

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

### Executive Summary

### Study Design and Endpoints

### Patient Characteristics

### Efficacy Results

### Safety Results

### Abbreviations and References

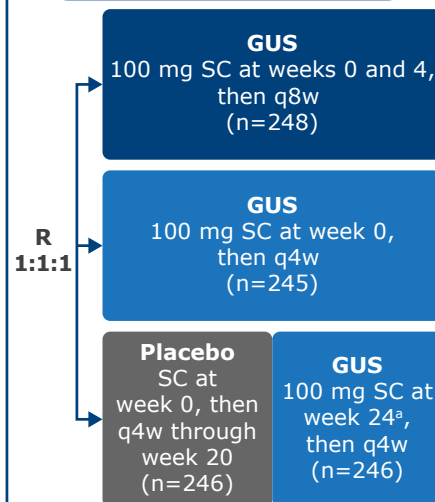
#### Overview<sup>1-3</sup>

A phase 3, randomized, multicenter, double-blind, placebo-controlled study was conducted to evaluate the efficacy and safety of GUS in biologic-naïve adult patients with active PsA  
N=739

#### Selected Eligibility Criteria<sup>1,2</sup>

- Adults with PsA ≥6 months per CASPAR criteria
- ≥5 tender and ≥5 swollen joints
- CRP ≥0.6 mg/dL
- Inadequate response or intolerance to standard therapies, including nonbiologic DMARDs, apremilast, and/or NSAIDs
- Stable doses of nonbiologic DMARDs, low-dose oral corticosteroids, or NSAIDs were permitted but not required

#### Study Design<sup>1,2</sup>

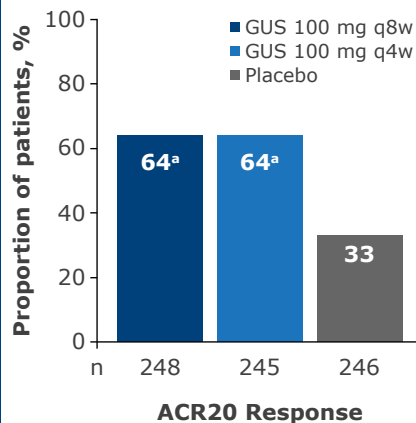


Safety follow-up: up to 112 weeks

<sup>a</sup>238 patients in the placebo group crossed over to GUS q4w; 8 patients received placebo only before study drug discontinuation.

#### Primary Endpoint<sup>1,2</sup>

A significantly greater proportion of patients achieved an ACR20 response at week 24 in the GUS groups vs the placebo group



<sup>a</sup>P<0.0001 vs placebo.

#### Major Secondary Endpoints<sup>1,2</sup>

Results at Week 24	GUS 100 mg q8w (n=248)	GUS 100 mg q4w (n=245)	Placebo (n=246)
HAQ-DI score <sup>a</sup>	-0.37 <sup>b</sup>	-0.40 <sup>b</sup>	-0.13
IGA PsO score 0 or 1 and ≥2 grade reduction <sup>c</sup>	70 <sup>b</sup>	68 <sup>b</sup>	19
PsA-modified vdH-S score <sup>a</sup>	0.52 <sup>d</sup>	0.29 <sup>e</sup>	0.95
SF-36 PCS score <sup>a</sup>	7.39 <sup>e</sup>	7.04 <sup>e</sup>	3.42
SF-36 MCS score <sup>a</sup>	4.17 <sup>d</sup>	4.22 <sup>d</sup>	2.14
Resolution of enthesitis (LEI score=0) <sup>c,f</sup>	50 <sup>g</sup>	45 <sup>g</sup>	29
Resolution of dactylitis (score=0) <sup>c,f</sup>	59 <sup>g</sup>	64 <sup>e</sup>	42

<sup>a</sup>Change from baseline (LS mean).

<sup>b</sup>P<0.0001 vs placebo. <sup>c</sup>Data are %.

<sup>d</sup>P=0.072 vs placebo. <sup>e</sup>P=0.011 vs placebo.

<sup>f</sup>Data were pooled across DISCOVER-1 and 2.

<sup>g</sup>P=0.0301 vs placebo.

#### Safety<sup>1,3</sup>

Through Week 24	GUS 100 mg q8w (n=248)	GUS 100 mg q4w (n=245)	Placebo (n=246)
Mean duration of follow-up, weeks	23.9	23.8	24.0
≥1 AE, n (%)	114 (46.0)	113 (46.0)	100 (41.0)
≥1 SAE, n (%)	3.0 (1.0)	8.0 (3.0)	7.0 (3.0)
Treatment discontinuation due to AEs, n (%)	2.0 (1.0)	6.0 (2.0)	4.0 (2.0)
Through Week 52	GUS 100 mg q8w (n=248)	GUS 100 mg q4w (n=245)	Placebo to GUS 100 mg q4w (n=238)
Mean duration of follow-up, years	1.0	1.0	0.5
≥1 AE, n (%)	155 (62.5)	152 (62.0)	87 (36.6)
≥1 SAE, n (%)	10 (4.0)	11 (4.5)	10 (4.2)
Treatment discontinuation due to AEs, n (%)	3 (1.2)	9 (3.7)	4 (1.7)

