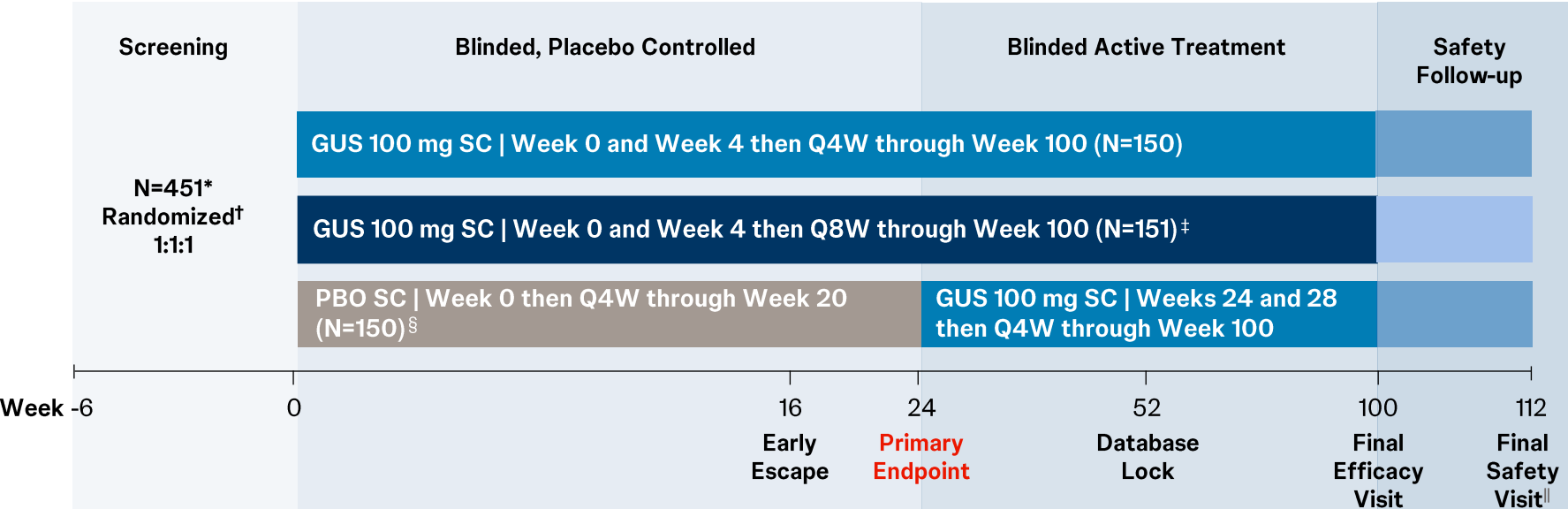


SOLSTICE: Study of Guselkumab in Adult Patients With Active PsA With Inadequate Response and/or Intolerance to One Prior TNF Inhibitor –Week 52 Results

SOLSTICE | Trial Design^{1,2}



STUDY DESIGN

Phase 3b, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of guselkumab SC administered Q4W and Q8W in adult patients with active PsA who had an inadequate response or intolerance to 1 prior TNF inhibitor therapy^{1,2}

Primary Endpoint (multiplicity controlled)

ACR20 response at Week 24

Select Major Secondary Endpoints (multiplicity controlled)

IGA 0/1 PASI 90 response at Week 24^{||}

PASI 90 response at Week 24

HAQ-DI at Week 24[#]

FACIT-F at Week 24[#]

MDA at Week 24

Select Major Secondary Endpoints (weakly controlled)

ACR50 at Week 24

ACR70 at Week 24

INCLUSION CRITERIA

✓

Age ≥18 years

Active PsA (≥3 swollen joints; ≥3 tender joints; CRP ≥0.3 mg/dL); CASPAR criteria met

Inadequate response and/or intolerance to 1 prior TNF inhibitor therapy

Active plaque PsO (≥1 PsO plaque ≥2 cm and/or nail PsO) or documented history of plaque PsO

