

SUPPLEMENTARY INFORMATION

Table S1: CASPAR criteria[1]

Evidence of current psoriasis, a personal history of psoriasis, or a family history of psoriasis (2 points) <ul style="list-style-type: none"> • Current psoriasis is defined as psoriatic skin or scalp disease present today as judged by a rheumatologist or dermatologist.† • A personal history of psoriasis is defined as a history of psoriasis that may be obtained from a patient, family physician, dermatologist, rheumatologist, or other qualified health care provider. • A family history of psoriasis is defined as a history of psoriasis in a first- or second-degree relative according to patient report.
Typical psoriatic nail dystrophy including onycholysis, pitting, and hyperkeratosis observed on current physical examination (1 point)
A negative test result for the presence of rheumatoid factor by any method except latex (1 point)
Either current dactylitis, defined as swelling of an entire digit, or a history of dactylitis recorded by a rheumatologist (1 point)
Radiographic evidence of juxta-articular new bone formation appearing as ill-defined ossification near joint margins (but excluding osteophyte formation) on plain radiographs of the hand or foot (1 point)

† Current psoriasis is assigned a score of 2; all other features are assigned a score of 1.

Table S2: Effects of certolizumab pegol treatment on ACR components at week 24

ACR component	Mean change from baseline ± SD		
	Placebo (n=136)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W (n=135)
Swollen joint count	-0.5 ± 9.2	-7.9 ± 8.7	-7.4 ± 6.5
Tender joint count	-2.9 ± 11.5	-13.0 ± 14.6	-10.2 ± 12.6
Patient's assessment of pain	-11.2 ± 21.8	-28.6 ± 28.8	-28.4 ± 25.5
Patient's assessment of disease activity	-8.0 ± 24.0	-29.2 ± 28.4	-27.8 ± 25.3
Physician's assessment of disease activity	-16.5 ± 24.6	-37.2 ± 21.1	-37.1 ± 23.7
HAQ-DI	-0.17 ± 0.43	-0.52 ± 0.66	-0.43 ± 0.54
CRP* (mg/L)	-3.9 ± 17.4	-10.8 ± 27.2	-6.3 ± 17.2

ACR: American College of Rheumatology; CRP: C-reactive protein; CZP: Certolizumab pegol; HAQ-DI: Health assessment questionnaire – disability index; Q2W: Every 2 weeks; Q4W: Every 4 weeks. p<0.001 CZP 200 mg Q2W and CZP 400 mg Q4W vs. placebo; * Normal range of CRP < 7.9 mg/L

Table S3: ACR20 responders at week 12 by regional subgroups

Region	Placebo (n=136)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W (n=135)
North America, % (n)	21.9 (7/32)	51.6 (16/31)	62.9 (22/35)
Latin America, % (n)	63.2 (12/19)	85.7 (18/21)	65.0 (13/20)
West Europe, % (n)	27.3 (6/22)	64.7 (11/17)	62.5 (10/16)
East Europe, % (n)	12.7 (8/63)	50.7 (35/69)	39.1 (25/64)

CZP: Certolizumab pegol; Q2W: Every 2 weeks; Q4W: Every 4 weeks.

Table S4: Effects of certolizumab pegol treatment on enthesitis and dactylitis at week 24

Outcome,	Placebo (n=136)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W (n=135)
Leeds Enthesitis Index, n	91	88	84
Mean change from baseline ± SD	-1.1 ± 1.8	-2.0 ± 1.8 [†]	-1.8 ± 1.9 [‡]
Leeds Dactylitis Index, n	35	35	38
Mean change from baseline ± SD	-22.0 ± 46.9	-40.7 ± 34.6 [‡]	-53.5 ± 69.1 [†]

CZP: Certolizumab pegol; Q2W: Every 2 weeks; Q4W: Every 4 weeks; SD: standard deviation. [†]p<0.001; [‡]p≤0.003.

Table S5: Baseline demographics and disease severity characteristics, by prior TNF inhibitor use*

	No prior TNF exposure (n=329)	Prior TNF exposure (n=80)
Demographic characteristics		
Age, years	47.3 ± 11.3	48.7 +/- 11.7
Sex, % female	55.6	53.8
Weight, kg	83.7 ± 18.4	87.5 ± 20.1
BMI, kg/m ²	29.5 ± 6.5	31.0 ± 6.4
Arthritis characteristics		
Time from psoriatic arthritis diagnosis [∞] , years	8.2 ± 8.4	10.1 ± 7.2
CRP** (mg/L), median (min-max)	8.0 (0.1-140.6)	10.3 (0.1-238.0)
ESR (mm/h), median (min-max)	33.0 (4 -120)	38.0 (5 -125)
Tender joint count (0-68 joints), mean	19.8	22.4
Swollen joint count (0-66 joints), mean	10.2	12.6
HAQ-DI (range 0-3)	1.3 ± 0.7	1.4 ± 0.7
Enthesitis, % [†]	62.3	72.5
Dactylitis, % [‡]	26.4	26.3
Psoriasis characteristics		
Psoriasis BSA ≥3%, %	59.6	70.0
PASI, mean [#]	11.6	12.0
Nail involvement, %	72.6	76.3
mNAPSI, mean	3.3	3.2
Concomitant MTX at baseline, %	65.0	55.0
No concomitant DMARDs at baseline, %	32.2	42.5
Prior use of DMARDs, %		
1	50.8	50.0
≥ 2	48.9	40.1
Prior use of NSAIDs, %	86.9	80.0

