FREQUENCY AND PATIENT-REPORTED IMPACT OF PSORIATIC ARTHRITIS AND OTHER COMORBIDITIES IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS FROM THE VISIBLE TRIAL

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BACKGROUND

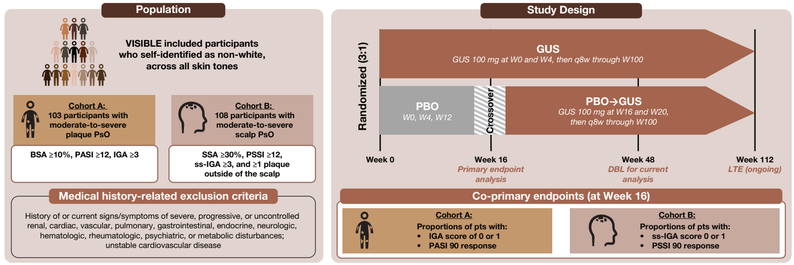
- Psoriasis frequently occurs with psoriatic arthritis (PsA) and/or cardiovascular and metabolic conditions
- VISIBLE (NCT05272150) evaluated the efficacy of guselkumab versus placebo in skin of color participants with moderate-to-severe body or scalp predominant plaque psoriasis
- As a first of its kind study 100% dedicated to people of color, VISIBLE provides insights into the frequency of psoriatic comorbidities in a diverse population

OBJECTIVES

- To examine the frequency of comorbid cardiometabolic conditions and PsA at baseline in VISIBLE clinical trial participants
- To evaluate treatment-related changes in patient-reported PsA impact in the subset of VISIBLE participants with PsA

METHODS

Figure 1. VISIBLE Population and Study Design



BSA=Body surface area; DBL=Database lock; GUS=Guselkumab; IGA=Investigator's Global Assessment; LTE=Long-term extension; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; Pts=Participants; q8w=Every 8 weeks; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

Comorbid medical conditions were identified based on medical history and/or laboratory results and vital signs at screening/baseline of the VISIBLE study (Table 1)

Table 1. Criteria for Identification of Baseline Psoriatic Comorbidities in VISIBLE

Hypertension	• MedDRA preferred term of Hypertension OR • Systolic BP ≥130 mmHg or diastolic BP ≥80 mmHg at ≥2 assessments across screening, Week 0, and Week 4
Diabetes	• MedDRA preferred term of Diabetes mellitus or Type 2 diabetes mellitus OR • HbA1c ≥6.5% at Week 0
Dyslipidemia	• MedDRA preferred term of Blood cholesterol increased, Hypercholesterolemia, High-density lipoprotein decreased, Hyperlipidemia, or Hypertriglyceridemia OR • Total cholesterol ≥200 mg/dL, LDL ≥160 mg/dL, triglycerides ≥200 mg/dL, or HDL <40 (males) or <50 (females) mg/dL at Week 0
Metabolic syndrome	Any 3 of the following criteria at Week 0: • BMI >30 kg/m^2 • Triglycerides ≥150 mg/dL • HDL <40 (males) or <50 (females) mg/dL • BP ≥130/85 mmHg • Fasting glucose ≥110 mg/dL
PsA	• Rheumatologist-confirmed diagnosis of PsA OR • PEST score ≥3 at screening

BMI=Body mass index; BP=Blood pressure; HbA1c=Hemoglobin A1C; HDL=High-density lipoprotein; LDL=Low-density lipoprotein; MedDRA=Medical Dictionary for Regulatory Activities; PEST=Psoriasis Epidemiology Screening Tool; PsA=Psoriatic arthritis

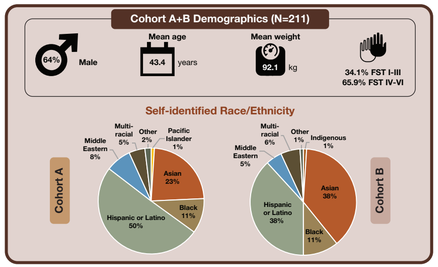
Patient-reported impact and symptoms of PsA by PSAID-12

