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

Andrew Blauvelt, MD, MBA, Kim A. Papp, MD, PhD, Christopher E. M. Griffiths, MD, Bruce Randazzo, MD, PhD, Yasmine Wasfi, MD, PhD, Yaung-Kaung Shen, PhD, Shu Li, PhD, and Alexa B. Kimball, MPH, MD. *J Am Acad Dermatol*. 2017;76(3):405-417.

Study Objective: Compare the efficacy and safety of guselkumab with adalimumab and placebo in patients with moderate to severe plaque psoriasis treated for 1 year.

Indication
TREMFYA™ is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Dosing and Administration
TREMFYA™ is administered as a 100 mg subcutaneous injection once every 8 weeks, after starter doses at weeks 0 and 4. TREMFYA™ is intended for use under the guidance and supervision of a physician. Patients may self-inject with TREMFYA™ after physician approval and proper training.

Selected Important Safety Information
TREMFYA™ may increase the risk of infection. If a clinically important or serious infection develops discontinue TREMFYA™ until infection resolves. Evaluate patients for tuberculosis infection before TREMFYA™ use. Patients treated with TREMFYA™ should not receive live vaccines. Please see related and other Important Safety Information on pages xx-xx.

Note: This analysis includes patients who were treated with TREMFYA™ supplies that were manufactured outside of the U.S. Furthermore, since the publication cited within was released in March 2017, several changes have been made to correct content errors.

This publication contains information about TREMFYA™ that is not included in the full Prescribing Information.
Please see the enclosed full Prescribing Information for TREMFYA™ for adequate directions for use for the approved indication.

Tremfya™ (guselkumab)

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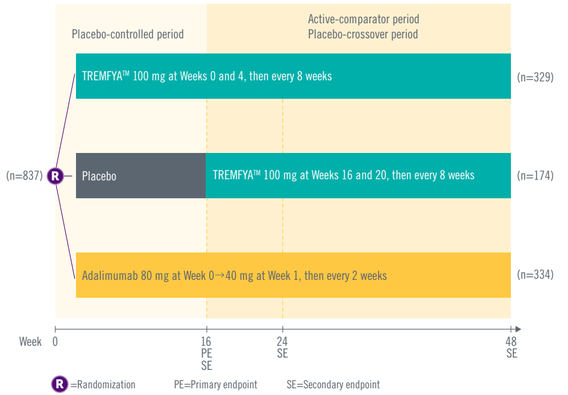
In moderate to severe plaque psoriasis:

STUDY DESIGN

A phase III, multicenter (101 global sites), randomized, double-blind, placebo- and active comparator-controlled trial

VOYAGE 1 STUDY



Co-primary endpoints:

— Proportion of patients achieving an IGA score of cleared/minimal disease (IGA 0/1) and PASI 90 with TREMFYA™ vs placebo at Week 16

Inclusion criteria:

- Patients ≥18 years of age
- Moderate to severe plaque psoriasis defined as Investigator Global Assessment (IGA) score ≥3, Psoriasis Area and Severity Index (PASI) score ≥12, body surface area involvement ≥10% for at least 6 months
- Patients had to be candidates for systemic therapy or phototherapy

Exclusion criteria included:

- History or current signs of a severe, progressive, or uncontrolled medical condition or current or history of malignancy, except non-melanoma skin cancer, within 5 years
- History or symptoms of active tuberculosis
- Any previous treatment with TREMFYA™ or adalimumab; with other anti-TNF-α therapy within 3 months; with other treatment targeting IL-12/23, IL-17, or IL-23 within 6 months; or with any systemic immunosuppressants (eg, methotrexate) or phototherapy within 4 weeks

Mean Baseline Characteristics (Overall population):

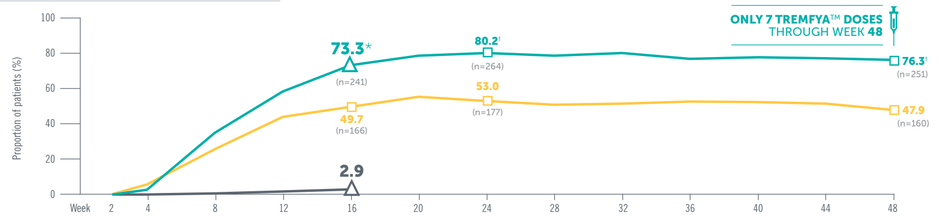
- Age: 43.7 years
- BMI, kg/m^2: 29.6
- PASI Score [0 to 72]: 21.9
- DLQI score [0 to 30]: 14.0
- PSSD symptom score [0 to 100]: 53.0
- Prior treatments:
  - — Topical agents: 91.1%
  - — Phototherapy: 54.3%
  - — Conventional systemic agents: 61.8%
  - — Biologic agents: 20.9%
  - — IGA score: Moderate (IGA 3) 74.6%; Severe (IGA 4) 25.1%

