Anhang 4-G:
Ergänzende Unterlagen

Axicabtagen-Ciloleucel (Yescarta®)

Gilead Sciences GmbH

Behandlung von Patienten mit rezidiviertem oder refraktärem DLBCL und HGBL nach Erstlinien-Chemoimmuntherapie

Stand: 27.06.2024

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
Subjects with any concomitant medication	170 (100)	168 (100)	338 (100)
ACARBOSE	1 (1)	0	1 (0)
ACETAZOLAMIDE	2 (1)	0	2 (1)
ACETYLCYSTEINE	2 (1)	0	2 (1)
ACETYLSALICYLIC ACID	19 (11)	22 (13)	41 (12)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE	1 (1)	0	1 (0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1)	2 (1)	4 (1)
ACICLOVIR	122 (72)	84 (50)	206 (61)
ADENOSINE	1 (1)	0	1 (0)
ADENOSINE TRIPHOSPHATE	0	1 (1)	1 (0)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (1)	0	1 (0)
ALBUMIN HUMAN	11 (6)	9 (5)	20 (6)
ALENDRONIC ACID	2 (1)	2 (1)	4 (1)
ALFUZOSIN	0	1 (1)	1 (0)
ALGELDRATE;MAGNESIUM HYDROXIDE	1 (1)	0	1 (0)
ALIZAPRIDE	3 (2)	3 (2)	6 (2)
ALLANTOIN;DL- LACTIC ACID;GLYCEROL;HYETELLOSE;MACROGOL;OCTENIDINE HYDROCHLORIDE	0	2 (1)	2 (1)
ALLOPURINOL	124 (73)	75 (45)	199 (59)
ALOE VERA	0	1 (1)	1 (0)
ALPRAZOLAM	6 (4)	8 (5)	14 (4)
ALTEPLASE	24 (14)	12 (7)	36 (11)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ALUMINIUM HYDROXIDE	1 (1)	1 (1)	2 (1)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE;LIDOCAINE HYDROCHLORIDE;MAGNESIUM HYDROXIDE;MAGNESIUM TRISILICATE	0	1 (1)	1 (0)
ALUMINIUM HYDROXIDE;DIPHENHYDRAMINE;LIDOCAINE;MAGNESIUM HYDROXIDE;SIMETICONE	1 (1)	2 (1)	3 (1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;OXETACAINE	0	1 (1)	1 (0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0	1 (1)	1 (0)
ALUMINIUM;MAGNESIUM HYDROXIDE;SIMETICONE	9 (5)	8 (5)	17 (5)
ALUMINUM MAGNESIUM HYDROXIDE	1 (1)	5 (3)	6 (2)
AMIDOTRIZOIC ACID	2 (1)	1 (1)	3 (1)
AMIKACIN	5 (3)	3 (2)	8 (2)
AMILORIDE	1 (1)	3 (2)	4 (1)
AMINO ACIDS NOS	1 (1)	0	1 (0)
AMINOCAPROIC ACID	1 (1)	0	1 (0)
AMIODARONE	6 (4)	4 (2)	10 (3)
AMITRIPTYLINE	4 (2)	4 (2)	8 (2)
AMITRIPTYLINE;GABAPENTIN	1 (1)	0	1 (0)
AMLODIPINE	14 (8)	20 (12)	34 (10)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
AMOXICILLIN	3 (2)	4 (2)	7 (2)
AMOXICILLIN;CLAVULANIC ACID	17 (10)	20 (12)	37 (11)
AMOXICILLIN;SULBACTAM	1 (1)	0	1 (0)
AMPHOTERICIN B	5 (3)	9 (5)	14 (4)
AMPHOTERICIN B, LIPOSOME	2 (1)	0	2 (1)
AMPICILLIN;SULBACTAM	1 (1)	1 (1)	2 (1)
ANAKINRA	2 (1)	0	2 (1)
ANASTROZOLE	1 (1)	0	1 (0)
ANESTHETICS	0	1 (1)	1 (0)
ANTICOAGULANT CITRATE DEXTROSE	1 (1)	15 (9)	16 (5)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	1 (1)	0	1 (0)
APIXABAN	8 (5)	4 (2)	12 (4)
APREPITANT	1 (1)	43 (26)	44 (13)
ARIPIPRAZOLE	0	1 (1)	1 (0)
ASCORBIC ACID	4 (2)	2 (1)	6 (2)
ASCORBIC ACID;VITAMIN B COMPLEX	1 (1)	0	1 (0)
ATENOLOL	4 (2)	4 (2)	8 (2)
ATORVASTATIN	14 (8)	17 (10)	31 (9)
ATOVAQUONE	11 (6)	0	11 (3)
ATROPINE	1 (1)	0	1 (0)
ATROPINE;DIPHENOXYLATE	4 (2)	4 (2)	8 (2)
AZITHROMYCIN	15 (9)	8 (5)	23 (7)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
AZTREONAM	5 (3)	2 (1)	7 (2)
BACITRACIN	6 (4)	4 (2)	10 (3)
BACITRACIN;NEOMYCIN;POLYMYXIN B	4 (2)	4 (2)	8 (2)
BACITRACIN;POLYMYXIN B	1 (1)	0	1 (0)
BACLOFEN	12 (7)	16 (10)	28 (8)
BARIUM	5 (3)	7 (4)	12 (4)
BECLOMETASONE	0	1 (1)	1 (0)
BEMIPARIN SODIUM	1 (1)	2 (1)	3 (1)
BENAZEPRIL	2 (1)	1 (1)	3 (1)
BENZOCAINE	1 (1)	1 (1)	2 (1)
BENZOCAINE;MENTHOL	3 (2)	4 (2)	7 (2)
BENZONATATE	24 (14)	5 (3)	29 (9)
BENZYDAMINE	1 (1)	5 (3)	6 (2)
BENZYL ALCOHOL;BENZYL BENZOATE;BENZYL CINNAMATE;WOOL FAT;ZINC	0	1 (1)	1 (0)
BENZYL ALCOHOL;CETYLPYRIDINIUM	1 (1)	2 (1)	3 (1)
BENZYLPENICILLIN	1 (1)	1 (1)	2 (1)
BETAMETHASONE	0	2 (1)	2 (1)
BETAMETHASONE;CALCIPOTRIOL	1 (1)	0	1 (0)
BETAMETHASONE;CLOTRIMAZOLE	1 (1)	0	1 (0)
BETHANECHOL	1 (1)	0	1 (0)
BIFIDOBACTERIUM INFANTIS;LACTOBACILLUS ACIDOPHILUS	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
BIOTIN	1 (1)	0	1 (0)
BISACODYL	10 (6)	7 (4)	17 (5)
BISOPROLOL	5 (3)	3 (2)	8 (2)
BISOPROLOL;HYDROCHLOROTHIAZIDE	0	1 (1)	1 (0)
BLOOD CELLS, PACKED HUMAN	47 (28)	77 (46)	124 (37)
BRIMONIDINE;TIMOLOL	2 (1)	0	2 (1)
BRINZOLAMIDE	1 (1)	0	1 (0)
BROTIZOLAM	1 (1)	0	1 (0)
BUDESONIDE	0	1 (1)	1 (0)
BUDESONIDE;FORMOTEROL	0	1 (1)	1 (0)
BUMETANIDE	1 (1)	2 (1)	3 (1)
BUPIVACAINE	1 (1)	1 (1)	2 (1)
BUPIVACAINE;EPINEPHRINE	0	1 (1)	1 (0)
BUPRENORPHINE	0	2 (1)	2 (1)
BUPROPION	3 (2)	5 (3)	8 (2)
BUSPIRONE	1 (1)	0	1 (0)
BUTALBITAL;CAFFEINE;PARACETAMOL	7 (4)	4 (2)	11 (3)
CAFFEINE	5 (3)	0	5 (1)
CAFFEINE;PARACETAMOL	0	1 (1)	1 (0)
CAFFEINE;SODIUM BENZOATE	1 (1)	0	1 (0)
CALAMINE;MENTHOL;ZINC OXIDE	0	1 (1)	1 (0)
CALAMINE;PRAMOCAINE	1 (1)	0	1 (0)
CALCITONIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CALCIUM	3 (2)	4 (2)	7 (2)
CALCIUM ACETATE	1 (1)	0	1 (0)
CALCIUM ASCORBATE	0	1 (1)	1 (0)
CALCIUM CARBONATE	21 (12)	23 (14)	44 (13)
CALCIUM CARBONATE;COLECALCIFEROL	11 (6)	9 (5)	20 (6)
CALCIUM CHLORIDE	5 (3)	11 (7)	16 (5)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	0	2 (1)	2 (1)
CALCIUM CHLORIDE;GLUCOSE MONOHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM LACTATE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	15 (9)	11 (7)	26 (8)
CALCIUM CHLORIDE;SODIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CALCIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	1 (1)	1 (0)
CALCIUM CITRATE	1 (1)	0	1 (0)
CALCIUM FOLINATE	3 (2)	3 (2)	6 (2)
CALCIUM GLUCONATE	20 (12)	32 (19)	52 (15)
CALCIUM GLUCONATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
CALCIUM LEVOMEFOLATE;CYANOCOBALAMIN;MAGNESIUM;MAGNESIUM GLYCEROPHOSPHATE;PYRIDOXINE HYDROCHLORIDE;TAURINE	1 (1)	0	1 (0)
CALCIUM;COLECALCIFEROL	1 (1)	3 (2)	4 (1)
CALCIUM;MAGNESIUM	1 (1)	0	1 (0)
CALCIUM;MAGNESIUM;POTASSIUM	0	1 (1)	1 (0)
CALCIUM;VITAMIN D NOS	1 (1)	0	1 (0)
CAMPHOR;MENTHOL	1 (1)	2 (1)	3 (1)
CANAGLIFLOZIN	2 (1)	1 (1)	3 (1)
CANDESARTAN	2 (1)	0	2 (1)
CANNABIS SATIVA	1 (1)	2 (1)	3 (1)
CAPECITABINE	0	1 (1)	1 (0)
CARBIDOPA;LEVODOPA	1 (1)	0	1 (0)
CARBOMER	1 (1)	1 (1)	2 (1)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	0	1 (1)	1 (0)
CARBOPLATIN	1 (1)	0	1 (0)
CARMELLOSE	1 (1)	2 (1)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CARMELLOSE;GLYCEROL	0	1 (1)	1 (0)
CARMELLOSE;SORBINICATE	11 (6)	8 (5)	19 (6)
CARMUSTINE	0	1 (1)	1 (0)
CARVEDILOL	2 (1)	5 (3)	7 (2)
CASPOFUNGIN	4 (2)	1 (1)	5 (1)
CEFALEXIN	0	4 (2)	4 (1)
CEFAZOLIN	8 (5)	15 (9)	23 (7)
CEFDINIR	2 (1)	1 (1)	3 (1)
CEFEPIME	90 (53)	44 (26)	134 (40)
CEFOTAXIME	1 (1)	1 (1)	2 (1)
CEFPODOXIME	4 (2)	2 (1)	6 (2)
CEFTAZIDIME	15 (9)	3 (2)	18 (5)
CEFTRIAXONE	11 (6)	5 (3)	16 (5)
CEFUROXIME	3 (2)	1 (1)	4 (1)
CELECOXIB	5 (3)	1 (1)	6 (2)
CETIRIZINE	21 (12)	25 (15)	46 (14)
CETIRIZINE;PSEUDOEPHEDRINE	1 (1)	0	1 (0)
CETYLPYRIDINIUM;CHLORHEXIDINE	0	2 (1)	2 (1)
CHLORHEXIDINE	19 (11)	19 (11)	38 (11)
CHLORHEXIDINE GLUCONATE;MACROGOL;SACCHARIN SODIUM;SODIUM BICARBONATE;SODIUM EDETATE	0	1 (1)	1 (0)
CHLORHEXIDINE;LIDOCAINE	1 (1)	1 (1)	2 (1)
CHLORPHENAMINE	4 (2)	6 (4)	10 (3)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CHLORPHENAMINE;HYDROCODONE	2 (1)	0	2 (1)
CHLORPROMAZINE	1 (1)	3 (2)	4 (1)
CHONDROITIN;GLUCOSAMINE	1 (1)	2 (1)	3 (1)
CHONDROITIN;GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (1)	1 (0)
CIDOFOVIR	1 (1)	0	1 (0)
CILASTATIN;IMIPENEM	1 (1)	1 (1)	2 (1)
CINCHOCAINE	0	1 (1)	1 (0)
CINNAMOMUM VERUM	0	1 (1)	1 (0)
CINNARIZINE	0	1 (1)	1 (0)
CIPROFLOXACIN	47 (28)	47 (28)	94 (28)
CITALOPRAM	3 (2)	2 (1)	5 (1)
CITRIC ACID;POTASSIUM BICARBONATE	0	1 (1)	1 (0)
CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE	1 (1)	0	1 (0)
CLARITHROMYCIN	2 (1)	0	2 (1)
CLAVULANIC ACID	1 (1)	0	1 (0)
CLEMASTINE	12 (7)	15 (9)	27 (8)
CLINDAMYCIN	3 (2)	5 (3)	8 (2)
CLOBETASOL	2 (1)	1 (1)	3 (1)
CLONAZEPAM	4 (2)	2 (1)	6 (2)
CLONIDINE	4 (2)	2 (1)	6 (2)
CLOPIDOGREL	1 (1)	2 (1)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CLOTRIMAZOLE	6 (4)	7 (4)	13 (4)
COCAINE HYDROCHLORIDE	1 (1)	1 (1)	2 (1)
CODEINE	4 (2)	4 (2)	8 (2)
CODEINE PHOSPHATE	2 (1)	0	2 (1)
CODEINE;GUAIFENESIN	2 (1)	1 (1)	3 (1)
CODEINE;PARACETAMOL	3 (2)	6 (4)	9 (3)
COLCHICINE	1 (1)	0	1 (0)
COLECALCIFEROL	27 (16)	24 (14)	51 (15)
COLISTIN	3 (2)	2 (1)	5 (1)
COLLAGENASE	1 (1)	0	1 (0)
CORTISONE	0	1 (1)	1 (0)
CURCUMIN	3 (2)	4 (2)	7 (2)
CYANOCOBALAMIN	12 (7)	10 (6)	22 (7)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1 (1)	2 (1)	3 (1)
CYCLIZINE	1 (1)	4 (2)	5 (1)
CYCLOBENZAPRINE	4 (2)	6 (4)	10 (3)
CYCLOPHOSPHAMIDE	0	2 (1)	2 (1)
CYTARABINE	0	2 (1)	2 (1)
DALTEPARIN	9 (5)	9 (5)	18 (5)
DAPSONE	11 (6)	1 (1)	12 (4)
DAPTOMYCIN	6 (4)	2 (1)	8 (2)
DESONIDE	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
DESVENLAFAXINE	2 (1)	0	2 (1)
DEXAMETHASONE	81 (48)	125 (74)	206 (61)
DEXAMETHASONE;GENTAMICIN	0	1 (1)	1 (0)
DEXAMETHASONE;TOBRAMYCIN	1 (1)	0	1 (0)
DEXAMFETAMINE	1 (1)	0	1 (0)
DEXCHLORPHENIRAMINE	4 (2)	5 (3)	9 (3)
DEXCHLORPHENIRAMINE MALEATE	3 (2)	3 (2)	6 (2)
DEXMEDETOMIDINE	6 (4)	0	6 (2)
DEXPANTHENOL	2 (1)	4 (2)	6 (2)
DEXTRAN;HYPROMELLOSE	2 (1)	1 (1)	3 (1)
DEXTRIN	0	1 (1)	1 (0)
DEXTROMETHORPHAN	3 (2)	2 (1)	5 (1)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (1)	0	1 (0)
DEXTROMETHORPHAN;GUAIFENESIN	6 (4)	4 (2)	10 (3)
DIAZEPAM	2 (1)	4 (2)	6 (2)
DICLOFENAC	4 (2)	3 (2)	7 (2)
DICYCLOVERINE	3 (2)	2 (1)	5 (1)
DIETARY SUPPLEMENT	0	1 (1)	1 (0)
DIGOXIN	2 (1)	2 (1)	4 (1)
DILTIAZEM	4 (2)	3 (2)	7 (2)
DIMENHYDRINATE	3 (2)	2 (1)	5 (1)
DIMETICONE;GLYCEROL;PETROLATUM	1 (1)	2 (1)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
DIMETINDENE MALEATE	0	1 (1)	1 (0)
DIOSMECTITE	1 (1)	1 (1)	2 (1)
DIPHENHYDRAMINE	123 (72)	101 (60)	224 (66)
DIPHENHYDRAMINE;LIDOCAINE	1 (1)	0	1 (0)
DIPHENHYDRAMINE;PARACETAMOL	1 (1)	0	1 (0)
DIPHENHYDRAMINE;ZINC ACETATE	1 (1)	1 (1)	2 (1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (1)	1 (1)	2 (1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	6 (4)	3 (2)	9 (3)
DOCUSATE	40 (24)	42 (25)	82 (24)
DOCUSATE;SENNA ALEXANDRINA	37 (22)	26 (15)	63 (19)
DOMPERIDONE	2 (1)	6 (4)	8 (2)
DOPAMINE	2 (1)	0	2 (1)
DORZOLAMIDE	1 (1)	0	1 (0)
DOXEPIN	2 (1)	0	2 (1)
DOXYCYCLINE	9 (5)	6 (4)	15 (4)
DOXYLAMINE SUCCINATE;FOLIC ACID;PYRIDOXINE	0	2 (1)	2 (1)
DRONABINOL	1 (1)	1 (1)	2 (1)
DULAGLUTIDE	1 (1)	0	1 (0)
DULOXETINE	5 (3)	2 (1)	7 (2)
DUTASTERIDE	0	1 (1)	1 (0)
DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
EDOXABAN	2 (1)	0	2 (1)
ELECTROLYTE SOLUTIONS [UMBRELLA TERM]	1 (1)	2 (1)	3 (1)
ELECTROLYTES NOS	9 (5)	8 (5)	17 (5)
ELECTROLYTES NOS;GLUCOSE	0	2 (1)	2 (1)
ELECTROLYTES NOS;MACROGOL	1 (1)	0	1 (0)
ELTROMBOPAG	1 (1)	0	1 (0)
EMOLLIENTS AND PROTECTIVES	2 (1)	1 (1)	3 (1)
EMPAGLIFLOZIN	1 (1)	0	1 (0)
EMU OIL	1 (1)	0	1 (0)
ENALAPRIL	4 (2)	2 (1)	6 (2)
ENOXAPARIN	74 (44)	67 (40)	141 (42)
ENOXOLONE;HYALURONATE SODIUM;POVIDONE	0	4 (2)	4 (1)
ENTECAVIR	5 (3)	5 (3)	10 (3)
EPHEDRINE	2 (1)	2 (1)	4 (1)
EPINEPHRINE	1 (1)	0	1 (0)
EPINEPHRINE;LIDOCAINE	0	7 (4)	7 (2)
EPIRUBICIN	0	1 (1)	1 (0)
EPOETIN ALFA	0	1 (1)	1 (0)
EPTIFIBATIDE	0	1 (1)	1 (0)
ERGOCALCIFEROL	4 (2)	8 (5)	12 (4)
ERGOCALCIFEROL;RETINOL	1 (1)	0	1 (0)
ERTAPENEM	1 (1)	2 (1)	3 (1)
ERYTHROMYCIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ESCITALOPRAM	6 (4)	3 (2)	9 (3)
ESKETAMINE	0	1 (1)	1 (0)
ESOMEPRAZOLE	6 (4)	10 (6)	16 (5)
ESTRADIOL	0	3 (2)	3 (1)
ETHINYLESTRADIOL;LEVONORGESTREL	0	1 (1)	1 (0)
ETOMIDATE	6 (4)	0	6 (2)
ETOPOSIDE	0	4 (2)	4 (1)
EXENATIDE	0	1 (1)	1 (0)
EZETIMIBE	0	1 (1)	1 (0)
FACTOR I (FIBRINOGEN)	2 (1)	0	2 (1)
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIHAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	5 (3)	0	5 (1)
FAMCICLOVIR	1 (1)	2 (1)	3 (1)
FAMOTIDINE	38 (22)	41 (24)	79 (23)
FENOFIBRATE	3 (2)	0	3 (1)
FENOTEROL;IPRATROPIUM	1 (1)	0	1 (0)
FENTANYL	30 (18)	45 (27)	75 (22)
FERROUS FUMARATE	2 (1)	0	2 (1)
FERROUS GLUCONATE	1 (1)	1 (1)	2 (1)
FERROUS SULFATE	4 (2)	6 (4)	10 (3)
FERROUS SULFATE;FOLIC ACID	1 (1)	0	1 (0)
FEXOFENADINE	4 (2)	2 (1)	6 (2)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
FIDAXOMICIN	1 (1)	0	1 (0)
FILGRASTIM	72 (42)	93 (55)	165 (49)
FINASTERIDE	3 (2)	3 (2)	6 (2)
FISH OIL	2 (1)	3 (2)	5 (1)
FLECAINIDE	1 (1)	0	1 (0)
FLUCLOXACILLIN	0	2 (1)	2 (1)
FLUCONAZOLE	107 (63)	71 (42)	178 (53)
FLUDEOXYGLUCOSE (18F)	12 (7)	16 (10)	28 (8)
FLUDROCORTISONE	2 (1)	0	2 (1)
FLUNITRAZEPAM	0	1 (1)	1 (0)
FLUOCINONIDE	1 (1)	1 (1)	2 (1)
FLUOROURACIL	1 (1)	0	1 (0)
FLUOXETINE	1 (1)	5 (3)	6 (2)
FLUTICASONE	11 (6)	9 (5)	20 (6)
FLUTICASONE;SALMETEROL	4 (2)	1 (1)	5 (1)
FLUVOXAMINE	1 (1)	0	1 (0)
FOLIC ACID	9 (5)	6 (4)	15 (4)
FOLIC ACID;MINERALS NOS;VITAMINS NOS	0	1 (1)	1 (0)
FOLINIC ACID	1 (1)	0	1 (0)
FONDAPARINUX	0	2 (1)	2 (1)
FORMOTEROL;MOMETASONE	2 (1)	0	2 (1)
FOSAPREPITANT	0	49 (29)	49 (14)
FOSCARNET	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
FOSFOMYCIN	0	1 (1)	1 (0)
FOSPHENYTOIN	1 (1)	0	1 (0)
FUROSEMIDE	49 (29)	72 (43)	121 (36)
GABAPENTIN	20 (12)	15 (9)	35 (10)
GADOBENIC ACID MEGLUMINE	4 (2)	0	4 (1)
GADOBUTROL	6 (4)	4 (2)	10 (3)
GANCICLOVIR	2 (1)	0	2 (1)
GENTAMICIN	1 (1)	2 (1)	3 (1)
GLIBENCLAMIDE	2 (1)	0	2 (1)
GLICLAZIDE	1 (1)	0	1 (0)
GLIMEPIRIDE	2 (1)	0	2 (1)
GLIPIZIDE	1 (1)	2 (1)	3 (1)
GLUCAGON	0	1 (1)	1 (0)
GLUCOSAMINE	0	1 (1)	1 (0)
GLUCOSE	6 (4)	10 (6)	16 (5)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPER OXIDASE;LYSOZYME	1 (1)	2 (1)	3 (1)
GLUCOSE;MAGNESIUM SULFATE	1 (1)	1 (1)	2 (1)
GLUCOSE;MAGNESIUM;POTASSIUM; SODIUM CHLORIDE	0	1 (1)	1 (0)
GLUCOSE;POTASSIUM CHLORIDE	0	2 (1)	2 (1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
GLUCOSE;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
GLUCOSE;SODIUM BICARBONATE	2 (1)	1 (1)	3 (1)
GLUCOSE;SODIUM CHLORIDE	7 (4)	17 (10)	24 (7)
GLYCEROL	3 (2)	0	3 (1)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (1)	0	1 (0)
GLYCERYL TRINITRATE	1 (1)	3 (2)	4 (1)
GLYCINE MAX EXTRACT;WHEY PROTEIN	2 (1)	0	2 (1)
GLYCINE MAX SEED OIL;LECITHIN	2 (1)	0	2 (1)
GLYCOPYRRONIUM	1 (1)	0	1 (0)
GRANISETRON	2 (1)	13 (8)	15 (4)
GRANULOCYTE COLONY STIMULATING FACTOR	0	3 (2)	3 (1)
GUAIFENESIN	13 (8)	4 (2)	17 (5)
HALOPERIDOL	12 (7)	6 (4)	18 (5)
HEME IRON POLYPEPTIDE	1 (1)	0	1 (0)
HEPARIN	19 (11)	27 (16)	46 (14)
HEPATITIS A VACCINE	0	2 (1)	2 (1)
HEPATITIS B VACCINE	6 (4)	3 (2)	9 (3)
HERICIUM ERINACEUS MYCELIUM	1 (1)	0	1 (0)
HIB VACCINE CONJ	6 (4)	3 (2)	9 (3)
HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE	1 (1)	0	1 (0)
HOMATROPINE;HYDROCODONE	1 (1)	0	1 (0)
HYALURONIC ACID	1 (1)	1 (1)	2 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
HYDRALAZINE	7 (4)	5 (3)	12 (4)
HYDROCHLOROTHIAZIDE	3 (2)	8 (5)	11 (3)
HYDROCHLOROTHIAZIDE;LISINOPRIL	0	1 (1)	1 (0)
HYDROCHLOROTHIAZIDE;LOSARTAN	0	4 (2)	4 (1)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1 (1)	0	1 (0)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	0	1 (1)	1 (0)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	2 (1)	2 (1)
HYDROCODONE	3 (2)	2 (1)	5 (1)
HYDROCODONE;PARACETAMOL	5 (3)	17 (10)	22 (7)
HYDROCORTISONE	12 (7)	42 (25)	54 (16)
HYDROCORTISONE;LIDOCAINE	0	1 (1)	1 (0)
HYDROCORTISONE;PRAMOCAINE	1 (1)	0	1 (0)
HYDROMORPHONE	37 (22)	23 (14)	60 (18)
HYDROXYCHLOROQUINE	1 (1)	0	1 (0)
HYDROXYZINE	3 (2)	3 (2)	6 (2)
HYETELLOSE;OCTENIDINE HYDROCHLORIDE;PROPYLENE GLYCOL	0	1 (1)	1 (0)
HYOSCINE	1 (1)	5 (3)	6 (2)
HYPROMELLOSE	5 (3)	8 (5)	13 (4)
IBANDRONATE SODIUM	0	1 (1)	1 (0)
IBUPROFEN	27 (16)	7 (4)	34 (10)
ICHTHAMMOL;TITANIUM DIOXIDE;ZINC OXIDE	0	1 (1)	1 (0)
IFOSFAMIDE	0	3 (2)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
IMMUNOGLOBULIN HUMAN NORMAL	28 (16)	2 (1)	30 (9)
INDOMETACIN	3 (2)	0	3 (1)
INFLUENZA VACCINE	5 (3)	6 (4)	11 (3)
INFLUENZA VACCINE INACT	6 (4)	2 (1)	8 (2)
INFLUENZA VACCINE INACT SPLIT 4V	1 (1)	1 (1)	2 (1)
INSULIN	18 (11)	8 (5)	26 (8)
INSULIN ASPART	11 (6)	7 (4)	18 (5)
INSULIN DETEMIR	2 (1)	1 (1)	3 (1)
INSULIN GLARGINE	16 (9)	4 (2)	20 (6)
INSULIN GLULISINE	0	1 (1)	1 (0)
INSULIN LISPRO	20 (12)	12 (7)	32 (9)
INVESTIGATIONAL DRUG	1 (1)	0	1 (0)
IODIXANOL	1 (1)	0	1 (0)
IOHEXOL	16 (9)	14 (8)	30 (9)
IOMEPROL	0	3 (2)	3 (1)
IOPAMIDOL	3 (2)	5 (3)	8 (2)
IOXITALAMATE MEGLUMINE	0	1 (1)	1 (0)
IOXITALAMIC ACID	0	2 (1)	2 (1)
IPRATROPIUM	8 (5)	3 (2)	11 (3)
IPRATROPIUM;SALBUTAMOL	11 (6)	5 (3)	16 (5)
IRBESARTAN	2 (1)	1 (1)	3 (1)
IRON	1 (1)	0	1 (0)
ISAVUCONAZONIUM	3 (2)	1 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ISOPHANE INSULIN	2 (1)	4 (2)	6 (2)
IVERMECTIN	0	1 (1)	1 (0)
KETAMINE	4 (2)	1 (1)	5 (1)
KETOROLAC	5 (3)	3 (2)	8 (2)
LABETALOL	2 (1)	0	2 (1)
LACOSAMIDE	4 (2)	0	4 (1)
LACTOBACILLUS ACIDOPHILUS	1 (1)	1 (1)	2 (1)
LACTOBACILLUS RHAMNOSUS	1 (1)	0	1 (0)
LACTULOSE	20 (12)	16 (10)	36 (11)
LAMIVUDINE	3 (2)	1 (1)	4 (1)
LAMOTRIGINE	0	1 (1)	1 (0)
LANSOPRAZOLE	6 (4)	9 (5)	15 (4)
LATANOPROST	2 (1)	0	2 (1)
LATANOPROST;TIMOLOL	0	1 (1)	1 (0)
LENOGRASTIM	1 (1)	5 (3)	6 (2)
LERCANIDIPINE	1 (1)	0	1 (0)
LETERMOVIR	1 (1)	0	1 (0)
LEUPRORELIN	1 (1)	0	1 (0)
LEVETIRACETAM	125 (74)	1 (1)	126 (37)
LEVOCETIRIZINE	1 (1)	0	1 (0)
LEVOFLOXACIN	64 (38)	45 (27)	109 (32)
LEVOMEPROMAZINE	0	5 (3)	5 (1)
LEVONORGESTREL	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
LEVOSALBUTAMOL	6 (4)	2 (1)	8 (2)
LEVOSALBUTAMOL HYDROCHLORIDE	0	1 (1)	1 (0)
LEVOTHYROXINE	11 (6)	14 (8)	25 (7)
LIDOCAINE	42 (25)	45 (27)	87 (26)
LIDOCAINE;NIFEDIPINE	1 (1)	0	1 (0)
LIDOCAINE;PRILOCAINE	7 (4)	7 (4)	14 (4)
LINAGLIPTIN	0	1 (1)	1 (0)
LINAGLIPTIN;METFORMIN	1 (1)	0	1 (0)
LINEZOLID	3 (2)	0	3 (1)
LINUM USITATISSIMUM SEED OIL	0	1 (1)	1 (0)
LIPEGFILGRASTIM	0	2 (1)	2 (1)
LIRAGLUTIDE	1 (1)	0	1 (0)
LISDEXAMFETAMINE MESILATE	0	2 (1)	2 (1)
LISINOPRIL	11 (6)	9 (5)	20 (6)
LITHIUM	0	2 (1)	2 (1)
LOPERAMIDE	35 (21)	45 (27)	80 (24)
LOPINAVIR;RITONAVIR	1 (1)	0	1 (0)
LORATADINE	32 (19)	31 (18)	63 (19)
LORATADINE;PSEUDOEPHEDRINE	14 (8)	1 (1)	15 (4)
LORAZEPAM	60 (35)	65 (39)	125 (37)
LORMETAZEPAM	0	1 (1)	1 (0)
LOSARTAN	6 (4)	8 (5)	14 (4)
LOVASTATIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
LUBIPROSTONE	0	1 (1)	1 (0)
LYNESTRENOL	1 (1)	0	1 (0)
LYSINE	0	1 (1)	1 (0)
MACROGOL	59 (35)	74 (44)	133 (39)
MAGIC MOUTHWASH	5 (3)	19 (11)	24 (7)
MAGNESIUM	3 (2)	3 (2)	6 (2)
MAGNESIUM AMINO ACID CHELATE	11 (6)	11 (7)	22 (7)
MAGNESIUM ASPARTATE DIHYDRATE	3 (2)	3 (2)	6 (2)
MAGNESIUM BROMIDE;MAGNESIUM FLUORIDE;MAGNESIUM HYDROXIDE	0	2 (1)	2 (1)
MAGNESIUM CHELATE	0	2 (1)	2 (1)
MAGNESIUM CHLORIDE	0	2 (1)	2 (1)
MAGNESIUM CITRATE	7 (4)	8 (5)	15 (4)
MAGNESIUM GLUCONATE	0	1 (1)	1 (0)
MAGNESIUM HYDROXIDE	7 (4)	2 (1)	9 (3)
MAGNESIUM OXIDE	26 (15)	27 (16)	53 (16)
MAGNESIUM SULFATE	79 (46)	81 (48)	160 (47)
MAGNESIUM SULFATE;MANNITOL;POTASSIUM	0	3 (2)	3 (1)
MAGNESIUM SULFATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2 (1)	6 (4)	8 (2)
MAGNESIUM;POTASSIUM;SODIUM	1 (1)	0	1 (0)
MAGNESIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
MANNITOL	2 (1)	16 (10)	18 (5)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
MARAVIROC	1 (1)	0	1 (0)
MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)	1 (1)	0	1 (0)
MEBEVERINE	0	1 (1)	1 (0)
MECLOZINE	1 (1)	1 (1)	2 (1)
MEFENAMIC ACID	0	1 (1)	1 (0)
MEGESTROL	2 (1)	1 (1)	3 (1)
MELATONIN	25 (15)	14 (8)	39 (12)
MELPERONE	1 (1)	0	1 (0)
MEMANTINE	0	1 (1)	1 (0)
MENTHA X PIPERITA OIL;METHYL SALICYLATE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
MENTHOL	1 (1)	3 (2)	4 (1)
MEROPENEM	33 (19)	12 (7)	45 (13)
MESNA	0	19 (11)	19 (6)
METAMIZOLE	9 (5)	6 (4)	15 (4)
METFORMIN	16 (9)	14 (8)	30 (9)
METFORMIN;SITAGLIPTIN	1 (1)	0	1 (0)
METHADONE	2 (1)	1 (1)	3 (1)
METHOCARBAMOL	2 (1)	2 (1)	4 (1)
METHOTREXATE	0	3 (2)	3 (1)
METHYLNALTREXONE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
METHYLPHENIDATE	1 (1)	0	1 (0)
METHYLPREDNISOLONE	21 (12)	14 (8)	35 (10)
METHYLTHIONINIUM CHLORIDE	0	1 (1)	1 (0)
METOCLOPRAMIDE	34 (20)	43 (26)	77 (23)
METOPROLOL	25 (15)	22 (13)	47 (14)
METOPROLOL SUCCINATE	1 (1)	1 (1)	2 (1)
METRONIDAZOLE	17 (10)	13 (8)	30 (9)
MICAFUNGIN	7 (4)	2 (1)	9 (3)
MICONAZOLE	2 (1)	0	2 (1)
MIDAZOLAM	24 (14)	34 (20)	58 (17)
MIDODRINE	4 (2)	1 (1)	5 (1)
MINERALS NOS;VITAMINS NOS	0	1 (1)	1 (0)
MINOCYCLINE	4 (2)	0	4 (1)
MIRTAZAPINE	8 (5)	3 (2)	11 (3)
MOMETASONE	0	2 (1)	2 (1)
MONASCUS PURPUREUS	0	1 (1)	1 (0)
MONTELUKAST	5 (3)	2 (1)	7 (2)
MORPHINE	24 (14)	28 (17)	52 (15)
MOXIFLOXACIN	3 (2)	0	3 (1)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	1 (1)	1 (1)	2 (1)
MULTIVITAMINS, OTHER COMBINATIONS	0	1 (1)	1 (0)
MULTIVITAMINS, PLAIN	28 (16)	15 (9)	43 (13)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
MUPIROCIN	10 (6)	2 (1)	12 (4)
NADROPARIN	4 (2)	3 (2)	7 (2)
NALOXEGOL	1 (1)	1 (1)	2 (1)
NALOXONE	0	3 (2)	3 (1)
NALOXONE;OXYCODONE	1 (1)	1 (1)	2 (1)
NAPHAZOLINE;PHENIRAMINE	0	1 (1)	1 (0)
NAPROXEN	5 (3)	5 (3)	10 (3)
NEBIVOLOL	1 (1)	0	1 (0)
NEOSTIGMINE	1 (1)	0	1 (0)
NETUPITANT;PALONOSETRON	0	7 (4)	7 (2)
NICARDIPINE	1 (1)	0	1 (0)
NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	1 (1)	1 (0)
NICOTINE	7 (4)	5 (3)	12 (4)
NICOTINIC ACID	0	1 (1)	1 (0)
NIFEDIPINE	3 (2)	1 (1)	4 (1)
NITROFURANTOIN	0	3 (2)	3 (1)
NIVOLUMAB	0	1 (1)	1 (0)
NOREPINEPHRINE	11 (6)	4 (2)	15 (4)
NUTRIENTS NOS	2 (1)	3 (2)	5 (1)
NYSTATIN	22 (13)	21 (13)	43 (13)
OCTREOTIDE	1 (1)	3 (2)	4 (1)
OLANZAPINE	9 (5)	20 (12)	29 (9)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
OLMESARTAN	2 (1)	1 (1)	3 (1)
OMEGA-3 FATTY ACIDS	6 (4)	2 (1)	8 (2)
OMEPRAZOLE	28 (16)	41 (24)	69 (20)
ONDANSETRON	103 (61)	146 (87)	249 (74)
OSELTAMIVIR	5 (3)	2 (1)	7 (2)
OTHER VIRAL VACCINES	8 (5)	1 (1)	9 (3)
OXALIPLATIN	0	1 (1)	1 (0)
OXAZEPAM	4 (2)	2 (1)	6 (2)
OXYBUTYNIN	2 (1)	1 (1)	3 (1)
OXYCODONE	67 (39)	57 (34)	124 (37)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	1 (1)	0	1 (0)
OXYCODONE;PARACETAMOL	7 (4)	1 (1)	8 (2)
OXYGEN	46 (27)	13 (8)	59 (17)
OXYMETAZOLINE	4 (2)	1 (1)	5 (1)
PALONOSETRON	1 (1)	22 (13)	23 (7)
PANCRELIPASE	0	1 (1)	1 (0)
PANTOPRAZOLE	62 (36)	68 (40)	130 (38)
PANTOTHENIC ACID	0	1 (1)	1 (0)
PARACETAMOL	167 (98)	153 (91)	320 (95)
PARAFFIN	1 (1)	0	1 (0)
PARAFFIN, LIQUID	1 (1)	0	1 (0)
PARAFFIN, LIQUID;SODIUM PICOSULFATE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN;WOOL FAT	1 (1)	0	1 (0)
PAROXETINE	1 (1)	0	1 (0)
PASSIFLORA INCARNATA	1 (1)	0	1 (0)
PEGFILGRASTIM	10 (6)	101 (60)	111 (33)
PEGVISOMANT	1 (1)	0	1 (0)
PEMBROLIZUMAB	1 (1)	0	1 (0)
PEMETREXED	1 (1)	0	1 (0)
PENICILLIN NOS	0	2 (1)	2 (1)
PENTAMIDINE	20 (12)	5 (3)	25 (7)
PERFLUBUTANE POLYMER MICROSPHERES	0	1 (1)	1 (0)
PERINDOPRIL ARGININE	0	1 (1)	1 (0)
PETHIDINE	13 (8)	5 (3)	18 (5)
PETROLATUM	4 (2)	2 (1)	6 (2)
PHENAZOPYRIDINE	3 (2)	2 (1)	5 (1)
PHENETICILLIN	0	3 (2)	3 (1)
PHENOL	1 (1)	2 (1)	3 (1)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	1 (1)	1 (0)
PHENYLEPHRINE	5 (3)	3 (2)	8 (2)
PHENYTOIN	0	1 (1)	1 (0)
PHOSPHORIC ACID SODIUM;SODIUM PHOSPHATE DIBASIC	1 (1)	0	1 (0)
PHOSPHORUS	5 (3)	3 (2)	8 (2)
PHYTOMENADIONE	10 (6)	7 (4)	17 (5)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PIMECROLIMUS	1 (1)	1 (1)	2 (1)
PIOGLITAZONE	0	1 (1)	1 (0)
PIPERACILLIN	1 (1)	0	1 (0)
PIPERACILLIN;TAZOBACTAM	66 (39)	26 (15)	92 (27)
PIRITRAMIDE	0	1 (1)	1 (0)
PITAVASTATIN	1 (1)	0	1 (0)
PLANTAGO AFRA	2 (1)	0	2 (1)
PLANTAGO OVATA	3 (2)	1 (1)	4 (1)
PLANTAGO OVATA HUSK	1 (1)	1 (1)	2 (1)
PLASMA	2 (1)	2 (1)	4 (1)
PLATELETS	10 (6)	84 (50)	94 (28)
PLERIXAFOR	0	36 (21)	36 (11)
PNEUMOCOCCAL VACCINE 13V	8 (5)	4 (2)	12 (4)
PNEUMOCOCCAL VACCINE CONJ	0	1 (1)	1 (0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (1)	2 (1)	3 (1)
POLIO VACCINE INACT	6 (4)	2 (1)	8 (2)
POLYETHYLENE	0	1 (1)	1 (0)
POLYVINYL ALCOHOL;POVIDONE	2 (1)	1 (1)	3 (1)
POSACONAZOLE	6 (4)	1 (1)	7 (2)
POTASSIUM	0	8 (5)	8 (2)
POTASSIUM ACETATE	0	1 (1)	1 (0)
POTASSIUM BICARBONATE	1 (1)	1 (1)	2 (1)
POTASSIUM CHLORIDE	105 (62)	97 (58)	202 (60)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	6 (4)	16 (10)	22 (7)
POTASSIUM CHLORIDE;SODIUM PHOSPHATE	1 (1)	0	1 (0)
POTASSIUM CITRATE	1 (1)	1 (1)	2 (1)
POTASSIUM GLUCONATE	0	2 (1)	2 (1)
POTASSIUM PHOSPHATE DIBASIC	3 (2)	2 (1)	5 (1)
POTASSIUM PHOSPHATE DIBASIC;SODIUM	0	1 (1)	1 (0)
POTASSIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE	2 (1)	0	2 (1)
POTASSIUM PHOSPHATE MONOBASIC	35 (21)	26 (15)	61 (18)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE	13 (8)	19 (11)	32 (9)
POTASSIUM;SODIUM	2 (1)	0	2 (1)
POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
POTASSIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
POVIDONE-IODINE	0	1 (1)	1 (0)
PRAMOCAINE	2 (1)	0	2 (1)
PRAVASTATIN	1 (1)	5 (3)	6 (2)
PREDNISOLONE	0	27 (16)	27 (8)
PREDNISONE	5 (3)	8 (5)	13 (4)
PREGABALIN	8 (5)	7 (4)	15 (4)
PROBENECID	1 (1)	0	1 (0)
PROBIOTICS NOS	3 (2)	1 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PROCHLORPERAZINE	76 (45)	83 (49)	159 (47)
PROMETHAZINE	15 (9)	7 (4)	22 (7)
PROPOFOL	15 (9)	11 (7)	26 (8)
PROPRANOLOL	1 (1)	0	1 (0)
PROTAMINE	1 (1)	0	1 (0)
PROTEIN	1 (1)	1 (1)	2 (1)
PRUNUS DOMESTICA FRUIT;SENNA ALEXANDRINA LEAF	1 (1)	0	1 (0)
PSEUDOEPHEDRINE	3 (2)	0	3 (1)
PTEROSTILBENE	0	1 (1)	1 (0)
PYRIDOXINE	3 (2)	6 (4)	9 (3)
PYRIDOXINE;THIAMINE	0	1 (1)	1 (0)
QUETIAPINE	5 (3)	2 (1)	7 (2)
QUINAPRIL	1 (1)	0	1 (0)
RABEPRAZOLE	2 (1)	1 (1)	3 (1)
RACECADOTRIL	0	1 (1)	1 (0)
RACEPINEFRINE	1 (1)	0	1 (0)
RAMELTEON	5 (3)	1 (1)	6 (2)
RAMIPRIL	0	3 (2)	3 (1)
RANITIDINE	13 (8)	19 (11)	32 (9)
RASBURICASE	4 (2)	2 (1)	6 (2)
REMDESIVIR	2 (1)	0	2 (1)
REMIFENTANIL	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
RESVERATROL	0	1 (1)	1 (0)
RIBAVIRIN	0	2 (1)	2 (1)
RISEDRONATE SODIUM	1 (1)	0	1 (0)
RITUXIMAB	0	6 (4)	6 (2)
RIVAROXABAN	10 (6)	7 (4)	17 (5)
RIZATRIPTAN	2 (1)	2 (1)	4 (1)
ROCURONIUM	11 (6)	2 (1)	13 (4)
ROFLUMILAST	0	1 (1)	1 (0)
ROLAPITANT	1 (1)	3 (2)	4 (1)
ROMIPLOSTIM	0	1 (1)	1 (0)
ROPINIROLE	1 (1)	1 (1)	2 (1)
ROSUVASTATIN	5 (3)	6 (4)	11 (3)
SACCHAROMYCES BOULARDII	0	1 (1)	1 (0)
SALBUTAMOL	19 (11)	12 (7)	31 (9)
SAXAGLIPTIN	1 (1)	0	1 (0)
SENNA ALEXANDRINA	39 (23)	42 (25)	81 (24)
SERENOA REPENS	0	2 (1)	2 (1)
SERTRALINE	2 (1)	3 (2)	5 (1)
SEVELAMER	1 (1)	2 (1)	3 (1)
SILDENAFIL	3 (2)	0	3 (1)
SILTUXIMAB	1 (1)	0	1 (0)
SILYBUM MARIANUM	3 (2)	0	3 (1)
SIMETICONE	15 (9)	10 (6)	25 (7)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
SIMVASTATIN	8 (5)	6 (4)	14 (4)
SITAGLIPTIN	1 (1)	2 (1)	3 (1)
SITOSTEROL	0	1 (1)	1 (0)
SODIUM	1 (1)	0	1 (0)
SODIUM ACETATE	0	1 (1)	1 (0)
SODIUM ACETATE;SODIUM CHLORIDE	1 (1)	0	1 (0)
SODIUM BICARBONATE	10 (6)	18 (11)	28 (8)
SODIUM BICARBONATE;SODIUM CHLORIDE	9 (5)	20 (12)	29 (9)
SODIUM BICARBONATE;WATER FOR INJECTION	1 (1)	0	1 (0)
SODIUM CHLORIDE	122 (72)	99 (59)	221 (65)
SODIUM CITRATE	1 (1)	1 (1)	2 (1)
SODIUM CITRATE;SODIUM LAURYL SULFATE	0	1 (1)	1 (0)
SODIUM FLUORIDE	0	2 (1)	2 (1)
SODIUM GLYCEROPHOSPHATE	0	2 (1)	2 (1)
SODIUM HYPOCHLORITE	1 (1)	0	1 (0)
SODIUM PERCHLORATE	1 (1)	0	1 (0)
SODIUM PHOSPHATE	33 (19)	12 (7)	45 (13)
SODIUM PICOSULFATE	2 (1)	2 (1)	4 (1)
SODIUM POLYSTYRENE SULFONATE	0	1 (1)	1 (0)
SOLIFENACIN SUCCINATE	0	1 (1)	1 (0)
SOLUTIONS FOR PARENTERAL NUTRITION	6 (4)	8 (5)	14 (4)
SOTALOL	1 (1)	0	1 (0)
SPIRONOLACTONE	2 (1)	2 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
STEM CELLS NOS	0	1 (1)	1 (0)
STOMATOLOGICAL PREPARATIONS	0	2 (1)	2 (1)
SUCRALFATE	3 (2)	6 (4)	9 (3)
SUGAMMADEX	3 (2)	1 (1)	4 (1)
SULFAMETHOXAZOLE	1 (1)	1 (1)	2 (1)
SULFAMETHOXAZOLE;TRIMETHOPRIM	98 (58)	75 (45)	173 (51)
SUMATRIPTAN	5 (3)	0	5 (1)
SUXAMETHONIUM	4 (2)	0	4 (1)
TACROLIMUS	2 (1)	0	2 (1)
TADALAFIL	1 (1)	2 (1)	3 (1)
TAMSULOSIN	9 (5)	3 (2)	12 (4)
TAZOBACTAM	1 (1)	0	1 (0)
TECHNETIUM (99M TC) ETIFENIN	0	1 (1)	1 (0)
TECHNETIUM TC 99M	0	2 (1)	2 (1)
TEICOPLANIN	4 (2)	1 (1)	5 (1)
TEMAZEPAM	9 (5)	5 (3)	14 (4)
TENOFOVIR	2 (1)	3 (2)	5 (1)
TESTOSTERONE	3 (2)	0	3 (1)
TESTOSTERONE UNDECANOATE	1 (1)	0	1 (0)
TETRACOSACTIDE	5 (3)	0	5 (1)
THIAMINE	8 (5)	10 (6)	18 (5)
THIOCTIC ACID	0	1 (1)	1 (0)
TICAGRELOR	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
TINZAPARIN	2 (1)	2 (1)	4 (1)
TIOTROPIUM	1 (1)	0	1 (0)
TIZANIDINE	1 (1)	1 (1)	2 (1)
TOBRAMYCIN	2 (1)	0	2 (1)
TOCILIZUMAB	114 (67)	0	114 (34)
TOPIRAMATE	1 (1)	1 (1)	2 (1)
TORASEMIDE	0	2 (1)	2 (1)
TRAMADOL	40 (24)	28 (17)	68 (20)
TRANEXAMIC ACID	0	1 (1)	1 (0)
TRAVOPROST	1 (1)	0	1 (0)
TRAZODONE	13 (8)	8 (5)	21 (6)
TRIAMCINOLONE	6 (4)	5 (3)	11 (3)
TRIAMTERENE	1 (1)	0	1 (0)
TRIMETHOPRIM	1 (1)	1 (1)	2 (1)
TROPICAMIDE	1 (1)	0	1 (0)
UBIDECARENONE	4 (2)	1 (1)	5 (1)
UBIQUINOL	0	1 (1)	1 (0)
UMECLIDINIUM;VILANTEROL	0	1 (1)	1 (0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (1)	1 (0)
UREA	1 (1)	0	1 (0)
UROKINASE	0	1 (1)	1 (0)
URSODEOXYCHOLIC ACID	8 (5)	6 (4)	14 (4)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
VACCINIUM MACROCARPON	2 (1)	1 (1)	3 (1)
VALACICLOVIR	57 (34)	43 (26)	100 (30)
VALERIANA OFFICINALIS ROOT	1 (1)	0	1 (0)
VALGANCICLOVIR	2 (1)	1 (1)	3 (1)
VALPROATE SODIUM	1 (1)	0	1 (0)
VALPROIC ACID	1 (1)	1 (1)	2 (1)
VALSARTAN	1 (1)	0	1 (0)
VANCOMYCIN	76 (45)	28 (17)	104 (31)
VARICELLA ZOSTER VACCINE	0	1 (1)	1 (0)
VECURONIUM	2 (1)	0	2 (1)
VENLAFAXINE	3 (2)	6 (4)	9 (3)
VERAPAMIL	1 (1)	1 (1)	2 (1)
VITAMIN B COMPLEX	3 (2)	3 (2)	6 (2)
VITAMIN B12 AND FOLIC ACID	1 (1)	0	1 (0)
VITAMIN D NOS	3 (2)	5 (3)	8 (2)
VITAMIN K NOS	4 (2)	4 (2)	8 (2)
VITAMINS, OTHER COMBINATIONS	4 (2)	0	4 (1)
VORICONAZOLE	4 (2)	2 (1)	6 (2)
WARFARIN	1 (1)	2 (1)	3 (1)
XYLOMETAZOLINE	1 (1)	1 (1)	2 (1)
ZAFIRLUKAST	1 (1)	1 (1)	2 (1)
ZALEPLON	3 (2)	2 (1)	5 (1)
ZANAMIVIR	1 (1)	1 (1)	2 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ZINC	0	1 (1)	1 (0)
ZINC GLUCONATE	0	1 (1)	1 (0)
ZINC OXIDE	0	1 (1)	1 (0)
ZINC SULFATE	0	1 (1)	1 (0)
ZINGIBER OFFICINALE RHIZOME	1 (1)	0	1 (0)
ZOLEDRONIC ACID	0	1 (1)	1 (0)
ZOLPIDEM	14 (8)	5 (3)	19 (6)
ZOPICLONE	1 (1)	7 (4)	8 (2)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Anhang 4-G1.2: Exposition gegenüber patientenindividueller Therapie - RCT mit dem zu bewertenden Arzneimittel - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-2 (Anhang): Exposition gegenüber der verschiedenen Behandlungen der patientenindividuellen Therapie - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.3.3.3.3. Exposure to Study Treatment (Standard of Care) (Safety Analysis Set)

	Standard of Care (N = 168)
Subjects received any standard of care second-line salvage chemotherapy	168 (100)
Number of cycles received	
1 cycle	16 (10)
2 cycles	91 (54)
3 cycles	61 (36)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	3 (2)
Number of subjects responded with CR/PR and received HDT-ASCT	62 (37)
After 2 cycles	20 (12)
After 3 cycles	42 (25)
Rituximab + Ifosfamide, Carboplatin, and Etoposide (R-ICE)	84 (50)
Number of cycles received	
1 cycle	8 (5)
2 cycles	47 (28)
3 cycles	29 (17)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	2 (1)
Number of subjects responded with CR/PR and received HDT-ASCT	35 (21)
After 2 cycles	13 (8)
After 3 cycles	22 (13)
Rituximab + Etoposide, Methylprednisolone, Cytarabine, and Cisplatin (R-ESHAP)	5 (3)
Number of cycles received	
1 cycle	1 (1)
2 cycles	1 (1)
3 cycles	3 (2)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	0 (0)
Number of subjects responded with CR/PR and received HDT-ASCT	2 (1)
After 3 cycles	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: ASCT, autologous stem cell transplant; CR, complete response; HDT, high-dose therapy; PR, partial response.
Note: Subjects who responded with PR or CR after 2 or 3 cycles of second-line salvage chemotherapy may have proceeded to HDT and ASCT.
a. Subjects who responded with CR/PR at Day 50 visit but didn't proceed with HDT-ASCT due to disease progression, or those who initiated HDT but did not complete ASCT, are excluded.

Data Source: ADSL, ADEX Program Name: t_ex_soc.sas Output Generated: 20210820T09:46

Table 14.3.3.3.3. Exposure to Study Treatment (Standard of Care) (Safety Analysis Set)

	Standard of Care (N = 168)
Rituximab + Gemcitabine, Dexamethasone, and Cisplatin/Carboplatin (R-GDP)	42 (25)
Number of cycles received	
1 cycle	4 (2)
2 cycles	20 (12)
3 cycles	18 (11)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	1 (1)
Number of subjects responded with CR/PR and received HDT-ASCT	15 (9)
After 2 cycles	5 (3)
After 3 cycles	10 (6)
Rituximab + Dexamethasone, High-dose Cytarabine and Cisplatin/Oxaliplatin (R-DHAP/R-DHAX)	37 (22)
Number of cycles received	
1 cycle	3 (2)
2 cycles	23 (14)
3 cycles	11 (7)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	0 (0)
Number of subjects responded with CR/PR and received HDT-ASCT	10 (6)
After 2 cycles	2 (1)
After 3 cycles	8 (5)

Data cutoff date = 18MAR2021
Abbreviations: ASCT, autologous stem cell transplant; CR, complete response; HDT, high-dose therapy; PR, partial response.
Note: Subjects who responded with PR or CR after 2 or 3 cycles of second-line salvage chemotherapy may have proceeded to HDT and ASCT.
a. Subjects who responded with CR/PR at Day 50 visit but didn't proceed with HDT-ASCT due to disease progression, or those who initiated HDT but did not complete ASCT, are excluded.

Data Source: ADSL, ADEX Program Name: t_ex_soc.sas Output Generated: 20210820T09:46

Anhang 4-G2: Ergänzende Darstellung der Studienergebnisse in der RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.1: Ergänzende Darstellung zu PFS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.1.1: PFS nach Prüfarztbeurteilung und nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-3 (Anhang): Ergebnisse zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	96 (53)	103 (58)
Censored, n (%)	84 (47)	76 (42)
Stratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), stratified	0.490 (0.368, 0.652)	NA
Unstratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), unstratified	0.524 (0.396, 0.694)	NA
KM median (95% CI) PFS time (months)	14.7 (5.4, NE)	3.7 (2.9, 5.3)
Min, Max PFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	85 (47)	98 (55)
Death from any cause, n (%)	11 (6)	5 (3)
Censoring reason		
Response ongoing, n (%)	79 (44)	34 (19)
New lymphoma therapy, n (%)	5 (3)	37 (21)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	2 (1)
Lost to follow up, n (%)	0 (0)	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

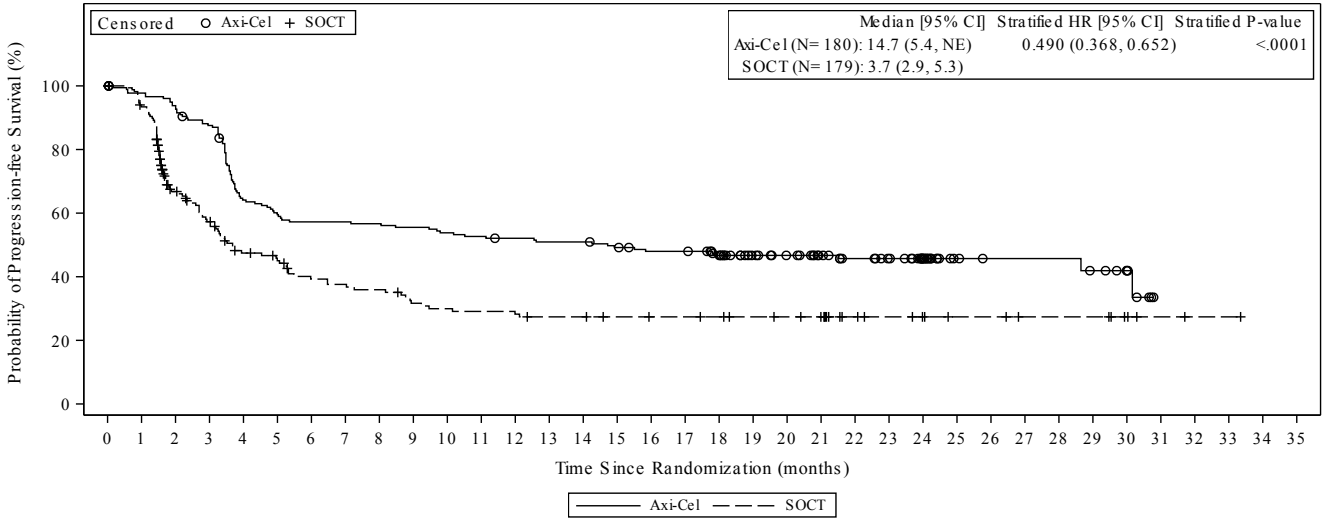
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Progression-free rate, % (95% CI) by KME		
3 month	87.6 (81.7, 91.6)	57.3 (49.0, 64.8)
6 month	57.2 (49.6, 64.2)	39.3 (31.1, 47.3)
9 month	55.5 (47.9, 62.5)	31.7 (23.9, 39.7)
12 month	52.1 (44.4, 59.2)	28.2 (20.8, 36.2)
15 month	49.2 (41.6, 56.3)	27.4 (20.0, 35.3)
18 month	46.7 (39.1, 53.9)	27.4 (20.0, 35.3)
21 month	46.7 (39.1, 53.9)	27.4 (20.0, 35.3)
24 month	45.7 (38.1, 53.0)	27.4 (20.0, 35.3)
27 month	45.7 (38.1, 53.0)	27.4 (20.0, 35.3)
30 month	41.9 (31.9, 51.6)	27.4 (20.0, 35.3)
33 month	NE (NE, NE)	27.4 (20.0, 35.3)
Median (95% CI) follow-up time (months) (reverse KM approach)	22.6 (20.8, 24.0)	19.6 (14.6, 21.2)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Abbildung 1 (Anhang): Kaplan-Meier Plot zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Figure 14.2.4.1.2. Kaplan-Meier Plot of Progression-free Survival Per Investigator Assessment (Full Analysis Set)



Subjects at Risk

Axi-Cel	180	173	166	154	112	104	100	100	99	97	94	92	90	88	88	84	80	80	73	61	56	49	43	39	28	14	12	12	12	10	6	0			
SOCT	179	155	94	78	61	56	47	45	43	37	35	34	33	31	31	29	28	28	27	25	24	22	15	13	11	9	9	7	7	7	4	2	1	1	0

Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; SCT, stem cell transplant; SOCT, standard of care therapy.
Note: Progression-free survival is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Tabelle 4-4 (Anhang): Ergebnisse zu PFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.4.1.1. Progression-free Survival Per Central Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	93 (52)	81 (45)
Censored, n (%)	87 (48)	98 (55)
Hazard ratio (95% CI), stratified	0.562 (0.414, 0.762)	NA
Hazard ratio (95% CI), unstratified	0.594 (0.440, 0.802)	NA
KM median (95% CI) PFS time (months)	14.9 (7.2, NE)	5.0 (3.4, 8.5)
Min, Max PFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	82 (46)	75 (42)
Death from any cause, n (%)	11 (6)	6 (3)
Censoring reason		
Response ongoing, n (%)	76 (42)	28 (16)
New lymphoma therapy, n (%)	9 (5)	61 (34)
Subsequent stem cell transplant, n (%)	0 (0)	2 (1)
Axicabtagene ciloleucel retreatment, n (%)	2 (1)	0 (0)
Response assessed but no disease at baseline and post-baseline, n (%)	0 (0)	3 (2)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	1 (1)
Lost to follow up, n (%)	0 (0)	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Table 14.2.4.1.1. Progression-free Survival Per Central Assessment (Full Analysis Set)

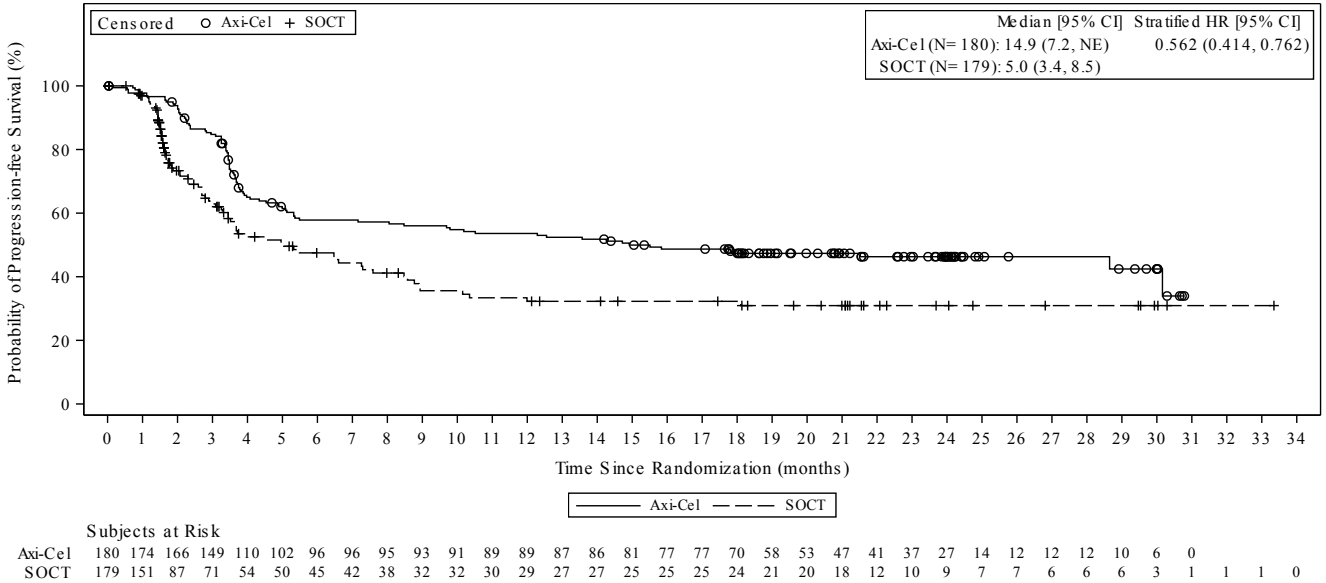
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Progression-free rate, % (95% CI) by KME		
3 month	84.7 (78.5, 89.3)	62.9 (53.9, 70.6)
6 month	57.8 (50.1, 64.8)	47.5 (38.2, 56.3)
9 month	56.0 (48.3, 63.1)	35.6 (26.6, 44.7)
12 month	53.6 (45.8, 60.7)	32.3 (23.5, 41.4)
15 month	50.0 (42.2, 57.2)	32.3 (23.5, 41.4)
18 month	47.3 (39.6, 54.7)	32.3 (23.5, 41.4)
21 month	47.3 (39.6, 54.7)	30.9 (22.2, 40.1)
24 month	46.3 (38.5, 53.7)	30.9 (22.2, 40.1)
27 month	46.3 (38.5, 53.7)	30.9 (22.2, 40.1)
30 month	42.4 (32.3, 52.2)	30.9 (22.2, 40.1)
33 month	NE (NE, NE)	30.9 (22.2, 40.1)
Median (95% CI) follow-up time (months) (reverse KM approach)	21.6 (20.7, 23.7)	12.1 (3.7, 18.3)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Abbildung 2 (Anhang): Kaplan-Meier Plot zu PFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Figure 14.2.4.1.1. Kaplan-Meier Plot of Progression-free Survival Per Central Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.
Note: Progression-free survival is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Anhang 4-G2.1.2: PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-5 (Anhang): Ergebnisse zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	101 (56)	106 (59)
Censored, n (%)	79 (44)	73 (41)
Hazard ratio (95% CI), stratified	0.506 (0.383, 0.669)	NA
Hazard ratio (95% CI), unstratified	0.529 (0.402, 0.697)	NA
KM median (95% CI) PFS time (months)	14.7 (5.4, 43.5)	3.7 (2.9, 5.3)
Min, Max PFS time (months)	0, 55	0, 54
Event		
Disease progression, n (%)	86 (48)	100 (56)
Death from any cause, n (%)	15 (8)	6 (3)
Censoring reason		
Response ongoing, n (%)	71 (39)	29 (16)
New lymphoma therapy, n (%)	6 (3)	37 (21)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	2 (1)
Lost to follow up, n (%)	2 (1)	4 (2)

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20230426T10:11

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

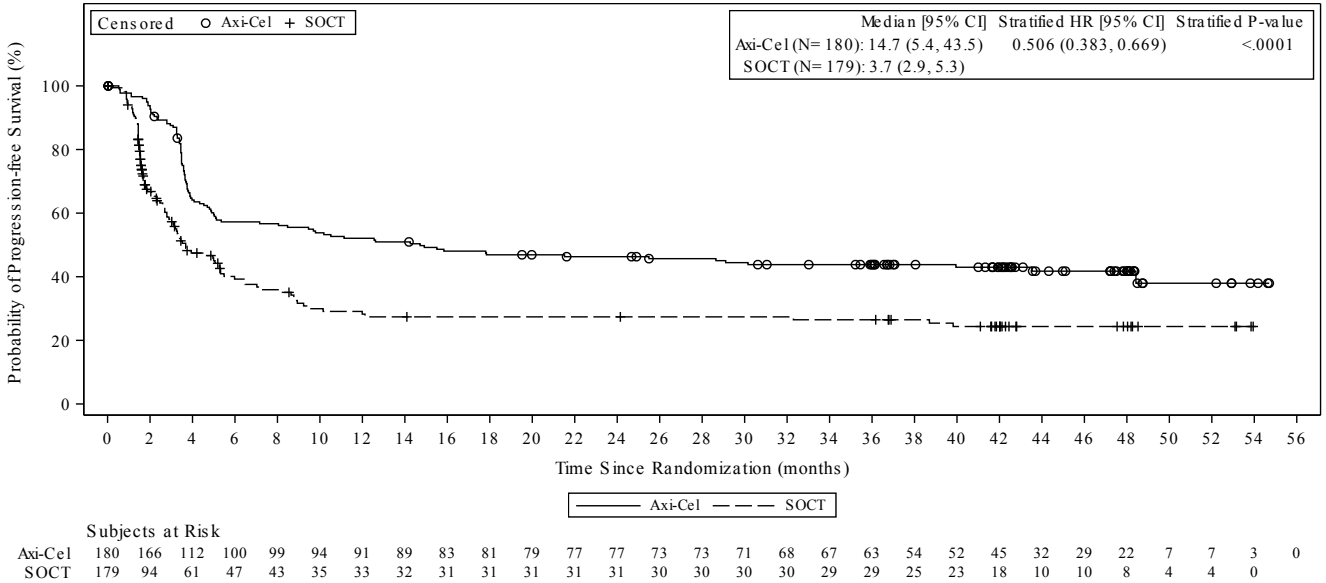
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Progression-free rate, % (95% CI) by KME		
3 month	87.6 (81.7, 91.6)	57.3 (49.0, 64.8)
6 month	57.2 (49.6, 64.2)	39.3 (31.1, 47.3)
9 month	55.5 (47.9, 62.5)	31.7 (23.9, 39.7)
12 month	52.1 (44.4, 59.2)	28.2 (20.8, 36.2)
15 month	49.2 (41.6, 56.4)	27.4 (20.0, 35.3)
18 month	46.9 (39.3, 54.1)	27.4 (20.0, 35.3)
21 month	46.9 (39.3, 54.1)	27.4 (20.0, 35.3)
24 month	46.3 (38.8, 53.5)	27.4 (20.0, 35.3)
27 month	45.7 (38.2, 52.9)	27.4 (20.0, 35.3)
30 month	44.4 (36.9, 51.6)	27.4 (20.0, 35.3)
33 month	43.8 (36.3, 51.0)	26.5 (19.1, 34.3)
36 month	43.8 (36.3, 51.0)	26.5 (19.1, 34.3)
39 month	43.8 (36.3, 51.0)	25.4 (18.2, 33.3)
42 month	43.0 (35.5, 50.2)	24.4 (17.2, 32.2)
45 month	41.8 (34.1, 49.2)	24.4 (17.2, 32.2)
48 month	41.8 (34.1, 49.2)	24.4 (17.2, 32.2)
51 month	38.0 (28.1, 47.7)	24.4 (17.2, 32.2)
54 month	38.0 (28.1, 47.7)	NE (NE, NE)
Median (95% CI) follow-up time (months) (reverse KM approach)	42.6 (41.7, 45.1)	41.6 (36.2, 42.0)

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20230426T10:11

Abbildung 3 (Anhang): Kaplan-Meier Plot zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.2.4.1.2. Kaplan-Meier Plot of Progression-free Survival Per Investigator Assessment (Full Analysis Set)



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Data Cutoff Date = 25JAN2023

Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; SCT, stem cell transplant; SOCT, standard of care therapy.

Note: Progression-free survival is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.

Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20230503T12:55

Anhang 4-G2.2: ORR nach Prüfarztbeurteilung und nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-6 (Anhang): Ergebnisse zu ORR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.2.1.2. Summary of Objective Response Rate and Best Overall Response Per Investigator Assessment (Full Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR), n (%)	149 (83)	80 (45)
95% CI for ORR	(76.5, 88.0)	(37.3, 52.3)
Difference in ORR (95% CI)	38.1 (28.1, 47.0)	-
Complete response, n (%)	110 (61)	61 (34)
95% CI for response rate	(53.6, 68.3)	(27.2, 41.5)
Partial response, n (%)	39 (22)	19 (11)
95% CI for response rate	(15.9, 28.4)	(6.5, 16.1)
Stable disease, n (%)	9 (5)	30 (17)
95% CI for response rate	(2.3, 9.3)	(11.6, 23.1)
Progressive disease, n (%)	17 (9)	55 (31)
95% CI for response rate	(5.6, 14.7)	(24.1, 38.0)
Not evaluable, n (%)	1 (1)	0 (0)
95% CI for response rate	(0.0, 3.1)	(0.0, 2.0)
Not done, n (%)	4 (2)	14 (8)
95% CI for response rate	(0.6, 5.6)	(4.3, 12.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; ORR, objective response rate; PR, partial response.
Note: 95% CI for rate is from the Clopper-Pearson method, and the 95% CI for the difference in ORR (standard of care arm as reference group) is from Wilson's score method with continuity correction.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Data Source: ADSL, ADEFF Program Name: t_orr.sas Output Generated: 20210820T09:03

Tabelle 4-7 (Anhang): Ergebnisse zu ORR nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.2.1.1. Summary of Objective Response Rate and Best Overall Response Per Central Assessment (Full Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR), n (%)	150 (83)	90 (50)
95% CI for ORR	(77.1, 88.5)	(42.7, 57.8)
Difference in ORR (95% CI)	33.1 (23.2, 42.1)	-
Stratified CMH test p-value	<.0001	-
Complete response, n (%)	117 (65)	58 (32)
95% CI for response rate	(57.6, 71.9)	(25.6, 39.8)
Partial response, n (%)	33 (18)	32 (18)
95% CI for response rate	(13.0, 24.8)	(12.6, 24.3)
Stable disease, n (%)	5 (3)	33 (18)
95% CI for response rate	(0.9, 6.4)	(13.0, 24.9)
Progressive disease, n (%)	21 (12)	38 (21)
95% CI for response rate	(7.4, 17.3)	(15.5, 28.0)
Undefined/ no disease, n (%)	0 (0)	4 (2)
95% CI for response rate	(0.0, 2.0)	(0.6, 5.6)
Not evaluable, n (%)	0 (0)	0 (0)
95% CI for response rate	(0.0, 2.0)	(0.0, 2.0)
Not done, n (%)	4 (2)	14 (8)
95% CI for response rate	(0.6, 5.6)	(4.3, 12.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CMH, Cochran-Mantel-Haenszel; CR, complete response; ORR, objective response rate; PR, partial response.
Note: 95% CI for rate is from the Clopper-Pearson method, and the 95% CI for the difference in ORR (standard of care arm as reference group) is from Wilson's score method with continuity correction.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: One-sided p-value from CMH test is presented.

Data Source: ADSL, ADEFF Program Name: t_orr.sas Output Generated: 20210820T09:03

Anhang 4-G2.3: Ergänzende Darstellung zu DOR - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.3.1: DOR nach Prüfarztbeurteilung und Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-8 (Anhang): Ergebnisse zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR)	149	80
Events, n (%)	68 (46)	40 (50)
Censored, n (%)	81 (54)	40 (50)
Hazard ratio (95% CI), stratified	0.769 (0.516, 1.147)	NA
Hazard ratio (95% CI), unstratified	0.839 (0.567, 1.241)	NA
KM median (95% CI) DOR (months)	26.5 (13.1, NE)	7.8 (5.0, NE)
Min, Max DOR (months)	0, 29	0, 32
Events		
Disease progression, n (%)	60 (40)	38 (48)
Death from any cause, n (%)	8 (5)	2 (3)
Censoring reasons		
Response ongoing, n (%)	79 (53)	34 (43)
New lymphoma therapy, n (%)	2 (1)	5 (6)
Lost to follow up, n (%)	0 (0)	1 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

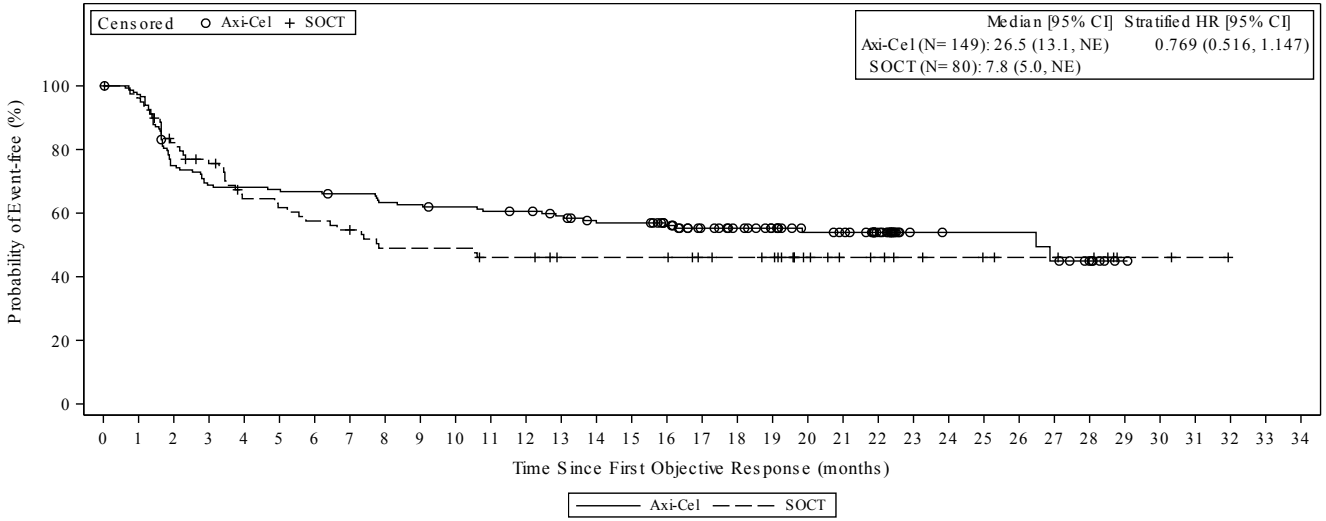
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Event-free rate, % (95% CI) by KME		
3 month	68.8 (60.6, 75.6)	75.6 (64.4, 83.7)
6 month	66.8 (58.5, 73.7)	57.5 (45.5, 67.8)
9 month	62.6 (54.3, 69.9)	49.0 (37.1, 59.8)
12 month	60.6 (52.2, 67.9)	46.1 (34.4, 57.0)
15 month	56.9 (48.5, 64.5)	46.1 (34.4, 57.0)
18 month	55.3 (46.7, 62.9)	46.1 (34.4, 57.0)
21 month	53.9 (45.2, 61.8)	46.1 (34.4, 57.0)
24 month	53.9 (45.2, 61.8)	46.1 (34.4, 57.0)
27 month	44.9 (31.4, 57.6)	46.1 (34.4, 57.0)
30 month	NE (NE, NE)	46.1 (34.4, 57.0)
Median (95% CI) follow-up time (months) (reverse KM approach)	20.7 (18.8, 21.9)	19.6 (17.3, 21.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Abbildung 4 (Anhang): Kaplan-Meier Plot zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Figure 14.2.3.1.2. Kaplan-Meier Plot of Duration of Response Per Investigator Assessment (Full Analysis Set)



Subjects at Risk

Axi-Cel	149	144	110	101	100	99	98	96	92	91	89	87	86	82	76	76	69	59	54	48	41	39	29	13	12	12	12	10	6	1	0		
SOCT	80	76	63	56	46	44	41	38	34	34	34	31	31	28	28	28	28	25	24	23	16	13	12	10	9	8	7	7	6	2	2	1	0

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Data Cutoff Date = 18MAR2021

Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.

Note: Duration of response is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.

Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Tabelle 4-9 (Anhang): Ergebnisse zu DOR nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 14.2.3.1.1. Duration of Response Per Central Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR)	150	90
Events, n (%)	66 (44)	37 (41)
Censored, n (%)	84 (56)	53 (59)
Stratified log-rank p-value	0.0695	NA
Hazard ratio (95% CI), stratified	0.736 (0.488, 1.108)	NA
Unstratified log-rank p-value	0.1442	NA
Hazard ratio (95% CI), unstratified	0.805 (0.537, 1.205)	NA
KM median (95% CI) DOR (months)	26.9 (13.6, NE)	8.9 (5.7, NE)
Min, Max DOR (months)	0, 29	0, 32
Events		
Disease progression, n (%)	58 (39)	34 (38)
Death from any cause, n (%)	8 (5)	3 (3)
Censoring reasons		
Response ongoing, n (%)	76 (51)	28 (31)
New lymphoma therapy, n (%)	6 (4)	23 (26)
Subsequent stem cell transplant, n (%)	0 (0)	1 (1)
Axicabtagene ciloleucel retreatment, n (%)	2 (1)	0 (0)
Lost to follow up, n (%)	0 (0)	1 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Table 14.2.3.1.1. Duration of Response Per Central Assessment (Full Analysis Set)

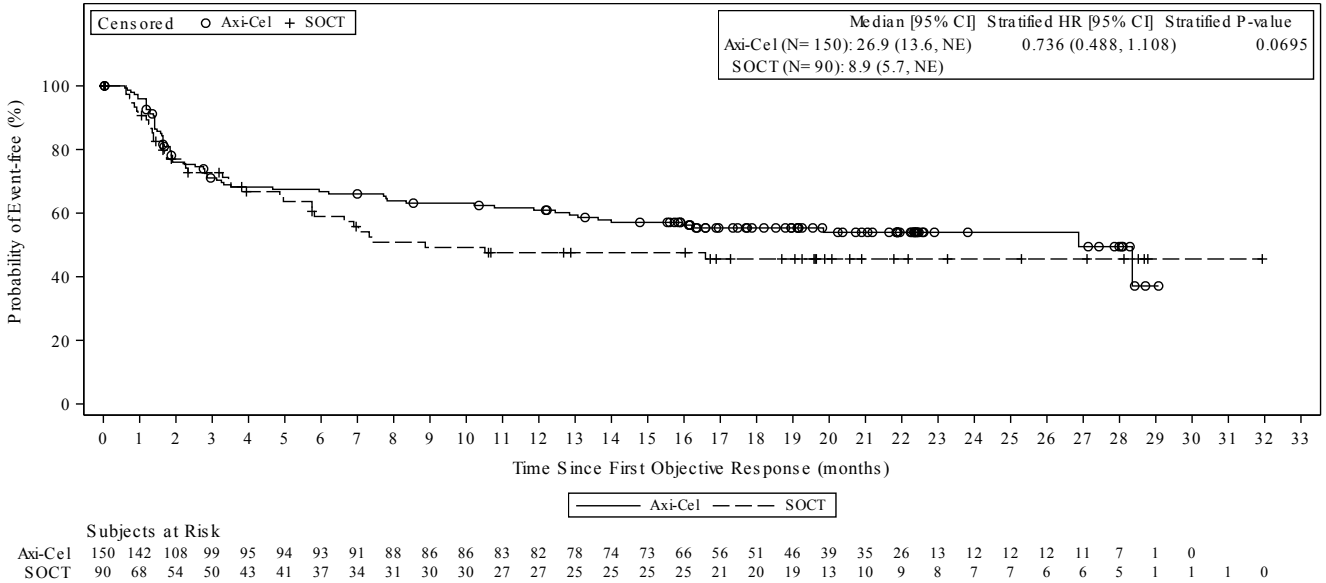
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Event-free rate, % (95% CI) by KME		
3 month	71.1 (62.9, 77.7)	72.7 (60.9, 81.5)
6 month	66.8 (58.4, 73.8)	58.9 (46.4, 69.5)
9 month	63.1 (54.7, 70.5)	49.2 (36.8, 60.5)
12 month	60.9 (52.4, 68.4)	47.6 (35.2, 58.9)
15 month	57.1 (48.5, 64.8)	47.6 (35.2, 58.9)
18 month	55.3 (46.7, 63.2)	45.6 (33.2, 57.1)
21 month	54.0 (45.1, 62.0)	45.6 (33.2, 57.1)
24 month	54.0 (45.1, 62.0)	45.6 (33.2, 57.1)
27 month	49.5 (37.6, 60.3)	45.6 (33.2, 57.1)
30 month	NE (NE, NE)	45.6 (33.2, 57.1)
Median (95% CI) follow-up time (months) (reverse KM approach)	19.5 (18.2, 21.7)	17.3 (12.7, 19.6)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Abbildung 5 (Anhang): Kaplan-Meier Plot zu DOR nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Figure 14.2.3.1.1. Kaplan-Meier Plot of Duration of Response Per Central Assessment (Full Analysis Set)



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Data Cutoff Date = 18MAR2021

Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.

Note: Duration of response is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.

Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Anhang 4-G2.3.2: DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-10 (Anhang): Ergebnisse zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR)	149	80
Events, n (%)	73 (49)	43 (54)
Censored, n (%)	76 (51)	37 (46)
Hazard ratio (95% CI), stratified	0.791 (0.539, 1.162)	NA
Hazard ratio (95% CI), unstratified	0.824 (0.565, 1.202)	NA
KM median (95% CI) DOR (months)	41.7 (13.6, NE)	7.8 (5.0, NE)
Min, Max DOR (months)	0, 53	0, 53
Events		
Disease progression, n (%)	61 (41)	40 (50)
Death from any cause, n (%)	12 (8)	3 (4)
Censoring reasons		
Response ongoing, n (%)	71 (48)	29 (36)
New lymphoma therapy, n (%)	3 (2)	5 (6)
Lost to follow up, n (%)	2 (1)	3 (4)

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20230426T10:48

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

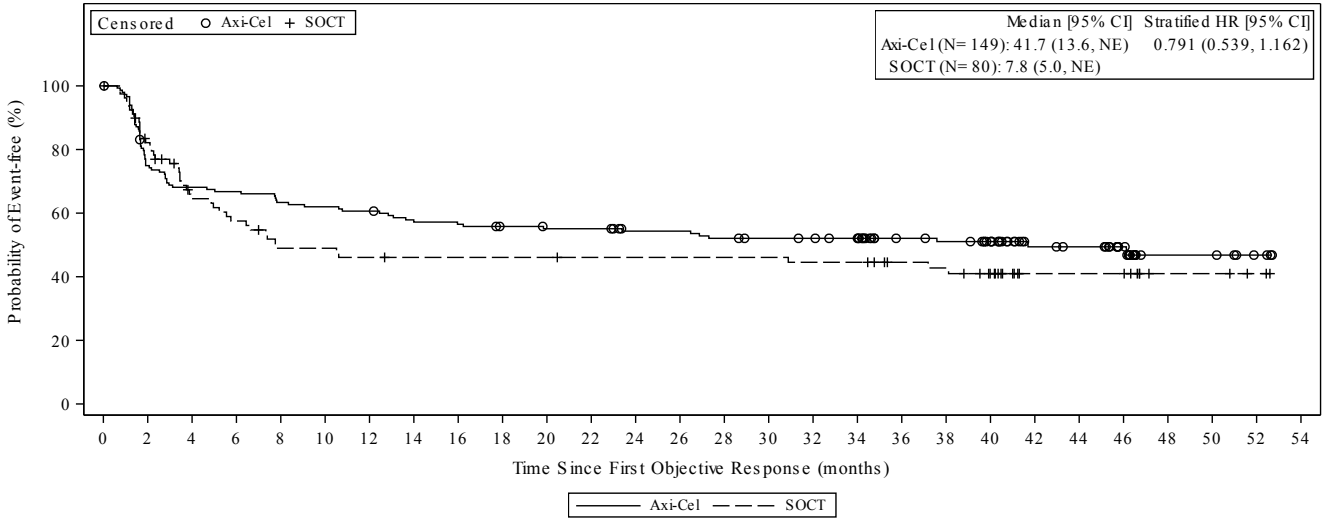
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Event-free rate, % (95% CI) by KME		
3 month	68.8 (60.6, 75.6)	75.6 (64.4, 83.7)
6 month	66.8 (58.5, 73.7)	57.5 (45.5, 67.8)
9 month	62.7 (54.3, 69.9)	49.0 (37.1, 59.8)
12 month	60.6 (52.3, 68.0)	46.1 (34.4, 57.0)
15 month	57.2 (48.8, 64.7)	46.1 (34.4, 57.0)
18 month	55.8 (47.4, 63.4)	46.1 (34.4, 57.0)
21 month	55.1 (46.7, 62.7)	46.1 (34.4, 57.0)
24 month	54.3 (45.9, 62.0)	46.1 (34.4, 57.0)
27 month	52.8 (44.4, 60.6)	46.1 (34.4, 57.0)
30 month	52.1 (43.6, 59.8)	46.1 (34.4, 57.0)
33 month	52.1 (43.6, 59.8)	44.5 (32.9, 55.5)
36 month	52.1 (43.6, 59.8)	44.5 (32.9, 55.5)
39 month	51.1 (42.6, 58.9)	41.0 (29.4, 52.2)
42 month	49.4 (40.6, 57.6)	41.0 (29.4, 52.2)
45 month	49.4 (40.6, 57.6)	41.0 (29.4, 52.2)
48 month	46.8 (37.1, 55.9)	41.0 (29.4, 52.2)
51 month	46.8 (37.1, 55.9)	41.0 (29.4, 52.2)
Median (95% CI) follow-up time (months) (reverse KM approach)	40.5 (39.7, 43.3)	40.3 (39.5, 41.2)

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20230426T10:48

Abbildung 6 (Anhang): Kaplan-Meier Plot zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.2.3.1.2. Kaplan-Meier Plot of Duration of Response Per Investigator Assessment (Full Analysis Set)



Subjects at Risk

Axi-Cel	149	110	100	98	93	91	89	83	82	79	77	77	72	72	69	67	66	64	52	50	45	30	28	20	7	7	3	0
SOCT	80	63	46	41	34	34	32	31	31	31	31	30	30	30	30	30	29	29	25	24	19	10	10	10	4	4	2	0

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Data Cutoff Date = 25JAN2023
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.
Note: Duration of response is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20230503T12:55

Anhang 4-G2.4: Ergänzende Darstellung zu Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.4.1: Rücklaufquoten nach Visite zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-11 (Anhang): Rücklaufquoten nach Visite zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 1.2.2 EQ-5D-5L VAS Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	294 (99.3%)	165 (100.0%)	129 (98.5%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	145 (87.9%)	65 (49.6%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	80 (48.5%)	32 (24.4%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	93 (31.4%)	70 (42.4%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	45 (15.2%)	33 (20.0%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010111	1 (0.3%)	0 (0.0%)	1 (0.8%)
	011100	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	2 (1.2%)	3 (2.3%)
	111000	49 (16.6%)	35 (21.2%)	14 (10.7%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111100	32 (10.8%)	20 (12.1%)	12 (9.2%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	10 (6.1%)	6 (4.6%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	2 (0.7%)	0 (0.0%)	2 (1.5%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	85 (28.7%)	20 (12.1%)	65 (49.6%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	38 (23.0%)	16 (12.2%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	105 (63.6%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	2 (0.7%)	0 (0.0%)	2 (1.5%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	85 (28.7%)	20 (12.1%)	65 (49.6%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	38 (23.0%)	16 (12.2%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	36 (12.2%)	22 (13.3%)	14 (10.7%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	10 (6.1%)	6 (4.6%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	7 (4.2%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	8 (4.8%)	5 (3.8%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: QoL, quality of life; VAS, visual analog scale; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Anhang 4-G2.4.2: Mittelwert und Veränderung zu Screening zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-12 (Anhang): Mittelwert und Veränderung zu Screening zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 3.2.2 EQ-5D-5L VAS Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	294	165	129
	Mean (STDEV)	73.3 (19.3)	72.4 (18.7)	74.4 (20.1)
	Median (Q1, Q3)	80.0 (60.0, 90.0)	75.0 (60.0, 85.0)	80.0 (65.0, 90.0)
	Min, Max	10.0, 100.0	20.0, 100.0	10.0, 100.0
	95% CI	71.0, 75.5	69.5, 75.2	70.9, 77.9
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	70.1 (20.2)	70.2 (19.8)	69.9 (20.9)
	Median (Q1, Q3)	75.0 (60.0, 85.0)	75.0 (60.0, 85.0)	70.0 (55.0, 90.0)
	Min, Max	5.0, 100.0	15.0, 100.0	5.0, 100.0
	95% CI	67.7, 72.4	67.1, 73.2	66.2, 73.6
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-3.0 (17.9)	-1.9 (18.7)	-4.4 (16.7)
	Median (Q1, Q3)	0.0 (-15.0, 5.0)	0.0 (-10.0, 10.0)	0.0 (-15.0, 5.0)
	Min, Max	-55.0, 60.0	-55.0, 60.0	-50.0, 50.0
	95% CI	-5.1, -0.9	-4.8, 1.0	-7.4, -1.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	65 (22.6%)	41 (25.2%)	24 (19.4%)
	Stable	121 (42.2%)	69 (42.3%)	52 (41.9%)
	Worsened	101 (35.2%)	53 (32.5%)	48 (38.7%)
Study Day 100				
Score at Study Day 100	n	210	145	65
	Mean (STDEV)	74.8 (18.8)	77.1 (18.2)	69.7 (19.2)
	Median (Q1, Q3)	80.0 (65.0, 90.0)	80.0 (70.0, 90.0)	70.0 (60.0, 85.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	10.0, 100.0	10.0, 100.0	20.0, 97.0
	95% CI	72.2, 77.3	74.1, 80.1	64.9, 74.4
Change from Screening at Study Day 100	n	209	145	64
	Mean (STDEV)	0.2 (19.6)	4.0 (18.4)	-8.2 (19.8)
	Median (Q1, Q3)	0.0 (-10.0, 10.0)	5.0 (-5.0, 15.0)	-5.0 (-20.0, 5.0)
	Min, Max	-70.0, 52.0	-70.0, 52.0	-70.0, 35.0
	95% CI	-2.4, 2.9	1.0, 7.0	-13.1, -3.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	70 (33.5%)	60 (41.4%)	10 (15.6%)
	Stable	84 (40.2%)	58 (40.0%)	26 (40.6%)
	Worsened	55 (26.3%)	27 (18.6%)	28 (43.8%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	78.8 (17.4)	81.0 (15.3)	74.5 (20.2)
	Median (Q1, Q3)	80.0 (70.0, 90.0)	85.0 (75.0, 90.0)	80.0 (62.5, 90.0)
	Min, Max	6.0, 100.0	20.0, 100.0	6.0, 100.0
	95% CI	76.2, 81.5	78.1, 83.9	69.1, 79.9
Change from Screening at Study Day 150	n	164	110	54
	Mean (STDEV)	5.4 (21.0)	9.1 (19.4)	-2.2 (22.2)
	Median (Q1, Q3)	5.0 (-5.0, 15.0)	5.0 (-5.0, 20.0)	0.0 (-10.0, 10.0)
	Min, Max	-55.0, 56.0	-45.0, 56.0	-55.0, 53.0
	95% CI	2.2, 8.7	5.5, 12.8	-8.2, 3.9
Percent Improved, Stable, or Worsened at Study Day 150	Improved	72 (43.9%)	54 (49.1%)	18 (33.3%)
	Stable	56 (34.1%)	38 (34.5%)	18 (33.3%)
	Worsened	36 (22.0%)	18 (16.4%)	18 (33.3%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	81.1 (15.3)	81.3 (14.0)	80.8 (17.9)
	Median (Q1, Q3)	85.0 (75.0, 90.0)	85.0 (75.0, 90.0)	85.0 (77.5, 92.5)
	Min, Max	10.0, 100.0	40.0, 100.0	10.0, 100.0
	95% CI	78.5, 83.8	78.3, 84.2	75.1, 86.6
Change from Screening at Study Month 9	n	127	88	39
	Mean (STDEV)	9.3 (19.8)	11.4 (19.9)	4.4 (19.0)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	8.0 (0.0, 15.0)
	Min, Max	-50.0, 60.0	-45.0, 60.0	-50.0, 35.0
	95% CI	5.8, 12.7	7.2, 15.6	-1.8, 10.6
Percent Improved, Stable, or Worsened at Study Month 9	Improved	73 (57.5%)	53 (60.2%)	20 (51.3%)
	Stable	38 (29.9%)	25 (28.4%)	13 (33.3%)
	Worsened	16 (12.6%)	10 (11.4%)	6 (15.4%)
Study Month 12				
Score at Study Month 12	n	112	80	32
	Mean (STDEV)	81.2 (17.5)	80.7 (18.3)	82.5 (15.6)
	Median (Q1, Q3)	89.5 (75.0, 93.5)	85.0 (75.0, 93.5)	90.0 (77.5, 92.5)
	Min, Max	8.0, 100.0	8.0, 100.0	50.0, 100.0
	95% CI	77.9, 84.5	76.6, 84.8	76.9, 88.1
Change from Screening at Study Month 12	n	111	80	31
	Mean (STDEV)	9.1 (19.3)	10.1 (19.9)	6.6 (17.8)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	5.0 (-5.0, 15.0)
	Min, Max	-72.0, 60.0	-72.0, 60.0	-35.0, 40.0
	95% CI	5.5, 12.8	5.7, 14.6	0.0, 13.1
Percent Improved, Stable, or Worsened at Study Month 12	Improved	62 (55.9%)	47 (58.8%)	15 (48.4%)
	Stable	33 (29.7%)	24 (30.0%)	9 (29.0%)
	Worsened	16 (14.4%)	9 (11.3%)	7 (22.6%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	82.1 (17.5)	80.5 (19.0)	86.3 (12.5)
	Median (Q1, Q3)	90.0 (75.0, 95.0)	85.0 (75.0, 95.0)	90.0 (85.0, 95.0)
	Min, Max	20.0, 100.0	20.0, 100.0	50.0, 99.0
	95% CI	78.5, 85.7	75.9, 85.1	81.2, 91.3
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	10.0 (18.9)	10.7 (20.7)	8.2 (13.7)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	9.0 (-5.0, 15.0)
	Min, Max	-45.0, 60.0	-45.0, 60.0	-15.0, 40.0
	95% CI	6.1, 13.9	5.7, 15.8	2.6, 13.7
Percent Improved, Stable, or Worsened at Study Month 15	Improved	52 (55.9%)	38 (56.7%)	14 (53.8%)
	Stable	29 (31.2%)	20 (29.9%)	9 (34.6%)
	Worsened	12 (12.9%)	9 (13.4%)	3 (11.5%)
Study Month 18				
Score at Study Month 18	n	93	70	23
	Mean (STDEV)	85.1 (11.8)	85.2 (12.3)	84.6 (10.6)
	Median (Q1, Q3)	86.0 (80.0, 95.0)	90.0 (80.0, 95.0)	80.0 (80.0, 95.0)
	Min, Max	40.0, 100.0	40.0, 100.0	55.0, 100.0
	95% CI	82.6, 87.5	82.3, 88.2	80.0, 89.2
Change from Screening at Study Month 18	n	93	70	23
	Mean (STDEV)	13.7 (16.4)	15.1 (17.1)	9.3 (13.6)
	Median (Q1, Q3)	13.0 (0.0, 20.0)	11.5 (2.0, 22.0)	15.0 (-5.0, 20.0)
	Min, Max	-15.0, 70.0	-15.0, 70.0	-15.0, 30.0
	95% CI	10.3, 17.1	11.0, 19.2	3.4, 15.2
Percent Improved, Stable, or Worsened at Study Month 18	Improved	58 (62.4%)	45 (64.3%)	13 (56.5%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	29 (31.2%)	22 (31.4%)	7 (30.4%)
	Worsened	6 (6.5%)	3 (4.3%)	3 (13.0%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	86.1 (13.3)	85.8 (14.6)	86.7 (10.0)
	Median (Q1, Q3)	90.0 (80.0, 95.0)	90.0 (80.0, 95.0)	90.0 (79.5, 95.0)
	Min, Max	40.0, 100.0	40.0, 100.0	70.0, 99.0
	95% CI	82.8, 89.3	81.4, 90.2	82.0, 91.3
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	12.8 (16.3)	14.0 (17.2)	10.1 (14.3)
	Median (Q1, Q3)	10.0 (3.0, 20.0)	12.0 (2.0, 20.0)	9.5 (4.0, 17.5)
	Min, Max	-25.0, 60.0	-25.0, 60.0	-20.0, 45.0
	95% CI	8.7, 16.8	8.8, 19.1	3.4, 16.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	41 (63.1%)	29 (64.4%)	12 (60.0%)
	Stable	19 (29.2%)	13 (28.9%)	6 (30.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	45	33	12
	Mean (STDEV)	85.2 (14.9)	82.8 (16.4)	91.9 (5.5)
	Median (Q1, Q3)	90.0 (80.0, 95.0)	85.0 (80.0, 95.0)	92.5 (90.0, 96.0)
	Min, Max	20.0, 100.0	20.0, 100.0	80.0, 99.0
	95% CI	80.8, 89.7	77.0, 88.6	88.4, 95.4
Change from Screening at Study Month 24	n	45	33	12
	Mean (STDEV)	11.2 (17.8)	10.9 (18.8)	12.2 (15.3)
	Median (Q1, Q3)	15.0 (0.0, 20.0)	15.0 (0.0, 20.0)	13.5 (1.5, 23.0)
	Min, Max	-45.0, 50.0	-45.0, 50.0	-15.0, 40.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	5.9, 16.6	4.2, 17.5	2.4, 21.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	28 (62.2%)	21 (63.6%)	7 (58.3%)
	Stable	12 (26.7%)	8 (24.2%)	4 (33.3%)
	Worsened	5 (11.1%)	4 (12.1%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation; VAS, visual analog scale.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Anhang 4-G2.4.3: MMRM-Analyse und Verlaufskurven zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-13 (Anhang): Ergebnisse der MMRM Analyse zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 4.2.2 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	8056.7		
	AIC (Smaller is Better)	8098.7		
	AICC (Smaller is Better)	8099.7		
	BIC (Smaller is Better)	8176.2		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-3.0 (-6.7, 0.7)	-5.4 (-9.3, -1.4)
	Difference in Mean Change from Screening (95% CI)		2.4 (-1.8, 6.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		3.3 (-0.5, 7.2)	-10.3 (-15.2, -5.5)
	Difference in Mean Change from Screening (95% CI)		13.7 (8.5, 18.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.3 (3.1, 11.5)	-3.9 (-9.2, 1.4)
	Difference in Mean Change from Screening (95% CI)		11.3 (5.4, 17.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		8.3 (4.1, 12.6)	4.5 (-1.1, 10.1)
	Difference in Mean Change from Screening (95% CI)		3.8 (-2.3, 10.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		7.2 (2.9, 11.6)	7.0 (1.1, 12.9)
	Difference in Mean Change from Screening (95% CI)		0.3 (-6.3, 6.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		6.3 (1.7, 10.9)	9.7 (3.4, 16.0)
	Difference in Mean Change from Screening (95% CI)		-3.4 (-10.4, 3.6)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	8042.3		
	AIC (Smaller is Better)	8084.3		
	AICC (Smaller is Better)	8085.3		
	BIC (Smaller is Better)	8161.8		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.0 (-8.9, 0.9)	-5.9 (-10.9, -0.9)
	Difference in Mean Change from Screening (95% CI)		1.9 (-2.8, 6.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		2.3 (-2.7, 7.3)	-10.9 (-16.3, -5.6)
	Difference in Mean Change from Screening (95% CI)		13.2 (7.9, 18.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.2 (0.9, 11.6)	-4.5 (-10.4, 1.3)
	Difference in Mean Change from Screening (95% CI)		10.8 (4.7, 16.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		7.2 (1.8, 12.6)	3.8 (-2.3, 9.9)
	Difference in Mean Change from Screening (95% CI)		3.4 (-3.0, 9.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.1 (0.6, 11.6)	6.3 (-0.1, 12.7)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-6.9, 6.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.2 (-0.5, 10.8)	9.1 (2.3, 15.9)
	Difference in Mean Change from Screening (95% CI)		-3.9 (-11.1, 3.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	7945.5		
	AIC (Smaller is Better)	7987.5		
	AICC (Smaller is Better)	7988.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8065		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.1 (-14.6, 0.5)	-6.5 (-13.8, 0.7)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-5.1, 4.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.7 (-8.4, 6.9)	-11.7 (-19.2, -4.1)
	Difference in Mean Change from Screening (95% CI)		10.9 (5.4, 16.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.1 (-4.7, 11.0)	-5.2 (-13.1, 2.6)
	Difference in Mean Change from Screening (95% CI)		8.4 (2.3, 14.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.0 (-3.8, 11.9)	3.0 (-5.0, 11.0)
	Difference in Mean Change from Screening (95% CI)		1.0 (-5.3, 7.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.9 (-5.0, 10.8)	5.5 (-2.9, 13.9)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-9.4, 4.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		2.0 (-6.1, 10.0)	8.2 (-0.4, 16.9)
	Difference in Mean Change from Screening (95% CI)		-6.3 (-13.5, 1.0)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; nd, not displayed; VAS, visual analog scale.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 7 (Anhang): Verlaufskurven zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

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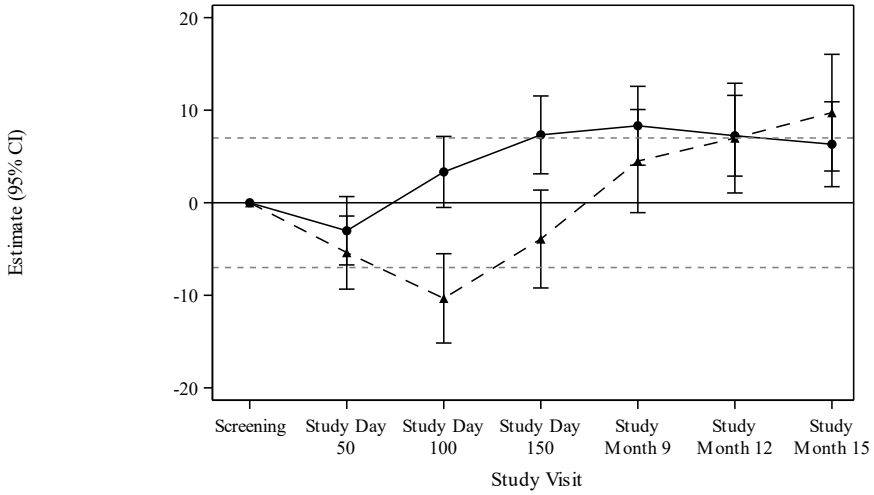
Figure 4.2.2.1 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	145	110	88	80	67
Standard of Care Therapy	129	126	65	56	40	32	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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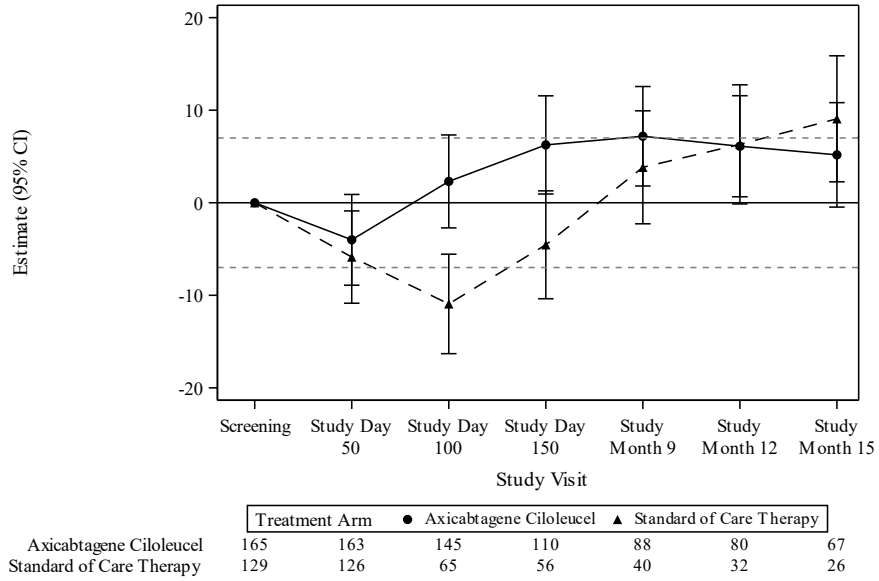
Figure 4.2.2.2 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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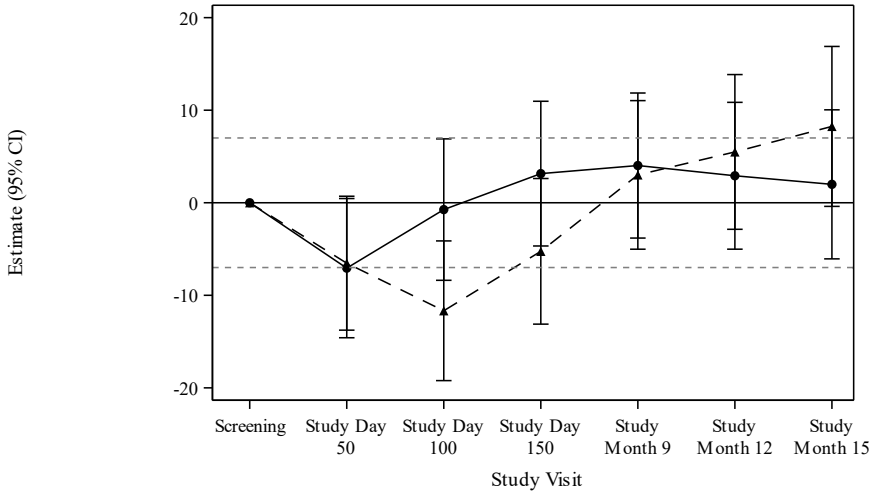
Figure 4.2.2.3 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	145	110	88	80	67
Standard of Care Therapy	129	126	65	56	40	32	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Anhang 4-G2.4.4: Zeit bis zur ersten Verbesserung zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-14 (Anhang): Zeit bis zur ersten Verbesserung der EQ-5D VAS (MID 15 Punkte) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Time to first improvement among patients who had improvement by treatment

PRO*	Arm	Number of patients with improvement (N)	Median time to improvement (Months)	Median time to improvement (Days)
EQ-5D-5L VAS (MID = 15)	Axi-cel	27	3.68	112
	SOC	12	10.71	325.5

* The minimally important difference (MID) is 10 points for EORTC QLQ-C30 measures, and it is 15 points for EQ-5D-5L VAS score.
QoL analysis set overall: N=165 for Axi-cel, N=131 for SOC
Datacut: 18 March 2021

Anhang 4-G2.5: Ergänzende Darstellung zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.5.1: Rücklaufquoten nach Visite zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-15 (Anhang): Rücklaufquoten nach Visite zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 1.1.07 EORTC QLQ-C30 Fatigue Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.08 EORTC QLQ-C30 Nausea and Vomiting Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.09 EORTC QLQ-C30 Pain Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	97 (32.8%)	73 (44.2%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	150 (50.7%)	106 (64.2%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.10 EORTC QLQ-C30 Dyspnea Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	145 (87.9%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	100000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	18 (10.9%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	34 (20.6%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	20 (12.1%)	66 (50.4%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	20 (12.1%)	66 (50.4%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.11 EORTC QLQ-C30 Insomnia Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.12 EORTC QLQ-C30 Appetite Loss Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	64 (21.6%)	44 (26.7%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	72 (43.6%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	105 (63.6%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	11 (3.7%)	6 (3.6%)	5 (3.8%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.13 EORTC QLQ-C30 Constipation Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	127 (42.9%)	87 (52.7%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	77 (26.0%)	17 (10.3%)	60 (45.8%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	5 (1.7%)	3 (1.8%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	71 (43.0%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	38 (12.8%)	23 (13.9%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	19 (6.4%)	13 (7.9%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.14 EORTC QLQ-C30 Diarrhea Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	287 (97.0%)	163 (98.8%)	124 (94.7%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	3 (1.0%)	0 (0.0%)	3 (2.3%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	46 (15.5%)	35 (21.2%)	11 (8.4%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	9 (3.0%)	2 (1.2%)	7 (5.3%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	51 (17.2%)	38 (23.0%)	13 (9.9%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	9 (3.0%)	2 (1.2%)	7 (5.3%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	51 (17.2%)	38 (23.0%)	13 (9.9%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Anhang 4-G2.5.2: Mittelwert und Veränderung zu Screening zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-16 (Anhang): Mittelwert und Veränderung zu Screening zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 3.1.07 EORTC QLQ-C30 Fatigue Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	29.7 (23.5)	31.6 (23.9)	27.4 (22.9)
	Median (Q1, Q3)	22.2 (11.1, 33.3)	33.3 (11.1, 44.4)	22.2 (11.1, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	27.1, 32.4	27.9, 35.3	23.4, 31.4
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	42.3 (26.1)	43.9 (27.9)	40.2 (23.6)
	Median (Q1, Q3)	33.3 (22.2, 66.7)	33.3 (33.3, 66.7)	33.3 (22.2, 55.6)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	39.2, 45.3	39.6, 48.2	36.0, 44.3
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	12.2 (25.5)	12.2 (27.0)	12.2 (23.5)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (-11.1, 33.3)	11.1 (0.0, 22.2)
	Min, Max	-66.7, 88.9	-55.6, 88.9	-66.7, 66.7
	95% CI	9.2, 15.1	8.0, 16.3	8.1, 16.4
Percent Improved, Stable, or Worsened at Study Day 50	Improved	66 (22.8%)	43 (26.4%)	23 (18.3%)
	Stable	57 (19.7%)	31 (19.0%)	26 (20.6%)
	Worsened	166 (57.4%)	89 (54.6%)	77 (61.1%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	32.9 (27.4)	29.1 (25.6)	41.5 (29.4)
	Median (Q1, Q3)	33.3 (11.1, 44.4)	33.3 (0.0, 44.4)	33.3 (22.2, 66.7)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	29.2, 36.6	25.0, 33.3	34.1, 48.8
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	3.9 (24.4)	-2.5 (21.0)	18.6 (25.6)
	Median (Q1, Q3)	0.0 (-11.1, 22.2)	0.0 (-11.1, 11.1)	16.7 (0.0, 33.3)
	Min, Max	-66.7, 77.8	-55.6, 66.7	-66.7, 77.8
	95% CI	0.6, 7.3	-5.9, 1.0	12.2, 25.0
Percent Improved, Stable, or Worsened at Study Day 100	Improved	65 (31.0%)	57 (39.0%)	8 (12.5%)
	Stable	61 (29.0%)	48 (32.9%)	13 (20.3%)
	Worsened	84 (40.0%)	41 (28.1%)	43 (67.2%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	27.7 (23.4)	24.6 (22.9)	33.9 (23.3)
	Median (Q1, Q3)	33.3 (11.1, 33.3)	22.2 (0.0, 33.3)	33.3 (22.2, 44.4)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	24.1, 31.3	20.2, 28.9	27.7, 40.2
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-1.7 (24.7)	-7.8 (22.9)	10.3 (23.8)
	Median (Q1, Q3)	0.0 (-11.1, 11.1)	-11.1 (-22.2, 0.0)	11.1 (0.0, 22.2)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-5.5, 2.1	-12.2, -3.5	4.0, 16.7
Percent Improved, Stable, or Worsened at Study Day 150	Improved	68 (41.2%)	58 (53.2%)	10 (17.9%)
	Stable	47 (28.5%)	30 (27.5%)	17 (30.4%)
	Worsened	50 (30.3%)	21 (19.3%)	29 (51.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	23.1 (21.9)	21.3 (22.2)	26.9 (21.2)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	22.2 (0.0, 33.3)	22.2 (11.1, 38.9)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 77.8
	95% CI	19.3, 26.9	16.6, 26.0	20.2, 33.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-8.0 (27.0)	-12.2 (23.6)	1.4 (31.4)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-22.2, 22.2)
	Min, Max	-66.7, 88.9	-66.7, 88.9	-66.7, 77.8
	95% CI	-12.7, -3.3	-17.3, -7.2	-8.7, 11.4
Percent Improved, Stable, or Worsened at Study Month 9	Improved	66 (51.6%)	51 (58.0%)	15 (37.5%)
	Stable	33 (25.8%)	23 (26.1%)	10 (25.0%)
	Worsened	29 (22.7%)	14 (15.9%)	15 (37.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	22.3 (23.6)	23.3 (24.4)	19.9 (21.8)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	22.2 (0.0, 33.3)	11.1 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 88.9
	95% CI	17.9, 26.7	17.9, 28.8	12.1, 27.6
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.6 (23.9)	-11.4 (21.3)	-5.4 (29.0)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-22.2, 11.1)
	Min, Max	-77.8, 66.7	-66.7, 33.3	-77.8, 66.7
	95% CI	-14.1, -5.2	-16.2, -6.6	-15.7, 4.9
Percent Improved, Stable, or Worsened at Study Month 12	Improved	63 (56.3%)	47 (59.5%)	16 (48.5%)
	Stable	25 (22.3%)	20 (25.3%)	5 (15.2%)
	Worsened	24 (21.4%)	12 (15.2%)	12 (36.4%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	21.6 (23.6)	23.2 (25.2)	17.5 (18.9)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	16.8, 26.5	17.1, 29.4	9.9, 25.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-10.3 (23.9)	-12.3 (25.7)	-5.1 (17.8)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-11.1, 11.1)
	Min, Max	-66.7, 44.4	-66.7, 44.4	-55.6, 22.2
	95% CI	-15.2, -5.4	-18.5, -6.0	-12.3, 2.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	52 (55.9%)	41 (61.2%)	11 (42.3%)
	Stable	22 (23.7%)	14 (20.9%)	8 (30.8%)
	Worsened	19 (20.4%)	12 (17.9%)	7 (26.9%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	20.3 (21.5)	20.3 (23.4)	20.3 (14.5)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	11.1 (0.0, 33.3)	22.2 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 44.4
	95% CI	15.9, 24.7	14.8, 25.9	14.0, 26.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-11.1 (22.5)	-13.8 (22.7)	-2.9 (20.2)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-33.3, 0.0)	0.0 (-11.1, 11.1)
	Min, Max	-77.8, 33.3	-77.8, 33.3	-55.6, 33.3
	95% CI	-15.7, -6.5	-19.2, -8.4	-11.6, 5.8
Percent Improved, Stable, or Worsened at Study Month 18	Improved	50 (53.2%)	40 (56.3%)	10 (43.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	24 (25.5%)	20 (28.2%)	4 (17.4%)
	Worsened	20 (21.3%)	11 (15.5%)	9 (39.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	17.8 (20.2)	18.3 (22.4)	16.7 (14.6)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (0.0, 33.3)	22.2 (0.0, 27.8)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 44.4
	95% CI	12.8, 22.8	11.6, 25.0	9.8, 23.5
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-14.0 (24.2)	-16.8 (24.1)	-7.8 (23.9)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-27.8, 11.1)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-55.6, 33.3
	95% CI	-20.0, -8.0	-24.0, -9.5	-19.0, 3.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	36 (55.4%)	27 (60.0%)	9 (45.0%)
	Stable	19 (29.2%)	14 (31.1%)	5 (25.0%)
	Worsened	10 (15.4%)	4 (8.9%)	6 (30.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	19.4 (21.6)	21.9 (23.4)	13.0 (14.9)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	16.7 (0.0, 33.3)	5.6 (0.0, 27.8)
	Min, Max	0.0, 77.8	0.0, 77.8	0.0, 33.3
	95% CI	12.9, 26.0	13.5, 30.3	3.5, 22.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-12.6 (23.3)	-14.2 (25.6)	-8.3 (15.8)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	-5.6 (-22.2, 5.6)
	Min, Max	-88.9, 33.3	-88.9, 33.3	-33.3, 11.1

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-19.7, -5.5	-23.5, -5.0	-18.4, 1.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	26 (59.1%)	20 (62.5%)	6 (50.0%)
	Stable	8 (18.2%)	5 (15.6%)	3 (25.0%)
	Worsened	10 (22.7%)	7 (21.9%)	3 (25.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.08 EORTC QLQ-C30 Nausea and Vomiting Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	4.8 (12.4)	5.8 (13.0)	3.6 (11.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 83.3	0.0, 66.7	0.0, 83.3
	95% CI	3.4, 6.2	3.8, 7.8	1.5, 5.6
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	8.4 (15.7)	7.1 (14.5)	10.2 (17.0)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 83.3	0.0, 100.0
	95% CI	6.6, 10.2	4.8, 9.3	7.2, 13.2
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	3.6 (18.9)	1.2 (18.3)	6.6 (19.2)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 83.3	-66.7, 83.3	-83.3, 83.3
	95% CI	1.4, 5.8	-1.6, 4.1	3.2, 10.0
Percent Improved, Stable, or Worsened at Study Day 50	Improved	34 (11.8%)	23 (14.1%)	11 (8.7%)
	Stable	176 (60.9%)	103 (63.2%)	73 (57.9%)
	Worsened	79 (27.3%)	37 (22.7%)	42 (33.3%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	8.8 (19.4)	6.1 (16.4)	15.1 (23.9)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	6.2, 11.4	3.4, 8.7	9.1, 21.1
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	4.0 (20.7)	0.7 (16.5)	11.7 (26.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 100.0	-50.0, 83.3	-83.3, 100.0
	95% CI	1.2, 6.9	-2.0, 3.4	5.1, 18.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	23 (11.0%)	20 (13.7%)	3 (4.7%)
	Stable	145 (69.0%)	109 (74.7%)	36 (56.3%)
	Worsened	42 (20.0%)	17 (11.6%)	25 (39.1%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	5.9 (13.1)	4.6 (12.0)	8.3 (14.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	3.8, 7.9	2.3, 6.9	4.3, 12.3
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	1.5 (14.2)	-0.6 (12.2)	5.7 (16.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-50.0, 66.7	-33.3, 33.3	-50.0, 66.7
	95% CI	-0.7, 3.7	-2.9, 1.7	1.1, 10.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	21 (12.7%)	17 (15.6%)	4 (7.1%)
	Stable	114 (69.1%)	78 (71.6%)	36 (64.3%)
	Worsened	30 (18.2%)	14 (12.8%)	16 (28.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	4.2 (10.9)	4.5 (11.8)	3.3 (8.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	2.3, 6.1	2.0, 7.0	0.6, 6.1
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-1.7 (16.2)	-1.5 (15.3)	-2.1 (18.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-83.3, 66.7	-50.0, 66.7	-83.3, 33.3
	95% CI	-4.5, 1.1	-4.8, 1.7	-7.9, 3.7
Percent Improved, Stable, or Worsened at Study Month 9	Improved	21 (16.4%)	16 (18.2%)	5 (12.5%)
	Stable	95 (74.2%)	64 (72.7%)	31 (77.5%)
	Worsened	12 (9.4%)	8 (9.1%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	4.5 (11.4)	4.4 (10.9)	4.5 (12.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	2.3, 6.6	2.0, 6.9	0.0, 9.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-0.7 (14.2)	-1.5 (13.4)	1.0 (16.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 33.3	-50.0, 66.7
	95% CI	-3.4, 1.9	-4.5, 1.5	-4.7, 6.7
Percent Improved, Stable, or Worsened at Study Month 12	Improved	16 (14.3%)	13 (16.5%)	3 (9.1%)
	Stable	83 (74.1%)	57 (72.2%)	26 (78.8%)
	Worsened	13 (11.6%)	9 (11.4%)	4 (12.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	3.8 (13.9)	4.5 (15.8)	1.9 (7.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	0.9, 6.6	0.6, 8.3	-1.0, 4.8
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-0.2 (14.6)	-0.5 (16.9)	0.6 (5.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 100.0	-50.0, 100.0	-16.7, 16.7
	95% CI	-3.2, 2.8	-4.6, 3.6	-1.7, 3.0
Percent Improved, Stable, or Worsened at Study Month 15	Improved	12 (12.9%)	11 (16.4%)	1 (3.8%)
	Stable	74 (79.6%)	51 (76.1%)	23 (88.5%)
	Worsened	7 (7.5%)	5 (7.5%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	3.2 (11.8)	3.1 (12.1)	3.6 (11.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0
	95% CI	0.8, 5.6	0.2, 5.9	-1.2, 8.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-1.6 (11.2)	-2.1 (10.1)	0.0 (14.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 33.3	-33.3, 33.3	-50.0, 33.3
	95% CI	-3.9, 0.7	-4.5, 0.3	-6.1, 6.1
Percent Improved, Stable, or Worsened at Study Month 18	Improved	13 (13.8%)	11 (15.5%)	2 (8.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	74 (78.7%)	56 (78.9%)	18 (78.3%)
	Worsened	7 (7.4%)	4 (5.6%)	3 (13.0%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	3.8 (14.7)	5.2 (17.3)	0.8 (3.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 16.7
	95% CI	0.2, 7.5	-0.0, 10.4	-0.9, 2.6
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	0.3 (16.0)	2.2 (16.9)	-4.2 (13.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 100.0	-16.7, 100.0	-50.0, 16.7
	95% CI	-3.7, 4.2	-2.9, 7.3	-10.3, 2.0
Percent Improved, Stable, or Worsened at Study Month 21	Improved	8 (12.3%)	4 (8.9%)	4 (20.0%)
	Stable	52 (80.0%)	37 (82.2%)	15 (75.0%)
	Worsened	5 (7.7%)	4 (8.9%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	3.4 (9.2)	4.2 (10.4)	1.4 (4.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 50.0	0.0, 50.0	0.0, 16.7
	95% CI	0.6, 6.2	0.4, 7.9	-1.7, 4.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	0.0 (12.5)	0.5 (14.3)	-1.4 (4.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-33.3, 50.0	-33.3, 50.0	-16.7, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-3.8, 3.8	-4.7, 5.7	-4.4, 1.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	7 (15.9%)	6 (18.8%)	1 (8.3%)
	Stable	31 (70.5%)	20 (62.5%)	11 (91.7%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.09 EORTC QLQ-C30 Pain Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	26.0 (28.4)	25.9 (26.6)	26.1 (30.7)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	22.7, 29.2	21.8, 29.9	20.8, 31.4
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	21.4 (26.3)	21.1 (25.8)	21.8 (27.0)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	18.3, 24.4	17.1, 25.1	17.1, 26.6
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-4.6 (26.8)	-4.9 (26.7)	-4.1 (27.0)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-83.3, 100.0	-83.3, 83.3	-66.7, 100.0
	95% CI	-7.7, -1.5	-9.0, -0.8	-8.9, 0.7
Percent Improved, Stable, or Worsened at Study Day 50	Improved	106 (36.7%)	65 (39.9%)	41 (32.5%)
	Stable	118 (40.8%)	59 (36.2%)	59 (46.8%)
	Worsened	65 (22.5%)	39 (23.9%)	26 (20.6%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	19.2 (26.3)	21.5 (28.0)	14.1 (21.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 25.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	15.6, 22.8	16.9, 26.0	8.7, 19.4
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-4.5 (24.8)	-3.4 (23.6)	-7.0 (27.3)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-83.3, 66.7	-66.7, 66.7	-83.3, 50.0
	95% CI	-7.9, -1.1	-7.3, 0.4	-13.9, -0.2
Percent Improved, Stable, or Worsened at Study Day 100	Improved	73 (34.8%)	50 (34.2%)	23 (35.9%)
	Stable	94 (44.8%)	64 (43.8%)	30 (46.9%)
	Worsened	43 (20.5%)	32 (21.9%)	11 (17.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	16.5 (22.9)	19.1 (24.7)	11.3 (18.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 83.3
	95% CI	13.0, 20.0	14.4, 23.8	6.5, 16.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-6.5 (26.5)	-4.5 (25.0)	-10.4 (29.1)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-100.0, 83.3	-66.7, 83.3	-100.0, 33.3
	95% CI	-10.6, -2.5	-9.3, 0.2	-18.2, -2.6
Percent Improved, Stable, or Worsened at Study Day 150	Improved	59 (35.5%)	37 (33.6%)	22 (39.3%)
	Stable	71 (42.8%)	50 (45.5%)	21 (37.5%)
	Worsened	36 (21.7%)	23 (20.9%)	13 (23.2%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	15.8 (23.0)	18.0 (23.5)	10.8 (21.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 83.3
	95% CI	11.7, 19.8	13.0, 23.0	3.9, 17.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-8.9 (25.6)	-5.9 (24.1)	-15.4 (27.8)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 8.3)	-16.7 (-33.3, 0.0)
	Min, Max	-83.3, 50.0	-66.7, 50.0	-83.3, 33.3
	95% CI	-13.3, -4.4	-11.0, -0.8	-24.3, -6.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	55 (43.0%)	33 (37.5%)	22 (55.0%)
	Stable	45 (35.2%)	33 (37.5%)	12 (30.0%)
	Worsened	28 (21.9%)	22 (25.0%)	6 (15.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	15.0 (22.8)	17.5 (25.2)	9.1 (14.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 50.0
	95% CI	10.8, 19.3	11.9, 23.1	4.0, 14.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.4 (26.2)	-7.2 (25.7)	-14.6 (26.9)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 33.3
	95% CI	-14.3, -4.5	-12.9, -1.4	-24.2, -5.1
Percent Improved, Stable, or Worsened at Study Month 12	Improved	48 (42.9%)	30 (38.0%)	18 (54.5%)
	Stable	46 (41.1%)	35 (44.3%)	11 (33.3%)
	Worsened	18 (16.1%)	14 (17.7%)	4 (12.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	13.8 (21.9)	16.9 (24.4)	5.8 (10.5)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	9.3, 18.3	11.0, 22.9	1.5, 10.0
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-8.4 (27.4)	-5.2 (27.2)	-16.7 (26.7)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-8.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 16.7
	95% CI	-14.1, -2.8	-11.9, 1.4	-27.4, -5.9
Percent Improved, Stable, or Worsened at Study Month 15	Improved	34 (36.6%)	21 (31.3%)	13 (50.0%)
	Stable	44 (47.3%)	33 (49.3%)	11 (42.3%)
	Worsened	15 (16.1%)	13 (19.4%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	14.7 (20.7)	16.4 (22.6)	9.4 (12.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	10.5, 19.0	11.1, 21.8	4.2, 14.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-9.4 (25.0)	-6.6 (23.7)	-18.1 (27.5)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-100.0, 16.7
	95% CI	-14.5, -4.3	-12.2, -1.0	-30.0, -6.2
Percent Improved, Stable, or Worsened at Study Month 18	Improved	39 (41.5%)	25 (35.2%)	14 (60.9%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	37 (39.4%)	32 (45.1%)	5 (21.7%)
	Worsened	18 (19.1%)	14 (19.7%)	4 (17.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	12.1 (19.4)	14.1 (21.9)	7.5 (11.4)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	7.2, 16.9	7.5, 20.7	2.1, 12.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-13.8 (27.3)	-10.4 (25.7)	-21.7 (29.7)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-41.7, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-100.0, 16.7
	95% CI	-20.6, -7.1	-18.1, -2.7	-35.6, -7.8
Percent Improved, Stable, or Worsened at Study Month 21	Improved	31 (47.7%)	19 (42.2%)	12 (60.0%)
	Stable	24 (36.9%)	18 (40.0%)	6 (30.0%)
	Worsened	10 (15.4%)	8 (17.8%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	13.6 (20.7)	16.1 (22.6)	6.9 (13.2)
	Median (Q1, Q3)	0.0 (0.0, 25.0)	0.0 (0.0, 33.3)	0.0 (0.0, 8.3)
	Min, Max	0.0, 83.3	0.0, 83.3	0.0, 33.3
	95% CI	7.3, 19.9	8.0, 24.3	-1.5, 15.3
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-11.7 (29.5)	-7.3 (31.7)	-23.6 (19.4)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, -16.7)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-66.7, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-20.7, -2.8	-18.7, 4.1	-35.9, -11.3
Percent Improved, Stable, or Worsened at Study Month 24	Improved	21 (47.7%)	11 (34.4%)	10 (83.3%)
	Stable	18 (40.9%)	16 (50.0%)	2 (16.7%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.10 EORTC QLQ-C30 Dyspnea Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	13.1 (21.1)	15.6 (23.4)	9.9 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	10.6, 15.5	12.0, 19.2	6.9, 12.9
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	17.0 (22.4)	16.0 (21.4)	18.4 (23.7)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.4, 19.6	12.6, 19.3	14.2, 22.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	3.6 (24.1)	0.2 (24.7)	8.0 (22.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 66.7	-66.7, 100.0
	95% CI	0.8, 6.4	-3.6, 4.0	4.0, 12.0
Percent Improved, Stable, or Worsened at Study Day 50	Improved	38 (13.2%)	31 (19.0%)	7 (5.6%)
	Stable	185 (64.2%)	98 (60.1%)	87 (69.6%)
	Worsened	65 (22.6%)	34 (20.9%)	31 (24.8%)
Study Day 100				
Score at Study Day 100	n	209	145	64
	Mean (STDEV)	16.9 (25.1)	13.1 (22.0)	25.5 (29.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	13.5, 20.3	9.5, 16.7	18.1, 32.9
Change from Screening at Study Day 100	n	209	145	64
	Mean (STDEV)	3.2 (26.6)	-2.1 (22.3)	15.1 (31.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-33.3, 100.0
	95% CI	-0.4, 6.8	-5.7, 1.6	7.3, 22.9
Percent Improved, Stable, or Worsened at Study Day 100	Improved	35 (16.7%)	28 (19.3%)	7 (10.9%)
	Stable	131 (62.7%)	100 (69.0%)	31 (48.4%)
	Worsened	43 (20.6%)	17 (11.7%)	26 (40.6%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	15.6 (25.4)	12.5 (23.9)	21.4 (27.3)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.7, 19.5	8.0, 17.1	14.1, 28.7
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	1.0 (29.5)	-3.7 (28.8)	10.1 (29.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 100.0
	95% CI	-3.5, 5.6	-9.1, 1.8	2.3, 17.9
Percent Improved, Stable, or Worsened at Study Day 150	Improved	32 (19.4%)	28 (25.7%)	4 (7.1%)
	Stable	104 (63.0%)	67 (61.5%)	37 (66.1%)
	Worsened	29 (17.6%)	14 (12.8%)	15 (26.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	12.0 (22.4)	9.1 (20.7)	18.3 (25.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	8.1, 15.9	4.7, 13.5	10.3, 26.3
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-3.4 (26.1)	-8.0 (24.2)	6.7 (27.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-7.9, 1.2	-13.1, -2.8	-2.1, 15.4
Percent Improved, Stable, or Worsened at Study Month 9	Improved	30 (23.4%)	24 (27.3%)	6 (15.0%)
	Stable	79 (61.7%)	58 (65.9%)	21 (52.5%)
	Worsened	19 (14.8%)	6 (6.8%)	13 (32.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	10.7 (22.0)	12.7 (24.6)	6.1 (13.1)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	6.6, 14.8	7.1, 18.2	1.4, 10.7
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-4.5 (23.0)	-5.1 (24.5)	-3.0 (19.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 33.3
	95% CI	-8.8, -0.2	-10.6, 0.4	-9.9, 3.8
Percent Improved, Stable, or Worsened at Study Month 12	Improved	25 (22.3%)	20 (25.3%)	5 (15.2%)
	Stable	77 (68.8%)	52 (65.8%)	25 (75.8%)
	Worsened	10 (8.9%)	7 (8.9%)	3 (9.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	11.8 (22.3)	12.9 (24.6)	9.0 (15.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	7.2, 16.4	6.9, 18.9	2.9, 15.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-3.6 (27.1)	-6.0 (30.1)	2.6 (16.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-9.2, 2.0	-13.3, 1.4	-3.9, 9.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	20 (21.5%)	18 (26.9%)	2 (7.7%)
	Stable	60 (64.5%)	40 (59.7%)	20 (76.9%)
	Worsened	13 (14.0%)	9 (13.4%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	8.9 (18.4)	9.9 (19.8)	5.8 (12.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	5.1, 12.6	5.2, 14.6	0.2, 11.4
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-8.2 (23.3)	-8.9 (23.9)	-5.8 (21.7)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
	95% CI	-12.9, -3.4	-14.6, -3.3	-15.2, 3.6
Percent Improved, Stable, or Worsened at Study Month 18	Improved	25 (26.6%)	20 (28.2%)	5 (21.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	61 (64.9%)	45 (63.4%)	16 (69.6%)
	Worsened	8 (8.5%)	6 (8.5%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	10.3 (20.3)	9.6 (20.9)	11.7 (19.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	5.2, 15.3	3.4, 15.9	2.5, 20.8
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-7.2 (28.6)	-10.4 (28.3)	0.0 (28.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-66.7, 66.7
	95% CI	-14.3, -0.1	-18.9, -1.9	-13.4, 13.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	19 (29.2%)	15 (33.3%)	4 (20.0%)
	Stable	38 (58.5%)	26 (57.8%)	12 (60.0%)
	Worsened	8 (12.3%)	4 (8.9%)	4 (20.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	10.6 (18.7)	13.5 (20.5)	2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	4.9, 16.3	6.2, 20.9	-3.3, 8.9
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-5.3 (24.8)	-7.3 (27.7)	0.0 (14.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-12.9, 2.3	-17.3, 2.7	-9.0, 9.0
Percent Improved, Stable, or Worsened at Study Month 24	Improved	9 (20.5%)	8 (25.0%)	1 (8.3%)
	Stable	30 (68.2%)	20 (62.5%)	10 (83.3%)
	Worsened	5 (11.4%)	4 (12.5%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.11 EORTC QLQ-C30 Insomnia Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	26.2 (27.7)	27.7 (28.9)	24.4 (26.1)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	23.1, 29.4	23.2, 32.1	19.9, 28.9
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	24.0 (26.7)	24.7 (27.1)	22.9 (26.2)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	20.9, 27.1	20.6, 28.9	18.3, 27.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	-2.3 (30.1)	-3.1 (30.5)	-1.3 (29.8)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 66.7
	95% CI	-5.8, 1.2	-7.8, 1.6	-6.6, 3.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	78 (27.1%)	41 (25.2%)	37 (29.6%)
	Stable	150 (52.1%)	89 (54.6%)	61 (48.8%)
	Worsened	60 (20.8%)	33 (20.2%)	27 (21.6%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	24.0 (28.5)	22.6 (29.5)	27.1 (25.8)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	20.1, 27.8	17.8, 27.4	20.6, 33.5
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-2.5 (32.3)	-5.9 (33.4)	5.2 (28.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 66.7
	95% CI	-6.9, 1.9	-11.4, -0.5	-1.9, 12.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	62 (29.5%)	51 (34.9%)	11 (17.2%)
	Stable	97 (46.2%)	66 (45.2%)	31 (48.4%)
	Worsened	51 (24.3%)	29 (19.9%)	22 (34.4%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	21.0 (26.1)	20.8 (27.1)	21.4 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	17.0, 25.0	15.6, 25.9	15.0, 27.9
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-6.3 (30.0)	-8.6 (29.9)	-1.8 (30.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-10.9, -1.6	-14.2, -2.9	-9.8, 6.3
Percent Improved, Stable, or Worsened at Study Day 150	Improved	53 (32.1%)	36 (33.0%)	17 (30.4%)
	Stable	83 (50.3%)	57 (52.3%)	26 (46.4%)
	Worsened	29 (17.6%)	16 (14.7%)	13 (23.2%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	18.2 (22.5)	18.9 (23.6)	16.7 (20.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	14.3, 22.2	13.9, 23.9	10.3, 23.1
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-11.2 (27.8)	-11.0 (29.3)	-11.7 (24.5)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-66.7, 33.3
	95% CI	-16.1, -6.3	-17.2, -4.8	-19.5, -3.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	52 (40.6%)	36 (40.9%)	16 (40.0%)
	Stable	57 (44.5%)	37 (42.0%)	20 (50.0%)
	Worsened	19 (14.8%)	15 (17.0%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	19.9 (27.4)	21.9 (28.2)	15.2 (25.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.8, 25.1	15.6, 28.3	6.2, 24.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.8 (30.6)	-10.5 (30.9)	-8.1 (30.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-15.5, -4.1	-17.5, -3.6	-18.7, 2.6
Percent Improved, Stable, or Worsened at Study Month 12	Improved	44 (39.3%)	31 (39.2%)	13 (39.4%)
	Stable	51 (45.5%)	37 (46.8%)	14 (42.4%)
	Worsened	17 (15.2%)	11 (13.9%)	6 (18.2%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	18.3 (23.8)	19.9 (26.0)	14.1 (16.8)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	13.4, 23.2	13.6, 26.2	7.3, 20.9
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-11.1 (27.5)	-11.9 (29.4)	-9.0 (22.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 33.3
	95% CI	-16.8, -5.4	-19.1, -4.8	-18.0, 0.0
Percent Improved, Stable, or Worsened at Study Month 15	Improved	35 (37.6%)	27 (40.3%)	8 (30.8%)
	Stable	47 (50.5%)	31 (46.3%)	16 (61.5%)
	Worsened	11 (11.8%)	9 (13.4%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	17.4 (24.8)	16.9 (25.7)	18.8 (22.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	12.3, 22.5	10.8, 23.0	9.3, 28.4
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-12.1 (28.9)	-14.1 (30.2)	-5.8 (23.9)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 66.7
	95% CI	-18.0, -6.1	-21.2, -6.9	-16.1, 4.5
Percent Improved, Stable, or Worsened at Study Month 18	Improved	37 (39.4%)	30 (42.3%)	7 (30.4%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	48 (51.1%)	34 (47.9%)	14 (60.9%)
	Worsened	9 (9.6%)	7 (9.9%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	20.0 (27.5)	22.2 (29.3)	15.0 (22.9)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	13.2, 26.8	13.4, 31.0	4.3, 25.7
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-14.4 (30.6)	-14.8 (33.0)	-13.3 (25.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	-33.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-21.9, -6.8	-24.7, -4.9	-25.1, -1.6
Percent Improved, Stable, or Worsened at Study Month 21	Improved	29 (44.6%)	18 (40.0%)	11 (55.0%)
	Stable	28 (43.1%)	22 (48.9%)	6 (30.0%)
	Worsened	8 (12.3%)	5 (11.1%)	3 (15.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	16.7 (24.4)	19.8 (26.6)	8.3 (15.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	9.3, 24.1	10.2, 29.4	-1.2, 17.9
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-13.6 (27.2)	-13.5 (30.4)	-13.9 (17.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-21.9, -5.4	-24.5, -2.6	-24.8, -3.0
Percent Improved, Stable, or Worsened at Study Month 24	Improved	19 (43.2%)	14 (43.8%)	5 (41.7%)
	Stable	23 (52.3%)	16 (50.0%)	7 (58.3%)
	Worsened	2 (4.5%)	2 (6.3%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.12 EORTC QLQ-C30 Appetite Loss Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	13.6 (22.8)	14.3 (22.8)	12.7 (22.8)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.0, 16.2	10.8, 17.8	8.8, 16.7
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	24.9 (29.2)	28.6 (30.7)	20.1 (26.4)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	21.5, 28.3	23.9, 33.4	15.5, 24.8
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	11.1 (34.5)	14.3 (36.3)	6.9 (31.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 100.0
	95% CI	7.1, 15.1	8.7, 19.9	1.3, 12.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	38 (13.1%)	22 (13.5%)	16 (12.7%)
	Stable	149 (51.6%)	76 (46.6%)	73 (57.9%)
	Worsened	102 (35.3%)	65 (39.9%)	37 (29.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	18.2 (29.6)	13.2 (25.8)	29.6 (34.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 66.7)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.1, 22.2	9.0, 17.5	21.0, 38.3
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	5.4 (30.0)	-0.9 (26.0)	20.1 (33.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 100.0
	95% CI	1.3, 9.5	-5.2, 3.3	11.6, 28.6
Percent Improved, Stable, or Worsened at Study Day 100	Improved	32 (15.3%)	29 (19.9%)	3 (4.8%)
	Stable	125 (59.8%)	92 (63.0%)	33 (52.4%)
	Worsened	52 (24.9%)	25 (17.1%)	27 (42.9%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	11.5 (22.6)	9.2 (21.2)	16.1 (24.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	8.0, 15.0	5.1, 13.2	9.5, 22.7
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-1.6 (25.5)	-5.8 (24.4)	6.5 (25.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-5.5, 2.3	-10.4, -1.2	-0.4, 13.4
Percent Improved, Stable, or Worsened at Study Day 150	Improved	36 (21.8%)	29 (26.6%)	7 (12.5%)
	Stable	102 (61.8%)	69 (63.3%)	33 (58.9%)
	Worsened	27 (16.4%)	11 (10.1%)	16 (28.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	7.6 (20.2)	5.7 (19.1)	11.7 (22.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	4.0, 11.1	1.6, 9.7	4.6, 18.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-6.5 (28.1)	-8.7 (25.5)	-1.7 (32.9)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-11.4, -1.6	-14.1, -3.3	-12.2, 8.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	32 (25.0%)	24 (27.3%)	8 (20.0%)
	Stable	84 (65.6%)	59 (67.0%)	25 (62.5%)
	Worsened	12 (9.4%)	5 (5.7%)	7 (17.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	7.1 (18.1)	5.9 (17.5)	10.1 (19.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	3.7, 10.5	2.0, 9.8	3.2, 17.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-6.5 (27.2)	-8.4 (26.4)	-2.0 (28.8)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
	95% CI	-11.6, -1.5	-14.4, -2.5	-12.2, 8.2
Percent Improved, Stable, or Worsened at Study Month 12	Improved	28 (25.0%)	21 (26.6%)	7 (21.2%)
	Stable	73 (65.2%)	53 (67.1%)	20 (60.6%)
	Worsened	11 (9.8%)	5 (6.3%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	7.2 (20.2)	6.5 (20.3)	9.0 (20.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	3.0, 11.3	1.5, 11.4	0.8, 17.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-6.1 (27.3)	-7.5 (26.5)	-2.6 (29.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-11.7, -0.5	-13.9, -1.0	-14.6, 9.4
Percent Improved, Stable, or Worsened at Study Month 15	Improved	22 (23.7%)	17 (25.4%)	5 (19.2%)
	Stable	64 (68.8%)	47 (70.1%)	17 (65.4%)
	Worsened	7 (7.5%)	3 (4.5%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	6.4 (17.1)	6.1 (17.2)	7.2 (17.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	2.9, 9.9	2.0, 10.2	-0.2, 14.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-8.2 (23.3)	-8.5 (20.9)	-7.2 (30.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
	95% CI	-12.9, -3.4	-13.4, -3.5	-20.3, 5.8
Percent Improved, Stable, or Worsened at Study Month 18	Improved	23 (24.5%)	17 (23.9%)	6 (26.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	66 (70.2%)	51 (71.8%)	15 (65.2%)
	Worsened	5 (5.3%)	3 (4.2%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	64	44	20
	Mean (STDEV)	2.6 (9.0)	3.0 (9.7)	1.7 (7.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3
	95% CI	0.4, 4.9	0.1, 6.0	-1.8, 5.2
Change from Screening at Study Month 21	n	64	44	20
	Mean (STDEV)	-8.9 (23.2)	-6.1 (19.4)	-15.0 (29.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
	95% CI	-14.6, -3.1	-12.0, -0.2	-28.8, -1.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	15 (23.4%)	8 (18.2%)	7 (35.0%)
	Stable	46 (71.9%)	34 (77.3%)	12 (60.0%)
	Worsened	3 (4.7%)	2 (4.5%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	6.1 (19.4)	6.3 (19.7)	5.6 (19.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	0.2, 12.0	-0.9, 13.4	-6.7, 17.8
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-5.3 (22.7)	-8.3 (25.4)	2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	0.0, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-12.2, 1.6	-17.5, 0.8	-3.3, 8.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	7 (15.9%)	7 (21.9%)	0 (0.0%)
	Stable	34 (77.3%)	23 (71.9%)	11 (91.7%)
	Worsened	3 (6.8%)	2 (6.3%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.13 EORTC QLQ-C30 Constipation Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	14.4 (25.1)	14.5 (24.8)	14.2 (25.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.5, 17.3	10.7, 18.4	9.8, 18.7
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	11.9 (21.0)	7.6 (17.1)	17.5 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	9.4, 14.3	4.9, 10.2	13.2, 21.7
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-2.9 (29.6)	-7.2 (27.7)	2.6 (31.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-100.0, 100.0
	95% CI	-6.3, 0.5	-11.4, -2.9	-2.8, 8.1
Percent Improved, Stable, or Worsened at Study Day 50	Improved	60 (20.8%)	42 (25.8%)	18 (14.3%)
	Stable	180 (62.3%)	104 (63.8%)	76 (60.3%)
	Worsened	49 (17.0%)	17 (10.4%)	32 (25.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	9.6 (21.5)	10.5 (23.1)	7.4 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	6.6, 12.5	6.7, 14.3	3.0, 11.8
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-3.7 (26.2)	-3.4 (27.0)	-4.2 (24.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-7.2, -0.1	-7.8, 1.0	-10.4, 1.9
Percent Improved, Stable, or Worsened at Study Day 100	Improved	44 (21.1%)	30 (20.5%)	14 (22.2%)
	Stable	142 (67.9%)	99 (67.8%)	43 (68.3%)
	Worsened	23 (11.0%)	17 (11.6%)	6 (9.5%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	6.9 (17.5)	8.3 (19.9)	4.2 (11.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	4.2, 9.6	4.5, 12.0	1.2, 7.1
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-6.1 (24.2)	-4.3 (24.0)	-9.5 (24.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 33.3
	95% CI	-9.8, -2.3	-8.8, 0.3	-16.1, -3.0
Percent Improved, Stable, or Worsened at Study Day 150	Improved	40 (24.2%)	24 (22.0%)	16 (28.6%)
	Stable	111 (67.3%)	75 (68.8%)	36 (64.3%)
	Worsened	14 (8.5%)	10 (9.2%)	4 (7.1%)
Study Month 9				
Score at Study Month 9	n	127	87	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	6.0 (17.5)	7.7 (20.1)	2.5 (8.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.0, 9.1	3.4, 12.0	-0.3, 5.3
Change from Screening at Study Month 9	n	127	87	40
	Mean (STDEV)	-7.6 (22.3)	-3.8 (17.9)	-15.8 (28.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 33.3
	95% CI	-11.5, -3.7	-7.7, -0.0	-24.9, -6.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	29 (22.8%)	15 (17.2%)	14 (35.0%)
	Stable	92 (72.4%)	67 (77.0%)	25 (62.5%)
	Worsened	6 (4.7%)	5 (5.7%)	1 (2.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	5.7 (17.8)	6.8 (19.5)	3.0 (12.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	2.3, 9.0	2.4, 11.1	-1.5, 7.6
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-7.4 (25.2)	-6.3 (25.1)	-10.1 (25.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 33.3
	95% CI	-12.2, -2.7	-11.9, -0.7	-19.2, -1.0
Percent Improved, Stable, or Worsened at Study Month 12	Improved	27 (24.1%)	18 (22.8%)	9 (27.3%)
	Stable	77 (68.8%)	55 (69.6%)	22 (66.7%)
	Worsened	8 (7.1%)	6 (7.6%)	2 (6.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	7.2 (19.6)	9.0 (22.2)	2.6 (9.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.1, 11.2	3.6, 14.4	-1.1, 6.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-5.4 (19.8)	-2.0 (17.3)	-14.1 (23.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 33.3
	95% CI	-9.5, -1.3	-6.2, 2.2	-23.6, -4.6
Percent Improved, Stable, or Worsened at Study Month 15	Improved	18 (19.4%)	8 (11.9%)	10 (38.5%)
	Stable	70 (75.3%)	55 (82.1%)	15 (57.7%)
	Worsened	5 (5.4%)	4 (6.0%)	1 (3.8%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	5.3 (14.9)	3.8 (14.4)	10.1 (15.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	2.3, 8.4	0.3, 7.2	3.4, 16.9
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-4.3 (19.1)	-4.7 (16.2)	-2.9 (26.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
	95% CI	-8.2, -0.3	-8.5, -0.9	-14.3, 8.5
Percent Improved, Stable, or Worsened at Study Month 18	Improved	18 (19.1%)	12 (16.9%)	6 (26.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	68 (72.3%)	56 (78.9%)	12 (52.2%)
	Worsened	8 (8.5%)	3 (4.2%)	5 (21.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	8.7 (18.9)	9.6 (20.9)	6.7 (13.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	4.0, 13.4	3.4, 15.9	0.3, 13.1
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-0.5 (22.4)	1.5 (23.5)	-5.0 (19.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 33.3
	95% CI	-6.1, 5.0	-5.6, 8.5	-14.2, 4.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	9 (13.8%)	4 (8.9%)	5 (25.0%)
	Stable	48 (73.8%)	35 (77.8%)	13 (65.0%)
	Worsened	8 (12.3%)	6 (13.3%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	5.3 (14.3)	4.2 (11.2)	8.3 (20.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 33.3	0.0, 66.7
	95% CI	1.0, 9.6	0.1, 8.2	-4.8, 21.5
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-3.0 (18.8)	-1.0 (15.8)	-8.3 (25.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-8.7, 2.7	-6.7, 4.7	-24.3, 7.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	5 (11.4%)	2 (6.3%)	3 (25.0%)
	Stable	36 (81.8%)	28 (87.5%)	8 (66.7%)
	Worsened	3 (6.8%)	2 (6.3%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.14 EORTC QLQ-C30 Diarrhea Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	8.7 (17.7)	8.3 (16.2)	9.2 (19.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	6.6, 10.7	5.8, 10.8	5.8, 12.5
Study Day 50				
Score at Study Day 50	n	287	163	124
	Mean (STDEV)	9.6 (19.4)	8.8 (18.8)	10.8 (20.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	7.4, 11.9	5.9, 11.7	7.2, 14.3
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	0.8 (23.9)	0.4 (22.5)	1.3 (25.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 100.0
	95% CI	-2.0, 3.6	-3.1, 3.9	-3.2, 5.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	43 (15.0%)	25 (15.3%)	18 (14.5%)
	Stable	196 (68.3%)	114 (69.9%)	82 (66.1%)
	Worsened	48 (16.7%)	24 (14.7%)	24 (19.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	12.9 (25.5)	7.1 (17.6)	26.5 (34.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	9.4, 16.4	4.2, 10.0	17.8, 35.1
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	4.6 (29.3)	-0.7 (22.6)	16.9 (38.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 100.0
	95% CI	0.6, 8.6	-4.4, 3.0	7.3, 26.6
Percent Improved, Stable, or Worsened at Study Day 100	Improved	29 (13.9%)	23 (15.8%)	6 (9.5%)
	Stable	139 (66.5%)	107 (73.3%)	32 (50.8%)
	Worsened	41 (19.6%)	16 (11.0%)	25 (39.7%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	7.8 (18.3)	7.3 (18.8)	8.9 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	5.0, 10.6	3.7, 10.8	4.3, 13.6
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	0.6 (23.9)	-0.9 (26.1)	3.6 (18.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 33.3
	95% CI	-3.1, 4.3	-5.8, 4.0	-1.4, 8.6
Percent Improved, Stable, or Worsened at Study Day 150	Improved	25 (15.1%)	21 (19.1%)	4 (7.1%)
	Stable	114 (68.7%)	73 (66.4%)	41 (73.2%)
	Worsened	27 (16.3%)	16 (14.5%)	11 (19.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	9.4 (20.9)	8.0 (18.2)	12.5 (25.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	5.7, 13.0	4.1, 11.8	4.2, 20.8
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	1.8 (25.6)	-0.0 (24.8)	5.8 (27.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 100.0
	95% CI	-2.6, 6.3	-5.2, 5.2	-2.8, 14.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	19 (14.8%)	14 (15.9%)	5 (12.5%)
	Stable	89 (69.5%)	62 (70.5%)	27 (67.5%)
	Worsened	20 (15.6%)	12 (13.6%)	8 (20.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	7.4 (16.0)	6.8 (15.5)	9.1 (17.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	4.5, 10.4	3.3, 10.2	3.0, 15.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-0.0 (20.5)	-1.7 (21.3)	4.0 (18.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-3.8, 3.8	-6.5, 3.1	-2.4, 10.5
Percent Improved, Stable, or Worsened at Study Month 12	Improved	15 (13.4%)	12 (15.2%)	3 (9.1%)
	Stable	81 (72.3%)	58 (73.4%)	23 (69.7%)
	Worsened	16 (14.3%)	9 (11.4%)	7 (21.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	8.2 (18.2)	8.5 (18.7)	7.7 (17.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	4.5, 12.0	3.9, 13.0	0.8, 14.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-0.0 (23.6)	-1.0 (25.3)	2.6 (18.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 33.3
	95% CI	-4.9, 4.9	-7.2, 5.2	-5.0, 10.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	14 (15.1%)	11 (16.4%)	3 (11.5%)
	Stable	66 (71.0%)	48 (71.6%)	18 (69.2%)
	Worsened	13 (14.0%)	8 (11.9%)	5 (19.2%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	7.1 (16.1)	6.6 (16.5)	8.7 (15.0)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.8, 10.4	2.7, 10.5	2.2, 15.2
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-0.7 (20.7)	-2.3 (22.1)	4.3 (15.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3
	95% CI	-5.0, 3.5	-7.6, 2.9	-2.2, 10.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	14 (14.9%)	13 (18.3%)	1 (4.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	66 (70.2%)	48 (67.6%)	18 (78.3%)
	Worsened	14 (14.9%)	10 (14.1%)	4 (17.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	4.6 (13.0)	5.9 (14.7)	1.7 (7.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	1.4, 7.8	1.5, 10.3	-1.8, 5.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-2.1 (19.4)	-0.7 (20.7)	-5.0 (16.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3
	95% CI	-6.9, 2.8	-7.0, 5.5	-12.6, 2.6
Percent Improved, Stable, or Worsened at Study Month 21	Improved	8 (12.3%)	4 (8.9%)	4 (20.0%)
	Stable	51 (78.5%)	36 (80.0%)	15 (75.0%)
	Worsened	6 (9.2%)	5 (11.1%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	3.0 (9.7)	4.2 (11.2)	0.0 (0.0)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 33.3	0.0, 33.3	0.0, 0.0
	95% CI	0.1, 6.0	0.1, 8.2	nd
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-3.8 (20.6)	-4.2 (23.6)	-2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-10.1, 2.5	-12.7, 4.3	-8.9, 3.3
Percent Improved, Stable, or Worsened at Study Month 24	Improved	6 (13.6%)	5 (15.6%)	1 (8.3%)
	Stable	35 (79.5%)	24 (75.0%)	11 (91.7%)
	Worsened	3 (6.8%)	3 (9.4%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Anhang 4-G2.5.3: MMRM-Analyse und Verlaufskurven zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-17 (Anhang): Ergebnisse der MMRM Analyse zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 4.1.07 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8704.2		
	AIC (Smaller is Better)	8746.2		
	AICC (Smaller is Better)	8747.2		
	BIC (Smaller is Better)	8823.7		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		13.0 (8.0, 17.9)	13.1 (7.8, 18.5)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-6.1, 5.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.5 (-7.2, 2.2)	17.9 (12.0, 23.8)
	Difference in Mean Change from Screening (95% CI)		-20.4 (-26.7, -14.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-7.3 (-12.4, -2.1)	7.1 (0.8, 13.5)
	Difference in Mean Change from Screening (95% CI)		-14.4 (-21.4, -7.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-11.5 (-17.3, -5.7)	-0.4 (-8.1, 7.4)
	Difference in Mean Change from Screening (95% CI)		-11.1 (-19.8, -2.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-9.8 (-15.5, -4.1)	-9.3 (-17.1, -1.4)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-9.2, 8.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-8.9 (-14.8, -3.0)	-7.6 (-15.8, 0.7)
	Difference in Mean Change from Screening (95% CI)		-1.4 (-10.6, 7.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8686.2		
	AIC (Smaller is Better)	8728.2		
	AICC (Smaller is Better)	8729.2		
	BIC (Smaller is Better)	8805.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		15.3 (9.1, 21.4)	16.5 (10.1, 22.9)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-7.8, 5.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.4 (-6.5, 5.6)	20.0 (13.5, 26.5)
	Difference in Mean Change from Screening (95% CI)		-20.4 (-26.9, -14.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.0 (-11.4, 1.3)	9.7 (2.7, 16.6)
	Difference in Mean Change from Screening (95% CI)		-14.7 (-21.9, -7.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-9.3 (-16.2, -2.3)	2.1 (-6.1, 10.3)
	Difference in Mean Change from Screening (95% CI)		-11.4 (-20.3, -2.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.5 (-14.4, -0.6)	-6.8 (-15.2, 1.5)
	Difference in Mean Change from Screening (95% CI)		-0.7 (-9.6, 8.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-6.7 (-13.7, 0.3)	-5.0 (-13.8, 3.7)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-11.1, 7.8)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8587.4		
	AIC (Smaller is Better)	8629.4		
	AICC (Smaller is Better)	8630.3		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8706.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		17.2 (7.8, 26.6)	16.1 (6.9, 25.3)
	Difference in Mean Change from Screening (95% CI)		1.1 (-5.5, 7.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.5 (-7.8, 10.8)	19.5 (10.2, 28.8)
	Difference in Mean Change from Screening (95% CI)		-18.0 (-24.6, -11.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-3.1 (-12.6, 6.4)	9.1 (-0.4, 18.6)
	Difference in Mean Change from Screening (95% CI)		-12.1 (-19.2, -5.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.3 (-17.2, 2.7)	1.6 (-8.9, 12.0)
	Difference in Mean Change from Screening (95% CI)		-8.8 (-17.5, -0.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-5.3 (-15.3, 4.6)	-7.4 (-18.1, 3.3)
	Difference in Mean Change from Screening (95% CI)		2.0 (-6.9, 10.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-4.6 (-14.6, 5.4)	-5.6 (-16.6, 5.4)
	Difference in Mean Change from Screening (95% CI)		1.0 (-8.4, 10.4)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.08 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8055.3		
	AIC (Smaller is Better)	8097.3		
	AICC (Smaller is Better)	8098.3		
	BIC (Smaller is Better)	8174.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.9 (-0.6, 6.5)	8.2 (4.3, 12.0)
	Difference in Mean Change from Screening (95% CI)		-5.3 (-9.6, -1.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.8 (-2.1, 5.8)	13.9 (8.7, 19.0)
	Difference in Mean Change from Screening (95% CI)		-12.0 (-17.8, -6.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.3 (-1.9, 4.6)	4.3 (0.3, 8.4)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-7.3, 1.3)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.2 (-3.3, 3.7)	-2.6 (-7.2, 2.0)
	Difference in Mean Change from Screening (95% CI)		2.8 (-2.2, 7.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.2 (-3.7, 3.3)	-0.2 (-5.0, 4.6)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.1, 5.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.1 (-3.8, 4.0)	-1.2 (-6.7, 4.2)
	Difference in Mean Change from Screening (95% CI)		1.3 (-4.7, 7.3)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8042.4		
	AIC (Smaller is Better)	8084.4		
	AICC (Smaller is Better)	8085.3		
	BIC (Smaller is Better)	8161.9		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.3 (-2.0, 6.7)	7.4 (2.8, 12.0)
	Difference in Mean Change from Screening (95% CI)		-5.1 (-9.8, -0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.3 (-3.4, 6.0)	13.3 (7.8, 18.8)
	Difference in Mean Change from Screening (95% CI)		-12.0 (-17.9, -6.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		0.7 (-3.5, 5.0)	3.7 (-0.8, 8.2)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-7.5, 1.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-0.4 (-4.9, 4.1)	-3.3 (-8.4, 1.8)
	Difference in Mean Change from Screening (95% CI)		2.8 (-2.4, 8.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.8 (-5.3, 3.7)	-0.9 (-6.1, 4.4)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.2, 5.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.5 (-5.3, 4.3)	-1.9 (-7.7, 4.0)
	Difference in Mean Change from Screening (95% CI)		1.4 (-4.8, 7.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	7967.9		
	AIC (Smaller is Better)	8009.9		
	AICC (Smaller is Better)	8010.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8087.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.9 (-3.9, 9.7)	7.5 (0.9, 14.2)
	Difference in Mean Change from Screening (95% CI)		-4.7 (-9.5, 0.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.7 (-5.3, 8.7)	13.5 (6.2, 20.8)
	Difference in Mean Change from Screening (95% CI)		-11.8 (-17.8, -5.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.2 (-5.6, 7.9)	4.0 (-2.7, 10.6)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-7.4, 1.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.1 (-6.8, 7.0)	-3.0 (-10.0, 4.0)
	Difference in Mean Change from Screening (95% CI)		3.1 (-2.1, 8.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.1 (-7.0, 6.7)	-0.7 (-7.9, 6.5)
	Difference in Mean Change from Screening (95% CI)		0.5 (-4.8, 5.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-7.0, 7.1)	-1.6 (-9.2, 6.0)
	Difference in Mean Change from Screening (95% CI)		1.6 (-4.5, 7.8)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.09 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8735.5		
	AIC (Smaller is Better)	8777.5		
	AICC (Smaller is Better)	8778.5		
	BIC (Smaller is Better)	8855		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.1 (-9.4, 1.2)	-3.6 (-9.3, 2.1)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-6.7, 5.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.4 (-8.6, 1.8)	-6.8 (-13.2, -0.3)
	Difference in Mean Change from Screening (95% CI)		3.4 (-3.4, 10.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.0 (-9.7, 1.7)	-10.2 (-17.2, -3.2)
	Difference in Mean Change from Screening (95% CI)		6.2 (-1.5, 14.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-5.7 (-11.3, -0.1)	-12.8 (-20.0, -5.5)
	Difference in Mean Change from Screening (95% CI)		7.0 (-0.9, 14.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-6.5 (-12.3, -0.6)	-13.5 (-21.2, -5.9)
	Difference in Mean Change from Screening (95% CI)		7.1 (-1.3, 15.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-6.3 (-12.5, -0.0)	-15.3 (-23.9, -6.8)
	Difference in Mean Change from Screening (95% CI)		9.0 (-0.5, 18.6)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8719.9		
	AIC (Smaller is Better)	8761.9		
	AICC (Smaller is Better)	8762.9		
	BIC (Smaller is Better)	8839.4		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-5.3 (-12.1, 1.4)	-4.5 (-11.4, 2.5)
	Difference in Mean Change from Screening (95% CI)		-0.8 (-7.8, 6.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.6 (-11.3, 2.1)	-7.7 (-14.8, -0.5)
	Difference in Mean Change from Screening (95% CI)		3.0 (-4.1, 10.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.2 (-12.3, 2.0)	-11.0 (-18.8, -3.3)
	Difference in Mean Change from Screening (95% CI)		5.9 (-2.2, 13.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.9 (-14.0, 0.3)	-13.6 (-21.6, -5.6)
	Difference in Mean Change from Screening (95% CI)		6.7 (-1.5, 14.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.6 (-14.9, -0.3)	-14.3 (-22.7, -6.0)
	Difference in Mean Change from Screening (95% CI)		6.7 (-2.0, 15.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-7.4 (-15.0, 0.2)	-16.2 (-25.4, -6.9)
	Difference in Mean Change from Screening (95% CI)		8.7 (-1.1, 18.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8627.2		
	AIC (Smaller is Better)	8669.2		
	AICC (Smaller is Better)	8670.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8746.7		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.6 (-18.2, 3.0)	-8.6 (-18.8, 1.6)
	Difference in Mean Change from Screening (95% CI)		1.0 (-6.0, 8.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-6.8 (-17.4, 3.7)	-11.9 (-22.3, -1.5)
	Difference in Mean Change from Screening (95% CI)		5.1 (-2.1, 12.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-7.4 (-18.1, 3.4)	-15.3 (-26.1, -4.5)
	Difference in Mean Change from Screening (95% CI)		8.0 (-0.2, 16.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-9.0 (-19.8, 1.9)	-17.8 (-28.8, -6.8)
	Difference in Mean Change from Screening (95% CI)		8.8 (0.4, 17.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-9.7 (-20.6, 1.3)	-18.4 (-29.7, -7.1)
	Difference in Mean Change from Screening (95% CI)		8.8 (-0.0, 17.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-9.5 (-20.7, 1.7)	-20.3 (-32.3, -8.3)
	Difference in Mean Change from Screening (95% CI)		10.8 (0.8, 20.7)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.10 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8748.8		
	AIC (Smaller is Better)	8790.8		
	AICC (Smaller is Better)	8791.7		
	BIC (Smaller is Better)	8868.2		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		0.9 (-3.8, 5.6)	8.8 (3.7, 13.8)
	Difference in Mean Change from Screening (95% CI)		-7.8 (-13.4, -2.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.8 (-6.8, 3.3)	15.2 (8.6, 21.8)
	Difference in Mean Change from Screening (95% CI)		-16.9 (-24.2, -9.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.3 (-8.2, 3.6)	11.5 (3.9, 19.1)
	Difference in Mean Change from Screening (95% CI)		-13.8 (-22.5, -5.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.3 (-12.8, -1.8)	7.7 (0.5, 15.0)
	Difference in Mean Change from Screening (95% CI)		-15.0 (-23.1, -6.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.7 (-8.9, 1.6)	-3.3 (-10.4, 3.8)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-8.1, 7.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-4.6 (-10.3, 1.1)	1.6 (-6.0, 9.2)
	Difference in Mean Change from Screening (95% CI)		-6.2 (-14.7, 2.4)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8728.8		
	AIC (Smaller is Better)	8770.8		
	AICC (Smaller is Better)	8771.8		
	BIC (Smaller is Better)	8848.3		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		5.6 (-0.6, 11.7)	12.8 (6.4, 19.1)
	Difference in Mean Change from Screening (95% CI)		-7.2 (-13.3, -1.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		2.9 (-3.6, 9.3)	18.6 (11.5, 25.8)
	Difference in Mean Change from Screening (95% CI)		-15.8 (-23.1, -8.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		2.3 (-4.7, 9.3)	15.0 (7.0, 23.0)
	Difference in Mean Change from Screening (95% CI)		-12.7 (-21.3, -4.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.5 (-9.3, 4.3)	11.5 (3.6, 19.4)
	Difference in Mean Change from Screening (95% CI)		-14.0 (-22.3, -5.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.2 (-5.4, 7.8)	0.5 (-7.2, 8.2)
	Difference in Mean Change from Screening (95% CI)		0.7 (-7.2, 8.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-6.9, 7.0)	5.2 (-3.1, 13.5)
	Difference in Mean Change from Screening (95% CI)		-5.1 (-14.0, 3.7)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8649.2		
	AIC (Smaller is Better)	8691.2		
	AICC (Smaller is Better)	8692.2		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8768.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		9.1 (-0.5, 18.7)	15.1 (5.8, 24.5)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-12.4, 0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		6.4 (-3.4, 16.1)	21.0 (11.1, 30.9)
	Difference in Mean Change from Screening (95% CI)		-14.6 (-22.1, -7.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		5.8 (-4.4, 16.0)	17.3 (6.8, 27.8)
	Difference in Mean Change from Screening (95% CI)		-11.5 (-20.3, -2.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.1 (-9.0, 11.1)	13.9 (3.5, 24.4)
	Difference in Mean Change from Screening (95% CI)		-12.9 (-21.2, -4.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		4.8 (-5.1, 14.6)	3.1 (-7.3, 13.5)
	Difference in Mean Change from Screening (95% CI)		1.7 (-6.4, 9.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.6 (-6.5, 13.8)	7.7 (-3.0, 18.4)
	Difference in Mean Change from Screening (95% CI)		-4.0 (-13.0, 4.9)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.11 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9082.5		
	AIC (Smaller is Better)	9124.5		
	AICC (Smaller is Better)	9125.4		
	BIC (Smaller is Better)	9202		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-1.1 (-7.2, 5.0)	0.1 (-6.5, 6.6)
	Difference in Mean Change from Screening (95% CI)		-1.1 (-8.2, 5.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.6 (-11.0, 1.8)	5.9 (-2.2, 14.1)
	Difference in Mean Change from Screening (95% CI)		-10.5 (-19.3, -1.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-6.0 (-12.6, 0.5)	-1.3 (-9.4, 6.8)
	Difference in Mean Change from Screening (95% CI)		-4.7 (-13.5, 4.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.7 (-14.2, -1.2)	-5.6 (-14.1, 2.9)
	Difference in Mean Change from Screening (95% CI)		-2.1 (-11.3, 7.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.8 (-11.9, 2.2)	-4.5 (-13.9, 5.0)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-10.8, 10.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-7.0 (-13.7, -0.4)	-4.2 (-13.2, 4.8)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-12.6, 6.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9065		
	AIC (Smaller is Better)	9107		
	AICC (Smaller is Better)	9108		
	BIC (Smaller is Better)	9184.5		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		0.5 (-7.3, 8.3)	2.4 (-5.6, 10.3)
	Difference in Mean Change from Screening (95% CI)		-1.9 (-9.8, 6.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.2 (-11.2, 4.9)	7.6 (-1.2, 16.3)
	Difference in Mean Change from Screening (95% CI)		-10.7 (-19.9, -1.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.4 (-12.6, 3.8)	0.6 (-8.3, 9.4)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-14.1, 4.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.0 (-14.3, 2.3)	-3.7 (-13.0, 5.5)
	Difference in Mean Change from Screening (95% CI)		-2.3 (-11.8, 7.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.2 (-11.8, 5.5)	-2.6 (-12.7, 7.5)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-11.3, 10.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-5.3 (-13.7, 3.0)	-2.3 (-12.0, 7.5)
	Difference in Mean Change from Screening (95% CI)		-3.1 (-13.2, 7.1)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8981.1		
	AIC (Smaller is Better)	9023.1		
	AICC (Smaller is Better)	9024.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9100.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		4.1 (-8.4, 16.5)	4.7 (-7.4, 16.7)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-8.8, 7.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.4 (-12.2, 13.0)	10.0 (-2.5, 22.5)
	Difference in Mean Change from Screening (95% CI)		-9.5 (-18.9, -0.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.7 (-13.4, 12.1)	2.9 (-9.8, 15.5)
	Difference in Mean Change from Screening (95% CI)		-3.5 (-13.0, 5.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.2 (-15.0, 10.5)	-1.2 (-14.2, 11.7)
	Difference in Mean Change from Screening (95% CI)		-1.0 (-10.8, 8.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		0.6 (-12.4, 13.6)	-0.2 (-13.8, 13.4)
	Difference in Mean Change from Screening (95% CI)		0.8 (-10.3, 11.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.5 (-14.3, 11.3)	0.2 (-13.2, 13.6)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-12.2, 8.7)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.12 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9034.9		
	AIC (Smaller is Better)	9076.9		
	AICC (Smaller is Better)	9077.9		
	BIC (Smaller is Better)	9154.4		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		17.1 (10.7, 23.5)	9.7 (2.8, 16.7)
	Difference in Mean Change from Screening (95% CI)		7.4 (-0.5, 15.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.2 (-4.7, 7.1)	23.6 (15.9, 31.3)
	Difference in Mean Change from Screening (95% CI)		-22.4 (-30.6, -14.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.7 (-7.4, 4.1)	5.8 (-1.4, 13.0)
	Difference in Mean Change from Screening (95% CI)		-7.5 (-15.1, 0.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-5.7 (-12.0, 0.7)	0.2 (-8.0, 8.4)
	Difference in Mean Change from Screening (95% CI)		-5.9 (-14.8, 3.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-5.8 (-12.0, 0.5)	-0.6 (-8.9, 7.7)
	Difference in Mean Change from Screening (95% CI)		-5.2 (-14.2, 3.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-3.2 (-9.8, 3.4)	-1.9 (-11.0, 7.2)
	Difference in Mean Change from Screening (95% CI)		-1.3 (-11.3, 8.7)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9015.7		
	AIC (Smaller is Better)	9057.7		
	AICC (Smaller is Better)	9058.6		
	BIC (Smaller is Better)	9135.2		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		21.0 (13.2, 28.7)	11.8 (3.6, 20.0)
	Difference in Mean Change from Screening (95% CI)		9.2 (0.5, 17.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		5.3 (-2.2, 12.8)	26.3 (18.0, 34.6)
	Difference in Mean Change from Screening (95% CI)		-21.0 (-29.4, -12.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		2.6 (-4.8, 10.0)	8.6 (0.7, 16.5)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-13.8, 1.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.3 (-9.2, 6.6)	3.0 (-6.0, 11.9)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-13.6, 5.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-1.4 (-9.2, 6.5)	2.3 (-6.8, 11.3)
	Difference in Mean Change from Screening (95% CI)		-3.6 (-12.9, 5.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.2 (-6.9, 9.4)	1.0 (-8.8, 10.8)
	Difference in Mean Change from Screening (95% CI)		0.2 (-10.0, 10.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8928.4		
	AIC (Smaller is Better)	8970.4		
	AICC (Smaller is Better)	8971.4		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9047.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		25.3 (13.3, 37.3)	15.0 (3.1, 26.8)
	Difference in Mean Change from Screening (95% CI)		10.3 (1.4, 19.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		9.4 (-2.4, 21.3)	29.6 (17.8, 41.5)
	Difference in Mean Change from Screening (95% CI)		-20.2 (-28.8, -11.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.9 (-4.9, 18.7)	11.5 (-0.1, 23.1)
	Difference in Mean Change from Screening (95% CI)		-4.6 (-12.8, 3.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.0 (-9.1, 15.1)	5.9 (-6.4, 18.3)
	Difference in Mean Change from Screening (95% CI)		-2.9 (-12.5, 6.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		3.1 (-9.0, 15.2)	5.1 (-7.5, 17.6)
	Difference in Mean Change from Screening (95% CI)		-2.0 (-11.6, 7.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.6 (-6.7, 17.9)	3.9 (-9.2, 16.9)
	Difference in Mean Change from Screening (95% CI)		1.8 (-8.6, 12.2)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.13 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8564.1		
	AIC (Smaller is Better)	8606.1		
	AICC (Smaller is Better)	8607.1		
	BIC (Smaller is Better)	8683.6		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-6.1 (-11.6, -0.5)	3.7 (-2.3, 9.6)
	Difference in Mean Change from Screening (95% CI)		-9.8 (-16.5, -3.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.0 (-8.6, 2.5)	-6.2 (-13.0, 0.5)
	Difference in Mean Change from Screening (95% CI)		3.2 (-4.2, 10.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.2 (-9.6, 1.2)	-9.9 (-16.4, -3.3)
	Difference in Mean Change from Screening (95% CI)		5.7 (-1.5, 12.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-3.9 (-9.0, 1.1)	-13.8 (-20.0, -7.6)
	Difference in Mean Change from Screening (95% CI)		9.9 (3.3, 16.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-6.0 (-11.7, -0.3)	-12.9 (-20.1, -5.7)
	Difference in Mean Change from Screening (95% CI)		6.9 (-1.0, 14.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.6 (-7.5, 2.4)	-13.5 (-20.1, -6.9)
	Difference in Mean Change from Screening (95% CI)		10.9 (4.1, 17.8)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8546.2		
	AIC (Smaller is Better)	8588.2		
	AICC (Smaller is Better)	8589.2		
	BIC (Smaller is Better)	8665.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.5 (-11.3, 2.4)	6.3 (-0.7, 13.4)
	Difference in Mean Change from Screening (95% CI)		-10.8 (-18.2, -3.4)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.5 (-8.4, 5.4)	-4.1 (-11.6, 3.4)
	Difference in Mean Change from Screening (95% CI)		2.6 (-5.3, 10.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.8 (-9.7, 4.0)	-8.0 (-15.3, -0.7)
	Difference in Mean Change from Screening (95% CI)		5.1 (-2.4, 12.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.6 (-9.2, 4.1)	-11.9 (-19.0, -4.8)
	Difference in Mean Change from Screening (95% CI)		9.3 (2.4, 16.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.6 (-11.6, 2.5)	-10.8 (-18.8, -2.9)
	Difference in Mean Change from Screening (95% CI)		6.2 (-2.1, 14.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.3 (-7.9, 5.3)	-11.8 (-19.2, -4.3)
	Difference in Mean Change from Screening (95% CI)		10.5 (3.3, 17.6)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8458.6		
	AIC (Smaller is Better)	8500.6		
	AICC (Smaller is Better)	8501.6		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8578.1		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.3 (-15.0, 6.5)	5.5 (-5.0, 15.9)
	Difference in Mean Change from Screening (95% CI)		-9.7 (-17.3, -2.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.3 (-12.1, 9.6)	-4.8 (-15.5, 6.0)
	Difference in Mean Change from Screening (95% CI)		3.5 (-4.6, 11.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.5 (-13.3, 8.3)	-8.6 (-19.2, 2.0)
	Difference in Mean Change from Screening (95% CI)		6.1 (-1.5, 13.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.2 (-12.8, 8.5)	-12.5 (-22.9, -2.0)
	Difference in Mean Change from Screening (95% CI)		10.3 (3.2, 17.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.2 (-15.1, 6.7)	-11.5 (-22.6, -0.5)
	Difference in Mean Change from Screening (95% CI)		7.3 (-1.0, 15.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.7 (-11.4, 9.9)	-12.3 (-23.2, -1.4)
	Difference in Mean Change from Screening (95% CI)		11.5 (4.2, 18.9)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.14 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8852.3		
	AIC (Smaller is Better)	8894.3		
	AICC (Smaller is Better)	8895.3		
	BIC (Smaller is Better)	8971.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-1.2 (-6.0, 3.5)	-0.3 (-5.4, 4.8)
	Difference in Mean Change from Screening (95% CI)		-0.9 (-6.5, 4.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.1 (-7.5, 3.3)	15.5 (8.4, 22.7)
	Difference in Mean Change from Screening (95% CI)		-17.6 (-25.5, -9.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.9 (-7.2, 3.3)	-0.1 (-6.7, 6.4)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-9.1, 5.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.5 (-7.3, 4.2)	2.7 (-5.1, 10.5)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-13.0, 4.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.1 (-8.2, 2.1)	0.4 (-6.7, 7.5)
	Difference in Mean Change from Screening (95% CI)		-3.5 (-11.2, 4.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.6 (-6.3, 5.2)	0.3 (-7.9, 8.5)
	Difference in Mean Change from Screening (95% CI)		-0.9 (-10.0, 8.2)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8834.5		
	AIC (Smaller is Better)	8876.5		
	AICC (Smaller is Better)	8877.4		
	BIC (Smaller is Better)	8954		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.2 (-4.8, 7.1)	-0.1 (-6.3, 6.1)
	Difference in Mean Change from Screening (95% CI)		1.3 (-5.0, 7.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.5 (-6.0, 7.0)	16.3 (8.8, 23.8)
	Difference in Mean Change from Screening (95% CI)		-15.8 (-24.0, -7.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		0.4 (-6.0, 6.9)	0.4 (-6.7, 7.6)
	Difference in Mean Change from Screening (95% CI)		0.0 (-7.6, 7.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.8 (-6.1, 7.8)	3.5 (-4.8, 11.7)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-11.6, 6.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.7 (-7.2, 5.8)	1.2 (-6.4, 8.9)
	Difference in Mean Change from Screening (95% CI)		-2.0 (-10.0, 6.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.9 (-5.1, 8.8)	1.0 (-7.7, 9.6)
	Difference in Mean Change from Screening (95% CI)		0.9 (-8.5, 10.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8760.4		
	AIC (Smaller is Better)	8802.4		
	AICC (Smaller is Better)	8803.4		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8879.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		4.8 (-4.9, 14.5)	3.3 (-6.1, 12.6)
	Difference in Mean Change from Screening (95% CI)		1.5 (-4.9, 8.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.2 (-5.9, 14.2)	19.6 (9.3, 29.8)
	Difference in Mean Change from Screening (95% CI)		-15.4 (-23.8, -7.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		4.1 (-5.9, 14.2)	3.7 (-6.4, 13.7)
	Difference in Mean Change from Screening (95% CI)		0.5 (-7.5, 8.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.5 (-5.9, 14.8)	6.8 (-4.1, 17.7)
	Difference in Mean Change from Screening (95% CI)		-2.4 (-11.5, 6.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.9 (-7.1, 12.9)	4.7 (-5.9, 15.3)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-10.1, 6.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.5 (-4.8, 15.8)	4.4 (-6.8, 15.6)
	Difference in Mean Change from Screening (95% CI)		1.1 (-8.4, 10.6)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 8 (Anhang): Verlaufskurven zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