# TREMFYA® (guselkumab)

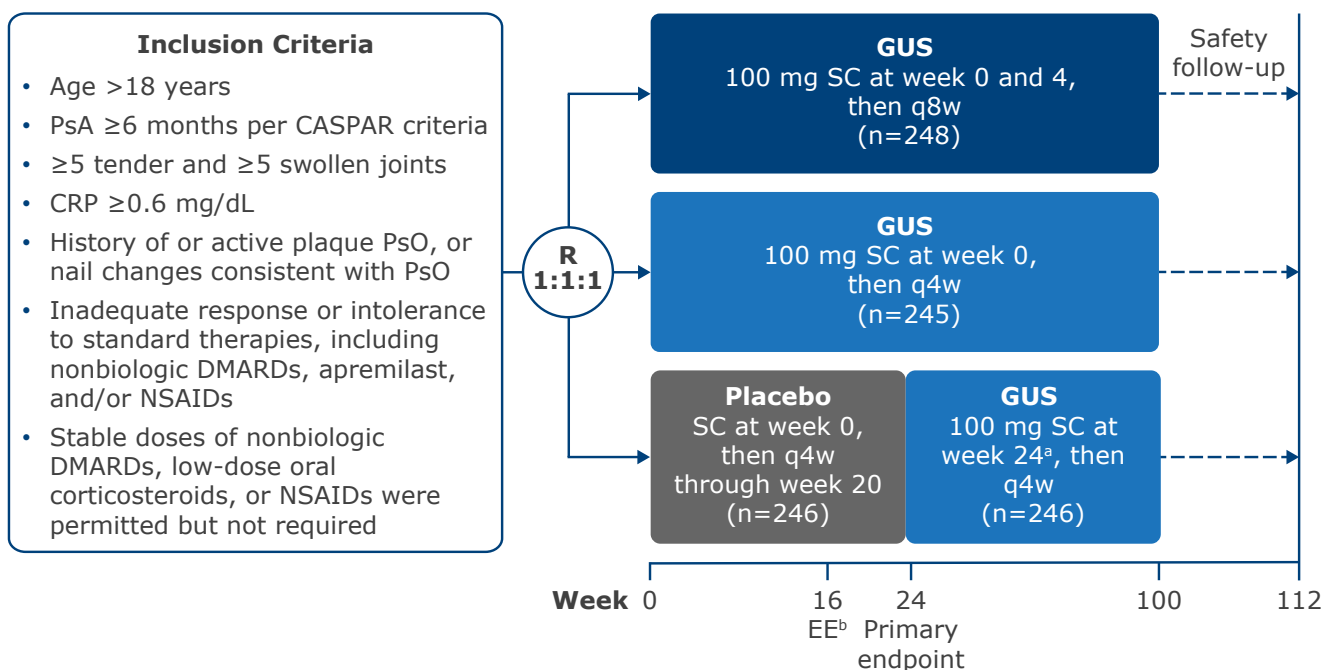
## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	<b>Study Design and Endpoints</b>	Patient Characteristics	Efficacy Results	Safety Results	Abbreviations and References
-------------------	-----------------------------------	-------------------------	------------------	----------------	------------------------------

<b>Study Design</b>	Endpoints	Data Handling Rules
---------------------	-----------	---------------------

- DISCOVER-2 was a phase 3, randomized, double-blind, multicenter, placebo-controlled study conducted in biologic-naïve adult patients with active PsA who had inadequate response to or intolerance of standard therapies, including nonbiologic DMARDs, apremilast, and NSAIDs.<sup>1-3</sup>



<sup>a</sup>238 patients in the placebo group crossed over to GUS q4w; 8 patients received placebo only before study drug discontinuation.

<sup>b</sup>Patients were eligible to initiate/increase background medications if there was <5% improvement from baseline in tender and swollen joint counts at week 16.

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	<b>Study Design and Endpoints</b>	Patient Characteristics	Efficacy Results	Safety Results	Abbreviations and References
	Study Design	<b>Endpoints</b>		Data Handling Rules	

### Primary Endpoint<sup>1,2</sup>

- Proportion of patients achieving an ACR20 response at week 24

### Major Secondary Endpoints<sup>a,1,2</sup>

- Change from baseline in PsA-modified vdH-S score at week 24
- IGA PsO score of 0 or 1 and  $\geq 2$  grade reduction from baseline at week 24
- Resolution of dactylitis and enthesitis at week 24 (pooled data across DISCOVER-1 and DISCOVER-2) in patients who had dactylitis and enthesitis at baseline<sup>4</sup>
- Change from baseline in HAQ-DI score at week 24
- Change from baseline in SF-36 PCS and SF-36 MCS scores at week 24

### Uncontrolled Secondary Endpoints<sup>b,1,2</sup>

- Proportion of patients achieving PASI75, PASI90, and PASI100 at week 24
- Proportion of patients achieving  $\geq 0.35$  improvement from baseline in HAQ-DI scores at week 24
- Change in the DAS28-CRP at week 24
- MDA response at week 24

<sup>a</sup>Endpoints were adjusted for multiplicity as per US statistical protocol.

