

**Table 2. Week 6 Efficacy Results of GEMINI I<sup>1</sup>**

Endpoint	Placebo N=149	Vedolizumab N=225
Clinical response	26%	47% <sup>*</sup>
Clinical remission <sup>§</sup>	5%	17% <sup>†</sup>
Mucosal healing <sup>¶</sup>	25%	41% <sup>‡</sup>

<sup>\*</sup>p<0.0001

<sup>†</sup>p≤0.001

<sup>‡</sup>p<0.05

<sup>§</sup>Clinical remission: Complete Mayo score of ≤2 points and no individual subscore >1 point

<sup>¶</sup>Mucosal healing: Mayo endoscopic subscore of ≤1 point

**Table 3. Week 52 Efficacy Results of GEMINI I<sup>1</sup>**

Endpoint	Placebo N = 126 <sup>*</sup>	Vedolizumab Every 8 Weeks N = 122	Vedolizumab Every 4 Weeks N = 125
Clinical remission	16%	42% <sup>†</sup>	45% <sup>†</sup>
Durable clinical response <sup>¶</sup>	24%	57% <sup>†</sup>	52% <sup>†</sup>
Mucosal healing	20%	52% <sup>†</sup>	56% <sup>†</sup>
Durable clinical remission <sup>#</sup>	9%	20% <sup>§</sup>	24% <sup>‡</sup>
Corticosteroid-free clinical remission <sup>▲</sup>	14%	31% <sup>§</sup>	45% <sup>†</sup>

<sup>\*</sup>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.

<sup>†</sup>p<0.0001

<sup>‡</sup>p<0.001

<sup>§</sup>p<0.05

<sup>¶</sup>Durable clinical response: Clinical response at Weeks 6 and 52

<sup>#</sup>Durable clinical remission: Clinical remission at Weeks 6 and 52

<sup>▲</sup>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=72 for placebo, n=70 for vedolizumab every eight weeks, and n=73 for vedolizumab every four weeks