MEAN PERCENTAGE IMPROVEMENT IN PSORIASIS AREA AND SEVERITY INDEX (PASI) RESPONSE AND ABSOLUTE PASI THROUGH 5 YEARS OF CONTINUOUS TREATMENT WITH GUSELKUMAB IN VOYAGE 1

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BACKGROUND/OBJECTIVE

- VOYAGE 1, a 5-year, Phase 3, randomized, double-blinded, placebo (PBO)- and active comparator-controlled study compared guselkumab (GUS), a fully human anti-interleukin-23 monoclonal antibody, with PBO and adalimumab (ADA) in patients with moderate to severe plaque psoriasis[1]
- The objective of this analysis was to assess percentage improvement in Psoriasis Area and Severity Index (PASI) as well as absolute PASI response through 5 years of continuous GUS treatment

METHODS

- In VOYAGE 1, 837 patients were randomized in a 2:1:2 ratio to receive:
  - GUS 100 mg administered by subcutaneous (SC) injection at Weeks 0 and 4, then every 8 weeks (q8w) (n=329)
  - PBO at Weeks 0, 4, and 12, followed by GUS 100 mg SC at Weeks 16 and 20, then q8w (n=174)
  - ADA 80 mg SC at Week 0, 40 mg at Week 1, then 40 mg every 2 weeks through Week 47, followed by GUS 100 mg at Week 52, then q8w (n=334)
- Patients entered open-label GUS treatment during Weeks 52-252
- Analyses were performed to summarize the following through Week 252:
  - Mean and median percentage improvement from baseline in PASI
  - Median absolute PASI with interquartile range (IQR)
- In addition to patients randomized to GUS, PBO, and ADA at baseline, treatment groups analyzed:
  - GUS Group: Includes patients randomized to GUS at baseline and those randomized to PBO at baseline who crossed over to GUS at Week 16
  - ADA crossover to GUS (ADA→GUS) Group: Includes patients randomized to ADA at baseline who crossed over to GUS at Week 52
  - Combined GUS Group: Includes the GUS Group and ADA→GUS Group, as defined above
- Through Week 48, last observation carried forward (LOCF) was applied for all missing data regardless of the reason after application of treatment failure rules (TFR), whereupon zero was assigned to PASI percent improvement and baseline PASI was used for those who discontinued study agent due to lack of efficacy or worsening of psoriasis, or used a protocol-prohibited psoriasis treatment. Starting at Week 52, analyses were performed using observed data after applying TFR.
- Safety was evaluated through Week 264

CONCLUSIONS

- **Continuous treatment with GUS provided robust and durable skin responses based on percentage improvement in PASI as well as absolute PASI through 5 years**
- **No new safety concerns were identified through Week 264**

RESULTS

Baseline demographics, disease characteristics, and prior psoriasis treatments were generally similar across treatment groups (Table 1)

Table 1. Baseline Demographics and Disease Characteristics

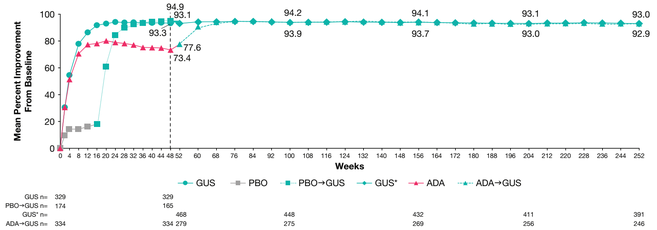
	PBO	GUS	ADA	Total
Randomized patients, n	174	329	334	837
Age [years]	44.9 ± 12.9	43.9 ± 12.7	42.9 ± 12.6	43.7 ± 12.7
Male, n (%)	119 (68.4)	240 (72.9)	249 (74.6)	608 (72.6)
Body mass index (kg/m²)	28.9 ± 6.9	29.7 ± 6.2	29.8 ± 6.5	29.6 ± 6.5
Body surface area (%)	25.8 ± 15.9	28.3 ± 17.1	28.6 ± 16.7	27.9 ± 16.7
PASI (0-72)	20.4 ± 8.7	22.1 ± 9.5	22.4 ± 9.0	21.9 ± 9.2
IGA score (moderate), %	75.3	76.6	72.2	74.6
IGA score (severe), %	24.7	23.4	26.9	25.1
Duration of psoriasis [years]	17.6 ± 12.4	17.9 ± 12.3	17.0 ± 11.3	17.5 ± 11.9
Patients with psoriatic arthritis, n (%)	30 (17.2)	64 (19.5)	62 (18.6)	156 (18.6)
Prior psoriasis treatments, n (%)				
Topical agents	154 (88.5)	299 (90.9)	309 (92.8)	762 (91.1)
Phototherapy (PUVA or UVB)	86 (49.4)	188 (57.3)	180 (53.9)	454 (54.3)
Non-biologic systemics	92 (52.9)	210 (63.8)	215 (64.4)	517 (61.8)
Biologics	34 (19.5)	71 (21.6)	70 (21.0)	175 (20.9)

Data shown are mean ±SD, unless otherwise indicated.
ADA=Adalimumab; GUS=Guselkumab; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PUVA=Psoralen and Utraviolet A; SD=Standard deviation; UVB=Ultraviolet B

