1617

# Self-reported pain outcomes in patients with moderate to severe plaque psoriasis treated with certolizumab pegol: Three-year results from two phase 3 trials (CIMPASI-1 and CIMPASI-2)

Alice B. Gottlieb,[1] Julia-Tatjana Maul,[2] Lynda Spelman,[3] Phoebe Rich,[4] Boni Elewski,[5] Nicola Tilt,[6] José-Manuel López-Pinto,[7] Christine de la Loge,[8] Matthias Augustin[9]

## Objective

***To assess the impact of certolizumab pegol (CZP) treatment on pain over three years for patients with moderate to severe plaque psoriasis (PSO).***

## Background

- CZP is an Fc-free PEGylated, anti-tumour necrosis factor biologic that has shown durable clinical improvements over three years in patients with PSO.[1]
- In addition to skin lesions, moderate to severe PSO is associated with pain and discomfort.[2,3] It is therefore important to understand the effect of biologic treatment on pain.
- Here, the impact of CZP treatment on pain is assessed using the pain-related items from the Dermatology and Life Quality Index (DLQI), the 36-Item Short Form (SF-36) Health Survey, and the European Quality of Life Five Dimension Three Level (EQ-5D-3L) instrument over three years.

## Methods

- Data are pooled from the identically designed CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 trials.[1]
- Patients received treatment as shown in **Figure 1**.
- Three questionnaires utilised incorporated pain-related items:
  - Question #1 (Q1) of the DLQI relates to skin pain, itch, soreness and stinging (range 0–3; score of 0 represents no skin pain, itch, soreness or stinging)[4]
  - The pain/discomfort dimension of the EQ-5D-3L instrument (range 1–3; score of 1 represents no pain/discomfort)[5]
  - The bodily pain score of the SF-36 Health Survey, calculated as the mean of two pain-related questions (scores are standardised against a normative sample from the US general population in 2009, for whom the mean score was 50 [standard deviation: 10];[6] higher scores represent lower pain).[7]
- Data are reported as observed for all CZP-randomised patients, overall and by baseline self-reported psoriatic arthritis (PsA) status. Data are additionally shown by sex.

## Results

- Baseline demographic and disease characteristics are presented in **Table 1**.
- At baseline, 20.2% (73/361) of CZP-randomised patients reported concomitant PsA.
- The proportion of all CZP-randomised patients who reported no skin pain, itch, soreness or stinging (DLQI) or no pain or discomfort (EQ-5D-3L) increased from Week 0 to Week 16 and these improvements were maintained through Week 144 (**Figures 2A**–**2B**).
- The mean bodily pain score (SF-36) improved from Week 0 to Week 16 for all CZP-randomised patients and these improvements were maintained through Week 144 (**Figure 2C**).
- Patients with concomitant PsA had a higher pain-related burden, at baseline and throughout the studies, across all metrics compared to those without concomitant PsA (**Figure 2**).
- Considering this higher baseline burden, CZP treatment resulted in similar relative improvements in the pain-related items of the DLQI, EQ-5D-3L and SF-36 for patients with and without concomitant PsA (**Figure 2**).
- The percentage of patients with concomitant PsA reporting no pain in the DLQI and EQ-5D-3L decreased slightly from Week 16 to Week 144 (**Figures 2A**–**2B**). However, due to the small number of included patients with concomitant PsA, these results should be interpreted with caution.
- Scores at baseline and throughout the study period were similar for male and female patients across all three pain items (**Figure 3**).

## Conclusions

***CZP treatment was associated with durable improvements in pain outcomes for PSO patients through three years across patient subgroups.***

***Male and female patients reported similar pain outcomes both at baseline and following CZP treatment across all metrics.***

***Comparable relative improvements in pain and bodily discomfort were observed following CZP treatment for patients with concomitant PsA and those without when considering their higher baseline pain burden.***


## Summary

Results from the following pain-related items (comprising 1–2 questions per questionnaire) are reported for all CZP-randomised patients, and by PsA status and sex:

**DLQI**

**Question 1:** Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?

☐ Not at all [0] ☐ A little [1] ☐ A lot [2] ☐ Very much [3]

**EQ-5D-3L (Pain/Discomfort)**

☐ I have no pain or discomfort [1]
☐ I have moderate pain or discomfort [2]
☐ I have extreme pain or discomfort [3]

