

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
-Any adverse events-	-All Grades-	27 (84.4%)	32 (97.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	1 ( 3.0%)
	3	5 (15.6%)	7 (21.2%)
	2	15 (46.9%)	25 (75.8%)
	1	25 (78.1%)	31 (93.9%)
<b>BLOOD AND LYMPHATIC SYSTEM DISORDERS</b>			
-Overall-	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Leukopenia	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Neutropenia	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
<b>CARDIAC DISORDERS</b>			
-Overall-	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Palpitations	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
<b>EAR AND LABYRINTH DISORDERS</b>			
-Overall-	-All Grades-	0 (0.0%)	3 ( 9.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	2 ( 6.1%)
	1	0 (0.0%)	1 ( 3.0%)
Deafness Neurosensory	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)

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<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Ear Disorder	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Vertigo	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
<b>ENDOCRINE DISORDERS</b>			
-Overall-	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Hypothyroidism	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
EYE DISORDERS	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
Cataract	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
Dry Eye	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)

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<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Lacrimation Increased	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
<b>GASTROINTESTINAL DISORDERS</b>			
-Overall-	-All Grades-	14 (43.8%)	24 (72.7%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	2 ( 6.1%)
	2	7 (21.9%)	8 (24.2%)
	1	11 (34.4%)	23 (69.7%)
Abdominal Discomfort	-All Grades-	2 ( 6.3%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
Abdominal Distension	-All Grades-	1 ( 3.1%)	3 ( 9.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	2 ( 6.1%)
	1	1 ( 3.1%)	2 ( 6.1%)
Abdominal Pain	-All Grades-	3 ( 9.4%)	6 (18.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	2 ( 6.3%)	1 ( 3.0%)
	1	2 ( 6.3%)	5 (15.2%)
Abdominal Pain Lower	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	2 ( 6.1%)
Abdominal Pain Upper	-All Grades-	1 ( 3.1%)	6 (18.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	1 ( 3.1%)	2 ( 6.1%)
	1	1 ( 3.1%)	6 (18.2%)
Aphthous Stomatitis	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)

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<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Ascites	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
Constipation	1	0 (0.0%)	0 (0.0%)
	-All Grades-	3 ( 9.4%)	9 (27.3%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	2 ( 6.3%)	0 (0.0%)
Diarrhoea	1	3 ( 9.4%)	9 (27.3%)
	-All Grades-	5 (15.6%)	5 (15.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	2 ( 6.1%)
Dry Mouth	1	4 (12.5%)	3 ( 9.1%)
	-All Grades-	0 (0.0%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Duodenitis	1	0 (0.0%)	4 (12.1%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
Dyspepsia	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
Dysphagia	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Flatulence	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)

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

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Patients with Treatment-Emergent Adverse Events by Highest NCI CTCAE Grade  
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<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Nausea	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	6 (18.8%)	13 (39.4%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	3 ( 9.4%)	0 (0.0%)
Paraesthesia Oral	1	5 (15.6%)	13 (39.4%)
	-All Grades-	2 ( 6.3%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Rectal Haemorrhage	1	2 ( 6.3%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Salivary Hypersecretion	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
Small Intestinal Obstruction	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Stomatitis	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	3 ( 9.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
Vomiting	1	0 (0.0%)	3 ( 9.1%)
	-All Grades-	1 ( 3.1%)	7 (21.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	3 ( 9.1%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	1 ( 3.1%)	6 (18.2%)
	-Overall-	12 (37.5%)	13 (39.4%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)

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Safety-Evaluable Patients

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Asthenia	3	0 (0.0%)	1 ( 3.0%)
	2	3 ( 9.4%)	4 (12.1%)
	1	11 (34.4%)	12 (36.4%)
	-All Grades-	0 (0.0%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Chest Pain	2	0 (0.0%)	2 ( 6.1%)
	1	0 (0.0%)	2 ( 6.1%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
Fatigue	1	0 (0.0%)	0 (0.0%)
	-All Grades-	10 (31.3%)	7 (21.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	1 ( 3.1%)	2 ( 6.1%)
	1	10 (31.3%)	7 (21.2%)
Influenza Like Illness	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	2 ( 6.3%)	1 ( 3.0%)
Mucosal Inflammation	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	2 ( 6.3%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Oedema	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
Pain	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Pyrexia	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)

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	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	2 ( 6.1%)
<b>IMMUNE SYSTEM DISORDERS</b>			
-Overall-	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
Hypersensitivity	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Hypogammaglobulinaemia	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
<b>INFECTIONS AND INFESTATIONS</b>			
-Overall-	-All Grades-	9 (28.1%)	10 (30.3%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	2 ( 6.3%)	0 (0.0%)
	2	4 (12.5%)	6 (18.2%)
	1	3 ( 9.4%)	6 (18.2%)
Bronchitis	-All Grades-	2 ( 6.3%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	2 ( 6.3%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Cystitis	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
Device Related Infection	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)