<sup>b</sup>Endpoints were not adjusted for multiplicity as per US statistical protocol.

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	<b>Study Design and Endpoints</b>	Patient Characteristics	Efficacy Results	Safety Results	Abbreviations and References
-------------------	-----------------------------------	-------------------------	------------------	----------------	------------------------------

Study Design	Endpoints	<b>Data Handling Rules</b>
--------------	-----------	----------------------------

- Data handling rules were applied to all efficacy analyses from week 0 to 24.<sup>1,2</sup>
- Patients who met treatment failure criteria (discontinued study treatment, terminated study participation, initiated or increased DMARD or oral corticosteroid use, or initiated protocol-prohibited PSA treatment) were considered nonresponders for binary endpoints and as having no improvement from baseline for continuous endpoints.<sup>1,2</sup>
- NRI data were derived from randomized patients who received  $\geq 1$  dose of study agent.<sup>1,2</sup>
- Missing data were handled as follows:<sup>1,2</sup>
  - Patients with missing response endpoint data through week 52 were considered nonresponders.
  - Missing continuous endpoint data due to study agent discontinuation were imputed as no change.
  - Other missing continuous endpoint data were imputed using multiple imputation.

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	<b>Patient Characteristics</b>	Efficacy Results	Safety Results	Abbreviations and References
-------------------	----------------------------	--------------------------------	------------------	----------------	------------------------------

<b>Select Patient Baseline Demographics</b>	Medication Use at Baseline
---	----------------------------

- Baseline demographics were generally similar between the treatment groups.<sup>1</sup>

### Select Patient Baseline Demographics<sup>1</sup>

Characteristic	GUS 100 mg q8w n=248	GUS 100 mg q4w n=245	Placebo n=246
Age, years, mean	44.9	45.9	46.3
Sex, n (%)			
Female	119 (48)	103 (42)	129 (52)
Male	129 (52)	142 (58)	117 (48)
Number of swollen joints, 0-66, mean (SD)	11.7 (6.8)	12.9 (7.8)	12.3 (6.9)
Number of tender joints, 0-68, mean (SD)	19.8 (11.9)	22.4 (13.5)	21.6 (13.1)
Patient's assessment of pain, 0-10 cm VAS, mean (SD)	6.3 (2.0)	6.2 (2.0)	6.3 (1.8)
Patient's global assessment-arthritis, 0-10 cm VAS, mean (SD)	6.5 (1.9)	6.4 (1.9)	6.5 (1.8)
Physician's global assessment, 0-10 cm VAS, mean (SD)	6.6 (1.6)	6.6 (1.5)	6.6 (1.5)
HAQ-DI score, 0-3, mean (SD)	1.3 (0.6)	1.2 (0.6)	1.3 (0.6)
CRP, mg/dL, median (IQR)	1.3 (0.7-2.5)	1.2 (0.6-2.3)	1.2 (0.5-2.6)
IGA score of 3 or 4, mean (SD)	108 (44)	117 (48)	115 (47)
PASI score, 0-72, mean (SD)	9.7 (11.7)	10.8 (11.7)	9.3 (9.8)
PsA duration, years, mean (SD)	5.1 (5.5)	5.5 (5.9)	5.8 (5.6)
Psoriatic BSA, 0%-100%, mean (SD)	17.0 (21.0)	18.2 (20.0)	17.1 (20.0)
PsA-modified vdH-S score, 0-528, mean (SD)	23.0 (37.8)	27.2 (42.2)	23.8 (37.8)
Patients with enthesitis, mean (SD)	158 (64)	170 (69)	178 (72)
LEI score, 1-6, <sup>a</sup> mean (SD)	2.6 (1.5)	3.0 (1.7)	2.8 (1.6)
Patients with dactylitis, n (%)	111 (45)	121 (49)	99 (40)
Dactylitis score, 1-60, <sup>b</sup> mean (SD)	8.0 (9.6)	8.6 (9.6)	8.4 (9.3)
SF-36, mean (SD)			
PCS, 0-100	32.6 (7.9)	33.3 (7.1)	32.4 (7.0)
MCS, 0-100	47.4 (10.8)	48.4 (11.0)	47.2 (12.0)

<sup>a</sup>Among patients with available LEI score at baseline (q4w group, n=166; q8w group, n=157; and placebo group, n=175).  
<sup>b</sup>Among patients with dactylitis score at baseline (q4w group, n=121; q8w group, n=111; and placebo group, n=99).

