Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
-Any Adverse events-	0	27(84.4%)	32(97.0%)
	1	25(78.1%)	31(93.9%)
	2	15(46.9%)	25(75.8%)
	3	5(15.6%)	7(21.2%)
	4	(0.0%)	1(3.0%)
	5	(0.0%)	(0.0%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	.		
-overall-	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Leukopenia	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Neutropenia	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
CARDIAC DISORDERS	.		
-overall-	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Palpitations	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
EAR AND LABYRINTH DISORDERS	.		
-overall-	0	(0.0%)	3(9.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Deafness Neurosensory	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Ear Disorder	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Vertigo	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
ENDOCRINE DISORDERS	.		
-overall-	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypothyroidism	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
EYE DISORDERS	.		
-overall-	0	1(3.1%)	1(3.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Cataract	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dry Eye	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Lacrimation Increased	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
GASTROINTESTINAL DISORDERS	.		

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
-overall-	0	14(43.8%)	24(72.7%)
	1	7(21.9%)	16(48.5%)
	2	6(18.8%)	6(18.2%)
	3	1(3.1%)	2(6.1%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Nausea	0	21(65.6%)	13(39.4%)
	1	5(15.6%)	13(39.4%)
	2	3(9.4%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Abdominal Discomfort	0	3(9.4%)	1(3.0%)
	1	1(3.1%)	1(3.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Abdominal Distension	0	5(15.6%)	3(9.1%)
	1	1(3.1%)	2(6.1%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Abdominal Pain	0	11(34.4%)	6(18.2%)
	1	2(6.3%)	5(15.2%)
	2	2(6.3%)	1(3.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Abdominal Pain Lower	0	3(9.4%)	2(6.1%)
	1	1(3.1%)	2(6.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Abdominal Pain Upper	0	11(34.4%)	6(18.2%)
	1	1(3.1%)	6(18.2%)
	2	1(3.1%)	2(6.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Aphthous Stomatitis	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Ascites	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Constipation	0	14(43.8%)	9(27.3%)
	1	3(9.4%)	9(27.3%)
	2	2(6.3%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Diarrhoea	0	10(31.3%)	5(15.2%)
	1	4(12.5%)	3(9.1%)
	2	1(3.1%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dry Mouth	0	(0.0%)	4(12.1%)
	1	(0.0%)	4(12.1%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Duodenitis	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dyspepsia	0	2(6.3%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dysphagia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Flatulence	0	2(6.3%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Frequent Bowel Movements	0	2(6.3%)	1(3.0%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
Gastritis	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Haematochezia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Haemorrhoids	0	(0.0%)	2(6.1%)
	1	(0.0%)	2(6.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypoaesthesia Oral	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Infrequent Bowel Movements	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Lip Swelling	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Mouth Haemorrhage	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Paraesthesia Oral	0	3(9.4%)	1(3.0%)
	1	2(6.3%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Rectal Haemorrhage	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Salivary Hypersecretion	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Small Intestinal Obstruction	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Stomatitis	0	(0.0%)	4(12.1%)
	1	(0.0%)	3(9.1%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Vomiting	0	10(31.3%)	7(21.2%)
	1	1(3.1%)	6(18.2%)
	2	(0.0%)	3(9.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	.		
-overall-	0	12(37.5%)	13(39.4%)
	1	9(28.1%)	8(24.2%)
	2	3(9.4%)	4(12.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Fatigue	0	21(65.6%)	7(21.2%)
	1	10(31.3%)	7(21.2%)
	2	1(3.1%)	2(6.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Asthenia	0	(0.0%)	4(12.1%)
	1	(0.0%)	2(6.1%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Chest Pain	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Influenza Like Illness	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Mucosal Inflammation	0	3(9.4%)	1(3.0%)
	1	2(6.3%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Oedema	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pain	0	2(6.3%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pyrexia	0	(0.0%)	3(9.1%)
	1	(0.0%)	2(6.1%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
IMMUNE SYSTEM DISORDERS	.		
-overall-	0	1(3.1%)	1(3.0%)
	1	1(3.1%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypersensitivity	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypogammaglobulinaemia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
INFECTIONS AND INFESTATIONS	.		
