Celgene, Covagen, Crescendo, Janssen, LEO, Lilly, Merck, Novartis, Pfizer, SUN, and UCB; speakers' bureau for AbbVie, Amgen, BMS, Celgene, Genentech, Janssen, Lilly, Pfizer, and UCB, R. Landewé Grant/research support from: Abbott, Amgen, Centocor, Novartis, Pfizer, Roche, Schering-Plough, UCB, Wyeth, Employee of: Director of Rheumatology Consultancy BV, Speakers bureau: Abbott, Amgen, Bristol-Myers Squibb, Centocor, Merck, Pfizer, Roche, Schering-Plough, UCB, Wyeth, S. Mpofu Shareholder of: Novartis, Employee of: Novartis, P. Rahman Consultant for: Abbott, AbbVie, Amgen, BMS, Celgene, Janssen, Novartis, Pfizer and Roche, pharmaceutical companies dealing with biologic agents in Rheumatology, H. Tahir Grant/research support from: Novartis, Pfizer, Consultant for: Abbvie, Novartis, Pfizer, UCB, Eli-Lilly, Janssen, A. Singhal Grant/research support from: AbbVie, Gilead, Sanofi, Regeneron, Amgen, Roche, BMS, Janssen, Lilly, Novartis, Pfizer, UCB, Astra Zeneca, MedImmune, FujiFilm, Nichi-Iko, Mallinckrodt, Speakers bureau: AbbVie, E. Boettcher Consultant for: Amgen, Roche, Eli Lilly, Pfizer, MSD, Novartis, Speakers bureau: Amgen, Roche, Eli Lilly, Pfizer, MSD, Novartis, S. Navarra Consultant for: Pfizer, Novartis, AstraZeneca, Janssen, Astellas, Roche, Speakers bureau: Pfizer, Novartis, AstraZeneca, Janssen, Astellas, Roche, X. Zhu Employee of: Novartis, A. Readie Shareholder of: Novartis stock, Employee of: Novartis, L. Pricop Shareholder of: Novartis stock, Employee of: Novartis, K. Abrams Shareholder of: Novartis stock, Employee of: Novartis

DOI: 10.1136/annrheumdis-2018-eular.6131

OP0307

EFFICACY AND SAFETY OF RISANKIZUMAB, A SELECTIVE IL-23P19 INHIBITOR, IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OVER 24 WEEKS: RESULTS FROM A PHASE 2 TRIAL

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Background: Interleukin-23 (IL-23), a key regulator of multiple effector cytokines, has been implicated in the pathogenesis of psoriatic lesions, synovitis, enthesitis, and bone erosion. Risankizumab (RZB) is a humanised IgG1 monoclonal antibody that binds to p19 subunit of IL-23, selectively inhibiting this critical cytokine.
Objectives: To report the efficacy and safety of different doses of RZB in patients (pts) with active psoriatic arthritis (PsA) over 24 weeks.
Methods: In this double-blind, parallel-design, dose-ranging Phase 2 study, pts with active PsA (stratified by prior TNFi use and concurrent MTX use) were randomised in a 2:2:2:1:2 ratio to receive RZB (150 mg at weeks [Wks] 0, 4, 8, 12, and 16 [Arm 1], 150 mg at Wks 0, 4, and 16 [Arm 2], 150 mg at Wks 0 and 12 [Arm 3], 75 mg single dose at Wk 0 [Arm 4]) or matching placebo (PBO, Arm 5). Pts completing Wk 24 visit had an option to enter a separate open-label extension (OLE) study; pts not entering the OLE were followed until Wk 32. Efficacy assessments included ACR20/50/70, PASI, minimal disease activity (MDA), DAS28(CRP), dactylitis count, SPARCC enthesitis index, pain-VAS, HAQ-DI, and mTSS scores.
Results: Of the 185 pts who received the study drug, 173 (93.5%) completed 16 Wks of treatment and 145 (78.4%) entered OLE at Wk 24. The primary endpoint of ACR20 response at Wk 16 was achieved by pts in each of the RZB arms.[1] At Wk 24, ACR20/50/70 responses were significantly higher in pts receiving RZB (pooled across all RZB arms) compared with PBO (table 1). PASI75/90/100 responses at Wk 24 were significantly higher in RZB-treated pts compared with PBO. At Wk 24, RZB-treated pts achieved significantly higher MDA responses as well as greater improvements in DAS28(CRP) and Pain–VAS. Improvements in HAQ-DI and enthesitis from BL were numerically greater in RZB arms. At Wk 24, RZB-treated pts (pooled across all RZB arms) showed significant improvement from BL in mTSS compared with PBO. Treatment-emergent adverse events (TEAEs), collected up to Wk 32, were comparable across treatment arms (table 2); the most common TEAE was infection. There were no deaths or cases of tuberculosis in RZB-treated pts; 2 adjudicated major adverse cardiovascular events were reported in RZB arms.