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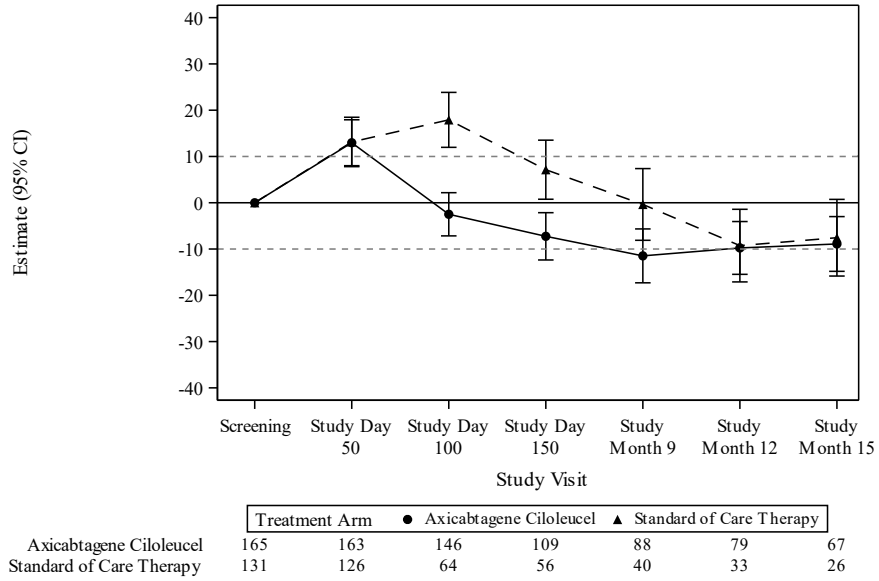
Figure 4.1.07.1 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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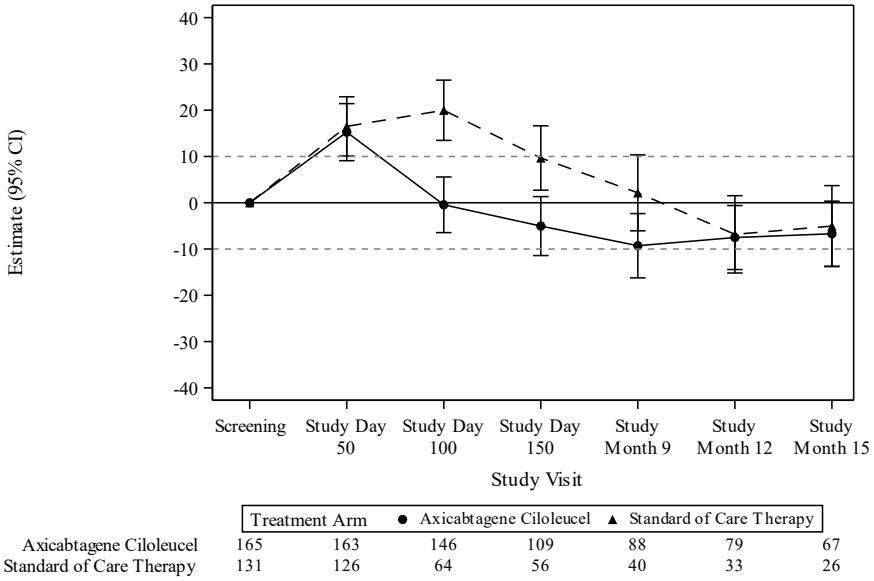
Figure 4.1.07.2 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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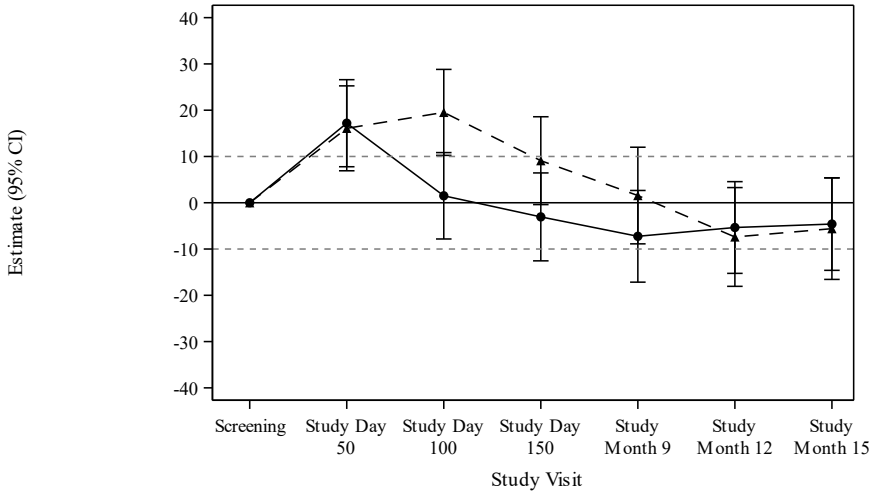
Figure 4.1.07.3 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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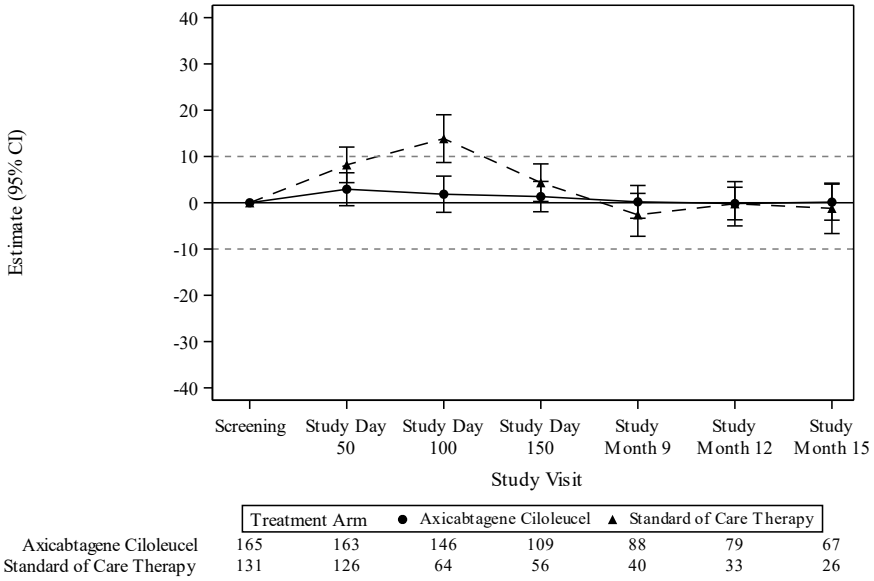
Figure 4.1.08.1 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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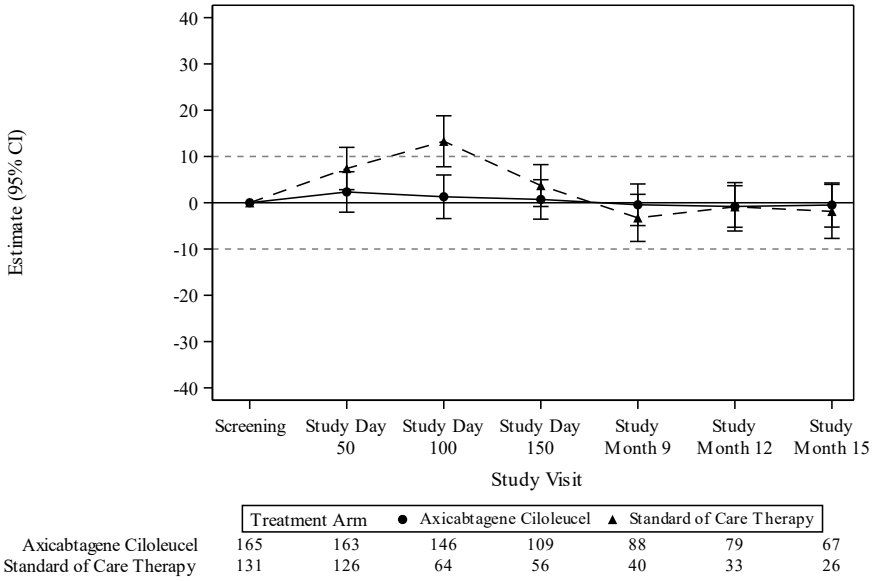
Figure 4.1.08.2 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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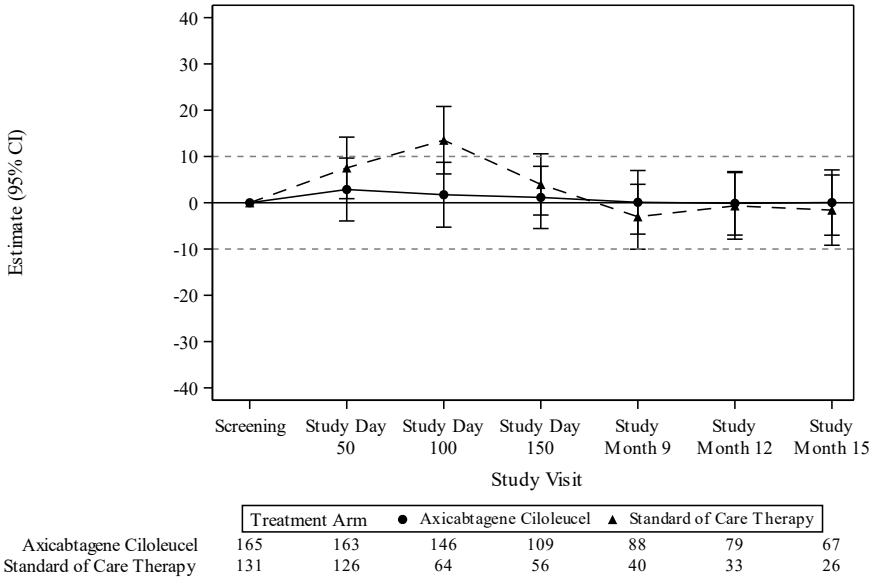
Figure 4.1.08.3 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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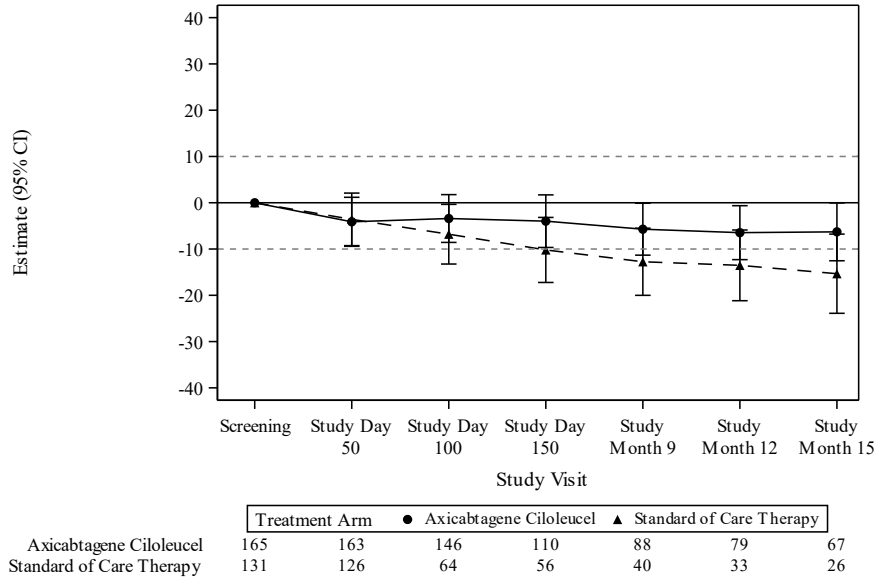
Figure 4.1.09.1 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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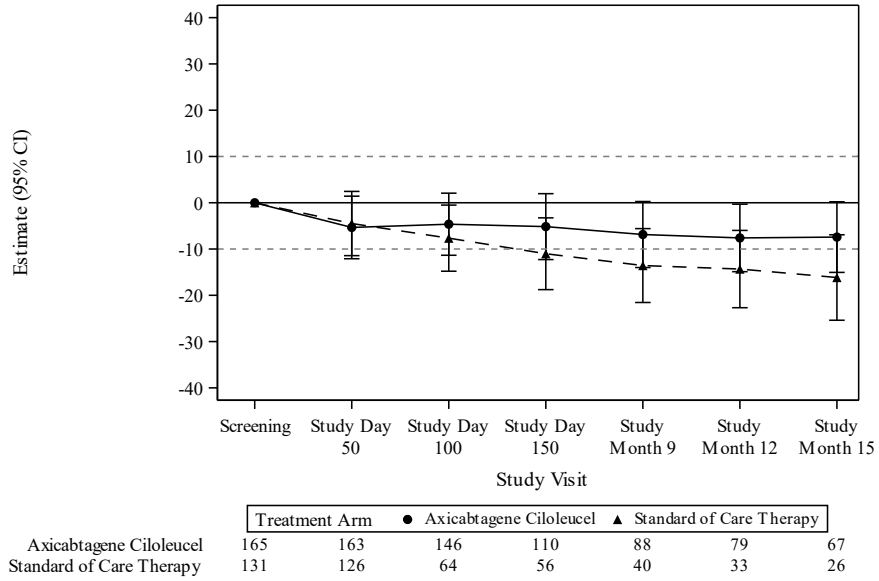
Version: 1.0 (10Aug2021)

Figure 4.1.09.2 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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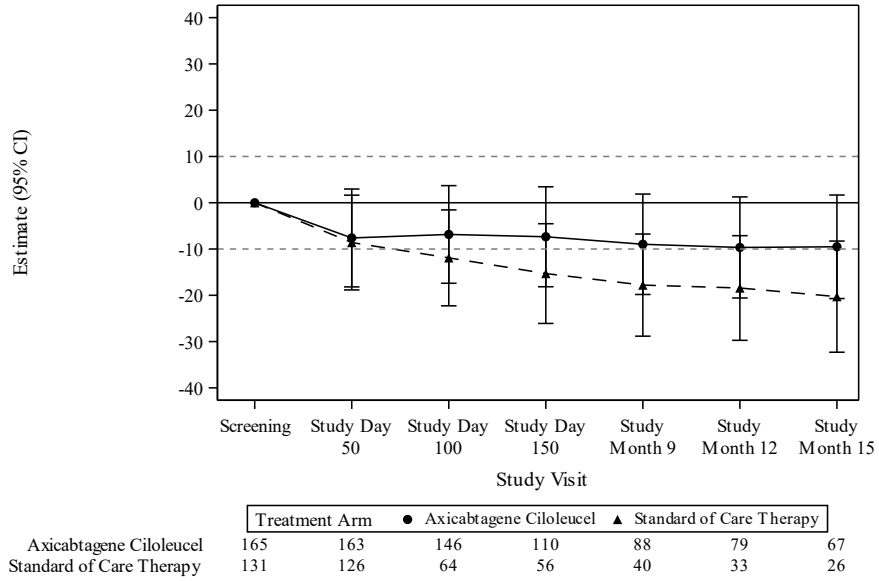
Version: 1.0 (10Aug2021)

Figure 4.1.09.3 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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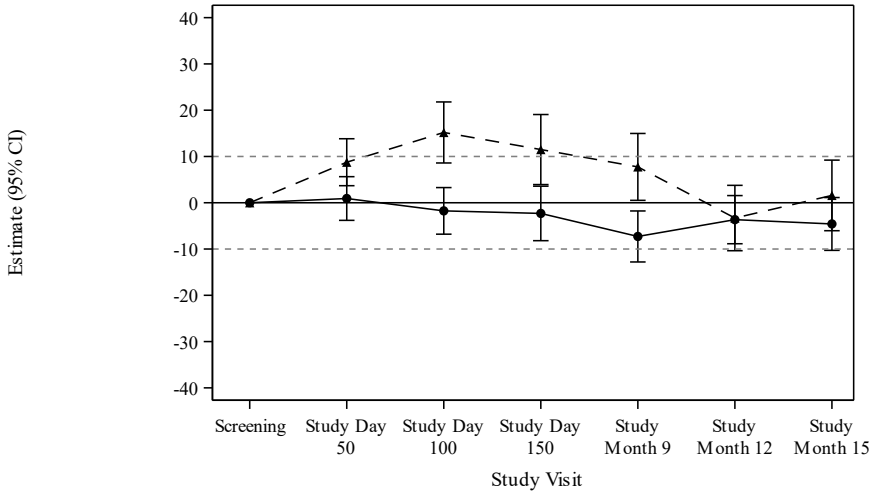
Figure 4.1.10.1 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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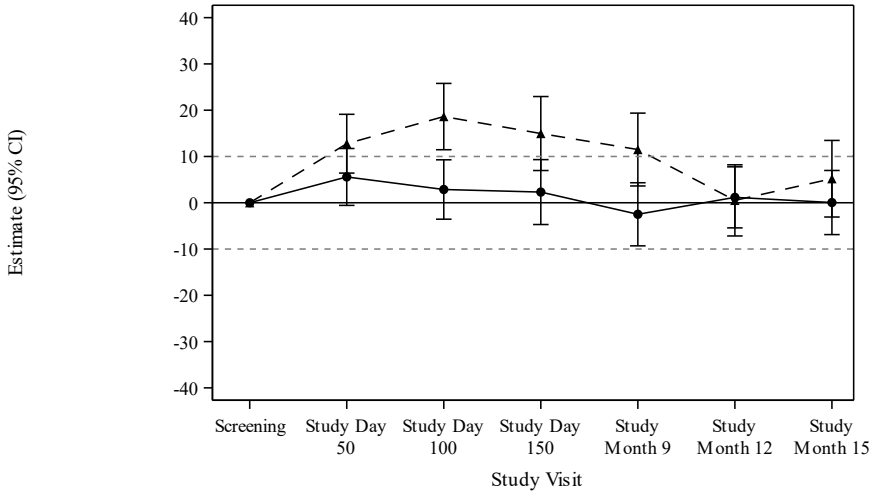
Figure 4.1.10.2 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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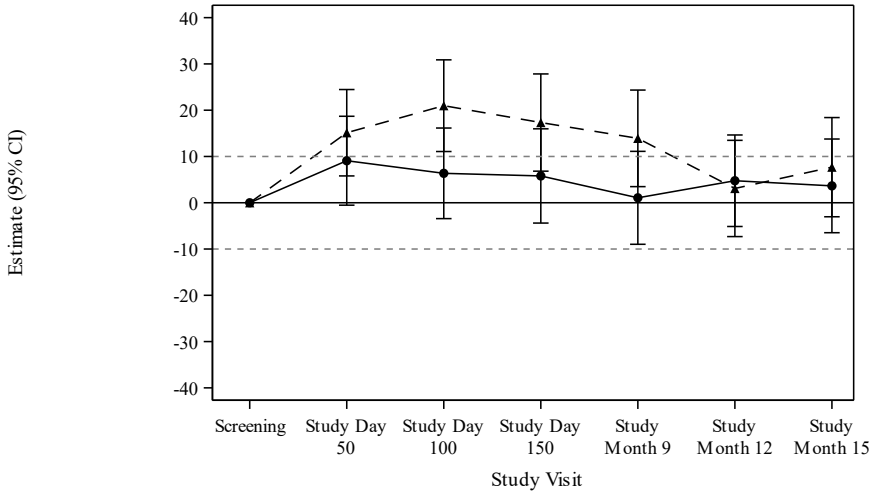
Figure 4.1.10.3 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)

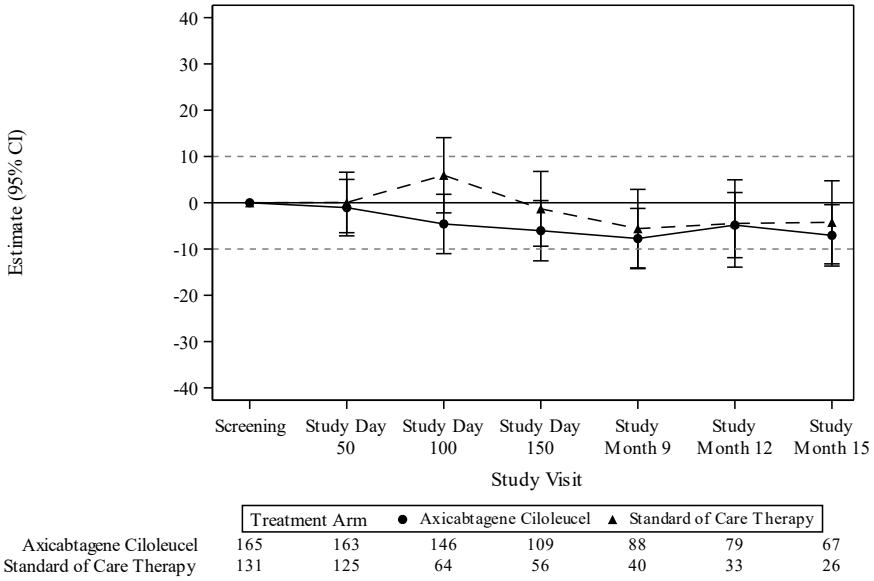


Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

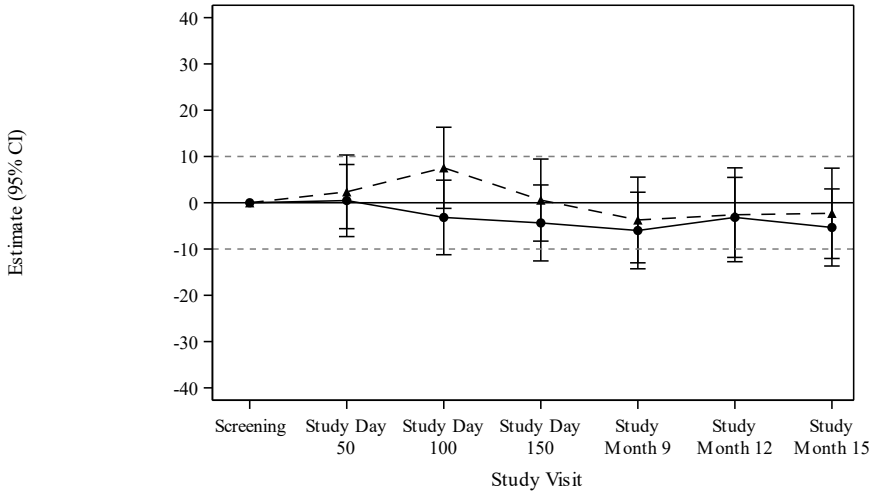
Figure 4.1.11.1 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Figure 4.1.11.2 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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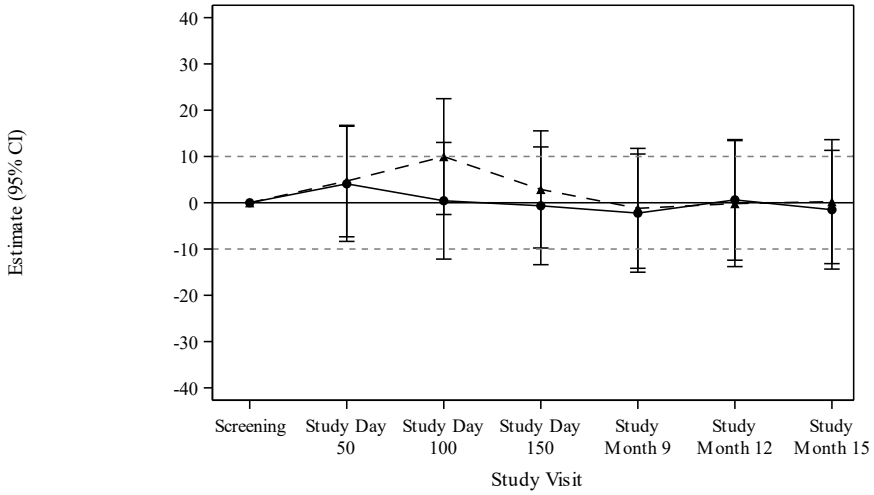
Figure 4.1.11.3 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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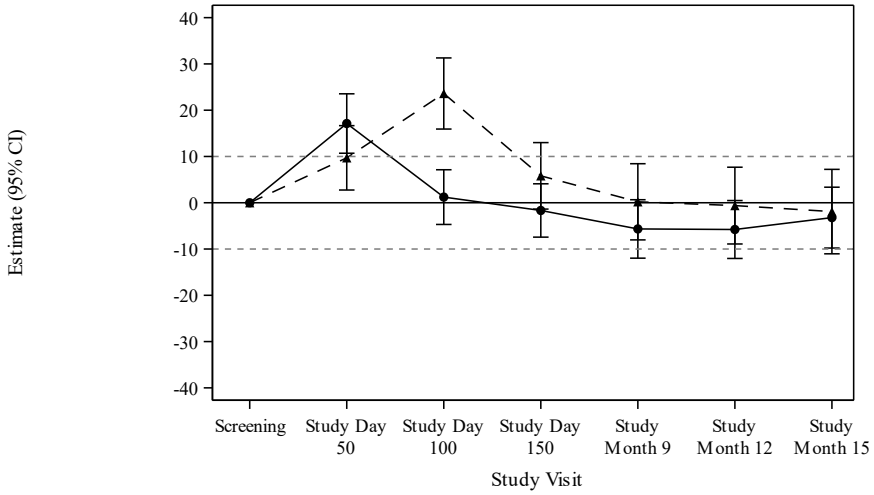
Version: 1.0 (10Aug2021)

Figure 4.1.12.1 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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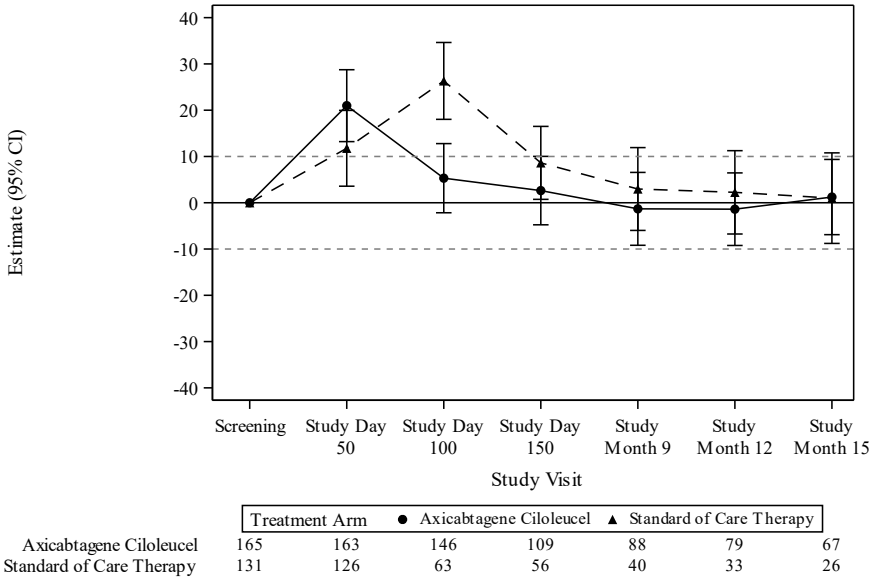
Version: 1.0 (10Aug2021)

Figure 4.1.12.2 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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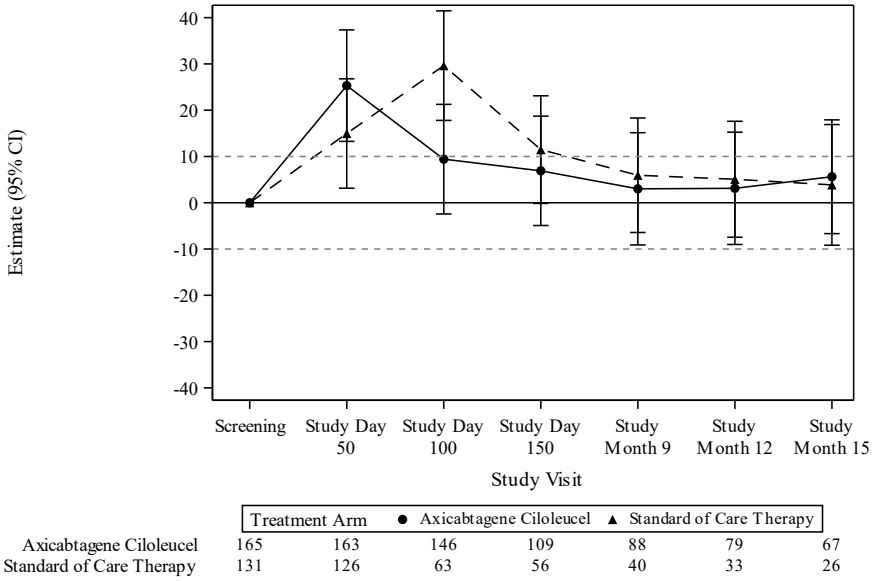
Figure 4.1.12.3 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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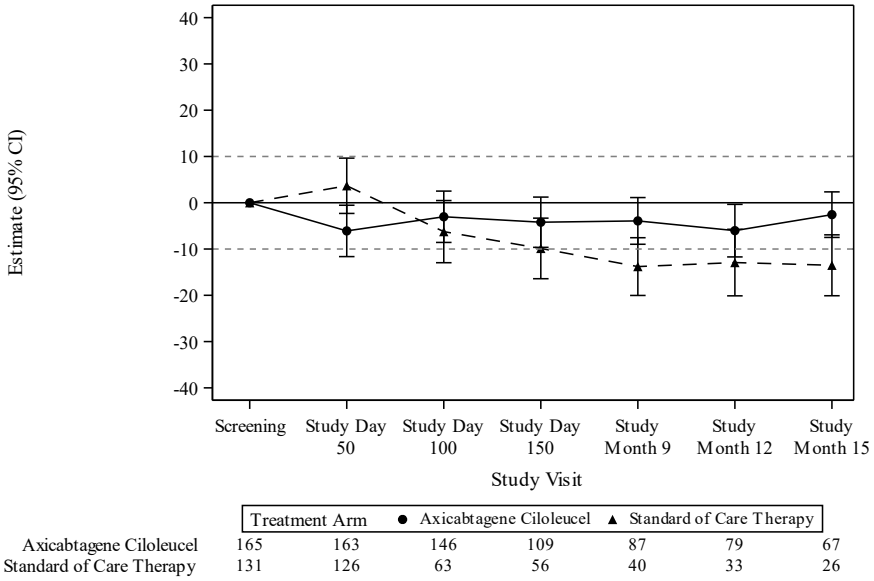
Version: 1.0 (10Aug2021)

Figure 4.1.13.1 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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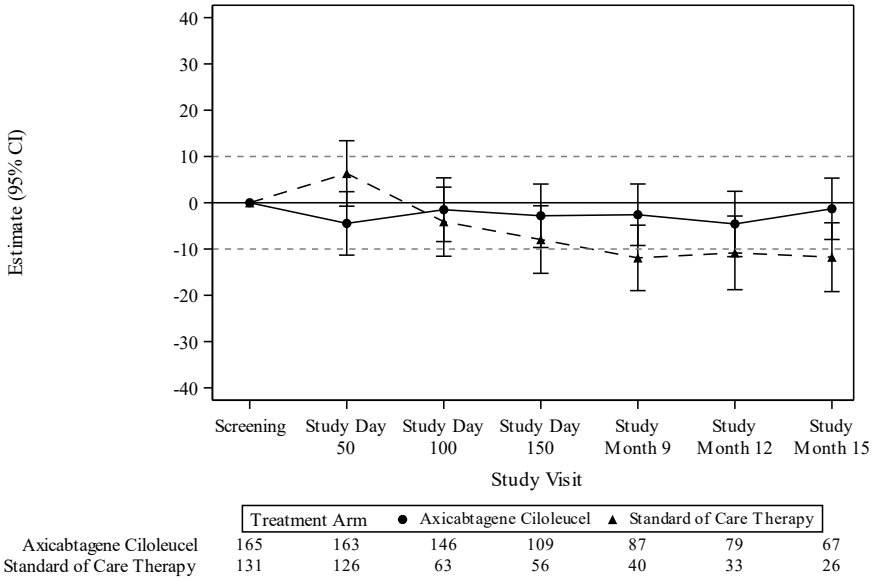
Version: 1.0 (10Aug2021)

Figure 4.1.13.2 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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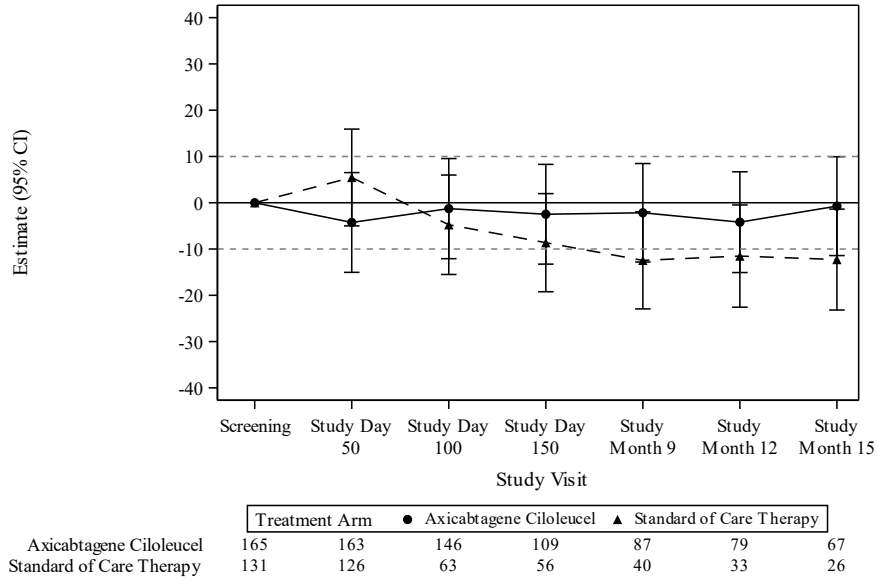
Figure 4.1.13.3 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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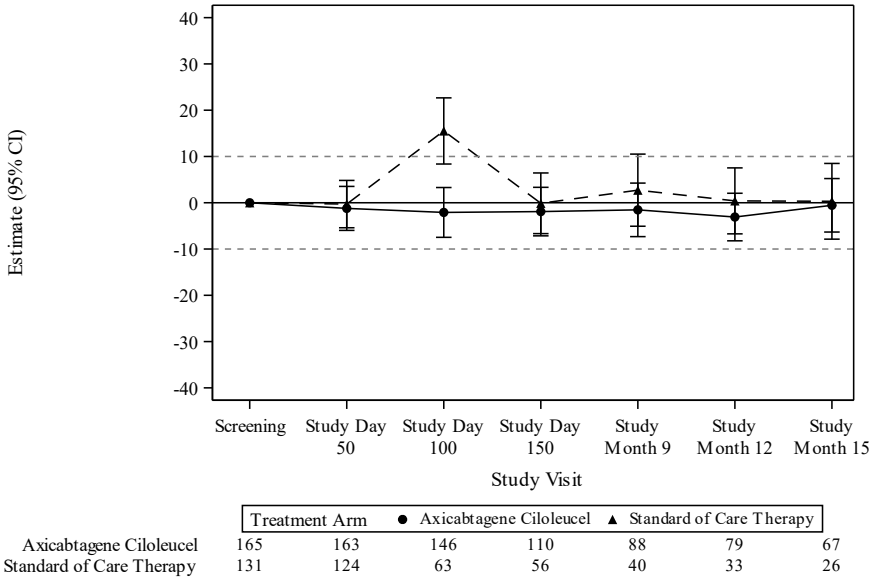
Figure 4.1.14.1 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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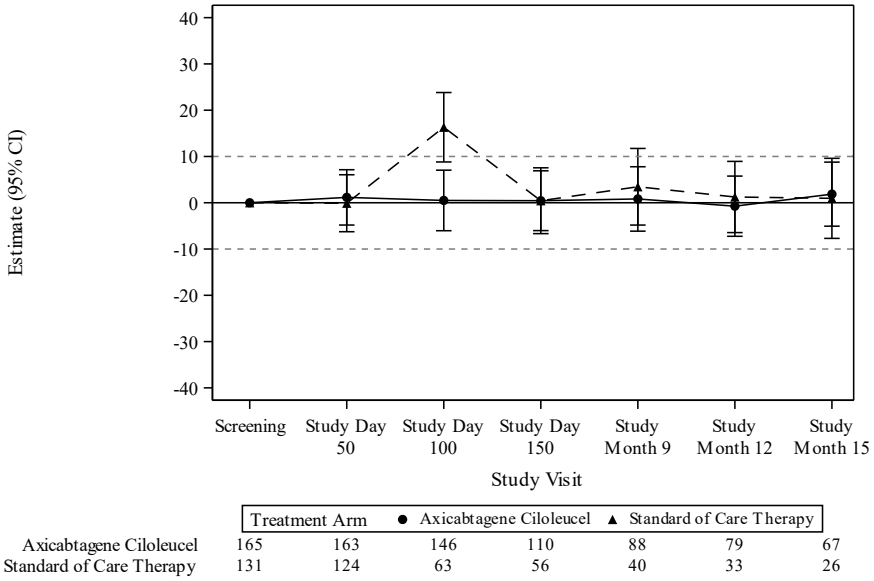
Figure 4.1.14.2 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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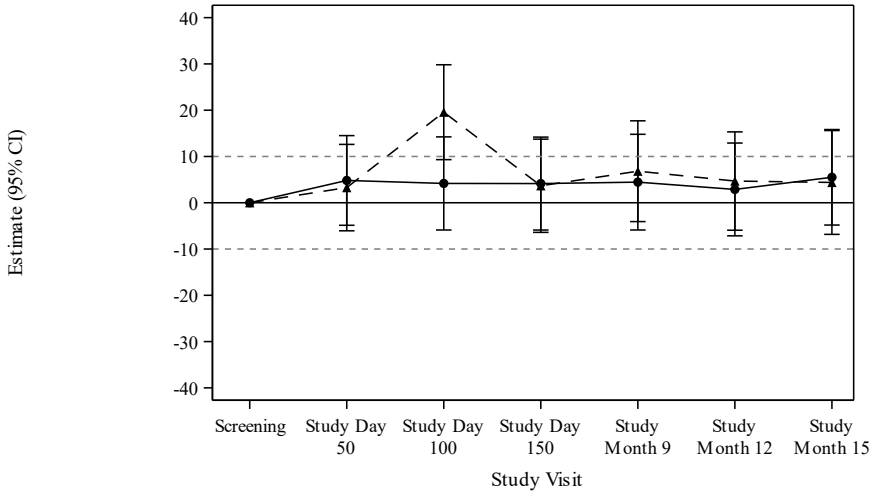
Figure 4.1.14.3 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Treatment Arm	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
● Axicabtagene Ciloleucel	165	163	146	110	88	79	67
▲ Standard of Care Therapy	131	124	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Anhang 4-G2.5.4: Zeit bis zur ersten Verbesserung zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-18 (Anhang): Zeit bis zur ersten Verbesserung der Symptomskalen/-items des EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Time to first improvement among patients who had improvement by treatment

PRO*	Arm	Number of patients with improvement (N)	Median time to improvement (Months)	Median time to improvement (Days)
EORTC-QLQ-C30 Dyspnea	Axi-cel	33	1.05	32
	SOC	10	0.39	12
Loss of Appetite	Axi-cel	26	1.10	33.5
	SOC	12	1.55	47
Insomnia	Axi-cel	45	1.15	35
	SOC	26	0.30	9
Fatigue	Axi-cel	40	3.34	101.5
	SOC	18	1.73	52.5
Nausea and Vomiting	Axi-cel	14	1.13	34.5
	SOC	4	0.82	25
Pain	Axi-cel	40	1.17	35.5
	SOC	32	1.48	45
Constipation	Axi-cel	20	1.51	46
	SOC	16	0.23	7
Diarrhea	Axi-cel	20	0.90	27.5
	SOC	10	0.21	6.5
Financial Difficulties	Axi-cel	31	1.09	33
	SOC	18	0.21	6.5

* The minimally important difference (MID) is 10 points for EORTC QLQ-C30 measures, and it is 15 points for EQ-5D-5L VAS score.
QoL analysis set overall: N=165 for Axi-cel, N=131 for SOC
Datacut: 18 March 2021

Anhang 4-G2.6: Ergänzende Darstellung zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.6.1: Rücklaufquoten nach Visite zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-19 (Anhang): Rücklaufquoten nach Visite zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 1.1.01 EORTC QLQ-C30 Global Health Status/QoL Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	165 (100.0%)	130 (99.2%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	208 (70.3%)	146 (88.5%)	62 (47.3%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	7 (2.4%)	1 (0.6%)	6 (4.6%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	73 (44.2%)	22 (16.8%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	106 (64.2%)	42 (32.1%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	19 (6.4%)	14 (8.5%)	5 (3.8%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.02 EORTC QLQ-C30 Physical Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	164 (99.4%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	1 (0.6%)	0 (0.0%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	16 (9.7%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	1 (0.6%)	0 (0.0%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	85 (28.7%)	18 (10.9%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	1 (0.6%)	0 (0.0%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	85 (28.7%)	18 (10.9%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.03 EORTC QLQ-C30 Role Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	97 (32.8%)	73 (44.2%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	150 (50.7%)	106 (64.2%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.04 EORTC QLQ-C30 Emotional Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.05 EORTC QLQ-C30 Cognitive Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.06 EORTC QLQ-C30 Social Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	165 (100.0%)	130 (99.2%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Anhang 4-G2.6.2: Mittelwert und Veränderung zu Screening zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-20 (Anhang): Mittelwert und Veränderung zu Screening zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 3.1.01 EORTC QLQ-C30 Global Health Status/QoL Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	165	130
	Mean (STDEV)	69.3 (21.3)	68.6 (19.9)	70.1 (23.1)
	Median (Q1, Q3)	75.0 (50.0, 83.3)	66.7 (50.0, 83.3)	75.0 (50.0, 83.3)
	Min, Max	0.0, 100.0	16.7, 100.0	0.0, 100.0
	95% CI	66.8, 71.7	65.6, 71.7	66.1, 74.1
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	61.1 (21.8)	60.9 (21.2)	61.3 (22.7)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	66.7 (50.0, 75.0)	58.3 (41.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	58.6, 63.6	57.7, 64.2	57.3, 65.3
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-7.9 (21.3)	-7.4 (20.2)	-8.5 (22.7)
	Median (Q1, Q3)	-8.3 (-16.7, 0.0)	-8.3 (-16.7, 8.3)	-8.3 (-25.0, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 58.3	-66.7, 66.7
	95% CI	-10.4, -5.4	-10.5, -4.3	-12.6, -4.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	50 (17.4%)	31 (19.0%)	19 (15.3%)
	Stable	119 (41.5%)	62 (38.0%)	57 (46.0%)
	Worsened	118 (41.1%)	70 (42.9%)	48 (38.7%)
Study Day 100				
Score at Study Day 100	n	208	146	62
	Mean (STDEV)	66.5 (22.0)	70.4 (21.0)	57.1 (21.8)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	75.0 (58.3, 83.3)	62.5 (41.7, 75.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 91.7
	95% CI	63.5, 69.5	67.0, 73.9	51.6, 62.7
Change from Screening at Study Day 100	n	208	146	62
	Mean (STDEV)	-3.6 (21.9)	1.3 (19.6)	-15.3 (22.7)
	Median (Q1, Q3)	0.0 (-16.7, 8.3)	0.0 (-8.3, 16.7)	-16.7 (-33.3, 0.0)
	Min, Max	-75.0, 83.3	-58.3, 83.3	-75.0, 33.3
	95% CI	-6.6, -0.7	-1.9, 4.5	-21.1, -9.5
Percent Improved, Stable, or Worsened at Study Day 100	Improved	46 (22.1%)	39 (26.7%)	7 (11.3%)
	Stable	95 (45.7%)	73 (50.0%)	22 (35.5%)
	Worsened	67 (32.2%)	34 (23.3%)	33 (53.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	72.2 (19.8)	74.4 (19.8)	68.0 (19.1)
	Median (Q1, Q3)	75.0 (66.7, 83.3)	83.3 (66.7, 83.3)	66.7 (58.3, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	69.2, 75.3	70.6, 78.1	62.9, 73.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	2.5 (24.9)	5.9 (24.9)	-4.2 (23.7)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (-8.3, 16.7)	0.0 (-25.0, 8.3)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-50.0, 50.0
	95% CI	-1.3, 6.3	1.2, 10.6	-10.5, 2.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	48 (28.9%)	36 (32.7%)	12 (21.4%)
	Stable	85 (51.2%)	59 (53.6%)	26 (46.4%)
	Worsened	33 (19.9%)	15 (13.6%)	18 (32.1%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	74.7 (21.0)	75.1 (20.9)	73.8 (21.2)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 87.5)	79.2 (66.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	71.0, 78.3	70.7, 79.5	67.0, 80.5
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	6.6 (23.0)	8.0 (22.7)	3.5 (23.7)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 20.8)	8.3 (-8.3, 16.7)
	Min, Max	-66.7, 58.3	-66.7, 58.3	-66.7, 50.0
	95% CI	2.6, 10.6	3.2, 12.8	-4.0, 11.1
Percent Improved, Stable, or Worsened at Study Month 9	Improved	53 (41.4%)	38 (43.2%)	15 (37.5%)
	Stable	53 (41.4%)	38 (43.2%)	15 (37.5%)
	Worsened	22 (17.2%)	12 (13.6%)	10 (25.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	76.4 (20.3)	75.3 (23.0)	79.0 (11.8)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 91.7)	83.3 (66.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	72.6, 80.2	70.2, 80.5	74.9, 83.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	8.8 (23.5)	8.6 (24.9)	9.1 (20.2)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (-8.3, 16.7)
	Min, Max	-66.7, 83.3	-66.7, 83.3	-16.7, 50.0
	95% CI	4.4, 13.2	3.1, 14.2	1.9, 16.3
Percent Improved, Stable, or Worsened at Study Month 12	Improved	49 (43.8%)	35 (44.3%)	14 (42.4%)
	Stable	46 (41.1%)	33 (41.8%)	13 (39.4%)
	Worsened	17 (15.2%)	11 (13.9%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	76.6 (19.9)	74.4 (21.0)	82.4 (15.3)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	75.0 (66.7, 83.3)	83.3 (83.3, 91.7)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	72.5, 80.7	69.2, 79.5	76.2, 88.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	9.2 (21.3)	9.0 (22.3)	9.9 (18.9)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	12.5 (0.0, 25.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-25.0, 41.7
	95% CI	4.8, 13.6	3.5, 14.4	2.3, 17.6
Percent Improved, Stable, or Worsened at Study Month 15	Improved	40 (43.0%)	27 (40.3%)	13 (50.0%)
	Stable	41 (44.1%)	32 (47.8%)	9 (34.6%)
	Worsened	12 (12.9%)	8 (11.9%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	77.6 (16.0)	78.1 (16.3)	76.1 (15.3)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 83.3)	75.0 (66.7, 83.3)
	Min, Max	33.3, 100.0	33.3, 100.0	50.0, 100.0
	95% CI	74.3, 80.9	74.2, 81.9	69.5, 82.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	9.3 (20.9)	10.2 (20.9)	6.5 (21.3)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	0.0 (-8.3, 16.7)
	Min, Max	-41.7, 66.7	-41.7, 66.7	-33.3, 50.0
	95% CI	5.0, 13.6	5.3, 15.2	-2.7, 15.7
Percent Improved, Stable, or Worsened at Study Month 18	Improved	40 (42.6%)	30 (42.3%)	10 (43.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	40 (42.6%)	32 (45.1%)	8 (34.8%)
	Worsened	14 (14.9%)	9 (12.7%)	5 (21.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	82.3 (16.2)	81.7 (17.5)	83.8 (13.4)
	Median (Q1, Q3)	83.3 (75.0, 91.7)	83.3 (75.0, 91.7)	83.3 (79.2, 91.7)
	Min, Max	33.3, 100.0	33.3, 100.0	50.0, 100.0
	95% CI	78.3, 86.3	76.4, 86.9	77.5, 90.0
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	11.5 (20.9)	10.0 (21.5)	15.0 (19.6)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 16.7)	16.7 (0.0, 25.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-16.7, 50.0
	95% CI	6.4, 16.7	3.5, 16.5	5.8, 24.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	29 (44.6%)	18 (40.0%)	11 (55.0%)
	Stable	30 (46.2%)	23 (51.1%)	7 (35.0%)
	Worsened	6 (9.2%)	4 (8.9%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	79.5 (20.1)	76.0 (21.9)	88.9 (10.3)
	Median (Q1, Q3)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)	87.5 (83.3, 100.0)
	Min, Max	8.3, 100.0	8.3, 100.0	66.7, 100.0
	95% CI	73.4, 85.7	68.2, 83.9	82.4, 95.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	9.8 (20.0)	8.6 (21.0)	13.2 (17.2)
	Median (Q1, Q3)	8.3 (-4.2, 16.7)	8.3 (-8.3, 16.7)	12.5 (0.0, 20.8)
	Min, Max	-33.3, 50.0	-33.3, 50.0	-8.3, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	3.8, 15.9	1.0, 16.2	2.3, 24.1
Percent Improved, Stable, or Worsened at Study Month 24	Improved	20 (45.5%)	14 (43.8%)	6 (50.0%)
	Stable	18 (40.9%)	12 (37.5%)	6 (50.0%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.02 EORTC QLQ-C30 Physical Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	164	131
	Mean (STDEV)	84.3 (18.2)	83.5 (17.7)	85.3 (18.9)
	Median (Q1, Q3)	86.7 (80.0, 100.0)	86.7 (80.0, 100.0)	93.3 (80.0, 100.0)
	Min, Max	6.7, 100.0	6.7, 100.0	6.7, 100.0
	95% CI	82.2, 86.4	80.8, 86.2	82.0, 88.6
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	73.6 (22.6)	70.7 (24.5)	77.3 (19.5)
	Median (Q1, Q3)	80.0 (60.0, 93.3)	73.3 (53.3, 86.7)	80.0 (66.7, 93.3)
	Min, Max	0.0, 100.0	0.0, 100.0	13.3, 100.0
	95% CI	71.0, 76.2	66.9, 74.5	73.9, 80.7
Change from Screening at Study Day 50	n	288	162	126
	Mean (STDEV)	-10.9 (20.1)	-12.9 (21.7)	-8.3 (17.5)
	Median (Q1, Q3)	-6.7 (-20.0, 0.0)	-6.7 (-26.7, 0.0)	-6.7 (-20.0, 0.0)
	Min, Max	-93.3, 40.0	-93.3, 33.3	-73.3, 40.0
	95% CI	-13.2, -8.6	-16.3, -9.5	-11.4, -5.2
Percent Improved, Stable, or Worsened at Study Day 50	Improved	28 (9.7%)	20 (12.3%)	8 (6.3%)
	Stable	135 (46.9%)	64 (39.5%)	71 (56.3%)
	Worsened	125 (43.4%)	78 (48.1%)	47 (37.3%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	79.5 (21.3)	82.0 (20.9)	74.0 (21.4)
	Median (Q1, Q3)	86.7 (66.7, 100.0)	86.7 (73.3, 100.0)	80.0 (60.0, 93.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	20.0, 100.0
	95% CI	76.6, 82.4	78.5, 85.4	68.7, 79.4
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-5.8 (19.1)	-1.8 (17.8)	-15.0 (19.1)
	Median (Q1, Q3)	0.0 (-13.3, 6.7)	0.0 (-6.7, 6.7)	-13.3 (-30.0, 0.0)
	Min, Max	-93.3, 53.3	-93.3, 53.3	-66.7, 26.7
	95% CI	-8.4, -3.2	-4.7, 1.1	-19.8, -10.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	32 (15.2%)	29 (19.9%)	3 (4.7%)
	Stable	108 (51.4%)	81 (55.5%)	27 (42.2%)
	Worsened	70 (33.3%)	36 (24.7%)	34 (53.1%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	83.9 (18.9)	84.4 (19.7)	82.9 (17.3)
	Median (Q1, Q3)	86.7 (80.0, 100.0)	86.7 (80.0, 100.0)	86.7 (80.0, 93.3)
	Min, Max	0.0, 100.0	0.0, 100.0	20.0, 100.0
	95% CI	81.0, 86.8	80.7, 88.1	78.2, 87.5
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-0.9 (19.9)	1.3 (18.9)	-5.2 (21.3)
	Median (Q1, Q3)	0.0 (-6.7, 6.7)	0.0 (-6.7, 6.7)	0.0 (-13.3, 0.0)
	Min, Max	-73.3, 73.3	-66.7, 53.3	-73.3, 73.3
	95% CI	-4.0, 2.1	-2.3, 4.9	-10.9, 0.5
Percent Improved, Stable, or Worsened at Study Day 150	Improved	30 (18.2%)	26 (23.9%)	4 (7.1%)
	Stable	98 (59.4%)	64 (58.7%)	34 (60.7%)
	Worsened	37 (22.4%)	19 (17.4%)	18 (32.1%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	85.9 (17.5)	86.4 (17.3)	84.7 (18.1)
	Median (Q1, Q3)	93.3 (80.0, 100.0)	93.3 (80.0, 100.0)	91.1 (80.0, 93.3)
	Min, Max	6.7, 100.0	6.7, 100.0	26.7, 100.0
	95% CI	82.8, 88.9	82.7, 90.1	78.9, 90.5
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	2.0 (19.5)	4.1 (17.1)	-2.4 (23.5)
	Median (Q1, Q3)	0.0 (-6.7, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 1.1)
	Min, Max	-73.3, 73.3	-53.3, 53.3	-73.3, 73.3
	95% CI	-1.4, 5.4	0.4, 7.7	-10.0, 5.1
Percent Improved, Stable, or Worsened at Study Month 9	Improved	35 (27.3%)	28 (31.8%)	7 (17.5%)
	Stable	75 (58.6%)	49 (55.7%)	26 (65.0%)
	Worsened	18 (14.1%)	11 (12.5%)	7 (17.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	86.0 (20.1)	84.7 (22.1)	89.1 (14.1)
	Median (Q1, Q3)	93.3 (83.3, 100.0)	93.3 (80.0, 100.0)	93.3 (86.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	82.2, 89.7	79.7, 89.6	84.1, 94.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	2.5 (20.6)	3.4 (20.8)	0.4 (20.3)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	3.3 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-73.3, 73.3	-73.3, 46.7	-66.7, 73.3
	95% CI	-1.3, 6.4	-1.3, 8.1	-6.8, 7.6
Percent Improved, Stable, or Worsened at Study Month 12	Improved	36 (32.1%)	29 (36.7%)	7 (21.2%)
	Stable	56 (50.0%)	36 (45.6%)	20 (60.6%)
	Worsened	20 (17.9%)	14 (17.7%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	87.2 (19.2)	85.2 (21.5)	92.1 (10.0)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (80.0, 100.0)	93.3 (86.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	60.0, 100.0
	95% CI	83.2, 91.1	80.0, 90.5	88.1, 96.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	3.2 (18.4)	3.9 (19.3)	1.6 (16.1)
	Median (Q1, Q3)	0.0 (-6.7, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-60.0, 66.7	-60.0, 53.3	-25.0, 66.7
	95% CI	-0.6, 7.0	-0.9, 8.6	-4.9, 8.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	29 (31.2%)	25 (37.3%)	4 (15.4%)
	Stable	50 (53.8%)	32 (47.8%)	18 (69.2%)
	Worsened	14 (15.1%)	10 (14.9%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	88.0 (15.7)	86.9 (17.0)	91.3 (10.3)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (86.7, 100.0)	93.3 (86.7, 100.0)
	Min, Max	6.7, 100.0	6.7, 100.0	60.0, 100.0
	95% CI	84.8, 91.2	82.9, 91.0	86.8, 95.8
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	4.5 (15.8)	5.0 (15.1)	3.2 (17.9)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-33.3, 60.0	-26.7, 46.7	-33.3, 60.0
	95% CI	1.3, 7.8	1.4, 8.6	-4.5, 10.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	26 (27.7%)	21 (29.6%)	5 (21.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	60 (63.8%)	44 (62.0%)	16 (69.6%)
	Worsened	8 (8.5%)	6 (8.5%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	90.0 (17.3)	88.8 (19.4)	92.7 (11.2)
	Median (Q1, Q3)	100.0 (86.7, 100.0)	100.0 (86.7, 100.0)	100.0 (90.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	85.7, 94.3	83.0, 94.6	87.4, 97.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	5.5 (17.7)	6.0 (16.1)	4.3 (21.4)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (0.0, 13.3)	0.0 (-3.3, 10.0)
	Min, Max	-33.3, 73.3	-26.7, 60.0	-33.3, 73.3
	95% CI	1.1, 9.9	1.2, 10.8	-5.7, 14.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	20 (30.8%)	15 (33.3%)	5 (25.0%)
	Stable	40 (61.5%)	27 (60.0%)	13 (65.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	88.9 (17.6)	85.8 (19.7)	97.2 (4.5)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (83.3, 100.0)	100.0 (93.3, 100.0)
	Min, Max	26.7, 100.0	26.7, 100.0	86.7, 100.0
	95% CI	83.6, 94.3	78.7, 92.9	94.4, 100.1
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	4.2 (14.6)	3.7 (16.5)	5.6 (8.0)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (-3.3, 10.0)	3.3 (0.0, 13.3)
	Min, Max	-26.7, 60.0	-26.7, 60.0	-6.7, 20.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-0.2, 8.7	-2.2, 9.7	0.5, 10.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	12 (27.3%)	8 (25.0%)	4 (33.3%)
	Stable	27 (61.4%)	19 (59.4%)	8 (66.7%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.03 EORTC QLQ-C30 Role Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	77.5 (26.7)	78.4 (25.0)	76.3 (28.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	74.4, 80.5	74.5, 82.2	71.4, 81.3
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	60.9 (31.5)	58.0 (33.2)	64.7 (28.9)
	Median (Q1, Q3)	66.7 (33.3, 83.3)	66.7 (33.3, 83.3)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	57.3, 64.5	52.8, 63.1	59.6, 69.8
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-16.6 (31.8)	-20.2 (31.7)	-11.9 (31.5)
	Median (Q1, Q3)	-16.7 (-33.3, 0.0)	-16.7 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 83.3	-100.0, 50.0	-83.3, 83.3
	95% CI	-20.3, -12.9	-25.1, -15.3	-17.5, -6.4
Percent Improved, Stable, or Worsened at Study Day 50	Improved	46 (15.9%)	22 (13.5%)	24 (19.0%)
	Stable	93 (32.2%)	53 (32.5%)	40 (31.7%)
	Worsened	150 (51.9%)	88 (54.0%)	62 (49.2%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	70.0 (31.7)	75.7 (28.3)	57.0 (35.4)
	Median (Q1, Q3)	83.3 (50.0, 100.0)	83.3 (66.7, 100.0)	66.7 (33.3, 83.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	65.7, 74.3	71.1, 80.3	48.2, 65.9
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-9.8 (29.8)	-3.5 (24.7)	-24.0 (35.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-50.0, 0.0)
	Min, Max	-100.0, 50.0	-100.0, 50.0	-100.0, 33.3
	95% CI	-13.8, -5.7	-7.6, 0.5	-32.8, -15.2
Percent Improved, Stable, or Worsened at Study Day 100	Improved	44 (21.0%)	36 (24.7%)	8 (12.5%)
	Stable	84 (40.0%)	66 (45.2%)	18 (28.1%)
	Worsened	82 (39.0%)	44 (30.1%)	38 (59.4%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	77.9 (27.4)	82.9 (26.1)	68.2 (27.6)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (66.7, 100.0)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	73.7, 82.1	78.0, 87.8	60.8, 75.5
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-1.3 (29.8)	4.8 (27.3)	-13.4 (30.9)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 16.7)	-16.7 (-33.3, 0.0)
	Min, Max	-83.3, 100.0	-83.3, 100.0	-83.3, 100.0
	95% CI	-5.9, 3.3	-0.3, 10.0	-21.7, -5.1
Percent Improved, Stable, or Worsened at Study Day 150	Improved	49 (29.5%)	41 (37.3%)	8 (14.3%)
	Stable	64 (38.6%)	45 (40.9%)	19 (33.9%)
	Worsened	53 (31.9%)	24 (21.8%)	29 (51.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	80.3 (26.3)	82.0 (26.0)	76.7 (26.9)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	75.7, 84.9	76.5, 87.5	68.1, 85.3
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	3.0 (30.8)	5.7 (28.1)	-2.9 (35.6)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (0.0, 16.7)	0.0 (-33.3, 16.7)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-66.7, 100.0
	95% CI	-2.4, 8.4	-0.3, 11.6	-14.3, 8.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	47 (36.7%)	35 (39.8%)	12 (30.0%)
	Stable	49 (38.3%)	34 (38.6%)	15 (37.5%)
	Worsened	32 (25.0%)	19 (21.6%)	13 (32.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	81.5 (26.9)	79.1 (29.8)	87.4 (17.2)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	76.5, 86.6	72.4, 85.8	81.3, 93.5
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	4.8 (29.2)	4.2 (28.1)	6.1 (32.2)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-33.3, 100.0
	95% CI	-0.7, 10.2	-2.1, 10.5	-5.4, 17.5
Percent Improved, Stable, or Worsened at Study Month 12	Improved	37 (33.0%)	27 (34.2%)	10 (30.3%)
	Stable	49 (43.8%)	36 (45.6%)	13 (39.4%)
	Worsened	26 (23.2%)	16 (20.3%)	10 (30.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	83.5 (24.9)	82.3 (27.0)	86.5 (18.3)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	78.4, 88.6	75.7, 88.9	79.2, 93.9
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	5.4 (29.4)	5.2 (27.9)	5.8 (33.6)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 100.0	-83.3, 66.7	-50.0, 100.0
	95% CI	-0.7, 11.4	-1.6, 12.0	-7.8, 19.4
Percent Improved, Stable, or Worsened at Study Month 15	Improved	32 (34.4%)	25 (37.3%)	7 (26.9%)
	Stable	41 (44.1%)	28 (41.8%)	13 (50.0%)
	Worsened	20 (21.5%)	14 (20.9%)	6 (23.1%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	85.3 (22.9)	85.0 (24.1)	86.2 (19.2)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	80.6, 90.0	79.3, 90.7	77.9, 94.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	8.7 (30.4)	8.5 (27.7)	9.4 (38.2)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-83.3, 100.0	-83.3, 83.3	-66.7, 100.0
	95% CI	2.5, 14.9	1.9, 15.0	-7.1, 25.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	38 (40.4%)	27 (38.0%)	11 (47.8%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	36 (38.3%)	30 (42.3%)	6 (26.1%)
	Worsened	20 (21.3%)	14 (19.7%)	6 (26.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	88.5 (20.4)	87.4 (22.8)	90.8 (13.8)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.4, 93.5	80.6, 94.3	84.4, 97.3
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	11.8 (28.8)	11.5 (26.3)	12.5 (34.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 100.0	-33.3, 100.0	-33.3, 100.0
	95% CI	4.7, 18.9	3.6, 19.4	-3.7, 28.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	28 (43.1%)	20 (44.4%)	8 (40.0%)
	Stable	27 (41.5%)	19 (42.2%)	8 (40.0%)
	Worsened	10 (15.4%)	6 (13.3%)	4 (20.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	88.6 (21.2)	84.9 (23.7)	98.6 (4.8)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (66.7, 100.0)	100.0 (100.0, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	83.3, 100.0
	95% CI	82.2, 95.1	76.3, 93.4	95.6, 101.7
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	11.7 (27.7)	10.4 (29.3)	15.3 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 100.0	-33.3, 100.0	0.0, 66.7

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	3.3, 20.2	-0.1, 21.0	-0.0, 30.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	16 (36.4%)	12 (37.5%)	4 (33.3%)
	Stable	22 (50.0%)	14 (43.8%)	8 (66.7%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.04 EORTC QLQ-C30 Emotional Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	77.3 (20.9)	76.9 (20.4)	77.9 (21.4)
	Median (Q1, Q3)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	8.3, 100.0
	95% CI	74.9, 79.7	73.7, 80.0	74.2, 81.6
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	77.8 (22.1)	79.5 (22.2)	75.6 (21.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	75.0 (66.7, 91.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	75.2, 80.3	76.1, 82.9	71.7, 79.4
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	0.6 (20.3)	2.8 (21.6)	-2.3 (18.2)
	Median (Q1, Q3)	0.0 (-8.3, 8.3)	0.0 (-8.3, 16.7)	0.0 (-16.7, 8.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-50.0, 50.0
	95% CI	-1.8, 3.0	-0.5, 6.2	-5.5, 0.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	67 (23.3%)	44 (27.0%)	23 (18.4%)
	Stable	158 (54.9%)	89 (54.6%)	69 (55.2%)
	Worsened	63 (21.9%)	30 (18.4%)	33 (26.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	81.3 (20.2)	82.3 (20.6)	79.0 (19.1)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	91.7 (75.0, 100.0)	83.3 (66.7, 100.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	25.0, 100.0
	95% CI	78.6, 84.1	79.0, 85.7	74.2, 83.8
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	3.6 (21.0)	5.3 (21.5)	-0.6 (19.5)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	8.3 (-8.3, 16.7)	0.0 (-8.3, 8.3)
	Min, Max	-58.3, 66.7	-58.3, 66.7	-41.7, 66.7
	95% CI	0.7, 6.4	1.8, 8.9	-5.5, 4.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	59 (28.2%)	48 (32.9%)	11 (17.5%)
	Stable	111 (53.1%)	73 (50.0%)	38 (60.3%)
	Worsened	39 (18.7%)	25 (17.1%)	14 (22.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	83.6 (18.6)	85.0 (18.0)	80.8 (19.4)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	8.3, 100.0
	95% CI	80.8, 86.4	81.6, 88.4	75.6, 86.0
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	6.9 (18.0)	7.9 (18.6)	4.9 (16.6)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (0.0, 8.3)
	Min, Max	-58.3, 50.0	-58.3, 50.0	-36.1, 50.0
	95% CI	4.1, 9.6	4.4, 11.4	0.4, 9.3
Percent Improved, Stable, or Worsened at Study Day 150	Improved	49 (29.5%)	38 (34.5%)	11 (19.6%)
	Stable	102 (61.4%)	64 (58.2%)	38 (67.9%)
	Worsened	15 (9.0%)	8 (7.3%)	7 (12.5%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	84.6 (18.5)	86.7 (16.8)	80.0 (21.4)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (79.2, 100.0)	83.3 (70.8, 100.0)
	Min, Max	8.3, 100.0	8.3, 100.0	8.3, 100.0
	95% CI	81.4, 87.9	83.2, 90.3	73.2, 86.8
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	9.9 (18.5)	11.3 (19.1)	6.8 (16.9)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)
	Min, Max	-50.0, 83.3	-33.3, 83.3	-50.0, 50.0
	95% CI	6.6, 13.1	7.2, 15.3	1.4, 12.2
Percent Improved, Stable, or Worsened at Study Month 9	Improved	44 (34.4%)	33 (37.5%)	11 (27.5%)
	Stable	76 (59.4%)	51 (58.0%)	25 (62.5%)
	Worsened	8 (6.3%)	4 (4.5%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	85.0 (19.6)	84.2 (20.7)	87.1 (16.7)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	81.4, 88.7	79.5, 88.8	81.2, 93.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	9.7 (21.2)	8.9 (22.4)	11.8 (18.0)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (-8.3, 16.7)	8.3 (0.0, 25.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-16.7, 58.3
	95% CI	5.8, 13.7	3.8, 13.9	5.4, 18.2
Percent Improved, Stable, or Worsened at Study Month 12	Improved	42 (37.5%)	28 (35.4%)	14 (42.4%)
	Stable	57 (50.9%)	41 (51.9%)	16 (48.5%)
	Worsened	13 (11.6%)	10 (12.7%)	3 (9.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	84.1 (19.8)	82.3 (20.9)	88.8 (16.0)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	83.3 (75.0, 100.0)	95.8 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	80.1, 88.2	77.2, 87.4	82.3, 95.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	10.8 (20.2)	9.8 (21.7)	13.5 (15.6)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)
	Min, Max	-41.7, 58.3	-41.7, 58.3	-16.7, 41.7
	95% CI	6.7, 15.0	4.5, 15.1	7.1, 19.8
Percent Improved, Stable, or Worsened at Study Month 15	Improved	36 (38.7%)	25 (37.3%)	11 (42.3%)
	Stable	48 (51.6%)	34 (50.7%)	14 (53.8%)
	Worsened	9 (9.7%)	8 (11.9%)	1 (3.8%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	86.6 (15.9)	86.6 (16.7)	86.6 (13.2)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	66.7, 100.0
	95% CI	83.3, 89.8	82.6, 90.5	80.9, 92.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	12.8 (19.3)	13.6 (19.9)	10.4 (17.5)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	0.0 (0.0, 25.0)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7
	95% CI	8.8, 16.7	8.9, 18.3	2.8, 18.0
Percent Improved, Stable, or Worsened at Study Month 18	Improved	42 (44.7%)	33 (46.5%)	9 (39.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	47 (50.0%)	34 (47.9%)	13 (56.5%)
	Worsened	5 (5.3%)	4 (5.6%)	1 (4.3%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	86.2 (18.9)	85.9 (20.4)	86.7 (15.4)
	Median (Q1, Q3)	91.7 (83.3, 100.0)	91.7 (83.3, 100.0)	91.7 (79.2, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	41.7, 100.0
	95% CI	81.5, 90.8	79.8, 92.1	79.5, 93.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	13.0 (18.9)	12.4 (20.1)	14.4 (16.2)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	16.7 (4.2, 25.0)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7
	95% CI	8.4, 17.7	6.4, 18.4	6.9, 22.0
Percent Improved, Stable, or Worsened at Study Month 21	Improved	30 (46.2%)	19 (42.2%)	11 (55.0%)
	Stable	30 (46.2%)	23 (51.1%)	7 (35.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	86.6 (17.1)	83.9 (18.6)	93.8 (9.5)
	Median (Q1, Q3)	95.8 (75.0, 100.0)	91.7 (66.7, 100.0)	100.0 (83.3, 100.0)
	Min, Max	25.0, 100.0	25.0, 100.0	75.0, 100.0
	95% CI	81.4, 91.7	77.2, 90.5	87.7, 99.8
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	13.4 (20.7)	11.5 (21.4)	18.8 (18.8)
	Median (Q1, Q3)	8.3 (0.0, 29.2)	8.3 (-8.3, 25.0)	25.0 (0.0, 33.3)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	7.1, 19.8	3.8, 19.2	6.8, 30.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	21 (47.7%)	13 (40.6%)	8 (66.7%)
	Stable	19 (43.2%)	16 (50.0%)	3 (25.0%)
	Worsened	4 (9.1%)	3 (9.4%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.05 EORTC QLQ-C30 Cognitive Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	87.9 (17.2)	88.1 (16.4)	87.7 (18.2)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	33.3, 100.0
	95% CI	85.9, 89.9	85.6, 90.6	84.5, 90.8
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	84.0 (20.7)	85.8 (19.7)	81.7 (21.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	81.6, 86.4	82.7, 88.8	77.9, 85.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	-3.8 (17.8)	-2.4 (17.3)	-5.7 (18.3)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 66.7	-50.0, 66.7	-66.7, 33.3
	95% CI	-5.9, -1.8	-5.0, 0.3	-9.0, -2.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	51 (17.7%)	30 (18.4%)	21 (16.8%)
	Stable	153 (53.1%)	91 (55.8%)	62 (49.6%)
	Worsened	84 (29.2%)	42 (25.8%)	42 (33.6%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	85.9 (19.3)	87.0 (20.2)	83.3 (16.9)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	83.3, 88.5	83.7, 90.3	79.1, 87.6
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-2.3 (18.9)	-0.6 (18.3)	-6.3 (19.7)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-50.0, 50.0
	95% CI	-4.9, 0.3	-3.6, 2.4	-11.3, -1.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	42 (20.1%)	30 (20.5%)	12 (19.0%)
	Stable	108 (51.7%)	84 (57.5%)	24 (38.1%)
	Worsened	59 (28.2%)	32 (21.9%)	27 (42.9%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	86.9 (17.4)	88.8 (17.9)	83.3 (15.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	84.3, 89.6	85.4, 92.2	79.1, 87.6
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-0.4 (17.6)	1.7 (17.3)	-4.5 (17.5)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 50.0
	95% CI	-3.1, 2.3	-1.6, 4.9	-9.2, 0.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	36 (21.7%)	27 (24.5%)	9 (16.1%)
	Stable	86 (51.8%)	60 (54.5%)	26 (46.4%)
	Worsened	44 (26.5%)	23 (20.9%)	21 (37.5%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	86.3 (20.2)	87.3 (21.4)	84.2 (17.3)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	82.8, 89.9	82.8, 91.9	78.6, 89.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-0.4 (20.1)	0.6 (20.1)	-2.5 (20.2)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-8.3, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-50.0, 50.0
	95% CI	-3.9, 3.1	-3.7, 4.8	-8.9, 3.9
Percent Improved, Stable, or Worsened at Study Month 9	Improved	30 (23.4%)	23 (26.1%)	7 (17.5%)
	Stable	62 (48.4%)	43 (48.9%)	19 (47.5%)
	Worsened	36 (28.1%)	22 (25.0%)	14 (35.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	86.8 (21.4)	86.1 (23.3)	88.4 (15.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	82.8, 90.8	80.8, 91.3	82.8, 94.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	0.4 (20.9)	0.4 (21.0)	0.5 (21.0)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 66.7
	95% CI	-3.5, 4.4	-4.3, 5.1	-7.0, 8.0
Percent Improved, Stable, or Worsened at Study Month 12	Improved	29 (25.9%)	22 (27.8%)	7 (21.2%)
	Stable	55 (49.1%)	38 (48.1%)	17 (51.5%)
	Worsened	28 (25.0%)	19 (24.1%)	9 (27.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	87.8 (20.0)	88.3 (21.3)	86.5 (16.3)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	91.7 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	83.7, 91.9	83.1, 93.5	79.9, 93.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	2.7 (20.0)	4.0 (19.3)	-0.6 (21.8)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 66.7
	95% CI	-1.4, 6.8	-0.7, 8.7	-9.5, 8.2
Percent Improved, Stable, or Worsened at Study Month 15	Improved	25 (26.9%)	20 (29.9%)	5 (19.2%)
	Stable	50 (53.8%)	38 (56.7%)	12 (46.2%)
	Worsened	18 (19.4%)	9 (13.4%)	9 (34.6%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	88.7 (17.8)	89.4 (18.3)	86.2 (16.4)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (83.3, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	50.0, 100.0
	95% CI	85.0, 92.3	85.1, 93.8	79.1, 93.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	1.8 (19.5)	3.5 (18.9)	-3.6 (20.7)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-33.3, 50.0
	95% CI	-2.2, 5.8	-0.9, 8.0	-12.6, 5.3
Percent Improved, Stable, or Worsened at Study Month 18	Improved	24 (25.5%)	21 (29.6%)	3 (13.0%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	46 (48.9%)	35 (49.3%)	11 (47.8%)
	Worsened	24 (25.5%)	15 (21.1%)	9 (39.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	88.7 (20.2)	87.8 (23.1)	90.8 (11.4)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.7, 93.7	80.8, 94.7	85.5, 96.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	3.1 (20.4)	3.0 (20.8)	3.3 (19.9)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (-8.3, 16.7)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 50.0
	95% CI	-2.0, 8.1	-3.3, 9.2	-6.0, 12.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	20 (30.8%)	14 (31.1%)	6 (30.0%)
	Stable	30 (46.2%)	21 (46.7%)	9 (45.0%)
	Worsened	15 (23.1%)	10 (22.2%)	5 (25.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	90.2 (16.2)	88.5 (17.7)	94.4 (10.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (91.7, 100.0)
	Min, Max	33.3, 100.0	33.3, 100.0	66.7, 100.0
	95% CI	85.2, 95.1	82.2, 94.9	87.5, 101.3
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	2.7 (15.2)	1.6 (14.3)	5.6 (17.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 8.3)	0.0 (0.0, 0.0)
	Min, Max	-33.3, 50.0	-33.3, 33.3	-16.7, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-2.0, 7.3	-3.6, 6.7	-5.8, 16.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	10 (22.7%)	8 (25.0%)	2 (16.7%)
	Stable	27 (61.4%)	18 (56.3%)	9 (75.0%)
	Worsened	7 (15.9%)	6 (18.8%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.06 EORTC QLQ-C30 Social Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	165	130
	Mean (STDEV)	76.7 (24.2)	76.5 (23.8)	76.9 (24.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	73.9, 79.4	72.8, 80.1	72.6, 81.2
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	65.5 (27.9)	65.5 (29.2)	65.3 (26.2)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	66.7 (50.0, 100.0)	66.7 (50.0, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	62.2, 68.7	61.0, 70.1	60.7, 70.0
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-10.9 (26.2)	-10.7 (27.4)	-11.2 (24.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-83.3, 66.7	-83.3, 66.7	-66.7, 50.0
	95% CI	-14.0, -7.9	-15.0, -6.5	-15.5, -6.8
Percent Improved, Stable, or Worsened at Study Day 50	Improved	50 (17.4%)	32 (19.6%)	18 (14.5%)
	Stable	106 (36.9%)	59 (36.2%)	47 (37.9%)
	Worsened	131 (45.6%)	72 (44.2%)	59 (47.6%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	71.9 (29.1)	77.5 (26.1)	58.7 (31.7)
	Median (Q1, Q3)	66.7 (50.0, 100.0)	83.3 (66.7, 100.0)	66.7 (33.3, 83.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	67.9, 75.8	73.2, 81.8	50.8, 66.7
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-6.1 (31.0)	1.6 (26.6)	-23.8 (33.3)
	Median (Q1, Q3)	0.0 (-33.3, 16.7)	0.0 (0.0, 16.7)	-16.7 (-50.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 50.0
	95% CI	-10.3, -1.8	-2.8, 6.0	-32.2, -15.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	56 (26.8%)	50 (34.2%)	6 (9.5%)
	Stable	77 (36.8%)	60 (41.1%)	17 (27.0%)
	Worsened	76 (36.4%)	36 (24.7%)	40 (63.5%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	79.8 (23.0)	84.2 (19.9)	71.1 (26.1)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (66.7, 100.0)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	76.3, 83.3	80.5, 88.0	64.1, 78.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	1.8 (27.6)	9.1 (24.5)	-12.5 (27.9)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 33.3)	-8.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 50.0
	95% CI	-2.4, 6.0	4.5, 13.7	-20.0, -5.0
Percent Improved, Stable, or Worsened at Study Day 150	Improved	58 (34.9%)	48 (43.6%)	10 (17.9%)
	Stable	63 (38.0%)	45 (40.9%)	18 (32.1%)
	Worsened	45 (27.1%)	17 (15.5%)	28 (50.0%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	83.5 (23.5)	87.3 (21.9)	75.0 (25.0)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)	66.7 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	79.3, 87.6	82.7, 91.9	67.0, 83.0
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	6.5 (30.4)	12.5 (29.4)	-6.7 (28.7)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	8.3 (0.0, 33.3)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 50.0
	95% CI	1.2, 11.8	6.3, 18.7	-15.8, 2.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	53 (41.4%)	44 (50.0%)	9 (22.5%)
	Stable	47 (36.7%)	30 (34.1%)	17 (42.5%)
	Worsened	28 (21.9%)	14 (15.9%)	14 (35.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	84.5 (25.4)	83.3 (27.6)	87.4 (19.1)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	79.8, 89.3	77.1, 89.5	80.6, 94.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	7.9 (31.5)	9.7 (34.2)	3.5 (23.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 16.7)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 50.0
	95% CI	2.0, 13.8	2.0, 17.4	-4.8, 11.9
Percent Improved, Stable, or Worsened at Study Month 12	Improved	45 (40.2%)	35 (44.3%)	10 (30.3%)
	Stable	42 (37.5%)	28 (35.4%)	14 (42.4%)
	Worsened	25 (22.3%)	16 (20.3%)	9 (27.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	86.2 (24.0)	84.8 (26.2)	89.7 (17.0)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	81.3, 91.1	78.4, 91.2	82.9, 96.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	11.1 (31.8)	13.4 (33.2)	5.1 (27.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-50.0, 50.0
	95% CI	4.6, 17.7	5.3, 21.5	-5.9, 16.2
Percent Improved, Stable, or Worsened at Study Month 15	Improved	46 (49.5%)	36 (53.7%)	10 (38.5%)
	Stable	33 (35.5%)	23 (34.3%)	10 (38.5%)
	Worsened	14 (15.1%)	8 (11.9%)	6 (23.1%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	87.6 (19.8)	87.3 (21.5)	88.4 (13.7)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.5, 91.7	82.2, 92.4	82.5, 94.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	12.6 (27.4)	15.3 (27.7)	4.3 (25.2)
	Median (Q1, Q3)	8.3 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-50.0, 83.3	-50.0, 83.3	-33.3, 50.0
	95% CI	7.0, 18.2	8.7, 21.8	-6.6, 15.3
Percent Improved, Stable, or Worsened at Study Month 18	Improved	47 (50.0%)	37 (52.1%)	10 (43.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	28 (29.8%)	22 (31.0%)	6 (26.1%)
	Worsened	19 (20.2%)	12 (16.9%)	7 (30.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	91.0 (20.0)	90.0 (22.6)	93.3 (12.6)
	Median (Q1, Q3)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (91.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	86.1, 96.0	83.2, 96.8	87.5, 99.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	14.6 (24.6)	17.0 (24.7)	9.2 (23.9)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-33.3, 50.0
	95% CI	8.5, 20.7	9.6, 24.5	-2.0, 20.3
Percent Improved, Stable, or Worsened at Study Month 21	Improved	32 (49.2%)	24 (53.3%)	8 (40.0%)
	Stable	26 (40.0%)	17 (37.8%)	9 (45.0%)
	Worsened	7 (10.8%)	4 (8.9%)	3 (15.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	89.8 (22.2)	85.9 (25.1)	100.0 (0.0)
	Median (Q1, Q3)	100.0 (100.0, 100.0)	100.0 (66.7, 100.0)	100.0 (100.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	100.0, 100.0
	95% CI	83.0, 96.5	76.9, 95.0	nd
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	15.9 (25.4)	16.1 (27.9)	15.3 (18.1)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	8.3 (0.0, 33.3)
	Min, Max	-33.3, 66.7	-33.3, 66.7	0.0, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	8.2, 23.6	6.1, 26.2	3.8, 26.8
Percent Improved, Stable, or Worsened at Study Month 24	Improved	24 (54.5%)	18 (56.3%)	6 (50.0%)
	Stable	15 (34.1%)	9 (28.1%)	6 (50.0%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Anhang 4-G2.6.3: MMRM-Analyse und Verlaufskurven zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-21 (Anhang): Ergebnisse der MMRM Analyse zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Table 4.1.01 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8434.5		
	AIC (Smaller is Better)	8476.5		
	AICC (Smaller is Better)	8477.4		
	BIC (Smaller is Better)	8554		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-9.6 (-14.0, -5.3)	-10.5 (-15.2, -5.9)
	Difference in Mean Change from Screening (95% CI)		0.9 (-4.1, 5.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.2 (-4.5, 4.2)	-18.3 (-23.8, -12.8)
	Difference in Mean Change from Screening (95% CI)		18.1 (12.3, 23.9)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.4 (-1.7, 8.5)	-6.4 (-12.8, 0.0)
	Difference in Mean Change from Screening (95% CI)		9.8 (2.6, 17.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		5.3 (0.1, 10.5)	0.9 (-5.9, 7.8)
	Difference in Mean Change from Screening (95% CI)		4.4 (-3.3, 12.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		4.9 (-0.4, 10.3)	6.4 (-0.9, 13.6)
	Difference in Mean Change from Screening (95% CI)		-1.5 (-9.6, 6.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.8 (-1.5, 9.0)	8.7 (1.5, 15.9)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-13.0, 3.1)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8418.4		
	AIC (Smaller is Better)	8460.4		
	AICC (Smaller is Better)	8461.3		
	BIC (Smaller is Better)	8537.9		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-11.9 (-17.5, -6.3)	-12.0 (-17.7, -6.3)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.5, 5.8)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.5 (-8.1, 3.2)	-19.7 (-25.7, -13.7)
	Difference in Mean Change from Screening (95% CI)		17.2 (11.2, 23.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.1 (-5.2, 7.3)	-7.9 (-14.8, -1.0)
	Difference in Mean Change from Screening (95% CI)		8.9 (1.5, 16.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		2.8 (-3.5, 9.2)	-0.6 (-8.0, 6.7)
	Difference in Mean Change from Screening (95% CI)		3.4 (-4.4, 11.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.5 (-4.0, 8.9)	4.8 (-2.9, 12.5)
	Difference in Mean Change from Screening (95% CI)		-2.3 (-10.7, 6.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.3 (-5.1, 7.7)	7.2 (-0.5, 14.8)
	Difference in Mean Change from Screening (95% CI)		-5.8 (-14.1, 2.4)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8337.1		
	AIC (Smaller is Better)	8379.1		
	AICC (Smaller is Better)	8380.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8456.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.1 (-22.0, -4.2)	-11.9 (-20.5, -3.4)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-6.9, 4.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.8 (-12.7, 5.2)	-19.5 (-28.2, -10.8)
	Difference in Mean Change from Screening (95% CI)		15.8 (9.5, 22.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.2 (-9.5, 9.1)	-7.7 (-17.1, 1.7)
	Difference in Mean Change from Screening (95% CI)		7.5 (-0.2, 15.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.5 (-7.9, 10.9)	-0.4 (-10.2, 9.3)
	Difference in Mean Change from Screening (95% CI)		1.9 (-6.2, 10.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.1 (-8.4, 10.6)	5.0 (-5.0, 15.0)
	Difference in Mean Change from Screening (95% CI)		-3.9 (-12.3, 4.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-9.4, 9.4)	7.3 (-2.6, 17.3)
	Difference in Mean Change from Screening (95% CI)		-7.3 (-15.6, 1.0)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed; QoL, quality of life.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.02 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8182.3		
	AIC (Smaller is Better)	8224.3		
	AICC (Smaller is Better)	8225.3		
	BIC (Smaller is Better)	8301.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.5 (-17.4, -9.6)	-8.6 (-12.8, -4.3)
	Difference in Mean Change from Screening (95% CI)		-5.0 (-9.6, -0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.1 (-5.9, 1.6)	-15.2 (-20.0, -10.4)
	Difference in Mean Change from Screening (95% CI)		13.1 (8.0, 18.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.1 (-3.1, 5.3)	-4.0 (-9.3, 1.4)
	Difference in Mean Change from Screening (95% CI)		5.1 (-0.9, 11.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		2.9 (-1.4, 7.2)	-0.7 (-6.4, 4.9)
	Difference in Mean Change from Screening (95% CI)		3.6 (-2.7, 9.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.2 (-3.5, 5.8)	3.9 (-2.5, 10.2)
	Difference in Mean Change from Screening (95% CI)		-2.7 (-9.8, 4.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.8 (-2.7, 6.3)	4.6 (-1.5, 10.8)
	Difference in Mean Change from Screening (95% CI)		-2.9 (-9.7, 4.0)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8169.1		
	AIC (Smaller is Better)	8211.1		
	AICC (Smaller is Better)	8212		
	BIC (Smaller is Better)	8288.6		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.1 (-18.1, -8.2)	-8.2 (-13.4, -3.1)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-10.1, 0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.7 (-6.6, 3.1)	-14.9 (-20.2, -9.7)
	Difference in Mean Change from Screening (95% CI)		13.2 (7.9, 18.5)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.5 (-3.8, 6.8)	-3.6 (-9.5, 2.2)
	Difference in Mean Change from Screening (95% CI)		5.1 (-1.0, 11.3)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.3 (-2.0, 8.7)	-0.4 (-6.5, 5.8)
	Difference in Mean Change from Screening (95% CI)		3.7 (-2.7, 10.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.6 (-4.0, 7.3)	4.2 (-2.6, 11.0)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-9.9, 4.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		2.2 (-3.3, 7.7)	5.0 (-1.6, 11.6)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-9.8, 4.2)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8081		
	AIC (Smaller is Better)	8123		
	AICC (Smaller is Better)	8124		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8200.5		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-15.6 (-23.2, -8.1)	-8.9 (-16.3, -1.5)
	Difference in Mean Change from Screening (95% CI)		-6.7 (-11.9, -1.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.3 (-11.8, 3.3)	-15.5 (-23.1, -8.0)
	Difference in Mean Change from Screening (95% CI)		11.3 (5.9, 16.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.1 (-8.9, 6.7)	-4.1 (-12.0, 3.8)
	Difference in Mean Change from Screening (95% CI)		3.1 (-3.1, 9.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.7 (-7.2, 8.6)	-0.8 (-8.9, 7.4)
	Difference in Mean Change from Screening (95% CI)		1.4 (-5.1, 7.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-1.0 (-9.1, 7.0)	3.7 (-4.9, 12.4)
	Difference in Mean Change from Screening (95% CI)		-4.8 (-12.2, 2.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.4 (-8.4, 7.5)	4.5 (-4.0, 13.0)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-12.0, 2.2)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.03 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9112.3		
	AIC (Smaller is Better)	9154.3		
	AICC (Smaller is Better)	9155.3		
	BIC (Smaller is Better)	9231.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-20.6 (-26.7, -14.5)	-12.0 (-18.6, -5.4)
	Difference in Mean Change from Screening (95% CI)		-8.6 (-16.0, -1.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.4 (-9.2, 2.4)	-23.2 (-30.8, -15.7)
	Difference in Mean Change from Screening (95% CI)		19.8 (11.8, 27.9)	nd
	Study Day 150 Mean Change from Screening (95% CI)		4.0 (-2.2, 10.2)	-11.1 (-19.0, -3.2)
	Difference in Mean Change from Screening (95% CI)		15.1 (6.4, 23.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.6 (-2.2, 11.3)	-2.0 (-11.0, 7.0)
	Difference in Mean Change from Screening (95% CI)		6.6 (-3.4, 16.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.4 (-4.4, 9.3)	9.6 (0.2, 19.1)
	Difference in Mean Change from Screening (95% CI)		-7.2 (-17.6, 3.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		4.1 (-2.8, 11.1)	7.1 (-2.6, 16.8)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-13.7, 7.8)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9096.5		
	AIC (Smaller is Better)	9138.5		
	AICC (Smaller is Better)	9139.5		
	BIC (Smaller is Better)	9216		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-21.2 (-28.8, -13.5)	-12.4 (-20.4, -4.4)
	Difference in Mean Change from Screening (95% CI)		-8.8 (-17.0, -0.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.0 (-11.5, 3.5)	-23.7 (-31.9, -15.4)
	Difference in Mean Change from Screening (95% CI)		19.7 (11.4, 28.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.4 (-4.5, 11.2)	-11.5 (-20.2, -2.9)
	Difference in Mean Change from Screening (95% CI)		14.9 (6.0, 23.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.9 (-4.4, 12.3)	-2.5 (-12.1, 7.2)
	Difference in Mean Change from Screening (95% CI)		6.4 (-3.9, 16.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.7 (-6.7, 10.2)	9.1 (-1.1, 19.3)
	Difference in Mean Change from Screening (95% CI)		-7.3 (-18.0, 3.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.5 (-5.0, 12.0)	6.6 (-3.7, 17.0)
	Difference in Mean Change from Screening (95% CI)		-3.1 (-14.2, 7.9)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8979.6		
	AIC (Smaller is Better)	9021.6		
	AICC (Smaller is Better)	9022.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9099.1		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-23.2 (-34.5, -11.8)	-11.4 (-22.6, -0.3)
	Difference in Mean Change from Screening (95% CI)		-11.7 (-19.8, -3.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-5.9 (-17.2, 5.4)	-22.6 (-34.0, -11.3)
	Difference in Mean Change from Screening (95% CI)		16.7 (8.5, 25.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.4 (-10.1, 12.9)	-10.4 (-22.0, 1.2)
	Difference in Mean Change from Screening (95% CI)		11.8 (2.9, 20.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.8 (-10.0, 13.7)	-1.3 (-13.7, 11.1)
	Difference in Mean Change from Screening (95% CI)		3.2 (-7.1, 13.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.6 (-12.5, 11.4)	10.2 (-2.7, 23.2)
	Difference in Mean Change from Screening (95% CI)		-10.8 (-21.5, -0.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.3 (-10.6, 13.3)	7.7 (-5.2, 20.7)
	Difference in Mean Change from Screening (95% CI)		-6.4 (-17.3, 4.5)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.04 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8251.5		
	AIC (Smaller is Better)	8293.5		
	AICC (Smaller is Better)	8294.4		
	BIC (Smaller is Better)	8371		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.7 (-2.3, 5.7)	-3.1 (-7.4, 1.2)
	Difference in Mean Change from Screening (95% CI)		4.9 (0.2, 9.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.9 (0.8, 9.0)	-1.2 (-6.5, 4.1)
	Difference in Mean Change from Screening (95% CI)		6.1 (0.4, 11.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.0 (3.0, 11.0)	2.3 (-2.8, 7.3)
	Difference in Mean Change from Screening (95% CI)		4.8 (-0.6, 10.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		9.7 (5.5, 14.0)	4.0 (-1.6, 9.6)
	Difference in Mean Change from Screening (95% CI)		5.7 (-0.4, 11.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.7 (2.1, 11.4)	8.9 (2.6, 15.2)
	Difference in Mean Change from Screening (95% CI)		-2.2 (-9.2, 4.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		6.4 (1.9, 10.8)	8.0 (2.0, 14.1)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-8.4, 5.0)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8236.9		
	AIC (Smaller is Better)	8278.9		
	AICC (Smaller is Better)	8279.8		
	BIC (Smaller is Better)	8356.4		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.1 (-3.9, 6.2)	-4.6 (-9.8, 0.5)
	Difference in Mean Change from Screening (95% CI)		5.8 (0.5, 11.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.4 (-0.8, 9.6)	-2.0 (-7.7, 3.7)
	Difference in Mean Change from Screening (95% CI)		6.4 (0.5, 12.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.5 (1.4, 11.7)	1.4 (-4.1, 6.9)
	Difference in Mean Change from Screening (95% CI)		5.1 (-0.5, 10.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		9.2 (3.9, 14.6)	3.1 (-2.9, 9.2)
	Difference in Mean Change from Screening (95% CI)		6.1 (-0.2, 12.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.2 (0.6, 11.8)	8.0 (1.3, 14.6)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-8.9, 5.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.8 (0.3, 11.3)	7.0 (0.5, 13.5)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-8.1, 5.7)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8155.9		
	AIC (Smaller is Better)	8197.9		
	AICC (Smaller is Better)	8198.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8275.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.1 (-15.1, 0.8)	-12.1 (-19.7, -4.4)
	Difference in Mean Change from Screening (95% CI)		4.9 (-0.4, 10.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.8 (-11.9, 4.2)	-9.5 (-17.5, -1.5)
	Difference in Mean Change from Screening (95% CI)		5.6 (-0.5, 11.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.7 (-9.7, 6.3)	-6.3 (-14.2, 1.7)
	Difference in Mean Change from Screening (95% CI)		4.5 (-1.3, 10.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.9 (-7.2, 9.0)	-4.4 (-12.6, 3.9)
	Difference in Mean Change from Screening (95% CI)		5.3 (-1.0, 11.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-2.1 (-10.4, 6.2)	0.4 (-8.4, 9.1)
	Difference in Mean Change from Screening (95% CI)		-2.5 (-9.8, 4.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.4 (-10.7, 5.8)	-0.6 (-9.2, 8.1)
	Difference in Mean Change from Screening (95% CI)		-1.9 (-8.9, 5.2)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.05 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8021.6		
	AIC (Smaller is Better)	8063.6		
	AICC (Smaller is Better)	8064.6		
	BIC (Smaller is Better)	8141.1		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.0 (-7.6, -0.4)	-7.5 (-11.4, -3.6)
	Difference in Mean Change from Screening (95% CI)		3.5 (-0.6, 7.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.2 (-6.0, 1.6)	-7.1 (-12.0, -2.2)
	Difference in Mean Change from Screening (95% CI)		5.0 (-0.3, 10.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.7 (-4.5, 3.1)	-5.5 (-10.3, -0.7)
	Difference in Mean Change from Screening (95% CI)		4.8 (-0.4, 10.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.8 (-6.1, 2.6)	-3.9 (-9.7, 1.8)
	Difference in Mean Change from Screening (95% CI)		2.2 (-4.2, 8.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.2 (-7.7, 1.2)	-0.5 (-6.6, 5.5)
	Difference in Mean Change from Screening (95% CI)		-2.7 (-9.4, 4.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.3 (-5.6, 3.1)	-3.0 (-8.9, 3.0)
	Difference in Mean Change from Screening (95% CI)		1.7 (-4.9, 8.3)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8007.2		
	AIC (Smaller is Better)	8049.2		
	AICC (Smaller is Better)	8050.2		
	BIC (Smaller is Better)	8126.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-5.6 (-10.4, -0.9)	-9.2 (-14.0, -4.4)
	Difference in Mean Change from Screening (95% CI)		3.6 (-1.1, 8.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.7 (-8.6, 1.2)	-8.4 (-13.7, -3.1)
	Difference in Mean Change from Screening (95% CI)		4.7 (-0.8, 10.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.3 (-7.2, 2.6)	-6.8 (-12.1, -1.6)
	Difference in Mean Change from Screening (95% CI)		4.5 (-0.9, 9.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-3.4 (-8.7, 2.0)	-5.3 (-11.4, 0.8)
	Difference in Mean Change from Screening (95% CI)		1.9 (-4.7, 8.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.8 (-10.2, 0.6)	-1.9 (-8.3, 4.6)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-9.9, 4.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.9 (-8.2, 2.5)	-4.3 (-10.7, 2.0)
	Difference in Mean Change from Screening (95% CI)		1.5 (-5.3, 8.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	7919.5		
	AIC (Smaller is Better)	7961.5		
	AICC (Smaller is Better)	7962.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8039		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-8.3 (-15.6, -1.1)	-10.5 (-17.6, -3.5)
	Difference in Mean Change from Screening (95% CI)		2.2 (-2.5, 6.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-6.3 (-13.8, 1.1)	-9.9 (-17.3, -2.5)
	Difference in Mean Change from Screening (95% CI)		3.5 (-2.1, 9.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.0 (-12.4, 2.4)	-8.2 (-15.5, -0.9)
	Difference in Mean Change from Screening (95% CI)		3.1 (-2.3, 8.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.1 (-13.8, 1.6)	-6.7 (-14.7, 1.2)
	Difference in Mean Change from Screening (95% CI)		0.6 (-5.9, 7.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.5 (-15.3, 0.2)	-3.3 (-11.4, 4.9)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-11.2, 2.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-5.6 (-13.3, 2.1)	-5.8 (-13.9, 2.4)
	Difference in Mean Change from Screening (95% CI)		0.1 (-6.7, 6.9)	nd

Data cutoff date = 18MAR2021
Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.
[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.06 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8908.4		
	AIC (Smaller is Better)	8950.4		
	AICC (Smaller is Better)	8951.4		
	BIC (Smaller is Better)	9027.9		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.0 (-18.3, -7.8)	-12.9 (-18.6, -7.3)
	Difference in Mean Change from Screening (95% CI)		-0.1 (-6.2, 6.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.1 (-6.7, 4.6)	-23.9 (-31.2, -16.7)
	Difference in Mean Change from Screening (95% CI)		22.8 (15.0, 30.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.2 (0.7, 11.7)	-10.7 (-17.6, -3.7)
	Difference in Mean Change from Screening (95% CI)		16.9 (9.3, 24.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		11.1 (4.8, 17.4)	-3.1 (-11.5, 5.3)
	Difference in Mean Change from Screening (95% CI)		14.2 (4.8, 23.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		5.9 (-1.1, 12.9)	10.0 (0.4, 19.5)
	Difference in Mean Change from Screening (95% CI)		-4.1 (-14.9, 6.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		8.7 (1.6, 15.7)	8.9 (-1.0, 18.8)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-11.3, 10.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8892.6		
	AIC (Smaller is Better)	8934.6		
	AICC (Smaller is Better)	8935.6		
	BIC (Smaller is Better)	9012.1		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-12.0 (-18.8, -5.1)	-11.4 (-18.3, -4.4)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-7.4, 6.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.1 (-7.3, 7.0)	-22.9 (-30.7, -15.1)
	Difference in Mean Change from Screening (95% CI)		22.8 (14.6, 31.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.3 (0.1, 14.4)	-9.5 (-17.2, -1.8)
	Difference in Mean Change from Screening (95% CI)		16.8 (8.9, 24.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		12.2 (4.4, 20.0)	-1.9 (-10.9, 7.2)
	Difference in Mean Change from Screening (95% CI)		14.1 (4.4, 23.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.9 (-1.3, 15.2)	11.1 (1.0, 21.2)
	Difference in Mean Change from Screening (95% CI)		-4.2 (-15.2, 6.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		9.7 (1.4, 18.0)	10.1 (-0.3, 20.5)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-11.8, 11.0)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8793.9		
	AIC (Smaller is Better)	8835.9		
	AICC (Smaller is Better)	8836.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8913.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-11.0 (-21.5, -0.4)	-8.8 (-19.0, 1.4)
	Difference in Mean Change from Screening (95% CI)		-2.2 (-9.1, 4.8)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.9 (-9.9, 11.7)	-20.0 (-30.8, -9.2)
	Difference in Mean Change from Screening (95% CI)		20.9 (12.6, 29.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		8.2 (-2.5, 19.0)	-6.5 (-17.1, 4.1)
	Difference in Mean Change from Screening (95% CI)		14.8 (7.0, 22.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		13.1 (1.9, 24.3)	1.2 (-10.4, 12.8)
	Difference in Mean Change from Screening (95% CI)		11.9 (2.4, 21.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		8.0 (-3.5, 19.5)	14.0 (1.5, 26.4)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-16.9, 4.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		10.9 (-0.5, 22.4)	12.8 (0.1, 25.4)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-12.9, 9.3)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 9 (Anhang): Verlaufskurven zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

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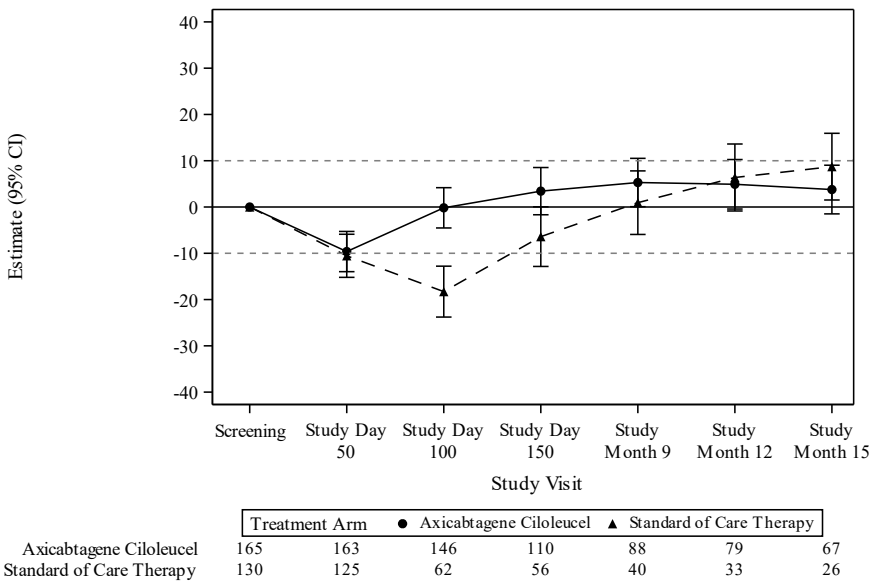
Figure 4.1.01.1 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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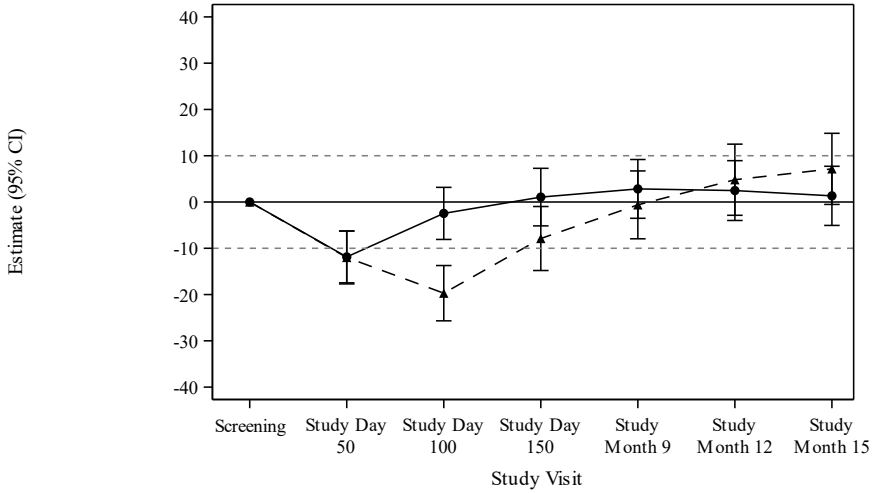
Figure 4.1.01.2 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Treatment Arm	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
● Axicabtagene Ciloleucel	165	163	146	110	88	79	67
▲ Standard of Care Therapy	130	125	62	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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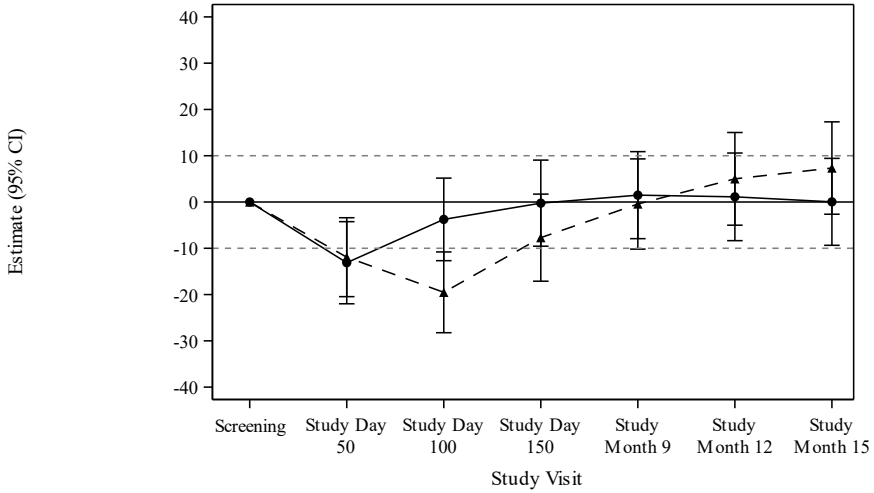
Figure 4.1.01.3 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Treatment Arm	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
● Axicabtagene Ciloleucel	165	163	146	110	88	79	67
▲ Standard of Care Therapy	130	125	62	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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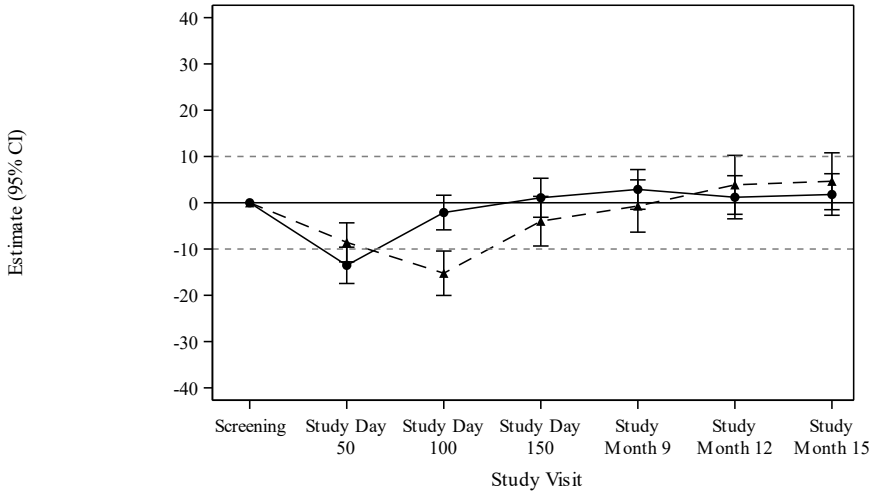
Figure 4.1.02.1 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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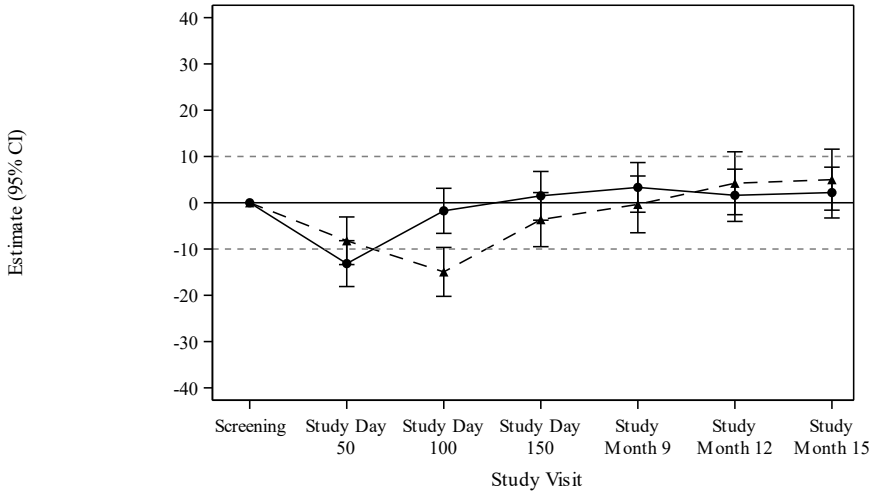
Figure 4.1.02.2 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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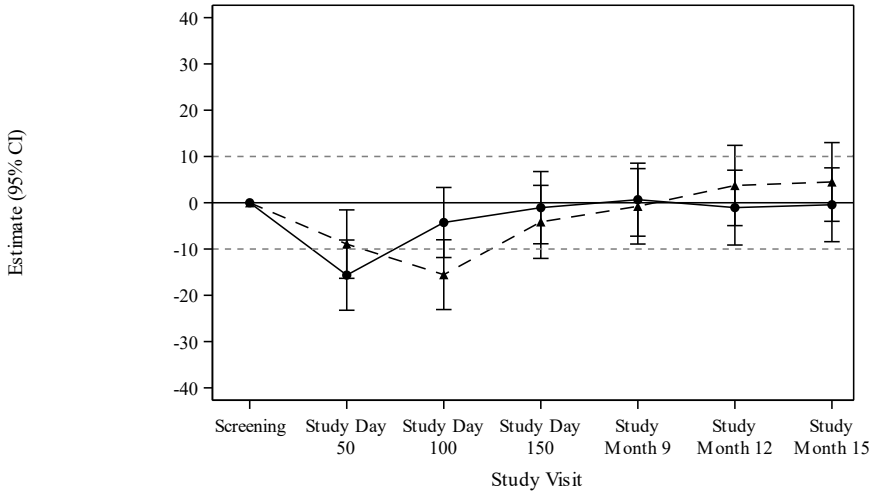
Figure 4.1.02.3 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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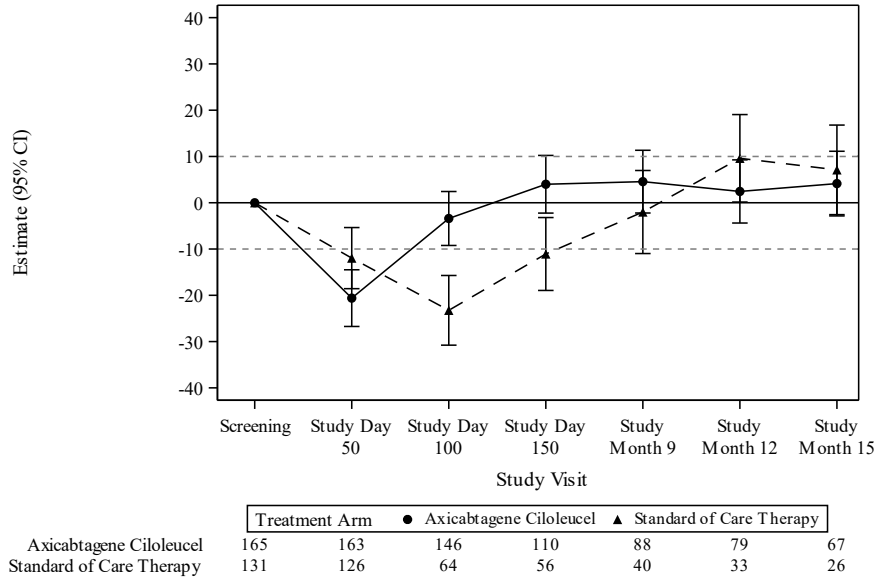
Figure 4.1.03.1 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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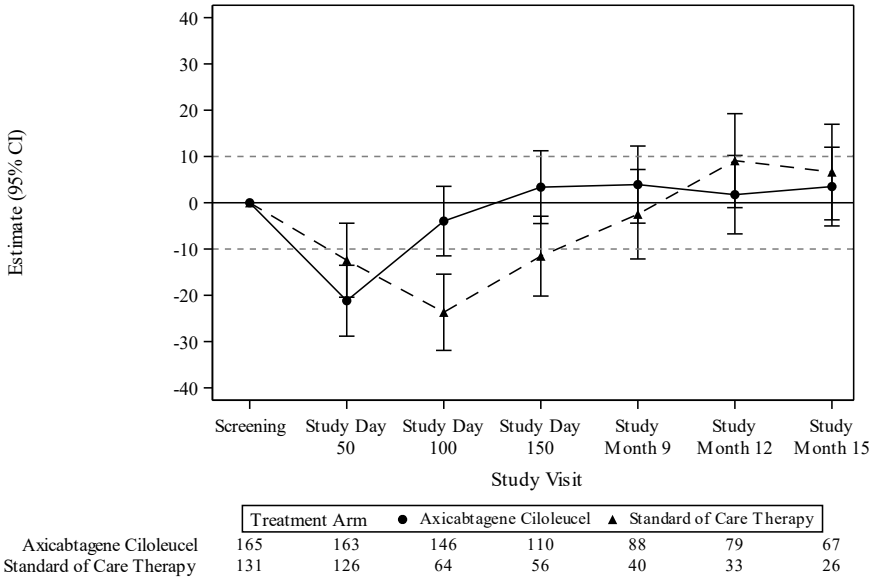
Figure 4.1.03.2 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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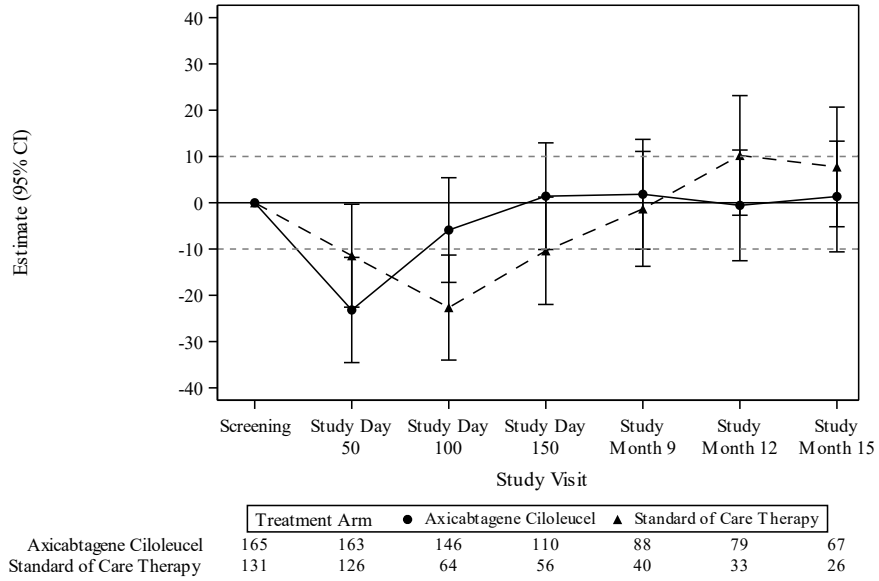
Figure 4.1.03.3 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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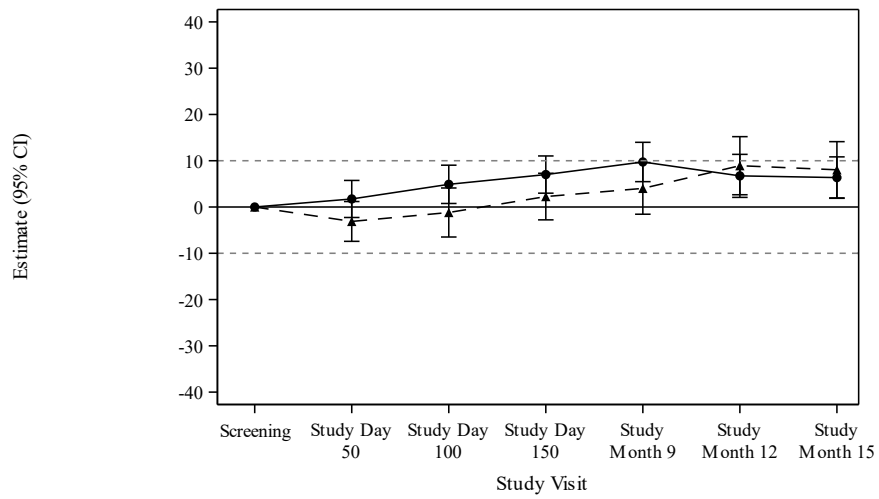
Figure 4.1.04.1 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Treatment Arm	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
● Axicabtagene Ciloleucel	165	163	146	110	88	79	67
▲ Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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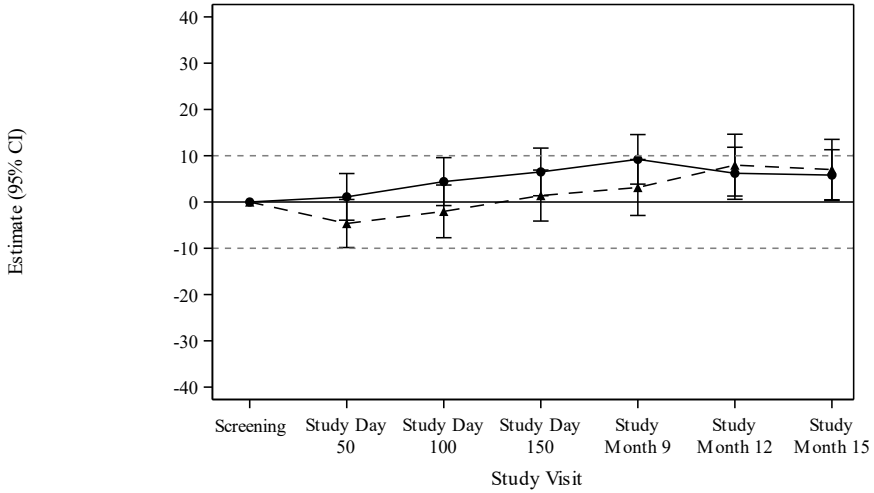
Figure 4.1.04.2 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Treatment Arm	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
● Axicabtagene Ciloleucel	165	163	146	110	88	79	67
▲ Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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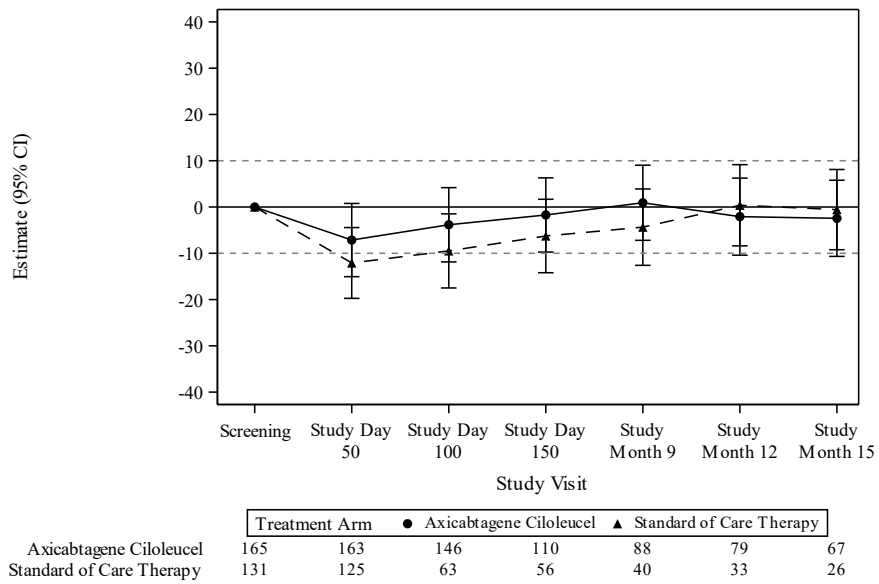
Figure 4.1.04.3 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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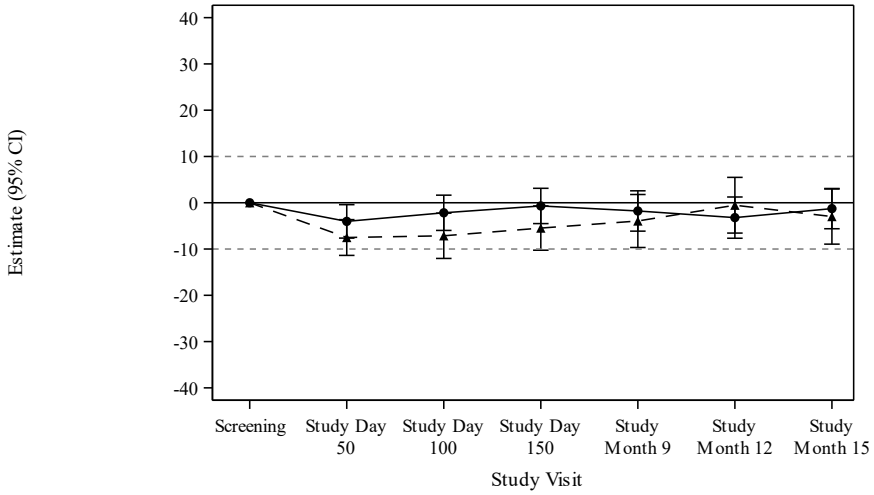
Figure 4.1.05.1 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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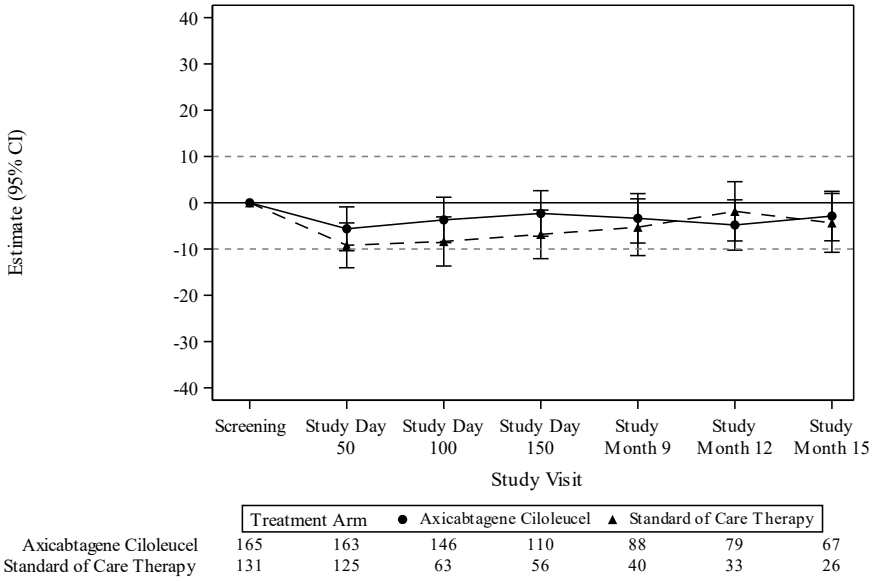
Figure 4.1.05.2 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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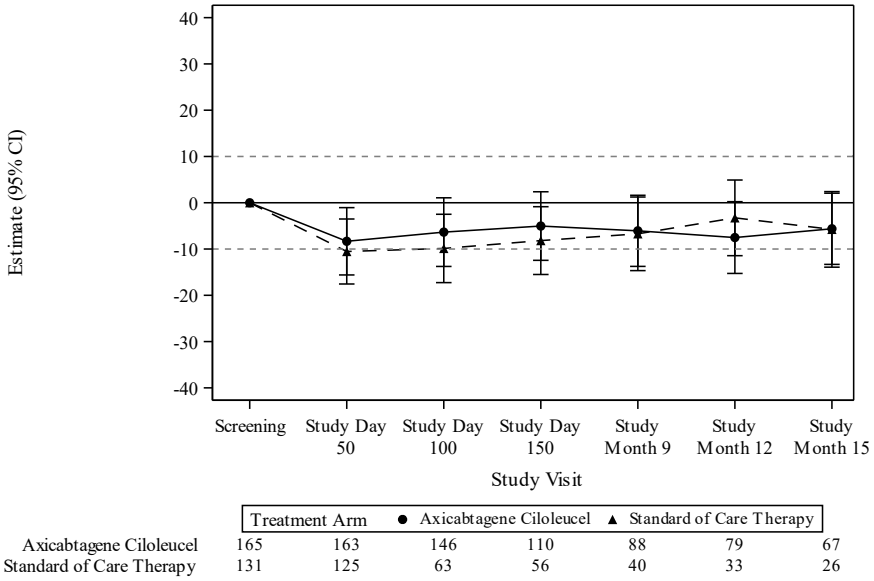
Figure 4.1.05.3 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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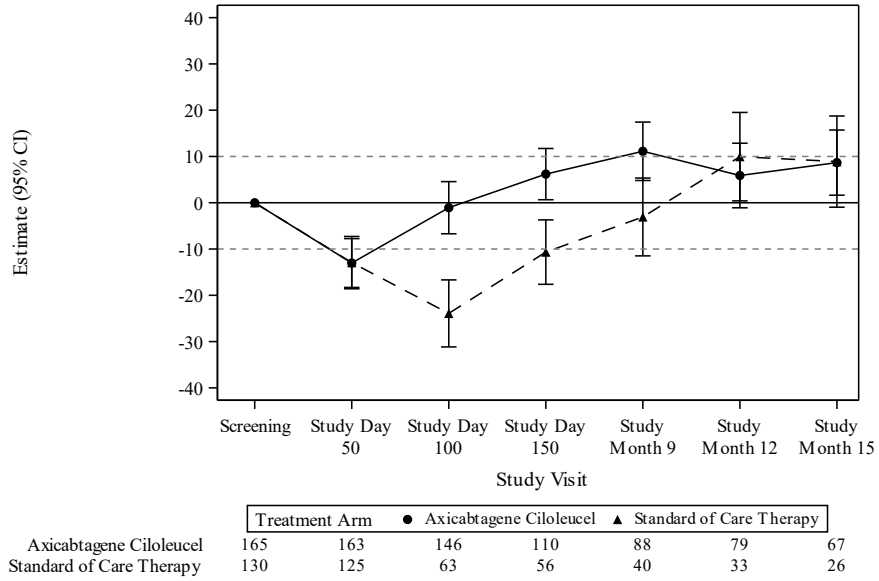
PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

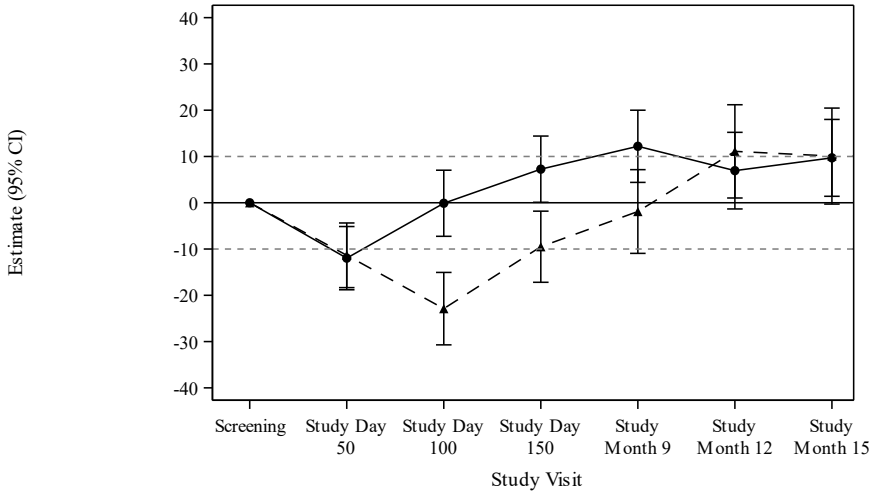
Figure 4.1.06.1 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Figure 4.1.06.2 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)

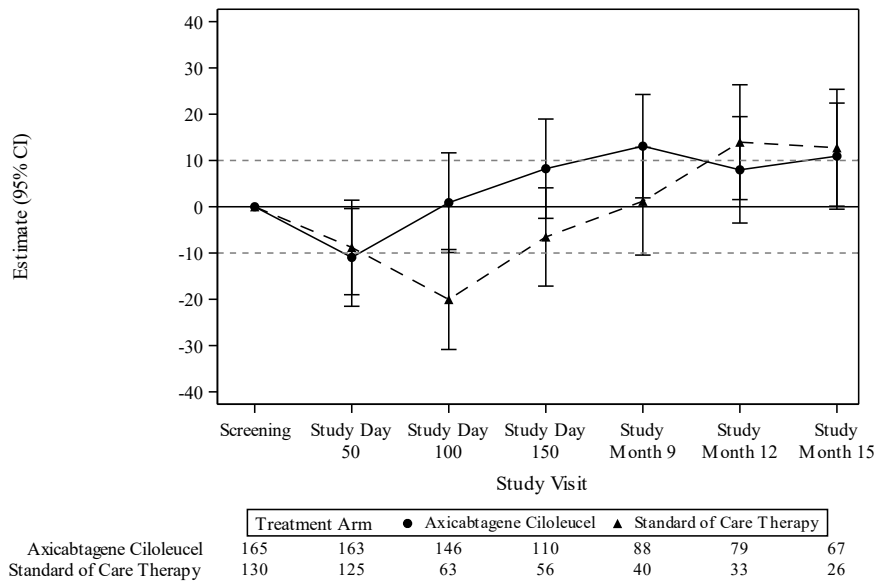


Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	130	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Figure 4.1.06.3 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Anhang 4-G2.6.4: Zeit bis zur ersten Verbesserung zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-22 (Anhang): Zeit bis zur ersten Verbesserung der Funktionsskalen/des globalen Gesundheitsstatus des EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Time to first improvement among patients who had improvement by treatment

PRO*	Arm	Number of patients with improvement (N)	Median time to improvement (Months)	Median time to improvement (Days)
Global Health Status	Axi-cel	31	3.39	103
	SOC	18	5.33	162
Physical function	Axi-cel	18	3.49	106
	SOC	7	5.30	161
Role Functioning	Axi-cel	29	3.32	101
	SOC	12	0.82	25
Emotional Functioning	Axi-cel	26	1.17	35.5
	SOC	15	1.55	47
Cognitive Functioning	Axi-cel	22	0.89	27
	SOC	21	1.51	46
Social Functioning	Axi-cel	39	1.74	53
	SOC	21	1.68	51

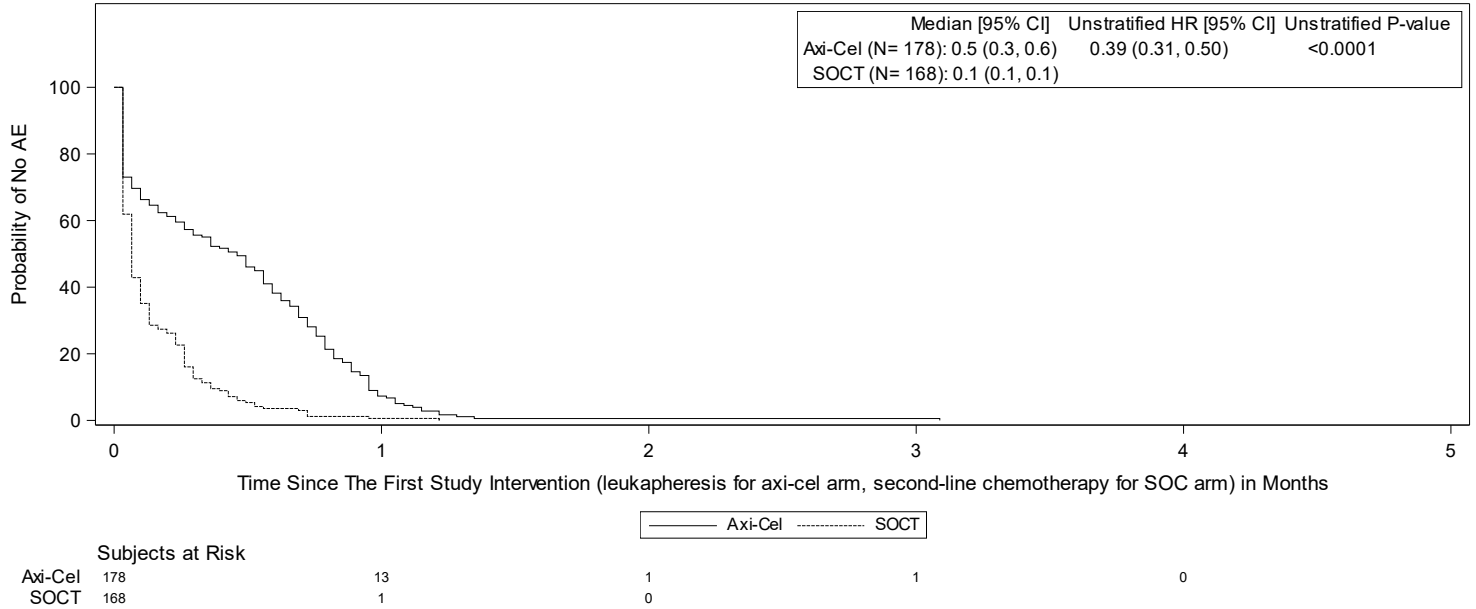
* The minimally important difference (MID) is 10 points for EORTC QLQ-C30 measures, and it is 15 points for EQ-5D-5L VAS score.
QoL analysis set overall: N=165 for Axi-cel, N=131 for SOC
Datacut: 18 March 2021

Anhang 4-G2.7: Ergänzende Darstellung zu unerwünschte Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.7.1: Kaplan-Meier Plots zu Gesamtraten an UE ohne erkrankungsbezogene Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Abbildung 10 (Anhang): Kaplan-Meier-Plots zu UE ohne erkrankungssbezogene Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.4.1.4. Kaplan-Meier Plot of Time To First TEAE excluding events in SOC Neoplasms benign, malignant and unspecified (Modified Safety Analysis Set)



Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240405T11:55

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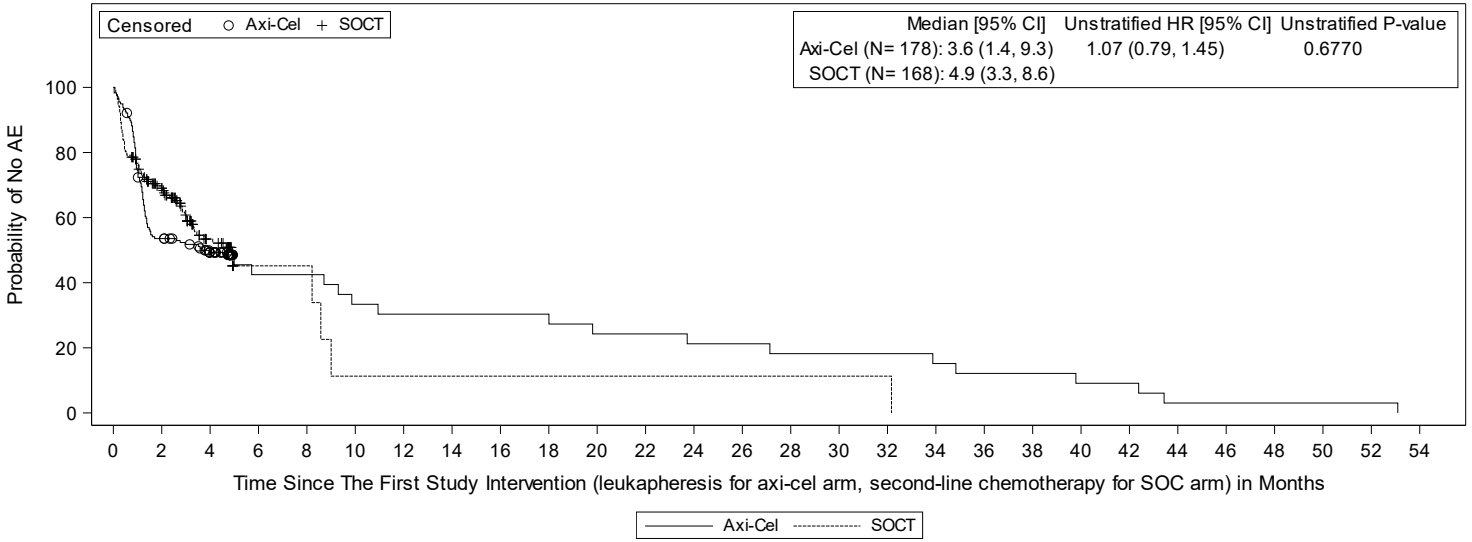
Figure 14.5.4.1.5. Kaplan-Meier Plot of Time To First Serious TEAE excluding events in SOC Neoplasms benign, malignant and unspecified (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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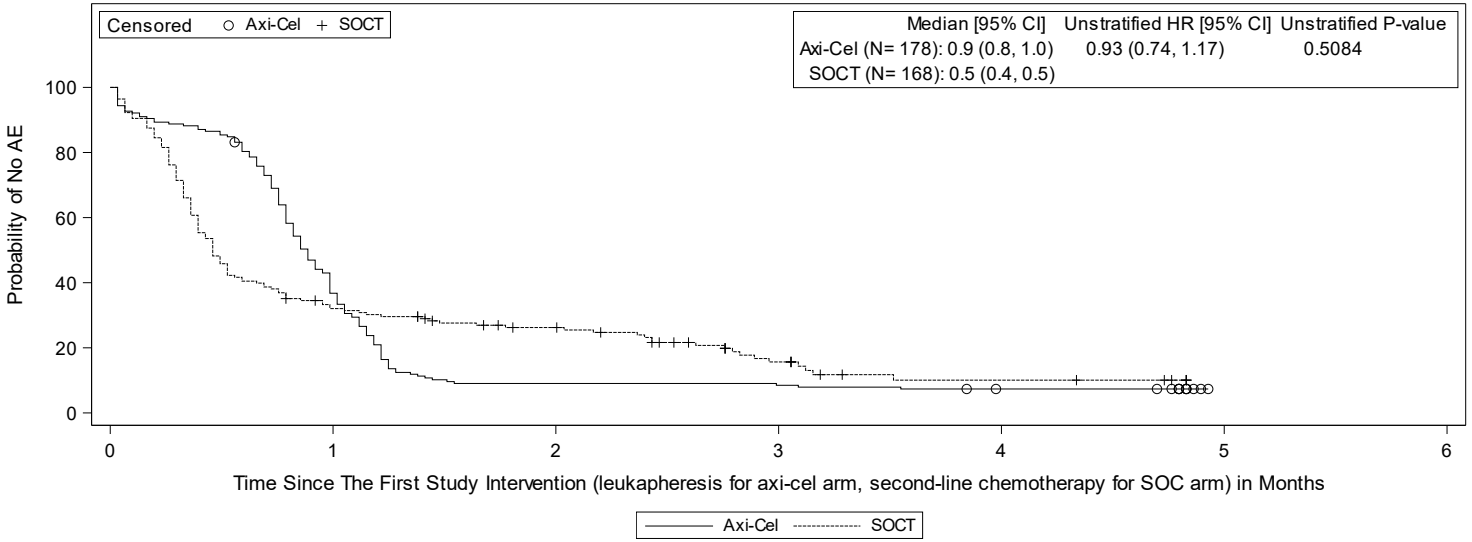
Figure 14.5.4.1.6. Kaplan-Meier Plot of Time To First Severe TEAE excluding events in SOC Neoplasms benign, malignant and unspecified (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	65	16	15	11	0
SOCT	168	52	36	15	6	0

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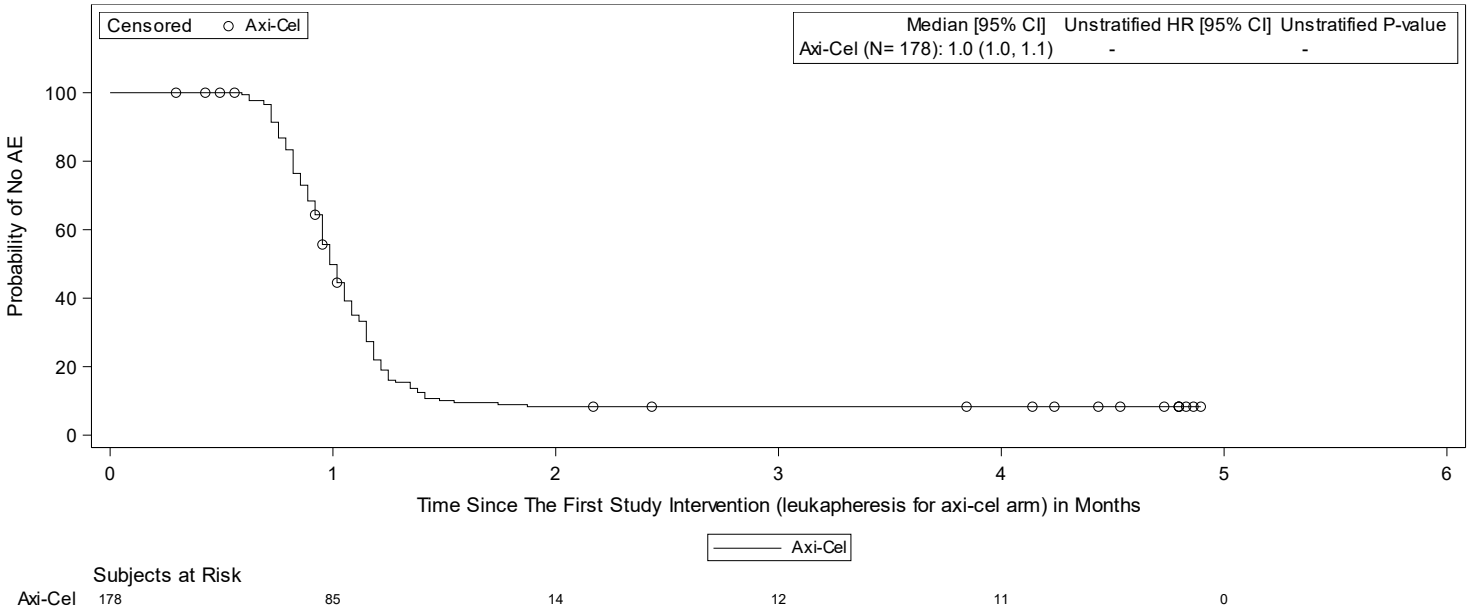
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240405T11:55

Anhang 4-G2.7.2: Kaplan-Meier Plots zu UE von speziellem Interesse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Abbildung 11 (Anhang): Kaplan-Meier-Plots zu UE von speziellem Interesse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.4.1.7. Kaplan-Meier Plot of Time To First Cytokine Release Syndrome (CRS) (Modified Safety Analysis Set)



Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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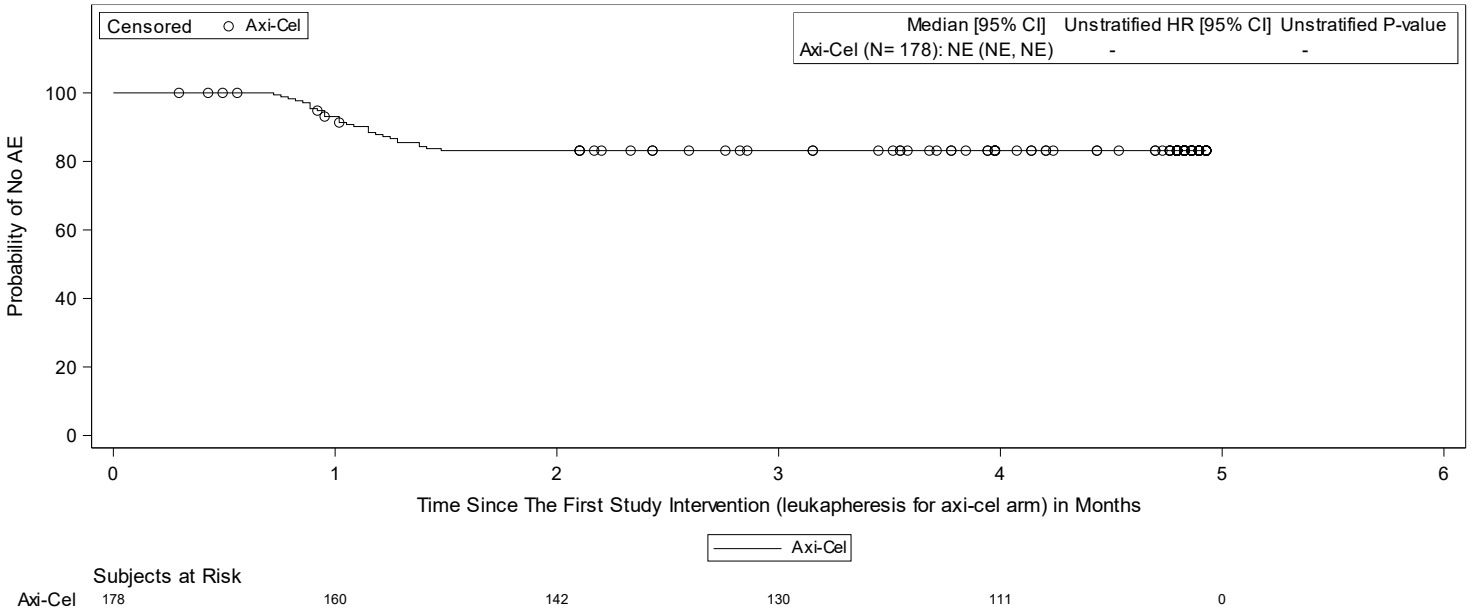
Figure 14.5.4.1.8. Kaplan-Meier Plot of Time To First Serious Cytokine Release Syndrome (CRS) (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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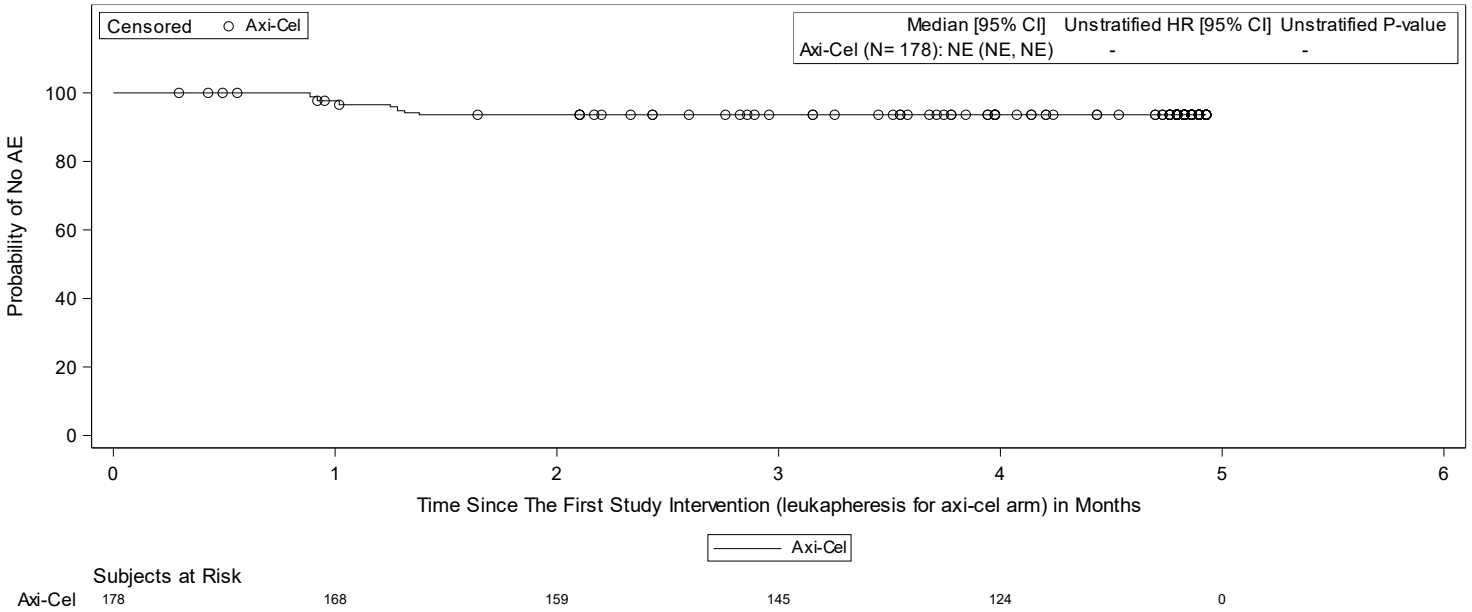
Figure 14.5.4.1.9. Kaplan-Meier Plot of Time To First Severe Cytokine Release Syndrome (CRS) (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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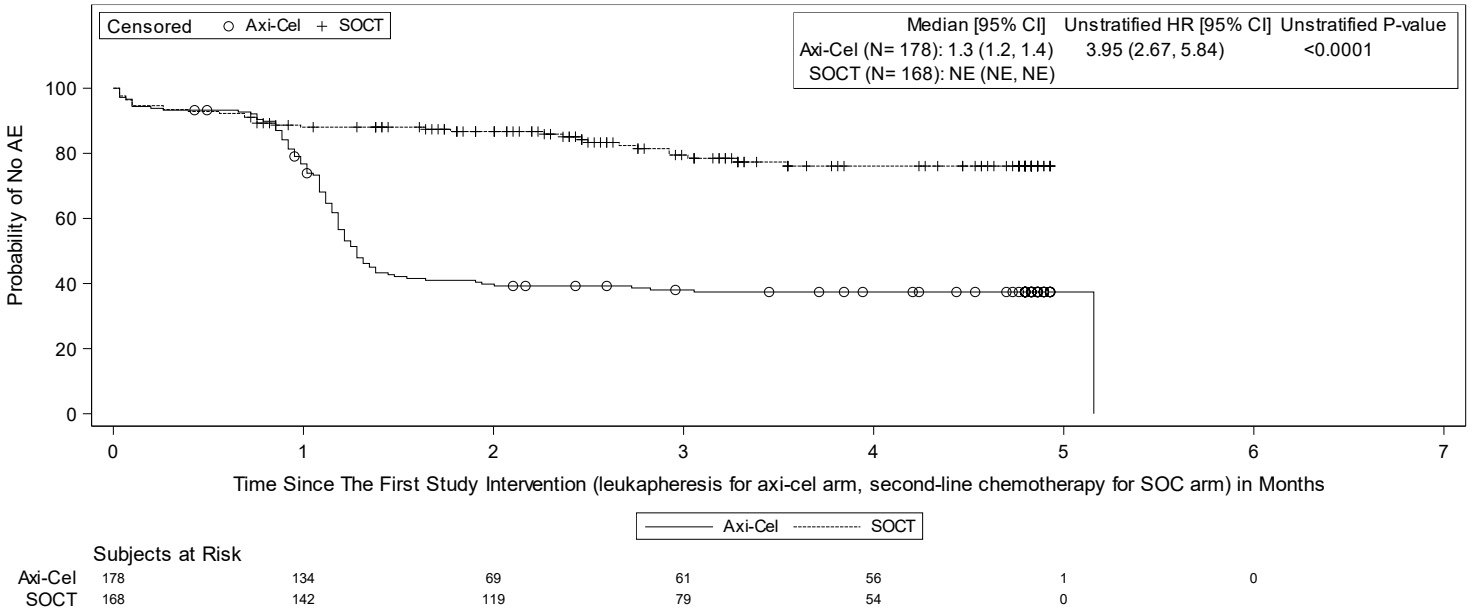
Figure 14.5.4.1.10. Kaplan-Meier Plot of Time To First Neurologic Toxicity (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	134	69	61	56	1	0
SOCT	168	142	119	79	54	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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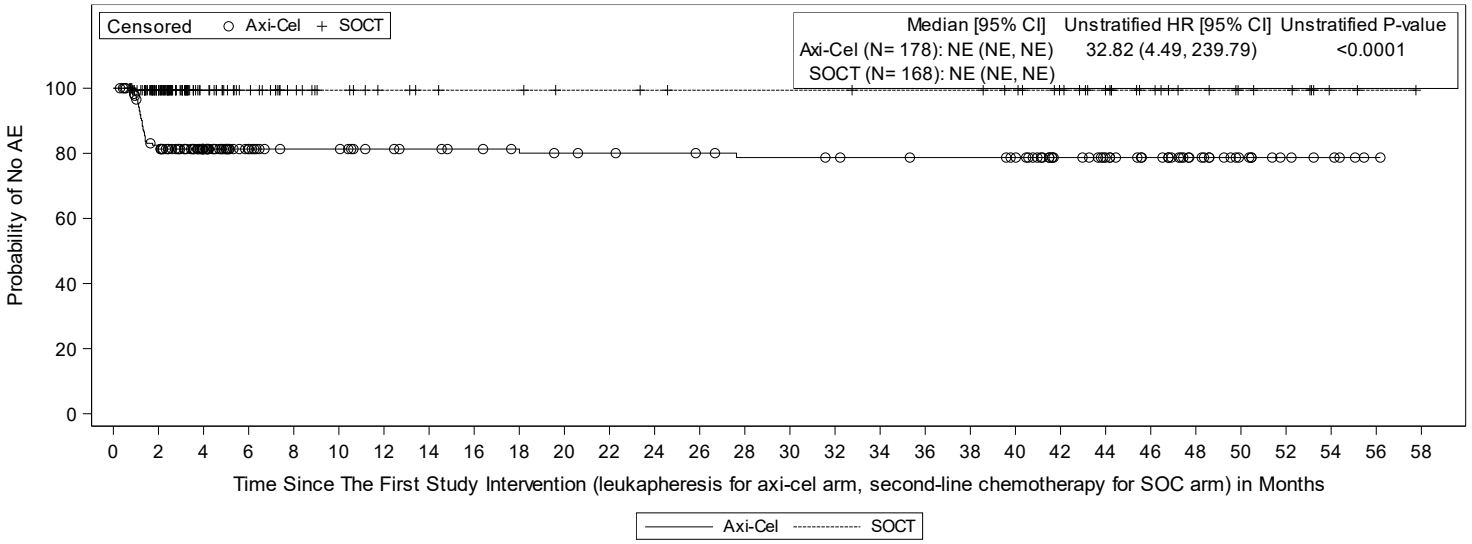
Figure 14.5.4.1.11. Kaplan-Meier Plot of Time To First Serious Neurologic Toxicity (Modified Safety Analysis Set)



