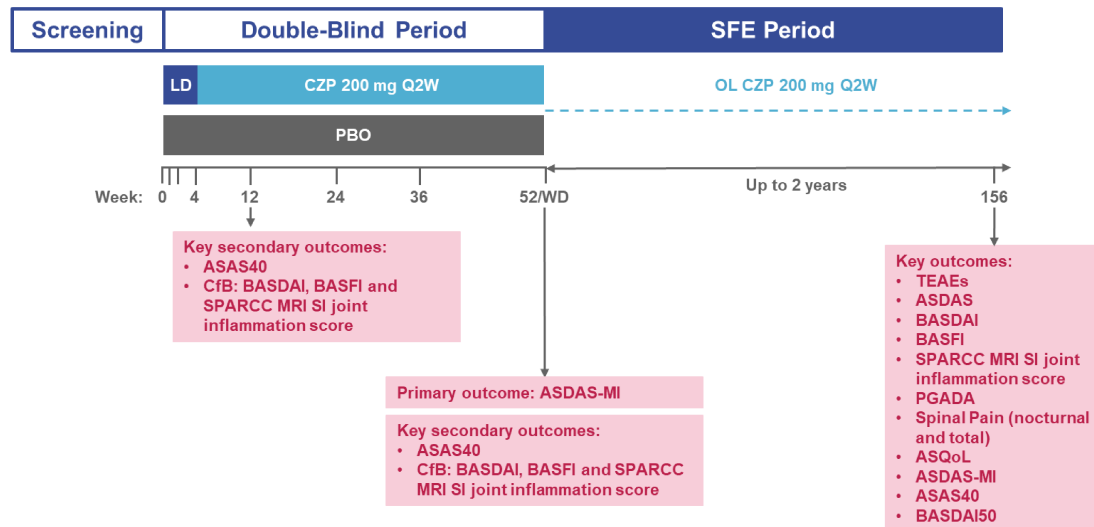


## SUPPLEMENTARY MATERIAL

**Supplementary Figure 1.** C-axSpAnd study design, including the SFE period



ASAS40: Assessment in Axial SpondyloArthritis international Society  $\geq 40\%$  improvement; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASDAS-MI: Ankylosing Spondylitis Disease Activity Score major improvement; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASDAI50: Bath Ankylosing Spondylitis Disease Activity Index  $\geq 50\%$  improvement; BASFI: Bath Ankylosing Spondylitis Functional Index; CfB: change from baseline; CZP: certolizumab pegol; LD: loading dose of 400 mg at Weeks 0, 2, 4; nr-axSpA: non-radiographic axial spondyloarthritis; OL: open-label; PBO: placebo; PGADA: Patients Global Assessment of Disease Activity; Q2W: every 2 weeks; SFE: safety follow-up extension; SI: sacroiliac; SPARCC: SpondyloArthritis Research Consortium of Canada; TEAEs: treatment emergent adverse events; TNFi: tumour necrosis factor inhibitor.

**Supplementary Table 1.** Concomitant NBBM taken during the SFE

|   | <b>All SFE patients<br/>(N=243)</b> |
|---|-------------------------------------|
| <b>Any concomitant NSAID medications,<sup>a</sup> n (%)</b>   | <b>184 (75.7)</b>                   |
| Diclofenac  | 38 (15.6)                           |
| Meloxicam   | 41 (16.9)                           |
| Celecoxib   | 31 (12.8)                           |
| Etoricoxib  | 30 (12.3)                           |
| Ibuprofen   | 12 (4.9)                            |
| Naproxen  | 8 (3.3)                             |
| Nimesulide  | 18 (7.4)                            |
| Ketoprofen  | 18 (7.4)                            |
| Aceclofenac   | 7 (2.9)                             |
| Piroxicam   | 3 (1.2)                             |
| Indometacin   | 2 (0.8)                             |
| Ketorolac   | 4 (1.6)                             |
| Bromfenac   | 1 (0.4)                             |
| Lornoxicam  | 2 (0.8)                             |
| Acemetacin  | 1 (0.4)                             |
| Etodolac  | 1 (0.4)                             |
| Flurbiprofen  | 1 (0.4)                             |
| Nabumetone  | 1 (0.4)                             |
| Tiaprofenic acid  | 1 (0.4)                             |
| <b>Any concomitant csDMARD medications,<sup>b</sup> n (%)</b> | <b>77 (31.7)</b>                    |
| Methotrexate  | 39 (16.0)                           |
| Sulfasalazine   | 37 (15.2)                           |
| Hydroxychloroquine  | 3 (1.2)                             |
| Leflunomide   | 2 (0.8)                             |
| Azathioprine  | 1 (0.4)                             |

Concomitant medications are assigned to treatment group according to whether they were taken at least one day in common with the study medication during that period. More than one medication could be reported for an individual patient. <sup>a</sup>Active principle as per medical review by the Program Physician. <sup>b</sup>Salt forms have been combined with the main ingredient. csDMARD: conventional synthetic disease-modifying anti-rheumatic drug; NBBM: non-biologic background medication; NSAID: non-steroidal anti-inflammatory drug; SFE: safety follow-up extension.

