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

| | | Study Drug | | |
System Organ Class/Preferred Term	Placebo (N=21) [AEs]　　n (%)	Low Dose (N=23) [AEs]　　n (%)	High Dose (N=20) [AEs]　　n (%)	Total (N=43) [AEs]　　n (%)
Any Adverse Events	25　12 (57.1%)	50　18 (78.3%)	28　15 (75.0%)	78　33 (76.7%)
GASTROINTESTINAL DISORDERS	12　10 (47.6%)	29　15 (65.2%)	12　9 (45.0%)	41　24 (55.8%)
Abdominal discomfort	1　1 (4.8%)	2　2 (8.7%)	1　1 (5.0%)	3　3 (7.0%)
Abdominal pain	2　2 (9.5%)	5　3 (13.0%)	4　4 (20.0%)	9　7 (16.3%)
Diarrhoea	4　3 (14.3%)	12　9 (39.1%)	2　2 (10.0%)	14　11 (25.6%)
Dyspepsia	4　4 (19.0%)	8　8 (34.8%)	4　4 (20.0%)	12　12 (27.9%)
Gastrooesophageal reflux disease	1　1 (4.8%)	2　2 (8.7%)	1　1 (5.0%)	3　3 (7.0%)
NERVOUS SYSTEM DISORDERS	4　3 (14.3%)	12　8 (34.8%)	4　4 (20.0%)	16　12 (27.9%)
Headache	4　3 (14.3%)	12　8 (34.8%)	4　4 (20.0%)	16　12 (27.9%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9　8 (38.1%)	9　7 (30.4%)	12　7 (35.0%)	21　14 (32.6%)
Exfoliative rash	1　1 (4.8%)	3　2 (8.7%)	1　1 (5.0%)	4　3 (7.0%)
Rash	6　6 (28.6%)	6　5 (21.7%)	5　5 (25.0%)	11　10 (23.3%)
Rash pruritic	2　2 (9.5%)	6　5 (21.7%)	6　5 (25.0%)	6　5 (25.0%)

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.