ABSTRACT NUMBER: 2583

Apremilast Reduces Axial Inflammation in Patients with Psoriatic Arthritis as Assessed by CANDEN MRI Scoring: Results from a Phase 4 Study

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SESSION INFORMATION

Date: Monday, November 18, 2024

Session Type: Abstract Session

Title: Abstracts: SpA Including PsA – Treatment II

Session Time: 1:00PM-2:30PM

Background/Purpose: Apremilast is an oral phosphodiesterase-4 inhibitor with a unique immunomodulatory mechanism of action and is approved for the treatment of psoriatic arthritis (PsA). Although peripheral arthritis is the most frequent clinical feature in patients with PsA, axial involvement may occur in up to 50% of patients, causing inflammatory back pain, stiffness, and changes on imaging. Here, we used whole-body magnetic resonance imaging (WB-MRI) to evaluate the efficacy of apremilast 30 mg twice daily on axial inflammation in patients with PsA.

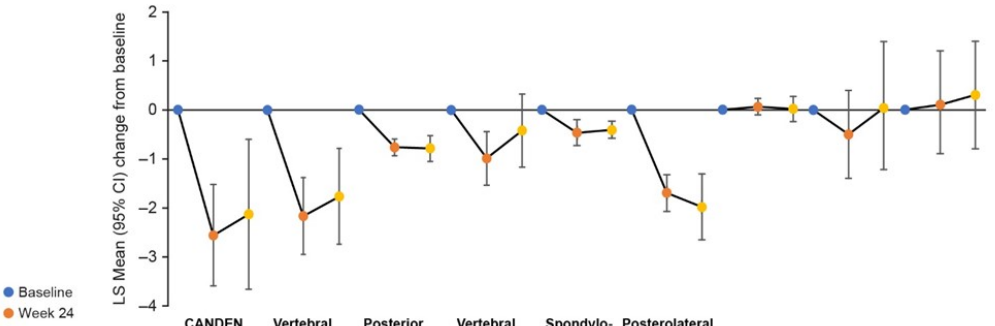
Methods: MOSAIC (NCT03783026) was a phase 4, single-arm, open-label trial that evaluated apremilast treatment (with or without stable methotrexate) in patients with active PsA (per Classification Criteria for Psoriatic Arthritis [CASPAR]) for up to 48 weeks. Contrast-enhanced WB-MRI was performed at baseline, week 24, and week 48, and images were evaluated and adjudicated by two experienced readers blinded to time point and response to apremilast. In patients deemed to have PsA spondylitis by the investigator and a baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Item 2 (back pain) ≥4, MRI axial inflammation was assessed by calculating the least squares mean change from baseline to weeks 24 and 48 in the Canada-Denmark (CANDEN) total spine inflammation score and subscores (assessing individual anatomical locations including posterolateral elements), the Spondyloarthritis Research Consortium of Canada (SPARCC) spine

score, and the SPARCC sacroiliac joint (SIJ) inflammation score.

Results: Overall, 122 patients were treated with apremilast. At baseline, the mean age was 47 years, 55% were women, mean PsA duration was 1.9 years, mean CANDEN spine score was 5.8, mean SPARCC spine score was 5.4, and mean SPARCC SIJ inflammation score was 2.7. Of 40 patients deemed to have PsA spondylitis by the investigator and a BASDAI Item 2 ≥4, 39 patients were analyzed for axial inflammation. At weeks 24 and 48, CANDEN total spine inflammation score, vertebral body, posterior elements, corner, non-corner, and posterolateral elements inflammation subscores were significantly reduced with apremilast relative to baseline. No significant change in facet joint inflammation subscore, SPARCC spine, or SPARCC SIJ scores were observed (**Figure 1**).

Conclusion: In patients with early PsA, apremilast reduced axial inflammation as assessed by the CANDEN MRI scoring system, which provides a comprehensive and detailed anatomy-based quantification of inflammatory changes in the spine. Apremilast significantly reduced inflammation in both vertebral bodies and posterolateral elements of the spine after 24 and 48 weeks of treatment.

Figure 1. LS mean changes from baseline to weeks 24 and 48 in CANDEN spine total score and component subscores, SPARCC spine score, and SPARCC SIJ score.