Abstract OP0307 – Table 1. Summary of efficacy results at week 24*

Endpoints	Risankizumab (RZB)					Placebo
	Arm 1 N=42	Arm 2 N=42	Arm 3 N=39	Arm 4 N=20	Arms 1–4 N=143	Arm 5 N=42
ACR20 (%)	42.9	47.6	59.0**	40.0	48.3*	31.0
ACR50 (%)	19.0	16.7	33.3**	20.0	22.4**	7.1
ACR70 (%)	11.9	11.9	15.4*	15.0	13.3**	2.4
PASI 75 (%)[b]	68.8***	70.0***	69.6***	55.6*	67.6***	14.3
PASI 90 (%)[b]	60.0***	52.9**	47.6**	55.6**	53.2***	10.0
PASI 100 (%)[b]	46.7**	35.3**	28.6*	44.4*	37.1***	5.0
MDA (%)	19.0	28.6**	25.6*	30.0*	25.2***	7.1
ΔDAS28(CRP)[c]	-1.1	-1.4**	-1.6***	-1.7***	-1.4***	-0.6
ΔDactylitis Count[c,d]	-1.3	-2.3	-3.6	-3.5	-2.5	-2.6
ΔSPARCC Enthesitis Index[c,d]	-1.3	-2.7*	-1.6	-3.4*	-2.0	-1.1
ΔPain–VAS[c]	-6.9	-11.2	-19.1**	-6.4	-11.5*	-3.2
ΔHAQ-DI[c]	-0.19	-0.11	-0.21	-0.13	-0.16	-0.09
ΔmTSS[c]	-0.3	0.2	-0.5*	-0.2	-0.2*	0.6

Arm 1, 150 mg RZB at weeks 0, 4, 8, 12, and 16; Arm 2, 150 RZB at weeks 0, 4, and 16 (PBO at weeks 8 and 12); Arm 3, 150 mg RZB at weeks 0 and 12 (PBO at weeks 4, 8, and 12); Arm 4, 75 mg RZB at week 0 (PBO at weeks 4, 8, 12, and 16); Arm 5, PBO at weeks 0, 4, 8, 12, and 16.
P-values for comparison versus placebo: ***, P <0.001; **, P <0.01; *, P <0.05.
[a]Categorical endpoints are based on NRI analyses using Cochran-Mantel-Haenszel test; continuous variables are based on MMRM analyses and mTSS is based on ANCOVA. [b]PASI responses calculated only in patients with psoriasis affecting ≥3% BSA at baseline; Arm 1, N=16; Arm 2, N=20, Arm 3, N=23, Arm 4, N=9; Arm 5, N=21. [c]LS Mean for change from baseline are presented. [d]Dactylitis count and SPARCC enthesitis index assessed only in patients with active dactylitis (Arm 1, N=9; Arm 2, N=11, Arm 3, N=11, Arm 4, N=5; Arm 5, N=8) and enthesitis (Arm 1, N=28; Arm 2, N=24, Arm 3, N=28, Arm 4, N=11; Arm 5, N=28) at baseline, respectively.
ACR20/50/70 = 20/50/70% improvement in American college of rheumatology score; ANCOVA = analysis of co-variance; BSA = body surface area; DAS28(CRP) = 28-joint disease activity score based on C-reactive protein; Δ = change from baseline to week 24; HAQ-DI = health assessment questionnaire-disability index; MDA = minimal disease activity; MMRM = mixed effect model repeat measurement; mTSS = modified total Sharp score; NRI = non-responder imputation; PASI75/90/100 = 75/90/100% improvement in psoriasis area and severity index; PBO = placebo; RZB = risankizumab; SPARCC = Spondyloarthritis Research Consortium of Canada; VAS=visual analog scale.