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	<b>Patient Characteristics</b>	Efficacy Results	Safety Results	Abbreviations and References
-------------------	----------------------------	--------------------------------	------------------	----------------	------------------------------

Select Patient Baseline Demographics	<b>Medication Use at Baseline</b>
--------------------------------------	-----------------------------------

- Medication use at baseline were generally similar between the treatment groups.<sup>1</sup>

### Medication Use at Baseline<sup>1</sup>

Characteristic	GUS 100 mg q8w n=248	GUS 100 mg q4w n=245	Placebo n=246
Previous apremilast use, mean (SD)	4 (2)	5 (2)	4 (2)
Drug use at baseline			
DMARDs	170 (69)	170 (69)	172 (70)
Methotrexate, n (%)	141 (57)	146 (60)	156 (63)
Methotrexate dose, mg/week, mean (SD)	15.3 (5.2)	15.6 (5.0)	15.2 (4.6)
Oral corticosteroids for PsA, n (%)	50 (20)	46 (19)	49 (20)
Dose equivalent to prednisone, mg/day, mean (SD)	6.8 (2.5)	7.0 (2.4)	7.8 (2.5)
NSAIDs for PsA, n (%)	165 (67)	171 (70)	168 (68)

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

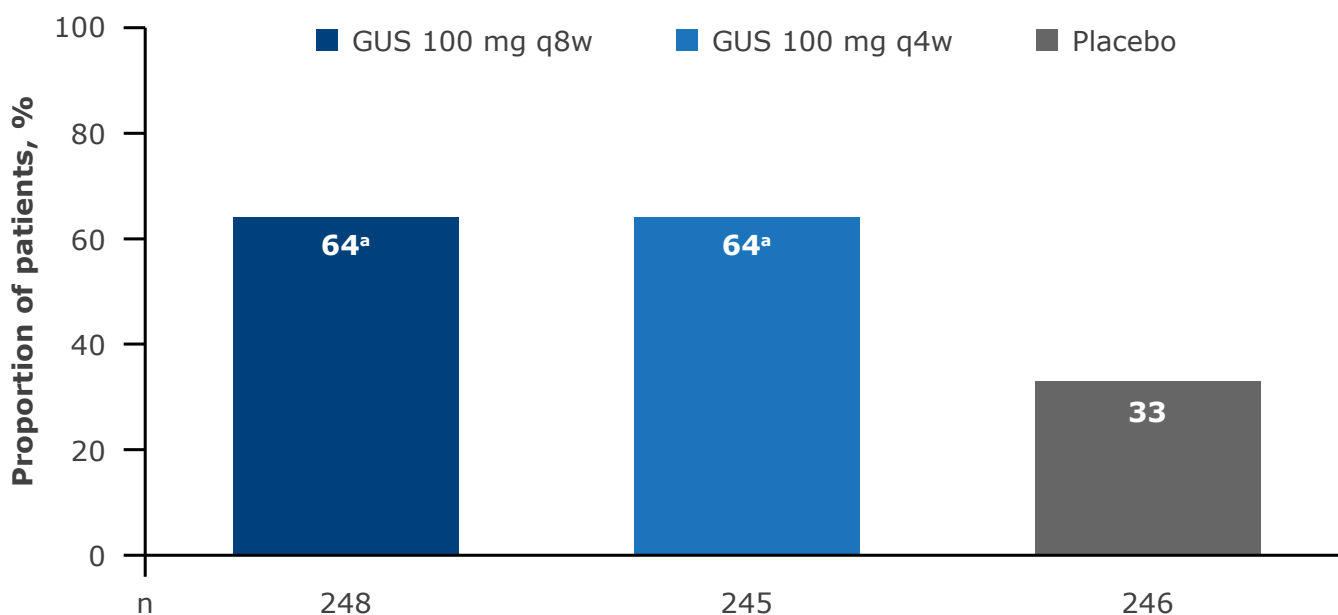
Executive Summary	Study Design and Endpoints	Patient Characteristics	<b>Efficacy Results</b>	Safety Results	Abbreviations and References
-------------------	----------------------------	-------------------------	-------------------------	----------------	------------------------------

<b>Efficacy Through Week 24</b>	Efficacy at Week 52
---------------------------------	---------------------

<b>Primary Endpoint</b>	Secondary Endpoints
-------------------------	---------------------

- A significantly greater proportion of patients achieved an ACR20 response at week 24 in the GUS groups vs the placebo group.<sup>1,2</sup>

### ACR20 Response at Week 24<sup>1,2</sup>



<sup>a</sup> $P < 0.0001$  vs placebo.

