Maintenance of Response With Guselkumab for up to 3 Years' Treatment in the Phase 3 VOYAGE 1 Trial of Patients With Plaque Psoriasis

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Introduction/Objective

- Guselkumab is a fully human monoclonal antibody that binds and blocks interleukin-23
- VOYAGE 1 is a phase 3, double-blind, placebo- and active comparator-controlled trial that showed significantly higher proportions of patients with moderate to severe plaque psoriasis achieving several outcome measures, including Psoriasis Area and Severity Index (PASI) 90 response and Investigator's Global Assessment (IGA) of cleared (0) or minimal (1) scores, with guselkumab versus placebo at Week 16 and guselkumab versus adalimumab at Week 24.[1]
- Study results through up to 3 years of continuous treatment with guselkumab were examined

Methods

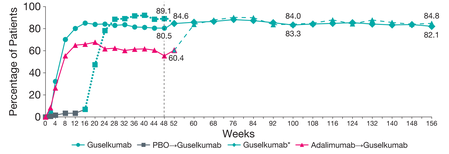
- In VOYAGE 1 (n=837), patients were randomized as follows (Figure 1):
  - Guselkumab 100 mg administered by subcutaneous (SC) injection at Weeks 0, 4, and 12, then every 8 weeks (q8wk)
  - Placebo (PBO) at Weeks 0, 4, and 12, followed by guselkumab 100 mg SC at Weeks 16 and 20, then q8wk
  - Adalimumab 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 100 mg SC q8wk through Week 156
- Efficacy was assessed using prespecified analyses: non-responder imputation (NRI) through Week 48 (patients with missing efficacy data after application of treatment failure rules [TFR] were counted as non-responders, without regard to the reason for missing data) and TFR starting at Week 52 (patients were considered non-responders after discontinuing due to lack of efficacy or worsening of psoriasis, or after use of a prohibited treatment)
- Data for patients randomized to gusekumab and for those originally randomized to placebo and then crossed over to guselkumab at Week 16 were combined (guselkumab group)

Figure 1. VOYAGE 1 Study Design Through 156 Weeks

R = Randomization PE = Primary endpoint SE = Secondary endpoint
q2w = every 2 weeks q8w = every 8 weeks

Results

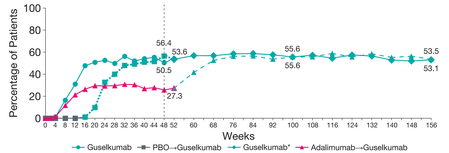
Figure 2. Proportion of Patients Who Achieved IGA Score of 0 or 1 Through Week 156, *Primary Analysis*[†]



Guselkumab n= 329	329			
PBO→Gus n= 174	165			
Guselkumab* n=	468	448		429
Ada→Gus n= 334	278	275		269

[†]*NRI through Week 48, then TFR beyond Week 48.*
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

Figure 3. Proportion of Patients Who Achieved IGA Score of 0 Through Week 156, *Primary Analysis*[†]



Guselkumab n= 329	329			
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Guselkumab* n=	468	448		429
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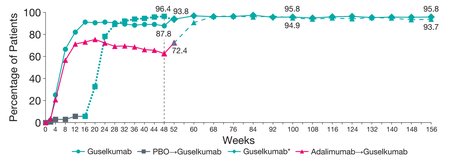
[†]*NRI through Week 48, then TFR beyond Week 48.*
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

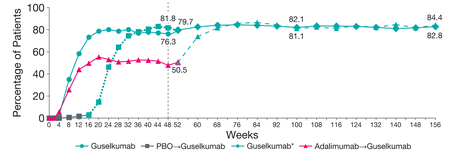
Figure 4. Proportion of Patients Who Achieved PASI 75 Response Through Week 156, *Primary Analysis*[†]



Guselkumab n= 329	329			
PBO→Gus n= 174	165			
Guselkumab* n=	468	448		431
Ada→Gus n= 334	279	275		269

[†]*NRI through Week 48, then TFR beyond Week 48.*
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

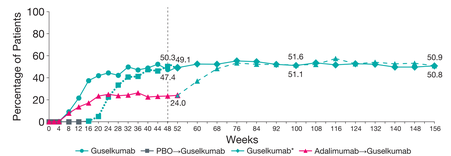
Figure 5. Proportion of Patients Who Achieved PASI 90 Response Through Week 156, *Primary Analysis*[†]



Guselkumab n= 329	329			
PBO→Gus n= 174	165			
Guselkumab* n=	468	448		431
Ada→Gus n= 334	279	275		269

[†]*NRI through Week 48, then TFR beyond Week 48.*
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