EXCLUSION CRITERIA

✗

Other inflammatory diseases

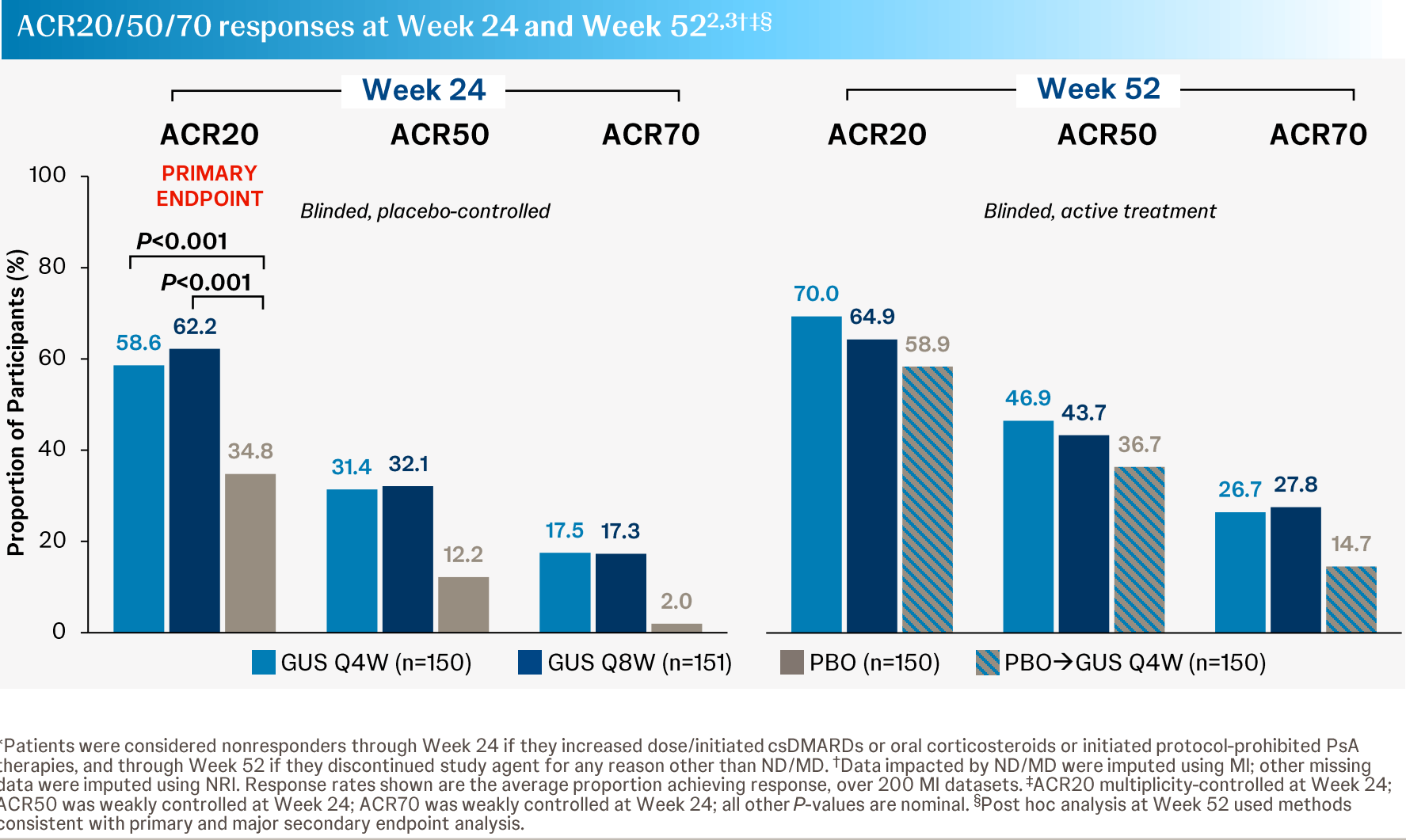
Received >1 anti-TNFα agent, Janus kinase inhibitor, or immunosuppressants

