# **Associations Between Clinical Characteristics and Screening MRI Findings in Biologic-naive PsA Patients with MRI-confirmed Axial Involvement: STAR Study Exploratory Analysis**

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## Background

- Patients (pts) with psoriatic arthritis (PsA) can develop axial inflammation in the sacroiliac joints (SIJ) and/or spine Although validated classification criteria exist for axial spondyloarthritis, established criteria for classifying axial PsA are lacking
- STAR (NCT04929210):
- A Phase 4, multicenter, randomized, controlled trial of biologic-naïve PsA pts with magnetic resonance imaging (MRI)-confirmed axial inflammation
- Prospectively evaluating the efficacy of guselkumab (GUS), a human IL-23p19-subunit inhibitor, on axial symptoms and objective measures (MRI) of axial inflammation<sup>1</sup>

## **Objective**

This exploratory analysis of available screening MRI data from STAR compared clinical characteristics between pts meeting or not meeting STAR MRI eligibility criteria

## Results

Among 487 pts screened at the time of this analysis, those with available SIJ and/or spine MRI were included



<sup>a</sup>26 pts had only the SIJ MRI and are not included in the categories above; <sup>b</sup>28 pts had only the spine MRI and are not included in the categories above; <sup>c</sup>433 pts had MRI for both the SIJ and spine. MRI=Magnetic resonance imaging; Pts=Patients: SIJ=Sacroiliac ioints

Approximately half of the overall screened population had inflammatory back pain with moderate-to-high levels			Pt Clinical Characteristics by Screening MRI Status	SIJ MRI		Spine MRI		SIJ and Spine MRI	
<ul> <li>of peripheral and spinal disease activity</li> <li>A majority of screened pts had a history of nail, scalp, and palmoplantar psoriasis</li> </ul>		Negative (N=302)		Positive (N=157)	Negative (N=323)	Positive (N=138)	Both Negative (N=257)	Both Positive (N=65)	
• Mean j	oint counts/visual analog scale (VAS) scores indicated moderate-to-h	high levels of disease activity/spinal pain							
BL Pt Demographics and Clinical Characteristics at Screening		Pts Screened (N=487)	Pt Demographics						
Demographics			Age, yrs	47.4 (12.7)	44.7 (11. 8)*	46.2 (12.9)	47.9 (11.0)	46.6 (12.9)	44.2 (10.4)
	Age. vrs	46.7 (12.4)	ΠΠ			2			
ŤŤ	Male sex, n (%) HLA-B27 antigen positive, n (%)	263 (54%) 71ª (36%)	<b>PsA Characteristics</b>		50	•			
PsA Characteristics									
	<b>PsA disease duration,</b> yrs <b>CRP,</b> mg/dL	3.7 <sup>b</sup> (4.1) 1.7 <sup>c</sup> (2.4)	<b>CRP,</b> mg/dL	1.5 (2.3) <sup>a</sup> 2.0 (2.7)	2.0 (2.7)*	1.5 (2.2) <sup>b</sup>	1.9 (2.8)*	<b>1.4 (2.1)</b> °	2.5 (3.1)*
	Swollen Joint Count (0-66) Tender Joint Count (0-68) BASDAI (VAS 0-10)	7.8 <sup>d</sup> (5.2) 14.4 <sup>d</sup> (10.9) 7.1 <sup>e</sup> (1.3)	<b>SJC</b> (0-66)	8.0 (5.4) <sup>d</sup>	7.5 (5.0)	8.1 (5.7) <sup>b</sup>	7.1 (4.4)	8.1 (5.5)°	6.6 (4.0)*
	Spinal pain (VAS 0-10)	7.4° (1.5)							
Medical History, n (%)			15 5 (11 O)d	17 6 (9 9)*	151 (110)b	106 (94)	15 6 (12 2)c	111 (6 9)*	
	Inflammatory back pain	125 <sup>f</sup> (48%)		15.5 (11.9)*	12.0 (0.0)	15.1 (11.9)~	12.0 (0.4)	15.0 (12.3)	11.1 (0.0)
	Dactylitis	106 <sup>f</sup> (41%)							
	Enthesitis	94 <sup>f</sup> (36%)	BASDAI (VAS 0-10)	7.1 (1.3) <sup>e</sup>	7.2 (1.2) <sup>f</sup>	7.1 (1.3) <sup>g</sup>	6.9 (1.3) <sup>h</sup>	7.1 (1.3) <sup>i</sup>	7.1 (1.3)
	Uveitis	5 <sup>f</sup> (2%)							
	Nail psoriasis	151 <sup>g</sup> (59%)							
	Scalp psoriasis	162 <sup>f</sup> (63%)	Spinal pain (VAS 0-10)	<b>7.3 (1.6)</b> <sup>e</sup>	<b>7.7 (1.4)</b> *,f	7.4 (1.6) <sup>g</sup>	7.6 (1.4) <sup>h</sup>	<b>7.3 (1.6)</b> <sup>i</sup>	7.8 (1.4)*
	Inverse psoriasis	17 <sup>f</sup> (7%)							
	Genital psoriasis	25 <sup>f</sup> (10%)							
	Palmoplantar psoriasis	137 <sup>f</sup> (53%)							