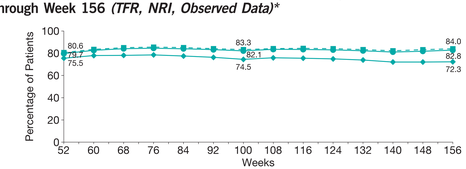
Figure 6. Proportion of Patients Who Achieved PASI 100 Response Through Week 156, *Primary Analysis*[†]



Guselkumab n= 329	329			
PBO→Gus n= 174	165			
Guselkumab* n=	468	448		431
Ada→Gus n= 334	279	275		269

[†]*NRI through Week 48, then TFR beyond Week 48.*
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

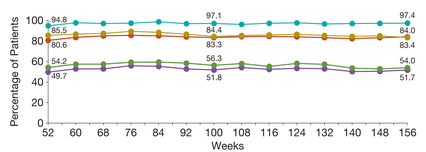
Figure 7. Proportion of Patients Who Achieved PASI 90 Response From Week 52 Through Week 156 *(TFR, NRI, Observed Data)



TFR: Gus n=	468	448		431
NRI: Gus n=	494	494		494
Observed Data: Gus n=	463	442		424

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

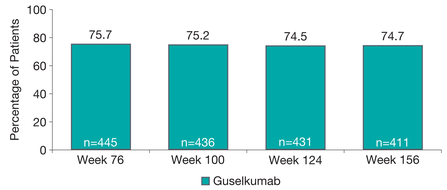
Figure 8. Proportion of Patients Who Achieved PASI 75, PASI 90, PASI 100, IGA Score of 0 or 1, and IGA Score of 0 (Weeks 52-156), *As Observed*



PASI: Guselkumab* n=	463	442		424
IGA: Guselkumab* n=	463	442		422

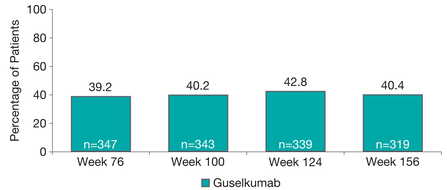
**Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.*

Figure 9. DLQI Score of 0 or 1 at Weeks 76-156 (TFR)*



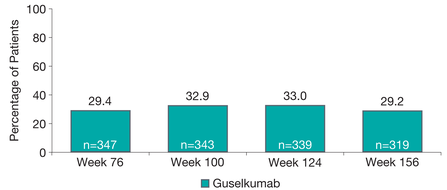
DLQI=Dermatology Life Quality Index
**Patients with baseline DLQI score >1.*
Weeks 76-156: Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.

Figure 10. PSSD Symptom Score=0 at Weeks 76-156 (TFR)*



PSSD=Psoriasis Symptom and Sign Diary
**Patients with baseline PSSD symptom score >0.*
Weeks 76-156: Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.

Figure 11. PSSD Sign Score=0 at Weeks 76-156 (TFR)*



PSSD=Psoriasis Symptom and Sign Diary
**Patients with baseline PSSD sign score >0.*
Weeks 76-156: Includes patients randomized to guselkumab at baseline and to placebo who crossed over to guselkumab at Week 16.

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

	Guselkumab (Weeks 0-48)	Guselkumab (Weeks 0-100)	Guselkumab (Weeks 0-156)
Treated patients, n	494	494	494
Avg. duration of follow-up, weeks	41.6	89.4	139.2
≥1 AE, n (%)	350 (70.9%)	395 (80.0%)	426 (86.2%)
Discontinued due to ≥1 AE, n (%)	10 (2.0%)	14 (2.8%)	21 (4.3%)
≥1 SAE, n (%)	21 (4.3%)	45 (9.1%)	66 (13.4%)
Infections, n (%)	248 (50.2%)	302 (61.1%)	335 (67.8%)
Requiring antibiotics	79 (16.0%)	124 (25.1%)	154 (31.2%)
Serious infections	3 (0.6%)	6 (1.2%)	11 (2.2%)
Malignancies other than NMSC, n (%)	2 (0.4%)	6 (1.2%)	9 (1.8%)
NMSC, n (%)	2 (0.4%)	2 (0.4%)	3 (0.6%)
MACE, n (%)	1 (0.2%)	1 (0.2%)	2 (0.4%)
Deaths, n (%)	0	2 (0.4%)	4 (0.8%)

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

Conclusions

- High levels of response were stably maintained through up to 3 years of continuous guselkumab treatment in patients with moderate to severe plaque psoriasis, regardless of the data handling rules utilized
- Treatment with guselkumab was well-tolerated

Reference

1. Blauvelt A., et al. *J Am Acad Dermatol.* 2017;76(3):405-17.

This poster was supported by Janssen Research & Development, LLC