History of chronic or recurrent infectious disease

Allergies or hypersensitivity to guselkumab or its excipients

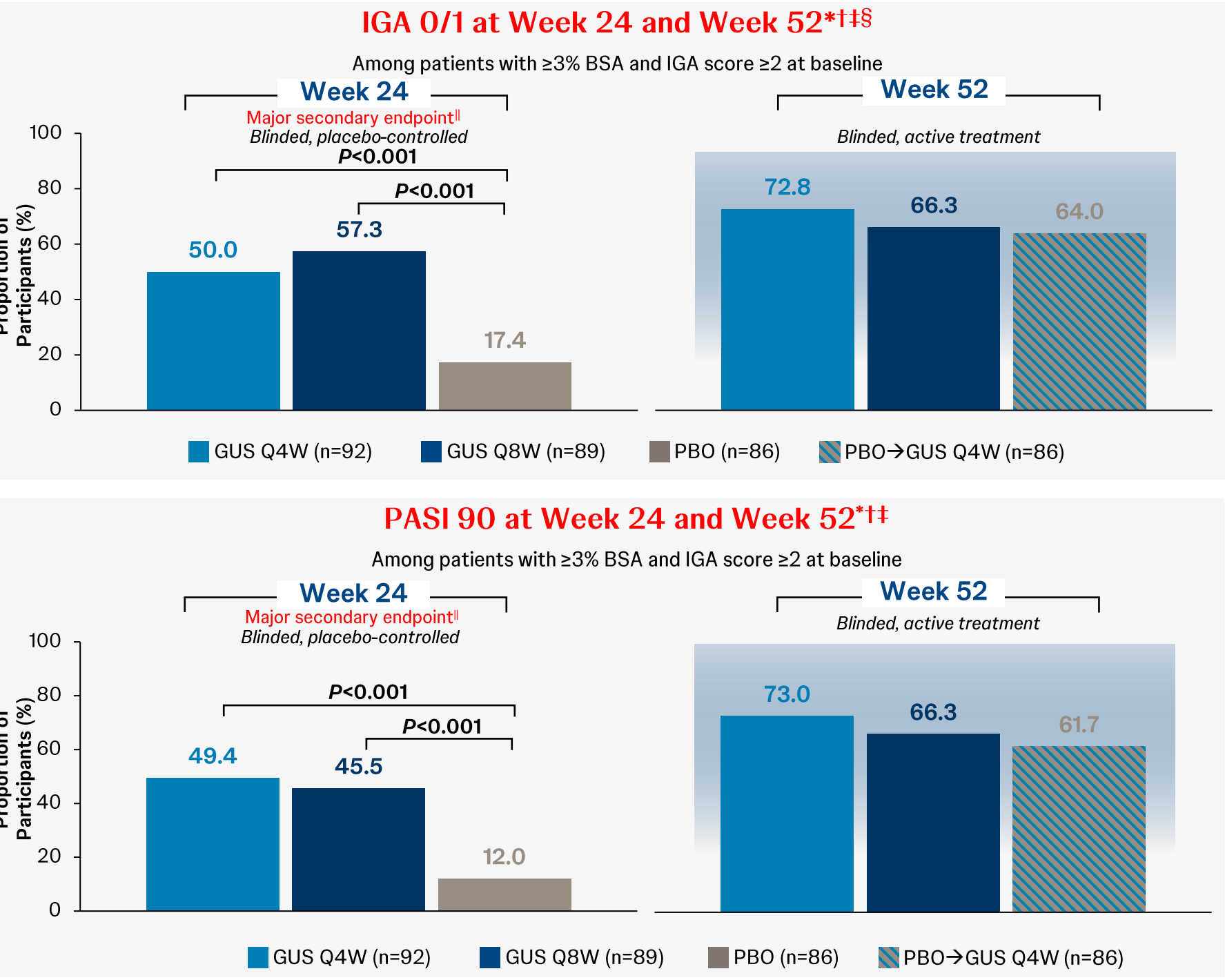
*Total number randomized=453, the full analysis set of 451 excludes 1 patient who was double randomized. †Randomization was stratified by baseline use of csDMARDs. ‡PBO SC was administered at week 8 then Q8W through Week 100 to maintain blinding. §At Week 24, patients taking placebo crossed over to receive GUS 100 mg Q4W thereafter through Week 100. ||Final safety follow-up at Week 112 is 12 weeks after final study agent administration. ^{||}IGA 0 or 1 and ≥2-grade reduction from BL. [#]LS mean change from baseline.

