SUPPLEMENT 5. Participants with Drug-Related Adverse Events

	Bezlotoxumab		Placebo	
	n	(%)	n	(%)
Participants in population	107		36	
with one or more drug-related adverse events	17	(15.9)	3	(8.3)
Ear and labyrinth disorders	**1**	**(0.9)**	**0**	**(0.0)**
Vertigo	1	(0.9)	0	(0.0)
Gastrointestinal disorders	**6**	**(5.6)**	**2**	**(5.6)**
Abdominal pain	1	(0.9)	1	(2.8)
Anal inflammation	1	(0.9)	0	(0.0)
Intussusception	1	(0.9)	0	(0.0)
Large intestine polyp	0	(0.0)	1	(2.8)
Nausea	2	(1.9)	0	(0.0)
Vomiting	2	(1.9)	1	(2.8)
General disorders and administration site conditions	**4**	**(3.7)**	**1**	**(2.8)**
Asthenia	0	(0.0)	1	(2.8)
Fatigue	2	(1.9)	0	(0.0)
Infusion site rash	1	(0.9)	0	(0.0)
Pyrexia	2	(1.9)	0	(0.0)
Infections and infestations	**1**	**(0.9)**	**0**	**(0.0)**
Infection	1	(0.9)	0	(0.0)
Investigations	**4**	**(3.7)**	**1**	**(2.8)**
Alanine aminotransferase increased	3	(2.8)	0	(0.0)
Aspartate aminotransferase increased	3	(2.8)	0	(0.0)
Blood bicarbonate increased	1	(0.9)	0	(0.0)
Blood lactate dehydrogenase increased	2	(1.9)	0	(0.0)
Blood pressure decreased	0	(0.0)	1	(2.8)
Blood pressure systolic decreased	1	(0.9)	0	(0.0)
Clostridium test positive	1	(0.9)	0	(0.0)
Metabolism and nutrition disorders	**1**	**(0.9)**	**0**	**(0.0)**
Hyperphagia	1	(0.9)	0	(0.0)
Musculoskeletal and connective tissue disorders	**1**	**(0.9)**	**0**	**(0.0)**
Pain in extremity	1	(0.9)	0	(0.0)
Nervous system disorders	**3**	**(2.8)**	**2**	**(5.6)**
Dizziness	0	(0.0)	1	(2.8)
Dysgeusia	0	(0.0)	1	(2.8)
Headache	3	(2.8)	2	(5.6)
Respiratory, thoracic and mediastinal disorders	**0**	**(0.0)**	**1**	**(2.8)**
Dyspnoea	0	(0.0)	1	(2.8)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**1**	**(2.8)**
Pruritus	0	(0.0)	1	(2.8)
Rash	0	(0.0)	1	(2.8)

Relationship to study drug was determined by the investigator.
Medical Dictionary for Regulatory Activities (MedDRA) version 25.0 was used in the reporting of this study.
This table includes adverse events that occurred from Day 1 through Week 12 (Day 85 ±5 days).