Subjects at Risk

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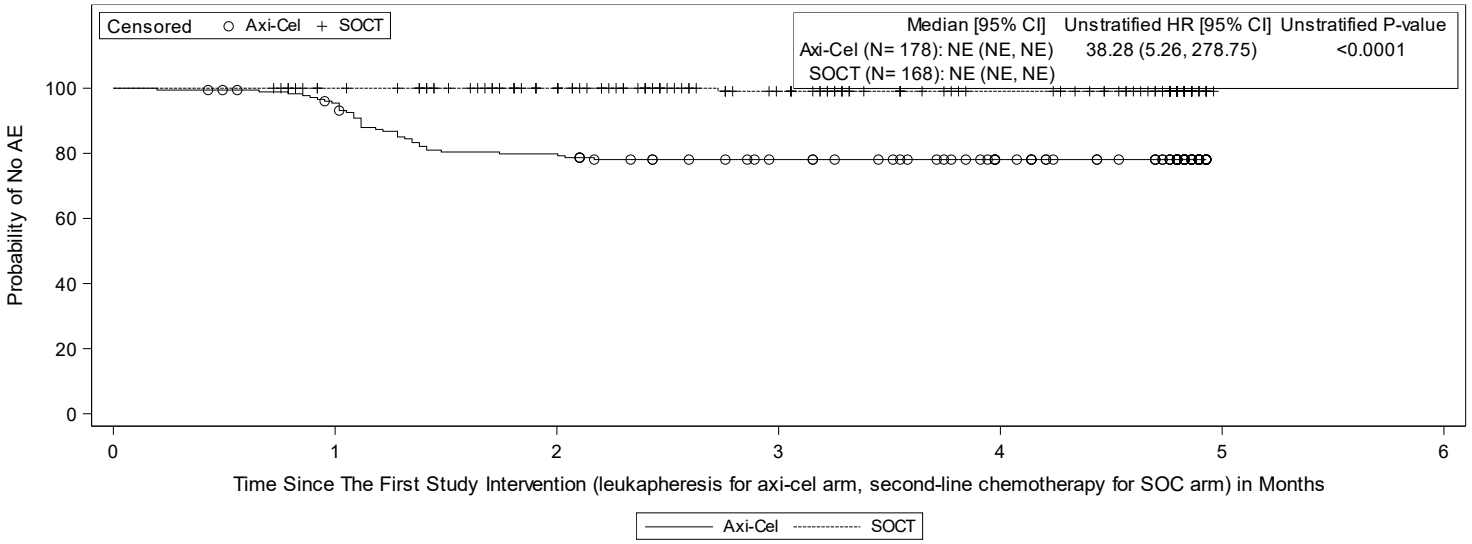
Figure 14.5.4.1.12. Kaplan-Meier Plot of Time To First Severe Neurologic Toxicity (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	166	138	123	106	0
SOCT	168	160	136	100	74	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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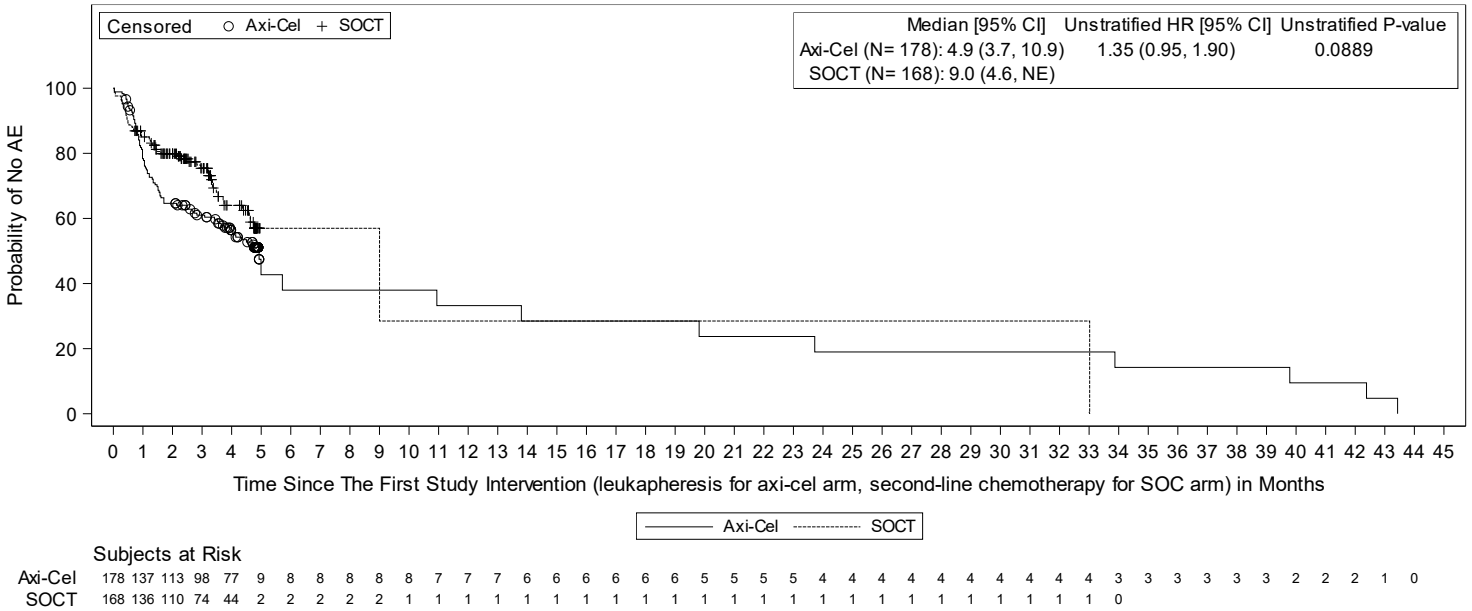
Figure 14.5.4.1.13. Kaplan-Meier Plot of Time To First Infections (Modified Safety Analysis Set)



Subjects at Risk

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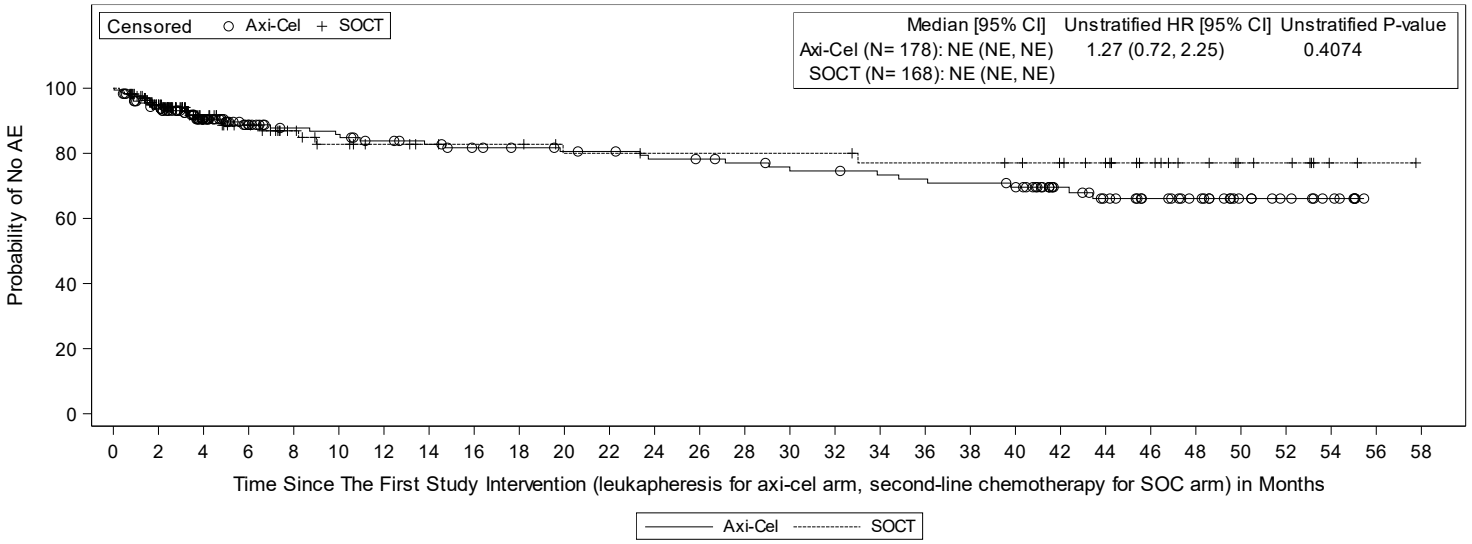
Figure 14.5.4.1.14. Kaplan-Meier Plot of Time To First Serious Infections (Modified Safety Analysis Set)



Subjects at Risk

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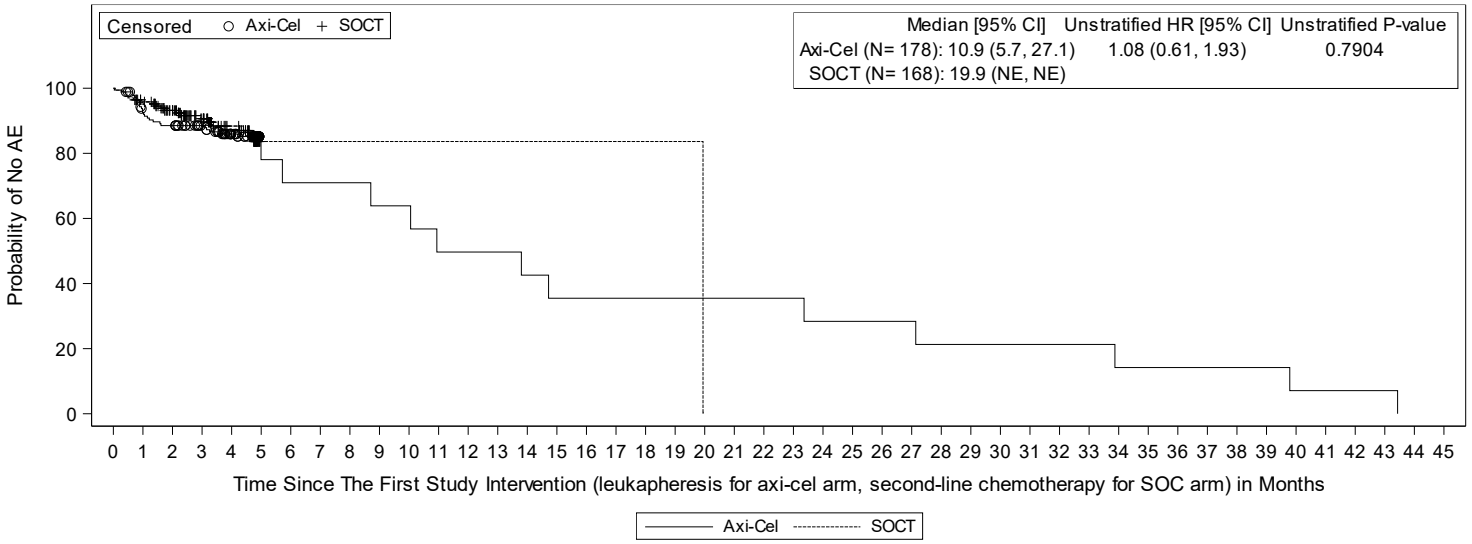
Figure 14.5.4.1.15. Kaplan-Meier Plot of Time To First Severe Infections (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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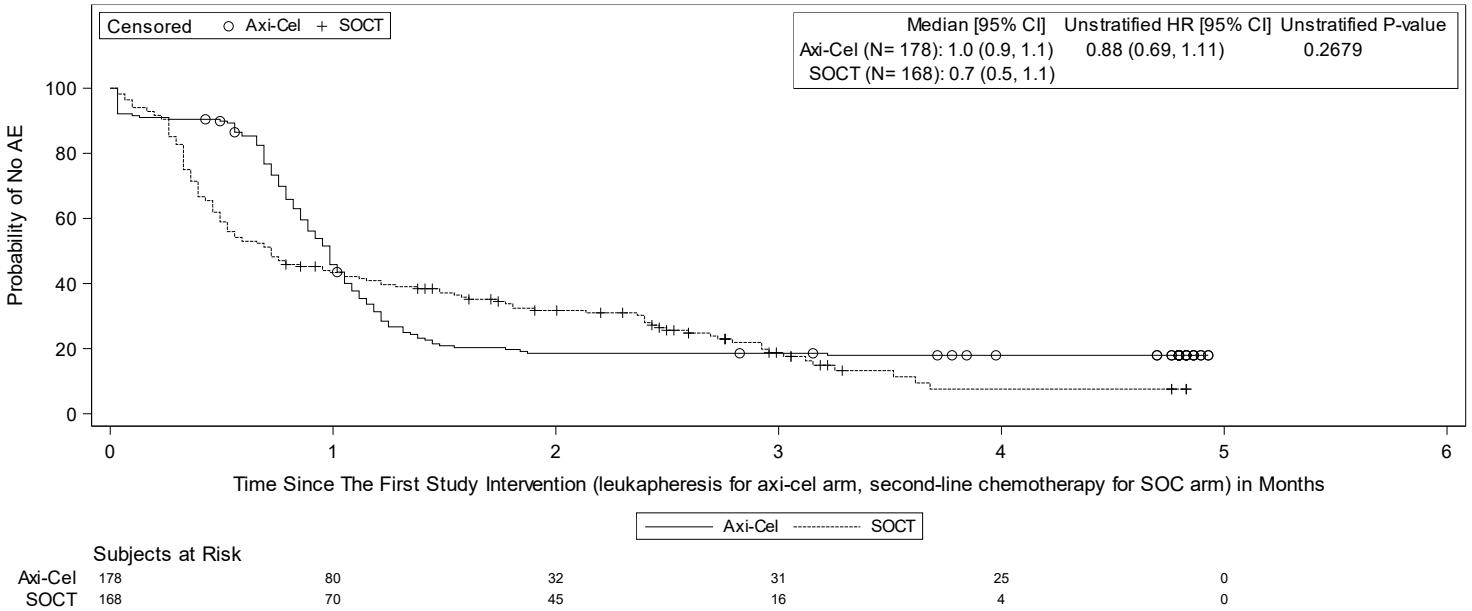
Figure 14.5.4.1.16. Kaplan-Meier Plot of Time To First Cytopenias (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	80	32	31	25	0
SOCT	168	70	45	16	4	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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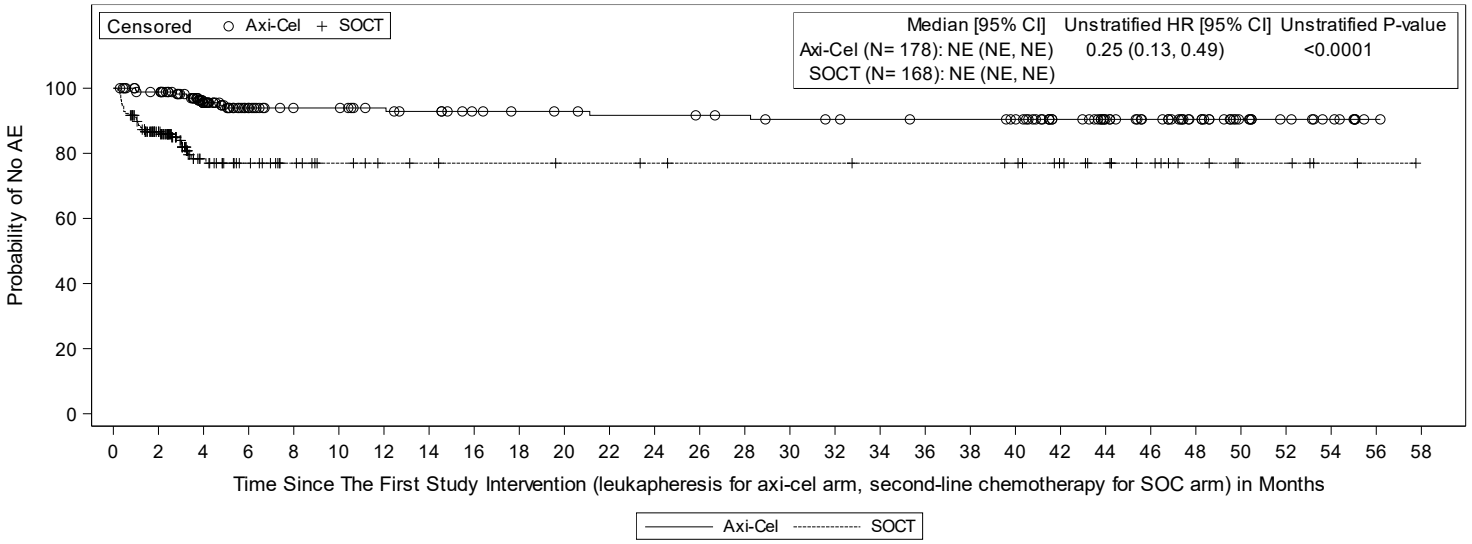
Figure 14.5.4.1.17. Kaplan-Meier Plot of Time To First Serious Cytopenias (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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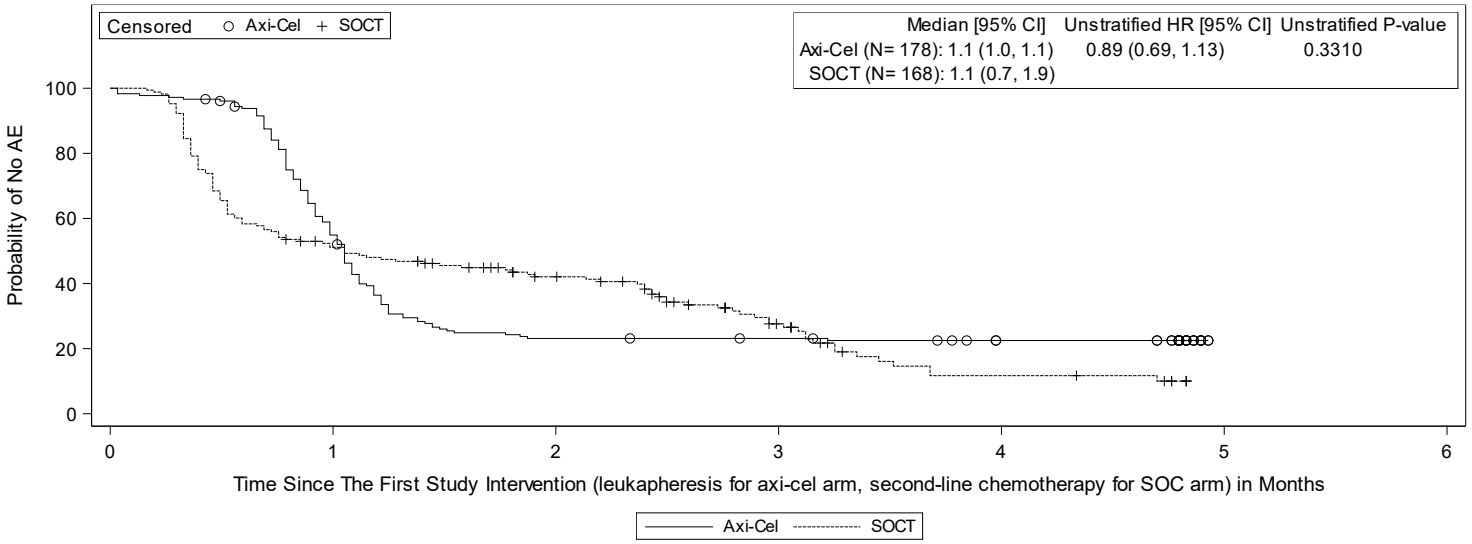
Figure 14.5.4.1.18. Kaplan-Meier Plot of Time To First Severe Cytopenias (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	96	40	38	31	0
SOCT	168	83	58	26	8	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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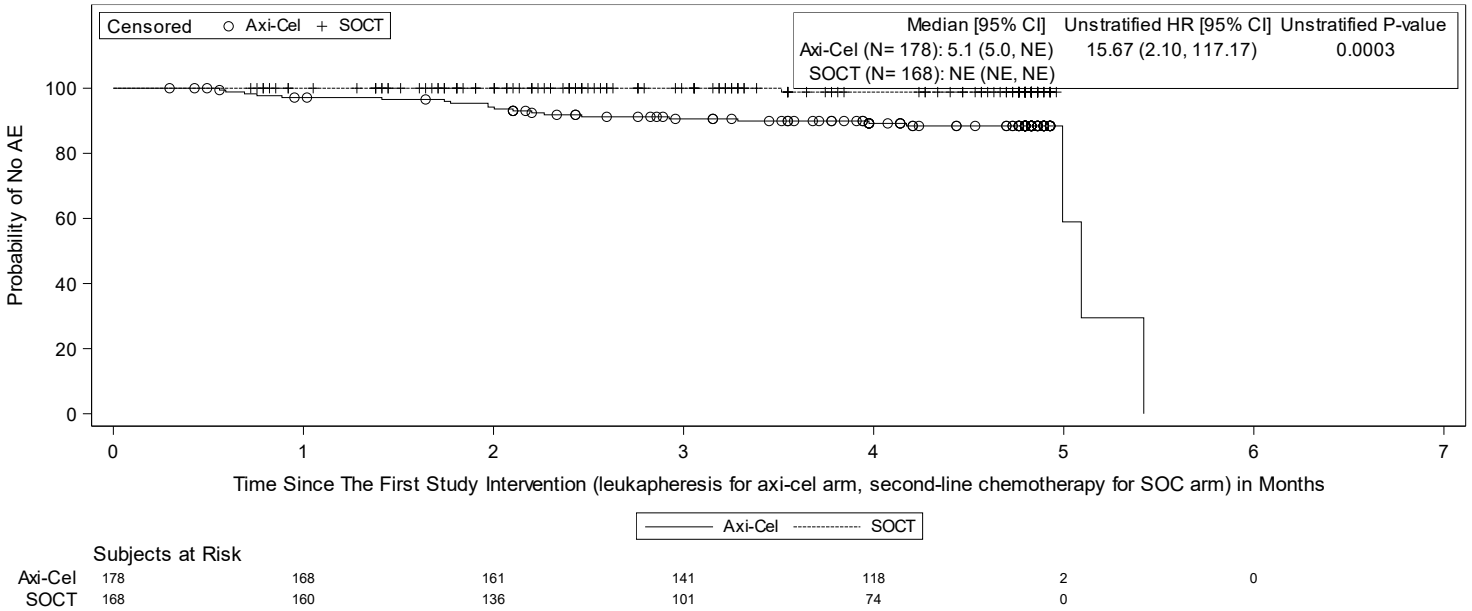
Figure 14.5.4.1.19. Kaplan-Meier Plot of Time To First Hypogammaglobulinemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	161	141	118	2	0
SOCT	168	160	136	101	74	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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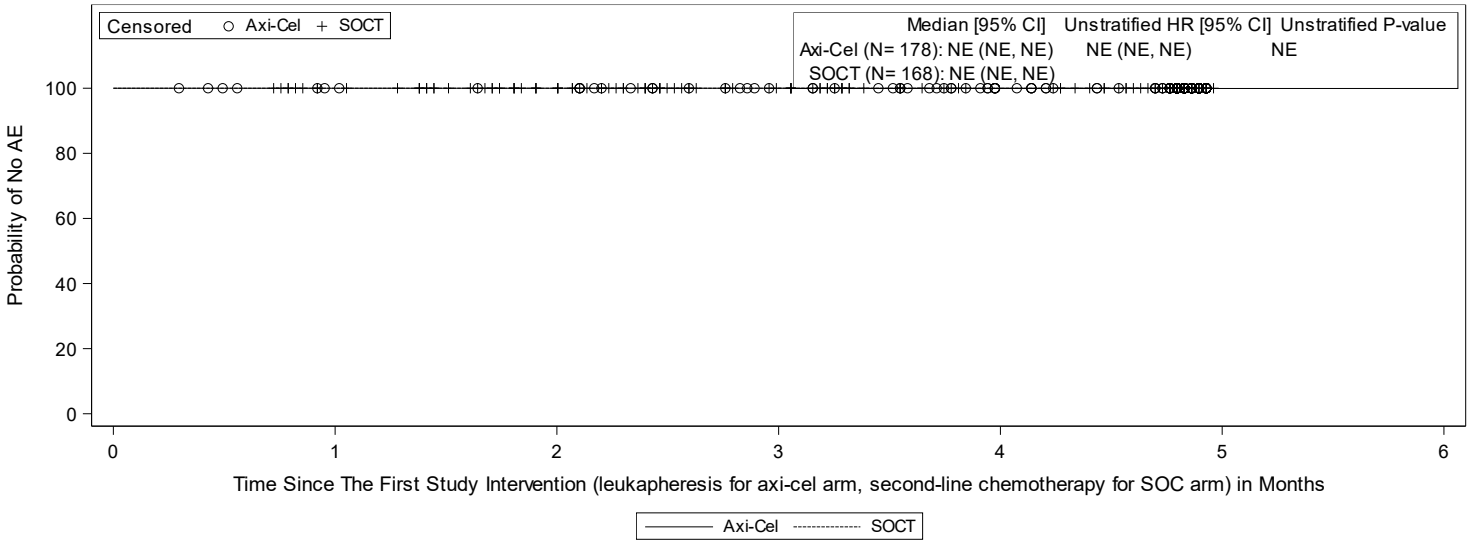
Figure 14.5.4.1.20. Kaplan-Meier Plot of Time To First Serious Hypogammaglobulinemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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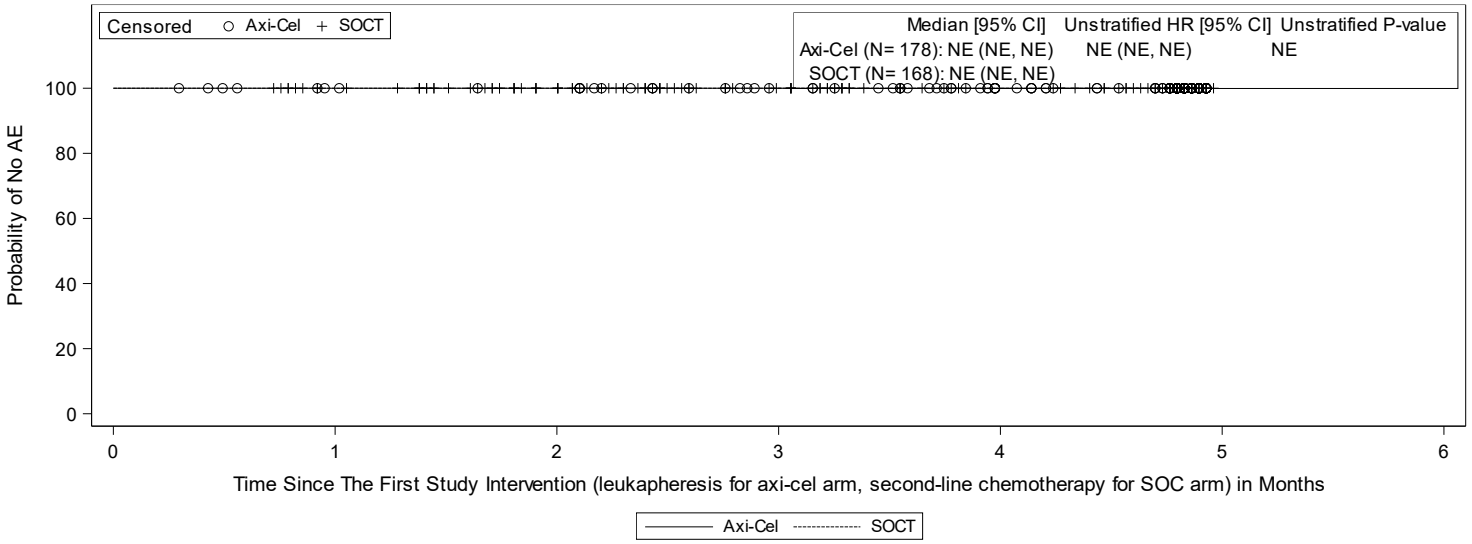
Figure 14.5.4.1.21. Kaplan-Meier Plot of Time To First Severe Hypogammaglobulinemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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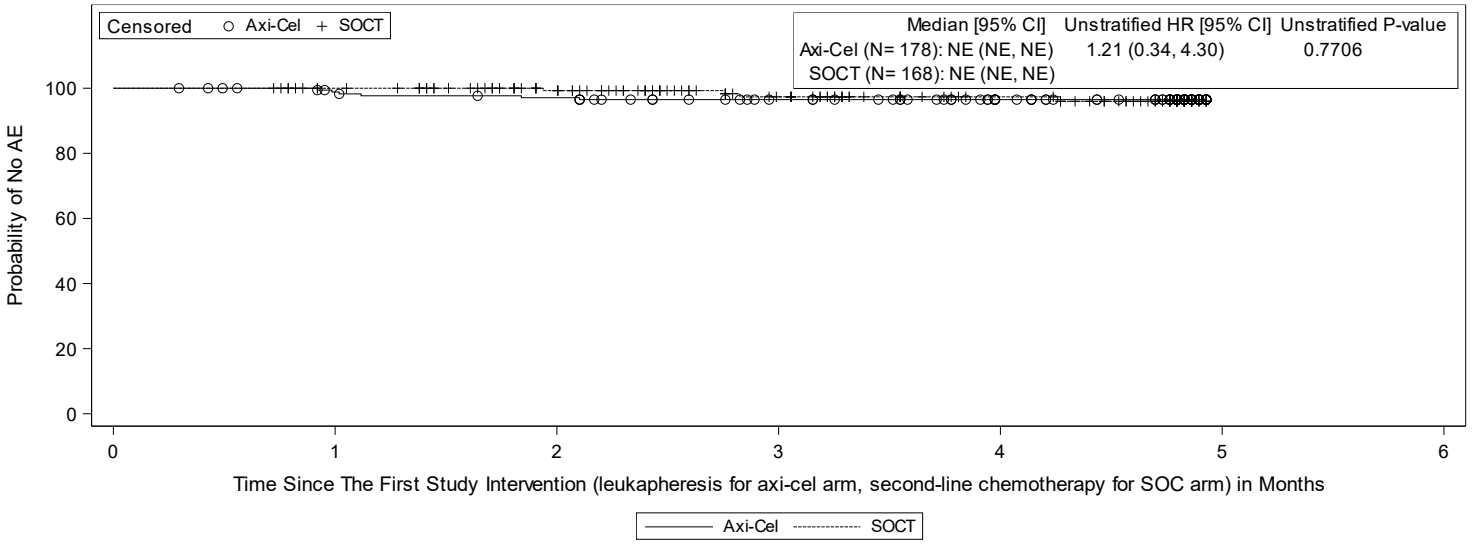
Figure 14.5.4.1.22. Kaplan-Meier Plot of Time To First Bone marrow failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	170	165	150	129	0
SOCT	168	160	135	98	72	0

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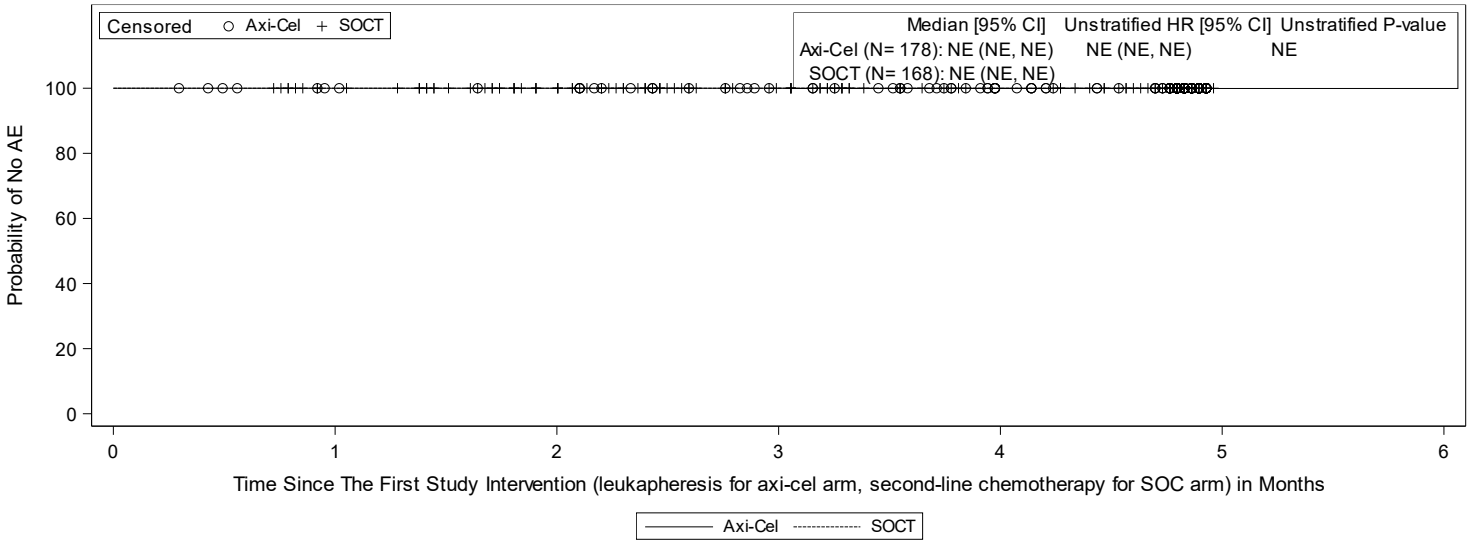
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.23. Kaplan-Meier Plot of Time To First Serious Bone marrow failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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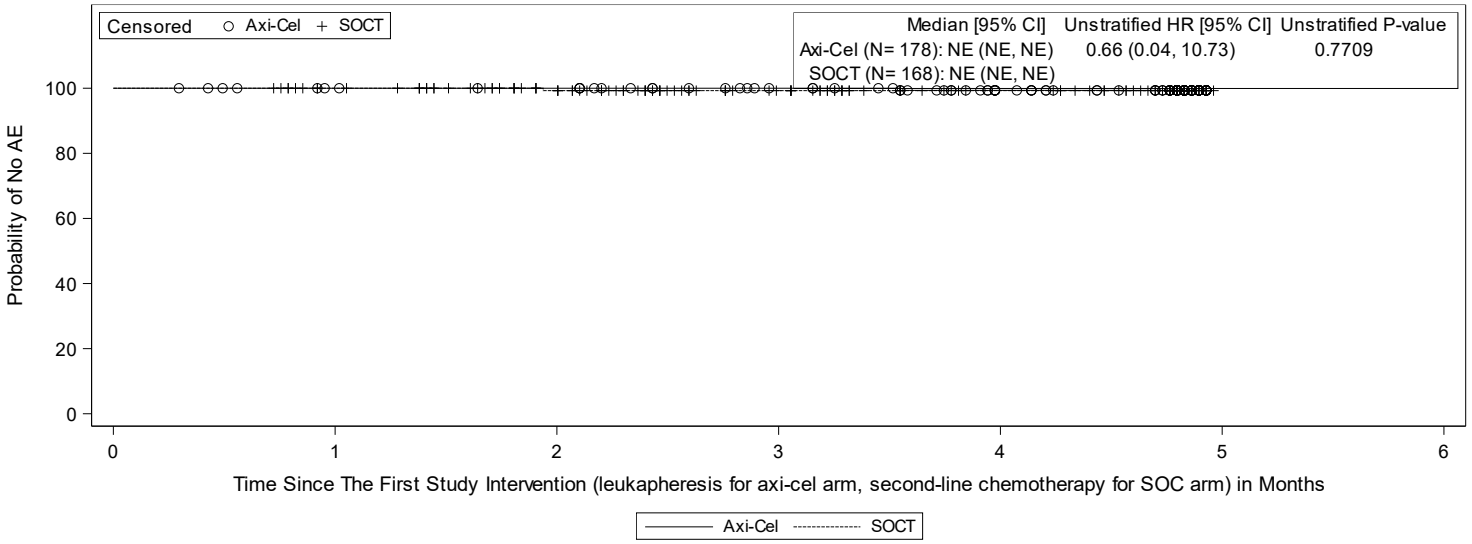
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.24. Kaplan-Meier Plot of Time To First Severe Bone marrow failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	135	100	74	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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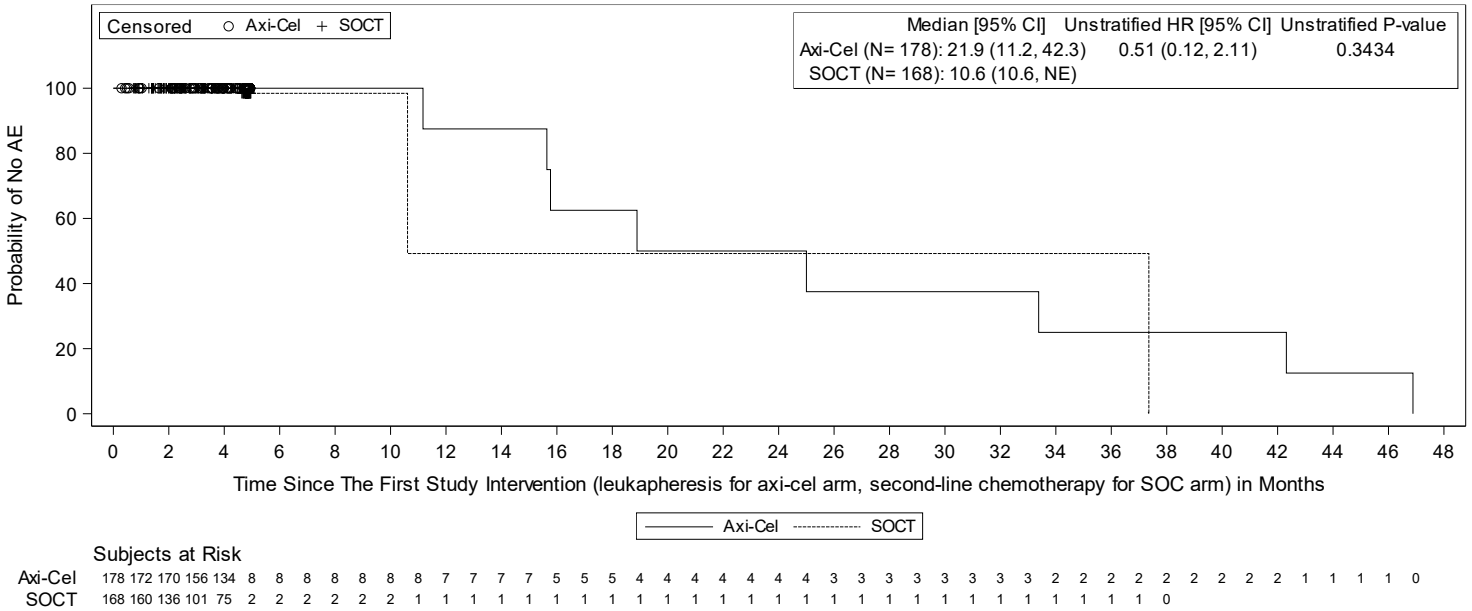
Figure 14.5.4.1.25. Kaplan-Meier Plot of Time To First Secondary Malignancy (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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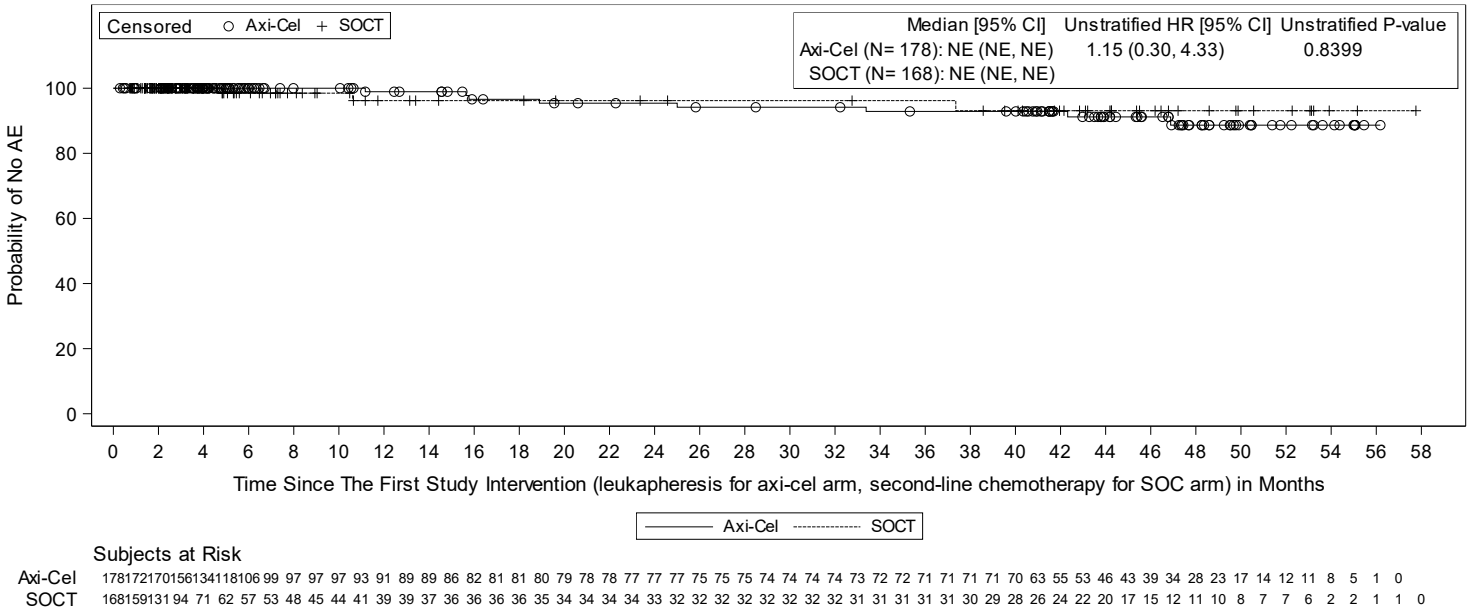
Figure 14.5.4.1.26. Kaplan-Meier Plot of Time To First Serious Secondary Malignancy (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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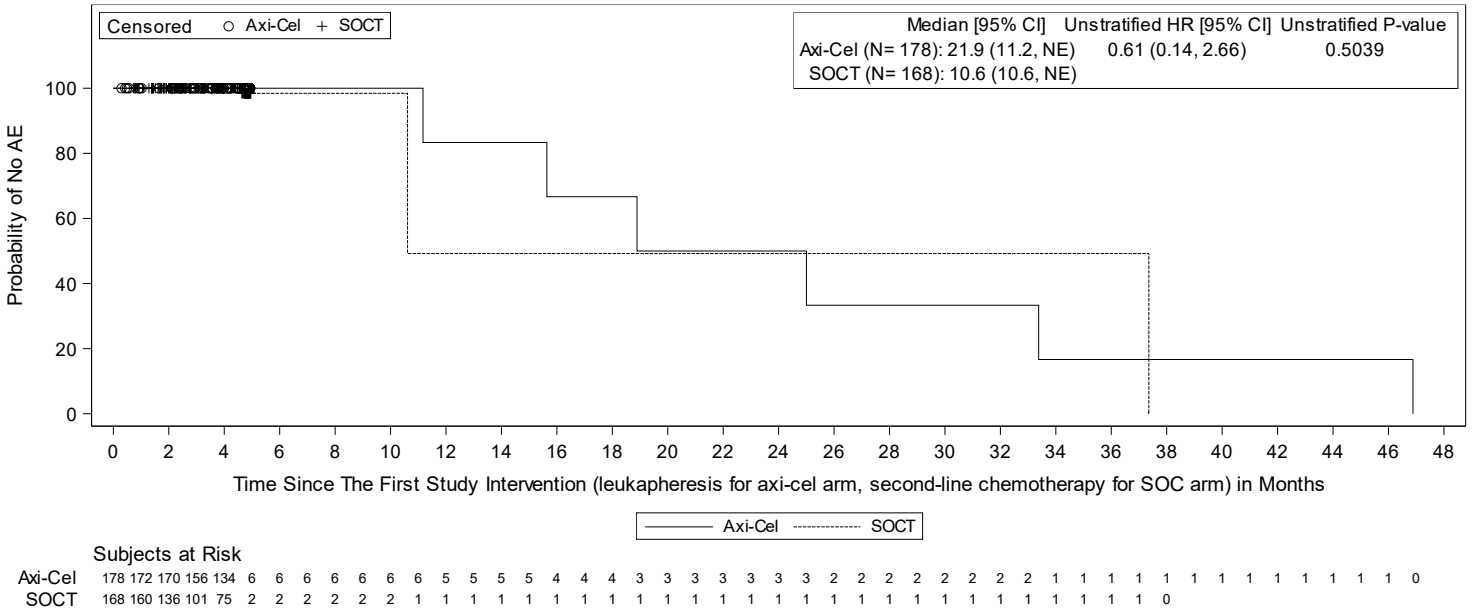
Figure 14.5.4.1.27. Kaplan-Meier Plot of Time To First Severe Secondary Malignancy (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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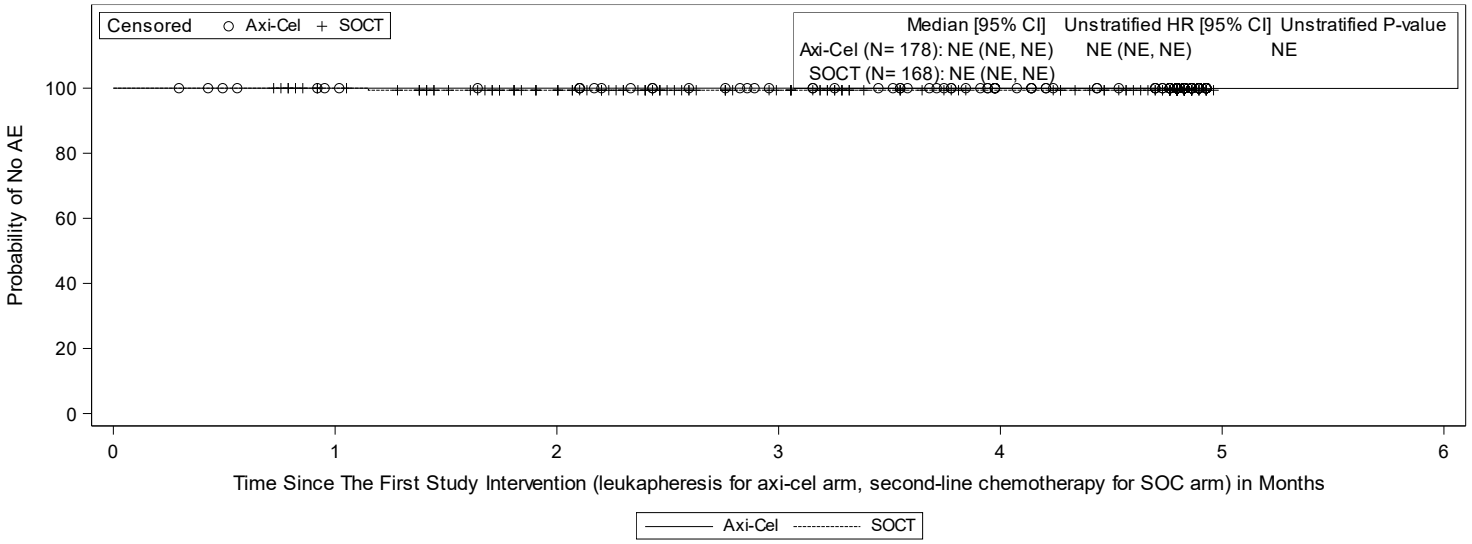
Figure 14.5.4.1.28. Kaplan-Meier Plot of Time To First Tumor Lysis Syndrome (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	135	100	75	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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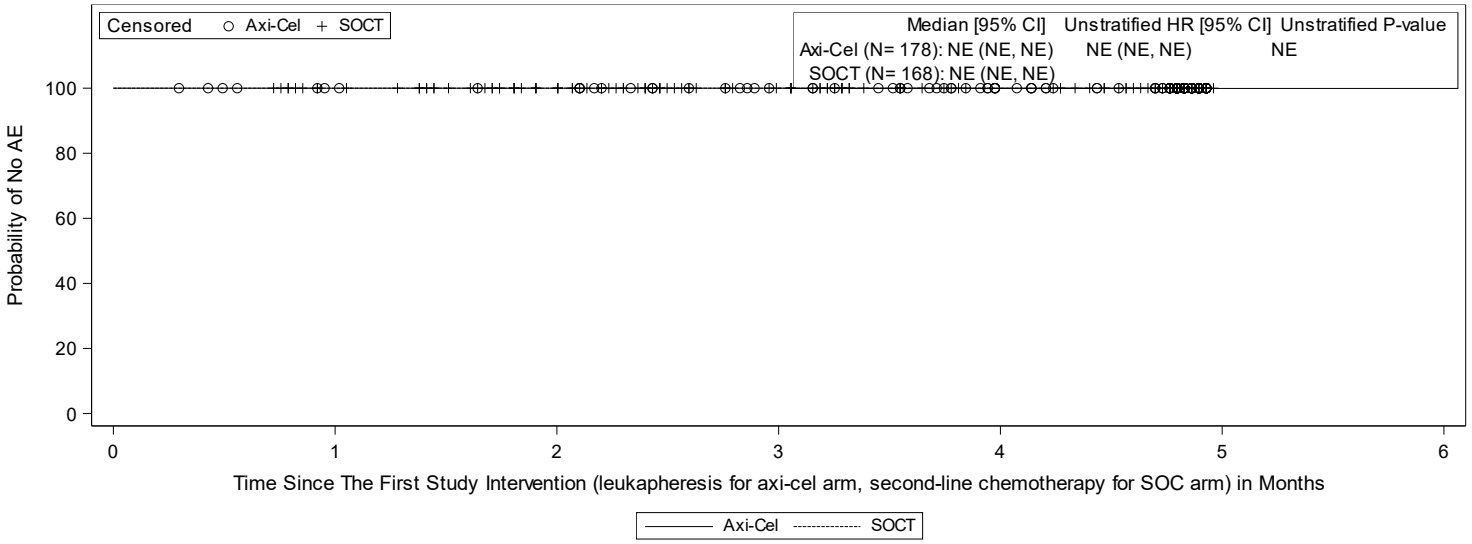
Figure 14.5.4.1.29. Kaplan-Meier Plot of Time To First Serious Tumor Lysis Syndrome (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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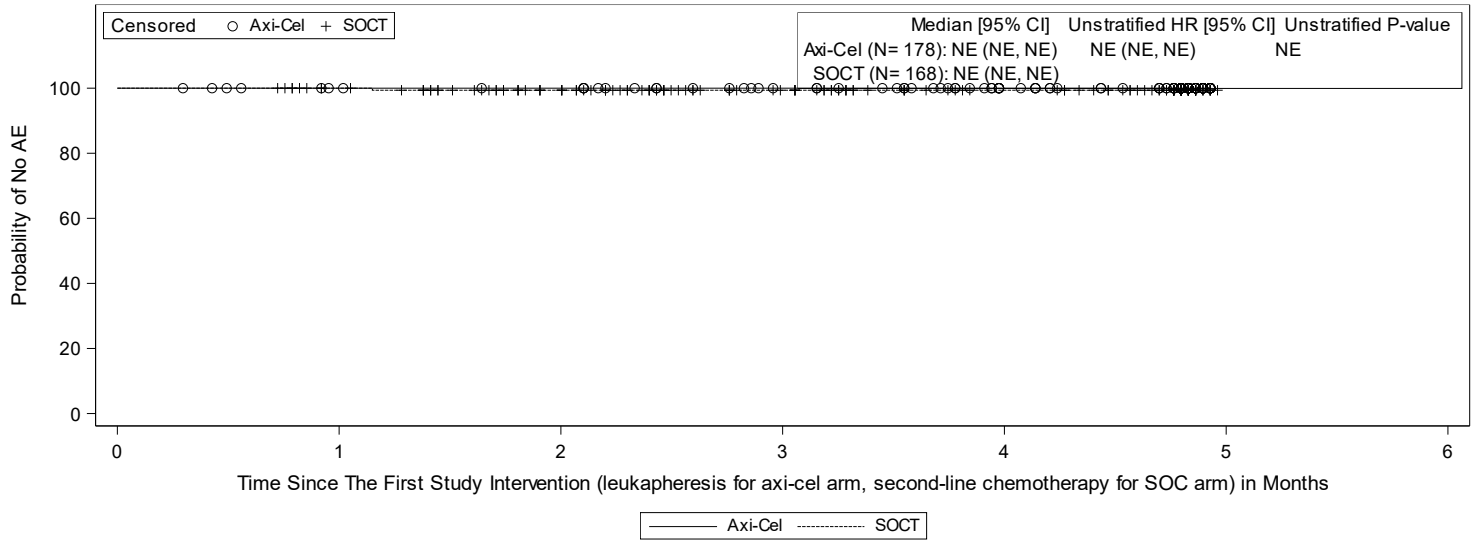
Figure 14.5.4.1.30. Kaplan-Meier Plot of Time To First Severe Tumor Lysis Syndrome (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	135	100	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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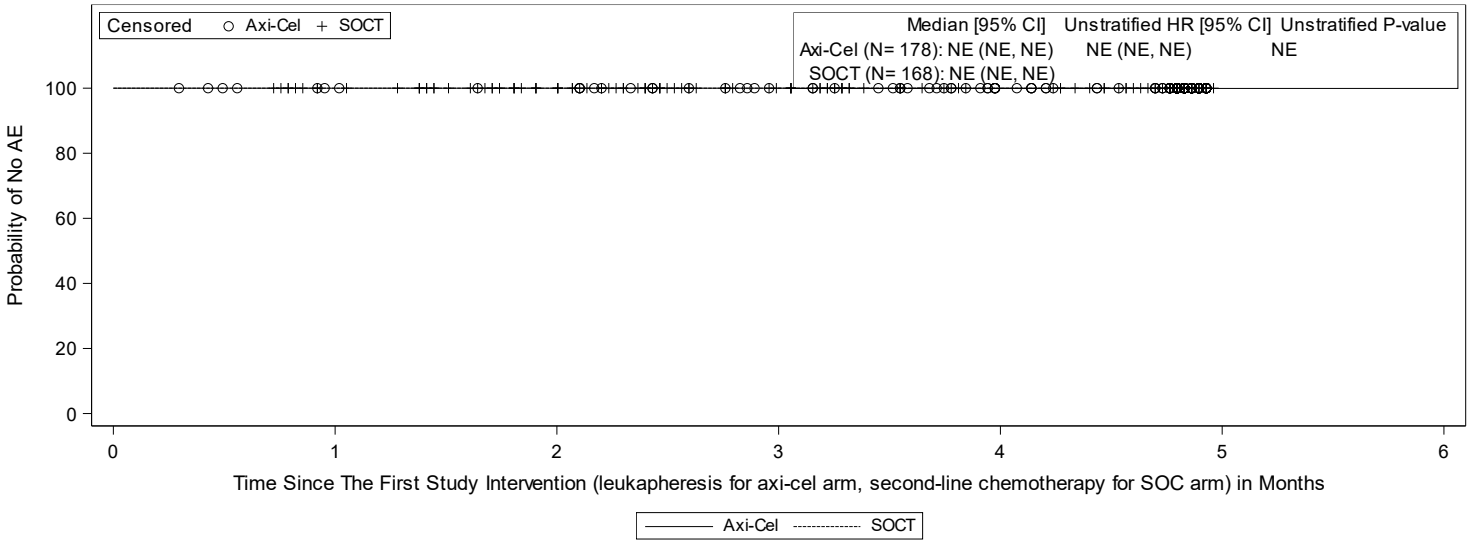
Figure 14.5.4.1.31. Kaplan-Meier Plot of Time To First Graft-versus-host Disease (GVHD) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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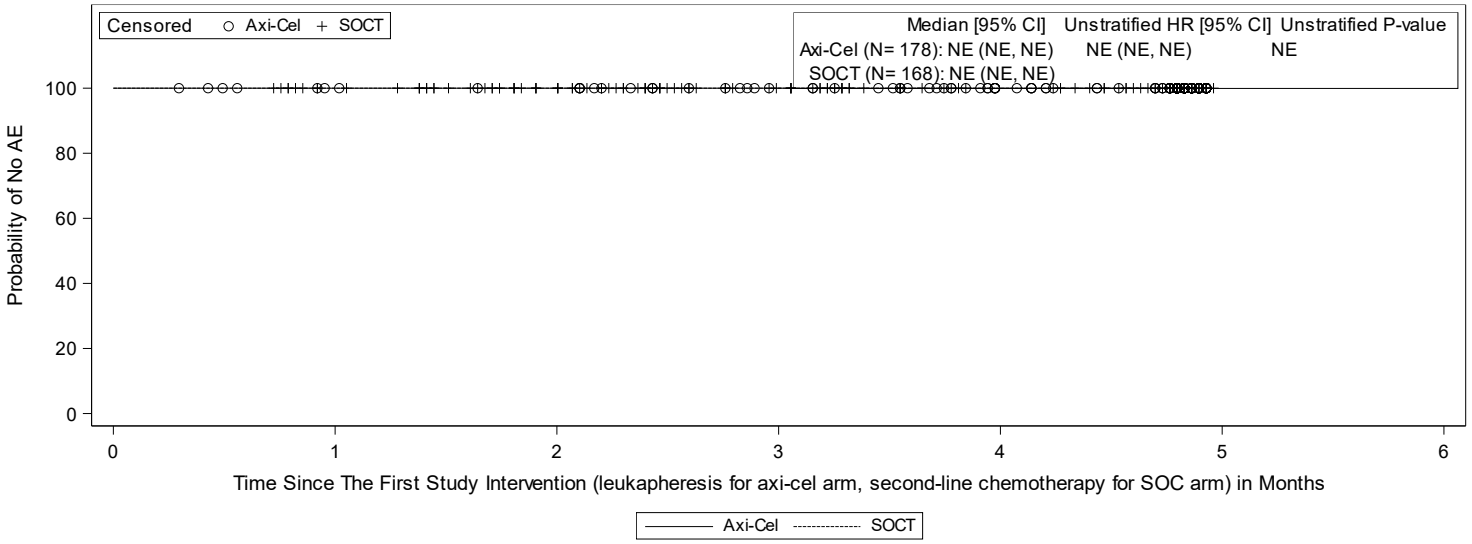
Figure 14.5.4.1.32. Kaplan-Meier Plot of Time To First Serious Graft-versus-host Disease (GVHD) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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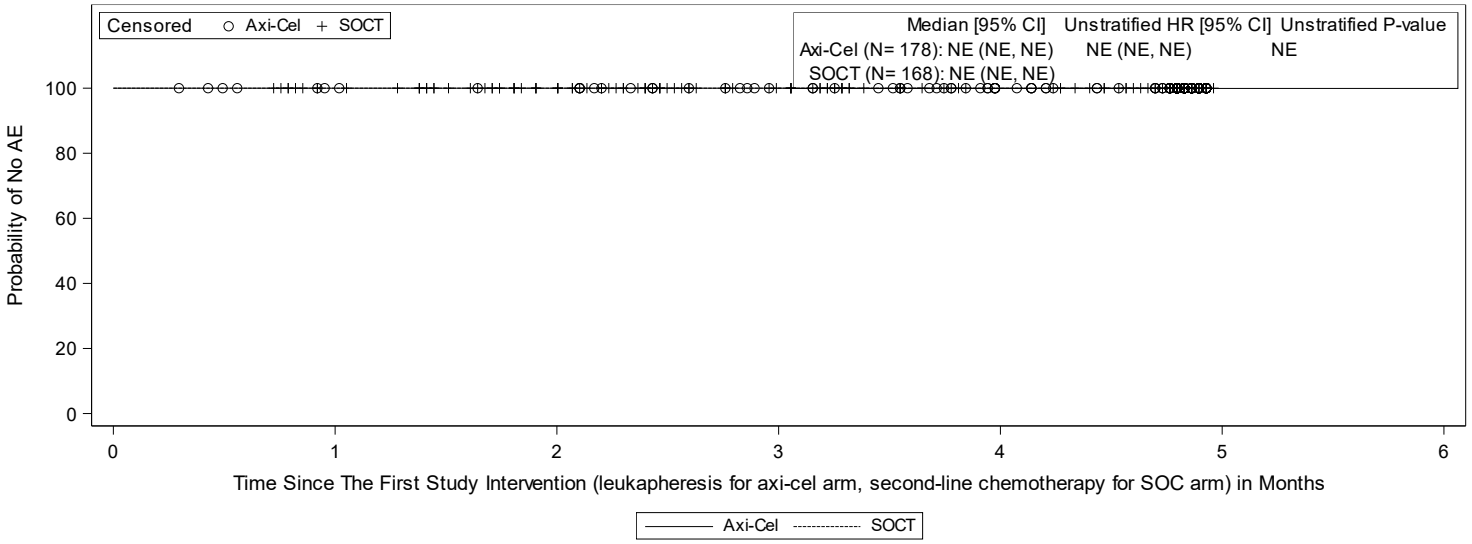
Figure 14.5.4.1.33. Kaplan-Meier Plot of Time To First Severe Graft-versus-host Disease (GVHD) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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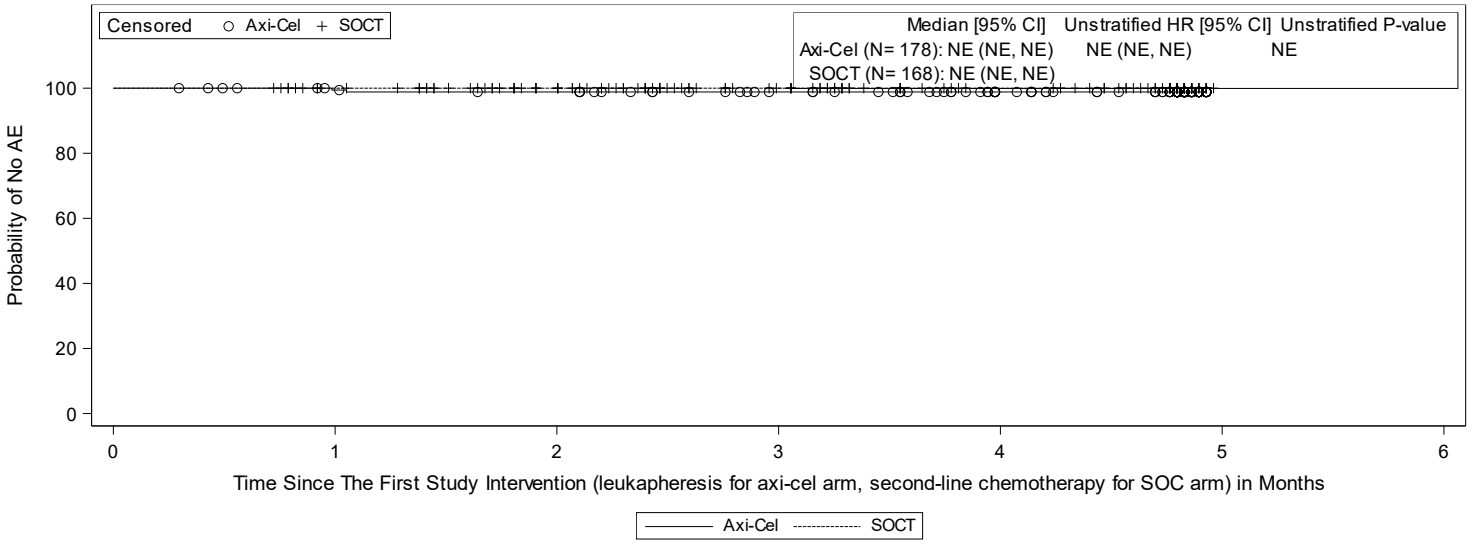
Figure 14.5.4.1.34. Kaplan-Meier Plot of Time To First Immunogenicity (Anti-axi-cel Antibody) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	171	168	154	132	0
SOCT	168	160	136	101	75	0

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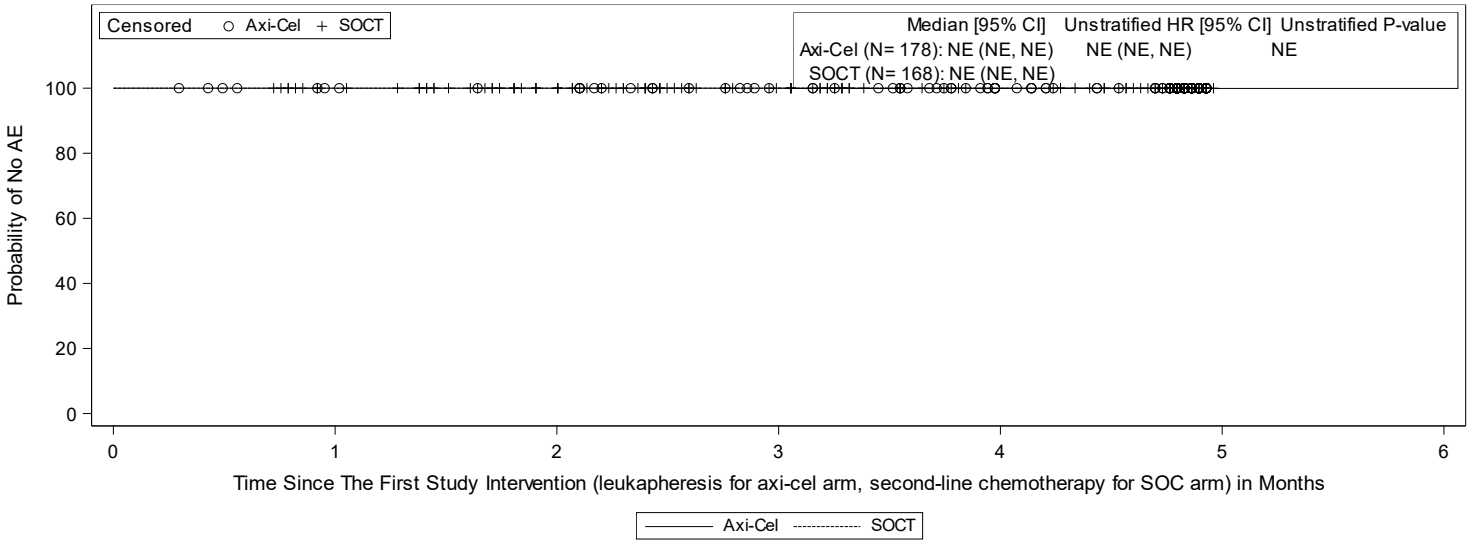
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.35. Kaplan-Meier Plot of Time To First Serious Immunogenicity (Anti-axi-cel Antibody) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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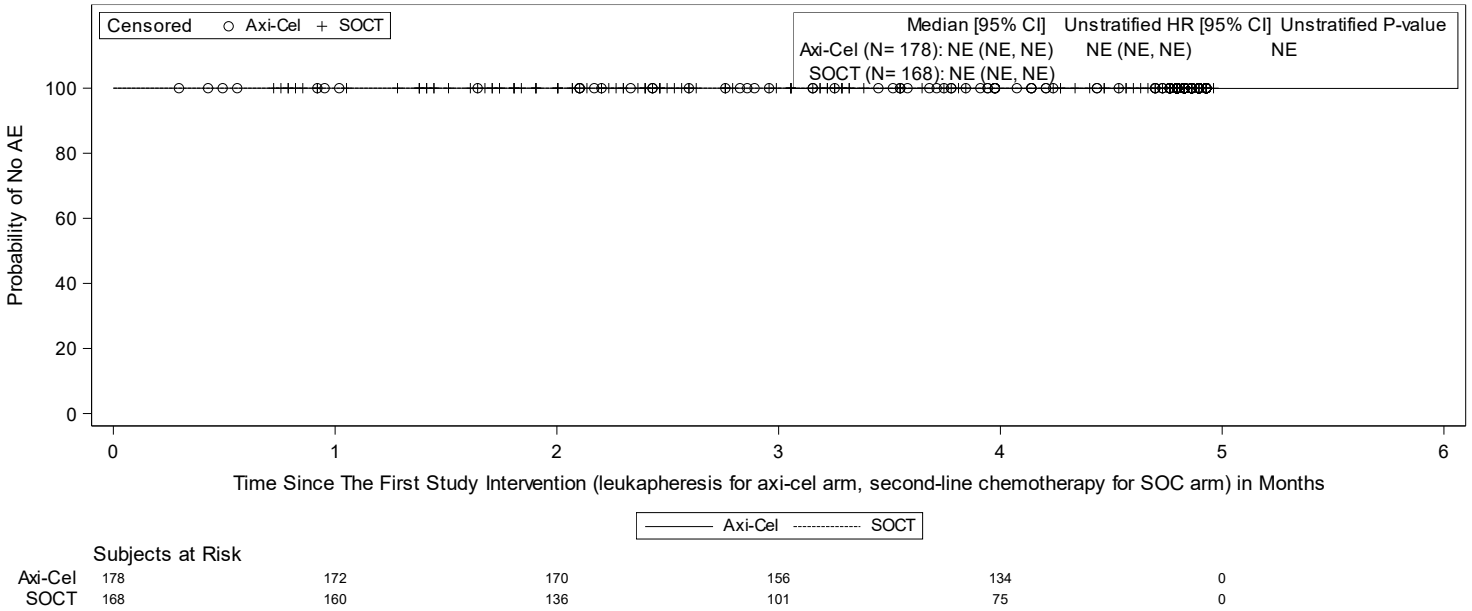
Figure 14.5.4.1.36. Kaplan-Meier Plot of Time To First Severe Immunogenicity (Anti-axi-cel Antibody) (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

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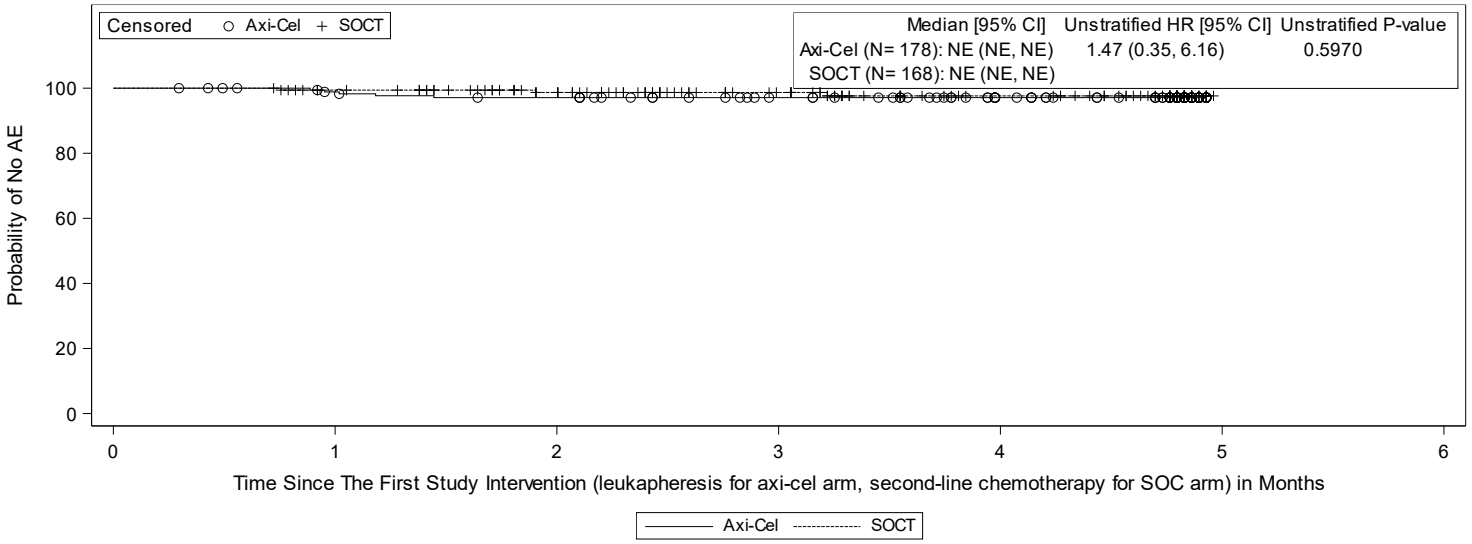
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.37. Kaplan-Meier Plot of Time To First Cardiac Failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	170	165	151	130	0
SOCT	168	160	135	100	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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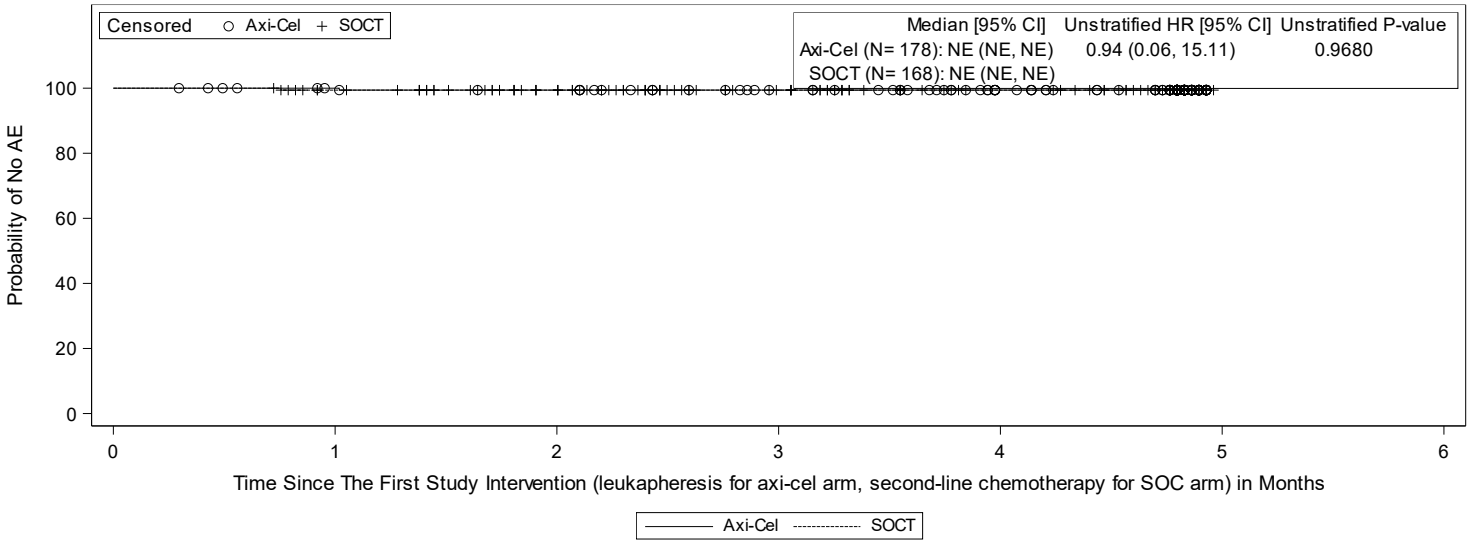
Figure 14.5.4.1.38. Kaplan-Meier Plot of Time To First Serious Cardiac Failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	169	155	133	0
SOCT	168	160	136	101	75	0

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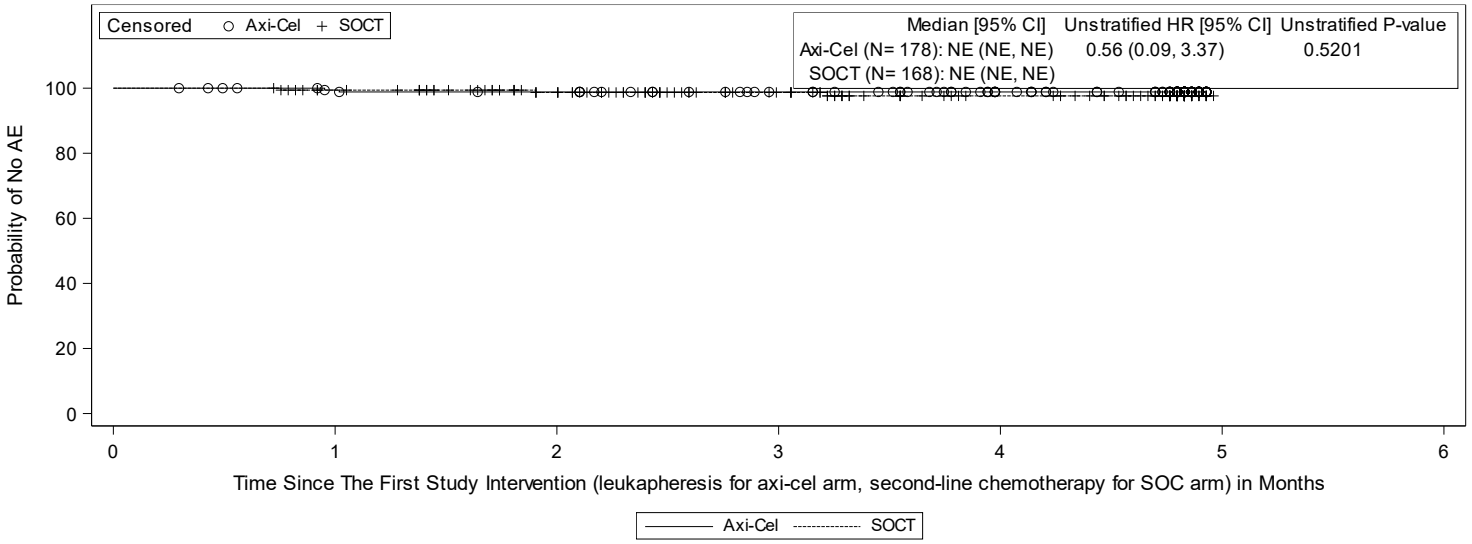
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.39. Kaplan-Meier Plot of Time To First Severe Cardiac Failure (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	171	168	154	132	0
SOCT	168	160	135	100	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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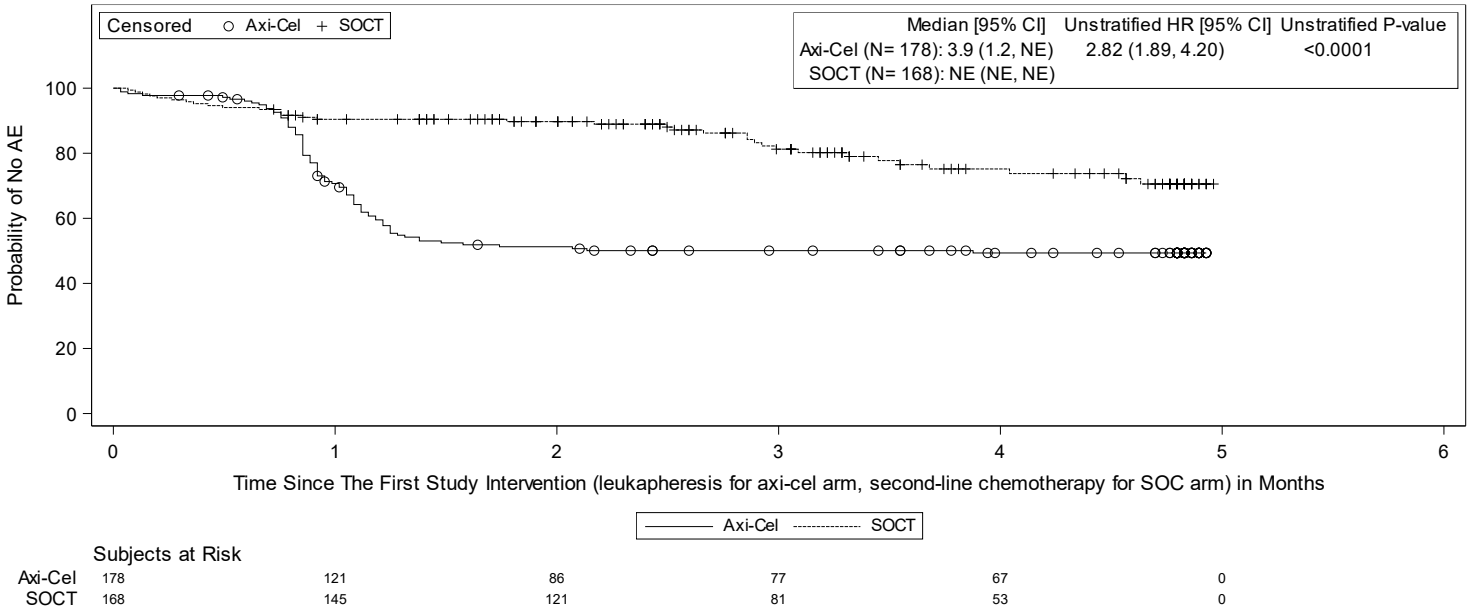
Figure 14.5.4.1.40. Kaplan-Meier Plot of Time To First Cardiac Arrhythmias (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	121	86	77	67	0
SOCT	168	145	121	81	53	0

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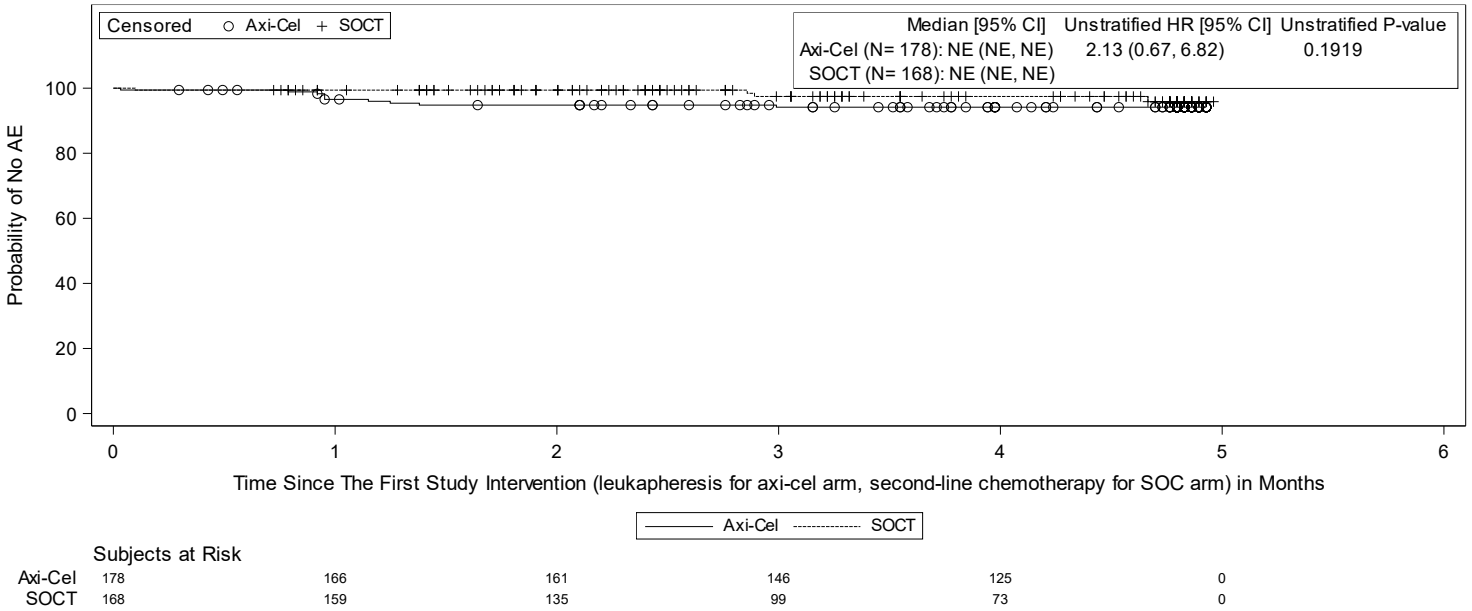
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.41. Kaplan-Meier Plot of Time To First Serious Cardiac Arrhythmias (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	166	161	146	125	0
SOCT	168	159	135	99	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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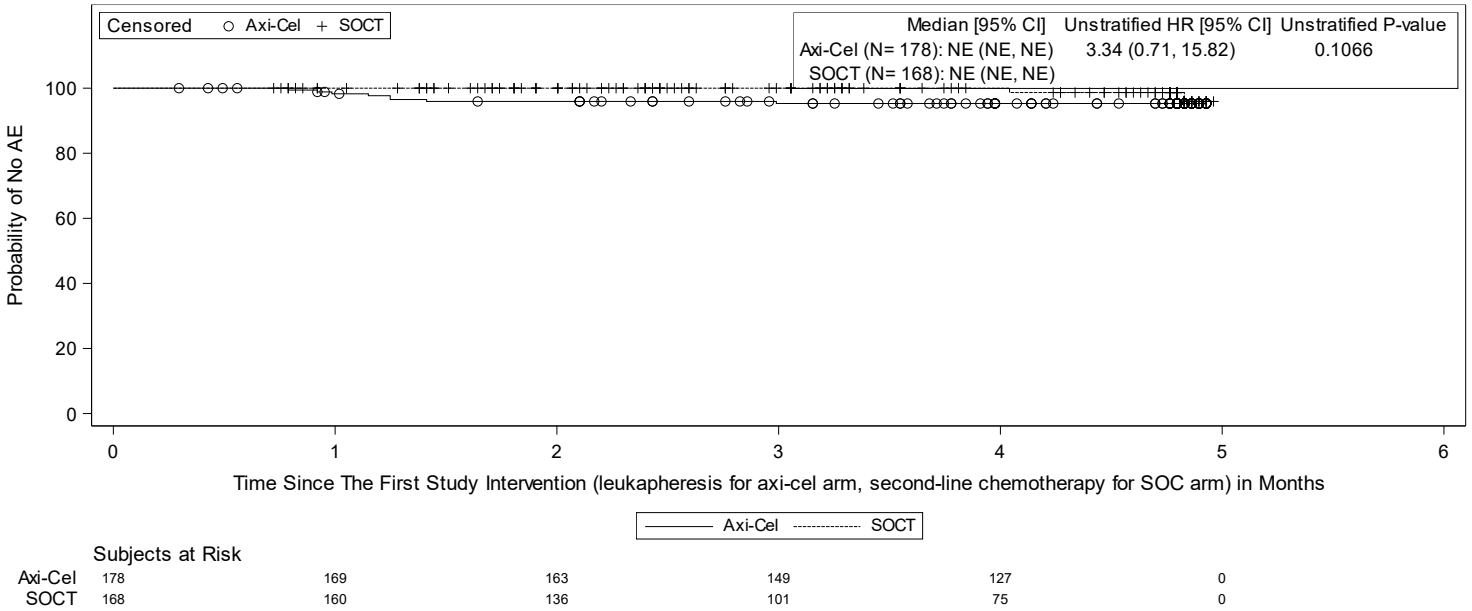
Figure 14.5.4.1.42. Kaplan-Meier Plot of Time To First Severe Cardiac Arrhythmias (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	163	149	127	0
SOCT	168	160	136	101	75	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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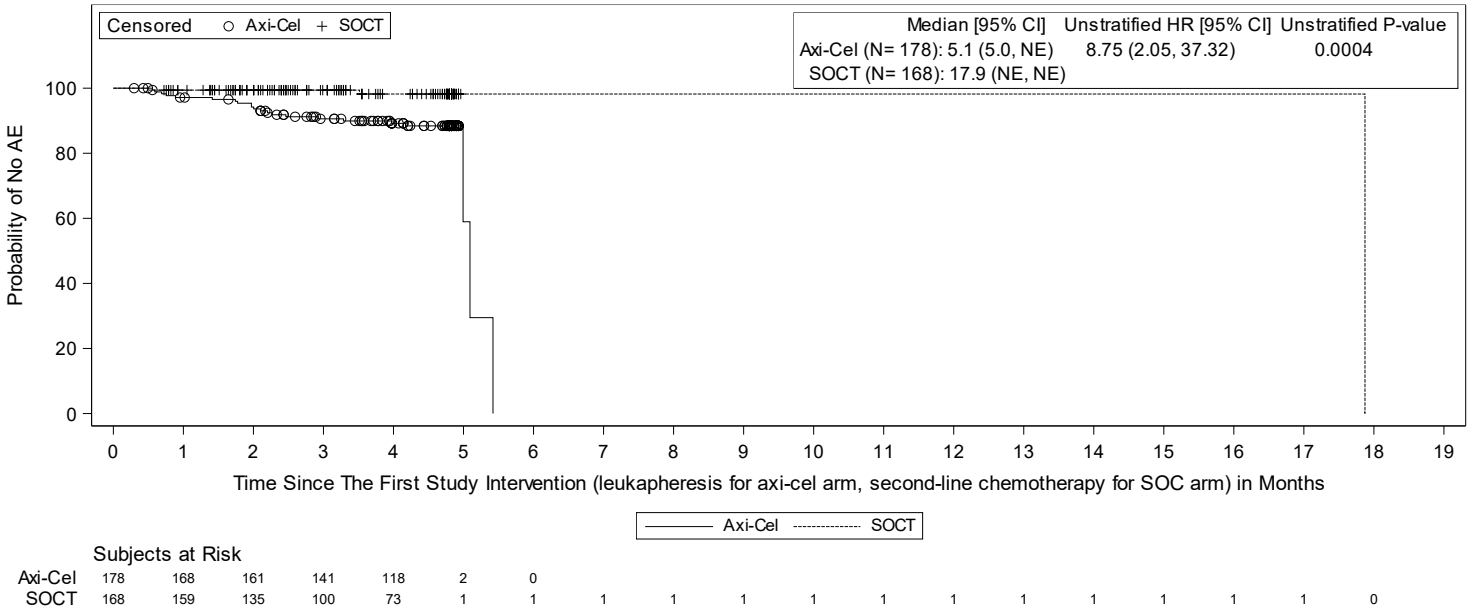
Figure 14.5.4.1.97. Kaplan-Meier Plot of Time To First Autoimmune Disorder (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	161	141	118	2	0												
SOCT	168	159	135	100	73	1	1	1	1	1	1	1	1	1	1	1	1	1	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

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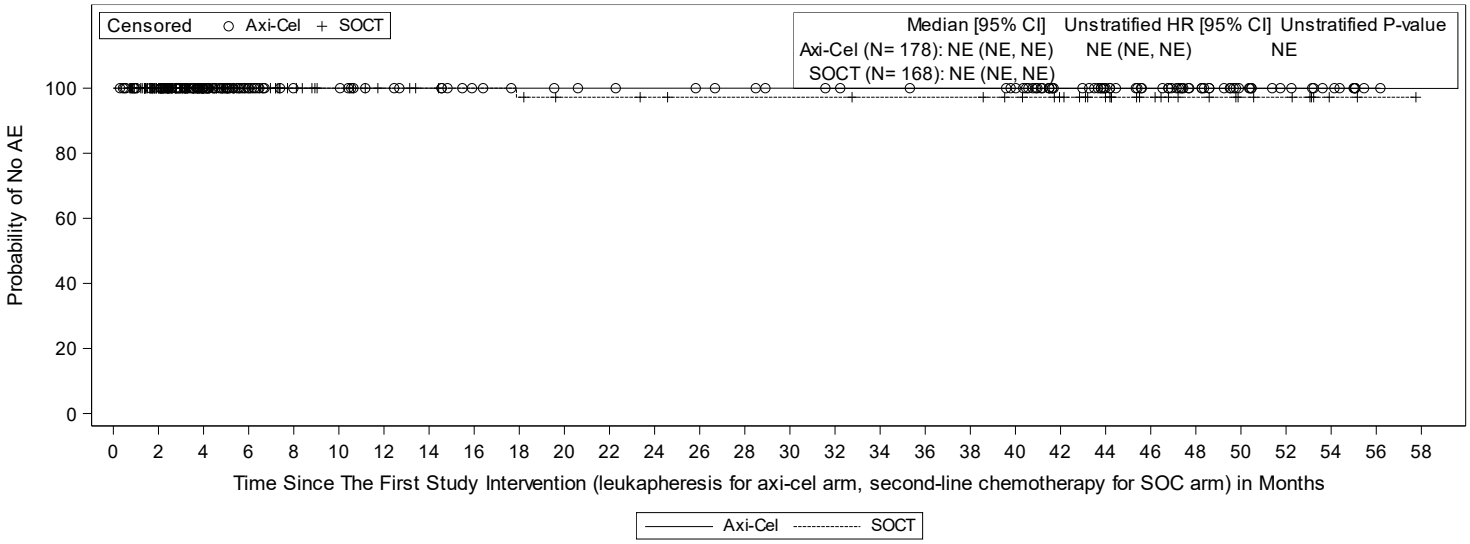
Figure 14.5.4.1.98. Kaplan-Meier Plot of Time To First Serious Autoimmune Disorder (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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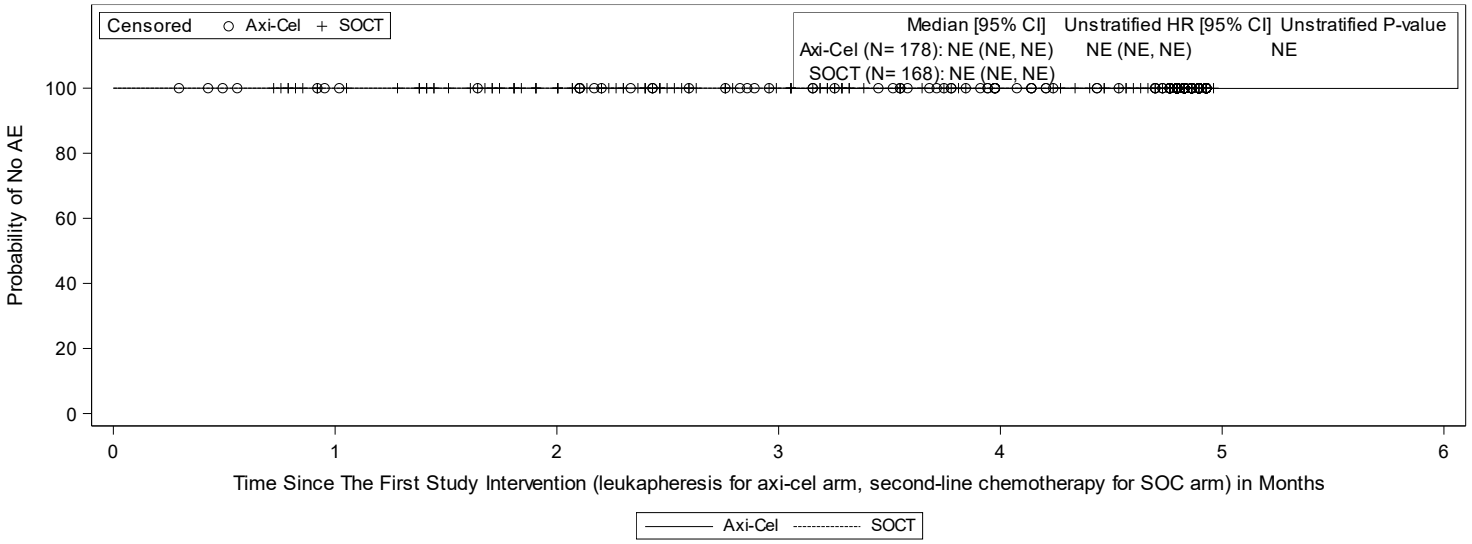
Figure 14.5.4.1.99. Kaplan-Meier Plot of Time To First Severe Autoimmune Disorder (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	170	156	134	0
SOCT	168	160	136	101	75	0

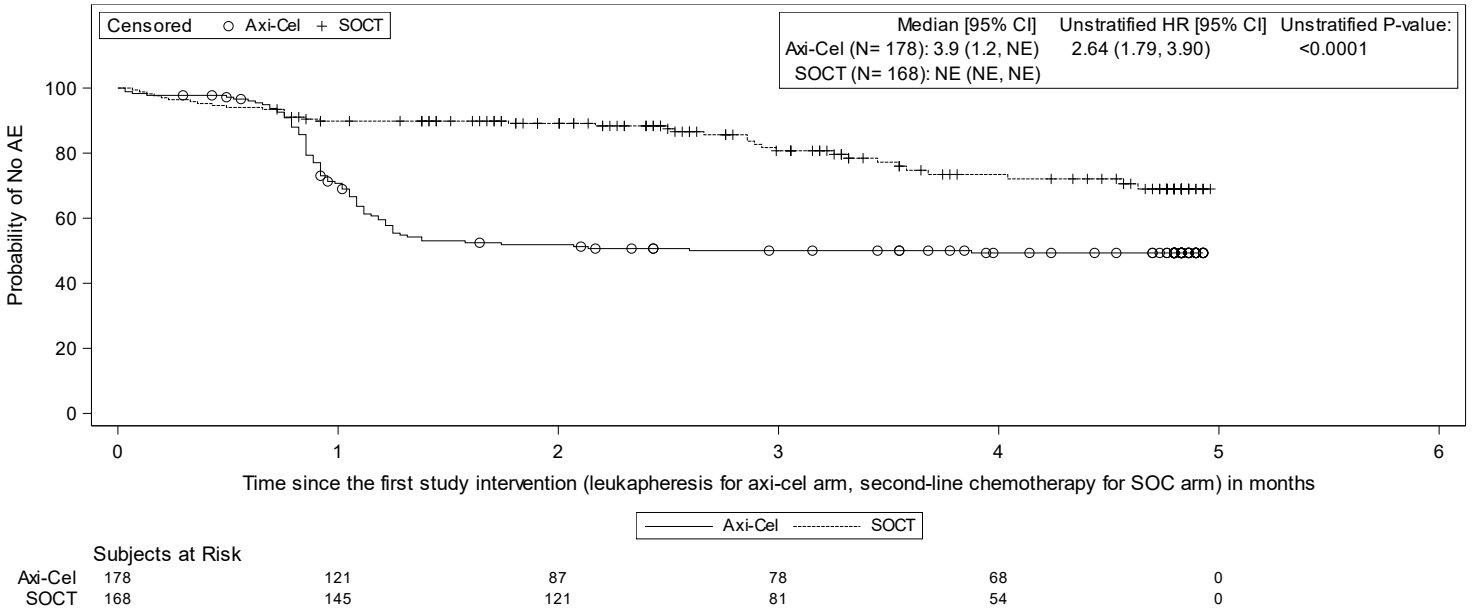
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_aesi.sas Output Generated: 20240524T14:56

Anhang 4-G2.7.3: Kaplan-Meier Plots zu häufigen UE, schweren UE und SUE nach SOC/PT mit statistisch signifikantem Behandlungseffekt - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Abbildung 12 (Anhang): Kaplan-Meier Plots zu häufige UE (jeglicher Grad) nach SOC/PT mit statistisch signifikantem Behandlungseffekt - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.1.1.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Cardiac Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	121	87	78	68	0
SOCT	168	145	121	81	54	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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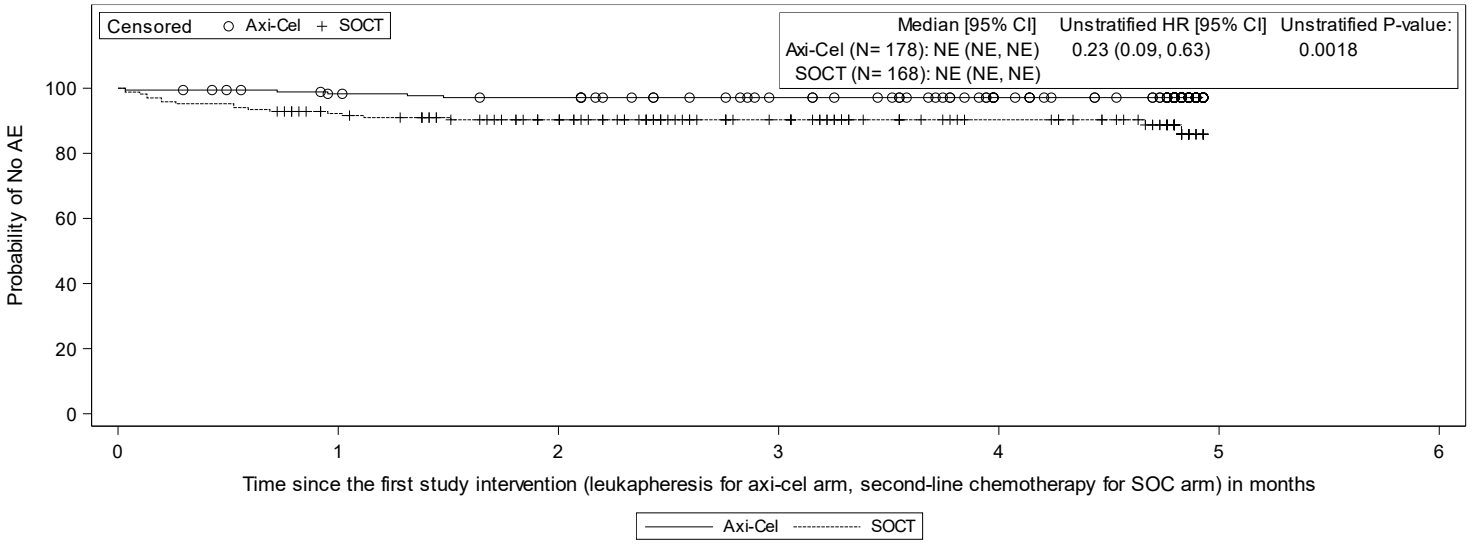
Figure 14.5.1.1.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Ear And Labyrinth Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	165	151	129	0
SOCT	168	147	124	92	66	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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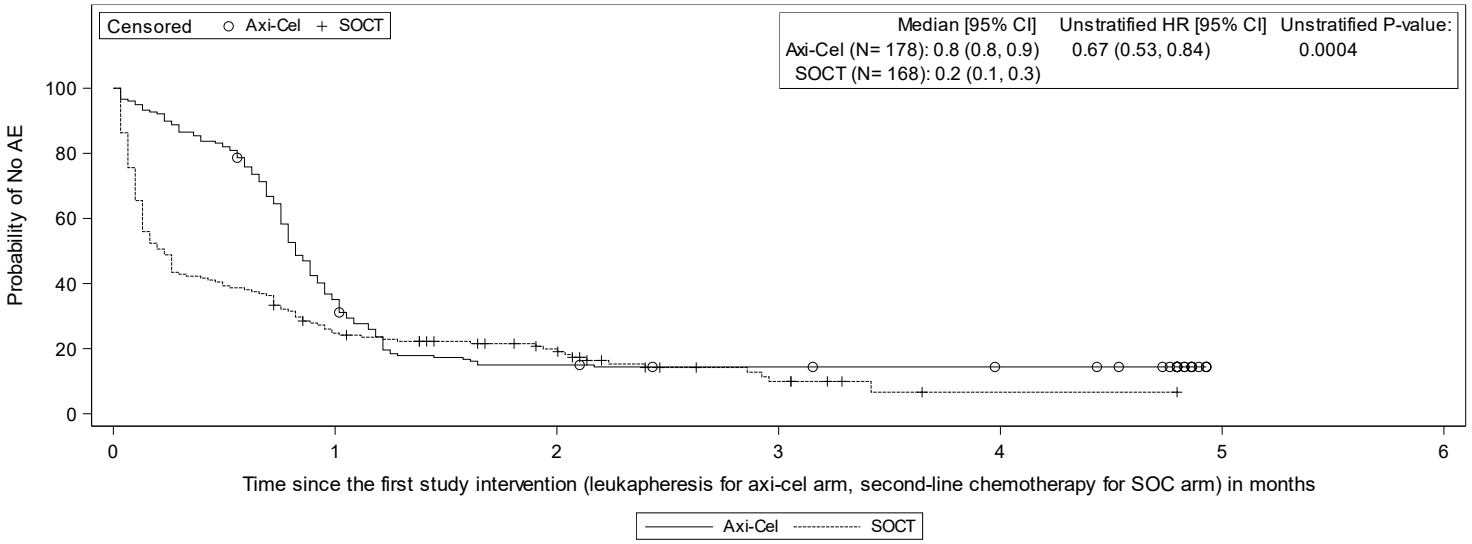
Figure 14.5.1.1.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Gastrointestinal Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	62	26	23	21	0
SOCT	168	40	24	7	1	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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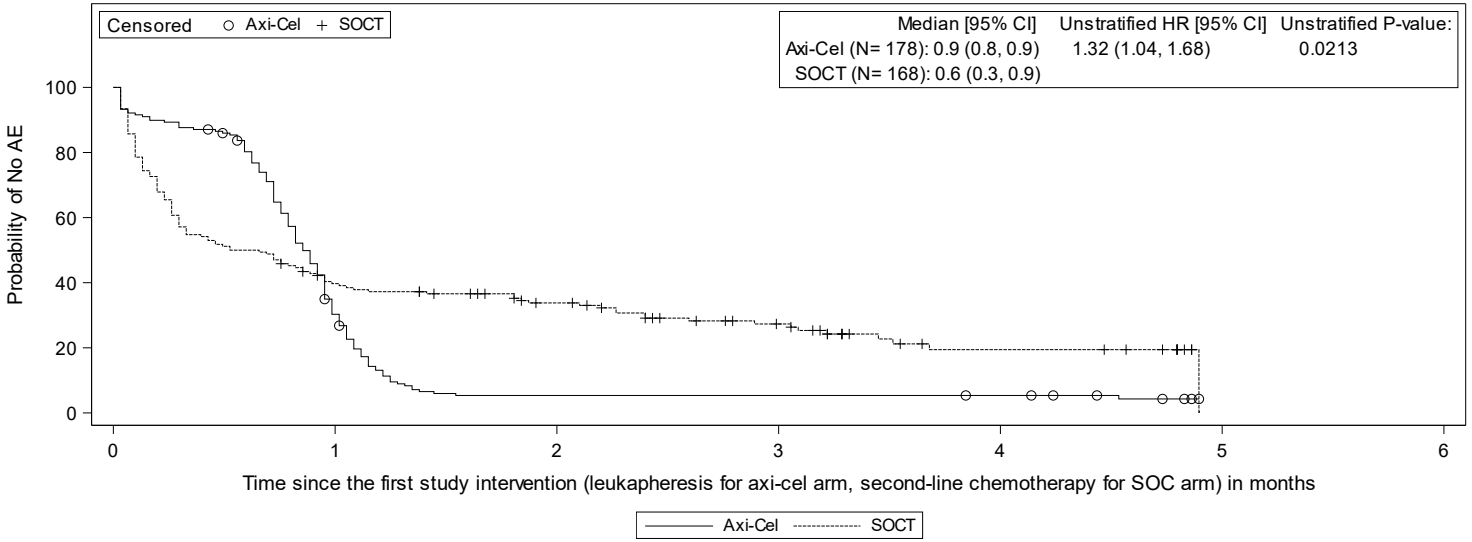
Figure 14.5.1.1.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent General Disorders And Administration Site Conditions (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	52	9	9	8	0
SOCT	168	64	46	28	11	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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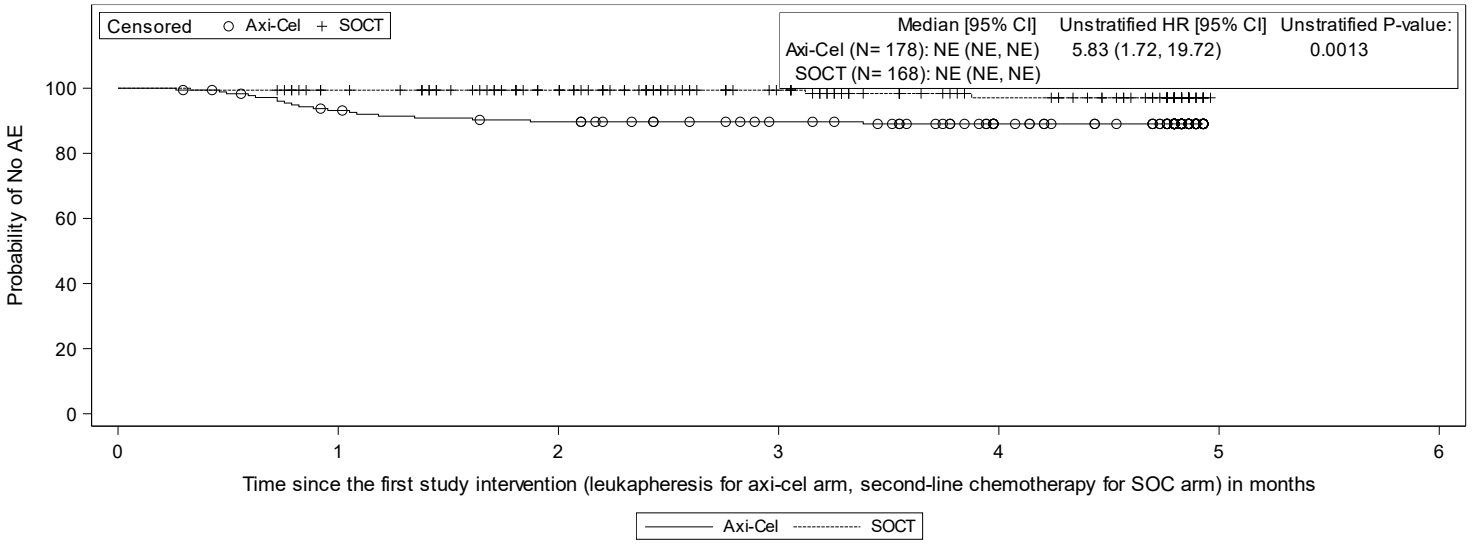
Figure 14.5.1.1.5. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hepatobiliary Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	162	154	142	121	0
SOCT	168	159	135	101	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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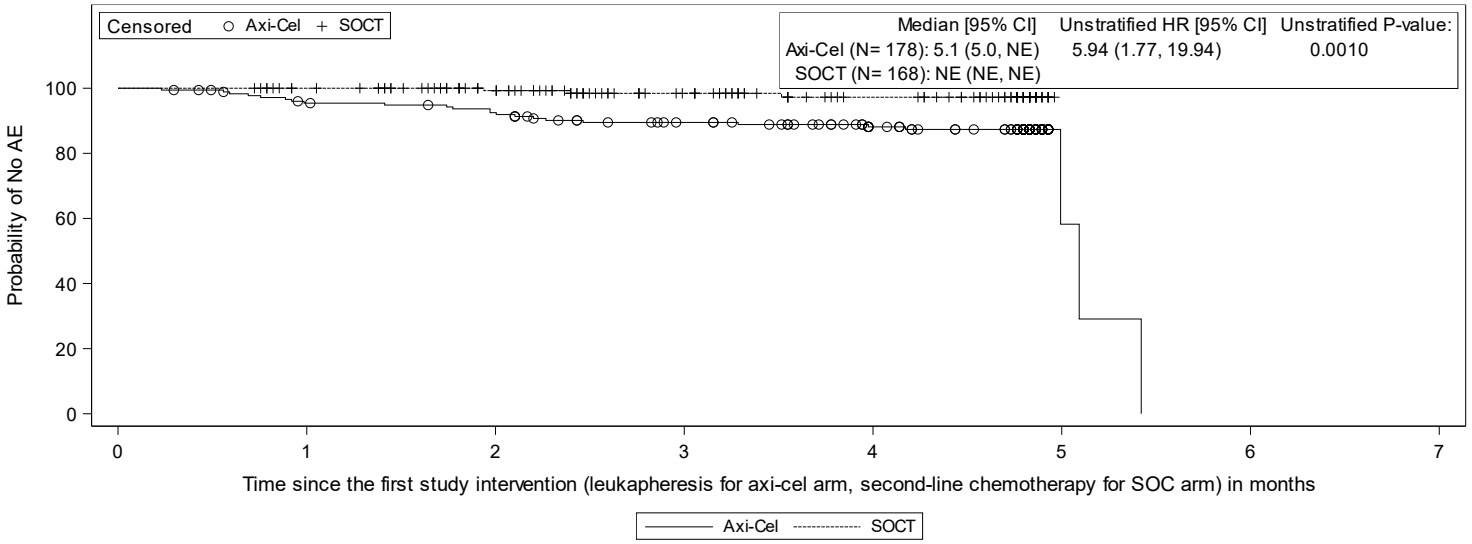
Figure 14.5.1.1.6. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Immune System Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	165	158	140	117	2	0
SOCT	168	160	135	99	72	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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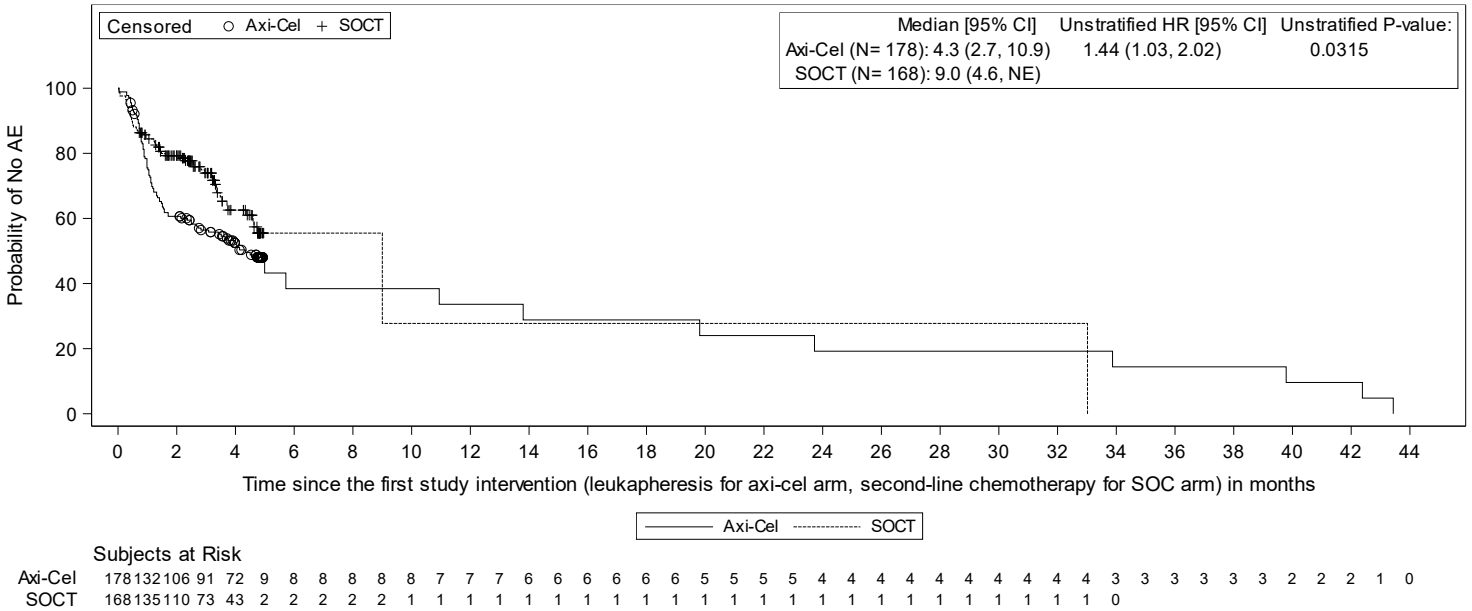
Figure 14.5.1.1.7. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Infections And Infestations (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	132	106	91	72	9	8	8	8	8	8	7	7	7	6	6	6	6	6	6	5	5	5	5	4	4	4	4	4	4	4	4	4	4	3	3	3	3	3	3	2	2	2	1	0
SOCT	168	135	110	73	43	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0										

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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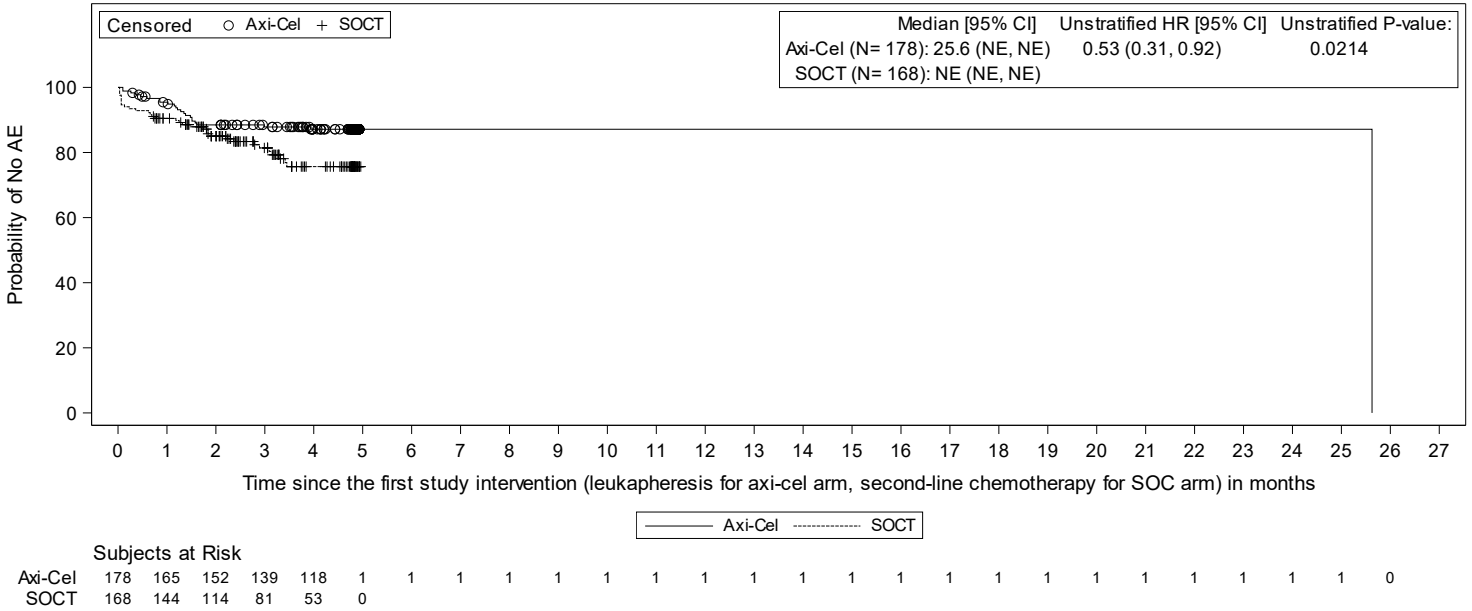
Figure 14.5.1.1.8. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Injury, Poisoning And Procedural Complications (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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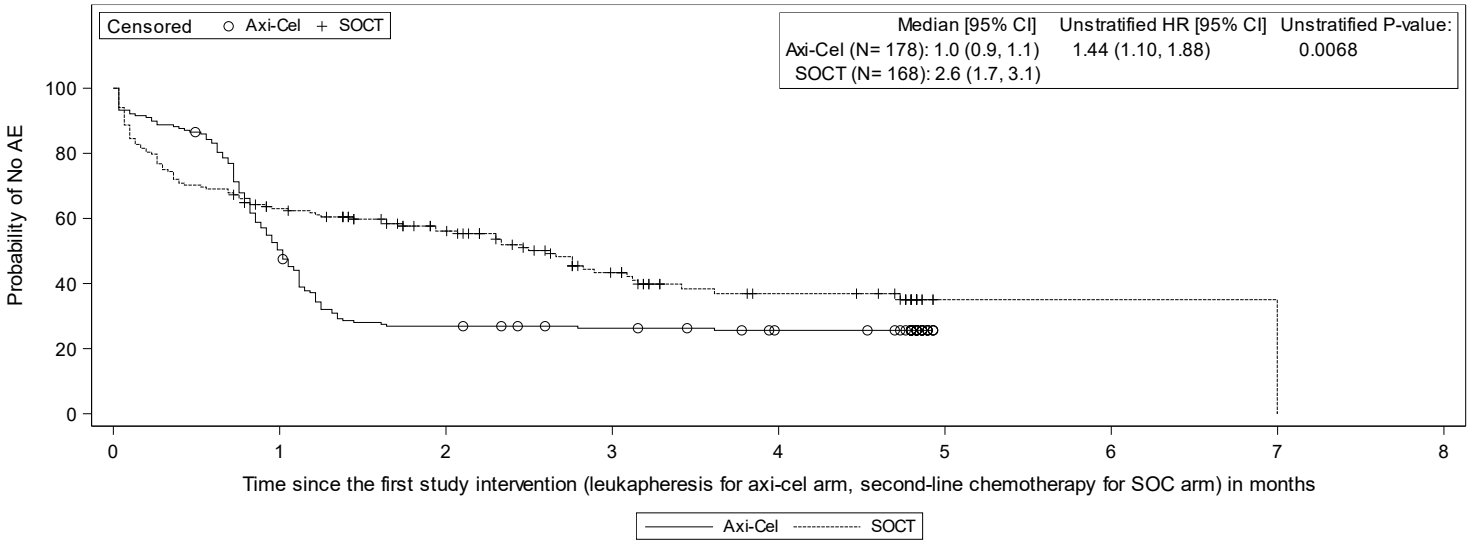
Figure 14.5.1.1.9. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Metabolism And Nutrition Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	89	47	42	36	0		
SOCT	168	100	73	41	23	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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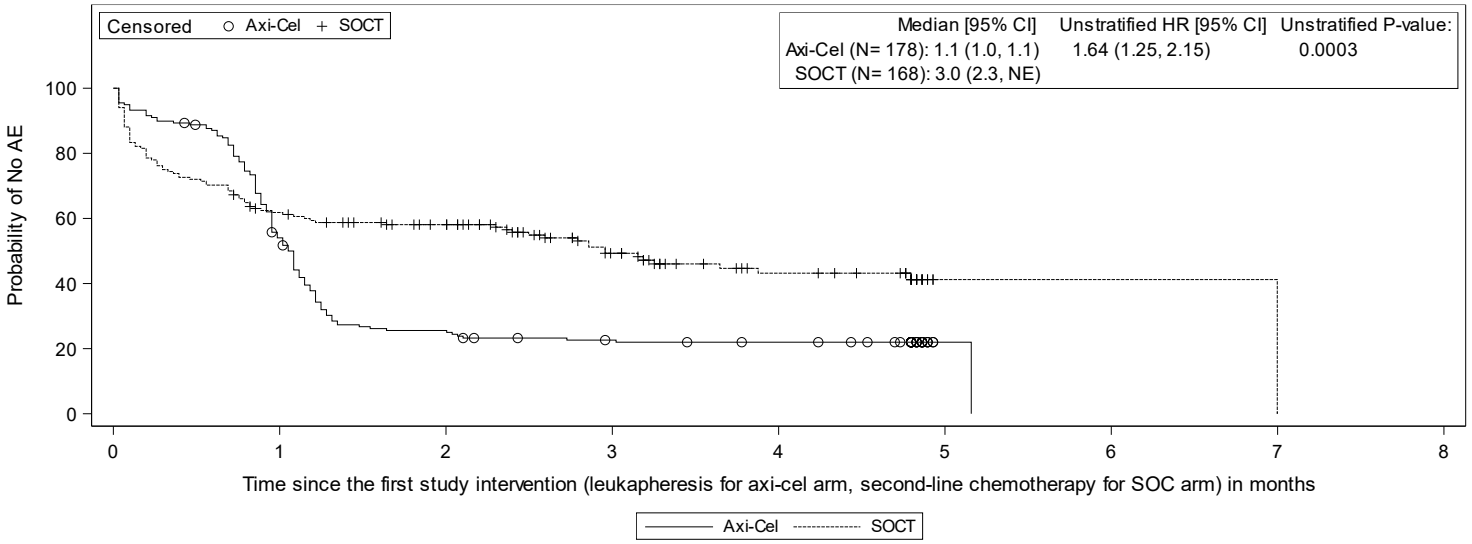
Figure 14.5.1.1.10. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Nervous System Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	94	44	35	32	1	0	
SOCT	168	101	84	50	29	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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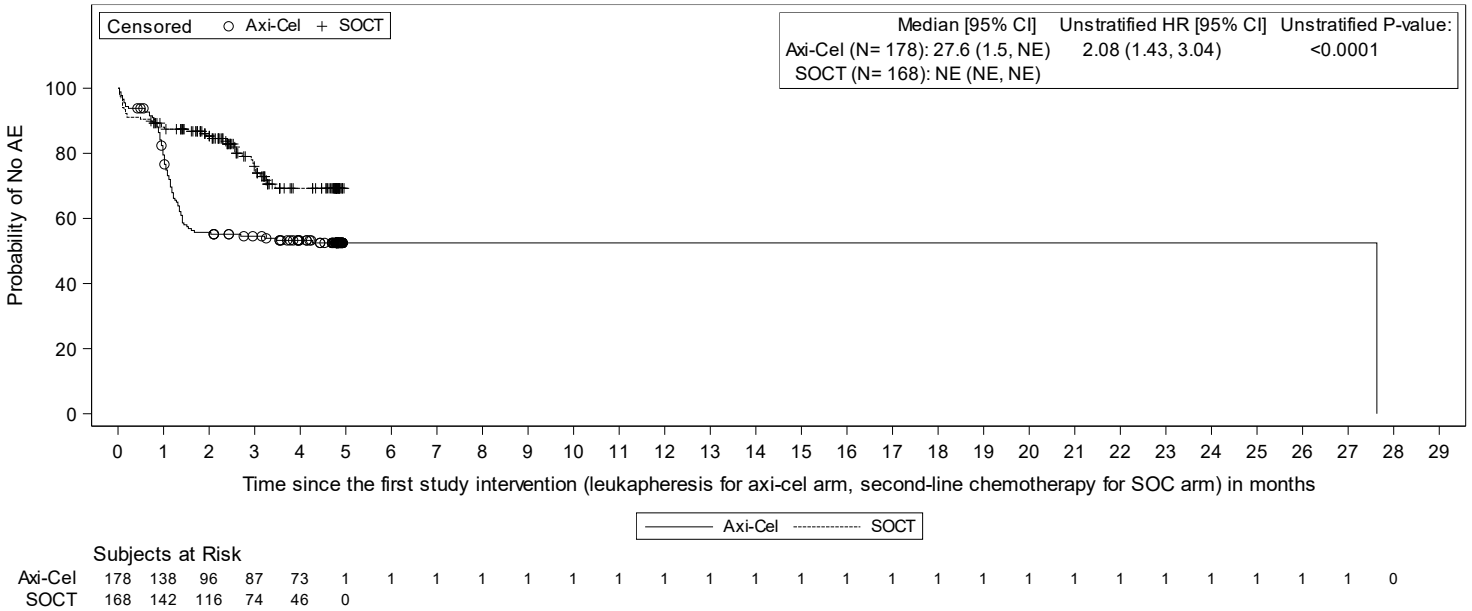
Figure 14.5.1.1.11. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Psychiatric Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	138	96	87	73	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	168	142	116	74	46	0																						

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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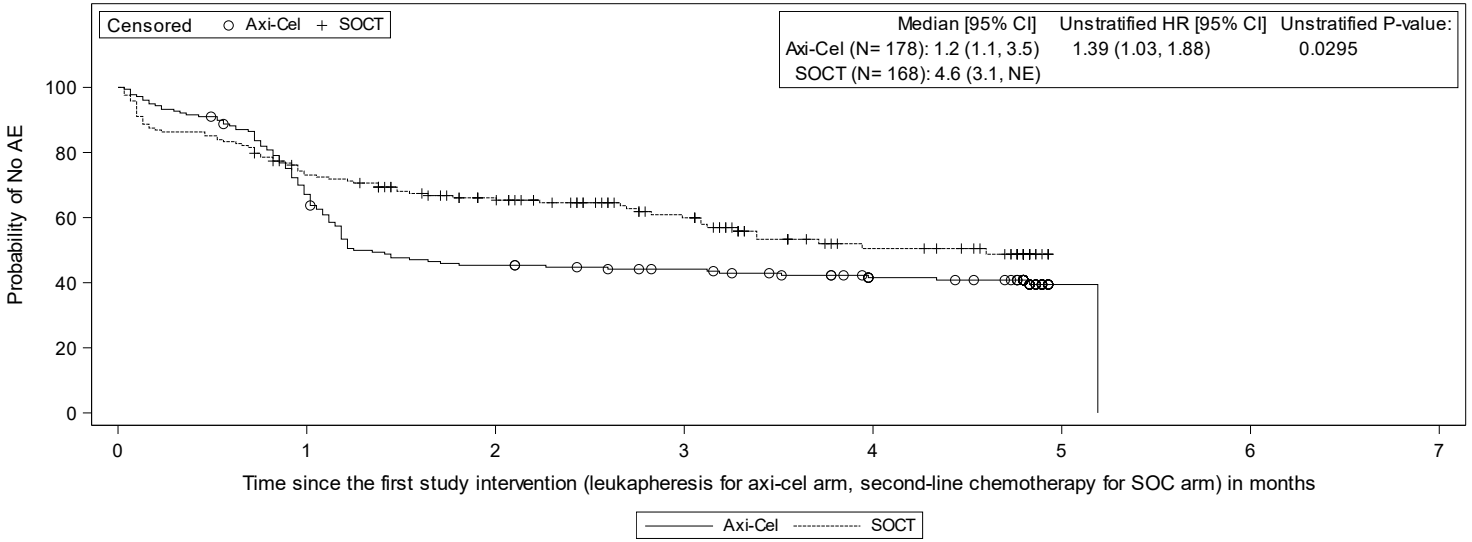
Figure 14.5.1.1.12. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Respiratory, Thoracic And Mediastinal Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	118	79	71	55	1	0
SOCT	168	119	92	63	34	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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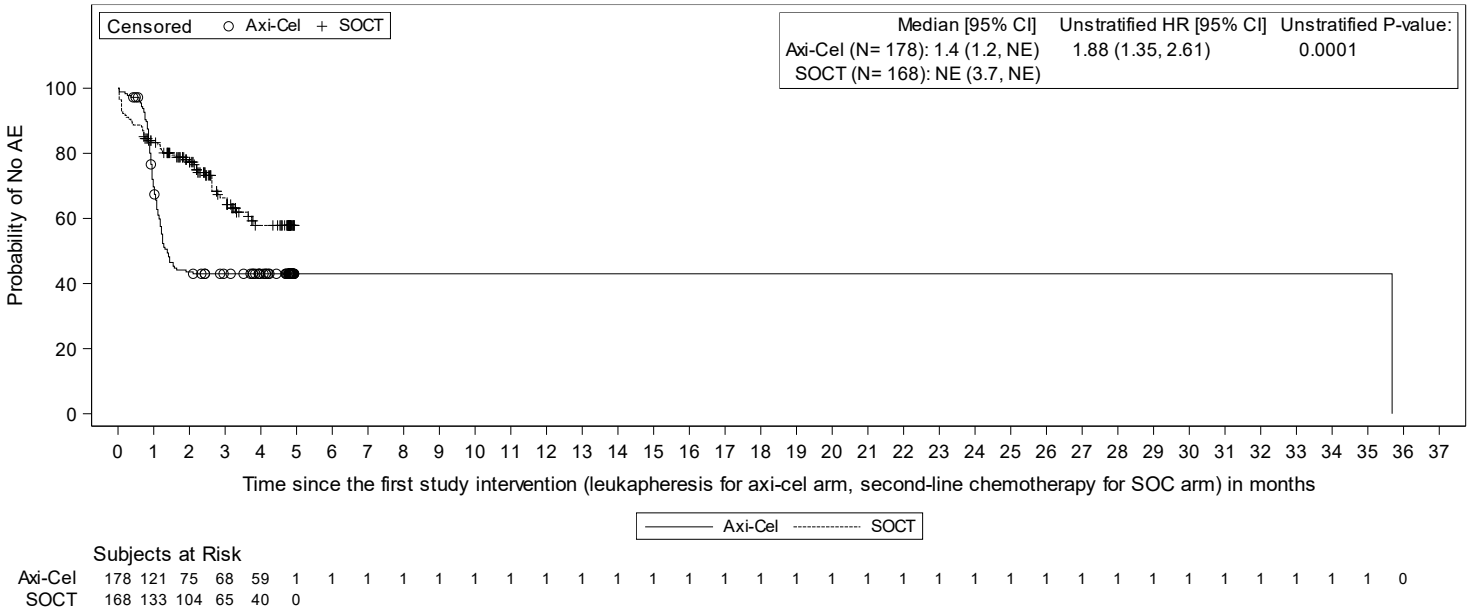
Figure 14.5.1.1.13. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Vascular Disorders (Modified Safety Analysis Set)



Subjects at Risk

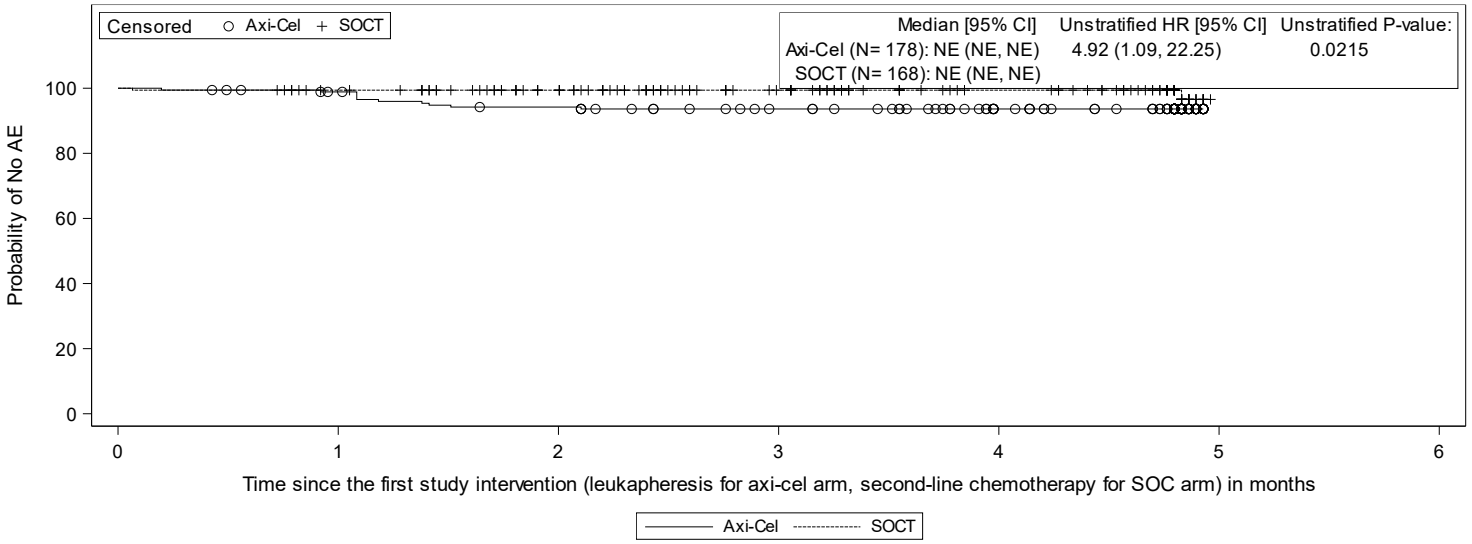
Axi-Cel	178	121	75	68	59	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	168	133	104	65	40	0																																	

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Agitation (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	171	161	148	126	0
SOCT	168	160	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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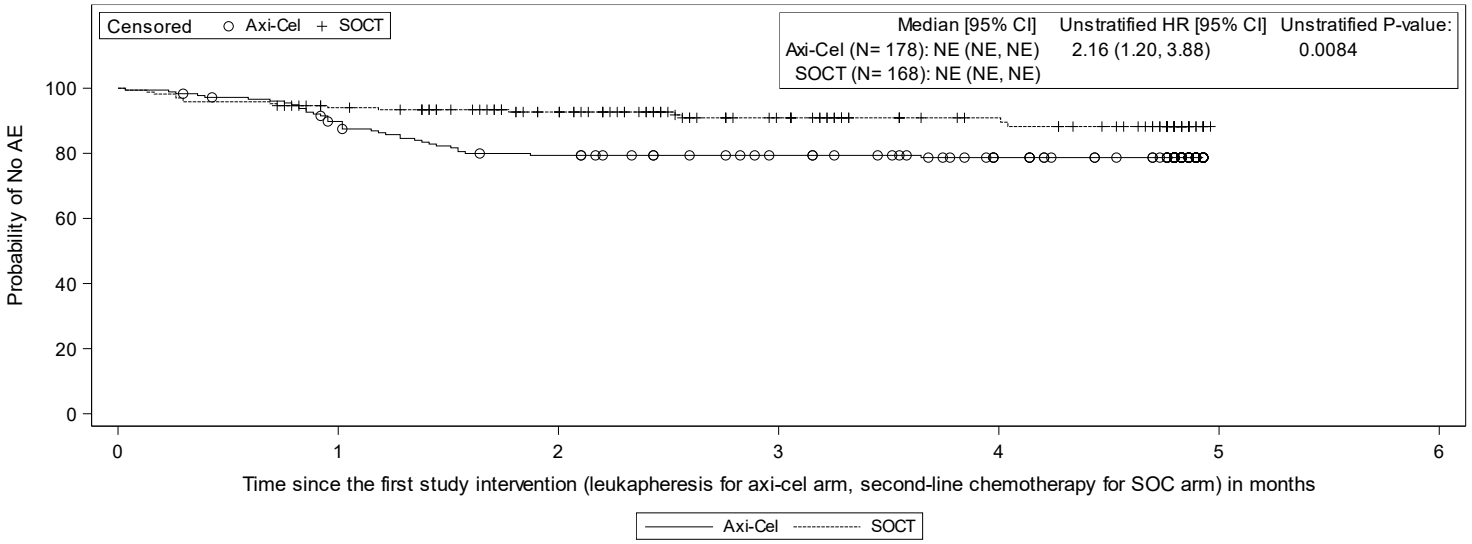
Figure 14.5.1.2.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Alanine Aminotransferase Increased (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	156	136	124	108	0
SOCT	168	151	127	91	68	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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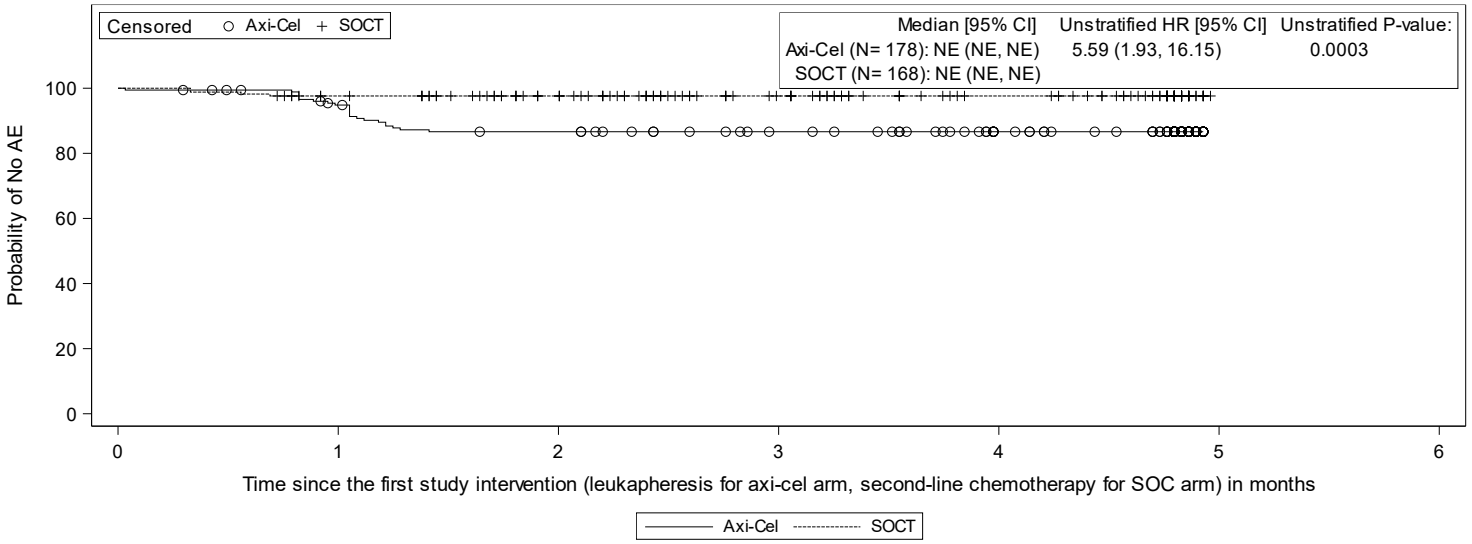
Figure 14.5.1.2.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent C-Reactive Protein Increased (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	163	147	135	116	0
SOCT	168	157	134	100	74	0

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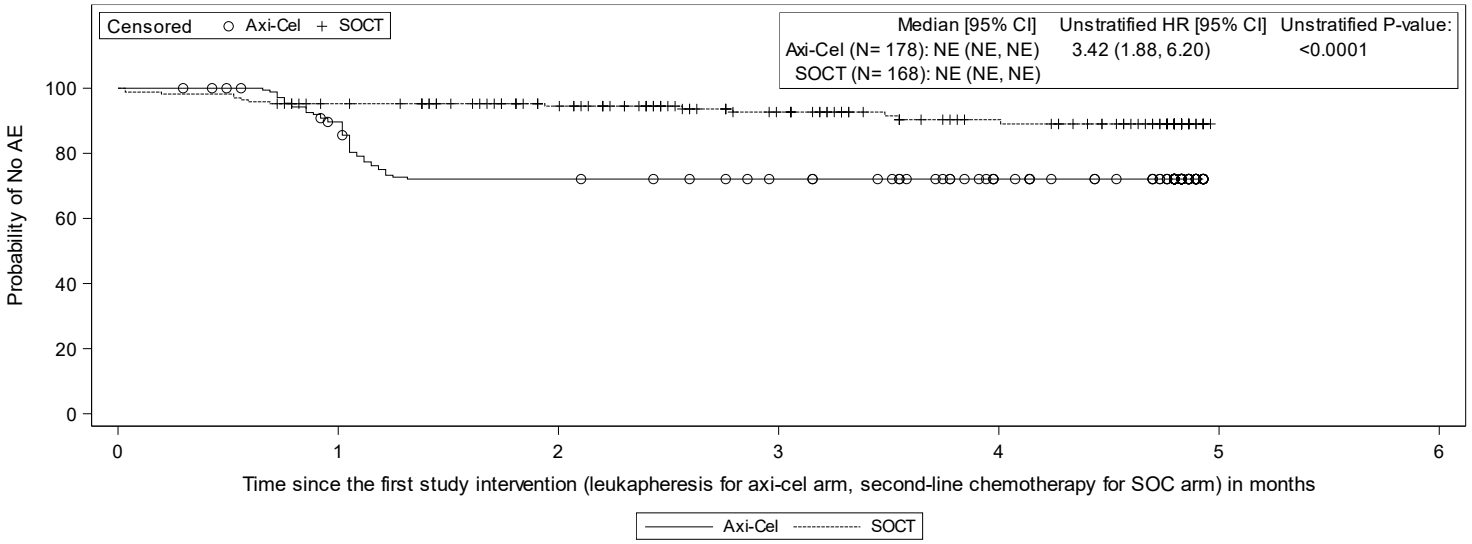
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Chills (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	154	123	117	100	0
SOCT	168	153	129	95	69	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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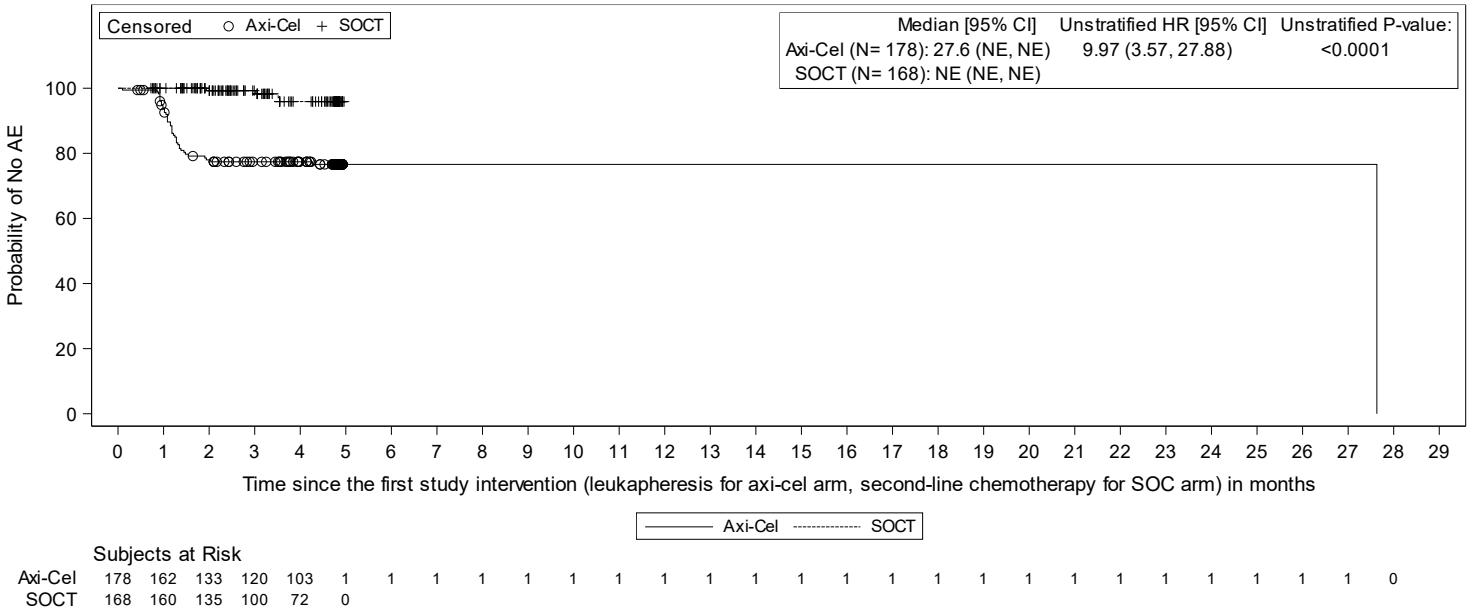
Figure 14.5.1.2.5. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Confusional State (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	162	133	120	103	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	168	160	135	100	72	0																						

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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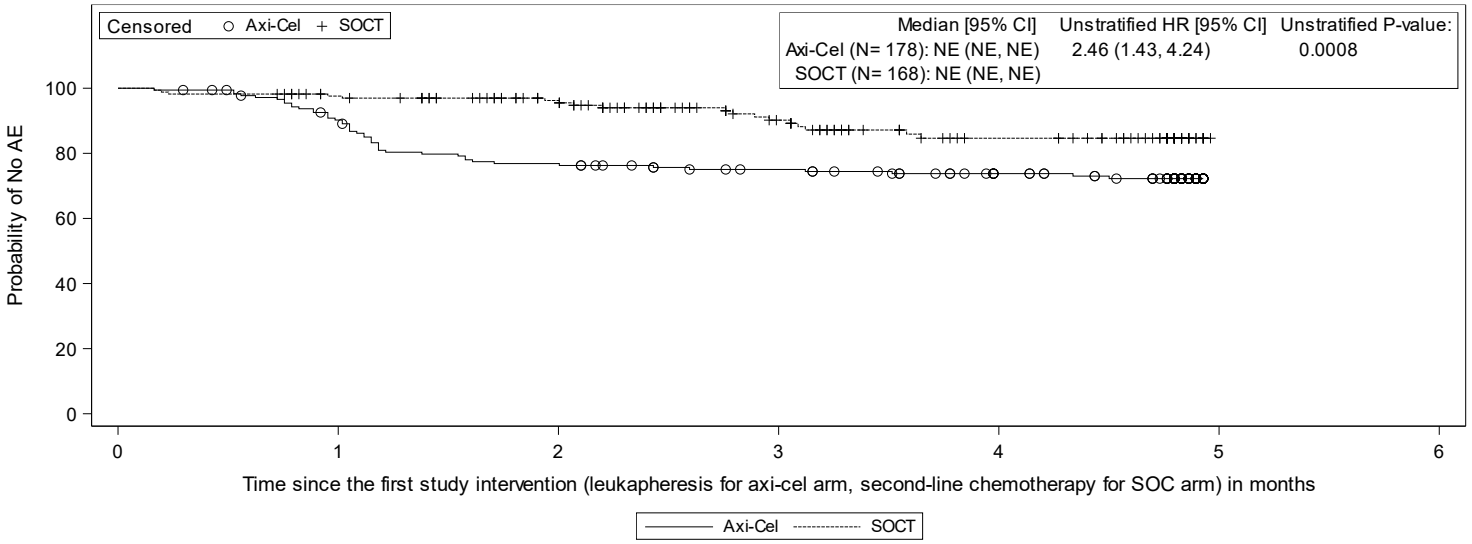
Figure 14.5.1.2.6. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Cough (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	156	132	119	101	0
SOCT	168	156	132	92	62	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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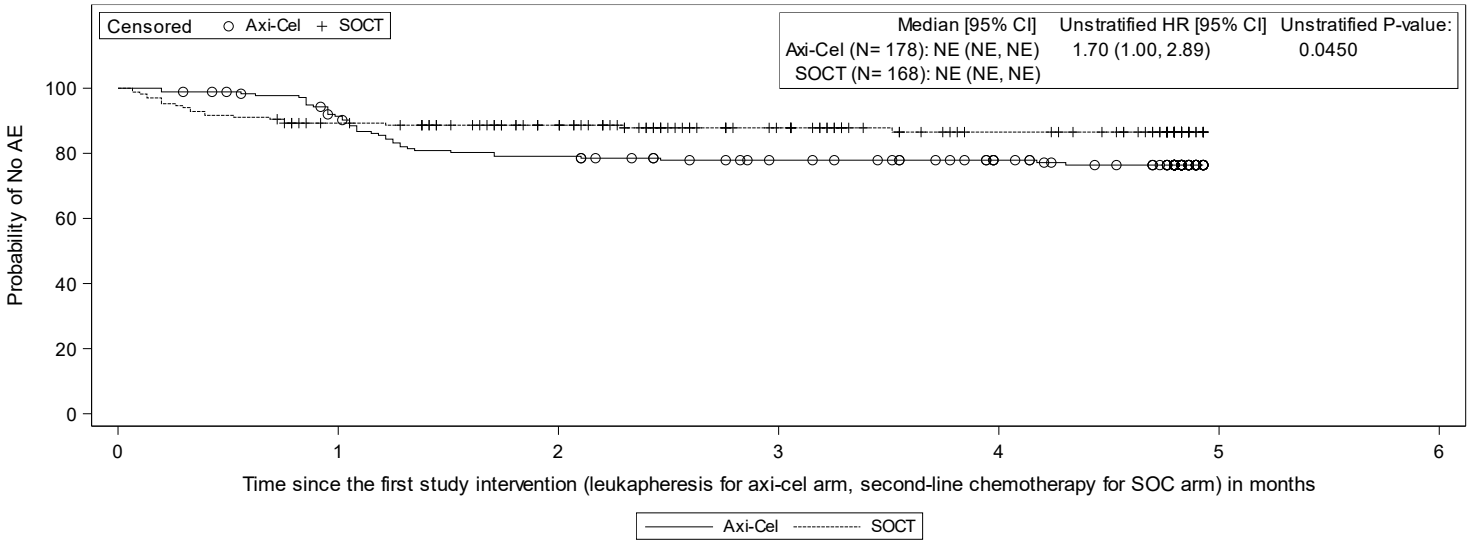
Figure 14.5.1.2.7. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Dizziness (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	157	135	122	108	0
SOCT	168	143	119	84	60	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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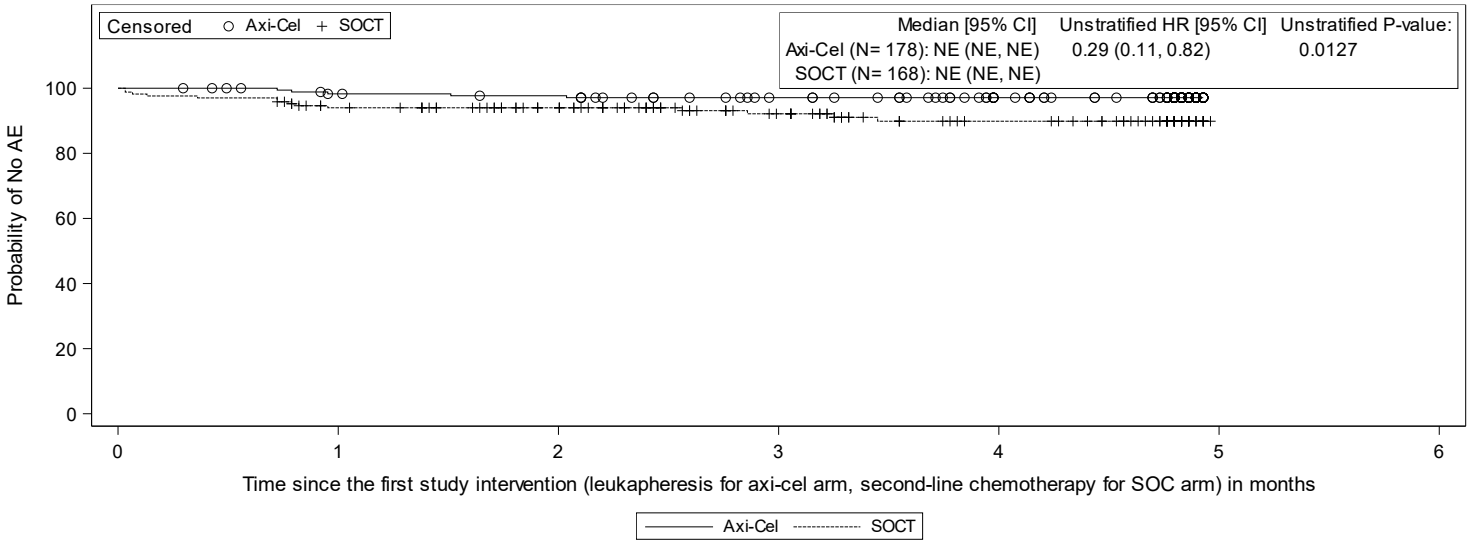
Figure 14.5.1.2.8. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Dysgeusia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	166	151	130	0
SOCT	168	150	129	94	68	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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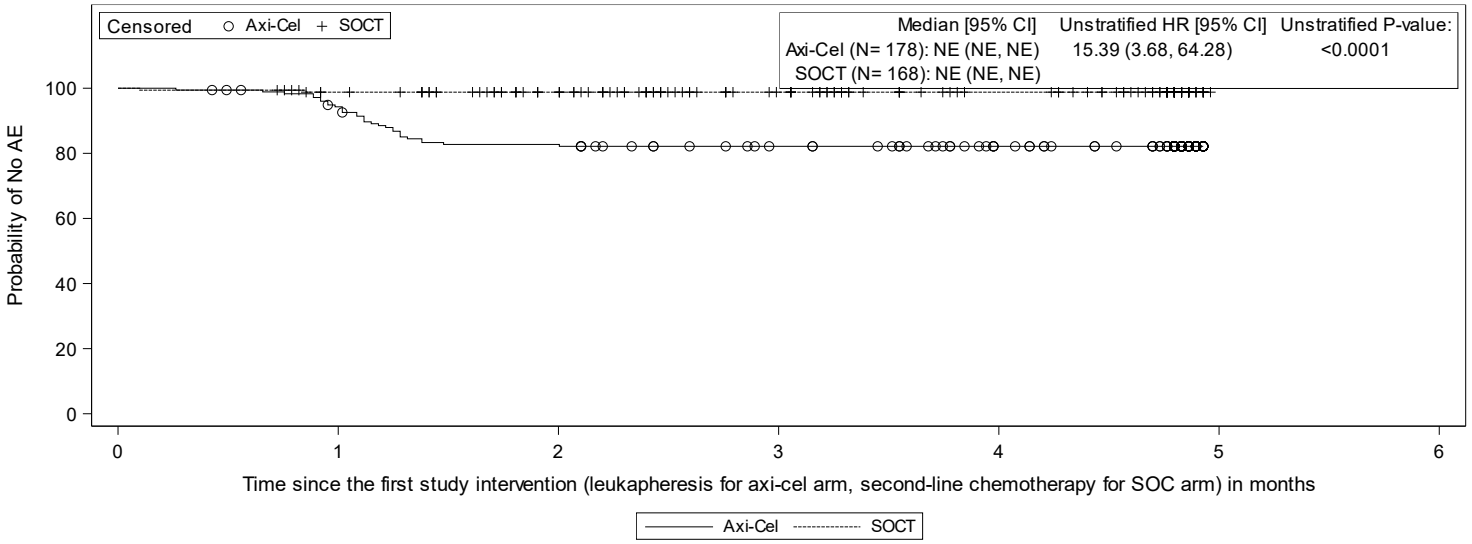
Figure 14.5.1.2.9. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Encephalopathy (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	164	143	129	111	0
SOCT	168	159	136	101	75	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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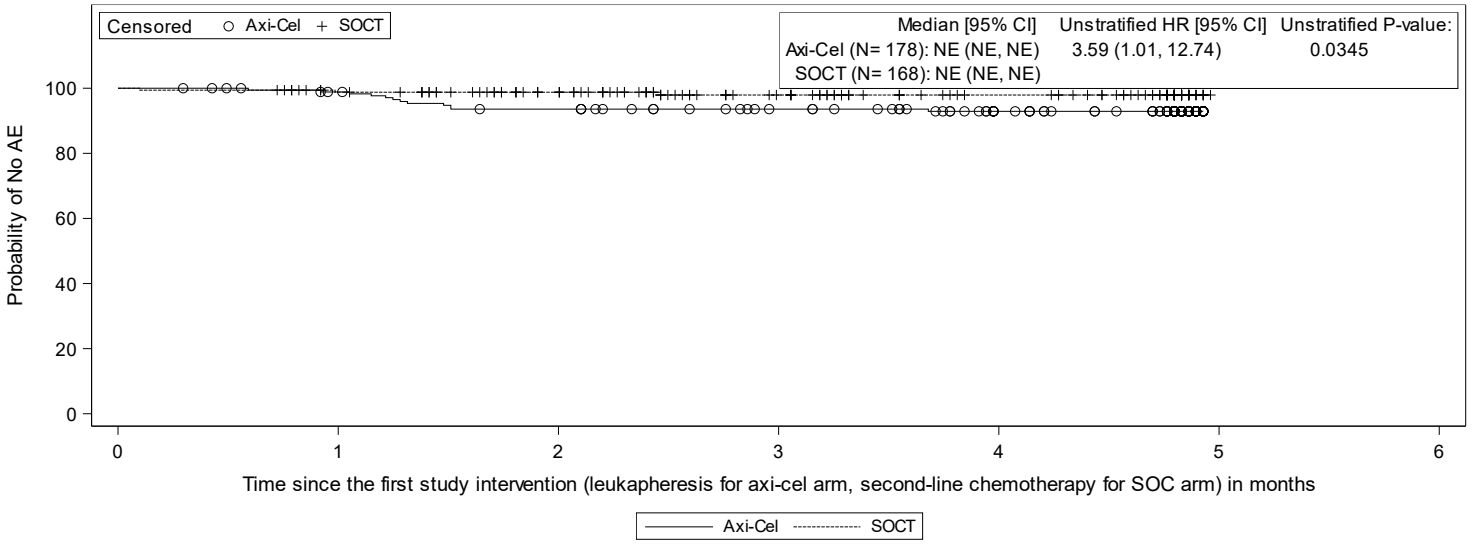
Figure 14.5.1.2.10. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Erythema (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	170	159	145	123	0
SOCT	168	158	134	98	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:19

