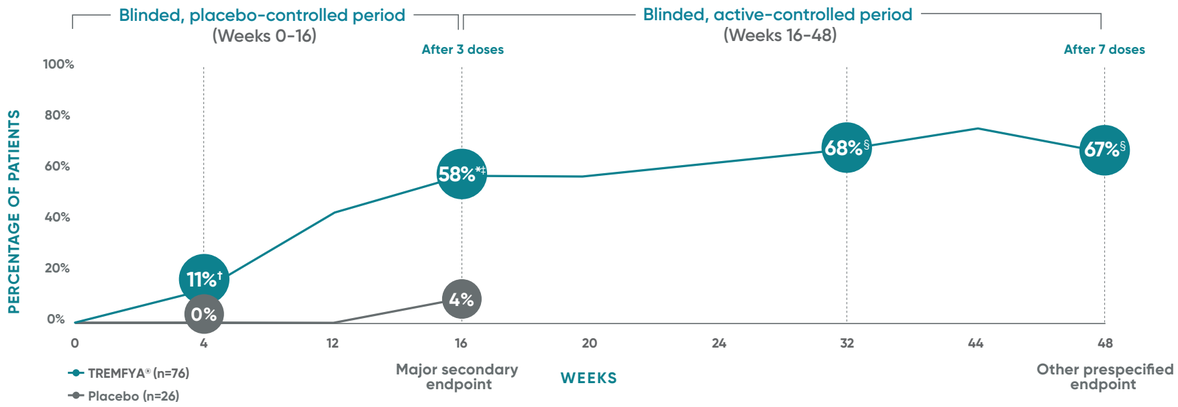
Actual patient from the VISIBLE study. Individual results may vary.

Images are Janssen-owned from blinded trial: NCT05272150.

IN MODERATE TO SEVERE PLAQUE PsO

Complete scalp skin clearance rates after 3 doses and after 7 doses[2,4]

ss-IGA 0 at Week 16 and Week 48 (NRI)



See VISIBLE study design on page 7

Weeks 32 and 48 data were prespecified and not multiplicity controlled. The same patients may not have responded at each time point.

NRI=nonresponder imputation.

*P<0.001.

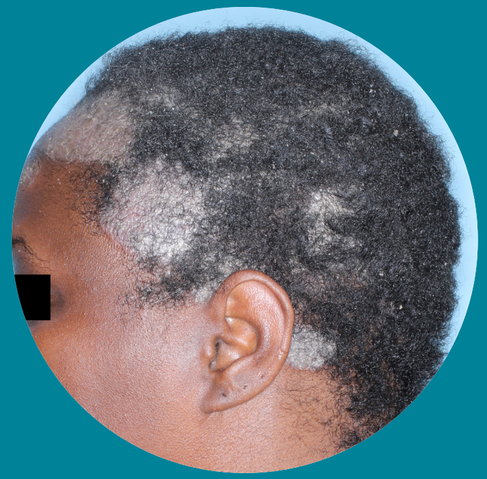
†**Efficacy measures at Week 4 were prespecified and were not multiplicity controlled. Therefore, *P* values are nominal and no statistical comparisons can be made.**

‡Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.

§Week 48 data include patients randomized to TREMFYA® at baseline. Data for placebo crossover patients are not shown.

Cohort B

WEEK 0



PSSI=72

WEEK 4

Fitzpatrick VI

WEEK 16

PSSI=0
(100% PSSI improvement)

WEEK 48

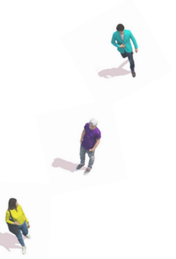
PSSI=0
(100% PSSI improvement)

Actual patient from the VISIBLE study. Individual results may vary.

Images are Janssen-owned from blinded trial: NCT05272150.

