Methods: Adults with active PsA (DISCOVER 1: ≥3 tender/swollen joints and C-Reactive protein [CRP] ≥0.3 mg/dL; DISCOVER 2: ≥5 tender/swollen joints and CRP ≥0.6 mg/dL) were randomized to subcutaneous GUS 100 mg at w0, w4, then every 8 w (w8), GUS 100 mg wq8w; or PBO. At w24, PBO pts switched to GUS 100 mg q8w; at w36, pts were randomized to either IXE 80 mg q4w or PBO. Safety was reported through w60 in DISCOVER 1 and through w52 in DISCOVER 2.

Results: Baseline characteristics were similar between treatment groups in the pooled studies. Through w24 and 1 year, numbers of pts per 100 patient years with ≥1 event were similar among treatment groups for adverse events (AEs), serious AEs, infections, serious infections, and discontinuations due to AE. Safety was reported through w60 in DISCOVER 1 and through w52 in DISCOVER 2.

Conclusion: GUS regimens of wq8w and wq4w were well tolerated in PsA pts and generally comparable with the previously established safety profile of GUS.
ACR50 (Figure 1). Of the 132 pts treated with ADA who achieved ACR50 at Wk 24, 55% (N=72) maintained ACR50 at every visit. In total, 80% (N=105) of ACR50 achieved maintained DAPSA<14 at Wk 24, 68% (N=119) maintained low DA at every visit. Of the low DA achieved at Wk 24, 82% (N=142) of pts maintained low DA with some (13% (N=23)) fluctuations between moderate and low DA. Of the 171 pts treated with ADA who achieved low DA at Wk 24; 57% (N=97) maintained low DA at every visit. In total, 77% (N=131) of low DA achieved at Wk 24 maintained low DA with some (20% (N=54)) fluctuations between moderate and low DA (Table 1).

Conclusion: This analysis demonstrates that a numerically higher proportion of pts treated with IXE versus ADA showed consistency of response, as measured by ACR50 and DAPSA responses, over time and for each visit at the pt level.

REFERENCES:

Table 1. Consistency over time of the effect of ADA in pts with PsA.

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<th>ACR50</th>
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<td>Response, % (n)</td>
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<td>Low DA, % (n)</td>
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Patients who achieved the response at Wk 24 and maintained low DA from Wk 24 and maintained out to Wk 52 with some fluctuations

Maintained endpoint at every visit

Had some fluctuations

* fluctuations between ACR50 and ACR20, or between low and moderate disease activity.

Figure 1. Heatmap diagram describing consistency over time of the effect of IXE in pts with PsA who achieved DAPSA<14 (low disease activity) at Wk 24.

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AB0540 COMPARISON OF EQ-5D HEALTH STATUS IN PSONIRITIC ARTHRITIS PATIENTS WITH OR WITHOUT AXIAL DISEASE: RESULTS OF SUBANALYSIS OF THE PATERA STUDY

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Background: Netakimab (NTK) is an anti-interleukin-17A monoclonal antibody approved for psoriasis, ankylosing spondylitis, psoriatic arthritis (PsA) in Russia and Belarus. PATERA is an ongoing phase 3 international double-blind, placebo-controlled clinical study of NTK in PsA (NCT03598751).

Objectives: A subanalysis was performed to assess the effect of NTK on domains of the 5-level EuroQol 5 Dimensions questionnaire (EQ-5D-5L) in patients with inflammatory back pain (IBP) (IBP(+)) and without (IBP(-)) at baseline according to self-reported ASAS IBP criteria, 2009.

Methods: 194 adult patients with PsA (CASPAR criteria, 2006) with inadequate response to csDMARD or one TNFi, were randomly assigned to receive NTK 120mg or placebo at weeks 0,1,2,4,6,8,10,14,18,22. The proportion of patients reported >1 problem in each domain was evaluated. Patients with missing values were considered as non-responders in the analysis.

Results: 97 PsA patients (N=54 IBP(+), N=43 IBP(-)) received NTK. The sub-populations didn't differ significantly in gender, age, and PsA activity at baseline. Comparable percentage of patients reported any problems for each domain at baseline (p≥0.05) (data not shown). IBP(-) subpopulation had a greater improvement for all domains except of anxiety/depression. The absolute declines for IBP(+) vs IBP(-) patients were as followed: 24.1% vs 41.9% (mobility), 18.5% vs 32.7% (usual activity), 19.4% vs 36.5% (housework), 24.7% vs 41.2% (self-care), and 24.0% vs 51.1% (usual activities). The absolute declines for IBP(+) vs IBP(-) patients were as followed: 24.1% vs 41.9% (mobility), 18.5% vs 32.7% (usual activity), 21.7% vs 28.9% (housework), 26.3% vs 38.1% (self-care), and 24.0% vs 51.1% (usual activities). However, the only significant difference between IBP(+) and IBP(-) was observed in usual activity (Figure 1).

Conclusion: NTK resulted in the growing improvement of each EQ-5D-SL domain through 24 weeks irrespectively of the presence of IBP. IBP(-) subjects showed trend to greater benefit compared to IBP(+).