**SF-36 (Bodily Pain)**

**Question 1:** How much bodily pain have you had during the past 4 weeks?

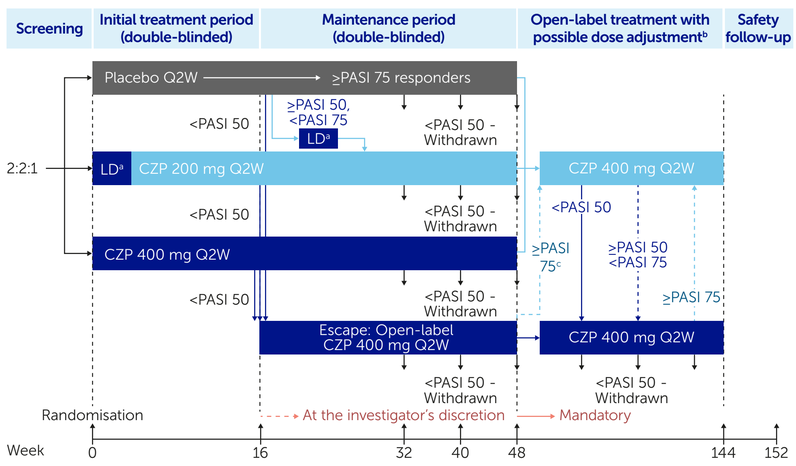
☐ None [100] ☐ Very mild [80] ☐ Mild [60] ☐ Moderate [40] ☐ Severe [20] ☐ Very severe [0]

**Question 2:** During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ None at all [100] ☐ A little bit [75] ☐ Moderately [50] ☐ Quite a bit [25] ☐ Extremely [0]

**Conclusion:** CZP treatment was associated with durable improvements in pain outcomes for patients with moderate to severe PSO through three years.


### Figure 1 Study design (CIMPASI-1 and CIMPASI-2)




[a]Patients randomised to CZP 200 mg received a loading dose of CZP 400 mg at Weeks 0, 2 and 4 or Weeks 16, 18 and 20; [b]Dose adjustments were permitted through Weeks 60–132; dose escalation was mandatory in patients not achieving PASI 50, and at the investigator's discretion in patients achieving PASI 50 but not PASI 75; patients who had received CZP 400 mg Q2W for at least 12 weeks could have had their dose reduced, at the investigator's discretion, if they achieved PASI 75, and were mandatorily withdrawn if they did not achieve PASI 50; [c]Patients entering the open-label period from the CZP 400 mg Q2W escape arm continued to receive CZP 400 mg Q2W but may have had their dose reduced to CZP 200 mg Q2W at Week 48, at the discretion of the investigator, if they achieved PASI 75.