SOLSTICE | Efficacy Data



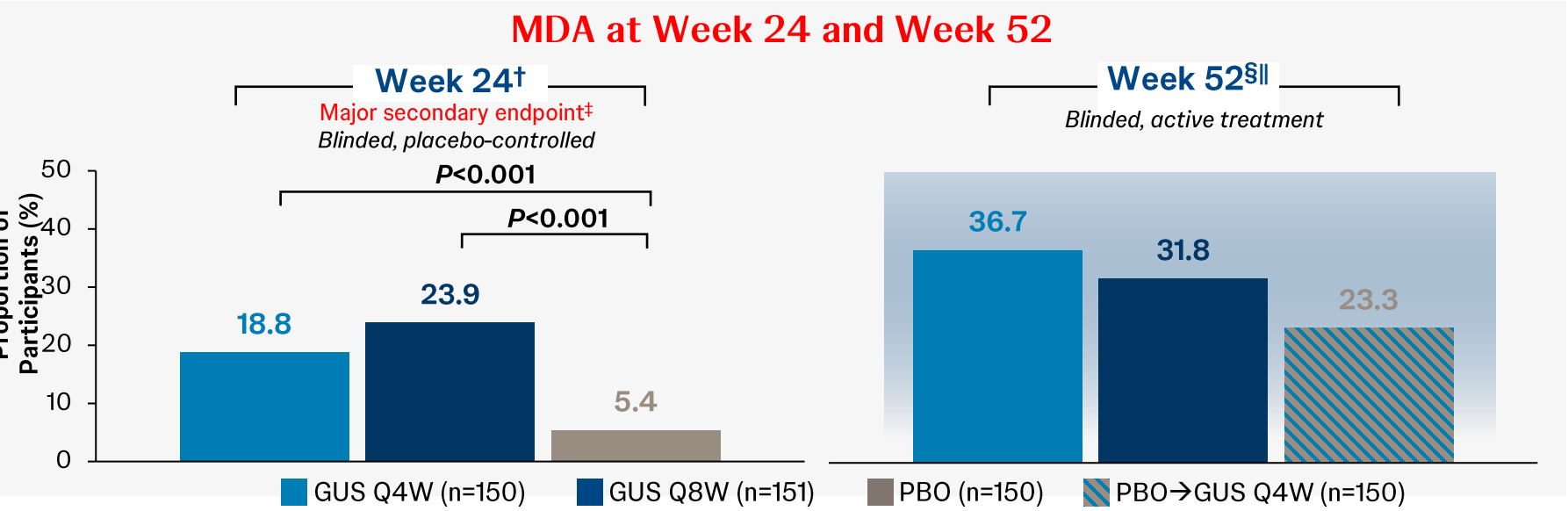
*Patients were considered nonresponders through Week 24 if they increased dose/initiated csDMARDs or oral corticosteroids or initiated protocol-prohibited PsA therapies, and through Week 52 if they discontinued study agent for any reason other than ND/MD. †Data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI. Response rates shown are the average proportion achieving response, over 200 MI datasets. ‡ACR20 multiplicity-controlled at Week 24; ACR50 was weakly controlled at Week 24; ACR70 was weakly controlled at Week 24; all other P-values are nominal. §Post hoc analysis at Week 52 used methods consistent with primary and major secondary endpoint analysis.