Abstract OP0307 – Table 2. Overview of treatment-emergent adverse events (TEAEs) over 32 weeks

TEAEs, n (%)	Risankizumab (RZB)				Placebo
	Arm 1 N=42	Arm 2 N=42	Arm 3 N=39	Arm 4 N=20	Arm 5 N=42
Any AE	27 (64.3)	22 (52.4)	27 (69.2)	13 (65.0)	31 (73.8)
Drug related AEs[a]	8 (19.0)	7 (16.7)	8 (20.5)	4 (20.0)	8 (19.0)
Serious AE[b]	3 (7.1)	0	2 (5.1)	3 (15.0)	2 (4.8)
Drug related serious AE[a]	1 (2.4)	0	2 (5.1)	1 (5.0)	0
Severe AE	3 (7.1)	0	2 (5.1)	1 (5.0)	4 (9.5)
AE leading to drug discontinuation	3 (7.1)	0	0	1 (5.0)	2 (4.8)
Infection[c]	16 (38.1)	13 (31.0)	16 (41.0)	6 (30.0)	12 (28.6)
Serious infection	0	0	0	2 (10.0)[d]	0
Serious hypersensitivity	1 (2.4)[e]	0	0	0	0
Adjudicated MACE	1 (2.4)[f]	0	0	1 (5.0)[g]	0
Malignancy	0	0	0	1 (5.0)[h]	0
Depression	0	0	2 (5.1)	0	0

Arm 1, 150 mg RZB at weeks 0, 4, 8, 12, and 16; Arm 2, 150 RZB at weeks 0, 4, and 16 (PBO at weeks 8 and 12); Arm 3, 150 mg RZB at weeks 0 and 12 (PBO at weeks 4, 8, and 12); Arm 4, 75 mg RZB at week 0 (PBO at weeks 4, 8, 12, and 16); Arm 5, PBO at weeks 0, 4, 8, 12, and 16.
[a]Investigator assessed AE as possibly related to study drug. [b]No serious adverse event type was reported in more than one patient. [c]The most frequently reported AE was upper respiratory tract infection. [d]1 patient with urinary tract infection, influenza, and sepsis; 1 patient with gastroenteritis and pyelonephritis. [e]An event of investigator reported anaphylactic reaction occurred after the 1st injection of risankizumab. The sponsor assessed the event details as not consistent with IgE-mediated anaphylaxis. [f]1 patient with ischemic stroke. [g]1 patient with type 1 myocardial infarction. [h]1 patient with ovarian cancer.
AEs = adverse events; IgE = immunoglobulin E; MACE = major adverse cardiovascular event; PBO = placebo; RZB = risankizumab; TEAE = treatment emergent adverse event.

Conclusions: Pts with active PsA treated with RZB maintained improvement in joint and skin symptoms through 24 wks. RZB-treated pts (pooled across all RZB arms) showed evidence for inhibition of radiographic progression. RZB was well-tolerated with no new or unexpected safety findings.

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[1] Mease PJ, et al. *Arthritis Rheumatol* 2017;69(suppl 10).

Acknowledgements: AbbVie and Boehringer Ingelheim (BI) funded the study (NCT02719171); BI contributed to its design and participated in data collection and both participated in data analysis and interpretation of the data, and in writing, review, and approval of the publication. AbbVie, BI, and the authors thank all study investigators for their contributions and the patients who participated in this study. Statistical support: Andrew Topp; medical writing: Deepa Venkitaramani, PhD, both of Abbvie.

