

Phase IIIb, open Label.

Patients received subcutaneous CZP 400 mg at weeks 0, 2 and 4 and q4w up to w52. Endoscopic evaluations performed at w 0, 10 and 54.

Primary outcome: Mean change in CDEIS score at w10;

Secondary outcomes: endoscopic response, remission (CDEIS score <6), complete remission (CDEIS score <3) and mucosal healing at w10 and 54.

Results:

- In the ITT population (n.89) the mean SD CDEIS score was 14.5 +/-5.3 at baseline; mean decrease in CDEIS score at week 10 was 5.7 (4.6 to 6.8, p<0.0001).
- Endoscopic response, endoscopic remission, complete endoscopic remission and mucosal healing at w10 were 54%, 37%, 10% and 4%, respectively. At w54 the corresponding rates were 49%, 27%, 14% and 8%, respectively.

Conclusion:

Following CZP treatment in patients with active CD, endoscopic lesions were improved as shown by the decrease in mean CDEIS score and by endoscopic response and remission rates. These benefits were achieved as early as w10 and were generally maintained through w54.

Endoscopic improvement of mucosal lesions in patients with moderate-severe ileocolonic CD following treatment with certolizumab pegol**Table 2** CDEIS score, endoscopic response, endoscopic remission, complete endoscopic remission and mucosal healing by visit (local results only)

Population	N	Week	Mean ±SD CDEIS score	Response, % (95% CI)	Remission, % (95% CI)	Complete remission, % (95% CI)	Mucosal healing, % (95% CI)
Intention-to-treat	89	0	14.5±5.3				
		10	8.8±6.1	54 (43 to 65)	37 (27 to 48)	10 (5 to 18)	4 (1 to 11)
		54	9.8±6.2	49 (39 to 60)	27 (18 to 37)	14 (7 to 22)	8 (3 to 16)
Subpopulation with endoscopic assessment at time point	78	0	14.7±5.3				
		10	8.3±6.0	62 (50 to 72)	42 (31 to 54)	12 (5 to 21)	5 (1 to 13)
		54	9.6±6.4	62 (48 to 75)	28 (17 to 42)	19 (9 to 32)	13 (6 to 25)

Response defined as decrease in CDEIS score of ≥5, remission defined as CDEIS score <6, complete remission defined as CDEIS score <3, mucosal healing defined as no ulcers. CDEIS, Crohn's Disease Endoscopic Index of Severity.

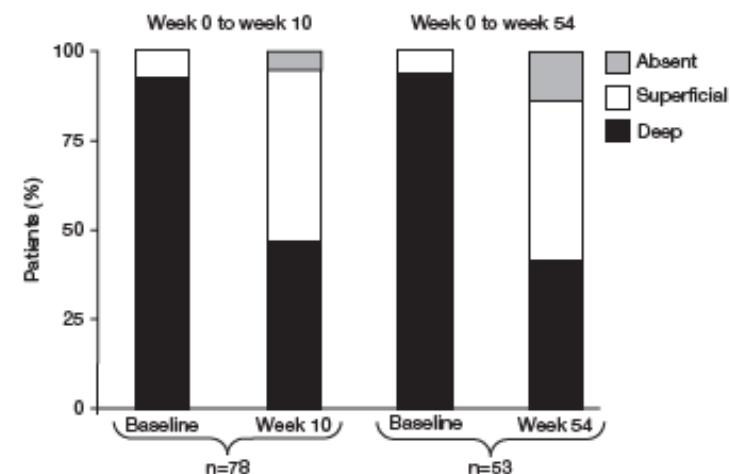


Figure 3 Ulceration classification in patients with endoscopic evaluation at baseline/week 10 and baseline/week 54.

