Supplementary Table 6. Key Safety Results in the Non-Asian Countries Subgroup in GEMINI 2 Patients: Maintenance Phase

Parameter	ITT			Non-ITT		Placebo combined	Vedolizumab combined
	Placebo	Vedolizumab q8w	Vedolizumab q4w	Placebo[a]	Vedolizumab q8w[a]		
No.	146	143	142	131	478	277	763
Any AE	124 (85)	125 (87)	121 (85)	102 (78)	418 (87)	226 (82)	664 (87)
Drug-related AE	49 (34)	59 (41)	61 (43)	41 (31)	184 (38)	90 (32)	304 (40)
AE resulting in study discontinuation	15 (10)	9 (6)	8 (6)	14 (11)	67 (14)	29 (10)	84 (11)
SAE	22 (15)	24 (17)	22 (15)	22 (17)	139 (29)	44 (16)	185 (24)
Serious infection AE	5 (3)	4 (3)	7 (5)	4 (3)	27 (6)	9 (3)	38 (5)
Drug-related SAE	4 (3)	4 (3)	5 (4)	2 (2)	23 (5)	6 (2)	32 (4)
Serious AE resulting in study discontinuation	7 (5)	6 (4)	4 (3)	8 (6)	43 (9)	15 (5)	53 (7)
Deaths	0	0	0	1 (< 1)	2 (< 1)	1 (< 1)	2 (< 1)

Values are presented as number (%).
Intent-to-treat (ITT) = patients who showed response to vedolizumab at 6 weeks and were randomized as part of the double-blind maintenance phase (maintenance ITT population); Non-ITT placebo = patients that were randomized to placebo during the induction phase and continued to received double-blind placebo during maintenance phase (maintenance safety population only); Non-ITT vedolizumab q4w = patients that did not show response to vedolizumab at 6 weeks and received open-label vedolizumab during the maintenance phase (maintenance safety population only); Placebo combined = all patients that received placebo during the maintenance phase; Vedolizumab combined = all patients that received vedolizumab during the maintenance phase.
[a]Patient numbers do not exactly match those shown in disposition (Fig. 1) because those patients who were discontinued from the study during the induction phase continued to be included in the safety population and have been counted within these groups.
AE, adverse event; q4w, every 4 weeks; q8w, every 8 weeks; SAE, serious AE.