Long-Term Improvements in Health-Related Quality of Life of Patients with Moderate to Severe Plaque Psoriasis Treated with Certolizumab Pegol: Results from the CIMPASI-1 and CIMPASI-2 Phase 3 Trials

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Objectives

To assess health-related quality of life over 144 weeks using data from two certolizumab pegol phase 3 trials in moderate to severe plaque psoriasis with the 36-item Short Form survey data.

Background

- The Fc-free, PEGylated anti-tumor necrosis factor (TNF) agent certolizumab pegol (CZP) has shown durable clinical improvements, and a safety profile consistent with the anti-TNF class, over 144 weeks of treatment in patients with moderate to severe plaque psoriasis (PSO).[1,2]
- PSO can negatively impact health-related quality of life (HRQoL), with links to pain and discomfort, social stigmatisation, and psychological distress.[3] Therefore, it is important to understand whether clinical responses translate into long-term improvements in HRQoL.
- Durable improvements in HRQoL have been reported over 144 weeks of CZP treatment using the Dermatology Life Quality Index (DLQI).[1]
- To complement these positive DLQI results, we report results from the 36-item Short Form survey (SF-36).[4]

Methods

- Data were pooled from the CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 trials (Figure 1).[1]
- We report mean change from baseline across all SF-36 domains:
  - For all patients randomized to CZP (combined 200 mg and 400 mg every two weeks [Q2W]) through Weeks 0–144.
  - At Week 48 separately for patients randomized to CZP 200 mg or CZP 400 mg Q2W.
- All data are observed case (OC).

Results

Patient Population

- Baseline demographics (Table 1) and SF-36 values (Table 2) were balanced across treatment groups.

All CZP-Randomized Patients to Three Years

- Increases in SF-36 domain scores were rapid for patients receiving CZP, with improvements apparent from Week 8 (Figure 2A and Figure 2B).
- Improvements at Week 16 were greater for CZP-treated patients compared with placebo across all domains, and were durable to Week 144 (Figure 2A and Figure 2B).

CZP Dose Comparison after One Year

- At Week 48, greater improvements in all mental SF-36 domains were observed among patients randomized to CZP 400 mg Q2W compared with CZP 200 mg Q2W (Figure 3).
- Improvements were also observed across physical domains at Week 48, although differences between the two dose groups were smaller (Figure 3).

Synopsis

SF-36 is a widely used, general questionnaire to assess HRQoL across 8 mental and physical domains.[4]

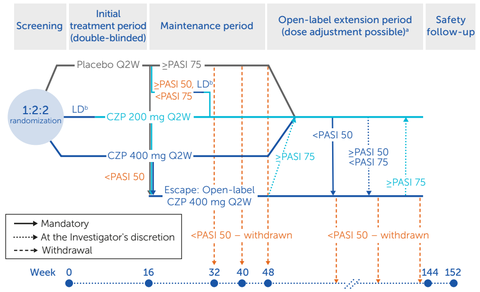
Mental domains:
- ☐ Vitality
- ☐ Social functioning
- ☐ Role emotional
- ☐ Mental health

Physical domains:
- ☐ Physical functioning
- ☐ Role physical
- ☐ Bodily pain
- ☐ General health

Scores in each domain **range from 0–100** and were derived to have a **mean score of 50 in the US general population.**[4]

Increased scores represent an improvement in HRQoL.

Figure 1 CIMPASI-1 and CIMPASI-2 study design



[a]Dose adjustments were mandatory or at the investigator's discretion, based on PASI response; [b]Loading dose of CZP 400 mg Q2W at Weeks 0, 2, and 4 or Weeks 16, 18, and 20. Adults with PSO ≥6 months (PASI >12, BSA affected ≥10% and PGA ≥3 on a 5-point scale) were enrolled. At Week 48 patients entering the open-label period from blinded treatment received CZP 200 mg Q2W, with subsequent dose adjustments permitted. Patients not achieving PASI 50 at Week 16 entered the escape arm for treatment with CZP 400 mg Q2W; at Week 48 these patients continued to receive CZP 400 mg Q2W or, if they achieved PASI 75, could have had their dose reduced at the investigator's discretion.

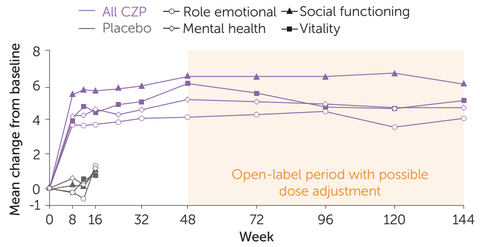
Table 1 Demographics and baseline characteristics