In the efficacy analysis set of participants with PsA (either prior rheumatologist-confirmed diagnosis of PsA or Psoriasis Epidemiology Screening Tool [PEST] score ≥3 at the VISIBLE screening visit), PsA impact was measured using the Psoriatic Arthritis Impact of Disease 12 (PsAID-12) instrument:

- Numeric rating scale covering 12 physical and psychological domains considered important to patients with PsA[1]
- Final PsAID-12 scores range from 0 to 10 (higher results indicate worse status)

RESULTS

VISIBLE participant baseline characteristics are reflective of a diverse population with extensive skin/scalp psoriasis across all skin tones



Baseline Disease Characteristics

Cohort A (N=103)		
	PsO disease duration, y	14.9 (10.5)
	PASI score (0-72)	20.8 (9.1)
	BSA, %	26.8 (19.3)
	IGA score, n (%)	
	3	78 (75.7)
	4	25 (24.3)
Cohort B (N=102)		
	PsO disease duration, y	11.3 (10.6)
	PSSI score (0-72)	34.3 (13.2)
	SSA, %	59.8 (26.0)
	ss-IGA score, n (%)	
	3	84 (82.4)
	4	18 (17.6)

BMI=Body mass index; BSA=Body surface area; FST=Fitzpatrick skin type; IGA=Investigator Global Assessment; PASI=Psoriasis Area and Severity Index; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; SD=Standard deviation; SSA=Scalp surface area; ss-IGA=Scalp-specific Investigator Global Assessment. Data are means (standard deviation) unless otherwise specified.

VISIBLE participants have a high burden of psoriasis comorbidities at baseline (Table 2)

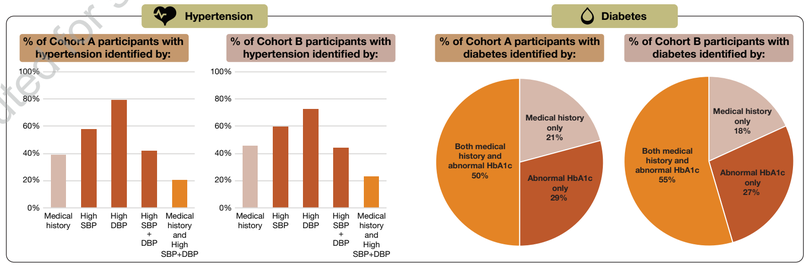
Table 2. Rates of Psoriasis Comorbidities in VISIBLE Participants

Comorbid condition	Cohort A PBO (N=26)	Cohort A GUS (N=77)	Cohort A Total (N=103)	Cohort B PBO (N=27)	Cohort B GUS (N=81)	Cohort B Total (N=108)
Hypertension	57.7% (n=15)	70.1% (n=54)	67.0% (n=69)	51.9% (n=14)	61.7% (n=50)	59.3% (n=64)
Diabetes	19.2% (n=5)	24.7% (n=19)	23.3% (n=24)	14.8% (n=4)	22.2% (n=18)	20.4% (n=22)
Dyslipidemia	92.3% (n=24)	71.4% (n=55)	76.7% (n=79)	63.0% (n=17)	67.9% (n=55)	66.7% (n=72)
Metabolic syndrome	42.3% (n=11)	37.7% (n=29)	38.8% (n=40)	14.8% (n=4)	29.6% (n=24)	25.9% (n=28)
PsA	30.1% (n=8)	32.5% (n=25)	32.0% (n=33)	23.1% (n=6)[a]	28.9% (n=22)[a]	27.5% (n=28)[a]

GUS=Guselkumab; PBO=Placebo; PsA=Psoriatic arthritis. [a]Efficacy analysis set: N=207 (PBO: N=26; GUS: N=76).

