

Table 1. Efficacy Endpoints at Week 16 ^{#μ}

Endpoints, n (%)	PBO N = 37	3 mg BID N = 39	6 mg BID N = 37	12 mg BID N = 36	24 mg BID N = 36	24 mg QD N = 35
Clinical Remission	4 (11)	5 (13)	10 (27)*	4 (11)	8 (22)	5 (14)
Endoscopic Remission	0 (0)	4 (10)*	3 (8)	3 (8)*	8 (22)***	5 (14)**
Clinical Response [†]	12 (32)	17 (44)	21 (57)**	17 (47)	22 (61)**	17 (49)
Modified Clinical Remission [‡]	4 (12)	6 (16)	10 (30)*	9 (27)	11 (37)**	6 (19)
Endoscopic Response ^γ	5 (14)	9 (23)	16 (43)***	14 (39)***	18 (50)***	17 (49)***
Endoscopic Improvement ^α	1 (3)	5 (13)	7 (21)**	10 (29)***	10 (33)***	8 (25)**
CDAI<150	6 (16)	8 (21)	11 (30)	14 (39)**	11 (31)	7 (20)
CR100	10 (27)	13 (33)	15 (41)	16 (44)	20 (56)**	11 (31)
CR70	13 (35)	18 (46)	20 (54)	16 (44)	23 (64)**	17 (49)
Change in hsCRP, Mean (SD)	-0.1 (12.0)	-3.0 (19.6)	-3.9 (19.5)	-6.6 (27.1)	-14.8 (26.4)***	-2.7 (13.7)

CDAI<150, Crohn's disease activity index <150; CR70 or 100, reduction from baseline in CDAI score of 70 or 100 points.

Co-primary endpoints are in bold text.

^μFor endoscopic remission, response and improvement, measurements were at Week 12/16, as scored by the central reader.

[†]Clinical response: ≥30% reduction from baseline in AP or SF, with neither worse than baseline.

[‡]Modified Clinical remission: average daily SF ≤ 2.8 and average daily AP ≤ 1.0 with both not worse than baseline.

^γEndoscopic response: ≥25% decrease in SES-CD from baseline.

^αEndoscopic improvement: >50% decrease in SES-CD from baseline or endoscopic remission.

[#] Non-responder imputation.

*, ** and ***: statistically significant at .1, .05, and .01 levels, respectively.