	CANDEN Spine Total Score	Vertebral Body Subscore	Posterior Elements Subscore	Vertebral Body Corner Subscore	Spondylo-discitis Subscore	Posterolateral Elements Subscore	Facet Joint Subscore	SPARCC Spine score	SPARCC SIJ score
Baseline mean (SD) (N = 39)	5.76 (11.61)	4.95 (10.49)	0.81 (2.49)	2.74 (5.67)	1.69 (4.07)	0.99 (3.55)	0.33 (0.92)	5.35 (10.88)	2.67 (4.99)
Baseline mean (SD) of the patient group measured at week 24 (N = 32)	4.75 (8.76)	3.83 (7.14)	0.92 (2.73)	2.05 (3.56)	1.22 (2.51)	1.14 (3.90)	0.34 (0.96)	4.20 (7.77)	2.95 (5.43)
LS mean change from baseline at week 24 (95% CI) (N = 32)	−2.56 (−3.59, −1.52)	−2.17 (−2.96, −1.38)	−0.77 (−0.94, −0.60)	−0.99 (−1.54, −0.44)	−0.47 (−0.73, −0.20)	−1.70 (−2.08, −1.33)	0.06 (−0.11, 0.22)	−0.5 (−1.4, 0.4)	0.1 (−0.9, 1.2)
Baseline mean (SD) of the patient group measured at week 48 (N = 27)	4.67 (9.29)	3.57 (7.44)	1.09 (2.95)	1.93 (3.68)	1.00 (2.43)	1.33 (4.23)	0.41 (1.04)	3.91 (8.00)	2.80 (5.61)
LS mean change from baseline at week 48 (95% CI) (N = 27)	−2.13 (−3.66, −0.60)	−1.77 (−2.75, −0.78)	−0.79 (−1.06, −0.53)	−0.42 (−1.17, 0.33)	−0.41 (−0.58, −0.23)	−1.99 (−2.66, −1.31)	0.02 (−0.23, 0.28)	0.04 (−1.3, 1.4)	0.3 (−0.8, 1.4)

CANDEN, Canada-Denmark scoring system; CI, confidence interval; LS, least-squares; SD, standard deviation; SIJ, sacroiliac joint; SPARCC, Spondyloarthritis Research Consortium of Canada scoring system

LS mean changes from baseline to weeks 24 and 48 in CANDEN spine total score and component subscores, SPARCC spine score, and SPARCC SIJ score.

Disclosures: M. Ostergaard: Abbott, 2, 5, 6, BMS, 6, Centocor, 5, Merck, 2, 6, Mundipharma, 6, Pfizer, 2, 5, 6, Roche, 2, UCB Pharma, 2, 6; **W. Maksymowych**: AbbVie, 2, 5, 6, Boehringer Ingelheim, 2, 6, Bristol Myers Squibb (BMS), 2, 6, CARE Arthritis Limited, 4, Celgene, 2, 6, Eli Lilly, 2, 6, Galapagos, 2, 5, 6, Janssen, 2, 5, 6, Novartis, 2, 5, 6, Pfizer, 2, 5, 6, UCB Pharma, 2, 5, 6; **R. Lambert**: CARE Arthritis, 2, Image Analysis Group, 2; **M. Boesen**: AbbVie/Abbott, 5, 6, Celgene, 5, 6, Eli Lilly, 6, Image Analysis Group, 6, 11, Novartis, 5, 6, Pfizer, 6, UCB, 6; **G. Valenzuela**: AbbVie/Abbott, 2, 6, Alexion, 2, Amgen, 2, 6, AstraZeneca, 6, Boehringer-Ingelheim, 2, 6, Bristol-Myers Squibb(BMS), 6, Celgene, 2, 6, Centocor, 6, Eli Lilly, 2, 6, Esaote, 2, Exagen, 2, Genentech, 2, 6, Gilead, 2, Global Health Living, 2, Horizon, 2, 6, Image Analysis Group, 2, Janssen, 2, 6, Mallinckrodt, 5, 6, Merck/MSD, 2, Novartis, 2, 5, 6, Pfizer, 2, 6, Pharmacia, 6, Radius, 6, Regeneron, 2, 6, Sandoz, 2, Sanofi, 2, 6, Takeda, 6, UCB, 2, 6; **M. Bubb**:

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