**Supplementary Table 2.** Baseline patient demographics and characteristics for patients who completed the double-blind period but did not enter the safety follow-up extension study

|                                    | <b>CZP 200 mg<br/>Q2W<br/>(n=21)</b> | <b>Placebo<br/>(n=20)</b> | <b>All patients<br/>(n=41)</b> |
|------------------------------------|--------------------------------------|---------------------------|--------------------------------|
| Male, n (%)                        | 9 (42.9)                             | 11 (55.0)                 | 20 (48.8)                      |
| Age, years, mean (SD)              | 37.0 (12.7)                          | 37.6 (10.9)               | 37.3 (11.7)                    |
| BMI, kg/m <sup>2</sup> , mean (SD) | 26.5 (5.9) <sup>a</sup>              | 28.0 (7.6)                | 27.2 (6.8) <sup>b</sup>        |
| Race                               |                                      |                           |                                |
| White, n (%)                       | 20 (95.2)                            | 19 (95.0)                 | 39 (95.1)                      |
| Other, n (%)                       | 1 (4.8)                              | 1 (5.0)                   | 2 (4.9)                        |
| Symptom duration, years            |                                      |                           |                                |
| Mean, (SD)                         | 10.5 (9.3)                           | 10.1 (8.1)                | 10.3 (8.7)                     |
| Median (min, max)                  | 5.6 (1.3, 31.5)                      | 7.4 (1.4, 24.9)           | 6.7 (1.3, 31.5)                |
| Time since first diagnosis, years  |                                      |                           |                                |
| Mean, (SD)                         | 4.7 (6.2)                            | 4.4 (6.1)                 | 4.6 (6.1)                      |
| Median (min, max)                  | 2.2 (0.2, 27.4)                      | 1.8 (0.0, 24.9)           | 2.1 (0.0, 27.4)                |
| CRP, mg/L                          |                                      |                           |                                |
| mean (SD)                          | 14.3 (20.7)                          | 12.5 (15.3)               | 13.4 (18.1)                    |
| >ULN <sup>c</sup> , n (%)          | 8 (38.1)                             | 9 (45.0)                  | 17 (41.5)                      |
| HLA-B27 positive, n (%)            | 15 (71.4)                            | 14 (70.0)                 | 29 (70.7)                      |

Baseline patient demographics and characteristics for patients who completed the double-blind period but did not enter the SFE are reported at Week 0 of the study, upon entry into the double-blind phase. <sup>a</sup>n=20. <sup>b</sup>n=40. <sup>c</sup>ULN for CRP defined as 9 or 9.99 mg/L. BMI: body mass index; CRP: C-reactive protein; HLA-B27: human leukocyte antigen B27; Q2W: every 2 weeks; SD: standard deviation; SFE: safety follow-up extension; ULN: upper limit of normal.

**Supplementary Table 3.** Incidence of treatment-emergent adverse events in patients receiving additional background medication

| n (%) [#]   | SFE: Weeks 52–156    |               |
|---|----------------------|---------------|
|   | CZP 200 mg Q2W (n=9) | Placebo (n=5) |
| Any TEAE  | 9 (100) [74]         | 5 (100) [23]  |
| Severe TEAEs  | 2 (22.2) [2]         | 0             |
| Subject discontinuations due to TEAEs                 | 0                    | 0             |
| Permanent withdrawal of study medication due to TEAEs | 0                    | 0             |
| Drug-related TEAEs                                    | 6 (66.7) [10]        | 2 (40.0) [10] |
| Serious TEAEs   | 2 (22.2) [2]         | 1 (20.0) [1]  |
| Deaths  | 0                    | 0             |

SFE safety set. #: number of individual TEAE occurrences; CZP: certolizumab pegol; Q2W: every 2 weeks; SFE: safety follow-up extension; TEAE: treatment-emergent adverse event.