Durability of DLQI Improvements Among Patients with Moderate to Severe Plaque Psoriasis Treated with Certolizumab Pegol: Three-Year Results from Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2)

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Objective

To assess the impact of certolizumab pegol on dermatology life quality subdomains over the course of 144 weeks of treatment in patients with moderate to severe plaque psoriasis.

Introduction

- Certolizumab pegol (CZP) is an Fc-free, PEGylated, anti-tumor necrosis factor agent that has shown durable clinical improvements 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 stigmatization, and psychological distress.[3] Therefore, it is important to understand whether clinical responses translate into long-term improvements in HRQoL.
- Here, we present Dermatology Life Quality Index (DLQI) results over 144 weeks of CZP treatment to evaluate the impact of CZP across different DLQI subdomains and to expand upon DLQI remission rates (DLQI 0/1) previously reported.[1]

Methods

- Data were pooled from CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272), phase 3 trials in adults with moderate to severe PSO; detailed study designs have been described previously (Figure 1).[1,4]
- DLQI by initial CZP randomization group through Week 144 is reported, as observed.
- We report:
  - Absolute scores for total DLQI and DLQI subdomains through Weeks 0–144.
  - Rate of DLQI subdomain remission, defined as a score of 0, indicating no impact of skin disease on that concept, at Weeks 48 and 144.

Results

- Baseline demographics are shown in Table 1 and patient numbers with available DLQI data at each week are shown in Table 2.
- Improvements in total DLQI observed over the first 48 weeks of CZP treatment were durable through to Week 144 (Figure 2).
- Across all DLQI subdomains, baseline mean scores were similar between treatment groups (Table 3).
- At baseline, the DLQI subdomains with the highest scores were symptoms and feelings, daily activities, and leisure, indicating greatest impact of disease on these areas (Table 3).
- Improvements in the scores for these DLQI subdomains over the first 48 weeks were durable through to Week 144 for both treatment groups (Figure 3).
- Remission rates at Week 48 across subdomains of interest were also maintained until Week 144 for both treatment groups (Figure 4).

Synopsis

Methods

The DLQI questionnaire is comprised of **10 questions**, each providing a score of 0–3 where **higher scores indicate a greater impact of skin on that aspect of a patient's quality of life.**[5]

Here, we present analyses based on total DLQI and individual subdomains:

Score range of 0–6 (2 questions each)

Symptoms and feelings
- Itchy/sore/painful stinging
- Embarrassed/self-conscious

Daily activities
- Interference with shopping/home/garden
- Influence on clothes worn

Personal relationships
- Problems with partners/friends/relatives
- Any sexual difficulties

Leisure
- Affects social/leisure activities
- Makes it difficult to do any sports

Score range of 0–3 (1 question each)

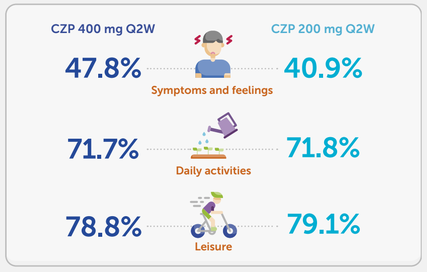
Work and school
- Prevents or causes problems with work or studying

Treatment
- How much of a problem is treatment

Results

The DLQI subdomains with the highest scores at baseline were **symptoms and feelings**, **daily activities**, and **leisure**.

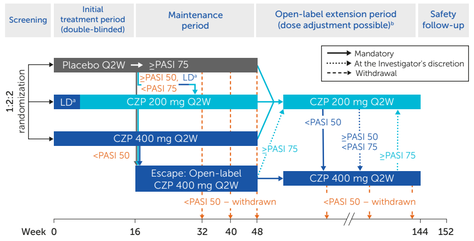
Remission rates (score of 0) in these subdomains after 144 weeks of treatment for patients randomized to **CZP 400 mg Q2W** and **CZP 200 mg Q2W** were as follows:



Conclusion

Improvements in DLQI among CZP-treated patients were durable from Week 48 to Week 144.

Figure 1 CIMPASI-1 and CIMPASI-2 study design



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. [a]Loading dose of CZP 400 mg Q2W at Weeks 0, 2 and 4 or Weeks 16, 18 and 20. [b]Dose adjustments were mandatory or at the discretion of the Investigator, based on PASI response.