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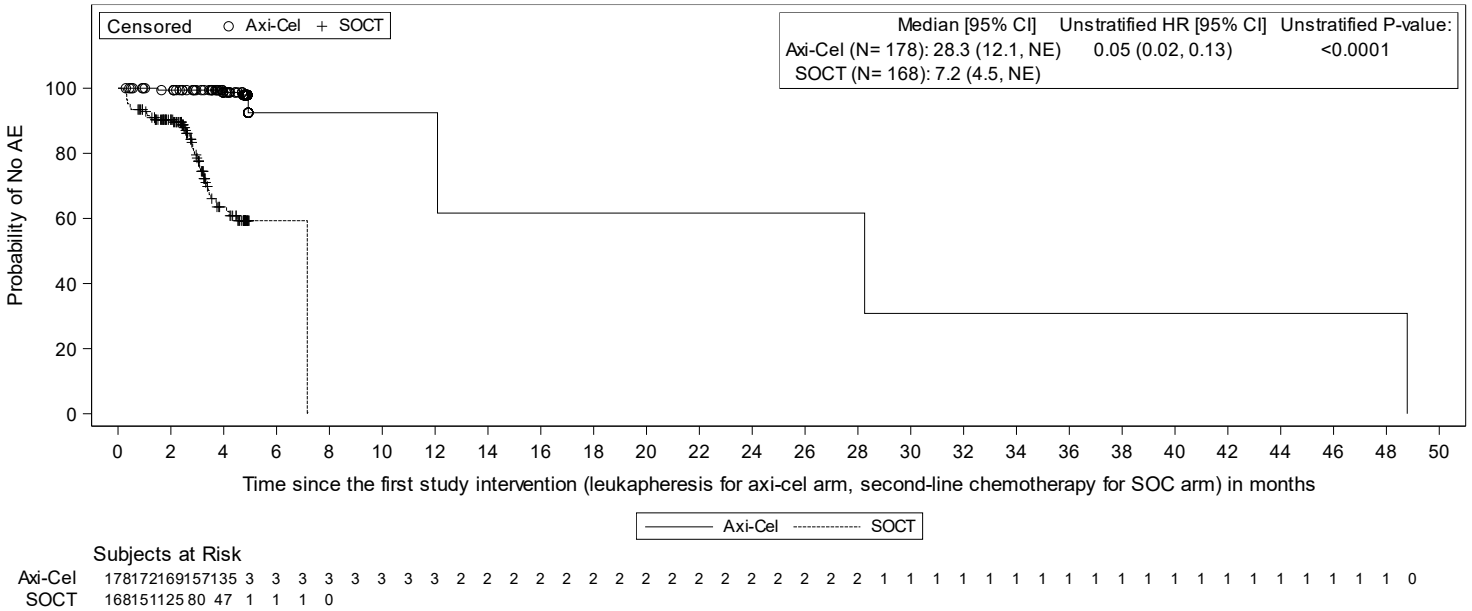
Figure 14.5.1.2.11. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Febrile Neutropenia (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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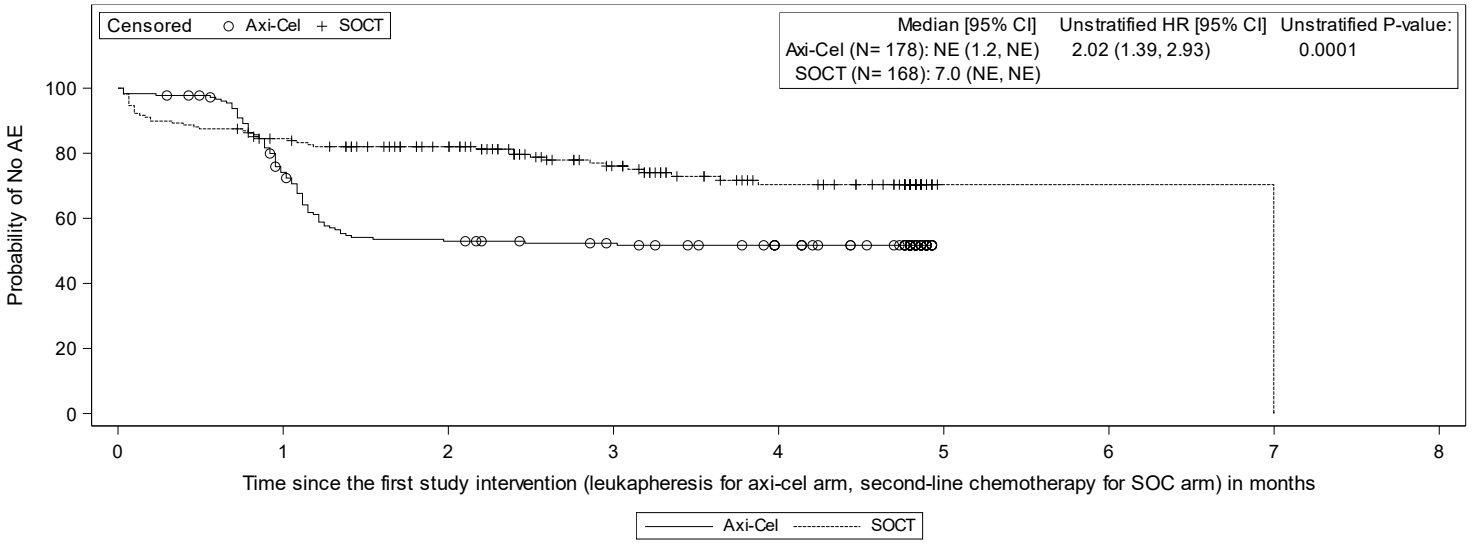
Figure 14.5.1.2.12. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Headache (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	127	90	83	72	0		
SOCT	168	137	116	80	53	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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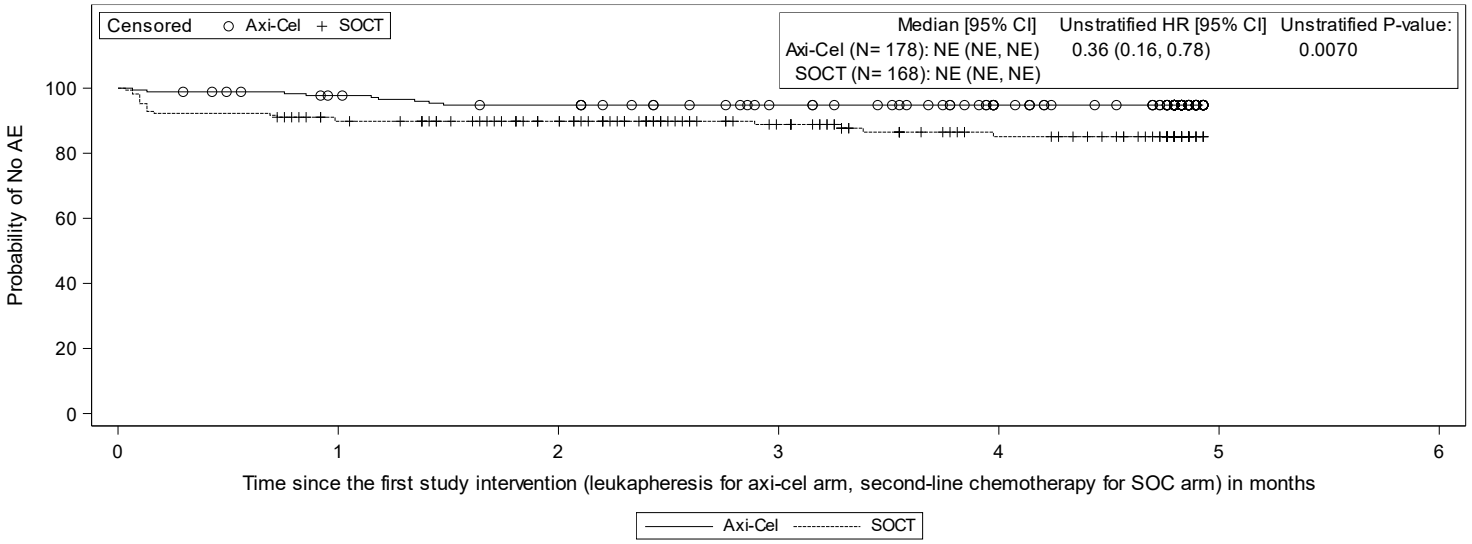
Figure 14.5.1.2.13. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hiccups (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	161	148	128	0
SOCT	168	144	123	89	61	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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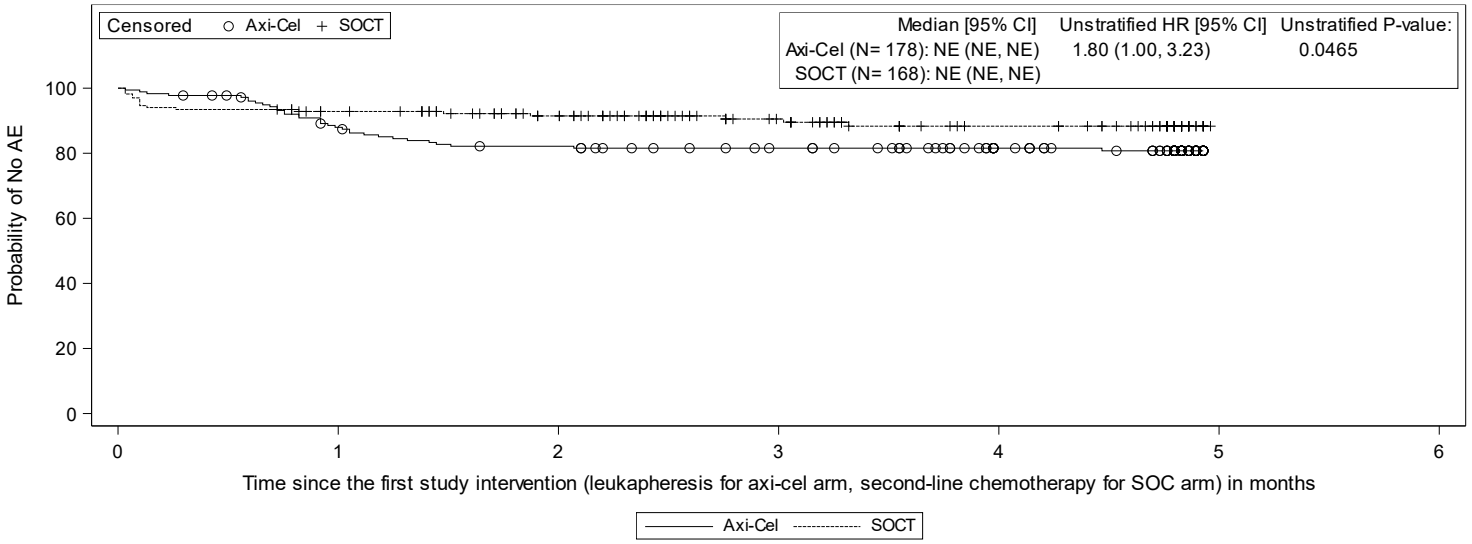
Figure 14.5.1.2.14. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hyperglycaemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	152	140	129	107	0
SOCT	168	149	125	90	65	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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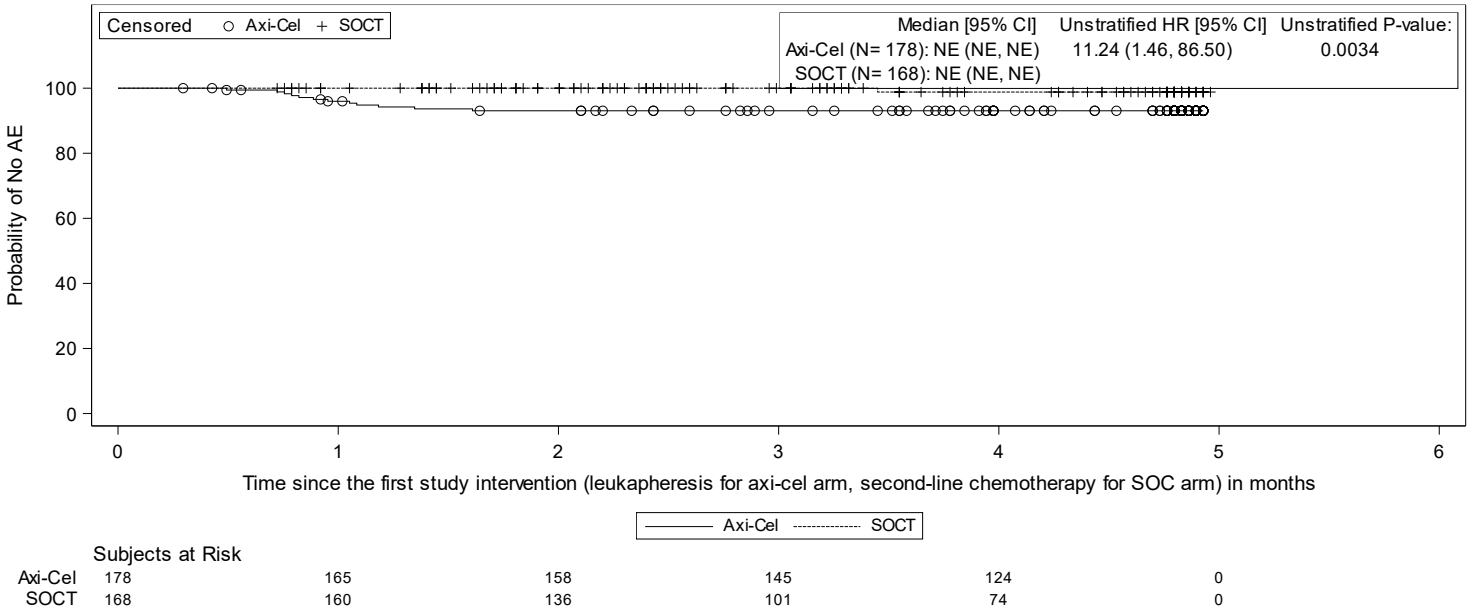
Figure 14.5.1.2.15. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hypertransaminasaemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	165	158	145	124	0
SOCT	168	160	136	101	74	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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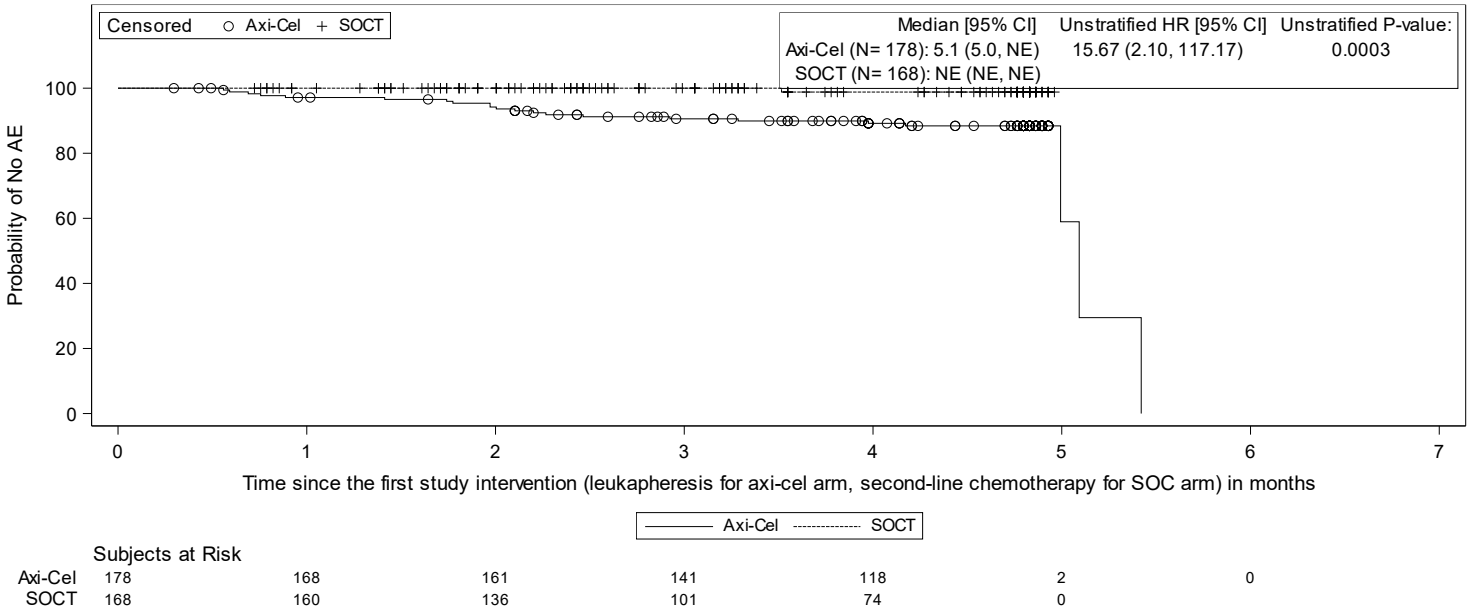
Figure 14.5.1.2.16. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hypogammaglobulinaemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	161	141	118	2	0
SOCT	168	160	136	101	74	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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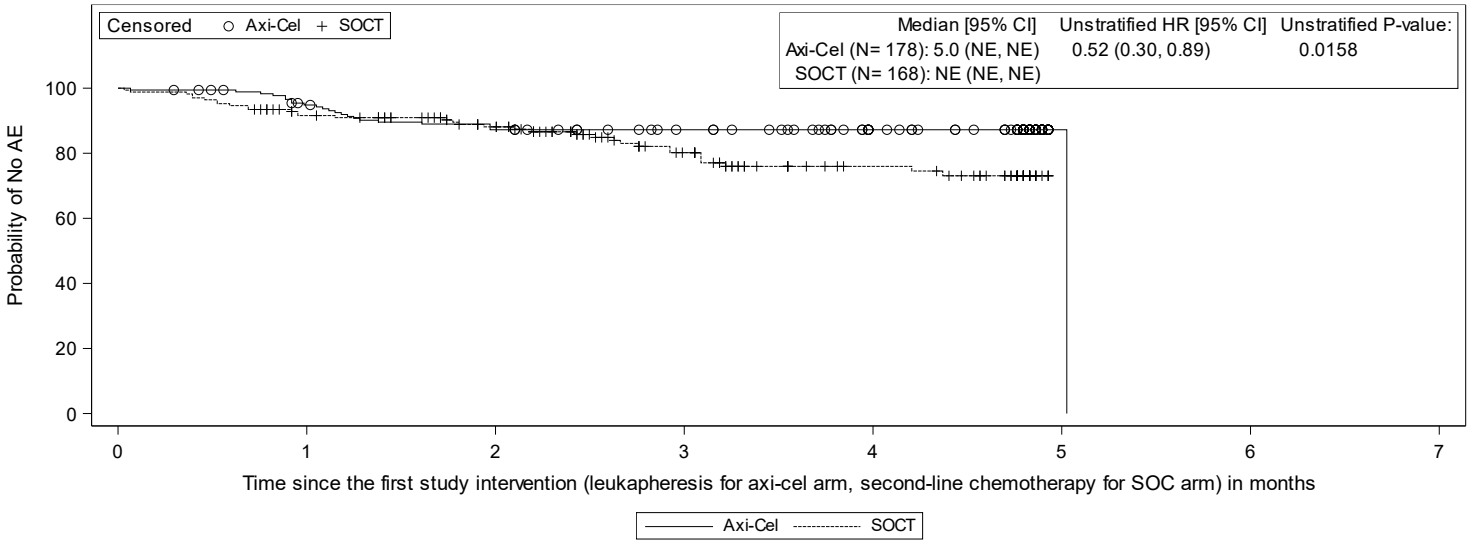
Figure 14.5.1.2.17. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hypomagnesaemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	163	149	138	118	1	0
SOCT	168	146	121	81	53	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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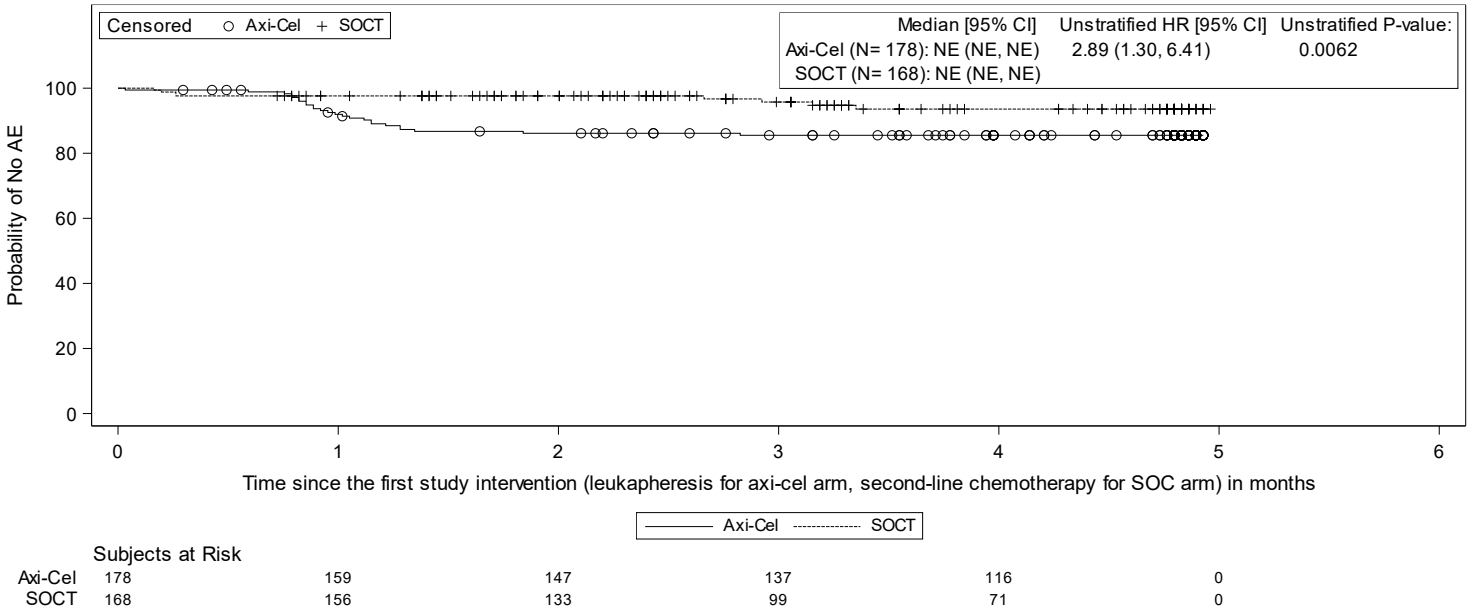
Figure 14.5.1.2.18. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hyponatraemia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	159	147	137	116	0
SOCT	168	156	133	99	71	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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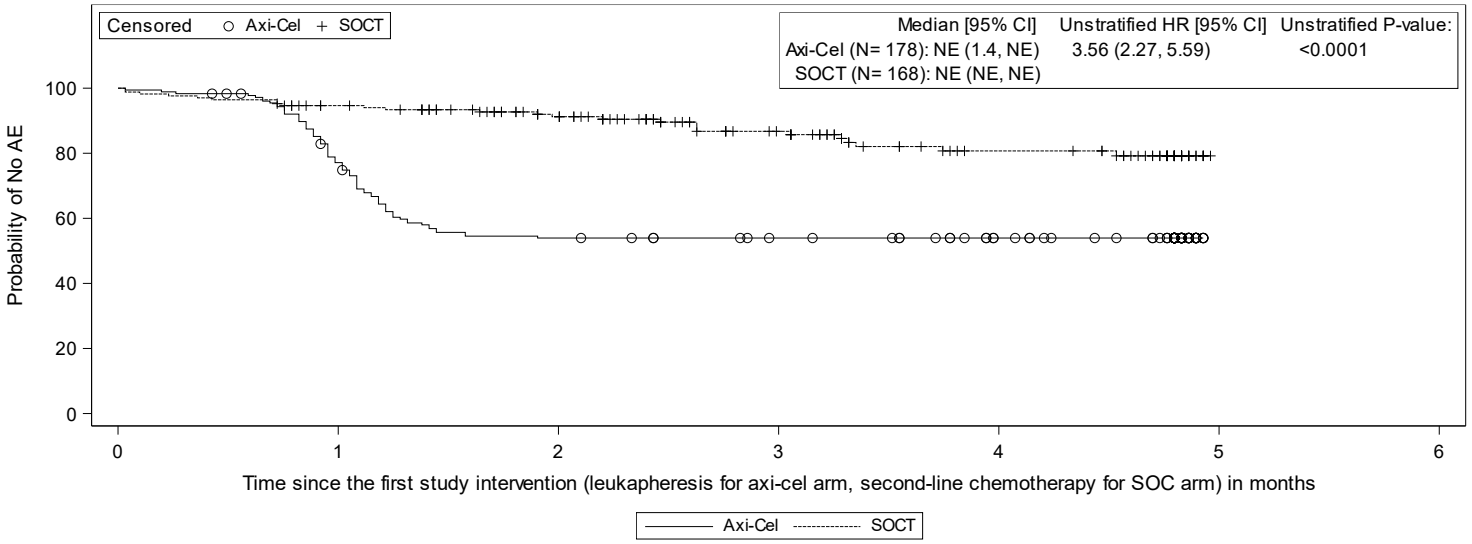
Figure 14.5.1.2.19. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hypotension (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	134	93	86	74	0
SOCT	168	151	123	85	56	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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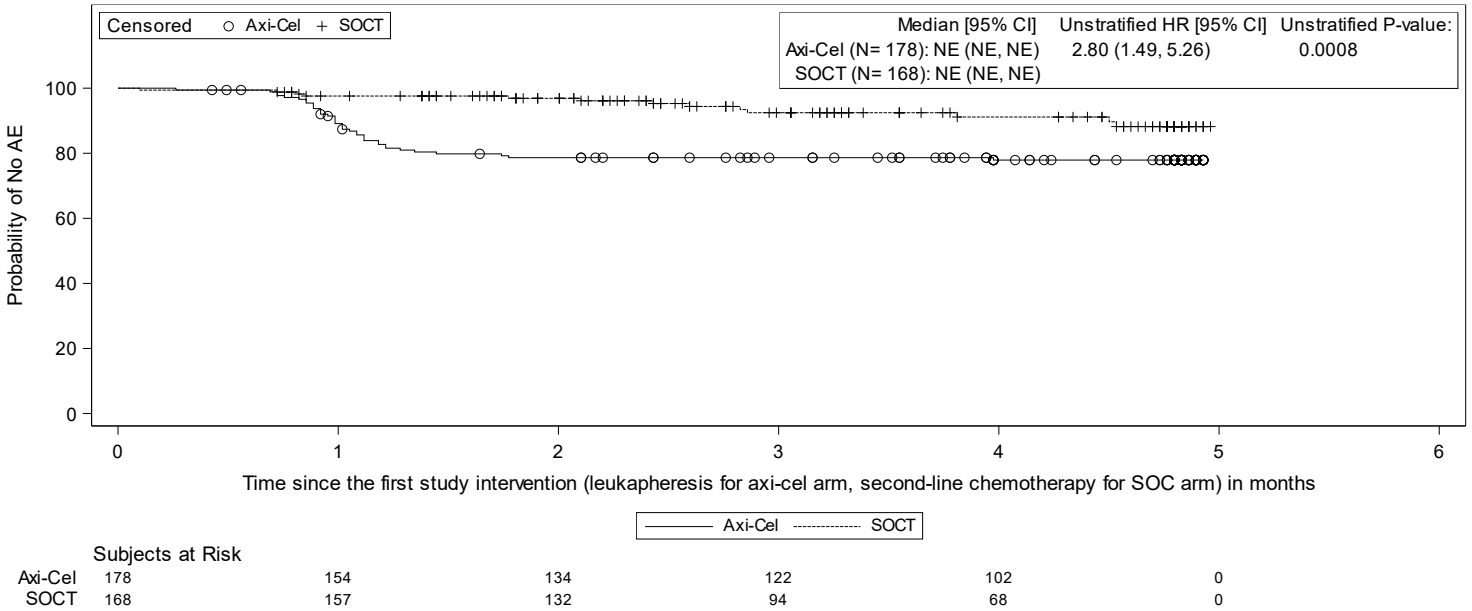
Figure 14.5.1.2.20. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Hypoxia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	154	134	122	102	0
SOCT	168	157	132	94	68	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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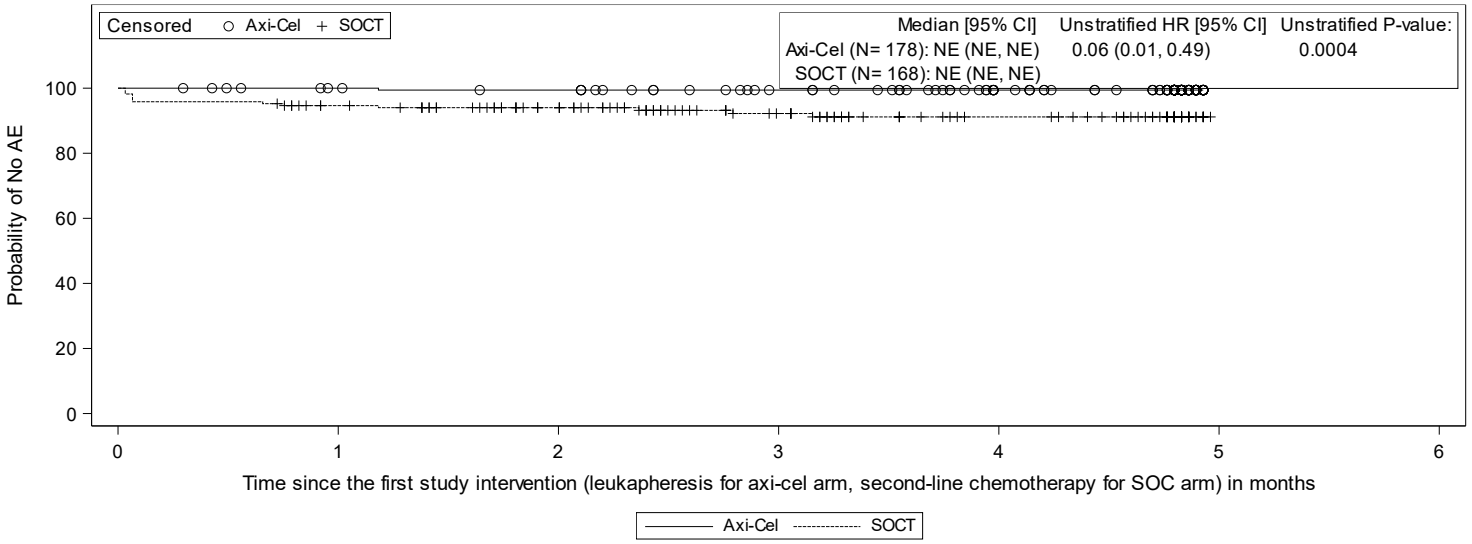
Figure 14.5.1.2.21. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Infusion Related Reaction (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	172	169	155	133	0
SOCT	168	151	127	92	65	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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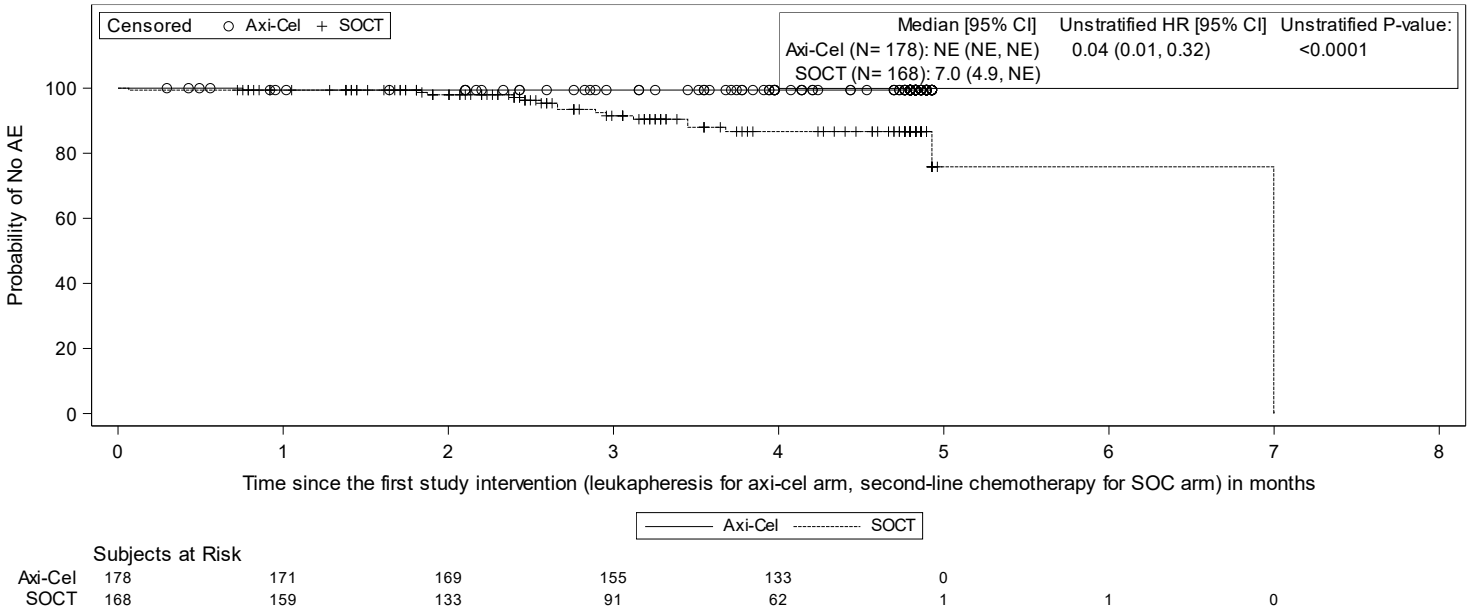
Figure 14.5.1.2.22. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Mucosal Inflammation (Modified Safety Analysis Set)



Subjects at Risk

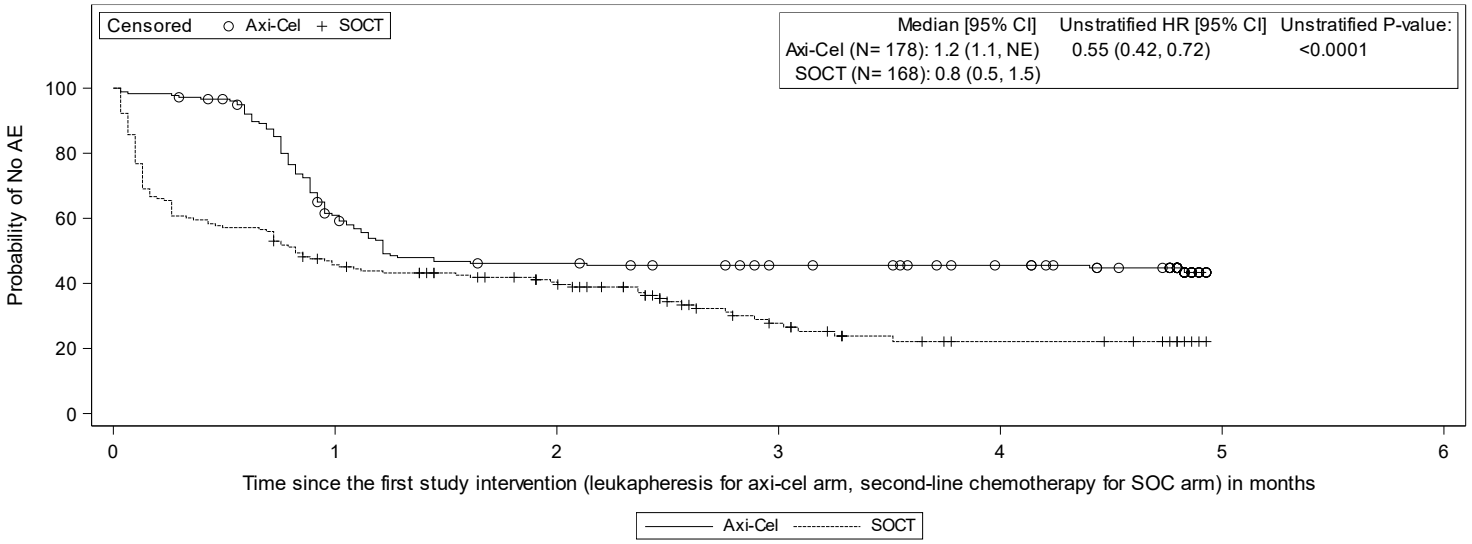
Axi-Cel	178	171	169	155	133	0		
SOCT	168	159	133	91	62	1	1	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.23. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Nausea (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	104	77	69	62	0
SOCT	168	74	54	23	10	0

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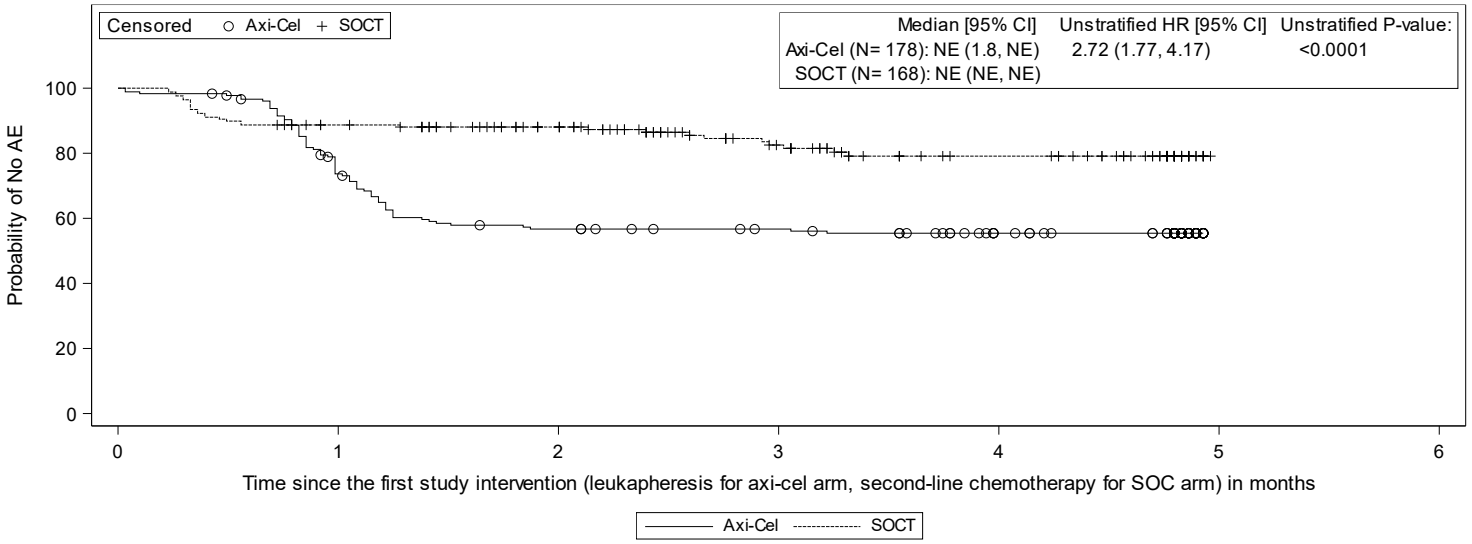
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.24. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Neutropenia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	127	96	89	73	0
SOCT	168	142	119	80	56	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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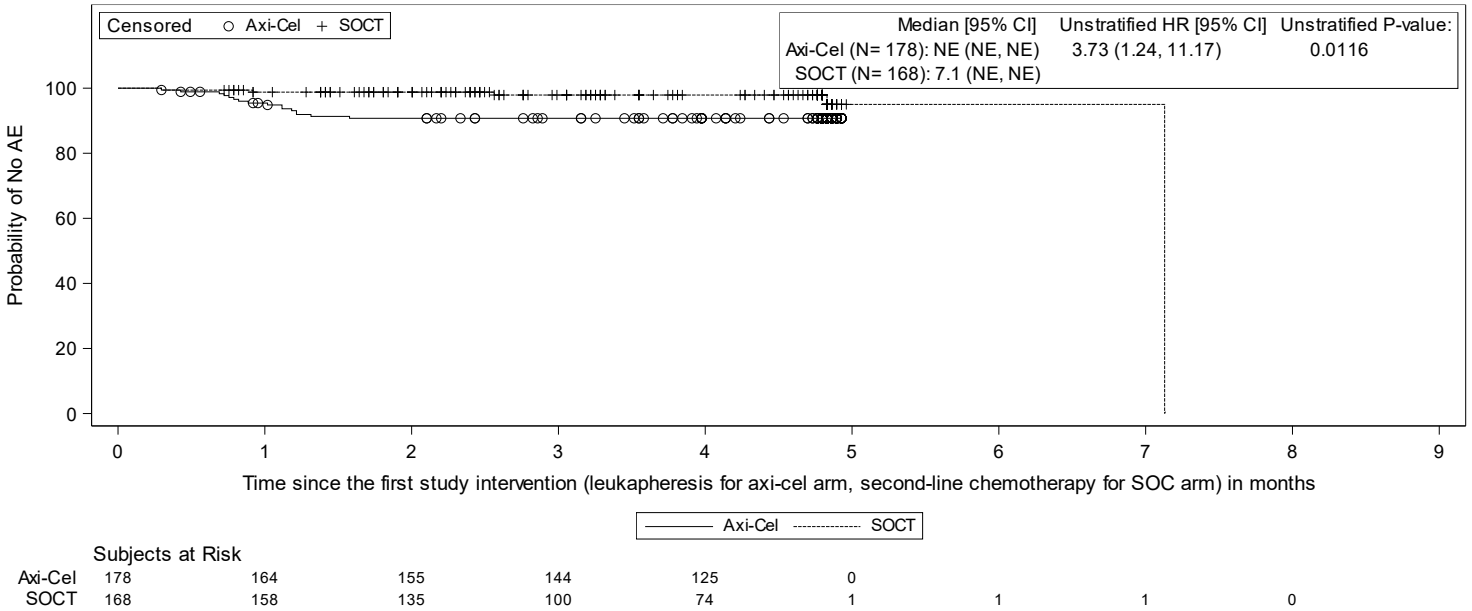
Figure 14.5.1.2.25. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Oral Candidiasis (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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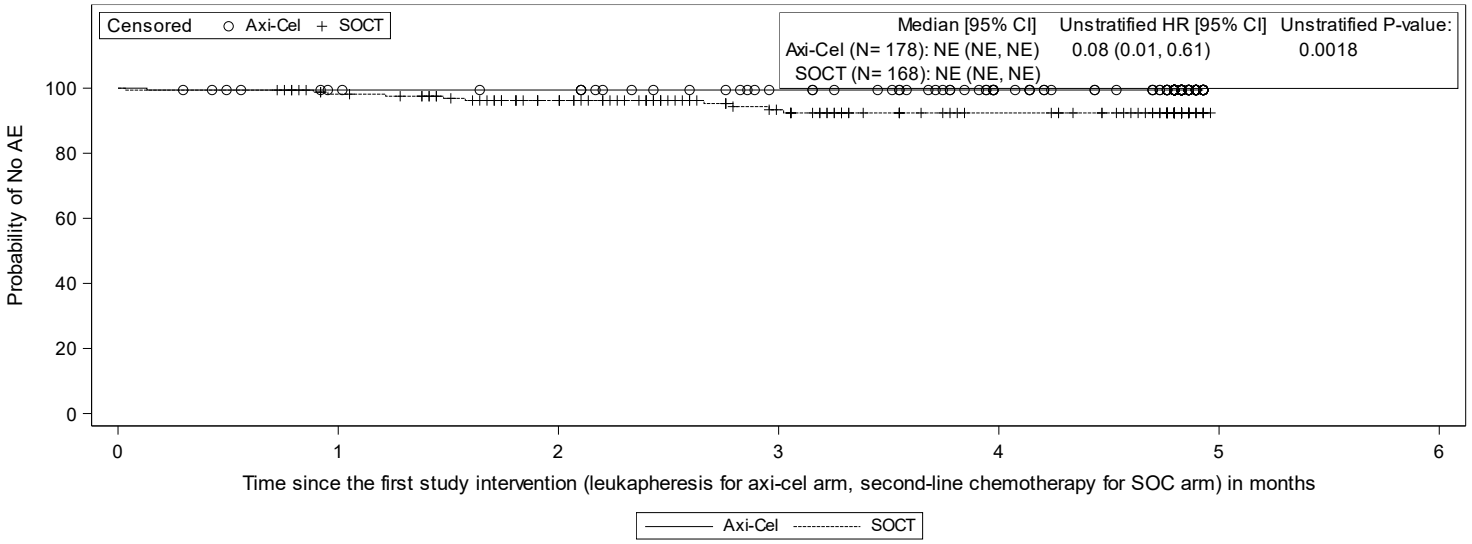
Figure 14.5.1.2.26. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Peripheral Sensory Neuropathy (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	171	169	156	134	0
SOCT	168	157	131	95	68	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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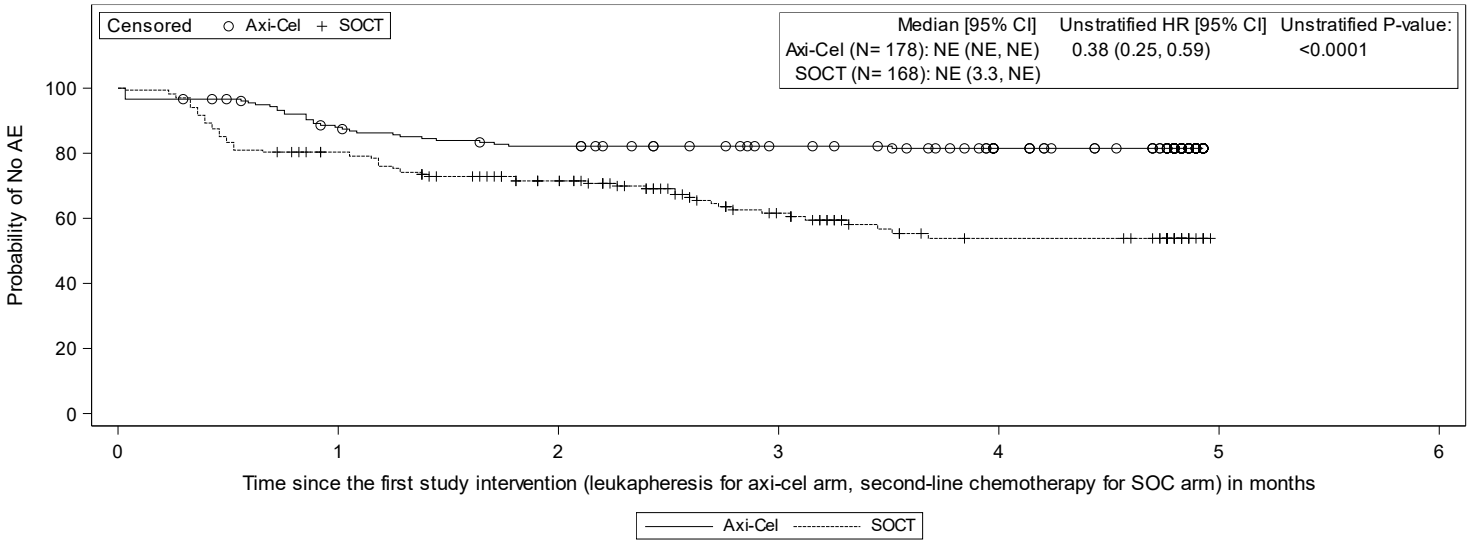
Figure 14.5.1.2.27. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Platelet Count Decreased (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	152	140	127	109	0
SOCT	168	129	99	59	35	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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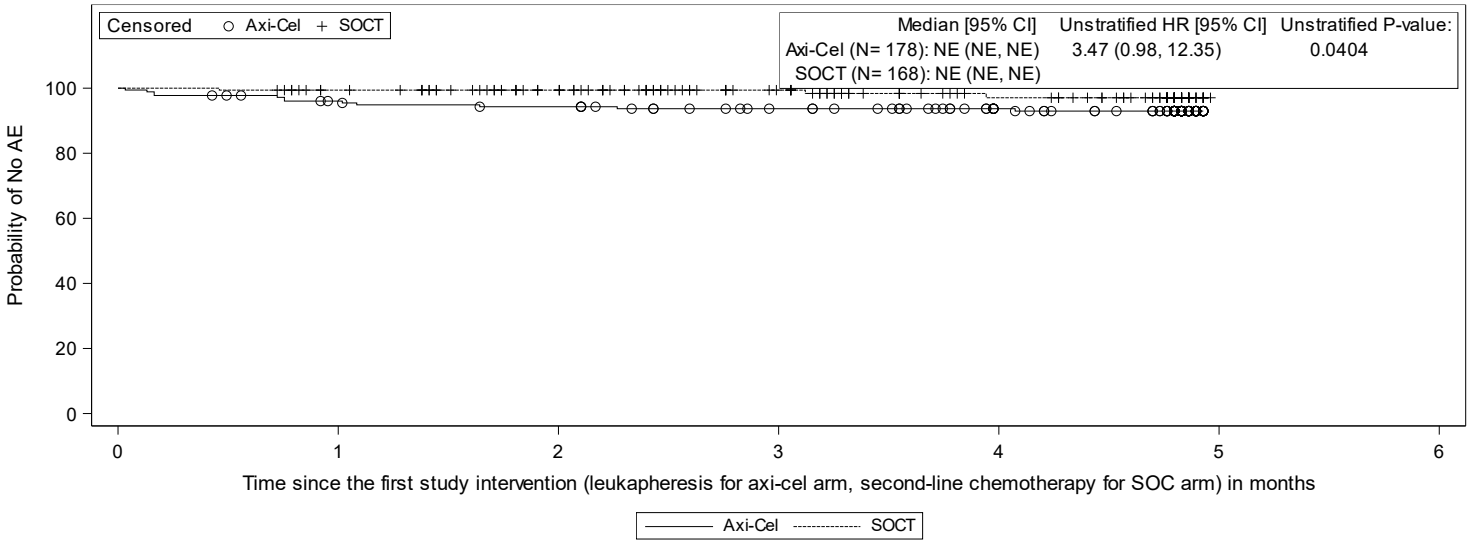
Figure 14.5.1.2.28. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Pleural Effusion (Modified Safety Analysis Set)



Subjects at Risk

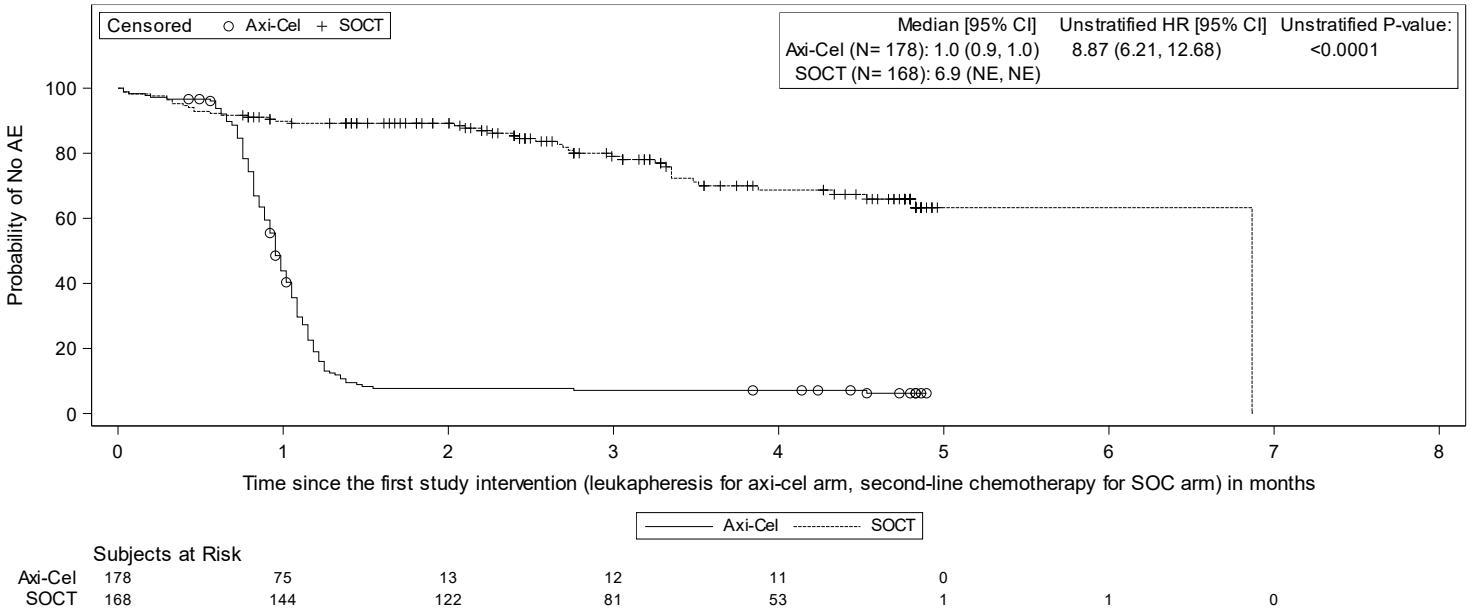
Axi-Cel	178	166	161	148	127	0
SOCT	168	159	135	101	73	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.29. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Pyrexia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	75	13	12	11	0		
SOCT	168	144	122	81	53	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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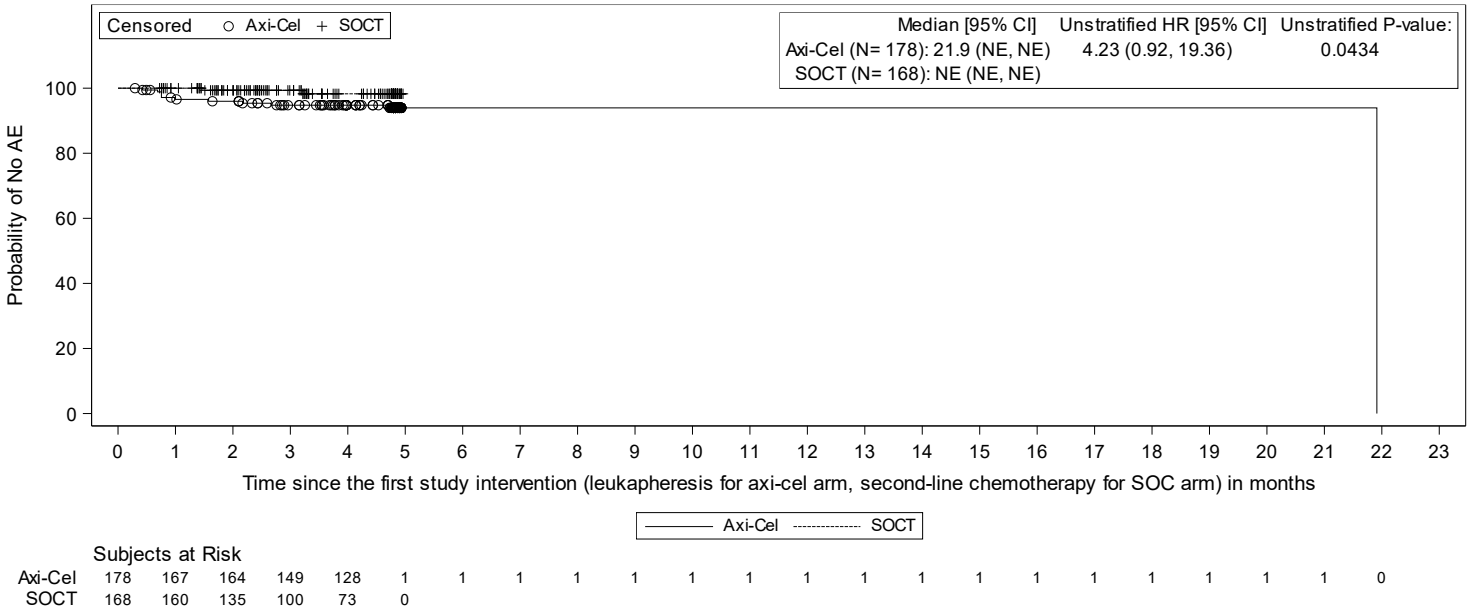
Figure 14.5.1.2.30. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Rhinovirus Infection (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	167	164	149	128	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	168	160	135	100	73	0																	

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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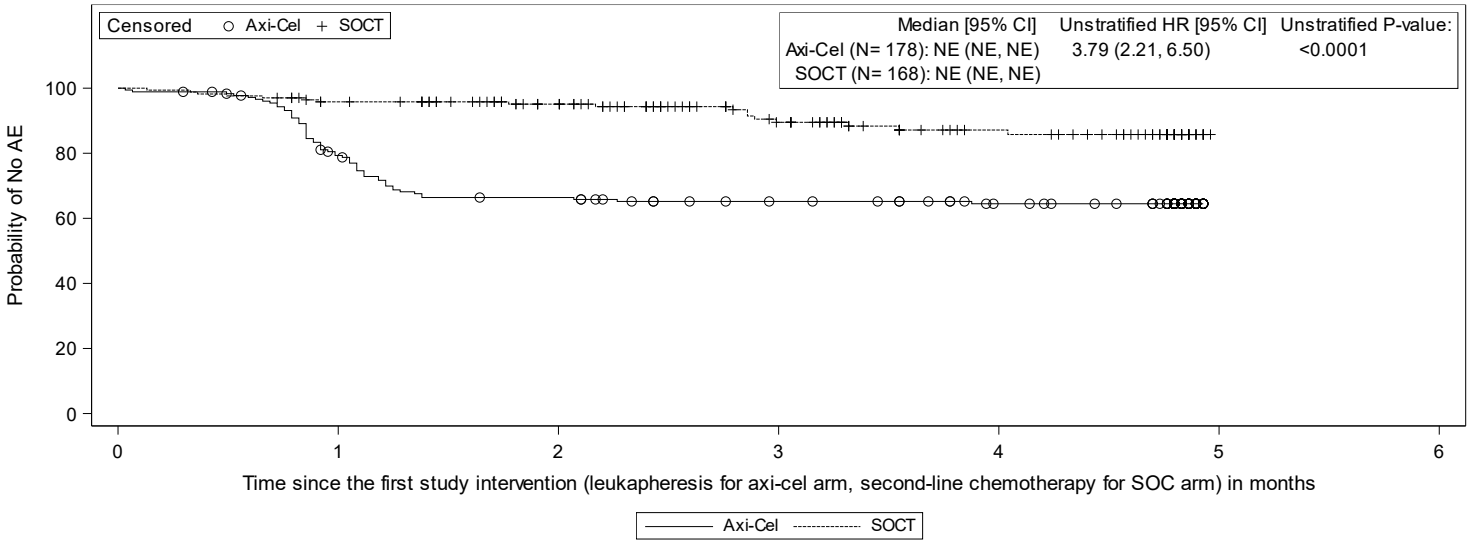
Figure 14.5.1.2.31. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Sinus Tachycardia (Modified Safety Analysis Set)



Subjects at Risk

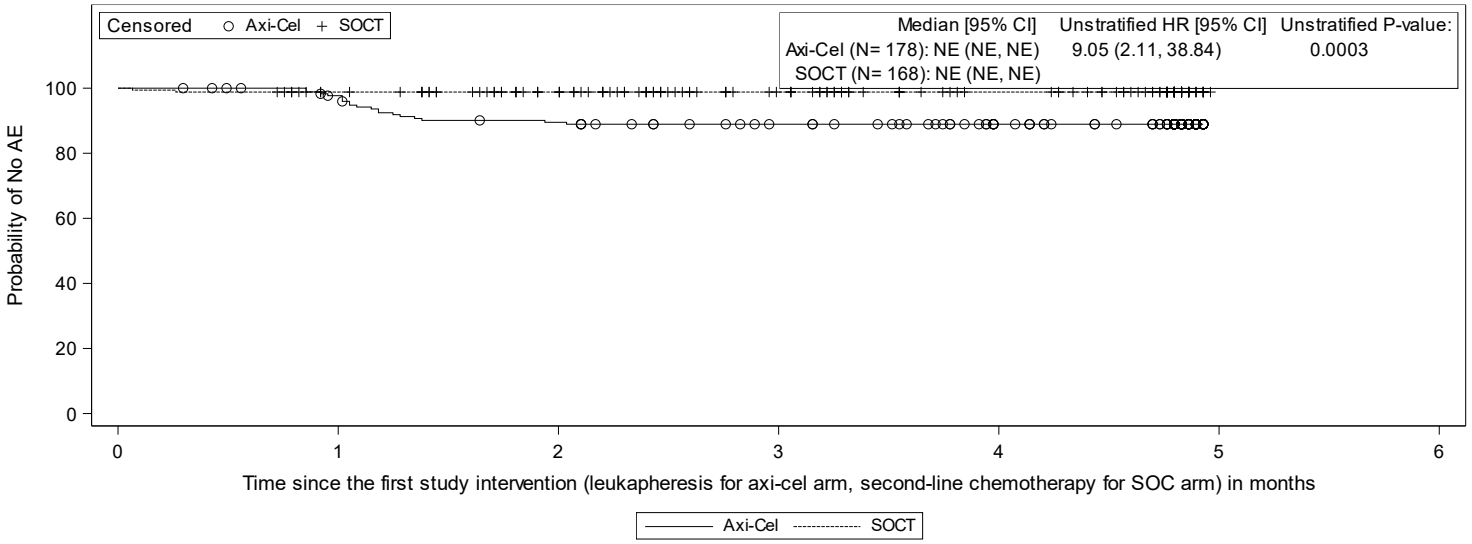
Axi-Cel	178	136	112	100	89	0
SOCT	168	154	130	91	63	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.32. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Somnolence (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	152	139	119	0
SOCT	168	158	135	100	75	0

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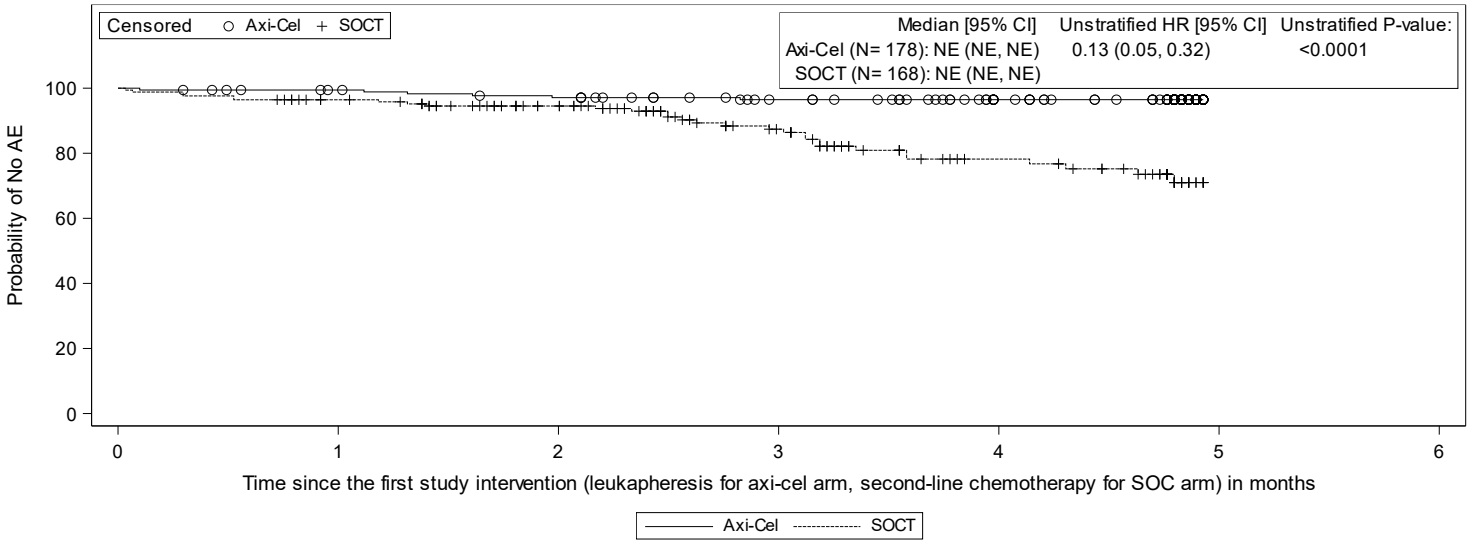
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.33. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Stomatitis (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	171	165	150	128	0
SOCT	168	154	128	87	53	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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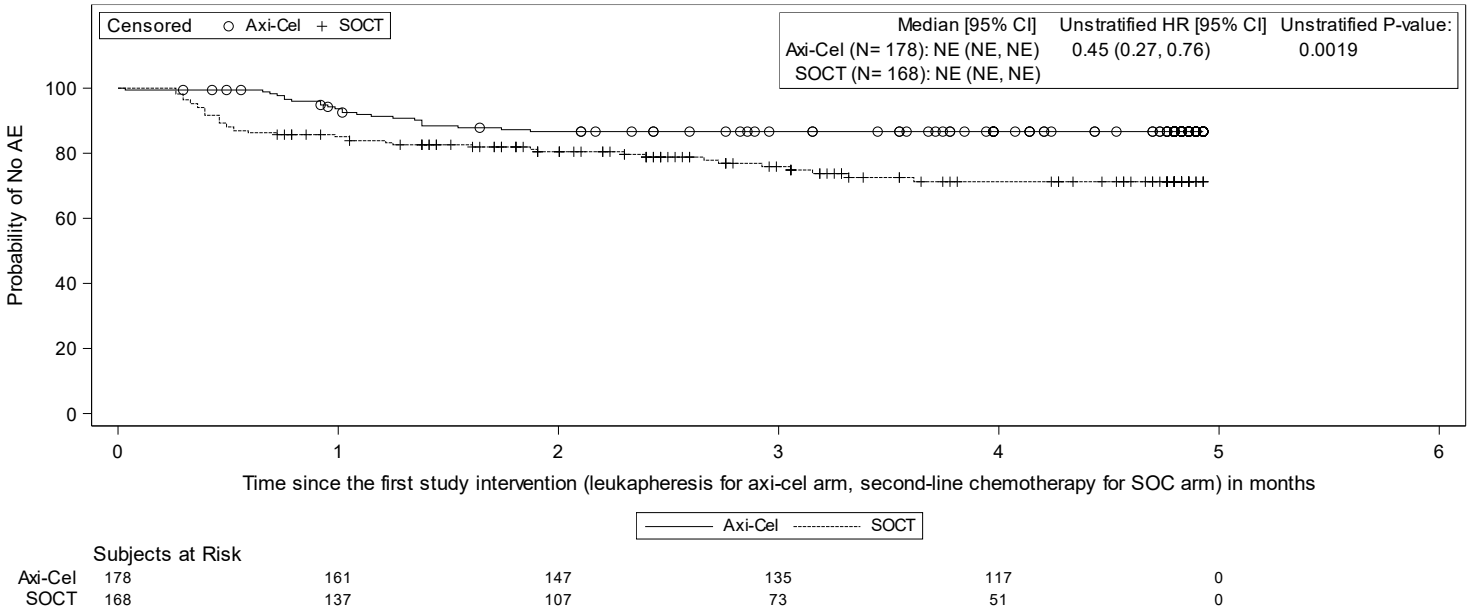
Figure 14.5.1.2.34. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Thrombocytopenia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	161	147	135	117	0
SOCT	168	137	107	73	51	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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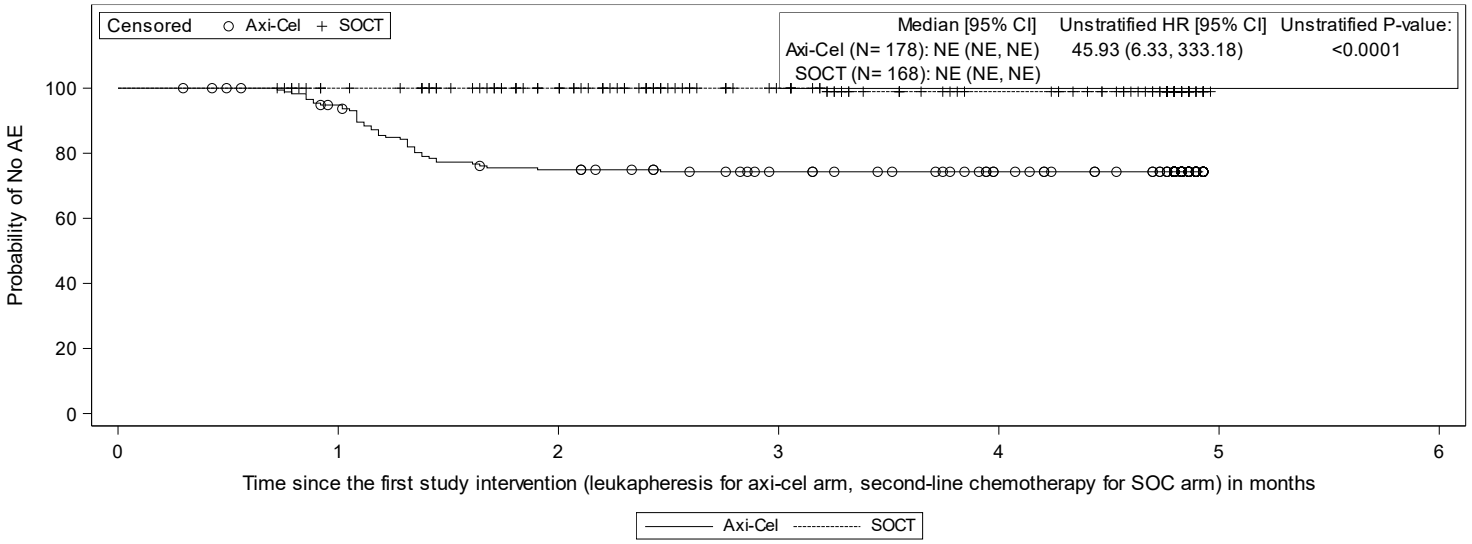
Figure 14.5.1.2.35. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Tremor (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	163	127	114	100	0
SOCT	168	160	136	101	74	0

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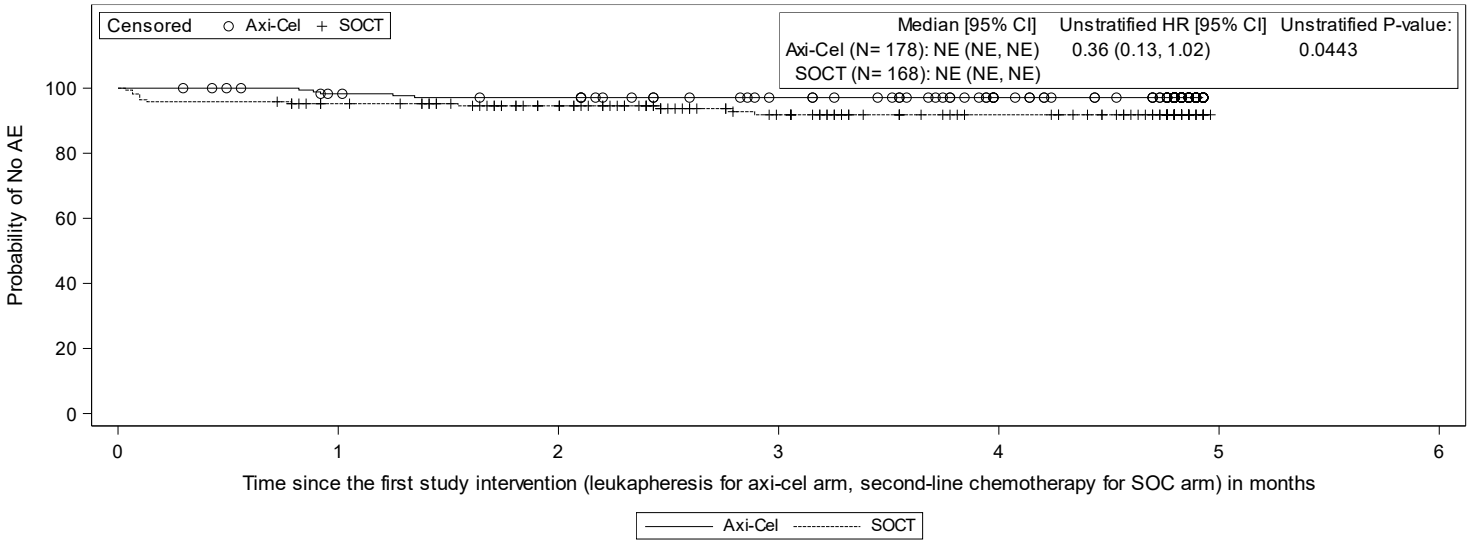
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.1.2.36. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Weight Increased (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	165	152	131	0
SOCT	168	153	130	94	68	0

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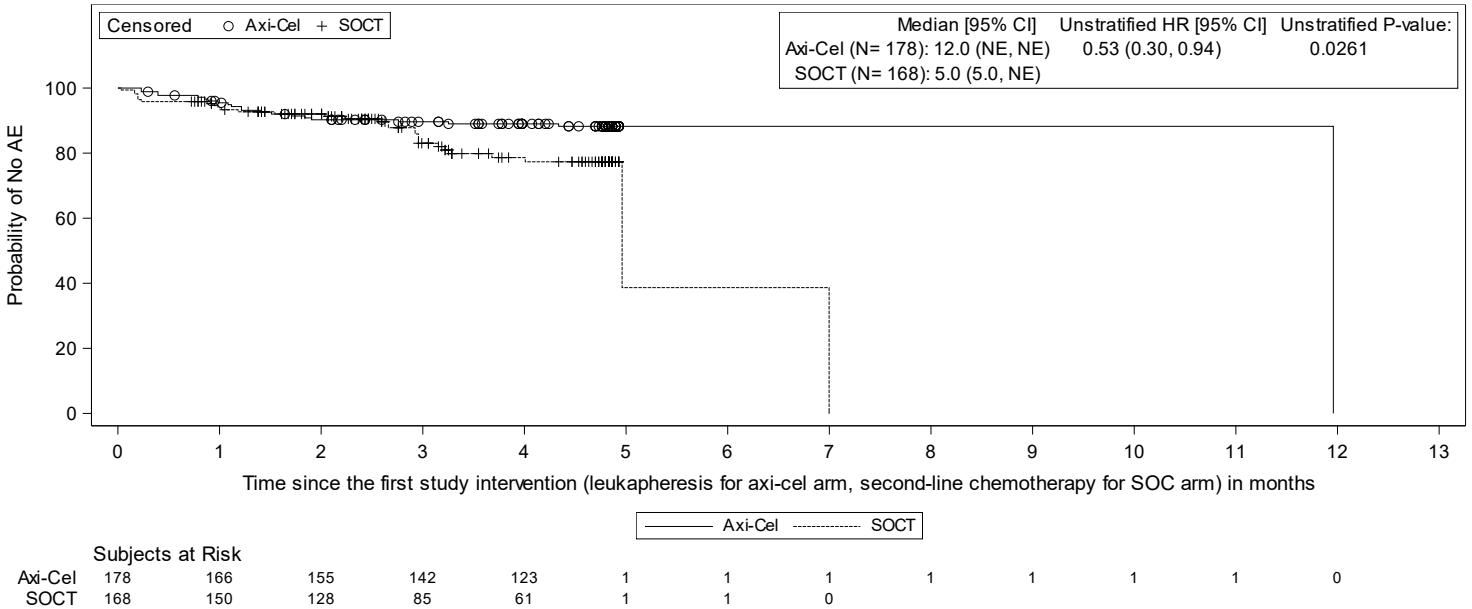
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Abbildung 13 (Anhang): Kaplan-Meier Plots zu häufige schwere UE nach SOC/PT mit statistisch signifikantem Behandlungseffekt - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.3.1.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Gastrointestinal Disorders (Modified Safety Analysis Set)



Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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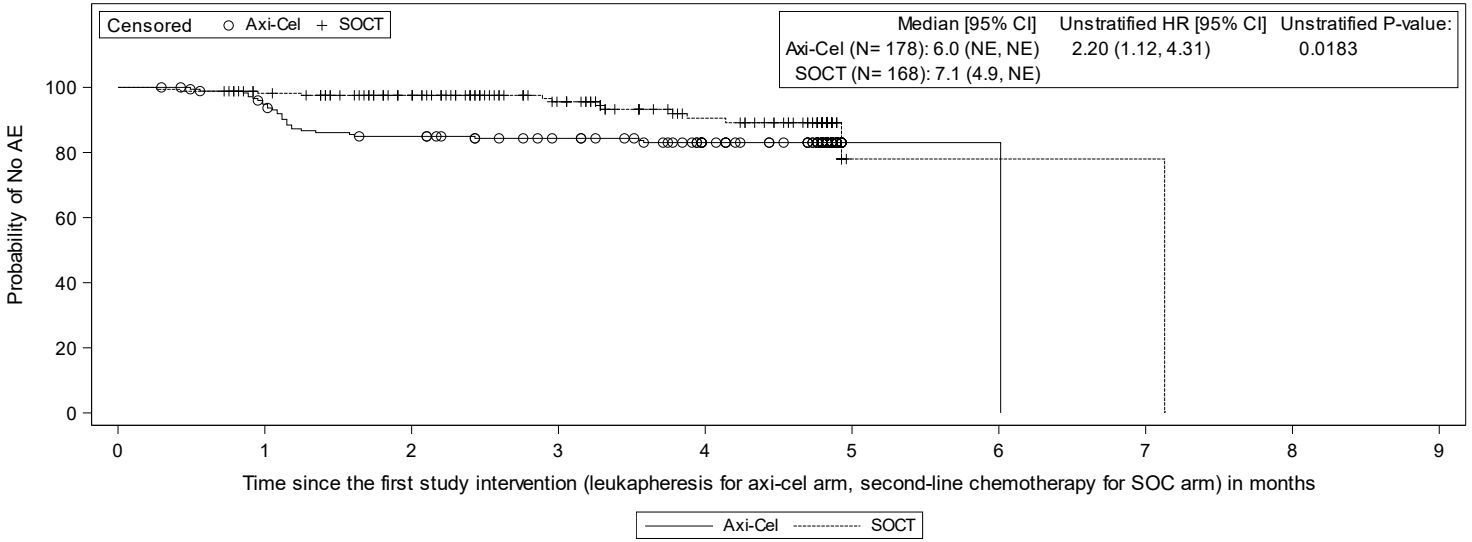
Figure 14.5.3.1.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe General Disorders And Administration Site Conditions (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	164	145	134	114	1	1	0	
SOCT	168	157	132	95	65	1	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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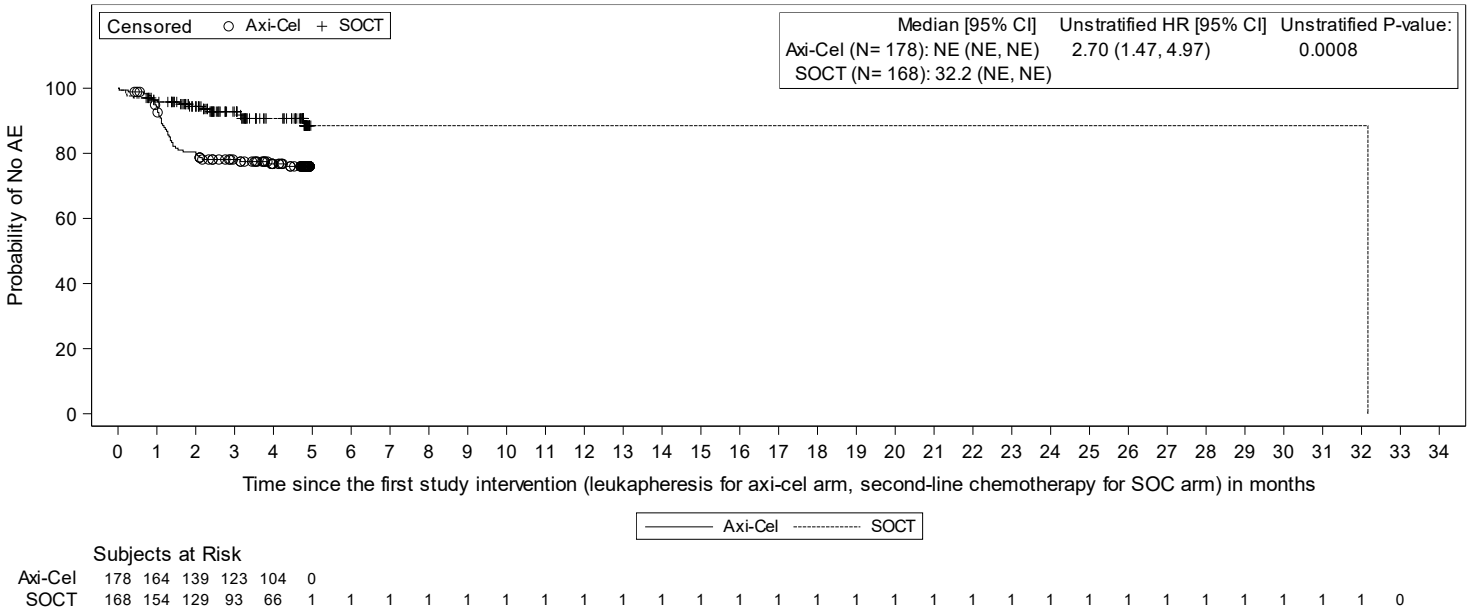
Figure 14.5.3.1.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Nervous System Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	164	139	123	104	0																													
SOCT	168	154	129	93	66	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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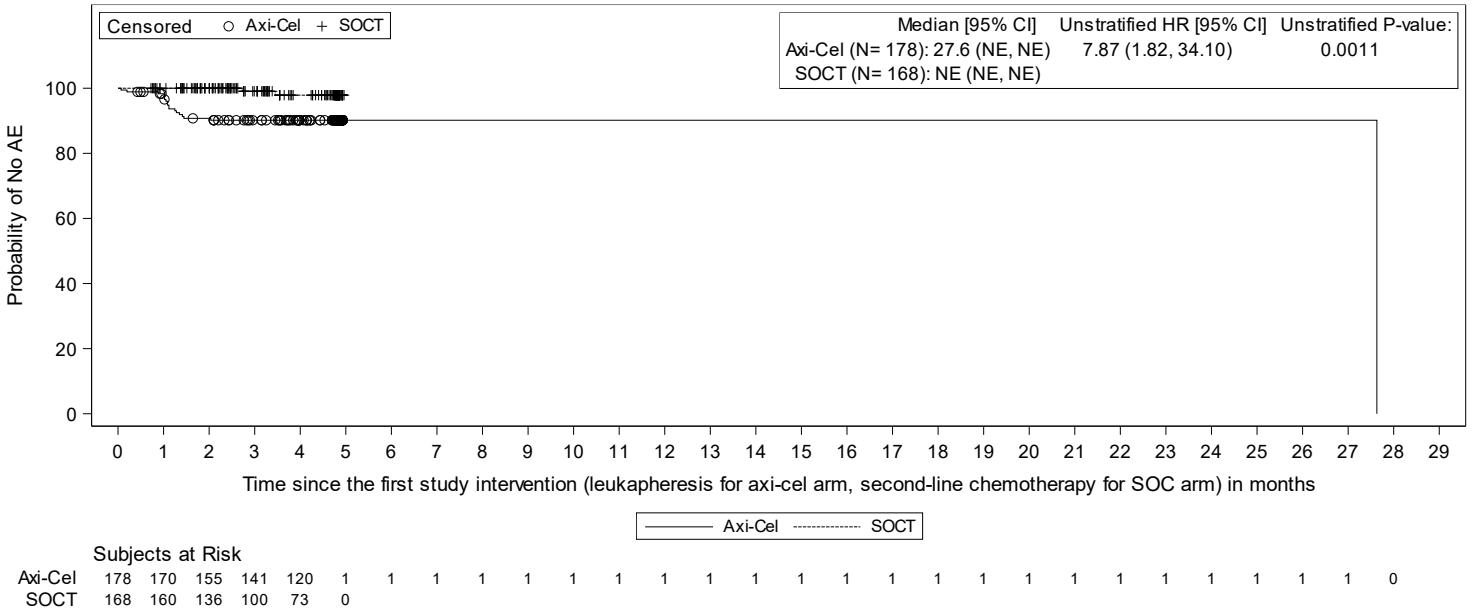
Figure 14.5.3.1.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Psychiatric Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	170	155	141	120	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	168	160	136	100	73	0																						

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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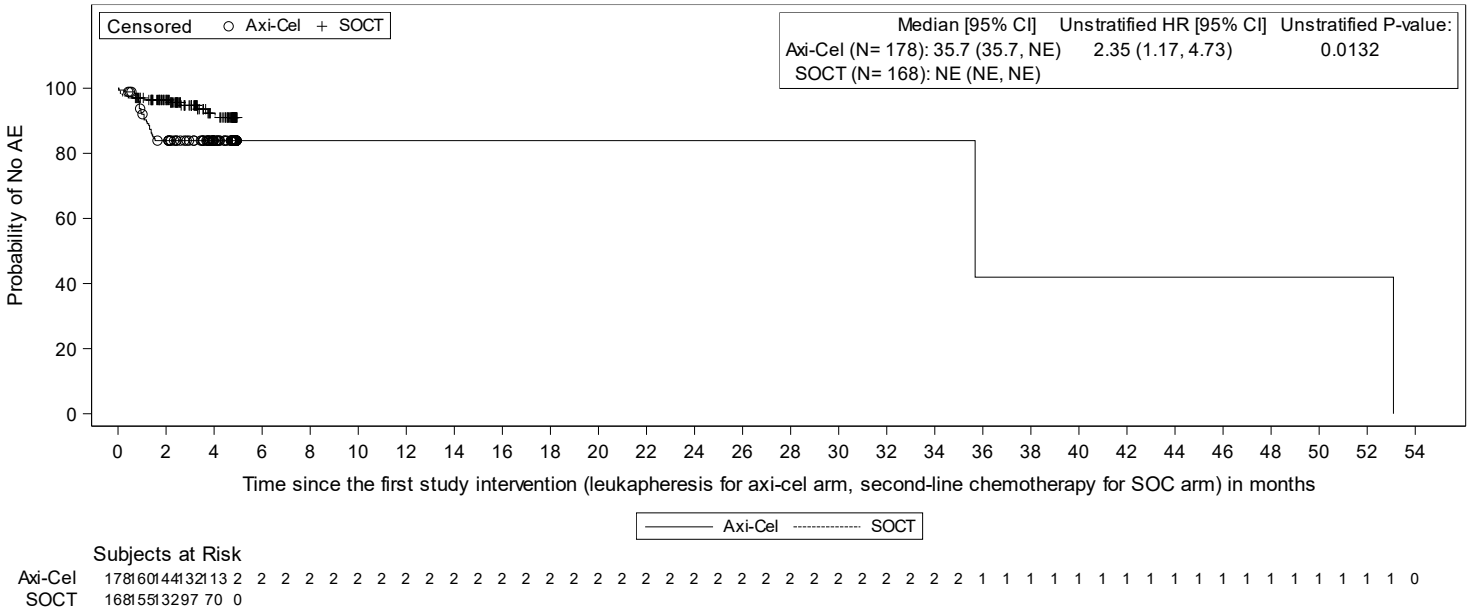
Figure 14.5.3.1.5. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Vascular Disorders (Modified Safety Analysis Set)



Subjects at Risk

| | | |

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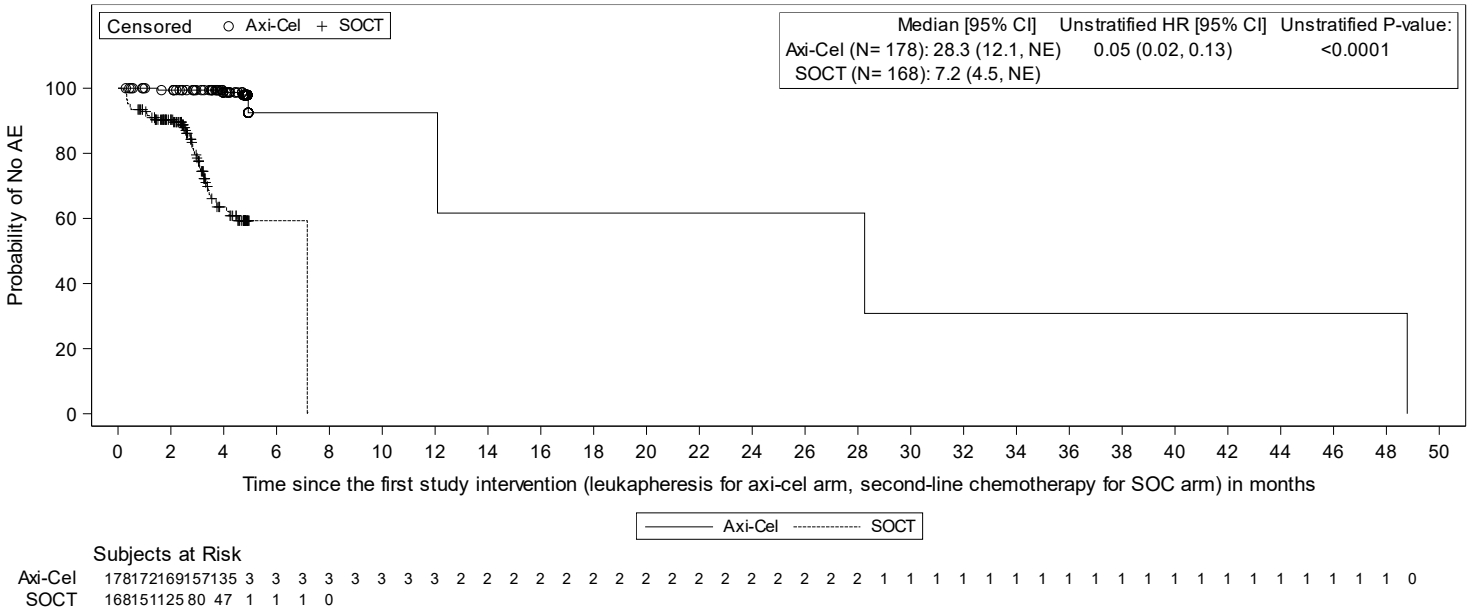
Figure 14.5.3.2.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Febrile Neutropenia (Modified Safety Analysis Set)



Subjects at Risk

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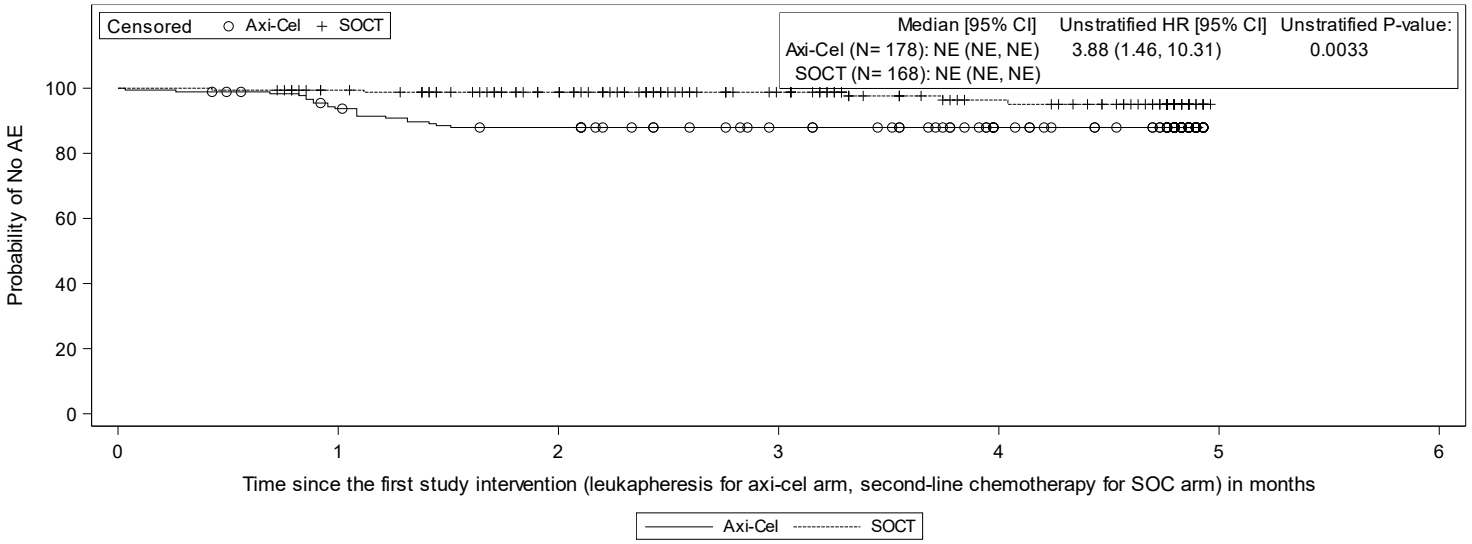
Figure 14.5.3.2.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Hypotension (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	163	151	138	118	0
SOCT	168	159	135	100	73	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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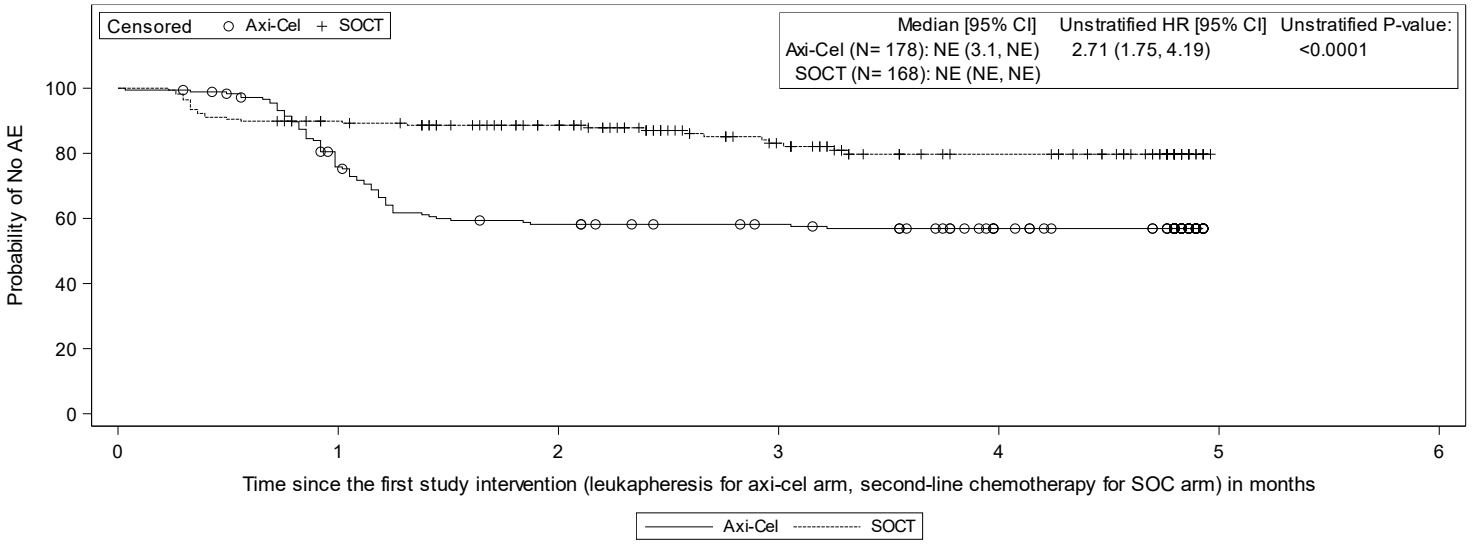
Figure 14.5.3.2.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Neutropenia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	130	98	91	75	0
SOCT	168	144	120	81	57	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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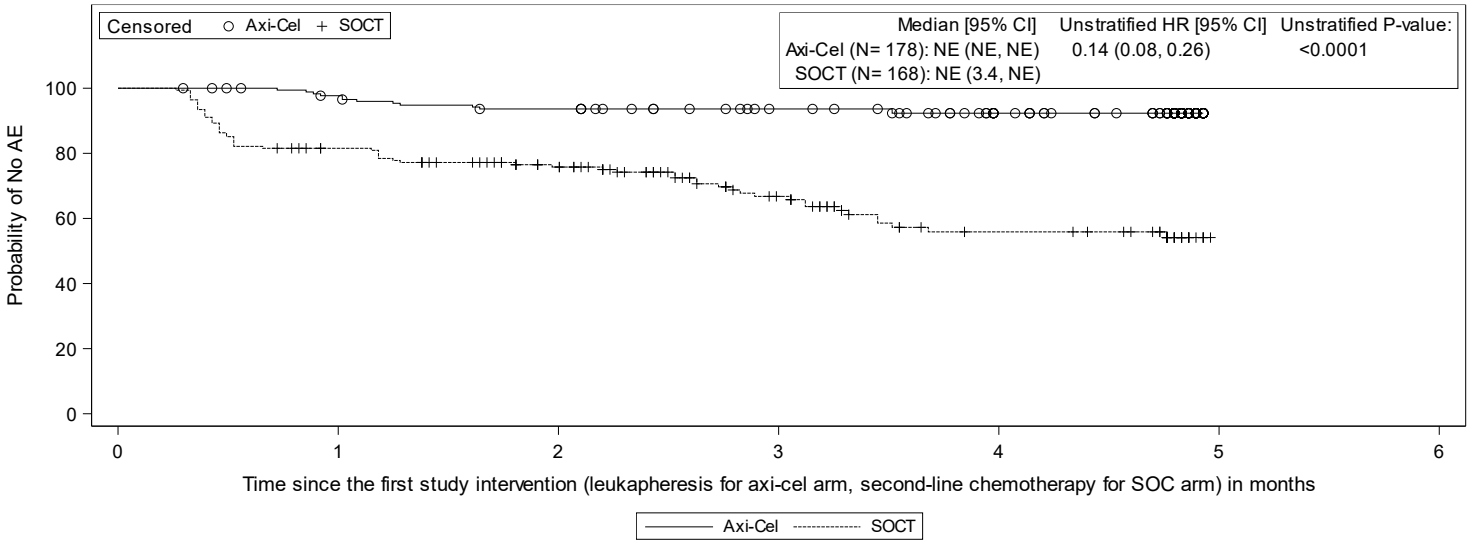
Figure 14.5.3.2.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Platelet Count Decreased (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	160	146	125	0
SOCT	168	131	105	66	39	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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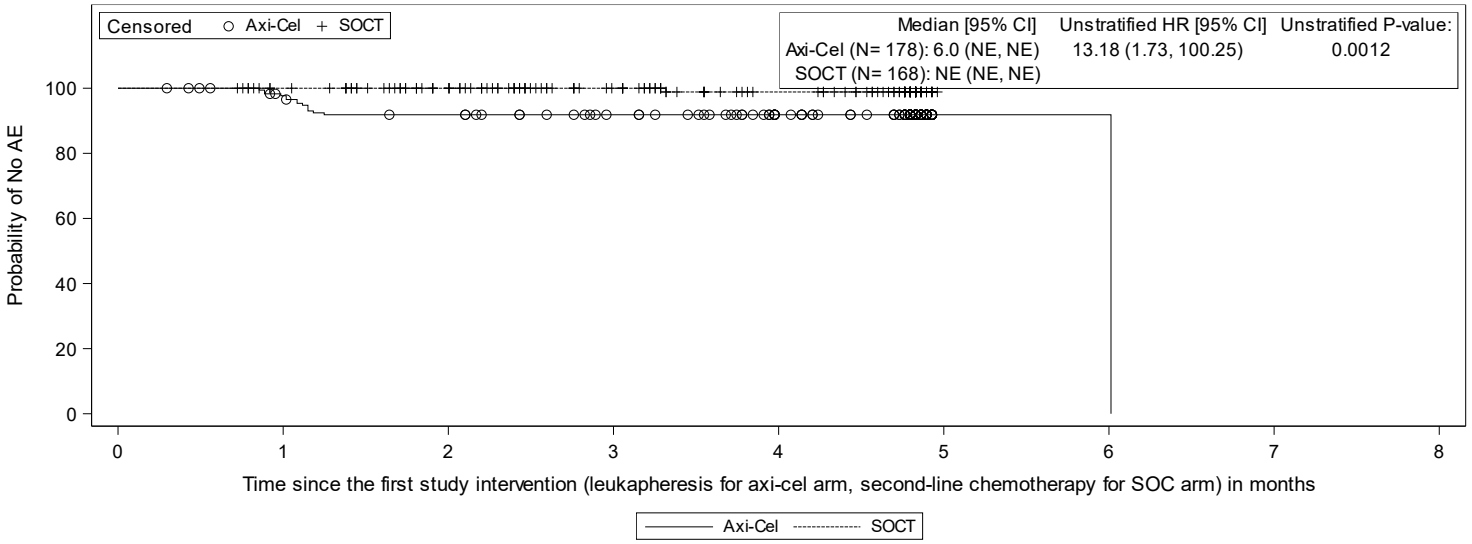
Figure 14.5.3.2.5. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Pyrexia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	168	156	144	123	1	1	0
SOCT	168	160	136	101	74	0		

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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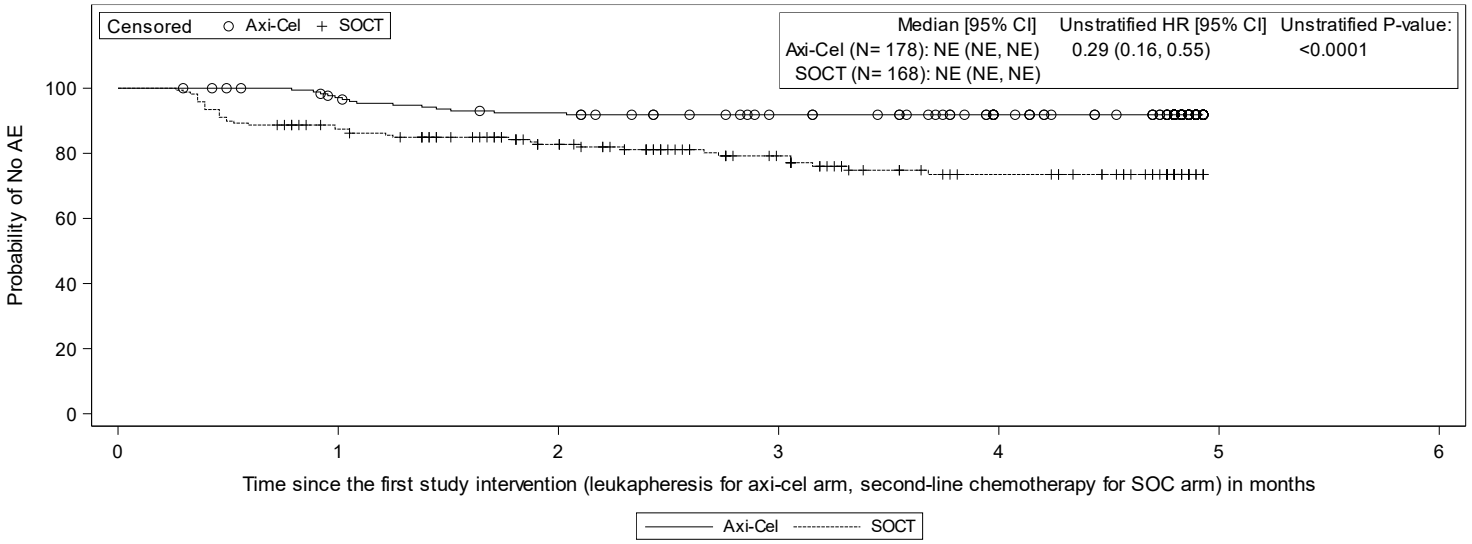
Figure 14.5.3.2.6. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Severe Thrombocytopenia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	167	157	144	125	0
SOCT	168	140	109	76	53	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Abbildung 14 (Anhang): Kaplan-Meier Plots zu häufige SUE nach SOC/PT mit statistisch signifikantem Behandlungseffekt - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

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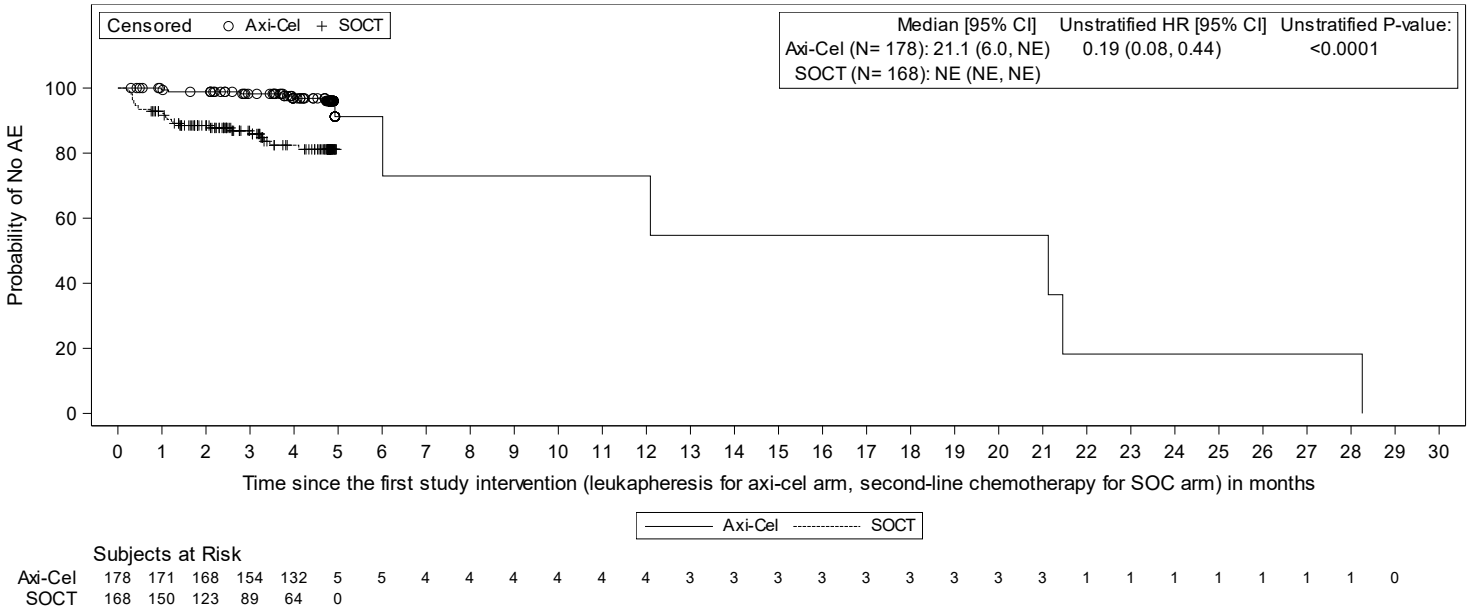
Figure 14.5.2.1.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Blood And Lymphatic System Disorders (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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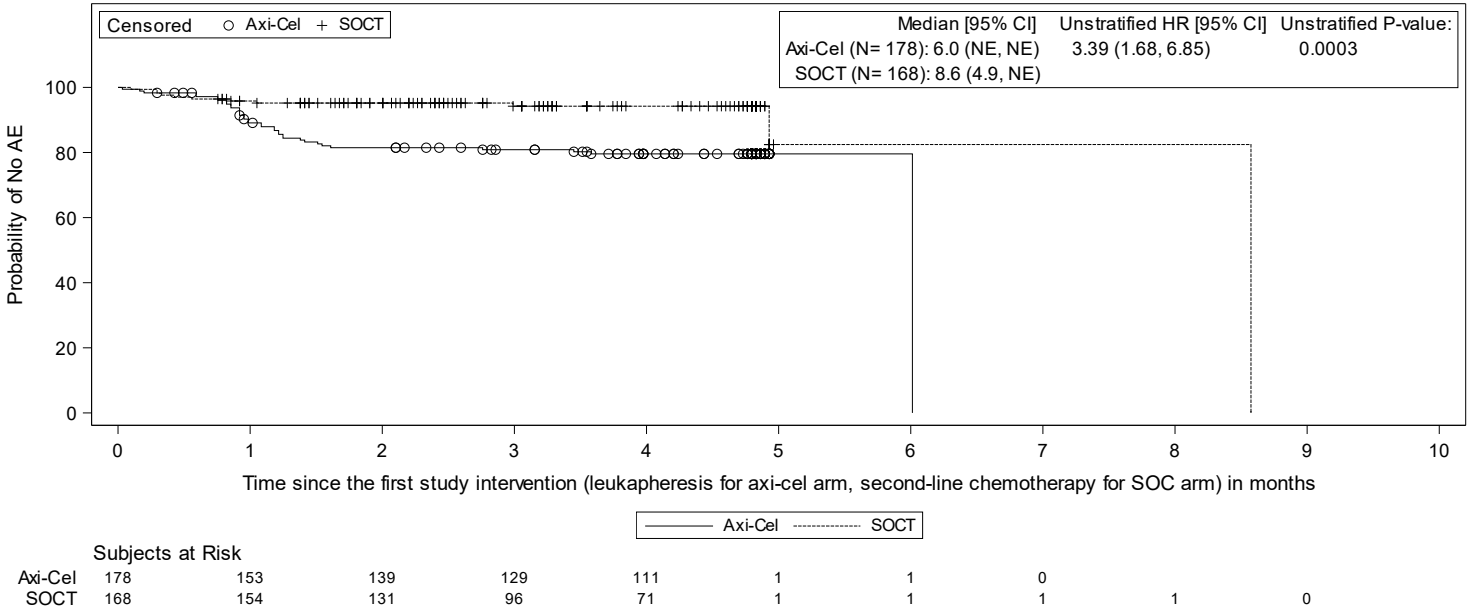
Figure 14.5.2.1.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious General Disorders And Administration Site Conditions (Modified Safety Analysis Set)



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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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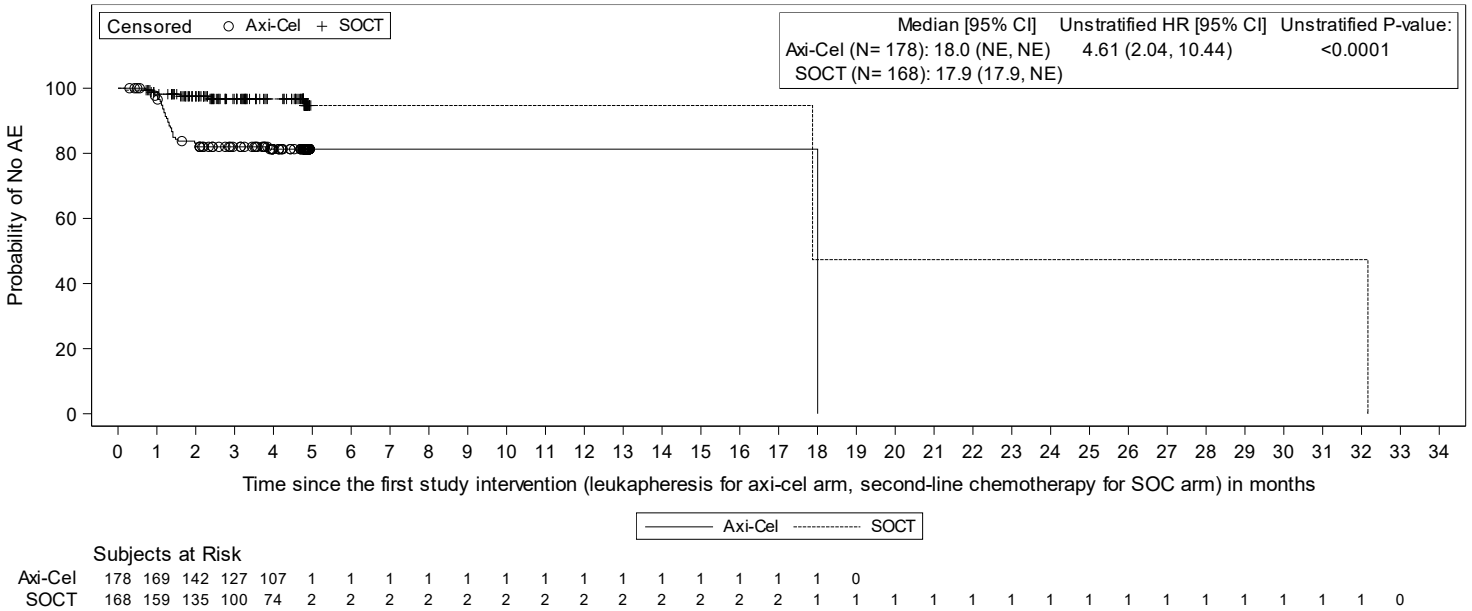
Figure 14.5.2.1.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Nervous System Disorders (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	169	142	127	107	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0															
SOCT	168	159	135	100	74	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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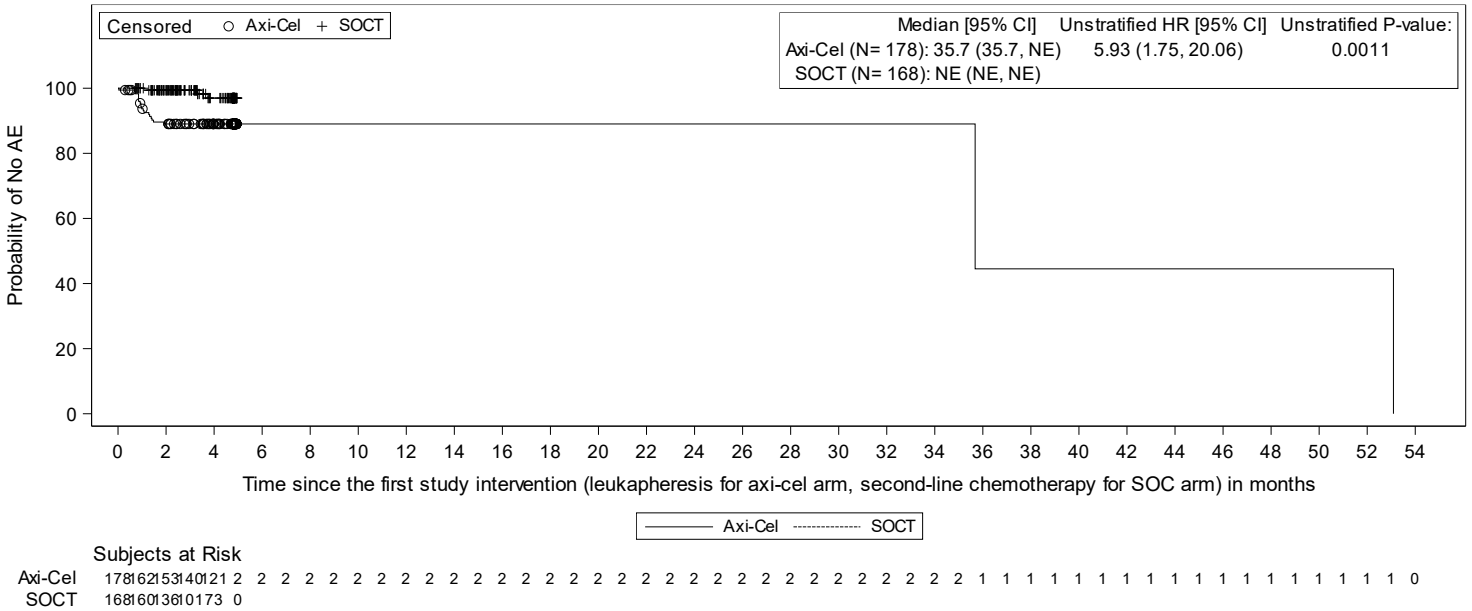
Figure 14.5.2.1.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Vascular Disorders (Modified Safety Analysis Set)



Subjects at Risk

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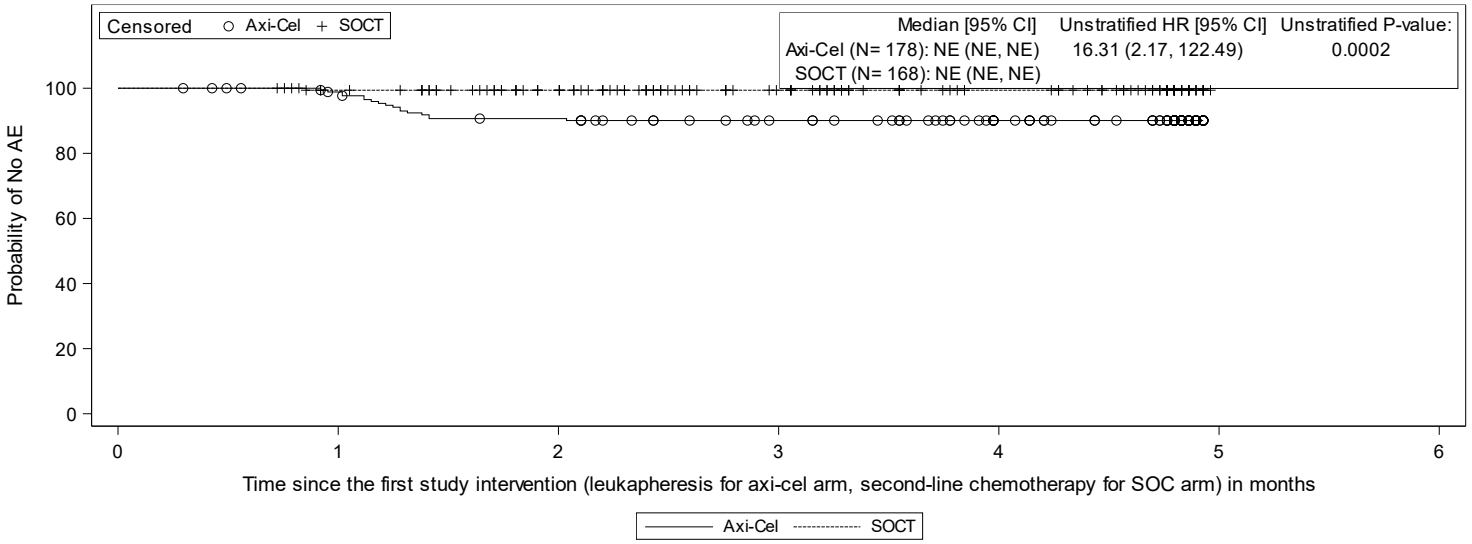
Figure 14.5.2.2.1. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Encephalopathy (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	170	154	140	119	0
SOCT	168	160	136	101	75	0

Page 1 of 8

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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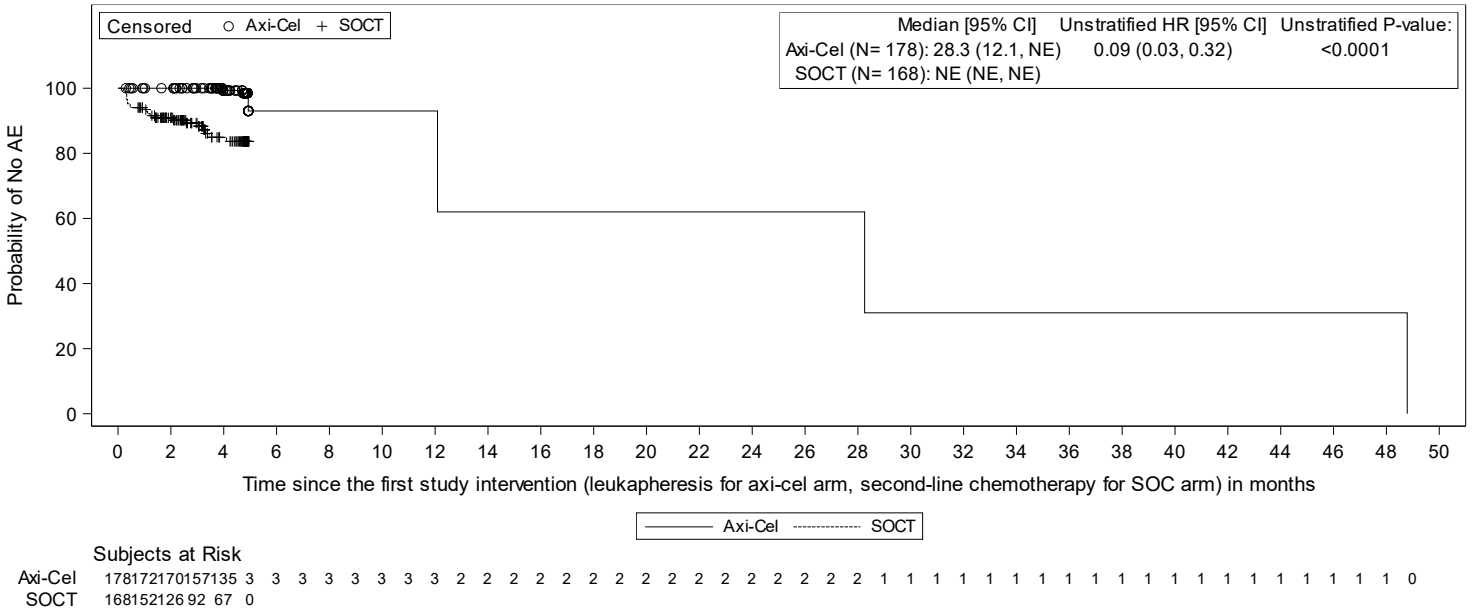
Figure 14.5.2.2.2. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Febrile Neutropenia (Modified Safety Analysis Set)



Subjects at Risk

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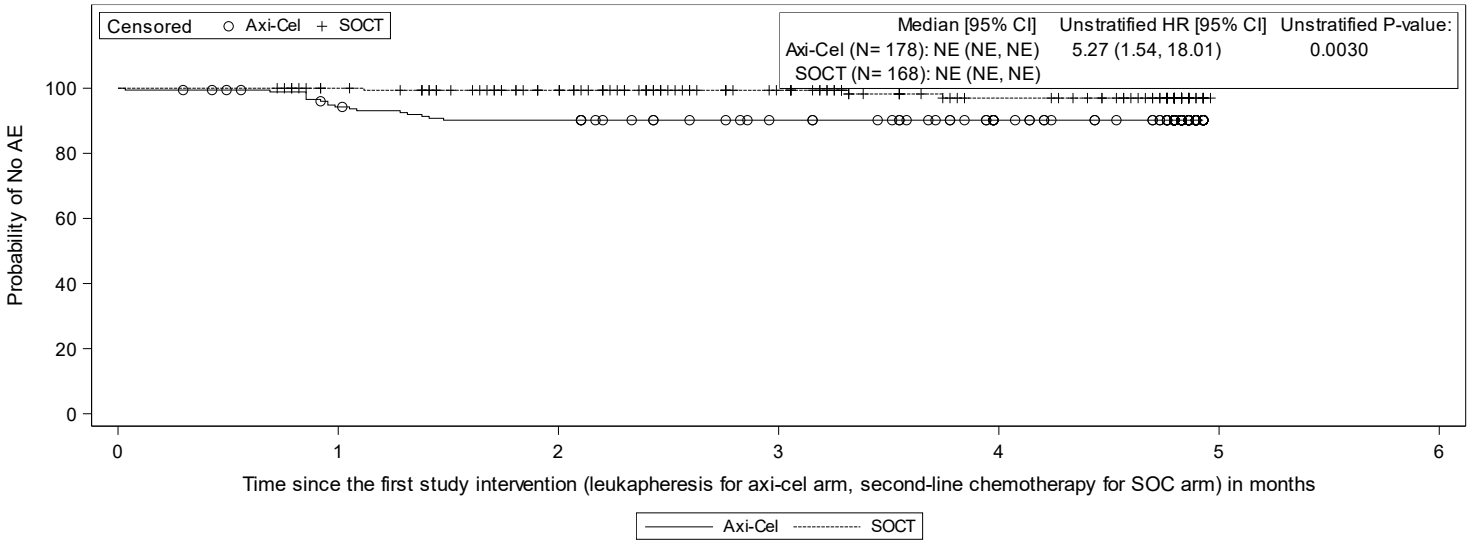
Figure 14.5.2.2.3. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Hypotension (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	163	155	142	123	0
SOCT	168	160	136	101	73	0

Page 1 of 8

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

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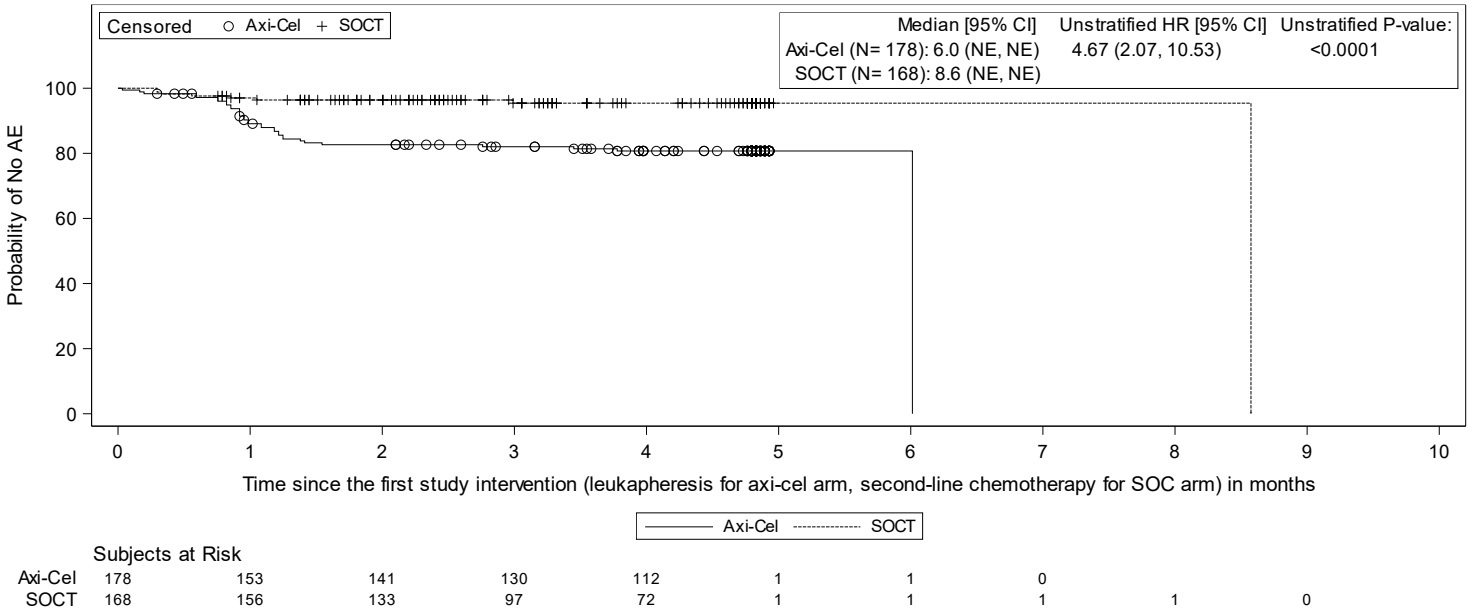
Figure 14.5.2.2.4. Kaplan-Meier Plot Of Time To The First Treatment-Emergent Serious Pyrexia (Modified Safety Analysis Set)



Subjects at Risk

Axi-Cel	178	153	141	130	112	1	1	0		
SOCT	168	156	133	97	72	1	1	1	1	0

Page 1 of 8

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADTTEAE Program Name: f_km_teae.sas Output Generated: 20240405T08:20

Anhang 4-G3: Ergänzende Darstellung der Subgruppenanalyse in der RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G3.1: Ergänzende Subgruppenanalysen zu OS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 23. Januar 2023)

Tabelle 4-23 (Anhang): Ergebnisse der Subgruppenanalyse für OS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

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Table 14.2.5.2.10.1. Overall Survival by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to OS (mons) 95% CIs	Standard of Care n/N (%)	Median time to OS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Age	Age < 65	56/129 (43)	NE (25.3,NE)	64/121 (53)	32.3 (14.5,NE)	0.73 (0.51,1.04)	0.0835	0.7782
	Age ≥ 65	26/51 (51)	43.5 (20.9,NE)	31/58 (53)	19.5 (12.3,NE)	0.79 (0.47,1.33)	0.3795	
Sex	Male	55/110 (50)	48.4 (20.9,NE)	72/127 (57)	20.4 (14.1,52.0)	0.75 (0.53,1.07)	0.1082	0.9327
	Female	27/70 (39)	NE (29.2,NE)	23/52 (44)	NE (10.8,NE)	0.80 (0.46,1.40)	0.4297	
Race	White	67/145 (46)	NE (25.6,NE)	84/152 (55)	20.4 (13.6,NE)	0.71 (0.52,0.98)	0.0388	0.4276
	Other	15/35 (43)	NE (18.6,NE)	11/27 (41)	52.0 (14.7,NE)	1.00 (0.46,2.18)	0.9966	
ECOG performance status	0	44/95 (46)	NE (20.8,NE)	47/100 (47)	52.0 (20.0,NE)	0.94 (0.63,1.43)	0.7859	0.0787
	1	38/85 (45)	NE (28.3,NE)	48/79 (61)	13.6 (9.2,37.0)	0.56 (0.37,0.87)	0.0078	
Geographic Region	North America	64/140 (46)	NE (28.6,NE)	68/130 (52)	35.1 (15.2,NE)	0.77 (0.55,1.09)	0.1417	0.6462
	Rest of the world	18/40 (45)	NE (14.9,NE)	27/49 (55)	25.7 (8.6,NE)	0.66 (0.36,1.20)	0.1715	
Central laboratory double hit/triple hit/double expressor status	HGBL - double hit/triple hit	14/32 (44)	NE (14.0,NE)	14/25 (56)	20.0 (7.3,NE)	0.71 (0.34,1.48)	0.3543	0.8829
	Double expressor lymphoma	26/57 (46)	NE (18.6,NE)	33/62 (53)	32.3 (12.6,NE)	0.73 (0.44,1.23)	0.2379	

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; NA, not applicable; NE, not estimable; OS, overall survival.
Note: OS is defined as the time from the randomization date to the date of death from any cause. Subjects who have not died by the analysis data cutoff date will be censored at their last contact date prior to the data cutoff date with the exception that subjects known to be alive or determined to have died after the data cutoff date will be censored at the data cutoff date.
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: The subjects who were still being alive and had the last known alive data from the public records subsequent to study discontinuation due to reasons such as full consent withdrawn, lost to follow up, investigator decision, or other reason were not categorized in these four categories. Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTE Program Name: t_os_hr_sg.sas Output Generated: 20240602T11:07

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Table 14.2.5.2.10.1. Overall Survival by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to OS (mons) 95% CIs	Standard of Care n/N (%)	Median time to OS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Double hit/triple hit/double expressor status (per investigator)	HGBL - double hit/triple hit	16/40 (40)	NE (14.8,NE)	17/34 (50)	38.7 (7.3,NE)	0.70 (0.36,1.39)	0.3096	0.9811
	Double expressor lymphoma	23/44 (52)	41.7 (13.7,NE)	23/35 (66)	18.5 (8.9,52.0)	0.67 (0.37,1.19)	0.1672	
Central lab molecular subgroup	Germinal center B-cell like	45/108 (42)	NE (29.1,NE)	51/102 (50)	38.7 (18.8,NE)	0.75 (0.50,1.12)	0.1621	0.4648
	Activated B-cell like	10/16 (63)	19.7 (10.2,NE)	6/9 (67)	10.4 (3.8,NE)	0.75 (0.27,2.09)	0.5837	
	Unclassified	7/18 (39)	NE (14.4,NE)	10/13 (77)	19.8 (4.4,37.0)	0.39 (0.15,1.04)	0.0513	
Molecular subgroup (per investigator)	Germinal center B-cell like	45/96 (47)	NE (20.9,NE)	43/84 (51)	38.4 (14.5,NE)	0.85 (0.56,1.29)	0.4457	0.1680
	Non-germinal center B-cell like	19/47 (40)	NE (25.3,NE)	32/54 (59)	19.8 (10.4,37.0)	0.50 (0.28,0.88)	0.0139	
Central laboratory disease type	Diffuse large B-cell lymphoma	60/126 (48)	NE (23.8,NE)	65/120 (54)	32.3 (14.7,NE)	0.79 (0.55,1.12)	0.1779	0.8372
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/32 (44)	NE (14.0,NE)	14/26 (54)	20.0 (7.3,NE)	0.74 (0.35,1.55)	0.4183	
Disease type (per investigator)	Diffuse large B-cell lymphoma not otherwise specified	51/110 (46)	NE (23.9,NE)	62/116 (53)	31.1 (14.1,NE)	0.74 (0.51,1.07)	0.1049	0.9900
	Large cell transformation from follicular lymphoma	9/19 (47)	NE (12.5,NE)	15/27 (56)	20.0 (7.3,NE)	0.72 (0.32,1.66)	0.4442	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	18/43 (42)	NE (14.8,NE)	13/27 (48)	NE (7.0,NE)	0.80 (0.39,1.64)	0.5497	

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; NA, not applicable; NE, not estimable; OS, overall survival.
Note: OS is defined as the time from the randomization date to the date of death from any cause. Subjects who have not died by the analysis data cutoff date will be censored at their last contact date prior to the data cutoff date with the exception that subjects known to be alive or determined to have died after the data cutoff date will be censored at the data cutoff date.
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: The subjects who were still being alive and had the last known alive data from the public records subsequent to study discontinuation due to reasons such as full consent withdrawn, lost to follow up, investigator decision, or other reason were not categorized in these four categories. Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTE Program Name: t_os_hr_sg.sas Output Generated: 20240602T11:07

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.2.5.2.10.1. Overall Survival by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to OS (mons) 95% CIs	Standard of Care n/N (%)	Median time to OS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Disease type (per investigator)	Other	4/8 (50)	NE (NE, NE)	5/9 (56)	NE (NE, NE)	NE (NE,NE)	NE	
Derived second-line age-adjusted IPI score	0 - 1	36/94 (38)	NE (NE,NE)	39/100 (39)	NE (38.7,NE)	0.91 (0.58,1.44)	0.7002	0.1063
	2 - 3	46/86 (53)	25.3 (13.7,NE)	56/79 (71)	10.8 (7.7,17.6)	0.57 (0.39,0.85)	0.0045	
Second-line age-adjusted IPI score per IXRS	0 - 1	37/98 (38)	NE (NE,NE)	40/100 (40)	NE (38.4,NE)	0.85 (0.54,1.32)	0.4620	0.3165
	2 - 3	45/82 (55)	23.9 (12.8,NE)	55/79 (70)	11.1 (8.3,19.4)	0.64 (0.43,0.95)	0.0248	
Derived refractory/relapse subgroup	Primary refractory	67/133 (50)	43.5 (18.6,NE)	73/132 (55)	19.8 (11.1,NE)	0.80 (0.57,1.11)	0.1791	0.3760
	Relapse ≤ 12 months of the completion of the first line therapy	15/46 (33)	NE (NE,NE)	22/46 (48)	52.0 (17.6,NE)	0.57 (0.29,1.10)	0.0873	
Response to first-line therapy per IXRS	Primary refractory	66/133 (50)	48.4 (20.8,NE)	72/131 (55)	19.8 (11.2,NE)	0.79 (0.57,1.10)	0.1655	0.4523
	Relapse ≤ 12 months of first line therapy	16/47 (34)	NE (NE,NE)	23/48 (48)	52.0 (17.6,NE)	0.59 (0.31,1.12)	0.1036	

Data cutoff date = 25JAN2023
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; NA, not applicable; NE, not estimable; OS, overall survival.
Note: OS is defined as the time from the randomization date to the date of death from any cause. Subjects who have not died by the analysis data cutoff date will be censored at their last contact date prior to the data cutoff date with the exception that subjects known to be alive or determined to have died after the data cutoff date will be censored at the data cutoff date.
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: The subjects who were still being alive and had the last known alive data from the public records subsequent to study discontinuation due to reasons such as full consent withdrawn, lost to follow up, investigator decision, or other reason were not categorized in these four categories. Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTE Program Name: t_os_hr_sg.sas Output Generated: 20240602T11:07

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Anhang 4-G3.2: Ergänzende Subgruppenanalysen zu EFS (post-hoc mEFS 1) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-24 (Anhang): Ergebnisse der Subgruppenanalyse für post-hoc mEFS 1 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.2.1.1.11.1. Event-free Survival Per Central Assessment (post-hoc mEFS 1) by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to EFS (mons) 95% CIs	Standard of Care n/N (%)	Median time to EFS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Age	Age < 65	80/129 (62)	5.4 (3.9,14.3)	89/121 (74)	1.8 (1.6,2.9)	0.47 (0.34,0.63)	<0.0001	0.4626
	Age ≥ 65	28/51 (55)	15.8 (5.0,NE)	44/58 (76)	2.6 (1.7,4.1)	0.36 (0.22,0.59)	<0.0001	
Sex	Male	73/110 (66)	5.3 (4.3,10.5)	95/127 (75)	2.0 (1.6,2.7)	0.44 (0.33,0.60)	<0.0001	0.9469
	Female	35/70 (50)	21.5 (4.9,NE)	38/52 (73)	3.9 (1.7,6.5)	0.43 (0.27,0.68)	0.0002	
Race	White	87/145 (60)	5.5 (4.9,14.9)	118/152 (78)	2.1 (1.7,2.8)	0.43 (0.32,0.57)	<0.0001	0.6383
	Other	21/35 (60)	14.3 (3.5,NE)	15/27 (56)	2.5 (1.5,NE)	0.57 (0.29,1.11)	0.0920	
ECOG performance status	0	59/95 (62)	5.4 (3.8,14.9)	71/100 (71)	3.2 (2.1,5.0)	0.56 (0.40,0.79)	0.0008	0.0186
	1	49/85 (58)	11.0 (4.7,30.2)	62/79 (78)	1.7 (1.6,2.0)	0.32 (0.21,0.46)	<0.0001	
Geographic Region	North America	86/140 (61)	5.4 (4.5,15.8)	95/130 (73)	2.0 (1.6,3.2)	0.46 (0.35,0.62)	<0.0001	0.4953
	Rest of the world	22/40 (55)	10.5 (3.7,NE)	38/49 (78)	2.2 (1.6,3.4)	0.37 (0.22,0.63)	0.0001	
Central laboratory double hit/triple hit/double expressor status	HGBL - double hit/triple hit	15/31 (48)	21.5 (3.7,NE)	21/25 (84)	1.7 (1.5,5.1)	0.34 (0.18,0.67)	0.0010	0.2375
	Double expressor lymphoma	35/57 (61)	6.3 (3.9,28.6)	47/62 (76)	2.7 (1.7,6.0)	0.52 (0.33,0.81)	0.0029	

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; CR, complete response.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), failure to achieve a CR or PR by Day 50 (for SOC arm only), Failure to achieve CR at Day 150 by central assessment (or if applicable, up to and including month 9) for both arms, NALT due to efficacy concern (SD/PD per investigator) or death from any cause. The cases of disease progression per central are counted under "disease progression".
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSL, ADTTEGBA Program Name: t_efs_sg.sas Output Generated: 20240603T08:55

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Table 14.2.1.1.11.1. Event-free Survival Per Central Assessment (post-hoc mEFS 1) by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to EFS (mons) 95% CIs	Standard of Care n/N (%)	Median time to EFS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Double hit/triple hit/double expressor status (per investigator)	HGBL - double hit/triple hit	21/40 (53)	21.5 (4.0,NE)	25/34 (74)	1.9 (1.5,5.5)	0.41 (0.23,0.74)	0.0021	0.8536
	Double expressor lymphoma	29/44 (66)	4.5 (3.5,14.3)	28/35 (80)	2.0 (1.6,2.9)	0.42 (0.25,0.72)	0.0009	
Central lab molecular subgroup	Germinal center B-cell like	64/108 (59)	9.8 (4.6,21.5)	79/102 (77)	2.3 (1.7,3.1)	0.43 (0.31,0.61)	<0.0001	0.1050
	Activated B-cell like	10/16 (63)	7.2 (2.2,NE)	7/9 (78)	1.6 (0.7,NE)	0.31 (0.10,0.91)	0.0244	
	Unclassified	8/18 (44)	28.6 (5.4,NE)	10/13 (77)	1.5 (0.9,3.2)	0.19 (0.07,0.51)	0.0002	
Molecular subgroup (per investigator)	Germinal center B-cell like	59/96 (61)	5.3 (3.9,17.8)	62/84 (74)	2.3 (1.6,4.1)	0.49 (0.34,0.70)	<0.0001	0.1795
	Non-germinal center B-cell like	26/47 (55)	9.8 (4.6,NE)	42/54 (78)	1.8 (1.6,2.9)	0.32 (0.19,0.53)	<0.0001	
Central laboratory disease type	Diffuse large B-cell lymphoma	79/126 (63)	5.4 (4.3,14.3)	90/120 (75)	2.1 (1.7,3.1)	0.49 (0.36,0.67)	<0.0001	0.2498
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	15/31 (48)	21.5 (3.7,NE)	21/26 (81)	1.7 (1.5,5.1)	0.34 (0.18,0.67)	0.0010	
Disease type (per investigator)	Diffuse large B-cell lymphoma not otherwise specified	66/110 (60)	5.5 (4.6,15.5)	86/116 (74)	1.8 (1.6,2.8)	0.40 (0.29,0.56)	<0.0001	0.0445
	Large cell transformation from follicular lymphoma	11/19 (58)	17.8 (3.6,NE)	24/27 (89)	2.7 (1.7,8.2)	0.39 (0.19,0.81)	0.0081	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	23/43 (53)	21.5 (3.9,NE)	18/27 (67)	1.7 (1.5,4.5)	0.45 (0.24,0.84)	0.0094	

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; CR, complete response.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), failure to achieve a CR or PR by Day 50 (for SOC arm only), Failure to achieve CR at Day 150 by central assessment (or if applicable, up to and including month 9) for both arms, NALT due to efficacy concern (SD/PD per investigator) or death from any cause. The cases of disease progression per central are counted under “disease progression”.
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSL, ADTTEGBA Program Name: t_efs_sg.sas Output Generated: 20240603T08:55

Table 14.2.1.1.11.1. Event-free Survival Per Central Assessment (post-hoc mEFS 1) by Subgroup (Full Analysis Set)

Subgroup	Level	Axicabtagene Ciloleucel n/N (%)	Median time to EFS (mons) 95% CIs	Standard of Care n/N (%)	Median time to EFS (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Disease type (per investigator)	Other	8/8 (100)	3.6 (2.3,4.6)	5/9 (56)	7.0 (0.5,NE)	3.37 (0.84,13.46)	0.0711	
Derived second-line age-adjusted IPI score	0 - 1	52/94 (55)	14.3 (5.3,NE)	62/100 (62)	2.8 (1.7,3.7)	0.49 (0.34,0.71)	0.0001	0.3509
	2 - 3	56/86 (65)	5.0 (3.9,10.2)	71/79 (90)	1.8 (1.6,2.7)	0.38 (0.27,0.55)	<0.0001	
Second-line age-adjusted IPI score per IXRS	0 - 1	53/98 (54)	14.9 (5.5,NE)	64/100 (64)	2.8 (1.7,3.7)	0.45 (0.31,0.64)	<0.0001	0.8088
	2 - 3	55/82 (67)	4.5 (3.7,9.8)	69/79 (87)	1.8 (1.6,2.7)	0.43 (0.30,0.61)	<0.0001	
Derived refractory/relapse subgroup	Primary refractory	86/133 (65)	5.0 (3.8,7.2)	101/132 (77)	1.7 (1.6,2.3)	0.44 (0.33,0.59)	<0.0001	0.8783
	Relapse ≤ 12 months of the completion of the first line therapy	22/46 (48)	NE (12.3,NE)	32/46 (70)	5.0 (2.8,8.6)	0.36 (0.21,0.62)	0.0001	
Response to first-line therapy per IXRS	Primary refractory	84/133 (63)	5.1 (3.9,8.0)	100/131 (76)	1.7 (1.6,2.3)	0.43 (0.32,0.57)	<0.0001	0.7685
	Relapse ≤ 12 months of first line therapy	24/47 (51)	21.5 (12.3,NE)	33/48 (69)	5.0 (2.8,8.6)	0.40 (0.24,0.68)	0.0005	

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; CR, complete response.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), failure to achieve a CR or PR by Day 50 (for SOC arm only), Failure to achieve CR at Day 150 by central assessment (or if applicable, up to and including month 9) for both arms, NALT due to efficacy concern (SD/PD per investigator) or death from any cause. The cases of disease progression per central are counted under “disease progression”.
Note: Log-rank test was used to calculate unstratified P-value (2-sided); Cox model with covariates treatment, subgroup, subgroup*treatment interaction was used to calculate P-value for interaction (2-sided).
Note: Percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSL, ADTTEGBA Program Name: t_efs_sg.sas Output Generated: 20240603T08:55

Anhang 4-G3.3: Ergänzende Subgruppenanalysen zu Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-25 (Anhang): Ergebnisse der Subgruppenanalyse für Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Version: 1.0 (15July2022)

Table 2 EQ-5D-5L VAS Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	18/119	8/89	1.43 (0.62, 3.28)	0.5840
	Relapse <= 12 Months of First Line therapy	9/46	4/42	2.19 (0.69, 6.93)	
Age	<65 Years	21/119	10/89	1.47 (0.70, 3.09)	0.6079
	≥65 Years	6/46	2/42	2.41 (0.47, 12.30)	
Second line age adjusted IPI score per IXRS	0 - 1	17/96	9/75	1.28 (0.57, 2.88)	0.3381
	2 - 3	10/69	3/56	2.65 (0.74, 9.44)	
Sex	Male	19/101	9/95	1.87 (0.86, 4.09)	0.6313
	Female	8/64	3/36	1.40 (0.37, 5.27)	
Geographic region	North America	23/128	9/94	1.74 (0.81, 3.73)	0.4971
	Europe	3/31	3/34	0.91 (0.18, 4.47)	
ECOG - performance status	0	17/89	8/81	1.83 (0.80, 4.19)	0.7255
	1	10/76	4/50	1.46 (0.46, 4.67)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	10/94	1.15 (0.52, 2.54)	0.6478
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/28	2/17	1.78 (0.38, 8.34)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy; VAS, visual analog scale.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Anhang 4-G3.4: Ergänzende Subgruppenanalysen zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-26 (Anhang): Ergebnisse der Subgruppenanalyse für Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Version: 1.0 (15July2022)

Table 1.7 EORTC QLQ-C30 Fatigue Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	26/119	13/89	1.37 (0.71, 2.67)	0.2488
	Relapse <= 12 Months of First Line therapy	14/46	5/42	2.73 (1.00, 7.44)	
Age	<65 Years	31/119	14/89	1.60 (0.85, 3.02)	0.7864
	≥65 Years	9/46	4/42	2.01 (0.62, 6.47)	
Second line age adjusted IPI score per IXRS	0 - 1	25/96	13/75	1.41 (0.73, 2.75)	0.3861
	2 - 3	15/69	5/56	2.43 (0.87, 6.73)	
Sex	Male	25/101	15/95	1.55 (0.82, 2.93)	0.4255
	Female	15/64	3/36	2.55 (0.75, 8.68)	
Geographic region	North America	34/128	15/94	1.60 (0.87, 2.93)	0.7101
	Europe	6/31	3/34	2.04 (0.52, 7.95)	
ECOG - performance status	0	20/89	10/81	1.76 (0.83, 3.75)	0.8121
	1	20/76	8/50	1.57 (0.70, 3.55)	
Central laboratory disease type	Diffuse large B-cell lymphoma	25/117	14/94	1.35 (0.70, 2.58)	0.2328
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/28	2/17	3.66 (0.79, 16.99)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.8 EORTC QLQ-C30 Nausea and Vomiting Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	11/119	3/89	2.65 (0.74, 9.46)	0.9650
	Relapse <= 12 Months of First Line therapy	3/46	1/42	2.77 (0.30, 25.76)	
Age	<65 Years	11/119	3/89	2.66 (0.74, 9.50)	0.9955
	≥65 Years	3/46	1/42	2.54 (0.26, 25.03)	
Second line age adjusted IPI score per IXRS	0 - 1	7/96	3/75	1.73 (0.45, 6.72)	0.3553
	2 - 3	7/69	1/56	5.69 (0.69, 46.72)	
Sex	Male	9/101	3/95	2.69 (0.73, 9.87)	0.9955
	Female	5/64	1/36	2.77 (0.32, 23.85)	
Geographic region	North America	12/128	3/94	2.88 (0.81, 10.23)	0.5153
	Europe	1/31	1/34	1.00 (0.07, 14.34)	
ECOG - performance status	0	6/89	2/81	2.61 (0.53, 12.84)	0.9537
	1	8/76	2/50	2.54 (0.54, 11.97)	
Central laboratory disease type	Diffuse large B-cell lymphoma	8/117	3/94	2.03 (0.54, 7.55)	NE[a]
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/28	0/17	NE[a]	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.9 EORTC QLQ-C30 Pain Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	28/119	20/89	0.95 (0.54, 1.69)	0.8035
	Relapse <= 12 Months of First Line therapy	12/46	12/42	0.85 (0.38, 1.86)	
Age	<65 Years	32/119	23/89	0.96 (0.56, 1.64)	0.6134
	≥65 Years	8/46	9/42	0.73 (0.29, 1.85)	
Second line age adjusted IPI score per IXRS	0 - 1	20/96	20/75	0.69 (0.37, 1.28)	0.1766
	2 - 3	20/69	12/56	1.32 (0.65, 2.70)	
Sex	Male	26/101	19/95	1.25 (0.69, 2.26)	0.0558
	Female	14/64	13/36	0.48 (0.23, 1.01)	
Geographic region	North America	33/128	25/94	0.88 (0.53, 1.48)	0.5024
	Europe	4/31	7/34	0.56 (0.17, 1.84)	
ECOG - performance status	0	19/89	18/81	0.89 (0.47, 1.70)	0.9486
	1	21/76	14/50	0.88 (0.45, 1.73)	
Central laboratory disease type	Diffuse large B-cell lymphoma	28/117	25/94	0.82 (0.48, 1.40)	0.4001
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/28	3/17	1.54 (0.41, 5.83)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Table 1.10 EORTC QLQ-C30 Dyspnea Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	24/119	9/89	1.89 (0.87, 4.08)	0.1640
	Relapse <= 12 Months of First Line therapy	9/46	1/42	8.83 (1.16, 67.42)[+]	
Age	<65 Years	26/119	10/89	1.92 (0.92, 4.00)	NE[a]
	≥65 Years	7/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	19/96	7/75	2.00 (0.84, 4.79)	0.3948
	2 - 3	14/69	3/56	3.92 (1.12, 13.71)[+]	
Sex	Male	20/101	5/95	3.78 (1.41, 10.19)[+]	0.1728
	Female	13/64	5/36	1.36 (0.49, 3.81)	
Geographic region	North America	30/128	8/94	2.76 (1.26, 6.04)[+]	0.5645
	Europe	3/31	2/34	1.61 (0.27, 9.51)	
ECOG - performance status	0	16/89	4/81	3.68 (1.22, 11.09)[+]	0.3182
	1	17/76	6/50	1.78 (0.70, 4.54)	
Central laboratory disease type	Diffuse large B-cell lymphoma	21/117	7/94	2.37 (1.00, 5.61)	0.8703
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/28	2/17	2.74 (0.63, 11.92)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.
[+] 95% CI does not include 1.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Table 1.11 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	30/119	21/89	0.94 (0.54, 1.64)	0.0472*
	Relapse <= 12 Months of First Line therapy	15/46	5/42	2.96 (1.09, 8.06)+	
Age	<65 Years	35/119	17/89	1.45 (0.81, 2.60)	0.4667
	≥65 Years	10/46	9/42	0.93 (0.38, 2.29)	
Second line age adjusted IPI score per IXRS	0 - 1	24/96	18/75	0.94 (0.51, 1.72)	0.1086
	2 - 3	21/69	8/56	2.16 (0.95, 4.92)	
Sex	Male	20/101	18/95	0.93 (0.50, 1.75)	0.1885
	Female	25/64	8/36	1.83 (0.83, 4.05)	
Geographic region	North America	37/128	19/94	1.33 (0.76, 2.32)	0.6719
	Europe	7/31	7/34	1.07 (0.38, 2.97)	
ECOG - performance status	0	23/89	18/81	1.05 (0.57, 1.94)	0.3062
	1	22/76	8/50	1.83 (0.81, 4.11)	
Central laboratory disease type	Diffuse large B-cell lymphoma	30/117	20/94	1.13 (0.64, 1.99)	0.1190
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/28	1/17	6.16 (0.75, 50.49)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
+ 95% CI does not include 1.Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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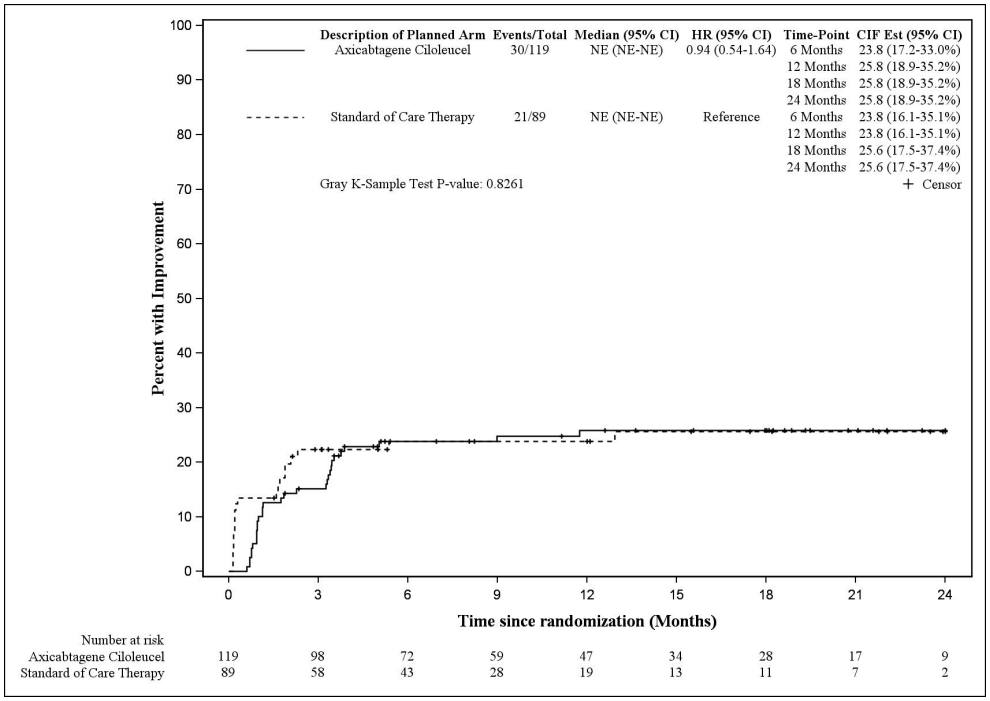
Figure 1.11.1 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement for Primary Refractory



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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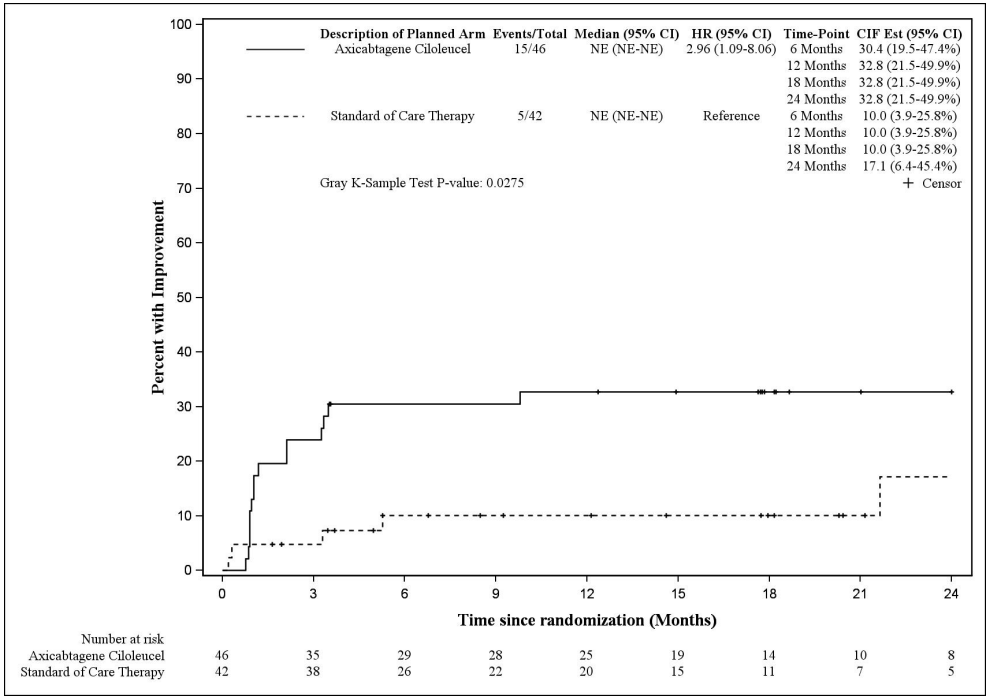
Figure 1.11.2 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement for Relapse less than 12 Months of First Line therapy



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
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Table 1.12 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement by Subgroup

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Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	20/119	11/89	1.23 (0.59, 2.57)	0.1906
	Relapse <= 12 Months of First Line therapy	6/46	1/42	5.61 (0.67, 47.37)	
Age	<65 Years	21/119	8/89	1.92 (0.85, 4.34)	0.4266
	≥65 Years	5/46	4/42	1.09 (0.30, 3.95)	
Second line age adjusted IPI score per IXRS	0 - 1	12/96	10/75	0.85 (0.37, 1.97)	0.0237*
	2 - 3	14/69	2/56	5.96 (1.37, 25.94)+	
Sex	Male	17/101	7/95	2.18 (0.91, 5.23)	0.2417
	Female	9/64	5/36	0.98 (0.33, 2.92)	
Geographic region	North America	25/128	10/94	1.76 (0.84, 3.68)	0.3371
	Europe	1/31	2/34	0.54 (0.05, 5.98)	
ECOG - performance status	0	13/89	5/81	2.31 (0.82, 6.47)	0.3272
	1	13/76	7/50	1.15 (0.46, 2.87)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	8/94	1.53 (0.66, 3.57)	0.5996
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	1/17	2.97 (0.34, 25.94)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
+ 95% CI does not include 1.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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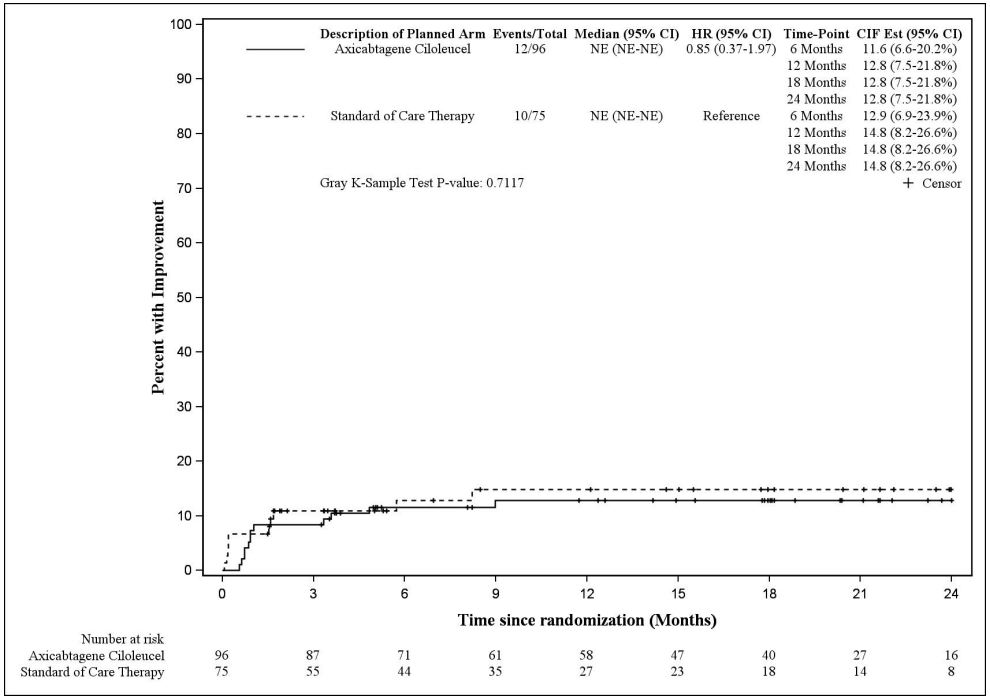
Figure 1.12.1 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement for IPI 0-1



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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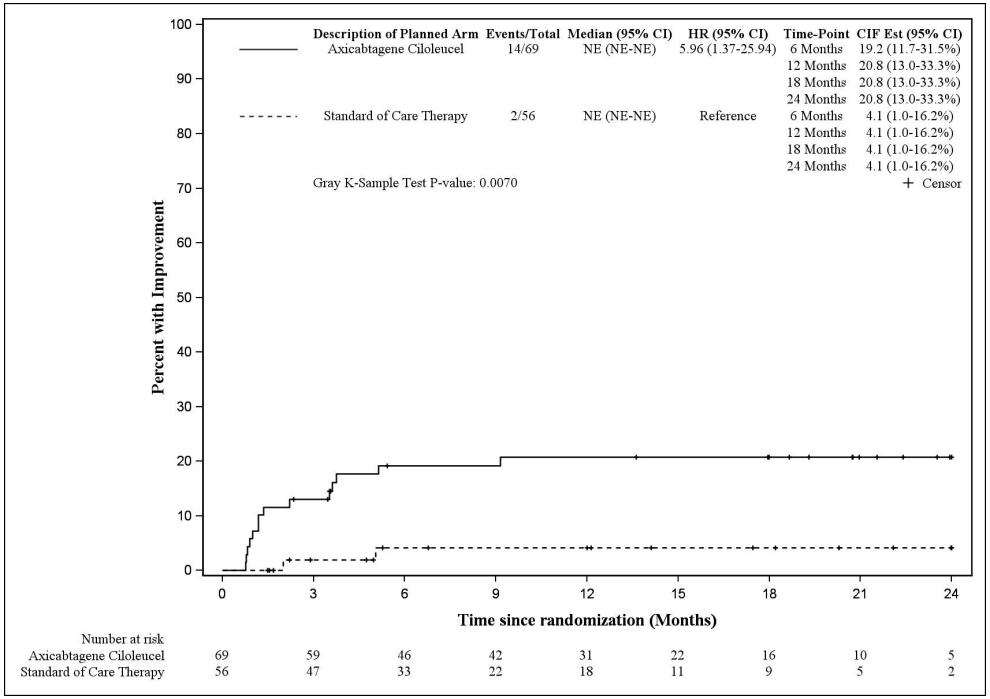
Figure 1.12.2 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement for IPI 2-3



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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Table 1.13 EORTC QLQ-C30 Constipation Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	15/119	10/89	1.03 (0.47, 2.27)	0.6132
	Relapse <= 12 Months of First Line therapy	5/46	6/42	0.71 (0.22, 2.28)	
Age	<65 Years	14/119	10/89	0.96 (0.43, 2.15)	0.8561
	≥65 Years	6/46	6/42	0.83 (0.27, 2.56)	
Second line age adjusted IPI score per IXRS	0 - 1	8/96	10/75	0.56 (0.22, 1.41)	0.1307
	2 - 3	12/69	6/56	1.56 (0.59, 4.14)	
Sex	Male	12/101	10/95	1.03 (0.45, 2.36)	0.5532
	Female	8/64	6/36	0.70 (0.25, 2.00)	
Geographic region	North America	18/128	14/94	0.86 (0.43, 1.72)	0.6842
	Europe	1/31	2/34	0.54 (0.05, 5.80)	
ECOG - performance status	0	8/89	5/81	1.39 (0.46, 4.22)	0.2682
	1	12/76	11/50	0.63 (0.28, 1.40)	
Central laboratory disease type	Diffuse large B-cell lymphoma	11/117	13/94	0.62 (0.28, 1.37)	0.9035
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/28	2/17	0.50 (0.08, 3.29)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
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Table 1.14 EORTC QLQ-C30 Diarrhea Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	14/119	8/89	1.24 (0.52, 2.98)	0.3848
	Relapse <= 12 Months of First Line therapy	6/46	2/42	2.81 (0.58, 13.77)	
Age	<65 Years	14/119	8/89	1.27 (0.53, 3.04)	0.4226
	≥65 Years	6/46	2/42	2.69 (0.54, 13.44)	
Second line age adjusted IPI score per IXRS	0 - 1	11/96	8/75	1.03 (0.41, 2.57)	0.1557
	2 - 3	9/69	2/56	3.69 (0.80, 17.00)	
Sex	Male	11/101	7/95	1.44 (0.56, 3.72)	0.8586
	Female	9/64	3/36	1.66 (0.45, 6.20)	
Geographic region	North America	17/128	7/94	1.75 (0.72, 4.23)	0.5830
	Europe	3/31	3/34	1.07 (0.22, 5.22)	
ECOG - performance status	0	10/89	5/81	1.83 (0.62, 5.36)	0.6322
	1	10/76	5/50	1.24 (0.42, 3.64)	
Central laboratory disease type	Diffuse large B-cell lymphoma	14/117	7/94	1.56 (0.63, 3.88)	0.8316
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/28	1/17	1.14 (0.11, 11.68)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Anhang 4-G3.5: Ergänzende Subgruppenanalysen zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-27 (Anhang): Ergebnisse der Subgruppenanalyse für gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

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Table 1.1 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	24/119	15/89	1.05 (0.56, 2.00)	0.3391
	Relapse <= 12 Months of First Line therapy	7/46	3/42	2.04 (0.53, 7.81)	
Age	<65 Years	22/119	15/89	0.98 (0.51, 1.87)	0.1928
	≥65 Years	9/46	3/42	2.59 (0.70, 9.55)	
Second line age adjusted IPI score per IXRS	0 - 1	19/96	10/75	1.30 (0.61, 2.77)	0.8388
	2 - 3	12/69	8/56	1.16 (0.48, 2.81)	
Sex	Male	24/101	11/95	1.93 (0.95, 3.92)	0.0274*
	Female	7/64	7/36	0.46 (0.16, 1.31)	
Geographic region	North America	25/128	14/94	1.19 (0.62, 2.27)	0.9689
	Europe	5/31	4/34	1.26 (0.35, 4.57)	
ECOG - performance status	0	16/89	8/81	1.71 (0.74, 3.98)	0.2406
	1	15/76	10/50	0.85 (0.38, 1.87)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	14/94	0.77 (0.38, 1.58)	0.0797
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/28	1/17	5.65 (0.68, 46.71)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; QoL, quality of life; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
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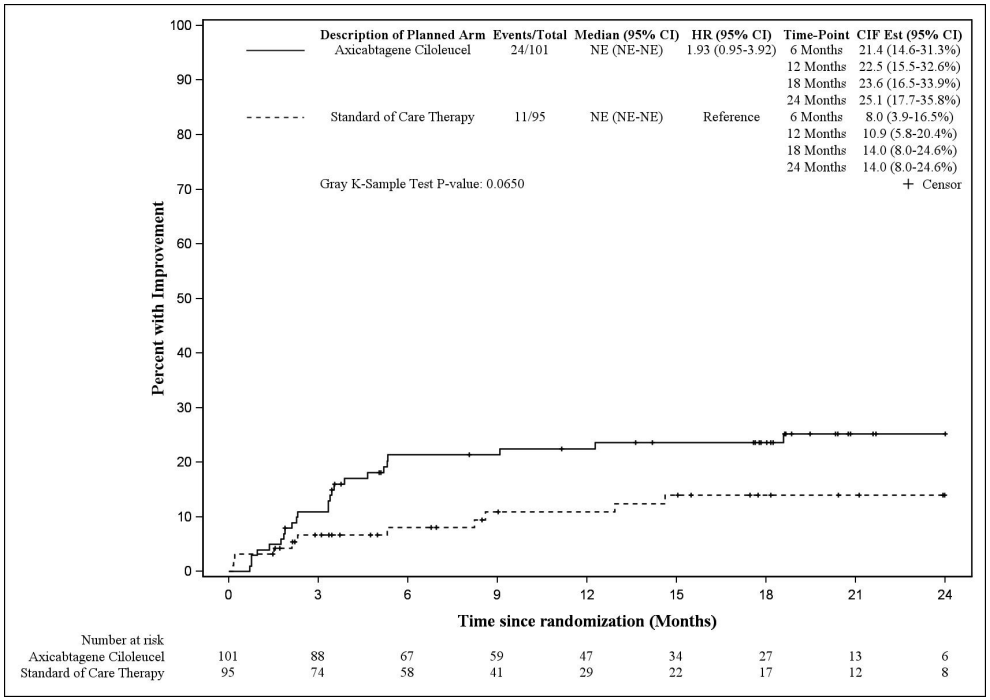
Figure 1.1.1 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement for Male Subgroup



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable; QoL, quality of life.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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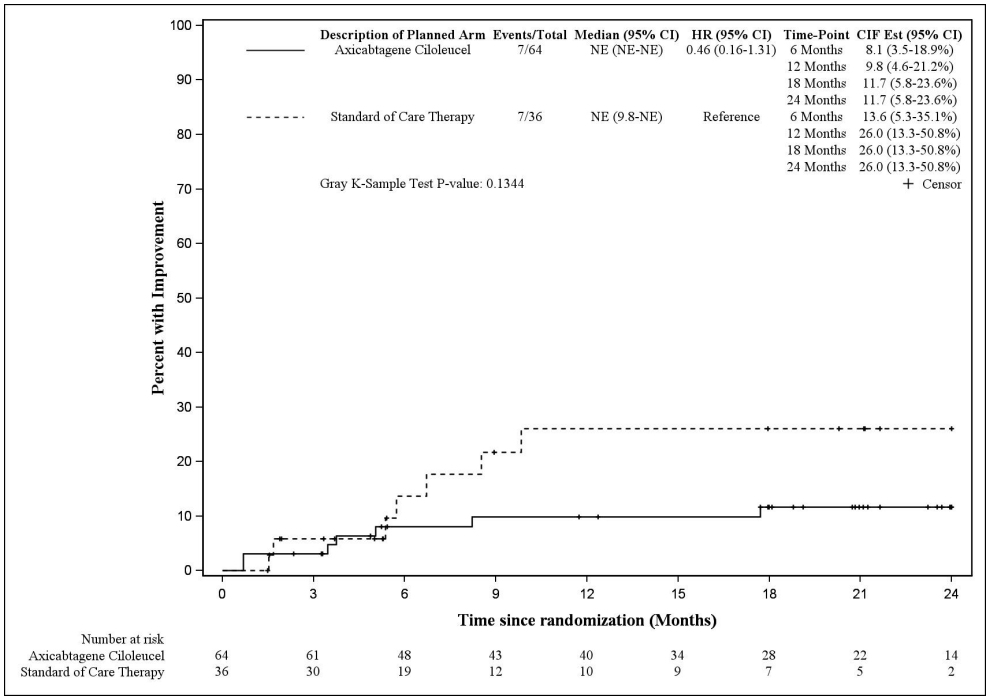
Figure 1.1.2 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement for Female Subgroup



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable; QoL, quality of life.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.2 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	13/119	5/89	1.72 (0.61, 4.83)	0.7738
	Relapse <= 12 Months of First Line therapy	5/46	2/42	2.30 (0.45, 11.58)	
Age	<65 Years	12/119	7/89	1.21 (0.47, 3.07)	NE[a]
	≥65 Years	6/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	10/96	6/75	1.14 (0.41, 3.19)	0.1430
	2 - 3	8/69	1/56	6.40 (0.80, 50.98)	
Sex	Male	13/101	2/95	5.91 (1.34, 25.94)[+]	0.0113[*]
	Female	5/64	5/36	0.50 (0.15, 1.74)	
Geographic region	North America	14/128	4/94	2.40 (0.79, 7.26)	0.5615
	Europe	4/31	3/34	1.33 (0.30, 5.92)	
ECOG - performance status	0	10/89	5/81	1.66 (0.57, 4.86)	0.7104
	1	8/76	2/50	2.49 (0.54, 11.61)	
Central laboratory disease type	Diffuse large B-cell lymphoma	11/117	4/94	2.02 (0.64, 6.37)	0.4193
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	3/17	0.98 (0.25, 3.92)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.
[*] Statistically significant (p-value <0.05)
[+] 95% CI does not include 1.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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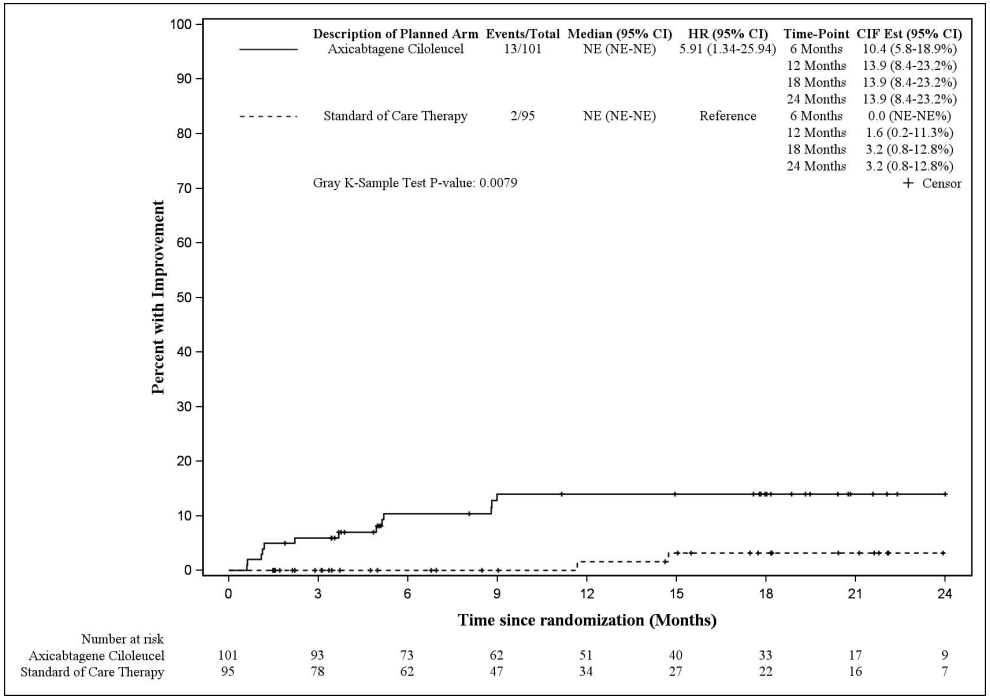
Version: 1.0 (15July2022)

Figure 1.2.1 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement for Male



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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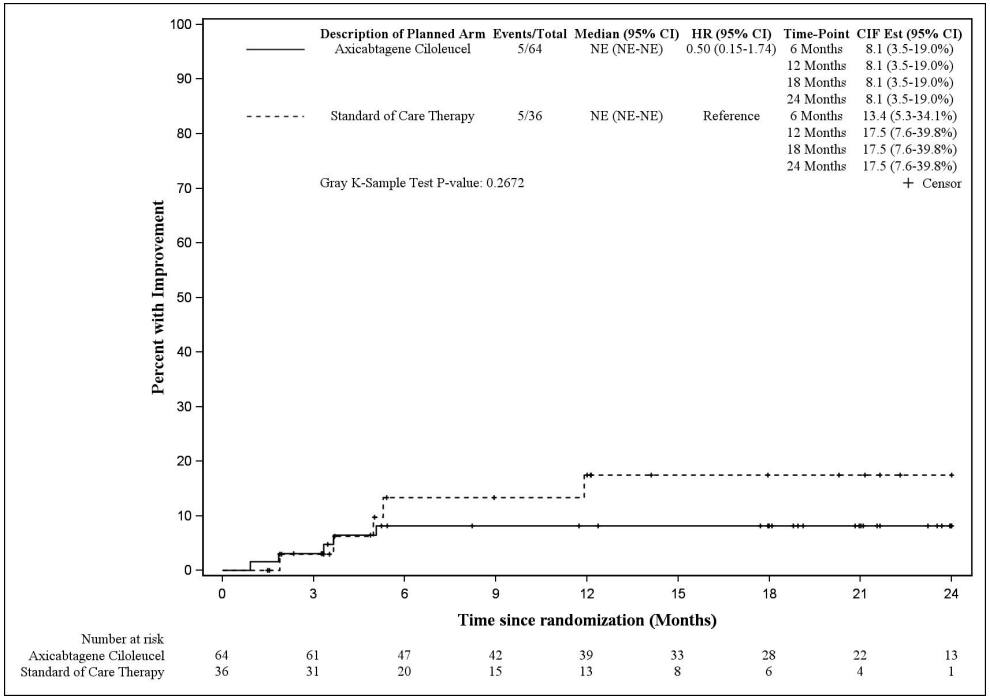
Version: 1.0 (15July2022)

Figure 1.2.2 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement for Female



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.3 EORTC QLQ-C30 Role Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	22/119	9/89	1.64 (0.75, 3.55)	0.7183
	Relapse <= 12 Months of First Line therapy	7/46	3/42	2.19 (0.58, 8.36)	
Age	<65 Years	24/119	12/89	1.39 (0.70, 2.79)	NE[a]
	≥65 Years	5/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	15/96	7/75	1.52 (0.62, 3.74)	0.5556
	2 - 3	14/69	5/56	2.23 (0.81, 6.18)	
Sex	Male	19/101	7/95	2.46 (1.03, 5.84)[+]	0.2049
	Female	10/64	5/36	1.00 (0.34, 2.91)	
Geographic region	North America	25/128	10/94	1.74 (0.83, 3.63)	0.8854
	Europe	4/31	2/34	1.81 (0.35, 9.45)	
ECOG - performance status	0	12/89	6/81	1.72 (0.65, 4.56)	0.9952
	1	17/76	6/50	1.70 (0.67, 4.31)	
Central laboratory disease type	Diffuse large B-cell lymphoma	19/117	10/94	1.39 (0.65, 2.99)	0.6171
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/28	2/17	2.16 (0.48, 9.86)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.