Skin Efficacy at Week 24 and Week 52^{2,3}

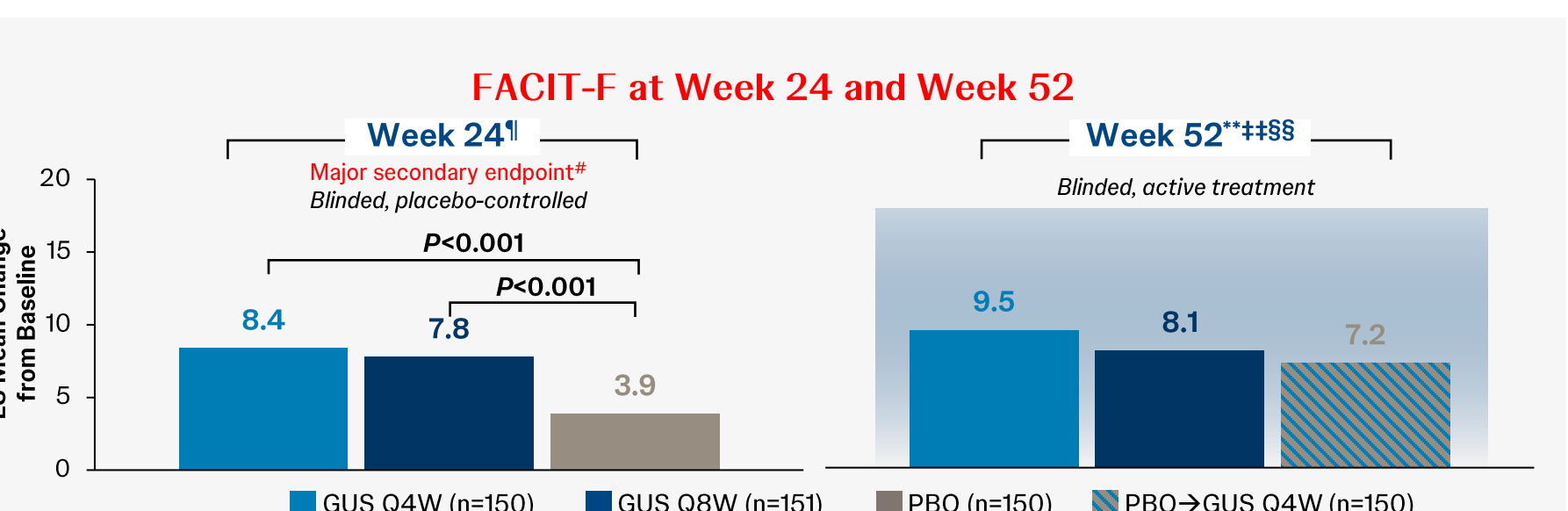
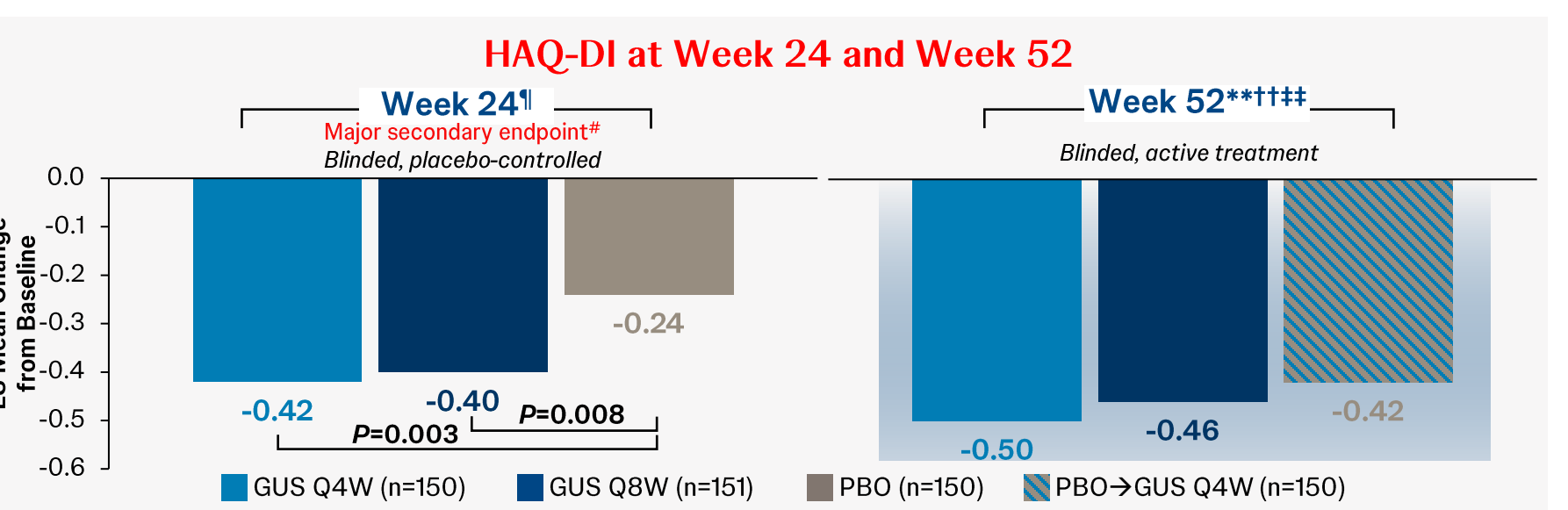


SOLSTICE | Additional Efficacy Data

MDA score at Week 24 and Week 52^{2,3*}



Patient Reported Outcomes^{2-4*}



*Efficacy analyses include all randomized patients; 1 patient was randomized to 2 sites/treatment groups simultaneously and was excluded from all analyses. [†]After applying treatment failure rules (no change from BL or nonresponder), data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI. [‡]At week 24, the major secondary endpoints of change in IGA, PASI90, HAQ-DI, FACIT-F, and MDA were multiplicity controlled. [§]Patients were considered nonresponders through Week 24 if they increased dose/initiated csDMARDs or oral corticosteroids or initiated protocol-prohibited PsA therapies, and through Week 52 if they discontinued study agent for any reason other than ND/MD. ^{||}Data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI. Response rates shown are the average proportion achieving response, over 200 MI datasets. ^{††}After applying treatment failure rules (no change from BL or nonresponder), data impacted by ND/MD were not used; other missing data were imputed using MI for continuous endpoints and NRI for binary endpoints. ^{##}Major secondary endpoints are multiplicity controlled; *P*-values were based on analysis of covariance for continuous endpoints and generalized linear mixed models for binary endpoints. ^{**}Missing Data Imputation: Missing data were imputed using MI after applying the ICE strategies. The N includes all subjects with change data at Week 52 after applying the ICE Strategy and Missing Data Imputation. ^{††}Analysis Model: After applying the ICE Strategy and Missing Data Imputation, data at Week 52 was analyzed using an ANCOVA model for each MI dataset. The explanatory variables of the ANCOVA model included baseline HAQ-DI score, treatment group, and baseline use of non-biologic DMARDs. ^{##}The LS Means and CI were based on combining ANCOVA results from each MI dataset. The corresponding N includes all subjects with change data at Week 52 after applying the ICE Strategy and Missing Data Imputation. ^{§§}Analysis Model: After applying the ICE Strategy and Missing Data Imputation, data at Week 52 was analyzed using an ANCOVA model for each MI dataset. The explanatory variables of the ANCOVA model included baseline FACIT score, treatment group, and baseline use of non-biologic DMARDs.

