https://doi.org/10.5217/ir.2019.09160 • Intest Res 2021;19(1):83-94

Supplementary Table 3. Key Safety Results in the Asian Countries Subgroup of GEMINI 2 Patients: Induction Phase

Parameter	Placebo	Vedolizumab (cohort 1)	Vedolizumab (cohort 2)	Vedolizumab (combined)
No.	17	34	24	58
Any AE	10 (59)	12 (35)	11 (46)	23 (40)
Drug-related AE	4 (24)	2 (6)	3 (13)	5 (9)
AE resulting in study discontinuation	0	0	1 (4)	1 (2)
SAE	1 (6)	2 (6)	1 (4)	3 (5)
Serious infection AE	0	0	1 (4)	1 (2)
Drug-related SAE	0	0	0	0
Serious AE resulting in study discontinuation	0	0	0	0
Deaths	0	0	0	0

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.