[+] 95% CI does not include 1.Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.4 EORTC QLQ-C30 Emotional Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	17/119	9/89	1.30 (0.58, 2.91)	0.9600
	Relapse <= 12 Months of First Line therapy	9/46	6/42	1.36 (0.49, 3.79)	
Age	<65 Years	21/119	12/89	1.23 (0.61, 2.50)	0.8426
	≥65 Years	5/46	3/42	1.41 (0.33, 6.04)	
Second line age adjusted IPI score per IXRS	0 - 1	16/96	12/75	0.94 (0.45, 1.99)	0.1725
	2 - 3	10/69	3/56	2.69 (0.75, 9.67)	
Sex	Male	20/101	12/95	1.53 (0.75, 3.11)	0.6067
	Female	6/64	3/36	1.03 (0.27, 4.04)	
Geographic region	North America	19/128	12/94	1.08 (0.52, 2.22)	0.5523
	Europe	5/31	3/34	1.75 (0.43, 7.23)	
ECOG - performance status	0	13/89	9/81	1.27 (0.54, 2.96)	0.9340
	1	13/76	6/50	1.29 (0.49, 3.37)	
Central laboratory disease type	Diffuse large B-cell lymphoma	14/117	10/94	1.05 (0.47, 2.38)	0.9273
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/28	3/17	1.13 (0.29, 4.43)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.5 EORTC QLQ-C30 Cognitive Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	16/119	16/89	0.67 (0.34, 1.34)	0.4743
	Relapse <= 12 Months of First Line therapy	6/46	5/42	1.10 (0.34, 3.61)	
Age	<65 Years	16/119	15/89	0.75 (0.37, 1.51)	0.8622
	≥65 Years	6/46	6/42	0.85 (0.28, 2.63)	
Second line age adjusted IPI score per IXRS	0 - 1	13/96	14/75	0.66 (0.31, 1.42)	0.5026
	2 - 3	9/69	7/56	1.01 (0.38, 2.69)	
Sex	Male	14/101	12/95	1.05 (0.48, 2.27)	0.1529
	Female	8/64	9/36	0.44 (0.17, 1.12)	
Geographic region	North America	19/128	15/94	0.87 (0.44, 1.71)	0.4927
	Europe	3/31	6/34	0.51 (0.13, 2.04)	
ECOG - performance status	0	9/89	11/81	0.71 (0.29, 1.73)	0.9183
	1	13/76	10/50	0.77 (0.34, 1.74)	
Central laboratory disease type	Diffuse large B-cell lymphoma	13/117	13/94	0.75 (0.35, 1.61)	0.9336
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	4/17	0.73 (0.20, 2.65)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Version: 1.0 (15July2022)

Table 1.6 EORTC QLQ-C30 Social Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	32/119	17/89	1.34 (0.75, 2.41)	0.8474
	Relapse <= 12 Months of First Line therapy	7/46	4/42	1.57 (0.46, 5.35)	
Age	<65 Years	30/119	18/89	1.21 (0.68, 2.17)	0.3020
	≥65 Years	9/46	3/42	2.60 (0.70, 9.66)	
Second line age adjusted IPI score per IXRS	0 - 1	25/96	17/75	1.07 (0.58, 1.98)	0.1231
	2 - 3	14/69	4/56	2.85 (0.94, 8.67)	
Sex	Male	25/101	16/95	1.45 (0.77, 2.71)	0.9954
	Female	14/64	5/36	1.47 (0.52, 4.12)	
Geographic region	North America	32/128	16/94	1.43 (0.78, 2.61)	0.6178
	Europe	5/31	5/34	0.95 (0.29, 3.16)	
ECOG - performance status	0	16/89	13/81	1.03 (0.50, 2.13)	0.2658
	1	23/76	8/50	1.92 (0.86, 4.29)	
Central laboratory disease type	Diffuse large B-cell lymphoma	24/117	15/94	1.21 (0.64, 2.31)	0.8134
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/28	3/17	1.43 (0.38, 5.40)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

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Anhang 4-G3.6: Ergänzende Subgruppenanalysen zu unerwünschte Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Anhang 4-G3.6.1: Subgruppenanalyse (tabellarische Darstellung) der Gesamtraten UE sowie UE von speziellem Interesse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-28 (Anhang): Ergebnisse der Subgruppenanalyse für UE und UE von speziellem Interesse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Age < 65	127/127 (100)	0.5 (0.3,0.6)	113/113 (100)	0.1 (0.1,0.1)	0.36 (0.27,0.48)	<0.0001	0.4687
	Age ≥ 65	51/51 (100)	0.4 (0.1,0.6)	55/55 (100)	0.1 (0.0,0.1)	0.45 (0.30,0.68)	<0.0001	
Any serious TEAE	Age < 65	75/127 (59)	4.7 (1.4,9.9)	52/113 (46)	4.7 (3.0,9.0)	1.04 (0.72,1.50)	0.8162	0.8260
	Age ≥ 65	33/51 (65)	1.5 (1.0,10.9)	26/55 (47)	4.1 (2.3,NE)	1.02 (0.60,1.75)	0.9277	
Any severe TEAE (Grade>=3)	Age < 65	115/127 (91)	0.9 (0.8,1.0)	95/113 (84)	0.5 (0.4,0.7)	0.93 (0.71,1.23)	0.6201	0.8301
	Age ≥ 65	49/51 (96)	0.9 (0.8,1.0)	45/55 (82)	0.4 (0.3,0.5)	0.90 (0.59,1.36)	0.6050	
Any TE neurologic event	Age < 65	76/127 (60)	1.3 (1.2,2.7)	19/113 (17)	NE (NE,NE)	4.42 (2.67,7.32)	<0.0001	0.6513
	Age ≥ 65	34/51 (67)	1.1 (1.0,1.5)	14/55 (25)	NE (NE,NE)	3.40 (1.82,6.37)	<0.0001	
Any serious TE neurologic event	Age < 65	22/127 (17)	NE (NE,NE)	1/113 (1)	NE (NE,NE)	20.28 (2.73,150.44)	<0.0001	0.9889
	Age ≥ 65	12/51 (24)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Age < 65	25/127 (20)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9893
	Age ≥ 65	13/51 (25)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	15.42 (2.02,117.93)	0.0004	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Age < 65	109/127 (86)	1.0 (1.0,1.1)	-	-	-	-	-
	Age ≥ 65	48/51 (94)	1.0 (0.9,1.0)	-	-	-	-	
Any serious TE CRS	Age < 65	17/127 (13)	NE (NE,NE)	-	-	-	-	-
	Age ≥ 65	12/51 (24)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Age < 65	7/127 (6)	NE (NE,NE)	-	-	-	-	-
	Age ≥ 65	4/51 (8)	NE (NE,NE)	-	-	-	-	
Any TE infection	Age < 65	58/127 (46)	13.8 (4.1,33.9)	32/113 (28)	9.0 (4.8,NE)	1.27 (0.81,1.98)	0.2937	0.3372
	Age ≥ 65	35/51 (69)	3.1 (1.3,4.9)	21/55 (38)	4.6 (3.5,NE)	1.69 (0.97,2.95)	0.0606	
Any serious TE infection	Age < 65	25/127 (20)	NE (NE,NE)	9/113 (8)	NE (NE,NE)	1.71 (0.79,3.68)	0.1687	0.2726
	Age ≥ 65	12/51 (24)	NE (36.1,NE)	9/55 (16)	NE (19.9,NE)	0.84 (0.35,2.02)	0.6961	
Any severe TE infection (Grade >= 3)	Age < 65	20/127 (16)	14.7 (8.7,39.8)	11/113 (10)	NE (NE,NE)	1.03 (0.47,2.28)	0.9414	0.4864
	Age ≥ 65	17/51 (33)	10.1 (5.0,23.4)	9/55 (16)	19.9 (NE,NE)	1.26 (0.54,2.95)	0.5947	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Age < 65	99/127 (78)	1.0 (0.9,1.1)	90/113 (80)	0.7 (0.5,1.2)	0.85 (0.63,1.13)	0.2499	0.4668
	Age ≥ 65	44/51 (86)	0.9 (0.7,1.0)	45/55 (82)	0.6 (0.4,1.3)	0.97 (0.63,1.47)	0.8699	
Any serious TE cytopenias	Age < 65	6/127 (5)	NE (NE,NE)	20/113 (18)	NE (NE,NE)	0.19 (0.07,0.47)	<0.0001	0.2799
	Age ≥ 65	6/51 (12)	NE (NE,NE)	11/55 (20)	NE (NE,NE)	0.39 (0.14,1.06)	0.0573	
Any severe TE cytopenias (Grade >= 3)	Age < 65	91/127 (72)	1.1 (1.0,1.2)	84/113 (74)	1.2 (0.7,2.4)	0.85 (0.63,1.14)	0.2700	0.3629
	Age ≥ 65	44/51 (86)	1.0 (0.9,1.0)	42/55 (76)	0.7 (0.5,2.1)	1.01 (0.65,1.55)	0.9807	
Any TE hypogammaglobulinemia	Age < 65	11/127 (9)	5.1 (5.0,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9930
	Age ≥ 65	11/51 (22)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	11.45 (1.48,88.76)	0.0032	
Any serious TE hypogammaglobulinemia	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Age < 65	3/127 (2)	NE (NE,NE)	2/113 (2)	NE (NE,NE)	1.09 (0.18,6.58)	0.9236	0.8514
	Age ≥ 65	3/51 (6)	NE (NE,NE)	2/55 (4)	NE (NE,NE)	1.49 (0.25,8.96)	0.6582	
Any serious TE bone marrow failure	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Age < 65	1/127 (1)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9965
	Age ≥ 65	0/51 (0)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Age < 65	4/127 (3)	17.3 (15.6,NE)	1/113 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1573	0.9961
	Age ≥ 65	4/51 (8)	33.7 (11.2,NE)	2/55 (4)	24.0 (10.6,NE)	0.38 (0.05,2.76)	0.3209	
Any serious TE secondary malignancy	Age < 65	4/127 (3)	NE (NE,NE)	1/113 (1)	NE (NE,NE)	1.75 (0.20,15.65)	0.6134	0.5955
	Age ≥ 65	4/51 (8)	NE (NE,NE)	2/55 (4)	NE (37.4,NE)	0.73 (0.13,4.05)	0.7150	
Any severe TE secondary malignancy (Grade >= 3)	Age < 65	3/127 (2)	18.9 (15.6,NE)	1/113 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1573	0.9960
	Age ≥ 65	3/51 (6)	25.0 (11.2,NE)	2/55 (4)	24.0 (10.6,NE)	0.58 (0.08,4.26)	0.5860	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	Age < 65	2/127 (2)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	Age < 65	2/127 (2)	NE (NE,NE)	2/113 (2)	NE (NE,NE)	0.86 (0.12,6.08)	0.8761	0.3871
	Age ≥ 65	3/51 (6)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	2.95 (0.31,28.44)	0.3272	
Any serious TE cardiac failure	Age < 65	0/127 (0)	NE (NE,NE)	1/113 (1)	NE (NE,NE)	NE (NE,NE)	NE	0.9974
	Age ≥ 65	1/51 (2)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	2/113 (2)	NE (NE,NE)	NE (NE,NE)	NE	0.9950
	Age ≥ 65	2/51 (4)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	1.89 (0.17,21.03)	0.5972	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.1. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Age < 65	62/127 (49)	2.1 (1.2,NE)	24/113 (21)	NE (NE,NE)	2.67 (1.67,4.28)	<0.0001	0.7081
	Age ≥ 65	25/51 (49)	3.9 (1.1,NE)	10/55 (18)	NE (NE,NE)	3.15 (1.51,6.58)	0.0012	
Any serious TE cardiac arrhythmias	Age < 65	5/127 (4)	NE (NE,NE)	3/113 (3)	NE (NE,NE)	1.26 (0.30,5.32)	0.7511	0.3141
	Age ≥ 65	5/51 (10)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	5.28 (0.62,45.21)	0.0889	
Any severe TE cardiac arrhythmias (Grade >= 3)	Age < 65	6/127 (5)	NE (NE,NE)	1/113 (1)	NE (NE,NE)	4.81 (0.58,40.07)	0.1085	0.5744
	Age ≥ 65	2/51 (4)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	1.79 (0.16,20.17)	0.6317	
Any TE autoimmune disorder	Age < 65	11/127 (9)	5.1 (5.0,NE)	1/113 (1)	NE (NE,NE)	6.22 (0.78,49.89)	0.0491	0.5033
	Age ≥ 65	11/51 (22)	NE (NE,NE)	2/55 (4)	17.9 (NE,NE)	11.45 (1.48,88.76)	0.0032	
Any serious TE autoimmune disorder	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	1/55 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Age < 65	0/127 (0)	NE (NE,NE)	0/113 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE,NE)	0/55 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Male	109/109 (100)	0.6 (0.4,0.6)	120/120 (100)	0.1 (0.1,0.1)	0.35 (0.26,0.47)	<0.0001	0.4082
	Female	69/69 (100)	0.2 (0.1,0.4)	48/48 (100)	0.1 (0.0,0.1)	0.44 (0.29,0.67)	<0.0001	
Any serious TEAE	Male	62/109 (57)	5.7 (1.6,9.9)	51/120 (43)	4.7 (3.3,NE)	1.01 (0.69,1.49)	0.9559	0.5842
	Female	46/69 (67)	1.4 (1.0,4.7)	27/48 (56)	2.9 (1.1,NE)	0.98 (0.61,1.60)	0.9495	
Any severe TEAE (Grade>=3)	Male	98/109 (90)	0.9 (0.9,1.0)	96/120 (80)	0.5 (0.4,0.7)	0.94 (0.71,1.25)	0.6621	0.5527
	Female	66/69 (96)	0.8 (0.8,0.9)	44/48 (92)	0.4 (0.3,0.7)	0.79 (0.54,1.17)	0.2233	
Any TE neurologic event	Male	65/109 (60)	1.3 (1.2,1.9)	20/120 (17)	NE (NE,NE)	4.46 (2.69,7.37)	<0.0001	0.3305
	Female	45/69 (65)	1.2 (1.1,2.0)	13/48 (27)	NE (NE,NE)	3.00 (1.61,5.59)	0.0003	
Any serious TE neurologic event	Male	20/109 (18)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9890
	Female	14/69 (20)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	10.36 (1.36,78.86)	0.0050	
Any severe TE neurologic event (Grade >= 3)	Male	22/109 (20)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	24.91 (3.36,184.82)	<0.0001	0.9893
	Female	16/69 (23)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Male	97/109 (89)	1.0 (1.0,1.1)	-	-	-	-	-
	Female	60/69 (87)	1.0 (1.0,1.1)	-	-	-	-	
Any serious TE CRS	Male	12/109 (11)	NE (NE,NE)	-	-	-	-	-
	Female	17/69 (25)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Male	5/109 (5)	NE (NE,NE)	-	-	-	-	-
	Female	6/69 (9)	NE (NE,NE)	-	-	-	-	
Any TE infection	Male	53/109 (49)	5.0 (4.0,10.9)	36/120 (30)	9.0 (4.6,NE)	1.26 (0.82,1.95)	0.2866	0.8462
	Female	40/69 (58)	4.0 (1.2,42.4)	17/48 (35)	NE (3.5,NE)	1.42 (0.80,2.52)	0.2315	
Any serious TE infection	Male	23/109 (21)	NE (NE,NE)	12/120 (10)	NE (NE,NE)	1.27 (0.62,2.57)	0.5119	0.8044
	Female	14/69 (20)	NE (NE,NE)	6/48 (13)	NE (19.9,NE)	1.24 (0.47,3.25)	0.6667	
Any severe TE infection (Grade >= 3)	Male	23/109 (21)	10.9 (5.7,23.4)	13/120 (11)	NE (NE,NE)	0.91 (0.42,1.98)	0.8120	0.8358
	Female	14/69 (20)	33.9 (33.9,NE)	7/48 (15)	19.9 (NE,NE)	1.15 (0.45,2.94)	0.7638	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Male	85/109 (78)	1.0 (0.9,1.1)	92/120 (77)	0.8 (0.5,1.6)	0.85 (0.63,1.15)	0.2865	0.9549
	Female	58/69 (84)	0.9 (0.8,1.0)	43/48 (90)	0.6 (0.5,0.9)	0.84 (0.57,1.26)	0.3899	
Any serious TE cytopenias	Male	5/109 (5)	NE (NE,NE)	21/120 (18)	NE (NE,NE)	0.17 (0.06,0.46)	<0.0001	0.2691
	Female	7/69 (10)	NE (NE,NE)	10/48 (21)	NE (NE,NE)	0.36 (0.14,0.96)	0.0343	
Any severe TE cytopenias (Grade >= 3)	Male	78/109 (72)	1.1 (1.1,1.2)	85/120 (71)	1.8 (0.6,2.4)	0.80 (0.59,1.10)	0.1620	0.4486
	Female	57/69 (83)	0.9 (0.8,1.0)	41/48 (85)	0.8 (0.5,1.3)	0.99 (0.66,1.49)	0.9737	
Any TE hypogammaglobulinemia	Male	12/109 (11)	5.0 (5.0,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9915
	Female	10/69 (14)	5.4 (NE,NE)	1/48 (2)	NE (NE,NE)	6.11 (0.77,48.29)	0.0500	
Any serious TE hypogammaglobulinemia	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Male	4/109 (4)	NE (NE,NE)	3/120 (3)	NE (NE,NE)	1.17 (0.26,5.25)	0.8388	0.9677
	Female	2/69 (3)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	1.31 (0.12,14.48)	0.8258	
Any serious TE bone marrow failure	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Male	1/109 (1)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	0.72 (0.04,11.68)	0.8151	1.0000
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Male	3/109 (3)	25.0 (11.2,NE)	3/120 (3)	10.6 (10.6,NE)	0.87 (0.14,5.37)	0.8844	0.9968
	Female	5/69 (7)	18.9 (15.6,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	Male	3/109 (3)	NE (NE,NE)	3/120 (3)	NE (NE,NE)	0.51 (0.10,2.55)	0.4059	0.9928
	Female	5/69 (7)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	Male	3/109 (3)	25.0 (11.2,NE)	3/120 (3)	10.6 (10.6,NE)	0.87 (0.14,5.37)	0.8844	0.9967
	Female	3/69 (4)	18.9 (15.6,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Male	0/109 (0)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	Male	2/109 (2)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	Male	2/109 (2)	NE (NE,NE)	2/120 (2)	NE (NE,NE)	0.92 (0.13,6.61)	0.9360	0.6349
	Female	3/69 (4)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	2.14 (0.22,20.62)	0.4985	
Any serious TE cardiac failure	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Female	1/69 (1)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	0.72 (0.04,11.43)	0.8117	
Any severe TE cardiac failure (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	2/120 (2)	NE (NE,NE)	NE (NE,NE)	NE	0.9950
	Female	2/69 (3)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	1.42 (0.13,15.69)	0.7725	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.2. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Male	55/109 (50)	2.1 (1.2,NE)	23/120 (19)	NE (NE,NE)	2.94 (1.80,4.78)	<0.0001	0.7586
	Female	32/69 (46)	NE (1.1,NE)	11/48 (23)	NE (NE,NE)	2.53 (1.27,5.02)	0.0058	
Any serious TE cardiac arrhythmias	Male	4/109 (4)	NE (NE,NE)	2/120 (2)	NE (NE,NE)	1.72 (0.31,9.48)	0.5304	0.9755
	Female	6/69 (9)	NE (NE,NE)	2/48 (4)	NE (NE,NE)	2.09 (0.42,10.38)	0.3540	
Any severe TE cardiac arrhythmias (Grade >= 3)	Male	6/109 (6)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	5.77 (0.69,48.14)	0.0669	0.3844
	Female	2/69 (3)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	1.39 (0.13,15.39)	0.7849	
Any TE autoimmune disorder	Male	12/109 (11)	5.0 (5.0,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9909
	Female	10/69 (14)	5.4 (NE,NE)	3/48 (6)	17.9 (NE,NE)	3.46 (0.76,15.81)	0.0889	
Any serious TE autoimmune disorder	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Male	0/109 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Female	0/69 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	White	144/144 (100)	0.4 (0.3,0.6)	145/145 (100)	0.1 (NE,NE)	0.41 (0.32,0.53)	<0.0001	0.8593
	Other	34/34 (100)	0.5 (0.1,0.6)	23/23 (100)	0.1 (0.0,0.1)	0.29 (0.15,0.55)	<0.0001	
Any serious TEAE	White	89/144 (62)	3.6 (1.4,9.3)	69/145 (48)	3.7 (3.0,8.2)	0.97 (0.69,1.35)	0.8388	0.3587
	Other	19/34 (56)	2.6 (0.9,NE)	9/23 (39)	32.2 (1.0,NE)	1.36 (0.61,3.03)	0.4484	
Any severe TEAE (Grade>=3)	White	133/144 (92)	0.9 (0.8,1.0)	121/145 (83)	0.5 (0.4,0.5)	0.94 (0.73,1.21)	0.6352	0.9489
	Other	31/34 (91)	0.8 (0.7,1.0)	19/23 (83)	0.5 (0.4,0.8)	0.86 (0.48,1.53)	0.5977	
Any TE neurologic event	White	89/144 (62)	1.3 (1.2,1.5)	31/145 (21)	NE (NE,NE)	3.55 (2.35,5.35)	<0.0001	0.1896
	Other	21/34 (62)	1.3 (1.1,NE)	2/23 (9)	NE (NE,NE)	9.90 (2.31,42.31)	0.0001	
Any serious TE neurologic event	White	28/144 (19)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	28.88 (3.93,212.39)	<0.0001	0.9898
	Other	6/34 (18)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	White	28/144 (19)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	30.07 (4.09,221.01)	<0.0001	0.9892
	Other	10/34 (29)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	White	127/144 (88)	1.0 (1.0,1.1)	-	-	-	-	-
	Other	30/34 (88)	0.9 (0.8,1.1)	-	-	-	-	
Any serious TE CRS	White	19/144 (13)	NE (NE,NE)	-	-	-	-	-
	Other	10/34 (29)	NE (1.3,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	White	7/144 (5)	NE (NE,NE)	-	-	-	-	-
	Other	4/34 (12)	NE (NE,NE)	-	-	-	-	
Any TE infection	White	77/144 (53)	4.9 (3.5,10.9)	46/145 (32)	9.0 (4.6,NE)	1.34 (0.92,1.94)	0.1257	0.9682
	Other	16/34 (47)	39.8 (1.1,NE)	7/23 (30)	NE (3.4,NE)	1.41 (0.58,3.47)	0.4464	
Any serious TE infection	White	33/144 (23)	NE (NE,NE)	16/145 (11)	NE (NE,NE)	1.31 (0.71,2.40)	0.3820	0.6668
	Other	4/34 (12)	NE (NE,NE)	2/23 (9)	NE (NE,NE)	1.13 (0.20,6.23)	0.8926	
Any severe TE infection (Grade >= 3)	White	32/144 (22)	10.9 (5.7,23.4)	17/145 (12)	19.9 (NE,NE)	1.15 (0.61,2.15)	0.6616	0.4429
	Other	5/34 (15)	39.8 (NE,NE)	3/23 (13)	NE (NE,NE)	0.82 (0.18,3.68)	0.7981	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	White	115/144 (80)	1.0 (0.9,1.1)	117/145 (81)	0.7 (0.5,1.0)	0.83 (0.64,1.08)	0.1504	0.2457
	Other	28/34 (82)	1.0 (0.7,1.2)	18/23 (78)	2.4 (0.5,2.5)	1.21 (0.66,2.21)	0.5242	
Any serious TE cytopenias	White	8/144 (6)	NE (NE,NE)	29/145 (20)	NE (NE,NE)	0.19 (0.09,0.42)	<0.0001	0.0738
	Other	4/34 (12)	NE (NE,NE)	2/23 (9)	NE (NE,NE)	0.95 (0.17,5.26)	0.9577	
Any severe TE cytopenias (Grade >= 3)	White	110/144 (76)	1.1 (1.0,1.1)	109/145 (75)	1.0 (0.6,1.8)	0.87 (0.66,1.13)	0.2892	0.6262
	Other	25/34 (74)	1.1 (0.8,1.2)	17/23 (74)	2.4 (0.5,2.8)	1.00 (0.53,1.86)	0.9883	
Any TE hypogammaglobulinemia	White	17/144 (12)	5.1 (5.1,NE)	1/145 (1)	NE (NE,NE)	13.26 (1.75,100.45)	0.0011	0.9916
	Other	5/34 (15)	5.0 (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	White	5/144 (3)	NE (NE,NE)	4/145 (3)	NE (NE,NE)	1.06 (0.28,3.96)	0.9330	0.9924
	Other	1/34 (3)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE bone marrow failure	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	White	1/144 (1)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	0.72 (0.04,11.62)	0.8143	1.0000
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	White	7/144 (5)	18.9 (11.2,42.3)	3/145 (2)	10.6 (10.6,NE)	0.47 (0.11,2.02)	0.2983	0.9966
	Other	1/34 (3)	33.4 (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	White	7/144 (5)	NE (NE,NE)	3/145 (2)	NE (NE,NE)	1.05 (0.27,4.08)	0.9416	0.9930
	Other	1/34 (3)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	White	5/144 (3)	18.9 (11.2,NE)	3/145 (2)	10.6 (10.6,NE)	0.55 (0.12,2.57)	0.4407	0.9966
	Other	1/34 (3)	33.4 (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	White	0/144 (0)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	White	0/144 (0)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	White	2/144 (1)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	White	4/144 (3)	NE (NE,NE)	3/145 (2)	NE (NE,NE)	1.24 (0.28,5.55)	0.7798	0.9929
	Other	1/34 (3)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	White	0/144 (0)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	NE (NE,NE)	NE	0.9992
	Other	1/34 (3)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	White	1/144 (1)	NE (NE,NE)	3/145 (2)	NE (NE,NE)	0.29 (0.03,2.78)	0.2516	0.9941
	Other	1/34 (3)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.3. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	White	69/144 (48)	NE (1.2,NE)	28/145 (19)	NE (NE,NE)	2.86 (1.84,4.45)	<0.0001	0.8087
	Other	18/34 (53)	1.2 (0.9,NE)	6/23 (26)	NE (2.9,NE)	2.46 (0.97,6.22)	0.0487	
Any serious TE cardiac arrhythmias	White	7/144 (5)	NE (NE,NE)	4/145 (3)	NE (NE,NE)	1.52 (0.44,5.23)	0.5014	0.9908
	Other	3/34 (9)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac arrhythmias (Grade >= 3)	White	6/144 (4)	NE (NE,NE)	2/145 (1)	NE (NE,NE)	2.56 (0.51,12.79)	0.2350	0.9926
	Other	2/34 (6)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	White	17/144 (12)	5.1 (5.1,NE)	3/145 (2)	17.9 (NE,NE)	7.38 (1.70,32.01)	0.0017	0.9908
	Other	5/34 (15)	5.0 (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	White	0/144 (0)	NE (NE,NE)	1/145 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	White	0/144 (0)	NE (NE,NE)	0/145 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE,NE)	0/23 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	0	95/95 (100)	0.4 (0.2,0.6)	94/94 (100)	0.1 (0.0,0.1)	0.38 (0.27,0.53)	<0.0001	0.5824
	1	83/83 (100)	0.5 (0.2,0.6)	74/74 (100)	0.1 (NE,NE)	0.41 (0.29,0.58)	<0.0001	
Any serious TEAE	0	53/95 (56)	5.7 (1.4,9.9)	39/94 (41)	4.9 (3.4,NE)	1.12 (0.73,1.71)	0.6042	0.3479
	1	55/83 (66)	1.6 (1.2,10.9)	39/74 (53)	3.0 (2.0,NE)	0.95 (0.62,1.45)	0.7984	
Any severe TEAE (Grade>=3)	0	88/95 (93)	0.9 (0.8,1.0)	73/94 (78)	0.4 (0.4,0.5)	0.96 (0.70,1.32)	0.7883	0.7276
	1	76/83 (92)	0.9 (0.8,1.0)	67/74 (91)	0.5 (0.4,0.8)	0.89 (0.64,1.24)	0.4762	
Any TE neurologic event	0	50/95 (53)	1.9 (1.3,NE)	21/94 (22)	NE (NE,NE)	2.68 (1.61,4.46)	<0.0001	0.0337
	1	60/83 (72)	1.2 (1.1,1.3)	12/74 (16)	NE (NE,NE)	6.44 (3.44,12.04)	<0.0001	
Any serious TE neurologic event	0	13/95 (14)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9870
	1	21/83 (25)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	18.81 (2.53,140.15)	<0.0001	
Any severe TE neurologic event (Grade >= 3)	0	13/95 (14)	NE (NE,NE)	1/94 (1)	NE (NE,NE)	13.23 (1.73,101.11)	0.0012	0.9881
	1	25/83 (30)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	0	84/95 (88)	1.0 (1.0,1.1)	-	-	-	-	-
	1	73/83 (88)	1.0 (0.9,1.1)	-	-	-	-	
Any serious TE CRS	0	14/95 (15)	NE (NE,NE)	-	-	-	-	-
	1	15/83 (18)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	0	5/95 (5)	NE (NE,NE)	-	-	-	-	-
	1	6/83 (7)	NE (NE,NE)	-	-	-	-	
Any TE infection	0	45/95 (47)	4.9 (3.7,23.7)	35/94 (37)	9.0 (3.5,NE)	1.10 (0.70,1.72)	0.6790	0.2324
	1	48/83 (58)	4.3 (1.7,10.9)	18/74 (24)	NE (4.6,NE)	1.86 (1.06,3.24)	0.0264	
Any serious TE infection	0	16/95 (17)	NE (NE,NE)	13/94 (14)	NE (NE,NE)	0.89 (0.43,1.86)	0.7597	0.2057
	1	21/83 (25)	NE (43.4,NE)	5/74 (7)	NE (NE,NE)	2.26 (0.84,6.11)	0.0995	
Any severe TE infection (Grade >= 3)	0	15/95 (16)	10.1 (8.7,NE)	12/94 (13)	19.9 (NE,NE)	0.94 (0.43,2.06)	0.8869	0.8170
	1	22/83 (27)	13.8 (5.0,27.1)	8/74 (11)	NE (NE,NE)	1.38 (0.57,3.30)	0.4725	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	0	79/95 (83)	1.0 (0.9,1.1)	73/94 (78)	0.8 (0.5,1.5)	1.00 (0.73,1.39)	0.9833	0.3550
	1	64/83 (77)	1.0 (0.8,1.1)	62/74 (84)	0.7 (0.5,1.0)	0.76 (0.53,1.08)	0.1129	
Any serious TE cytopenias	0	5/95 (5)	NE (NE,NE)	15/94 (16)	NE (NE,NE)	0.25 (0.09,0.69)	0.0038	0.9278
	1	7/83 (8)	NE (NE,NE)	16/74 (22)	NE (NE,NE)	0.24 (0.09,0.59)	0.0009	
Any severe TE cytopenias (Grade >= 3)	0	74/95 (78)	1.1 (1.0,1.2)	68/94 (72)	1.3 (0.6,2.4)	1.02 (0.73,1.42)	0.9269	0.4012
	1	61/83 (73)	1.0 (0.9,1.1)	58/74 (78)	0.9 (0.5,1.9)	0.76 (0.53,1.09)	0.1314	
Any TE hypogammaglobulinemia	0	12/95 (13)	5.0 (5.0,NE)	1/94 (1)	NE (NE,NE)	9.19 (1.18,71.83)	0.0101	0.9903
	1	10/83 (12)	5.1 (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	0	3/95 (3)	NE (NE,NE)	3/94 (3)	NE (NE,NE)	0.89 (0.18,4.43)	0.8890	0.5396
	1	3/83 (4)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	2.12 (0.22,20.76)	0.5092	
Any serious TE bone marrow failure	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	0	1/95 (1)	NE (NE,NE)	1/94 (1)	NE (NE,NE)	0.79 (0.05,12.63)	0.8644	1.0000
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	0	4/95 (4)	15.7 (11.2,NE)	2/94 (2)	24.0 (10.6,NE)	0.70 (0.11,4.42)	0.7073	0.9957
	1	4/83 (5)	29.2 (18.9,NE)	1/74 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.0807	
Any serious TE secondary malignancy	0	4/95 (4)	NE (NE,NE)	2/94 (2)	NE (NE,NE)	1.19 (0.22,6.50)	0.8444	0.8820
	1	4/83 (5)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	1.00 (0.11,8.98)	0.9973	
Any severe TE secondary malignancy (Grade >= 3)	0	3/95 (3)	15.6 (11.2,NE)	2/94 (2)	24.0 (10.6,NE)	0.58 (0.08,4.26)	0.5860	0.9958
	1	3/83 (4)	25.0 (18.9,NE)	1/74 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.0807	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	0	1/95 (1)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	1/83 (1)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	0	3/95 (3)	NE (NE,NE)	2/94 (2)	NE (NE,NE)	1.38 (0.23,8.27)	0.7231	0.9315
	1	2/83 (2)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	1.79 (0.16,19.73)	0.6301	
Any serious TE cardiac failure	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	1	1/83 (1)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	0.90 (0.06,14.36)	0.9396	
Any severe TE cardiac failure (Grade >= 3)	0	1/95 (1)	NE (NE,NE)	2/94 (2)	NE (NE,NE)	0.44 (0.04,4.81)	0.4851	0.7900
	1	1/83 (1)	NE (NE,NE)	1/74 (1)	NE (NE,NE)	0.90 (0.06,14.36)	0.9396	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.4. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	0	51/95 (54)	1.4 (1.1,NE)	23/94 (24)	NE (NE,NE)	2.77 (1.69,4.54)	<0.0001	0.7592
	1	36/83 (43)	NE (1.2,NE)	11/74 (15)	NE (NE,NE)	3.16 (1.61,6.23)	0.0004	
Any serious TE cardiac arrhythmias	0	6/95 (6)	NE (NE,NE)	2/94 (2)	NE (NE,NE)	2.83 (0.57,14.03)	0.1837	0.5938
	1	4/83 (5)	NE (NE,NE)	2/74 (3)	NE (NE,NE)	1.48 (0.27,8.19)	0.6518	
Any severe TE cardiac arrhythmias (Grade >= 3)	0	5/95 (5)	NE (NE,NE)	2/94 (2)	NE (NE,NE)	2.28 (0.44,11.78)	0.3128	0.9921
	1	3/83 (4)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	0	12/95 (13)	5.0 (5.0,NE)	3/94 (3)	17.9 (NE,NE)	5.33 (1.19,23.85)	0.0143	0.9894
	1	10/83 (12)	5.1 (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	0	0/95 (0)	NE (NE,NE)	1/94 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	0	0/95 (0)	NE (NE,NE)	0/94 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	1	0/83 (0)	NE (NE,NE)	0/74 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	North America	138/138 (100)	0.4 (0.2,0.5)	120/120 (100)	0.1 (0.0,0.1)	0.42 (0.32,0.56)	<0.0001	0.0451
	Rest of the world	40/40 (100)	0.8 (0.5,0.9)	48/48 (100)	0.1 (0.1,0.1)	0.29 (0.18,0.48)	<0.0001	
Any serious TEAE	North America	87/138 (63)	2.8 (1.3,9.9)	55/120 (46)	4.1 (3.1,8.6)	1.13 (0.80,1.60)	0.4861	0.4029
	Rest of the world	21/40 (53)	5.7 (1.4,9.3)	23/48 (48)	4.7 (2.1,NE)	0.76 (0.40,1.42)	0.3822	
Any severe TEAE (Grade>=3)	North America	127/138 (92)	0.8 (0.8,0.9)	101/120 (84)	0.5 (0.4,0.6)	0.98 (0.75,1.28)	0.8926	0.1025
	Rest of the world	37/40 (93)	1.1 (1.0,1.2)	39/48 (81)	0.4 (0.4,0.7)	0.75 (0.47,1.19)	0.2101	
Any TE neurologic event	North America	92/138 (67)	1.2 (1.1,1.3)	23/120 (19)	NE (NE,NE)	4.94 (3.12,7.83)	<0.0001	0.0359
	Rest of the world	18/40 (45)	5.2 (1.3,NE)	10/48 (21)	NE (NE,NE)	1.95 (0.89,4.25)	0.0867	
Any serious TE neurologic event	North America	27/138 (20)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9887
	Rest of the world	7/40 (18)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	8.20 (1.01,66.68)	0.0185	
Any severe TE neurologic event (Grade >= 3)	North America	33/138 (24)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	31.73 (4.34,231.99)	<0.0001	0.9905
	Rest of the world	5/40 (13)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	North America	124/138 (90)	1.0 (0.9,1.0)	-	-	-	-	-
	Rest of the world	33/40 (83)	1.2 (1.1,1.3)	-	-	-	-	
Any serious TE CRS	North America	25/138 (18)	NE (NE,NE)	-	-	-	-	-
	Rest of the world	4/40 (10)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	North America	10/138 (7)	NE (NE,NE)	-	-	-	-	-
	Rest of the world	1/40 (3)	NE (NE,NE)	-	-	-	-	
Any TE infection	North America	69/138 (50)	5.0 (3.7,13.8)	36/120 (30)	9.0 (4.6,NE)	1.38 (0.91,2.08)	0.1239	0.9948
	Rest of the world	24/40 (60)	4.0 (2.1,NE)	17/48 (35)	NE (3.2,NE)	1.33 (0.70,2.50)	0.3771	
Any serious TE infection	North America	26/138 (19)	NE (NE,NE)	11/120 (9)	NE (NE,NE)	1.33 (0.65,2.71)	0.4339	0.9547
	Rest of the world	11/40 (28)	NE (14.7,NE)	7/48 (15)	NE (19.9,NE)	1.29 (0.49,3.36)	0.6050	
Any severe TE infection (Grade >= 3)	North America	24/138 (17)	13.8 (5.0,39.8)	12/120 (10)	NE (NE,NE)	1.04 (0.49,2.21)	0.9151	0.6528
	Rest of the world	13/40 (33)	10.1 (8.7,NE)	8/48 (17)	19.9 (NE,NE)	1.39 (0.56,3.46)	0.4727	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	North America	111/138 (80)	0.9 (0.8,1.0)	95/120 (79)	0.8 (0.5,1.5)	0.98 (0.75,1.30)	0.9096	0.0192
	Rest of the world	32/40 (80)	1.2 (1.2,1.4)	40/48 (83)	0.6 (0.4,1.1)	0.61 (0.38,0.98)	0.0374	
Any serious TE cytopenias	North America	11/138 (8)	NE (NE,NE)	26/120 (22)	NE (NE,NE)	0.24 (0.12,0.48)	<0.0001	0.7869
	Rest of the world	1/40 (3)	NE (NE,NE)	5/48 (10)	NE (NE,NE)	0.20 (0.02,1.75)	0.1087	
Any severe TE cytopenias (Grade >= 3)	North America	105/138 (76)	1.0 (0.9,1.0)	90/120 (75)	1.4 (0.7,2.4)	0.95 (0.71,1.27)	0.7239	0.0964
	Rest of the world	30/40 (75)	1.3 (1.2,1.5)	36/48 (75)	0.7 (0.5,1.8)	0.69 (0.42,1.13)	0.1326	
Any TE hypogammaglobulinemia	North America	17/138 (12)	5.1 (5.0,NE)	1/120 (1)	NE (NE,NE)	10.97 (1.44,83.54)	0.0037	0.9917
	Rest of the world	5/40 (13)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	North America	5/138 (4)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	4.00 (0.46,34.34)	0.1726	0.1241
	Rest of the world	1/40 (3)	NE (NE,NE)	3/48 (6)	NE (NE,NE)	0.31 (0.03,2.95)	0.2780	
Any serious TE bone marrow failure	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Rest of the world	1/40 (3)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	0.89 (0.05,14.26)	0.9317	
Any TE secondary malignancy	North America	8/138 (6)	21.9 (11.2,42.3)	3/120 (3)	10.6 (10.6,NE)	0.50 (0.12,2.06)	0.3263	0.9999
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	North America	8/138 (6)	NE (NE,NE)	3/120 (3)	NE (NE,NE)	1.03 (0.27,3.90)	0.9611	1.0000
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	North America	6/138 (4)	21.9 (11.2,NE)	3/120 (3)	10.6 (10.6,NE)	0.59 (0.13,2.60)	0.4837	0.9999
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	North America	1/138 (1)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	1/40 (3)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	North America	5/138 (4)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	4.14 (0.48,35.51)	0.1602	0.9933
	Rest of the world	0/40 (0)	NE (NE,NE)	2/48 (4)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	North America	1/138 (1)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9969
	Rest of the world	0/40 (0)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	North America	2/138 (1)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	1.52 (0.14,16.97)	0.7315	0.9933
	Rest of the world	0/40 (0)	NE (NE,NE)	2/48 (4)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.5. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	North America	73/138 (53)	1.2 (1.1,NE)	28/120 (23)	NE (NE,NE)	2.70 (1.74,4.18)	<0.0001	0.9887
	Rest of the world	14/40 (35)	NE (1.6,NE)	6/48 (13)	NE (NE,NE)	2.96 (1.14,7.71)	0.0195	
Any serious TE cardiac arrhythmias	North America	10/138 (7)	NE (NE,NE)	3/120 (3)	NE (NE,NE)	2.76 (0.76,10.04)	0.1086	0.9918
	Rest of the world	0/40 (0)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac arrhythmias (Grade >= 3)	North America	6/138 (4)	NE (NE,NE)	1/120 (1)	NE (NE,NE)	4.74 (0.57,39.54)	0.1135	0.6142
	Rest of the world	2/40 (5)	NE (NE,NE)	1/48 (2)	NE (NE,NE)	2.02 (0.18,22.41)	0.5598	
Any TE autoimmune disorder	North America	17/138 (12)	5.1 (5.0,NE)	1/120 (1)	NE (NE,NE)	10.97 (1.44,83.54)	0.0037	0.7727
	Rest of the world	5/40 (13)	NE (NE,NE)	2/48 (4)	17.9 (NE,NE)	4.84 (0.56,41.61)	0.1121	
Any serious TE autoimmune disorder	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	1/48 (2)	NE (17.9,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	North America	0/138 (0)	NE (NE,NE)	0/120 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE,NE)	0/48 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	HGBL - double hit/triple hit	32/32 (100)	0.5 (0.1,0.7)	24/24 (100)	0.1 (0.1,0.2)	0.49 (0.28,0.87)	0.0073	0.4338
	Double expressor lymphoma	56/56 (100)	0.2 (0.1,0.5)	62/62 (100)	0.1 (0.0,0.1)	0.41 (0.27,0.63)	<0.0001	
Any serious TEAE	HGBL - double hit/triple hit	22/32 (69)	1.2 (0.9,18.9)	9/24 (38)	4.7 (3.3,NE)	1.95 (0.88,4.33)	0.0928	0.0851
	Double expressor lymphoma	31/56 (55)	25.0 (1.1,34.8)	32/62 (52)	4.6 (2.1,9.0)	0.95 (0.57,1.57)	0.8280	
Any severe TEAE (Grade>=3)	HGBL - double hit/triple hit	32/32 (100)	0.8 (0.6,0.9)	16/24 (67)	1.1 (0.3,3.7)	2.24 (1.18,4.24)	0.0105	0.0037
	Double expressor lymphoma	47/56 (84)	0.9 (0.7,1.1)	56/62 (90)	0.5 (0.4,0.7)	0.69 (0.47,1.03)	0.0628	
Any TE neurologic event	HGBL - double hit/triple hit	25/32 (78)	1.1 (0.9,1.2)	4/24 (17)	NE (NE,NE)	7.85 (2.68,23.03)	<0.0001	0.1748
	Double expressor lymphoma	36/56 (64)	1.4 (1.1,2.7)	13/62 (21)	NE (NE,NE)	3.66 (1.93,6.91)	<0.0001	
Any serious TE neurologic event	HGBL - double hit/triple hit	8/32 (25)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9930
	Double expressor lymphoma	8/56 (14)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	8.52 (1.06,68.25)	0.0153	
Any severe TE neurologic event (Grade >= 3)	HGBL - double hit/triple hit	9/32 (28)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	9/56 (16)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	HGBL - double hit/triple hit	29/32 (91)	0.9 (0.8,1.0)	-	-	-	-	-
	Double expressor lymphoma	51/56 (91)	1.0 (0.9,1.1)	-	-	-	-	
Any serious TE CRS	HGBL - double hit/triple hit	6/32 (19)	NE (NE,NE)	-	-	-	-	-
	Double expressor lymphoma	11/56 (20)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	HGBL - double hit/triple hit	3/32 (9)	NE (NE,NE)	-	-	-	-	-
	Double expressor lymphoma	4/56 (7)	NE (NE,NE)	-	-	-	-	
Any TE infection	HGBL - double hit/triple hit	20/32 (63)	3.1 (1.1,33.9)	5/24 (21)	NE (4.6,NE)	2.56 (0.94,7.01)	0.0570	0.4268
	Double expressor lymphoma	30/56 (54)	4.8 (1.5,NE)	20/62 (32)	9.0 (3.7,NE)	1.48 (0.83,2.64)	0.1753	
Any serious TE infection	HGBL - double hit/triple hit	5/32 (16)	NE (33.9,NE)	2/24 (8)	NE (4.6,NE)	0.83 (0.16,4.32)	0.8257	0.1954
	Double expressor lymphoma	15/56 (27)	NE (34.8,NE)	3/62 (5)	NE (NE,NE)	4.67 (1.35,16.18)	0.0075	
Any severe TE infection (Grade >= 3)	HGBL - double hit/triple hit	6/32 (19)	13.8 (10.9,NE)	3/24 (13)	NE (4.6,NE)	0.33 (0.05,2.04)	0.2134	0.0585
	Double expressor lymphoma	13/56 (23)	10.1 (5.7,NE)	4/62 (6)	NE (NE,NE)	2.75 (0.86,8.79)	0.0741	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	HGBL - double hit/triple hit	27/32 (84)	0.8 (0.6,1.0)	15/24 (63)	1.1 (0.4,NE)	1.62 (0.85,3.08)	0.1323	0.0583
	Double expressor lymphoma	45/56 (80)	1.0 (0.9,1.1)	52/62 (84)	0.7 (0.5,1.8)	0.81 (0.54,1.22)	0.3071	
Any serious TE cytopenias	HGBL - double hit/triple hit	3/32 (9)	NE (NE,NE)	4/24 (17)	NE (3.3,NE)	0.23 (0.05,1.07)	0.0431	0.5302
	Double expressor lymphoma	2/56 (4)	NE (NE,NE)	9/62 (15)	NE (NE,NE)	0.19 (0.04,0.87)	0.0169	
Any severe TE cytopenias (Grade >= 3)	HGBL - double hit/triple hit	26/32 (81)	0.9 (0.8,1.1)	12/24 (50)	3.0 (0.4,NE)	1.92 (0.95,3.86)	0.0616	0.0274
	Double expressor lymphoma	41/56 (73)	1.1 (1.0,1.2)	49/62 (79)	1.1 (0.6,2.4)	0.77 (0.51,1.17)	0.2180	
Any TE hypogammaglobulinemia	HGBL - double hit/triple hit	5/32 (16)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	10/56 (18)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	1/24 (4)	NE (4.3,NE)	NE (NE,NE)	NE	0.9966
	Double expressor lymphoma	1/56 (2)	NE (NE,NE)	2/62 (3)	NE (NE,NE)	0.44 (0.04,4.84)	0.4877	
Any serious TE bone marrow failure	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	HGBL - double hit/triple hit	2/32 (6)	15.0 (11.2,NE)	1/24 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	0.9978
	Double expressor lymphoma	3/56 (5)	25.0 (15.6,NE)	1/62 (2)	NE (NE,NE)	0.00 (0.00,NE)	0.2117	
Any serious TE secondary malignancy	HGBL - double hit/triple hit	2/32 (6)	NE (NE,NE)	1/24 (4)	NE (10.6,NE)	0.41 (0.04,4.49)	0.4473	0.4346
	Double expressor lymphoma	3/56 (5)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	1.76 (0.18,16.95)	0.6208	
Any severe TE secondary malignancy (Grade >= 3)	HGBL - double hit/triple hit	2/32 (6)	15.0 (11.2,NE)	1/24 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	0.9981
	Double expressor lymphoma	2/56 (4)	20.3 (15.6,NE)	1/62 (2)	NE (NE,NE)	0.00 (0.00,NE)	0.2117	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	HGBL - double hit/triple hit	1/32 (3)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	HGBL - double hit/triple hit	2/32 (6)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9951
	Double expressor lymphoma	2/56 (4)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	2.18 (0.20,24.07)	0.5135	
Any serious TE cardiac failure	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	HGBL - double hit/triple hit	1/32 (3)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9971
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	1/62 (2)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.6. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	HGBL - double hit/triple hit	19/32 (59)	1.2 (0.9,NE)	5/24 (21)	NE (3.3,NE)	3.76 (1.40,10.12)	0.0048	0.3072
	Double expressor lymphoma	22/56 (39)	NE (1.4,NE)	12/62 (19)	NE (NE,NE)	2.15 (1.06,4.34)	0.0293	
Any serious TE cardiac arrhythmias	HGBL - double hit/triple hit	4/32 (13)	NE (NE,NE)	2/24 (8)	NE (4.7,NE)	1.43 (0.26,7.84)	0.6801	0.9938
	Double expressor lymphoma	1/56 (2)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac arrhythmias (Grade >= 3)	HGBL - double hit/triple hit	3/32 (9)	NE (NE,NE)	1/24 (4)	NE (4.0,NE)	2.08 (0.21,20.23)	0.5202	0.9951
	Double expressor lymphoma	1/56 (2)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	HGBL - double hit/triple hit	5/32 (16)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	10/56 (18)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	HGBL - double hit/triple hit	0/32 (0)	NE (NE,NE)	0/24 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE,NE)	0/62 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	HGBL - double hit/triple hit	40/40 (100)	0.5 (0.3,0.7)	31/31 (100)	0.1 (0.1,0.2)	0.39 (0.24,0.66)	<0.0001	0.6561
	Double expressor lymphoma	44/44 (100)	0.3 (0.1,0.6)	33/33 (100)	0.1 (0.0,0.1)	0.54 (0.33,0.87)	0.0048	
Any serious TEAE	HGBL - double hit/triple hit	26/40 (65)	1.3 (1.0,18.9)	14/31 (45)	4.1 (3.1,NE)	1.21 (0.61,2.38)	0.5815	0.9979
	Double expressor lymphoma	30/44 (68)	1.4 (0.9,18.0)	14/33 (42)	32.2 (1.1,NE)	1.38 (0.72,2.64)	0.3258	
Any severe TEAE (Grade>=3)	HGBL - double hit/triple hit	39/40 (98)	0.8 (0.7,0.9)	24/31 (77)	0.5 (0.4,1.1)	1.35 (0.80,2.26)	0.2489	0.1619
	Double expressor lymphoma	40/44 (91)	0.8 (0.7,1.0)	28/33 (85)	0.5 (0.3,0.5)	0.80 (0.49,1.31)	0.3667	
Any TE neurologic event	HGBL - double hit/triple hit	27/40 (68)	1.1 (1.0,1.2)	5/31 (16)	NE (NE,NE)	6.06 (2.31,15.85)	<0.0001	0.8870
	Double expressor lymphoma	28/44 (64)	1.3 (1.1,2.8)	5/33 (15)	NE (NE,NE)	6.07 (2.34,15.79)	<0.0001	
Any serious TE neurologic event	HGBL - double hit/triple hit	10/40 (25)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	HGBL - double hit/triple hit	11/40 (28)	NE (NE,NE)	1/31 (3)	NE (NE,NE)	9.65 (1.25,74.77)	0.0076	0.9932
	Double expressor lymphoma	8/44 (18)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	HGBL - double hit/triple hit	37/40 (93)	0.9 (0.8,1.0)	-	-	-	-	-
	Double expressor lymphoma	38/44 (86)	1.0 (0.9,1.1)	-	-	-	-	
Any serious TE CRS	HGBL - double hit/triple hit	5/40 (13)	NE (NE,NE)	-	-	-	-	-
	Double expressor lymphoma	13/44 (30)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	HGBL - double hit/triple hit	2/40 (5)	NE (NE,NE)	-	-	-	-	-
	Double expressor lymphoma	6/44 (14)	NE (NE,NE)	-	-	-	-	
Any TE infection	HGBL - double hit/triple hit	24/40 (60)	5.0 (1.4,23.7)	9/31 (29)	NE (4.6,NE)	1.48 (0.66,3.30)	0.3335	0.7232
	Double expressor lymphoma	24/44 (55)	3.4 (1.6,NE)	9/33 (27)	NE (3.4,NE)	1.84 (0.85,4.00)	0.1153	
Any serious TE infection	HGBL - double hit/triple hit	8/40 (20)	NE (43.4,NE)	5/31 (16)	NE (6.5,NE)	0.62 (0.20,1.90)	0.3959	0.2498
	Double expressor lymphoma	11/44 (25)	NE (34.8,NE)	2/33 (6)	NE (NE,NE)	2.88 (0.62,13.32)	0.1585	
Any severe TE infection (Grade >= 3)	HGBL - double hit/triple hit	9/40 (23)	13.8 (5.0,NE)	6/31 (19)	19.9 (4.6,NE)	0.55 (0.18,1.66)	0.2778	0.1827
	Double expressor lymphoma	13/44 (30)	23.4 (8.7,NE)	3/33 (9)	NE (NE,NE)	2.33 (0.64,8.52)	0.1874	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	HGBL - double hit/triple hit	32/40 (80)	0.8 (0.7,1.0)	22/31 (71)	0.8 (0.4,3.0)	1.11 (0.64,1.91)	0.7158	0.2396
	Double expressor lymphoma	37/44 (84)	1.0 (0.8,1.2)	29/33 (88)	0.5 (0.4,1.1)	0.73 (0.44,1.19)	0.1937	
Any serious TE cytopenias	HGBL - double hit/triple hit	3/40 (8)	NE (NE,NE)	6/31 (19)	NE (3.3,NE)	0.20 (0.05,0.81)	0.0138	0.7540
	Double expressor lymphoma	3/44 (7)	NE (NE,NE)	8/33 (24)	NE (NE,NE)	0.21 (0.05,0.79)	0.0114	
Any severe TE cytopenias (Grade >= 3)	HGBL - double hit/triple hit	31/40 (78)	0.9 (0.8,1.1)	20/31 (65)	1.0 (0.4,3.7)	1.09 (0.62,1.92)	0.7679	0.2740
	Double expressor lymphoma	35/44 (80)	1.0 (0.9,1.2)	28/33 (85)	0.5 (0.5,2.5)	0.71 (0.43,1.17)	0.1731	
Any TE hypogammaglobulinemia	HGBL - double hit/triple hit	6/40 (15)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	HGBL - double hit/triple hit	1/40 (3)	NE (NE,NE)	1/31 (3)	NE (NE,NE)	0.63 (0.04,10.23)	0.7419	1.0000
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE bone marrow failure	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	HGBL - double hit/triple hit	2/40 (5)	15.0 (11.2,NE)	1/31 (3)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	NE
	Double expressor lymphoma	3/44 (7)	33.4 (25.0,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	HGBL - double hit/triple hit	2/40 (5)	NE (NE,NE)	1/31 (3)	NE (10.6,NE)	0.75 (0.07,8.27)	0.8121	0.9957
	Double expressor lymphoma	3/44 (7)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	HGBL - double hit/triple hit	2/40 (5)	15.0 (11.2,NE)	1/31 (3)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	NE
	Double expressor lymphoma	2/44 (5)	29.2 (25.0,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	HGBL - double hit/triple hit	1/40 (3)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	HGBL - double hit/triple hit	2/40 (5)	NE (NE,NE)	1/31 (3)	NE (NE,NE)	1.38 (0.12,15.38)	0.7910	0.9960
	Double expressor lymphoma	2/44 (5)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/44 (2)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	HGBL - double hit/triple hit	1/40 (3)	NE (NE,NE)	1/31 (3)	NE (NE,NE)	0.63 (0.04,10.21)	0.7426	0.9969
	Double expressor lymphoma	1/44 (2)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.7. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	HGBL - double hit/triple hit	23/40 (58)	1.2 (0.9,NE)	6/31 (19)	NE (4.0,NE)	3.89 (1.58,9.58)	0.0014	0.9059
	Double expressor lymphoma	24/44 (55)	1.4 (1.1,NE)	5/33 (15)	NE (4.6,NE)	4.63 (1.76,12.17)	0.0006	
Any serious TE cardiac arrhythmias	HGBL - double hit/triple hit	4/40 (10)	NE (NE,NE)	2/31 (6)	NE (NE,NE)	1.46 (0.27,8.00)	0.6615	0.9946
	Double expressor lymphoma	3/44 (7)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac arrhythmias (Grade >= 3)	HGBL - double hit/triple hit	2/40 (5)	NE (NE,NE)	1/31 (3)	NE (NE,NE)	1.34 (0.12,15.05)	0.8100	0.9953
	Double expressor lymphoma	4/44 (9)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	HGBL - double hit/triple hit	6/40 (15)	NE (NE,NE)	1/31 (3)	17.9 (NE,NE)	> 10,000 (0.00,NE)	0.0435	0.9999
	Double expressor lymphoma	5/44 (11)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	1/31 (3)	NE (17.9,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	HGBL - double hit/triple hit	0/40 (0)	NE (NE,NE)	0/31 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE,NE)	0/33 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Germinal center B-cell like	107/107 (100)	0.5 (0.2,0.6)	100/100 (100)	0.1 (0.1,0.1)	0.41 (0.30,0.55)	<0.0001	0.2762
	Activated B-cell like	16/16 (100)	0.2 (0.0,0.3)	9/9 (100)	0.0 (0.0,0.3)	0.91 (0.39,2.16)	0.7911	
	Unclassified	18/18 (100)	0.7 (0.0,0.8)	12/12 (100)	0.1 (0.0,0.4)	0.30 (0.12,0.75)	0.0028	
Any serious TEAE	Germinal center B-cell like	61/107 (57)	5.0 (1.4,9.9)	49/100 (49)	4.1 (2.8,NE)	0.92 (0.62,1.36)	0.6616	0.5389
	Activated B-cell like	10/16 (63)	1.4 (0.6,NE)	3/9 (33)	3.7 (2.3,NE)	1.98 (0.53,7.39)	0.2972	
	Unclassified	14/18 (78)	1.4 (0.9,42.4)	4/12 (33)	NE (0.5,NE)	1.75 (0.56,5.53)	0.3304	
Any severe TEAE (Grade>=3)	Germinal center B-cell like	98/107 (92)	0.9 (0.8,1.0)	84/100 (84)	0.5 (0.4,0.5)	0.87 (0.65,1.18)	0.3631	0.4045
	Activated B-cell like	14/16 (88)	0.8 (0.4,1.1)	8/9 (89)	2.2 (0.1,3.5)	1.61 (0.64,4.00)	0.2992	
	Unclassified	16/18 (89)	0.9 (0.7,1.1)	9/12 (75)	0.5 (0.2,NE)	0.77 (0.33,1.78)	0.5405	
Any TE neurologic event	Germinal center B-cell like	63/107 (59)	1.2 (1.1,3.1)	20/100 (20)	NE (NE,NE)	3.84 (2.32,6.36)	<0.0001	0.7371
	Activated B-cell like	11/16 (69)	1.2 (1.0,1.5)	1/9 (11)	NE (0.0,NE)	8.40 (1.07,65.68)	0.0148	
	Unclassified	13/18 (72)	1.2 (1.1,1.9)	2/12 (17)	3.5 (2.3,NE)	6.03 (1.35,26.97)	0.0074	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

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Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any serious TE neurologic event	Germinal center B-cell like	21/107 (20)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	21.10 (2.84,156.91)	<0.0001	0.9999
	Activated B-cell like	2/16 (13)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Germinal center B-cell like	25/107 (23)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	25.26 (3.42,186.43)	<0.0001	0.9999
	Activated B-cell like	2/16 (13)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE CRS	Germinal center B-cell like	94/107 (88)	1.0 (0.9,1.0)	-	-	-	-	-
	Activated B-cell like	13/16 (81)	1.1 (0.8,1.1)	-	-	-	-	
	Unclassified	16/18 (89)	1.0 (0.9,1.2)	-	-	-	-	
Any serious TE CRS	Germinal center B-cell like	16/107 (15)	NE (NE,NE)	-	-	-	-	-
	Activated B-cell like	3/16 (19)	NE (1.3,NE)	-	-	-	-	
	Unclassified	6/18 (33)	NE (1.2,NE)	-	-	-	-	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any severe TE CRS (Grade >= 3)	Germinal center B-cell like	5/107 (5)	NE (NE,NE)	-	-	-	-	-
	Activated B-cell like	1/16 (6)	NE (NE,NE)	-	-	-	-	
	Unclassified	4/18 (22)	NE (NE,NE)	-	-	-	-	
Any TE infection	Germinal center B-cell like	52/107 (49)	5.0 (4.3,13.8)	28/100 (28)	NE (4.8,NE)	1.38 (0.86,2.22)	0.1749	0.8159
	Activated B-cell like	8/16 (50)	3.5 (0.7,NE)	2/9 (22)	3.2 (2.8,NE)	2.01 (0.41,9.79)	0.3783	
	Unclassified	15/18 (83)	1.2 (1.0,4.0)	5/12 (42)	3.5 (0.5,NE)	1.68 (0.59,4.79)	0.3174	
Any serious TE infection	Germinal center B-cell like	16/107 (15)	NE (NE,NE)	8/100 (8)	NE (NE,NE)	1.11 (0.47,2.63)	0.8041	0.9999
	Activated B-cell like	3/16 (19)	NE (10.1,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	9/18 (50)	42.4 (3.3,NE)	2/12 (17)	NE (1.4,NE)	1.58 (0.33,7.60)	0.5664	
Any severe TE infection (Grade >= 3)	Germinal center B-cell like	19/107 (18)	13.8 (5.0,39.8)	11/100 (11)	NE (NE,NE)	0.81 (0.35,1.87)	0.6183	0.9882
	Activated B-cell like	4/16 (25)	10.1 (1.6,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	6/18 (33)	5.7 (3.3,NE)	3/12 (25)	NE (0.5,NE)	0.93 (0.22,3.95)	0.9231	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

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Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Germinal center B-cell like	89/107 (83)	0.9 (0.9,1.0)	81/100 (81)	0.7 (0.5,1.3)	0.96 (0.71,1.30)	0.7868	0.1646
	Activated B-cell like	14/16 (88)	1.0 (0.7,1.1)	7/9 (78)	1.1 (0.3,NE)	2.33 (0.81,6.71)	0.0935	
	Unclassified	10/18 (56)	1.5 (0.8,NE)	8/12 (67)	0.6 (0.3,NE)	0.53 (0.21,1.35)	0.1759	
Any serious TE cytopenias	Germinal center B-cell like	7/107 (7)	NE (NE,NE)	22/100 (22)	NE (NE,NE)	0.20 (0.08,0.47)	<0.0001	0.9589
	Activated B-cell like	1/16 (6)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE,NE)	1/12 (8)	NE (NE,NE)	0.34 (0.02,6.40)	0.4579	
Any severe TE cytopenias (Grade >= 3)	Germinal center B-cell like	86/107 (80)	1.0 (0.9,1.1)	75/100 (75)	1.2 (0.6,2.5)	1.03 (0.75,1.41)	0.8451	0.4267
	Activated B-cell like	10/16 (63)	1.1 (0.7,NE)	6/9 (67)	3.1 (0.3,NE)	1.02 (0.36,2.85)	0.9729	
	Unclassified	10/18 (56)	1.5 (0.9,NE)	7/12 (58)	0.8 (0.3,NE)	0.62 (0.23,1.63)	0.3223	
Any TE hypogammaglobulinemia	Germinal center B-cell like	9/107 (8)	5.0 (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	5/16 (31)	5.1 (2.5,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	5.4 (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any serious TE hypogammaglobulinemia	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE bone marrow failure	Germinal center B-cell like	3/107 (3)	NE (NE,NE)	2/100 (2)	NE (NE,NE)	1.31 (0.22,7.84)	0.7683	0.8094
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE,NE)	1/12 (8)	NE (4.3,NE)	0.24 (0.01,4.11)	0.2860	
Any serious TE bone marrow failure	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any severe TE bone marrow failure (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Germinal center B-cell like	5/107 (5)	18.9 (11.2,NE)	1/100 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1926	1.0000
	Activated B-cell like	2/16 (13)	33.7 (25.0,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	15.8 (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	Germinal center B-cell like	5/107 (5)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	2.25 (0.26,19.29)	0.4487	1.0000
	Activated B-cell like	2/16 (13)	NE (25.0,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	Germinal center B-cell like	5/107 (5)	18.9 (11.2,NE)	1/100 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1926	1.0000
	Activated B-cell like	1/16 (6)	25.0 (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any serious TE graft-versus-host disease	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE Immunogenicity (anti-axi-cel antibody)	Germinal center B-cell like	1/107 (1)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any severe TE Immunogenicity (anti-axicel antibody) (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	Germinal center B-cell like	3/107 (3)	NE (NE,NE)	3/100 (3)	NE (NE,NE)	0.87 (0.18,4.32)	0.8656	1.0000
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	Germinal center B-cell like	1/107 (1)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	0.92 (0.06,14.77)	0.9555	1.0000
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	Germinal center B-cell like	1/107 (1)	NE (NE,NE)	3/100 (3)	NE (NE,NE)	0.28 (0.03,2.66)	0.2332	1.0000
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Germinal center B-cell like	57/107 (53)	1.6 (1.1,NE)	22/100 (22)	NE (NE,NE)	2.94 (1.80,4.82)	<0.0001	0.9003
	Activated B-cell like	7/16 (44)	NE (0.9,NE)	1/9 (11)	NE (0.7,NE)	5.13 (0.63,41.80)	0.0861	
	Unclassified	8/18 (44)	NE (1.1,NE)	2/12 (17)	NE (3.4,NE)	2.67 (0.56,12.67)	0.1953	
Any serious TE cardiac arrhythmias	Germinal center B-cell like	6/107 (6)	NE (NE,NE)	3/100 (3)	NE (NE,NE)	1.70 (0.42,6.81)	0.4498	1.0000
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac arrhythmias (Grade >= 3)	Germinal center B-cell like	5/107 (5)	NE (NE,NE)	1/100 (1)	NE (NE,NE)	4.26 (0.50,36.58)	0.1500	1.0000
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	Germinal center B-cell like	9/107 (8)	5.0 (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	5/16 (31)	5.1 (2.5,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	5.4 (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

Table 14.3.1.2.8. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any serious TE autoimmune disorder	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Germinal center B-cell like	0/107 (0)	NE (NE,NE)	0/100 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE,NE)	0/9 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE,NE)	0/12 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240602T17:59

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Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Germinal center B-cell like	94/94 (100)	0.5 (0.3,0.6)	78/78 (100)	0.1 (0.1,0.1)	0.46 (0.33,0.64)	<0.0001	0.2359
	Non-germinal center B-cell like	47/47 (100)	0.4 (0.2,0.6)	49/49 (100)	0.1 (0.0,0.1)	0.32 (0.20,0.52)	<0.0001	
Any serious TEAE	Germinal center B-cell like	54/94 (57)	2.8 (1.3,5.7)	36/78 (46)	4.6 (3.0,NE)	1.25 (0.81,1.91)	0.3072	0.5749
	Non-germinal center B-cell like	29/47 (62)	4.0 (1.2,25.0)	19/49 (39)	9.0 (2.9,NE)	1.14 (0.62,2.10)	0.6727	
Any severe TEAE (Grade>=3)	Germinal center B-cell like	86/94 (91)	0.8 (0.8,0.9)	61/78 (78)	0.6 (0.4,1.2)	1.18 (0.85,1.65)	0.3187	0.0411
	Non-germinal center B-cell like	43/47 (91)	1.0 (0.8,1.1)	42/49 (86)	0.5 (0.3,0.5)	0.70 (0.45,1.08)	0.0968	
Any TE neurologic event	Germinal center B-cell like	57/94 (61)	1.3 (1.2,2.0)	14/78 (18)	NE (NE,NE)	4.24 (2.35,7.63)	<0.0001	0.4938
	Non-germinal center B-cell like	27/47 (57)	1.5 (1.2,NE)	11/49 (22)	NE (3.5,NE)	3.04 (1.51,6.16)	0.0011	
Any serious TE neurologic event	Germinal center B-cell like	20/94 (21)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	6/47 (13)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Germinal center B-cell like	26/94 (28)	NE (NE,NE)	1/78 (1)	NE (NE,NE)	23.55 (3.20,173.59)	<0.0001	0.9913
	Non-germinal center B-cell like	3/47 (6)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Germinal center B-cell like	84/94 (89)	1.0 (0.9,1.0)	-	-	-	-	-
	Non-germinal center B-cell like	38/47 (81)	1.1 (1.0,1.2)	-	-	-	-	
Any serious TE CRS	Germinal center B-cell like	16/94 (17)	NE (NE,NE)	-	-	-	-	-
	Non-germinal center B-cell like	7/47 (15)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Germinal center B-cell like	5/94 (5)	NE (NE,NE)	-	-	-	-	-
	Non-germinal center B-cell like	3/47 (6)	NE (NE,NE)	-	-	-	-	
Any TE infection	Germinal center B-cell like	45/94 (48)	4.9 (3.1,10.9)	23/78 (29)	NE (4.8,NE)	1.46 (0.87,2.42)	0.1460	0.6439
	Non-germinal center B-cell like	23/47 (49)	5.7 (3.5,NE)	15/49 (31)	9.0 (3.5,NE)	1.13 (0.58,2.22)	0.7144	
Any serious TE infection	Germinal center B-cell like	13/94 (14)	NE (NE,NE)	7/78 (9)	NE (NE,NE)	1.15 (0.45,2.90)	0.7743	0.5517
	Non-germinal center B-cell like	12/47 (26)	NE (29.1,NE)	5/49 (10)	NE (33.0,NE)	1.58 (0.55,4.55)	0.3939	
Any severe TE infection (Grade >= 3)	Germinal center B-cell like	16/94 (17)	10.9 (5.0,NE)	9/78 (12)	19.9 (NE,NE)	1.38 (0.58,3.24)	0.4637	0.9522
	Non-germinal center B-cell like	11/47 (23)	10.1 (5.7,NE)	4/49 (8)	NE (NE,NE)	1.68 (0.49,5.77)	0.4058	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Germinal center B-cell like	77/94 (82)	0.9 (0.8,1.0)	60/78 (77)	1.0 (0.6,1.7)	1.06 (0.76,1.50)	0.7195	0.0791
	Non-germinal center B-cell like	34/47 (72)	1.1 (0.9,1.2)	41/49 (84)	0.5 (0.5,1.0)	0.66 (0.42,1.04)	0.0671	
Any serious TE cytopenias	Germinal center B-cell like	7/94 (7)	NE (NE,NE)	14/78 (18)	NE (NE,NE)	0.26 (0.11,0.66)	0.0023	0.4179
	Non-germinal center B-cell like	2/47 (4)	NE (NE,NE)	9/49 (18)	NE (NE,NE)	0.16 (0.03,0.79)	0.0109	
Any severe TE cytopenias (Grade >= 3)	Germinal center B-cell like	72/94 (77)	1.1 (0.9,1.1)	55/78 (71)	1.8 (0.8,2.8)	1.07 (0.75,1.53)	0.7011	0.0619
	Non-germinal center B-cell like	32/47 (68)	1.1 (1.0,1.2)	40/49 (82)	0.7 (0.5,1.6)	0.62 (0.39,0.99)	0.0399	
Any TE hypogammaglobulinemia	Germinal center B-cell like	12/94 (13)	5.0 (5.0,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9924
	Non-germinal center B-cell like	7/47 (15)	5.4 (NE,NE)	1/49 (2)	NE (NE,NE)	4.64 (0.55,38.92)	0.1211	
Any serious TE hypogammaglobulinemia	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Germinal center B-cell like	2/94 (2)	NE (NE,NE)	2/78 (3)	NE (NE,NE)	0.69 (0.10,4.92)	0.7078	0.9936
	Non-germinal center B-cell like	2/47 (4)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE bone marrow failure	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	1/47 (2)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Germinal center B-cell like	2/94 (2)	13.4 (11.2,NE)	2/78 (3)	10.6 (NE,NE)	0.00 (0.00,NE)	0.0464	0.9987
	Non-germinal center B-cell like	3/47 (6)	25.0 (15.8,NE)	1/49 (2)	37.4 (NE,NE)	1.14 (0.10,13.27)	0.9183	
Any serious TE secondary malignancy	Germinal center B-cell like	2/94 (2)	NE (NE,NE)	2/78 (3)	NE (NE,NE)	0.45 (0.06,3.23)	0.4174	0.5391
	Non-germinal center B-cell like	3/47 (6)	NE (NE,NE)	1/49 (2)	NE (37.4,NE)	1.00 (0.10,9.70)	0.9991	
Any severe TE secondary malignancy (Grade >= 3)	Germinal center B-cell like	2/94 (2)	13.4 (11.2,NE)	2/78 (3)	10.6 (NE,NE)	0.00 (0.00,NE)	0.0464	0.9989
	Non-germinal center B-cell like	1/47 (2)	25.0 (NE,NE)	1/49 (2)	37.4 (NE,NE)	> 10,000 (0.00,NE)	0.3173	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	1/49 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	1/49 (2)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	Germinal center B-cell like	2/94 (2)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	Germinal center B-cell like	3/94 (3)	NE (NE,NE)	2/78 (3)	NE (NE,NE)	1.10 (0.18,6.64)	0.9150	0.9930
	Non-germinal center B-cell like	2/47 (4)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	1/47 (2)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	Germinal center B-cell like	1/94 (1)	NE (NE,NE)	2/78 (3)	NE (NE,NE)	0.33 (0.03,3.69)	0.3458	0.9947
	Non-germinal center B-cell like	1/47 (2)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.9. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Germinal center B-cell like	52/94 (55)	1.2 (1.1,NE)	11/78 (14)	NE (NE,NE)	5.25 (2.74,10.09)	<0.0001	0.0047
	Non-germinal center B-cell like	16/47 (34)	NE (1.4,NE)	13/49 (27)	NE (3.4,NE)	1.22 (0.58,2.54)	0.5941	
Any serious TE cardiac arrhythmias	Germinal center B-cell like	4/94 (4)	NE (NE,NE)	2/78 (3)	NE (NE,NE)	1.47 (0.27,8.07)	0.6567	0.6921
	Non-germinal center B-cell like	3/47 (6)	NE (NE,NE)	1/49 (2)	NE (NE,NE)	2.83 (0.29,27.37)	0.3491	
Any severe TE cardiac arrhythmias (Grade >= 3)	Germinal center B-cell like	2/94 (2)	NE (NE,NE)	1/78 (1)	NE (NE,NE)	1.45 (0.13,16.13)	0.7614	0.7531
	Non-germinal center B-cell like	1/47 (2)	NE (NE,NE)	1/49 (2)	NE (4.8,NE)	0.64 (0.04,11.04)	0.7568	
Any TE autoimmune disorder	Germinal center B-cell like	12/94 (13)	5.0 (5.0,NE)	1/78 (1)	17.9 (NE,NE)	> 10,000 (0.00,NE)	0.0028	0.9916
	Non-germinal center B-cell like	7/47 (15)	5.4 (NE,NE)	1/49 (2)	NE (NE,NE)	4.64 (0.55,38.92)	0.1211	
Any serious TE autoimmune disorder	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	1/78 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Germinal center B-cell like	0/94 (0)	NE (NE,NE)	0/78 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE,NE)	0/49 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Diffuse large B-cell lymphoma	125/125 (100)	0.4 (0.2,0.5)	119/119 (100)	0.1 (NE,NE)	0.40 (0.30,0.53)	<0.0001	0.5099
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	32/32 (100)	0.5 (0.1,0.7)	25/25 (100)	0.1 (0.1,0.2)	0.48 (0.27,0.85)	0.0051	
Any serious TEAE	Diffuse large B-cell lymphoma	74/125 (59)	4.0 (1.4,9.9)	57/119 (48)	4.9 (2.8,8.6)	0.98 (0.69,1.40)	0.9125	0.0693
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	22/32 (69)	1.2 (0.9,18.9)	9/25 (36)	4.7 (3.3,NE)	2.07 (0.93,4.59)	0.0662	
Any severe TEAE (Grade>=3)	Diffuse large B-cell lymphoma	112/125 (90)	0.9 (0.8,1.0)	101/119 (85)	0.5 (0.4,0.5)	0.79 (0.60,1.04)	0.0905	0.0076
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	32/32 (100)	0.8 (0.6,0.9)	17/25 (68)	1.1 (0.3,3.7)	2.08 (1.11,3.88)	0.0180	
Any TE neurologic event	Diffuse large B-cell lymphoma	74/125 (59)	1.3 (1.2,2.7)	22/119 (18)	NE (NE,NE)	3.98 (2.47,6.42)	<0.0001	0.1597
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	25/32 (78)	1.1 (0.9,1.2)	4/25 (16)	NE (NE,NE)	8.23 (2.80,24.13)	<0.0001	
Any serious TE neurologic event	Diffuse large B-cell lymphoma	22/125 (18)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	20.77 (2.80,154.17)	<0.0001	0.9888
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/32 (25)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Diffuse large B-cell lymphoma	25/125 (20)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	24.68 (3.34,182.15)	<0.0001	0.9877
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Diffuse large B-cell lymphoma	109/125 (87)	1.0 (1.0,1.1)	-	-	-	-	-
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/32 (91)	0.9 (0.8,1.0)	-	-	-	-	
Any serious TE CRS	Diffuse large B-cell lymphoma	20/125 (16)	NE (NE,NE)	-	-	-	-	-
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Diffuse large B-cell lymphoma	7/125 (6)	NE (NE,NE)	-	-	-	-	-
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE,NE)	-	-	-	-	
Any TE infection	Diffuse large B-cell lymphoma	64/125 (51)	4.8 (3.5,19.8)	38/119 (32)	9.0 (4.4,NE)	1.35 (0.90,2.03)	0.1458	0.2434
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	20/32 (63)	3.1 (1.1,33.9)	5/25 (20)	NE (4.6,NE)	2.71 (0.99,7.42)	0.0427	
Any serious TE infection	Diffuse large B-cell lymphoma	28/125 (22)	NE (NE,NE)	12/119 (10)	NE (NE,NE)	1.66 (0.84,3.28)	0.1410	0.7396
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/32 (16)	NE (33.9,NE)	2/25 (8)	NE (4.6,NE)	0.93 (0.18,4.82)	0.9306	
Any severe TE infection (Grade >= 3)	Diffuse large B-cell lymphoma	25/125 (20)	10.1 (5.7,27.1)	14/119 (12)	19.9 (NE,NE)	1.18 (0.60,2.34)	0.6346	0.2987
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	13.8 (10.9,NE)	3/25 (12)	NE (4.6,NE)	0.36 (0.06,2.22)	0.2545	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Diffuse large B-cell lymphoma	100/125 (80)	1.0 (0.9,1.1)	96/119 (81)	0.7 (0.5,1.4)	0.85 (0.64,1.13)	0.2663	0.0674
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	27/32 (84)	0.8 (0.6,1.0)	16/25 (64)	1.1 (0.4,NE)	1.52 (0.81,2.86)	0.1790	
Any serious TE cytopenias	Diffuse large B-cell lymphoma	8/125 (6)	NE (NE,NE)	21/119 (18)	NE (NE,NE)	0.27 (0.12,0.61)	0.0008	0.6220
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE,NE)	4/25 (16)	NE (3.3,NE)	0.27 (0.06,1.22)	0.0689	
Any severe TE cytopenias (Grade >= 3)	Diffuse large B-cell lymphoma	93/125 (74)	1.1 (1.0,1.2)	91/119 (76)	1.1 (0.7,2.4)	0.84 (0.62,1.12)	0.2242	0.0343
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	26/32 (81)	0.9 (0.8,1.1)	13/25 (52)	3.0 (0.4,NE)	1.77 (0.89,3.49)	0.0942	
Any TE hypogammaglobulinemia	Diffuse large B-cell lymphoma	17/125 (14)	5.1 (5.0,NE)	1/119 (1)	NE (NE,NE)	11.56 (1.52,87.99)	0.0028	0.9903
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/32 (16)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Diffuse large B-cell lymphoma	4/125 (3)	NE (NE,NE)	2/119 (2)	NE (NE,NE)	1.67 (0.30,9.12)	0.5507	0.9940
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	1/25 (4)	NE (4.3,NE)	NE (NE,NE)	NE	
Any serious TE bone marrow failure	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Diffuse large B-cell lymphoma	1/125 (1)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	0.69 (0.04,11.09)	0.7906	1.0000
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Diffuse large B-cell lymphoma	6/125 (5)	29.2 (15.6,NE)	1/119 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1737	0.9963
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	15.0 (11.2,NE)	1/25 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	
Any serious TE secondary malignancy	Diffuse large B-cell lymphoma	6/125 (5)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	2.87 (0.34,23.89)	0.3075	0.3295
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (NE,NE)	1/25 (4)	NE (10.6,NE)	0.53 (0.05,5.85)	0.5976	
Any severe TE secondary malignancy (Grade >= 3)	Diffuse large B-cell lymphoma	4/125 (3)	29.2 (15.6,NE)	1/119 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1737	0.9975
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	15.0 (11.2,NE)	1/25 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	Diffuse large B-cell lymphoma	1/125 (1)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	Diffuse large B-cell lymphoma	2/125 (2)	NE (NE,NE)	2/119 (2)	NE (NE,NE)	0.85 (0.12,6.08)	0.8720	0.9941
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	2/119 (2)	NE (NE,NE)	NE (NE,NE)	NE	0.9971
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.10. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Diffuse large B-cell lymphoma	61/125 (49)	2.1 (1.2,NE)	24/119 (20)	NE (NE,NE)	2.82 (1.76,4.53)	<0.0001	0.6600
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/32 (59)	1.2 (0.9,NE)	6/25 (24)	NE (4.0,NE)	3.30 (1.31,8.31)	0.0070	
Any serious TE cardiac arrhythmias	Diffuse large B-cell lymphoma	5/125 (4)	NE (NE,NE)	2/119 (2)	NE (NE,NE)	2.06 (0.40,10.67)	0.3780	0.7961
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE,NE)	2/25 (8)	NE (4.7,NE)	1.51 (0.27,8.25)	0.6352	
Any severe TE cardiac arrhythmias (Grade >= 3)	Diffuse large B-cell lymphoma	5/125 (4)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	4.10 (0.48,35.26)	0.1642	0.7223
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE,NE)	1/25 (4)	NE (4.0,NE)	2.19 (0.23,21.29)	0.4884	
Any TE autoimmune disorder	Diffuse large B-cell lymphoma	17/125 (14)	5.1 (5.0,NE)	2/119 (2)	17.9 (NE,NE)	13.40 (1.78,100.89)	0.0011	0.9905
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/32 (16)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	1/119 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE,NE)	0/119 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Diffuse large B-cell lymphoma not otherwise specified	108/108 (100)	0.3 (0.2,0.6)	110/110 (100)	0.1 (NE,NE)	0.43 (0.32,0.58)	<0.0001	0.8106
	Large cell transformation from follicular lymphoma	19/19 (100)	0.5 (0.1,0.9)	25/25 (100)	0.1 (0.0,0.1)	0.31 (0.15,0.64)	0.0002	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	43/43 (100)	0.5 (0.3,0.7)	25/25 (100)	0.1 (0.0,0.2)	0.32 (0.18,0.57)	<0.0001	
	Other	8/8 (100)	0.5 (0.0,0.8)	8/8 (100)	0.1 (0.0,0.3)	0.38 (0.12,1.21)	0.0585	
Any serious TEAE	Diffuse large B-cell lymphoma not otherwise specified	63/108 (58)	4.0 (1.4,18.0)	47/110 (43)	4.9 (3.0,9.0)	1.11 (0.75,1.63)	0.6041	0.6353
	Large cell transformation from follicular lymphoma	12/19 (63)	9.3 (0.9,NE)	15/25 (60)	2.8 (0.8,NE)	0.64 (0.28,1.47)	0.2878	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	27/43 (63)	3.6 (1.0,18.9)	11/25 (44)	4.7 (3.1,NE)	1.27 (0.62,2.62)	0.5119	
	Other	6/8 (75)	1.2 (0.9,NE)	5/8 (63)	2.2 (0.2,NE)	0.91 (0.26,3.18)	0.8851	
Any severe TEAE (Grade>=3)	Diffuse large B-cell lymphoma not otherwise specified	97/108 (90)	0.9 (0.8,1.0)	91/110 (83)	0.5 (0.4,0.5)	0.87 (0.65,1.17)	0.3506	0.3523
	Large cell transformation from follicular lymphoma	17/19 (89)	1.1 (0.6,1.2)	22/25 (88)	0.5 (0.3,1.0)	0.76 (0.40,1.45)	0.4026	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	42/43 (98)	0.8 (0.7,0.9)	20/25 (80)	0.5 (0.4,1.1)	1.34 (0.78,2.31)	0.2758	
	Other	8/8 (100)	1.0 (0.0,NE)	7/8 (88)	0.3 (0.0,1.2)	0.68 (0.24,1.91)	0.4332	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE neurologic event	Diffuse large B-cell lymphoma not otherwise specified	69/108 (64)	1.3 (1.2,1.5)	18/110 (16)	NE (NE,NE)	5.04 (2.99,8.50)	<0.0001	0.1512
	Large cell transformation from follicular lymphoma	10/19 (53)	2.8 (1.0,NE)	7/25 (28)	NE (2.8,NE)	2.16 (0.82,5.68)	0.1096	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	28/43 (65)	1.2 (1.0,NE)	5/25 (20)	NE (NE,NE)	4.17 (1.60,10.88)	0.0014	
	Other	3/8 (38)	NE (0.2,NE)	3/8 (38)	3.0 (0.8,NE)	0.92 (0.18,4.62)	0.9227	
Any serious TE neurologic event	Diffuse large B-cell lymphoma not otherwise specified	20/108 (19)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (27.6,NE)	1/25 (4)	NE (NE,NE)	3.08 (0.31,30.60)	0.3131	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/43 (21)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (1.2,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	24/108 (22)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/43 (23)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	6.38 (0.82,49.86)	0.0421	
	Other	2/8 (25)	NE (1.4,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Diffuse large B-cell lymphoma not otherwise specified	94/108 (87)	1.0 (1.0,1.1)	-	-	-	-	-
	Large cell transformation from follicular lymphoma	17/19 (89)	1.1 (0.9,1.1)	-	-	-	-	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	40/43 (93)	0.9 (0.8,1.0)	-	-	-	-	
	Other	6/8 (75)	1.1 (0.8,NE)	-	-	-	-	
Any serious TE CRS	Diffuse large B-cell lymphoma not otherwise specified	17/108 (16)	NE (NE,NE)	-	-	-	-	-
	Large cell transformation from follicular lymphoma	5/19 (26)	NE (1.1,NE)	-	-	-	-	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE,NE)	-	-	-	-	
	Other	1/8 (13)	NE (1.2,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	6/108 (6)	NE (NE,NE)	-	-	-	-	-
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE,NE)	-	-	-	-	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE,NE)	-	-	-	-	
	Other	1/8 (13)	NE (1.2,NE)	-	-	-	-	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE infection	Diffuse large B-cell lymphoma not otherwise specified	53/108 (49)	4.9 (4.0,39.8)	34/110 (31)	9.0 (3.7,NE)	1.31 (0.85,2.03)	0.2244	0.9535
	Large cell transformation from follicular lymphoma	10/19 (53)	19.8 (1.2,NE)	9/25 (36)	4.6 (2.6,NE)	1.28 (0.50,3.26)	0.5982	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	5.0 (1.4,23.7)	7/25 (28)	NE (3.0,NE)	1.39 (0.58,3.34)	0.4534	
	Other	6/8 (75)	2.0 (0.5,NE)	3/8 (38)	3.2 (0.4,NE)	1.96 (0.49,7.86)	0.3278	
Any serious TE infection	Diffuse large B-cell lymphoma not otherwise specified	23/108 (21)	NE (NE,NE)	11/110 (10)	NE (NE,NE)	1.47 (0.71,3.06)	0.2959	0.6652
	Large cell transformation from follicular lymphoma	4/19 (21)	NE (19.8,NE)	2/25 (8)	NE (NE,NE)	1.61 (0.28,9.20)	0.5921	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/43 (19)	NE (43.4,NE)	4/25 (16)	NE (4.8,NE)	0.64 (0.19,2.13)	0.4619	
	Other	2/8 (25)	9.9 (0.9,NE)	1/8 (13)	NE (3.2,NE)	2.95 (0.22,38.81)	0.3974	
Any severe TE infection (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	23/108 (21)	10.1 (5.7,23.4)	12/110 (11)	NE (NE,NE)	1.37 (0.65,2.87)	0.4067	0.6126
	Large cell transformation from follicular lymphoma	4/19 (21)	27.1 (NE,NE)	2/25 (8)	NE (NE,NE)	1.78 (0.30,10.67)	0.5236	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/43 (21)	13.8 (5.0,NE)	5/25 (20)	19.9 (4.3,NE)	0.54 (0.17,1.73)	0.2947	
	Other	1/8 (13)	NE (0.9,NE)	1/8 (13)	NE (3.2,NE)	0.79 (0.05,12.68)	0.8679	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Diffuse large B-cell lymphoma not otherwise specified	85/108 (79)	1.0 (0.9,1.1)	87/110 (79)	0.7 (0.5,1.2)	0.84 (0.62,1.14)	0.2667	0.7332
	Large cell transformation from follicular lymphoma	16/19 (84)	1.1 (0.7,1.3)	22/25 (88)	0.8 (0.4,1.8)	0.82 (0.43,1.57)	0.5418	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	35/43 (81)	0.8 (0.7,1.0)	18/25 (72)	0.7 (0.4,3.0)	1.07 (0.60,1.90)	0.8201	
	Other	7/8 (88)	1.0 (0.0,1.4)	8/8 (100)	0.8 (0.3,1.5)	0.83 (0.30,2.31)	0.7205	
Any serious TE cytopenias	Diffuse large B-cell lymphoma not otherwise specified	7/108 (6)	NE (NE,NE)	17/110 (15)	NE (NE,NE)	0.28 (0.11,0.69)	0.0032	0.8495
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE,NE)	8/25 (32)	NE (3.4,NE)	0.13 (0.02,1.04)	0.0228	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE,NE)	4/25 (16)	NE (3.3,NE)	0.22 (0.05,1.02)	0.0364	
	Other	1/8 (13)	NE (1.0,NE)	2/8 (25)	NE (0.3,NE)	0.48 (0.04,5.28)	0.5377	
Any severe TE cytopenias (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	78/108 (72)	1.1 (1.0,1.2)	82/110 (75)	0.9 (0.6,2.2)	0.79 (0.58,1.08)	0.1352	0.6832
	Large cell transformation from follicular lymphoma	16/19 (84)	1.2 (0.8,1.3)	20/25 (80)	1.3 (0.5,2.7)	1.05 (0.54,2.05)	0.8831	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	34/43 (79)	0.9 (0.8,1.0)	17/25 (68)	1.0 (0.4,3.0)	1.05 (0.58,1.89)	0.8660	
	Other	7/8 (88)	1.0 (0.0,1.4)	7/8 (88)	1.1 (0.3,NE)	1.42 (0.49,4.13)	0.5103	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE hypogammaglobulinemia	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	5.1 (5.0,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (0.7,NE)	1/8 (13)	NE (3.5,NE)	1.79 (0.16,19.77)	0.6301	
Any serious TE hypogammaglobulinemia	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

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Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Diffuse large B-cell lymphoma not otherwise specified	4/108 (4)	NE (NE,NE)	2/110 (2)	NE (NE,NE)	1.84 (0.34,10.07)	0.4761	0.8895
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	0.47 (0.03,7.66)	0.5884	
	Other	1/8 (13)	NE (1.8,NE)	1/8 (13)	NE (2.8,NE)	0.73 (0.05,11.70)	0.8247	
Any serious TE bone marrow failure	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	1/8 (13)	NE (3.5,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE secondary malignancy	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	33.4 (15.8,NE)	1/110 (1)	37.4 (NE,NE)	0.93 (0.09,9.20)	0.9526	1.0000
	Large cell transformation from follicular lymphoma	1/19 (5)	15.6 (NE,NE)	1/25 (4)	NE (NE,NE)	0.00 (0.00,NE)	0.2801	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	15.0 (11.2,NE)	1/25 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE secondary malignancy	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	1.92 (0.22,16.45)	0.5466	0.8539
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	0.65 (0.04,10.86)	0.7624	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE,NE)	1/25 (4)	NE (10.6,NE)	0.66 (0.06,7.33)	0.7371	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE secondary malignancy (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	3/108 (3)	33.4 (25.0,NE)	1/110 (1)	37.4 (NE,NE)	1.14 (0.10,13.27)	0.9183	1.0000
	Large cell transformation from follicular lymphoma	1/19 (5)	15.6 (NE,NE)	1/25 (4)	NE (NE,NE)	0.00 (0.00,NE)	0.2801	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	15.0 (11.2,NE)	1/25 (4)	10.6 (NE,NE)	0.00 (0.00,NE)	0.1573	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE graft-versus-host disease	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	Diffuse large B-cell lymphoma not otherwise specified	1/108 (1)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac failure	Diffuse large B-cell lymphoma not otherwise specified	3/108 (3)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	2.98 (0.31,28.61)	0.3214	0.9574
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	1.04 (0.09,11.59)	0.9722	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE cardiac failure	Diffuse large B-cell lymphoma not otherwise specified	1/108 (1)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	1/108 (1)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	0.96 (0.06,15.42)	0.9791	0.9945
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	0.48 (0.03,7.73)	0.5952	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	Diffuse large B-cell lymphoma not otherwise specified	52/108 (48)	2.1 (1.2,NE)	20/110 (18)	NE (NE,NE)	3.12 (1.86,5.24)	<0.0001	0.2181
	Large cell transformation from follicular lymphoma	7/19 (37)	NE (1.1,NE)	7/25 (28)	NE (4.6,NE)	1.23 (0.43,3.52)	0.6957	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	1.2 (0.9,NE)	4/25 (16)	NE (3.3,NE)	4.61 (1.59,13.32)	0.0018	
	Other	4/8 (50)	NE (0.8,NE)	3/8 (38)	2.9 (0.9,NE)	1.34 (0.30,6.01)	0.6890	
Any serious TE cardiac arrhythmias	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE,NE)	1/110 (1)	NE (NE,NE)	4.54 (0.53,39.07)	0.1306	0.8258
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	NE (NE,NE)	1/25 (4)	NE (4.7,NE)	2.19 (0.24,19.65)	0.4730	
	Other	1/8 (13)	NE (1.2,NE)	1/8 (13)	NE (2.9,NE)	0.79 (0.05,12.68)	0.8679	
Any severe TE cardiac arrhythmias (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9991
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE,NE)	1/25 (4)	NE (NE,NE)	1.00 (0.09,11.18)	0.9985	
	Other	1/8 (13)	NE (1.2,NE)	1/8 (13)	4.8 (NE,NE)	0.54 (0.03,9.36)	0.6680	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.11. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE autoimmune disorder	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	5.1 (5.0,NE)	1/110 (1)	NE (NE,NE)	7.50 (0.95,59.43)	0.0248	0.8572
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE,NE)	1/25 (4)	17.9 (NE,NE)	> 10,000 (0.00,NE)	0.0769	
	Other	2/8 (25)	NE (0.7,NE)	1/8 (13)	NE (3.5,NE)	1.79 (0.16,19.77)	0.6301	
Any serious TE autoimmune disorder	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	1/25 (4)	NE (17.9,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE,NE)	0/110 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE,NE)	0/25 (0)	NE (NE,NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE,NE)	0/8 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	0 - 1	94/94 (100)	0.5 (0.3,0.7)	93/93 (100)	0.1 (0.1,0.1)	0.34 (0.24,0.47)	<0.0001	0.1201
	2 - 3	84/84 (100)	0.3 (0.1,0.5)	75/75 (100)	0.1 (0.0,0.1)	0.47 (0.34,0.66)	<0.0001	
Any serious TEAE	0 - 1	55/94 (59)	8.7 (1.7,18.0)	40/93 (43)	4.9 (3.0,NE)	1.02 (0.67,1.57)	0.9096	0.8116
	2 - 3	53/84 (63)	1.4 (1.2,5.7)	38/75 (51)	4.1 (2.0,NE)	1.04 (0.68,1.60)	0.8542	
Any severe TEAE (Grade>=3)	0 - 1	84/94 (89)	1.0 (0.9,1.0)	75/93 (81)	0.5 (0.4,0.8)	0.89 (0.65,1.23)	0.4781	0.6603
	2 - 3	80/84 (95)	0.8 (0.7,0.9)	65/75 (87)	0.5 (0.4,0.6)	0.96 (0.69,1.35)	0.8205	
Any TE neurologic event	0 - 1	53/94 (56)	1.3 (1.2,NE)	23/93 (25)	NE (NE,NE)	2.52 (1.54,4.12)	0.0001	0.0132
	2 - 3	57/84 (68)	1.2 (1.1,1.4)	10/75 (13)	NE (NE,NE)	7.54 (3.84,14.82)	<0.0001	
Any serious TE neurologic event	0 - 1	15/94 (16)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	14.44 (1.91,109.36)	0.0006	0.9873
	2 - 3	19/84 (23)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	0 - 1	16/94 (17)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	15.91 (2.11,119.94)	0.0003	0.9867
	2 - 3	22/84 (26)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	0 - 1	85/94 (90)	1.0 (1.0,1.1)	-	-	-	-	-
	2 - 3	72/84 (86)	1.0 (0.9,1.0)	-	-	-	-	
Any serious TE CRS	0 - 1	15/94 (16)	NE (NE,NE)	-	-	-	-	-
	2 - 3	14/84 (17)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	0 - 1	5/94 (5)	NE (NE,NE)	-	-	-	-	-
	2 - 3	6/84 (7)	NE (NE,NE)	-	-	-	-	
Any TE infection	0 - 1	54/94 (57)	4.5 (3.1,13.8)	27/93 (29)	33.0 (4.6,NE)	1.64 (1.02,2.62)	0.0379	0.1839
	2 - 3	39/84 (46)	5.0 (2.8,19.8)	26/75 (35)	9.0 (4.4,NE)	1.08 (0.65,1.80)	0.7618	
Any serious TE infection	0 - 1	21/94 (22)	NE (NE,NE)	8/93 (9)	NE (NE,NE)	1.79 (0.79,4.05)	0.1586	0.1539
	2 - 3	16/84 (19)	NE (43.4,NE)	10/75 (13)	NE (9.0,NE)	0.85 (0.37,1.92)	0.6896	
Any severe TE infection (Grade >= 3)	0 - 1	18/94 (19)	14.7 (5.7,33.9)	7/93 (8)	19.9 (NE,NE)	1.43 (0.57,3.61)	0.4416	0.1964
	2 - 3	19/84 (23)	10.1 (5.0,NE)	13/75 (17)	NE (NE,NE)	0.86 (0.40,1.83)	0.6876	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	0 - 1	74/94 (79)	1.1 (1.0,1.2)	74/93 (80)	1.1 (0.5,1.8)	0.91 (0.65,1.26)	0.5496	0.9186
	2 - 3	69/84 (82)	0.9 (0.8,1.0)	61/75 (81)	0.6 (0.5,0.7)	0.83 (0.58,1.17)	0.2728	
Any serious TE cytopenias	0 - 1	7/94 (7)	NE (NE,NE)	15/93 (16)	NE (NE,NE)	0.32 (0.13,0.79)	0.0096	0.3724
	2 - 3	5/84 (6)	NE (NE,NE)	16/75 (21)	NE (NE,NE)	0.19 (0.07,0.52)	0.0004	
Any severe TE cytopenias (Grade >= 3)	0 - 1	69/94 (73)	1.1 (1.0,1.2)	69/93 (74)	1.8 (0.7,2.4)	0.88 (0.63,1.24)	0.4663	0.7315
	2 - 3	66/84 (79)	1.0 (0.8,1.1)	57/75 (76)	0.8 (0.5,1.4)	0.88 (0.62,1.26)	0.4847	
Any TE hypogammaglobulinemia	0 - 1	13/94 (14)	5.4 (NE,NE)	1/93 (1)	NE (NE,NE)	10.62 (1.38,81.74)	0.0046	0.9902
	2 - 3	9/84 (11)	5.0 (5.0,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	0 - 1	3/94 (3)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	1.27 (0.21,7.59)	0.7946	0.9568
	2 - 3	3/84 (4)	NE (NE,NE)	2/75 (3)	NE (NE,NE)	1.14 (0.19,6.92)	0.8858	
Any serious TE bone marrow failure	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	0 - 1	1/94 (1)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	0.71 (0.04,11.40)	0.8052	1.0000
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	0 - 1	3/94 (3)	33.4 (15.8,NE)	2/93 (2)	24.0 (10.6,NE)	0.58 (0.08,4.26)	0.5860	0.9945
	2 - 3	5/84 (6)	18.9 (11.2,NE)	1/75 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1492	
Any serious TE secondary malignancy	0 - 1	3/94 (3)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	0.85 (0.14,5.09)	0.8583	0.8074
	2 - 3	5/84 (6)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	1.19 (0.13,10.58)	0.8756	
Any severe TE secondary malignancy (Grade >= 3)	0 - 1	1/94 (1)	33.4 (NE,NE)	2/93 (2)	24.0 (10.6,NE)	1.41 (0.08,23.57)	0.8084	0.9965
	2 - 3	5/84 (6)	18.9 (11.2,NE)	1/75 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1492	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	0 - 1	1/94 (1)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	1/84 (1)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	0 - 1	2/94 (2)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	0.89 (0.12,6.34)	0.9070	0.4967
	2 - 3	3/84 (4)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	2.69 (0.28,25.83)	0.3732	
Any serious TE cardiac failure	0 - 1	0/94 (0)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	NE (NE,NE)	NE	0.9965
	2 - 3	1/84 (1)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	0 - 1	1/94 (1)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	0.43 (0.04,4.76)	0.4780	0.7428
	2 - 3	1/84 (1)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	0.86 (0.05,13.81)	0.9167	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.12. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	0 - 1	44/94 (47)	NE (1.2,NE)	22/93 (24)	NE (NE,NE)	2.22 (1.33,3.71)	0.0017	0.1643
	2 - 3	43/84 (51)	1.6 (1.1,NE)	12/75 (16)	NE (NE,NE)	3.88 (2.04,7.36)	<0.0001	
Any serious TE cardiac arrhythmias	0 - 1	4/94 (4)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	1.70 (0.31,9.30)	0.5371	0.7742
	2 - 3	6/84 (7)	NE (NE,NE)	2/75 (3)	NE (NE,NE)	2.59 (0.52,12.90)	0.2263	
Any severe TE cardiac arrhythmias (Grade >= 3)	0 - 1	7/94 (7)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	6.32 (0.78,51.49)	0.0480	0.2443
	2 - 3	1/84 (1)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	0.66 (0.04,11.00)	0.7718	
Any TE autoimmune disorder	0 - 1	13/94 (14)	5.4 (NE,NE)	3/93 (3)	17.9 (NE,NE)	5.78 (1.30,25.62)	0.0090	0.9893
	2 - 3	9/84 (11)	5.0 (5.0,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	0 - 1	0/94 (0)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	0 - 1	0/94 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/84 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	0 - 1	98/98 (100)	0.6 (0.4,0.7)	93/93 (100)	0.1 (0.1,0.1)	0.32 (0.23,0.45)	<0.0001	0.1156
	2 - 3	80/80 (100)	0.2 (0.1,0.5)	75/75 (100)	0.1 (0.0,0.1)	0.51 (0.36,0.72)	<0.0001	
Any serious TEAE	0 - 1	56/98 (57)	8.7 (2.8,19.8)	42/93 (45)	4.9 (3.0,NE)	0.90 (0.59,1.37)	0.6290	0.2568
	2 - 3	52/80 (65)	1.3 (1.1,5.0)	36/75 (48)	4.6 (2.1,NE)	1.23 (0.80,1.90)	0.3452	
Any severe TEAE (Grade>=3)	0 - 1	86/98 (88)	1.0 (0.9,1.1)	77/93 (83)	0.5 (0.4,0.6)	0.80 (0.58,1.09)	0.1472	0.0961
	2 - 3	78/80 (98)	0.8 (0.7,0.9)	63/75 (84)	0.5 (0.4,0.7)	1.15 (0.82,1.61)	0.4207	
Any TE neurologic event	0 - 1	56/98 (57)	1.4 (1.2,NE)	22/93 (24)	NE (NE,NE)	2.69 (1.64,4.41)	<0.0001	0.0306
	2 - 3	54/80 (68)	1.2 (1.1,1.3)	11/75 (15)	NE (NE,NE)	6.86 (3.57,13.17)	<0.0001	
Any serious TE neurologic event	0 - 1	16/98 (16)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	14.74 (1.96,111.16)	0.0005	0.9873
	2 - 3	18/80 (23)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	0 - 1	16/98 (16)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	15.21 (2.02,114.68)	0.0004	0.9872
	2 - 3	22/80 (28)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	0 - 1	89/98 (91)	1.1 (1.0,1.1)	-	-	-	-	-
	2 - 3	68/80 (85)	1.0 (0.9,1.0)	-	-	-	-	
Any serious TE CRS	0 - 1	16/98 (16)	NE (NE,NE)	-	-	-	-	-
	2 - 3	13/80 (16)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	0 - 1	6/98 (6)	NE (NE,NE)	-	-	-	-	-
	2 - 3	5/80 (6)	NE (NE,NE)	-	-	-	-	
Any TE infection	0 - 1	53/98 (54)	4.9 (3.5,19.8)	29/93 (31)	33.0 (4.6,NE)	1.35 (0.85,2.15)	0.1980	0.8325
	2 - 3	40/80 (50)	5.0 (1.6,10.9)	24/75 (32)	9.0 (4.4,NE)	1.37 (0.82,2.29)	0.2248	
Any serious TE infection	0 - 1	23/98 (23)	NE (42.4,NE)	9/93 (10)	NE (NE,NE)	1.56 (0.72,3.38)	0.2608	0.3092
	2 - 3	14/80 (18)	NE (NE,NE)	9/75 (12)	NE (9.0,NE)	1.00 (0.43,2.36)	0.9936	
Any severe TE infection (Grade >= 3)	0 - 1	17/98 (17)	14.7 (5.7,33.9)	9/93 (10)	19.9 (NE,NE)	0.98 (0.41,2.32)	0.9608	0.8273
	2 - 3	20/80 (25)	10.1 (5.0,27.1)	11/75 (15)	NE (NE,NE)	1.16 (0.53,2.54)	0.7076	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	0 - 1	78/98 (80)	1.1 (1.0,1.2)	75/93 (81)	1.0 (0.5,1.8)	0.86 (0.62,1.19)	0.3516	0.6725
	2 - 3	65/80 (81)	0.8 (0.8,1.0)	60/75 (80)	0.7 (0.5,0.9)	0.90 (0.63,1.29)	0.5688	
Any serious TE cytopenias	0 - 1	8/98 (8)	NE (NE,NE)	17/93 (18)	NE (NE,NE)	0.30 (0.13,0.70)	0.0034	0.4420
	2 - 3	4/80 (5)	NE (NE,NE)	14/75 (19)	NE (NE,NE)	0.19 (0.06,0.60)	0.0015	
Any severe TE cytopenias (Grade >= 3)	0 - 1	72/98 (73)	1.1 (1.0,1.2)	71/93 (76)	1.2 (0.6,2.4)	0.81 (0.58,1.12)	0.1957	0.2167
	2 - 3	63/80 (79)	1.0 (0.8,1.1)	55/75 (73)	0.9 (0.5,2.4)	1.01 (0.70,1.45)	0.9745	
Any TE hypogammaglobulinemia	0 - 1	13/98 (13)	5.4 (NE,NE)	1/93 (1)	NE (NE,NE)	9.97 (1.30,76.73)	0.0064	0.9901
	2 - 3	9/80 (11)	5.0 (5.0,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE hypogammaglobulinemia	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	0 - 1	3/98 (3)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	1.22 (0.20,7.29)	0.8298	0.9831
	2 - 3	3/80 (4)	NE (NE,NE)	2/75 (3)	NE (NE,NE)	1.21 (0.20,7.31)	0.8375	
Any serious TE bone marrow failure	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	0 - 1	1/98 (1)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	0.68 (0.04,10.91)	0.7806	1.0000
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	0 - 1	5/98 (5)	33.4 (15.6,NE)	2/93 (2)	24.0 (10.6,NE)	0.48 (0.08,2.97)	0.4237	0.9965
	2 - 3	3/80 (4)	18.9 (11.2,NE)	1/75 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1703	
Any serious TE secondary malignancy	0 - 1	5/98 (5)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	1.22 (0.24,6.28)	0.8134	0.8553
	2 - 3	3/80 (4)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	1.09 (0.11,10.64)	0.9391	
Any severe TE secondary malignancy (Grade >= 3)	0 - 1	3/98 (3)	33.4 (15.6,NE)	2/93 (2)	24.0 (10.6,NE)	0.58 (0.08,4.26)	0.5860	0.9965
	2 - 3	3/80 (4)	18.9 (11.2,NE)	1/75 (1)	NE (NE,NE)	0.00 (0.00,NE)	0.1703	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE tumor lysis syndrome	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE tumor lysis syndrome	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE tumor lysis syndrome (Grade >= 3)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE graft-versus-host disease	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE graft-versus-host disease	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE graft-versus-host disease (Grade >= 3)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE Immunogenicity (anti-axi-cel antibody)	0 - 1	1/98 (1)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	1/80 (1)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE Immunogenicity (anti-axi-cel antibody)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE Immunogenicity (anti-axi-cel antibody) (Grade >= 3)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE cardiac failure	0 - 1	2/98 (2)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	0.85 (0.12,6.09)	0.8739	0.4592
	2 - 3	3/80 (4)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	2.82 (0.29,27.12)	0.3480	
Any serious TE cardiac failure	0 - 1	0/98 (0)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	NE (NE,NE)	NE	0.9965
	2 - 3	1/80 (1)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE cardiac failure (Grade >= 3)	0 - 1	1/98 (1)	NE (NE,NE)	2/93 (2)	NE (NE,NE)	0.41 (0.04,4.57)	0.4553	0.7064
	2 - 3	1/80 (1)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	0.90 (0.06,14.44)	0.9418	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.13. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cardiac arrhythmias	0 - 1	46/98 (47)	NE (1.2,NE)	23/93 (25)	NE (NE,NE)	2.09 (1.26,3.45)	0.0031	0.0785
	2 - 3	41/80 (51)	1.4 (1.1,NE)	11/75 (15)	NE (NE,NE)	4.35 (2.23,8.48)	<0.0001	
Any serious TE cardiac arrhythmias	0 - 1	5/98 (5)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	4.28 (0.50,36.73)	0.1482	0.4121
	2 - 3	5/80 (6)	NE (NE,NE)	3/75 (4)	NE (NE,NE)	1.41 (0.34,5.96)	0.6340	
Any severe TE cardiac arrhythmias (Grade >= 3)	0 - 1	8/98 (8)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	6.99 (0.87,56.02)	0.0329	0.9917
	2 - 3	0/80 (0)	NE (NE,NE)	1/75 (1)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE autoimmune disorder	0 - 1	13/98 (13)	5.4 (NE,NE)	3/93 (3)	17.9 (NE,NE)	5.46 (1.23,24.20)	0.0121	0.9892
	2 - 3	9/80 (11)	5.0 (5.0,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any serious TE autoimmune disorder	0 - 1	0/98 (0)	NE (NE,NE)	1/93 (1)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE autoimmune disorder (Grade >= 3)	0 - 1	0/98 (0)	NE (NE,NE)	0/93 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	2 - 3	0/80 (0)	NE (NE,NE)	0/75 (0)	NE (NE,NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

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Table 14.3.1.2.14. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TEAE	Primary refractory	131/131 (100)	0.4 (0.2,0.5)	125/125 (100)	0.1 (0.1,0.1)	0.44 (0.33,0.57)	<0.0001	0.0771
	Relapse ≤ 12 months of the completion of the first line therapy	46/46 (100)	0.6 (0.0,0.7)	43/43 (100)	0.1 (0.0,0.1)	0.30 (0.17,0.50)	<0.0001	
Any serious TEAE	Primary refractory	79/131 (60)	3.6 (1.4,8.7)	50/125 (40)	4.9 (3.3,NE)	1.24 (0.86,1.79)	0.2560	0.0238
	Relapse ≤ 12 months of the completion of the first line therapy	29/46 (63)	2.8 (1.2,33.4)	28/43 (65)	2.9 (0.6,9.0)	0.66 (0.39,1.14)	0.1310	
Any severe TEAE (Grade>=3)	Primary refractory	121/131 (92)	0.9 (0.8,0.9)	101/125 (81)	0.5 (0.4,0.6)	0.97 (0.74,1.27)	0.8378	0.5032
	Relapse ≤ 12 months of the completion of the first line therapy	42/46 (91)	1.0 (0.8,1.1)	39/43 (91)	0.5 (0.3,0.8)	0.84 (0.53,1.31)	0.4215	
Any TE neurologic event	Primary refractory	79/131 (60)	1.3 (1.2,2.0)	19/125 (15)	NE (NE,NE)	4.93 (2.98,8.15)	<0.0001	0.0897
	Relapse ≤ 12 months of the completion of the first line therapy	31/46 (67)	1.2 (1.1,1.5)	14/43 (33)	NE (3.3,NE)	2.61 (1.38,4.94)	0.0020	
Any serious TE neurologic event	Primary refractory	23/131 (18)	NE (NE,NE)	1/125 (1)	NE (NE,NE)	21.47 (2.90,159.09)	<0.0001	0.9900
	Relapse ≤ 12 months of the completion of the first line therapy	11/46 (24)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE neurologic event (Grade >= 3)	Primary refractory	28/131 (21)	NE (NE,NE)	1/125 (1)	NE (NE,NE)	28.22 (3.84,207.44)	<0.0001	0.9897
	Relapse ≤ 12 months of the completion of the first line therapy	10/46 (22)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.14. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE CRS	Primary refractory	113/131 (86)	1.0 (1.0,1.1)	-	-	-	-	-
	Relapse ≤ 12 months of the completion of the first line therapy	44/46 (96)	1.0 (1.0,1.1)	-	-	-	-	
Any serious TE CRS	Primary refractory	21/131 (16)	NE (NE,NE)	-	-	-	-	-
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	NE (NE,NE)	-	-	-	-	
Any severe TE CRS (Grade >= 3)	Primary refractory	8/131 (6)	NE (NE,NE)	-	-	-	-	-
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	NE (NE,NE)	-	-	-	-	
Any TE infection	Primary refractory	65/131 (50)	5.0 (3.5,19.8)	31/125 (25)	NE (4.8,NE)	1.65 (1.07,2.56)	0.0226	0.0806
	Relapse ≤ 12 months of the completion of the first line therapy	27/46 (59)	4.7 (1.5,5.7)	22/43 (51)	3.5 (2.8,NE)	0.92 (0.52,1.63)	0.7712	
Any serious TE infection	Primary refractory	28/131 (21)	NE (NE,NE)	10/125 (8)	NE (NE,NE)	1.82 (0.88,3.77)	0.1020	0.0809
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE,NE)	8/43 (19)	NE (19.9,NE)	0.58 (0.22,1.55)	0.2737	
Any severe TE infection (Grade >= 3)	Primary refractory	26/131 (20)	10.9 (5.0,27.1)	13/125 (10)	NE (NE,NE)	1.21 (0.60,2.47)	0.5925	0.2771
	Relapse ≤ 12 months of the completion of the first line therapy	10/46 (22)	14.7 (5.7,NE)	7/43 (16)	19.9 (NE,NE)	0.78 (0.27,2.21)	0.6365	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.14. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE cytopenias	Primary refractory	108/131 (82)	1.0 (0.8,1.0)	95/125 (76)	0.6 (0.5,1.1)	0.97 (0.73,1.28)	0.8054	0.2233
	Relapse ≤ 12 months of the completion of the first line therapy	35/46 (76)	1.1 (0.9,1.2)	40/43 (93)	1.0 (0.6,1.6)	0.67 (0.42,1.07)	0.0850	
Any serious TE cytopenias	Primary refractory	10/131 (8)	NE (NE,NE)	24/125 (19)	NE (NE,NE)	0.24 (0.11,0.51)	<0.0001	0.7586
	Relapse ≤ 12 months of the completion of the first line therapy	2/46 (4)	NE (NE,NE)	7/43 (16)	NE (NE,NE)	0.23 (0.05,1.10)	0.0437	
Any severe TE cytopenias (Grade >= 3)	Primary refractory	105/131 (80)	1.0 (0.9,1.1)	90/125 (72)	1.0 (0.5,1.9)	0.99 (0.74,1.31)	0.9249	0.1681
	Relapse ≤ 12 months of the completion of the first line therapy	30/46 (65)	1.1 (1.0,1.9)	36/43 (84)	1.8 (0.7,2.5)	0.66 (0.40,1.07)	0.0878	
Any TE hypogammaglobulinemia	Primary refractory	15/131 (11)	5.1 (5.0,NE)	0/125 (0)	NE (NE,NE)	NE (NE,NE)	NE	0.9919
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE,NE)	1/43 (2)	NE (NE,NE)	6.14 (0.76,49.94)	0.0523	
Any serious TE hypogammaglobulinemia	Primary refractory	0/131 (0)	NE (NE,NE)	0/125 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE hypogammaglobulinemia (Grade >= 3)	Primary refractory	0/131 (0)	NE (NE,NE)	0/125 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; HR, hazard ratio; IXRS, interactive voice/web response system; MedDRA, Medical Dictionary for Regulatory Activities; NA, not applicable; NE, not estimable; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_aesum_sg.sas Output Generated: 20240524T11:15

Table 14.3.1.2.14. Overall Summary and Analysis of Time to the First Treatment-emergent Adverse Events by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

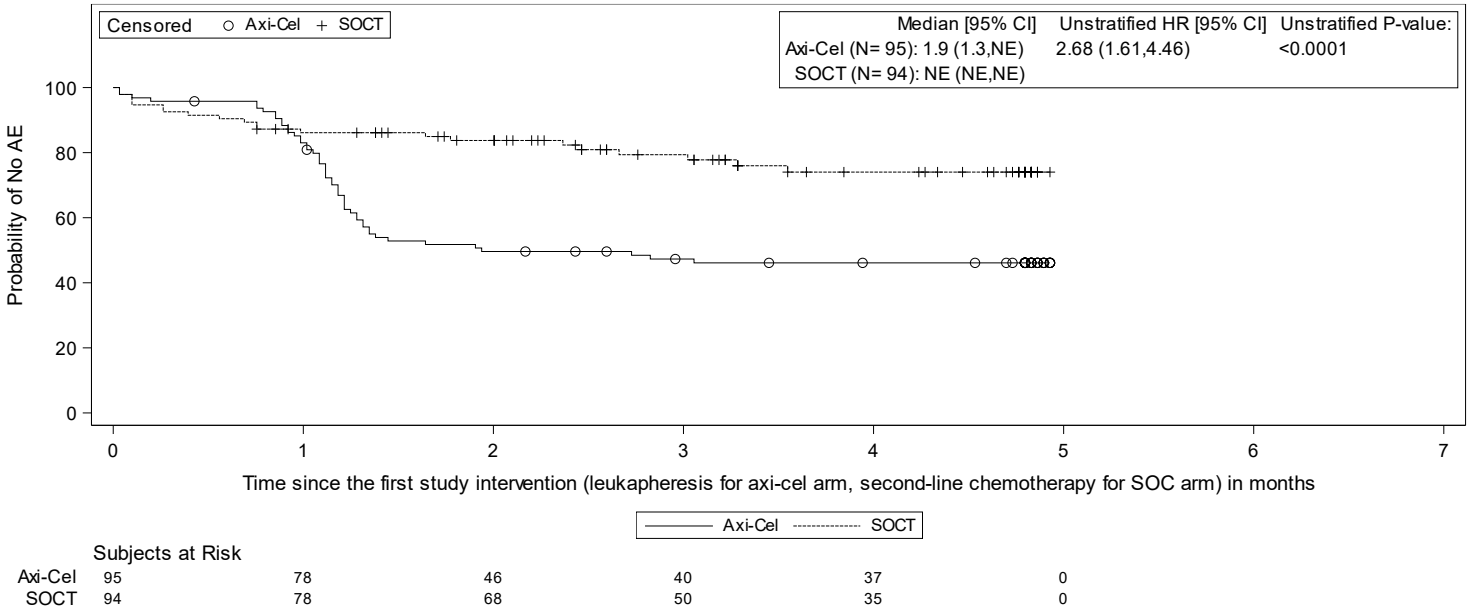
MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Any TE bone marrow failure	Primary refractory	4/131 (3)	NE (NE,NE)	2/125 (2)	NE (NE,NE)	1.69 (0.31,9.25)	0.5426	0.6388
	Relapse ≤ 12 months of the completion of the first line therapy	2/46 (4)	NE (NE,NE)	2/43 (5)	NE (NE,NE)	0.81 (0.11,5.79)	0.8371	
Any serious TE bone marrow failure	Primary refractory	0/131 (0)	NE (NE,NE)	0/125 (0)	NE (NE,NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any severe TE bone marrow failure (Grade >= 3)	Primary refractory	1/131 (1)	NE (NE,NE)	1/125 (1)	NE (NE,NE)	0.62 (0.04,10.13)	0.7369	1.0000
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE,NE)	0/43 (0)	NE (NE,NE)	NE (NE,NE)	NE	
Any TE secondary malignancy	Primary refractory	5/131 (4)	15.8 (11.2,NE)	1/125 (1)	10.6 (NE,NE)	0.00 (0.00,NE)	0.0253	0.3159
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	25.0 (18.9,NE)	2/43 (5)	37.4 (NE,NE)	1.74 (0.18,17.35)	0.6307	
Any serious TE secondary malignancy	Primary refractory	5/131 (4)	NE (NE,NE)	1/125 (1)	NE (NE,NE)	2.14 (0.25,18.36)	0.4758	0.4130
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	NE (NE,NE)	2/43 (5)	NE (NE,NE)	0.75 (0.13,4.53)	0.7566	
Any severe TE secondary malignancy (Grade >= 3)	Primary refractory	3/131 (2)	15.6 (11.2,NE)	1/125 (1)	10.6 (NE,NE)	0.00 (0.00,NE)	0.0833	0.3375
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	25.0 (18.9,NE)	2/43 (5)	37.4 (NE,NE)	1.74 (0.18,17.35)	0.6307	

Anhang 4-G3.6.2: Kaplan-Meier Plots der Subgruppenanalysen für UE von speziellem Interesse mit statistisch signifikantem Interaktionsterm - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Abbildung 15 (Anhang): Kaplan-Meier Plots für Subgruppenanalysen für UE von speziellem Interesse (stat. sign. Interaktionsterm) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.4.1.75. Kaplan-Meier Plot of Time To First neurologic event by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	78	46	40	37	0
SOCT	94	78	68	50	35	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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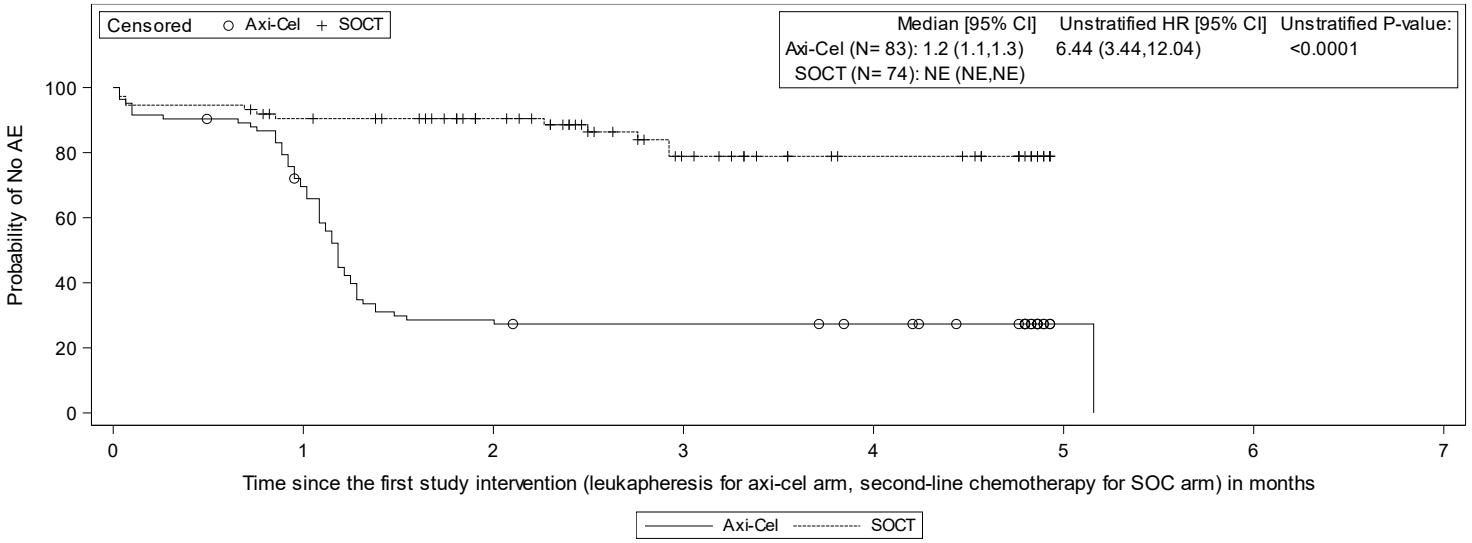
Figure 14.5.4.1.75. Kaplan-Meier Plot of Time To First neurologic event by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	56	23	21	19	1	0
SOCT	74	64	51	29	19	0	

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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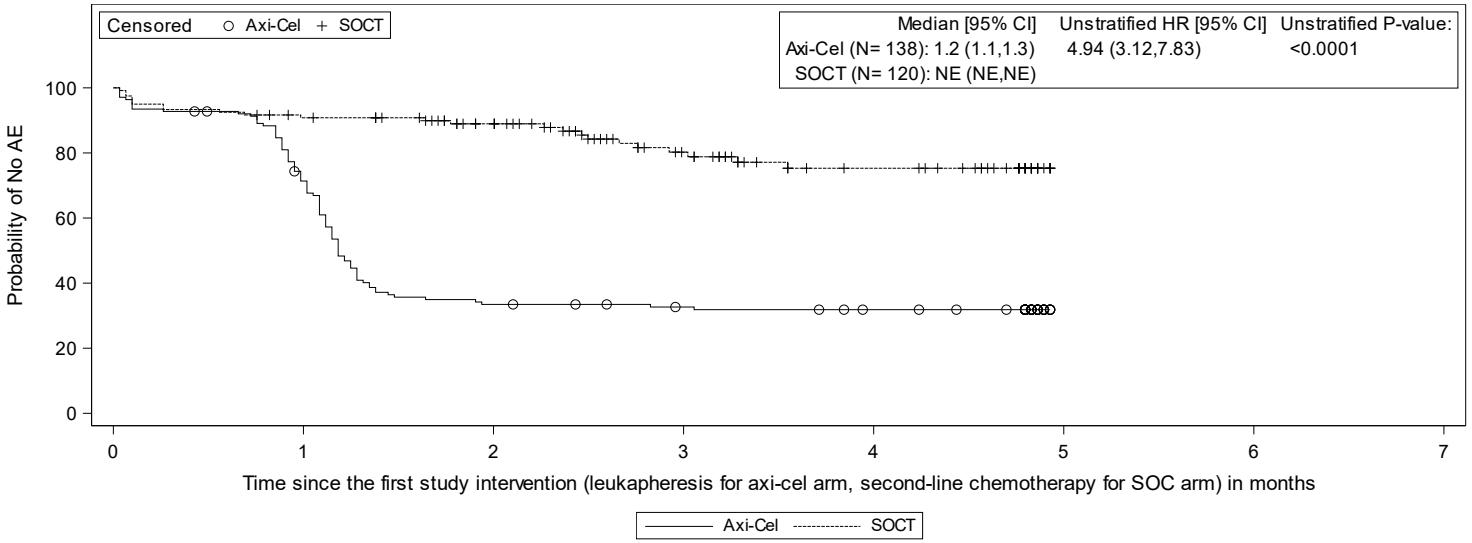
Figure 14.5.4.1.77. Kaplan-Meier Plot of Time To First neurologic event by Geographic Region (Modified Safety Analysis Set)

North America



Subjects at Risk

Axi-Cel	138	96	45	40	36	0
SOCT	120	106	87	56	37	0

Page 1 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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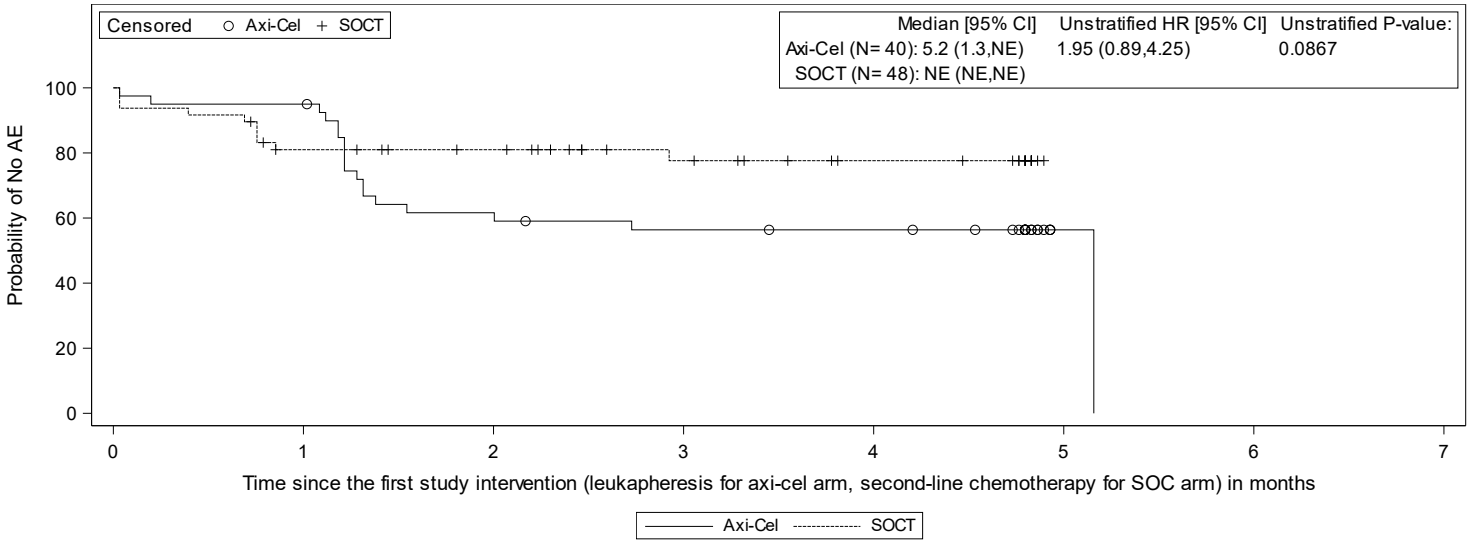
Figure 14.5.4.1.77. Kaplan-Meier Plot of Time To First neurologic event by Geographic Region (Modified Safety Analysis Set)

Rest of the world



Subjects at Risk

Axi-Cel	40	38	24	21	20	1	0
SOCT	48	36	32	23	17	0	

Page 2 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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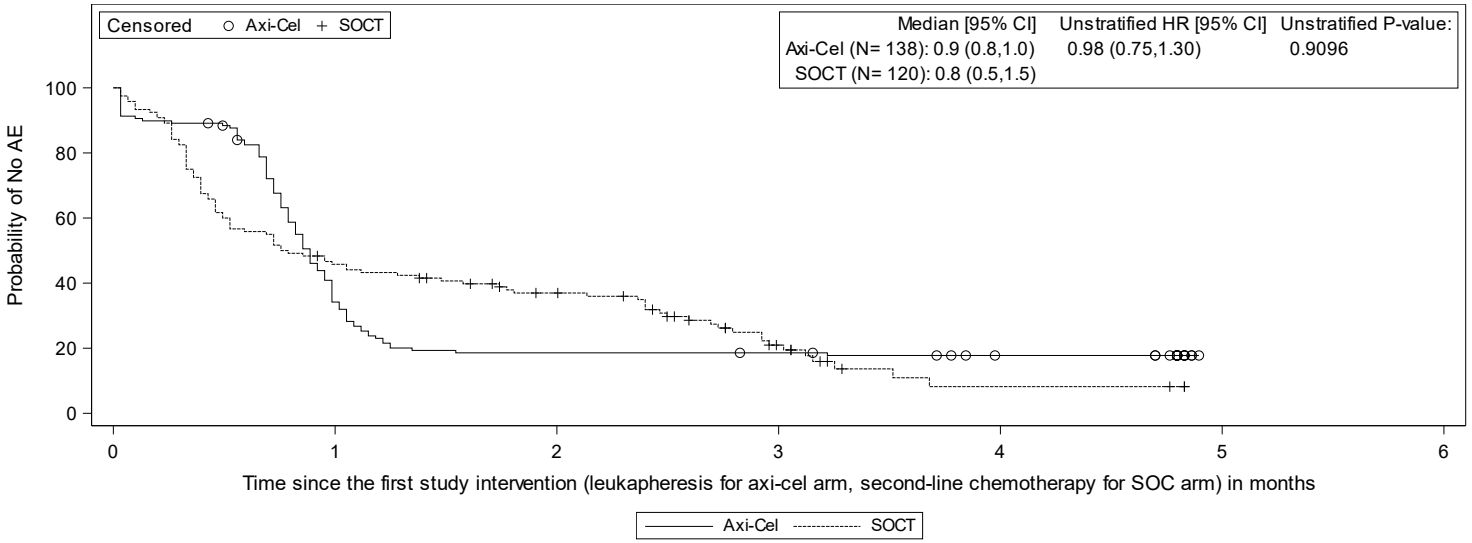
Figure 14.5.4.1.78. Kaplan-Meier Plot of Time To First cytopenias by Geographic Region (Modified Safety Analysis Set)

North America



Subjects at Risk

Axi-Cel	138	46	25	24	18	0
SOCT	120	54	38	14	3	0

Page 1 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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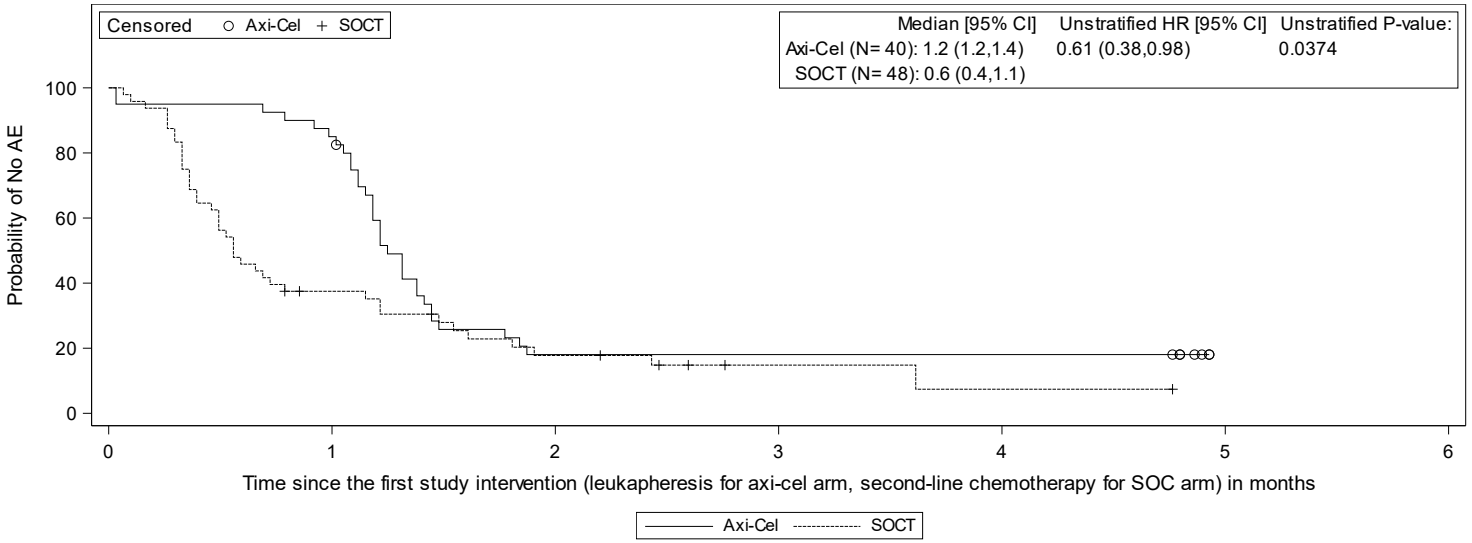
Figure 14.5.4.1.78. Kaplan-Meier Plot of Time To First cytopenias by Geographic Region (Modified Safety Analysis Set)

Rest of the world



Subjects at Risk

Axi-Cel	40	34	7	7	7	0
SOCT	48	16	7	2	1	0

Page 2 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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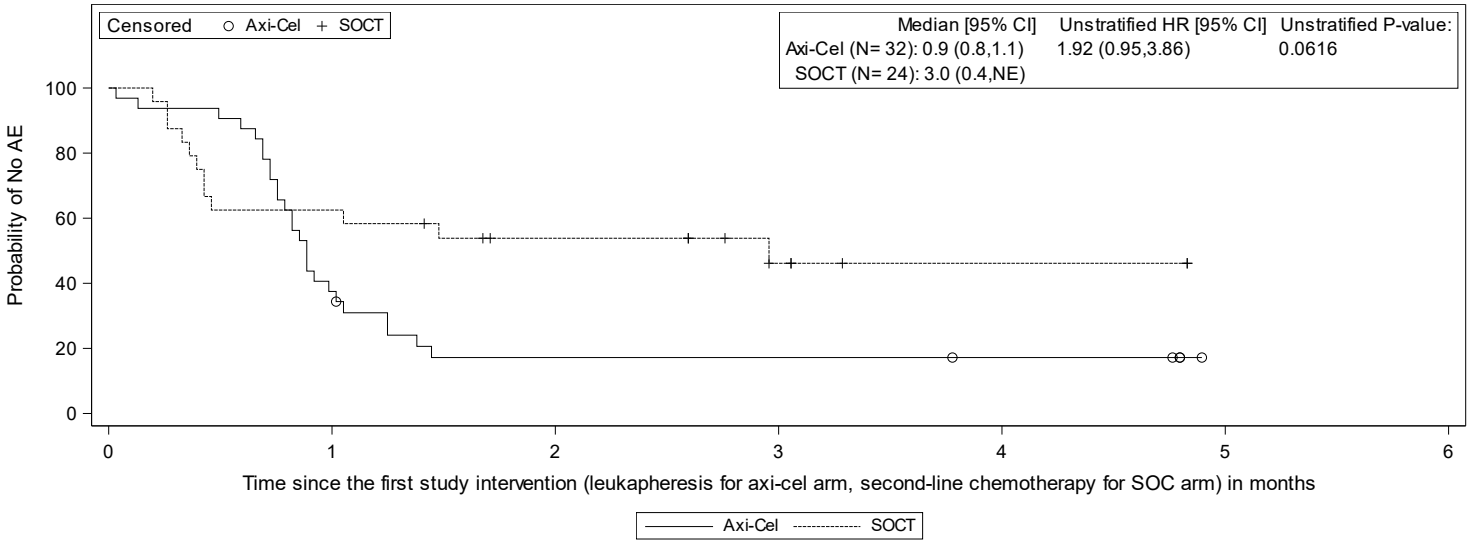
Figure 14.5.4.1.80. Kaplan-Meier Plot of Time To First severe cytopenias by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

HGBL - double hit/triple hit



Subjects at Risk

Axi-Cel	32	12	5	5	4	0
SOCT	24	15	10	5	2	0

Page 1 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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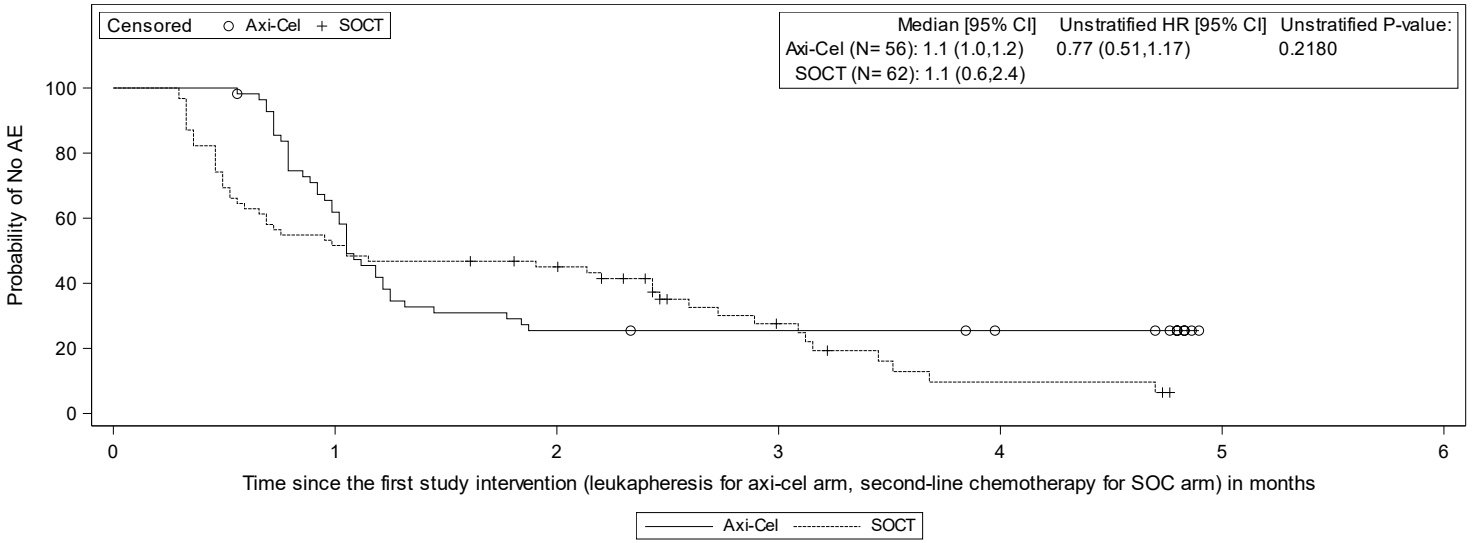
Figure 14.5.4.1.80. Kaplan-Meier Plot of Time To First severe cytopenias by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

Double expressor lymphoma



Subjects at Risk

Axi-Cel	56	34	14	13	11	0
SOCT	62	32	26	10	3	0

Page 2 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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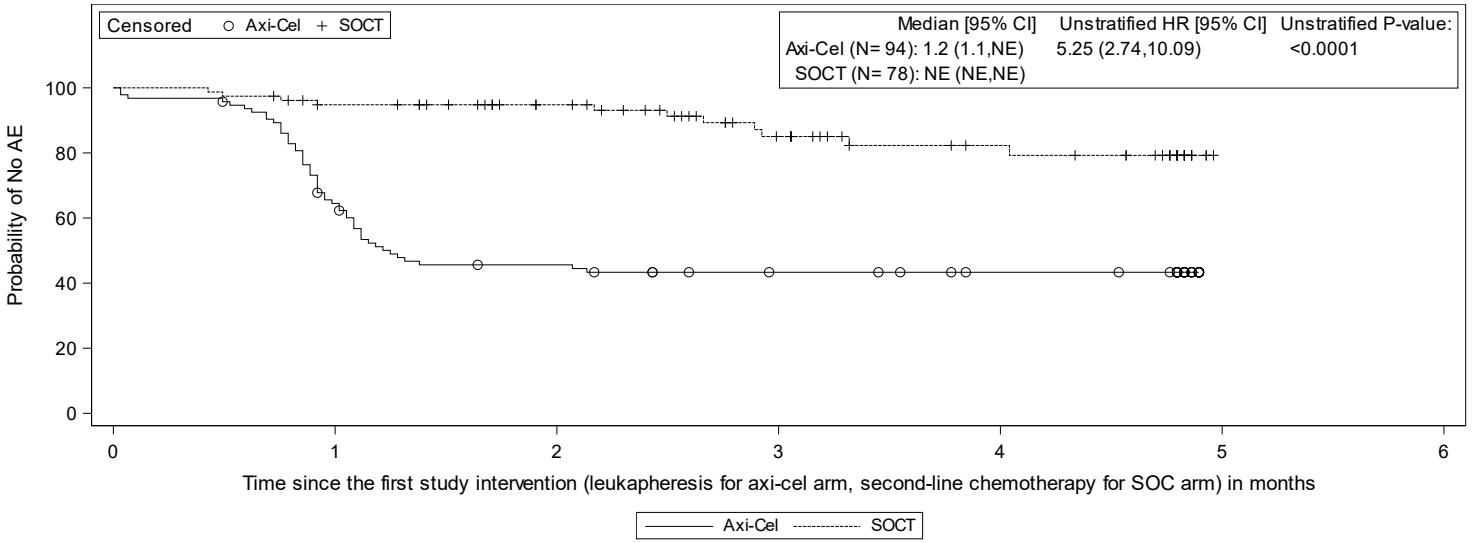
Figure 14.5.4.1.82. Kaplan-Meier Plot of Time To First cardiac arrhythmias by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	59	40	33	29	0
SOCT	78	70	58	39	27	0

Page 1 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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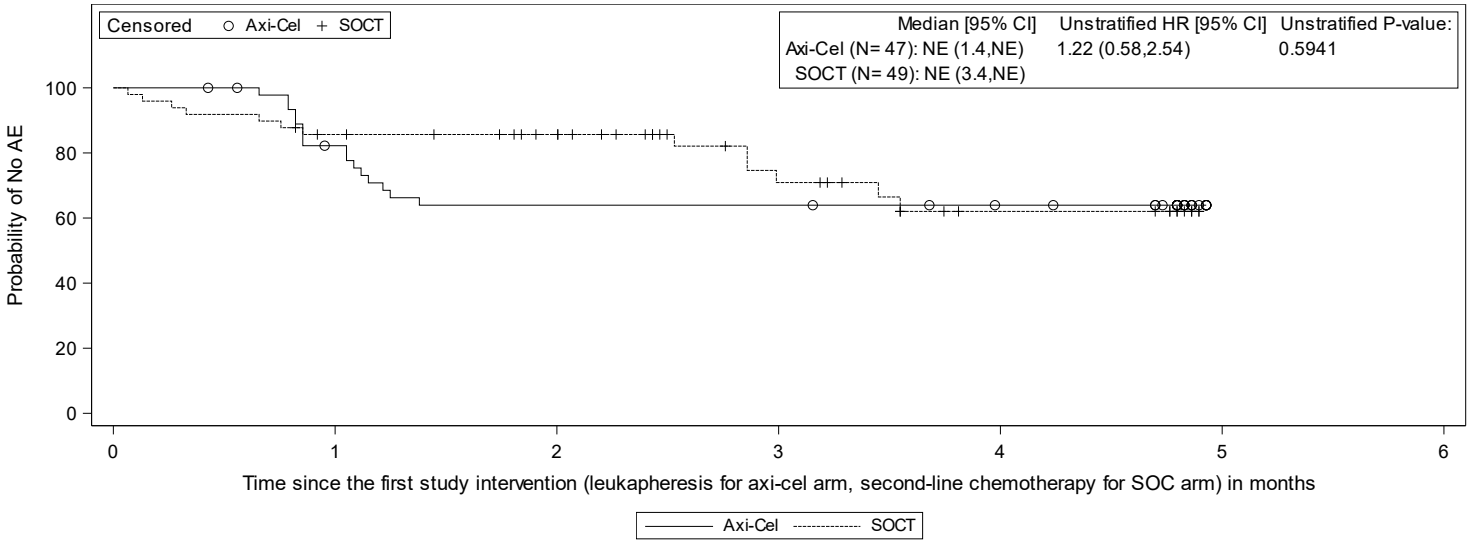
Figure 14.5.4.1.82. Kaplan-Meier Plot of Time To First cardiac arrhythmias by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	36	28	28	25	0
SOCT	49	40	34	19	10	0

Page 2 of 18

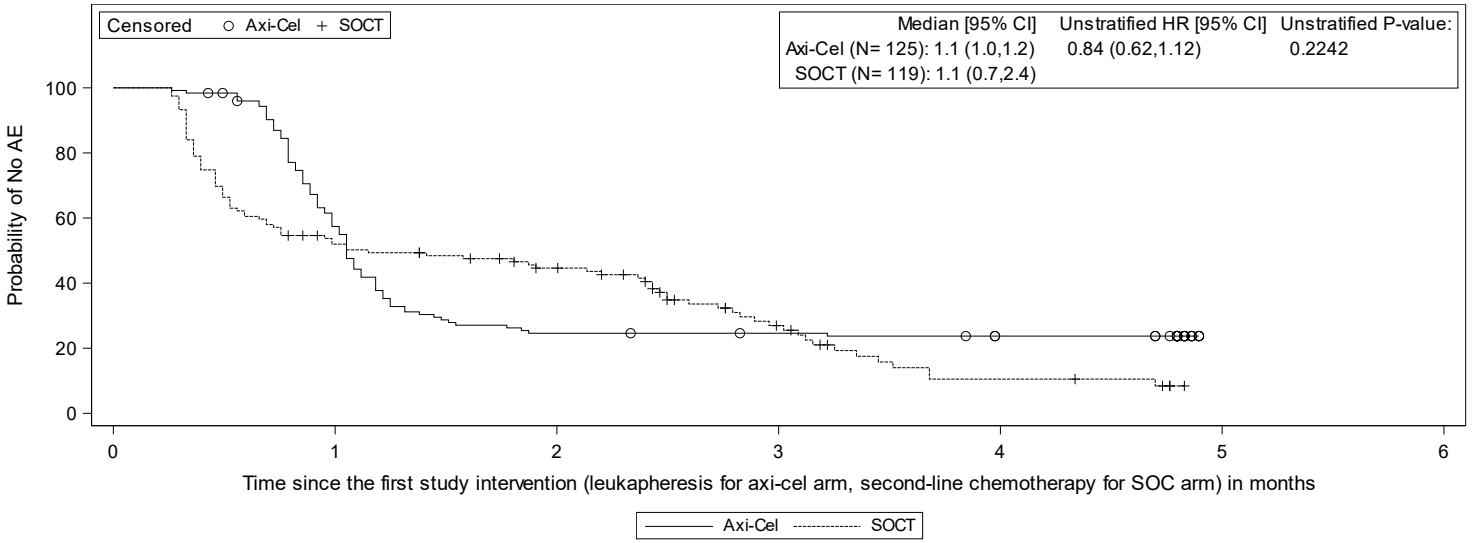
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.84. Kaplan-Meier Plot of Time To First severe cytopenias by disease type per central lab (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma



Subjects at Risk

Axi-Cel	125	70	30	28	24	0
SOCT	119	59	45	19	6	0

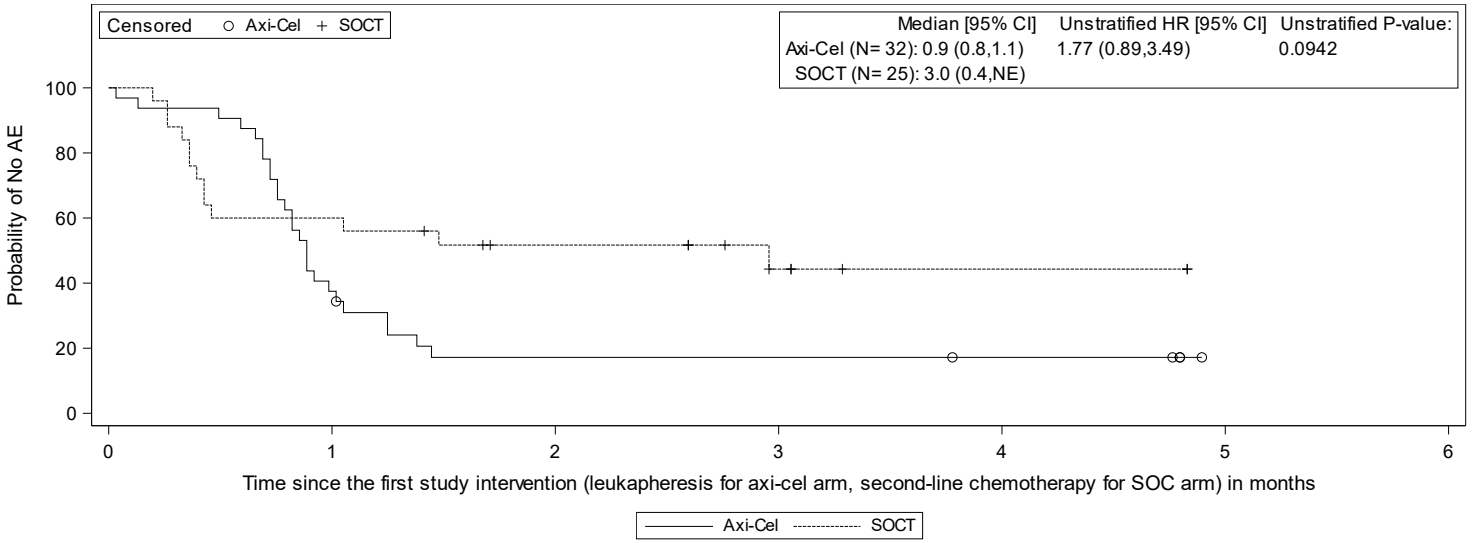
Page 1 of 18

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Figure 14.5.4.1.84. Kaplan-Meier Plot of Time To First severe cytopenias by disease type per central lab (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	32	12	5	5	4	0
SOCT	25	15	10	5	2	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

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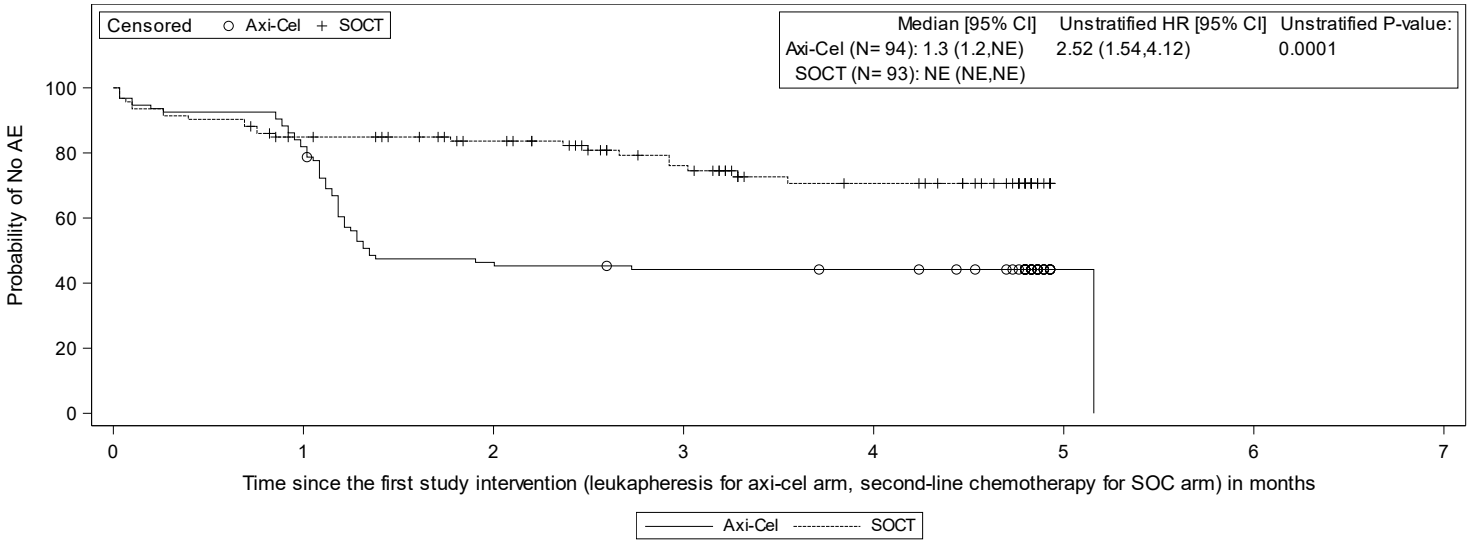
Figure 14.5.4.1.85. Kaplan-Meier Plot of Time To First neurologic event by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	94	77	43	40	39	1	0
SOCT	93	75	65	48	34	0	

Page 1 of 18

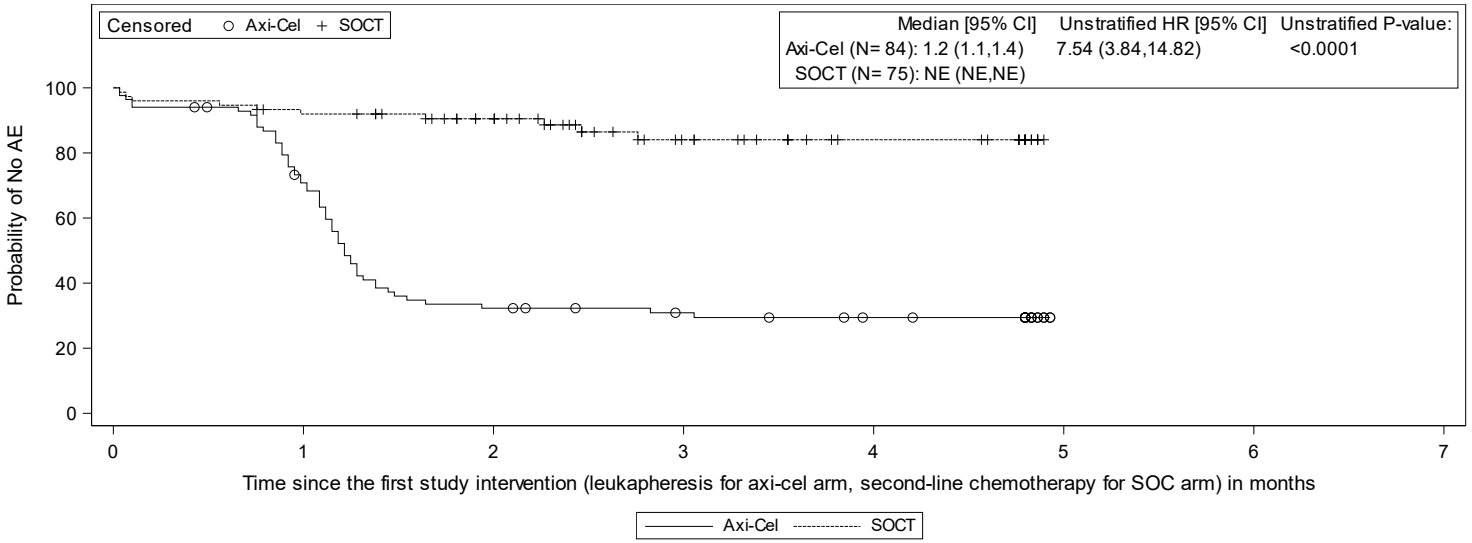
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.85. Kaplan-Meier Plot of Time To First neurologic event by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	84	57	26	21	17	0
SOCT	75	67	54	31	20	0

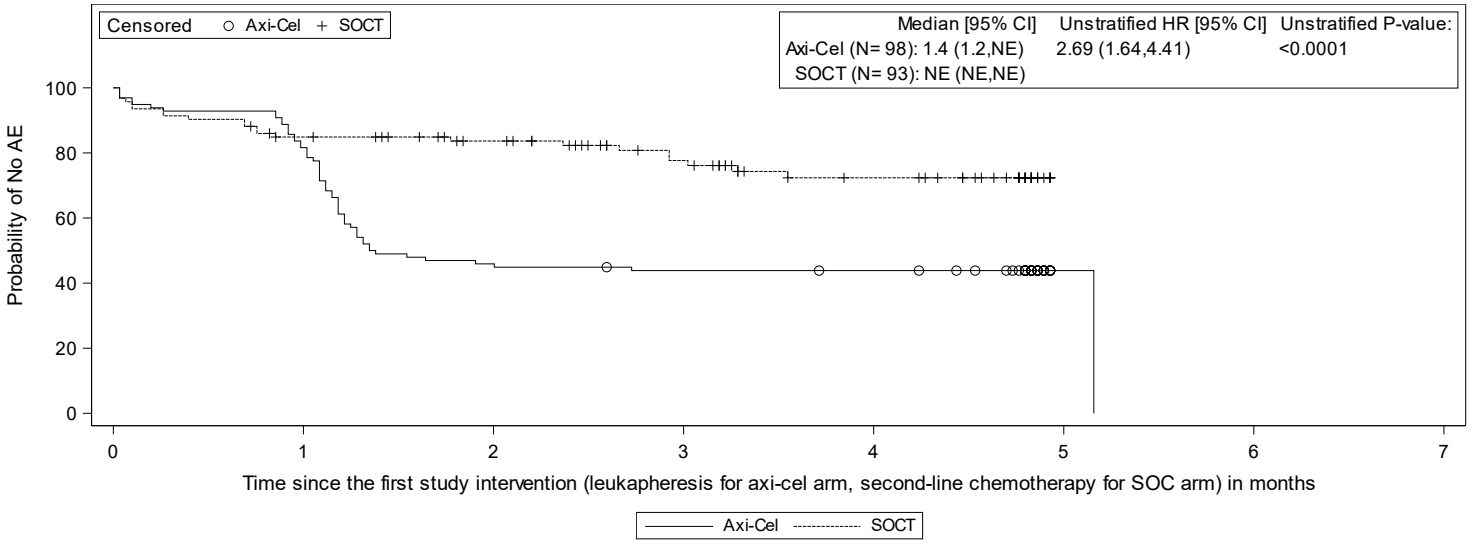
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.86. Kaplan-Meier Plot of Time To First neurologic event by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	80	45	42	41	1	0
SOCT	93	76	66	50	35	0	

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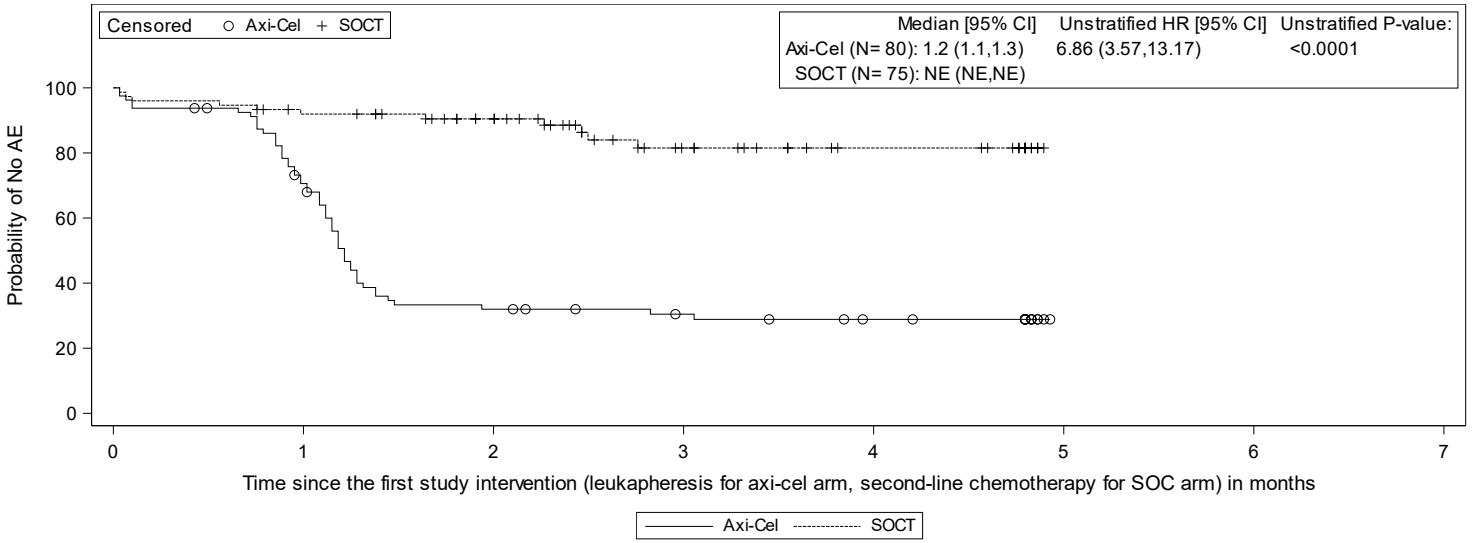
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.86. Kaplan-Meier Plot of Time To First neurologic event by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	54	24	19	15	0
SOCT	75	66	53	29	19	0

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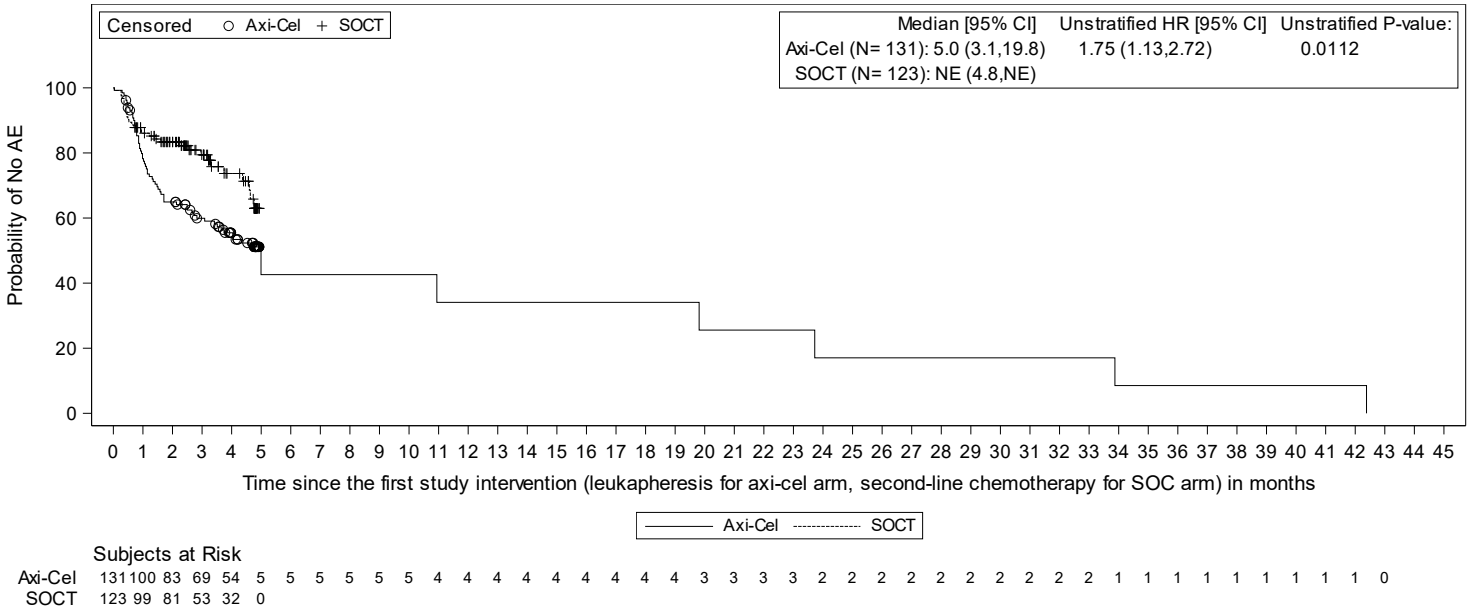
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_aesi_sg.sas Output Generated: 20240516T05:57

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.90. Kaplan-Meier Plot of Time To First infection by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

Primary Refractory



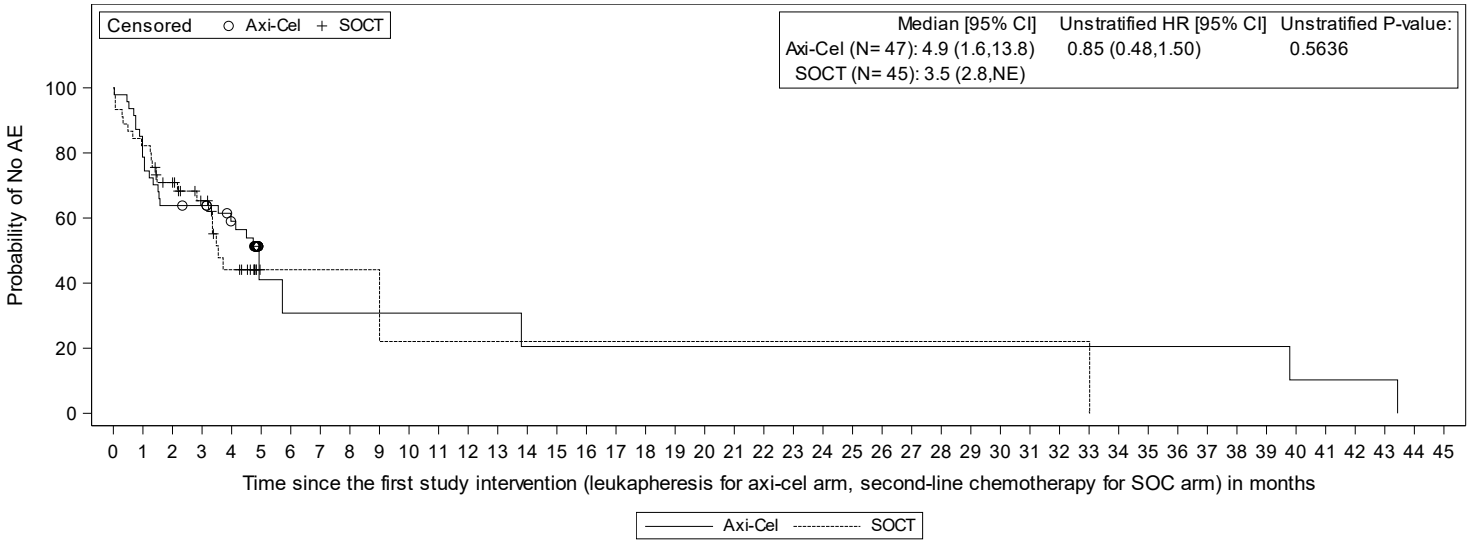
Subjects at Risk

| | | |

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.90. Kaplan-Meier Plot of Time To First infection by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

