Table 4. Efficacy Results for GEMINI II and III Studies at Week 6 and Week 10

Study Endpoint	**Placebo**	**Vedolizumab**
GEMINI II Study		
Clinical remission, Week 6		
Overall	7% (n = 148)	15%* (n = 220)
TNFα Antagonist(s) Failure	4% (n = 70)	11% (n = 105)
TNFα Antagonist(s) Naïve	9% (n = 76)	17% (n = 109)
Enhanced clinical response, Week 6		
Overall	26% (n = 148)	31%[†] (n = 220)
TNFα Antagonist(s) Failure	23% (n = 70)	24% (n = 105)
TNFα Antagonist(s) Naïve	30% (n = 76)	42% (n = 109)
Serum CRP change from baseline to Week 6, median (mcg/mL)		
Overall[‡]	-0.5 (n = 147)	-0.9 (n = 220)
GEMINI III Study		
Clinical remission, Week 6		
Overall[‡]	12% (n = 207)	19% (n = 209)
TNFα Antagonist(s) Failure[¶]	12% (n = 157)	15%[§] (n = 158)
TNFα Antagonist(s) Naïve	12% (n = 50)	31% (n = 51)
Clinical remission, Week 10		
Overall	13% (n = 207)	29% (n = 209)
TNFα Antagonist(s) Failure[¶,‡]	12% (n = 157)	27% (n = 158)
TNFα Antagonist(s) Naïve	16% (n = 50)	35% (n = 51)
Sustained clinical remission[#,¶]		
Overall	8% (n = 207)	15% (n = 209)
TNFα Antagonist(s) Failure[¶,‡]	8% (n = 157)	12% (n = 158)
TNFα Antagonist(s) Naïve	8% (n = 50)	26% (n = 51)
Enhanced clinical response, Week 6		
Overall^	23% (n = 207)	39% (n = 209)
TNFα Antagonist(s) Failure[‡]	22% (n = 157)	39% (n = 158)
TNFα Antagonist(s) Naïve^	24% (n = 50)	39% (n = 51)

*p<0.05

[†]not statistically significant

[‡]secondary endpoint to be viewed as exploratory by pre-specified statistical testing procedure

[§]not statistically significant, the other endpoints were therefore not tested statistically

[¶]n=157 for placebo and n=158 for vedolizumab

[#]Sustained clinical remission: clinical remission at Weeks 6 and 10

^Exploratory Endpoint

Table 5. Efficacy Results for GEMINI II at Week 52

	Placebo N=153*	Vedolizumab Every 8 Weeks N=154	Vedolizumab Every 4 Weeks N=154
Clinical remission	22%	39%†	36%‡
Enhanced clinical response	30%	44%‡	45%‡
Corticosteroid-free clinical remission§	16%	32%‡	29%‡
Durable clinical remission¶	14%	21%	16%

*The placebo group includes those subjects who received vedolizumab at Week 0 and Week 2, and were randomised to receive placebo from Week 6 through Week 52.

†$p<0.001$

‡$p<0.05$

§Corticosteroid-free clinical remission: Patients using oral corticosteroids at baseline who had discontinued corticosteroids beginning at Week 6 and were in clinical remission at Week 52. Patient numbers were n=82 for placebo, n=82 for vedolizumab every eight weeks, and n=80 for vedolizumab every four weeks

¶Durable clinical remission: Clinical remission at ≥80% of study visits including final visit (Week 52)