- The proportion of patients with methotrexate at baseline who achieved an ACR20 response at week 24 was 60% (85/141) and 63% (92/146) in the GUS q8w and q4w groups, respectively.<sup>1,2</sup>

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	<b>Efficacy Results</b>	Safety Results	Abbreviations and References
-------------------	----------------------------	-------------------------	-------------------------	----------------	------------------------------

<b>Efficacy Through Week 24</b>	Efficacy at Week 52
---------------------------------	---------------------

Primary Endpoint	<b>Secondary Endpoints</b>
------------------	----------------------------

- Summary of results through week 24 are summarized in the following table:

### Summary of Secondary Endpoint Results Through Week 24<sup>1,5</sup>

Endpoints	GUS 100 mg q8w n=248	GUS 100 mg q4w n=245	Placebo n=246
ACR20 response at week 16, <sup>a</sup> n (%)	137 (55)	137 (56)	83 (34)
<i>P</i> -value	<0.0001	<0.0001	-
ACR50 response at week 16, <sup>a</sup> n (%)	71 (29)	51 (21)	23 (9)
<i>P</i> -value	<0.0001	0.0004	-
ACR50 response at week 24, <sup>a</sup> n (%)	78 (32)	81 (33)	35 (14)
<i>P</i> -value	<0.0001	<0.0001	-
ACR70 response at week 24, <sup>a</sup> n (%)	46 (19)	32 (13)	10 (4)
<i>P</i> -value	<0.0001	0.0004	-
PsA-modified vdH-S score, <sup>b</sup> LS mean	0.52	0.29	0.95
Adjusted <i>P</i> -value	0.072	0.011	-
IGA PsO score 0 or 1 and ≥2 grade reduction, <sup>b-d</sup> n/N (%)	124/176 (70)	126/184 (68)	35/183 (19)
Adjusted <i>P</i> -value	<0.0001	<0.0001	-
Resolution of dactylitis (score=0) at week 24, <sup>e,f</sup> n/N (%)	95/160 (59)	101/159 (64)	65/154 (42)
Adjusted <i>P</i> -value	0.0301	0.011	-
Resolution of enthesitis (LEI score=0) at week 24, <sup>g,h</sup> n/N (%)	114/230 (50)	109/243 (45)	75/255 (29)
Adjusted <i>P</i> -value	0.0301	0.0301	-
HAQ-DI score, <sup>b</sup> LS mean	-0.37	-0.40	-0.13
Adjusted <i>P</i> -value	<0.0001	<0.0001	-
SF-36 PCS score, <sup>b</sup> LS mean	7.39	7.04	3.42
Adjusted <i>P</i> -value	0.011	0.011	-
SF-36 MCS score, <sup>b</sup> LS mean	4.17	4.22	2.14
Adjusted <i>P</i> -value	0.072	0.072	-

<sup>a</sup>Not part of the sequential testing procedure but was prespecified to be tested upon achieving statistical significance for ACR20 at week 24.  
<sup>b</sup>Change from baseline at week 24.  
<sup>c</sup>IGA PsO score 0=cleared; 1=minimal.  
<sup>d</sup>Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. Placebo, n=183; GUS 100 mg q4w, n=184 and q8w, n=176.  
<sup>e</sup>Pooled data from the phase 3 DISCOVER-1 and DISCOVER-2 studies among patients with dactylitis at baseline.  
<sup>f</sup>Placebo, n=154; GUS 100 mg q4w, n=159 and q8w, n=160.  
<sup>g</sup>Pooled data from the phase 3 DISCOVER-1 and DISCOVER-2 studies among patients with enthesitis at baseline.  
<sup>h</sup>Placebo, n=255; GUS 100 mg q4w, n=243 and q8w, n=230.

### Summary of Uncontrolled Secondary Endpoint Results Through Week 24



# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary

Study Design and Endpoints

Patient Characteristics

Efficacy Results

Safety Results

Abbreviations and References



### Summary of Uncontrolled Secondary Endpoint Results Through Week 24<sup>1,5</sup>

Endpoints	GUS 100 mg q8w n=248	GUS 100 mg q4w n=245	Placebo n=246
PASI75 at week 24, <sup>a</sup> n/N (%)	139/176 (79)	144/184 (78)	42/183 (23)
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-
PASI90 at week 24, <sup>a</sup> n/N (%)	121/176 (69)	112/184 (61)	18/183 (10)
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-
PASI100 at week 24, <sup>a</sup> n/N (%)	80/176 (45)	82/184 (45)	5/183 (3)
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-
HAQ-DI ≥0.35 improvement at week 24, <sup>c</sup> n/N (%)	114/228 (50)	128/228 (56)	74/236 (31)
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-
MDA at week 24, n (%)	62 (25)	46 (19)	15 (6)
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-
DAS28-CRP, LS mean change at week 24, %	-1.59	-1.62	-0.97
Unadjusted <i>P</i> -value <sup>b</sup>	<0.0001	<0.0001	-

<sup>a</sup>Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. Placebo, n=183; GUS 100 mg q4w, n=184 and q8w, n=176.  
<sup>b</sup>Unadjusted (nominal) *P*-values are not controlled for multiplicity and should be interpreted only as supportive.  
<sup>c</sup>Assessed in patients with HAQ-DI 0.35 or greater at baseline.

BSA, body surface area; DAS28-CRP, 28-joint disease activity score based on C-reactive protein; HAQ-DI, Health Assessment Questionnaire-Disability Index; IGA, Investigator's Global Assessment; MDA, minimal disease activity; PASI75/90/100, ≥75%/90%/100% improvement in Psoriasis Area and Severity Index; q4w, every 4 weeks; q8w, every 8 weeks.

