Table_14.3.1.1
Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

		Study Drug		
	Placebo (N=21)	Low Dose (N=23)	High Dose (N=20)	Total (N=43)
System Organ Class/Preferred Term	[AEs] n (%)	[AEs] n (%)	[AEs] n (%)	[AEs] n (%)
Any Adverse Events	15 9 (42.9%)	36 14 (60.9%)	13 6 (30.0%)	49 20 (46.5%)
GASTROINTESTINAL DISORDERS	4 4 (19.0%)	20 12 (52.2%)	4 2 (10.0%)	24 14 (32.6%)
Abdominal discomfort		1 1 (4.3%)	1 1 (5.0%)	2 2 (4.7%)
Abdominal pain	1 1 (4.8%)	3 2 (8.7%)	2 2 (10.0%)	5 4 (9.3%)
Diarrhoea	1 1 (4.8%)	9 7 (30.4%)	2 2 (10.0%)	9 7 (30.4%)
Dyspepsia	3 3 (14.3%)	5 5 (21.7%)	1 1 (5.0%)	6 6 (14.0%)
Gastrooesophageal reflux disease	3 3 (14.3%)	2 2 (8.7%)	1 1 (5.0%)	2 2 (8.7%)
NERVOUS SYSTEM DISORDERS	4 3 (14.3%)	9 5 (21.7%)	2 2 (10.0%)	11 7 (16.3%)
Headache	4 3 (14.3%)	9 5 (21.7%)	2 2 (10.0%)	11 7 (16.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	7 7 (33.3%)	7 6 (26.1%)	7 4 (20.0%)	14 10 (23.3%)
Exfoliative rash	4 3 (14.3%)	1 1 (4.3%)	2 2 (10.0%)	1 1 (4.3%)
Rash	5 5 (23.8%)	6 5 (21.7%)	3 3 (15.0%)	9 8 (18.6%)
Rash pruritic	2 2 (9.5%)	6 5 (21.7%)	4 3 (15.0%)	4 3 (15.0%)

Note 1: A subject who reported two or more different preferred terms in the same system organ class is counted only once in the system organ class.
Note 2: Subjects with adverse events in different systems organ class are counted only once in the overall total.
Note 3: N is the number of subjects within the treatment group in the population, n is the number of subjects who reported the adverse event and % is calculated by n/N*100. [AEs] is the number of AE reports.