



Durability of response in plaque psoriasis patients receiving certolizumab pegol over 48 Weeks in phase 3 studies: CIMPASI-1, CIMPASI-2, CIMPACT

Introduction: The Fc-free, PEGylated, anti-tumour necrosis factor certolizumab pegol (CZP) has demonstrated efficacy and safety in plaque psoriasis (PSO).^{1,2}

Objectives: To assess durability of the initial clinical response to CZP in PSO phase 3 trials.

Methods: Data were pooled from CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272), CIMPACT (NCT02346240). Study designs have been reported previously.^{1,2} Patients (adults with PSO [PASI \geq 12, \geq 10% BSA, PGA \geq 3/5] \geq 6 months) were randomised 2:2:1 (CIMPASI-1/2) or 3:3:1:3 (CIMPACT) to CZP 400mg every two weeks (wks) (Q2W), 200mg Q2W (400mg loading dose Wks0/2/4), placebo, or etanercept (CIMPACT only). At Wk16: in CIMPASI-1/2 CZP-treated PASI50 responders continued the same dose; in CIMPACT PASI75 responders were re-randomised to doses including CZP 400mg Q2W, CZP 200mg Q2W and placebo. This pooled analysis only includes patients who achieved PASI75 at Wk16 and received the same CZP dose through Wks0-48. Patients not achieving PASI50 at Wks32/40/48 were subsequently classified as non-responders. We report Wk48 PASI75 and PASI90 in patients who achieved the same response at Wk16. Missing data were imputed using Markov Chain Monte Carlo (MCMC) imputation. Sensitivity analyses used non-responder imputation (NRI).

Results: At Wk16, 180 CZP 400mg Q2W/173 CZP 200mg Q2W patients achieved PASI75; 98.0%/86.1% also achieved PASI75 at Wk48 (MCMC). 116 CZP 400mg Q2W/100 CZP 200mg Q2W patients achieved PASI90 at Wk16; 89.0%/80.1% also achieved PASI90 at Wk48 (MCMC).

Sensitivity analyses showed similar trends (NRI).

Conclusions: Patients in both CZP dose groups demonstrated durability of their Wk16 response to Wk48. Greatest durability was seen in patients treated with CZP 400mg Q2W.

Gottlieb AB. et al. *J Am Acad Dermatol* 2018;79:302–14.e6

Lebwohl M. et al. *J Am Acad Dermatol* 2018;79:266–76.e5