Mode of identification of comorbidities, whether by medical history and/or laboratory values/vital signs, provides information about whether a participant has a well-controlled comorbidity, undiagnosed comorbidity, or sub-optimally controlled comorbidity (Figure 2)

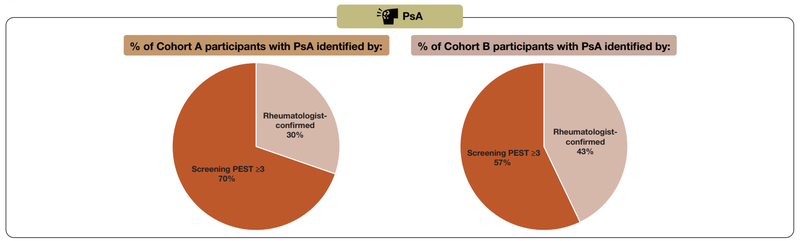
Figure 2. Identification of Hypertension and Diabetes by Medical History and/or Laboratory Values/Vital Signs



HbA1c=Hemoglobin A1C; DBP=Diastolic blood pressure; SBP=Systolic blood pressure.

Comorbid PsA at baseline was identified based on history of rheumatologist-confirmed PsA or PEST score ≥3 at the VISIBLE screening visit (Figure 3)

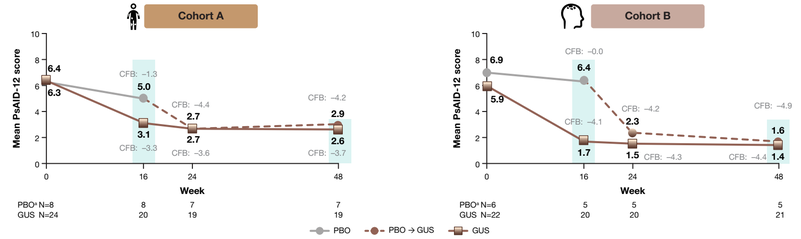
Figure 3. Identification of Comorbid PsA by Rheumatologist-Confirmed Diagnosis vs Screening PEST



PEST=Psoriasis Epidemiology Screening Tool; PsA=Psoriatic arthritis.

Mean baseline PsAID-12 scores for participants with PsA in both cohorts indicate substantial PsA burden at enrollment

Figure 4. Mean PsAID-12 Scores Over Time Among VISIBLE Participants With PsA



CFB=Mean change from baseline; GUS=Guselkumab; PBO=Placebo; PsAID-12=Psoriatic Arthritis Impact of Disease 12. *For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in Weeks 24 and 48. When participants discontinued study agent due to lack of efficacy, worsening of psoriasis, or use of a prohibited psoriasis treatment, baseline values (at Week 0) were assigned from that point onward.

Overall, Cohort A and B participants randomized to guselkumab achieved clinically meaningful improvements (mean decrease from baseline of ≥3 points) and mean PsAID-12 scores indicative of patient-acceptable scores (≤3.95) at Week 16 that were sustained at Week 48 (Figure 4)

CONCLUSIONS

- VISIBLE participants have a high burden of psoriasis-associated comorbidities, including pre-existing hypertension, diabetes, dyslipidemia, metabolic syndrome, and PsA
- Substantial proportions of VISIBLE participants had pre-existing PsA and cardiometabolic disease that was either undiagnosed or diagnosed but sub-optimally controlled at enrollment
- Participants with PsA reported high impact at baseline but achieved rapid and clinically meaningful improvements with guselkumab treatment at Week 16 that were sustained through Week 48
- Moderate to severe plaque psoriasis often comes with multiple comorbidities that could be managed in collaboration with other medical specialties

