

VISIBLE COHORT A: GUSELKUMAB DEMONSTRATED SKIN CLEARANCE THROUGH WEEK 48 IN PARTICIPANTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS ACROSS ALL SKIN TONES



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BACKGROUND



VISIBLE is an ongoing, Phase 3b, multicenter, randomized, double-blinded, placebo (PBO)-controlled study of guselkumab (GUS) for the treatment of participants with moderate-to-severe plaque psoriasis (PsO) across all skin tones



VISIBLE comprises 2 cohorts:



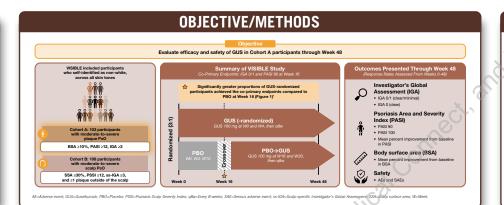
 $\textbf{Cohort A:} \ \text{participants with moderate-to-severe plaque PsO}$

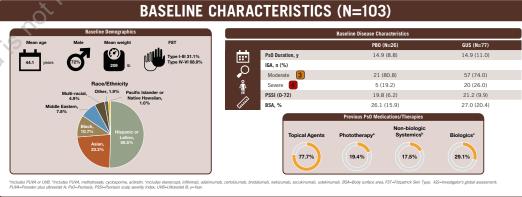


Cohort B: participants with moderate-to-severe scalp PsO



VISIBLE was intentionally designed to address historical disparities in clinical trials and enable healthcare professionals to make evidence-based medical decisions for people of all skin tones





CONCLUSIONS



Through Week 48, VISIBLE Cohort A study results showed:



of GUS-randomized participants achieved clear/almost clear skin (IGA 0/1 and PASI 90)



mean % improvement from baseline in BSA and PASI among GUS-randomized participants



>50% of GUS-randomized participants achieved complete clearance



No new safety signals were identified

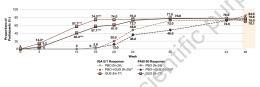


Clinical responses achieved at Week 16 were maintained or improved through Week 48 with continuous GUS treatment, demonstrating high efficacy and durable responses in participants across all skin tones

Significantly greater IGA 0/1 and PASI 90 response rates were achieved by GUS-randomized vs PBO-treated participants at Week 16. and response rates were sustained or improved through Week 48

By Week 48, response rates were similar for GUS-randomized and PBO \rightarrow GUS participants

Figure 1. Proportions of Participants Achieving IGA 0/1 and PASI 90 Through Week 48



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Figure 2. Participant Who Achieved IGA 0/1 and PASI 90 at Week 16 and Complete Skin Clearance (IGA 0 and PASI 100) at Week 48



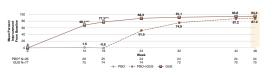
A=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index.

The GUS-randomized group achieved >94% mean improvement in BSA and PASI through Week 48 (Figures 3 and 4)

RESULTS

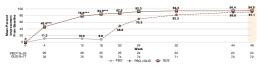
Mean percent improvement in BSA and PASI continuously increased from Week 16 through Week 48

Figure 3. Mean Percent Improvement From Baseline in BSA Through Week 48



****pc.0001 is PBO, p-values were based on the mixed-effect model for repeated measures. Fior participants who were randomized to PBO at Week O, only time and consistent or SUS at or after Week I, only time and consistent or SUS at or after Week I. Gene included. When participants discontinued study agand us to last of efficacy, worsening of PsO, or use of a prohibited PsO treatment, zero change from baseline was assigned from that point award. Missing data were not imputed SSM-degree states quite Sectionships in Chemicality Side Study Sectionships (Schemichter Side August Study Sectionships) (Schemichter Side August Side Study Sectionships) (Schemichter Side August Sectionships) (Schemichter Side Study Sectionships) (Schemichter Side Stud

Figure 4. Mean Percent Improvement From Baseline in PASI Through Week 48

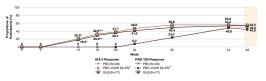


***p-0.001 vs PBO, p-values were based on the mixed-effect model for repeated measures. *For participants who were randomized to PBO at Week O, only those who crossed over to GUS at or after Week I 6 were included. When participants discontinued study agent due to lack of efficacy, worsening of PsO, or use of a protabled PsO treatment, zero change from baseline was assigned from that point onward. Missing data were not

Significantly greater proportions of GUS-randomized participants achieved complete skin clearance (IGA 0 and PASI 100) compared to PBO at Week 16, with response rates continuing to improve through Week 48

 By Week 48, response rates were similar for GUS-randomized and PBO→GUS participants

Figure 5. Proportions of Participants Achieving IGA 0 and PASI 100 Through Week 48



"pc.QG or PBO, ""pc.QG vs PBO, ""pc.QG vs PBO, ""pc.QG vs PBO, "pvalues were based on the Cochain-Mantel-Henrate lest statified by Fitzpatrick Skin "ppc (HIMPA)", Ppc priticipants who were andomized to PBO at Week Q, only hose who crossed over In GLS at or after Week 1 is were included in Weeks 20-48. Participants who discontinued study agent due to lack of efficacy, worsening of PbO, or use of a prohibited PbO treatment prior to designated vide were considered non-responders from that plan for Insent. Participants with missing data were considered non-responders at that

(IGA 0 and PASI 100) at Week 16 and Week 48 Week 0 Week 16 Week 48

Figure 6. Participants Who Achieved Complete Skin Clearance



dy surface area; GUS-Guselkumab; IGA-Investigator's Global Assessment; PASI-Psoriasis Area and Severit,

Safety findings were consistent with the established GUS safety profile, with no new safety signals identified through Week 48

Table 1. Key Safety Information Through Week 48

	PBO→GUS° Week 16-48	GUS Week 0-48
Safety analysis set, N	25	77
Average duration of follow-up (weeks)	31.5	46.3
Participants with ≥1 AE	5 (20.0%)	48 (62.3%)
Participants with ≥1 AE leading to discontinuation of study agent	0	2 (2.6%)
Participants with ≥1 SAE	1 (4.0%)*	1 (1.3%) ^h
Participants with ≥1 injection site reaction	0	0
Infections	5 (20.0%)	28 (36.4%)
Serious infections	1 (4.0%)	1 (1.3%)
tata shown are n (%), unless otherwise indicated.		
Through Week 48 There Were No Cases of: Deeth Mailignancy Active_TB	MACE ISD Serum-like sickness or anaphylaxis	

rificipants were counted only once for any given event, regardless of the number of times they experienced the event. Als were coded using MedDRA version 25.1. "Includes any PBO participants who crossed over to receive GUS. 'Als leading to discontinuation among GUS-treate rificipants were 1 event each of preparatory and impediginates allopic demantis. 'Als in in PBO treated participant was 1 event of policy for a policy participant was 1. event of policy plants and "Al-Adverse event, GUS-Gusekumste, IBD-inflammatory bowel disease; CM-Major advisors confidences cuts received and seven event. The Inflammatory bowel disease; CM-Major advisors confidences cuts received and seven event. The Inflammatory bowel disease; CM-Major advisors confidences cuts received and seven event. The Inflammatory bowel disease;

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