Maintenance of Response With up to 4 Years of Continuous Guselkumab Treatment: Results From the VOYAGE 1 Phase 3 Trial

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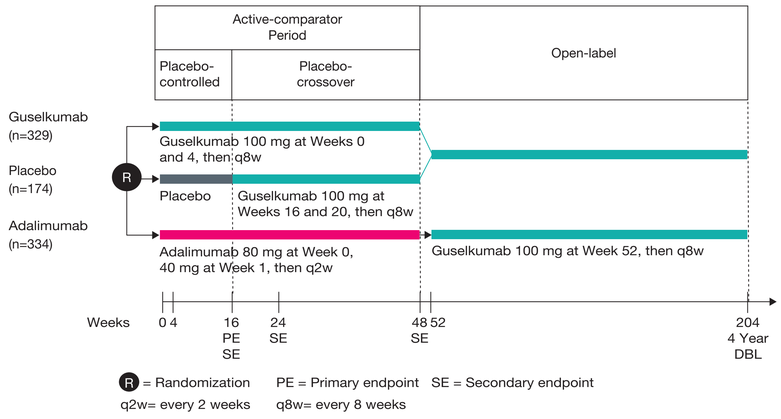
Introduction/Objective

- Guselkumab is a fully human monoclonal antibody that binds and blocks interleukin-23 function
- VOYAGE 1 is an ongoing, Phase 3, double-blinded, placebo- and active comparator-controlled study that evaluates the efficacy and safety of guselkumab in patients with moderate-to-severe plaque psoriasis[1,2]
- Here, efficacy results following up to 4 years of continuous guselkumab treatment are presented

Methods

- In VOYAGE 1 (n=837), patients were randomized as follows (Figure 1):
  - Guselkumab 100 mg administered by subcutaneous (SC) injection at Weeks 0, 4, and 12, then every 8 weeks (q8wk)
  - Placebo at Weeks 0, 4, and 12, followed by guselkumab 100 mg SC at Weeks 16 and 20, then q8wk
  - Adalimumab 80 mg SC at Week 0, 40 mg at Week 1, then 40 mg q2wk through Week 47
  - Starting at Week 52, all patients received open-label guselkumab treatment through Week 204
- Efficacy assessments included proportions of patients achieving Psoriasis Area and Severity Index (PASI) 90, PASI 100, Investigator's Global Assessment (IGA) score of cleared (0) or minimal (1), and IGA score of 0
- Patient-reported outcomes included proportions of patients achieving a Dermatology Life Quality Index (DLQI) score of 0 or 1 (no effect on a patient's health-related quality of life) and Psoriasis Symptoms and Signs Diary (PSSD) summary scores of 0 (no symptoms or signs of psoriasis)
- Efficacy was analyzed using prespecified treatment failure rules (TFR), nonresponder imputation (NRI), and As Observed (OBS) methodology
  - For TFR, patients who discontinued due to lack of efficacy, worsening of psoriasis, or use of a protocol-prohibited psoriasis treatment were considered nonresponders
  - For NRI, patients with missing efficacy data (regardless of the reason) after application of TFR were counted as nonresponders
  - For OBS, only patient data from each visit were used; missing data were not imputed
- Data for patients randomized to guselkumab and for those originally randomized to placebo who then crossed over to guselkumab at Week 16 were combined (guselkumab group) and presented in this analysis

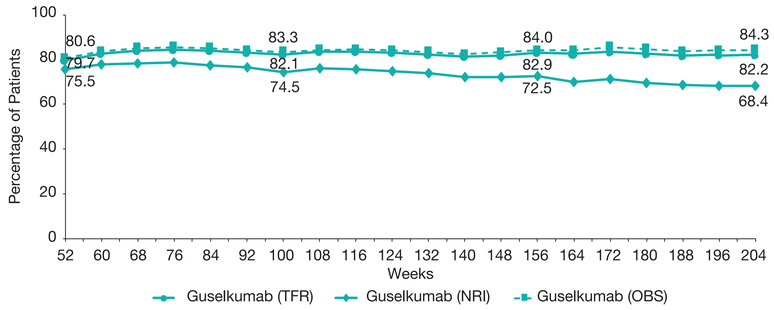
Figure 1. VOYAGE 1 Study Design Through 204 Weeks



Results

- PASI 90 responses were well-maintained with up to 4 years of continuous guselkumab treatment (Figure 2)
- At Week 204, PASI 90 response rates were 82.2%, 68.4%, and 84.3%, respectively, based on TFR, NRI, and OBS analyses (Figure 2)
- Similarly, PASI 100, IGA score of 0 or 1, and IGA score of 0 responses were stably maintained from Week 52 through Week 204 (Figures 3-5)