* Except where indicated otherwise, values are the mean ± SD. There were no significant differences between treatment groups at baseline. BMI: Body mass index; BSA: Body surface area; CRP: C-reactive protein; CZP: Certolizumab pegol; DI: Disability index; DMARDs: Disease modifying antirheumatic drugs; ESR: Erythrocyte sedimentation rate; HAQ: Health Assessment Questionnaire; NSAIDs: Nonsteroidal anti-inflammatory drugs; mNAPSI: modified nail psoriasis severity index; MTX: Methotrexate; PASI: Psoriasis area and severity index; Q2W: Every 2 weeks; Q4W: Every 4 weeks; TNF: Tumor necrosis factor; VAS: Visual analogue scale

[∞]From the start date of the primary disease

[†] Presence of enthesitis at baseline defined as a Baseline Leeds Enthesitis Index score > 0

[‡] Presence of dactylitis at baseline assessed using Leeds Dactylitis Index

[#] PASI – scores for those patients with psoriasis body surface area ≥ 3% at baseline

** Normal range of CRP < 7.9 mg/L

^{††} n=135

Table S6: Baseline demographics and disease severity characteristics, by concomitant DMARD use at baseline*

	No concomitant DMARD use (n=122)	Concomitant DMARD use (n=287)
Demographic characteristics		
Age, years	46.1 ± 11.8	48.2 ± 11.2
Sex, % female	56.6	54.7
Weight, kg	84.5 ± 20.9	84.4 ± 17.8
BMI, kg/m ²	29.7 ± 7.2	29.8 ± 6.2
Arthritis characteristics		
Time from psoriatic arthritis diagnosis [∞] , years	9.0 ± 8.2	8.4 ± 8.2
CRP** (mg/L), median (min-max)	7.0 (0.2-238.0)	8.0 (0.1-143.0)
ESR (mm/h), median (min-max)	34.0 (4-125)	33.5 (5-125)
Tender joint count (0-68 joints), mean	21.7	19.7
Swollen joint count (0-66 joints), mean	11.2	10.4
HAQ-DI (range 0-3)	1.34	1.29
Enthesitis, % [†]	65.6	63.8
Dactylitis, % [‡]	26.2	26.5
Psoriasis characteristics		
Psoriasis BSA ≥3%, %	66.4	59.6
PASI, mean [#]	13.0	11.1
Nail involvement, %	69.7	74.9
mNAPSI, mean	3.6	3.2
Prior use of DMARDs, %		
1	56.6	48.1
≥ 2	36.8	51.5
Prior TNF inhibitor exposure, %		
	26.2	16.7

* Except where indicated otherwise, values are the mean ± SD. There were no significant differences between treatment groups at baseline. BMI: Body mass index; BSA: Body surface area; CRP: C-reactive protein; CZP: Certolizumab pegol; DI: Disability index; DMARDs: Disease modifying antirheumatic drugs; ESR: Erythrocyte sedimentation rate; HAQ: Health Assessment Questionnaire; NSAIDs: Nonsteroidal anti-inflammatory drugs; mNAPSI: modified nail psoriasis severity index; MTX: Methotrexate; PASI: Psoriasis area and severity index; Q2W: Every 2 weeks; Q4W: Every 4 weeks; TNF: Tumor necrosis factor; VAS: Visual analogue scale

† Presence of enthesitis at baseline defined as a Baseline Leeds Enthesitis Index score > 0

‡ Presence of dactylitis at baseline assessed using Leeds Dactylitis Index

PASI – scores for those patients with psoriasis body surface area ≥ 3% at baseline

** Normal range of CRP < 7.9 mg/L

†† n=135

Table S7: ACR20 week 12 responder rate by prior use of DMARDs subgroup

	Placebo n=136 % (n)	CZP 200 mg Q2W n=138 % (n)	CZP 400 mg Q4W n=135 % (n)
Subgroup			
Prior use of sDMARDs			
1	29.7 (22/74)	68.9 (42/61)	58.3 (42/72)
≥2	18.3 (11/60)	52.1 (38/73)	46.7 (28/60)

