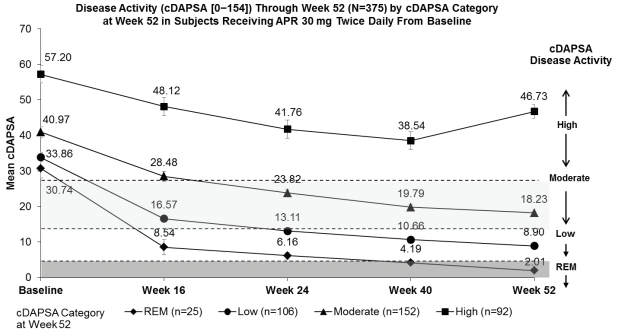
to calculate responses at Week 52 were included and grouped according to the cDAPSA categories reached at Week 52 (REM: ≤4; LDA: >4 to ≤13; moderate disease activity: >13 to ≤27; high disease activity: >27). We then traced their mean cDAPSA trajectory from BL to Week 52. Mean disease activity in core PsA domains were reported longitudinally by cDAPSA category reached at Week 52.

**Results:** A total of 375 APR subjects were included in the analyses. Achievement of REM or LDA by Week 52 was associated with lower mean cDAPSA at BL, and these subjects had continuous improvements in disease activity from BL to Week 52 (Figure). Among subjects who achieved REM or LDA by Week 52, most were classified as having LDA (mean cDAPSA: 8.5) or moderate disease activity (mean cDAPSA: 16.6), respectively, at Week 16. Furthermore, subjects who achieved REM or LDA by Week 52 showed early improvement, with no/mild articular and extra-articular disease activity by Week 52 with APR (Table).

**Conclusion:** In the subgroup of subjects who achieved cDAPSA REM or LDA, early improvement was seen in disease activity by Week 16 and sustained to Week 52 with continued treatment. Subjects achieving cDAPSA REM or LDA exhibited no or mild disease activity in enthesitis, dactylitis, function and skin psoriasis by Week 52.




Includes subjects assigned to receive APR 30 mg twice daily at baseline who had cDAPSA components available at Week 52. Data are as observed. High disease activity, cDAPSA >27; moderate disease activity, cDAPSA >13 to ≤27; low disease activity, cDAPSA >4 to ≤13; remission (REM), cDAPSA ≤4. Error bars represent standard error of the mean.

**Articular and Extra-Articular Disease Activity in Subjects With REM or LDA at Week 52**

| | Subjects With REM at Week 52 n=25 | | | | Subjects With LDA at Week 52 n=106 | | | |
|---|---|---|---|---|---|---|---|---|
| | Time Point | | | | Time Point | | | |
| Mean | BL | Week 16 | Week 24 | Week 52 | BL | Week 16 | Week 24 | Week 52 |
| SJC ( 0-66) | 9.1 | 2.2 | 1.2 | 0.1 | 8.8 | 3.5 | 2.0 | 1.1 |
| TJC (0-68) | 12.2 | 3.2 | 1.8 | 0.4 | 14.8 | 6.1 | 4.5 | 2.5 |
| PAP (VAS 0-100 mm) | 50.6 | 14.4 | 13.1 | 7.2 | 51.2 | 32.5 | 32.5 | 25.1 |
| PtGA (VAS 0-100mm) | 44.5 | 17.0 | 18.6 | 7.7 | 51.5 | 38.7 | 34.2 | 28.0 |
| PhGA (VAS 0-100 mm) | 48.8 | 16.0 | 12.4 | 8.4 | 50.7 | 24.0 | 18.9 | 13.7 |
| PASI* (0-72) | 9.5 | 4.2 | 3.5 | 2.7 | 8.2 | 3.7 | 3.4 | 4.0 |
| MASES§ (0-13) | 1.9 | 0.4 | 0.1 | 0.4 | 3.3 | 1.7 | 1.2 | 1.2 |
| Dactylitis count‡ | 2.3 | 0.7 | 0.2 | 0.0 | 2.8 | 1.0 | 0.6 | 0.5 |
| HAQ-DI (0-3) | 0.9 | 0.3 | 0.2 | 0.1 | 1.0 | 0.7 | 0.7 | 0.6 |

Includes subjects assigned to receive APR 30 mg twice daily at BL who had cDAPSA (as calculated with SJC [0-66] and TJC [0-68]) components available at Week 52. Data are as observed and n values vary by time point based on number of subjects with available data for a given end point. *Assessed in subjects with ≥3% psoriasis-involved body surface area at BL. §Assessed in subjects with enthesitis at BL. ‡Assessed in subjects with dactylitis at BL.
REM, cDAPSA ≤4; LDA, cDAPSA >4 to ≤13. VAS=visual analog scale; MASES=Maastricht Ankylosing Spondylitis Enthesitis Score.