In moderate to severe plaque psoriasis:

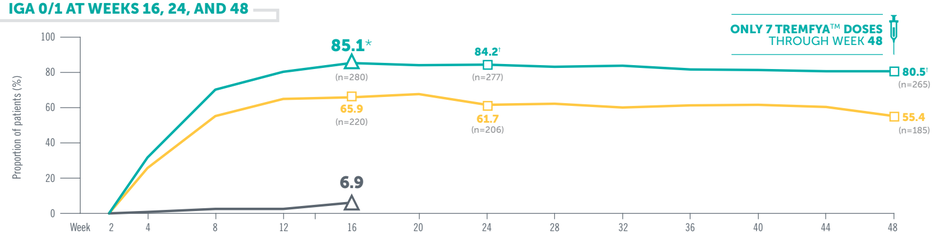
STUDY RESULTS

TREMFYA™ (guselkumab) was superior to placebo in achieving PASI 90 and IGA 0/1 at Week 16 (co-primary endpoints) and superior to adalimumab in achieving PASI 90 and IGA 0/1 at Weeks 16, 24, and 48 (major secondary endpoints)[1]

PASI 90 AT WEEKS 16, 24, AND 48



IGA 0/1 AT WEEKS 16, 24, AND 48



TREMFYA™ (n=329) — Adalimumab (n=334) — Placebo (n=174) — △ Co-primary endpoints — □ Major secondary endpoints

*P<0.001 vs Placebo. †P<0.001 vs adalimumab.

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA™ may increase the risk of infection. If a clinically important or serious infection develops discontinue TREMFYA™ until infection resolves. Evaluate patients for tuberculosis infection before TREMFYA™ use. Patients treated with TREMFYA™ should not receive live vaccines. Please see related and other Important Safety Information on pages xx-xx.

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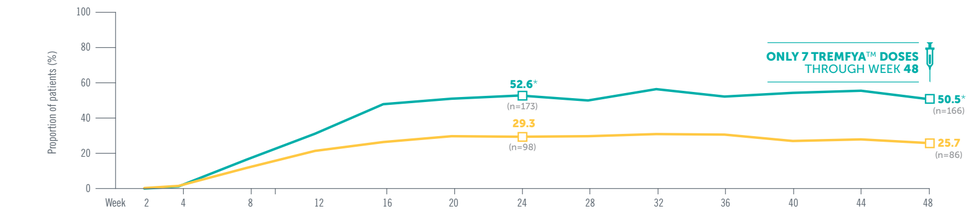
In moderate to severe plaque psoriasis:

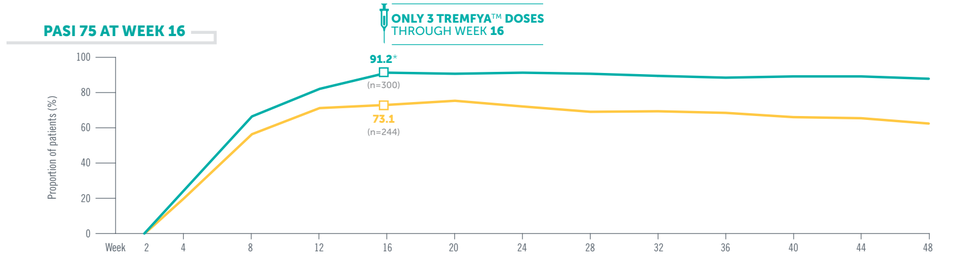
STUDY RESULTS

TREMFYA™ (guselkumab) was superior to adalimumab in achieving PASI 75 and IGA 0 (major secondary endpoints)

IGA 0 AT WEEKS 24 AND 48



PASI 75 AT WEEK 16



TREMFYA™ (n=329) — Adalimumab (n=334) — △ Co-primary endpoints — □ Major secondary endpoints

*$P<0.001$ vs adalimumab.