IN MODERATE TO SEVERE PLAQUE PsO

VISIBLE safety data were consistent with pivotal trials



VOYAGE 1 and VOYAGE 2 (pooled pivotal trials): Adverse events in the 16-week, placebo-controlled period[2,5]

n (%) [events per 100 PYs of follow-up]	Adverse events	Serious adverse events	Infections	Serious infections
TREMFYA® (n=823)	**405 (49.2%)** [330.1]	**16 (1.9%)** [6.3]	**191 (23.2%)** [97.9]	**1 (0.1%)** [0.4]
Placebo (n=422)	**197 (46.7%)** [316.9]	**6 (1.4%)** [4.7]	**90 (21.3%)** [86.4]	**1 (0.2%)** [0.8]

- The most common (≥1%) infections were upper respiratory infections, gastroenteritis, tinea infections, and herpes simplex infections; all cases were mild to moderate in severity and did not lead to discontinuation of TREMFYA®[5]
- **Through Week 48, no new adverse reactions were identified with TREMFYA® use and the frequency of the adverse reactions was similar to the safety profile observed during the first 16 weeks of treatment.[5]**

VISIBLE trial: Adverse events in the 16-week, placebo-controlled period (pooled data from Cohorts A and B)[2*]

n (%) [events per 100 PYs of follow-up]	Adverse events	Serious adverse events	Infections	Serious infections
TREMFYA®† (n=158)	**58 (36.7%)** [159.7]	**0 (0.0%)** [0.0]	**28 (17.7%)** [71.7]	**0 (0.0%)** [0.0]
Placebo (n=53)	**9 (17.0%)** [100.3]	**1 (1.9%)** [6.3]	**4 (7.5%)** [43.9]	**1 (1.9%)** [6.3]

No new safety signals were reported in VISIBLE through Week 48

PYs=patient-years.

*Study is currently ongoing.

†Patients received 100 mg TREMFYA® at Week 0, Week 4, and every 8 weeks thereafter.

Tremfya® (guselkumab)

Important safety information

INDICATIONS

TREMFYA® (guselkumab) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

TREMFYA® is indicated for the treatment of adults with active psoriatic arthritis.

TREMFYA® is indicated for the treatment of adults with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating treatment with TREMFYA®. Initiate treatment of latent TB prior to administering TREMFYA®. Monitor patients for signs and symptoms of active TB during and after TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection.

Immunizations

Prior to initiating TREMFYA®, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common adverse reactions associated with TREMFYA® include: plaque psoriasis and psoriatic arthritis adverse reactions (≥1%): upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections. Ulcerative colitis adverse reactions: induction (≥2%): respiratory tract infections; maintenance (≥3%): injection site reactions, arthralgia, and upper respiratory tract infections.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

Please see the full Prescribing Information and Medication Guide for TREMFYA®.
Provide the Medication Guide to your patients and encourage discussion.

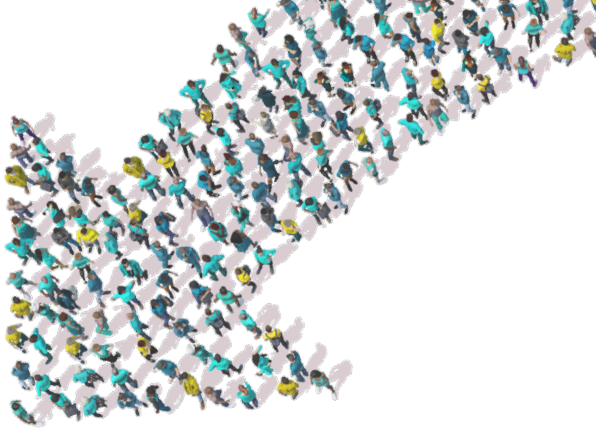
Dosage Forms and Strengths: TREMFYA® is available in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and a 200 mg/20 mL (10 mg/mL) single-dose vial for intravenous infusion.

cp-82625v6

BSA=body surface area; **IGA**=Investigator's Global Assessment; **MMRM**=Mixed-Effect Model Repeated Measures; **NRI**=nonresponder imputation; **PASI**=Psoriasis Area and Severity Index; **PsA**=psoriatic arthritis; **PsO**=psoriasis; **PSSI**=Psoriasis Scalp Severity Index; **q8w**=every 8 weeks; **SSA**=scalp surface area; **ss-IGA**=scalp-specific Investigator's Global Assessment.