References: 1. Di Carlo M, et al. *J Rheumatol.* 2017;44(3):279–85. **Acknowledgments:** The authors are grateful to the VISIBLE study participants and their families and to the VISIBLE investigators and study site personnel. Medical writing support was provided by Erin Bekes, PhD of Certara Synchrogenix under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298-1304) and was funded by Janssen Scientific Affairs, LLC. This poster was supported by Janssen Scientific Affairs, LLC. **Disclosures: LSG:** investigator/advisor and/or speaker for AbbVie, Amgen, Arctis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **GH:** consultant, speaker, or research support from Abbvie, Amgen, Athenex, Beiersdorf, Bristol Myers Squibb, Boehringer Ingelheim, Bond Avillion, Castle Biosciences, Celgene, CeraVe, Dermavant, Dermtech, Janssen, LEO Pharma, Lilly, MC2, MedX, Novartis, Ortho Dermatologics, Pfizer, Regeneron/Sanofi, Sun Pharma, Takeda, and UCB. **MS:** consultant/received honoraria from AbbVie, Apogee, Arcutis, Bristol Myers Squibb, Dermavant, Galderma, Incyte, Janssen, LEO, Lilly USA, Novartis, Ortho Dermatologics, Regeneron, Sanofi-Genzyme, Takeda, and UCB; served as a speaker for AbbVie, Arcutis, Bristol Myers Squibb, Dermavant, Janssen, Lilly USA, Pfizer, Regeneron, Sanofi-Genzyme, and UCB; served as an investigator for AbbVie, Cara, CorEvitas Atopic Dermatitis Registry, CorEvitas Psoriasis Registry, Dermavant, Dermira, Lilly USA, Mindera, Novartis, and Union. **T Bhutani:** principal investigator for studies being sponsored by AbbVie, Castle, CorEvitas, Dermavant, Galderma, Mindera, and Pfizer; additional research funding from Novartis and Regeneron; served as an advisor for AbbVie, Arcutis, Boehringer-Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, Pfizer, Novartis, Sun, and UCB. **OC, TA, KR, DC:** employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company. **AR:** advisor and/or speaker for Arcutis, Dermavant, Eli Lilly, EPI Health, Janssen, Leo, Novartis, Sciton, Sun, and UCB; owns stock in Strathspey Crown. **GY:** principal investigator for studies being sponsored by AbbVie, Amgen, Aralez, Janssen, Lilly and Sanofi; served as an advisor for AbbVie, Amgen, Aralez, Arcutis, Bausch Health, Biodermа, Bristol Myers Squibb, Byrdie, Galderma, Incyte, Janssen, Johnson & Johnson, Leo, L'Oréal, Medexus, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, UCB, and Unilever. **JY:** speaker/consultant/honoraria/trialist for AbbVie, Amgen, Anacor, Arcutis, Astella, Bausch, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Coherus, Dermira, Eli Lilly, Forward, Galderma, Janssen, Leo, Medimmune, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun, Takeda, UCB, and Xenon. **TM, LLG:** employees of Janssen Research and Development, LLC, a Johnson & Johnson company. **LG:** investigator, speaker, or consultant to Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Galderma, Highlitt, Incyte, Janssen, Lilly, OrthoDerm, Pfizer, UCB, and Ventyx. **AF:** advisor and/or investigator for Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Galderma, Incyte, Janssen, Novartis, Pfizer, Regeneron, Sanofi, and Sun Pharma. **SK:** advisory board member/consultant for Abbvie, Amgen, Arcutis Biotherapeutics, Aslan Pharmaceuticals, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Dermavant, Galderma, Incyte Corporation, Johnson & Johnson, Leo Pharma, Novartis Pharmaceuticals Corporation, Pfizer, Regeneron Pharmaceuticals, and Sanofi; has served as an investigator for Galderma, Incyte, Pfizer, and Sanofi. **AA:** received grants (funds to institution) from AbbVie, Amgen, Arcutis, Castle, Dermavant, Galderma, and LEO; served on an advisory board or consultant for AbbVie, Allergan, Almirall, Alphyn, Apogee, Arcutis, Avita, Bausch Health, Beiersdorf, Bristol Myers Squibb, Canfield, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Genentech, Incyte, Janssen, LEO, L'Oréal, Ortho, Pfizer, Sanofi-Regeneron, Swiss American, UCB, and VisualDx; served as a speaker for Bristol Myers Squibb, Janssen, Johnson & Johnson, L'Oréal, Regeneron, and Sanofi-Genzyme; has received royalties from Springer, Wiley-Blackwell, and Wolter Kluwer Health; has received equipment from Aerolase.

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