Relapse ≤ 12 Months of first line therapy



Subjects at Risk

| | | |

Anhang 4-G3.6.3: Subgruppenanalyse häufiger UE nach SOC/PT (tabellarische Darstellung und Kaplan-Meier Plots für Subgruppenanalysen mit statistisch signifikantem Interaktionsterm) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-29 (Anhang): Ergebnisse der Subgruppenanalyse häufiger UE nach SOC/PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Age < 65	6/127 (5)	12.1 (12.1, NE)	34/113 (30)	NE (3.4, NE)	0.06 (0.02,0.16)	<0.0001	0.7131
	Age ≥ 65	1/51 (2)	28.3 (NE, NE)	12/55 (22)	7.2 (NE, NE)	0.00 (0.00,NE)	<0.0001	
Neutropenia	Age < 65	55/127 (43)	NE (1.4, NE)	16/113 (14)	NE (NE, NE)	3.41 (1.95,5.95)	<0.0001	0.2298
	Age ≥ 65	22/51 (43)	NE (1.1, NE)	13/55 (24)	NE (NE, NE)	1.85 (0.93,3.68)	0.0726	
Thrombocytopenia	Age < 65	13/127 (10)	NE (NE, NE)	30/113 (27)	NE (NE, NE)	0.31 (0.16,0.60)	0.0002	0.0585
	Age ≥ 65	10/51 (20)	NE (NE, NE)	11/55 (20)	NE (NE, NE)	0.94 (0.40,2.21)	0.8833	
Cardiac disorders	Age < 65	61/127 (48)	NE (1.2, NE)	25/113 (22)	NE (NE, NE)	2.50 (1.57,3.99)	<0.0001	0.7050
	Age ≥ 65	26/51 (51)	2.1 (1.1, NE)	11/55 (20)	NE (NE, NE)	2.97 (1.46,6.04)	0.0015	
Sinus tachycardia	Age < 65	43/127 (34)	NE (NE, NE)	13/113 (12)	NE (NE, NE)	3.28 (1.76,6.11)	<0.0001	0.4255
	Age ≥ 65	18/51 (35)	NE (3.9, NE)	4/55 (7)	NE (NE, NE)	5.42 (1.83,16.04)	0.0006	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Age < 65	4/127 (3)	NE (NE, NE)	14/113 (12)	NE (NE, NE)	0.23 (0.08,0.70)	0.0049	0.9619
	Age ≥ 65	1/51 (2)	NE (NE, NE)	4/55 (7)	NE (NE, NE)	0.21 (0.02,1.96)	0.1361	
Gastrointestinal disorders	Age < 65	108/127 (85)	0.8 (0.8, 0.9)	96/113 (85)	0.2 (0.1, 0.5)	0.67 (0.51,0.89)	0.0038	0.8787
	Age ≥ 65	43/51 (84)	0.9 (0.8, 1.0)	47/55 (85)	0.2 (0.1, 0.6)	0.65 (0.43,0.99)	0.0405	
Nausea	Age < 65	71/127 (56)	1.2 (1.0, 4.8)	79/113 (70)	0.8 (0.3, 2.0)	0.56 (0.40,0.77)	0.0003	0.7094
	Age ≥ 65	25/51 (49)	2.1 (1.1, NE)	37/55 (67)	1.0 (0.4, 2.5)	0.53 (0.32,0.88)	0.0112	
Stomatitis	Age < 65	5/127 (4)	NE (NE, NE)	21/113 (19)	NE (NE, NE)	0.15 (0.05,0.39)	<0.0001	0.7280
	Age ≥ 65	1/51 (2)	NE (NE, NE)	8/55 (15)	NE (NE, NE)	0.09 (0.01,0.71)	0.0043	
General disorders and administration site conditions	Age < 65	118/127 (93)	0.9 (0.8, 1.0)	83/113 (73)	0.7 (0.3, 1.0)	1.34 (1.00,1.79)	0.0458	0.7275
	Age ≥ 65	47/51 (92)	0.8 (0.7, 0.9)	42/55 (76)	0.5 (0.3, 1.1)	1.34 (0.87,2.07)	0.1795	
Chills	Age < 65	30/127 (24)	NE (NE, NE)	10/113 (9)	NE (NE, NE)	2.77 (1.35,5.68)	0.0035	0.2971

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Age ≥ 65	18/51 (35)	NE (1.2, NE)	4/55 (7)	NE (NE, NE)	5.35 (1.81,15.83)	0.0006	
Mucosal inflammation	Age < 65	1/127 (1)	NE (NE, NE)	12/113 (11)	NE (NE, NE)	0.05 (0.01,0.36)	<0.0001	0.9937
	Age ≥ 65	0/51 (0)	NE (NE, NE)	4/55 (7)	4.9 (4.9, NE)	NE (NE,NE)	NE	
Pyrexia	Age < 65	114/127 (90)	1.0 (1.0, 1.1)	29/113 (26)	NE (4.8, NE)	7.87 (5.14,12.03)	<0.0001	0.2788
	Age ≥ 65	47/51 (92)	0.9 (0.8, 1.0)	14/55 (25)	6.9 (3.5, NE)	12.41 (6.34,24.28)	<0.0001	
Hepatobiliary disorders	Age < 65	10/127 (8)	NE (NE, NE)	3/113 (3)	NE (NE, NE)	2.69 (0.74,9.83)	0.1184	0.9903
	Age ≥ 65	9/51 (18)	NE (NE, NE)	0/55 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	Age < 65	4/127 (3)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	8/51 (16)	NE (NE, NE)	0/55 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Age < 65	13/127 (10)	5.1 (5.0, NE)	1/113 (1)	NE (NE, NE)	7.94 (1.01,62.14)	0.0192	0.8415
	Age ≥ 65	11/51 (22)	NE (NE, NE)	2/55 (4)	NE (NE, NE)	5.89 (1.30,26.63)	0.0089	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Age < 65	11/127 (9)	5.1 (5.0, NE)	0/113 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9930
	Age ≥ 65	11/51 (22)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	11.45 (1.48,88.76)	0.0032	
Infections and infestations	Age < 65	63/127 (50)	13.8 (3.5, 33.9)	34/113 (30)	9.0 (4.6, NE)	1.37 (0.89,2.11)	0.1452	0.3651
	Age ≥ 65	35/51 (69)	2.7 (1.2, 4.5)	21/55 (38)	4.6 (3.5, NE)	1.79 (1.03,3.12)	0.0365	
Oral candidiasis	Age < 65	7/127 (6)	NE (NE, NE)	2/113 (2)	NE (NE, NE)	3.04 (0.63,14.67)	0.1441	0.6597
	Age ≥ 65	9/51 (18)	NE (NE, NE)	3/55 (5)	7.1 (NE, NE)	4.86 (1.05,22.58)	0.0253	
Rhinovirus infection	Age < 65	6/127 (5)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	5/51 (10)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Age < 65	14/127 (11)	NE (NE, NE)	23/113 (20)	NE (NE, NE)	0.45 (0.23,0.88)	0.0170	0.3502
	Age ≥ 65	9/51 (18)	25.6 (NE, NE)	10/55 (18)	NE (NE, NE)	0.76 (0.30,1.93)	0.5577	
Infusion related reaction	Age < 65	1/127 (1)	NE (NE, NE)	11/113 (10)	NE (NE, NE)	0.07 (0.01,0.54)	0.0007	0.9940

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Age ≥ 65	0/51 (0)	NE (NE, NE)	2/55 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Age < 65	26/127 (20)	NE (NE, NE)	12/113 (11)	NE (NE, NE)	1.87 (0.94,3.71)	0.0685	0.4931
	Age ≥ 65	11/51 (22)	NE (NE, NE)	4/55 (7)	NE (NE, NE)	3.00 (0.95,9.43)	0.0474	
C-reactive protein increased	Age < 65	15/127 (12)	NE (NE, NE)	3/113 (3)	NE (NE, NE)	4.55 (1.32,15.73)	0.0083	0.5772
	Age ≥ 65	8/51 (16)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	8.95 (1.12,71.56)	0.0122	
Platelet count decreased	Age < 65	18/127 (14)	NE (NE, NE)	38/113 (34)	NE (3.3, NE)	0.34 (0.19,0.60)	<0.0001	0.3864
	Age ≥ 65	14/51 (27)	NE (NE, NE)	26/55 (47)	3.4 (2.5, NE)	0.47 (0.24,0.91)	0.0211	
Weight increased	Age < 65	4/127 (3)	NE (NE, NE)	9/113 (8)	NE (NE, NE)	0.36 (0.11,1.17)	0.0761	0.9497
	Age ≥ 65	1/51 (2)	NE (NE, NE)	3/55 (5)	NE (NE, NE)	0.34 (0.04,3.25)	0.3243	
Metabolism and nutrition disorders	Age < 65	89/127 (70)	1.1 (0.9, 1.2)	58/113 (51)	2.8 (1.7, 4.7)	1.42 (1.02,1.98)	0.0357	0.7250

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Age ≥ 65	42/51 (82)	0.9 (0.8, 1.1)	35/55 (64)	2.1 (0.7, 3.2)	1.61 (1.02,2.56)	0.0385	
Hyperglycaemia	Age < 65	23/127 (18)	NE (NE, NE)	12/113 (11)	NE (NE, NE)	1.66 (0.83,3.35)	0.1481	0.6609
	Age ≥ 65	10/51 (20)	NE (NE, NE)	5/55 (9)	NE (NE, NE)	2.14 (0.73,6.26)	0.1562	
Hypomagnesaemia	Age < 65	15/127 (12)	NE (NE, NE)	21/113 (19)	NE (NE, NE)	0.54 (0.28,1.05)	0.0637	0.8376
	Age ≥ 65	8/51 (16)	5.0 (NE, NE)	13/55 (24)	NE (NE, NE)	0.51 (0.20,1.28)	0.1428	
Hyponatraemia	Age < 65	15/127 (12)	NE (NE, NE)	7/113 (6)	NE (NE, NE)	1.77 (0.72,4.35)	0.2076	0.1124
	Age ≥ 65	10/51 (20)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	11.47 (1.47,89.59)	0.0032	
Nervous system disorders	Age < 65	98/127 (77)	1.1 (1.0, 1.1)	60/113 (53)	2.9 (1.0, 3.9)	1.54 (1.12,2.14)	0.0074	0.5182
	Age ≥ 65	39/51 (76)	1.0 (0.9, 1.1)	27/55 (49)	4.8 (1.1, NE)	1.81 (1.09,2.98)	0.0183	
Dizziness	Age < 65	31/127 (24)	NE (NE, NE)	15/113 (13)	NE (NE, NE)	1.76 (0.95,3.27)	0.0666	0.8472
	Age ≥ 65	9/51 (18)	NE (NE, NE)	6/55 (11)	NE (NE, NE)	1.45 (0.51,4.09)	0.4787	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Age < 65	3/127 (2)	NE (NE, NE)	9/113 (8)	NE (NE, NE)	0.25 (0.07,0.92)	0.0239	0.7027
	Age ≥ 65	2/51 (4)	NE (NE, NE)	5/55 (9)	NE (NE, NE)	0.40 (0.08,2.08)	0.2604	
Encephalopathy	Age < 65	19/127 (15)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	17.79 (2.38,132.89)	0.0001	0.8764
	Age ≥ 65	12/51 (24)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	13.88 (1.80,106.78)	0.0009	
Headache	Age < 65	66/127 (52)	1.4 (1.1, NE)	29/113 (26)	NE (NE, NE)	2.24 (1.45,3.47)	0.0002	0.3339
	Age ≥ 65	17/51 (33)	NE (NE, NE)	14/55 (25)	7.0 (NE, NE)	1.48 (0.72,3.06)	0.2810	
Peripheral sensory neuropathy	Age < 65	1/127 (1)	NE (NE, NE)	8/113 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	0/51 (0)	NE (NE, NE)	2/55 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Age < 65	14/127 (11)	NE (NE, NE)	0/113 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9905
	Age ≥ 65	5/51 (10)	NE (NE, NE)	2/55 (4)	NE (NE, NE)	2.63 (0.51,13.57)	0.2285	
Tremor	Age < 65	32/127 (25)	NE (NE, NE)	0/113 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9880

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Age ≥ 65	12/51 (24)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	13.99 (1.82,107.62)	0.0008	
Psychiatric disorders	Age < 65	58/127 (46)	NE (1.4, NE)	27/113 (24)	NE (NE, NE)	2.01 (1.27,3.18)	0.0022	0.8885
	Age ≥ 65	25/51 (49)	27.6 (1.3, NE)	13/55 (24)	NE (NE, NE)	2.26 (1.15,4.45)	0.0149	
Agitation	Age < 65	8/127 (6)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Age ≥ 65	3/51 (6)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Age < 65	22/127 (17)	NE (NE, NE)	2/113 (2)	NE (NE, NE)	9.96 (2.34,42.39)	0.0001	0.8941
	Age ≥ 65	19/51 (37)	27.6 (2.0, NE)	2/55 (4)	NE (NE, NE)	11.38 (2.64,49.08)	<0.0001	
Respiratory, thoracic and mediastinal disorders	Age < 65	70/127 (55)	1.8 (1.2, NE)	46/113 (41)	NE (3.1, NE)	1.38 (0.95,2.01)	0.0861	0.8976
	Age ≥ 65	35/51 (69)	1.1 (0.9, 1.3)	26/55 (47)	4.6 (1.1, NE)	1.42 (0.85,2.37)	0.1731	
Cough	Age < 65	27/127 (21)	NE (NE, NE)	9/113 (8)	NE (NE, NE)	2.61 (1.23,5.56)	0.0097	0.9391
	Age ≥ 65	20/51 (39)	NE (2.0, NE)	9/55 (16)	NE (NE, NE)	2.47 (1.12,5.44)	0.0195	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Age < 65	7/127 (6)	NE (NE, NE)	16/113 (14)	NE (NE, NE)	0.34 (0.14,0.82)	0.0117	0.9318
	Age ≥ 65	2/51 (4)	NE (NE, NE)	5/55 (9)	NE (NE, NE)	0.41 (0.08,2.11)	0.2689	
Hypoxia	Age < 65	23/127 (18)	NE (NE, NE)	7/113 (6)	NE (NE, NE)	2.87 (1.23,6.69)	0.0107	0.9517
	Age ≥ 65	15/51 (29)	NE (NE, NE)	6/55 (11)	NE (NE, NE)	3.02 (1.17,7.80)	0.0159	
Pleural effusion	Age < 65	8/127 (6)	NE (NE, NE)	2/113 (2)	NE (NE, NE)	3.21 (0.68,15.17)	0.1202	0.8871
	Age ≥ 65	4/51 (8)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	4.15 (0.46,37.18)	0.1670	
Skin and subcutaneous tissue disorders								
Erythema	Age < 65	8/127 (6)	NE (NE, NE)	3/113 (3)	NE (NE, NE)	2.16 (0.57,8.15)	0.2460	0.9907
	Age ≥ 65	4/51 (8)	NE (NE, NE)	0/55 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Age < 65	72/127 (57)	1.4 (1.2, NE)	40/113 (35)	NE (3.1, NE)	1.71 (1.16,2.52)	0.0059	0.3709
	Age ≥ 65	28/51 (55)	1.3 (1.0, NE)	16/55 (29)	NE (3.7, NE)	2.29 (1.23,4.24)	0.0067	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.1. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Age < 65	54/127 (43)	NE (1.4, NE)	17/113 (15)	NE (NE, NE)	3.28 (1.90,5.66)	<0.0001	0.4863
	Age ≥ 65	26/51 (51)	1.9 (1.0, NE)	8/55 (15)	NE (NE, NE)	4.26 (1.92,9.44)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Male	3/109 (3)	12.1 (NE, NE)	28/120 (23)	NE (4.5, NE)	0.04 (0.01,0.18)	<0.0001	0.6097
	Female	4/69 (6)	28.3 (4.9, NE)	18/48 (38)	7.2 (3.4, NE)	0.05 (0.01,0.21)	<0.0001	
Neutropenia	Male	41/109 (38)	NE (NE, NE)	16/120 (13)	NE (NE, NE)	2.91 (1.63,5.19)	0.0001	0.5409
	Female	36/69 (52)	1.2 (1.1, NE)	13/48 (27)	NE (NE, NE)	2.28 (1.21,4.32)	0.0086	
Thrombocytopenia	Male	10/109 (9)	NE (NE, NE)	32/120 (27)	NE (NE, NE)	0.27 (0.13,0.55)	0.0001	0.0267
	Female	13/69 (19)	NE (NE, NE)	9/48 (19)	NE (NE, NE)	0.99 (0.42,2.32)	0.9827	
Cardiac disorders	Male	55/109 (50)	2.6 (1.2, NE)	23/120 (19)	NE (NE, NE)	2.92 (1.79,4.75)	<0.0001	0.4755
	Female	32/69 (46)	NE (1.1, NE)	13/48 (27)	NE (3.6, NE)	2.12 (1.11,4.04)	0.0190	
Sinus tachycardia	Male	36/109 (33)	NE (NE, NE)	11/120 (9)	NE (NE, NE)	3.83 (1.95,7.54)	<0.0001	0.8995
	Female	25/69 (36)	NE (2.3, NE)	6/48 (13)	NE (NE, NE)	3.48 (1.42,8.48)	0.0033	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Male	2/109 (2)	NE (NE, NE)	12/120 (10)	NE (NE, NE)	0.17 (0.04,0.78)	0.0093	0.5041
	Female	3/69 (4)	NE (NE, NE)	6/48 (13)	NE (NE, NE)	0.31 (0.08,1.24)	0.0806	
Gastrointestinal disorders	Male	90/109 (83)	0.9 (0.8, 1.0)	98/120 (82)	0.3 (0.2, 0.7)	0.69 (0.51,0.91)	0.0083	0.4168
	Female	61/69 (88)	0.8 (0.7, 0.8)	45/48 (94)	0.1 (0.1, 0.3)	0.55 (0.37,0.82)	0.0017	
Nausea	Male	57/109 (52)	1.3 (1.1, NE)	80/120 (67)	0.9 (0.5, 2.4)	0.55 (0.39,0.77)	0.0004	0.8266
	Female	39/69 (57)	1.1 (0.9, NE)	36/48 (75)	0.7 (0.1, 1.1)	0.53 (0.34,0.83)	0.0048	
Stomatitis	Male	2/109 (2)	NE (NE, NE)	17/120 (14)	NE (NE, NE)	0.08 (0.02,0.33)	<0.0001	0.4815
	Female	4/69 (6)	NE (NE, NE)	12/48 (25)	NE (4.3, NE)	0.18 (0.06,0.57)	0.0010	
General disorders and administration site conditions	Male	101/109 (93)	0.9 (0.8, 1.0)	86/120 (72)	0.8 (0.3, 1.1)	1.38 (1.03,1.85)	0.0299	0.4911
	Female	64/69 (93)	0.8 (0.8, 0.9)	39/48 (81)	0.3 (0.2, 0.7)	1.10 (0.73,1.68)	0.6344	
Chills	Male	33/109 (30)	NE (NE, NE)	10/120 (8)	NE (NE, NE)	3.80 (1.87,7.72)	<0.0001	0.6644

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Female	15/69 (22)	NE (NE, NE)	4/48 (8)	NE (NE, NE)	2.81 (0.93,8.46)	0.0548	
Mucosal inflammation	Male	1/109 (1)	NE (NE, NE)	11/120 (9)	NE (4.9, NE)	0.06 (0.01,0.49)	0.0004	0.9919
	Female	0/69 (0)	NE (NE, NE)	5/48 (10)	7.0 (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Male	100/109 (92)	1.0 (0.9, 1.1)	29/120 (24)	NE (4.8, NE)	8.52 (5.52,13.13)	<0.0001	0.9465
	Female	61/69 (88)	1.0 (0.9, 1.0)	14/48 (29)	6.9 (3.5, NE)	9.35 (4.95,17.64)	<0.0001	
Hepatobiliary disorders	Male	12/109 (11)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	4.07 (1.14,14.48)	0.0189	0.9902
	Female	7/69 (10)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	Male	9/109 (8)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	9.55 (1.21,75.50)	0.0089	0.9936
	Female	3/69 (4)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Male	13/109 (12)	5.0 (5.0, NE)	2/120 (2)	NE (NE, NE)	4.95 (1.10,22.38)	0.0211	0.9288
	Female	11/69 (16)	5.4 (NE, NE)	1/48 (2)	NE (NE, NE)	7.02 (0.90,54.92)	0.0304	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Male	12/109 (11)	5.0 (5.0, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9915
	Female	10/69 (14)	5.4 (NE, NE)	1/48 (2)	NE (NE, NE)	6.11 (0.77,48.29)	0.0500	
Infections and infestations	Male	56/109 (51)	5.0 (3.4, 13.8)	36/120 (30)	9.0 (4.6, NE)	1.41 (0.92,2.15)	0.1149	0.5976
	Female	42/69 (61)	2.8 (1.1, 33.9)	19/48 (40)	NE (2.6, NE)	1.38 (0.80,2.40)	0.2414	
Oral candidiasis	Male	8/109 (7)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	8.27 (1.03,66.42)	0.0178	0.2340
	Female	8/69 (12)	NE (NE, NE)	4/48 (8)	7.1 (NE, NE)	1.91 (0.51,7.18)	0.3326	
Rhinovirus infection	Male	6/109 (6)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Female	5/69 (7)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Male	13/109 (12)	NE (NE, NE)	17/120 (14)	NE (NE, NE)	0.70 (0.34,1.44)	0.3268	0.1597
	Female	10/69 (14)	25.6 (NE, NE)	16/48 (33)	NE (3.1, NE)	0.34 (0.15,0.77)	0.0068	
Infusion related reaction	Male	0/109 (0)	NE (NE, NE)	6/120 (5)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Female	1/69 (1)	NE (NE, NE)	7/48 (15)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Male	26/109 (24)	NE (NE, NE)	11/120 (9)	NE (NE, NE)	2.53 (1.25,5.12)	0.0076	0.4274
	Female	11/69 (16)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	1.57 (0.55,4.52)	0.3994	
C-reactive protein increased	Male	16/109 (15)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	6.02 (1.75,20.65)	0.0011	0.8880
	Female	7/69 (10)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	5.01 (0.62,40.72)	0.0931	
Platelet count decreased	Male	21/109 (19)	NE (NE, NE)	42/120 (35)	NE (3.3, NE)	0.43 (0.26,0.74)	0.0015	0.3044
	Female	11/69 (16)	NE (NE, NE)	22/48 (46)	3.4 (1.4, NE)	0.29 (0.14,0.60)	0.0004	
Weight increased	Male	3/109 (3)	NE (NE, NE)	10/120 (8)	NE (NE, NE)	0.29 (0.08,1.07)	0.0472	0.4818
	Female	2/69 (3)	NE (NE, NE)	2/48 (4)	NE (NE, NE)	0.68 (0.10,4.81)	0.6942	
Metabolism and nutrition disorders	Male	77/109 (71)	1.1 (1.0, 1.2)	61/120 (51)	2.8 (1.6, NE)	1.39 (0.99,1.95)	0.0504	0.8235

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Female	54/69 (78)	0.8 (0.7, 1.0)	32/48 (67)	2.3 (0.7, 3.1)	1.45 (0.93,2.27)	0.0953	
Hyperglycaemia	Male	19/109 (17)	NE (NE, NE)	10/120 (8)	NE (NE, NE)	2.04 (0.95,4.40)	0.0616	0.4912
	Female	14/69 (20)	NE (NE, NE)	7/48 (15)	NE (NE, NE)	1.36 (0.55,3.37)	0.5050	
Hypomagnesaemia	Male	10/109 (9)	NE (NE, NE)	17/120 (14)	NE (NE, NE)	0.54 (0.25,1.18)	0.1183	0.6835
	Female	13/69 (19)	5.0 (NE, NE)	17/48 (35)	NE (3.1, NE)	0.43 (0.21,0.90)	0.0219	
Hyponatraemia	Male	15/109 (14)	NE (NE, NE)	7/120 (6)	NE (NE, NE)	2.23 (0.91,5.49)	0.0718	0.3139
	Female	10/69 (14)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	7.15 (0.92,55.87)	0.0282	
Nervous system disorders	Male	83/109 (76)	1.1 (1.0, 1.2)	62/120 (52)	3.0 (1.1, NE)	1.50 (1.08,2.09)	0.0143	0.3533
	Female	54/69 (78)	1.0 (0.9, 1.1)	25/48 (52)	4.8 (0.9, NE)	1.94 (1.19,3.15)	0.0063	
Dizziness	Male	26/109 (24)	NE (NE, NE)	11/120 (9)	NE (NE, NE)	2.49 (1.23,5.05)	0.0085	0.0620
	Female	14/69 (20)	NE (NE, NE)	10/48 (21)	NE (NE, NE)	0.89 (0.40,2.01)	0.7798	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Male	2/109 (2)	NE (NE, NE)	12/120 (10)	NE (NE, NE)	0.15 (0.03,0.68)	0.0047	0.1152
	Female	3/69 (4)	NE (NE, NE)	2/48 (4)	NE (NE, NE)	1.01 (0.17,6.06)	0.9898	
Encephalopathy	Male	17/109 (16)	NE (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9888
	Female	14/69 (20)	NE (NE, NE)	2/48 (4)	NE (NE, NE)	5.23 (1.19,23.00)	0.0143	
Headache	Male	50/109 (46)	NE (1.3, NE)	32/120 (27)	NE (NE, NE)	1.75 (1.12,2.72)	0.0125	0.2648
	Female	33/69 (48)	1.3 (1.1, NE)	11/48 (23)	7.0 (NE, NE)	2.79 (1.37,5.67)	0.0029	
Peripheral sensory neuropathy	Male	0/109 (0)	NE (NE, NE)	8/120 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Female	1/69 (1)	NE (NE, NE)	2/48 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Male	9/109 (8)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	9.73 (1.23,76.82)	0.0079	0.8423
	Female	10/69 (14)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	7.29 (0.93,56.95)	0.0261	
Tremor	Male	32/109 (29)	NE (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9877

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Female	12/69 (17)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	9.12 (1.19,70.17)	0.0096	
Psychiatric disorders	Male	49/109 (45)	NE (1.5, NE)	24/120 (20)	NE (NE, NE)	2.32 (1.42,3.79)	0.0005	0.3148
	Female	34/69 (49)	3.2 (1.3, NE)	16/48 (33)	NE (2.7, NE)	1.64 (0.90,2.99)	0.1004	
Agitation	Male	7/109 (6)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Female	4/69 (6)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Male	29/109 (27)	NE (NE, NE)	2/120 (2)	NE (NE, NE)	16.80 (4.01,70.41)	<0.0001	0.1768
	Female	12/69 (17)	27.6 (NE, NE)	2/48 (4)	NE (NE, NE)	4.07 (0.90,18.36)	0.0478	
Respiratory, thoracic and mediastinal disorders	Male	70/109 (64)	1.2 (1.1, 2.3)	53/120 (44)	3.4 (3.0, NE)	1.47 (1.02,2.10)	0.0337	0.8457
	Female	35/69 (51)	3.5 (1.0, NE)	19/48 (40)	NE (2.7, NE)	1.33 (0.76,2.33)	0.3110	
Cough	Male	30/109 (28)	NE (NE, NE)	13/120 (11)	NE (NE, NE)	2.45 (1.28,4.71)	0.0053	0.9837
	Female	17/69 (25)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	2.47 (0.91,6.69)	0.0662	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Male	9/109 (8)	NE (NE, NE)	21/120 (18)	NE (NE, NE)	0.40 (0.18,0.87)	0.0171	0.9997
	Female	0/69 (0)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypoxia	Male	25/109 (23)	NE (NE, NE)	8/120 (7)	NE (NE, NE)	3.40 (1.53,7.54)	0.0014	0.3550
	Female	13/69 (19)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	1.90 (0.68,5.34)	0.2142	
Pleural effusion	Male	6/109 (6)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Female	6/69 (9)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	Male	7/109 (6)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	2.28 (0.59,8.87)	0.2202	0.9913
	Female	5/69 (7)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Male	61/109 (56)	1.4 (1.2, NE)	36/120 (30)	NE (3.7, NE)	2.01 (1.33,3.05)	0.0007	0.4542
	Female	39/69 (57)	1.2 (1.1, NE)	20/48 (42)	NE (2.2, NE)	1.54 (0.89,2.64)	0.1143	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.2. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Male	46/109 (42)	NE (1.4, NE)	16/120 (13)	NE (NE, NE)	3.54 (2.00,6.25)	<0.0001	0.9687
	Female	34/69 (49)	1.4 (1.1, NE)	9/48 (19)	NE (NE, NE)	3.38 (1.62,7.07)	0.0006	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	White	5/144 (3)	28.3 (28.3, NE)	40/145 (28)	7.2 (4.1, NE)	0.04 (0.01,0.14)	<0.0001	0.3475
	Other	2/34 (6)	12.1 (4.9, NE)	6/23 (26)	NE (2.8, NE)	0.06 (0.01,0.49)	0.0004	
Neutropenia	White	61/144 (42)	NE (1.8, NE)	24/145 (17)	NE (NE, NE)	2.75 (1.71,4.42)	<0.0001	0.8061
	Other	16/34 (47)	NE (1.0, NE)	5/23 (22)	NE (2.6, NE)	2.36 (0.86,6.46)	0.0838	
Thrombocytopenia	White	19/144 (13)	NE (NE, NE)	38/145 (26)	NE (NE, NE)	0.43 (0.24,0.74)	0.0018	0.4605
	Other	4/34 (12)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	0.84 (0.19,3.78)	0.8249	
Cardiac disorders	White	68/144 (47)	NE (1.3, NE)	29/145 (20)	NE (NE, NE)	2.69 (1.74,4.15)	<0.0001	0.7699
	Other	19/34 (56)	1.2 (0.9, NE)	7/23 (30)	NE (2.9, NE)	2.27 (0.95,5.42)	0.0572	
Sinus tachycardia	White	46/144 (32)	NE (NE, NE)	14/145 (10)	NE (NE, NE)	3.62 (1.99,6.58)	<0.0001	0.8475
	Other	15/34 (44)	NE (1.1, NE)	3/23 (13)	NE (NE, NE)	4.08 (1.18,14.12)	0.0156	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	White	5/144 (3)	NE (NE, NE)	16/145 (11)	NE (NE, NE)	0.28 (0.10,0.76)	0.0078	0.9913
	Other	0/34 (0)	NE (NE, NE)	2/23 (9)	NE (NE, NE)	NE (NE,NE)	NE	
Gastrointestinal disorders	White	117/144 (81)	0.9 (0.8, 1.0)	123/145 (85)	0.2 (0.1, 0.4)	0.61 (0.47,0.79)	<0.0001	0.1655
	Other	34/34 (100)	0.7 (0.6, 0.9)	20/23 (87)	0.2 (0.1, 0.8)	1.01 (0.57,1.79)	0.9591	
Nausea	White	73/144 (51)	1.6 (1.1, NE)	98/145 (68)	0.9 (0.7, 2.1)	0.52 (0.38,0.71)	<0.0001	0.7594
	Other	23/34 (68)	1.0 (0.8, 1.3)	18/23 (78)	0.3 (0.1, 1.0)	0.60 (0.32,1.12)	0.0975	
Stomatitis	White	4/144 (3)	NE (NE, NE)	26/145 (18)	NE (NE, NE)	0.10 (0.03,0.29)	<0.0001	0.2999
	Other	2/34 (6)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	0.37 (0.06,2.22)	0.2563	
General disorders and administration site conditions	White	133/144 (92)	0.9 (0.8, 1.0)	108/145 (74)	0.7 (0.3, 1.0)	1.32 (1.02,1.72)	0.0336	0.7915
	Other	32/34 (94)	0.8 (0.7, 0.9)	17/23 (74)	0.5 (0.2, 2.4)	1.33 (0.73,2.44)	0.3480	
Chills	White	39/144 (27)	NE (NE, NE)	13/145 (9)	NE (NE, NE)	3.13 (1.67,5.88)	0.0002	0.4812

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Other	9/34 (26)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	6.94 (0.88,54.82)	0.0322	
Mucosal inflammation	White	1/144 (1)	NE (NE, NE)	15/145 (10)	7.0 (4.9, NE)	0.05 (0.01,0.36)	<0.0001	0.9919
	Other	0/34 (0)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	White	130/144 (90)	1.0 (1.0, 1.0)	34/145 (23)	6.9 (NE, NE)	9.76 (6.54,14.57)	<0.0001	0.2508
	Other	31/34 (91)	0.9 (0.8, 1.1)	9/23 (39)	4.8 (2.5, NE)	5.22 (2.37,11.52)	<0.0001	
Hepatobiliary disorders	White	19/144 (13)	NE (NE, NE)	3/145 (2)	NE (NE, NE)	6.28 (1.86,21.24)	0.0007	0.9994
	Other	0/34 (0)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	White	12/144 (8)	NE (NE, NE)	1/145 (1)	NE (NE, NE)	12.09 (1.57,93.02)	0.0022	0.9994
	Other	0/34 (0)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	White	19/144 (13)	5.1 (5.1, NE)	2/145 (1)	NE (NE, NE)	7.83 (1.81,33.94)	0.0011	0.4174
	Other	5/34 (15)	5.0 (NE, NE)	1/23 (4)	NE (NE, NE)	2.16 (0.24,19.37)	0.4825	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	White	17/144 (12)	5.1 (5.1, NE)	1/145 (1)	NE (NE, NE)	13.26 (1.75,100.45)	0.0011	0.9916
	Other	5/34 (15)	5.0 (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	White	81/144 (56)	4.0 (2.7, 10.9)	47/145 (32)	9.0 (4.6, NE)	1.46 (1.01,2.11)	0.0412	0.8037
	Other	17/34 (50)	39.8 (1.1, NE)	8/23 (35)	NE (2.8, NE)	1.36 (0.58,3.19)	0.4708	
Oral candidiasis	White	13/144 (9)	NE (NE, NE)	3/145 (2)	7.1 (NE, NE)	6.53 (1.47,28.99)	0.0044	0.1077
	Other	3/34 (9)	NE (NE, NE)	2/23 (9)	NE (NE, NE)	0.95 (0.16,5.69)	0.9539	
Rhinovirus infection	White	9/144 (6)	21.9 (NE, NE)	2/145 (1)	NE (NE, NE)	3.72 (0.79,17.55)	0.0749	0.9923
	Other	2/34 (6)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	White	20/144 (14)	25.6 (NE, NE)	29/145 (20)	NE (NE, NE)	0.56 (0.31,1.00)	0.0480	0.7261
	Other	3/34 (9)	NE (NE, NE)	4/23 (17)	NE (2.4, NE)	0.43 (0.10,1.94)	0.2569	
Infusion related reaction	White	1/144 (1)	NE (NE, NE)	11/145 (8)	NE (NE, NE)	0.08 (0.01,0.63)	0.0022	0.9941

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Other	0/34 (0)	NE (NE, NE)	2/23 (9)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	White	28/144 (19)	NE (NE, NE)	12/145 (8)	NE (NE, NE)	2.30 (1.17,4.54)	0.0127	0.5355
	Other	9/34 (26)	NE (NE, NE)	4/23 (17)	NE (NE, NE)	1.53 (0.47,4.96)	0.4756	
C-reactive protein increased	White	21/144 (15)	NE (NE, NE)	4/145 (3)	NE (NE, NE)	5.45 (1.87,15.88)	0.0005	0.9895
	Other	2/34 (6)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Platelet count decreased	White	28/144 (19)	NE (NE, NE)	53/145 (37)	NE (3.4, NE)	0.44 (0.28,0.69)	0.0003	0.2387
	Other	4/34 (12)	NE (NE, NE)	11/23 (48)	3.3 (2.1, NE)	0.18 (0.06,0.59)	0.0014	
Weight increased	White	5/144 (3)	NE (NE, NE)	11/145 (8)	NE (NE, NE)	0.42 (0.14,1.20)	0.0930	0.9923
	Other	0/34 (0)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	White	104/144 (72)	1.0 (0.9, 1.1)	83/145 (57)	2.5 (1.6, 3.1)	1.36 (1.02,1.83)	0.0342	0.3955

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Other	27/34 (79)	0.9 (0.8, 1.2)	10/23 (43)	NE (0.1, NE)	1.92 (0.92,3.98)	0.0702	
Hyperglycaemia	White	27/144 (19)	NE (NE, NE)	14/145 (10)	NE (NE, NE)	1.91 (1.00,3.64)	0.0457	0.5740
	Other	6/34 (18)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	1.31 (0.33,5.22)	0.7043	
Hypomagnesaemia	White	19/144 (13)	5.0 (NE, NE)	29/145 (20)	NE (NE, NE)	0.53 (0.30,0.96)	0.0343	0.8880
	Other	4/34 (12)	NE (NE, NE)	5/23 (22)	NE (3.1, NE)	0.47 (0.13,1.76)	0.2499	
Hyponatraemia	White	21/144 (15)	NE (NE, NE)	6/145 (4)	NE (NE, NE)	3.47 (1.40,8.60)	0.0043	0.3204
	Other	4/34 (12)	NE (NE, NE)	2/23 (9)	NE (NE, NE)	1.31 (0.24,7.19)	0.7520	
Nervous system disorders	White	112/144 (78)	1.1 (1.0, 1.1)	73/145 (50)	3.2 (2.3, NE)	1.75 (1.30,2.36)	0.0002	0.2479
	Other	25/34 (74)	1.1 (0.9, 1.3)	14/23 (61)	2.4 (0.7, NE)	1.16 (0.60,2.24)	0.6561	
Dizziness	White	27/144 (19)	NE (NE, NE)	19/145 (13)	NE (NE, NE)	1.33 (0.74,2.39)	0.3433	0.1204
	Other	13/34 (38)	NE (1.3, NE)	2/23 (9)	NE (NE, NE)	4.83 (1.09,21.41)	0.0216	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	White	5/144 (3)	NE (NE, NE)	11/145 (8)	NE (NE, NE)	0.39 (0.14,1.14)	0.0745	0.9916
	Other	0/34 (0)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	White	22/144 (15)	NE (NE, NE)	2/145 (1)	NE (NE, NE)	11.58 (2.72,49.25)	<0.0001	0.9892
	Other	9/34 (26)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	White	69/144 (48)	NE (1.2, NE)	36/145 (25)	7.0 (NE, NE)	2.22 (1.47,3.33)	<0.0001	0.2407
	Other	14/34 (41)	NE (1.1, NE)	7/23 (30)	NE (3.0, NE)	1.25 (0.50,3.09)	0.6329	
Peripheral sensory neuropathy	White	1/144 (1)	NE (NE, NE)	7/145 (5)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Other	0/34 (0)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	White	16/144 (11)	NE (NE, NE)	2/145 (1)	NE (NE, NE)	8.11 (1.86,35.27)	0.0009	0.9907
	Other	3/34 (9)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	White	35/144 (24)	NE (NE, NE)	1/145 (1)	NE (NE, NE)	39.03 (5.35,284.92)	<0.0001	0.9884

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Other	9/34 (26)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	White	66/144 (46)	27.6 (1.5, NE)	34/145 (23)	NE (NE, NE)	2.04 (1.35,3.09)	0.0006	0.8360
	Other	17/34 (50)	NE (0.9, NE)	6/23 (26)	NE (3.0, NE)	2.22 (0.87,5.63)	0.0849	
Agitation	White	8/144 (6)	NE (NE, NE)	2/145 (1)	NE (NE, NE)	3.76 (0.80,17.76)	0.0725	0.9920
	Other	3/34 (9)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	White	34/144 (24)	27.6 (NE, NE)	3/145 (2)	NE (NE, NE)	11.82 (3.62,38.57)	<0.0001	0.4691
	Other	7/34 (21)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	4.73 (0.58,38.47)	0.1081	
Respiratory, thoracic and mediastinal disorders	White	86/144 (60)	1.2 (1.1, 3.1)	59/145 (41)	NE (3.3, NE)	1.53 (1.09,2.13)	0.0116	0.1379
	Other	19/34 (56)	2.4 (1.0, NE)	13/23 (57)	1.5 (0.7, NE)	0.85 (0.42,1.72)	0.6470	
Cough	White	38/144 (26)	NE (NE, NE)	15/145 (10)	NE (NE, NE)	2.55 (1.40,4.64)	0.0015	0.6859
	Other	9/34 (26)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	1.94 (0.52,7.16)	0.3112	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	White	8/144 (6)	NE (NE, NE)	17/145 (12)	NE (NE, NE)	0.41 (0.18,0.96)	0.0344	0.3622
	Other	1/34 (3)	NE (NE, NE)	4/23 (17)	NE (NE, NE)	0.16 (0.02,1.42)	0.0577	
Hypoxia	White	33/144 (23)	NE (NE, NE)	9/145 (6)	NE (NE, NE)	3.89 (1.86,8.13)	<0.0001	0.0335
	Other	5/34 (15)	NE (NE, NE)	4/23 (17)	NE (4.5, NE)	0.73 (0.20,2.73)	0.6382	
Pleural effusion	White	9/144 (6)	NE (NE, NE)	3/145 (2)	NE (NE, NE)	2.68 (0.72,9.96)	0.1246	0.9910
	Other	3/34 (9)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	White	10/144 (7)	NE (NE, NE)	2/145 (1)	NE (NE, NE)	4.83 (1.06,22.06)	0.0247	0.3596
	Other	2/34 (6)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	1.18 (0.11,13.07)	0.8921	
Vascular disorders	White	78/144 (54)	1.4 (1.2, NE)	50/145 (34)	NE (3.6, NE)	1.74 (1.22,2.48)	0.0020	0.3191
	Other	22/34 (65)	1.2 (0.9, NE)	6/23 (26)	NE (2.5, NE)	2.79 (1.12,6.93)	0.0205	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.3. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	White	63/144 (44)	NE (1.4, NE)	20/145 (14)	NE (NE, NE)	3.74 (2.26,6.20)	<0.0001	0.5837
	Other	17/34 (50)	1.4 (1.1, NE)	5/23 (22)	NE (2.6, NE)	2.64 (0.97,7.19)	0.0467	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0	5/95 (5)	28.3 (28.3, NE)	25/94 (27)	7.2 (4.1, NE)	0.07 (0.02,0.25)	<0.0001	0.5698
	1	2/83 (2)	12.1 (4.9, NE)	21/74 (28)	NE (3.3, NE)	0.02 (0.00,0.16)	<0.0001	
Neutropenia	0	44/95 (46)	NE (1.2, NE)	20/94 (21)	NE (NE, NE)	2.37 (1.40,4.03)	0.0009	0.3829
	1	33/83 (40)	NE (1.2, NE)	9/74 (12)	NE (NE, NE)	3.53 (1.69,7.39)	0.0003	
Thrombocytopenia	0	15/95 (16)	NE (NE, NE)	24/94 (26)	NE (NE, NE)	0.54 (0.28,1.03)	0.0554	0.4156
	1	8/83 (10)	NE (NE, NE)	17/74 (23)	NE (NE, NE)	0.37 (0.16,0.85)	0.0148	
Cardiac disorders	0	50/95 (53)	1.6 (1.1, NE)	24/94 (26)	NE (NE, NE)	2.55 (1.56,4.15)	<0.0001	0.7190
	1	37/83 (45)	NE (1.2, NE)	12/74 (16)	NE (NE, NE)	3.01 (1.56,5.78)	0.0005	
Sinus tachycardia	0	35/95 (37)	NE (NE, NE)	11/94 (12)	NE (NE, NE)	3.65 (1.85,7.20)	<0.0001	0.8334
	1	26/83 (31)	NE (NE, NE)	6/74 (8)	NE (NE, NE)	4.14 (1.70,10.07)	0.0007	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	0	0/95 (0)	NE (NE, NE)	11/94 (12)	NE (NE, NE)	NE (NE,NE)	NE	0.9902
	1	5/83 (6)	NE (NE, NE)	7/74 (9)	NE (NE, NE)	0.57 (0.18,1.81)	0.3301	
Gastrointestinal disorders	0	78/95 (82)	0.9 (0.8, 0.9)	81/94 (86)	0.2 (0.1, 0.5)	0.61 (0.44,0.83)	0.0013	0.3620
	1	73/83 (88)	0.8 (0.8, 1.0)	62/74 (84)	0.2 (0.1, 0.7)	0.76 (0.54,1.07)	0.1058	
Nausea	0	43/95 (45)	NE (1.2, NE)	68/94 (72)	0.8 (0.4, 1.9)	0.43 (0.29,0.63)	<0.0001	0.0444
	1	53/83 (64)	1.1 (0.9, 1.3)	48/74 (65)	0.9 (0.3, 2.5)	0.74 (0.50,1.09)	0.1226	
Stomatitis	0	3/95 (3)	NE (NE, NE)	19/94 (20)	NE (NE, NE)	0.11 (0.03,0.39)	<0.0001	0.7057
	1	3/83 (4)	NE (NE, NE)	10/74 (14)	NE (4.8, NE)	0.16 (0.04,0.60)	0.0022	
General disorders and administration site conditions	0	90/95 (95)	0.9 (0.8, 1.0)	70/94 (74)	0.8 (0.3, 1.1)	1.50 (1.08,2.08)	0.0139	0.4751
	1	75/83 (90)	0.8 (0.8, 1.0)	55/74 (74)	0.4 (0.3, 0.9)	1.14 (0.80,1.63)	0.4684	
Chills	0	27/95 (28)	NE (NE, NE)	10/94 (11)	NE (NE, NE)	2.80 (1.35,5.78)	0.0036	0.3892

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	1	21/83 (25)	NE (NE, NE)	4/74 (5)	NE (NE, NE)	5.09 (1.75,14.85)	0.0009	
Mucosal inflammation	0	0/95 (0)	NE (NE, NE)	11/94 (12)	7.0 (4.9, NE)	NE (NE,NE)	NE	0.9934
	1	1/83 (1)	NE (NE, NE)	5/74 (7)	NE (NE, NE)	0.11 (0.01,0.99)	0.0188	
Pyrexia	0	87/95 (92)	1.0 (0.9, 1.1)	26/94 (28)	6.9 (4.5, NE)	9.62 (6.00,15.42)	<0.0001	0.7767
	1	74/83 (89)	1.0 (0.8, 1.0)	17/74 (23)	NE (4.8, NE)	8.08 (4.67,14.00)	<0.0001	
Hepatobiliary disorders	0	12/95 (13)	NE (NE, NE)	2/94 (2)	NE (NE, NE)	5.89 (1.32,26.33)	0.0084	0.9911
	1	7/83 (8)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	6.01 (0.74,49.04)	0.0566	
Hypertransaminasaemia	0	7/95 (7)	NE (NE, NE)	0/94 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	1	5/83 (6)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	0	13/95 (14)	5.0 (5.0, NE)	2/94 (2)	NE (NE, NE)	5.09 (1.13,22.99)	0.0184	0.7623
	1	11/83 (13)	5.1 (NE, NE)	1/74 (1)	NE (NE, NE)	7.84 (1.00,61.41)	0.0202	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	0	12/95 (13)	5.0 (5.0, NE)	1/94 (1)	NE (NE, NE)	9.19 (1.18,71.83)	0.0101	0.9903
	1	10/83 (12)	5.1 (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	0	49/95 (52)	4.5 (2.4, 23.7)	35/94 (37)	9.0 (3.5, NE)	1.32 (0.85,2.04)	0.2147	0.5326
	1	49/83 (59)	4.0 (1.7, 10.9)	20/74 (27)	NE (4.6, NE)	1.71 (1.00,2.93)	0.0453	
Oral candidiasis	0	10/95 (11)	NE (NE, NE)	2/94 (2)	7.1 (NE, NE)	9.86 (1.26,77.14)	0.0072	0.1703
	1	6/83 (7)	NE (NE, NE)	3/74 (4)	NE (NE, NE)	1.75 (0.44,7.01)	0.4239	
Rhinovirus infection	0	3/95 (3)	NE (NE, NE)	2/94 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	1	8/83 (10)	NE (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	0	8/95 (8)	NE (NE, NE)	16/94 (17)	NE (NE, NE)	0.43 (0.19,1.02)	0.0476	0.6261
	1	15/83 (18)	25.6 (NE, NE)	17/74 (23)	NE (NE, NE)	0.59 (0.29,1.21)	0.1460	
Infusion related reaction	0	0/95 (0)	NE (NE, NE)	5/94 (5)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	1	1/83 (1)	NE (NE, NE)	8/74 (11)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	0	16/95 (17)	NE (NE, NE)	7/94 (7)	NE (NE, NE)	2.27 (0.94,5.53)	0.0622	0.8142
	1	21/83 (25)	NE (NE, NE)	9/74 (12)	NE (NE, NE)	2.02 (0.92,4.42)	0.0716	
C-reactive protein increased	0	15/95 (16)	NE (NE, NE)	3/94 (3)	NE (NE, NE)	5.14 (1.49,17.75)	0.0039	0.7752
	1	8/83 (10)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	7.24 (0.90,57.86)	0.0284	
Platelet count decreased	0	11/95 (12)	NE (NE, NE)	37/94 (39)	NE (2.9, NE)	0.22 (0.11,0.44)	<0.0001	0.0410
	1	21/83 (25)	NE (NE, NE)	27/74 (36)	NE (3.1, NE)	0.60 (0.34,1.06)	0.0762	
Weight increased	0	5/95 (5)	NE (NE, NE)	10/94 (11)	NE (NE, NE)	0.46 (0.16,1.35)	0.1456	0.9895
	1	0/83 (0)	NE (NE, NE)	2/74 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	0	63/95 (66)	1.1 (1.0, 1.3)	51/94 (54)	2.8 (2.1, NE)	1.35 (0.93,1.96)	0.1066	0.6770

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	1	68/83 (82)	0.9 (0.8, 1.0)	42/74 (57)	1.9 (0.6, 3.6)	1.50 (1.02,2.22)	0.0364	
Hyperglycaemia	0	13/95 (14)	NE (NE, NE)	8/94 (9)	NE (NE, NE)	1.59 (0.66,3.83)	0.2985	0.7385
	1	20/83 (24)	NE (NE, NE)	9/74 (12)	NE (NE, NE)	1.93 (0.88,4.24)	0.0965	
Hypomagnesaemia	0	11/95 (12)	5.0 (NE, NE)	18/94 (19)	NE (NE, NE)	0.49 (0.22,1.06)	0.0630	0.7614
	1	12/83 (14)	NE (NE, NE)	16/74 (22)	NE (4.4, NE)	0.53 (0.25,1.13)	0.0940	
Hyponatraemia	0	15/95 (16)	NE (NE, NE)	5/94 (5)	NE (NE, NE)	2.98 (1.08,8.22)	0.0261	0.9236
	1	10/83 (12)	NE (NE, NE)	3/74 (4)	NE (NE, NE)	2.88 (0.79,10.48)	0.0931	
Nervous system disorders	0	69/95 (73)	1.1 (1.0, 1.1)	52/94 (55)	3.0 (1.1, NE)	1.46 (1.01,2.10)	0.0396	0.4518
	1	68/83 (82)	1.1 (1.0, 1.1)	35/74 (47)	3.6 (0.9, NE)	1.86 (1.23,2.81)	0.0025	
Dizziness	0	20/95 (21)	NE (NE, NE)	11/94 (12)	NE (NE, NE)	1.72 (0.82,3.59)	0.1436	0.9306
	1	20/83 (24)	NE (NE, NE)	10/74 (14)	NE (NE, NE)	1.67 (0.78,3.57)	0.1829	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	0	5/95 (5)	NE (NE, NE)	10/94 (11)	NE (NE, NE)	0.44 (0.15,1.29)	0.1231	0.9921
	1	0/83 (0)	NE (NE, NE)	4/74 (5)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	0	8/95 (8)	NE (NE, NE)	0/94 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9892
	1	23/83 (28)	NE (NE, NE)	2/74 (3)	NE (NE, NE)	11.08 (2.61,47.02)	<0.0001	
Headache	0	46/95 (48)	NE (1.1, NE)	24/94 (26)	7.0 (NE, NE)	2.27 (1.37,3.75)	0.0010	0.4720
	1	37/83 (45)	NE (1.2, NE)	19/74 (26)	NE (NE, NE)	1.75 (1.01,3.05)	0.0437	
Peripheral sensory neuropathy	0	0/95 (0)	NE (NE, NE)	4/94 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	1	1/83 (1)	NE (NE, NE)	6/74 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	0	6/95 (6)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	5.96 (0.72,49.50)	0.0599	0.6427
	1	13/83 (16)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	11.74 (1.54,89.73)	0.0025	
Tremor	0	20/95 (21)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	21.27 (2.85,158.51)	<0.0001	0.9861

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	1	24/83 (29)	NE (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	0	37/95 (39)	NE (4.3, NE)	27/94 (29)	NE (NE, NE)	1.36 (0.83,2.24)	0.2229	0.0242
	1	46/83 (55)	1.4 (1.2, NE)	13/74 (18)	NE (NE, NE)	3.58 (1.93,6.64)	<0.0001	
Agitation	0	4/95 (4)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	1	7/83 (8)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	0	13/95 (14)	NE (NE, NE)	4/94 (4)	NE (NE, NE)	3.16 (1.03,9.71)	0.0334	0.9857
	1	28/83 (34)	27.6 (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Respiratory, thoracic and mediastinal disorders	0	53/95 (56)	1.4 (1.1, NE)	41/94 (44)	4.6 (3.1, NE)	1.30 (0.86,1.96)	0.2055	0.6129
	1	52/83 (63)	1.2 (1.0, 3.5)	31/74 (42)	NE (2.0, NE)	1.50 (0.96,2.34)	0.0735	
Cough	0	24/95 (25)	NE (NE, NE)	11/94 (12)	NE (NE, NE)	2.23 (1.09,4.56)	0.0233	0.7186
	1	23/83 (28)	NE (NE, NE)	7/74 (9)	NE (NE, NE)	2.83 (1.21,6.62)	0.0119	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	0	7/95 (7)	NE (NE, NE)	12/94 (13)	NE (NE, NE)	0.53 (0.21,1.34)	0.1724	0.2116
	1	2/83 (2)	NE (NE, NE)	9/74 (12)	NE (NE, NE)	0.16 (0.03,0.76)	0.0084	
Hypoxia	0	22/95 (23)	NE (NE, NE)	7/94 (7)	NE (NE, NE)	3.35 (1.43,7.85)	0.0030	0.5691
	1	16/83 (19)	NE (NE, NE)	6/74 (8)	NE (NE, NE)	2.17 (0.84,5.56)	0.0993	
Pleural effusion	0	6/95 (6)	NE (NE, NE)	3/94 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	1	6/83 (7)	NE (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	0	4/95 (4)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	3.59 (0.40,32.17)	0.2218	0.9398
	1	8/83 (10)	NE (NE, NE)	2/74 (3)	NE (NE, NE)	3.50 (0.74,16.49)	0.0914	
Vascular disorders	0	51/95 (54)	1.4 (1.2, NE)	30/94 (32)	NE (3.6, NE)	2.03 (1.29,3.19)	0.0018	0.6501
	1	49/83 (59)	1.2 (1.1, NE)	26/74 (35)	NE (2.6, NE)	1.69 (1.05,2.72)	0.0287	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.4. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0	39/95 (41)	NE (1.4, NE)	15/94 (16)	NE (NE, NE)	3.01 (1.66,5.47)	0.0001	0.3993
	1	41/83 (49)	1.9 (1.1, NE)	10/74 (14)	NE (NE, NE)	4.35 (2.17,8.69)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	North America	5/138 (4)	28.3 (12.1, NE)	34/120 (28)	NE (3.7, NE)	0.03 (0.01,0.11)	<0.0001	0.1386
	Rest of the world	2/40 (5)	NE (NE, NE)	12/48 (25)	7.2 (NE, NE)	0.15 (0.03,0.69)	0.0049	
Neutropenia	North America	59/138 (43)	NE (1.2, NE)	22/120 (18)	NE (NE, NE)	2.58 (1.58,4.21)	<0.0001	0.8487
	Rest of the world	18/40 (45)	NE (1.4, NE)	7/48 (15)	NE (NE, NE)	3.13 (1.31,7.50)	0.0068	
Thrombocytopenia	North America	18/138 (13)	NE (NE, NE)	27/120 (23)	NE (NE, NE)	0.51 (0.28,0.93)	0.0255	0.4837
	Rest of the world	5/40 (13)	NE (NE, NE)	14/48 (29)	NE (3.6, NE)	0.34 (0.12,0.94)	0.0291	
Cardiac disorders	North America	74/138 (54)	1.2 (1.1, NE)	29/120 (24)	NE (NE, NE)	2.64 (1.72,4.06)	<0.0001	0.6898
	Rest of the world	13/40 (33)	NE (1.7, NE)	7/48 (15)	NE (NE, NE)	2.29 (0.91,5.76)	0.0680	
Sinus tachycardia	North America	56/138 (41)	NE (2.3, NE)	14/120 (12)	NE (NE, NE)	4.13 (2.30,7.43)	<0.0001	0.3052
	Rest of the world	5/40 (13)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	1.84 (0.44,7.73)	0.3950	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	North America	3/138 (2)	NE (NE, NE)	11/120 (9)	NE (NE, NE)	0.20 (0.06,0.74)	0.0076	0.7574
	Rest of the world	2/40 (5)	NE (NE, NE)	7/48 (15)	NE (NE, NE)	0.30 (0.06,1.45)	0.1123	
Gastrointestinal disorders	North America	123/138 (89)	0.8 (0.7, 0.8)	104/120 (87)	0.2 (0.1, 0.5)	0.75 (0.58,0.98)	0.0287	0.0433
	Rest of the world	28/40 (70)	1.1 (1.0, 1.6)	39/48 (81)	0.2 (0.1, 0.6)	0.46 (0.28,0.75)	0.0012	
Nausea	North America	77/138 (56)	1.1 (0.9, 4.8)	85/120 (71)	0.8 (0.4, 1.0)	0.56 (0.41,0.76)	0.0002	0.6918
	Rest of the world	19/40 (48)	NE (1.2, NE)	31/48 (65)	1.6 (0.3, 3.0)	0.51 (0.29,0.91)	0.0188	
Stomatitis	North America	6/138 (4)	NE (NE, NE)	22/120 (18)	NE (NE, NE)	0.16 (0.07,0.41)	<0.0001	0.9889
	Rest of the world	0/40 (0)	NE (NE, NE)	7/48 (15)	NE (4.8, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	North America	129/138 (93)	0.8 (0.8, 0.9)	90/120 (75)	0.7 (0.3, 1.0)	1.42 (1.08,1.89)	0.0113	0.2174
	Rest of the world	36/40 (90)	1.0 (1.0, 1.1)	35/48 (73)	0.4 (0.2, 1.1)	1.08 (0.67,1.75)	0.7353	
Chills	North America	38/138 (28)	NE (NE, NE)	13/120 (11)	NE (NE, NE)	2.68 (1.43,5.04)	0.0013	0.1823

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Rest of the world	10/40 (25)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	12.28 (1.57,95.98)	0.0020	
Mucosal inflammation	North America	1/138 (1)	NE (NE, NE)	8/120 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE, NE)	8/48 (17)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	North America	127/138 (92)	0.9 (0.9, 1.0)	28/120 (23)	NE (NE, NE)	10.96 (7.10,16.91)	<0.0001	0.0120
	Rest of the world	34/40 (85)	1.2 (1.1, 1.2)	15/48 (31)	6.9 (4.3, NE)	5.12 (2.69,9.74)	<0.0001	
Hepatobiliary disorders	North America	17/138 (12)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	5.00 (1.46,17.08)	0.0043	0.9913
	Rest of the world	2/40 (5)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	North America	12/138 (9)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	10.61 (1.38,81.67)	0.0047	0.9993
	Rest of the world	0/40 (0)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	North America	18/138 (13)	5.1 (5.0, NE)	3/120 (3)	NE (NE, NE)	3.92 (1.13,13.56)	0.0199	0.9898
	Rest of the world	6/40 (15)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	North America	17/138 (12)	5.1 (5.0, NE)	1/120 (1)	NE (NE, NE)	10.97 (1.44,83.54)	0.0037	0.9917
	Rest of the world	5/40 (13)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	North America	72/138 (52)	5.0 (2.8, 13.8)	38/120 (32)	9.0 (4.6, NE)	1.41 (0.94,2.10)	0.0938	0.6720
	Rest of the world	26/40 (65)	2.7 (1.4, 4.1)	17/48 (35)	NE (3.2, NE)	1.70 (0.92,3.14)	0.0883	
Oral candidiasis	North America	13/138 (9)	NE (NE, NE)	4/120 (3)	NE (NE, NE)	2.81 (0.91,8.64)	0.0593	0.9905
	Rest of the world	3/40 (8)	NE (NE, NE)	1/48 (2)	7.1 (NE, NE)	> 10,000 (0.00,NE)	0.0627	
Rhinovirus infection	North America	9/138 (7)	21.9 (NE, NE)	2/120 (2)	NE (NE, NE)	3.00 (0.63,14.23)	0.1461	0.9927
	Rest of the world	2/40 (5)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	North America	21/138 (15)	25.6 (NE, NE)	22/120 (18)	NE (NE, NE)	0.68 (0.37,1.25)	0.2136	0.0895
	Rest of the world	2/40 (5)	NE (NE, NE)	11/48 (23)	NE (NE, NE)	0.18 (0.04,0.80)	0.0110	
Infusion related reaction	North America	1/138 (1)	NE (NE, NE)	10/120 (8)	NE (NE, NE)	0.08 (0.01,0.61)	0.0017	0.9939

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Rest of the world	0/40 (0)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	North America	34/138 (25)	NE (NE, NE)	12/120 (10)	NE (NE, NE)	2.51 (1.30,4.86)	0.0045	0.1665
	Rest of the world	3/40 (8)	NE (NE, NE)	4/48 (8)	NE (NE, NE)	0.82 (0.18,3.65)	0.7890	
C-reactive protein increased	North America	10/138 (7)	NE (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9907
	Rest of the world	13/40 (33)	NE (1.4, NE)	4/48 (8)	NE (NE, NE)	3.97 (1.29,12.18)	0.0090	
Platelet count decreased	North America	30/138 (22)	NE (NE, NE)	46/120 (38)	NE (3.1, NE)	0.48 (0.30,0.76)	0.0014	0.0332
	Rest of the world	2/40 (5)	NE (NE, NE)	18/48 (38)	NE (2.6, NE)	0.10 (0.02,0.43)	0.0001	
Weight increased	North America	0/138 (0)	NE (NE, NE)	6/120 (5)	NE (NE, NE)	NE (NE,NE)	NE	0.9917
	Rest of the world	5/40 (13)	NE (NE, NE)	6/48 (13)	NE (NE, NE)	0.91 (0.28,2.99)	0.8785	
Metabolism and nutrition disorders	North America	110/138 (80)	0.9 (0.8, 1.0)	68/120 (57)	2.3 (1.1, 3.1)	1.60 (1.18,2.17)	0.0020	0.0641

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Rest of the world	21/40 (53)	1.4 (1.2, NE)	25/48 (52)	2.8 (1.6, NE)	0.92 (0.51,1.65)	0.7752	
Hyperglycaemia	North America	30/138 (22)	NE (NE, NE)	16/120 (13)	NE (NE, NE)	1.61 (0.88,2.95)	0.1212	0.5446
	Rest of the world	3/40 (8)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	3.37 (0.35,32.36)	0.2643	
Hypomagnesaemia	North America	18/138 (13)	5.0 (NE, NE)	26/120 (22)	NE (NE, NE)	0.48 (0.26,0.89)	0.0164	0.7013
	Rest of the world	5/40 (13)	NE (NE, NE)	8/48 (17)	NE (NE, NE)	0.65 (0.21,2.01)	0.4548	
Hyponatraemia	North America	23/138 (17)	NE (NE, NE)	7/120 (6)	NE (NE, NE)	2.86 (1.22,6.67)	0.0110	0.8295
	Rest of the world	2/40 (5)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	2.29 (0.21,25.22)	0.4873	
Nervous system disorders	North America	111/138 (80)	1.0 (0.9, 1.1)	64/120 (53)	3.0 (1.0, 4.8)	1.74 (1.27,2.38)	0.0004	0.3230
	Rest of the world	26/40 (65)	1.2 (1.1, NE)	23/48 (48)	3.9 (1.1, NE)	1.30 (0.74,2.30)	0.3550	
Dizziness	North America	35/138 (25)	NE (NE, NE)	15/120 (13)	NE (NE, NE)	1.96 (1.07,3.60)	0.0258	0.2241
	Rest of the world	5/40 (13)	NE (NE, NE)	6/48 (13)	NE (NE, NE)	0.90 (0.27,2.95)	0.8601	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	North America	4/138 (3)	NE (NE, NE)	10/120 (8)	NE (NE, NE)	0.30 (0.09,0.95)	0.0302	0.8621
	Rest of the world	1/40 (3)	NE (NE, NE)	4/48 (8)	NE (NE, NE)	0.28 (0.03,2.50)	0.2223	
Encephalopathy	North America	27/138 (20)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	25.50 (3.46,187.64)	<0.0001	0.2535
	Rest of the world	4/40 (10)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	4.55 (0.51,40.67)	0.1369	
Headache	North America	66/138 (48)	NE (1.1, NE)	28/120 (23)	NE (NE, NE)	2.28 (1.46,3.55)	0.0002	0.2136
	Rest of the world	17/40 (43)	NE (1.3, NE)	15/48 (31)	7.0 (3.4, NE)	1.36 (0.67,2.77)	0.3880	
Peripheral sensory neuropathy	North America	1/138 (1)	NE (NE, NE)	7/120 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Rest of the world	0/40 (0)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	North America	17/138 (12)	NE (NE, NE)	2/120 (2)	NE (NE, NE)	7.66 (1.77,33.16)	0.0013	0.9920
	Rest of the world	2/40 (5)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	North America	40/138 (29)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	40.26 (5.54,292.80)	<0.0001	0.9907

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
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Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Rest of the world	4/40 (10)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	North America	68/138 (49)	4.3 (1.3, NE)	33/120 (28)	NE (NE, NE)	1.95 (1.28,2.96)	0.0014	0.5961
	Rest of the world	15/40 (38)	NE (1.6, NE)	7/48 (15)	NE (NE, NE)	2.56 (1.04,6.28)	0.0337	
Agitation	North America	10/138 (7)	NE (NE, NE)	2/120 (2)	NE (NE, NE)	4.17 (0.91,19.09)	0.0450	0.9933
	Rest of the world	1/40 (3)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	North America	37/138 (27)	27.6 (NE, NE)	4/120 (3)	NE (NE, NE)	8.57 (3.05,24.09)	<0.0001	0.9887
	Rest of the world	4/40 (10)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Respiratory, thoracic and mediastinal disorders	North America	87/138 (63)	1.2 (1.0, 1.7)	56/120 (47)	3.4 (2.8, NE)	1.38 (0.99,1.94)	0.0578	0.7919
	Rest of the world	18/40 (45)	NE (1.4, NE)	16/48 (33)	NE (2.7, NE)	1.29 (0.66,2.53)	0.4584	
Cough	North America	39/138 (28)	NE (NE, NE)	14/120 (12)	NE (NE, NE)	2.53 (1.37,4.66)	0.0020	0.8666
	Rest of the world	8/40 (20)	NE (NE, NE)	4/48 (8)	NE (NE, NE)	2.02 (0.61,6.73)	0.2418	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
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Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	North America	5/138 (4)	NE (NE, NE)	16/120 (13)	NE (NE, NE)	0.24 (0.09,0.65)	0.0022	0.1250
	Rest of the world	4/40 (10)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	0.87 (0.23,3.26)	0.8399	
Hypoxia	North America	32/138 (23)	NE (NE, NE)	12/120 (10)	NE (NE, NE)	2.39 (1.23,4.65)	0.0079	0.3819
	Rest of the world	6/40 (15)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	6.95 (0.84,57.67)	0.0364	
Pleural effusion	North America	11/138 (8)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	2.98 (0.83,10.72)	0.0793	0.9926
	Rest of the world	1/40 (3)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	North America	7/138 (5)	NE (NE, NE)	2/120 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Rest of the world	5/40 (13)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	North America	75/138 (54)	1.2 (1.1, NE)	42/120 (35)	NE (3.2, NE)	1.73 (1.18,2.53)	0.0040	0.6406
	Rest of the world	25/40 (63)	1.4 (1.2, NE)	14/48 (29)	NE (3.6, NE)	2.26 (1.17,4.37)	0.0115	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
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Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
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Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.5. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	North America	58/138 (42)	NE (1.2, NE)	22/120 (18)	NE (NE, NE)	2.62 (1.60,4.29)	<0.0001	0.0571
	Rest of the world	22/40 (55)	1.6 (1.2, NE)	3/48 (6)	NE (NE, NE)	10.94 (3.27,36.62)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	HGBL - double hit/triple hit	2/32 (6)	NE (4.9, NE)	5/24 (21)	NE (3.3, NE)	0.17 (0.03,0.92)	0.0215	0.2826
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	16/62 (26)	NE (3.4, NE)	0.04 (0.01,0.30)	<0.0001	
Neutropenia	HGBL - double hit/triple hit	14/32 (44)	NE (1.0, NE)	5/24 (21)	NE (3.0, NE)	2.29 (0.82,6.38)	0.1010	0.5197
	Double expressor lymphoma	22/56 (39)	NE (1.8, NE)	7/62 (11)	NE (NE, NE)	3.81 (1.63,8.93)	0.0009	
Thrombocytopenia	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	6/24 (25)	NE (3.1, NE)	0.44 (0.12,1.56)	0.1895	0.5880
	Double expressor lymphoma	8/56 (14)	NE (NE, NE)	12/62 (19)	NE (NE, NE)	0.67 (0.27,1.64)	0.3780	
Cardiac disorders	HGBL - double hit/triple hit	19/32 (59)	1.2 (0.9, NE)	5/24 (21)	NE (3.3, NE)	3.76 (1.40,10.12)	0.0048	0.2188
	Double expressor lymphoma	21/56 (38)	NE (1.4, NE)	13/62 (21)	NE (NE, NE)	1.86 (0.93,3.72)	0.0736	
Sinus tachycardia	HGBL - double hit/triple hit	14/32 (44)	NE (1.0, NE)	2/24 (8)	NE (3.3, NE)	6.34 (1.43,28.00)	0.0052	0.2753
	Double expressor lymphoma	16/56 (29)	NE (NE, NE)	7/62 (11)	NE (NE, NE)	2.67 (1.10,6.50)	0.0238	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	2/24 (8)	NE (NE, NE)	0.36 (0.03,4.00)	0.3879	0.6382
	Double expressor lymphoma	2/56 (4)	NE (NE, NE)	11/62 (18)	NE (NE, NE)	0.17 (0.04,0.79)	0.0102	
Gastrointestinal disorders	HGBL - double hit/triple hit	28/32 (88)	0.8 (0.6, 1.0)	20/24 (83)	0.2 (0.1, 0.8)	0.76 (0.43,1.36)	0.3510	0.4915
	Double expressor lymphoma	47/56 (84)	0.9 (0.8, 1.0)	55/62 (89)	0.2 (0.1, 0.6)	0.64 (0.43,0.95)	0.0216	
Nausea	HGBL - double hit/triple hit	22/32 (69)	0.9 (0.8, 1.2)	14/24 (58)	1.0 (0.3, NE)	1.07 (0.55,2.10)	0.8361	0.0965
	Double expressor lymphoma	30/56 (54)	1.4 (1.1, NE)	45/62 (73)	1.5 (0.3, 2.5)	0.53 (0.34,0.85)	0.0072	
Stomatitis	HGBL - double hit/triple hit	0/32 (0)	NE (NE, NE)	3/24 (13)	NE (4.1, NE)	NE (NE,NE)	NE	0.9905
	Double expressor lymphoma	3/56 (5)	NE (NE, NE)	15/62 (24)	NE (4.8, NE)	0.15 (0.04,0.51)	0.0006	
General disorders and administration site conditions	HGBL - double hit/triple hit	31/32 (97)	0.8 (0.7, 0.8)	18/24 (75)	0.8 (0.2, 2.3)	1.92 (1.01,3.66)	0.0366	0.0676
	Double expressor lymphoma	52/56 (93)	0.9 (0.7, 1.0)	51/62 (82)	0.3 (0.1, 0.7)	0.89 (0.60,1.32)	0.5623	
Chills	HGBL - double hit/triple hit	12/32 (38)	NE (1.2, NE)	3/24 (13)	NE (4.0, NE)	3.33 (0.94,11.84)	0.0474	0.3963

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Double expressor lymphoma	18/56 (32)	NE (NE, NE)	3/62 (5)	NE (NE, NE)	7.44 (2.19,25.28)	0.0001	
Mucosal inflammation	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	3/24 (13)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/56 (0)	NE (NE, NE)	8/62 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	HGBL - double hit/triple hit	30/32 (94)	0.8 (0.8, 1.0)	4/24 (17)	NE (4.5, NE)	19.52 (5.57,68.42)	<0.0001	0.1709
	Double expressor lymphoma	51/56 (91)	1.0 (0.9, 1.1)	16/62 (26)	NE (4.3, NE)	9.32 (5.13,16.91)	<0.0001	
Hepatobiliary disorders	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/56 (4)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	HGBL - double hit/triple hit	6/32 (19)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9914
	Double expressor lymphoma	10/56 (18)	NE (NE, NE)	2/62 (3)	NE (NE, NE)	5.14 (1.12,23.47)	0.0187	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	HGBL - double hit/triple hit	5/32 (16)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	10/56 (18)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	HGBL - double hit/triple hit	20/32 (63)	3.1 (1.1, 33.9)	5/24 (21)	NE (4.6, NE)	2.56 (0.94,7.01)	0.0570	0.4449
	Double expressor lymphoma	31/56 (55)	4.0 (1.3, NE)	21/62 (34)	9.0 (3.7, NE)	1.60 (0.91,2.80)	0.0965	
Oral candidiasis	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/56 (9)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Rhinovirus infection	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	4/56 (7)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	4/24 (17)	NE (3.2, NE)	0.41 (0.09,1.88)	0.2369	0.8438
	Double expressor lymphoma	8/56 (14)	25.6 (NE, NE)	15/62 (24)	NE (NE, NE)	0.45 (0.19,1.12)	0.0771	
Infusion related reaction	HGBL - double hit/triple hit	0/32 (0)	NE (NE, NE)	2/24 (8)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Double expressor lymphoma	0/56 (0)	NE (NE, NE)	7/62 (11)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	HGBL - double hit/triple hit	9/32 (28)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	7.77 (0.98,61.39)	0.0214	0.1672
	Double expressor lymphoma	13/56 (23)	NE (NE, NE)	9/62 (15)	NE (NE, NE)	1.59 (0.68,3.71)	0.2830	
C-reactive protein increased	HGBL - double hit/triple hit	9/32 (28)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	7.73 (0.98,61.10)	0.0214	0.9073
	Double expressor lymphoma	8/56 (14)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	8.94 (1.12,71.46)	0.0118	
Platelet count decreased	HGBL - double hit/triple hit	8/32 (25)	NE (NE, NE)	6/24 (25)	NE (NE, NE)	0.91 (0.31,2.62)	0.8583	0.1138
	Double expressor lymphoma	10/56 (18)	NE (NE, NE)	29/62 (47)	3.5 (2.5, NE)	0.29 (0.14,0.59)	0.0003	
Weight increased	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	6/62 (10)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	HGBL - double hit/triple hit	29/32 (91)	0.9 (0.7, 1.1)	15/24 (63)	1.2 (0.4, NE)	1.84 (0.97,3.50)	0.0557	0.4343

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Double expressor lymphoma	42/56 (75)	1.0 (0.8, 1.1)	38/62 (61)	2.3 (0.8, 3.1)	1.35 (0.87,2.11)	0.1730	
Hyperglycaemia	HGBL - double hit/triple hit	7/32 (22)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	5.98 (0.74,48.63)	0.0569	0.2383
	Double expressor lymphoma	6/56 (11)	NE (NE, NE)	5/62 (8)	NE (NE, NE)	1.27 (0.39,4.16)	0.6952	
Hypomagnesaemia	HGBL - double hit/triple hit	5/32 (16)	NE (NE, NE)	6/24 (25)	NE (3.1, NE)	0.55 (0.17,1.81)	0.3159	0.6878
	Double expressor lymphoma	9/56 (16)	NE (NE, NE)	12/62 (19)	NE (NE, NE)	0.76 (0.32,1.81)	0.5383	
Hyponatraemia	HGBL - double hit/triple hit	9/32 (28)	NE (NE, NE)	2/24 (8)	NE (NE, NE)	3.38 (0.73,15.66)	0.0975	0.7705
	Double expressor lymphoma	9/56 (16)	NE (NE, NE)	4/62 (6)	NE (NE, NE)	2.45 (0.75,7.95)	0.1240	
Nervous system disorders	HGBL - double hit/triple hit	24/32 (75)	0.9 (0.9, 1.2)	12/24 (50)	3.3 (0.7, NE)	1.66 (0.82,3.36)	0.1453	0.9056
	Double expressor lymphoma	50/56 (89)	1.0 (0.9, 1.1)	37/62 (60)	2.3 (0.7, 3.0)	1.75 (1.13,2.70)	0.0094	
Dizziness	HGBL - double hit/triple hit	10/32 (31)	NE (4.2, NE)	4/24 (17)	NE (NE, NE)	1.86 (0.58,5.95)	0.2869	0.8549
	Double expressor lymphoma	17/56 (30)	NE (NE, NE)	11/62 (18)	NE (NE, NE)	1.60 (0.75,3.42)	0.2210	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	2/24 (8)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	8/62 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	HGBL - double hit/triple hit	8/32 (25)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	8/56 (14)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	HGBL - double hit/triple hit	10/32 (31)	NE (1.3, NE)	4/24 (17)	NE (NE, NE)	2.05 (0.64,6.56)	0.2134	0.7597
	Double expressor lymphoma	34/56 (61)	1.1 (1.1, NE)	17/62 (27)	NE (NE, NE)	2.60 (1.45,4.67)	0.0008	
Peripheral sensory neuropathy	HGBL - double hit/triple hit	0/32 (0)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	6/62 (10)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	4/56 (7)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	HGBL - double hit/triple hit	11/32 (34)	NE (1.3, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9921

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Double expressor lymphoma	11/56 (20)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	12.63 (1.63,97.86)	0.0017	
Psychiatric disorders	HGBL - double hit/triple hit	19/32 (59)	1.3 (1.0, NE)	7/24 (29)	NE (2.7, NE)	2.39 (1.00,5.70)	0.0411	0.7226
	Double expressor lymphoma	25/56 (45)	27.6 (1.4, NE)	13/62 (21)	NE (NE, NE)	2.09 (1.06,4.12)	0.0284	
Agitation	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	HGBL - double hit/triple hit	11/32 (34)	NE (1.3, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9915
	Double expressor lymphoma	14/56 (25)	27.6 (NE, NE)	1/62 (2)	NE (NE, NE)	14.76 (1.93,112.88)	0.0006	
Respiratory, thoracic and mediastinal disorders	HGBL - double hit/triple hit	21/32 (66)	1.1 (0.9, 4.8)	10/24 (42)	NE (1.1, NE)	1.77 (0.83,3.76)	0.1325	0.3659
	Double expressor lymphoma	34/56 (61)	1.2 (1.1, NE)	30/62 (48)	4.6 (1.4, NE)	1.24 (0.76,2.04)	0.3801	
Cough	HGBL - double hit/triple hit	6/32 (19)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	4.76 (0.57,39.56)	0.1096	0.4432
	Double expressor lymphoma	16/56 (29)	NE (NE, NE)	9/62 (15)	NE (NE, NE)	1.87 (0.83,4.24)	0.1262	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	4/24 (17)	NE (3.4, NE)	0.42 (0.09,1.94)	0.2553	0.6056
	Double expressor lymphoma	3/56 (5)	NE (NE, NE)	9/62 (15)	NE (NE, NE)	0.34 (0.09,1.25)	0.0867	
Hypoxia	HGBL - double hit/triple hit	6/32 (19)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9904
	Double expressor lymphoma	13/56 (23)	NE (NE, NE)	3/62 (5)	NE (NE, NE)	5.03 (1.43,17.67)	0.0050	
Pleural effusion	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	3/56 (5)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	7/56 (13)	NE (NE, NE)	2/62 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	20/32 (63)	1.2 (0.9, NE)	7/24 (29)	NE (3.1, NE)	2.88 (1.21,6.87)	0.0121	0.2794
	Double expressor lymphoma	31/56 (55)	1.4 (1.1, NE)	23/62 (37)	NE (2.6, NE)	1.68 (0.98,2.89)	0.0558	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.6. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	HGBL - double hit/triple hit	19/32 (59)	1.2 (1.0, NE)	4/24 (17)	NE (3.3, NE)	4.84 (1.64,14.32)	0.0016	0.5228
	Double expressor lymphoma	25/56 (45)	NE (1.2, NE)	10/62 (16)	NE (NE, NE)	3.34 (1.60,6.97)	0.0006	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	HGBL - double hit/triple hit	2/40 (5)	NE (4.9, NE)	9/31 (29)	7.2 (3.3, NE)	0.11 (0.02,0.54)	0.0012	0.4318
	Double expressor lymphoma	1/44 (2)	NE (NE, NE)	10/33 (30)	NE (3.1, NE)	0.04 (0.01,0.33)	<0.0001	
Neutropenia	HGBL - double hit/triple hit	17/40 (43)	NE (1.0, NE)	5/31 (16)	NE (NE, NE)	2.95 (1.08,8.00)	0.0255	0.8220
	Double expressor lymphoma	22/44 (50)	3.2 (1.0, NE)	7/33 (21)	NE (NE, NE)	2.59 (1.11,6.09)	0.0224	
Thrombocytopenia	HGBL - double hit/triple hit	4/40 (10)	NE (NE, NE)	10/31 (32)	NE (3.1, NE)	0.24 (0.08,0.79)	0.0104	0.4583
	Double expressor lymphoma	7/44 (16)	NE (NE, NE)	10/33 (30)	NE (2.9, NE)	0.47 (0.18,1.23)	0.1119	
Cardiac disorders	HGBL - double hit/triple hit	23/40 (58)	1.2 (0.9, NE)	6/31 (19)	NE (4.0, NE)	3.89 (1.58,9.58)	0.0014	0.8356
	Double expressor lymphoma	25/44 (57)	1.2 (1.0, NE)	5/33 (15)	NE (4.6, NE)	4.95 (1.89,12.97)	0.0003	
Sinus tachycardia	HGBL - double hit/triple hit	18/40 (45)	NE (1.0, NE)	2/31 (6)	NE (NE, NE)	8.66 (2.00,37.38)	0.0005	0.8744
	Double expressor lymphoma	18/44 (41)	NE (1.3, NE)	2/33 (6)	NE (NE, NE)	8.01 (1.86,34.56)	0.0009	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	3/31 (10)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Gastrointestinal disorders	HGBL - double hit/triple hit	34/40 (85)	0.8 (0.8, 0.9)	26/31 (84)	0.2 (0.1, 0.7)	0.63 (0.38,1.06)	0.0723	0.4951
	Double expressor lymphoma	38/44 (86)	0.8 (0.6, 1.0)	26/33 (79)	0.4 (0.1, 0.8)	0.89 (0.54,1.47)	0.6337	
Nausea	HGBL - double hit/triple hit	23/40 (58)	1.2 (0.9, NE)	21/31 (68)	0.5 (0.1, 3.0)	0.55 (0.31,1.00)	0.0453	0.7954
	Double expressor lymphoma	23/44 (52)	1.4 (1.0, NE)	21/33 (64)	1.2 (0.2, 3.3)	0.61 (0.33,1.11)	0.0996	
Stomatitis	HGBL - double hit/triple hit	0/40 (0)	NE (NE, NE)	4/31 (13)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	5/33 (15)	NE (NE, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	HGBL - double hit/triple hit	39/40 (98)	0.8 (0.7, 0.8)	24/31 (77)	1.0 (0.3, 3.2)	2.35 (1.29,4.27)	0.0033	0.7033
	Double expressor lymphoma	41/44 (93)	0.7 (0.6, 1.0)	23/33 (70)	0.7 (0.3, 2.9)	1.73 (1.00,2.99)	0.0435	
Chills	HGBL - double hit/triple hit	13/40 (33)	NE (1.2, NE)	3/31 (10)	NE (NE, NE)	3.61 (1.03,12.70)	0.0313	0.8398

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Double expressor lymphoma	11/44 (25)	NE (NE, NE)	3/33 (9)	NE (NE, NE)	2.92 (0.81,10.48)	0.0838	
Mucosal inflammation	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	5/31 (16)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	HGBL - double hit/triple hit	38/40 (95)	0.8 (0.8, 0.9)	5/31 (16)	6.9 (NE, NE)	45.16 (10.25,199.03)	<0.0001	0.1375
	Double expressor lymphoma	40/44 (91)	0.9 (0.8, 1.0)	7/33 (21)	NE (3.4, NE)	14.60 (5.92,35.99)	<0.0001	
Hepatobiliary disorders	HGBL - double hit/triple hit	6/40 (15)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	HGBL - double hit/triple hit	5/40 (13)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	HGBL - double hit/triple hit	7/40 (18)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	HGBL - double hit/triple hit	6/40 (15)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	HGBL - double hit/triple hit	24/40 (60)	5.0 (1.4, 23.7)	9/31 (29)	NE (4.6, NE)	1.49 (0.67,3.32)	0.3278	0.7023
	Double expressor lymphoma	24/44 (55)	3.4 (1.3, NE)	9/33 (27)	NE (3.4, NE)	1.92 (0.89,4.17)	0.0921	
Oral candidiasis	HGBL - double hit/triple hit	3/40 (8)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Rhinovirus infection	HGBL - double hit/triple hit	2/40 (5)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/44 (2)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	HGBL - double hit/triple hit	4/40 (10)	NE (NE, NE)	6/31 (19)	NE (NE, NE)	0.40 (0.11,1.45)	0.1501	0.2365
	Double expressor lymphoma	7/44 (16)	25.6 (NE, NE)	3/33 (9)	NE (NE, NE)	1.53 (0.38,6.12)	0.5451	
Infusion related reaction	HGBL - double hit/triple hit	0/40 (0)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Double expressor lymphoma	0/44 (0)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	HGBL - double hit/triple hit	11/40 (28)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9918
	Double expressor lymphoma	7/44 (16)	NE (NE, NE)	3/33 (9)	NE (NE, NE)	1.66 (0.43,6.45)	0.4592	
C-reactive protein increased	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	3.22 (0.68,15.18)	0.1164	0.9931
	Double expressor lymphoma	6/44 (14)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Platelet count decreased	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	10/31 (32)	NE (1.1, NE)	0.54 (0.21,1.36)	0.1808	0.8412
	Double expressor lymphoma	8/44 (18)	NE (NE, NE)	12/33 (36)	3.7 (2.7, NE)	0.37 (0.15,0.93)	0.0288	
Weight increased	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/44 (2)	NE (NE, NE)	2/33 (6)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	HGBL - double hit/triple hit	33/40 (83)	0.9 (0.8, 1.1)	17/31 (55)	3.1 (0.4, NE)	1.97 (1.08,3.62)	0.0239	0.9610

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Double expressor lymphoma	33/44 (75)	0.9 (0.6, 1.2)	16/33 (48)	2.8 (1.0, NE)	1.94 (1.06,3.53)	0.0264	
Hyperglycaemia	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	3.18 (0.68,14.97)	0.1216	0.3806
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	3/33 (9)	NE (NE, NE)	1.19 (0.28,5.00)	0.8130	
Hypomagnesaemia	HGBL - double hit/triple hit	5/40 (13)	NE (NE, NE)	8/31 (26)	NE (3.1, NE)	0.41 (0.13,1.25)	0.1042	0.1364
	Double expressor lymphoma	8/44 (18)	NE (NE, NE)	4/33 (12)	NE (NE, NE)	1.52 (0.46,5.06)	0.4928	
Hyponatraemia	HGBL - double hit/triple hit	11/40 (28)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	4.29 (0.95,19.36)	0.0387	0.9429
	Double expressor lymphoma	6/44 (14)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	4.62 (0.55,38.54)	0.1199	
Nervous system disorders	HGBL - double hit/triple hit	29/40 (73)	1.0 (0.9, 1.2)	16/31 (52)	3.9 (0.8, NE)	1.69 (0.90,3.17)	0.0946	0.5414
	Double expressor lymphoma	36/44 (82)	1.0 (0.9, 1.2)	15/33 (45)	3.2 (2.3, NE)	2.47 (1.34,4.55)	0.0026	
Dizziness	HGBL - double hit/triple hit	12/40 (30)	NE (NE, NE)	4/31 (13)	NE (NE, NE)	2.29 (0.74,7.12)	0.1390	0.9753
	Double expressor lymphoma	12/44 (27)	NE (NE, NE)	4/33 (12)	NE (NE, NE)	2.21 (0.71,6.89)	0.1604	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	3/31 (10)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	3/44 (7)	NE (NE, NE)	2/33 (6)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	6.47 (0.81,51.74)	0.0423	0.9926
	Double expressor lymphoma	12/44 (27)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	HGBL - double hit/triple hit	13/40 (33)	NE (1.3, NE)	7/31 (23)	7.0 (NE, NE)	1.77 (0.67,4.67)	0.2390	0.9713
	Double expressor lymphoma	17/44 (39)	NE (1.2, NE)	7/33 (21)	NE (NE, NE)	1.87 (0.77,4.50)	0.1573	
Peripheral sensory neuropathy	HGBL - double hit/triple hit	0/40 (0)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	0/44 (0)	NE (NE, NE)	3/33 (9)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	HGBL - double hit/triple hit	4/40 (10)	NE (NE, NE)	2/31 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	HGBL - double hit/triple hit	13/40 (33)	NE (1.4, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9894

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Double expressor lymphoma	7/44 (16)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	5.31 (0.65,43.28)	0.0803	
Psychiatric disorders	HGBL - double hit/triple hit	23/40 (58)	1.3 (1.0, NE)	10/31 (32)	NE (2.6, NE)	1.93 (0.92,4.06)	0.0750	0.3127
	Double expressor lymphoma	17/44 (39)	27.6 (1.5, NE)	10/33 (30)	NE (2.9, NE)	1.07 (0.48,2.39)	0.8604	
Agitation	HGBL - double hit/triple hit	4/40 (10)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	HGBL - double hit/triple hit	13/40 (33)	NE (1.3, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9894
	Double expressor lymphoma	8/44 (18)	27.6 (NE, NE)	1/33 (3)	NE (NE, NE)	4.77 (0.58,39.01)	0.1082	
Respiratory, thoracic and mediastinal disorders	HGBL - double hit/triple hit	28/40 (70)	1.1 (0.9, 4.0)	15/31 (48)	3.4 (1.1, NE)	1.51 (0.80,2.84)	0.1989	0.9922
	Double expressor lymphoma	28/44 (64)	1.1 (1.0, 3.1)	14/33 (42)	3.1 (3.0, NE)	1.56 (0.82,2.96)	0.1710	
Cough	HGBL - double hit/triple hit	10/40 (25)	NE (NE, NE)	3/31 (10)	NE (NE, NE)	2.75 (0.76,10.00)	0.1085	0.6830
	Double expressor lymphoma	11/44 (25)	NE (NE, NE)	4/33 (12)	NE (NE, NE)	1.73 (0.55,5.49)	0.3452	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	HGBL - double hit/triple hit	3/40 (8)	NE (NE, NE)	4/31 (13)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/44 (5)	NE (NE, NE)	4/33 (12)	NE (NE, NE)	NE (NE,NE)	NE	
Hypoxia	HGBL - double hit/triple hit	9/40 (23)	NE (NE, NE)	3/31 (10)	NE (NE, NE)	2.37 (0.64,8.77)	0.1833	0.3416
	Double expressor lymphoma	10/44 (23)	NE (NE, NE)	1/33 (3)	NE (4.5, NE)	8.05 (1.03,62.98)	0.0179	
Pleural effusion	HGBL - double hit/triple hit	4/40 (10)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	3/44 (7)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	HGBL - double hit/triple hit	2/40 (5)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	3/44 (7)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	23/40 (58)	1.2 (1.0, NE)	10/31 (32)	NE (3.1, NE)	1.88 (0.89,3.98)	0.0928	0.7677
	Double expressor lymphoma	30/44 (68)	1.2 (1.0, 1.4)	12/33 (36)	NE (1.9, NE)	2.38 (1.21,4.67)	0.0088	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.7. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	HGBL - double hit/triple hit	21/40 (53)	1.6 (1.0, NE)	6/31 (19)	NE (3.3, NE)	3.13 (1.26,7.79)	0.0090	0.7548
	Double expressor lymphoma	24/44 (55)	1.4 (1.0, NE)	6/33 (18)	NE (4.5, NE)	3.99 (1.63,9.81)	0.0011	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Germinal center B-cell like	5/107 (5)	28.3 (28.3, NE)	28/100 (28)	NE (4.1, NE)	0.06 (0.02,0.19)	<0.0001	0.6369
	Activated B-cell like	1/16 (6)	NE (NE, NE)	1/9 (11)	NE (3.1, NE)	0.18 (0.01,2.93)	0.1766	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Neutropenia	Germinal center B-cell like	49/107 (46)	NE (1.2, NE)	17/100 (17)	NE (NE, NE)	2.94 (1.69,5.10)	<0.0001	0.9998
	Activated B-cell like	5/16 (31)	NE (1.1, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Thrombocytopenia	Germinal center B-cell like	17/107 (16)	NE (NE, NE)	25/100 (25)	NE (NE, NE)	0.56 (0.30,1.04)	0.0624	0.4783
	Activated B-cell like	2/16 (13)	NE (NE, NE)	1/9 (11)	NE (0.7, NE)	1.19 (0.11,13.17)	0.8868	
	Unclassified	1/18 (6)	NE (NE, NE)	3/12 (25)	NE (0.5, NE)	0.20 (0.02,1.88)	0.1159	
Cardiac disorders	Germinal center B-cell like	59/107 (55)	1.4 (1.1, NE)	25/100 (25)	NE (NE, NE)	2.66 (1.67,4.26)	<0.0001	0.7869

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

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Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Cardiac disorders	Activated B-cell like	7/16 (44)	NE (0.9, NE)	1/9 (11)	NE (0.7, NE)	5.13 (0.63,41.80)	0.0861	
	Unclassified	6/18 (33)	NE (1.2, NE)	2/12 (17)	NE (3.4, NE)	1.87 (0.37,9.34)	0.4385	
Sinus tachycardia	Germinal center B-cell like	38/107 (36)	NE (NE, NE)	12/100 (12)	NE (NE, NE)	3.34 (1.74,6.39)	0.0001	0.9549
	Activated B-cell like	7/16 (44)	NE (0.9, NE)	1/9 (11)	NE (0.7, NE)	5.22 (0.64,42.59)	0.0849	
	Unclassified	4/18 (22)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Ear and labyrinth disorders	Germinal center B-cell like	2/107 (2)	NE (NE, NE)	8/100 (8)	NE (NE, NE)	0.21 (0.04,0.98)	0.0282	0.9999
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	2/12 (17)	NE (1.0, NE)	NE (NE,NE)	NE	
Gastrointestinal disorders	Germinal center B-cell like	90/107 (84)	0.8 (0.8, 0.9)	86/100 (86)	0.2 (0.1, 0.3)	0.63 (0.46,0.84)	0.0015	0.0963
	Activated B-cell like	15/16 (94)	0.6 (0.3, 0.9)	7/9 (78)	0.7 (0.0, NE)	2.25 (0.78,6.43)	0.1164	
	Unclassified	15/18 (83)	0.8 (0.7, 1.1)	8/12 (67)	0.8 (0.0, NE)	0.98 (0.42,2.32)	0.9681	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Nausea	Germinal center B-cell like	58/107 (54)	1.2 (1.0, NE)	73/100 (73)	0.7 (0.2, 1.6)	0.49 (0.35,0.70)	<0.0001	0.3225
	Activated B-cell like	10/16 (63)	1.0 (0.8, NE)	5/9 (56)	2.4 (0.0, NE)	0.99 (0.33,2.97)	0.9856	
	Unclassified	11/18 (61)	1.1 (0.8, NE)	7/12 (58)	1.0 (0.0, NE)	0.83 (0.32,2.15)	0.6990	
Stomatitis	Germinal center B-cell like	4/107 (4)	NE (NE, NE)	15/100 (15)	NE (NE, NE)	0.19 (0.06,0.56)	0.0009	0.8360
	Activated B-cell like	1/16 (6)	NE (NE, NE)	3/9 (33)	3.1 (2.8, NE)	0.06 (0.01,0.63)	0.0030	
	Unclassified	0/18 (0)	NE (NE, NE)	2/12 (17)	NE (3.2, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	Germinal center B-cell like	100/107 (93)	0.8 (0.8, 0.9)	75/100 (75)	0.7 (0.3, 1.1)	1.41 (1.04,1.93)	0.0253	0.6001
	Activated B-cell like	13/16 (81)	0.7 (0.6, 0.9)	7/9 (78)	0.5 (0.0, 1.0)	0.89 (0.35,2.24)	0.7983	
	Unclassified	17/18 (94)	1.0 (0.8, 1.0)	8/12 (67)	0.8 (0.1, NE)	1.14 (0.48,2.68)	0.7616	
Chills	Germinal center B-cell like	31/107 (29)	NE (NE, NE)	8/100 (8)	NE (NE, NE)	3.92 (1.80,8.54)	0.0002	0.7535
	Activated B-cell like	3/16 (19)	NE (1.1, NE)	1/9 (11)	NE (0.0, NE)	1.61 (0.17,15.46)	0.6746	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Unclassified	5/18 (28)	NE (1.1, NE)	1/12 (8)	NE (3.5, NE)	2.99 (0.34,26.02)	0.2936	
Mucosal inflammation	Germinal center B-cell like	1/107 (1)	NE (NE, NE)	10/100 (10)	NE (4.9, NE)	0.07 (0.01,0.54)	0.0008	1.0000
	Activated B-cell like	0/16 (0)	NE (NE, NE)	1/9 (11)	NE (0.1, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Germinal center B-cell like	97/107 (91)	0.9 (0.9, 1.0)	25/100 (25)	NE (NE, NE)	8.65 (5.45,13.74)	<0.0001	0.3798
	Activated B-cell like	13/16 (81)	0.8 (0.6, 1.1)	1/9 (11)	NE (0.5, NE)	15.08 (1.92,118.52)	0.0008	
	Unclassified	17/18 (94)	1.0 (0.8, 1.0)	4/12 (33)	3.5 (0.6, NE)	3.57 (1.17,10.86)	0.0140	
Hepatobiliary disorders	Germinal center B-cell like	10/107 (9)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	9.48 (1.21,74.12)	0.0087	1.0000
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	Germinal center B-cell like	7/107 (7)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia								
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Germinal center B-cell like	11/107 (10)	5.0 (NE, NE)	2/100 (2)	NE (NE, NE)	4.47 (0.98,20.42)	0.0342	0.9999
	Activated B-cell like	5/16 (31)	5.1 (2.5, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	5.4 (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Germinal center B-cell like	9/107 (8)	NE (NE, NE)	0/100 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
Hypogammaglobulinaemia								
	Activated B-cell like	5/16 (31)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	Germinal center B-cell like	55/107 (51)	5.0 (2.7, 19.8)	28/100 (28)	NE (4.8, NE)	1.54 (0.97,2.46)	0.0656	0.7905
	Activated B-cell like	8/16 (50)	4.0 (0.7, NE)	2/9 (22)	3.2 (2.8, NE)	2.49 (0.52,12.01)	0.2406	
	Unclassified	15/18 (83)	1.1 (0.9, 4.0)	5/12 (42)	3.5 (0.5, NE)	1.69 (0.60,4.82)	0.3131	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Oral candidiasis	Germinal center B-cell like	8/107 (7)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	4/16 (25)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Rhinovirus infection	Germinal center B-cell like	5/107 (5)	NE (NE, NE)	0/100 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE, NE)	1/9 (11)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Germinal center B-cell like	15/107 (14)	NE (NE, NE)	19/100 (19)	NE (NE, NE)	0.65 (0.33,1.28)	0.2055	0.4386
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	25.6 (NE, NE)	3/12 (25)	3.4 (0.1, NE)	0.12 (0.01,1.27)	0.0423	
Infusion related reaction	Germinal center B-cell like	0/107 (0)	NE (NE, NE)	5/100 (5)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Unclassified	0/18 (0)	NE (NE, NE)	2/12 (17)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Germinal center B-cell like	23/107 (21)	NE (NE, NE)	9/100 (9)	NE (NE, NE)	2.41 (1.12,5.22)	0.0207	0.9975
	Activated B-cell like	4/16 (25)	NE (1.4, NE)	1/9 (11)	NE (2.6, NE)	2.12 (0.23,19.23)	0.4943	
	Unclassified	4/18 (22)	NE (NE, NE)	1/12 (8)	NE (NE, NE)	2.50 (0.28,22.37)	0.3860	
C-reactive protein increased	Germinal center B-cell like	15/107 (14)	NE (NE, NE)	2/100 (2)	NE (NE, NE)	7.25 (1.66,31.72)	0.0020	0.0834
	Activated B-cell like	3/16 (19)	NE (1.1, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE, NE)	2/12 (17)	NE (0.7, NE)	0.30 (0.03,3.36)	0.3037	
Platelet count decreased	Germinal center B-cell like	20/107 (19)	NE (NE, NE)	39/100 (39)	NE (3.1, NE)	0.41 (0.24,0.71)	0.0009	0.9384
	Activated B-cell like	5/16 (31)	NE (1.1, NE)	5/9 (56)	2.8 (0.3, NE)	0.39 (0.11,1.43)	0.1395	
	Unclassified	4/18 (22)	NE (NE, NE)	4/12 (33)	NE (0.5, NE)	0.57 (0.14,2.29)	0.4183	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

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Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Weight increased	Germinal center B-cell like	5/107 (5)	NE (NE, NE)	5/100 (5)	NE (NE, NE)	0.88 (0.25,3.04)	0.8406	1.0000
	Activated B-cell like	0/16 (0)	NE (NE, NE)	2/9 (22)	NE (0.1, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	Germinal center B-cell like	78/107 (73)	1.0 (0.9, 1.1)	54/100 (54)	2.6 (1.9, 4.7)	1.47 (1.04,2.09)	0.0270	0.8817
	Activated B-cell like	16/16 (100)	1.0 (0.6, 1.1)	8/9 (89)	0.7 (0.0, 2.9)	2.06 (0.72,5.90)	0.1684	
	Unclassified	12/18 (67)	0.9 (0.7, NE)	5/12 (42)	2.7 (0.3, NE)	1.75 (0.61,5.00)	0.2817	
Hyperglycaemia	Germinal center B-cell like	23/107 (21)	NE (NE, NE)	11/100 (11)	NE (NE, NE)	1.95 (0.95,4.00)	0.0629	0.1160
	Activated B-cell like	1/16 (6)	NE (NE, NE)	3/9 (33)	NE (0.0, NE)	0.17 (0.02,1.62)	0.0791	
	Unclassified	4/18 (22)	NE (4.5, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypomagnesaemia	Germinal center B-cell like	14/107 (13)	5.0 (NE, NE)	19/100 (19)	NE (NE, NE)	0.56 (0.28,1.14)	0.1069	0.8670
	Activated B-cell like	2/16 (13)	NE (NE, NE)	1/9 (11)	NE (2.2, NE)	1.06 (0.10,11.77)	0.9624	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
	Unclassified	4/18 (22)	NE (NE, NE)	4/12 (33)	2.8 (0.7, NE)	0.48 (0.12,1.96)	0.2945	
Hypomagnesaemia Hyponatraemia	Germinal center B-cell like	17/107 (16)	NE (NE, NE)	3/100 (3)	NE (NE, NE)	5.36 (1.57,18.30)	0.0026	0.1442
	Activated B-cell like	2/16 (13)	NE (NE, NE)	2/9 (22)	3.2 (2.7, NE)	0.36 (0.05,2.77)	0.3090	
	Unclassified	3/18 (17)	NE (NE, NE)	1/12 (8)	NE (NE, NE)	1.91 (0.20,18.38)	0.5680	
Nervous system disorders	Germinal center B-cell like	81/107 (76)	1.1 (1.0, 1.1)	53/100 (53)	2.9 (1.2, NE)	1.61 (1.14,2.29)	0.0063	0.3030
	Activated B-cell like	13/16 (81)	1.0 (0.6, 1.5)	6/9 (67)	0.7 (0.0, NE)	1.24 (0.46,3.31)	0.6619	
	Unclassified	14/18 (78)	0.9 (0.8, 1.2)	3/12 (25)	NE (0.7, NE)	3.85 (1.10,13.51)	0.0214	
Dizziness	Germinal center B-cell like	22/107 (21)	NE (NE, NE)	15/100 (15)	NE (NE, NE)	1.27 (0.66,2.45)	0.4708	0.8582
	Activated B-cell like	5/16 (31)	NE (0.8, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	NE (NE, NE)	1/12 (8)	NE (NE, NE)	2.57 (0.29,23.01)	0.3777	
Dysgeusia	Germinal center B-cell like	1/107 (1)	NE (NE, NE)	7/100 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Activated B-cell like	0/16 (0)	NE (NE, NE)	2/9 (22)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	1/12 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	Germinal center B-cell like	23/107 (21)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	23.22 (3.14,171.98)	<0.0001	0.9999
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Germinal center B-cell like	46/107 (43)	NE (1.4, NE)	23/100 (23)	NE (NE, NE)	1.99 (1.21,3.29)	0.0059	0.2086
	Activated B-cell like	9/16 (56)	1.1 (0.8, NE)	5/9 (56)	2.2 (0.1, NE)	0.99 (0.33,2.98)	0.9877	
	Unclassified	10/18 (56)	1.2 (0.8, NE)	1/12 (8)	NE (NE, NE)	7.85 (1.00,61.52)	0.0185	
Peripheral sensory neuropathy	Germinal center B-cell like	1/107 (1)	NE (NE, NE)	7/100 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Somnolence	Germinal center B-cell like	11/107 (10)	NE (NE, NE)	0/100 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	Germinal center B-cell like	28/107 (26)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	29.32 (3.99,215.55)	<0.0001	0.9999
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	6/18 (33)	NE (1.3, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	Germinal center B-cell like	52/107 (49)	NE (1.3, NE)	24/100 (24)	NE (NE, NE)	2.31 (1.42,3.76)	0.0005	0.0706
	Activated B-cell like	7/16 (44)	4.3 (1.2, NE)	5/9 (56)	3.0 (0.0, NE)	0.54 (0.16,1.81)	0.3032	
	Unclassified	10/18 (56)	15.2 (1.1, NE)	1/12 (8)	NE (3.3, NE)	6.38 (0.80,50.60)	0.0428	
Agitation	Germinal center B-cell like	11/107 (10)	NE (NE, NE)	2/100 (2)	NE (NE, NE)	4.97 (1.10,22.46)	0.0204	1.0000
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

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Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Agitation	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Germinal center B-cell like	29/107 (27)	NE (NE, NE)	3/100 (3)	NE (NE, NE)	10.03 (3.05,32.94)	<0.0001	0.1716
	Activated B-cell like	5/16 (31)	NE (1.2, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	27.6 (NE, NE)	1/12 (8)	NE (3.5, NE)	0.34 (0.02,6.11)	0.4458	
Respiratory, thoracic and mediastinal disorders	Germinal center B-cell like	58/107 (54)	3.1 (1.1, NE)	40/100 (40)	NE (3.1, NE)	1.33 (0.89,2.00)	0.1585	0.9721
	Activated B-cell like	12/16 (75)	1.0 (0.4, 1.2)	6/9 (67)	2.8 (0.1, NE)	1.56 (0.58,4.20)	0.3755	
	Unclassified	12/18 (67)	1.3 (1.0, NE)	6/12 (50)	3.3 (0.5, NE)	1.22 (0.45,3.28)	0.6941	
Cough	Germinal center B-cell like	24/107 (22)	NE (NE, NE)	8/100 (8)	NE (NE, NE)	2.79 (1.25,6.21)	0.0087	0.7583
	Activated B-cell like	7/16 (44)	NE (0.9, NE)	3/9 (33)	3.1 (1.9, NE)	1.56 (0.40,6.11)	0.5228	
	Unclassified	5/18 (28)	NE (2.6, NE)	1/12 (8)	NE (NE, NE)	2.62 (0.30,22.67)	0.3601	
Hiccups	Germinal center B-cell like	6/107 (6)	NE (NE, NE)	13/100 (13)	NE (NE, NE)	0.38 (0.14,1.01)	0.0434	0.9594

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Activated B-cell like	0/16 (0)	NE (NE, NE)	1/9 (11)	NE (0.1, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	NE (NE, NE)	2/12 (17)	NE (3.3, NE)	0.46 (0.06,3.46)	0.4417	
Hypoxia	Germinal center B-cell like	19/107 (18)	NE (NE, NE)	7/100 (7)	NE (NE, NE)	2.52 (1.06,6.01)	0.0297	0.5330
	Activated B-cell like	3/16 (19)	NE (1.3, NE)	2/9 (22)	NE (2.4, NE)	0.75 (0.12,4.57)	0.7530	
	Unclassified	5/18 (28)	NE (1.2, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Pleural effusion	Germinal center B-cell like	8/107 (7)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	Germinal center B-cell like	4/107 (4)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.8. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Erythema	Unclassified	2/18 (11)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Germinal center B-cell like	61/107 (57)	1.2 (1.1, NE)	32/100 (32)	NE (NE, NE)	1.98 (1.28,3.04)	0.0015	0.6257
	Activated B-cell like	9/16 (56)	1.3 (0.9, NE)	3/9 (33)	2.8 (0.7, NE)	1.99 (0.54,7.43)	0.2896	
	Unclassified	10/18 (56)	1.3 (0.9, NE)	2/12 (17)	3.8 (3.1, NE)	3.93 (0.85,18.12)	0.0580	
Hypotension	Germinal center B-cell like	47/107 (44)	NE (1.2, NE)	16/100 (16)	NE (NE, NE)	3.23 (1.83,5.70)	<0.0001	0.9621
	Activated B-cell like	8/16 (50)	1.3 (1.0, NE)	2/9 (22)	NE (0.7, NE)	2.59 (0.55,12.30)	0.2045	
	Unclassified	8/18 (44)	NE (1.0, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240602T11:06

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Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Germinal center B-cell like	4/94 (4)	48.8 (4.9, NE)	24/78 (31)	7.2 (3.3, NE)	0.06 (0.02,0.19)	<0.0001	0.7650
	Non-germinal center B-cell like	2/47 (4)	12.1 (NE, NE)	11/49 (22)	NE (NE, NE)	0.06 (0.01,0.47)	0.0004	
Neutropenia	Germinal center B-cell like	40/94 (43)	NE (1.2, NE)	13/78 (17)	NE (NE, NE)	2.80 (1.50,5.25)	0.0007	0.9995
	Non-germinal center B-cell like	18/47 (38)	NE (1.4, NE)	7/49 (14)	NE (NE, NE)	2.80 (1.17,6.72)	0.0154	
Thrombocytopenia	Germinal center B-cell like	9/94 (10)	NE (NE, NE)	21/78 (27)	NE (NE, NE)	0.29 (0.13,0.64)	0.0011	0.2434
	Non-germinal center B-cell like	7/47 (15)	NE (NE, NE)	10/49 (20)	NE (NE, NE)	0.67 (0.25,1.76)	0.4064	
Cardiac disorders	Germinal center B-cell like	53/94 (56)	1.2 (1.1, NE)	13/78 (17)	NE (NE, NE)	4.45 (2.42,8.19)	<0.0001	0.0192
	Non-germinal center B-cell like	16/47 (34)	NE (1.4, NE)	12/49 (24)	NE (3.4, NE)	1.36 (0.64,2.88)	0.4188	
Sinus tachycardia	Germinal center B-cell like	38/94 (40)	NE (2.1, NE)	6/78 (8)	NE (NE, NE)	6.32 (2.67,14.97)	<0.0001	0.0394
	Non-germinal center B-cell like	13/47 (28)	NE (NE, NE)	8/49 (16)	NE (NE, NE)	1.69 (0.70,4.08)	0.2391	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

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Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Germinal center B-cell like	4/94 (4)	NE (NE, NE)	7/78 (9)	NE (NE, NE)	0.43 (0.13,1.48)	0.1689	0.6216
	Non-germinal center B-cell like	1/47 (2)	NE (NE, NE)	4/49 (8)	NE (4.8, NE)	0.20 (0.02,1.83)	0.1152	
Gastrointestinal disorders	Germinal center B-cell like	83/94 (88)	0.8 (0.8, 0.9)	63/78 (81)	0.3 (0.1, 0.8)	0.89 (0.64,1.24)	0.4754	0.0431
	Non-germinal center B-cell like	37/47 (79)	0.9 (0.7, 1.1)	42/49 (86)	0.3 (0.1, 0.5)	0.54 (0.34,0.84)	0.0043	
Nausea	Germinal center B-cell like	56/94 (60)	1.1 (0.9, 4.4)	51/78 (65)	0.8 (0.3, 2.5)	0.68 (0.46,0.99)	0.0411	0.4500
	Non-germinal center B-cell like	24/47 (51)	1.4 (1.1, NE)	33/49 (67)	1.0 (0.4, 2.6)	0.54 (0.32,0.92)	0.0210	
Stomatitis	Germinal center B-cell like	3/94 (3)	NE (NE, NE)	11/78 (14)	NE (NE, NE)	0.15 (0.04,0.55)	0.0011	0.4093
	Non-germinal center B-cell like	1/47 (2)	NE (NE, NE)	10/49 (20)	NE (NE, NE)	0.07 (0.01,0.55)	0.0010	
General disorders and administration site conditions	Germinal center B-cell like	90/94 (96)	0.8 (0.7, 0.9)	58/78 (74)	0.8 (0.3, 1.9)	1.78 (1.25,2.55)	0.0011	0.0266
	Non-germinal center B-cell like	39/47 (83)	1.0 (0.8, 1.1)	36/49 (73)	0.4 (0.2, 0.7)	0.84 (0.53,1.33)	0.4447	
Chills	Germinal center B-cell like	33/94 (35)	NE (NE, NE)	2/78 (3)	NE (NE, NE)	16.00 (3.84,66.69)	<0.0001	0.0016

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Non-germinal center B-cell like	8/47 (17)	NE (NE, NE)	8/49 (16)	NE (NE, NE)	0.94 (0.35,2.53)	0.9086	
Mucosal inflammation	Germinal center B-cell like	1/94 (1)	NE (NE, NE)	10/78 (13)	7.0 (NE, NE)	0.06 (0.01,0.51)	0.0005	0.9935
	Non-germinal center B-cell like	0/47 (0)	NE (NE, NE)	3/49 (6)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Germinal center B-cell like	87/94 (93)	0.9 (0.9, 1.0)	19/78 (24)	6.9 (NE, NE)	10.28 (5.99,17.65)	<0.0001	0.0496
	Non-germinal center B-cell like	38/47 (81)	1.1 (0.9, 1.1)	15/49 (31)	3.9 (3.0, NE)	5.02 (2.72,9.25)	<0.0001	
Hepatobiliary disorders	Germinal center B-cell like	10/94 (11)	NE (NE, NE)	2/78 (3)	NE (NE, NE)	4.04 (0.88,18.46)	0.0514	0.6768
	Non-germinal center B-cell like	7/47 (15)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	7.12 (0.87,58.05)	0.0322	
Hypertransaminasaemia	Germinal center B-cell like	7/94 (7)	NE (NE, NE)	1/78 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	4/47 (9)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Germinal center B-cell like	14/94 (15)	5.0 (5.0, NE)	1/78 (1)	NE (NE, NE)	9.42 (1.22,72.52)	0.0084	0.2816
	Non-germinal center B-cell like	7/47 (15)	5.4 (NE, NE)	2/49 (4)	NE (NE, NE)	2.30 (0.46,11.55)	0.2984	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Germinal center B-cell like	12/94 (13)	5.0 (5.0, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9924
	Non-germinal center B-cell like	7/47 (15)	5.4 (NE, NE)	1/49 (2)	NE (NE, NE)	4.64 (0.55,38.92)	0.1211	
Infections and infestations	Germinal center B-cell like	49/94 (52)	4.5 (1.5, 10.9)	24/78 (31)	NE (4.4, NE)	1.59 (0.97,2.60)	0.0641	0.5557
	Non-germinal center B-cell like	24/47 (51)	5.7 (2.4, NE)	16/49 (33)	9.0 (3.5, NE)	1.21 (0.63,2.32)	0.5630	
Oral candidiasis	Germinal center B-cell like	11/94 (12)	NE (NE, NE)	3/78 (4)	7.1 (NE, NE)	4.52 (1.00,20.45)	0.0313	0.5969
	Non-germinal center B-cell like	5/47 (11)	NE (NE, NE)	2/49 (4)	NE (NE, NE)	2.63 (0.51,13.57)	0.2292	
Rhinovirus infection	Germinal center B-cell like	2/94 (2)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	2/47 (4)	NE (NE, NE)	2/49 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Germinal center B-cell like	12/94 (13)	NE (NE, NE)	19/78 (24)	NE (NE, NE)	0.43 (0.21,0.89)	0.0199	0.4741
	Non-germinal center B-cell like	7/47 (15)	NE (NE, NE)	9/49 (18)	NE (NE, NE)	0.73 (0.27,1.97)	0.5354	
Infusion related reaction	Germinal center B-cell like	1/94 (1)	NE (NE, NE)	7/78 (9)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Non-germinal center B-cell like	0/47 (0)	NE (NE, NE)	4/49 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Germinal center B-cell like	19/94 (20)	NE (NE, NE)	6/78 (8)	NE (NE, NE)	2.60 (1.04,6.52)	0.0338	0.5150
	Non-germinal center B-cell like	8/47 (17)	NE (NE, NE)	5/49 (10)	NE (NE, NE)	1.48 (0.48,4.55)	0.4957	
C-reactive protein increased	Germinal center B-cell like	11/94 (12)	NE (NE, NE)	3/78 (4)	NE (NE, NE)	3.06 (0.85,10.96)	0.0698	0.5619
	Non-germinal center B-cell like	6/47 (13)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	6.45 (0.78,53.54)	0.0466	
Platelet count decreased	Germinal center B-cell like	17/94 (18)	NE (NE, NE)	26/78 (33)	NE (3.7, NE)	0.46 (0.25,0.85)	0.0112	0.3091
	Non-germinal center B-cell like	6/47 (13)	NE (NE, NE)	19/49 (39)	3.4 (2.5, NE)	0.21 (0.08,0.55)	0.0005	
Weight increased	Germinal center B-cell like	1/94 (1)	NE (NE, NE)	5/78 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	1/47 (2)	NE (NE, NE)	4/49 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	Germinal center B-cell like	67/94 (71)	1.0 (0.9, 1.1)	39/78 (50)	2.8 (2.3, NE)	1.67 (1.12,2.50)	0.0101	0.6874

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Non-germinal center B-cell like	35/47 (74)	1.0 (0.8, 1.1)	28/49 (57)	2.3 (1.1, 3.4)	1.44 (0.87,2.37)	0.1512	
Hyperglycaemia	Germinal center B-cell like	14/94 (15)	NE (NE, NE)	7/78 (9)	NE (NE, NE)	1.63 (0.66,4.05)	0.2856	0.8765
	Non-germinal center B-cell like	9/47 (19)	NE (NE, NE)	5/49 (10)	NE (NE, NE)	1.78 (0.59,5.32)	0.2969	
Hypomagnesaemia	Germinal center B-cell like	9/94 (10)	NE (NE, NE)	16/78 (21)	NE (NE, NE)	0.38 (0.17,0.85)	0.0150	0.3204
	Non-germinal center B-cell like	6/47 (13)	NE (NE, NE)	7/49 (14)	NE (NE, NE)	0.78 (0.26,2.35)	0.6630	
Hyponatraemia	Germinal center B-cell like	15/94 (16)	NE (NE, NE)	4/78 (5)	NE (NE, NE)	3.06 (1.01,9.23)	0.0365	0.6773
	Non-germinal center B-cell like	5/47 (11)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	5.13 (0.60,44.10)	0.0968	
Nervous system disorders	Germinal center B-cell like	76/94 (81)	1.1 (1.0, 1.1)	35/78 (45)	7.0 (2.6, NE)	2.28 (1.51,3.44)	<0.0001	0.1616
	Non-germinal center B-cell like	33/47 (70)	1.1 (0.9, 1.5)	26/49 (53)	2.9 (1.1, 4.8)	1.38 (0.82,2.31)	0.2205	
Dizziness	Germinal center B-cell like	21/94 (22)	NE (NE, NE)	6/78 (8)	NE (NE, NE)	2.85 (1.15,7.08)	0.0176	0.3407
	Non-germinal center B-cell like	11/47 (23)	NE (NE, NE)	7/49 (14)	NE (NE, NE)	1.52 (0.59,3.93)	0.3860	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Germinal center B-cell like	3/94 (3)	NE (NE, NE)	3/78 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	1/47 (2)	NE (NE, NE)	5/49 (10)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	Germinal center B-cell like	19/94 (20)	NE (NE, NE)	1/78 (1)	NE (NE, NE)	16.55 (2.21,123.61)	0.0002	0.9910
	Non-germinal center B-cell like	4/47 (9)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Germinal center B-cell like	44/94 (47)	NE (1.2, NE)	17/78 (22)	7.0 (NE, NE)	2.53 (1.42,4.49)	0.0010	0.3010
	Non-germinal center B-cell like	20/47 (43)	NE (1.1, NE)	14/49 (29)	NE (3.9, NE)	1.51 (0.76,2.99)	0.2343	
Peripheral sensory neuropathy	Germinal center B-cell like	1/94 (1)	NE (NE, NE)	5/78 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	0/47 (0)	NE (NE, NE)	2/49 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Germinal center B-cell like	11/94 (12)	NE (NE, NE)	2/78 (3)	NE (NE, NE)	4.47 (0.99,20.17)	0.0327	0.9911
	Non-germinal center B-cell like	3/47 (6)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	Germinal center B-cell like	25/94 (27)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9896

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Non-germinal center B-cell like	10/47 (21)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	11.04 (1.41,86.28)	0.0039	
Psychiatric disorders	Germinal center B-cell like	44/94 (47)	NE (1.3, NE)	15/78 (19)	NE (NE, NE)	2.73 (1.52,4.91)	0.0004	0.3071
	Non-germinal center B-cell like	20/47 (43)	NE (1.4, NE)	13/49 (27)	NE (3.3, NE)	1.54 (0.76,3.12)	0.2251	
Agitation	Germinal center B-cell like	7/94 (7)	NE (NE, NE)	1/78 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	2/47 (4)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Germinal center B-cell like	27/94 (29)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9875
	Non-germinal center B-cell like	9/47 (19)	NE (NE, NE)	4/49 (8)	NE (NE, NE)	2.11 (0.64,6.91)	0.2072	
Respiratory, thoracic and mediastinal disorders	Germinal center B-cell like	57/94 (61)	1.2 (1.1, 3.5)	28/78 (36)	NE (3.3, NE)	1.89 (1.20,2.97)	0.0050	0.0369
	Non-germinal center B-cell like	22/47 (47)	NE (1.1, NE)	23/49 (47)	3.4 (1.4, NE)	0.85 (0.47,1.53)	0.5771	
Cough	Germinal center B-cell like	23/94 (24)	NE (NE, NE)	7/78 (9)	NE (NE, NE)	2.69 (1.15,6.27)	0.0169	0.6844
	Non-germinal center B-cell like	12/47 (26)	NE (NE, NE)	6/49 (12)	NE (NE, NE)	1.92 (0.72,5.15)	0.1865	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Germinal center B-cell like	7/94 (7)	NE (NE, NE)	9/78 (12)	NE (NE, NE)	0.56 (0.21,1.52)	0.2494	0.9875
	Non-germinal center B-cell like	0/47 (0)	NE (NE, NE)	6/49 (12)	NE (NE, NE)	NE (NE,NE)	NE	
Hypoxia	Germinal center B-cell like	20/94 (21)	NE (NE, NE)	6/78 (8)	NE (NE, NE)	2.78 (1.12,6.93)	0.0217	0.5506
	Non-germinal center B-cell like	7/47 (15)	NE (NE, NE)	4/49 (8)	NE (NE, NE)	1.74 (0.51,5.97)	0.3737	
Pleural effusion	Germinal center B-cell like	6/94 (6)	NE (NE, NE)	2/78 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	2/47 (4)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	Germinal center B-cell like	5/94 (5)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	4/47 (9)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Germinal center B-cell like	49/94 (52)	1.5 (1.2, NE)	24/78 (31)	NE (3.3, NE)	1.83 (1.12,2.99)	0.0141	0.8467
	Non-germinal center B-cell like	26/47 (55)	1.4 (1.1, NE)	18/49 (37)	3.8 (2.8, NE)	1.71 (0.93,3.14)	0.0765	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

Table 14.3.1.1.1.9. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Germinal center B-cell like	40/94 (43)	NE (1.3, NE)	8/78 (10)	NE (NE, NE)	4.87 (2.28,10.43)	<0.0001	0.3038
	Non-germinal center B-cell like	21/47 (45)	NE (1.2, NE)	9/49 (18)	NE (NE, NE)	2.84 (1.29,6.21)	0.0062	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T15:22

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Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Diffuse large B-cell lymphoma	4/125 (3)	28.3 (28.3, NE)	34/119 (29)	7.2 (3.7, NE)	0.03 (0.01,0.13)	<0.0001	0.1475
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (4.9, NE)	6/25 (24)	NE (3.3, NE)	0.14 (0.03,0.73)	0.0075	
Neutropenia	Diffuse large B-cell lymphoma	52/125 (42)	NE (1.9, NE)	18/119 (15)	NE (NE, NE)	2.97 (1.73,5.07)	<0.0001	0.4769
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/32 (44)	NE (1.0, NE)	6/25 (24)	NE (3.0, NE)	1.90 (0.73,4.96)	0.1794	
Thrombocytopenia	Diffuse large B-cell lymphoma	16/125 (13)	NE (NE, NE)	29/119 (24)	NE (NE, NE)	0.45 (0.24,0.83)	0.0085	0.7723
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE, NE)	7/25 (28)	NE (3.1, NE)	0.38 (0.11,1.31)	0.1104	
Cardiac disorders	Diffuse large B-cell lymphoma	60/125 (48)	NE (1.2, NE)	26/119 (22)	NE (NE, NE)	2.51 (1.58,3.99)	<0.0001	0.5228
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/32 (59)	1.2 (0.9, NE)	6/25 (24)	NE (4.0, NE)	3.30 (1.31,8.31)	0.0070	
Sinus tachycardia	Diffuse large B-cell lymphoma	41/125 (33)	NE (NE, NE)	13/119 (11)	NE (NE, NE)	3.32 (1.78,6.21)	<0.0001	0.3418
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/32 (44)	NE (1.0, NE)	2/25 (8)	NE (4.0, NE)	6.67 (1.51,29.46)	0.0038	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Diffuse large B-cell lymphoma	4/125 (3)	NE (NE, NE)	15/119 (13)	NE (NE, NE)	0.22 (0.07,0.67)	0.0034	0.7224
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	0.38 (0.03,4.18)	0.4098	
Gastrointestinal disorders	Diffuse large B-cell lymphoma	108/125 (86)	0.8 (0.8, 0.9)	102/119 (86)	0.2 (0.1, 0.4)	0.71 (0.54,0.94)	0.0129	0.7895
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	28/32 (88)	0.8 (0.6, 1.0)	21/25 (84)	0.2 (0.1, 0.8)	0.74 (0.42,1.30)	0.2789	
Nausea	Diffuse large B-cell lymphoma	66/125 (53)	1.2 (1.1, NE)	87/119 (73)	0.8 (0.3, 1.6)	0.50 (0.36,0.69)	<0.0001	0.0593
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	22/32 (69)	0.9 (0.8, 1.2)	15/25 (60)	0.9 (0.3, NE)	1.01 (0.52,1.95)	0.9774	
Stomatitis	Diffuse large B-cell lymphoma	6/125 (5)	NE (NE, NE)	21/119 (18)	NE (NE, NE)	0.19 (0.08,0.47)	<0.0001	0.9904
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE, NE)	3/25 (12)	NE (4.1, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	Diffuse large B-cell lymphoma	114/125 (91)	0.9 (0.8, 1.0)	92/119 (77)	0.5 (0.3, 0.9)	1.15 (0.87,1.53)	0.3077	0.1921
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	31/32 (97)	0.8 (0.7, 0.8)	19/25 (76)	0.8 (0.2, 1.8)	1.90 (1.02,3.56)	0.0350	
Chills	Diffuse large B-cell lymphoma	34/125 (27)	NE (NE, NE)	5/119 (4)	NE (NE, NE)	7.18 (2.81,18.37)	<0.0001	0.3931

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	12/32 (38)	NE (1.2, NE)	3/25 (12)	NE (NE, NE)	3.49 (0.98,12.41)	0.0384	
Mucosal inflammation	Diffuse large B-cell lymphoma	0/125 (0)	NE (NE, NE)	13/119 (11)	7.0 (4.9, NE)	NE (NE,NE)	NE	0.9915
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	3/25 (12)	NE (3.4, NE)	0.19 (0.02,1.88)	0.1156	
Pyrexia	Diffuse large B-cell lymphoma	112/125 (90)	1.0 (0.9, 1.0)	31/119 (26)	6.9 (NE, NE)	7.93 (5.21,12.05)	<0.0001	0.1568
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	30/32 (94)	0.8 (0.8, 1.0)	5/25 (20)	NE (4.5, NE)	20.44 (5.83,71.63)	<0.0001	
Hepatobiliary disorders	Diffuse large B-cell lymphoma	10/125 (8)	NE (NE, NE)	2/119 (2)	NE (NE, NE)	4.44 (0.97,20.35)	0.0355	0.9903
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	Diffuse large B-cell lymphoma	6/125 (5)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Diffuse large B-cell lymphoma	18/125 (14)	5.1 (5.0, NE)	3/119 (3)	NE (NE, NE)	4.22 (1.22,14.60)	0.0134	0.9880
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Diffuse large B-cell lymphoma	17/125 (14)	5.1 (5.0, NE)	1/119 (1)	NE (NE, NE)	11.56 (1.52,87.99)	0.0028	0.9903
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/32 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	Diffuse large B-cell lymphoma	68/125 (54)	4.0 (1.7, 19.8)	40/119 (34)	9.0 (3.7, NE)	1.46 (0.98,2.17)	0.0604	0.2657
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	20/32 (63)	3.1 (1.1, 33.9)	5/25 (20)	NE (4.6, NE)	2.71 (0.99,7.42)	0.0427	
Oral candidiasis	Diffuse large B-cell lymphoma	11/125 (9)	NE (NE, NE)	5/119 (4)	7.1 (NE, NE)	2.52 (0.80,7.94)	0.1015	0.9925
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Rhinovirus infection	Diffuse large B-cell lymphoma	8/125 (6)	21.9 (NE, NE)	2/119 (2)	NE (NE, NE)	2.96 (0.61,14.32)	0.1567	0.9949
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Diffuse large B-cell lymphoma	17/125 (14)	25.6 (NE, NE)	25/119 (21)	NE (NE, NE)	0.53 (0.28,1.00)	0.0454	0.9729
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	4/25 (16)	NE (3.2, NE)	0.44 (0.10,2.01)	0.2770	
Infusion related reaction	Diffuse large B-cell lymphoma	1/125 (1)	NE (NE, NE)	10/119 (8)	NE (NE, NE)	0.09 (0.01,0.67)	0.0030	0.9942

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Diffuse large B-cell lymphoma	24/125 (19)	NE (NE, NE)	14/119 (12)	NE (NE, NE)	1.58 (0.81,3.05)	0.1731	0.1515
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	8.10 (1.03,64.04)	0.0181	
C-reactive protein increased	Diffuse large B-cell lymphoma	13/125 (10)	NE (NE, NE)	3/119 (3)	NE (NE, NE)	4.17 (1.19,14.63)	0.0152	0.6024
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	8.06 (1.02,63.74)	0.0180	
Platelet count decreased	Diffuse large B-cell lymphoma	22/125 (18)	NE (NE, NE)	49/119 (41)	3.7 (2.8, NE)	0.34 (0.20,0.56)	<0.0001	0.1050
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/32 (25)	NE (NE, NE)	6/25 (24)	NE (NE, NE)	0.95 (0.33,2.75)	0.9310	
Weight increased	Diffuse large B-cell lymphoma	4/125 (3)	NE (NE, NE)	9/119 (8)	NE (NE, NE)	0.38 (0.12,1.24)	0.0954	0.6667
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	0.77 (0.05,12.24)	0.8497	
Metabolism and nutrition disorders	Diffuse large B-cell lymphoma	90/125 (72)	1.0 (0.9, 1.1)	63/119 (53)	2.8 (2.1, 3.6)	1.53 (1.10,2.12)	0.0094	0.8001

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/32 (91)	0.9 (0.7, 1.1)	16/25 (64)	1.2 (0.4, NE)	1.72 (0.92,3.23)	0.0821	
Hyperglycaemia	Diffuse large B-cell lymphoma	21/125 (17)	NE (NE, NE)	12/119 (10)	NE (NE, NE)	1.61 (0.79,3.27)	0.1866	0.2611
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/32 (22)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	6.24 (0.77,50.73)	0.0499	
Hypomagnesaemia	Diffuse large B-cell lymphoma	17/125 (14)	5.0 (NE, NE)	22/119 (18)	NE (NE, NE)	0.60 (0.32,1.15)	0.1227	0.7034
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/32 (16)	NE (NE, NE)	7/25 (28)	NE (3.1, NE)	0.46 (0.14,1.46)	0.1755	
Hyponatraemia	Diffuse large B-cell lymphoma	14/125 (11)	NE (NE, NE)	6/119 (5)	NE (NE, NE)	2.15 (0.82,5.60)	0.1087	0.6186
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	3.54 (0.76,16.41)	0.0837	
Nervous system disorders	Diffuse large B-cell lymphoma	98/125 (78)	1.1 (1.0, 1.1)	65/119 (55)	2.9 (1.1, 4.8)	1.60 (1.17,2.20)	0.0029	0.6516
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/32 (75)	0.9 (0.9, 1.2)	12/25 (48)	3.3 (0.7, NE)	1.77 (0.88,3.58)	0.1015	
Dizziness	Diffuse large B-cell lymphoma	29/125 (23)	NE (NE, NE)	16/119 (13)	NE (NE, NE)	1.63 (0.88,3.00)	0.1134	0.7872
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/32 (31)	NE (4.2, NE)	4/25 (16)	NE (NE, NE)	1.96 (0.61,6.27)	0.2472	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Diffuse large B-cell lymphoma	3/125 (2)	NE (NE, NE)	8/119 (7)	NE (NE, NE)	0.31 (0.08,1.19)	0.0720	0.9230
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	0.33 (0.03,3.73)	0.3489	
Encephalopathy	Diffuse large B-cell lymphoma	20/125 (16)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	19.78 (2.65,147.38)	<0.0001	0.9888
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/32 (25)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Diffuse large B-cell lymphoma	61/125 (49)	3.0 (1.2, NE)	34/119 (29)	7.0 (NE, NE)	1.91 (1.25,2.91)	0.0023	0.8371
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/32 (31)	NE (1.3, NE)	4/25 (16)	NE (NE, NE)	2.15 (0.67,6.86)	0.1847	
Peripheral sensory neuropathy	Diffuse large B-cell lymphoma	1/125 (1)	NE (NE, NE)	10/119 (8)	NE (NE, NE)	0.08 (0.01,0.62)	0.0018	0.9994
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/32 (0)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Diffuse large B-cell lymphoma	12/125 (10)	NE (NE, NE)	0/119 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9911
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	3.24 (0.36,28.99)	0.2661	
Tremor	Diffuse large B-cell lymphoma	30/125 (24)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	30.82 (4.20,226.01)	<0.0001	0.9871

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/32 (34)	NE (1.3, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	Diffuse large B-cell lymphoma	56/125 (45)	27.6 (1.7, NE)	26/119 (22)	NE (NE, NE)	2.14 (1.34,3.42)	0.0010	0.9383
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/32 (59)	1.3 (1.0, NE)	8/25 (32)	NE (2.7, NE)	2.10 (0.92,4.81)	0.0702	
Agitation	Diffuse large B-cell lymphoma	7/125 (6)	NE (NE, NE)	2/119 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Diffuse large B-cell lymphoma	29/125 (23)	27.6 (NE, NE)	2/119 (2)	NE (NE, NE)	13.80 (3.29,57.92)	<0.0001	0.9865
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/32 (34)	NE (1.3, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Respiratory, thoracic and mediastinal disorders	Diffuse large B-cell lymphoma	73/125 (58)	1.4 (1.1, 3.5)	50/119 (42)	NE (3.0, NE)	1.43 (0.99,2.04)	0.0514	0.6605
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	21/32 (66)	1.1 (0.9, 4.8)	11/25 (44)	3.4 (1.1, NE)	1.61 (0.77,3.34)	0.1972	
Cough	Diffuse large B-cell lymphoma	37/125 (30)	NE (NE, NE)	14/119 (12)	NE (NE, NE)	2.53 (1.37,4.69)	0.0022	0.5663
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	4.97 (0.60,41.28)	0.0984	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Diffuse large B-cell lymphoma	5/125 (4)	NE (NE, NE)	15/119 (13)	NE (NE, NE)	0.29 (0.11,0.80)	0.0108	0.6115
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	5/25 (20)	NE (3.4, NE)	0.35 (0.08,1.51)	0.1445	
Hypoxia	Diffuse large B-cell lymphoma	29/125 (23)	NE (NE, NE)	10/119 (8)	NE (NE, NE)	2.86 (1.39,5.86)	0.0027	0.6151
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	NE (NE, NE)	1/25 (4)	NE (4.5, NE)	4.68 (0.56,39.05)	0.1167	
Pleural effusion	Diffuse large B-cell lymphoma	9/125 (7)	NE (NE, NE)	2/119 (2)	NE (NE, NE)	3.98 (0.86,18.48)	0.0566	0.9907
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								
Erythema	Diffuse large B-cell lymphoma	11/125 (9)	NE (NE, NE)	2/119 (2)	NE (NE, NE)	5.18 (1.15,23.35)	0.0169	0.2460
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	0.51 (0.03,8.51)	0.6306	
Vascular disorders	Diffuse large B-cell lymphoma	68/125 (54)	1.4 (1.2, NE)	40/119 (34)	NE (3.6, NE)	1.75 (1.18,2.59)	0.0044	0.3751
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	20/32 (63)	1.2 (0.9, NE)	8/25 (32)	NE (2.6, NE)	2.49 (1.09,5.71)	0.0243	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.10. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Diffuse large B-cell lymphoma	51/125 (41)	NE (1.4, NE)	17/119 (14)	NE (NE, NE)	3.24 (1.87,5.62)	<0.0001	0.6439
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/32 (59)	1.2 (1.0, NE)	5/25 (20)	NE (3.3, NE)	4.10 (1.52,11.06)	0.0024	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	28.3 (12.1, NE)	24/110 (22)	NE (NE, NE)	0.05 (0.01,0.21)	<0.0001	0.9343
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	10/25 (40)	4.1 (2.9, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (4.9, NE)	8/25 (32)	7.2 (3.1, NE)	0.10 (0.02,0.51)	0.0007	
	Other	0/8 (0)	NE (NE, NE)	4/8 (50)	3.3 (0.3, NE)	NE (NE,NE)	NE	
Neutropenia	Diffuse large B-cell lymphoma not otherwise specified	45/108 (42)	NE (1.8, NE)	20/110 (18)	NE (NE, NE)	2.42 (1.43,4.10)	0.0007	0.8737
	Large cell transformation from follicular lymphoma	9/19 (47)	NE (1.1, NE)	3/25 (12)	NE (NE, NE)	4.43 (1.20,16.42)	0.0145	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	18/43 (42)	NE (1.0, NE)	4/25 (16)	NE (NE, NE)	2.98 (1.01,8.82)	0.0373	
	Other	5/8 (63)	1.1 (0.0, NE)	2/8 (25)	NE (0.5, NE)	2.46 (0.47,12.73)	0.2679	
Thrombocytopenia	Diffuse large B-cell lymphoma not otherwise specified	16/108 (15)	NE (NE, NE)	21/110 (19)	NE (NE, NE)	0.71 (0.37,1.37)	0.3044	0.2876
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	10/25 (40)	NE (1.9, NE)	0.20 (0.04,0.94)	0.0232	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Thrombocytopenia	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	NE (NE, NE)	8/25 (32)	NE (3.1, NE)	0.23 (0.07,0.78)	0.0104	
	Other	1/8 (13)	NE (1.0, NE)	2/8 (25)	NE (0.5, NE)	0.40 (0.04,4.49)	0.4459	
Cardiac disorders	Diffuse large B-cell lymphoma not otherwise specified	51/108 (47)	NE (1.2, NE)	21/110 (19)	NE (NE, NE)	2.88 (1.73,4.79)	<0.0001	0.2160
	Large cell transformation from follicular lymphoma	8/19 (42)	NE (1.1, NE)	8/25 (32)	NE (1.8, NE)	1.24 (0.46,3.29)	0.6712	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	1.2 (0.9, NE)	4/25 (16)	NE (3.3, NE)	4.61 (1.59,13.32)	0.0018	
	Other	4/8 (50)	NE (0.8, NE)	3/8 (38)	2.9 (0.9, NE)	1.34 (0.30,6.01)	0.6890	
Sinus tachycardia	Diffuse large B-cell lymphoma not otherwise specified	37/108 (34)	NE (NE, NE)	9/110 (8)	NE (NE, NE)	4.74 (2.28,9.82)	<0.0001	0.1149
	Large cell transformation from follicular lymphoma	4/19 (21)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	1.79 (0.40,8.01)	0.4388	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	18/43 (42)	NE (1.0, NE)	2/25 (8)	NE (4.0, NE)	6.27 (1.45,27.07)	0.0047	
	Other	2/8 (25)	NE (0.8, NE)	3/8 (38)	2.9 (0.9, NE)	0.55 (0.09,3.32)	0.4916	
Ear and labyrinth disorders	Diffuse large B-cell lymphoma not otherwise specified	4/108 (4)	NE (NE, NE)	12/110 (11)	NE (NE, NE)	0.31 (0.10,0.96)	0.0312	0.9798

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE, NE)	3/25 (12)	NE (4.7, NE)	0.16 (0.02,1.55)	0.0708	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (0.5, NE)	NE (NE,NE)	NE	
Gastrointestinal disorders	Diffuse large B-cell lymphoma not otherwise specified	93/108 (86)	0.8 (0.7, 0.9)	94/110 (85)	0.3 (0.1, 0.5)	0.72 (0.54,0.96)	0.0196	0.0560
	Large cell transformation from follicular lymphoma	14/19 (74)	1.0 (0.8, 1.6)	23/25 (92)	0.1 (0.1, 0.2)	0.35 (0.17,0.68)	0.0010	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	37/43 (86)	0.8 (0.7, 0.9)	21/25 (84)	0.3 (0.1, 0.8)	0.71 (0.41,1.21)	0.1963	
	Other	7/8 (88)	0.9 (0.7, 1.2)	5/8 (63)	2.2 (0.0, NE)	1.43 (0.44,4.65)	0.5460	
Nausea	Diffuse large B-cell lymphoma not otherwise specified	60/108 (56)	1.2 (1.0, NE)	73/110 (66)	1.1 (0.7, 2.4)	0.66 (0.47,0.93)	0.0170	0.0203
	Large cell transformation from follicular lymphoma	6/19 (32)	NE (1.1, NE)	21/25 (84)	0.1 (0.1, 0.8)	0.18 (0.07,0.45)	<0.0001	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	1.2 (0.9, NE)	17/25 (68)	0.5 (0.3, 3.0)	0.53 (0.28,0.99)	0.0402	
	Other	6/8 (75)	1.1 (0.8, NE)	5/8 (63)	2.5 (0.0, NE)	0.94 (0.28,3.13)	0.9224	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Stomatitis	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE, NE)	17/110 (15)	NE (NE, NE)	0.22 (0.08,0.61)	0.0014	0.9957
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	4/25 (16)	NE (4.6, NE)	0.20 (0.02,1.87)	0.1223	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE, NE)	3/25 (12)	NE (4.1, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	5/8 (63)	2.6 (0.3, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	Diffuse large B-cell lymphoma not otherwise specified	98/108 (91)	0.9 (0.8, 1.0)	81/110 (74)	0.5 (0.3, 0.9)	1.19 (0.88,1.61)	0.2495	0.4429
	Large cell transformation from follicular lymphoma	18/19 (95)	1.0 (0.8, 1.1)	18/25 (72)	1.1 (0.2, 2.4)	1.66 (0.84,3.31)	0.1369	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	42/43 (98)	0.8 (0.7, 0.8)	20/25 (80)	0.8 (0.3, 2.3)	2.14 (1.16,3.98)	0.0108	
	Other	7/8 (88)	1.0 (0.0, 1.3)	6/8 (75)	0.2 (0.1, NE)	0.91 (0.30,2.77)	0.8657	
Chills	Diffuse large B-cell lymphoma not otherwise specified	29/108 (27)	NE (NE, NE)	8/110 (7)	NE (NE, NE)	3.97 (1.81,8.70)	0.0002	0.8969
	Large cell transformation from follicular lymphoma	4/19 (21)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	2.67 (0.49,14.57)	0.2383	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/43 (30)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	2.61 (0.74,9.17)	0.1178	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Other	2/8 (25)	NE (1.1, NE)	1/8 (13)	NE (2.6, NE)	1.80 (0.16,19.90)	0.6260	
Mucosal inflammation	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE, NE)	9/110 (8)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE, NE)	4/25 (16)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Diffuse large B-cell lymphoma not otherwise specified	96/108 (89)	1.0 (0.9, 1.1)	31/110 (28)	NE (4.3, NE)	6.79 (4.45,10.35)	<0.0001	0.0069
	Large cell transformation from follicular lymphoma	18/19 (95)	1.1 (0.9, 1.1)	3/25 (12)	NE (NE, NE)	22.74 (6.20,83.43)	<0.0001	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	41/43 (95)	0.8 (0.8, 0.9)	5/25 (20)	6.9 (4.5, NE)	35.94 (8.32,155.18)	<0.0001	
	Other	6/8 (75)	1.1 (0.8, NE)	4/8 (50)	2.7 (0.3, NE)	2.31 (0.64,8.41)	0.1910	
Hepatobiliary disorders	Diffuse large B-cell lymphoma not otherwise specified	9/108 (8)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	4.48 (0.96,20.78)	0.0361	0.9856
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.43 (0.22,26.79)	0.4542	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hepatobiliary disorders	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/43 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	1/8 (13)	NE (3.4, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypertransaminasaemia	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE, NE)	0/110 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Diffuse large B-cell lymphoma not otherwise specified	13/108 (12)	5.1 (5.0, NE)	2/110 (2)	NE (NE, NE)	4.37 (0.95,20.01)	0.0381	0.9507
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/43 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (0.7, NE)	1/8 (13)	NE (3.5, NE)	1.79 (0.16,19.77)	0.6301	
Hypogammaglobulinaemia	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	5.1 (5.0, NE)	0/110 (0)	NE (NE, NE)	NE (NE,NE)	NE	1.0000

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (0.7, NE)	1/8 (13)	NE (3.5, NE)	1.79 (0.16,19.77)	0.6301	
Infections and infestations	Diffuse large B-cell lymphoma not otherwise specified	56/108 (52)	4.3 (2.5, 39.8)	36/110 (33)	9.0 (3.7, NE)	1.39 (0.91,2.13)	0.1247	0.9291
	Large cell transformation from follicular lymphoma	12/19 (63)	1.7 (1.1, NE)	9/25 (36)	4.6 (2.6, NE)	1.75 (0.72,4.26)	0.2072	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	5.0 (1.4, 23.7)	7/25 (28)	NE (3.0, NE)	1.40 (0.58,3.36)	0.4476	
	Other	6/8 (75)	2.0 (0.5, NE)	3/8 (38)	3.2 (0.4, NE)	1.96 (0.49,7.86)	0.3278	
Oral candidiasis	Diffuse large B-cell lymphoma not otherwise specified	8/108 (7)	NE (NE, NE)	3/110 (3)	NE (NE, NE)	2.71 (0.72,10.23)	0.1248	0.9998
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	NE (NE, NE)	2/25 (8)	7.1 (4.8, NE)	2.30 (0.26,20.64)	0.4430	
	Other	1/8 (13)	NE (1.6, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Rhinovirus infection	Diffuse large B-cell lymphoma not otherwise specified	7/108 (6)	NE (NE, NE)	1/110 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Diffuse large B-cell lymphoma not otherwise specified	15/108 (14)	NE (NE, NE)	19/110 (17)	NE (NE, NE)	0.72 (0.36,1.42)	0.3376	0.6656
	Large cell transformation from follicular lymphoma	3/19 (16)	25.6 (NE, NE)	8/25 (32)	NE (2.2, NE)	0.25 (0.05,1.19)	0.0610	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	NE (NE, NE)	5/25 (20)	NE (3.2, NE)	0.36 (0.09,1.34)	0.1122	
	Other	1/8 (13)	NE (1.5, NE)	1/8 (13)	NE (1.8, NE)	0.87 (0.05,13.85)	0.9189	
Infusion related reaction	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE, NE)	7/110 (6)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	4/25 (16)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Diffuse large B-cell lymphoma not otherwise specified	22/108 (20)	NE (NE, NE)	13/110 (12)	NE (NE, NE)	1.65 (0.83,3.28)	0.1500	0.9911
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	1.22 (0.17,8.69)	0.8404	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/43 (26)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (1.5, NE)	1/8 (13)	NE (1.8, NE)	2.02 (0.18,22.34)	0.5590	
C-reactive protein increased	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	6.35 (1.42,28.37)	0.0053	0.7883
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	1.26 (0.08,20.19)	0.8690	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/43 (19)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	4.89 (0.61,39.13)	0.0966	
	Other	2/8 (25)	NE (1.1, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Platelet count decreased	Diffuse large B-cell lymphoma not otherwise specified	20/108 (19)	NE (NE, NE)	42/110 (38)	NE (3.1, NE)	0.38 (0.22,0.65)	0.0002	0.8705

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Platelet count decreased	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	9/25 (36)	NE (1.4, NE)	0.41 (0.11,1.52)	0.1678	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/43 (19)	NE (NE, NE)	9/25 (36)	NE (1.1, NE)	0.43 (0.17,1.13)	0.0759	
	Other	1/8 (13)	NE (1.2, NE)	4/8 (50)	2.5 (0.3, NE)	0.15 (0.02,1.36)	0.0533	
Weight increased	Diffuse large B-cell lymphoma not otherwise specified	3/108 (3)	NE (NE, NE)	10/110 (9)	NE (NE, NE)	0.27 (0.07,0.98)	0.0325	0.9795
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	0.57 (0.04,9.11)	0.6868	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (0.0, NE)	NE (NE,NE)	NE	
Metabolism and nutrition disorders	Diffuse large B-cell lymphoma not otherwise specified	80/108 (74)	1.0 (0.9, 1.1)	56/110 (51)	2.8 (1.9, NE)	1.63 (1.16,2.30)	0.0045	0.1341
	Large cell transformation from follicular lymphoma	11/19 (58)	1.2 (0.8, NE)	16/25 (64)	0.8 (0.2, 4.7)	0.62 (0.29,1.34)	0.2154	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	34/43 (79)	1.0 (0.8, 1.1)	15/25 (60)	2.6 (0.4, NE)	1.69 (0.90,3.18)	0.0932	
	Other	6/8 (75)	0.9 (0.4, NE)	6/8 (75)	2.3 (0.0, NE)	1.26 (0.40,4.02)	0.6916	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hyperglycaemia	Diffuse large B-cell lymphoma not otherwise specified	21/108 (19)	NE (NE, NE)	11/110 (10)	NE (NE, NE)	1.92 (0.92,3.99)	0.0745	0.7859
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	4/25 (16)	NE (NE, NE)	0.90 (0.20,4.04)	0.8942	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/43 (19)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	2.38 (0.51,11.22)	0.2567	
	Other	1/8 (13)	NE (0.6, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypomagnesaemia	Diffuse large B-cell lymphoma not otherwise specified	16/108 (15)	5.0 (NE, NE)	20/110 (18)	NE (NE, NE)	0.67 (0.34,1.31)	0.2347	0.6548
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	5/25 (20)	NE (NE, NE)	0.47 (0.09,2.40)	0.3503	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/43 (12)	NE (NE, NE)	8/25 (32)	NE (2.6, NE)	0.29 (0.09,0.90)	0.0232	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (2.1, NE)	NE (NE,NE)	NE	
Hyponatraemia	Diffuse large B-cell lymphoma not otherwise specified	13/108 (12)	NE (NE, NE)	6/110 (5)	NE (NE, NE)	2.12 (0.80,5.60)	0.1191	0.8735
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.53 (0.23,27.96)	0.4312	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/43 (23)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	5.86 (0.75,45.83)	0.0556	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hyponatraemia	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Nervous system disorders	Diffuse large B-cell lymphoma not otherwise specified	86/108 (80)	1.1 (1.0, 1.1)	56/110 (51)	3.0 (1.1, NE)	1.74 (1.24,2.45)	0.0010	0.9984
	Large cell transformation from follicular lymphoma	16/19 (84)	1.0 (0.6, 1.3)	14/25 (56)	1.0 (0.4, NE)	1.52 (0.74,3.12)	0.2493	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	30/43 (70)	1.0 (0.9, 1.2)	13/25 (52)	3.9 (0.8, NE)	1.62 (0.83,3.19)	0.1516	
	Other	5/8 (63)	0.9 (0.2, NE)	4/8 (50)	4.8 (0.2, NE)	1.61 (0.43,6.08)	0.4692	
Dizziness	Diffuse large B-cell lymphoma not otherwise specified	23/108 (21)	NE (NE, NE)	11/110 (10)	NE (NE, NE)	2.06 (1.00,4.23)	0.0439	0.3006
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	6/25 (24)	NE (NE, NE)	0.56 (0.14,2.26)	0.4106	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/43 (30)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	2.54 (0.72,8.91)	0.1308	
	Other	1/8 (13)	NE (1.7, NE)	1/8 (13)	NE (0.8, NE)	0.81 (0.05,12.98)	0.8815	
Dysgeusia	Diffuse large B-cell lymphoma not otherwise specified	3/108 (3)	NE (NE, NE)	10/110 (9)	NE (NE, NE)	0.26 (0.07,0.97)	0.0309	0.9933
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	0.17 (0.02,1.66)	0.0849	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (2.6, NE)	NE (NE,NE)	NE	
Encephalopathy	Diffuse large B-cell lymphoma not otherwise specified	22/108 (20)	NE (NE, NE)	0/110 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9078
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	1.29 (0.08,20.61)	0.8571	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/43 (19)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	4.76 (0.59,38.03)	0.1038	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Diffuse large B-cell lymphoma not otherwise specified	55/108 (51)	1.5 (1.1, NE)	29/110 (26)	NE (NE, NE)	2.12 (1.35,3.32)	0.0008	0.7169
	Large cell transformation from follicular lymphoma	10/19 (53)	1.3 (1.0, NE)	7/25 (28)	NE (2.4, NE)	1.91 (0.73,5.03)	0.1789	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/43 (30)	NE (NE, NE)	6/25 (24)	7.0 (3.9, NE)	1.59 (0.57,4.48)	0.3709	
	Other	5/8 (63)	1.2 (0.7, NE)	1/8 (13)	NE (3.1, NE)	6.60 (0.76,56.88)	0.0458	
Peripheral sensory neuropathy	Diffuse large B-cell lymphoma not otherwise specified	0/108 (0)	NE (NE, NE)	8/110 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Peripheral sensory neuropathy	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0/43 (0)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Diffuse large B-cell lymphoma not otherwise specified	13/108 (12)	NE (NE, NE)	0/110 (0)	NE (NE, NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	0.84 (0.14,5.00)	0.8438	
	Other	2/8 (25)	NE (1.1, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	Diffuse large B-cell lymphoma not otherwise specified	26/108 (24)	NE (NE, NE)	1/110 (1)	NE (NE, NE)	29.15 (3.95,214.86)	<0.0001	1.0000
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/43 (30)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (1.3, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Psychiatric disorders	Diffuse large B-cell lymphoma not otherwise specified	52/108 (48)	4.3 (1.4, NE)	24/110 (22)	NE (NE, NE)	2.46 (1.51,4.00)	0.0002	0.3497
	Large cell transformation from follicular lymphoma	7/19 (37)	27.6 (1.3, NE)	5/25 (20)	NE (NE, NE)	1.55 (0.47,5.07)	0.4660	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	22/43 (51)	2.7 (1.0, NE)	8/25 (32)	NE (2.6, NE)	1.72 (0.76,3.86)	0.1823	
	Other	2/8 (25)	NE (1.0, NE)	3/8 (38)	3.0 (0.0, NE)	0.38 (0.06,2.38)	0.2847	
Agitation	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	NE (NE, NE)	1/110 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	1/8 (13)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Diffuse large B-cell lymphoma not otherwise specified	25/108 (23)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	13.25 (3.14,55.96)	<0.0001	0.1335
	Large cell transformation from follicular lymphoma	3/19 (16)	27.6 (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	12/43 (28)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Confusional state	Other	1/8 (13)	NE (1.0, NE)	2/8 (25)	NE (1.9, NE)	0.37 (0.03,4.18)	0.4068	
Respiratory, thoracic and mediastinal disorders	Diffuse large B-cell lymphoma not otherwise specified	60/108 (56)	1.6 (1.2, NE)	49/110 (45)	3.9 (2.8, NE)	1.17 (0.80,1.72)	0.4028	0.7061
	Large cell transformation from follicular lymphoma	9/19 (47)	NE (1.1, NE)	7/25 (28)	NE (2.7, NE)	1.82 (0.68,4.89)	0.2298	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	31/43 (72)	1.1 (0.9, 1.7)	12/25 (48)	3.4 (1.2, NE)	1.72 (0.88,3.38)	0.1070	
	Other	5/8 (63)	1.6 (0.6, NE)	4/8 (50)	3.7 (0.1, NE)	1.31 (0.35,4.89)	0.6880	
Cough	Diffuse large B-cell lymphoma not otherwise specified	30/108 (28)	NE (NE, NE)	13/110 (12)	NE (NE, NE)	2.23 (1.16,4.29)	0.0131	0.6624
	Large cell transformation from follicular lymphoma	5/19 (26)	NE (1.4, NE)	1/25 (4)	NE (NE, NE)	7.16 (0.84,61.38)	0.0351	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/43 (26)	NE (NE, NE)	3/25 (12)	NE (NE, NE)	2.28 (0.64,8.19)	0.1918	
	Other	1/8 (13)	NE (1.6, NE)	1/8 (13)	NE (2.2, NE)	0.87 (0.05,13.85)	0.9189	
Hiccups	Diffuse large B-cell lymphoma not otherwise specified	6/108 (6)	NE (NE, NE)	17/110 (15)	NE (NE, NE)	0.33 (0.13,0.83)	0.0128	0.9907
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE, NE)	4/25 (16)	NE (3.4, NE)	0.34 (0.07,1.54)	0.1435	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypoxia	Diffuse large B-cell lymphoma not otherwise specified	21/108 (19)	NE (NE, NE)	7/110 (6)	NE (NE, NE)	3.06 (1.30,7.22)	0.0070	0.5944
	Large cell transformation from follicular lymphoma	4/19 (21)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	5.57 (0.62,49.82)	0.0835	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/43 (26)	NE (NE, NE)	3/25 (12)	NE (4.5, NE)	2.23 (0.62,8.02)	0.2061	
	Other	2/8 (25)	NE (0.9, NE)	2/8 (25)	NE (0.1, NE)	0.86 (0.12,6.09)	0.8760	
Pleural effusion	Diffuse large B-cell lymphoma not otherwise specified	7/108 (6)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Skin and subcutaneous tissue disorders								

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Erythema	Diffuse large B-cell lymphoma not otherwise specified	9/108 (8)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	4.60 (0.99,21.30)	0.0319	1.0000
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	1/8 (13)	NE (1.5, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Diffuse large B-cell lymphoma not otherwise specified	62/108 (57)	1.4 (1.1, NE)	31/110 (28)	NE (3.8, NE)	2.44 (1.58,3.76)	<0.0001	0.1220
	Large cell transformation from follicular lymphoma	10/19 (53)	1.5 (0.9, NE)	13/25 (52)	2.6 (0.8, NE)	0.90 (0.39,2.06)	0.8009	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/43 (56)	1.2 (1.0, NE)	8/25 (32)	NE (2.6, NE)	1.90 (0.85,4.27)	0.1106	
	Other	4/8 (50)	NE (0.9, NE)	4/8 (50)	2.2 (0.1, NE)	0.87 (0.22,3.49)	0.8346	
Hypotension	Diffuse large B-cell lymphoma not otherwise specified	49/108 (45)	NE (1.3, NE)	13/110 (12)	NE (NE, NE)	4.65 (2.52,8.58)	<0.0001	0.3499
	Large cell transformation from follicular lymphoma	8/19 (42)	NE (1.0, NE)	5/25 (20)	NE (3.3, NE)	2.29 (0.75,7.03)	0.1335	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	21/43 (49)	1.6 (1.0, NE)	5/25 (20)	NE (3.3, NE)	2.78 (1.05,7.40)	0.0311	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Table 14.3.1.1.1.11. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Other	2/8 (25)	NE (1.3, NE)	2/8 (25)	NE (2.2, NE)	0.87 (0.12,6.25)	0.8933	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0 - 1	3/94 (3)	12.1 (12.1, NE)	26/93 (28)	7.2 (3.7, NE)	0.02 (0.00,0.16)	<0.0001	0.4042
	2 - 3	4/84 (5)	28.3 (4.9, NE)	20/75 (27)	NE (4.1, NE)	0.07 (0.02,0.26)	<0.0001	
Neutropenia	0 - 1	43/94 (46)	NE (1.4, NE)	18/93 (19)	NE (NE, NE)	2.55 (1.47,4.42)	0.0005	0.6219
	2 - 3	34/84 (40)	NE (1.2, NE)	11/75 (15)	NE (NE, NE)	3.05 (1.54,6.02)	0.0007	
Thrombocytopenia	0 - 1	11/94 (12)	NE (NE, NE)	26/93 (28)	NE (NE, NE)	0.34 (0.17,0.69)	0.0018	0.2136
	2 - 3	12/84 (14)	NE (NE, NE)	15/75 (20)	NE (NE, NE)	0.65 (0.30,1.39)	0.2622	
Cardiac disorders	0 - 1	43/94 (46)	NE (1.2, NE)	25/93 (27)	NE (4.6, NE)	1.83 (1.12,3.00)	0.0145	0.0339
	2 - 3	44/84 (52)	1.4 (1.1, NE)	11/75 (15)	NE (NE, NE)	4.46 (2.30,8.66)	<0.0001	
Sinus tachycardia	0 - 1	30/94 (32)	NE (NE, NE)	9/93 (10)	NE (NE, NE)	3.62 (1.72,7.63)	0.0003	0.8510
	2 - 3	31/84 (37)	NE (3.9, NE)	8/75 (11)	NE (NE, NE)	3.96 (1.82,8.63)	0.0002	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	0 - 1	3/94 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.38 (0.10,1.49)	0.1500	0.3443
	2 - 3	2/84 (2)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	0.14 (0.03,0.65)	0.0036	
Gastrointestinal disorders	0 - 1	79/94 (84)	0.9 (0.8, 1.0)	81/93 (87)	0.2 (0.1, 0.3)	0.56 (0.41,0.77)	0.0002	0.0798
	2 - 3	72/84 (86)	0.7 (0.6, 0.8)	62/75 (83)	0.3 (0.1, 0.7)	0.82 (0.58,1.15)	0.2313	
Nausea	0 - 1	55/94 (59)	1.2 (1.0, NE)	65/93 (70)	0.8 (0.3, 2.4)	0.61 (0.42,0.87)	0.0059	0.4844
	2 - 3	41/84 (49)	4.4 (1.1, NE)	51/75 (68)	0.8 (0.3, 1.9)	0.49 (0.33,0.75)	0.0006	
Stomatitis	0 - 1	2/94 (2)	NE (NE, NE)	13/93 (14)	NE (NE, NE)	0.11 (0.02,0.48)	0.0004	0.7591
	2 - 3	4/84 (5)	NE (NE, NE)	16/75 (21)	NE (4.3, NE)	0.13 (0.04,0.41)	<0.0001	
General disorders and administration site conditions	0 - 1	89/94 (95)	0.9 (0.8, 1.0)	75/93 (81)	0.7 (0.3, 1.0)	1.22 (0.88,1.68)	0.2198	0.1686
	2 - 3	76/84 (90)	0.8 (0.7, 0.9)	50/75 (67)	0.5 (0.3, 1.4)	1.43 (0.99,2.07)	0.0507	
Chills	0 - 1	25/94 (27)	NE (NE, NE)	5/93 (5)	NE (NE, NE)	5.17 (1.98,13.53)	0.0002	0.2399

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	2 - 3	23/84 (27)	NE (NE, NE)	9/75 (12)	NE (NE, NE)	2.39 (1.11,5.18)	0.0219	
Mucosal inflammation	0 - 1	1/94 (1)	NE (NE, NE)	15/93 (16)	7.0 (4.9, NE)	0.05 (0.01,0.37)	<0.0001	0.9945
	2 - 3	0/84 (0)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	0 - 1	87/94 (93)	1.0 (1.0, 1.1)	28/93 (30)	6.9 (3.9, NE)	9.09 (5.71,14.46)	<0.0001	0.2927
	2 - 3	74/84 (88)	0.9 (0.8, 1.0)	15/75 (20)	NE (NE, NE)	9.28 (5.21,16.52)	<0.0001	
Hepatobiliary disorders	0 - 1	9/94 (10)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	8.32 (1.05,65.79)	0.0164	0.6107
	2 - 3	10/84 (12)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	4.52 (0.99,20.65)	0.0327	
Hypertransaminasaemia	0 - 1	6/94 (6)	NE (NE, NE)	0/93 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	6/84 (7)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	0 - 1	13/94 (14)	5.4 (NE, NE)	1/93 (1)	NE (NE, NE)	10.87 (1.41,83.64)	0.0041	0.4537
	2 - 3	11/84 (13)	5.0 (5.0, NE)	2/75 (3)	NE (NE, NE)	3.46 (0.74,16.11)	0.0921	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	0 - 1	13/94 (14)	5.4 (NE, NE)	1/93 (1)	NE (NE, NE)	10.62 (1.38,81.74)	0.0046	0.9902
	2 - 3	9/84 (11)	5.0 (5.0, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	0 - 1	56/94 (60)	4.0 (1.7, 13.8)	28/93 (30)	33.0 (3.7, NE)	1.75 (1.11,2.79)	0.0155	0.2050
	2 - 3	42/84 (50)	5.0 (1.7, 19.8)	27/75 (36)	9.0 (4.4, NE)	1.16 (0.71,1.91)	0.5479	
Oral candidiasis	0 - 1	10/94 (11)	NE (NE, NE)	3/93 (3)	7.1 (NE, NE)	4.77 (1.04,21.82)	0.0259	0.5911
	2 - 3	6/84 (7)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	2.76 (0.56,13.68)	0.1936	
Rhinovirus infection	0 - 1	3/94 (3)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	8/84 (10)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	0 - 1	8/94 (9)	NE (NE, NE)	20/93 (22)	NE (NE, NE)	0.32 (0.14,0.73)	0.0041	0.1001
	2 - 3	15/84 (18)	25.6 (NE, NE)	13/75 (17)	NE (NE, NE)	0.87 (0.41,1.87)	0.7285	
Infusion related reaction	0 - 1	0/94 (0)	NE (NE, NE)	9/93 (10)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	2 - 3	1/84 (1)	NE (NE, NE)	4/75 (5)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	0 - 1	15/94 (16)	NE (NE, NE)	10/93 (11)	NE (NE, NE)	1.40 (0.63,3.12)	0.4084	0.1459
	2 - 3	22/84 (26)	NE (NE, NE)	6/75 (8)	NE (NE, NE)	3.41 (1.38,8.41)	0.0047	
C-reactive protein increased	0 - 1	15/94 (16)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	7.53 (1.72,32.93)	0.0015	0.5226
	2 - 3	8/84 (10)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	3.71 (0.79,17.45)	0.0753	
Platelet count decreased	0 - 1	15/94 (16)	NE (NE, NE)	37/93 (40)	3.7 (3.1, NE)	0.30 (0.16,0.54)	<0.0001	0.3928
	2 - 3	17/84 (20)	NE (NE, NE)	27/75 (36)	NE (2.8, NE)	0.51 (0.28,0.94)	0.0271	
Weight increased	0 - 1	3/94 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.39 (0.10,1.52)	0.1608	0.8949
	2 - 3	2/84 (2)	NE (NE, NE)	5/75 (7)	NE (NE, NE)	0.31 (0.06,1.61)	0.1402	
Metabolism and nutrition disorders	0 - 1	64/94 (68)	1.1 (1.0, 1.2)	48/93 (52)	2.8 (1.9, NE)	1.41 (0.97,2.07)	0.0689	0.7946

