

# SOLSTICE: Efficacy of Guselkumab in Participants With Active Psoriatic Arthritis and Inadequate Response and/or Intolerance to One Prior Tumor Necrosis Factor Inhibitor Across Baseline Subgroups



## Key Takeaways

 In participants with active PsA who were TNFi-IR to one prior TNFi, guselkumab treatment demonstrated efficacy across PsA domains, including achievement of almost clear or clear skin at W24

 **Guselkumab treatment effect observed with both dosing regimens remained generally consistent across a broad range of subgroups of diverse patient profiles**

Joseph F. Merola,<sup>1</sup> Philip J. Mease,<sup>2,3</sup> Alexis Oggie,<sup>4</sup> Christopher T. Ritchlin,<sup>5</sup> Jose U. Scher,<sup>6</sup> Oyediran Adelakun,<sup>7</sup> Evan Leibowitz,<sup>7</sup> Yanli Wang,<sup>8</sup> Yevgeniy Krol,<sup>7</sup> Alice B. Gottlieb,<sup>9</sup>

<sup>1</sup>Department of Dermatology and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center and O'Donnell School of Public Health, Dallas, TX, USA; <sup>2</sup>Rheumatology Research, Providence Swedish Medical Center, Seattle, WA, USA; <sup>3</sup>University of Washington School of Medicine, Seattle, WA, USA; <sup>4</sup>Division of Rheumatology, University of Pennsylvania School of Medicine, Philadelphia, PA, USA; <sup>5</sup>Department of Medicine, Allergy/Immunology, and Rheumatology, University of Rochester Medical Center, Rochester, NY, USA; <sup>6</sup>New York University Grossman School of Medicine, New York, NY, USA; <sup>7</sup>Johnson & Johnson, Horsham, PA, USA; <sup>8</sup>Johnson & Johnson, Spring House, PA, USA; <sup>9</sup>Department of Dermatology, UT Southwestern Medical Center, Dallas, TX, USA

<sup>a</sup>Johnson & Johnson, Horsham, PA, USA; <sup>b</sup>Johnson & Johnson, Spring House, PA, USA; <sup>c</sup>Department of Dermatology, UT Southwestern Medical Center, Dallas, TX, USA

## Background

 Guselkumab (GUS), a fully human, dual-acting,<sup>1</sup> monoclonal antibody that selectively inhibits the interleukin (IL)-23p19 subunit, is approved to treat moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), and moderately to severely active Crohn's disease and ulcerative colitis<sup>2</sup>

 SOLSTICE is an ongoing Phase 3b, multicenter, randomized, double-blinded placebo (PBO)-controlled study evaluating the efficacy and safety of GUS in participants with active PsA who had an inadequate response (IR; inadequate efficacy and/or intolerance) to one prior tumor necrosis factor inhibitor (TNFI)

 At Week (W)24, GUS demonstrated significant improvements across PsA signs and symptoms, including joint and skin outcomes, compared with placebo<sup>3</sup>

## Objective

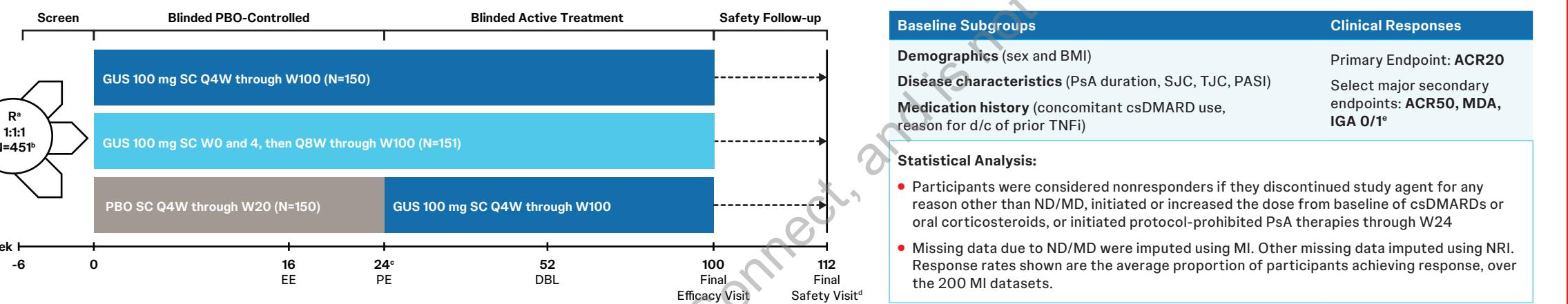
 This analysis assessed the consistency of GUS clinical responses at W24 across SOLSTICE participant subgroups