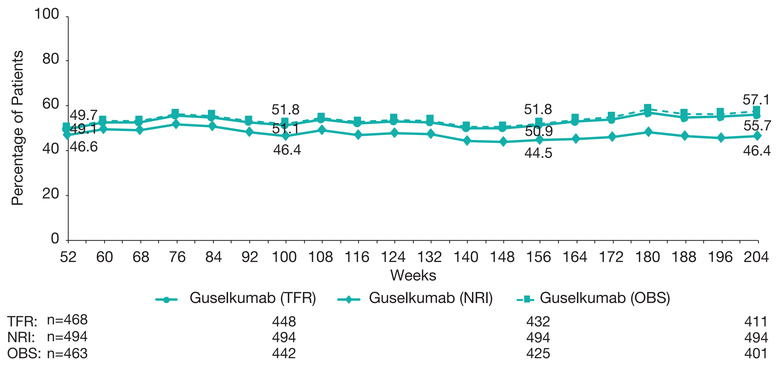
Figure 2. Proportion of Patients Who Achieved PASI 90 Response From Week 52 Through Week 204 (TFR, NRI, OBS)*



TFR:	n=468	448	432	411
NRI:	n=494	494	494	494
OBS:	n=463	442	425	401

*Includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16.

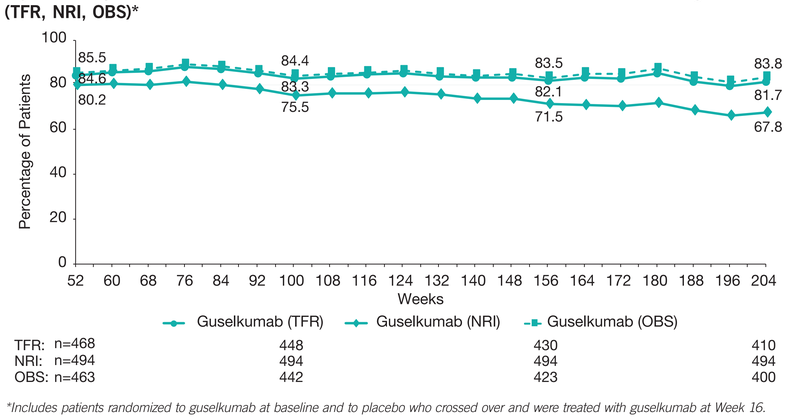
Figure 3. Proportion of Patients Who Achieved PASI 100 Response From Week 52 Through Week 204 (TFR, NRI, OBS)*



TFR:	n=468	448	432	411
NRI:	n=494	494	494	494
OBS:	n=463	442	425	401

*Includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16.

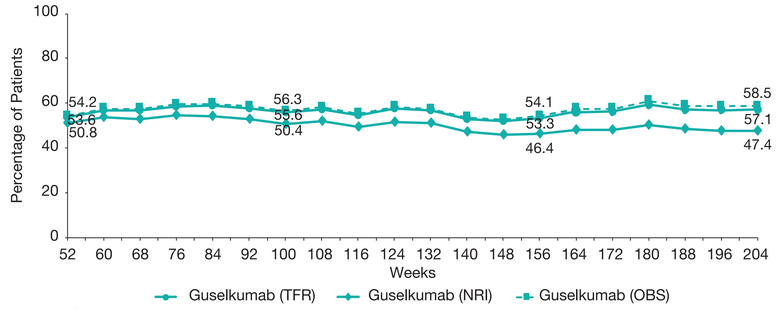
Figure 4. Proportion of Patients Who Achieved IGA Score of 0 or 1 From Week 52 Through Week 204 (TFR, NRI, OBS)*



TFR:	n=468	448	430	410
NRI:	n=494	494	494	494
OBS:	n=463	442	423	400

*Includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16.

Figure 5. Proportion of Patients Who Achieved IGA Score of 0 From Week 52 Through Week 204 (TFR, NRI, OBS)*

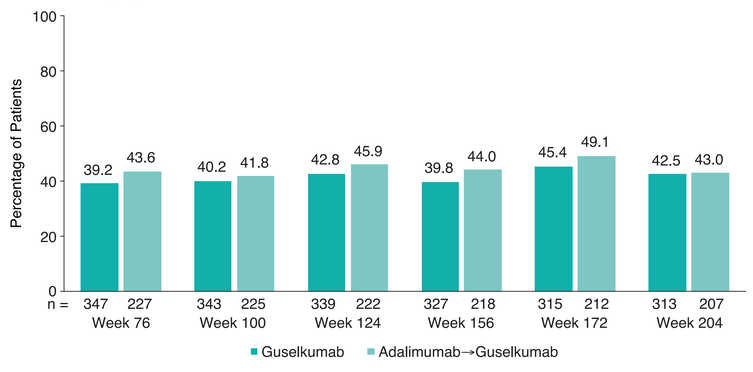


TFR:	n=468	448	430	410
NRI:	n=494	494	494	494
OBS:	n=463	442	423	400

*Includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16.

