2013. GEMINI I

Phase 3/ VEDO/UC/ Induct/Maintain

Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis

Randomized double-blind, placebo controlled trial.
Induction: VDZ 300mg IV w0 and w2 or placebo,disease evaluation w6
Maintenance: responders w6 randomised to continue VDZ q8w or q4w or placebo for up to 52w.

Primary outcome for induction therapy: clinical response w6
Secondary outcomes: clinical remission w6; mucosal healing w6.
Primary outcome for maintenance: remission w52
Secondary outcome for maintenance: durable clinical response & remission w52, steroid free remission.

Table 2. Outcome Measures at Week 6 in the Trial of Induction Therapy.

Outcome	Placebo (N=149)	Vedolizumab (N=225)	Percentage-Point Difference (95% CI)*	P Value
	no. (%)			
Clinical response†	38 (25.5)	106 (47.1)	21.7 (11.6–31.7)	<0.001
Clinical remission‡	8 (5.4)	38 (16.9)	11.5 (4.7–18.3)	0.001
Mucosal healing§	37 (24.8)	92 (40.9)	16.1 (6.4–25.9)	0.001

Results:
- Clinical response w6: 47.1% VDZ vs 25.5% pbo; p<0.001
- Clinical response w52:41.8%VDZq8 vs 44.8%VDZq4 vs 15.9% pbo; p<0.0001

Conclusions:
Vedolizumab more effective than placebo as induction and maintenance therapy for UC.

Table 3. Outcome Measures in the Trial of Maintenance Therapy.

Outcome	Placebo (N=126)	Vedolizumab Every 8 Wk (N=122)	Vedolizumab Every 4 Wk (N=125)	Between-Group Difference*			
				Every 8 Wk vs. Placebo	P Value	Every 4 Wk vs. Placebo	P Value
	number/total number (percent)			*percentage points (95% CI)*		*percentage points (95% CI)*	
Clinical remission at wk 52	20/126 (15.9)	51/122 (41.8)	56/125 (44.8)	26.1 (14.9–37.2)	<0.001	29.1 (17.9–40.4)	<0.001
Durable clinical response†	30/126 (23.8)	69/122 (56.6)	65/125 (52.0)	32.8 (20.8–44.7)	<0.001	28.5 (16.7–40.3)	<0.001
Durable clinical remission‡	11/126 (8.7)	25/122 (20.5)	30/125 (24.0)	11.8 (3.1–20.5)	0.008	15.3 (6.2–24.4)	0.001
Mucosal healing at wk 52	25/126 (19.8)	63/122 (51.6)	70/125 (56.0)	32.0 (20.3–43.8)	<0.001	36.3 (24.4–48.3)	<0.001
Glucocorticoid-free remission at wk 52§	10/72 (13.9)	22/70 (31.4)	33/73 (45.2)	17.6 (3.9–31.3)	0.01	31.4 (16.6–46.2)	<0.001

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