Adjusted <i>P</i> -value	0.0301	0.0301	-
HAQ-DI score, <sup>a</sup> LS mean	-0.37	-0.4	-0.13
Adjusted <i>P</i> -value	<0.0001	<0.0001	-
SF-36 PCS score, <sup>b</sup> LS mean	7.39	7.04	3.42
Adjusted <i>P</i> -value	0.011	0.011	-
SF-36 MCS score, <sup>b</sup> LS mean	4.17	4.22	2.14
Adjusted <i>P</i> -value	0.072	0.072	-

<sup>a</sup>Not part of the sequential testing procedure but was prespecified to be tested upon achieving statistical significance for ACR20 at week 24; <sup>b</sup>Change from baseline at week 24; <sup>c</sup>IGA PsO score 0=cleared; 1=minimal; <sup>d</sup>Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline. Placebo, n=183; GUS 100 mg q4w, n=184 and q8w, n=176; <sup>e</sup>Pooled data from the phase 3 DISCOVER-1 and DISCOVER-2 studies among patients with dactylitis at baseline; <sup>f</sup>Placebo, n=154; GUS 100 mg q4w, n=159 and q8w, n=160; <sup>g</sup>Pooled data from the phase 3 DISCOVER-1 and DISCOVER-2 studies among patients with enthesitis at baseline; <sup>h</sup>Placebo, n=255; GUS 100 mg q4w, n=243 and q8w, n=230.

### Summary of Uncontrolled Secondary Endpoint Results Through Week 24

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	<b>Efficacy Results</b>	Safety Results	Abbreviations and References
-------------------	----------------------------	-------------------------	-------------------------	----------------	------------------------------

Efficacy Through Week 24	<b>Efficacy at Week 52</b>
--------------------------	----------------------------

- Summary of results at week 52 are summarized in the following table:

### Summary of Efficacy Results at Week 52<sup>3</sup>

Endpoints	GUS 100 mg q8w n=248	GUS 100 mg q4w n=245	Placebo to GUS 100 mg q4w n=246
ACR20 response, %	74.6	70.6	64.2 <sup>a</sup>
ACR50 response, %	48.4	45.7	41.1 <sup>a</sup>
ACR70 response, %	27.8	26.1	17.9 <sup>a</sup>
Change from week 24 to 52 in PsA-modified vdH-S score, mean, <sup>b,c</sup> %	0.23	0.62	0.25
IGA PsO score 0 or 1 and ≥2 grade reduction from baseline, <sup>d,e</sup> %	74.4	79.3	79.2
PASI 90, <sup>d,e</sup> %	74.4	76.6	72.1
PASI 100, <sup>d,e</sup> %	52.8	57.6	51.9
Resolution of dactylitis (score=0), <sup>f,g</sup> %	75.6	74.8	70.1
Resolution of enthesitis (LEI score=0), <sup>h,i</sup> %	57.8	57.6	61.6
Change from baseline in HAQ-DI score, LS mean, <sup>j</sup> %	-0.45	-0.49	-0.35 <sup>a</sup>
Change from baseline in SF-36 PCS score, LS mean, <sup>j</sup> %	8.97	8.64	7.53 <sup>a</sup>
Change from baseline in SF-36 MCS score, LS mean, <sup>j</sup> %	4.31	4.43	4.04 <sup>a</sup>
MDA, %	31.0	34.3	29.7 <sup>a</sup>

<sup>a</sup>At week 24, 238 of the 246 patients in the placebo group crossed over to GUS q4w; 8 patients received placebo only before study drug discontinuation.

<sup>b</sup>Placebo to GUS 100 mg q4w, n=230; GUS 100 mg q4w, n=229 and q8w, n=235.

<sup>c</sup>Observed data are shown.

<sup>d</sup>Among patients with ≥3% BSA of psoriatic involvement and an IGA score ≥2 at baseline.

<sup>e</sup>Placebo to GUS 100 mg q4w, n=183 (176 patients crossed over at week 24, and 7 received placebo only before study drug discontinuation); GUS 100 mg q4w, n=184 and q8w, n=176.

<sup>f</sup>Pooled data from DISCOVER-1 and DISCOVER-2 among patients with dactylitis at baseline.

<sup>g</sup>Placebo to GUS 100 mg q4w, n=154 (142 patients crossed over at week 24, and 12 received placebo only before study drug discontinuation); GUS 100 mg q4w, n=159 and q8w, n=160.

<sup>h</sup>Pooled data from DISCOVER-1 and DISCOVER-2 among patients with enthesitis at baseline.

<sup>i</sup>Placebo to GUS 100 mg q4w, n=255 (243 patients crossed over at week 24, and 12 received placebo only before study drug discontinuation); GUS 100 mg q4w, n=243 and q8w, n=230.