Disclosure of Interest: P. Mease Grant/research support from: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB, Consultant for: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB, Speakers bureau: AbbVie, Amgen, Bristol Myers, Celgene, Genentech, Janssen, Leo, Lilly, Merck, Novartis, Pfizer, Sun Pharma, and UCB, H. Kellner Grant/research support from: AbbVie, BMS, MSD, Novartis, Pfizer, Roche and UCB, Consultant for: AbbVie, BMS, MSD, Novartis, Pfizer, Roche and UCB, Speakers bureau: AbbVie, BMS, MSD, Novartis, Pfizer, Roche and UCB, A. Morita Grant/research support from: AbbVie, Eli Lilly Japan K.K., Janssen Pharmaceutical K. K., Kyowa Hakko Kirin Co., Ltd, Leo Pharma, Maruho Co, Ltd, Mitsubishi-Tanabe Pharma, and Novartis, Consultant for: AbbVie, Eli Lilly Japan K.K., Janssen Pharmaceutical K. K., Kyowa Hakko Kirin Co., Ltd, Leo Pharma, Maruho Co, Ltd, Mitsubishi-Tanabe Pharma, and Novartis, Speakers bureau: AbbVie, Eli Lilly Japan K.K., Janssen Pharmaceutical K. K., Kyowa Hakko Kirin Co., Ltd, Leo Pharma, Maruho Co, Ltd, Mitsubishi-Tanabe Pharma, and Novartis, A. Kivitz Grant/research support from: AbbVie, Boehringer Ingelheim, Celgene, Genentech, Genzyme, Horizon, Janssen, Merck, Novartis, Pfizer, Sanofi, Sun Pharma Advanced

Research, Regeneron, and UCB, Consultant for: AbbVie, Boehringer Ingelheim, Celgene, Genentech, Genzyme, Horizon, Janssen, Merck, Novartis, Pfizer, Sanofi, Sun Pharma Advanced Research, Regeneron, and UCB, Speakers bureau: AbbVie, Boehringer Ingelheim, Celgene, Genentech, Genzyme, Horizon, Janssen, Merck, Novartis, Pfizer, Sanofi, Sun Pharma Advanced Research, Regeneron, and UCB, K. Papp Grant/research support from: AbbVie, Amgen, Astellas, Baxalta, Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Dermira, Eli Lilly, Forward Pharma, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp and Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Stiefel, Sun Pharma, Takeda, UCB, and Valeant, Consultant for: AbbVie, Amgen, Astellas, Baxalta, Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Dermira, Eli Lilly, Forward Pharma, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp and Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Stiefel, Sun Pharma, Takeda, UCB, and Valeant, Speakers bureau: AbbVie, Amgen, Astellas, Baxalta, Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Dermira, Eli Lilly, Forward Pharma, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa-Hakko Kirin, Leo Pharma, MedImmune, Merck-Serono, Merck Sharp and Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Stiefel, Sun Pharma, Takeda, UCB, and Valeant, S. Aslanyan Employee of: Boehringer Ingelheim, B. Berner Employee of: Boehringer Ingelheim, S. Chen Shareholder of: AbbVie, Employee of: AbbVie, A. Eldred Shareholder of: AbbVie, Employee of: AbbVie, F. Behrens Grant/research support from: AbbVie, Amgen, Celgene, Chugai, Eli Lilly, Genzyme Janssen, Novartis, Pfizer, Roche, Sandoz, and Sanofi, Consultant for: AbbVie, Amgen, Celgene, Chugai, Eli Lilly, Genzyme Janssen, Novartis, Pfizer, Roche, Sandoz, and Sanofi, Speakers bureau: AbbVie, Amgen, Celgene, Chugai, Eli Lilly, Genzyme Janssen, Novartis, Pfizer, Roche, Sandoz, and Sanofi

DOI: 10.1136/annrheumdis-2018-eular.2140

OP0308 EFFICACY AND SAFETY RESULTS OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OVER 56 WEEKS FROM A PHASE 2A, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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Objectives: Evaluate efficacy and safety of guselkumab (GUS) in patients (pts) with active psoriatic arthritis (PsA) over 56 weeks (wks).