-overall-	0	9(28.1%)	10(30.3%)
	1	3(9.4%)	4(12.1%)
	2	4(12.5%)	6(18.2%)
	3	2(6.3%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Influenza	0	5(15.6%)	3(9.1%)
	1	1(3.1%)	2(6.1%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Bronchitis	0	2(6.3%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	2(6.3%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Cystitis	0	2(6.3%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Device Related Infection	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Gastroenteritis	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Gastroenteritis Norovirus	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Herpes Zoster	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Infection	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Lower Respiratory Tract Infection	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Nasopharyngitis	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Oral Herpes	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pharyngitis	0	2(6.3%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Sinusitis	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Tonsillitis	0	(0.0%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Tooth Infection	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Upper Respiratory Tract Infection	0	2(6.3%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Urinary Tract Infection	0	2(6.3%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Vaginal Infection	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Viral Upper Respiratory Tract Infection	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	.		
-overall-	0	1(3.1%)	5(15.2%)
	1	(0.0%)	2(6.1%)
	2	1(3.1%)	3(9.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Contusion	0	3(9.4%)	2(6.1%)
	1	(0.0%)	2(6.1%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Procedural Pain	0	(0.0%)	3(9.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Thermal Burn	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Wrist Fracture	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
INVESTIGATIONS	.		
-overall-	0	4(12.5%)	6(18.2%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	1	2(6.3%)	3(9.1%)
	2	2(6.3%)	2(6.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Weight Decreased	0	6(18.8%)	5(15.2%)
	1	(0.0%)	3(9.1%)
	2	1(3.1%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Alanine Aminotransferase Increased	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Aspartate Aminotransferase Increased	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Blood Alkaline Phosphatase Increased	0	(0.0%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Blood Pressure Increased	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Blood Urea Increased	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Gamma-Glutamyltransferase Increased	0	3(9.4%)	1(3.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Vitamin B12 Decreased	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
METABOLISM AND NUTRITION DISORDERS	.		
-overall-	0	3(9.4%)	9(27.3%)
	1	2(6.3%)	3(9.1%)
	2	(0.0%)	5(15.2%)
	3	1(3.1%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Decreased Appetite	0	10(31.3%)	7(21.2%)
	1	1(3.1%)	4(12.1%)
	2	(0.0%)	4(12.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dehydration	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hyperchloraemia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypocalcaemia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypomagnesaemia	0	3(9.4%)	2(6.1%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hyponatraemia	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Type 2 Diabetes Mellitus	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	.		
-overall-	0	15(46.9%)	27(81.8%)
	1	10(31.3%)	12(36.4%)
	2	5(15.6%)	14(42.4%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	1(3.0%)
	5	(0.0%)	(0.0%)
Muscle Spasms	0	33(103.1%)	21(63.6%)
	1	4(12.5%)	17(51.5%)
	2	1(3.1%)	10(30.3%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	1(3.0%)
	5	(0.0%)	(0.0%)
Arthralgia	0	11(34.4%)	5(15.2%)
	1	5(15.6%)	3(9.1%)
	2	1(3.1%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Arthritis	0	2(6.3%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Back Pain	0	8(25.0%)	5(15.2%)
	1	3(9.4%)	3(9.1%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Bone Pain	0	2(6.3%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	1(3.1%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Groin Pain	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Joint Stiffness	0	2(6.3%)	1(3.0%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Muscular Weakness	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Musculoskeletal Chest Pain	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Musculoskeletal Pain	0	6(18.8%)	5(15.2%)
	1	1(3.1%)	4(12.1%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Myalgia	0	4(12.5%)	2(6.1%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	1	2(6.3%)	2(6.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Neck Pain	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pain In Extremity	0	4(12.5%)	2(6.1%)
	1	1(3.1%)	1(3.0%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Sensation Of Heaviness	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	.		
-overall-	0	1(3.1%)	1(3.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Acrochordon	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Lung Adenocarcinoma	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
NERVOUS SYSTEM DISORDERS	.		