<sup>j</sup>LS mean adjusted for baseline DMARD use (yes/no), CRP (<2.0 mg/dL vs ≥ 2.0 mg/dL), and baseline value.

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	Efficacy Results	<b>Safety Results</b>	Abbreviations and References
-------------------	----------------------------	-------------------------	------------------	-----------------------	------------------------------

<b>Safety Through Week 24</b>	Safety Through Week 52
-------------------------------	------------------------

- Summary of safety results through week 24 are summarized in the following table:

### Summary of Safety Results Through Week 24<sup>1</sup>

	<b>GUS 100 mg q8w n=248</b>	<b>GUS 100 mg q4w n=245</b>	<b>Placebo n=246</b>
Duration of follow-up, weeks, mean	23.9	23.8	24.0
Patients with ≥1 AE, n (%)	114 (46)	113 (46)	100 (41)
AEs occurring in ≥3% of patients in any group, n (%)			
Increased ALT	15 (6)	25 (10)	11 (4)
Increased AST	14 (6)	11 (4)	6 (2)
Bronchitis	1 (<1)	10 (4)	3 (1)
Nasopharyngitis	10 (4)	12 (5)	9 (4)
Upper respiratory tract infection	6 (2)	12 (5)	8 (3)
Patients with ≥1 SAE, n (%)	3 (1) <sup>a</sup>	8 (3) <sup>b</sup>	7 (3) <sup>c</sup>
AEs leading to discontinuation of study treatment, n (%)	2 (1) <sup>d</sup>	6 (2) <sup>e</sup>	4 (2) <sup>f</sup>
Infection, <sup>g</sup> n (%)	40 (16)	49 (20)	45 (18)
Serious infection	1 (<1)	3 (1)	1 (<1)
Injection-site reaction, n (%)	3 (1)	3 (1)	1 (<1)
Suicidal ideation, n (%)	0	1 (<1)	1 (<1)
Malignancy, n (%)	1 (<1)	0	1 (<1)
<sup>a</sup> One patient each with ankle fracture, coronary artery disease, and pyrexia. <sup>b</sup> One patient each with acute hepatitis B, blue toe syndrome, femur fracture, influenza pneumonia, ischemic stroke, lower limb fracture and metal poisoning, oophoritis, and osteoarthritis. <sup>c</sup> One patient each with clear cell renal cell carcinoma, isoniazid-induced liver injury, inflammatory bowel disease (suspected), obesity, postprocedural fistula, tubulointerstitial nephritis, and unstable angina. <sup>d</sup> One patient each with rash and malignant melanoma in situ. <sup>e</sup> One patient each with acute hepatitis B (de novo); allergic dermatitis; isoniazid-induced liver injury; ischemic stroke; rhinovirus infection; and injection-site erythema, swelling, and warmth. <sup>f</sup> One patient each with clear cell renal cell carcinoma, isoniazid-induced liver injury, inflammatory bowel disease (suspected), and tubulointerstitial nephritis. <sup>g</sup> Events identified by investigators as infections.			

- Through week 24, there were no reports of deaths, opportunistic infections, or active tuberculosis.<sup>1</sup>

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	Efficacy Results	<b>Safety Results</b>	Abbreviations and References
-------------------	----------------------------	-------------------------	------------------	-----------------------	------------------------------

Safety Through Week 24	<b>Safety Through Week 52</b>
------------------------	-------------------------------

- Summary of safety results through week 52 (608 patient-years of follow-up) are summarized in the following table:

### Summary of Safety Results Through Week 52<sup>3</sup>

	<b>GUS 100 mg q8w n=248</b>	<b>GUS 100 mg q4w n=245</b>	<b>Placebo to GUS 100 mg q4w (Weeks 24-52)<sup>a</sup> n=238</b>
Years of follow-up, mean	1.0	1.0	0.5
Overall patient-years of follow-up	243	239	127
Patients with ≥1 AE, n (%)	155 (62.5)	152 (62.0)	87 (36.6)
Patients with ≥1 SAE, n (%)	10 (4.0)	11 (4.5)	10 (4.2)
AEs leading to discontinuation of study treatment, n (%)	3 (1.2)	9 (3.7)	4 (1.7)
Infection, n (%)	71 (28.6)	67 (27.3)	41 (17.2)
Serious infection, n (%)	3 (1.2) <sup>b</sup>	3 (1.2) <sup>c</sup>	3 (1.3) <sup>d</sup>

<sup>a</sup>At 24 weeks, patients in the placebo group were crossed over to the GUS 100 mg q4w group; only AEs from week 24 to 52 are summarized for this group.  
<sup>b</sup>One patient with pyrexia prior to week 24 and urinary tract infection from week 24 to 52 and 1 patient each with cystitis and diverticulitis from week 24 to 52.  
<sup>c</sup>One patient each with acute hepatitis B, oophoritis, and influenza/pneumonia prior to week 24.  
<sup>d</sup>One patient each with influenza/tracheitis, pericarditis, and pneumonia from week 24 to 52.

