

See “Efficacy and safety of vedolizumab in ulcerative colitis in patients from Asian countries in the GEMINI 1 study” on page 71-82.

Supplementary Table 1. Key Safety Results in the Asian Countries Subgroup of GEMINI 1 Patients: Induction Phase

Parameter	Placebo ^a	Vedolizumab (cohort 1) ^a	Vedolizumab (cohort 2)	Vedolizumab (combined)
No.	29	29	55	84
Any AE	10 (34)	6 (21)	24 (44)	30 (36)
Drug-related AE	4 (14)	3 (10)	6 (11)	9 (11)
AE resulting in study discontinuation	1 (3)	0	0	0
SAE	3 (10)	0	1 (2)	1 (1)
Serious infection AE	0	0	0	0
Drug-related SAE	1 (3)	0	0	0
Serious AE resulting in study discontinuation	1 (3)	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.

^aData for the ITT population.

AE, adverse event; SAE, serious AE.