-overall-	0	13(40.6%)	24(72.7%)
	1	11(34.4%)	15(45.5%)
	2	2(6.3%)	9(27.3%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dysgeusia	0	36(112.5%)	22(66.7%)
	1	10(31.3%)	20(60.6%)
	2	(0.0%)	6(18.2%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Ageusia	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Anosmia	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dizziness	0	7(21.9%)	4(12.1%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	1	1(3.1%)	4(12.1%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dystonia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Headache	0	6(18.8%)	4(12.1%)
	1	1(3.1%)	4(12.1%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Neuropathy Peripheral	0	3(9.4%)	1(3.0%)
	1	2(6.3%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Paraesthesia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Parosmia	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Peripheral Sensory Neuropathy	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Syncope	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Tremor	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
PSYCHIATRIC DISORDERS	.		
-overall-	0	1(3.1%)	7(21.2%)
	1	1(3.1%)	5(15.2%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Anxiety	0	(0.0%)	3(9.1%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Depression	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Insomnia	0	3(9.4%)	2(6.1%)
	1	1(3.1%)	2(6.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Mood Swings	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
RENAL AND URINARY DISORDERS	.		
-overall-	0	3(9.4%)	1(3.0%)
	1	3(9.4%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dysuria	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Haematuria	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Hydronephrosis	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Nephrolithiasis	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Urinary Tract Disorder	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	.		
-overall-	0	1(3.1%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pelvic Pain	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	1(3.1%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Vulvovaginal Burning Sensation	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	.		
-overall-	0	4(12.5%)	7(21.2%)
	1	4(12.5%)	4(12.1%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	2(6.1%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Cough	0	6(18.8%)	4(12.1%)
	1	2(6.3%)	4(12.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dyspnoea	0	3(9.4%)	1(3.0%)
	1	2(6.3%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Emphysema	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Oropharyngeal Pain	0	3(9.4%)	2(6.1%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Pneumothorax	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pulmonary Embolism	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Respiratory Tract Congestion	0	2(6.3%)	1(3.0%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Rhinitis Allergic	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	.		
-overall-	0	10(31.3%)	21(63.6%)
	1	8(25.0%)	10(30.3%)
	2	2(6.3%)	11(33.3%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Alopecia	0	28(87.5%)	16(48.5%)
	1	5(15.6%)	15(45.5%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	2	1(3.1%)	7(21.2%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Dry Skin	0	3(9.4%)	2(6.1%)
	1	1(3.1%)	2(6.1%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Eczema	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Erythema	0	2(6.3%)	1(3.0%)
	1	1(3.1%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Exfoliative Rash	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hair Growth Abnormal	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
Nail Disorder	0	1(3.1%)	(0.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Pruritus	0	5(15.6%)	2(6.1%)
	1	3(9.4%)	1(3.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Rash	0	6(18.8%)	4(12.1%)
	1	2(6.3%)	2(6.1%)
	2	(0.0%)	2(6.1%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Rash Papular	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Skin Discolouration	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Skin Exfoliation	0	(0.0%)	1(3.0%)
	1	(0.0%)	1(3.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Skin Hyperpigmentation	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Skin Maceration	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
SURGICAL AND MEDICAL PROCEDURES	.		
-overall-	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Tooth Extraction	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
VASCULAR DISORDERS	.		
-overall-	0	3(9.4%)	4(12.1%)
	1	1(3.1%)	1(3.0%)
	2	2(6.3%)	2(6.1%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)

Table 14.3/2
Patients With Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade
Saftey-Evaluable Patients

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
	5	(0.0%)	(0.0%)
Hot Flush	0	3(9.4%)	2(6.1%)
	1	(0.0%)	1(3.0%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Deep Vein Thrombosis	0	(0.0%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	1(3.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Flushing	0	1(3.1%)	(0.0%)
	1	1(3.1%)	(0.0%)
	2	(0.0%)	(0.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)
Hypertension	0	2(6.3%)	1(3.0%)
	1	(0.0%)	(0.0%)
	2	1(3.1%)	1(3.0%)
	3	(0.0%)	(0.0%)
	4	(0.0%)	(0.0%)
	5	(0.0%)	(0.0%)