References: 1. Alexis A, Desai SR, Choi O, et al. Poster presented at: 2023 American Academy of Dermatology Annual Meeting; March 17-21, 2023; New Orleans, LA. **2.** Data on file. Janssen Biotech, Inc. **3.** Alexis A, et al. Presentation at: Fall Clinical Dermatology Conference; October 19-22, 2023; Las Vegas, NV. **4.** Alexis A, et al. Presented at: Maui Derm Hawaii; January 22-26, 2024; Maui, HI. **5.** TREMFYA® (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **6.** Blauvelt A, Papp KA, Griffiths CEM, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *J Am Acad Dermatol*. 2017;76(3):405-417. **7.** Reich K, Armstrong AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *J Am Acad Dermatol*. 2017;76(3):418-431. **8.** Griffiths CEM, Papp KA, Song M, et al. Maintenance of response through 5 years of continuous guselkumab treatment: results from the Phase 3 VOYAGE 1 Trial. Coastal Dermatology Symposium Poster. 2020. **9.** Reich K, Gordon KB, Strober BE, et al. Five-year maintenance of clinical response and health-related quality of life improvements in patients with moderate-to-severe psoriasis treated with guselkumab: results from VOYAGE 1 and VOYAGE 2. *Br J Dermatol*. 2021;185(6):1146-1159. **10.** Kaufman BP, Alexis AF. Psoriasis in skin of color: Insights into the epidemiology, clinical presentation, genetics, quality-of-life impact, and treatment of psoriasis in non-white racial/ethnic groups. *Am J Clin Dermatol*. 2018;19(3):405-423. **11.** Armstrong AW, Mehta MD, Schupp CW, et al. Psoriasis prevalence in adults in the United States. *JAMA Dermatol*. 2021;157(8):940-946. **12.** Dickerson T, Pratt A, O'Quinn M, et al. Racial disparities in the diagnosis of psoriasis. *Cutis*. 2022;110:26-28. **13.** Wilson BN, Sun M, Ashbaugh AG, et al. Assessment of skin of color and diversity and inclusion content of dermatologic published literature: an analysis and call to action. *Int J Women's Derm*. 2021;7:391-397. **14.** Ebede T, Papier A. Disparities in dermatology educational resources. *J Am Acad Dermatol*. 2006;55(4):687-690. **15.** Adelekun A, Onyekaba G, Lipoff JB. Skin color in dermatology textbooks: an updated evaluation and analysis. *J Am Acad Dermatol*. 2021;84(1):194-196. **16.** McMichael A, Stein Gold L, Soung J, et al. Poster presented at: 2023 Fall Clinical Dermatology Conference; October 19-22, 2023; Las Vegas, NV.

Tremfya® (guselkumab)



OFFER PATIENTS WITH MODERATE TO SEVERE PLAQUE PsO THE OPPORTUNITY FOR

Clear skin and VISIBLE results[1,2]

First-of-its-kind data*

Designed to measure clearance objectively in all skin tones and to further the understanding of post-inflammatory dyspigmentation[1,2]

With long-term results

VISIBLE demonstrated skin clearance improvement at 16 and 48 weeks[2]

Across all skin tones*

We are striving to build the largest library of PsO patient images

VISIBLE co-primary endpoints at Week 16 (NRI)[2-4†]
Cohort A: PASI 90: TREMFYA® 57% (44/77) vs placebo 4% (1/26) (*P*<0.001) and **IGA 0/1:** TREMFYA® 74% (57/77) vs placebo 0% (0/26) (*P*<0.001); **Cohort B: PSSI 90:** TREMFYA® 66% (50/76) vs placebo 4% (1/26) (*P*<0.001) and **ss-IGA 0/1:** TREMFYA® 68% (52/76) vs placebo 12% (3/26) (*P*<0.001).

VISIBLE major secondary endpoint at Week 16 (NRI)[2,3†]
Cohort A: PASI 100: TREMFYA® 30% (23/77) vs placebo 0% (0/26) (*P*=0.002).
Cohort B: ss-IGA 0: TREMFYA® 58% (44/76) vs placebo 4% (1/26) (*P*<0.001).

VISIBLE other prespecified endpoints at Week 48 (NRI)[2‡]
Cohort A: PASI 90: TREMFYA® 77% (59/77), **PASI 100:** TREMFYA® 55% (42/77), and **IGA 0/1:** TREMFYA® 70% (54/77);
Cohort B: PSSI 90: TREMFYA® 80% (61/76) and **ss-IGA 0/1:** TREMFYA® 86% (65/76).

NRI=nonresponder imputation.

Week 48 data were prespecified and not multiplicity controlled. **The same patients may not have responded at each time point.**

*First large-scale, prospective PsO biologic study in patients with skin of color across the entire spectrum of the Fitzpatrick scale (I-VI).
†Week 16 data include patients randomized to TREMFYA® or placebo arms at baseline.
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