Data are mean (SD) unless otherwise specified. "N=197; "N=144; "N=485; "N=485; "N=258; "N=257. BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; BL=Baseline; CRP=C-reactive protein; HLA=Human leukocyte antige PsA=Psoriatic arthritis; Pt=Patient; SD=Standard deviation; VAS=Visual analog scale; yrs=Years.

 
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Sub break br GSK, Immagene, Janssen, Novartis, Pfizer, SUN, UCB, and Ventyx; speaker fees from: AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. Previously presented at EULAR 2024; Vienna, Austria; June 12-15, 2024; Vienna, Austria; June 12-15, 2024; Suntec, Singapore; August 21-25, 2024.





CRP, age, spinal pain score, and tender joint counts were associated with the presence or absence of **MRI-detected** axial inflammation

• CRP levels were significantly higher in both SIJ+ vs SIJ– and Spine+ vs Spine– cohorts

imaging; PsA=Psoriatic arthritis; Pt=Patient; SD=Standard deviation; SIJ=Sacroiliac joints; SJC=Swollen joint count; TJC=Tender joint count; VAS=Visual analog scale; yrs=Years.

- The SIJ+ cohort was characterized by younger age, a higher spinal pain score, and fewer tender joints vs the SIJ– cohort
- Differences between the SIJ+/Spine+ (N=65) and SIJ–/Spine– (N=257) cohorts were generally consistent with those of the SIJ and spine cohorts



### STAR: Key Study Eligibility Criteria

- Age ≥18 years
- History of, or current, plaque psoriasis Diagnosis of PsA for  $\geq 6$  months prior to enrollment
- ≥3 swollen joints, ≥3 tender joints, CRP ≥0.3 mg/dL BASDAI ≥4
  - Spinal pain<sup>a</sup> (VAS  $\geq$ 4)
- Screening MRI-confirmed axial involvement (positive spine and/or SIJ MRI defined by blinded, centrally-read SPARCC score ≥3)
- Naïve to biologic agents and Janus kinase inhibitors
- sonance imaging: PsA=Psoriatic arthritis: SIJ=Sacroiliac joints: SPARCC=SpondvloartI

#### Spine MRI

- inflammation in the SIJ or spine Spine **Both Positive** Positive % (n/N) Negative (N=65) Odds Ratio (95% CI) Odds Ratio (95% CI) % (n/N) Sex: Male 47.0 (142/302) 65.6 (103/157)<sup>a</sup> 27.5 (11/40) 37.3 (50/134) HLA-B27 antigen positive<sup>b</sup> 44.2 (10.4) 40.9 (38/93) 52.5 (73/139) <sup>1</sup> Inflammatory back pain 37.6 (35/93) 41.0 (57/139) Dactylitis 34.4 (32/93) 39.6 (55/139) Enthesitis 2.5 (3.1)\*
- 6.6 (4.0)\*
- 11.1 (6.8)\*
- 7.1 (1.3)
- 7.8 (1.4)\*
- of PsA was documented in a