- Through week 52, there were no reports of deaths, opportunistic infections, or active tuberculosis.<sup>3</sup>
- Patients treated with GUS did not report any inflammatory bowel disease.<sup>3</sup>
- The rate of serious infections did not increase in patients treated with GUS from week 24 through week 52, and no additional malignancies or major adverse cardiovascular events were reported after week 24.<sup>3</sup>

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	Efficacy Results	Safety Results	<b>Abbreviations and References</b>
-------------------	----------------------------	-------------------------	------------------	----------------	-------------------------------------

<b>Abbreviations</b>	Literature Search	References
----------------------	-------------------	------------

<b>AE</b>	Adverse event	<b>MDA</b>	Minimal Disease Activity
<b>ACR</b>	American College of Rheumatology	<b>NSAIDs</b>	Nonsteroidal anti-inflammatory drugs
<b>ACR20/50/70</b>	≥20/50/70% improvement in the ACR response criteria	<b>NRI</b>	Nonresponder imputation
<b>ALT</b>	Alanine aminotransferase	<b>PASI</b>	Psoriasis Area and Severity Index
<b>AST</b>	Aspartate aminotransferase	<b>PASI75/90/100</b>	≥75/90/100% improvement in PASI
<b>BSA</b>	Body surface area	<b>PCS</b>	Physical Component Summary
<b>CASPAR</b>	Classification Criteria for Psoriatic Arthritis	<b>PsA</b>	Psoriatic arthritis
<b>CRP</b>	C-reactive protein	<b>PsO</b>	Psoriasis
<b>DAS28</b>	28-Joint Disease Activity Score	<b>q4w</b>	Every 4 weeks
<b>DMARDs</b>	Disease-modifying antirheumatic drugs	<b>q8w</b>	Every 8 weeks
<b>EE</b>	Early escape	<b>R</b>	Randomized
<b>GUS</b>	Guselkumab	<b>SAE</b>	Serious adverse event
<b>HAQ-DI</b>	Health Assessment Questionnaire-Disability Index	<b>SC</b>	Subcutaneously
<b>IGA</b>	Investigator's Global Assessment	<b>SD</b>	Standard deviation
<b>IQR</b>	Interquartile range	<b>SF-36</b>	Short Form-36
<b>LEI</b>	Leeds Enthesitis Index	<b>US</b>	United States
<b>LS</b>	Least squares	<b>VAS</b>	Visual Analog Scale
<b>MCS</b>	Mental Component Summary	<b>vdH-S</b>	van der Heijde-Sharp

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	Efficacy Results	Safety Results	<b>Abbreviations and References</b>
-------------------	----------------------------	-------------------------	------------------	----------------	-------------------------------------

Abbreviations	<b>Literature Search</b>	References
---------------	--------------------------	------------

A literature search of Ovid MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File databases (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 10 July 2020.

Summarized in this response are data from the phase 3 clinical trial, DISCOVER-2, that evaluated the efficacy and safety of GUS for the treatment of adult patients with active PsA through week 52. Additional data regarding the use of GUS for the treatment of adult patients with active PsA are available upon request.

Thank you for your interest in TREMFYA® (guselkumab). The information is presented in response to your unsolicited inquiry. This information is taken from the references cited, but is not intended to serve as a substitute for review of these references. This information is not intended to advocate the use of our product in any manner other than as described in the product monograph. Please refer to the TREMFYA® Product Monograph available at <http://www.janssen.com/canada/products> for full prescribing information.

For any questions, please contact Janssen Medical Information at:  
1.800.567.3331 or <http://www.janssenmedicalinformation.ca>

# TREMFYA® (guselkumab)

## Treatment of Active Psoriatic Arthritis (DISCOVER-2)

This PDF includes interactive elements that can be accessed by clicking tabs below the document title, rectangular blue boxes that open additional pop-ups, and navigation buttons near the page number(s).

Executive Summary	Study Design and Endpoints	Patient Characteristics	Efficacy Results	Safety Results	<b>Abbreviations and References</b>
-------------------	----------------------------	-------------------------	------------------	----------------	-------------------------------------

Abbreviations	Literature Search	<b>References</b>
---------------	-------------------	-------------------

1. Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1126-1136.
2. Mease PJ, Rahman P, Gottlieb AB, et al. Supplement to: Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1126-1136.
3. McInnes IB, Rahman P, Gottlieb AB, et al. Sustained efficacy and safety in guselkumab, a monoclonal antibody specific to the p19-subunit of interleukin-23, through 52 weeks in biologic-naive patients with active psoriatic arthritis. Poster presented at: The European League Against Rheumatism (EULAR); June 3-6, 2020; E-congress.
4. Deodhar A, Helliwell PS, Boehncke WH, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNF $\alpha$  inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020;395(10230):1115-1125.
5. Data on File. Statistical Analysis Plan CNTO1959PSA3002. Janssen Research & Development, LLC. EDMS-ERI-146207739. US-SRSM-3684; 2019.