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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Gastroenteritis	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Gastroenteritis Norovirus	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
Herpes Zoster	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
Infection	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Influenza	-All Grades-	2 ( 6.3%)	3 ( 9.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	1 ( 3.0%)
	1	1 ( 3.1%)	2 ( 6.1%)
Lower Respiratory Tract Infection	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Nasopharyngitis	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Oral Herpes	-All Grades-	0 (0.0%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	1 ( 3.0%)

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

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

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
	1	0 (0.0%)	0 (0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
-Overall-	-All Grades-	1 ( 3.1%)	5 (15.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	3 ( 9.1%)
	1	0 (0.0%)	3 ( 9.1%)
Contusion	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	2 ( 6.1%)
Procedural Pain	-All Grades-	0 (0.0%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	2 ( 6.1%)
	1	0 (0.0%)	1 ( 3.0%)
Thermal Burn	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Wrist Fracture	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
INVESTIGATIONS			
-Overall-	-All Grades-	4 (12.5%)	6 (18.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	2 ( 6.3%)	3 ( 9.1%)
	1	2 ( 6.3%)	4 (12.1%)
Alanine Aminotransferase Increased	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Aspartate Aminotransferase Increased	-All Grades-	0 (0.0%)	1 ( 3.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Blood Alkaline Phosphatase Increased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
Blood Pressure Increased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
Blood Urea Increased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
Gamma-Glutamyltransferase Increased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
Vitamin B12 Decreased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
Weight Decreased	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	5 (15.2%)
METABOLISM AND NUTRITION DISORDERS	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	2 ( 6.1%)
	1	0 (0.0%)	3 ( 9.1%)
	-Overall-	3 ( 9.4%)	9 (27.3%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	1 ( 3.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Decreased Appetite	2	0 (0.0%)	6 (18.2%)
	1	2 ( 6.3%)	7 (21.2%)
	-All Grades-	1 ( 3.1%)	7 (21.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
Dehydration	2	0 (0.0%)	4 (12.1%)
	1	1 ( 3.1%)	4 (12.1%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Hyperchloraemia	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Hypocalcaemia	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Hypomagnesaemia	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Hyponatraemia	2	0 (0.0%)	1 ( 3.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	0 (0.0%)
Type 2 Diabetes Mellitus	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-Overall-	15 (46.9%)	27 (81.8%)
	5	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Arthralgia	4	0 (0.0%)	1 ( 3.0%)
	3	0 (0.0%)	0 (0.0%)
	2	5 (15.6%)	15 (45.5%)
	1	13 (40.6%)	22 (66.7%)
	-All Grades-	6 (18.8%)	5 (15.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Arthritis	2	1 ( 3.1%)	2 ( 6.1%)
	1	5 (15.6%)	3 ( 9.1%)
	-All Grades-	2 ( 6.3%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Back Pain	-All Grades-	3 ( 9.4%)	5 (15.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	2 ( 6.1%)
	1	3 ( 9.4%)	3 ( 9.1%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Bone Pain	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Groin Pain	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Joint Stiffness	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
	-All Grades-	4 (12.5%)	21 (63.6%)
	5	0 (0.0%)	0 (0.0%)
Muscle Spasms	4	0 (0.0%)	1 ( 3.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	10 (30.3%)
	1	4 (12.5%)	17 (51.5%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Muscular Weakness	2	1 ( 3.1%)	10 (30.3%)
	1	4 (12.5%)	17 (51.5%)
Muscular Weakness	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Musculoskeletal Chest Pain	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Musculoskeletal Pain	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	5 (15.2%)
	5	0 (0.0%)	0 (0.0%)
Myalgia	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	1 ( 3.1%)	4 (12.1%)
	-All Grades-	2 ( 6.3%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
Neck Pain	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	2 ( 6.3%)	2 ( 6.1%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Pain In Extremity	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	2 ( 6.3%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
Sensation Of Heaviness	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
-Overall-	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Acrochordon	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Lung Adenocarcinoma	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM DISORDERS	1	0 (0.0%)	0 (0.0%)
	-Overall-	13 (40.6%)	24 (72.7%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	2 ( 6.3%)	9 (27.3%)
Ageusia	1	12 (37.5%)	24 (72.7%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
Anosmia	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
Dizziness	1	0 (0.0%)	0 (0.0%)
	-All Grades-	2 ( 6.3%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	1 ( 3.0%)
Dysgeusia	1	1 ( 3.1%)	4 (12.1%)
	-All Grades-	10 (31.3%)	22 (66.7%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	6 (18.2%)
Dystonia	1	10 (31.3%)	20 (60.6%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)