• Pt clinical characteristics and medical history documented at screening were compared between MRI positive (+) and MRI negative (–) cohorts to determine those associated with MRI-detected inflammation of the SIJ and/or spine

Analyses

- Sex and age, HLA-B27 antigen, swollen joint count, tender joint count, BASDAI, spinal pain, and CRF
- Medical history of inflammatory back pain, dactylitis, enthesitis, uveitis, nail psoriasis, scalp psoriasis, inverse psoriasis, genital psoriasis, and palmoplantar psoriasis
- MRI reading for SIJ and spine<sup>a</sup>
- 2 central readers and an adjudicator, requiring agreement by 2 readers to confirm a + or – MRI result
- Required only 1 confirmed +MRI result (SIJ or spine) for study entry

n SIJ or Spine central read results and the primary readers disaareed on MRI positivity at the other location, adjudication was no performed because pt eligibility was already determined. BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; CRP=C-reactive protein; HLA=Human leukocyte antigen; MRI=Magnetic resonance imaging; PsA=Psoriatic arthritis; Pt=Patient; SIJ=Sacroiliac joints.

Males comprised a significantly higher proportion of pts in both the SIJ+ vs SIJ– and Spine+ vs Spine- cohorts

- The Spine+ cohort comprised a significantly higher proportion of pts positive for the HLA-B27 antigen than the Spine– cohort; a numerically higher proportion of pts had a history of inflammatory back pain and nail **psoriasis** in the Spine+ vs Spine- cohort
- The SIJ+ cohort comprised a numerically higher proportion of pts with a history of inflammatory back pain, nail psoriasis, and scalp psoriasis than the SIJ- cohort
- Pts with a history of palmoplantar psoriasis appeared numerically less likely to exhibit MRI-detected axial



<sup>a</sup>95% CI excluding 1 indicates statistically significant difference. <sup>b</sup>HLA-B27 antigen marker was only captured in MRI-eligible pts, thus no comparison exists between the SIJ+/Spine+ and SIJ–/Spine– cohorts. CI=Confidence interval; HLA=Human leukocyte antigen; MRI=Magnetic resonance imaging; Pts=Patients; SIJ=Sacroiliac joints.

## Key Takeaways



Preliminary findings from the ongoing STAR study, evaluating biologic-naïve PsA pts with MRI-confirmed axial inflammation:

- Recognized positive association between serum CRP levels and axial involvement in PsA<sup>2,3</sup>
- Several clinical characteristics, including male sex, younger age, presence of HLA-B27 antigen, higher spinal pain score, and fewer tender joints, were associated with the presence of MRI-detected axial inflammation
- Fewer tender joints in the pts with MRI-detected axial inflammation may reflect the moderate-to-high levels of peripheral joint involvement seen across all screened pts



The associations between clinical features and SIJ/spine +/- MRI screening results will require confirmation in the overall study population

The STAR study (NCT04929210) is actively enrolling<sup>1</sup>

ative n/N)	Positive % (n/N)				
53/323)	70.3 (97/138)ª				
(13/55)	<b>41.2 (49/119)</b> ª				
52/115)	50.8 (61/120)				
48/113)	40.2 (49/122)				
45/113)	32.0 (39/122)				
3/115)	1.7 (2/120)				
60/113)	58.7 (71/121)				
75/114)	57.9 (70/121)				
3/114)	5.8 (7/121)				
12/114)	9.9 (12/121)				
66/114)	50.4 (61/121)				

Males also comprised a significantly higher proportion of pts in the SIJ+/Spine+ vs SIJ\_/Spine\_ cohorts

- The SIJ+/Spine+ cohort comprised a numerically higher proportion of pts with a history of inflammatory back pain
- Pts with a history of palmoplantar psoriasis appeared numerically less likely to exhibit MRI-detected axial inflammation in the SIJ and spine



More likely to be **MRI-positive** 

<sup>a</sup>95% CI excluding 1 indicates statistically significant difference. CI=Confidence interval; MRI=Magnetic resonance imaging; SIJ=Sacroiliac joints.