Methods: Pts w/active PsA (defined as ≥3 tender and ≥3 swollen joints, C-reactive protein ≥3 mg/L) and ≥3% body surface area (BSA) of plaque psoriasis despite current or previous treatment w/standard-of-care therapies, including previous TNF inhibitor therapy, were eligible to participate and were randomised 2:1 to receive GUS 100 mg subcutaneously or placebo (PBO) at wk 0, 4, and every 8 wks thereafter through wk44. At wk16, pts from either group with <5% improvement from baseline in both swollen and tender joint counts were eligible for early escape (EE) to open-label ustekinumab. All remaining PBO pts crossed-over to receive GUS 100 mg at wks24, 28, 36, and 44. At wk56, a post-treatment follow-up visit was conducted. Efficacy post wk24 through wk44 and wk56 was evaluated in pts who did not EE and continued treatment at wk24 (post wk24 efficacy analysis set) based on observed data. The wk24 data in this population were included as a reference.

Results: 149 pts were randomised to receive study agent (PBO: 49, GUS: 100). The study met its primary and all secondary endpoints through wk24. At wk24, 29 pts in the PBO group crossed over to receive GUS, of which 28 completed treatment through wk44. 86 pts in the GUS group continued treatment at wk24 and 84 pts completed treatment through wk44. Post wk24, ACR 20/50/70 and PASI 75/90/100 responses improved in PBO to GUS crossover pts and were well-maintained in GUS pts through wk44 (last efficacy assessments while on drug) and wk56 (final follow-up visit) (table 1). The efficacy results from wk24 through wk44 and wk56 are summarised in table 1.

Through wk56, 17.2% of PBO→GUS, 46.0% of GUS, and 39.5% of the combined GUS pts had ≥1 AEs, of which infections and infestations were the most commonly reported (3.4%, 27.0%, and 21.7%, respectively). Post wk24, there was no disproportional increase in overall AE frequency, or infections and infestations among GUS pts with longer exposure. Through wk56, among 129 pts who received GUS, there was 1 pt with malignancy (basal cell carcinoma), 1 pt with 2 serious infections (both pneumonia), 6 pts reported ≥1 SAEs (myocardial infarction, osteoarthritis, pupils unequal, radius fracture, pneumonia, ulcerative keratitis), 2 pts discontinued treatment due to AEs, 1 pt had neutropenia meeting NCI-CTCAE toxicity grade 3, and 6 pts were positive for antibodies to GUS. No deaths occurred through wk56.

Abstract OP0308 – Table 1 Efficacy results from Wk24 through Wk44 and Wk56 in post Wk24 efficacy analysis set based on the observed data