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

MedDRA System Organ Class and Preferred Term	NCI-CTCAE Grade	Placebo (n=32)	CMP-135 (n=33)
Headache	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	2 ( 6.3%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Neuropathy Peripheral	2	1 ( 3.1%)	0 (0.0%)
	1	1 ( 3.1%)	4 (12.1%)
	-All Grades-	2 ( 6.3%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Paraesthesia	2	0 (0.0%)	0 (0.0%)
	1	2 ( 6.3%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Parosmia	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Peripheral Sensory Neuropathy	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Syncope	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Tremor	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
PSYCHIATRIC DISORDERS	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-Overall-	1 ( 3.1%)	7 (21.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Anxiety	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	2 ( 6.1%)
	1	1 ( 3.1%)	5 (15.2%)
	-All Grades-	0 (0.0%)	3 ( 9.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Depression	2	0 (0.0%)	2 ( 6.1%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Insomnia	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	2 ( 6.1%)
Mood Swings	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
RENAL AND URINARY DISORDERS			
-Overall-	-All Grades-	3 ( 9.4%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	3 ( 9.4%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
Dysuria	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
Haematuria	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
Hydronephrosis	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Nephrolithiasis	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
Urinary Tract Disorder	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Pelvic Pain	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	1 ( 3.1%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Vulvovaginal Burning Sensation	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	-All Grades-	4 (12.5%)	7 (21.2%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	2 ( 6.1%)
	2	0 (0.0%)	2 ( 6.1%)
	1	4 (12.5%)	7 (21.2%)
	-All Grades-	2 ( 6.3%)	4 (12.1%)
Cough	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Dyspnoea	2	0 (0.0%)	0 (0.0%)
	1	2 ( 6.3%)	4 (12.1%)
	-All Grades-	2 ( 6.3%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Emphysema	2	0 (0.0%)	0 (0.0%)
	1	2 ( 6.3%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
Oropharyngeal Pain	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Pneumothorax	2	0 (0.0%)	1 ( 3.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Pulmonary Embolism	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
Respiratory Tract Congestion	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Rhinitis Allergic	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
	-Overall-	10 (31.3%)	21 (63.6%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	-Overall-	10 (31.3%)	21 (63.6%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Alopecia	3	0 (0.0%)	0 (0.0%)
	2	2 ( 6.3%)	11 (33.3%)
	1	9 (28.1%)	19 (57.6%)
	-All Grades-	6 (18.8%)	16 (48.5%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Dry Skin	2	1 ( 3.1%)	7 (21.2%)
	1	5 (15.6%)	15 (45.5%)
	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Eczema	1	1 ( 3.1%)	2 ( 6.1%)
	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Erythema	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	1 ( 3.0%)
Exfoliative Rash	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
Hair Growth Abnormal	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
Nail Disorder	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Pruritus	-All Grades-	3 ( 9.4%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
Rash	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	3 ( 9.4%)	1 ( 3.0%)
	-All Grades-	2 ( 6.3%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
Rash Papular	2	0 (0.0%)	2 ( 6.1%)
	1	2 ( 6.3%)	2 ( 6.1%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
Skin Discolouration	1	0 (0.0%)	1 ( 3.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Skin Exfoliation	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	1 ( 3.0%)
Skin Hyperpigmentation	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Skin Maceration	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
<b>SURGICAL AND MEDICAL PROCEDURES</b>			
Tooth Extraction	-Overall-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)

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

<b>MedDRA System Organ Class and Preferred Term</b>	<b>NCI-CTCAE Grade</b>	<b>Placebo (n=32)</b>	<b>CMP-135 (n=33)</b>
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)
VASCULAR DISORDERS			
-Overall-	-All Grades-	3 ( 9.4%)	4 (12.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	2 ( 6.3%)	2 ( 6.1%)
	1	1 ( 3.1%)	1 ( 3.0%)
Deep Vein Thrombosis	-All Grades-	0 (0.0%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	1 ( 3.0%)
	2	0 (0.0%)	0 (0.0%)
	1	0 (0.0%)	0 (0.0%)
Flushing	-All Grades-	1 ( 3.1%)	0 (0.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	0 (0.0%)	0 (0.0%)
	1	1 ( 3.1%)	0 (0.0%)
Hot Flush	-All Grades-	1 ( 3.1%)	2 ( 6.1%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	1 ( 3.0%)
	1	0 (0.0%)	1 ( 3.0%)
Hypertension	-All Grades-	1 ( 3.1%)	1 ( 3.0%)
	5	0 (0.0%)	0 (0.0%)
	4	0 (0.0%)	0 (0.0%)
	3	0 (0.0%)	0 (0.0%)
	2	1 ( 3.1%)	1 ( 3.0%)
	1	0 (0.0%)	0 (0.0%)