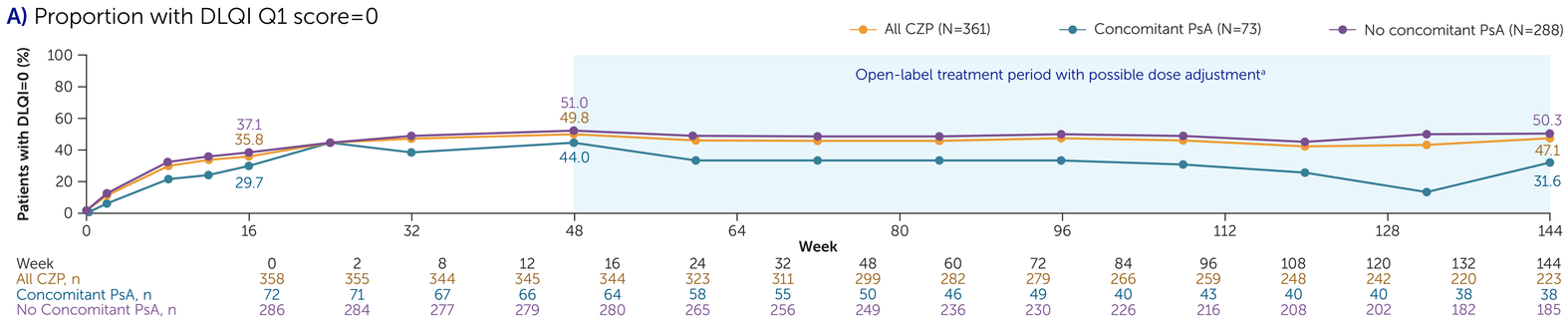
### Table 1 Baseline characteristics

| | All CZP[a] (N=361) | All CZP, Concomitant PsA (N=73) | All CZP, No Concomitant PsA (N=288) |
|---|---|---|---|
| **Age (years)**, mean ± SD | 45.3 ± 13.0 | 49.7 ± 12.8 | 44.2 ± 12.9 |
| **Caucasian**, n (%) | 333 (92.2) | 68 (93.2) | 265 (92.0) |
| **Male**, n (%) | 228 (63.2) | 43 (58.9) | 185 (64.2) |
| **BMI (kg/m²)**, mean ± SD | 31.6 ± 7.8 | 33.3 ± 8.6 | 31.1 ± 7.6 |
| **Weight (kg)**, mean ± SD | 93.6 ± 24.1 | 97.7 ± 26.7 | 92.6 ± 23.4 |
| **Concurrent PsA (self-reported)**, n (%) | 73 (20.2) | 73 (100) | 0 |
| **Prior biologic therapy**, n (%)[b] | 121 (33.5) | 36 (49.3) | 85 (29.5) |
| **Disease duration (years)**, mean ± SD | 18.1 ± 12.7 | 19.4 ± 12.7 | 17.7 ± 12.7 |
| **PASI**, mean ± SD | 19.4 ± 7.3 | 20.0 ± 9.5 | 19.2 ± 6.6 |
| **DLQI total**, mean ± SD | 14.0 ± 7.1[c] | 14.9 ± 7.0[d] | 13.7 ± 7.2[e] |
| **BSA affected (%)**, mean ± SD | 23.5 ± 14.6 | 24.6 ± 17.1 | 23.3 ± 13.9 |
| **PGA**, n (%) | | | |
| 3: moderate | 254 (70.4) | 50 (68.5) | 204 (70.8) |
| 4: severe | 107 (29.6) | 23 (31.5) | 84 (29.2) |
| **DLQI Q1=0**, n/N (%) | 5/358 (1.4) | 0/72 (0) | 5/286 (1.7) |
| **EQ-5D-3L Pain/Discomfort=1**, n/N (%) | 75/356 (21.1) | 7/72 (9.7) | 68/284 (23.9) |
| **SF-36 Bodily Pain**, mean ± SD | 45.9 ± 10.7[c] | 39.7 ± 10.4[d] | 47.5 ± 10.3[e] |

[a]Includes all patients randomised to CZP 200 mg Q2W or CZP 400 mg Q2W at Week 0. [b]Includes patients with multiple prior biologic use. [c]N=356. [d]N=72. [e]N=284.

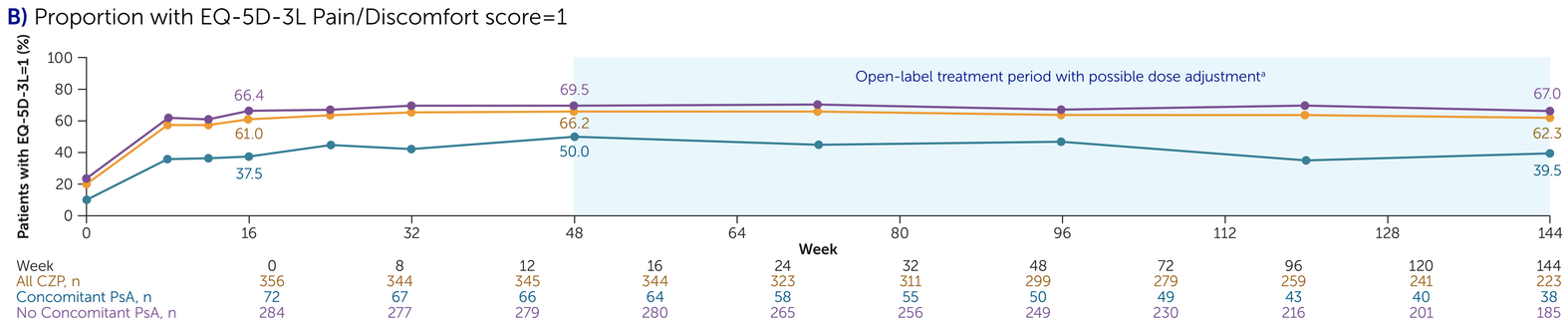
### Figure 2 Pain-related items to Week 144, overall and by PsA status (OC)

