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Supplementary Table 5. Key Safety Results in the Non-Asian Countries Subgroup in GEMINI 2 Patients: Induction Phase

Parameter	Placebo	Vedolizumab (cohort 1)	Vedolizumab (cohort 2)	Vedolizumab (combined)
No.	131	186	723	909
Any AE	78 (60)	112 (60)	415 (57)	527 (58)
Drug-related AE	27 (21)	49 (26)	162 (22)	211 (23)
AE resulting in study discontinuation	9 (7)	9 (5)	23 (3)	32 (4)
SAE	8 (6)	18 (10)	51 (7)	69 (8)
Serious infection AE	2 (2)	1 (< 1)	9 (1)	10 (1)
Drug-related SAE	0	3 (2)	4 (< 1)	7 (< 1)
Serious AE resulting in study discontinuation	5 (4)	5 (3)	15 (2)	20 (2)
Deaths	0	0	1 (< 1)	1 (< 1)

Values are presented as number (%).
Placebo and vedolizumab (cohort 1) = the groups that were part of the double-blind induction phase (induction intent-to-treat [ITT] population); Vedolizumab (cohort 2) = additional patients were enrolled to meet the maintenance phase sample size requirements and received open-label vedolizumab (induction safety population only); Vedolizumab (combined) = all patients that received vedolizumab during the induction phase.
AE, adverse event; SAE, serious AE.