Mean percentage improvement from baseline in PASI was 93% or greater at each time point in the GUS group from Week 52 through Week 252. A similar response was observed in the ADA→GUS group over time. (Figure 1)

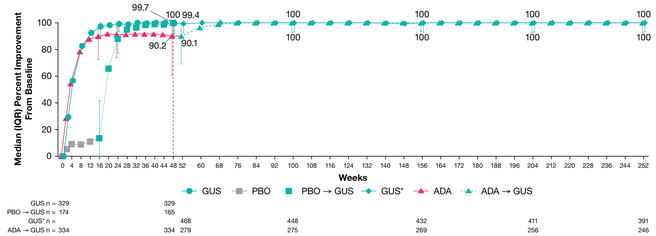
- Median percentage improvement from baseline in PASI over time is shown in Figure 2

Figure 1. Mean Percent Improvement From Baseline in PASI Through Week 252



*Includes patients randomized to GUS at baseline and those randomized to PBO at baseline who crossed over to GUS at Week 16.
ADA=Adalimumab; GUS=Guselkumab; PASI=Psoriasis Area and Severity Index; PBO=Placebo

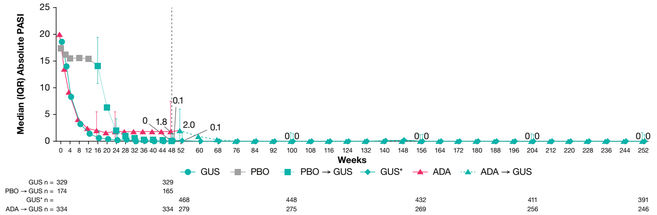
Figure 2. Median Percent Improvement From Baseline in PASI (IQR) Through Week 252



Error bars represent Q1 and Q3.
*Includes patients randomized to GUS at baseline and those randomized to PBO at baseline who crossed over to GUS at Week 16.
ADA=Adalimumab; GUS=Guselkumab; IQR=interquartile range; PASI=Psoriasis Area and Severity Index; PBO=Placebo

Median absolute PASI (IQR) was 0.10 (0.00; 1.65) in the GUS group (n=468) and 2.00 (0.20; 6.00) in the ADA→GUS group (n=279) at Week 52; and 0.00 (0.00; 1.20) in the GUS group (n=391) and 0.00 (0.00; 1.60) in the ADA→GUS group (n=246) at Week 252

Figure 3. Median Absolute PASI (IQR) Through Week 252



Error bars represent Q1 and Q3.
*Includes patients randomized to GUS at baseline and those randomized to PBO at baseline who crossed over to GUS at Week 16.
ADA=Adalimumab; GUS=Guselkumab; IQR=interquartile range; PASI=Psoriasis Area and Severity Index; PBO=Placebo

- No new safety signals were identified through Week 264 (Table 2)

Table 2. Adverse Events Through Week 264

	GUS*	ADA→GUS**	Combined GUS
Treated patients, n	494	280	774
Average duration of follow-up, weeks	226.4	199.0	216.5
≥1 AE	442 (89.5)	237 (84.6)	679 (87.7)
Discontinued due to ≥1 AE	33 (6.7)	14 (5.0)	47 (6.1)
≥1 SAE	95 (19.2)	32 (11.4)	127 (16.4)
Infections	357 (72.3)	190 (67.9)	547 (70.7)
Requiring antibiotics	188 (38.1)	101 (36.1)	289 (37.3)
Serious infections	18 (3.6)	4 (1.4)	22 (2.8)
Malignancies other than NMSC‡	15 (3.0)	3 (1.1)	18 (2.3)
NMSC	9 (1.8)	4 (1.4)	13 (1.7)
MACE	6 (1.2)	2 (0.7)	8 (1.0)
Suicidal ideation and behavior	3 (0.6)	2 (0.7)	5 (0.6)
Deaths	4 (0.8)	1 (0.4)	5 (0.6)

Data shown are n (%), unless otherwise indicated.
*Includes patients randomized to GUS at baseline and to PBO who crossed over to GUS at Week 16.
**Includes patients randomized to ADA at baseline who crossed over to GUS at Week 52.
‡Includes 4 colorectal, 3 breast, 2 each of head and neck, melanoma, and prostate, and 1 each of bladder, brain, lymphoma, sarcoma, and stomach.
AE=Adverse event; ADA=Adalimumab; GUS=Guselkumab; MACE=Major adverse cardiovascular event; NMSC=Nonmelanoma skin cancer; SAE=Serious adverse event

Disclosures

Joseph F. Merola has served as a consultant and/or investigator for Abbvie, Arena, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB. **Luis Puig** has served as a speaker/consultant/advisory board member for and/or received research funding from Abbvie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Fresenius-Kabi, Gebro, Janssen, JS BIOCAD, Leo Pharma, Lilly, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Sandoz, Samsung-Bioepis, Sanofi, and UCB. **Megan Miller, Yin You** and **Yaung-Kaung Shen** are employees of Janssen Research and Development, LLC, and **Ya-Wen Yang** is an employee of Immunology Global Medical Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson; employees may own stock in Johnson & Johnson, of which Janssen is a subsidiary. **Andrew Blauvelt** has served as a scientific advisor and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, EcoR1, Eli Lilly and Company, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharmaceutical, UCB, and Vibliome.

References

1. Blauvelt A, et al. *J Am Acad Dermatol.* 2017;76(3):405-417.

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