**A)** Proportion with DLQI Q1 score=0



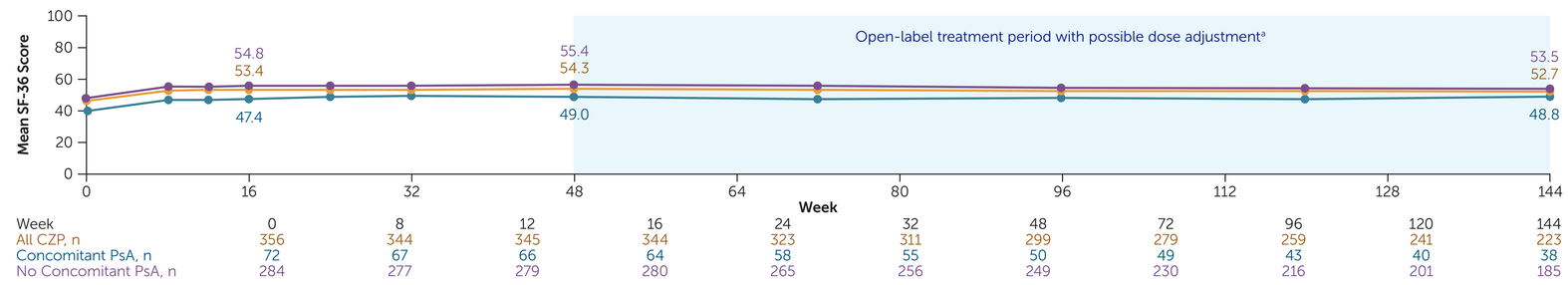

| Week | 0 | 2 | 8 | 12 | 16 | 24 | 32 | 48 | 60 | 72 | 84 | 96 | 108 | 120 | 132 | 144 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| All CZP, n | 358 | 355 | 344 | 345 | 344 | 323 | 311 | 299 | 282 | 279 | 266 | 259 | 248 | 242 | 220 | 223 |
| Concomitant PsA, n | 72 | 71 | 67 | 66 | 64 | 58 | 55 | 50 | 46 | 49 | 40 | 43 | 40 | 40 | 38 | 38 |
| No Concomitant PsA, n | 286 | 284 | 277 | 279 | 280 | 265 | 256 | 249 | 236 | 230 | 226 | 216 | 208 | 202 | 182 | 185 |

**B)** Proportion with EQ-5D-3L Pain/Discomfort score=1




| Week | 0 | 8 | 12 | 16 | 24 | 32 | 48 | 72 | 96 | 120 | 144 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| All CZP, n | 356 | 344 | 345 | 344 | 323 | 311 | 299 | 279 | 259 | 241 | 223 |
| Concomitant PsA, n | 72 | 67 | 66 | 64 | 58 | 55 | 50 | 49 | 43 | 40 | 38 |
| No Concomitant PsA, n | 284 | 277 | 279 | 280 | 265 | 256 | 249 | 230 | 216 | 201 | 185 |

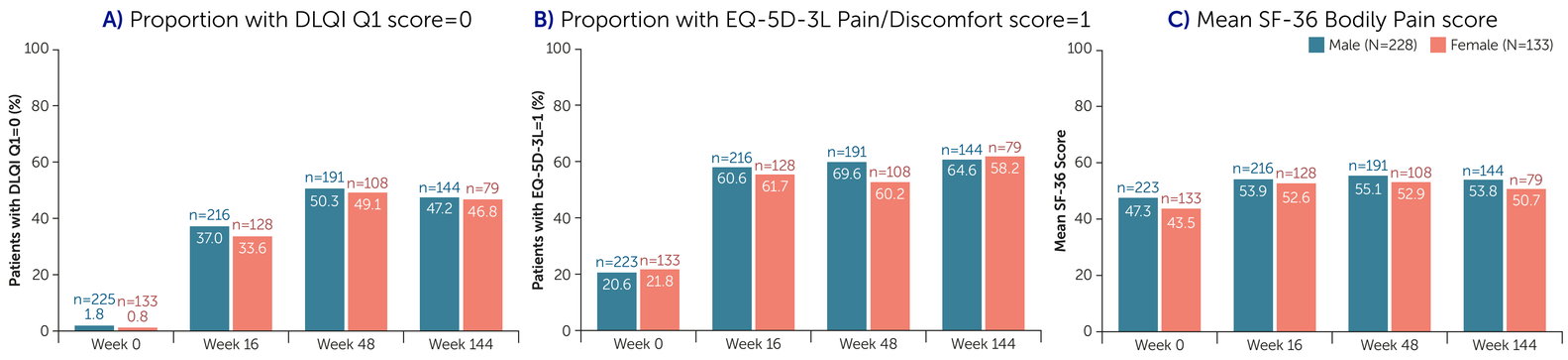
**C)** Mean SF-36 Bodily Pain score




| Week | 0 | 8 | 12 | 16 | 24 | 32 | 48 | 72 | 96 | 120 | 144 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| All CZP, n | 356 | 344 | 345 | 344 | 323 | 311 | 299 | 279 | 259 | 241 | 223 |
| Concomitant PsA, n | 72 | 67 | 66 | 64 | 58 | 55 | 50 | 49 | 43 | 40 | 38 |
| No Concomitant PsA, n | 284 | 277 | 279 | 280 | 265 | 256 | 249 | 230 | 216 | 201 | 185 |

[a]Dose adjustments were mandatory or at the investigator's discretion, based on PASI response.