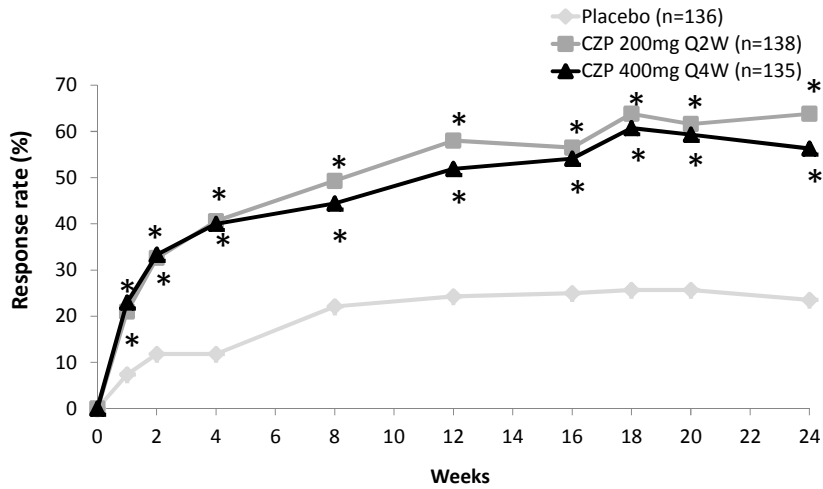
CZP: Certolizumab pegol; DMARDs: Disease modifying antirheumatic drugs; Q2W: Every 2 weeks; Q4W: Every 4 weeks

Table S8: TEAEs with an incidence of >3% in either CZP group during the 24-week double-blind period

System Organ Class Preferred Term	Placebo* (n=136) n(%)**	CZP 200 mg Q2W (n=138) n(%)**	CZP 400 mg Q4W (n=135) n(%)**
Gastrointestinal disorders	19 (14.0)	26 (18.8)	18 (13.3)
Diarrhea	4 (2.9)	7 (5.1)	5 (3.7)
Abdominal pain upper	2 (1.5)	5 (3.6)	3 (2.2)
General disorders and administration site conditions	11 (8.1)	13 (9.4)	26 (19.3)
Fatigue	2 (1.5)	4 (2.9)	4 (3.0)
Infections and infestations	52 (38.2)	60 (43.5)	54 (40.0)
Oral herpes	3 (2.2)	2 (1.4)	4 (3.0)
Bronchitis	6 (4.4)	4 (2.9)	4 (3.0)
Nasopharyngitis	10 (7.4)	18 (13.0)	9 (6.7)
Upper respiratory tract infection	7 (5.1)	12 (8.7)	13 (9.6)
Pharyngitis	3 (2.2)	6 (4.3)	4 (3.0)
Sinusitis	1 (0.7)	3 (2.2)	6 (4.4)
Urinary tract infection	9 (6.6)	3 (2.2)	4 (3.0)
Investigations	14 (10.3)	20 (14.5)	24 (17.8)
Alanine aminotransferase increased	2 (1.5)	4 (2.9)	7 (5.2)
Aspartate aminotransferase increased	1 (0.7)	4 (2.9)	6 (4.4)
Hepatic enzyme increased	2 (1.5)	5 (3.6)	4 (3.0)
Blood CPK increased	4 (2.9)	5 (3.6)	6 (4.4)
Nervous system disorders	10 (7.4)	10 (7.2)	12 (8.9)
Headache	2 (1.5)	6 (4.3)	5 (3.7)

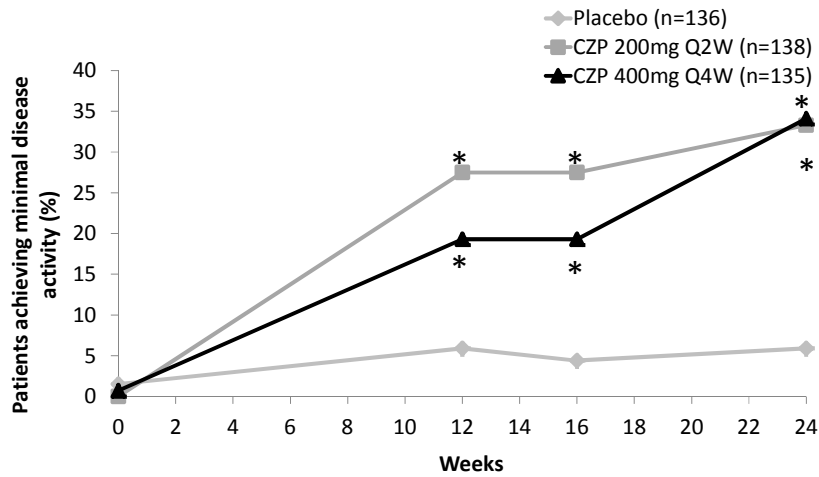
*placebo escape at week 16; **Not adjusted for exposure; CZP: Certolizumab pegol; Q2W: Every 2 weeks; Q4W: Every 4 weeks; CPK: creatine phosphokinase.

Figure S1: ACR20 response rates over time



*Nominal p value ≤ 0.001 versus placebo. Q2W: Every 2 weeks, Q4W: Every 4 weeks.

Figure S2: Patients achieving MDA response over time



*Nominal p value < 0.001 versus placebo. Q2W: Every 2 weeks, Q4W: Every 4 weeks.

REFERENCES

1. Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. *Arthritis and rheumatism* 2006;**54**(8):2665-73 doi: 10.1002/art.21972 [published Online First: 28 July 2006].