Pre-specified exploratory endpoint:

PASI 100 response rates in the TREMFYA™ (n=329) group were higher than placebo (n=174) and adalimumab (n=334) as follows:

- 37.4% vs 0.6% with placebo and 17.1% with adalimumab at Week 16
- 44.4% vs 24.9% with adalimumab at Week 24
- 47.4% vs 23.4% with adalimumab at Week 48

In moderate to severe plaque psoriasis:

STUDY RESULTS

Safety profile through Week 48

CUMULATIVE RATES OF SELECT SAFETY EVENTS; TREATED PATIENTS

	Weeks 0 to 16 Placebo-controlled period			Weeks 0 to 48 Active comparator-controlled period		Weeks 16 to 48
	TREMFYA™	Adalimumab	Placebo	TREMFYA™	Adalimumab	Placebo→TREMFYA™
Patients treated, n	329	333	174	329	333	165
Mean duration of follow-up, wk	16.27	16.14	15.88	46.47	45.56	31.88
At least 1 AE	170 (51.7)	170 (51.1)	86 (49.4)	243 (73.9)	248 (74.5)	107 (64.8)
Common AEs*						
Nasopharyngitis	30 (9.1)	35 (10.5)	17 (9.8)	83 (25.2)	74 (22.2)	34 (20.6)
Upper respiratory tract infection	25 (7.6)	16 (4.8)	9 (5.2)	47 (14.3)	42 (12.6)	17 (10.3)
Injection-site erythema	6 (1.8)	15 (4.5)	1 (0.6)	8 (2.4)	22 (6.6)	3 (1.8)
Headache	12 (3.6)	13 (3.9)	7 (4.0)	18 (5.5)	25 (7.5)	1 (0.6)
Arthralgia	11 (3.3)	9 (2.7)	3 (1.7)	18 (5.5)	16 (4.8)	2 (1.2)
Pruritus	5 (1.5)	7 (2.1)	10 (5.7)	8 (2.4)	12 (3.6)	0
Back pain	6 (1.8)	4 (1.2)	2 (1.1)	12 (3.6)	17 (5.1)	1 (0.6)
Discontinued study agent because of AE	4 (1.2)	3 (0.9)	2 (1.1)	9 (2.7)	12 (3.6)	1 (0.6)
At least 1 SAE	8 (2.4)	6 (1.8)	3 (1.7)	16 (4.9)	15 (4.5)	5 (3.0)
Infections	85 (25.8)	85 (25.5)	44 (25.3)	172 (52.3)	167 (50.2)	76 (46.1)
Requiring treatment	20 (6.1)	24 (7.2)	13 (7.5)	54 (16.4)	60 (18.0)	25 (15.2)
Serious infections	0	2 (0.6)	0	2 (0.6)	3 (0.9)	1 (0.6)
Malignancies†	0	0	0	2 (0.6)	0	0
NMSC‡	1 (0.3)	0	0	2 (0.6)	1 (0.3)	0
MACE§	1 (0.3)	1 (0.3)	0	1 (0.3)	1 (0.3)	0

Values are n (%) unless otherwise indicated.
AE=Adverse event; MACE=major adverse cardiovascular events; NMSC=nonmelanoma skin cancers; SAE=serious adverse event.
*Occurred in at least 5% of patients in any treatment group through Week 48.
† Includes malignancies other than NMSC (ie, prostate and breast cancer).
‡ Includes 3 basal cell carcinomas.
§ Includes sudden cardiac death, myocardial infarction, and stroke.

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In moderate to severe plaque psoriasis:

EFFICACY RESULTS SUMMARY

TREMFYA™ (guselkumab) was superior to placebo for the co-primary endpoints and to adalimumab for select major secondary endpoints

INDICATION

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

IMPORTANT SAFETY INFORMATION

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.

Instruct patients receiving TREMFYA™ to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a clinically important or serious infection develops or is not responding to standard therapy, monitor the patient closely 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 receiving TREMFYA™ for signs and symptoms of active TB during and after treatment. Do not administer TREMFYA™ to patients with active TB infection.

Immunizations

Prior to initiating TREMFYA™, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with TREMFYA™ should not receive live vaccines.

Adverse Reactions

The most common (≥1%) adverse reactions with TREMFYA™ include injection site erythema and gastroenteritis.

CO-PRIMARY ENDPOINTS

PASI 90 AT WEEK 16

73%

vs 3% placebo

IGA 0/1 AT WEEK 16

85%

vs 7% placebo

ADDITIONAL EFFICACY ENDPOINTS

PASI 75 AT WEEK 16

91%

vs 73% adalimumab

PASI 100 AT WEEK 24

44%

vs 25% adalimumab

IGA 0 AT WEEK 24

53%

vs 30% adalimumab

Please read the enclosed full Prescribing Information and Medication Guide for TREMFYA™. Provide the Medication Guide to your patients and encourage discussion.

Reference: 1. Blauvelt A, Papp KA, Griffiths CE, 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 [published online December 29, 2016]. *J Am Acad Dermatol.* 2017;76(3):405-417.

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