Table 4 Treatment-Emergent Adverse Events (TEAE) Reported in ≥10% of Subjects by System Organ Class, Preferred Term, and Treatment (Safety Analysis Set)

MedDRA System Organ Class Preferred Term, n (%)	Treatment:		Total
	OPE (N = 39)	IV Paclitaxel (N = 38)	(N = 40)
Number (%) of subjects with at least 1 TEAE:	36 (92.3%)	29 (76.3%)	38 (95.0%)
Gastrointestinal disorders	**23 (59.0%)**	**15 (39.5%)**	**29 (72.5%)**
Diarrhoea	11 (28.2%)	7 (18.4%)	16 (40.0%)
Nausea	11 (28.2%)	3 (7.9%)	13 (32.5%)
Vomiting	5 (12.8%)	2 (5.3%)	7 (17.5%)
General disorders and administration site conditions	**10 (25.6%)**	**4 (10.5%)**	**13 (32.5%)**
Fatigue	6 (15.4%)	2 (5.3%)	8 (20.0%)
Nervous system disorders	**7 (18.0%)**	**8 (21.1%)**	**12 (30.0%)**
Headache	3 (7.7%)	2 (5.3%)	5 (12.5%)
Musculoskeletal and connective tissue disorders	**5 (12.8%)**	**4 (10.5%)**	**8 (20.0%)**
Respiratory, thoracic and mediastinal disorders	**7 (18.0%)**	**2 (5.3%)**	**8 (20.0%)**
Vascular disorders	**3 (7.7%)**	**5 (13.2%)**	**8 (20.0%)**
Flushing	0	5 (13.2%)	5 (12.5%)
Skin and subcutaneous tissue disorders	**5 (12.8%)**	**3 (7.9%)**	**7 (17.5%)**
Infections and infestations	**2 (5.1%)**	**4 (10.5%)**	**6 (15.0%)**
Metabolism and nutrition disorders	**4 (10.3%)**	**1 (2.6%)**	**5 (12.5%)**
Blood and lymphatic system disorders	**4 (10.3%)**	**0**	**4 (10.0%)**
Renal and urinary disorders	**3 (7.7%)**	**1 (2.6%)**	**4 (10.0%)**