Additional file 7. Treatment-Related Adverse Events (any grade in ≥10% or any grade ≥3) and Infusion-Related Reactions in All Patients (N=249)

	Any Grade	Grade 1-2	Grade 3	Grade 4	Grade 5
Any treatment-related adverse event, n (%)[a]	177 (71.1)	148 (59.4)	24 (9.6)	4 (1.6)	1 (0.4)
Fatigue	45 (18.1)	41 (16.5)	4 (1.6)	0	0
Rash[b]	45 (18.1)	43 (17.3)	2 (0.8)	0	0
Diarrhea	20 (8.0)	19 (7.6)	1 (0.4)	0	0
Asthenia	15 (6.0)	13 (5.2)	2 (0.8)	0	0
Decreased appetite	12 (4.8)	11 (4.4)	1 (0.4)	0	0
Pneumonitis	9 (3.6)	6 (2.4)	2 (0.8)	0	1 (0.4)
Elevated lipase level	4 (1.6)	0	2 (0.8)	2 (0.8)	0
Elevated AST level	3 (1.2)	2 (0.8)	1 (0.4)	0	0
Elevated ALP level	3 (1.2)	2 (0.8)	1 (0.4)	0	0
Elevated blood creatine	3 (1.2)	2 (0.8)	1 (0.4)	0	0
Dehydration	3 (1.2)	2 (0.8)	1 (0.4)	0	0
Increased amylase	2 (0.8)	1 (0.4)	1 (0.4)	0	0
Back pain	2 (0.8)	1 (0.4)	1 (0.4)	0	0
Hypophosphatemia	2 (0.8)	1 (0.4)	1 (0.4)	0	0
Acute kidney injury	1 (0.4)	0	1 (0.4)	0	0
Adrenal insufficiency	1 (0.4)	0	1 (0.4)	0	0
Autoimmune hepatitis	1 (0.4)	0	1 (0.4)	0	0
Elevated blood CPK	1 (0.4)	0	0	1 (0.4)	0
General physical health deterioration	1 (0.4)	0	1 (0.4)	0	0
Guillain-Barré syndrome	1 (0.4)	0	1 (0.4)	0	0
Hepatitis	1 (0.4)	0	1 (0.4)	0	0
Hyperkalemia	1 (0.4)	0	0	1 (0.4)	0
Hypotremia	1 (0.4)	0	1 (0.4)	0	0
Leukocytosis	1 (0.4)	0	1 (0.4)	0	0
Osteonecrosis	1 (0.4)	0	1 (0.4)	0	0
Psoriasis	1 (0.4)	0	1 (0.4)	0	0
Infusion-related reaction[c]	78 (31.3)	75 (30.1)	3 (1.2)	0	0

ALP, alkaline phosphatase; AST, aspartate aminotransferase; CPK, creatine phosphokinase.

[a] The incidence of treatment-related, infusion-related reaction based on the single Medical Dictionary for Regulatory Activities preferred term is not listed.

[b] Rash includes preferred terms dermatitis exfoliative, erythema, erythema multiforme, pemphigoid, pruritus, pruritus generalized, rash, rash erythematous, rash macular, rash maculopapular, rash papular, rash pruritic, and rash pustular.

[c] Composite term, which includes adverse events categorized as infusion-related reaction, drug hypersensitivity, or hypersensitivity reaction that occurred on the day of infusion or day after infusion, in addition to signs and symptoms of infusion-related reaction that occurred on the same day of infusion and resolved within 2 days

(including adverse events classified by investigators as related or unrelated to treatment).