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	2 - 3	67/84 (80)	0.9 (0.8, 1.1)	45/75 (60)	2.3 (0.8, 3.1)	1.46 (0.99,2.13)	0.0484	
Hyperglycaemia	0 - 1	15/94 (16)	NE (NE, NE)	6/93 (6)	NE (NE, NE)	2.36 (0.92,6.10)	0.0665	0.4030
	2 - 3	18/84 (21)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	1.46 (0.69,3.10)	0.3156	
Hypomagnesaemia	0 - 1	12/94 (13)	NE (NE, NE)	20/93 (22)	NE (NE, NE)	0.50 (0.24,1.02)	0.0525	0.9333
	2 - 3	11/84 (13)	5.0 (NE, NE)	14/75 (19)	NE (NE, NE)	0.57 (0.25,1.29)	0.1732	
Hyponatraemia	0 - 1	13/94 (14)	NE (NE, NE)	5/93 (5)	NE (NE, NE)	2.45 (0.87,6.87)	0.0789	0.6710
	2 - 3	12/84 (14)	NE (NE, NE)	3/75 (4)	NE (NE, NE)	3.64 (1.03,12.91)	0.0323	
Nervous system disorders	0 - 1	70/94 (74)	1.1 (1.0, 1.2)	49/93 (53)	3.0 (2.3, NE)	1.52 (1.05,2.19)	0.0251	0.5597
	2 - 3	67/84 (80)	1.0 (0.9, 1.1)	38/75 (51)	3.2 (0.8, NE)	1.79 (1.19,2.67)	0.0038	
Dizziness	0 - 1	20/94 (21)	NE (NE, NE)	11/93 (12)	NE (NE, NE)	1.70 (0.81,3.55)	0.1515	0.9808
	2 - 3	20/84 (24)	NE (NE, NE)	10/75 (13)	NE (NE, NE)	1.68 (0.79,3.60)	0.1746	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	0 - 1	3/94 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.37 (0.10,1.45)	0.1375	0.6283
	2 - 3	2/84 (2)	NE (NE, NE)	7/75 (9)	NE (NE, NE)	0.22 (0.05,1.07)	0.0396	
Encephalopathy	0 - 1	8/94 (9)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	7.70 (0.96,61.58)	0.0227	0.4532
	2 - 3	23/84 (27)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	23.50 (3.17,174.04)	<0.0001	
Headache	0 - 1	47/94 (50)	2.0 (1.1, NE)	26/93 (28)	7.0 (NE, NE)	2.08 (1.28,3.38)	0.0025	0.9775
	2 - 3	36/84 (43)	NE (1.2, NE)	17/75 (23)	NE (NE, NE)	1.98 (1.11,3.52)	0.0180	
Peripheral sensory neuropathy	0 - 1	0/94 (0)	NE (NE, NE)	4/93 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	1/84 (1)	NE (NE, NE)	6/75 (8)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	0 - 1	11/94 (12)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	10.75 (1.39,83.29)	0.0044	0.8035
	2 - 3	8/84 (10)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	7.41 (0.93,59.25)	0.0264	
Tremor	0 - 1	19/94 (20)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	19.43 (2.60,145.14)	<0.0001	0.9858

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	2 - 3	25/84 (30)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	0 - 1	38/94 (40)	NE (3.5, NE)	27/93 (29)	NE (NE, NE)	1.34 (0.81,2.19)	0.2487	0.0155
	2 - 3	45/84 (54)	1.5 (1.2, NE)	13/75 (17)	NE (NE, NE)	3.75 (2.02,6.98)	<0.0001	
Agitation	0 - 1	6/94 (6)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	5/84 (6)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	0 - 1	16/94 (17)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	5.07 (1.48,17.42)	0.0041	0.1993
	2 - 3	25/84 (30)	27.6 (NE, NE)	1/75 (1)	NE (NE, NE)	24.99 (3.38,184.78)	<0.0001	
Respiratory, thoracic and mediastinal disorders	0 - 1	55/94 (59)	1.4 (1.1, NE)	39/93 (42)	4.6 (2.8, NE)	1.33 (0.88,2.01)	0.1694	0.7608
	2 - 3	50/84 (60)	1.2 (1.1, 4.8)	33/75 (44)	3.7 (2.2, NE)	1.46 (0.94,2.27)	0.0916	
Cough	0 - 1	22/94 (23)	NE (NE, NE)	14/93 (15)	NE (NE, NE)	1.43 (0.73,2.79)	0.2986	0.0289
	2 - 3	25/84 (30)	NE (NE, NE)	4/75 (5)	NE (NE, NE)	6.16 (2.14,17.71)	0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	0 - 1	7/94 (7)	NE (NE, NE)	11/93 (12)	NE (NE, NE)	0.56 (0.22,1.44)	0.2213	0.1808
	2 - 3	2/84 (2)	NE (NE, NE)	10/75 (13)	NE (NE, NE)	0.15 (0.03,0.71)	0.0057	
Hypoxia	0 - 1	19/94 (20)	NE (NE, NE)	10/93 (11)	NE (NE, NE)	1.84 (0.86,3.97)	0.1124	0.1110
	2 - 3	19/84 (23)	NE (NE, NE)	3/75 (4)	NE (NE, NE)	6.05 (1.79,20.48)	0.0009	
Pleural effusion	0 - 1	1/94 (1)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	0.35 (0.03,3.88)	0.3712	0.0581
	2 - 3	11/84 (13)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	9.98 (1.29,77.42)	0.0065	
Skin and subcutaneous tissue disorders								
Erythema	0 - 1	8/94 (9)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	2.41 (0.64,9.08)	0.1809	0.9900
	2 - 3	4/84 (5)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	0 - 1	51/94 (54)	1.4 (1.2, NE)	30/93 (32)	NE (3.6, NE)	1.89 (1.20,2.97)	0.0049	0.9843
	2 - 3	49/84 (58)	1.3 (1.1, NE)	26/75 (35)	NE (2.8, NE)	1.88 (1.16,3.03)	0.0085	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.12. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0 - 1	40/94 (43)	NE (1.4, NE)	13/93 (14)	NE (NE, NE)	3.45 (1.84,6.45)	<0.0001	0.8460
	2 - 3	40/84 (48)	NE (1.1, NE)	12/75 (16)	NE (NE, NE)	3.72 (1.95,7.10)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0 - 1	4/98 (4)	28.3 (12.1, NE)	27/93 (29)	7.2 (3.7, NE)	0.02 (0.00,0.14)	<0.0001	0.2449
	2 - 3	3/80 (4)	NE (4.9, NE)	19/75 (25)	NE (3.4, NE)	0.08 (0.02,0.29)	<0.0001	
Neutropenia	0 - 1	45/98 (46)	NE (1.4, NE)	19/93 (20)	NE (NE, NE)	2.39 (1.40,4.09)	0.0010	0.4068
	2 - 3	32/80 (40)	NE (1.2, NE)	10/75 (13)	NE (NE, NE)	3.34 (1.64,6.82)	0.0004	
Thrombocytopenia	0 - 1	13/98 (13)	NE (NE, NE)	28/93 (30)	NE (NE, NE)	0.36 (0.18,0.69)	0.0013	0.2370
	2 - 3	10/80 (13)	NE (NE, NE)	13/75 (17)	NE (NE, NE)	0.67 (0.29,1.53)	0.3349	
Cardiac disorders	0 - 1	45/98 (46)	NE (1.2, NE)	26/93 (28)	NE (4.6, NE)	1.74 (1.07,2.82)	0.0229	0.0135
	2 - 3	42/80 (53)	1.3 (1.1, NE)	10/75 (13)	NE (NE, NE)	5.06 (2.54,10.11)	<0.0001	
Sinus tachycardia	0 - 1	31/98 (32)	NE (NE, NE)	8/93 (9)	NE (NE, NE)	4.03 (1.85,8.78)	0.0001	0.8744
	2 - 3	30/80 (38)	NE (2.1, NE)	9/75 (12)	NE (NE, NE)	3.59 (1.70,7.57)	0.0003	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	0 - 1	3/98 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.37 (0.09,1.42)	0.1297	0.3978
	2 - 3	2/80 (3)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	0.15 (0.03,0.69)	0.0049	
Gastrointestinal disorders	0 - 1	82/98 (84)	0.9 (0.8, 1.0)	81/93 (87)	0.2 (0.1, 0.3)	0.54 (0.39,0.74)	<0.0001	0.0313
	2 - 3	69/80 (86)	0.7 (0.6, 0.8)	62/75 (83)	0.3 (0.1, 0.7)	0.86 (0.61,1.22)	0.3810	
Nausea	0 - 1	56/98 (57)	1.2 (1.0, NE)	66/93 (71)	0.8 (0.3, 2.0)	0.56 (0.39,0.80)	0.0010	0.9823
	2 - 3	40/80 (50)	2.1 (1.0, NE)	50/75 (67)	0.9 (0.3, 2.1)	0.54 (0.36,0.83)	0.0036	
Stomatitis	0 - 1	3/98 (3)	NE (NE, NE)	13/93 (14)	NE (NE, NE)	0.16 (0.04,0.55)	0.0010	0.7106
	2 - 3	3/80 (4)	NE (NE, NE)	16/75 (21)	NE (4.1, NE)	0.10 (0.03,0.37)	<0.0001	
General disorders and administration site conditions	0 - 1	93/98 (95)	1.0 (0.9, 1.0)	75/93 (81)	0.7 (0.3, 1.0)	1.18 (0.86,1.62)	0.2835	0.1067
	2 - 3	72/80 (90)	0.8 (0.7, 0.8)	50/75 (67)	0.5 (0.3, 1.8)	1.45 (1.00,2.10)	0.0457	
Chills	0 - 1	26/98 (27)	NE (NE, NE)	6/93 (6)	NE (NE, NE)	4.26 (1.75,10.35)	0.0005	0.5025

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	2 - 3	22/80 (28)	NE (NE, NE)	8/75 (11)	NE (NE, NE)	2.75 (1.22,6.19)	0.0105	
Mucosal inflammation	0 - 1	1/98 (1)	NE (NE, NE)	15/93 (16)	7.0 (4.9, NE)	0.05 (0.01,0.35)	<0.0001	0.9947
	2 - 3	0/80 (0)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	0 - 1	91/98 (93)	1.0 (1.0, 1.1)	28/93 (30)	6.9 (3.9, NE)	8.42 (5.34,13.27)	<0.0001	0.1759
	2 - 3	70/80 (88)	0.9 (0.8, 1.0)	15/75 (20)	NE (NE, NE)	9.81 (5.47,17.60)	<0.0001	
Hepatobiliary disorders	0 - 1	9/98 (9)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	7.86 (0.99,62.20)	0.0206	0.6727
	2 - 3	10/80 (13)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	4.80 (1.05,21.95)	0.0253	
Hypertransaminasaemia	0 - 1	6/98 (6)	NE (NE, NE)	0/93 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	6/80 (8)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	0 - 1	13/98 (13)	5.4 (NE, NE)	1/93 (1)	NE (NE, NE)	10.21 (1.33,78.60)	0.0056	0.5078
	2 - 3	11/80 (14)	5.0 (5.0, NE)	2/75 (3)	NE (NE, NE)	3.78 (0.81,17.59)	0.0687	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	0 - 1	13/98 (13)	5.4 (NE, NE)	1/93 (1)	NE (NE, NE)	9.97 (1.30,76.73)	0.0064	0.9901
	2 - 3	9/80 (11)	5.0 (5.0, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Infections and infestations	0 - 1	55/98 (56)	4.5 (2.5, 19.8)	30/93 (32)	33.0 (3.7, NE)	1.46 (0.92,2.29)	0.1032	0.8820
	2 - 3	43/80 (54)	4.0 (1.5, 10.9)	25/75 (33)	9.0 (4.4, NE)	1.46 (0.89,2.41)	0.1312	
Oral candidiasis	0 - 1	10/98 (10)	NE (NE, NE)	3/93 (3)	7.1 (NE, NE)	4.55 (1.00,20.82)	0.0319	0.6563
	2 - 3	6/80 (8)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	2.90 (0.59,14.38)	0.1706	
Rhinovirus infection	0 - 1	3/98 (3)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	8/80 (10)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	0 - 1	7/98 (7)	NE (NE, NE)	20/93 (22)	NE (NE, NE)	0.26 (0.11,0.62)	0.0011	0.0300
	2 - 3	16/80 (20)	25.6 (NE, NE)	13/75 (17)	NE (NE, NE)	1.00 (0.48,2.11)	0.9960	
Infusion related reaction	0 - 1	0/98 (0)	NE (NE, NE)	9/93 (10)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	2 - 3	1/80 (1)	NE (NE, NE)	4/75 (5)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	0 - 1	15/98 (15)	NE (NE, NE)	10/93 (11)	NE (NE, NE)	1.33 (0.60,2.96)	0.4826	0.0994
	2 - 3	22/80 (28)	NE (NE, NE)	6/75 (8)	NE (NE, NE)	3.62 (1.47,8.95)	0.0028	
C-reactive protein increased	0 - 1	16/98 (16)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	7.72 (1.77,33.56)	0.0012	0.4665
	2 - 3	7/80 (9)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	3.40 (0.71,16.37)	0.1043	
Platelet count decreased	0 - 1	17/98 (17)	NE (NE, NE)	37/93 (40)	NE (3.1, NE)	0.33 (0.18,0.58)	<0.0001	0.6082
	2 - 3	15/80 (19)	NE (NE, NE)	27/75 (36)	NE (2.6, NE)	0.47 (0.25,0.89)	0.0170	
Weight increased	0 - 1	3/98 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.38 (0.10,1.46)	0.1416	0.9648
	2 - 3	2/80 (3)	NE (NE, NE)	5/75 (7)	NE (NE, NE)	0.33 (0.06,1.69)	0.1604	
Metabolism and nutrition disorders	0 - 1	70/98 (71)	1.1 (1.0, 1.2)	49/93 (53)	2.6 (1.6, NE)	1.43 (0.99,2.07)	0.0548	0.8404

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	2 - 3	61/80 (76)	0.9 (0.8, 1.1)	44/75 (59)	2.3 (0.8, 3.1)	1.45 (0.98,2.15)	0.0555	
Hyperglycaemia	0 - 1	14/98 (14)	NE (NE, NE)	6/93 (6)	NE (NE, NE)	2.08 (0.80,5.43)	0.1239	0.6624
	2 - 3	19/80 (24)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	1.65 (0.78,3.47)	0.1810	
Hypomagnesaemia	0 - 1	14/98 (14)	5.0 (NE, NE)	19/93 (20)	NE (NE, NE)	0.56 (0.27,1.13)	0.0985	0.7510
	2 - 3	9/80 (11)	NE (NE, NE)	15/75 (20)	NE (NE, NE)	0.49 (0.21,1.12)	0.0838	
Hyponatraemia	0 - 1	12/98 (12)	NE (NE, NE)	4/93 (4)	NE (NE, NE)	2.76 (0.89,8.55)	0.0670	0.9001
	2 - 3	13/80 (16)	NE (NE, NE)	4/75 (5)	NE (NE, NE)	3.00 (0.98,9.22)	0.0441	
Nervous system disorders	0 - 1	74/98 (76)	1.1 (1.0, 1.2)	50/93 (54)	3.0 (1.0, NE)	1.47 (1.02,2.11)	0.0357	0.3987
	2 - 3	63/80 (79)	1.0 (0.9, 1.1)	37/75 (49)	3.2 (1.1, NE)	1.90 (1.26,2.86)	0.0017	
Dizziness	0 - 1	21/98 (21)	NE (NE, NE)	13/93 (14)	NE (NE, NE)	1.43 (0.72,2.86)	0.3057	0.4331
	2 - 3	19/80 (24)	NE (NE, NE)	8/75 (11)	NE (NE, NE)	2.14 (0.94,4.90)	0.0640	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	0 - 1	3/98 (3)	NE (NE, NE)	7/93 (8)	NE (NE, NE)	0.36 (0.09,1.39)	0.1201	0.6938
	2 - 3	2/80 (3)	NE (NE, NE)	7/75 (9)	NE (NE, NE)	0.23 (0.05,1.12)	0.0476	
Encephalopathy	0 - 1	8/98 (8)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	7.39 (0.92,59.12)	0.0266	0.4136
	2 - 3	23/80 (29)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	24.90 (3.36,184.48)	<0.0001	
Headache	0 - 1	51/98 (52)	1.4 (1.1, NE)	25/93 (27)	7.0 (NE, NE)	2.28 (1.40,3.71)	0.0006	0.5045
	2 - 3	32/80 (40)	NE (1.3, NE)	18/75 (24)	NE (NE, NE)	1.71 (0.96,3.05)	0.0646	
Peripheral sensory neuropathy	0 - 1	0/98 (0)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	1/80 (1)	NE (NE, NE)	7/75 (9)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	0 - 1	10/98 (10)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	9.32 (1.19,72.77)	0.0094	0.9688
	2 - 3	9/80 (11)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	8.84 (1.12,69.83)	0.0123	
Tremor	0 - 1	22/98 (22)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	21.82 (2.94,161.89)	<0.0001	0.9856

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	2 - 3	22/80 (28)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	0 - 1	40/98 (41)	NE (3.5, NE)	27/93 (29)	NE (NE, NE)	1.34 (0.82,2.18)	0.2409	0.0138
	2 - 3	43/80 (54)	1.5 (1.2, NE)	13/75 (17)	NE (NE, NE)	3.83 (2.05,7.16)	<0.0001	
Agitation	0 - 1	6/98 (6)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	2 - 3	5/80 (6)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	0 - 1	16/98 (16)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	4.85 (1.41,16.68)	0.0055	0.1721
	2 - 3	25/80 (31)	27.6 (NE, NE)	1/75 (1)	NE (NE, NE)	26.60 (3.60,196.68)	<0.0001	
Respiratory, thoracic and mediastinal disorders	0 - 1	55/98 (56)	1.5 (1.2, NE)	38/93 (41)	NE (3.1, NE)	1.29 (0.85,1.96)	0.2254	0.5804
	2 - 3	50/80 (63)	1.2 (1.0, 4.0)	34/75 (45)	3.3 (2.2, NE)	1.52 (0.98,2.36)	0.0560	
Cough	0 - 1	22/98 (22)	NE (NE, NE)	14/93 (15)	NE (NE, NE)	1.36 (0.69,2.66)	0.3688	0.0187
	2 - 3	25/80 (31)	NE (NE, NE)	4/75 (5)	NE (NE, NE)	6.54 (2.28,18.81)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	0 - 1	7/98 (7)	NE (NE, NE)	10/93 (11)	NE (NE, NE)	0.60 (0.23,1.57)	0.2906	0.1490
	2 - 3	2/80 (3)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	0.14 (0.03,0.64)	0.0032	
Hypoxia	0 - 1	20/98 (20)	NE (NE, NE)	8/93 (9)	NE (NE, NE)	2.36 (1.04,5.36)	0.0347	0.5265
	2 - 3	18/80 (23)	NE (NE, NE)	5/75 (7)	NE (NE, NE)	3.54 (1.31,9.55)	0.0076	
Pleural effusion	0 - 1	2/98 (2)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	0.73 (0.10,5.25)	0.7559	0.1049
	2 - 3	10/80 (13)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	9.48 (1.21,74.13)	0.0087	
Skin and subcutaneous tissue disorders								
Erythema	0 - 1	8/98 (8)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	2.30 (0.61,8.69)	0.2055	0.9898
	2 - 3	4/80 (5)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	0 - 1	55/98 (56)	1.4 (1.2, NE)	32/93 (34)	NE (3.6, NE)	1.80 (1.16,2.79)	0.0071	0.7274
	2 - 3	45/80 (56)	1.3 (1.0, NE)	24/75 (32)	NE (3.1, NE)	2.00 (1.21,3.29)	0.0053	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.13. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0 - 1	43/98 (44)	NE (1.4, NE)	15/93 (16)	NE (NE, NE)	3.01 (1.67,5.43)	0.0001	0.3780
	2 - 3	37/80 (46)	NE (1.1, NE)	10/75 (13)	NE (NE, NE)	4.46 (2.22,8.99)	<0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Primary refractory	6/131 (5)	28.3 (12.1, NE)	36/125 (29)	NE (3.7, NE)	0.04 (0.01,0.12)	<0.0001	0.5568
	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	10/43 (23)	7.2 (NE, NE)	0.07 (0.01,0.59)	0.0014	
Neutropenia	Primary refractory	61/131 (47)	NE (1.2, NE)	19/125 (15)	NE (NE, NE)	3.35 (2.00,5.61)	<0.0001	0.1176
	Relapse ≤ 12 months of the completion of the first line therapy	16/46 (35)	NE (1.9, NE)	10/43 (23)	NE (NE, NE)	1.58 (0.72,3.49)	0.2521	
Thrombocytopenia	Primary refractory	14/131 (11)	NE (NE, NE)	28/125 (22)	NE (NE, NE)	0.41 (0.21,0.77)	0.0046	0.4858
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE, NE)	13/43 (30)	NE (NE, NE)	0.58 (0.25,1.36)	0.2015	
Cardiac disorders	Primary refractory	63/131 (48)	3.9 (1.2, NE)	26/125 (21)	NE (NE, NE)	2.63 (1.66,4.16)	<0.0001	0.9593
	Relapse ≤ 12 months of the completion of the first line therapy	24/46 (52)	2.1 (1.1, NE)	10/43 (23)	NE (NE, NE)	2.69 (1.28,5.63)	0.0062	
Sinus tachycardia	Primary refractory	46/131 (35)	NE (NE, NE)	14/125 (11)	NE (NE, NE)	3.46 (1.90,6.29)	<0.0001	0.5690
	Relapse ≤ 12 months of the completion of the first line therapy	15/46 (33)	NE (NE, NE)	3/43 (7)	NE (NE, NE)	5.41 (1.57,18.71)	0.0027	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Primary refractory	4/131 (3)	NE (NE, NE)	13/125 (10)	NE (NE, NE)	0.26 (0.09,0.81)	0.0127	0.7305
	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	5/43 (12)	NE (NE, NE)	0.17 (0.02,1.46)	0.0665	
Gastrointestinal disorders	Primary refractory	110/131 (84)	0.8 (0.8, 0.9)	104/125 (83)	0.3 (0.1, 0.5)	0.72 (0.55,0.95)	0.0149	0.1959
	Relapse ≤ 12 months of the completion of the first line therapy	41/46 (89)	0.9 (0.8, 1.0)	39/43 (91)	0.1 (0.1, 0.4)	0.51 (0.33,0.80)	0.0021	
Nausea	Primary refractory	67/131 (51)	1.2 (1.1, NE)	81/125 (65)	1.0 (0.7, 2.4)	0.59 (0.42,0.81)	0.0010	0.5140
	Relapse ≤ 12 months of the completion of the first line therapy	29/46 (63)	1.2 (1.0, 4.8)	35/43 (81)	0.7 (0.1, 1.1)	0.47 (0.29,0.78)	0.0022	
Stomatitis	Primary refractory	5/131 (4)	NE (NE, NE)	17/125 (14)	NE (NE, NE)	0.19 (0.07,0.51)	0.0003	0.2923
	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	12/43 (28)	NE (3.6, NE)	0.06 (0.01,0.44)	0.0002	
General disorders and administration site conditions	Primary refractory	120/131 (92)	0.9 (0.8, 1.0)	85/125 (68)	0.8 (0.3, 1.8)	1.49 (1.12,1.99)	0.0050	0.0480
	Relapse ≤ 12 months of the completion of the first line therapy	45/46 (98)	0.9 (0.7, 1.0)	40/43 (93)	0.3 (0.2, 0.5)	0.98 (0.63,1.52)	0.9200	
Chills	Primary refractory	34/131 (26)	NE (NE, NE)	8/125 (6)	NE (NE, NE)	4.36 (2.02,9.44)	<0.0001	0.2868

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Relapse ≤ 12 months of the completion of the first line therapy	14/46 (30)	NE (NE, NE)	6/43 (14)	NE (NE, NE)	2.19 (0.84,5.70)	0.0969	
Mucosal inflammation	Primary refractory	1/131 (1)	NE (NE, NE)	13/125 (10)	NE (4.9, NE)	0.04 (0.01,0.33)	<0.0001	0.9944
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE, NE)	3/43 (7)	7.0 (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Primary refractory	116/131 (89)	1.0 (0.9, 1.0)	24/125 (19)	NE (NE, NE)	11.03 (6.99,17.40)	<0.0001	0.0496
	Relapse ≤ 12 months of the completion of the first line therapy	45/46 (98)	1.0 (0.9, 1.1)	19/43 (44)	6.9 (3.3, NE)	6.31 (3.43,11.61)	<0.0001	
Hepatobiliary disorders	Primary refractory	15/131 (11)	NE (NE, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9895
	Relapse ≤ 12 months of the completion of the first line therapy	4/46 (9)	NE (NE, NE)	3/43 (7)	NE (NE, NE)	1.17 (0.26,5.25)	0.8348	
Hypertransaminasaemia	Primary refractory	8/131 (6)	NE (NE, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	4/46 (9)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Primary refractory	16/131 (12)	5.1 (5.0, NE)	2/125 (2)	NE (NE, NE)	5.46 (1.23,24.28)	0.0122	0.8041
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	7.21 (0.90,57.64)	0.0293	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Primary refractory	15/131 (11)	5.1 (5.0, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9919
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	6.14 (0.76,49.94)	0.0523	
Infections and infestations	Primary refractory	69/131 (53)	5.0 (2.7, 13.8)	33/125 (26)	NE (4.6, NE)	1.72 (1.12,2.62)	0.0114	0.1101
	Relapse ≤ 12 months of the completion of the first line therapy	28/46 (61)	4.1 (1.2, 39.8)	22/43 (51)	3.5 (2.8, NE)	1.03 (0.58,1.83)	0.9124	
Oral candidiasis	Primary refractory	10/131 (8)	NE (NE, NE)	4/125 (3)	NE (NE, NE)	2.25 (0.70,7.22)	0.1595	0.9905
	Relapse ≤ 12 months of the completion of the first line therapy	6/46 (13)	NE (NE, NE)	1/43 (2)	7.1 (NE, NE)	> 10,000 (0.00,NE)	0.0156	
Rhinovirus infection	Primary refractory	6/131 (5)	NE (NE, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	5/46 (11)	NE (NE, NE)	2/43 (5)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Primary refractory	14/131 (11)	25.6 (NE, NE)	20/125 (16)	NE (NE, NE)	0.53 (0.26,1.06)	0.0679	0.8772
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE, NE)	13/43 (30)	NE (3.4, NE)	0.56 (0.24,1.32)	0.1820	
Infusion related reaction	Primary refractory	0/131 (0)	NE (NE, NE)	9/125 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	4/43 (9)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Primary refractory	30/131 (23)	NE (NE, NE)	11/125 (9)	NE (NE, NE)	2.59 (1.29,5.17)	0.0051	0.3035
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	5/43 (12)	NE (NE, NE)	1.28 (0.40,4.02)	0.6769	
C-reactive protein increased	Primary refractory	16/131 (12)	NE (NE, NE)	2/125 (2)	NE (NE, NE)	7.91 (1.82,34.39)	0.0010	0.4260
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	2/43 (5)	NE (NE, NE)	3.26 (0.68,15.68)	0.1180	
Platelet count decreased	Primary refractory	24/131 (18)	NE (NE, NE)	43/125 (34)	NE (3.7, NE)	0.45 (0.27,0.74)	0.0013	0.4974
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	NE (NE, NE)	21/43 (49)	3.4 (2.5, NE)	0.27 (0.12,0.62)	0.0009	
Weight increased	Primary refractory	4/131 (3)	NE (NE, NE)	9/125 (7)	NE (NE, NE)	0.39 (0.12,1.28)	0.1091	0.8542
	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	3/43 (7)	NE (NE, NE)	0.28 (0.03,2.70)	0.2396	
Metabolism and nutrition disorders	Primary refractory	97/131 (74)	1.0 (0.8, 1.1)	58/125 (46)	2.8 (2.3, NE)	1.85 (1.33,2.56)	0.0002	0.0044

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Relapse ≤ 12 months of the completion of the first line therapy	34/46 (74)	1.0 (0.9, 1.2)	35/43 (81)	0.8 (0.3, 2.5)	0.79 (0.49,1.28)	0.3283	
Hyperglycaemia	Primary refractory	24/131 (18)	NE (NE, NE)	10/125 (8)	NE (NE, NE)	2.29 (1.09,4.79)	0.0237	0.2685
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE, NE)	7/43 (16)	NE (NE, NE)	1.14 (0.43,3.07)	0.7883	
Hypomagnesaemia	Primary refractory	16/131 (12)	5.0 (NE, NE)	19/125 (15)	NE (NE, NE)	0.65 (0.33,1.28)	0.2057	0.3261
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	15/43 (35)	NE (3.1, NE)	0.37 (0.15,0.91)	0.0241	
Hyponatraemia	Primary refractory	17/131 (13)	NE (NE, NE)	2/125 (2)	NE (NE, NE)	8.09 (1.87,35.03)	0.0009	0.0429
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	NE (NE, NE)	6/43 (14)	NE (NE, NE)	1.22 (0.42,3.51)	0.7140	
Nervous system disorders	Primary refractory	99/131 (76)	1.0 (1.0, 1.1)	62/125 (50)	3.2 (1.6, NE)	1.67 (1.21,2.30)	0.0013	0.7112
	Relapse ≤ 12 months of the completion of the first line therapy	38/46 (83)	1.1 (1.0, 1.2)	25/43 (58)	2.6 (0.7, NE)	1.53 (0.91,2.58)	0.1011	
Dizziness	Primary refractory	32/131 (24)	NE (NE, NE)	14/125 (11)	NE (NE, NE)	2.08 (1.11,3.91)	0.0191	0.2051
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	NE (NE, NE)	7/43 (16)	NE (NE, NE)	0.99 (0.36,2.73)	0.9864	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Primary refractory	3/131 (2)	NE (NE, NE)	10/125 (8)	NE (NE, NE)	0.24 (0.07,0.88)	0.0200	0.6063
	Relapse ≤ 12 months of the completion of the first line therapy	2/46 (4)	NE (NE, NE)	4/43 (9)	NE (NE, NE)	0.43 (0.08,2.35)	0.3143	
Encephalopathy	Primary refractory	24/131 (18)	NE (NE, NE)	2/125 (2)	NE (NE, NE)	12.03 (2.84,50.88)	<0.0001	0.9899
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Primary refractory	62/131 (47)	NE (1.2, NE)	30/125 (24)	NE (NE, NE)	2.17 (1.40,3.35)	0.0004	0.5668
	Relapse ≤ 12 months of the completion of the first line therapy	21/46 (46)	NE (1.1, NE)	13/43 (30)	7.0 (NE, NE)	1.70 (0.83,3.45)	0.1393	
Peripheral sensory neuropathy	Primary refractory	1/131 (1)	NE (NE, NE)	10/125 (8)	NE (NE, NE)	0.08 (0.01,0.59)	0.0014	0.9994
	Relapse ≤ 12 months of the completion of the first line therapy	0/46 (0)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Primary refractory	13/131 (10)	NE (NE, NE)	2/125 (2)	NE (NE, NE)	6.20 (1.40,27.49)	0.0059	0.9912
	Relapse ≤ 12 months of the completion of the first line therapy	6/46 (13)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	Primary refractory	31/131 (24)	NE (NE, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9875

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Relapse ≤ 12 months of the completion of the first line therapy	13/46 (28)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	13.66 (1.79,104.47)	0.0009	
Psychiatric disorders	Primary refractory	60/131 (46)	27.6 (1.4, NE)	25/125 (20)	NE (NE, NE)	2.42 (1.51,3.86)	0.0001	0.2661
	Relapse ≤ 12 months of the completion of the first line therapy	23/46 (50)	4.3 (1.3, NE)	15/43 (35)	NE (3.0, NE)	1.56 (0.81,2.99)	0.1782	
Agitation	Primary refractory	7/131 (5)	NE (NE, NE)	2/125 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	4/46 (9)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Primary refractory	29/131 (22)	27.6 (NE, NE)	2/125 (2)	NE (NE, NE)	14.25 (3.39,59.81)	<0.0001	0.4053
	Relapse ≤ 12 months of the completion of the first line therapy	12/46 (26)	NE (NE, NE)	2/43 (5)	NE (NE, NE)	5.91 (1.32,26.41)	0.0081	
Respiratory, thoracic and mediastinal disorders	Primary refractory	76/131 (58)	1.4 (1.1, 4.3)	48/125 (38)	NE (3.1, NE)	1.53 (1.07,2.21)	0.0193	0.3378
	Relapse ≤ 12 months of the completion of the first line therapy	29/46 (63)	1.2 (1.1, 4.8)	24/43 (56)	3.3 (1.4, NE)	1.13 (0.66,1.95)	0.6528	
Cough	Primary refractory	34/131 (26)	NE (NE, NE)	11/125 (9)	NE (NE, NE)	2.89 (1.46,5.71)	0.0014	0.4266
	Relapse ≤ 12 months of the completion of the first line therapy	13/46 (28)	NE (NE, NE)	7/43 (16)	NE (NE, NE)	1.82 (0.72,4.56)	0.1956	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Primary refractory	6/131 (5)	NE (NE, NE)	16/125 (13)	NE (NE, NE)	0.31 (0.12,0.79)	0.0095	0.5671
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	NE (NE, NE)	5/43 (12)	NE (NE, NE)	0.52 (0.12,2.16)	0.3575	
Hypoxia	Primary refractory	29/131 (22)	NE (NE, NE)	9/125 (7)	NE (NE, NE)	3.09 (1.46,6.53)	0.0019	0.5969
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE, NE)	4/43 (9)	NE (NE, NE)	2.18 (0.67,7.10)	0.1818	
Pleural effusion	Primary refractory	10/131 (8)	NE (NE, NE)	1/125 (1)	NE (NE, NE)	8.83 (1.13,69.22)	0.0122	0.1133
	Relapse ≤ 12 months of the completion of the first line therapy	2/46 (4)	NE (NE, NE)	2/43 (5)	NE (NE, NE)	0.86 (0.12,6.15)	0.8835	
Skin and subcutaneous tissue disorders								
Erythema	Primary refractory	5/131 (4)	NE (NE, NE)	3/125 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of the completion of the first line therapy	7/46 (15)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Primary refractory	72/131 (55)	1.4 (1.2, NE)	41/125 (33)	NE (3.6, NE)	1.76 (1.20,2.59)	0.0033	0.4934
	Relapse ≤ 12 months of the completion of the first line therapy	28/46 (61)	1.2 (1.0, NE)	15/43 (35)	NE (3.2, NE)	2.35 (1.25,4.42)	0.0062	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.14. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Primary refractory	57/131 (44)	NE (1.4, NE)	19/125 (15)	NE (NE, NE)	3.27 (1.94,5.50)	<0.0001	0.4931
	Relapse ≤ 12 months of the completion of the first line therapy	23/46 (50)	NE (1.1, NE)	6/43 (14)	NE (NE, NE)	4.68 (1.90,11.53)	0.0002	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Primary refractory	6/131 (5)	28.3 (12.1, NE)	34/123 (28)	NE (3.7, NE)	0.04 (0.01,0.13)	<0.0001	0.7188
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	12/45 (27)	7.2 (NE, NE)	0.06 (0.01,0.48)	0.0003	
Neutropenia	Primary refractory	61/131 (47)	NE (1.2, NE)	19/123 (15)	NE (NE, NE)	3.31 (1.97,5.54)	<0.0001	0.1365
	Relapse ≤ 12 months of first line therapy	16/47 (34)	NE (NE, NE)	10/45 (22)	NE (NE, NE)	1.60 (0.72,3.53)	0.2390	
Thrombocytopenia	Primary refractory	14/131 (11)	NE (NE, NE)	28/123 (23)	NE (NE, NE)	0.40 (0.21,0.77)	0.0041	0.4518
	Relapse ≤ 12 months of first line therapy	9/47 (19)	NE (NE, NE)	13/45 (29)	NE (NE, NE)	0.59 (0.25,1.38)	0.2148	
Cardiac disorders	Primary refractory	62/131 (47)	NE (1.2, NE)	26/123 (21)	NE (NE, NE)	2.52 (1.59,4.00)	<0.0001	0.7935
	Relapse ≤ 12 months of first line therapy	25/47 (53)	2.1 (1.1, NE)	10/45 (22)	NE (NE, NE)	2.95 (1.41,6.15)	0.0024	
Sinus tachycardia	Primary refractory	45/131 (34)	NE (NE, NE)	14/123 (11)	NE (NE, NE)	3.30 (1.81,6.01)	<0.0001	0.4207
	Relapse ≤ 12 months of first line therapy	16/47 (34)	NE (NE, NE)	3/45 (7)	NE (NE, NE)	6.07 (1.77,20.85)	0.0011	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

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Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Ear and labyrinth disorders	Primary refractory	4/131 (3)	NE (NE, NE)	13/123 (11)	NE (NE, NE)	0.26 (0.08,0.80)	0.0114	0.7634
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	5/45 (11)	NE (NE, NE)	0.18 (0.02,1.51)	0.0740	
Gastrointestinal disorders	Primary refractory	108/131 (82)	0.8 (0.8, 0.9)	102/123 (83)	0.3 (0.1, 0.5)	0.70 (0.53,0.92)	0.0079	0.4002
	Relapse ≤ 12 months of first line therapy	43/47 (91)	0.9 (0.8, 1.0)	41/45 (91)	0.2 (0.1, 0.4)	0.57 (0.37,0.88)	0.0081	
Nausea	Primary refractory	65/131 (50)	1.4 (1.1, NE)	79/123 (64)	1.0 (0.7, 2.5)	0.57 (0.41,0.79)	0.0006	0.7558
	Relapse ≤ 12 months of first line therapy	31/47 (66)	1.1 (0.9, 4.4)	37/45 (82)	0.7 (0.2, 1.1)	0.51 (0.31,0.82)	0.0043	
Stomatitis	Primary refractory	5/131 (4)	NE (NE, NE)	16/123 (13)	NE (NE, NE)	0.19 (0.07,0.53)	0.0004	0.2483
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	13/45 (29)	NE (3.6, NE)	0.05 (0.01,0.42)	0.0001	
General disorders and administration site conditions	Primary refractory	119/131 (91)	0.9 (0.8, 1.0)	83/123 (67)	0.8 (0.3, 1.8)	1.47 (1.10,1.96)	0.0078	0.0930
	Relapse ≤ 12 months of first line therapy	46/47 (98)	0.8 (0.7, 0.9)	42/45 (93)	0.3 (0.2, 0.7)	1.02 (0.66,1.58)	0.9266	
Chills	Primary refractory	34/131 (26)	NE (NE, NE)	8/123 (7)	NE (NE, NE)	4.28 (1.98,9.26)	<0.0001	0.3358

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Chills	Relapse ≤ 12 months of first line therapy	14/47 (30)	NE (NE, NE)	6/45 (13)	NE (NE, NE)	2.28 (0.88,5.94)	0.0801	
Mucosal inflammation	Primary refractory	0/131 (0)	NE (NE, NE)	13/123 (11)	NE (4.9, NE)	NE (NE,NE)	NE	0.9927
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	3/45 (7)	7.0 (NE, NE)	0.46 (0.04,5.08)	0.5157	
Pyrexia	Primary refractory	115/131 (88)	1.0 (0.9, 1.0)	24/123 (20)	NE (NE, NE)	10.67 (6.76,16.84)	<0.0001	0.1174
	Relapse ≤ 12 months of first line therapy	46/47 (98)	1.0 (0.9, 1.1)	19/45 (42)	6.9 (3.3, NE)	6.82 (3.72,12.53)	<0.0001	
Hepatobiliary disorders	Primary refractory	15/131 (11)	NE (NE, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9896
	Relapse ≤ 12 months of first line therapy	4/47 (9)	NE (NE, NE)	3/45 (7)	NE (NE, NE)	1.21 (0.27,5.41)	0.8041	
Hypertransaminasaemia	Primary refractory	8/131 (6)	NE (NE, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of first line therapy	4/47 (9)	NE (NE, NE)	1/45 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Immune system disorders	Primary refractory	17/131 (13)	5.1 (5.0, NE)	2/123 (2)	NE (NE, NE)	5.84 (1.33,25.77)	0.0082	0.9193
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	1/45 (2)	NE (NE, NE)	6.34 (0.78,51.54)	0.0475	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypogammaglobulinaemia	Primary refractory	16/131 (12)	5.1 (5.0, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9915
	Relapse ≤ 12 months of first line therapy	6/47 (13)	NE (NE, NE)	1/45 (2)	NE (NE, NE)	5.26 (0.63,43.69)	0.0856	
Infections and infestations	Primary refractory	70/131 (53)	4.0 (2.5, 19.8)	32/123 (26)	NE (4.8, NE)	1.81 (1.18,2.77)	0.0056	0.0581
	Relapse ≤ 12 months of first line therapy	28/47 (60)	4.5 (1.3, 13.8)	23/45 (51)	3.5 (2.8, NE)	0.96 (0.54,1.68)	0.8754	
Oral candidiasis	Primary refractory	10/131 (8)	NE (NE, NE)	4/123 (3)	NE (NE, NE)	2.21 (0.69,7.09)	0.1698	0.9902
	Relapse ≤ 12 months of first line therapy	6/47 (13)	NE (NE, NE)	1/45 (2)	7.1 (NE, NE)	> 10,000 (0.00,NE)	0.0137	
Rhinovirus infection	Primary refractory	6/131 (5)	NE (NE, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of first line therapy	5/47 (11)	NE (NE, NE)	2/45 (4)	NE (NE, NE)	NE (NE,NE)	NE	
Injury, poisoning and procedural complications	Primary refractory	14/131 (11)	25.6 (NE, NE)	19/123 (15)	NE (NE, NE)	0.55 (0.27,1.11)	0.0902	0.9746
	Relapse ≤ 12 months of first line therapy	9/47 (19)	NE (NE, NE)	14/45 (31)	NE (3.4, NE)	0.54 (0.23,1.24)	0.1384	
Infusion related reaction	Primary refractory	0/131 (0)	NE (NE, NE)	8/123 (7)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Infusion related reaction	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	5/45 (11)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Alanine aminotransferase increased	Primary refractory	29/131 (22)	NE (NE, NE)	11/123 (9)	NE (NE, NE)	2.44 (1.22,4.89)	0.0092	0.4902
	Relapse ≤ 12 months of first line therapy	8/47 (17)	NE (NE, NE)	5/45 (11)	NE (NE, NE)	1.54 (0.50,4.70)	0.4477	
C-reactive protein increased	Primary refractory	16/131 (12)	NE (NE, NE)	2/123 (2)	NE (NE, NE)	7.76 (1.79,33.77)	0.0012	0.4576
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	2/45 (4)	NE (NE, NE)	3.38 (0.70,16.29)	0.1052	
Platelet count decreased	Primary refractory	22/131 (17)	NE (NE, NE)	42/123 (34)	NE (3.7, NE)	0.41 (0.24,0.69)	0.0005	0.9856
	Relapse ≤ 12 months of first line therapy	10/47 (21)	NE (NE, NE)	22/45 (49)	3.4 (2.5, NE)	0.35 (0.17,0.75)	0.0047	
Weight increased	Primary refractory	4/131 (3)	NE (NE, NE)	9/123 (7)	NE (NE, NE)	0.39 (0.12,1.26)	0.1023	0.8798
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	3/45 (7)	NE (NE, NE)	0.29 (0.03,2.76)	0.2486	
Metabolism and nutrition disorders	Primary refractory	95/131 (73)	1.0 (0.9, 1.1)	59/123 (48)	2.8 (1.9, NE)	1.69 (1.22,2.35)	0.0012	0.0692

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Metabolism and nutrition disorders	Relapse ≤ 12 months of first line therapy	36/47 (77)	1.0 (0.9, 1.1)	34/45 (76)	0.9 (0.4, 2.9)	0.99 (0.61,1.59)	0.9584	
Hyperglycaemia	Primary refractory	24/131 (18)	NE (NE, NE)	10/123 (8)	NE (NE, NE)	2.25 (1.07,4.70)	0.0269	0.3042
	Relapse ≤ 12 months of first line therapy	9/47 (19)	NE (NE, NE)	7/45 (16)	NE (NE, NE)	1.18 (0.44,3.18)	0.7365	
Hypomagnesaemia	Primary refractory	16/131 (12)	5.0 (NE, NE)	19/123 (15)	NE (NE, NE)	0.64 (0.32,1.26)	0.1891	0.3720
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	15/45 (33)	NE (3.1, NE)	0.38 (0.16,0.94)	0.0298	
Hyponatraemia	Primary refractory	17/131 (13)	NE (NE, NE)	2/123 (2)	NE (NE, NE)	7.93 (1.83,34.37)	0.0010	0.0491
	Relapse ≤ 12 months of first line therapy	8/47 (17)	NE (NE, NE)	6/45 (13)	NE (NE, NE)	1.26 (0.44,3.62)	0.6729	
Nervous system disorders	Primary refractory	97/131 (74)	1.1 (1.0, 1.1)	61/123 (50)	3.2 (1.2, NE)	1.60 (1.16,2.21)	0.0037	0.9236
	Relapse ≤ 12 months of first line therapy	40/47 (85)	1.1 (1.0, 1.1)	26/45 (58)	2.9 (0.7, NE)	1.73 (1.04,2.88)	0.0322	
Dizziness	Primary refractory	31/131 (24)	NE (NE, NE)	14/123 (11)	NE (NE, NE)	1.97 (1.05,3.71)	0.0318	0.3617
	Relapse ≤ 12 months of first line therapy	9/47 (19)	NE (NE, NE)	7/45 (16)	NE (NE, NE)	1.16 (0.43,3.12)	0.7651	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Dysgeusia	Primary refractory	3/131 (2)	NE (NE, NE)	10/123 (8)	NE (NE, NE)	0.24 (0.07,0.87)	0.0184	0.5811
	Relapse ≤ 12 months of first line therapy	2/47 (4)	NE (NE, NE)	4/45 (9)	NE (NE, NE)	0.44 (0.08,2.41)	0.3286	
Encephalopathy	Primary refractory	24/131 (18)	NE (NE, NE)	2/123 (2)	NE (NE, NE)	11.79 (2.79,49.89)	<0.0001	0.9896
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Headache	Primary refractory	62/131 (47)	NE (1.2, NE)	29/123 (24)	NE (NE, NE)	2.21 (1.42,3.43)	0.0003	0.4671
	Relapse ≤ 12 months of first line therapy	21/47 (45)	NE (1.1, NE)	14/45 (31)	7.0 (NE, NE)	1.62 (0.81,3.25)	0.1643	
Peripheral sensory neuropathy	Primary refractory	1/131 (1)	NE (NE, NE)	10/123 (8)	NE (NE, NE)	0.07 (0.01,0.58)	0.0013	0.9994
	Relapse ≤ 12 months of first line therapy	0/47 (0)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Somnolence	Primary refractory	12/131 (9)	NE (NE, NE)	2/123 (2)	NE (NE, NE)	5.58 (1.25,24.95)	0.0110	0.9910
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Tremor	Primary refractory	30/131 (23)	NE (NE, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9879

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Tremor	Relapse ≤ 12 months of first line therapy	14/47 (30)	NE (NE, NE)	1/45 (2)	NE (NE, NE)	15.52 (2.04,118.03)	0.0004	
Psychiatric disorders	Primary refractory	59/131 (45)	27.6 (1.5, NE)	24/123 (20)	NE (NE, NE)	2.42 (1.50,3.90)	0.0002	0.2966
	Relapse ≤ 12 months of first line therapy	24/47 (51)	4.3 (1.3, NE)	16/45 (36)	NE (3.0, NE)	1.60 (0.85,3.02)	0.1413	
Agitation	Primary refractory	7/131 (5)	NE (NE, NE)	2/123 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of first line therapy	4/47 (9)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Confusional state	Primary refractory	28/131 (21)	27.6 (NE, NE)	2/123 (2)	NE (NE, NE)	13.40 (3.19,56.34)	<0.0001	0.5215
	Relapse ≤ 12 months of first line therapy	13/47 (28)	NE (NE, NE)	2/45 (4)	NE (NE, NE)	6.75 (1.52,29.92)	0.0036	
Respiratory, thoracic and mediastinal disorders	Primary refractory	74/131 (56)	1.6 (1.1, NE)	47/123 (38)	NE (3.1, NE)	1.48 (1.03,2.14)	0.0335	0.5690
	Relapse ≤ 12 months of first line therapy	31/47 (66)	1.2 (1.0, 3.5)	25/45 (56)	3.3 (1.4, NE)	1.25 (0.74,2.12)	0.4044	
Cough	Primary refractory	34/131 (26)	NE (NE, NE)	11/123 (9)	NE (NE, NE)	2.84 (1.44,5.62)	0.0017	0.4714
	Relapse ≤ 12 months of first line therapy	13/47 (28)	NE (NE, NE)	7/45 (16)	NE (NE, NE)	1.87 (0.75,4.70)	0.1732	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hiccups	Primary refractory	6/131 (5)	NE (NE, NE)	15/123 (12)	NE (NE, NE)	0.32 (0.12,0.83)	0.0140	0.7373
	Relapse ≤ 12 months of first line therapy	3/47 (6)	NE (NE, NE)	6/45 (13)	NE (NE, NE)	0.44 (0.11,1.77)	0.2346	
Hypoxia	Primary refractory	29/131 (22)	NE (NE, NE)	9/123 (7)	NE (NE, NE)	3.03 (1.43,6.42)	0.0022	0.6482
	Relapse ≤ 12 months of first line therapy	9/47 (19)	NE (NE, NE)	4/45 (9)	NE (NE, NE)	2.27 (0.70,7.37)	0.1613	
Pleural effusion	Primary refractory	10/131 (8)	NE (NE, NE)	1/123 (1)	NE (NE, NE)	8.70 (1.11,68.17)	0.0131	0.1193
	Relapse ≤ 12 months of first line therapy	2/47 (4)	NE (NE, NE)	2/45 (4)	NE (NE, NE)	0.88 (0.12,6.29)	0.9003	
Skin and subcutaneous tissue disorders								
Erythema	Primary refractory	5/131 (4)	NE (NE, NE)	3/123 (2)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Relapse ≤ 12 months of first line therapy	7/47 (15)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Primary refractory	70/131 (53)	1.4 (1.2, NE)	41/123 (33)	NE (3.3, NE)	1.65 (1.12,2.43)	0.0099	0.1963
	Relapse ≤ 12 months of first line therapy	30/47 (64)	1.2 (1.0, 1.6)	15/45 (33)	NE (3.2, NE)	2.73 (1.46,5.10)	0.0010	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Table 14.3.1.1.1.15. Analysis of Time to the First Treatment-emergent Adverse Events by System Organ Class and Preferred Term with at least 10 patients with events in one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Primary refractory	55/131 (42)	NE (1.4, NE)	19/123 (15)	NE (NE, NE)	3.05 (1.81,5.14)	<0.0001	0.2520
	Relapse ≤ 12 months of first line therapy	25/47 (53)	1.4 (1.1, NE)	6/45 (13)	NE (NE, NE)	5.47 (2.24,13.37)	<0.0001	

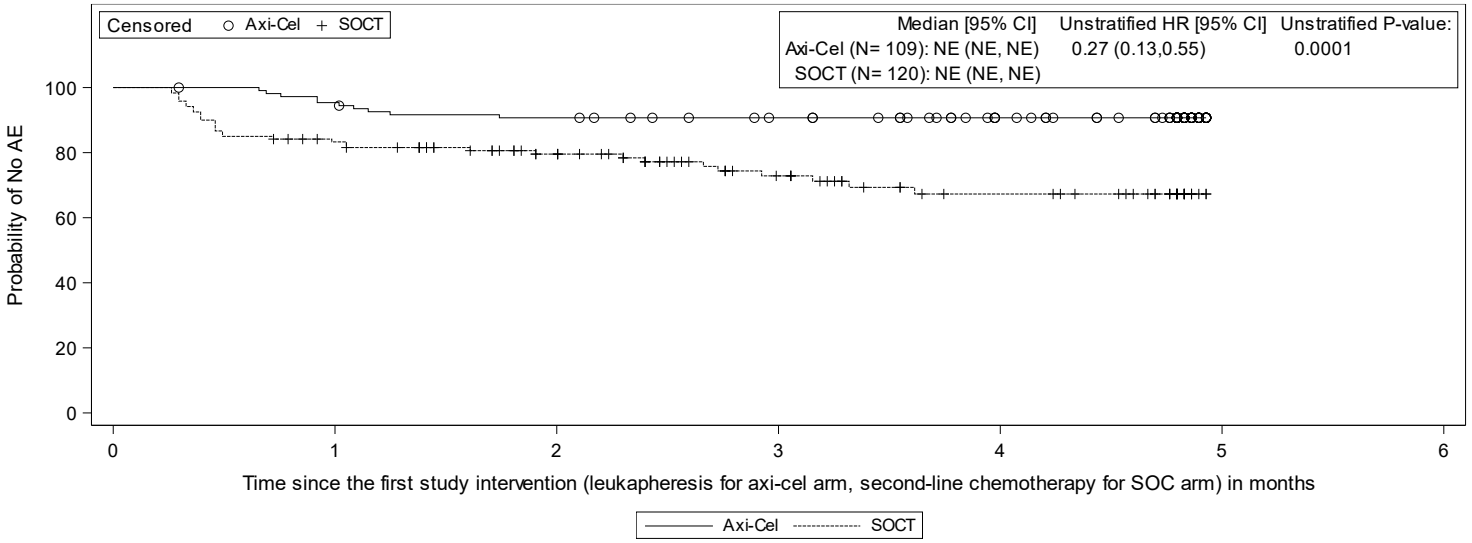
Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg.sas Output Generated: 20240411T17:12

Abbildung 16 (Anhang): Kaplan-Meier Plots für Subgruppenanalysen häufiger UE nach SOC/PT (stat. sign. Interaktionsterm) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Figure 14.5.4.1.43. Kaplan-Meier Plot of Time To First Thrombocytopenia by sex (Modified Safety Analysis Set)

Male



Subjects at Risk

Axi-Cel	109	103	97	90	75	0
SOCT	120	96	74	47	31	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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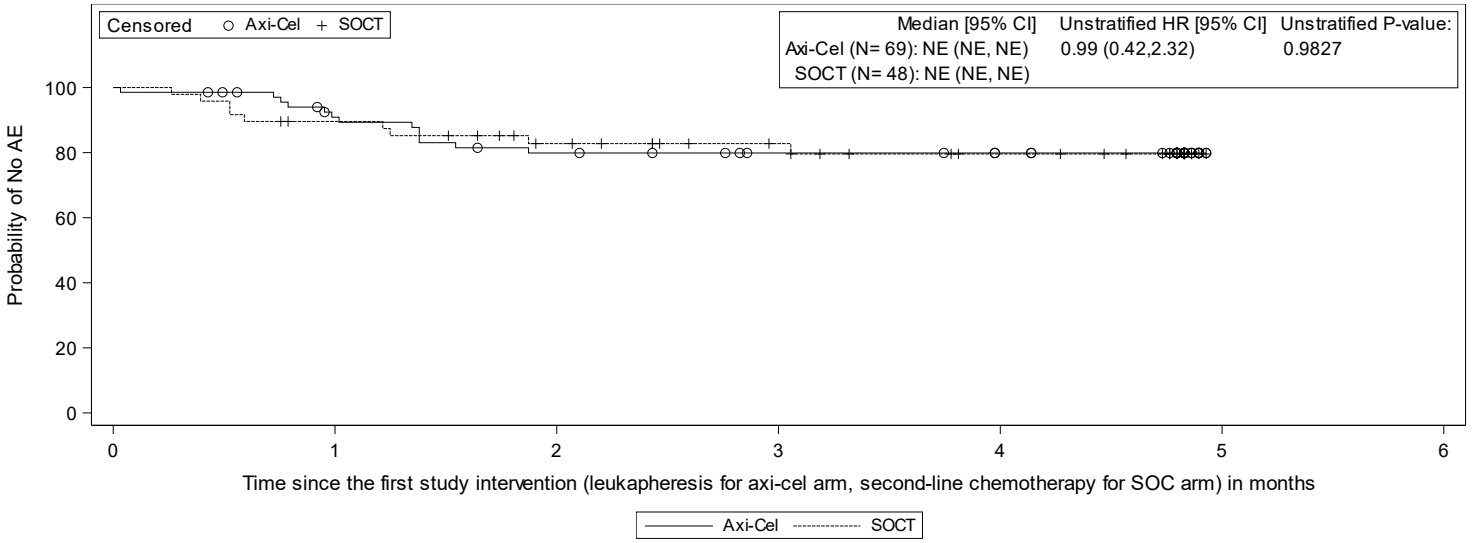
Figure 14.5.4.1.43. Kaplan-Meier Plot of Time To First Thrombocytopenia by sex (Modified Safety Analysis Set)

Femal



Subjects at Risk

Axi-Cel	69	58	50	45	42	0
SOCT	48	41	33	26	20	0

Page 2 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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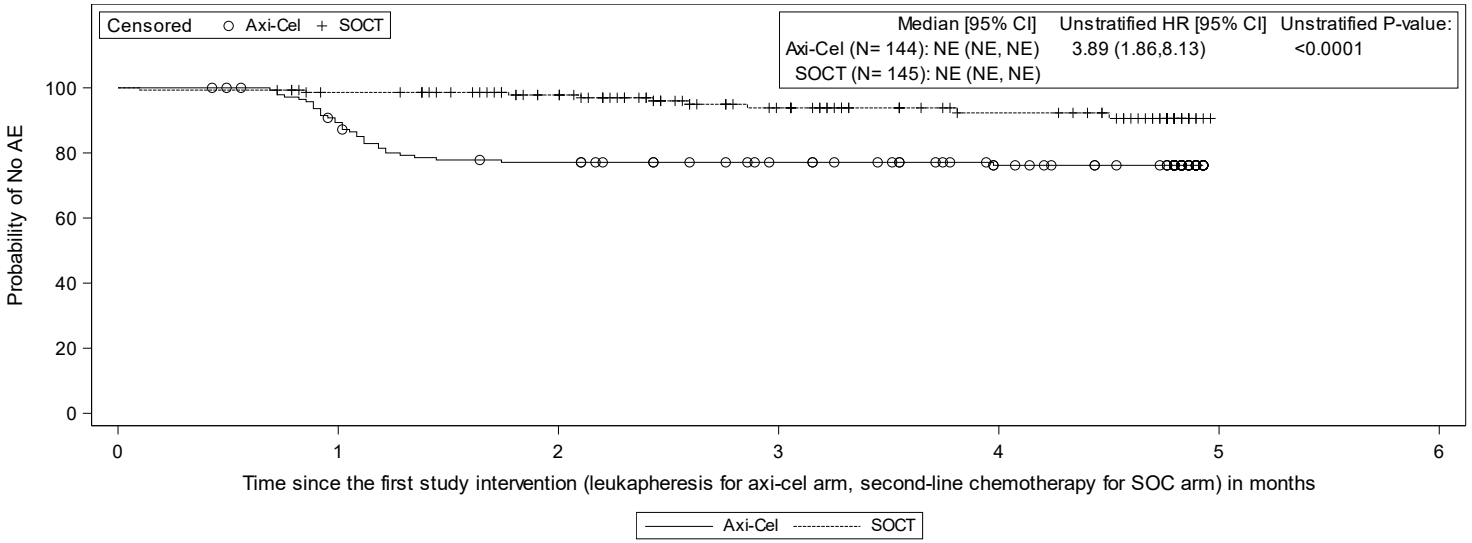
Figure 14.5.4.1.44. Kaplan-Meier Plot of Time To First Hypoxia by race (Modified Safety Analysis Set)

White



Subjects at Risk

Axi-Cel	144	125	106	95	81	0
SOCT	145	137	118	82	59	0

Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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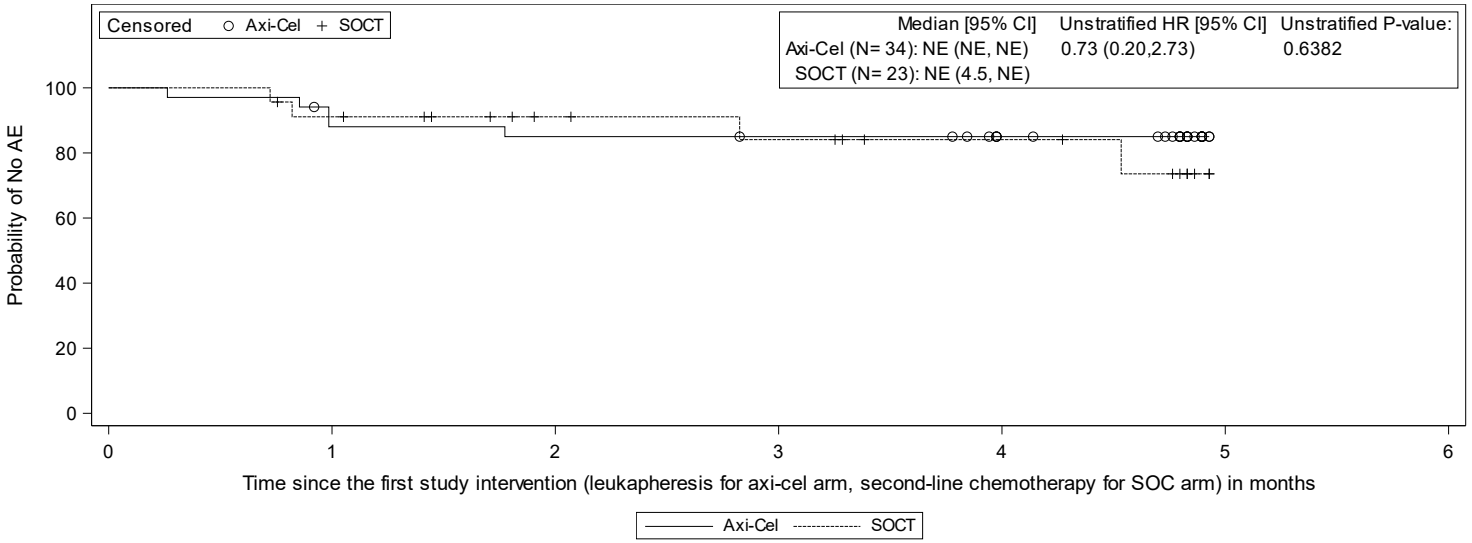
Figure 14.5.4.1.44. Kaplan-Meier Plot of Time To First Hypoxia by race (Modified Safety Analysis Set)

Other



Subjects at Risk

Axi-Cel	34	29	28	27	21	0
SOCT	23	20	14	12	9	0

Page 2 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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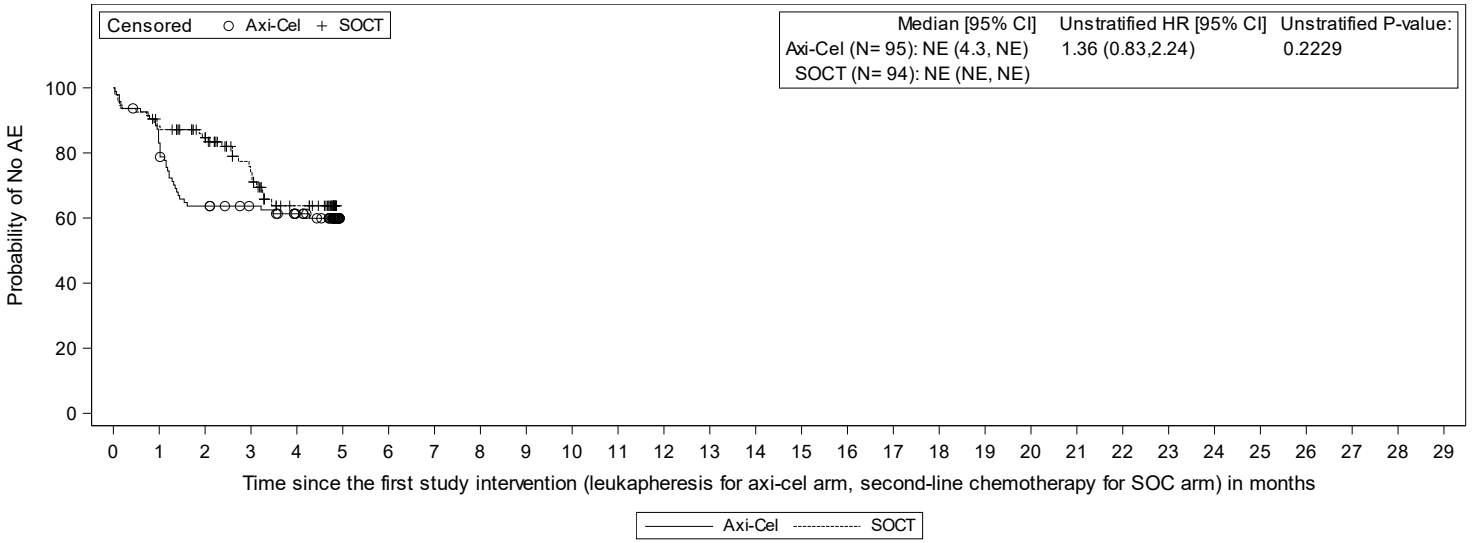
Figure 14.5.4.1.45. Kaplan-Meier Plot of Time To First Psychiatric disorders by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	78	59	54	47	0
SOCT	94	81	69	47	28	0

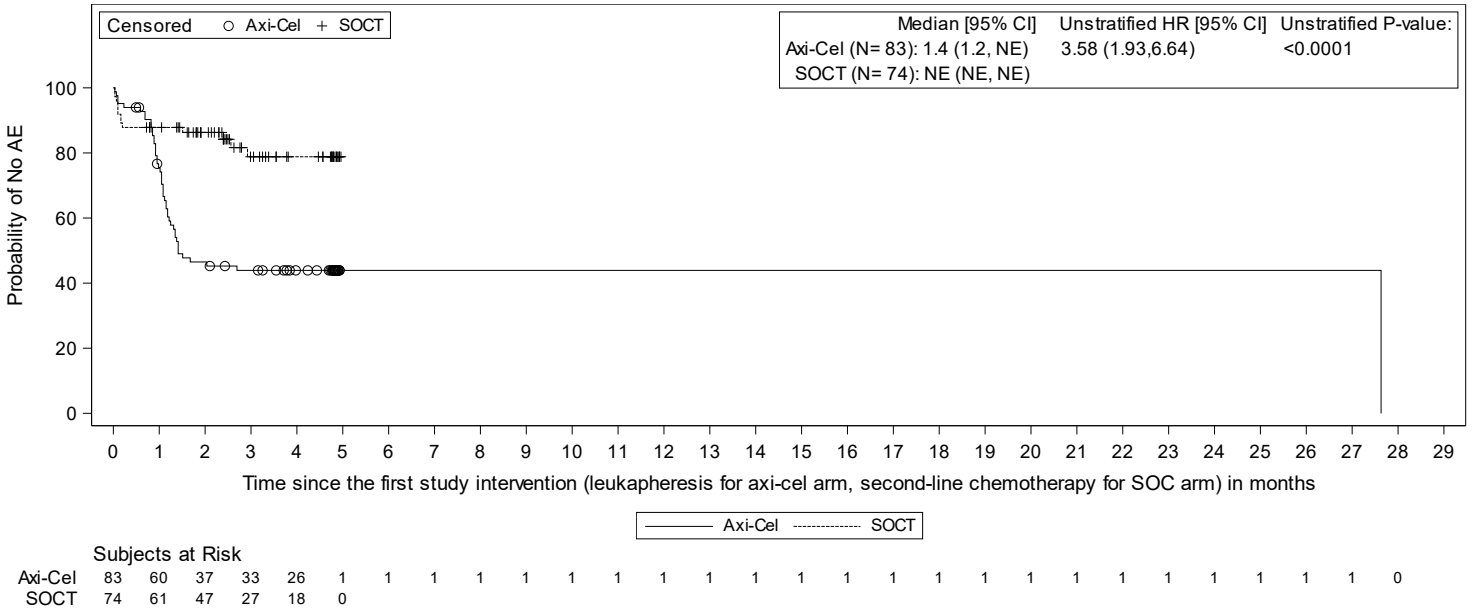
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Figure 14.5.4.1.45. Kaplan-Meier Plot of Time To First Psychiatric disorders by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	60	37	33	26	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	74	61	47	27	18	0																							

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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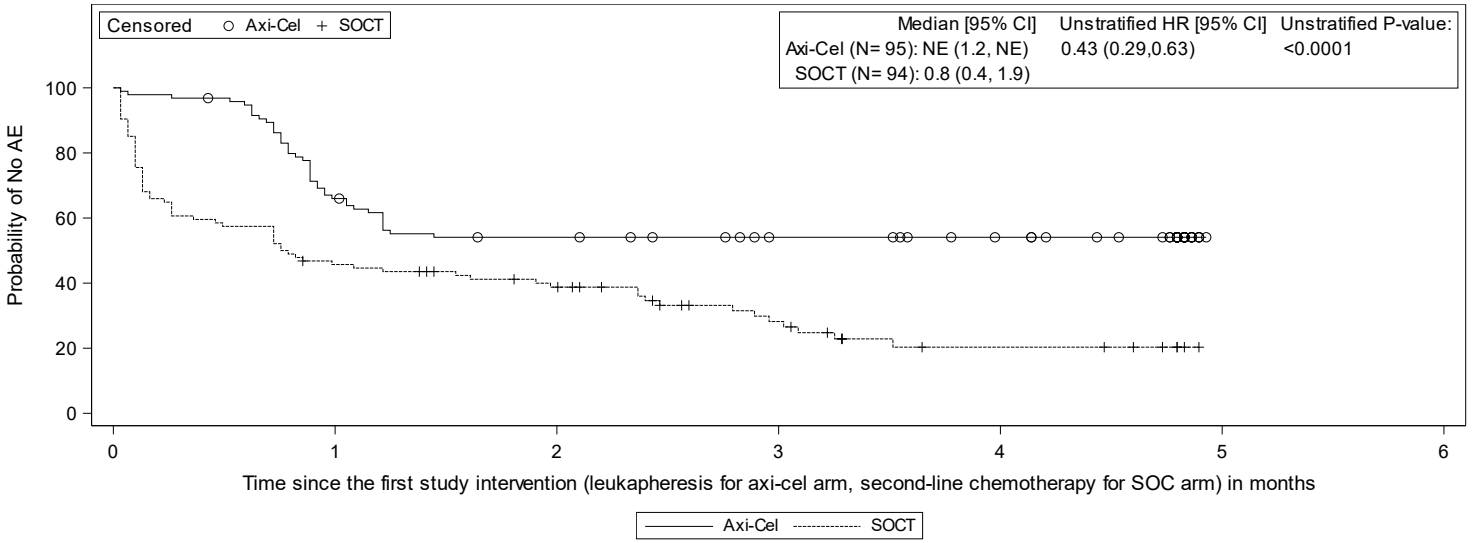
Figure 14.5.4.1.46. Kaplan-Meier Plot of Time To First Nausea by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	62	49	42	37	0
SOCT	94	42	32	17	7	0

Page 1 of 64

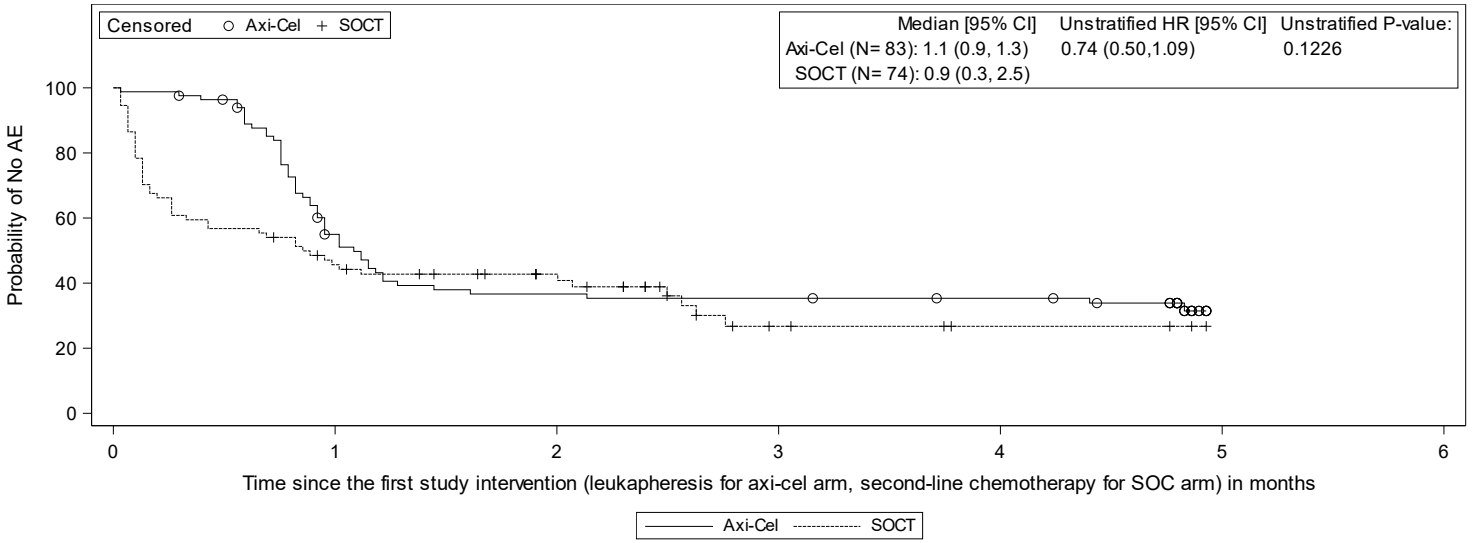
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.46. Kaplan-Meier Plot of Time To First Nausea by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	42	28	27	25	0
SOCT	74	32	22	6	3	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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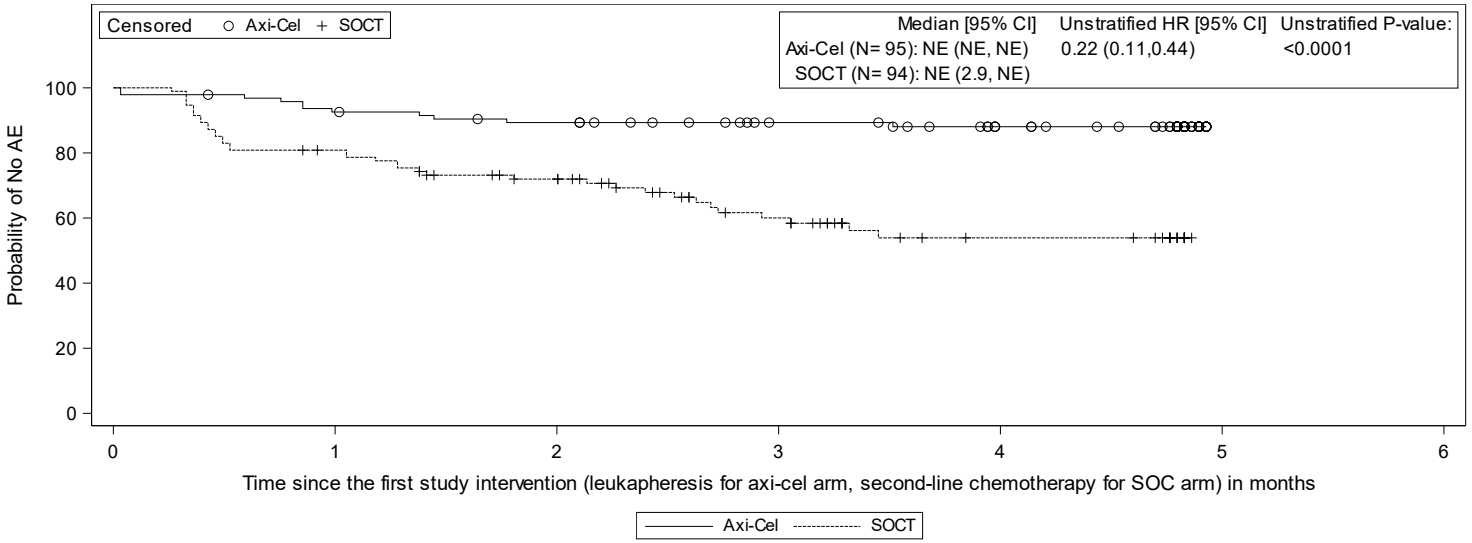
Figure 14.5.4.1.47. Kaplan-Meier Plot of Time To First Platelet count decreased by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	87	82	71	60	0
SOCT	94	74	59	37	21	0

Page 1 of 64

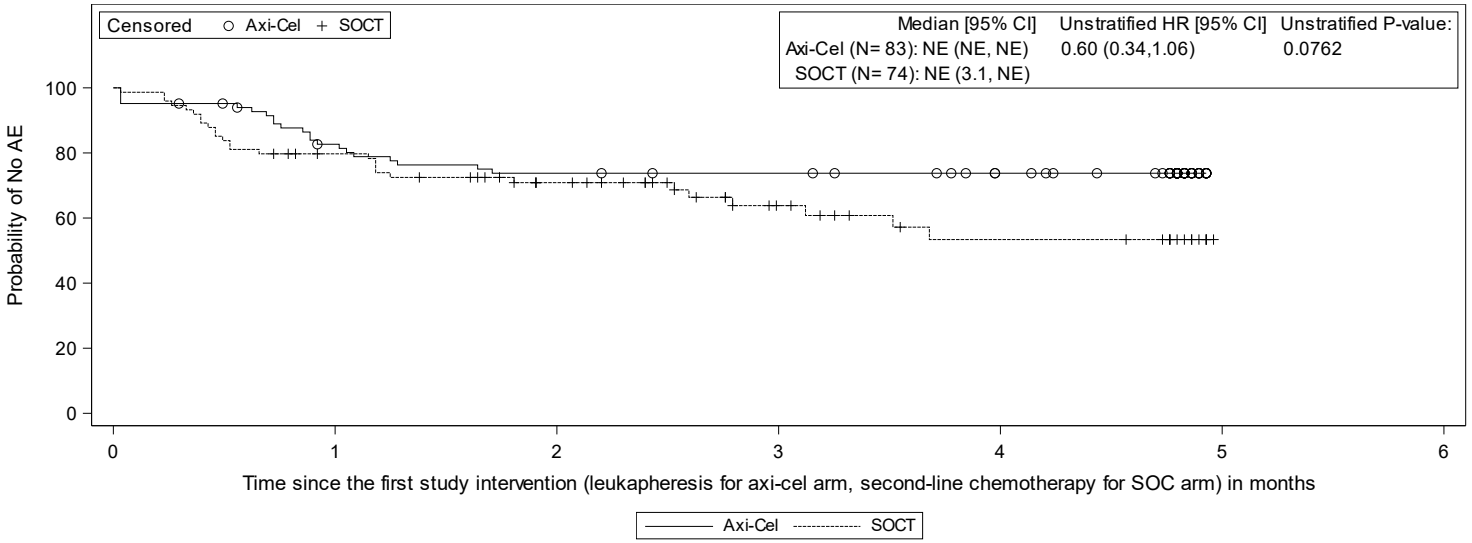
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.47. Kaplan-Meier Plot of Time To First Platelet count decreased by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	65	58	56	49	0
SOCT	74	55	40	22	14	0

Page 2 of 64

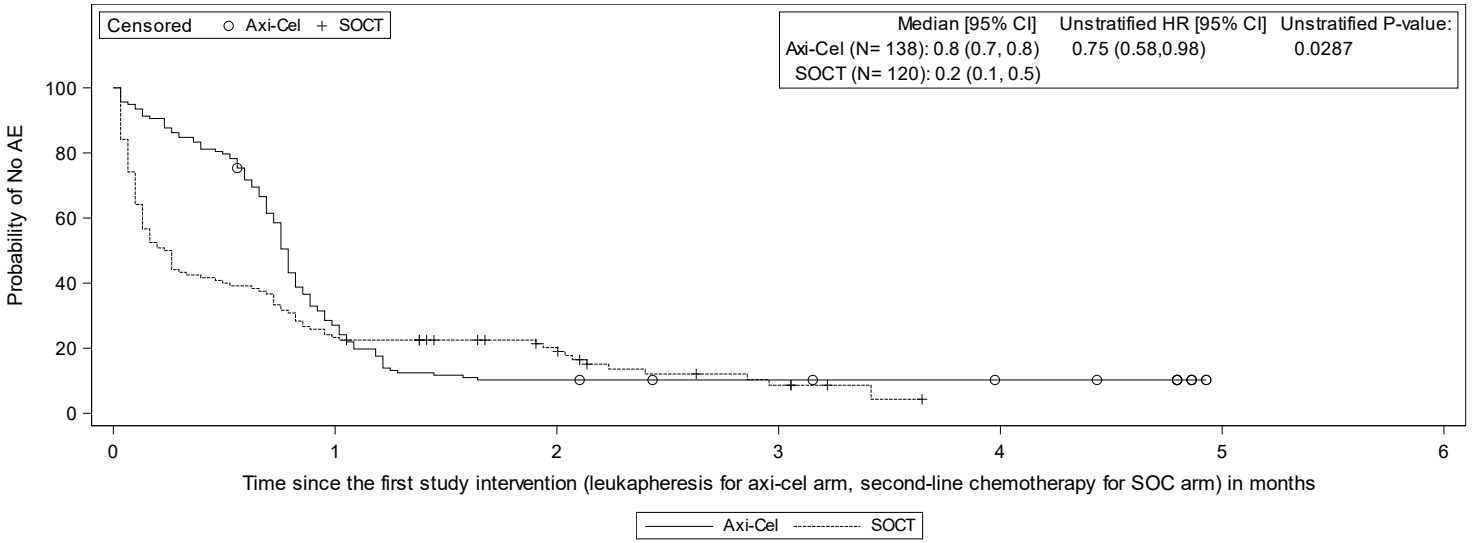
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.48. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by Geographic Region (Modified Safety Analysis Set)

North America



Subjects at Risk

Axi-Cel	138	37	14	12	10	0
SOCT	120	28	17	5	0	

Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

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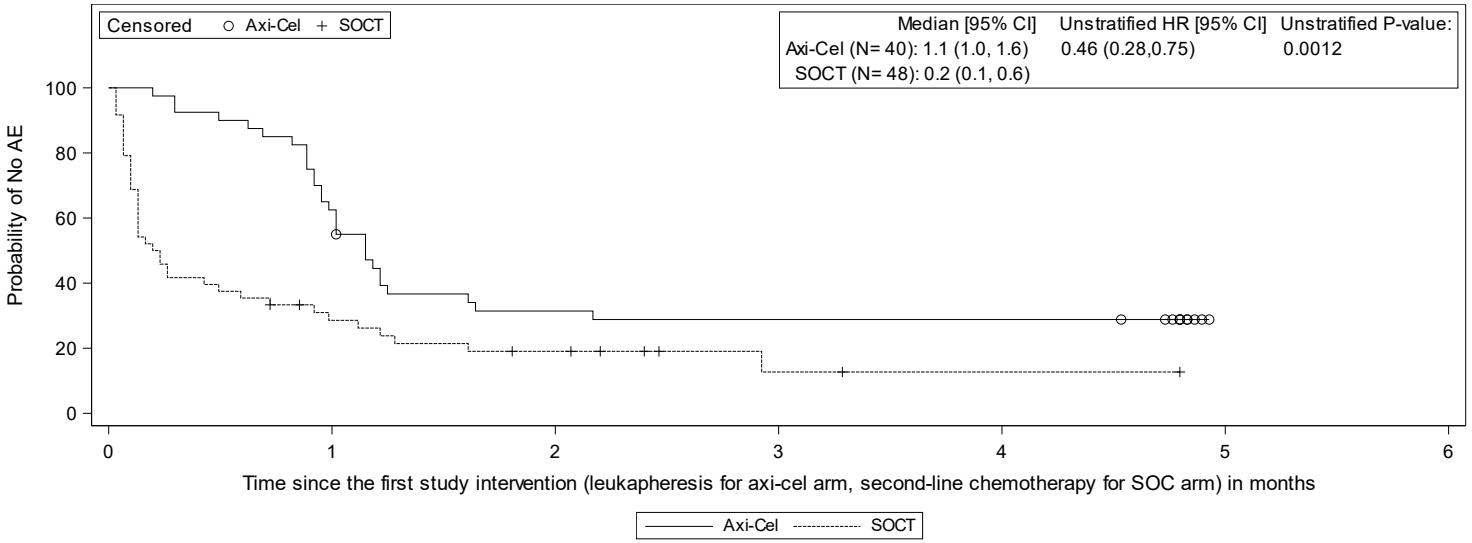
Figure 14.5.4.1.48. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by Geographic Region (Modified Safety Analysis Set)

Rest of the world



Subjects at Risk

Axi-Cel	40	25	12	11	11	0
SOCT	48	12	7	2	1	0

Page 2 of 64

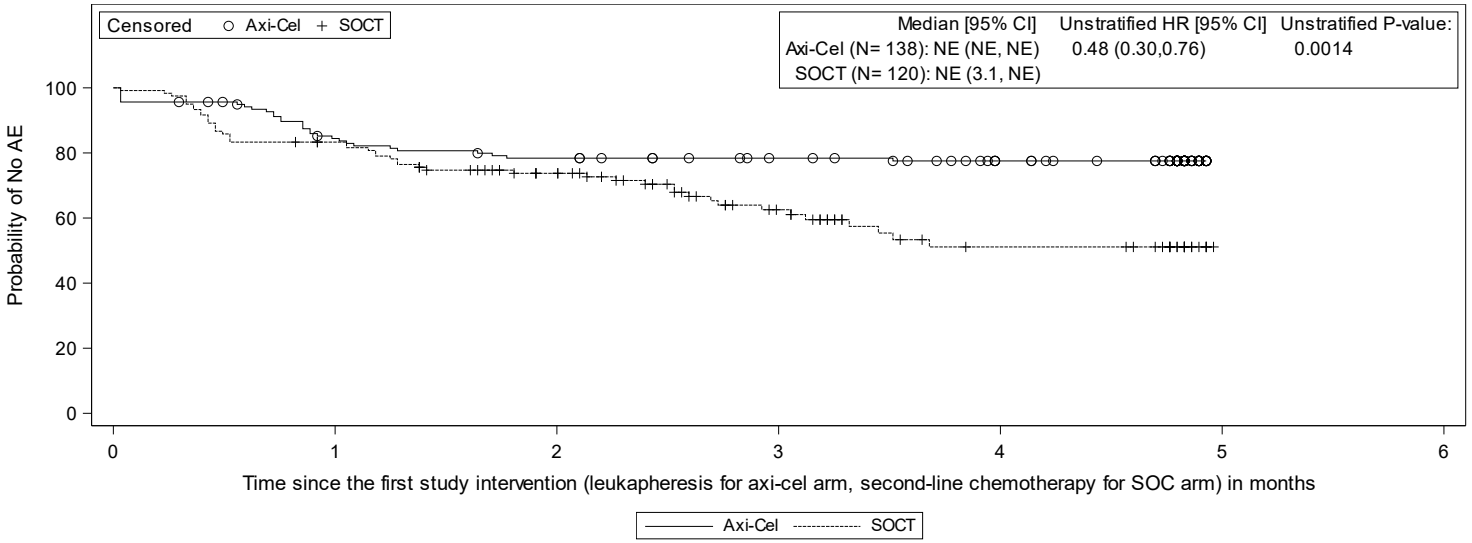
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.49. Kaplan-Meier Plot of Time To First Platelet count decreased by Geographic Region (Modified Safety Analysis Set)

North America



Subjects at Risk

Axi-Cel	138	112	103	94	81	0
SOCT	120	97	72	42	22	0

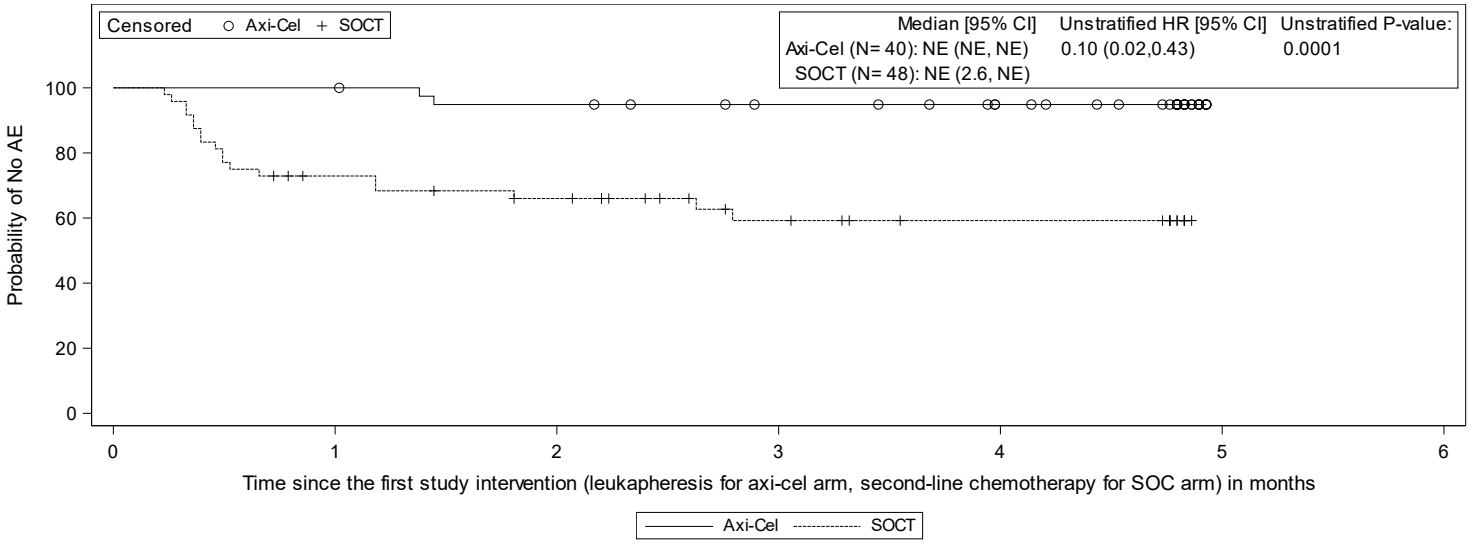
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Figure 14.5.4.1.49. Kaplan-Meier Plot of Time To First Platelet count decreased by Geographic Region (Modified Safety Analysis Set)

Rest of the world



Subjects at Risk

Axi-Cel	40	40	37	33	28	0
SOCT	48	32	27	17	13	0

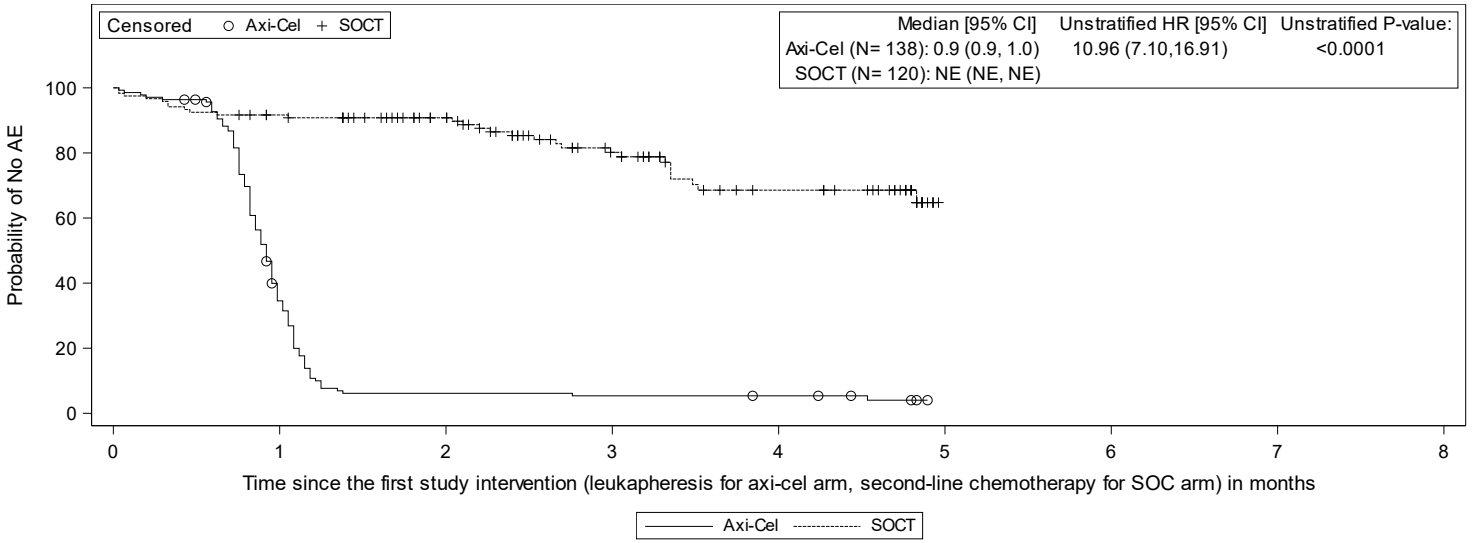
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.50. Kaplan-Meier Plot of Time To First Pyrexia by Geographic Region (Modified Safety Analysis Set)

North America



Subjects at Risk

Axi-Cel	138	45	8	7	6	0
SOCT	120	106	88	58	36	0

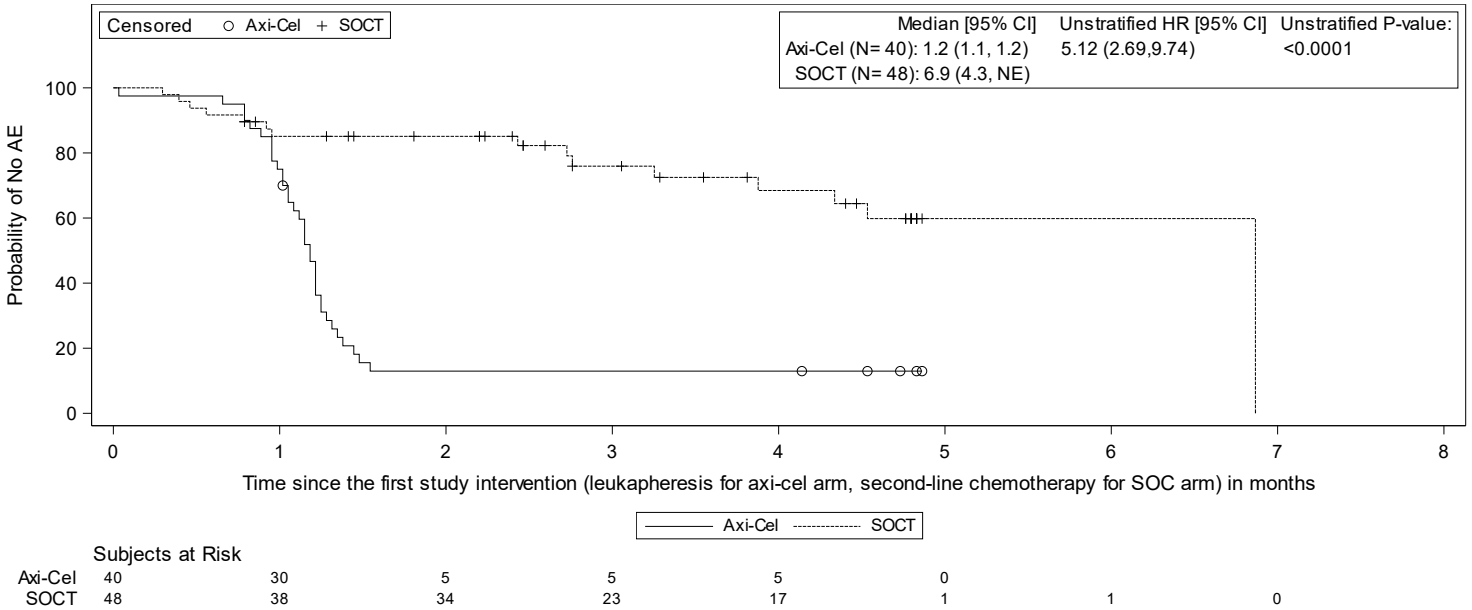
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE **Program Name: f_km_teae_sg.sas** **Output Generated: 20240412T11:19**

Figure 14.5.4.1.50. Kaplan-Meier Plot of Time To First Pyrexia by Geographic Region (Modified Safety Analysis Set)

Rest of the world



Subjects at Risk

Axi-Cel	40	30	5	5	5	0		
SOCT	48	38	34	23	17	1	1	0

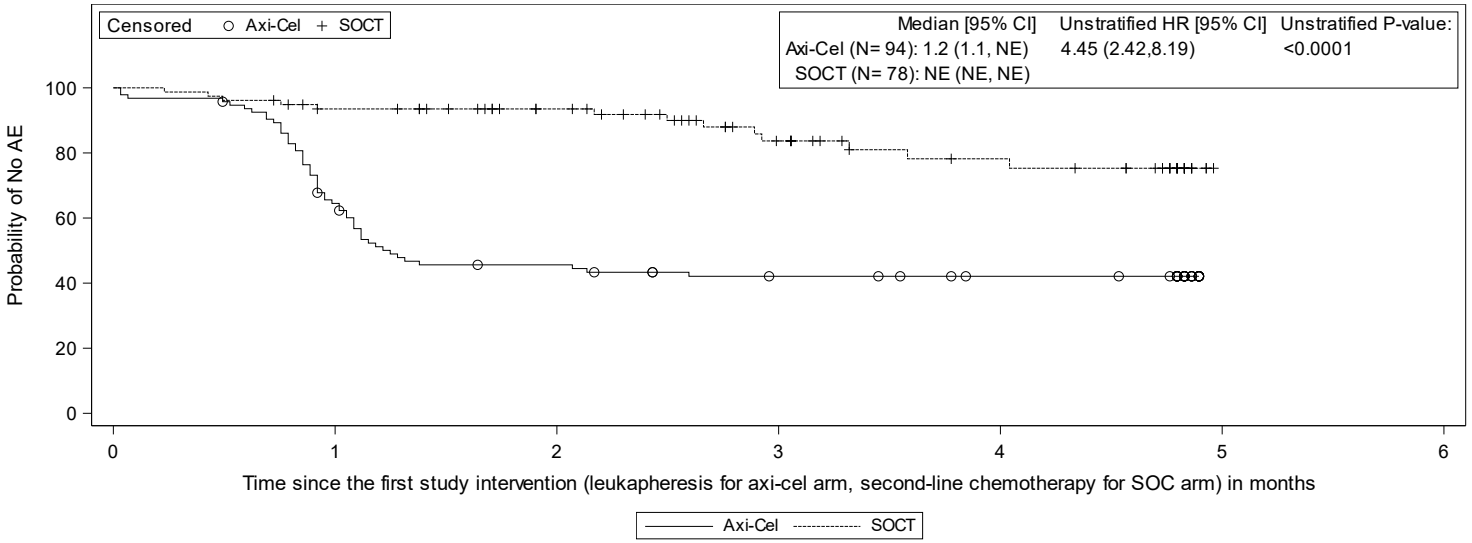
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.51. Kaplan-Meier Plot of Time To First Cardiac disorders by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	59	40	33	29	0
SOCT	78	69	57	38	27	0

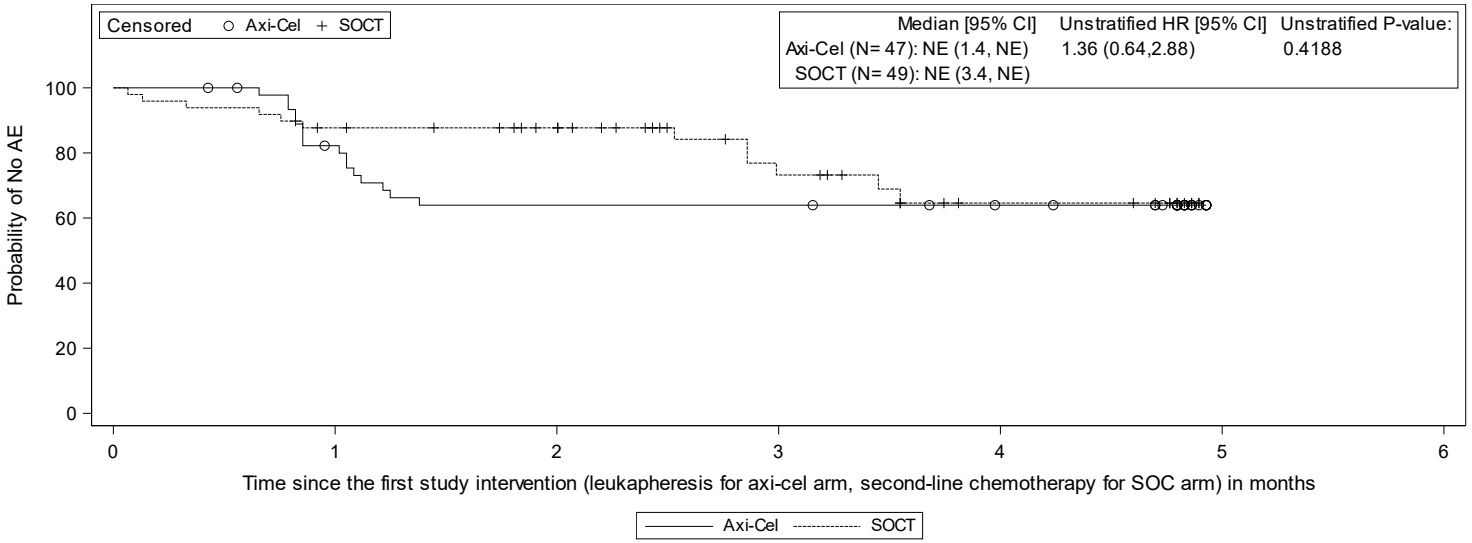
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.51. Kaplan-Meier Plot of Time To First Cardiac disorders by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	36	28	28	25	0
SOCT	49	41	35	20	11	0

Page 2 of 64

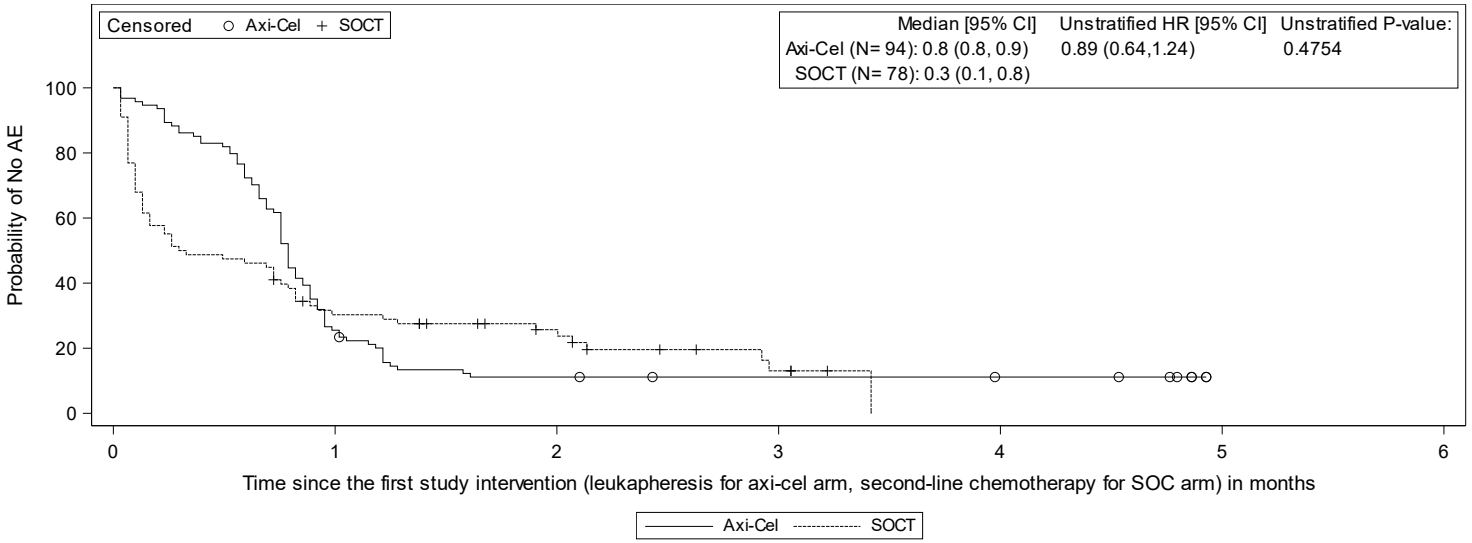
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:19

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.52. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	24	10	8	7	0
SOCT	78	22	13	4	0	

Page 1 of 64

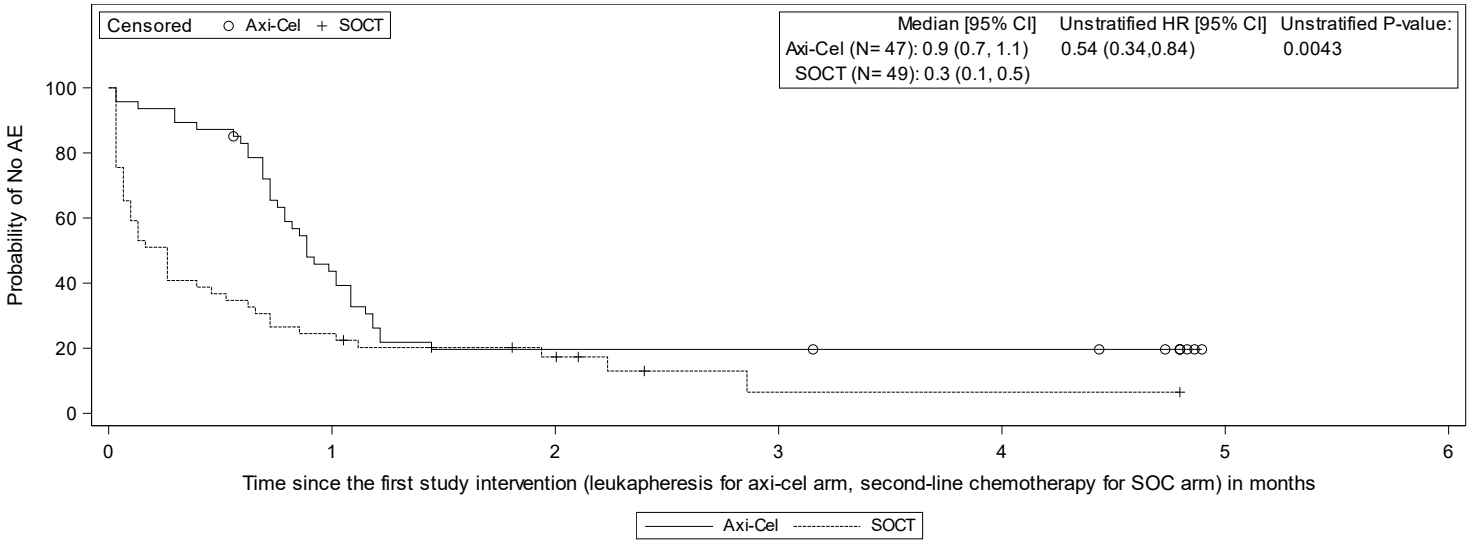
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.52. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	20	9	9	8	0
SOCT	49	12	6	1	1	0

Page 2 of 64

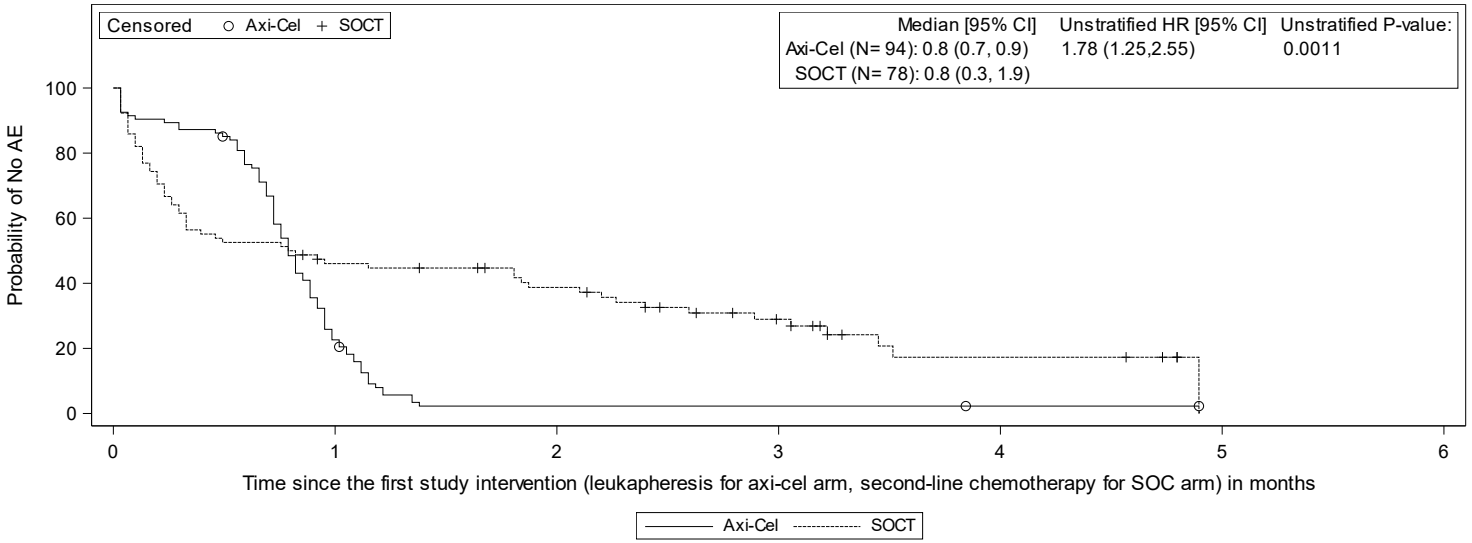
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.53. Kaplan-Meier Plot of Time To First General disorders and administration site conditions by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	21	2	2	1	0
SOCT	78	34	26	14	5	0

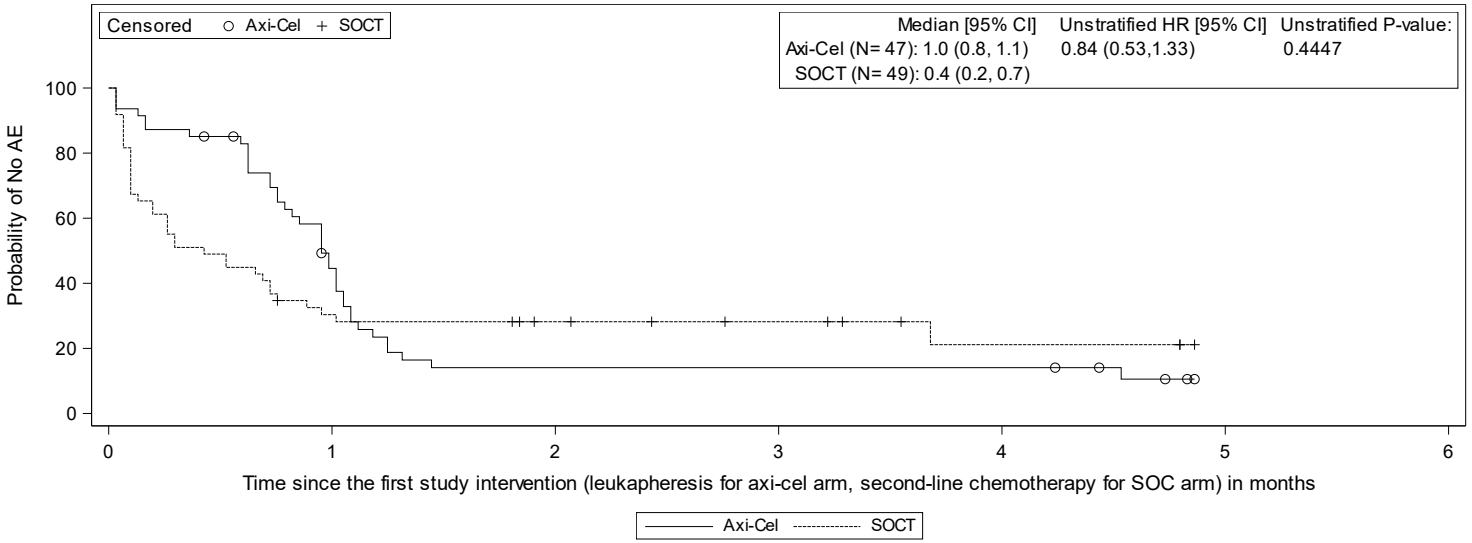
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.53. Kaplan-Meier Plot of Time To First General disorders and administration site conditions by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	19	6	6	6	0
SOCT	49	14	10	7	3	0

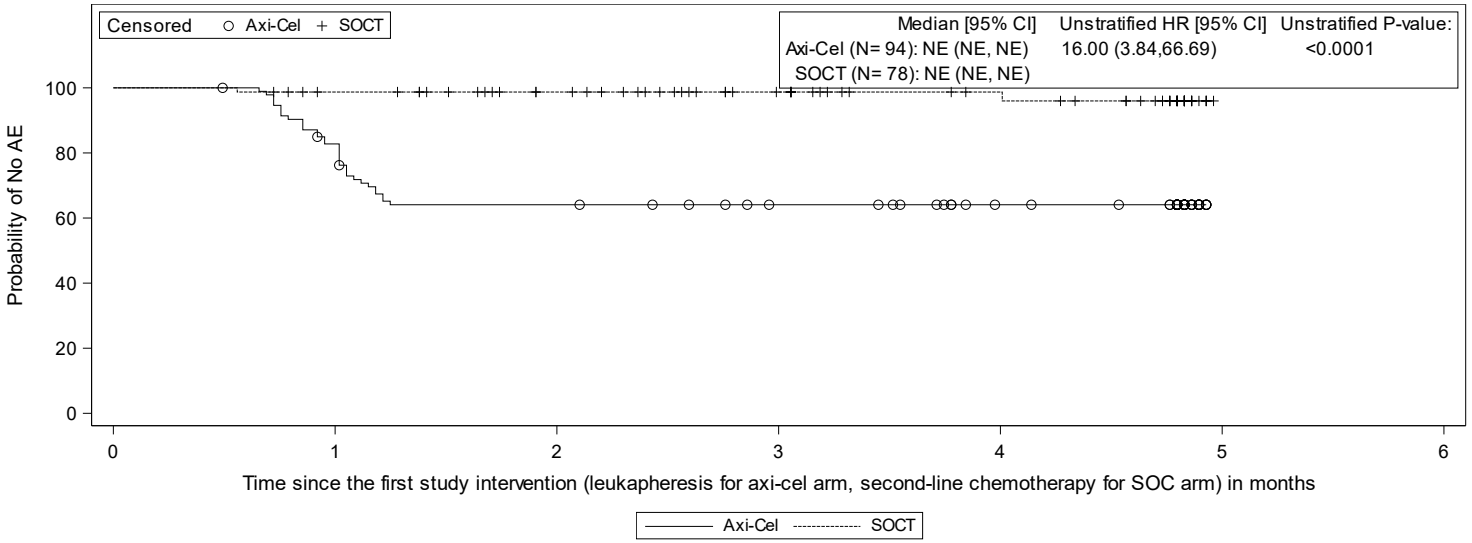
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.54. Kaplan-Meier Plot of Time To First Chills by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	76	58	52	43	0
SOCT	78	73	62	47	36	0

Page 1 of 64

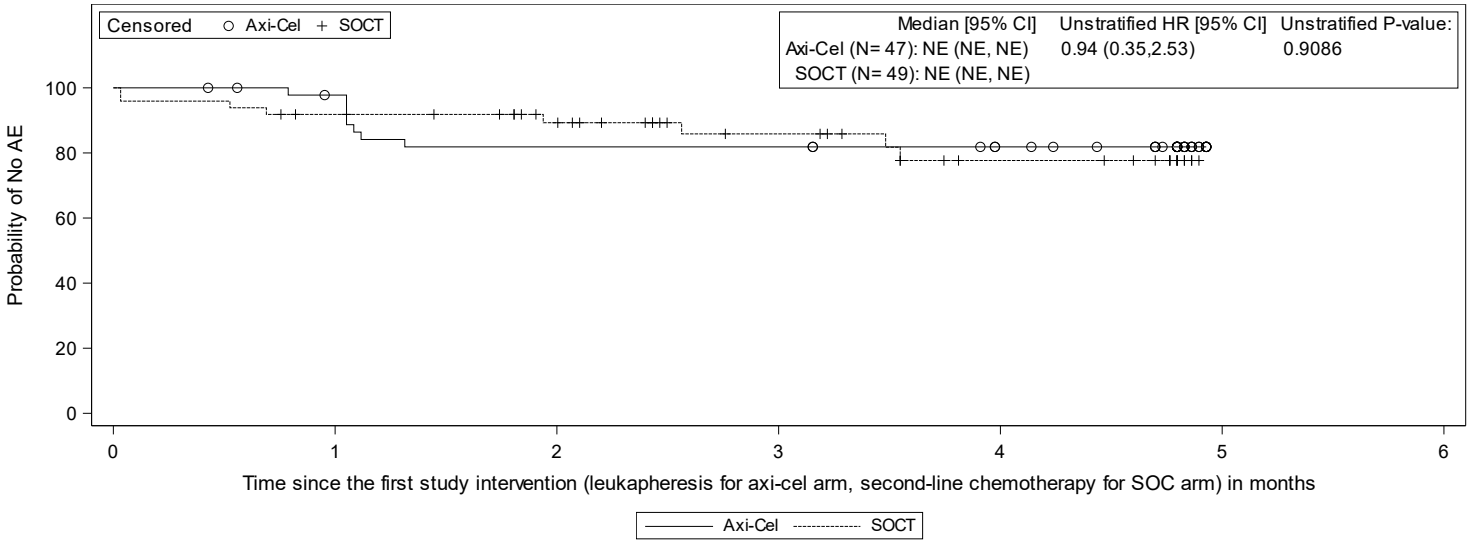
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.54. Kaplan-Meier Plot of Time To First Chills by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	43	36	36	31	0
SOCT	49	43	35	24	15	0

Page 2 of 64

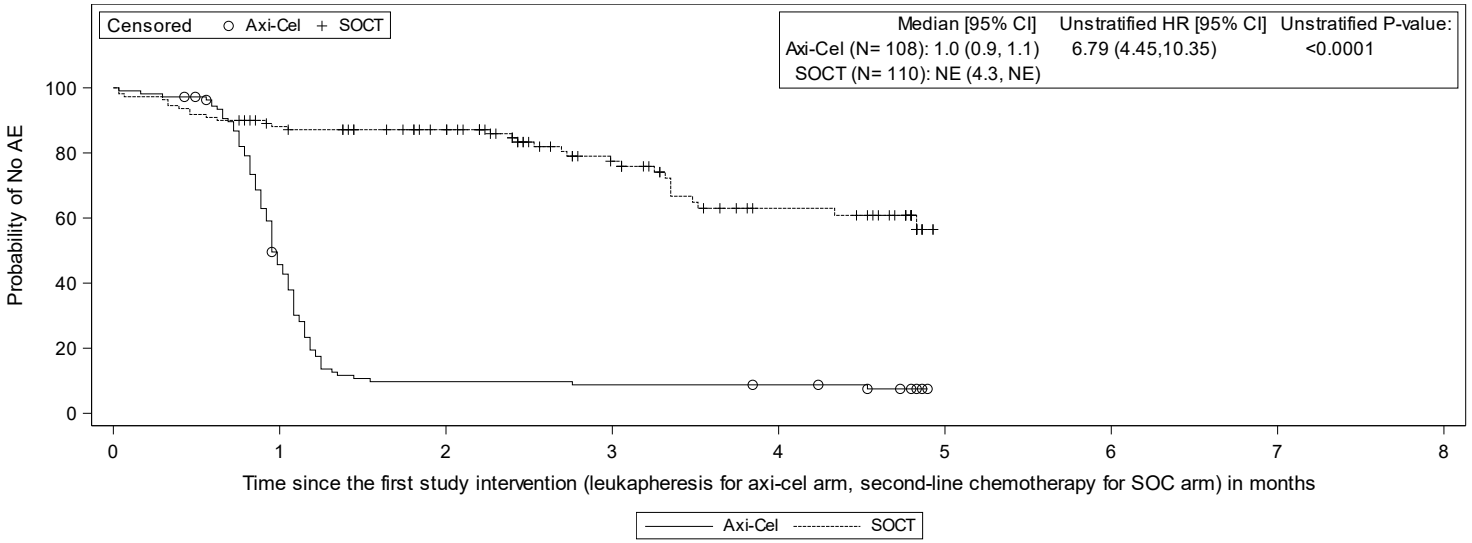
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.55. Kaplan-Meier Plot of Time To First Pyrexia by disease type per investigator (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma not otherwise specified



Subjects at Risk

Axi-Cel	108	47	10	9	8	0
SOCT	110	92	79	49	29	0

Page 1 of 64

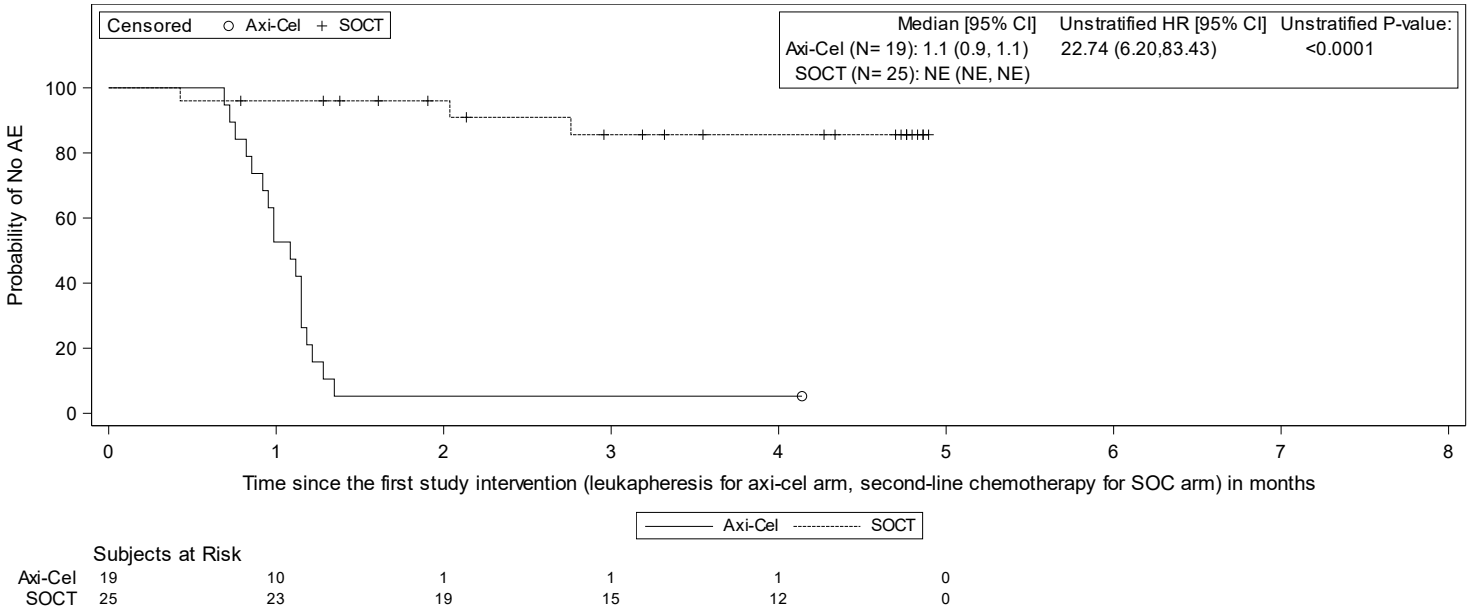
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.55. Kaplan-Meier Plot of Time To First Pyrexia by disease type per investigator (Modified Safety Analysis Set)

Large cell transformation from follicular lymphoma



Subjects at Risk

Axi-Cel	19	10	1	1	1	0
SOCT	25	23	19	15	12	0

Page 2 of 64

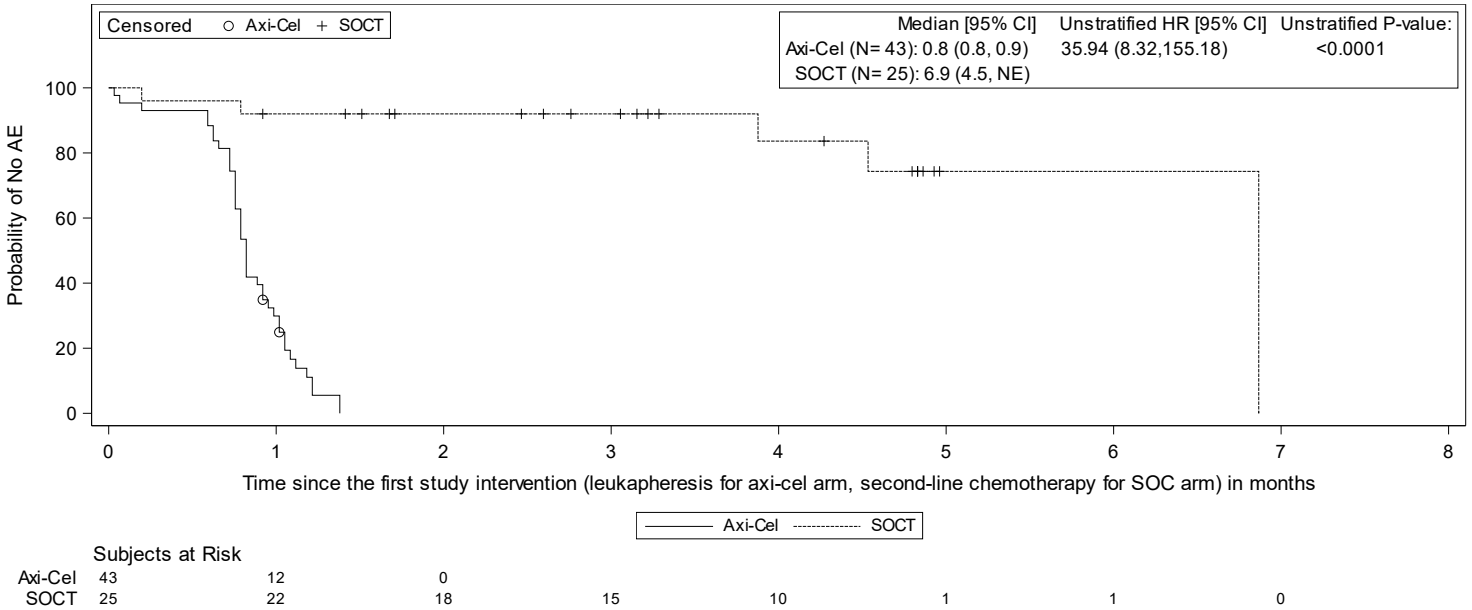
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.55. Kaplan-Meier Plot of Time To First Pyrexia by disease type per investigator (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	43	12	0					
SOCT	25	22	18	15	10	1	1	0

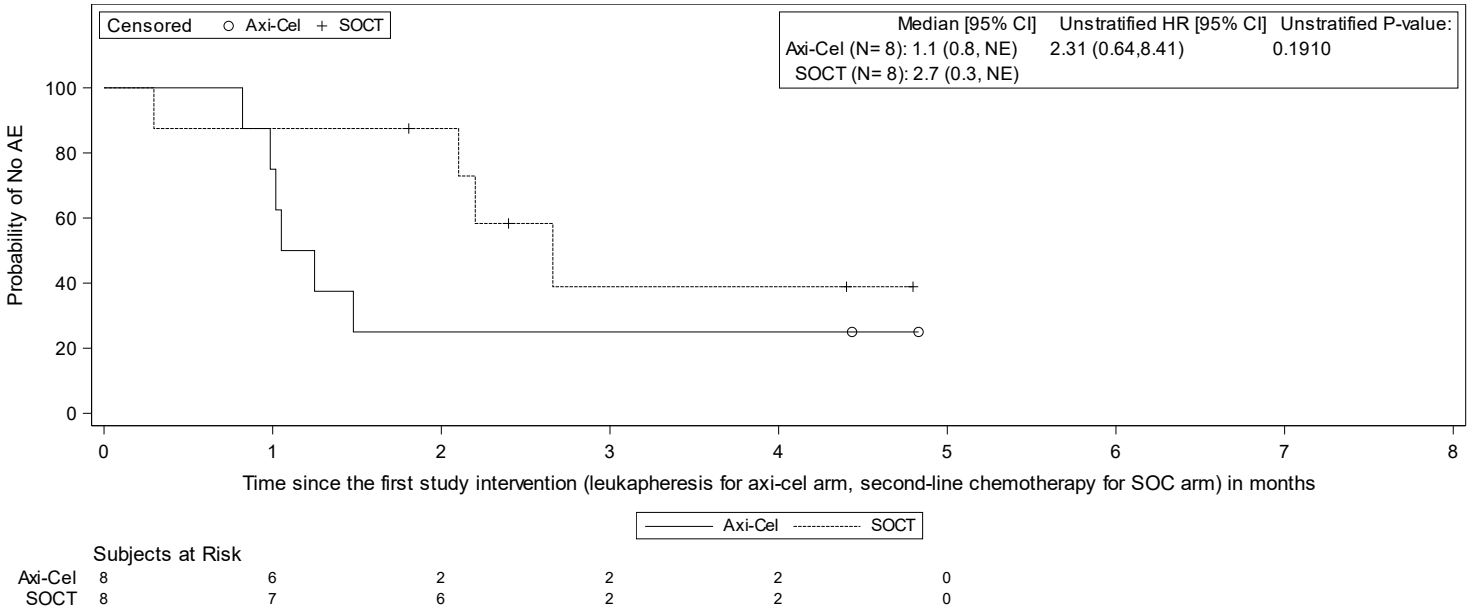
Page 3 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.55. Kaplan-Meier Plot of Time To First Pyrexia by disease type per investigator (Modified Safety Analysis Set)

Other



Subjects at Risk

Axi-Cel	8	6	2	2	2	0
SOCT	8	7	6	2	2	0

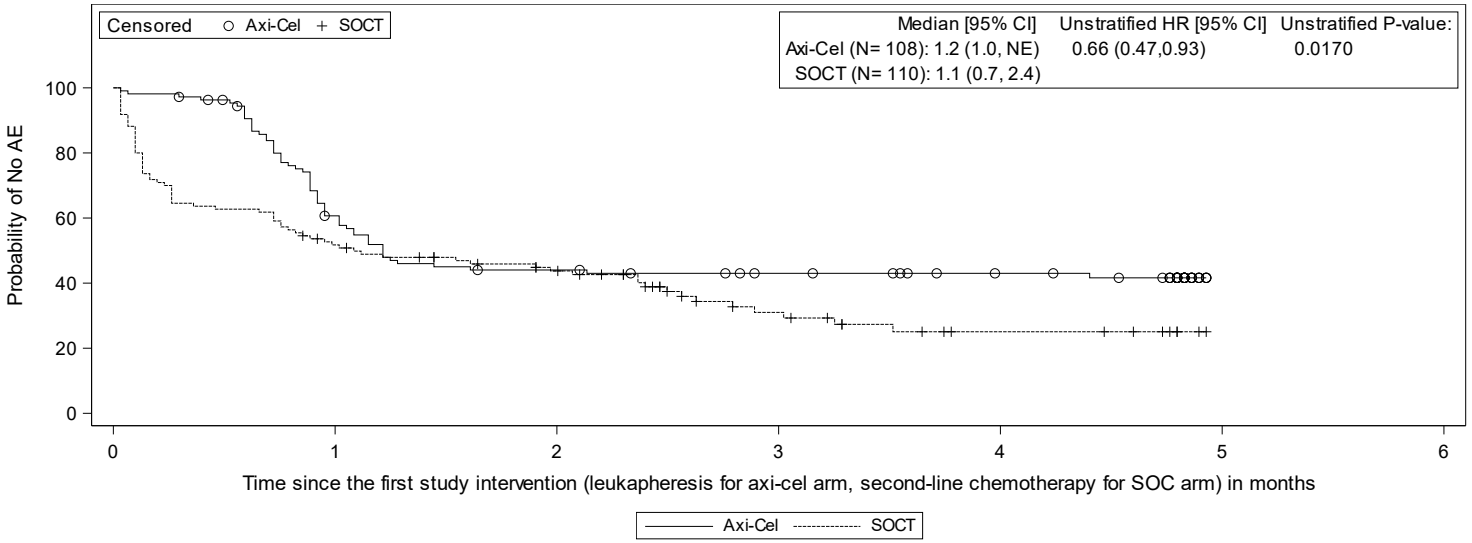
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.56. Kaplan-Meier Plot of Time To First Nausea by disease type per investigator (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma not otherwise specified



Subjects at Risk

Axi-Cel	108	62	44	38	32	0
SOCT	110	55	40	18	8	0

Page 1 of 64

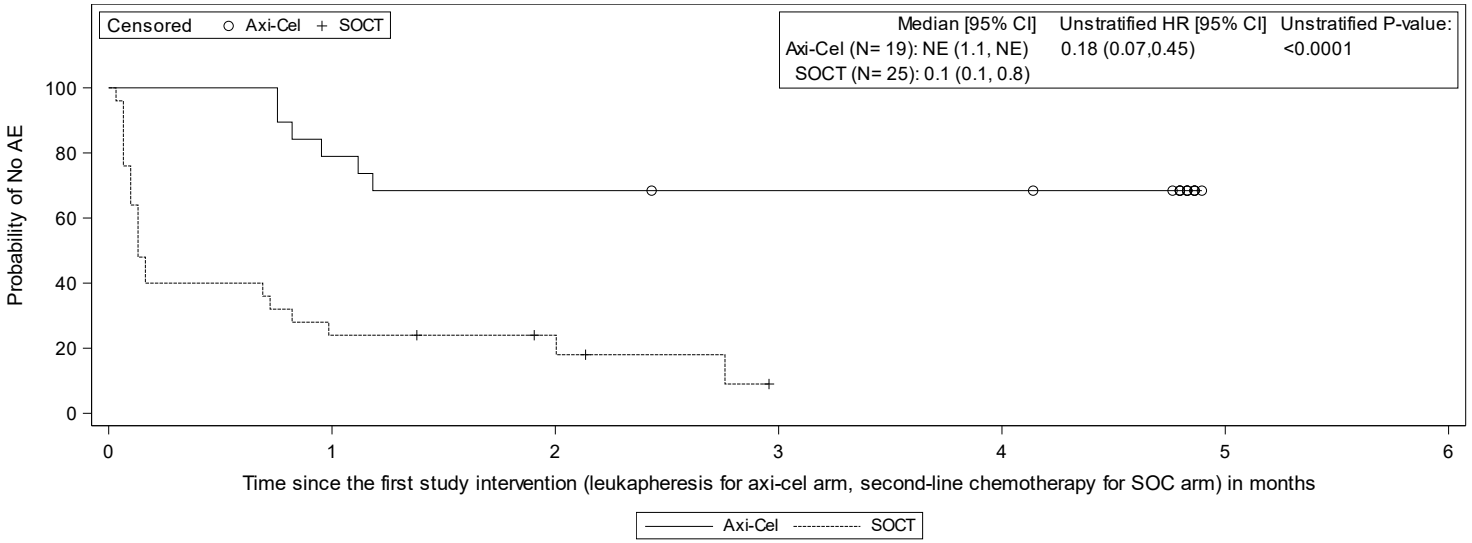
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.56. Kaplan-Meier Plot of Time To First Nausea by disease type per investigator (Modified Safety Analysis Set)

Large cell transformation from follicular lymphoma



Subjects at Risk

Axi-Cel	19	15	13	12	12	0
SOCT	25	6	4	0		

Page 2 of 64

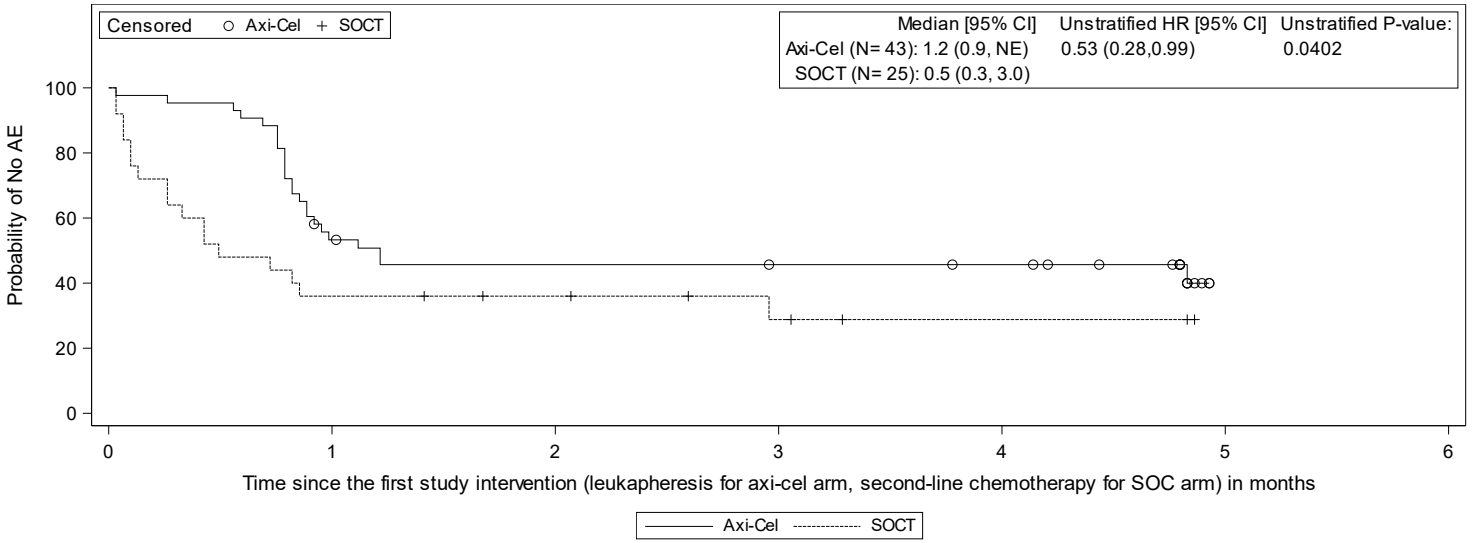
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.56. Kaplan-Meier Plot of Time To First Nausea by disease type per investigator (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	43	22	18	17	16	0
SOCT	25	9	7	4	2	0

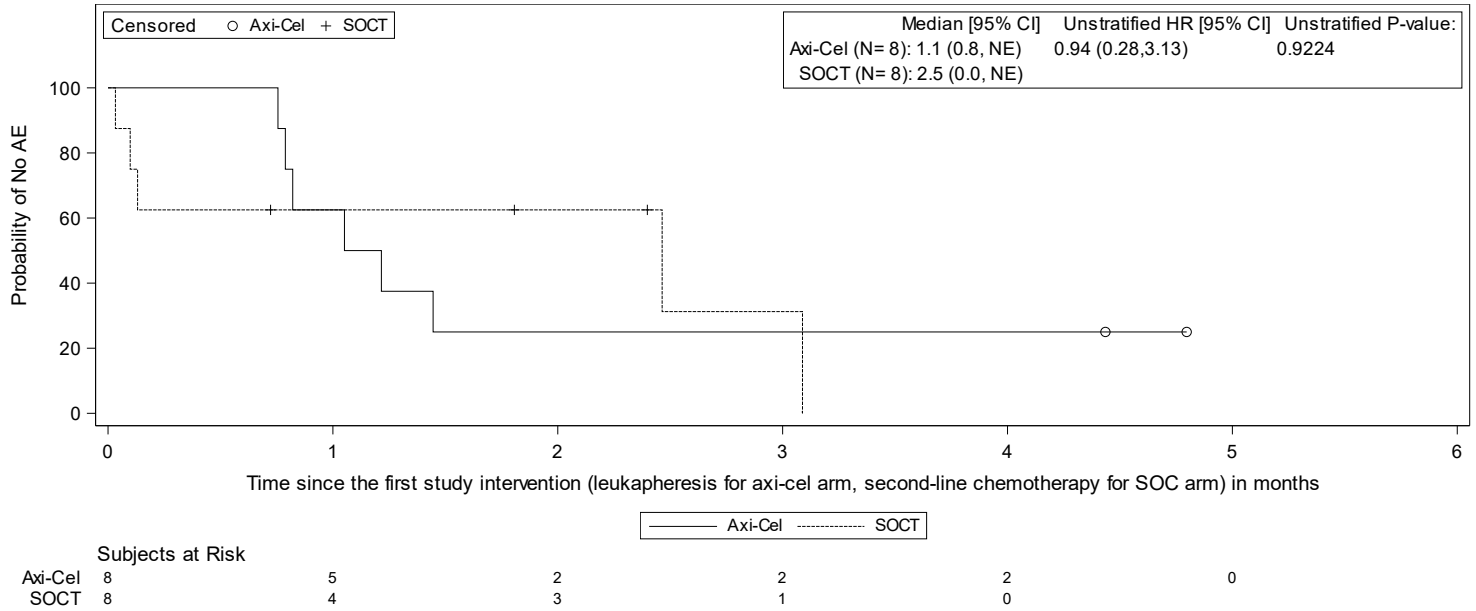
Page 3 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.56. Kaplan-Meier Plot of Time To First Nausea by disease type per investigator (Modified Safety Analysis Set)

Other



Subjects at Risk

Axi-Cel	8	5	2	2	2	0
SOCT	8	4	3	1	0	

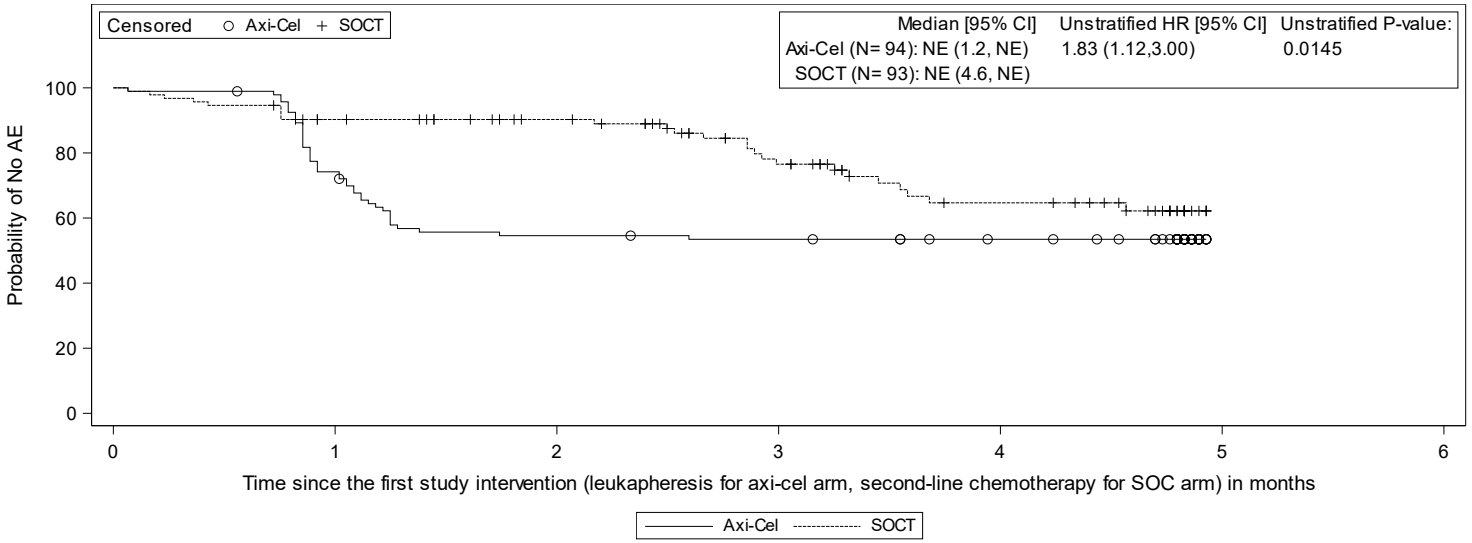
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.57. Kaplan-Meier Plot of Time To First Cardiac disorders by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	94	69	50	48	43	0
SOCT	93	79	69	48	31	0

Page 1 of 64

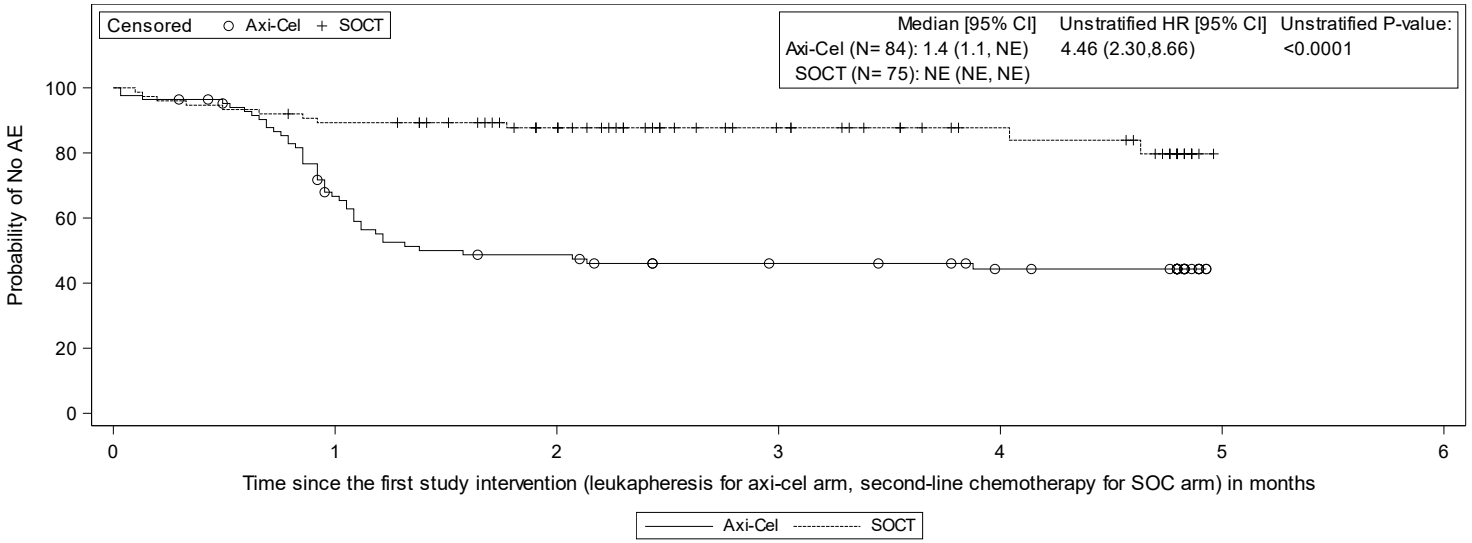
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.57. Kaplan-Meier Plot of Time To First Cardiac disorders by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	84	52	37	30	25	0
SOCT	75	66	52	33	23	0

Page 2 of 64

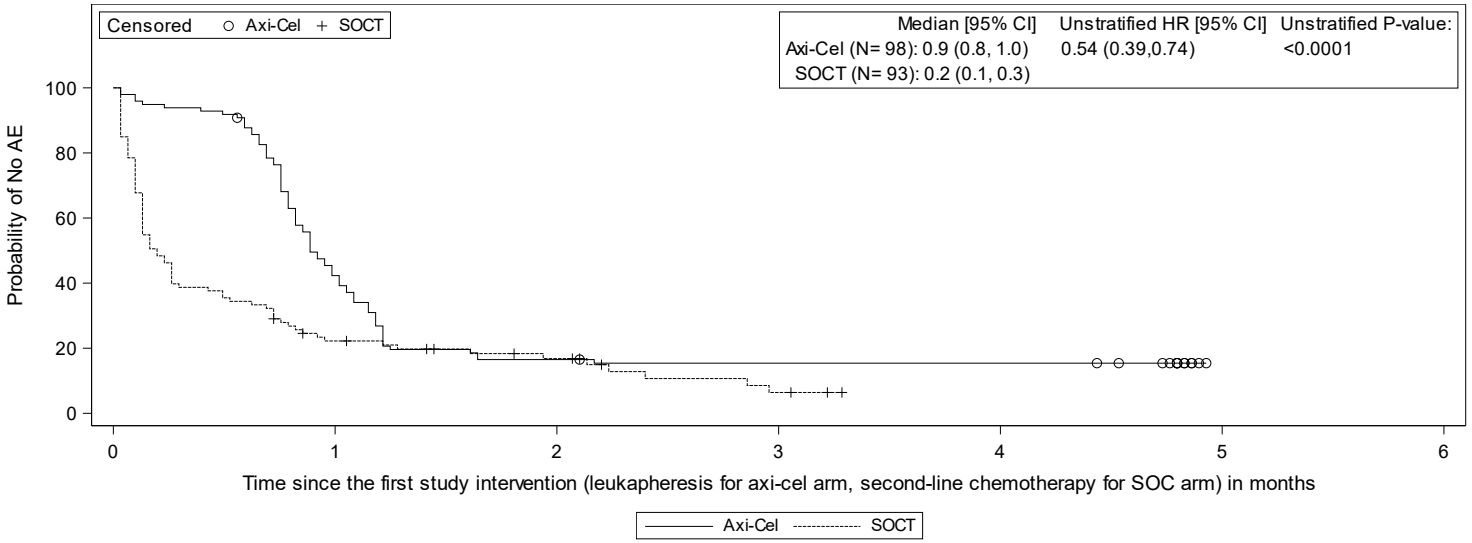
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.58. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	41	16	14	14	0
SOCT	93	19	11	3	0	

Page 1 of 64

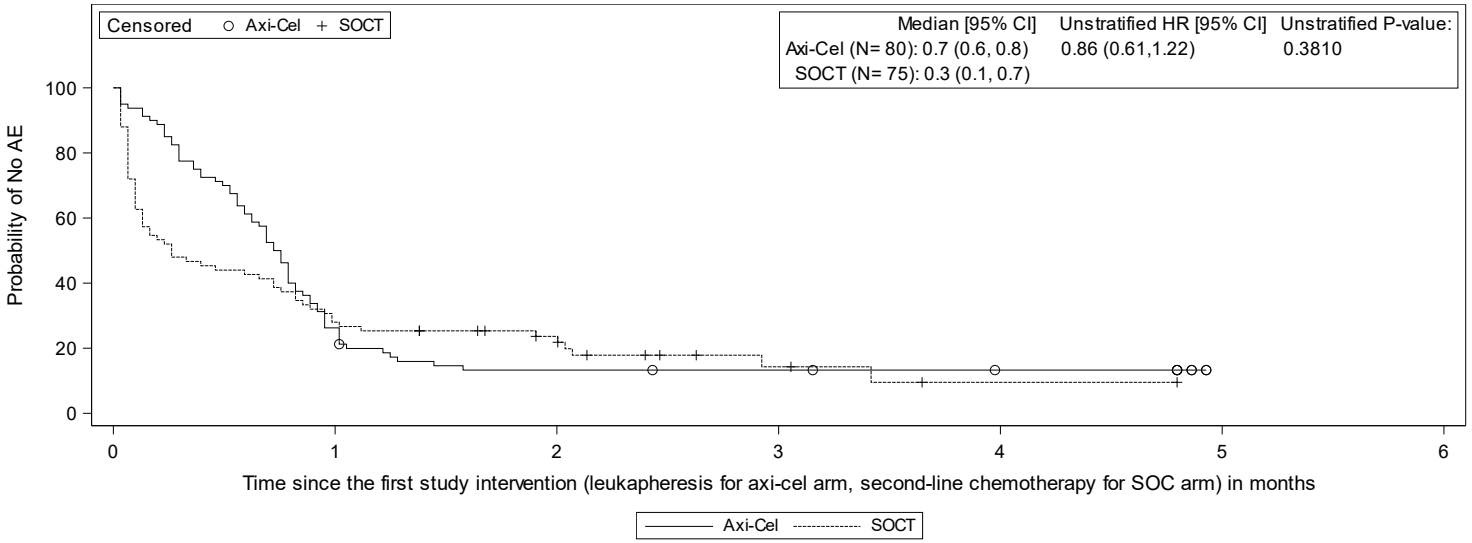
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.58. Kaplan-Meier Plot of Time To First Gastrointestinal disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	21	10	9	7	0
SOCT	75	21	13	4	1	0

Page 2 of 64

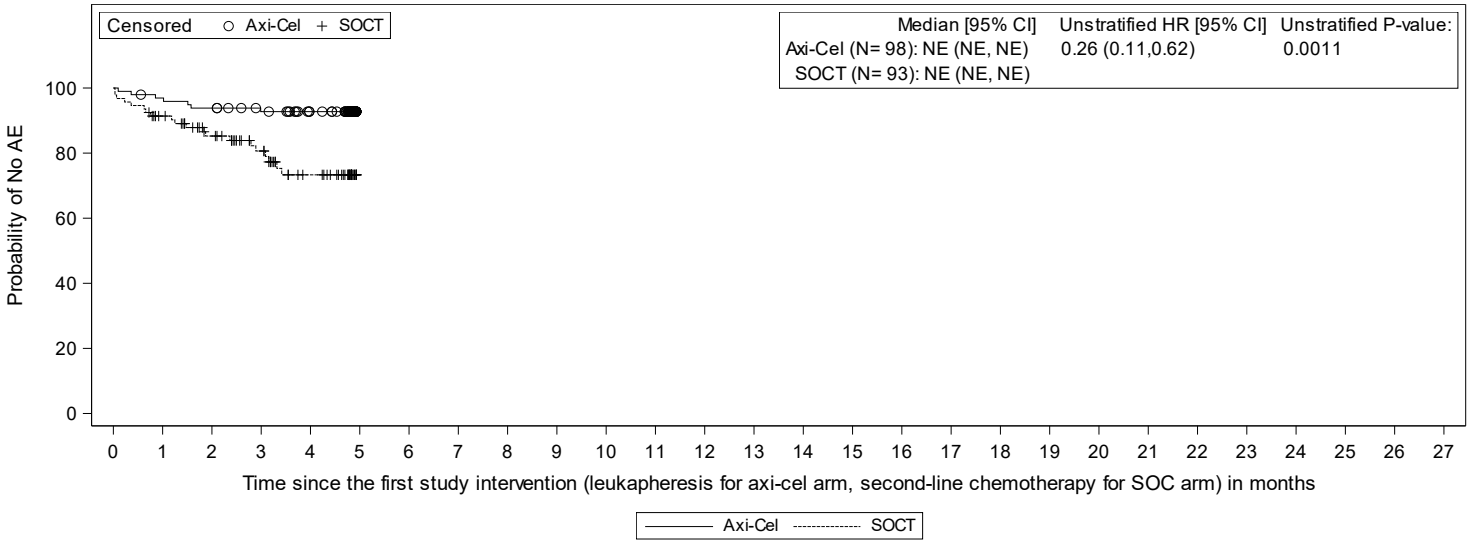
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.59. Kaplan-Meier Plot of Time To First Injury, poisoning and procedural complications by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	94	91	85	75	0
SOCT	93	80	65	50	33	0

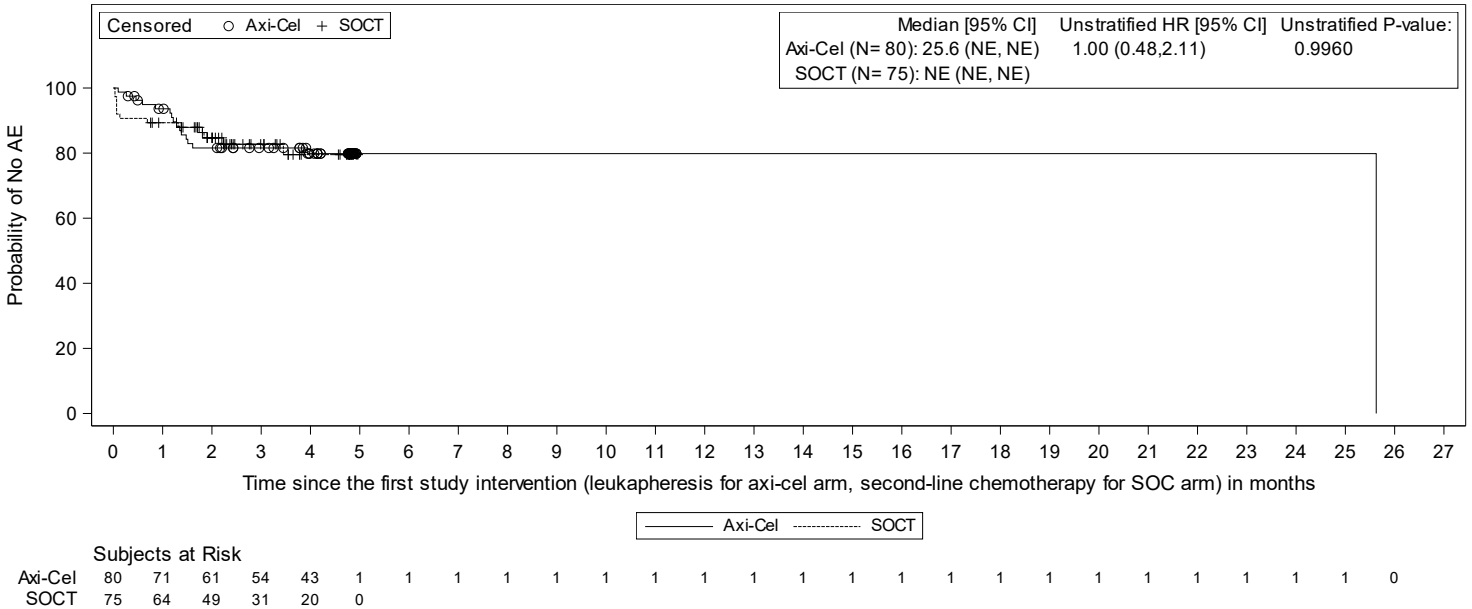
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.59. Kaplan-Meier Plot of Time To First Injury, poisoning and procedural complications by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	71	61	54	43	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	75	64	49	31	20	0																				

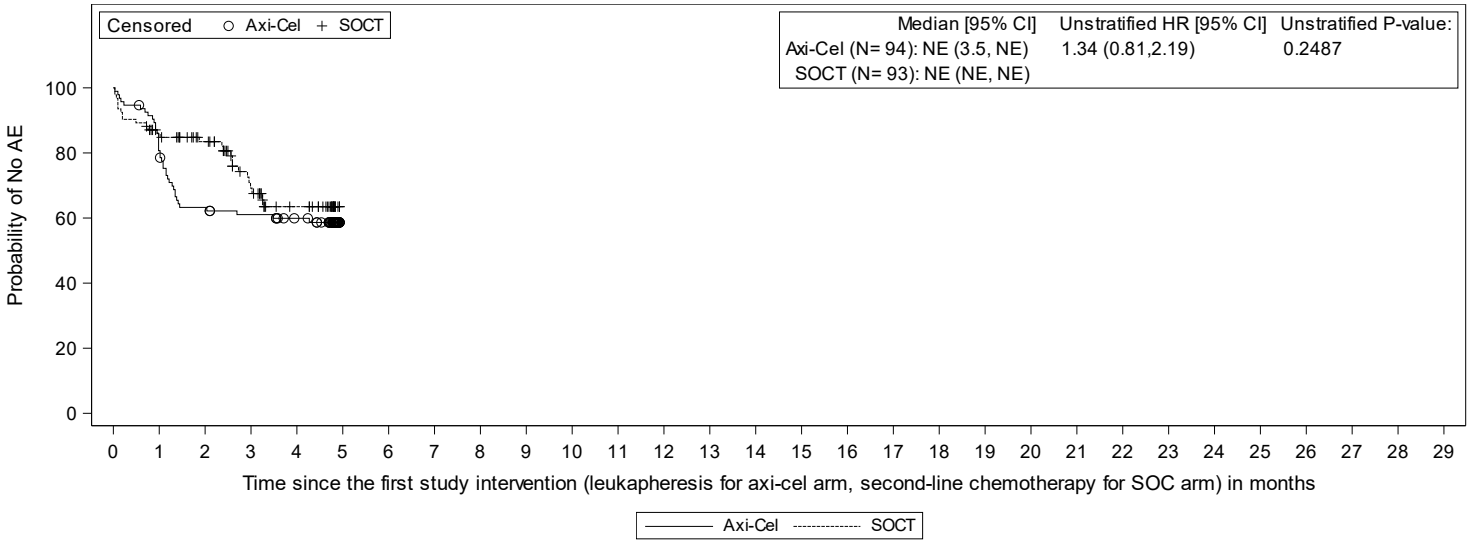
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.60. Kaplan-Meier Plot of Time To First Psychiatric disorders by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	94	75	58	54	48	0
SOCT	93	75	63	41	26	0

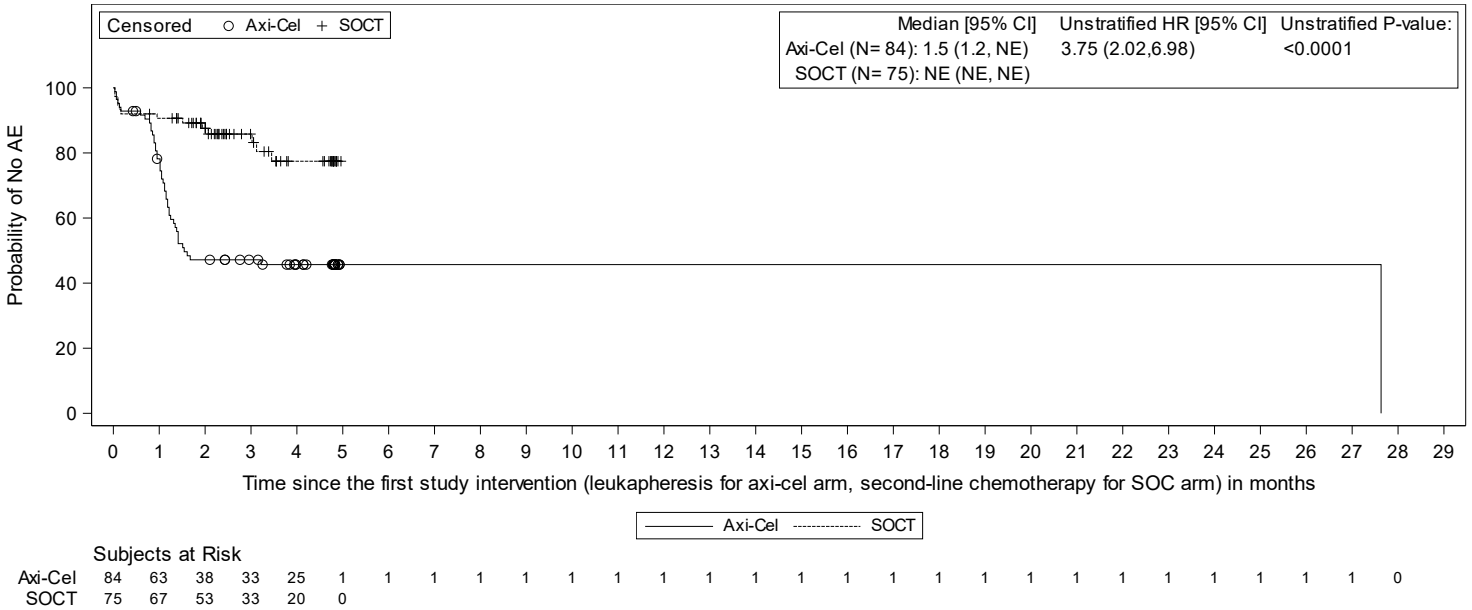
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.60. Kaplan-Meier Plot of Time To First Psychiatric disorders by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	84	63	38	33	25	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	75	67	53	33	20	0																							

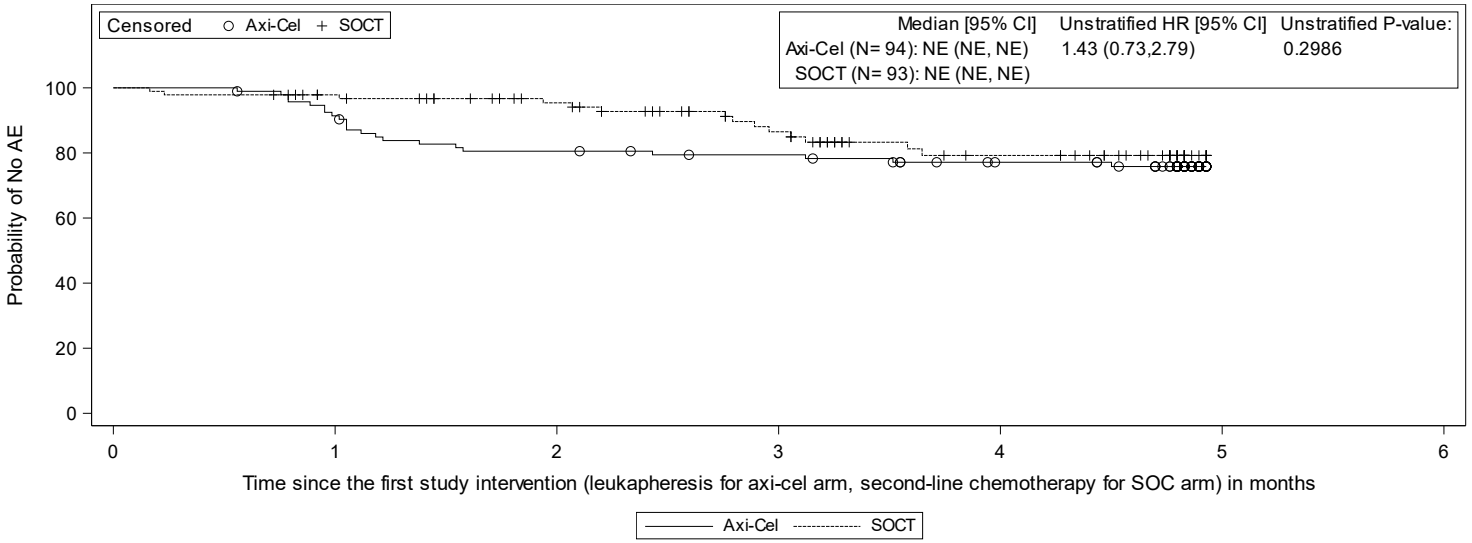
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.61. Kaplan-Meier Plot of Time To First Cough by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	94	85	74	70	61	0
SOCT	93	85	73	55	37	0

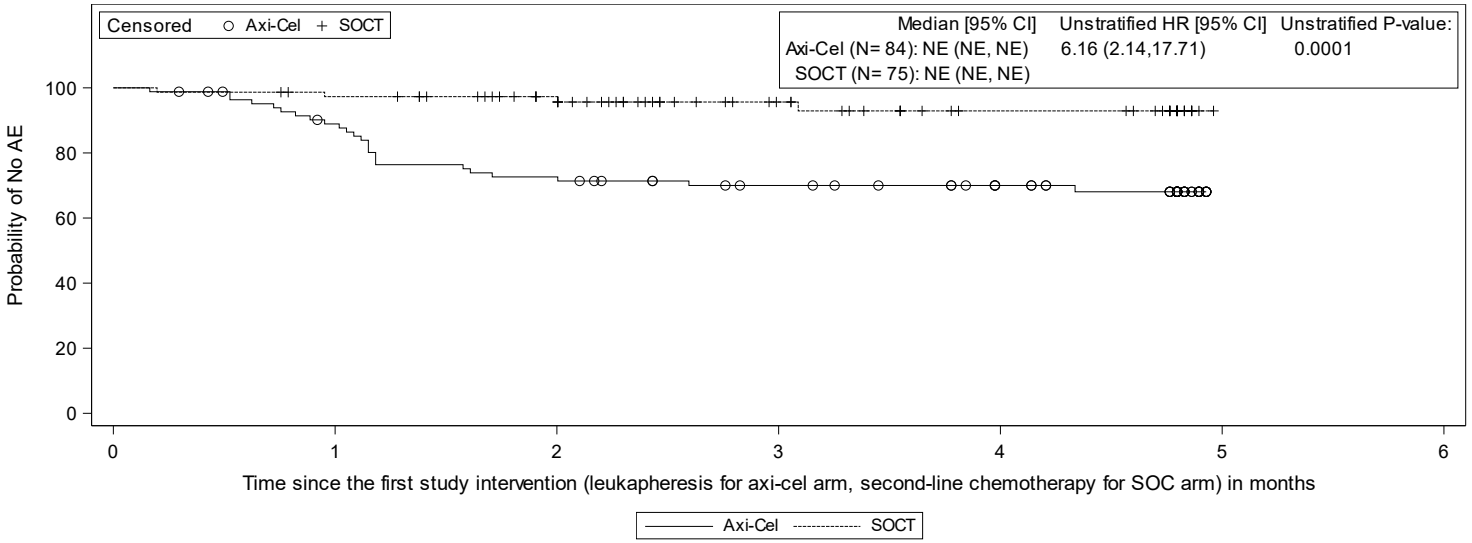
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.61. Kaplan-Meier Plot of Time To First Cough by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	84	71	58	49	40	0
SOCT	75	71	59	37	25	0

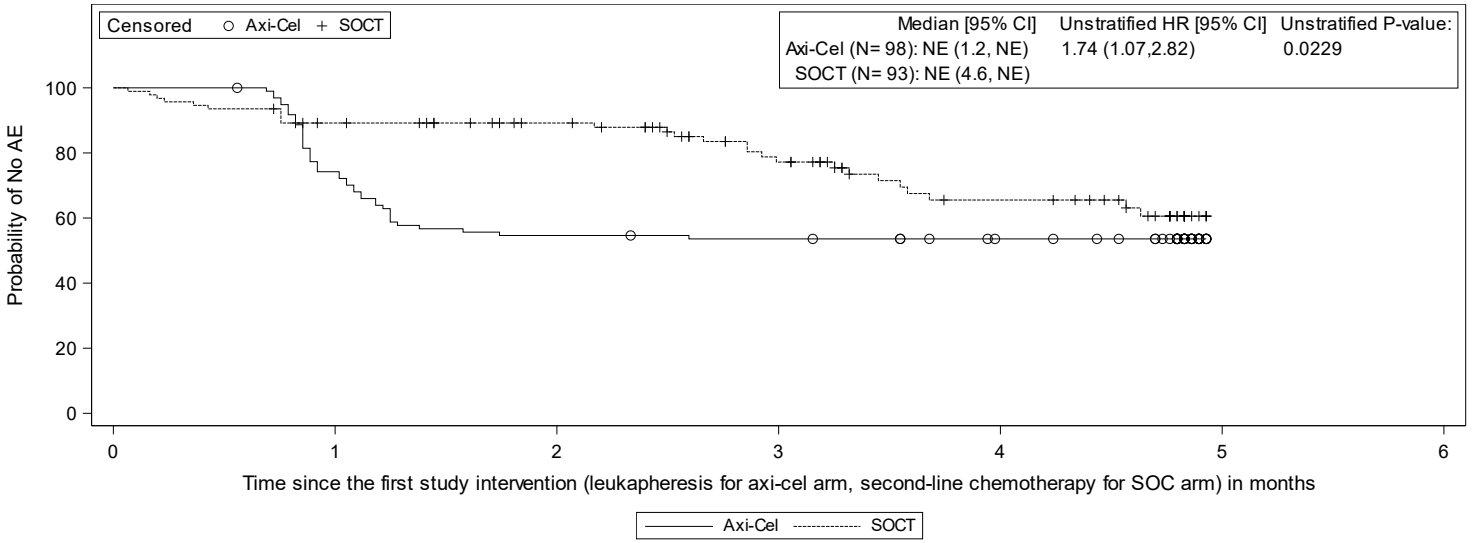
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.62. Kaplan-Meier Plot of Time To First Cardiac disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	72	53	51	45	0
SOCT	93	79	69	49	32	0