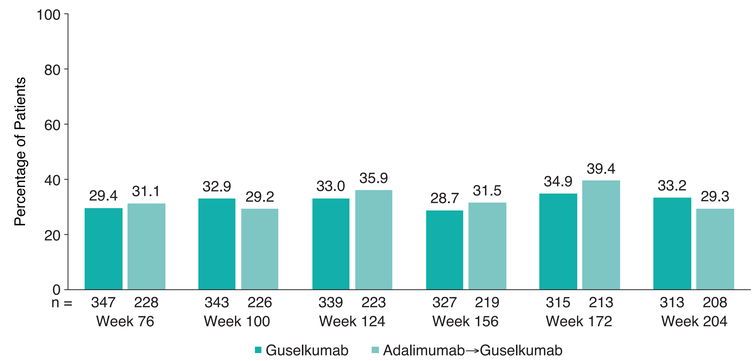
- Proportions of patients with PSSD summary scores of 0 and DLQI score of 0 or 1 were sustained from Week 76 through Week 204 (Figures 6-8)

Figure 6. PSSD Symptom Score=0 From Weeks 76-204 (TFR)*



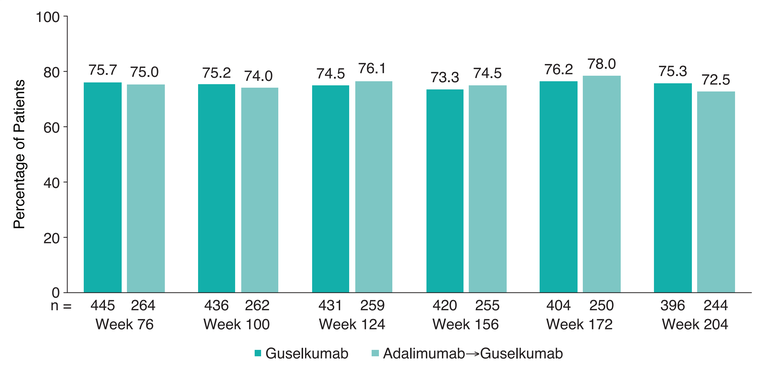
*Patients with baseline PSSD symptom score >0.
Weeks 76-204: Guselkumab – includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16; Adalimumab→Guselkumab – includes patients randomized to adalimumab at baseline and crossed over and were treated with guselkumab at or after Week 52.

Figure 7. PSSD Sign Score=0 From Weeks 76-204 (TFR)*



*Patients with baseline PSSD sign score >0.
Weeks 76-204: Guselkumab – includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16; Adalimumab→Guselkumab – includes patients randomized to adalimumab at baseline and crossed over and were treated with guselkumab at or after Week 52.

Figure 8. DLQI Score of 0 or 1 From Weeks 76-204 (TFR)*



*Patients with baseline DLQI score >1.
Weeks 76-204: Guselkumab – includes patients randomized to guselkumab at baseline and to placebo who crossed over and were treated with guselkumab at Week 16; Adalimumab→Guselkumab – includes patients randomized to adalimumab at baseline and crossed over and were treated with guselkumab at or after Week 52.

Table 1. Adverse Events (AEs) Through Weeks 48, 100, 156, and 204 Among Patients Randomized to Guselkumab and Placebo Crossover Patients

	Guselkumab			
	Weeks 0-48	Weeks 0-100	Weeks 0-156	Weeks 0-204
Treated patients, n	494	494	494	494
Average duration of follow-up, weeks	41.6	89.4	139.2	179.0
≥1 AE, n (%)	350 (70.9%)	395 (80.0%)	426 (86.2%)	437 (88.5%)
Discontinued due to ≥1 AE, n (%)	10 (2.0%)	14 (2.8%)	21 (4.3%)	29 (5.9%)
≥1 SAE, n (%)	21 (4.3%)	45 (9.1%)	66 (13.4%)	82 (16.6%)
Infections, n (%)	248 (50.2%)	302 (61.1%)	335 (67.8%)	347 (70.2%)
Requiring antibiotics	79 (16.0%)	124 (25.1%)	154 (31.2%)	169 (34.2%)
Serious infections	3 (0.6%)	6 (1.2%)	11 (2.2%)	15 (3.0%)
Malignancies other than NMSC, n (%)	2 (0.4%)	6 (1.2%)	9 (1.8%)	13 (2.6%)
NMSC, n (%)	2 (0.4%)	2 (0.4%)	3 (0.6%)	8 (1.6%)
MACE, n (%)	1 (0.2%)	1 (0.2%)	2 (0.4%)	3 (0.6%)
Deaths, n (%)	0	2 (0.4%)	4 (0.8%)	4 (0.8%)

MACE=Major adverse cardiovascular event; NMSC=Nonmelanoma skin cancer; SAE=Serious adverse event

Other Safety Events

- No opportunistic infections were reported
- No anaphylactic or serum sickness-like reactions were reported
- Common Terminology Criteria for Adverse Events (CTCAE) grade ≥2 in blood hematology and chemistry laboratory values were uncommon

Conclusions

- High efficacy response rates were maintained with up to 4 years of continuous guselkumab treatment in VOYAGE 1, regardless of the analysis method (TFR, NRI, and OBS)
- No new safety signals were identified

References

1. Blauvelt A., et al. *J Am Acad Dermatol.* 2017;76(3):405-417.
2. Griffiths C.E.M., et al. *J Drugs Dermatol.* 2018;17(8):826-832.

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