PASI IMPROVEMENT IN THE FIRST 12 WEEKS FROM THE PHASE 3 VOYAGE 1, VOYAGE 2, ORION, AND ECLIPSE GUSELKUMAB CLINICAL TRIALS

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BACKGROUND/OBJECTIVE

- Psoriasis (PsO) places a substantial clinical and humanistic burden on patients. Patients with moderate to severe plaque PsO may experience reduced health-related quality of life.[1]
- Guselkumab (GUS) demonstrated clinical benefits vs. placebo, adalimumab, and secukinumab in four phase 3, double-blind, randomized controlled trials (VOYAGE 1, VOYAGE 2, ORION, and ECLIPSE).[2-5]
- The objective of this analysis was to evaluate the relative PASI improvement from baseline over the early phase of treatment among GUS-treated subjects.

METHODS

- Analyses were performed using treatment failure rules in which patients who discontinued due to lack of efficacy or worsening of PsO, or who used a protocol prohibited PsO treatment were set to zero improvement, regardless of the observed data.
- In addition, for VOYAGE 1 & 2, LOCF was performed for the missing data after the treatment failure rules were applied.

CONCLUSIONS

- Patients treated with GUS showed high levels of relative PASI improvement from baseline (>90%) at week 12 after only two doses **(Figure 1; Table 2).**
- This is in line with previously reported GUS findings from the primary endpoints (week 16).

RESULTS

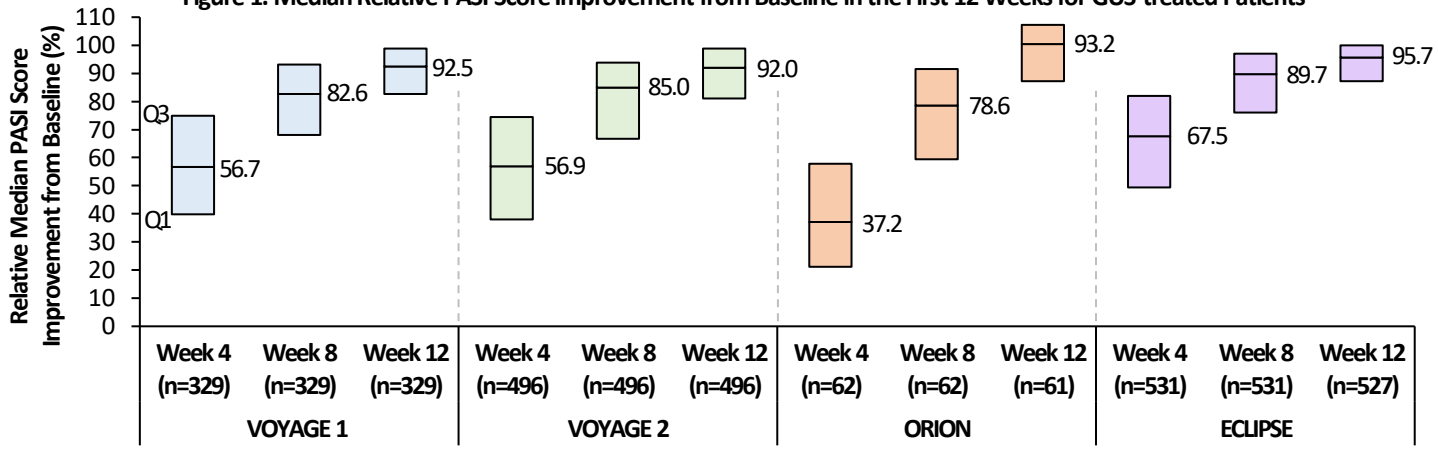
Table 1. Baseline Demographics and Disease Characteristics

Characteristic	VOYAGE 1 (n=329)	VOYAGE 2 (n=496)	ORION (n=62)	ECLIPSE (n=534)
Mean (SD) age, years	43.9 (12.7)	43.7 (12.2)	46.2 (12.9)	46.3 (13.7)
Male, n (%)	240 (72.9)	349 (70.4)	41 (66.1)	365 (68.4)
White, n (%)	262 (79.6)	408 (82.3)	57 (91.9)	499 (93.4)
Mean (SD) BMI, kg/m^2	29.7 (6.2)	29.6 (6.5)	31.4 (6.6)	29.8 (7.1)
Mean (SD) dur., years	17.9 (12.3)	17.9 (12.0)	19.1 (12.6)	18.5 (12.2)
Patients with PsA, n (%)	64 (19.5)	89 (17.9)	13 (21.0)	97 (18.2)
Mean (SD) % of BSA	28.3 (17.1)	28.5 (16.4)	20.1 (9.2)	23.7 (12.9)
Mean (SD) PASI score	22.1 (9.5)	21.9 (8.8)	17.9 (4.5)	20.0 (7.4)
IGA score = 3, n (%)	252 (76.6)	380 (76.6)	52 (83.9)	407 (76.2)
IGA score = 4, n (%)	77 (23.4)	115 (23.2)	10 (16.1)	127 (23.8)

Table 2. Relative PASI Score Improvement (%) from Baseline

Week	Value	VOYAGE 1	VOYAGE 2	ORION	ECLIPSE
4	Mean (SD)	54.6 (24.9)	54.0 (26.5)	41.0 (26.4)	64.6 (22.9)
	Median (IQR)	56.7 (39.8, 75.0)	56.9 (37.9, 74.5)	37.2 (21.1, 57.7)	67.5 (49.3, 81.9)
	[Range]	[-97.5, 100.0]	[-63.5, 100.0]	[0.0, 100.0]	[-47.6, 100.0]
8	Mean (SD)	77.9 (20.2)	76.9 (23.7)	71.8 (27.0)	84.4 (17.3)
	Median (IQR)	82.6 (68.1, 93.1)	85.0 (66.7, 93.8)	78.6 (59.5, 91.6)	89.7 (76.0, 97.1)
	[Range]	[-7.7, 100.0]	[-26.1, 100.0]	[0.0, 100.0]	[-36.2, 100.0]
12	Mean (SD)	86.5 (18.2)	84.8 (21.1)	85.0 (20.5)	90.9 (14.5)
	Median (IQR)	92.5 (82.6, 98.8)	92.0 (81.0, 98.9)	93.2 (80.0, 100.0)	95.7 (87.2, 100.0)
	[Range]	[-7.7, 100.0]	[-13.9, 100.0]	[7.2, 100.0]	[-78.8, 100.0]

Figure 1. Median Relative PASI Score Improvement from Baseline in the First 12 Weeks for GUS-treated Patients



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Abbreviations: BMI = body mass index; BSA = body surface area; GUS = guselkumab; IGA = Investigator's Global Assessment; IQR = interquartile range; LOCF = last observation carried forward; n = number; NR = not reported; PASI = Psoriasis Area and Severity Index; PsA = psoriatic arthritis; PsO = psoriasis; SD = standard deviation; W = week.

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https://www.congresshub.com/Immunology/FCDC2023/Guselkumab/Papp-PASI