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## AB0742 ACHIEVEMENT OF PASDAS LOW DISEASE ACTIVITY AND VERY LOW DISEASE ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH CERTOLIZUMAB PEGOL OVER 4 YEARS AND THE OVERLAP WITH DAPSA AND MDA DISEASE ACTIVITY TARGETS

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**Background:** Psoriatic Arthritis Disease Activity Score (PASDAS),[1]Disease Activity Index for Psoriatic Arthritis (DAPSA),[2] and the minimal disease activity (MDA) criteria[3] are instruments recommended for evaluating disease activity (DA) in psoriatic arthritis (PsA). RAPID-PsA demonstrated the sustained efficacy of certolizumab pegol (CZP) across the spectrum of PsA symptoms.[4] A substantial proportion of patients (pts) completing 4 years' treatment achieved DA targets; ~75% reached DAPSA low DA (LDA) or remission (REM), and almost 60% had MDA (≥5/7 MDA criteria), half of whom also achieved very low DA (VLDA) (7/7 MDA criteria).[5]

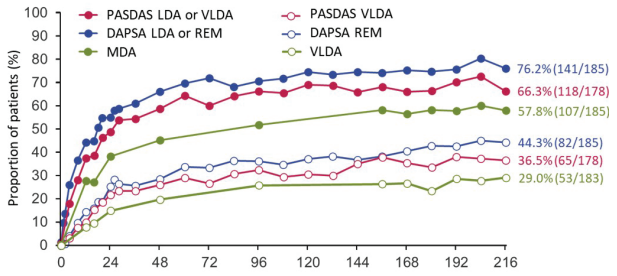
**Objectives:** To report the proportion of pts who achieved PASDAS VLDA and LDA over 216 weeks' (wks') CZP treatment, and the overlap in pts achieving PASDAS, DAPSA and MDA.

**Methods:** RAPID-PsA (NCT01087788) was double-blind and placebo-controlled to Wk24, dose-blind to Wk48, and open-label (OL) to Wk216.[5] Outcomes reported for pts randomised to CZP at Wk0 (200 mg every 2 wks or 400 mg every 4 wks, following a 400 mg loading dose at Wks0/2/4) are PASDAS change from baseline (CFB); pts achieving PASDAS LDA (>1.9−<3.2), PASDAS VLDA (≤1.9), DAPSA LDA (>4−≤14), DAPSA REM (≤4), MDA and VLDA to Wk216; and the overlap in pts achieving PASDAS VLDA, DAPSA REM, and VLDA, at Wk216. Data are summarized for observed cases per visit. Pts withdrawing between scheduled visits had their final assessment values assigned to the next scheduled visit timepoint.

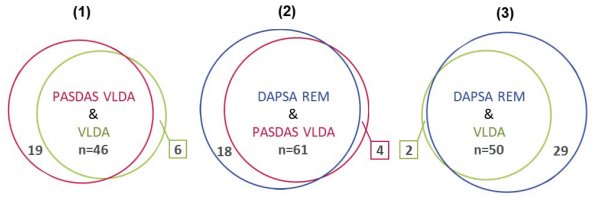
**Results:** Of 409 pts randomised, 273 received CZP from Wk0, of whom 248 (90.8%) completed Wk24 and 183 (67.0%) completed Wk216. The mean (SD) baseline PASDAS was 6.0 (1.0): in the high DA range, CFB at Wk216 was −3.4 (1.5). Of pts completing Wk216, 66.3% (118/178) were in PASDAS LDA or VLDA (PASDAS VLDA: 36.5% [n=65]): less than the proportion reaching DAPSA LDA or REM (76.2%), but more than those achieving MDA or VLDA (57.8%) (**Figure A**).

At Wk216, of pts achieving PASDAS VLDA, a large proportion (71% [46/65]) had VLDA based on MDA criteria (**Figure B1**) and most (94% [61/65]) achieved DAPSA REM (**Figure B2**). Almost all pts achieving VLDA (96.1% [50/52]) were also in DAPSA REM (**Figure B3**). After 4 years' CZP treatment, 25.8% (46/178) pts achieved the PASDAS VLDA, DAPSA REM and VLDA.