### Figure 3 Pain-related items to Week 144 by sex (OC)




**BMI:** body mass index; **BSA:** body surface area; **CZP:** certolizumab pegol; **DLQI:** Dermatology Life Quality Index; **EQ-5D-3L:** European Quality of Life Five Dimension Three Level; **LD:** loading dose; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI 50/75:** ≥50%/75% improvement from baseline PASI; **PGA:** Physician Global Assessment; **PsA:** psoriatic arthritis; **PSO:** plaque psoriasis; **Q1:** question #1; **Q2W:** every two weeks; **SD:** standard deviation; **SF-36:** 36-Item Short Form.

**Institutions:** [1]Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, New York, USA; [2]Department of Dermatology and Venereology, University Hospital of Zurich, Zurich, Switzerland; [3]Veracity Clinical Research and Probity Medical, Woolloongabba, Queensland, Australia; [4]Oregon Dermatology and Research Center, Portland, Oregon, USA; [5]Department of Dermatology, University Hospitals of Cleveland, Case Western Reserve University, Cleveland, Ohio, USA; [6]UCB Pharma, Slough, UK; [7]UCB Pharma, Brussels, Belgium; [8]PCOM Analytics, Avallon, France; [9]Institute for Health Services Research in Dermatology and Nursing, University Medical Centre Hamburg-Eppendorf, Hamburg, Germany.

**References:** [1]Gordon KB *et al.* BJD 2021;184:652–62; [2]Psoriasis. Available at: http:www.nhs.uk/conditions/psoriasis; [3]Ljosaa TM *et al.* Scand J Pain 2020;20:491–8; [4]Finlay AY *et al.* Clin Exp Dermatol 1994;19:210–6; [5]Devlin N *et al.* 2020;DOI:10.1007/978–3–030–47622–9_1; [6]Maruish ME *et al.* User's manual for the SF-36v2 Health Survey, QualityMetric Incorporated; [7]36-Item Short Form Survey (SF-36) Scoring Instructions. Available at: https://rand.org/health-care/surveys_tools/mos/36-item-short-form/scoring.html. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ABG, JTM, LS, PR, BE, NT, JMLP, CL, MA;** Drafting of the publication or revising it critically for important intellectual content: **ABG, JTM, LS, PR, BE, NT, JMLP, CL, MA;** Final approval of the publication: **ABG, JTM, LS, PR, BE, NT, JMLP, CL, MA**. **Author Disclosures: ABG:** Received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, Sanofi, UCB Pharma, XBiotech (stock options for an RA project); received research/educational grants from: AnaptysBio, Janssen, Novartis, Ortho Dermatologics, Sun Pharma and UCB Pharma: all funds go to Mount Sinai Medical School. **JTM:** Employee of USZ and holds a "Filling the GAP" scholarship; served as advisor and/or received speaking fees and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, LEO Pharma, Janssen-Cilag, MSD, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi, UCB Pharma. **LS:** Consultant, and/or scientific adviser, and/or investigator, and/or scientific officer, and/or speaker for Amgen, Anacor, AbbVie, Ascend, Astellas, AstraZeneca, Blaze Bioscience, Bristol Myers Squibb, Boehringer Ingelheim, Botanix, Celgene, Dermira, Eli Lilly, Galderma, Genentech, GSK, Hexima, Janssen, LEO Pharma, Mayne, Medimmune, Merck (MSD), Merck-Serono, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Roche, Samumed, Sanofi/Genzyme, SHR, Sun Pharma ANZ, Trius, UCB Pharma and Zai Lab. **PR:** Principal investigator, clinical trials: AbbVie, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Sun Pharma and UCB Pharma. **BE:** Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Incyte, LEO Pharma, Eli Lilly, Merck, Menlo, Novartis, Pfizer, Regeneron, Sun Pharma, Valeant and Vanda; consultant (honoraria) from Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, LEO Pharma, Eli Lilly, Menlo, Novartis, Pfizer, Sun Pharma, UCB Pharma, Valeant and Verrica. **NT:** Employee of UCB Pharma; stockholder of GSK and UCB Pharma. **JMLP:** Employee of UCB Pharma. **CL:** Consultant to UCB Pharma. **MA:** Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma and Xenoport.

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