

All Treatment-Emergent AEs

Safety-Evaluable Population Dictionary-Derived Term	Body System or Organ Class (N=13)	(N=13)	P1-CHRT1 (N=26)	P1-CHRT2	AL
<hr/>					
- Any event -					
Total number of patients with at least one event	12 (92.31%)	4 (30.77%)	16 (61.54%)		
Total number of events	71	13	84		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
Total number of patients with at least one event	10 (76.92%)	2 (15.38%)	12 (46.15%)		
Total number of events	16	4	20		
ASTHENIA	5 (38.46%)	0 (0%)	5 (19.23%)		
PYREXIA	3 (23.08%)	2 (15.38%)	5 (19.23%)		
INJECTION SITE REACTION	3 (23.08%)	0 (0%)	3 (11.54%)		
FATIGUE	1 (7.69%)	0 (0%)	1 (3.85%)		
GAIT DISTURBANCE	1 (7.69%)	0 (0%)	1 (3.85%)		
INJECTION SITE ERYTHEMA	0 (0%)	1 (7.69%)	1 (3.85%)		
INJECTION SITE INFLAMMATION	1 (7.69%)	0 (0%)	1 (3.85%)		
MUCOSAL INFLAMMATION	0 (0%)	1 (7.69%)	1 (3.85%)		
OEDEMA	1 (7.69%)	0 (0%)	1 (3.85%)		
GASTROINTESTINAL DISORDERS					
Total number of patients with at least one event	8 (61.54%)	0 (0%)	8 (30.77%)		
Total number of events	11	0	11		
ABDOMINAL PAIN	2 (15.38%)	0 (0%)	2 (7.69%)		
DIARRHOEA	2 (15.38%)	0 (0%)	2 (7.69%)		
NAUSEA	2 (15.38%)	0 (0%)	2 (7.69%)		
ABDOMINAL PAIN UPPER	1 (7.69%)	0 (0%)	1 (3.85%)		

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ANAL HAEMORRHAGE	1 (7.69%)	0 (0%)	1 (3.85%)
CONSTIPATION	1 (7.69%)	0 (0%)	1 (3.85%)
DYSPEPSIA	1 (7.69%)	0 (0%)	1 (3.85%)
VOMITING	1 (7.69%)	0 (0%)	1 (3.85%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
Total number of patients with at least one event	7 (53.85%)	1 (7.69%)	8 (30.77%)
Total number of events	12	1	13
COUGH	5 (38.46%)	0 (0%)	5 (19.23%)
DYSPNOEA	2 (15.38%)	0 (0%)	2 (7.69%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0 (0%)	1 (7.69%)	1 (3.85%)
DYSPHONIA	1 (7.69%)	0 (0%)	1 (3.85%)
DYSPNOEA EXERTIONAL	1 (7.69%)	0 (0%)	1 (3.85%)
PLEURITIC PAIN	1 (7.69%)	0 (0%)	1 (3.85%)
PRODUCTIVE COUGH	1 (7.69%)	0 (0%)	1 (3.85%)
RHINORRHOEA	1 (7.69%)	0 (0%)	1 (3.85%)
INFECTIONS AND INFESTATIONS			
Total number of patients with at least one event	3 (23.08%)	2 (15.38%)	5 (19.23%)
Total number of events	3	2	5
BRONCHITIS	1 (7.69%)	0 (0%)	1 (3.85%)
PNEUMONIA	1 (7.69%)	0 (0%)	1 (3.85%)
UPPER RESPIRATORY TRACT INFECTION	1 (7.69%)	0 (0%)	1 (3.85%)
VASCULAR DEVICE INFECTION	0 (0%)	1 (7.69%)	1 (3.85%)
VIRAL INFECTION	0 (0%)	1 (7.69%)	1 (3.85%)
METABOLISM AND NUTRITION DISORDERS			