**Figure: A)** Patients with PsA achieving PASDAS, DAPSA and MDA disease activity targets over 4 years' CZP treatment (OC)




**B)** Overlap in patients with PsA achieving PASDAS VLDA, DAPSA REM and VLDA upon completing 216 weeks' CZP treatment (OC)




Data are for OC per visit. Patients withdrawing between scheduled visits had their final assessment values assigned to the next scheduled visit timepoint. CZP: certolizumab pegol; DAPSA: Disease Activity index for PSoriatic Arthritis; LDA: low disease activity; MDA: Minimal Disease Activity; OC: observed case; PASDAS: Psoriatic Arthritis Disease Activity Score; PsA: psoriatic arthritis; REM: remission; VLDA: very low disease activity.

**Conclusion:** A substantial proportion of pts completing 4 years' CZP treatment achieved PASDAS LDA or VLDA, and the vast majority who achieved PASDAS VLDA at Wk216 also reached DAPSA REM and/or VLDA. 1 in 4 pts achieved the most stringent DA target with all 3 instruments.

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AB0743

## REAL-WORLD EFFECTIVENESS AND SAFETY OF APREMILAST IN BELGIAN PATIENTS WITH PSORIATIC ARTHRITIS: ANALYSIS FROM THE MULTICENTRE, PROSPECTIVE, NON-INTERVENTIONAL APOLO STUDY

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**Background:** Real-world evidence on effectiveness and safety data for patients (pts) with psoriatic arthritis (PsA) in the Belgium clinical practice setting is lacking.

**Objectives:** To assess the effectiveness and safety of apremilast (APR) in pts with active PsA from routine clinical practice in Belgium.

**Methods:** In this multicentre, prospective, non-interventional study (APOLO), the PsA Response Criteria (PsARC) response 6 months after APR initiation was the primary endpoint. PsARC response was defined as improvement in ≥2 and no worsening of any of the following 4 measures: tender joint count (TJC; 0-68), swollen joint count (SJC; 0-66), Physician's Global Assessment of Disease Activity (PhGA) and Patient's Global Assessment of Disease Activity (PtGA). Other endpoints included PsAID12, HAQ-DI, Physician's and Patient's Numerical Rating Scale (NRS) assessing disease activity for the most affected joint, psoriasis-affected body surface area (BSA), enthesitis, dactylitis, pain and pruritus. The current analysis is based on observed data.

**Results:** The first 55 of a planned 150 Belgian pts receiving APR for up to 6 months were evaluated. Mean age was 52.5 yrs, mean BMI was 27.1 kg/m$^2$ and 47.3% were female. Mean durations of psoriasis and PsA were 15.8 yrs and 8.1 yrs, respectively; ≈80% of pts were biologic-naive. At baseline (BL), mean (SD) SJC was 8.0 (5.4), mean (SD) TJC was 12.7 (9.5) and mean (SD) body surface affected was 12.3% (20.8%); 31.0% of pts had dactylitis and 47.8% had enthesitis. In total, 35 pts (63.6%) continued APR treatment for 6 months; 20 (36.4%) had discontinued APR (insufficient effectiveness: 21.8%; adverse events: 10.9%, intolerance: 3.6%). After 6 months of APR initiation, 69.6% of pts had a PsARC response. Mean changes from BL in SJC were −4.4 (Month 3) and −5.7 (Month 6), with improvements in SJC (defined as ≥30% decrease per PsARC) observed in most pts (Month 3: 78.3%; Month 6: 83.3%). Comparable results were seen for TJC: Mean changes from BL were −7.2 (Month 3) and −6.7 (Month 6), with improvements observed in most pts (Month 3: 78.3%; Month 6: 80%). Decreases in PhGA score of ≥1 from BL were observed in most pts at Months 3 (73.7%) and 6 (66.7%). Mean (SD) Physician's NRS scores decreased from 5.6 (2.6) at BL to 2.5 (2.0) at Month 6. Among pts with enthesitis at BL who had data available at Month 6, 54.5% achieved a score of 0. Among pts with dactylitis at BL who had data available at Month 6, 44.4% achieved a score of 0. BL mean (SD) PsAID12 score of 5.9 (1.6) decreased to 3.7 (1.8) at Month 6. Mean (SD) BSA improved from 12.3% (20.8%) at BL to 7.5% (14.7%) at Month 6. An improvement of ≥20% in HAQ-DI at Month 6 was achieved by 73.1% of pts. Improvements were also seen in PtGA score, overall pain and pruritus. No new safety and tolerability concerns from known overall safety profile of APR.

**Conclusion:** Results from this real-world PsA study confirmed an improvement in disease activity with APR in both physician-assessed and pt-reported outcomes for most pts. Overall, improvements were observed after 3 months of APR treatment and were maintained up to the 6-month observation period. Safety and tolerability were similar to the known profile of APR.

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