	PBO→GUS			GUS		
Efficacy Endpoints	Week 24*	Week 44	Week 56	Week 24	Week 44	Week 56
ACR 20	9/29 (31.0%)	21/28 (75.0%)	22/27 (81.5%)	57/86 (66.3%)	65/84 (77.4%)	61/83 (73.5%)
ACR 50	5/29 (17.2%)	13/28 (46.4%)	18/27 (66.7%)	34/86 (39.5%)	39/84 (46.4%)	44/83 (53.0%)
ACR 70	1/29 (3.4%)	7/28 (25.0%)	8/28 (28.6%)	14/86 (16.3%)	22/84 (26.2%)	27/83 (32.5%)
PASI 75	6/29 (20.7%)	23/28 (82.1%)	22/27 (81.5%)	71/86 (82.6%)	75/83 (90.4%)	70/82 (85.4%)
PASI 90	3/29 (10.3%)	21/28 (75.0%)	20/27 (74.1%)	61/86 (70.9%)	68/83 (81.9%)	64/82 (78.0%)
PASI 100	3/29 (10.3%)	19/28 (67.9%)	15/27 (55.6%)	38/86 (44.2%)	53/83 (63.9%)	47/82 (57.3%)
Mean (SD) change from baseline in HAQ-DI score	-0.19 (0.581)	-0.63 (0.612)	-0.67 (0.558)	-0.46 (0.530)	-0.54 (0.598)	-0.55 (0.621)
Median (IQR) percent change from baseline in Enthesitis Scorea	-50.0 (-100.0, 0.0)	-100.0 (-100.0, -60.0)	-100.0 (-100.0, -35.0)	-100.0 (-100.0, -50.0)	-100.0 (-100.0, -50.0)	-100.0 (-100.0, -50.0)
% of patients with unresolved enthesitisa	12/18 (66.7%)	8/17 (47.1%)	6/16 (37.5%)	26/67 (38.8%)	25/66 (37.9%)	19/65 (29.2%)
Median (IQR) percent change from baseline in dactylitisb	-45.0- (-70.8, 0.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -80.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -95.0)
% of patients with unresolved dactylitisb	13/16 (81.3%)	2/16 (12.5%)	1/16 (6.3%)	20/50 (40.0%)	10/49 (20.4%)	12/48 (25.0%)
Mean (SD) change from baseline in SF-36 physical component summary (PCS) score	2.13 (7.365)	8.02 (8.647)	N/A	7.40 (7.448)	8.34 (8.783)	N/A
Mean (SD) change from baseline in SF-36 mental component summary (MCS) score	0.51 (6.770)	5.53 (9.013)	N/A	5.45 (9.081)	4.56 (9.548)	N/A
% of patients achieving Minimal Disease Activity (MDA)	1/29 (3.4%)	8/28 (28.6%)	N/A	23/86 (26.7%)	29/84 (34.5%)	N/A

*Among the patients with enthesitis at baseline
[b]Among the patients with dactylitis at baseline
*Measured prior to receiving guselkumab

Conclusions: In pts with active PsA and ≥3% BSA of psoriasis, GUS demonstrated substantial benefits on joint symptoms, physical function, psoriasis, enthesitis, dactylitis, and quality of life, and efficacy was well-maintained through wk56. GUS was well-tolerated with no unexpected safety findings in this population after ~1 year of exposure.

Disclosure of Interest: A. Deodhar Grant/research support from: Janssen Research and Development, LLC, A. Gottlieb Grant/research support from: Janssen Research and Development, LLC, W.-H. Boehncke Grant/research support from: Janssen Research and Development, LLC, B. Dong Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC, Y. Wang Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC, Y. Zhuang Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC, W. Barchuk Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC, X. Xu Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC, E. Hsia Shareholder of: Johnson and Johnson, LLC, Employee of: Janssen Research and Development, LLC

DOI: 10.1136/annrheumdis-2018-eular.2059

OP0309 CHARACTERISATION OF CLINICAL BENEFITS IN SUBJECTS CLASSIFIED AS ACR20 NON-RESPONDERS AT WEEK 104 OF APREMILAST TREATMENT: SUBANALYSIS OF 3 LONG-TERM, PHASE III TRIALS

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Background: The PALACE 1, 2, and 3 trials evaluated the efficacy and safety of apremilast (APR) in subjects with active psoriatic arthritis (PsA) despite prior conventional disease-modifying anti-rheumatic drugs and/or biologics.

Objectives: The aim of this analysis is to further characterise the clinical benefits associated with long-term APR exposure in subjects who failed to achieve an ACR20 response at Week 104.

Methods: Subjects were randomised (1:1:1) to receive placebo (PBO), APR 30 mg BID (APR30), or APR 20 mg BID at baseline. Subjects who were randomised to APR30 at baseline and classified as ACR20 non-responders (ACR20NRs) at Week 104 were considered for this analysis. At Weeks 24, 52, and 104, ACR core components were examined as well as the proportions of