SOLSTICE | Safety Data Through Week 24 and Week 52^{2,3*†}

	Through Week 24 (PBO-controlled period)			Through Week 52		
	GUS Q4W (n=150)	GUS Q8W (n=151)	PBO (n=149)	GUS Q4W (n=150)	GUS Q8W (n=151)	PBO→ GUS Q4W [‡] (n=138)
Mean weeks of follow up	24.0	23.7	23.6	50.7	50.2	27.4
Mean number of GUS administrations	5.7	3.8	0.0	12.1	6.6	6.7
Patients with 1 or more, n (%)						
AE	70 (46.7)	81 (53.6)	72 (48.3)	97 (64.7)	101 (66.9)	64 (46.4)
SAE	2 (1.3)	4 (2.6)	6 (4.0)	5 (3.3)	10 (6.6)	2 (1.4)
AE leading to discontinuation of study agent	1 (0.7)	2 (1.3)	3 (2.0)	1 (0.7)	2 (1.3)	2 (1.4)
Infections	35 (23.3)	43 (28.5)	44 (29.5)	50 (33.3)	63 (41.7)	39 (28.3)
Opportunistic infections	0	0	0	0	0	0
Injection site reactions	1 (0.7)	2 (1.3)	1 (0.7)	6 (4.0)	3 (2.0)	1 (0.7)



Study remains blinded through Week 112



Through Week 24

- 2 serious infections (laryngitis, pyelonephritis)
- 1 malignancy (basal cell carcinoma),
- 2 VTE events (DVT and PE in same patient)
- 1 MACE (myocardial infarction)
- 1 death (MACE patient)



Through Week 52

- 2 malignancies (gastric, colon cancer [fatal])
- 1 serious infection (cellulitis)
- 1 death (colon cancer)

*Includes all pts who received ≥1 study agent administration. [†]Patients are counted only once for any given event, regardless of the number of times they actually experienced the event. [‡]Includes only patients who received GUS Q4W following crossover at Week 24. AEs are coded using Medical Dictionary for Regulatory Activities Version 27.0.

ACR, American College of Rheumatology; AE, adverse event; ANCOVA, analysis of covariance; BL, baseline; BSA, body surface area; CASPAR, CIASsification Criteria for Psoriatic Arthritis; CI, confidence interval; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DVT, deep vein thrombosis; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GUS, guselkumab; HAQ-DI, Health Assessment Questionnaire-Disability Index; ICE, intercurrent event; IGA, Investigator's Global Assessment of psoriasis; LS, least squares; MACE, major adverse cardiovascular event; MD, major disruption; MDA, minimal disease activity; MI, multiple imputation; ND, natural disaster; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; PE, pulmonary embolism; PsA, psoriatic arthritis; PsO, psoriasis; Q4W, every 4 weeks; Q8W, every 8 weeks; SAE, serious adverse event; SC, subcutaneous; TNF, tumor necrosis factor; VTE, venous thromboembolism; W, weeks.

1. ClinicalTrials.gov. Guselkumab in Active Psoriatic Arthritis Participants With Inadequate Response/Intolerance to One Prior Anti-TNF Alpha Agent (SOLSTICE). ClinicalTrials.gov identifier: NCT04936308. Updated August 20, 2026. Accessed August 24, 2026. Available at: <https://clinicaltrials.gov/study/NCT04936308>. 2. Ogdie A, et al. *Arthritis Rheumatol*. 2026;78(8):1674-1686. DOI:/art.70092. 3. Gottlieb AB, et al. RWCS 2026. Poster. 4. Data on file. Janssen Biotech, Inc.