## Methods

### Inclusion Criteria

- ✓ Age  $\geq 18$  years
- ✓ Active PsA ( $\geq 3$  SJC;  
 $\geq 3$  TJC; CRP  $\geq 0.3$  mg/dL);  
CASPAR criteria met
- ✓ Inadequate response  
and/or intolerance to  
1 prior TNFi therapy**
- ✓ Active ( $\geq 1$  PsO plaque  
 $\geq 2$  cm and/or nail PsO) or  
history of PsO

<sup>a</sup>Randomization was stratified by baseline use of cDMARDs. <sup>b</sup>Total number randomized=453, the full analysis set of 451 excludes 1 participant who was double randomized. <sup>c</sup>Crossover. <sup>d</sup>Final safety follow-up at W12 is 12 weeks after final study agent administration. <sup>e</sup>IGA 0/1 response was evaluated among participants who had a baseline BSA of PsO ≥3% and an IGA ≥2. <sup>f</sup>ACR20/50=≥20%/50% improvement in American College of Rheumatology response criteria. <sup>g</sup>BMI=body mass index. <sup>h</sup>BSA=body surface area. <sup>i</sup>CASPAR=Clinical classification criteria for Psoriatic Arthritis. <sup>j</sup>CRP=C-reactive protein. <sup>k</sup>cDMARD=conventional synthetic disease-modifying antirheumatic drug. <sup>l</sup>DBL=database lock. <sup>m</sup>dL=discontinuation. <sup>n</sup>EE=early escape. <sup>o</sup>IGA=Investigator's Global Assessment of psoriasis. <sup>p</sup>MD=Major Disruption (Ukraine and neighboring countries/territories beginning 24 February 2022). <sup>q</sup>MDA=Minimal Disease Activity. <sup>r</sup>MI=multiple imputation. <sup>s</sup>ND=Natural Disaster (COVID-19 site access restrictions). <sup>t</sup>NRI=nonresponder imputation. <sup>u</sup>PASI=Psoriasis Area and Severity Index. <sup>v</sup>PE=primary endpoint. <sup>w</sup>Q4W/Q8W=every 4/8 weeks. <sup>x</sup>R=randomization. <sup>y</sup>SC=subcutaneous. <sup>z</sup>SJC=sacroiliac joint count. <sup>z</sup>TJC=tender joint count.



## Results

**Overall baseline demographics and disease characteristics were well balanced across treatment groups.**

- Mean baseline disease assessments were consistent with moderately-to-severely active PsA

	PBO (N=150)	GUS 100 mg Q4W (N=150)	GUS 100 mg Q8W (N=151)
<b>Demographics</b>			
<b>Age, yrs</b>			
Mean	49.2	50.6	51.9
<b>Sex</b>			
Male, %	43	50	49
Female, %	57	50	51
<b>BMI, kg/m<sup>2</sup></b>			
Mean	30.0	30.0	30.9
<b>Disease Characteristics</b>			
<b>PsA Disease Duration, yrs</b>			
Mean	7.0	8.8	8.3
<b>SJC (0-66)</b>			
Mean	10.2	10.7	10.3
<b>TJC (0-68)</b>			
Mean	16.8	18.1	17.1
<b>CRP, mg/dL</b>			
Mean	1.4	1.2	1.3
<b>PASI (0-72), N</b>			
Mean	146	149	150
<b>Participants With a BSA <math>\geq</math>3% and IGA <math>\geq</math>2</b>			
<b>Participants, N (%)</b>	86 (57)	92 (61)	89 (59)
<b>PsO Disease Duration, yrs</b>			
Mean	16.5	18.7	17.3
<b>BSA, %</b>			
Mean	13.9	17.0	15.7
<b>PASI (0-72)</b>			
Mean	9.0	10.4	10.1
<b>IGA score</b>			
Mild (2), %	45	48	44
Moderate (3), %	49	40	51
Severe (4), %	6	12	6
<b>Medication History</b>			
<b>Concomitant csDMARD use at baseline</b>			
Yes, %	56	59	57
<b>Reason for d/c of prior anti-TNF</b>			
Inadequate Response, %	79	84	80