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Total number of patients with at least one event	3 (23.08%)	2 (15.38%)	5 (19.23%)
Total number of events	4	2	6
DECREASED APPETITE	1 (7.69%)	0 (0%)	1 (3.85%)
HYPERGLYCAEMIA	1 (7.69%)	0 (0%)	1 (3.85%)
HYPOALBUMINAEMIA	0 (0%)	1 (7.69%)	1 (3.85%)
HYPOKALAEMIA	1 (7.69%)	0 (0%)	1 (3.85%)
HYPOMAGNESAEMIA	1 (7.69%)	0 (0%)	1 (3.85%)
HYPONATRAEMIA	0 (0%)	1 (7.69%)	1 (3.85%)
NERVOUS SYSTEM DISORDERS			
Total number of patients with at least one event	5 (38.46%)	0 (0%)	5 (19.23%)
Total number of events	7	0	7
HEADACHE	2 (15.38%)	0 (0%)	2 (7.69%)
CEREBROVASCULAR ACCIDENT	1 (7.69%)	0 (0%)	1 (3.85%)
DIZZINESS	1 (7.69%)	0 (0%)	1 (3.85%)
DYSGEUSIA	1 (7.69%)	0 (0%)	1 (3.85%)
NEUROPATHY PERIPHERAL	1 (7.69%)	0 (0%)	1 (3.85%)
TREMOR	1 (7.69%)	0 (0%)	1 (3.85%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			
Total number of patients with at least one event	3 (23.08%)	1 (7.69%)	4 (15.38%)
Total number of events	3	1	4
ANAEMIA	2 (15.38%)	1 (7.69%)	3 (11.54%)
LEUKOCYTOSIS	1 (7.69%)	0 (0%)	1 (3.85%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
Total number of patients with at least one event	4 (30.77%)	0 (0%)	4 (15.38%)

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Total number of events	5	0	5
ARTHRALGIA	1 (7.69%)	0 (0%)	1 (3.85%)
BACK PAIN	1 (7.69%)	0 (0%)	1 (3.85%)
JOINT SWELLING	1 (7.69%)	0 (0%)	1 (3.85%)
MUSCLE SPASMS	1 (7.69%)	0 (0%)	1 (3.85%)
MUSCULOSKELETAL CHEST PAIN	1 (7.69%)	0 (0%)	1 (3.85%)
ENDOCRINE DISORDERS			
Total number of patients with at least one event	2 (15.38%)	1 (7.69%)	3 (11.54%)
Total number of events	2	1	3
HYPERTHYROIDISM	2 (15.38%)	1 (7.69%)	3 (11.54%)
INVESTIGATIONS			
Total number of patients with at least one event	1 (7.69%)	1 (7.69%)	2 (7.69%)
Total number of events	1	1	2
BLOOD THYROID STIMULATING HORMONE INCREASED	1 (7.69%)	0 (0%)	1 (3.85%)
GAMMA-GLUTAMYLTRANSFERASE INCREASED	0 (0%)	1 (7.69%)	1 (3.85%)
PSYCHIATRIC DISORDERS			
Total number of patients with at least one event	2 (15.38%)	0 (0%)	2 (7.69%)
Total number of events	2	0	2
INSOMNIA	2 (15.38%)	0 (0%)	2 (7.69%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
Total number of patients with at least one event	2 (15.38%)	0 (0%)	2 (7.69%)
Total number of events	2	0	2
RASH	1 (7.69%)	0 (0%)	1 (3.85%)

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RASH ERYTHEMATOUS	1 (7.69%)	0 (0%)	1 (3.85%)
CARDIAC DISORDERS			
Total number of patients with at least one event	0 (0%)	1 (7.69%)	1 (3.85%)
Total number of events	0	1	1
TACHYCARDIA	0 (0%)	1 (7.69%)	1 (3.85%)
EYE DISORDERS			
Total number of patients with at least one event	1 (7.69%)	0 (0%)	1 (3.85%)
Total number of events	1	0	1
PERIORBITAL OEDEMA	1 (7.69%)	0 (0%)	1 (3.85%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
Total number of patients with at least one event	1 (7.69%)	0 (0%)	1 (3.85%)
Total number of events	1	0	1
PROCEDURAL PAIN	1 (7.69%)	0 (0%)	1 (3.85%)
NOT CODED YET			
Total number of patients with at least one event	1 (7.69%)	0 (0%)	1 (3.85%)
Total number of events	1	0	1
NOT YET CODED	1 (7.69%)	0 (0%)	1 (3.85%)

[1] "Sat Nov 16 11:40:34 2019"

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