Table 1 Demographic and baseline characteristics

Mean ± SD unless stated	CZP 400 mg Q2W (n=175)	CZP 200 mg Q2W[a] (n=186)	All CZP (n=361)
Age (years)	45.0 ± 12.9	45.6 ± 13.2	45.3 ± 13.0
Male, n (%)	103 (58.9)	125 (67.2)	228 (63.2)
BMI, kg/m²	31.2 ± 7.9	32.0 ± 7.8	31.6 ± 7.8
Duration of PSO (years)	18.5 ± 12.6	17.7 ± 12.9	18.1 ± 12.7
PASI	19.6 ± 7.3	19.2 ± 7.2	19.4 ± 7.3
BSA (%)	23.6 ± 14.3	23.5 ± 14.9	23.5 ± 14.6
PGA score, n (%)			
3: moderate	126 (72.0)	128 (68.8)	254 (70.4)
4: severe	49 (28.0)	58 (31.2)	107 (29.6)
Total DLQI	13.7 ± 6.9	14.3 ± 7.4	14.0 ± 7.1
Prior biologic use, n (%)	59 (33.7)	62 (33.3)	121 (33.5)
anti-TNF	40 (22.9)	44 (23.7)	84 (23.3)
anti-IL17	8 (4.6)	16 (8.6)	24 (6.6)
anti-IL-12/IL-23	10 (5.7)	3 (1.6)	13 (3.6)

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

Figure 2 Total DLQI through Weeks 0–144 (OC)

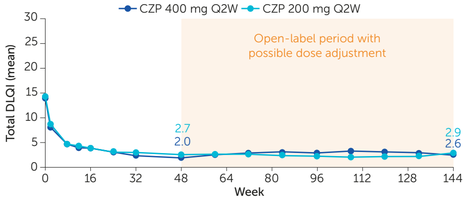


Table 2 Patient numbers with available DLQI data

Study Week	0	2	8	12	16	24	32	48	60	72	84	96	108	120	132	144
CZP 400 mg Q2W	173	172	171	168	170	159	152	148	140	141	136	131	124	123	114	113
CZP 200 mg Q2W	183	183	173	177	174	164	159	151	142	138	130	128	124	119	106	110

Figure 3 Absolute scores by DLQI subdomain through Weeks 0–144 (OC)

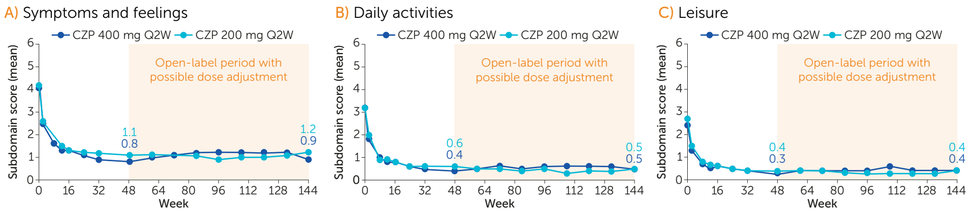
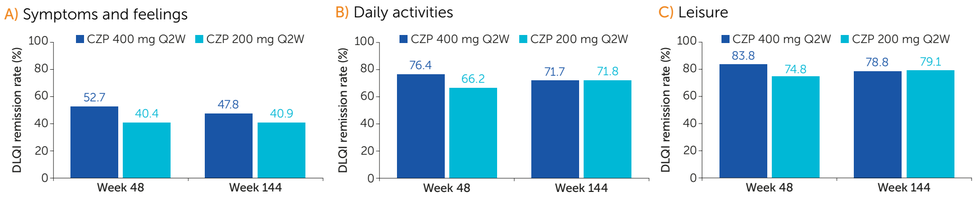


Figure 4 Remission rates for DLQI subdomains at Week 48 and 144 (OC)



Remission is defined as a score of 0, indicating no impact of skin disease on that concept.

Table 3 Baseline DLQI subdomain scores (OC)

Mean ± SD	CZP 400 mg Q2W (n=173)	CZP 200 mg Q2W[a] (n=183)	All CZP (n=356)
Symptoms and feelings	4.1 ± 1.4	4.2 ± 1.5	4.2 ± 1.4
Daily activities	3.2 ± 1.7	3.2 ± 1.9	3.2 ± 1.8
Leisure	2.4 ± 1.9	2.7 ± 2.0	2.5 ± 2.0
Work and school	0.9 ± 1.0	0.9 ± 1.0	0.9 ± 1.0
Personal relationships	1.9 ± 1.9	2.0 ± 1.9	1.9 ± 1.9
Treatment	1.2 ± 1.1	1.3 ± 1.1	1.3 ± 1.1

[a]CZP 200 mg Q2W patients received CZP 400 mg Q2W at Weeks 0, 2 and 4. Lower scores indicate greater quality of life. All subdomains are scored 0–6 with the exception of work and school and treatment which are scored 0–3.

Conclusions

Improvements in total DLQI were durable from Week 48 to Week 144 across both CZP treatment groups.

This pattern was reflected in the DLQI subdomains (symptoms and feelings, daily activities, and leisure) which had the greatest impact on patients' lives at baseline.

BMI: body mass index; BSA: body surface area; CZP: certolizumab pegol; DLQI: Dermatology Life Quality Index; IL: interleukin; OC: observed case; LD: loading dose; PASI: Psoriasis Area and Severity Index; PGA: Physician's Global Assessment; PSO: psoriasis; Q2W: every two weeks; SD: standard deviation; TNF: tumor necrosis factor.

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