Mean ± SD unless stated	CZP 200 mg Q2W (n=186)[a]	CZP 400 mg Q2W (n=175)	All CZP (n=361)	Placebo (n=100)
Demographics				
Age, years	45.6 ± 13.2	45.0 ± 12.9	45.3 ± 13.0	45.7 ± 13.8
Male, n (%)	125 (67.2)	103 (58.9)	228 (63.2)	61 (61.0)
BMI, kg/m^2	32.0 ± 7.8	31.2 ± 7.9	31.6 ± 7.8	31.2 ± 7.4
Baseline characteristics				
Disease duration, years	17.7 ± 12.9	18.5 ± 12.6	18.1 ± 12.7	16.9 ± 12.6
PASI	19.2 ± 7.2	19.6 ± 7.3	19.4 ± 7.3	18.6 ± 6.6
DLQI	14.3 ± 7.4	13.7 ± 6.9	14.0 ± 7.1	13.4 ± 7.8
BSA (%) affected	23.5 ± 14.9	23.6 ± 14.3	23.5 ± 14.6	23.1 ± 13.6
PGA, n (%)				
3: moderate	128 (68.8)	126 (72.0)	254 (70.4)	72 (72.0)
4: severe	58 (31.2)	49 (28.0)	107 (29.6)	28 (28.0)
Prior anti-TNF-use, n (%)	44 (23.7)	40 (22.9)	84 (23.3)	19 (19.0)

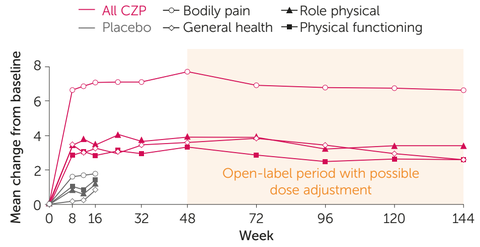
[a]CZP 200 mg Q2W patients received CZP 400 mg Q2W at Weeks 0, 2, and 4.

Figure 2 Mean change from baseline in SF-36 domain scores (OC)

A) Mental domains



B) Physical domains



C) Patient numbers with available SF-36 data

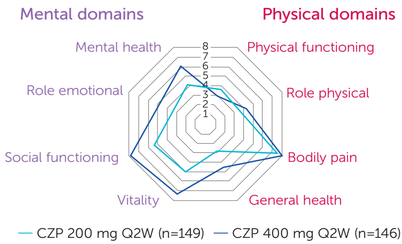
Study Week	0	8	12	16	24	32	48	72	96	120	144
All CZP	356	339	340	339	319	307	295	275	256	238	221
Placebo	97	92	88	87	-	-	-	-	-	-	-

The All CZP group includes all patients initially randomized to CZP 200 mg Q2W or CZP 400 mg Q2W. Patient numbers reflect those for whom SF-36 data were available at both baseline and the timepoint in question, from which change from baseline could be calculated. Placebo data are not shown past Week 16.

Table 2 Baseline SF-36 scores across all domains (OC)

Mean ± SD	CZP 200 mg Q2W (n=183)	CZP 400 mg Q2W (n=173)	All CZP (n=356)	Placebo (n=97)
SF-36 Domain				
Vitality	48.5 ± 9.8	47.6 ± 10.0	48.1 ± 9.9	47.2 ± 9.7
Social functioning	45.4 ± 11.1	45.1 ± 11.0	45.2 ± 11.0	45.0 ± 11.7
Role emotional	46.8 ± 10.4	46.1 ± 10.8	46.4 ± 10.6	46.7 ± 10.3
Mental health	46.8 ± 10.7	46.3 ± 10.1	46.5 ± 10.4	44.9 ± 12.0
Physical functioning	47.7 ± 9.6	49.1 ± 9.4	48.4 ± 9.5	48.5 ± 8.8
Role physical	46.7 ± 9.5	47.3 ± 10.0	47.0 ± 9.7	47.1 ± 8.8
Bodily pain	45.3 ± 10.4	46.6 ± 11.1	45.9 ± 10.7	45.5 ± 10.7
General health	47.1 ± 10.1	47.5 ± 9.3	47.3 ± 9.7	46.4 ± 10.4

Figure 3 Mean change from baseline in SF-36 domain scores at Week 48 by dose (OC)



Data are shown as observed for patients randomized to either CZP 200 mg or 400 mg Q2W, including those that entered the open-label CZP 400 mg Q2W escape arm at Week 16. Patient numbers reflect those for whom data were available at both baseline and Week 48, from which change from baseline could be calculated.

Conclusions

Improvements across all SF-36 domains were observed from Week 8 of CZP treatment, and were generally durable through Week 144. The greatest improvements were for bodily pain and social functioning, which were the most affected at baseline. These data complement the three-year DLQI results previously reported.[1]

BSA: body surface area; CZP: certolizumab pegol; DLQI: Dermatology Life Quality Index; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 50/75: ≥50/75% improvement from baseline in PASI; Q2W: every two weeks; PGA: Physician's Global Assessment; PSO: plaque psoriasis; SD: standard deviation; SF-36: 36-item Short Form survey; TNF: tumor necrosis factor.

Institutions: [1]Institute and Comprehensive Center for Inflammation Medicine, University Hospital of Lübeck, Lübeck, Germany; [2]Oregon Medical Research Center, Portland, Oregon, USA; [3]Center for Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf and Skinflammation® Center, Hamburg, Germany; [4]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK; [5]Division of Dermatology, Department of Medicine, University of Toronto, Toronto, ON, Canada; [6]Division of Dermatology, Department of Medicine, Women's College Hospital, Toronto, Ontario, Canada; [7]UCB Pharma, Slough, UK; [8]UCB Pharma, Brussels, Belgium; [9]UCB Pharma, Colombes, France; [10]Icahn School of Medicine at Mount Sinai, New York, New York, USA

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