Page 1 of 64

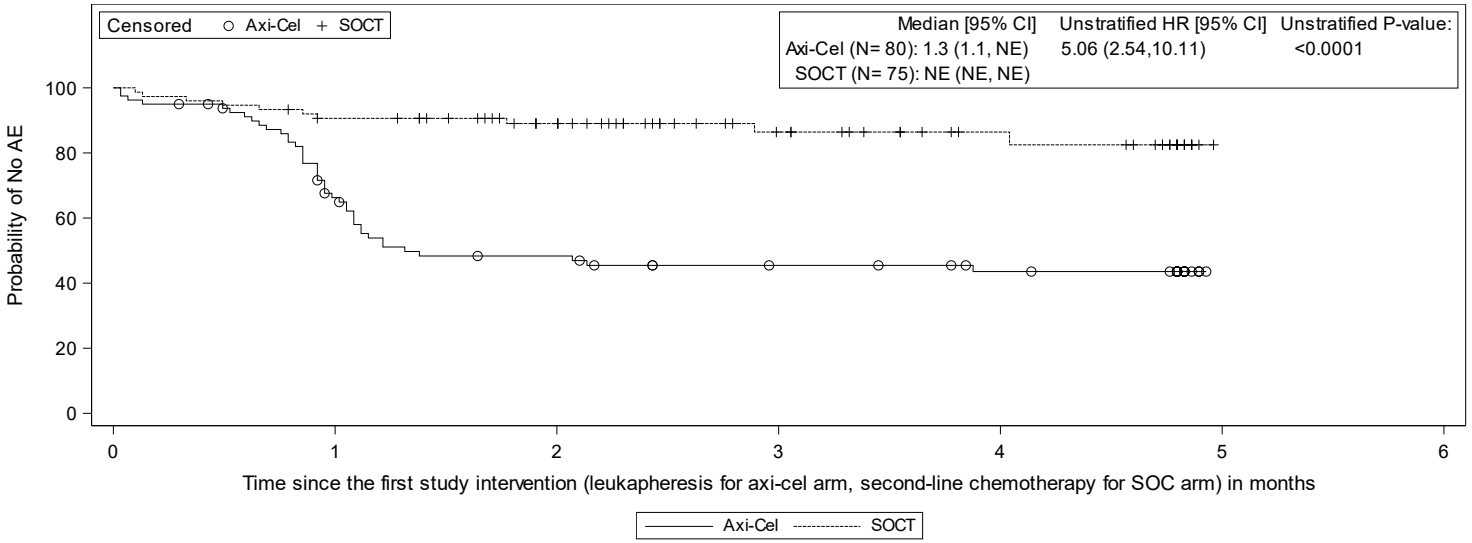
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.62. Kaplan-Meier Plot of Time To First Cardiac disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	49	34	27	23	0
SOCT	75	66	52	32	22	0

Page 2 of 64

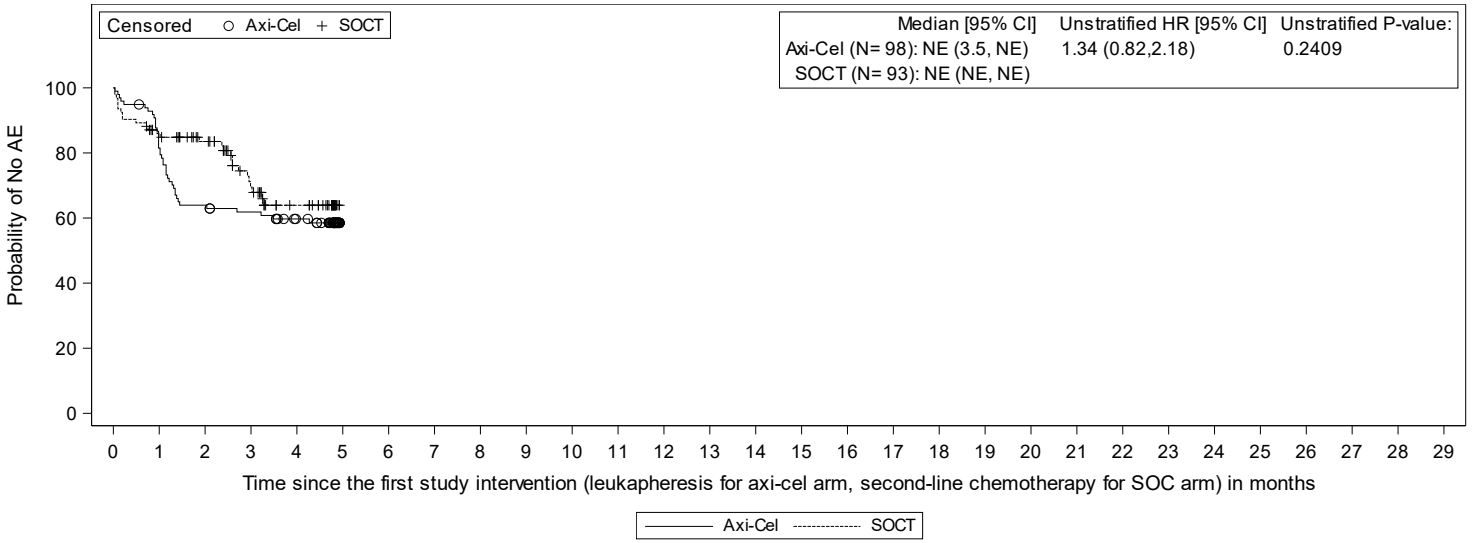
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.63. Kaplan-Meier Plot of Time To First Psychiatric disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	79	62	58	50	0
SOCT	93	76	64	42	26	0

Page 1 of 64

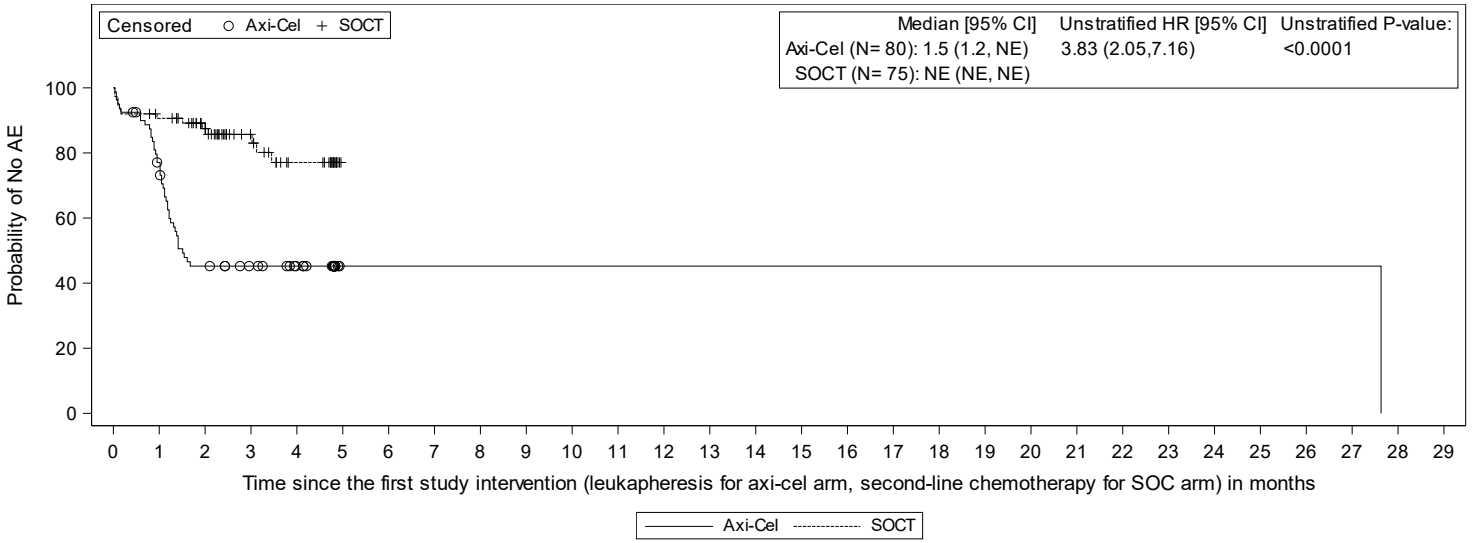
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.63. Kaplan-Meier Plot of Time To First Psychiatric disorders by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	59	34	29	23	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	75	66	52	32	20	0																							

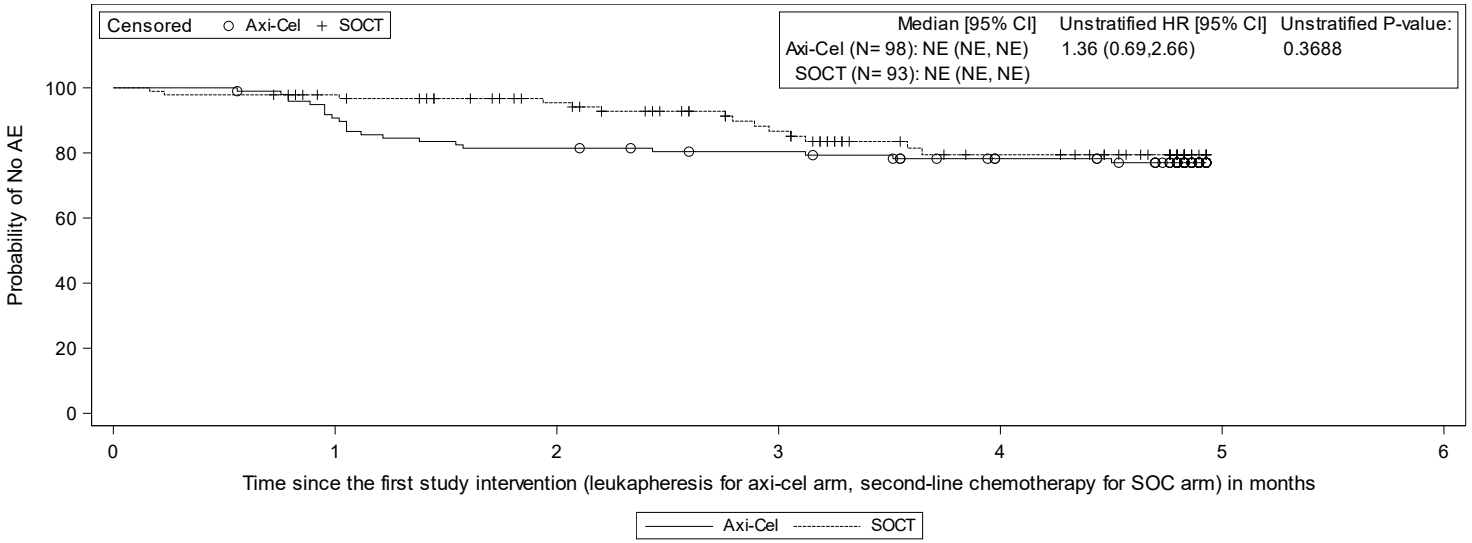
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.64. Kaplan-Meier Plot of Time To First Cough by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

0 - 1



Subjects at Risk

Axi-Cel	98	88	79	75	65	0
SOCT	93	86	74	56	37	0

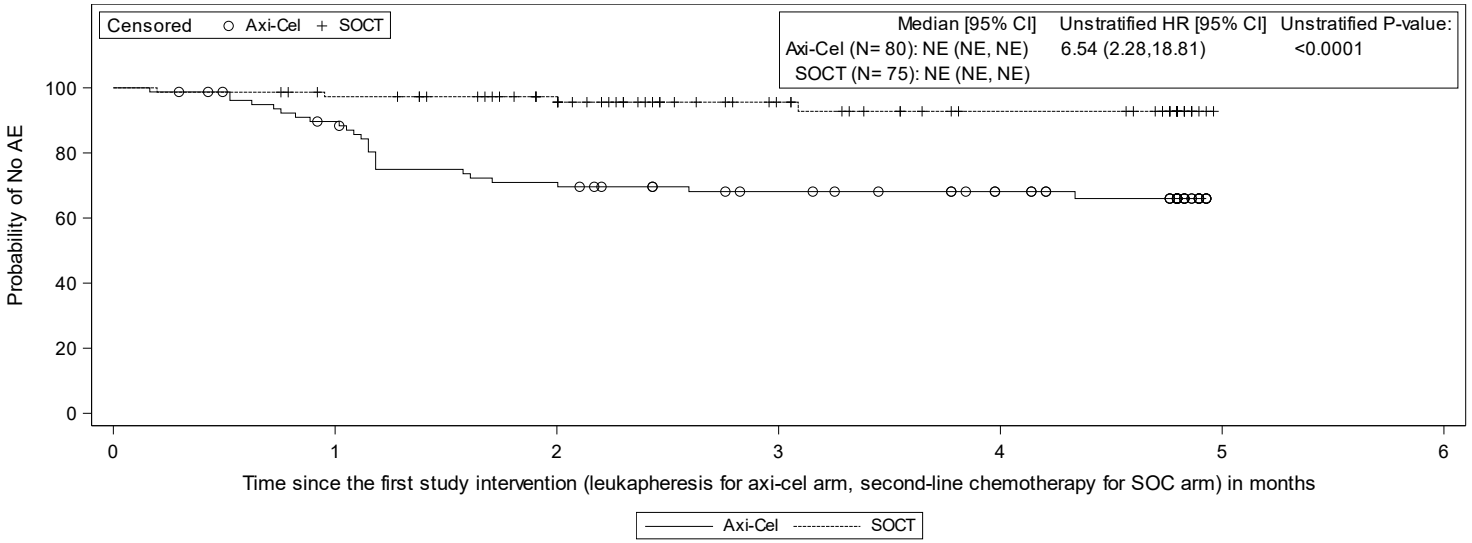
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.64. Kaplan-Meier Plot of Time To First Cough by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

2 - 3



Subjects at Risk

Axi-Cel	80	68	53	44	36	0
SOCT	75	70	58	36	25	0

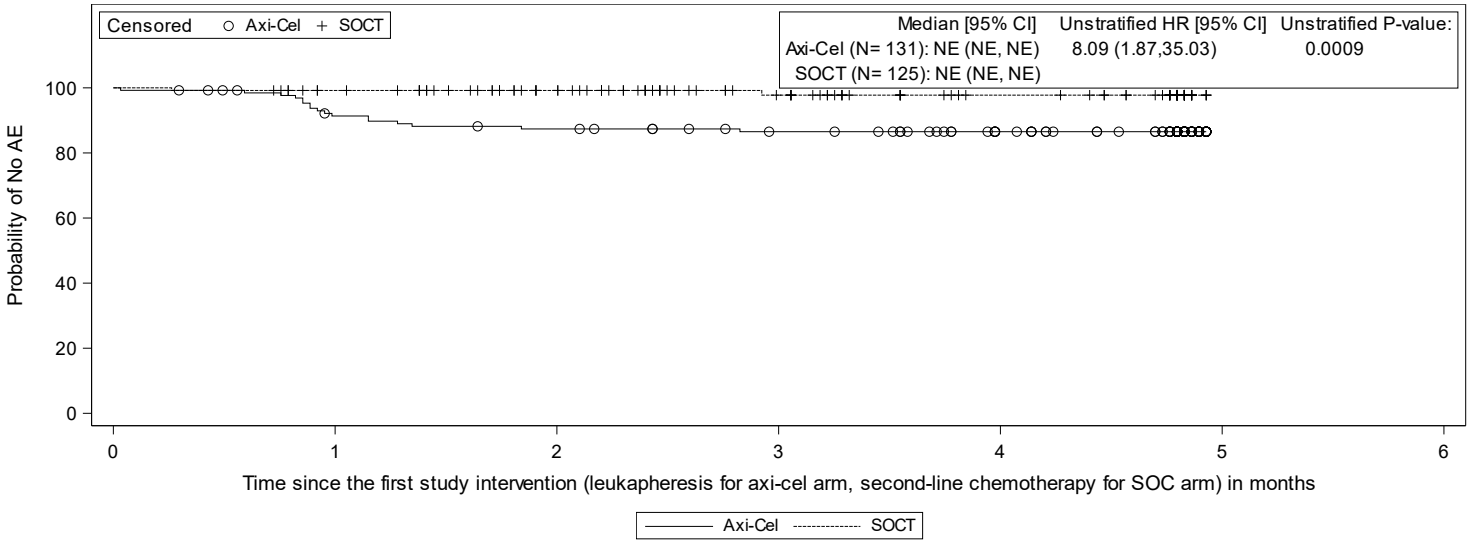
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.65. Kaplan-Meier Plot of Time To First Hyponatraemia by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Primary Refractory



Subjects at Risk

Axi-Cel	131	115	109	101	85	0
SOCT	125	117	96	67	46	0

Page 1 of 64

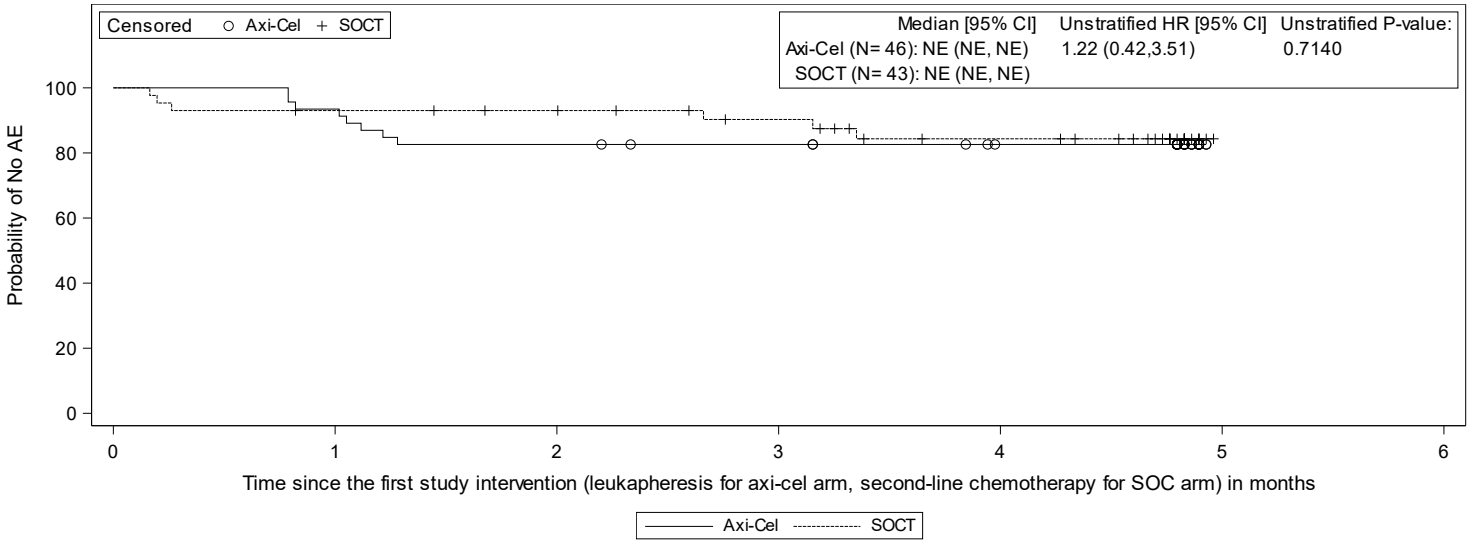
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.65. Kaplan-Meier Plot of Time To First Hyponatraemia by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Relapse ≤ 12 months of the completion of the first line therapy



Subjects at Risk

Axi-Cel	46	43	38	36	31	0
SOCT	43	39	37	32	25	0

Page 2 of 64

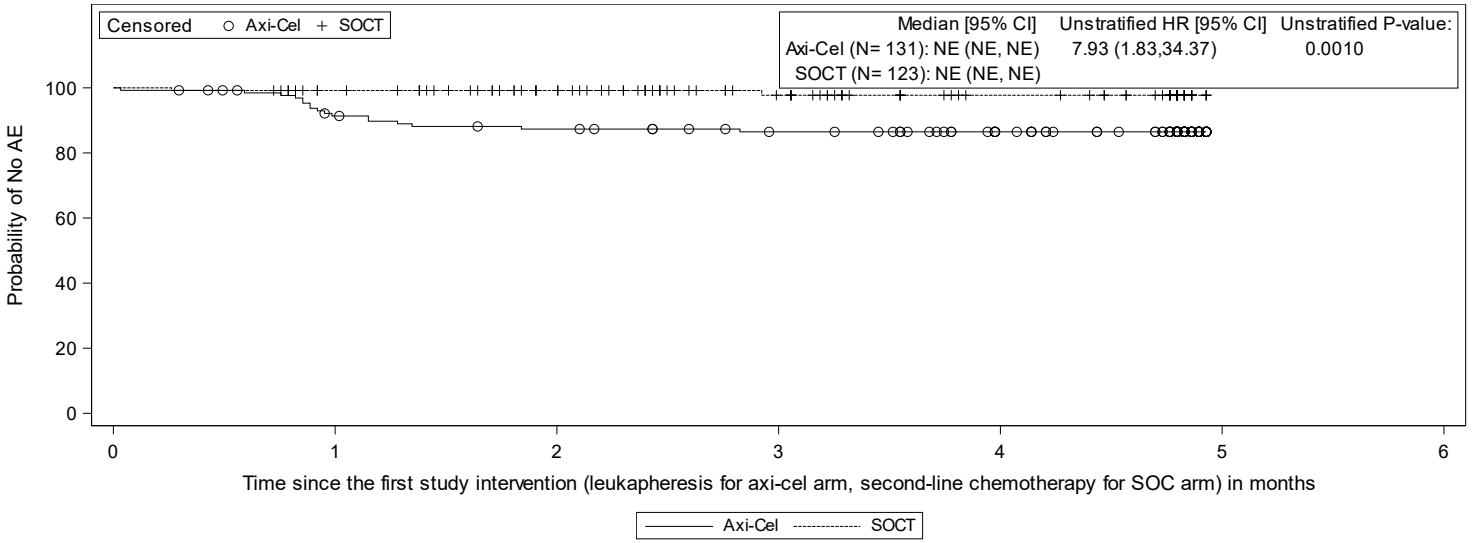
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.66. Kaplan-Meier Plot of Time To First Hyponatraemia by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

Primary Refractory



Subjects at Risk

Axi-Cel	131	115	108	100	84	0
SOCT	123	114	94	66	45	0

Page 1 of 64

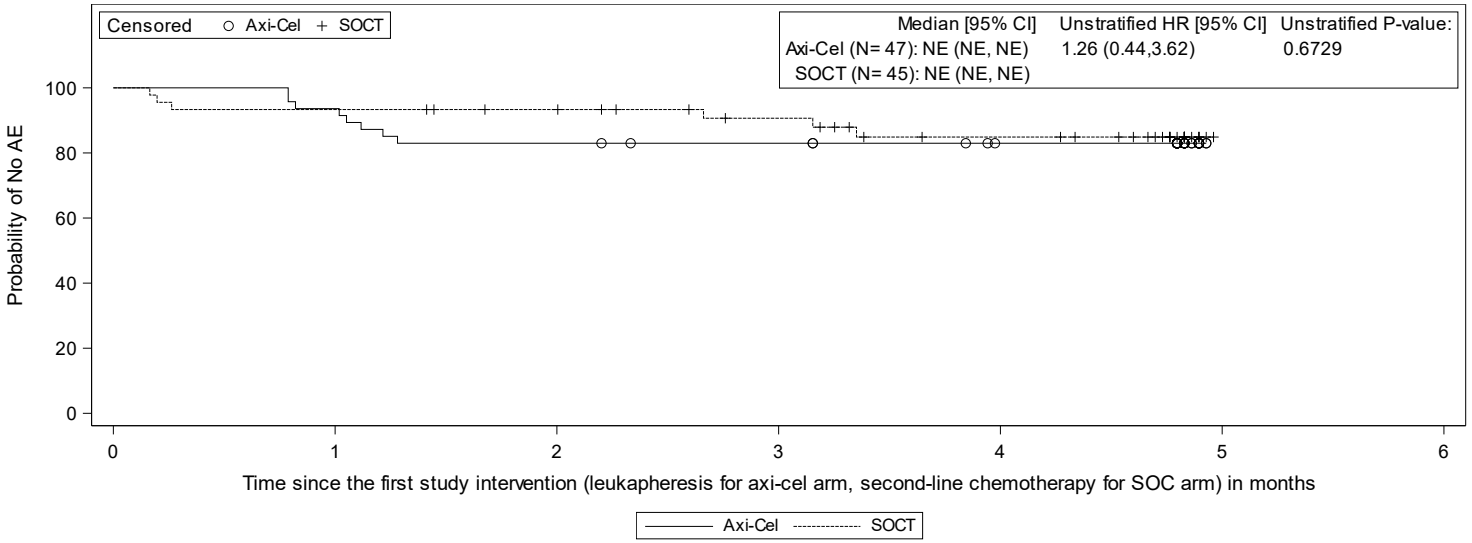
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.66. Kaplan-Meier Plot of Time To First Hyponatraemia by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

Relapse ≤ 12 Months of first line therapy



Subjects at Risk

Axi-Cel	47	44	39	37	32	0
SOCT	45	42	39	33	26	0

Page 2 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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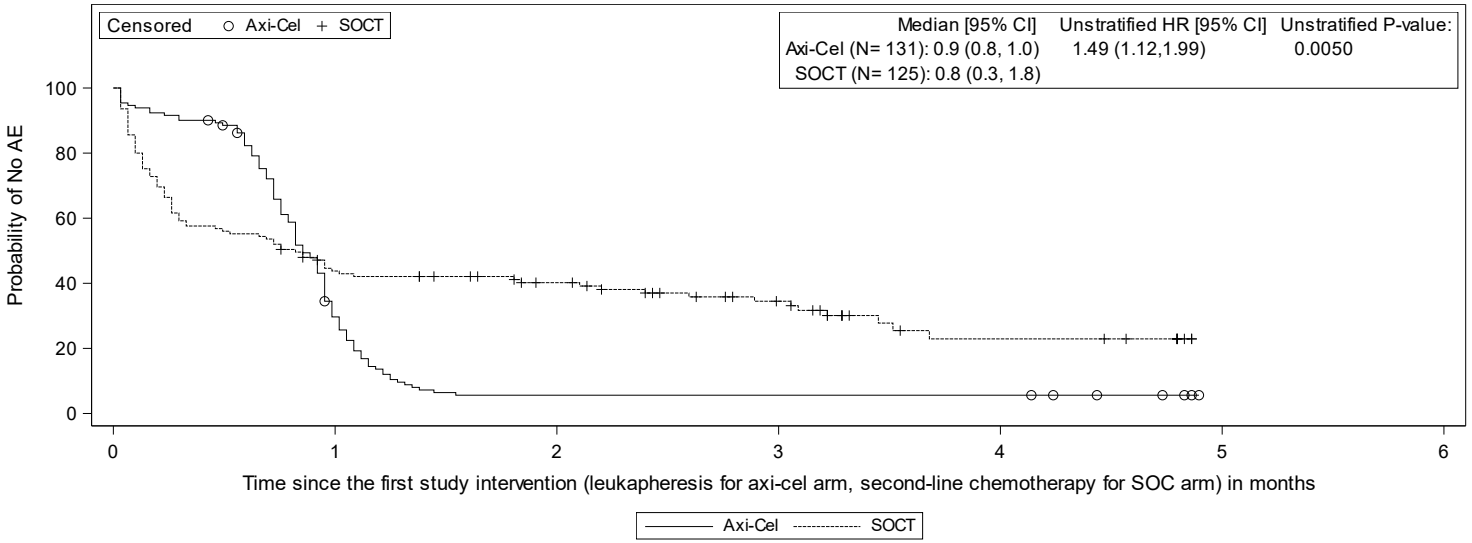
Figure 14.5.4.1.91. Kaplan-Meier Plot of Time To First General disorders and administration site conditions by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Primary Refractory



Subjects at Risk

Axi-Cel	131	37	7	7	7	0
SOCT	125	52	40	25	9	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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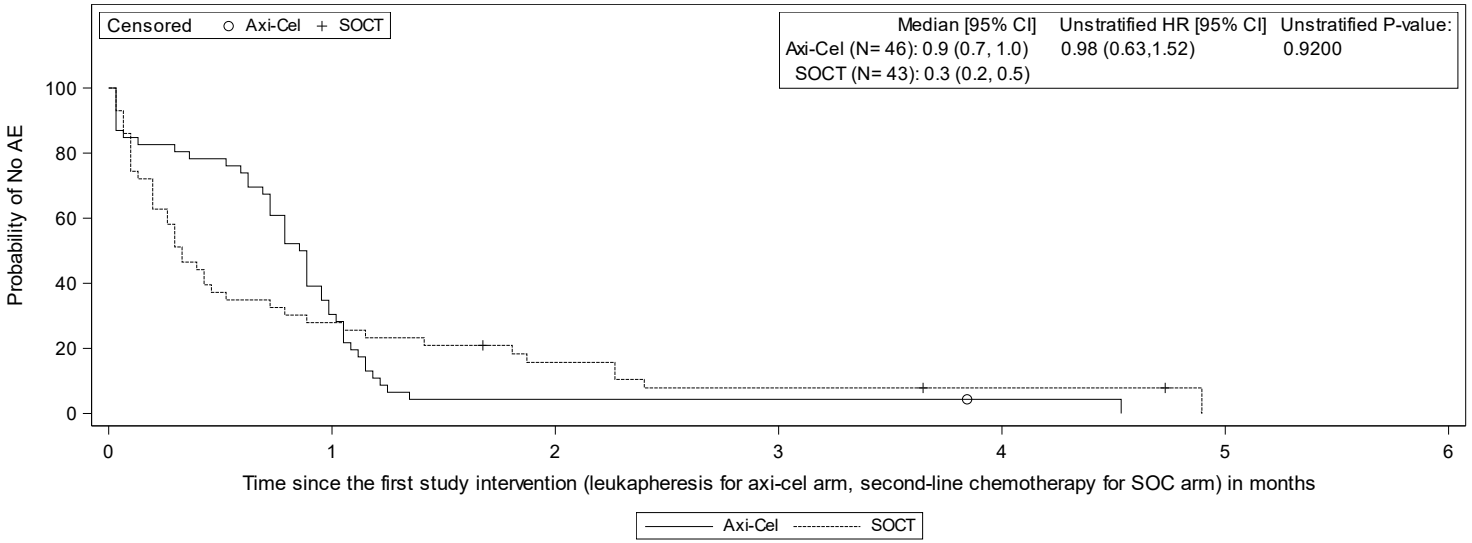
Figure 14.5.4.1.91. Kaplan-Meier Plot of Time To First General disorders and administration site conditions by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Relapse ≤ 12 months of the completion of the first line therapy



Subjects at Risk

Axi-Cel	46	14	2	2	1	0
SOCT	43	12	6	3	2	0

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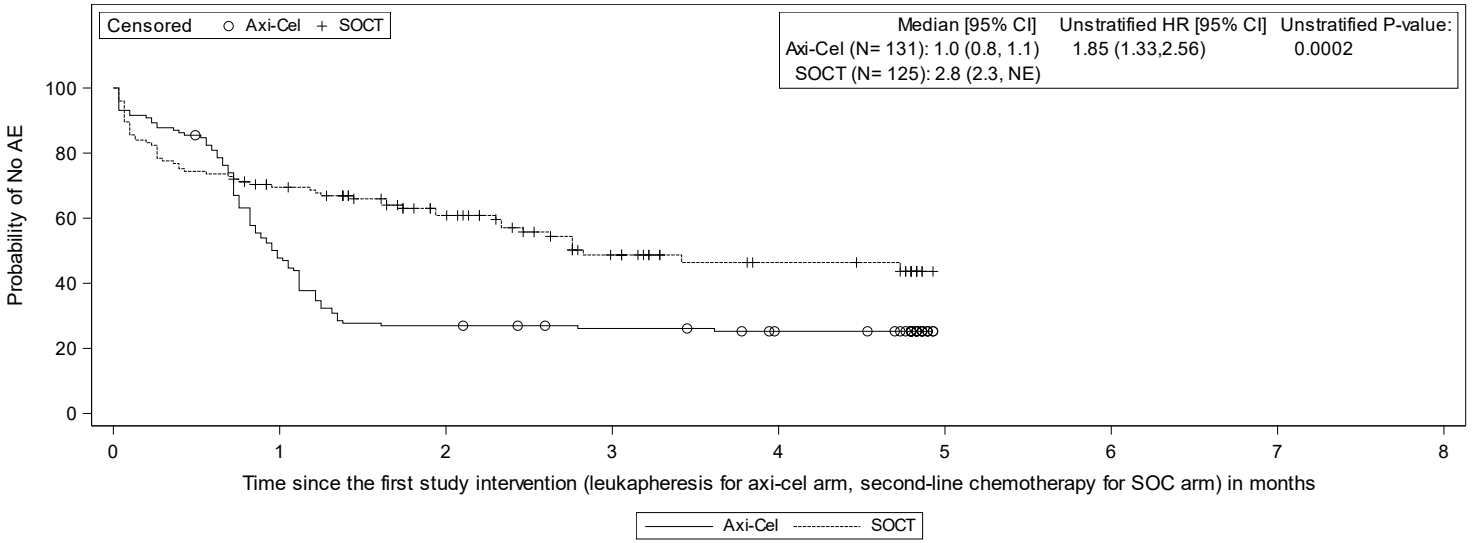
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.92. Kaplan-Meier Plot of Time To First Metabolism and nutrition disorders by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Primary Refractory



Subjects at Risk

Axi-Cel	131	62	35	31	26	0
SOCT	125	81	56	31	18	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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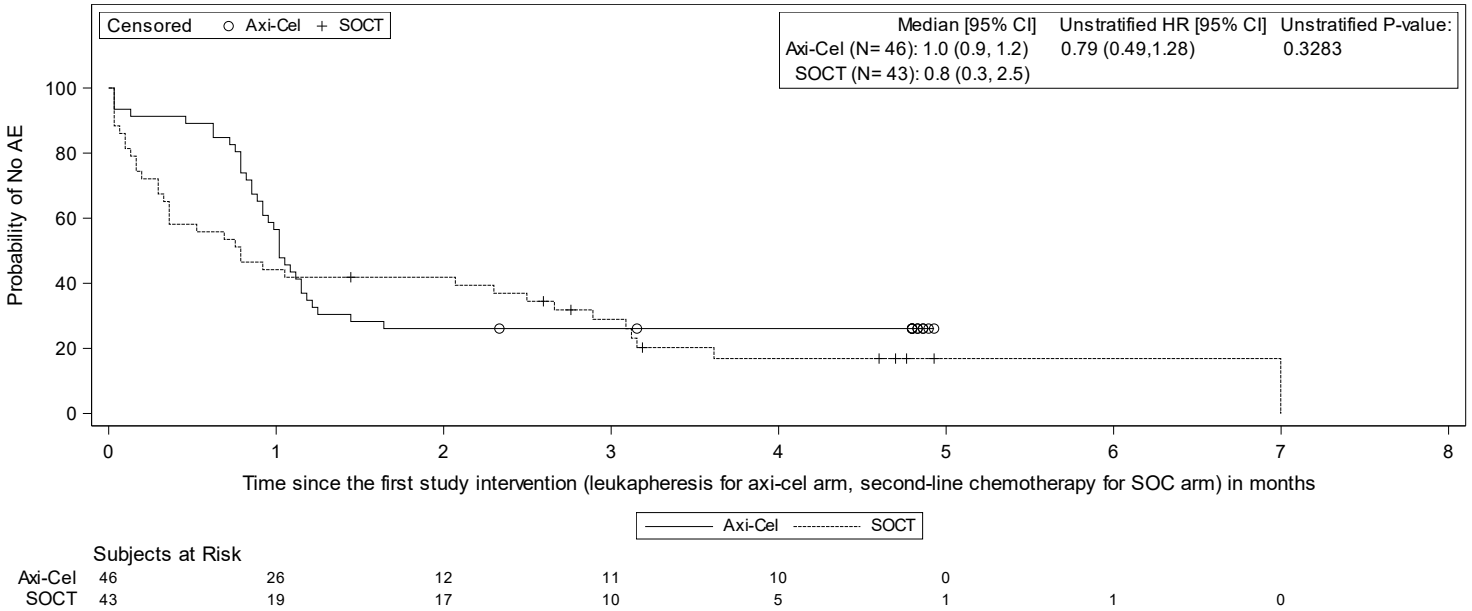
Figure 14.5.4.1.92. Kaplan-Meier Plot of Time To First Metabolism and nutrition disorders by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Relapse ≤ 12 months of the completion of the first line therapy



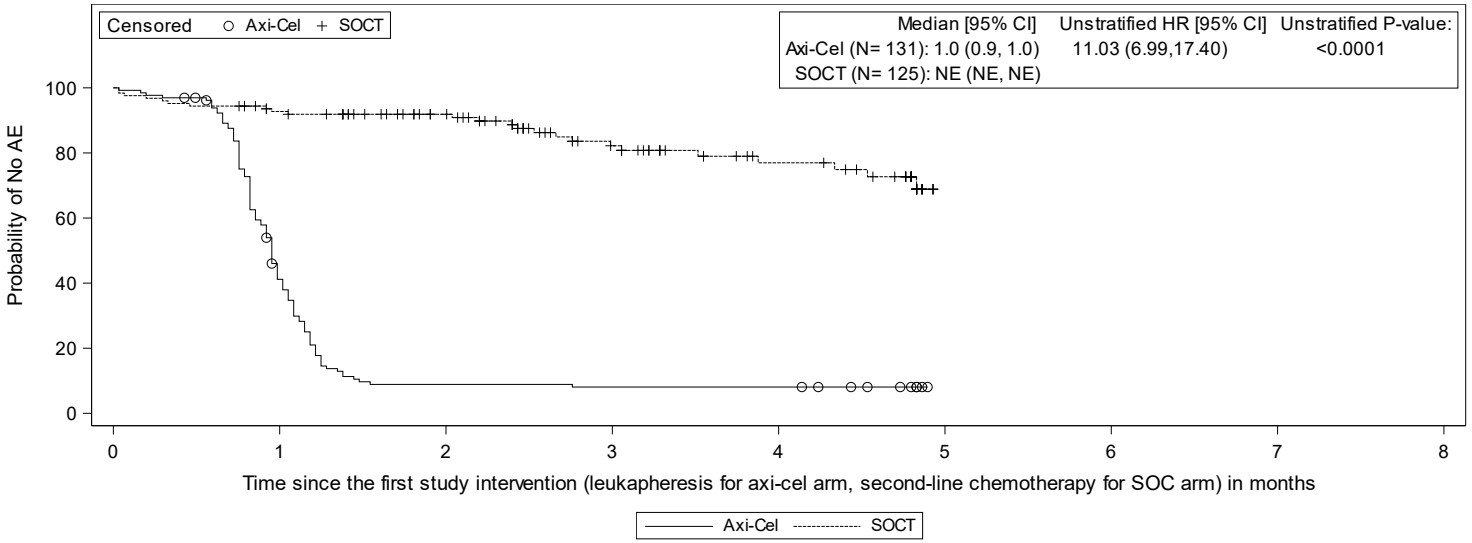
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.93. Kaplan-Meier Plot of Time To First Pyrexia by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Primary Refractory



Subjects at Risk

Axi-Cel	131	51	11	10	10	0
SOCT	125	110	91	58	38	0

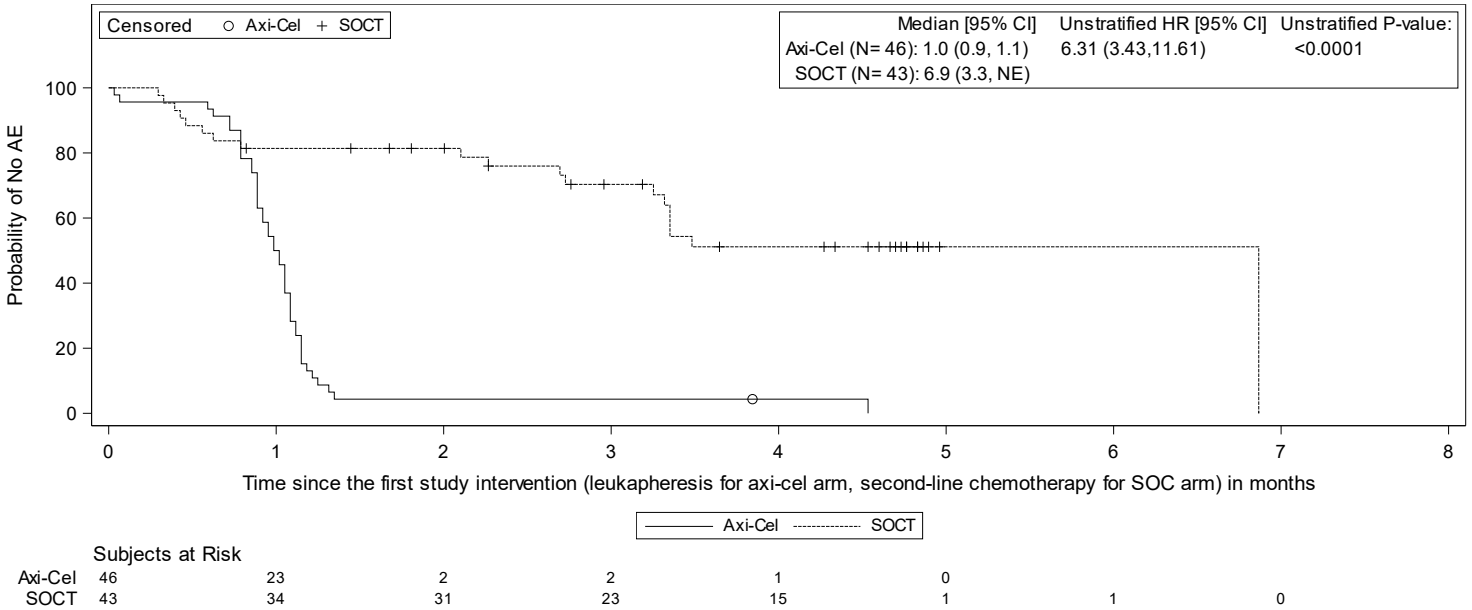
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE **Program Name: f_km_teae_sg.sas** **Output Generated: 20240412T11:20**

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.93. Kaplan-Meier Plot of Time To First Pyrexia by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

Relapse ≤ 12 months of the completion of the first line therapy



Subjects at Risk

Axi-Cel	46	23	2	2	1	0		
SOCT	43	34	31	23	15	1	1	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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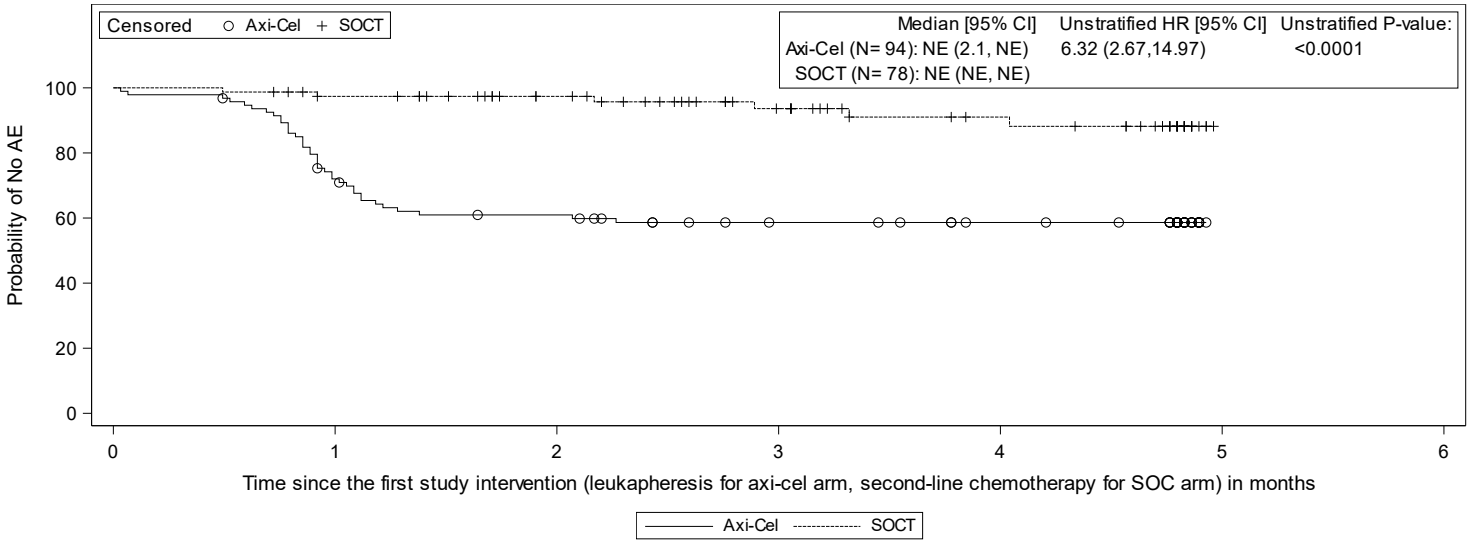
Figure 14.5.4.1.94. Kaplan-Meier Plot of Time To First Sinus tachycardia by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	66	54	44	39	0
SOCT	78	72	60	44	32	0

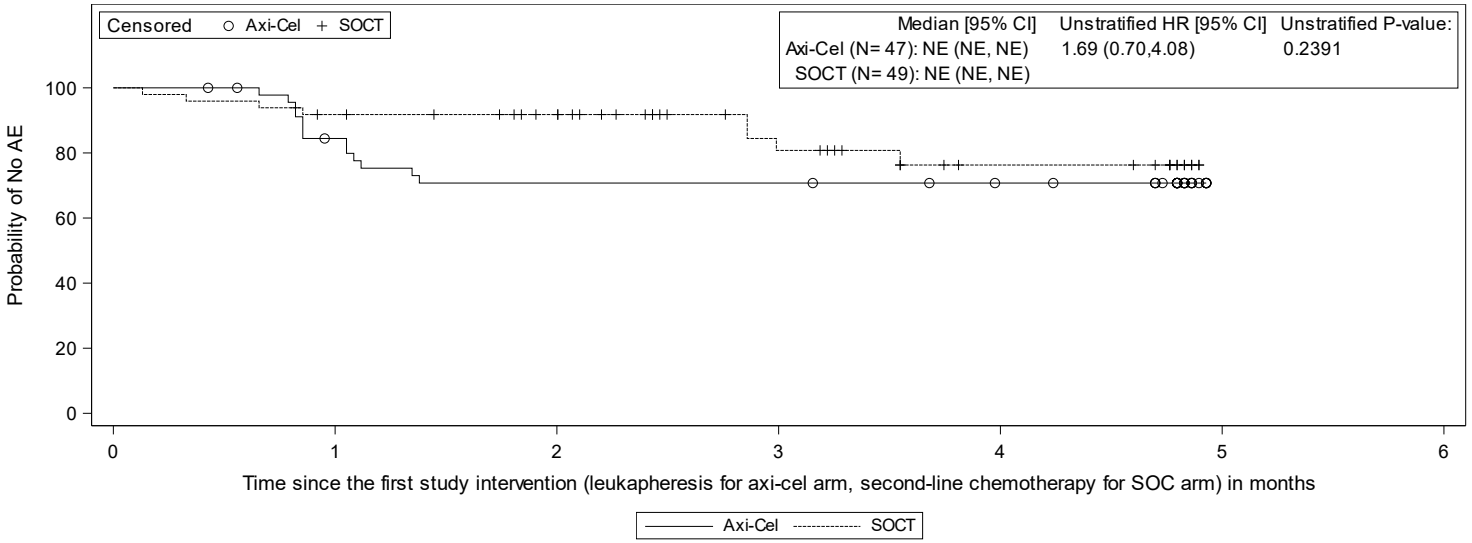
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.94. Kaplan-Meier Plot of Time To First Sinus tachycardia by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	37	31	31	28	0
SOCT	49	43	37	22	13	0

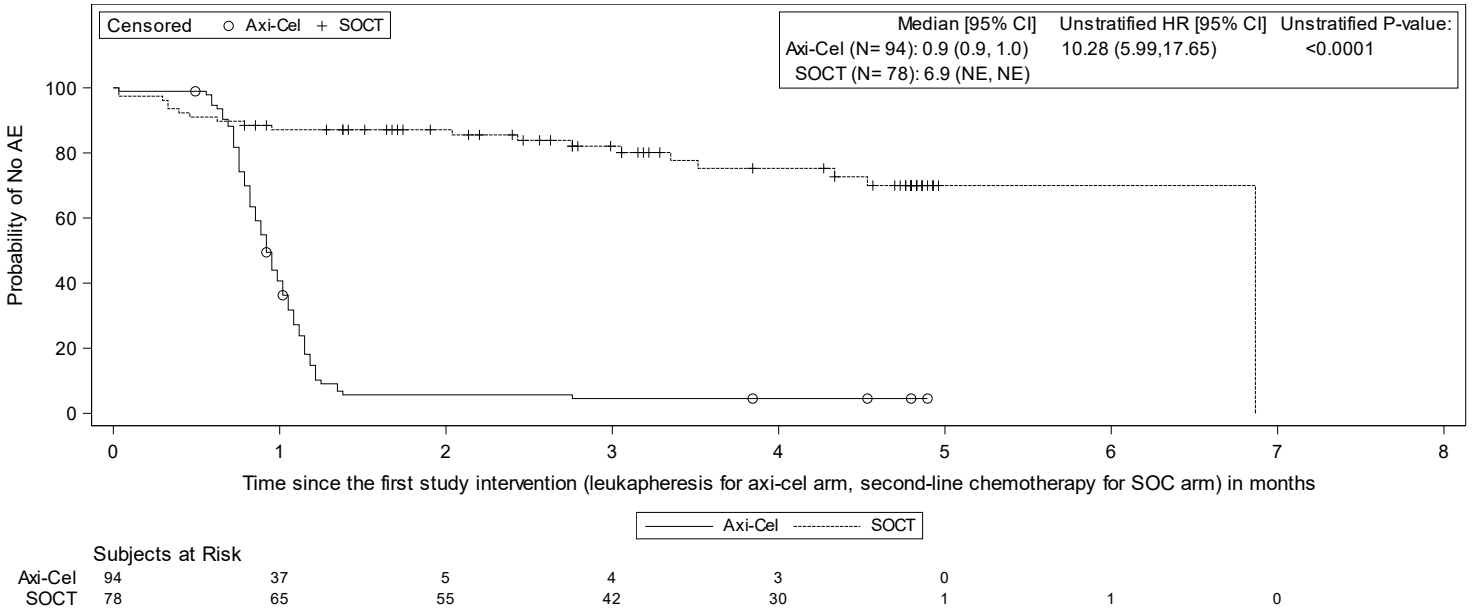
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.95. Kaplan-Meier Plot of Time To First Pyrexia by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	37	5	4	3	0		
SOCT	78	65	55	42	30	1	1	0

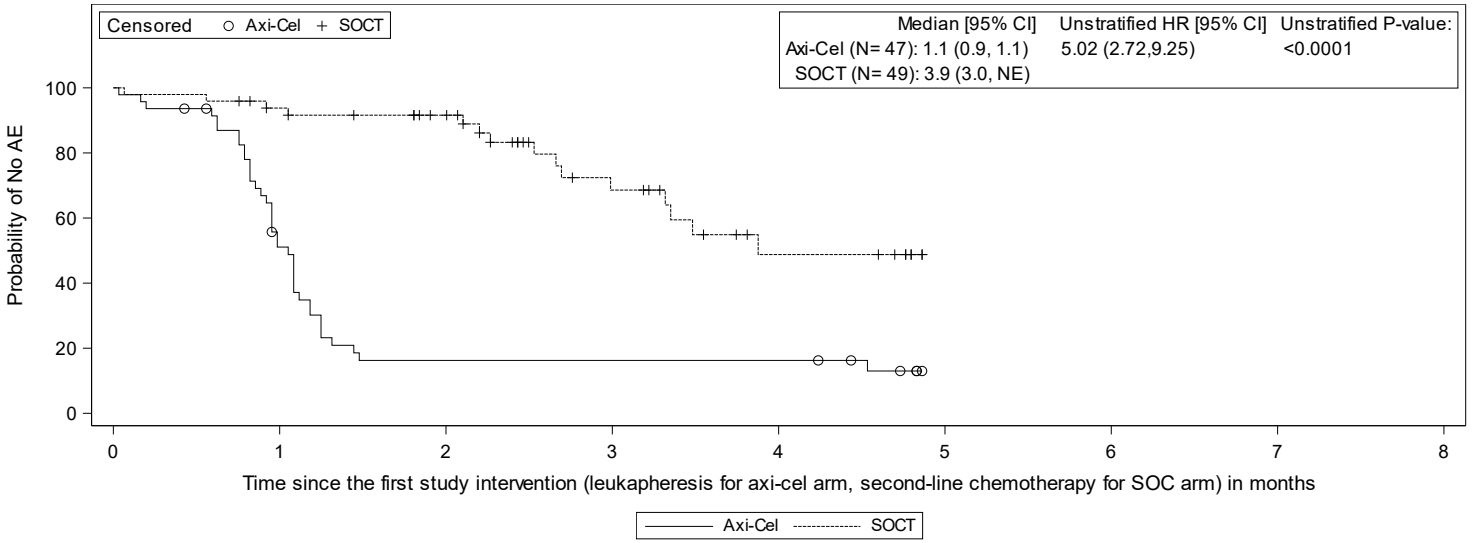
Page 1 of 64

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.95. Kaplan-Meier Plot of Time To First Pyrexia by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	22	7	7	7	0
SOCT	49	43	36	18	8	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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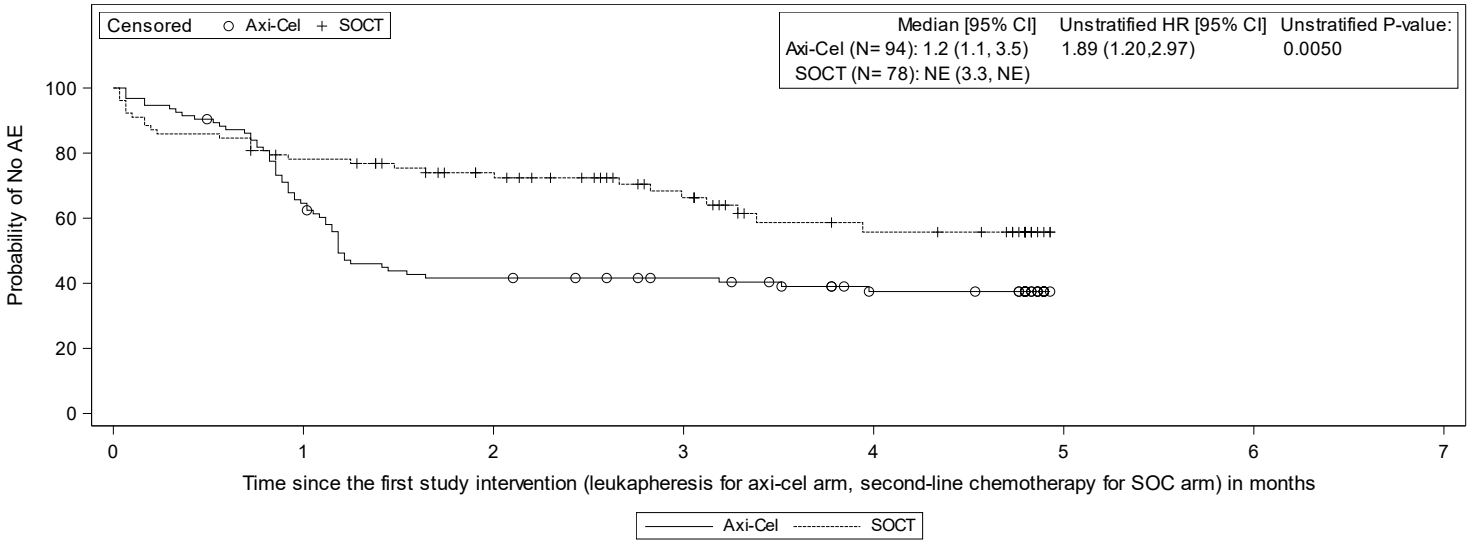
Figure 14.5.4.1.96. Kaplan-Meier Plot of Time To First Respiratory, thoracic and mediastinal disorders by molecular group per investigator (Modified Safety Analysis Set)

Germinal center B-cell like



Subjects at Risk

Axi-Cel	94	60	38	33	23	0
SOCT	78	59	47	32	19	0

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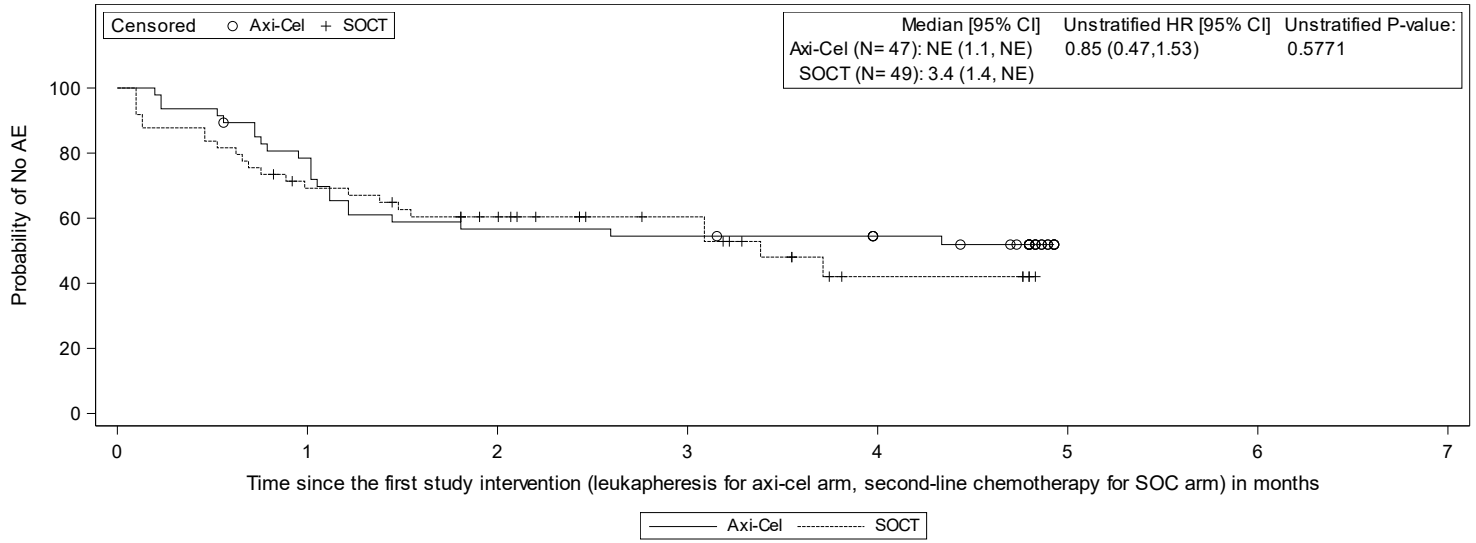
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Figure 14.5.4.1.96. Kaplan-Meier Plot of Time To First Respiratory, thoracic and mediastinal disorders by molecular group per investigator (Modified Safety Analysis Set)

Non-germinal center B-cell like



Subjects at Risk

Axi-Cel	47	36	26	25	21	0
SOCT	49	32	24	16	5	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Anhang 4-G3.6.4: Subgruppenanalyse häufiger schwerer UE nach SOC/PT (tabellarische Darstellung und Kaplan-Meier Plots für Subgruppenanalysen mit statistisch signifikantem Interaktionsterm) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-30 (Anhang): Ergebnisse der Subgruppenanalyse häufiger schwerer UE nach SOC/PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

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Table 14.3.1.1.3.1. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Age < 65	6/127 (5)	12.1 (12.1, NE)	34/113 (30)	NE (3.4, NE)	0.06 (0.02,0.16)	<0.0001	0.7131
	Age ≥ 65	1/51 (2)	28.3 (NE, NE)	12/55 (22)	7.2 (NE, NE)	0.00 (0.00,NE)	<0.0001	
Neutropenia	Age < 65	52/127 (41)	NE (1.4, NE)	15/113 (13)	NE (NE, NE)	3.45 (1.94,6.13)	<0.0001	0.2286
	Age ≥ 65	22/51 (43)	NE (1.2, NE)	13/55 (24)	NE (NE, NE)	1.85 (0.93,3.69)	0.0722	
Thrombocytopenia	Age < 65	6/127 (5)	NE (NE, NE)	27/113 (24)	NE (NE, NE)	0.15 (0.06,0.37)	<0.0001	0.0157
	Age ≥ 65	8/51 (16)	NE (NE, NE)	10/55 (18)	NE (NE, NE)	0.80 (0.32,2.04)	0.6432	
Gastrointestinal disorders	Age < 65	16/127 (13)	12.0 (NE, NE)	23/113 (20)	5.0 (NE, NE)	0.46 (0.24,0.89)	0.0180	0.4971
	Age ≥ 65	5/51 (10)	NE (NE, NE)	7/55 (13)	7.0 (NE, NE)	0.82 (0.25,2.68)	0.7362	
General disorders and administration site conditions	Age < 65	22/127 (17)	NE (NE, NE)	7/113 (6)	NE (NE, NE)	2.64 (1.13,6.20)	0.0202	0.4658
	Age ≥ 65	8/51 (16)	6.0 (NE, NE)	6/55 (11)	4.9 (4.9, NE)	1.48 (0.48,4.59)	0.4897	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.1. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Age < 65	11/127 (9)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	9.72 (1.25,75.39)	0.0074	0.9925
	Age ≥ 65	4/51 (8)	6.0 (NE, NE)	0/55 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Age < 65	6/127 (5)	NE (NE, NE)	35/113 (31)	NE (4.8, NE)	0.11 (0.04,0.26)	<0.0001	0.2796
	Age ≥ 65	7/51 (14)	NE (NE, NE)	25/55 (45)	3.5 (2.5, NE)	0.20 (0.09,0.47)	<0.0001	
Nervous system disorders	Age < 65	25/127 (20)	NE (NE, NE)	12/113 (11)	32.2 (NE, NE)	1.98 (0.97,4.02)	0.0545	0.1133
	Age ≥ 65	16/51 (31)	NE (NE, NE)	3/55 (5)	NE (NE, NE)	5.74 (1.67,19.77)	0.0017	
Psychiatric disorders	Age < 65	9/127 (7)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	7.76 (0.98,61.33)	0.0215	0.9365
	Age ≥ 65	9/51 (18)	27.6 (NE, NE)	1/55 (2)	NE (NE, NE)	8.86 (1.11,70.86)	0.0127	
Vascular disorders	Age < 65	21/127 (17)	35.7 (35.7, NE)	7/113 (6)	NE (NE, NE)	2.36 (0.99,5.62)	0.0450	0.9399
	Age ≥ 65	9/51 (18)	NE (NE, NE)	4/55 (7)	NE (NE, NE)	2.41 (0.74,7.84)	0.1308	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.1. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Age < 65	14/127 (11)	NE (NE, NE)	4/113 (4)	NE (NE, NE)	3.04 (1.00,9.24)	0.0395	0.4504
	Age ≥ 65	7/51 (14)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	7.45 (0.91,60.70)	0.0272	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.2. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Male	3/109 (3)	12.1 (NE, NE)	28/120 (23)	NE (4.5, NE)	0.04 (0.01,0.18)	<0.0001	0.6097
	Female	4/69 (6)	28.3 (4.9, NE)	18/48 (38)	7.2 (3.4, NE)	0.05 (0.01,0.21)	<0.0001	
Neutropenia	Male	39/109 (36)	NE (NE, NE)	16/120 (13)	NE (NE, NE)	2.75 (1.53,4.92)	0.0004	0.7818
	Female	35/69 (51)	1.8 (1.1, NE)	12/48 (25)	NE (NE, NE)	2.48 (1.29,4.80)	0.0048	
Thrombocytopenia	Male	8/109 (7)	NE (NE, NE)	28/120 (23)	NE (NE, NE)	0.24 (0.11,0.53)	0.0001	0.4194
	Female	6/69 (9)	NE (NE, NE)	9/48 (19)	NE (NE, NE)	0.44 (0.16,1.23)	0.1077	
Gastrointestinal disorders	Male	10/109 (9)	12.0 (NE, NE)	20/120 (17)	5.0 (NE, NE)	0.36 (0.16,0.79)	0.0084	0.2599
	Female	11/69 (16)	NE (NE, NE)	10/48 (21)	7.0 (NE, NE)	0.80 (0.33,1.93)	0.6208	
General disorders and administration site conditions	Male	17/109 (16)	NE (NE, NE)	7/120 (6)	NE (4.9, NE)	2.32 (0.96,5.62)	0.0552	0.7094
	Female	13/69 (19)	6.0 (NE, NE)	6/48 (13)	7.1 (NE, NE)	1.85 (0.66,5.19)	0.2371	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.2. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Male	9/109 (8)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	9.54 (1.21,75.40)	0.0088	0.9927
	Female	6/69 (9)	6.0 (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Male	9/109 (8)	NE (NE, NE)	40/120 (33)	NE (3.4, NE)	0.16 (0.08,0.33)	<0.0001	0.3938
	Female	4/69 (6)	NE (NE, NE)	20/48 (42)	NE (2.3, NE)	0.11 (0.04,0.31)	<0.0001	
Nervous system disorders	Male	22/109 (20)	NE (NE, NE)	9/120 (8)	32.2 (NE, NE)	2.86 (1.27,6.44)	0.0078	0.6916
	Female	19/69 (28)	NE (NE, NE)	6/48 (13)	NE (NE, NE)	2.22 (0.88,5.56)	0.0809	
Psychiatric disorders	Male	13/109 (12)	NE (NE, NE)	1/120 (1)	NE (NE, NE)	14.26 (1.86,109.01)	0.0007	0.2905
	Female	5/69 (7)	27.6 (NE, NE)	1/48 (2)	NE (NE, NE)	2.67 (0.30,23.95)	0.3609	
Vascular disorders	Male	16/109 (15)	35.7 (35.7, NE)	8/120 (7)	NE (NE, NE)	1.74 (0.73,4.17)	0.2052	0.3987
	Female	14/69 (20)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	3.53 (1.01,12.27)	0.0340	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.2. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Male	11/109 (10)	NE (NE, NE)	4/120 (3)	NE (NE, NE)	2.72 (0.86,8.58)	0.0757	0.4287
	Female	10/69 (14)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	7.50 (0.96,58.60)	0.0233	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.3. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	White	5/144 (3)	28.3 (28.3, NE)	40/145 (28)	7.2 (4.1, NE)	0.04 (0.01,0.14)	<0.0001	0.3475
	Other	2/34 (6)	12.1 (4.9, NE)	6/23 (26)	NE (2.8, NE)	0.06 (0.01,0.49)	0.0004	
Neutropenia	White	60/144 (42)	NE (1.9, NE)	23/145 (16)	NE (NE, NE)	2.85 (1.76,4.61)	<0.0001	0.5642
	Other	14/34 (41)	NE (1.1, NE)	5/23 (22)	NE (2.6, NE)	2.02 (0.73,5.63)	0.1666	
Thrombocytopenia	White	12/144 (8)	NE (NE, NE)	34/145 (23)	NE (NE, NE)	0.29 (0.15,0.56)	<0.0001	0.8164
	Other	2/34 (6)	NE (NE, NE)	3/23 (13)	NE (NE, NE)	0.41 (0.07,2.47)	0.3164	
Gastrointestinal disorders	White	19/144 (13)	NE (NE, NE)	25/145 (17)	5.0 (5.0, NE)	0.69 (0.37,1.27)	0.2303	0.0723
	Other	2/34 (6)	12.0 (NE, NE)	5/23 (22)	NE (2.7, NE)	0.11 (0.01,0.96)	0.0156	
General disorders and administration site conditions	White	20/144 (14)	6.0 (NE, NE)	12/145 (8)	7.1 (4.9, NE)	1.66 (0.79,3.48)	0.1751	0.2183
	Other	10/34 (29)	NE (NE, NE)	1/23 (4)	NE (NE, NE)	6.42 (0.82,50.25)	0.0414	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.3. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	White	13/144 (9)	6.0 (NE, NE)	1/145 (1)	NE (NE, NE)	12.00 (1.56,92.36)	0.0023	0.9927
	Other	2/34 (6)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	White	11/144 (8)	NE (NE, NE)	50/145 (34)	NE (3.4, NE)	0.15 (0.08,0.30)	<0.0001	0.5918
	Other	2/34 (6)	NE (NE, NE)	10/23 (43)	3.7 (2.5, NE)	0.09 (0.02,0.42)	0.0001	
Nervous system disorders	White	33/144 (23)	NE (NE, NE)	11/145 (8)	NE (NE, NE)	2.97 (1.50,5.88)	0.0011	0.4376
	Other	8/34 (24)	NE (NE, NE)	4/23 (17)	32.2 (NE, NE)	1.70 (0.45,6.40)	0.4292	
Psychiatric disorders	White	13/144 (9)	27.6 (NE, NE)	2/145 (1)	NE (NE, NE)	5.82 (1.30,26.04)	0.0090	0.9911
	Other	5/34 (15)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	White	22/144 (15)	53.1 (NE, NE)	10/145 (7)	NE (NE, NE)	2.04 (0.96,4.35)	0.0574	0.4376
	Other	8/34 (24)	35.7 (NE, NE)	1/23 (4)	NE (NE, NE)	4.83 (0.59,39.26)	0.1024	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.3. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	White	16/144 (11)	NE (NE, NE)	5/145 (3)	NE (NE, NE)	3.10 (1.13,8.48)	0.0201	0.9882
	Other	5/34 (15)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.4. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0	5/95 (5)	28.3 (28.3, NE)	25/94 (27)	7.2 (4.1, NE)	0.07 (0.02,0.25)	<0.0001	0.5698
	1	2/83 (2)	12.1 (4.9, NE)	21/74 (28)	NE (3.3, NE)	0.02 (0.00,0.16)	<0.0001	
Neutropenia	0	43/95 (45)	NE (1.2, NE)	19/94 (20)	NE (NE, NE)	2.47 (1.44,4.24)	0.0007	0.5291
	1	31/83 (37)	NE (3.2, NE)	9/74 (12)	NE (NE, NE)	3.29 (1.56,6.91)	0.0008	
Thrombocytopenia	0	8/95 (8)	NE (NE, NE)	23/94 (24)	NE (NE, NE)	0.29 (0.13,0.65)	0.0013	0.9525
	1	6/83 (7)	NE (NE, NE)	14/74 (19)	NE (NE, NE)	0.32 (0.12,0.83)	0.0132	
Gastrointestinal disorders	0	8/95 (8)	NE (NE, NE)	13/94 (14)	7.0 (NE, NE)	0.57 (0.23,1.39)	0.2083	0.6653
	1	13/83 (16)	12.0 (NE, NE)	17/74 (23)	5.0 (NE, NE)	0.49 (0.23,1.04)	0.0593	
General disorders and administration site conditions	0	12/95 (13)	NE (NE, NE)	10/94 (11)	7.1 (4.9, NE)	1.20 (0.50,2.86)	0.6795	0.0955
	1	18/83 (22)	6.0 (NE, NE)	3/74 (4)	NE (NE, NE)	4.75 (1.39,16.29)	0.0061	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.4. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	0	5/95 (5)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	4.75 (0.55,40.74)	0.1167	0.9914
	1	10/83 (12)	6.0 (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	0	2/95 (2)	NE (NE, NE)	34/94 (36)	NE (3.3, NE)	0.04 (0.01,0.16)	<0.0001	0.0219
	1	11/83 (13)	NE (NE, NE)	26/74 (35)	NE (3.1, NE)	0.28 (0.13,0.56)	0.0002	
Nervous system disorders	0	18/95 (19)	NE (NE, NE)	12/94 (13)	32.2 (NE, NE)	1.52 (0.72,3.22)	0.2716	0.0392
	1	23/83 (28)	NE (NE, NE)	3/74 (4)	NE (NE, NE)	7.23 (2.17,24.12)	0.0002	
Psychiatric disorders	0	5/95 (5)	NE (NE, NE)	2/94 (2)	NE (NE, NE)	2.30 (0.45,11.90)	0.3057	0.9902
	1	13/83 (16)	27.6 (NE, NE)	0/74 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	0	13/95 (14)	NE (NE, NE)	5/94 (5)	NE (NE, NE)	2.54 (0.90,7.12)	0.0671	0.7593
	1	17/83 (20)	35.7 (35.7, NE)	6/74 (8)	NE (NE, NE)	2.20 (0.85,5.67)	0.0934	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.4. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0	10/95 (11)	NE (NE, NE)	3/94 (3)	NE (NE, NE)	3.19 (0.88,11.60)	0.0627	0.7242
	1	11/83 (13)	NE (NE, NE)	2/74 (3)	NE (NE, NE)	5.02 (1.11,22.66)	0.0194	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.5. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	North America	5/138 (4)	28.3 (12.1, NE)	34/120 (28)	NE (3.7, NE)	0.03 (0.01,0.11)	<0.0001	0.1386
	Rest of the world	2/40 (5)	NE (NE, NE)	12/48 (25)	7.2 (NE, NE)	0.15 (0.03,0.69)	0.0049	
Neutropenia	North America	56/138 (41)	NE (3.1, NE)	22/120 (18)	NE (NE, NE)	2.44 (1.49,3.99)	0.0002	0.5430
	Rest of the world	18/40 (45)	NE (1.4, NE)	6/48 (13)	NE (NE, NE)	3.72 (1.48,9.38)	0.0028	
Thrombocytopenia	North America	12/138 (9)	NE (NE, NE)	24/120 (20)	NE (NE, NE)	0.37 (0.18,0.74)	0.0033	0.2567
	Rest of the world	2/40 (5)	NE (NE, NE)	13/48 (27)	NE (NE, NE)	0.14 (0.03,0.64)	0.0030	
Gastrointestinal disorders	North America	15/138 (11)	12.0 (NE, NE)	20/120 (17)	NE (NE, NE)	0.52 (0.26,1.04)	0.0602	0.5619
	Rest of the world	6/40 (15)	NE (NE, NE)	10/48 (21)	5.0 (5.0, NE)	0.72 (0.25,2.07)	0.5341	
General disorders and administration site conditions	North America	24/138 (17)	6.0 (NE, NE)	6/120 (5)	NE (NE, NE)	3.25 (1.32,8.01)	0.0066	0.1446
	Rest of the world	6/40 (15)	NE (NE, NE)	7/48 (15)	4.9 (4.9, NE)	0.97 (0.31,3.01)	0.9532	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.5. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	North America	12/138 (9)	6.0 (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9920
	Rest of the world	3/40 (8)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	3.23 (0.33,31.16)	0.2837	
Investigations								
Platelet count decreased	North America	12/138 (9)	NE (NE, NE)	43/120 (36)	NE (3.3, NE)	0.17 (0.09,0.32)	<0.0001	0.2216
	Rest of the world	1/40 (3)	NE (NE, NE)	17/48 (35)	NE (2.8, NE)	0.05 (0.01,0.38)	<0.0001	
Nervous system disorders	North America	33/138 (24)	NE (NE, NE)	12/120 (10)	32.2 (NE, NE)	2.56 (1.29,5.08)	0.0051	0.8654
	Rest of the world	8/40 (20)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	3.12 (0.83,11.75)	0.0766	
Psychiatric disorders	North America	15/138 (11)	27.6 (NE, NE)	1/120 (1)	NE (NE, NE)	12.51 (1.64,95.13)	0.0017	0.4045
	Rest of the world	3/40 (8)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	3.14 (0.33,30.30)	0.2970	
Vascular disorders	North America	22/138 (16)	35.7 (35.7, NE)	8/120 (7)	NE (NE, NE)	2.15 (0.95,4.90)	0.0606	0.6816
	Rest of the world	8/40 (20)	NE (NE, NE)	3/48 (6)	NE (NE, NE)	3.02 (0.80,11.40)	0.0853	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.5. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	North America	15/138 (11)	NE (NE, NE)	4/120 (3)	NE (NE, NE)	3.24 (1.07,9.80)	0.0270	0.5476
	Rest of the world	6/40 (15)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	6.79 (0.82,56.47)	0.0394	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.6. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	HGBL - double hit/triple hit	2/32 (6)	NE (4.9, NE)	5/24 (21)	NE (3.3, NE)	0.17 (0.03,0.92)	0.0215	0.2826
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	16/62 (26)	NE (3.4, NE)	0.04 (0.01,0.30)	<0.0001	
Neutropenia	HGBL - double hit/triple hit	13/32 (41)	NE (1.0, NE)	4/24 (17)	NE (3.0, NE)	2.71 (0.88,8.32)	0.0685	0.7864
	Double expressor lymphoma	21/56 (38)	NE (1.9, NE)	7/62 (11)	NE (NE, NE)	3.59 (1.53,8.46)	0.0017	
Thrombocytopenia	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	5/24 (21)	NE (3.1, NE)	0.40 (0.09,1.67)	0.1917	0.9777
	Double expressor lymphoma	4/56 (7)	NE (NE, NE)	10/62 (16)	NE (NE, NE)	0.38 (0.12,1.21)	0.0871	
Gastrointestinal disorders	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	5/24 (21)	NE (3.2, NE)	0.31 (0.07,1.34)	0.0989	0.5090
	Double expressor lymphoma	7/56 (13)	NE (NE, NE)	11/62 (18)	5.0 (NE, NE)	0.67 (0.26,1.78)	0.4211	
General disorders and administration site conditions	HGBL - double hit/triple hit	6/32 (19)	NE (NE, NE)	2/24 (8)	NE (3.9, NE)	1.77 (0.35,8.95)	0.4818	0.8146
	Double expressor lymphoma	9/56 (16)	6.0 (NE, NE)	3/62 (5)	NE (4.9, NE)	2.83 (0.75,10.67)	0.1085	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.6. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/56 (9)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	HGBL - double hit/triple hit	2/32 (6)	NE (NE, NE)	6/24 (25)	NE (NE, NE)	0.19 (0.04,0.97)	0.0254	0.8993
	Double expressor lymphoma	5/56 (9)	NE (NE, NE)	26/62 (42)	4.8 (2.8, NE)	0.14 (0.05,0.37)	<0.0001	
Nervous system disorders	HGBL - double hit/triple hit	9/32 (28)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9878
	Double expressor lymphoma	12/56 (21)	NE (NE, NE)	8/62 (13)	32.2 (NE, NE)	1.80 (0.71,4.57)	0.2116	
Psychiatric disorders	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/56 (9)	NE (NE, NE)	0/62 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	4/24 (17)	NE (3.3, NE)	0.44 (0.10,2.02)	0.2802	0.1064
	Double expressor lymphoma	8/56 (14)	NE (NE, NE)	3/62 (5)	NE (NE, NE)	2.92 (0.78,11.02)	0.0955	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.6. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	HGBL - double hit/triple hit	2/32 (6)	NE (NE, NE)	3/24 (13)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	6/56 (11)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.7. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	HGBL - double hit/triple hit	2/40 (5)	NE (4.9, NE)	9/31 (29)	7.2 (3.3, NE)	0.11 (0.02,0.54)	0.0012	0.4318
	Double expressor lymphoma	1/44 (2)	NE (NE, NE)	10/33 (30)	NE (3.1, NE)	0.04 (0.01,0.33)	<0.0001	
Neutropenia	HGBL - double hit/triple hit	16/40 (40)	NE (1.0, NE)	5/31 (16)	NE (NE, NE)	2.71 (0.99,7.40)	0.0422	0.8449
	Double expressor lymphoma	21/44 (48)	3.2 (1.0, NE)	7/33 (21)	NE (NE, NE)	2.48 (1.05,5.84)	0.0310	
Thrombocytopenia	HGBL - double hit/triple hit	3/40 (8)	NE (NE, NE)	9/31 (29)	NE (3.1, NE)	0.20 (0.05,0.74)	0.0077	0.5533
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	9/33 (27)	NE (3.1, NE)	0.36 (0.12,1.07)	0.0541	
Gastrointestinal disorders	HGBL - double hit/triple hit	3/40 (8)	NE (NE, NE)	8/31 (26)	7.0 (3.3, NE)	0.24 (0.06,0.95)	0.0277	0.0578
	Double expressor lymphoma	8/44 (18)	NE (NE, NE)	3/33 (9)	NE (NE, NE)	1.88 (0.50,7.10)	0.3438	
General disorders and administration site conditions	HGBL - double hit/triple hit	6/40 (15)	NE (NE, NE)	5/31 (16)	7.1 (4.1, NE)	0.90 (0.25,3.24)	0.8697	0.2366
	Double expressor lymphoma	8/44 (18)	6.0 (NE, NE)	1/33 (3)	NE (NE, NE)	5.30 (0.65,43.16)	0.0802	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.7. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	4/44 (9)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	HGBL - double hit/triple hit	2/40 (5)	NE (NE, NE)	10/31 (32)	NE (2.0, NE)	0.11 (0.02,0.53)	0.0009	0.5400
	Double expressor lymphoma	4/44 (9)	NE (NE, NE)	12/33 (36)	3.4 (3.1, NE)	0.15 (0.05,0.47)	0.0002	
Nervous system disorders	HGBL - double hit/triple hit	10/40 (25)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9908
	Double expressor lymphoma	13/44 (30)	NE (NE, NE)	5/33 (15)	32.2 (NE, NE)	2.31 (0.75,7.11)	0.1332	
Psychiatric disorders	HGBL - double hit/triple hit	5/40 (13)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	5/44 (11)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	4/40 (10)	35.7 (NE, NE)	5/31 (16)	NE (4.0, NE)	0.38 (0.09,1.62)	0.1754	0.0253
	Double expressor lymphoma	10/44 (23)	NE (NE, NE)	1/33 (3)	NE (NE, NE)	7.95 (1.02,62.13)	0.0186	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.7. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	HGBL - double hit/triple hit	2/40 (5)	NE (NE, NE)	3/31 (10)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	9/44 (20)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.8. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Germinal center B-cell like	5/107 (5)	28.3 (28.3, NE)	28/100 (28)	NE (4.1, NE)	0.06 (0.02,0.19)	<0.0001	0.6369
	Activated B-cell like	1/16 (6)	NE (NE, NE)	1/9 (11)	NE (3.1, NE)	0.18 (0.01,2.93)	0.1766	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Neutropenia	Germinal center B-cell like	46/107 (43)	NE (1.2, NE)	16/100 (16)	NE (NE, NE)	2.95 (1.67,5.22)	<0.0001	0.9998
	Activated B-cell like	5/16 (31)	NE (1.1, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Thrombocytopenia	Germinal center B-cell like	11/107 (10)	NE (NE, NE)	24/100 (24)	NE (NE, NE)	0.37 (0.18,0.75)	0.0040	0.7486
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE, NE)	3/12 (25)	NE (0.5, NE)	0.20 (0.02,1.88)	0.1159	
Gastrointestinal disorders	Germinal center B-cell like	8/107 (7)	NE (NE, NE)	18/100 (18)	5.0 (NE, NE)	0.36 (0.15,0.83)	0.0130	0.4296

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240602T17:46

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Table 14.3.1.1.3.8. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Gastrointestinal disorders	Activated B-cell like	4/16 (25)	NE (4.3, NE)	1/9 (11)	NE (2.7, NE)	1.74 (0.19,16.00)	0.6160	
	Unclassified	2/18 (11)	NE (NE, NE)	2/12 (17)	NE (1.5, NE)	0.51 (0.07,3.73)	0.4993	
General disorders and administration site conditions	Germinal center B-cell like	13/107 (12)	NE (NE, NE)	8/100 (8)	NE (4.9, NE)	1.44 (0.60,3.49)	0.4110	0.9999
	Activated B-cell like	3/16 (19)	NE (1.2, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	8/18 (44)	6.0 (1.2, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Germinal center B-cell like	5/107 (5)	NE (NE, NE)	0/100 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Activated B-cell like	3/16 (19)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Germinal center B-cell like	7/107 (7)	NE (NE, NE)	37/100 (37)	NE (3.4, NE)	0.13 (0.06,0.29)	<0.0001	0.8151
	Activated B-cell like	3/16 (19)	NE (3.5, NE)	5/9 (56)	3.1 (0.3, NE)	0.16 (0.03,0.75)	0.0098	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240602T17:46

Table 14.3.1.1.3.8. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Platelet count decreased	Unclassified	1/18 (6)	NE (NE, NE)	3/12 (25)	NE (0.5, NE)	0.15 (0.02,1.54)	0.0711	
Nervous system disorders	Germinal center B-cell like	28/107 (26)	NE (NE, NE)	8/100 (8)	NE (NE, NE)	3.33 (1.52,7.31)	0.0014	0.2294
	Activated B-cell like	2/16 (13)	NE (NE, NE)	2/9 (22)	NE (2.2, NE)	0.45 (0.06,3.26)	0.4159	
	Unclassified	3/18 (17)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	Germinal center B-cell like	13/107 (12)	NE (NE, NE)	2/100 (2)	NE (NE, NE)	6.10 (1.37,27.04)	0.0066	1.0000
	Activated B-cell like	0/16 (0)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	27.6 (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Germinal center B-cell like	17/107 (16)	35.7 (NE, NE)	6/100 (6)	NE (NE, NE)	2.44 (0.96,6.25)	0.0536	0.9999
	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	7/18 (39)	53.1 (1.3, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	Germinal center B-cell like	10/107 (9)	NE (NE, NE)	3/100 (3)	NE (NE, NE)	3.00 (0.82,10.91)	0.0800	0.9999

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240602T17:46

Table 14.3.1.1.3.8. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Activated B-cell like	2/16 (13)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	6/18 (33)	NE (1.3, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240602T17:46

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.9. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Germinal center B-cell like	4/94 (4)	48.8 (4.9, NE)	24/78 (31)	7.2 (3.3, NE)	0.06 (0.02,0.19)	<0.0001	0.7650
	Non-germinal center B-cell like	2/47 (4)	12.1 (NE, NE)	11/49 (22)	NE (NE, NE)	0.06 (0.01,0.47)	0.0004	
Neutropenia	Germinal center B-cell like	39/94 (41)	NE (1.2, NE)	13/78 (17)	NE (NE, NE)	2.71 (1.44,5.07)	0.0012	0.9466
	Non-germinal center B-cell like	18/47 (38)	NE (1.4, NE)	7/49 (14)	NE (NE, NE)	2.83 (1.18,6.78)	0.0146	
Thrombocytopenia	Germinal center B-cell like	7/94 (7)	NE (NE, NE)	19/78 (24)	NE (NE, NE)	0.24 (0.10,0.58)	0.0006	0.4729
	Non-germinal center B-cell like	4/47 (9)	NE (NE, NE)	8/49 (16)	NE (NE, NE)	0.46 (0.14,1.53)	0.1918	
Gastrointestinal disorders	Germinal center B-cell like	11/94 (12)	NE (NE, NE)	14/78 (18)	5.0 (5.0, NE)	0.61 (0.27,1.40)	0.2411	0.6502
	Non-germinal center B-cell like	4/47 (9)	12.0 (NE, NE)	5/49 (10)	NE (NE, NE)	0.54 (0.13,2.27)	0.3927	
General disorders and administration site conditions	Germinal center B-cell like	14/94 (15)	NE (NE, NE)	9/78 (12)	7.1 (NE, NE)	1.28 (0.54,3.07)	0.5749	0.1648
	Non-germinal center B-cell like	7/47 (15)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	7.52 (0.92,61.10)	0.0260	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.9. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Germinal center B-cell like	4/94 (4)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Non-germinal center B-cell like	5/47 (11)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Germinal center B-cell like	5/94 (5)	NE (NE, NE)	24/78 (31)	NE (4.8, NE)	0.13 (0.05,0.34)	<0.0001	0.8386
	Non-germinal center B-cell like	3/47 (6)	NE (NE, NE)	19/49 (39)	3.4 (2.8, NE)	0.08 (0.02,0.29)	<0.0001	
Nervous system disorders	Germinal center B-cell like	24/94 (26)	NE (NE, NE)	6/78 (8)	NE (NE, NE)	3.33 (1.36,8.15)	0.0051	0.0582
	Non-germinal center B-cell like	5/47 (11)	NE (NE, NE)	6/49 (12)	NE (4.8, NE)	0.66 (0.20,2.19)	0.4886	
Psychiatric disorders	Germinal center B-cell like	11/94 (12)	NE (NE, NE)	1/78 (1)	NE (NE, NE)	9.17 (1.18,71.04)	0.0097	0.3411
	Non-germinal center B-cell like	2/47 (4)	NE (NE, NE)	1/49 (2)	NE (NE, NE)	1.74 (0.15,19.55)	0.6505	
Vascular disorders	Germinal center B-cell like	12/94 (13)	35.7 (NE, NE)	5/78 (6)	NE (NE, NE)	1.73 (0.60,5.00)	0.3024	0.7378
	Non-germinal center B-cell like	11/47 (23)	53.1 (NE, NE)	4/49 (8)	NE (NE, NE)	2.61 (0.82,8.35)	0.0905	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.9. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Germinal center B-cell like	8/94 (9)	NE (NE, NE)	2/78 (3)	NE (NE, NE)	3.12 (0.66,14.72)	0.1299	0.8254
	Non-germinal center B-cell like	8/47 (17)	NE (NE, NE)	2/49 (4)	NE (NE, NE)	4.18 (0.89,19.74)	0.0487	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.10. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Diffuse large B-cell lymphoma	4/125 (3)	28.3 (28.3, NE)	34/119 (29)	7.2 (3.7, NE)	0.03 (0.01,0.13)	<0.0001	0.1475
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (4.9, NE)	6/25 (24)	NE (3.3, NE)	0.14 (0.03,0.73)	0.0075	
Neutropenia	Diffuse large B-cell lymphoma	50/125 (40)	NE (3.2, NE)	18/119 (15)	NE (NE, NE)	2.83 (1.65,4.86)	<0.0001	0.7116
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/32 (41)	NE (1.0, NE)	5/25 (20)	NE (3.0, NE)	2.15 (0.77,6.06)	0.1333	
Thrombocytopenia	Diffuse large B-cell lymphoma	10/125 (8)	NE (NE, NE)	27/119 (23)	NE (NE, NE)	0.29 (0.14,0.59)	0.0003	0.9118
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	6/25 (24)	NE (3.1, NE)	0.34 (0.08,1.37)	0.1090	
Gastrointestinal disorders	Diffuse large B-cell lymphoma	16/125 (13)	NE (NE, NE)	22/119 (18)	5.0 (5.0, NE)	0.64 (0.33,1.24)	0.1797	0.5853
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	5/25 (20)	NE (3.2, NE)	0.34 (0.08,1.44)	0.1252	
General disorders and administration site conditions	Diffuse large B-cell lymphoma	20/125 (16)	6.0 (NE, NE)	9/119 (8)	7.1 (4.9, NE)	2.30 (1.01,5.24)	0.0402	0.9608
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/32 (19)	NE (NE, NE)	2/25 (8)	NE (3.9, NE)	1.90 (0.38,9.53)	0.4305	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.10. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Diffuse large B-cell lymphoma	12/125 (10)	6.0 (NE, NE)	0/119 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Diffuse large B-cell lymphoma	9/125 (7)	NE (NE, NE)	45/119 (38)	NE (3.3, NE)	0.13 (0.06,0.27)	<0.0001	0.7362
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (NE, NE)	6/25 (24)	NE (NE, NE)	0.20 (0.04,1.03)	0.0323	
Nervous system disorders	Diffuse large B-cell lymphoma	28/125 (22)	NE (NE, NE)	14/119 (12)	32.2 (NE, NE)	1.94 (1.00,3.75)	0.0444	0.9869
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Psychiatric disorders	Diffuse large B-cell lymphoma	13/125 (10)	27.6 (NE, NE)	2/119 (2)	NE (NE, NE)	5.45 (1.22,24.37)	0.0125	0.9932
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Diffuse large B-cell lymphoma	24/125 (19)	35.7 (35.7, NE)	4/119 (3)	NE (NE, NE)	5.36 (1.85,15.56)	0.0005	0.0074
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	5/25 (20)	NE (3.3, NE)	0.37 (0.09,1.56)	0.1573	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.10. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Diffuse large B-cell lymphoma	16/125 (13)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	15.53 (2.06,117.06)	0.0003	0.0147
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/32 (6)	NE (NE, NE)	3/25 (12)	NE (4.0, NE)	0.40 (0.07,2.46)	0.3082	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.11. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	28.3 (12.1, NE)	24/110 (22)	NE (NE, NE)	0.05 (0.01,0.21)	<0.0001	0.9343
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	10/25 (40)	4.1 (2.9, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (4.9, NE)	8/25 (32)	7.2 (3.1, NE)	0.10 (0.02,0.51)	0.0007	
	Other	0/8 (0)	NE (NE, NE)	4/8 (50)	3.3 (0.3, NE)	NE (NE,NE)	NE	
Neutropenia	Diffuse large B-cell lymphoma not otherwise specified	43/108 (40)	NE (3.1, NE)	19/110 (17)	NE (NE, NE)	2.44 (1.42,4.19)	0.0008	0.8922
	Large cell transformation from follicular lymphoma	9/19 (47)	NE (1.1, NE)	3/25 (12)	NE (NE, NE)	4.40 (1.19,16.32)	0.0148	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	17/43 (40)	NE (1.0, NE)	4/25 (16)	NE (NE, NE)	2.75 (0.93,8.20)	0.0561	
	Other	5/8 (63)	1.1 (0.0, NE)	2/8 (25)	NE (0.6, NE)	2.82 (0.54,14.58)	0.1976	
Thrombocytopenia	Diffuse large B-cell lymphoma not otherwise specified	10/108 (9)	NE (NE, NE)	19/110 (17)	NE (NE, NE)	0.47 (0.22,1.02)	0.0495	0.4611
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	10/25 (40)	NE (1.9, NE)	0.10 (0.01,0.77)	0.0062	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.11. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Thrombocytopenia	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE, NE)	7/25 (28)	NE (3.1, NE)	0.20 (0.05,0.78)	0.0100	
	Other	0/8 (0)	NE (NE, NE)	1/8 (13)	NE (1.1, NE)	NE (NE,NE)	NE	
Gastrointestinal disorders	Diffuse large B-cell lymphoma not otherwise specified	15/108 (14)	12.0 (NE, NE)	12/110 (11)	NE (NE, NE)	1.03 (0.47,2.23)	0.9459	0.1677
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	8/25 (32)	5.0 (2.9, NE)	0.32 (0.07,1.54)	0.1314	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	NE (NE, NE)	8/25 (32)	7.0 (3.2, NE)	0.17 (0.04,0.69)	0.0052	
	Other	1/8 (13)	NE (1.7, NE)	2/8 (25)	NE (2.2, NE)	0.37 (0.03,4.18)	0.4068	
General disorders and administration site conditions	Diffuse large B-cell lymphoma not otherwise specified	20/108 (19)	NE (NE, NE)	6/110 (5)	NE (4.9, NE)	3.37 (1.35,8.41)	0.0056	0.2955
	Large cell transformation from follicular lymphoma	1/19 (5)	6.0 (NE, NE)	2/25 (8)	NE (NE, NE)	0.00 (0.00,NE)	0.1648	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/43 (14)	NE (NE, NE)	5/25 (20)	7.1 (3.9, NE)	0.65 (0.18,2.36)	0.5110	
	Other	3/8 (38)	NE (1.0, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Pyrexia	Diffuse large B-cell lymphoma not otherwise specified	11/108 (10)	NE (NE, NE)	1/110 (1)	NE (NE, NE)	11.31 (1.46,87.69)	0.0033	1.0000

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.11. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Large cell transformation from follicular lymphoma	1/19 (5)	6.0 (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (1.0, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	Diffuse large B-cell lymphoma not otherwise specified	7/108 (6)	NE (NE, NE)	41/110 (37)	3.7 (3.3, NE)	0.11 (0.05,0.25)	<0.0001	0.2419
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	7/25 (28)	NE (4.8, NE)	0.51 (0.13,1.99)	0.3257	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE, NE)	9/25 (36)	NE (1.1, NE)	0.09 (0.02,0.42)	0.0002	
	Other	1/8 (13)	NE (1.2, NE)	3/8 (38)	2.6 (0.4, NE)	0.21 (0.02,2.09)	0.1457	
Nervous system disorders	Diffuse large B-cell lymphoma not otherwise specified	27/108 (25)	NE (NE, NE)	10/110 (9)	32.2 (NE, NE)	3.04 (1.43,6.47)	0.0024	0.3542
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	2/25 (8)	NE (NE, NE)	1.85 (0.31,11.08)	0.4931	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/43 (21)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.11. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Nervous system disorders	Other	2/8 (25)	NE (1.4, NE)	3/8 (38)	4.8 (0.2, NE)	0.55 (0.09,3.33)	0.5133	
Psychiatric disorders	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	NE (NE, NE)	1/110 (1)	NE (NE, NE)	12.10 (1.57,93.13)	0.0022	0.8356
	Large cell transformation from follicular lymphoma	1/19 (5)	27.6 (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/43 (12)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.97 (0.35,25.48)	0.2964	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Diffuse large B-cell lymphoma not otherwise specified	24/108 (22)	53.1 (NE, NE)	4/110 (4)	NE (NE, NE)	6.12 (2.11,17.69)	0.0001	0.0067
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	35.7 (NE, NE)	5/25 (20)	NE (3.3, NE)	0.18 (0.03,0.93)	0.0222	
	Other	1/8 (13)	NE (1.3, NE)	2/8 (25)	NE (0.1, NE)	0.40 (0.04,4.49)	0.4459	
Hypotension	Diffuse large B-cell lymphoma not otherwise specified	17/108 (16)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	8.92 (2.06,38.65)	0.0004	0.0657
	Large cell transformation from follicular lymphoma	1/19 (5)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.11. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE, NE)	3/25 (12)	NE (4.0, NE)	0.30 (0.05,1.85)	0.1707	
	Other	1/8 (13)	NE (1.3, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.12. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0 - 1	3/94 (3)	12.1 (12.1, NE)	26/93 (28)	7.2 (3.7, NE)	0.02 (0.00,0.16)	<0.0001	0.4042
	2 - 3	4/84 (5)	28.3 (4.9, NE)	20/75 (27)	NE (4.1, NE)	0.07 (0.02,0.26)	<0.0001	
Neutropenia	0 - 1	43/94 (46)	NE (1.4, NE)	18/93 (19)	NE (NE, NE)	2.54 (1.46,4.41)	0.0006	0.6154
	2 - 3	31/84 (37)	NE (3.1, NE)	10/75 (13)	NE (NE, NE)	3.09 (1.51,6.31)	0.0011	
Thrombocytopenia	0 - 1	7/94 (7)	NE (NE, NE)	24/93 (26)	NE (NE, NE)	0.23 (0.10,0.53)	0.0002	0.3475
	2 - 3	7/84 (8)	NE (NE, NE)	13/75 (17)	NE (NE, NE)	0.41 (0.16,1.04)	0.0529	
Gastrointestinal disorders	0 - 1	10/94 (11)	12.0 (NE, NE)	16/93 (17)	7.0 (NE, NE)	0.46 (0.20,1.05)	0.0598	0.7078
	2 - 3	11/84 (13)	NE (NE, NE)	14/75 (19)	5.0 (NE, NE)	0.62 (0.28,1.40)	0.2474	
General disorders and administration site conditions	0 - 1	17/94 (18)	NE (NE, NE)	9/93 (10)	7.1 (4.9, NE)	2.00 (0.86,4.64)	0.1003	0.7657
	2 - 3	13/84 (15)	6.0 (NE, NE)	4/75 (5)	NE (NE, NE)	2.46 (0.79,7.68)	0.1098	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.12. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	0 - 1	10/94 (11)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	9.58 (1.23,74.87)	0.0082	0.9919
	2 - 3	5/84 (6)	6.0 (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	0 - 1	6/94 (6)	NE (NE, NE)	35/93 (38)	NE (3.3, NE)	0.11 (0.05,0.26)	<0.0001	0.5140
	2 - 3	7/84 (8)	NE (NE, NE)	25/75 (33)	NE (3.4, NE)	0.19 (0.08,0.44)	<0.0001	
Nervous system disorders	0 - 1	17/94 (18)	NE (NE, NE)	9/93 (10)	32.2 (NE, NE)	2.00 (0.86,4.64)	0.0992	0.3263
	2 - 3	24/84 (29)	NE (NE, NE)	6/75 (8)	NE (NE, NE)	3.54 (1.44,8.68)	0.0032	
Psychiatric disorders	0 - 1	7/94 (7)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	6.51 (0.80,52.93)	0.0435	0.8166
	2 - 3	11/84 (13)	27.6 (NE, NE)	1/75 (1)	NE (NE, NE)	9.18 (1.17,71.82)	0.0102	
Vascular disorders	0 - 1	13/94 (14)	53.1 (NE, NE)	5/93 (5)	NE (NE, NE)	2.24 (0.79,6.36)	0.1206	0.8847
	2 - 3	17/84 (20)	35.7 (NE, NE)	6/75 (8)	NE (NE, NE)	2.42 (0.95,6.19)	0.0563	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.12. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0 - 1	8/94 (9)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	3.63 (0.77,17.14)	0.0814	0.9566
	2 - 3	13/84 (15)	NE (NE, NE)	3/75 (4)	NE (NE, NE)	4.03 (1.15,14.15)	0.0185	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.13. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	0 - 1	4/98 (4)	28.3 (12.1, NE)	27/93 (29)	7.2 (3.7, NE)	0.02 (0.00,0.14)	<0.0001	0.2449
	2 - 3	3/80 (4)	NE (4.9, NE)	19/75 (25)	NE (3.4, NE)	0.08 (0.02,0.29)	<0.0001	
Neutropenia	0 - 1	45/98 (46)	NE (1.4, NE)	19/93 (20)	NE (NE, NE)	2.38 (1.39,4.08)	0.0010	0.4042
	2 - 3	29/80 (36)	NE (3.1, NE)	9/75 (12)	NE (NE, NE)	3.41 (1.61,7.21)	0.0006	
Thrombocytopenia	0 - 1	7/98 (7)	NE (NE, NE)	26/93 (28)	NE (NE, NE)	0.20 (0.09,0.46)	<0.0001	0.1298
	2 - 3	7/80 (9)	NE (NE, NE)	11/75 (15)	NE (NE, NE)	0.53 (0.21,1.38)	0.1868	
Gastrointestinal disorders	0 - 1	10/98 (10)	12.0 (NE, NE)	16/93 (17)	7.0 (NE, NE)	0.45 (0.20,1.02)	0.0487	0.5749
	2 - 3	11/80 (14)	NE (NE, NE)	14/75 (19)	5.0 (NE, NE)	0.65 (0.29,1.45)	0.2863	
General disorders and administration site conditions	0 - 1	17/98 (17)	NE (NE, NE)	9/93 (10)	7.1 (4.9, NE)	1.88 (0.81,4.37)	0.1338	0.6345
	2 - 3	13/80 (16)	6.0 (NE, NE)	4/75 (5)	NE (NE, NE)	2.61 (0.84,8.15)	0.0862	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.13. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	0 - 1	10/98 (10)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	9.18 (1.17,71.73)	0.0100	0.9916
	2 - 3	5/80 (6)	6.0 (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Investigations								
Platelet count decreased	0 - 1	7/98 (7)	NE (NE, NE)	35/93 (38)	NE (3.3, NE)	0.12 (0.05,0.28)	<0.0001	0.7321
	2 - 3	6/80 (8)	NE (NE, NE)	25/75 (33)	NE (3.1, NE)	0.17 (0.07,0.42)	<0.0001	
Nervous system disorders	0 - 1	17/98 (17)	NE (NE, NE)	9/93 (10)	32.2 (NE, NE)	1.91 (0.82,4.43)	0.1242	0.2471
	2 - 3	24/80 (30)	NE (NE, NE)	6/75 (8)	NE (NE, NE)	3.77 (1.54,9.24)	0.0018	
Psychiatric disorders	0 - 1	7/98 (7)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	6.24 (0.77,50.77)	0.0497	0.7667
	2 - 3	11/80 (14)	27.6 (NE, NE)	1/75 (1)	NE (NE, NE)	9.68 (1.24,75.72)	0.0079	
Vascular disorders	0 - 1	13/98 (13)	53.1 (NE, NE)	6/93 (6)	NE (NE, NE)	1.77 (0.66,4.71)	0.2502	0.4079
	2 - 3	17/80 (21)	35.7 (NE, NE)	5/75 (7)	NE (NE, NE)	3.11 (1.14,8.50)	0.0194	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.13. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	0 - 1	8/98 (8)	NE (NE, NE)	3/93 (3)	NE (NE, NE)	2.30 (0.61,8.71)	0.2055	0.3296
	2 - 3	13/80 (16)	NE (NE, NE)	2/75 (3)	NE (NE, NE)	6.47 (1.46,28.71)	0.0046	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.14. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Primary refractory	6/131 (5)	28.3 (12.1, NE)	36/125 (29)	NE (3.7, NE)	0.04 (0.01,0.12)	<0.0001	0.5568
	Relapse ≤ 12 months of the completion of the first line therapy	1/46 (2)	NE (NE, NE)	10/43 (23)	7.2 (NE, NE)	0.07 (0.01,0.59)	0.0014	
Neutropenia	Primary refractory	59/131 (45)	NE (1.2, NE)	19/125 (15)	NE (NE, NE)	3.24 (1.93,5.44)	<0.0001	0.1815
	Relapse ≤ 12 months of the completion of the first line therapy	15/46 (33)	NE (NE, NE)	9/43 (21)	NE (NE, NE)	1.67 (0.73,3.82)	0.2191	
Thrombocytopenia	Primary refractory	9/131 (7)	NE (NE, NE)	26/125 (21)	NE (NE, NE)	0.27 (0.13,0.59)	0.0004	0.6335
	Relapse ≤ 12 months of the completion of the first line therapy	5/46 (11)	NE (NE, NE)	11/43 (26)	NE (NE, NE)	0.36 (0.13,1.04)	0.0493	
Gastrointestinal disorders	Primary refractory	17/131 (13)	12.0 (NE, NE)	22/125 (18)	5.0 (NE, NE)	0.56 (0.29,1.06)	0.0718	0.7838
	Relapse ≤ 12 months of the completion of the first line therapy	4/46 (9)	NE (NE, NE)	8/43 (19)	7.0 (NE, NE)	0.47 (0.14,1.62)	0.2231	
General disorders and administration site conditions	Primary refractory	21/131 (16)	6.0 (NE, NE)	9/125 (7)	NE (4.9, NE)	1.87 (0.85,4.14)	0.1138	0.5164
	Relapse ≤ 12 months of the completion of the first line therapy	9/46 (20)	NE (NE, NE)	4/43 (9)	7.1 (NE, NE)	2.88 (0.78,10.65)	0.0966	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.14. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Primary refractory	10/131 (8)	6.0 (NE, NE)	0/125 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9924
	Relapse ≤ 12 months of the completion of the first line therapy	5/46 (11)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	4.64 (0.54,39.72)	0.1224	
Investigations								
Platelet count decreased	Primary refractory	10/131 (8)	NE (NE, NE)	41/125 (33)	NE (3.7, NE)	0.17 (0.08,0.34)	<0.0001	0.6036
	Relapse ≤ 12 months of the completion of the first line therapy	3/46 (7)	NE (NE, NE)	19/43 (44)	3.5 (3.1, NE)	0.10 (0.03,0.33)	<0.0001	
Nervous system disorders	Primary refractory	29/131 (22)	NE (NE, NE)	10/125 (8)	NE (NE, NE)	2.69 (1.31,5.52)	0.0051	0.9225
	Relapse ≤ 12 months of the completion of the first line therapy	12/46 (26)	NE (NE, NE)	5/43 (12)	32.2 (NE, NE)	2.76 (0.89,8.59)	0.0667	
Psychiatric disorders	Primary refractory	13/131 (10)	27.6 (NE, NE)	2/125 (2)	NE (NE, NE)	5.42 (1.21,24.28)	0.0130	0.9915
	Relapse ≤ 12 months of the completion of the first line therapy	5/46 (11)	NE (NE, NE)	0/43 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Primary refractory	22/131 (17)	35.7 (NE, NE)	9/125 (7)	NE (NE, NE)	2.14 (0.98,4.67)	0.0512	0.6734
	Relapse ≤ 12 months of the completion of the first line therapy	8/46 (17)	53.1 (NE, NE)	2/43 (5)	NE (NE, NE)	3.33 (0.69,16.04)	0.1112	

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Table 14.3.1.1.3.14. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by refractory / relapse subgroup per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Primary refractory	16/131 (12)	NE (NE, NE)	4/125 (3)	NE (NE, NE)	3.70 (1.24,11.10)	0.0121	0.8364
	Relapse ≤ 12 months of the completion of the first line therapy	5/46 (11)	NE (NE, NE)	1/43 (2)	NE (NE, NE)	4.60 (0.54,39.45)	0.1247	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.3.15. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders								
Febrile neutropenia	Primary refractory	6/131 (5)	28.3 (12.1, NE)	34/123 (28)	NE (3.7, NE)	0.04 (0.01,0.13)	<0.0001	0.7188
	Relapse ≤ 12 months of first line therapy	1/47 (2)	NE (NE, NE)	12/45 (27)	7.2 (NE, NE)	0.06 (0.01,0.48)	0.0003	
Neutropenia	Primary refractory	59/131 (45)	NE (1.2, NE)	19/123 (15)	NE (NE, NE)	3.20 (1.91,5.37)	<0.0001	0.2072
	Relapse ≤ 12 months of first line therapy	15/47 (32)	NE (NE, NE)	9/45 (20)	NE (NE, NE)	1.69 (0.74,3.87)	0.2077	
Thrombocytopenia	Primary refractory	9/131 (7)	NE (NE, NE)	25/123 (20)	NE (NE, NE)	0.28 (0.13,0.61)	0.0006	0.7234
	Relapse ≤ 12 months of first line therapy	5/47 (11)	NE (NE, NE)	12/45 (27)	NE (NE, NE)	0.34 (0.12,0.96)	0.0324	
Gastrointestinal disorders	Primary refractory	17/131 (13)	12.0 (NE, NE)	21/123 (17)	5.0 (NE, NE)	0.58 (0.30,1.12)	0.1011	0.6305
	Relapse ≤ 12 months of first line therapy	4/47 (9)	NE (NE, NE)	9/45 (20)	7.0 (NE, NE)	0.42 (0.13,1.39)	0.1412	
General disorders and administration site conditions	Primary refractory	20/131 (15)	6.0 (NE, NE)	9/123 (7)	NE (4.9, NE)	1.73 (0.78,3.85)	0.1726	0.3432
	Relapse ≤ 12 months of first line therapy	10/47 (21)	NE (NE, NE)	4/45 (9)	7.1 (NE, NE)	3.38 (0.93,12.29)	0.0494	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.3.15. Analysis of Time to the First Severe Treatment-emergent Adverse Events (Grade >= 3) by System Organ Class and Preferred Term with event is >=5% in at least one study arm by refractory / relapse subgroup per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Primary refractory	10/131 (8)	6.0 (NE, NE)	0/123 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9925
	Relapse ≤ 12 months of first line therapy	5/47 (11)	NE (NE, NE)	1/45 (2)	NE (NE, NE)	4.83 (0.56,41.37)	0.1112	
Investigations								
Platelet count decreased	Primary refractory	10/131 (8)	NE (NE, NE)	40/123 (33)	NE (3.7, NE)	0.17 (0.08,0.34)	<0.0001	0.5605
	Relapse ≤ 12 months of first line therapy	3/47 (6)	NE (NE, NE)	20/45 (44)	3.5 (3.1, NE)	0.10 (0.03,0.32)	<0.0001	
Nervous system disorders	Primary refractory	28/131 (21)	NE (NE, NE)	10/123 (8)	NE (NE, NE)	2.53 (1.23,5.22)	0.0091	0.7022
	Relapse ≤ 12 months of first line therapy	13/47 (28)	NE (NE, NE)	5/45 (11)	32.2 (NE, NE)	3.17 (1.03,9.74)	0.0335	
Psychiatric disorders	Primary refractory	13/131 (10)	27.6 (NE, NE)	2/123 (2)	NE (NE, NE)	5.33 (1.19,23.87)	0.0142	0.9912
	Relapse ≤ 12 months of first line therapy	5/47 (11)	NE (NE, NE)	0/45 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Primary refractory	21/131 (16)	35.7 (NE, NE)	9/123 (7)	NE (NE, NE)	1.99 (0.90,4.37)	0.0816	0.4765
	Relapse ≤ 12 months of first line therapy	9/47 (19)	53.1 (NE, NE)	2/45 (4)	NE (NE, NE)	4.02 (0.85,18.93)	0.0567	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

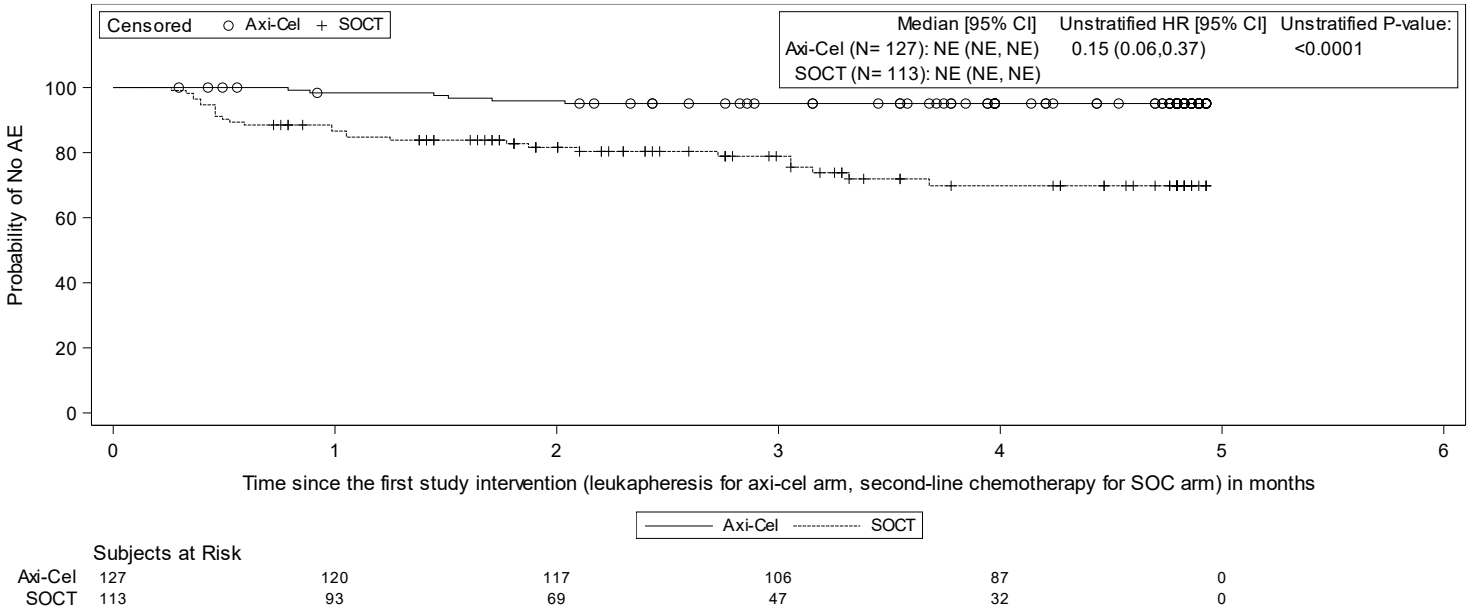
Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_g3.sas Output Generated: 20240411T17:11

Abbildung 17 (Anhang): Kaplan-Meier Plots für Subgruppenanalysen häufiger schwerer UE nach SOC/PT (stat. sign. Interaktionsterm) – RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Figure 14.5.4.1.67. Kaplan-Meier Plot of Time To First Severe Thrombocytopenia by age (Modified Safety Analysis Set)

Age < 65



Subjects at Risk

Axi-Cel	127	120	117	106	87	0
SOCT	113	93	69	47	32	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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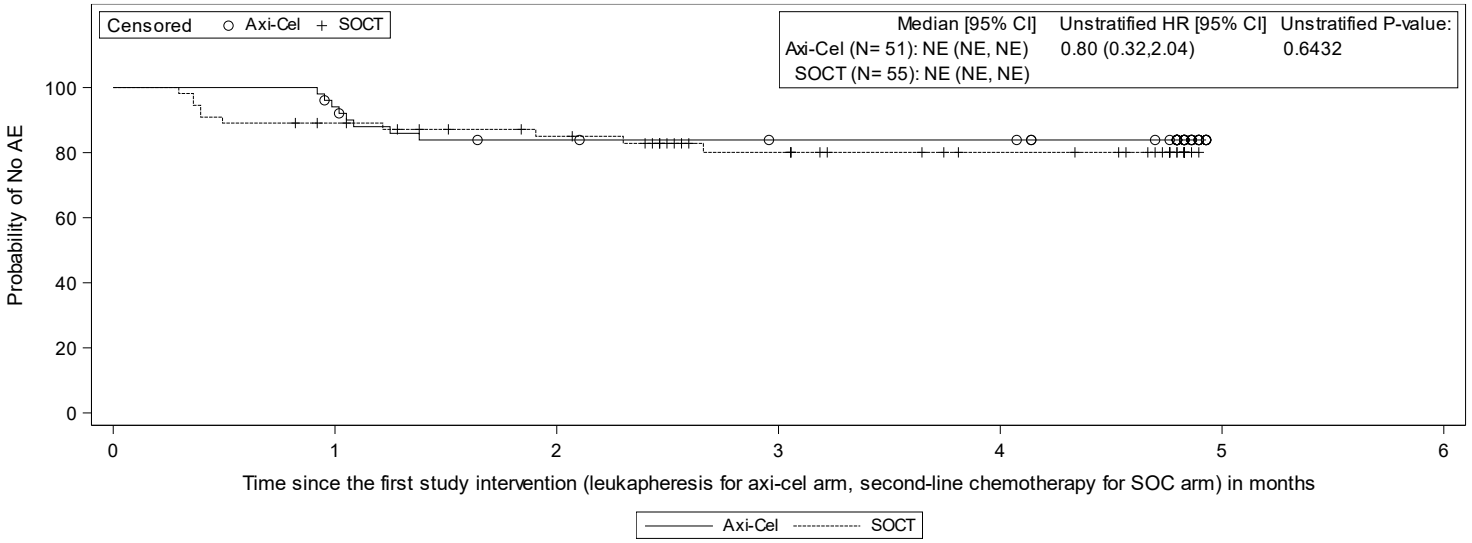
Figure 14.5.4.1.67. Kaplan-Meier Plot of Time To First Severe Thrombocytopenia by age (Modified Safety Analysis Set)

Age ≥ 65



Subjects at Risk

Axi-Cel	51	47	40	38	38	0
SOCT	55	47	40	29	21	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE **Program Name: f_km_teae_sg.sas** **Output Generated: 20240412T11:20**

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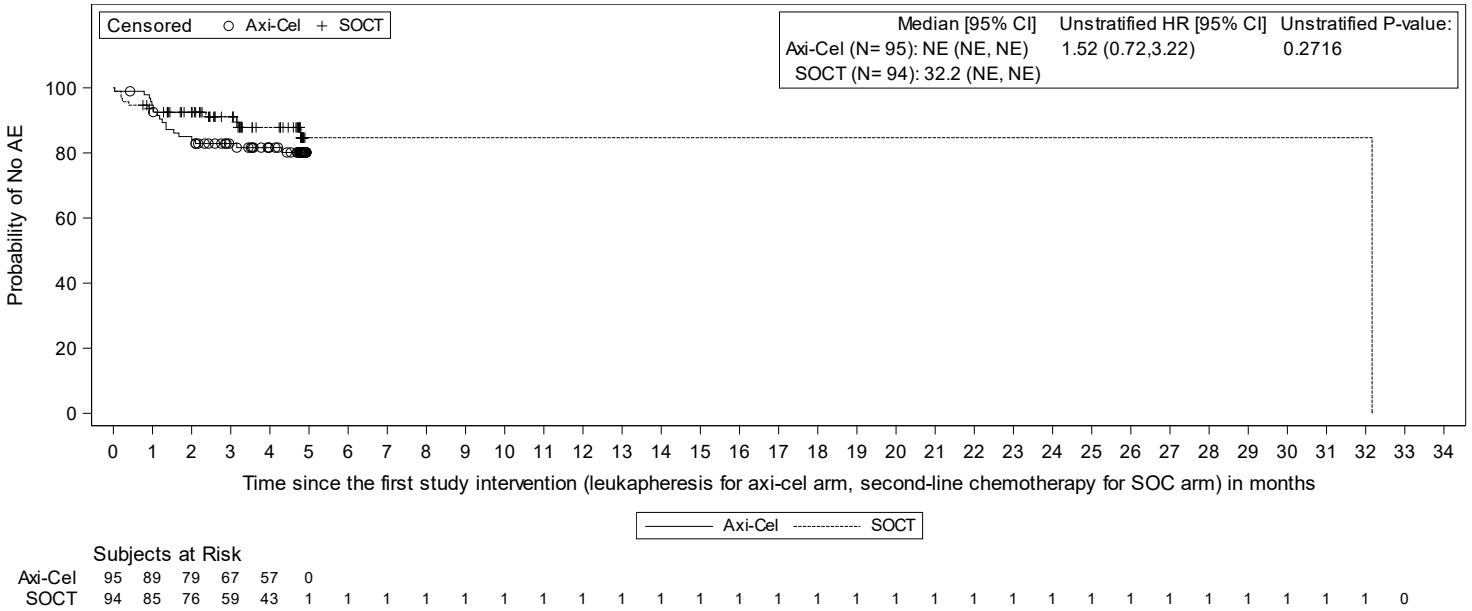
Figure 14.5.4.1.68. Kaplan-Meier Plot of Time To First Severe Nervous system disorders by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	89	79	67	57	0																											
SOCT	94	85	76	59	43	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0

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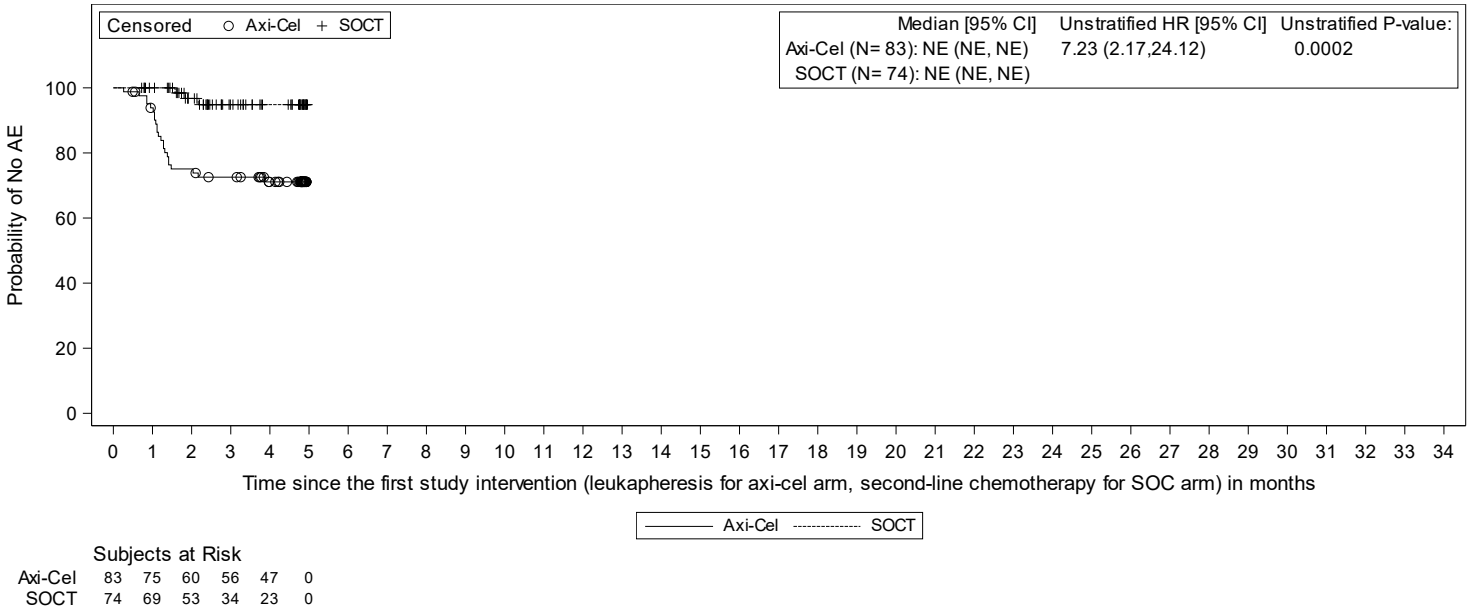
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.68. Kaplan-Meier Plot of Time To First Severe Nervous system disorders by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	75	60	56	47	0
SOCT	74	69	53	34	23	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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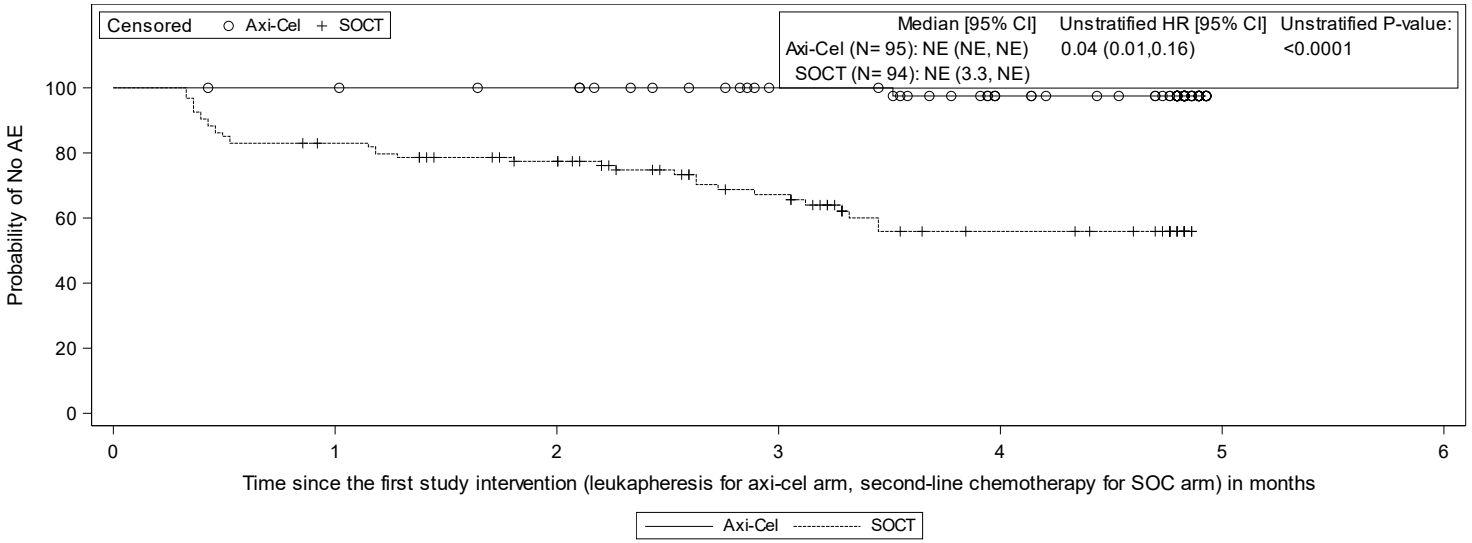
Figure 14.5.4.1.69. Kaplan-Meier Plot of Time To First Severe Platelet count decreased by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 0



Subjects at Risk

Axi-Cel	95	94	92	81	67	0
SOCT	94	76	64	43	24	0

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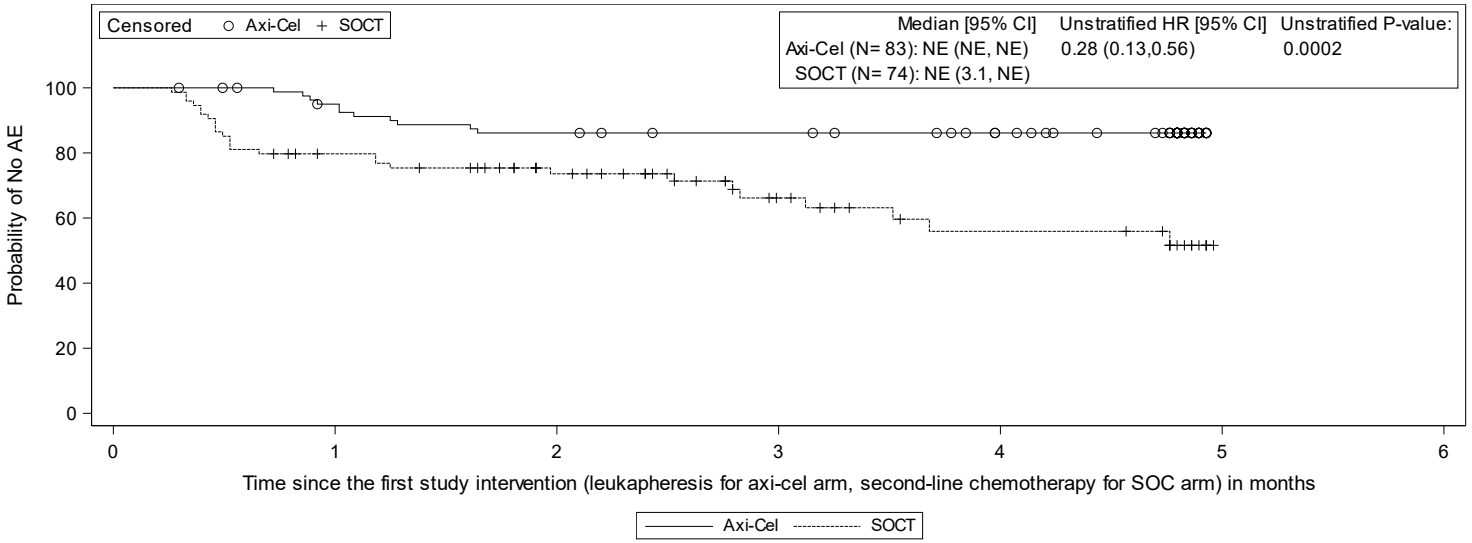
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE **Program Name: f_km_teae_sg.sas** **Output Generated: 20240412T11:20**

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.69. Kaplan-Meier Plot of Time To First Severe Platelet count decreased by ECOG status at screening (Modified Safety Analysis Set)

ECOG = 1



Subjects at Risk

Axi-Cel	83	75	68	65	58	0
SOCT	74	55	41	23	15	0

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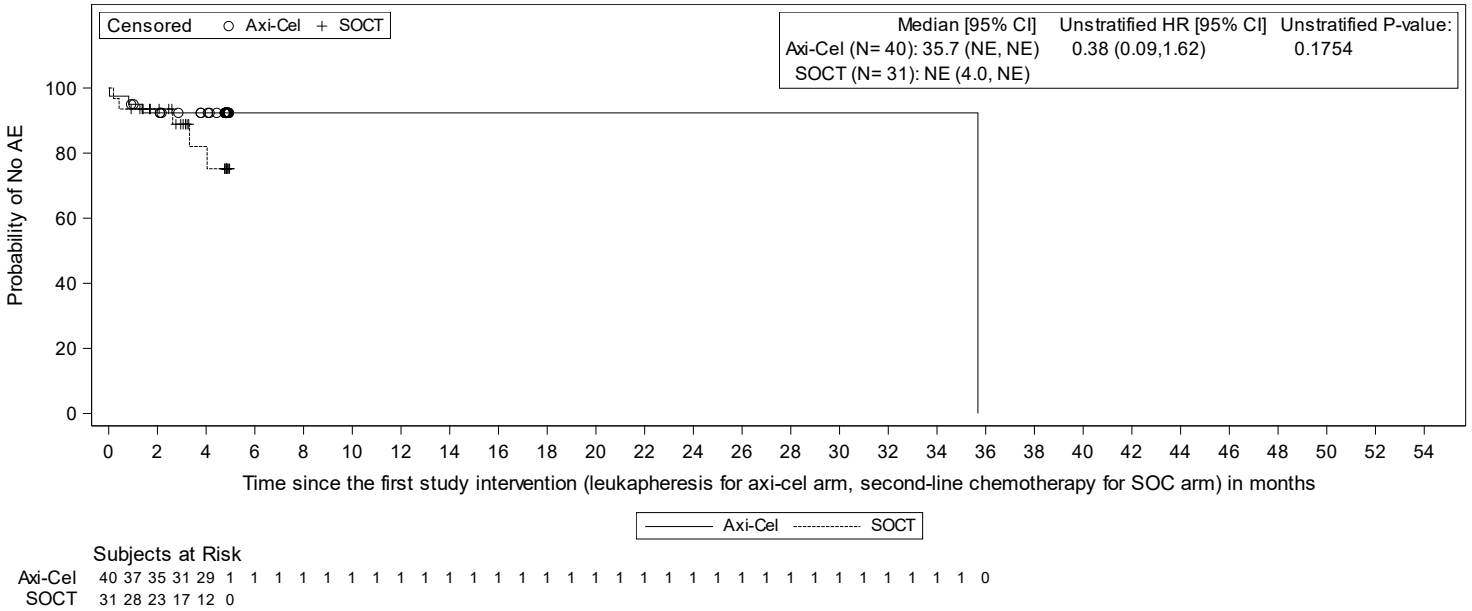
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.70. Kaplan-Meier Plot of Time To First Severe Vascular disorders by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

HGBL - double hit/triple hit



Subjects at Risk

Axi-Cel	40	37	35	31	29	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	31	28	23	17	12	0																														

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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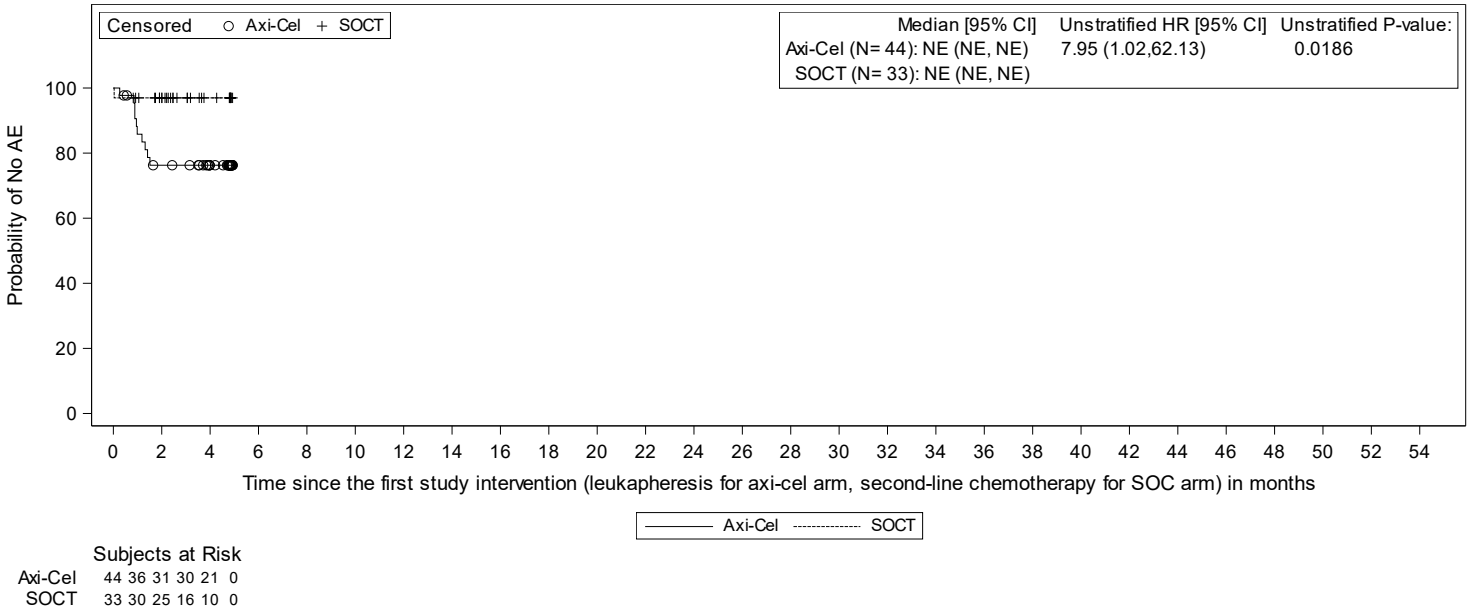
Figure 14.5.4.1.70. Kaplan-Meier Plot of Time To First Severe Vascular disorders by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

Double expressor lymphoma



Subjects at Risk

Axi-Cel	44	36	31	30	21	0
SOCT	33	30	25	16	10	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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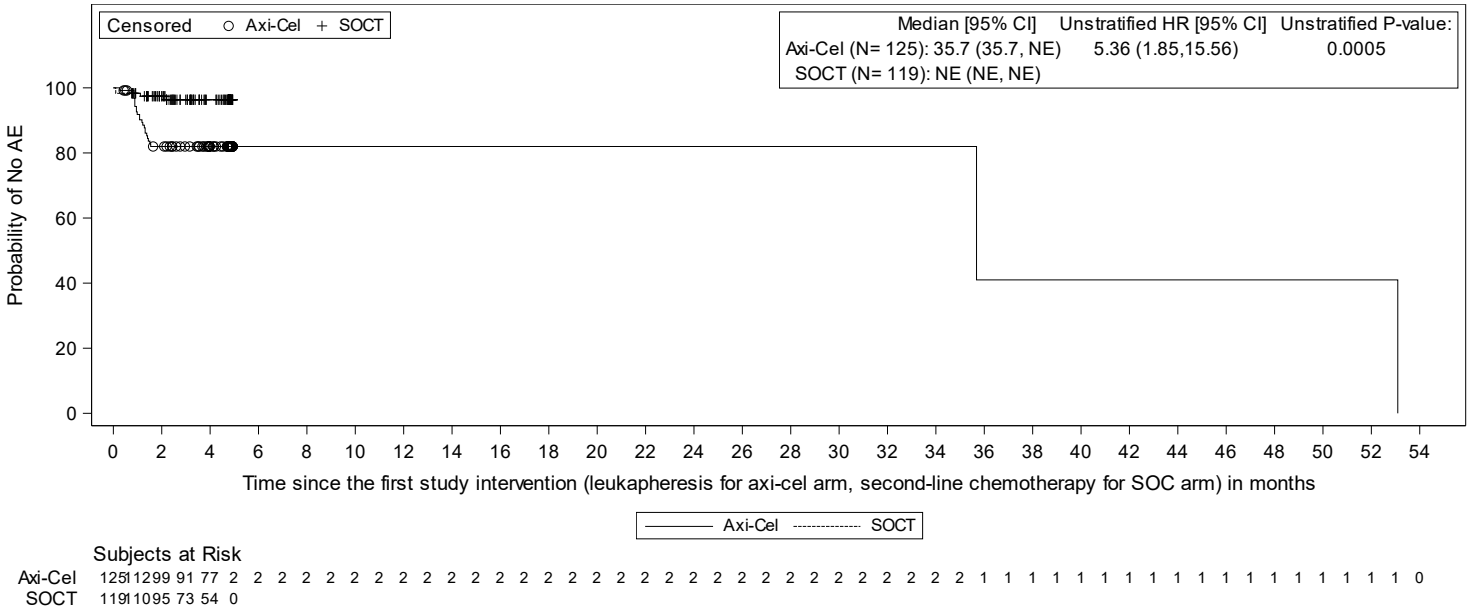
Figure 14.5.4.1.71. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per central lab (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma



Subjects at Risk

| | | |

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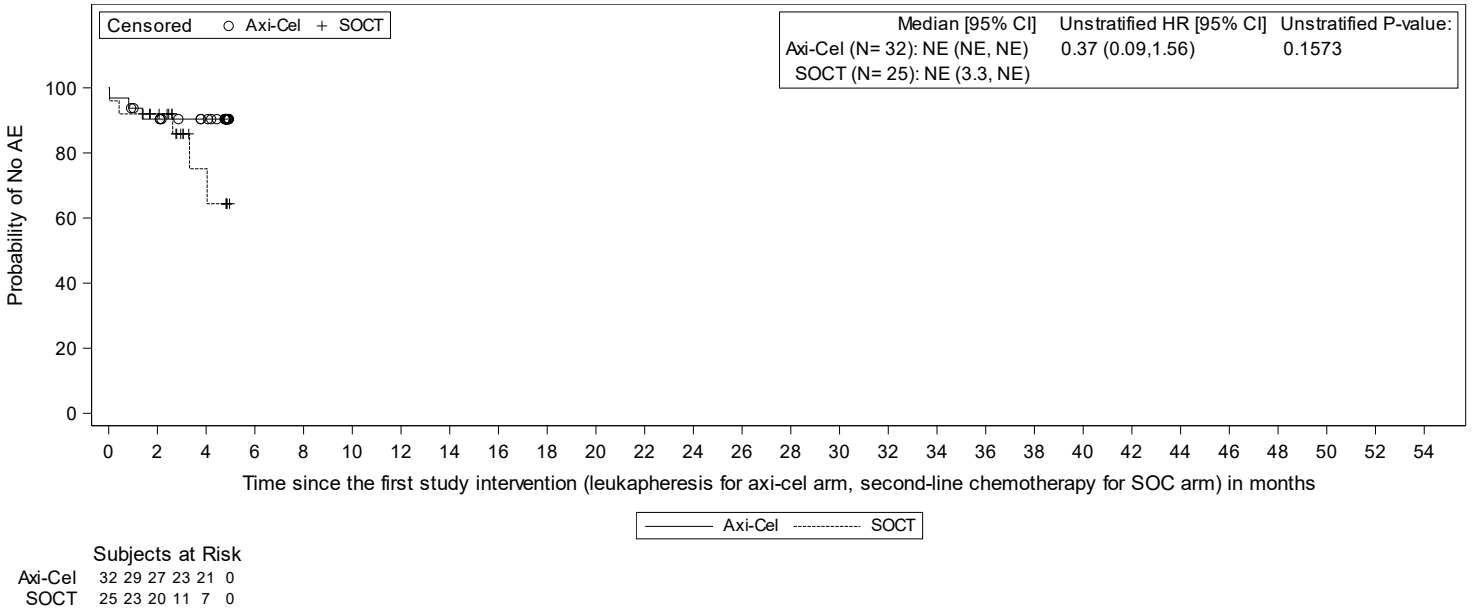
Figure 14.5.4.1.71. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per central lab (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	32	29	27	23	21	0
SOCT	25	23	20	11	7	0

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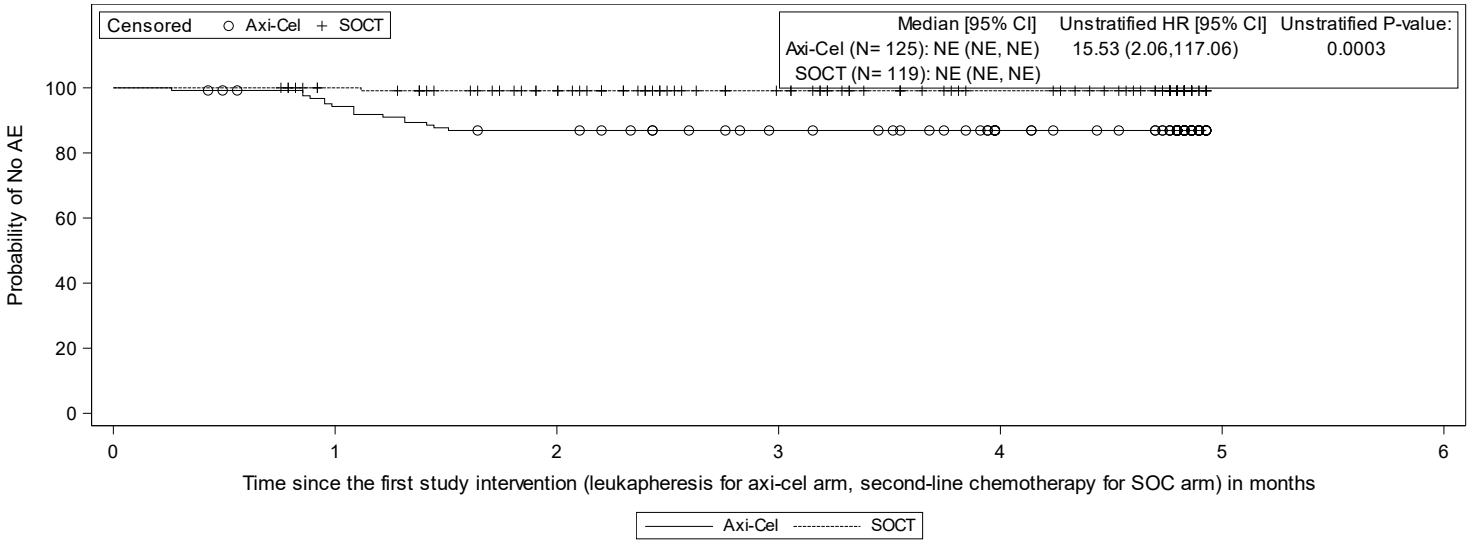
Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Kite Pharma, Inc. **Confidential** **Protocol: KTE-C19-107**

Figure 14.5.4.1.72. Kaplan-Meier Plot of Time To First Severe Hypotension by disease type per central lab (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma



Subjects at Risk

Axi-Cel	125	115	105	96	81	0
SOCT	119	112	97	74	55	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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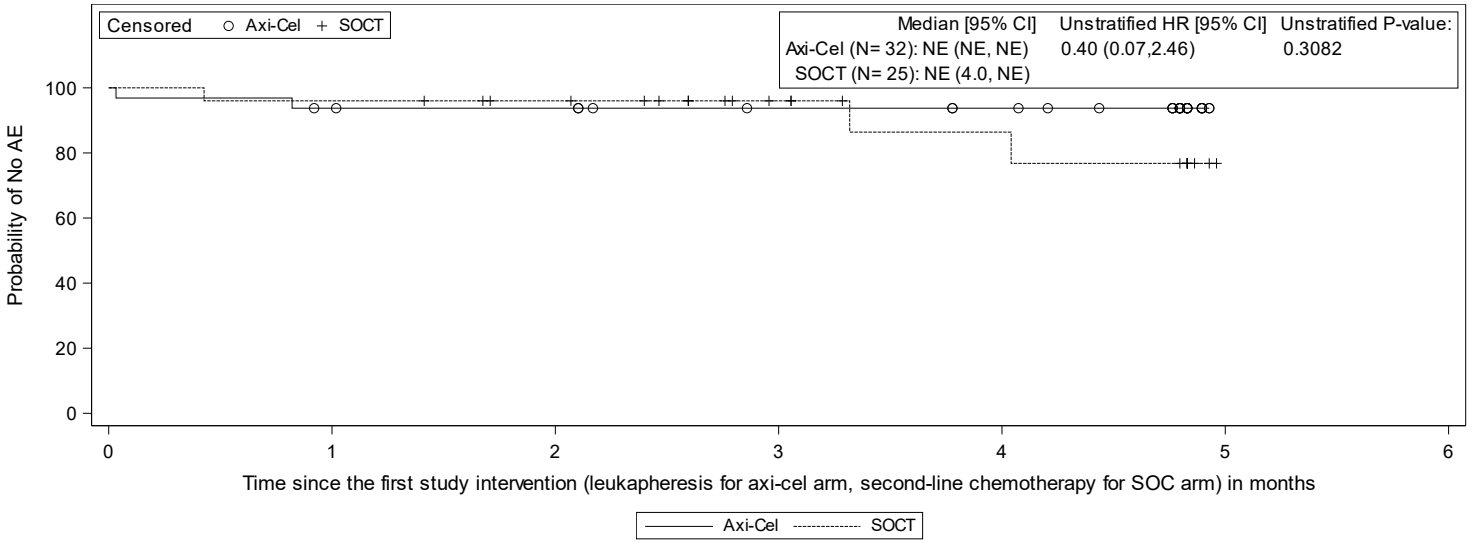
Figure 14.5.4.1.72. Kaplan-Meier Plot of Time To First Severe Hypotension by disease type per central lab (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	32	29	28	24	22	0
SOCT	25	24	21	13	9	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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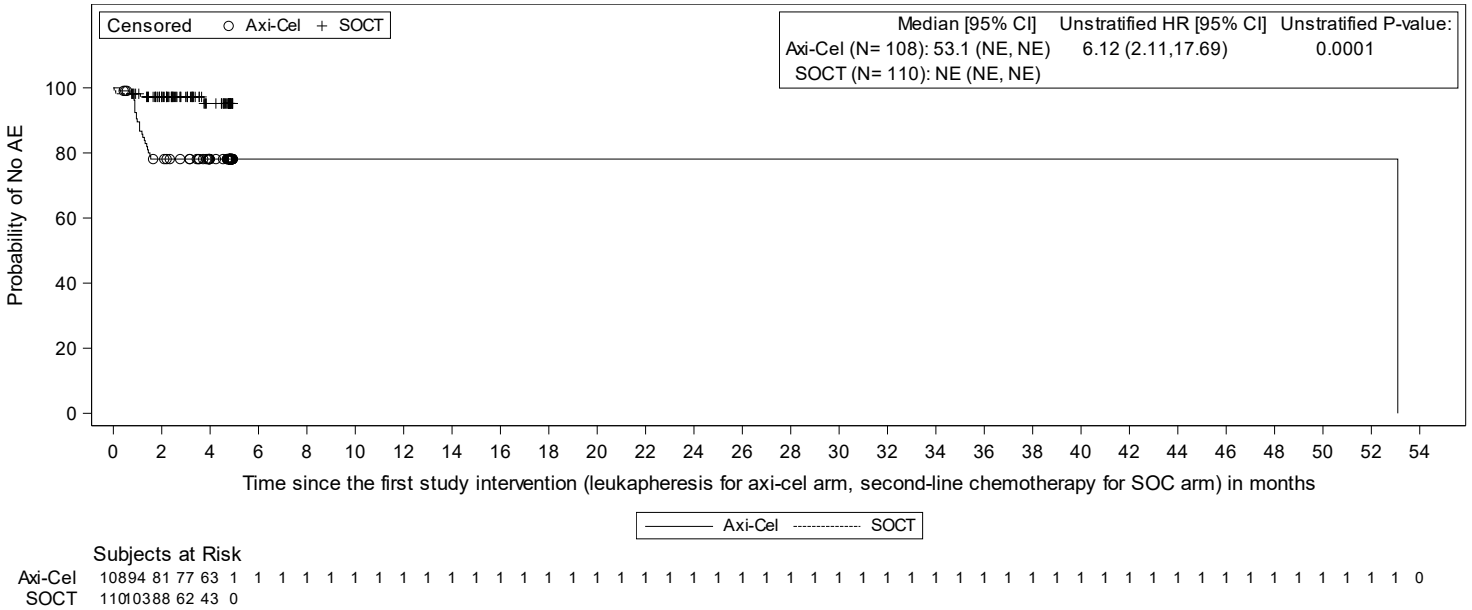
Figure 14.5.4.1.73. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per investigator (Modified Safety Analysis Set)

Diffuse large B-cell lymphoma not otherwise specified



Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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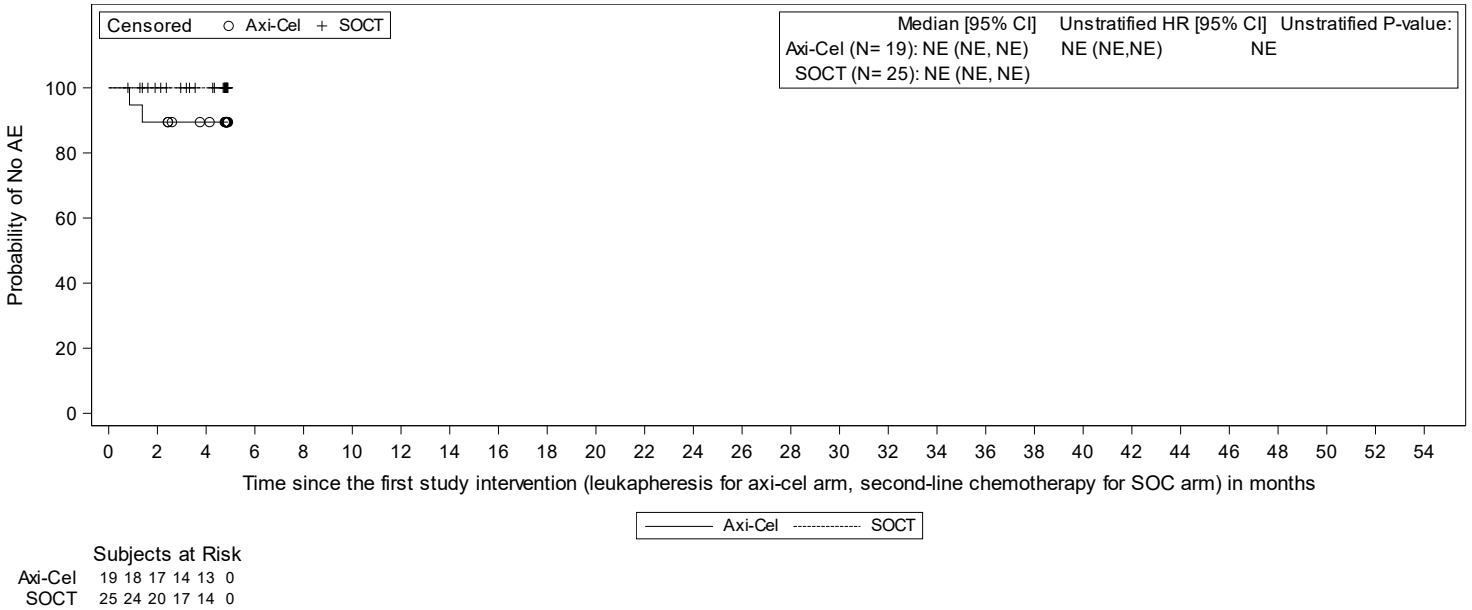
Figure 14.5.4.1.73. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per investigator (Modified Safety Analysis Set)

Large cell transformation from follicular lymphoma



Subjects at Risk

Axi-Cel	19	18	17	14	13	0
SOCT	25	24	20	17	14	0

Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE **Program Name: f_km_teae_sg.sas** **Output Generated: 20240412T11:20**

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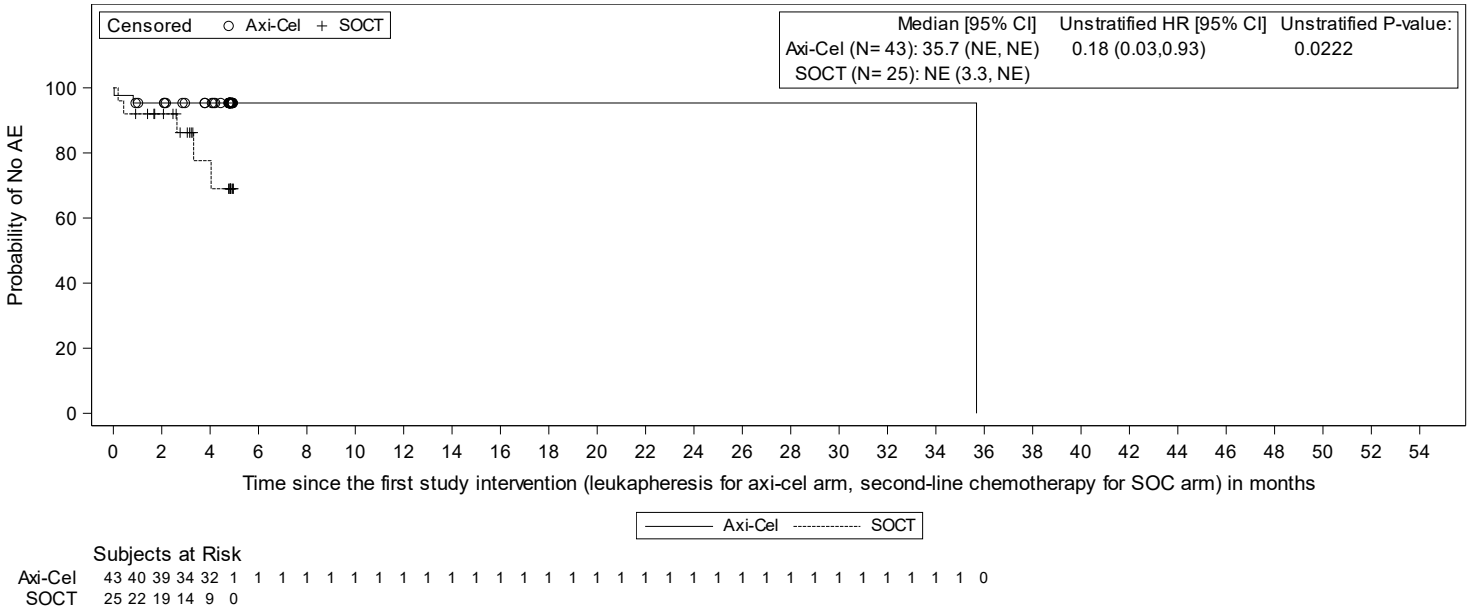
Figure 14.5.4.1.73. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per investigator (Modified Safety Analysis Set)

HGBL with or without MYC and BCL2 and/or BCL6 rearrangement



Subjects at Risk

Axi-Cel	43	40	39	34	32	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
SOCT	25	22	19	14	9	0																													

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

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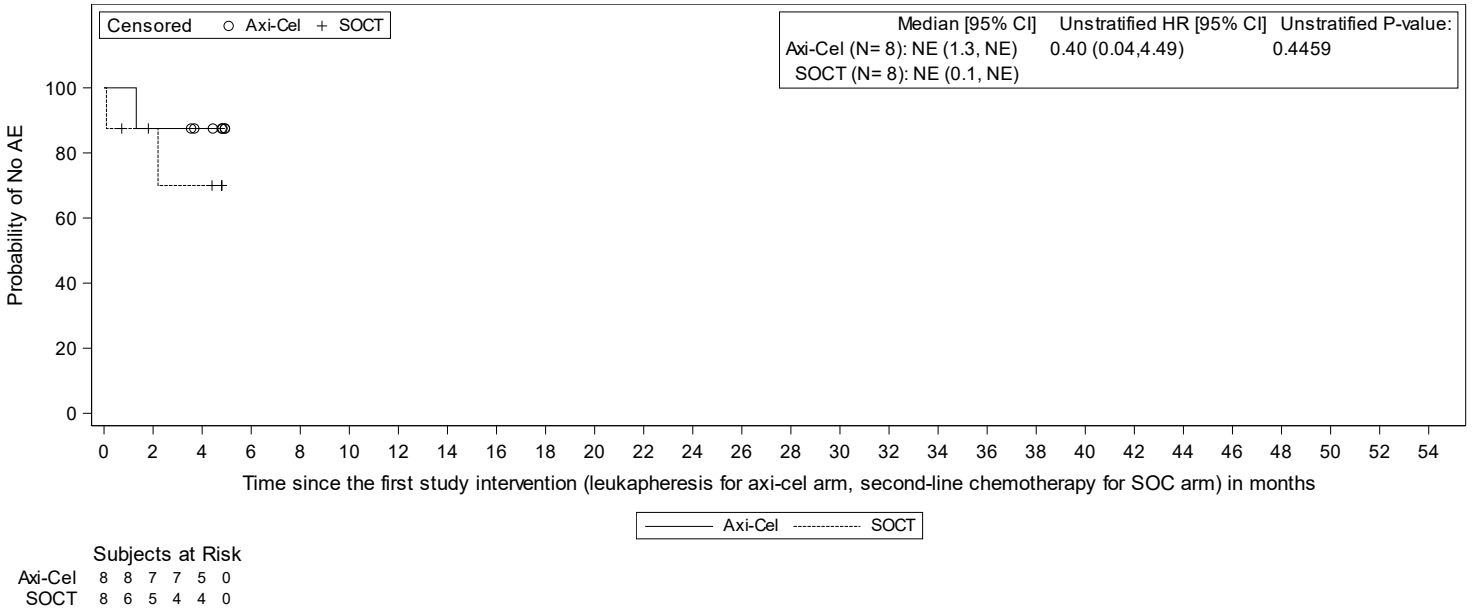
Figure 14.5.4.1.73. Kaplan-Meier Plot of Time To First Severe Vascular disorders by disease type per investigator (Modified Safety Analysis Set)

Other



Subjects at Risk

Axi-Cel	8	8	7	7	5	0
SOCT	8	6	5	4	4	0

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Data Cutoff Date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided).
Note: AEs are coded using MedDRA version 25.1.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: f_km_teae_sg.sas Output Generated: 20240412T11:20

Anhang 4-G3.6.5: Subgruppenanalyse häufiger SUE nach SOC/PT (tabellarische Darstellung und Kaplan-Meier Plots für Subgruppenanalysen mit statistisch signifikantem Interaktionsterm) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-31 (Anhang): Ergebnisse der Subgruppenanalyse häufiger SUE nach SOC/PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

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Table 14.3.1.1.2.1. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Age < 65	5/127 (4)	12.1 (NE, NE)	17/113 (15)	NE (NE, NE)	0.16 (0.05,0.47)	0.0002	0.9523
	Age ≥ 65	7/51 (14)	21.1 (6.0, NE)	9/55 (16)	NE (NE, NE)	0.28 (0.08,1.06)	0.0467	
Febrile neutropenia	Age < 65	5/127 (4)	12.1 (12.1, NE)	16/113 (14)	NE (NE, NE)	0.12 (0.04,0.43)	<0.0001	0.6649
	Age ≥ 65	1/51 (2)	28.3 (NE, NE)	6/55 (11)	NE (NE, NE)	0.00 (0.00,NE)	0.0089	
General disorders and administration site conditions	Age < 65	21/127 (17)	NE (NE, NE)	7/113 (6)	NE (NE, NE)	2.64 (1.12,6.22)	0.0206	0.3446
	Age ≥ 65	15/51 (29)	6.0 (NE, NE)	4/55 (7)	4.9 (4.9, NE)	5.31 (1.53,18.41)	0.0032	
Pyrexia	Age < 65	19/127 (15)	NE (NE, NE)	6/113 (5)	NE (NE, NE)	2.80 (1.12,7.02)	0.0217	0.1139
	Age ≥ 65	15/51 (29)	6.0 (NE, NE)	2/55 (4)	8.6 (NE, NE)	16.97 (2.24,128.57)	0.0002	
Nervous system disorders	Age < 65	23/127 (18)	NE (NE, NE)	5/113 (4)	32.2 (NE, NE)	5.27 (1.82,15.23)	0.0006	0.5701
	Age ≥ 65	10/51 (20)	18.0 (NE, NE)	3/55 (5)	17.9 (NE, NE)	3.05 (0.82,11.36)	0.0796	
Encephalopathy	Age < 65	11/127 (9)	NE (NE, NE)	1/113 (1)	NE (NE, NE)	10.00 (1.29,77.46)	0.0064	0.9915

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.1. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by age (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Age ≥ 65	6/51 (12)	NE (NE, NE)	0/55 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Age < 65	14/127 (11)	35.7 (35.7, NE)	2/113 (2)	NE (NE, NE)	5.28 (1.18,23.60)	0.0148	0.7805
	Age ≥ 65	7/51 (14)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	7.40 (0.91,60.32)	0.0280	
Hypotension	Age < 65	10/127 (8)	NE (NE, NE)	2/113 (2)	NE (NE, NE)	4.38 (0.96,20.01)	0.0372	0.6753
	Age ≥ 65	7/51 (14)	NE (NE, NE)	1/55 (2)	NE (NE, NE)	7.40 (0.91,60.32)	0.0280	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.2. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Male	4/109 (4)	12.1 (NE, NE)	17/120 (14)	NE (NE, NE)	0.14 (0.04,0.48)	0.0003	0.8400
	Female	8/69 (12)	21.1 (4.9, NE)	9/48 (19)	NE (NE, NE)	0.23 (0.07,0.77)	0.0095	
Febrile neutropenia	Male	2/109 (2)	12.1 (NE, NE)	13/120 (11)	NE (NE, NE)	0.06 (0.01,0.46)	0.0003	0.7876
	Female	4/69 (6)	28.3 (4.9, NE)	9/48 (19)	NE (NE, NE)	0.11 (0.02,0.54)	0.0012	
General disorders and administration site conditions	Male	18/109 (17)	NE (NE, NE)	7/120 (6)	NE (4.9, NE)	2.64 (1.10,6.34)	0.0240	0.5169
	Female	18/69 (26)	6.0 (NE, NE)	4/48 (8)	8.6 (NE, NE)	4.48 (1.32,15.23)	0.0082	
Pyrexia	Male	16/109 (15)	NE (NE, NE)	5/120 (4)	NE (NE, NE)	3.37 (1.23,9.22)	0.0120	0.4533
	Female	18/69 (26)	6.0 (NE, NE)	3/48 (6)	8.6 (NE, NE)	6.89 (1.60,29.72)	0.0026	
Nervous system disorders	Male	20/109 (18)	18.0 (NE, NE)	3/120 (3)	32.2 (NE, NE)	10.85 (2.53,46.44)	<0.0001	0.0679
	Female	13/69 (19)	NE (NE, NE)	5/48 (10)	17.9 (NE, NE)	2.35 (0.77,7.23)	0.1230	
Encephalopathy	Male	9/109 (8)	NE (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.2. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by sex (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Female	8/69 (12)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Male	11/109 (10)	35.7 (35.7, NE)	2/120 (2)	NE (NE, NE)	4.49 (0.97,20.86)	0.0361	0.7353
	Female	10/69 (14)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	7.48 (0.96,58.42)	0.0236	
Hypotension	Male	7/109 (6)	NE (NE, NE)	2/120 (2)	NE (NE, NE)	3.41 (0.70,16.53)	0.1056	0.5945
	Female	10/69 (14)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	7.48 (0.96,58.42)	0.0236	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.2.3. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	White	8/144 (6)	21.1 (6.0, NE)	24/145 (17)	NE (NE, NE)	0.16 (0.06,0.42)	<0.0001	0.2263
	Other	4/34 (12)	12.1 (4.9, NE)	2/23 (9)	NE (NE, NE)	0.57 (0.08,4.08)	0.5681	
Febrile neutropenia	White	4/144 (3)	28.3 (28.3, NE)	21/145 (14)	NE (NE, NE)	0.07 (0.02,0.31)	<0.0001	0.0680
	Other	2/34 (6)	12.1 (4.9, NE)	1/23 (4)	NE (NE, NE)	0.71 (0.04,11.40)	0.8096	
General disorders and administration site conditions	White	25/144 (17)	6.0 (NE, NE)	8/145 (6)	8.6 (4.9, NE)	3.52 (1.52,8.16)	0.0017	0.6934
	Other	11/34 (32)	NE (3.6, NE)	3/23 (13)	NE (NE, NE)	2.50 (0.70,8.95)	0.1450	
Pyrexia	White	24/144 (17)	6.0 (NE, NE)	6/145 (4)	8.6 (NE, NE)	4.86 (1.85,12.75)	0.0004	0.7505
	Other	10/34 (29)	NE (NE, NE)	2/23 (9)	NE (NE, NE)	3.52 (0.77,16.05)	0.0824	
Nervous system disorders	White	26/144 (18)	18.0 (NE, NE)	6/145 (4)	17.9 (NE, NE)	4.24 (1.74,10.34)	0.0005	0.7249
	Other	7/34 (21)	NE (NE, NE)	2/23 (9)	32.2 (NE, NE)	4.64 (0.57,37.76)	0.1129	
Encephalopathy	White	14/144 (10)	NE (NE, NE)	1/145 (1)	NE (NE, NE)	14.31 (1.88,108.78)	0.0007	0.9920

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.3. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by race (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Other	3/34 (9)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	White	14/144 (10)	53.1 (NE, NE)	3/145 (2)	NE (NE, NE)	4.19 (1.19,14.73)	0.0152	0.9904
	Other	7/34 (21)	35.7 (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	White	12/144 (8)	NE (NE, NE)	3/145 (2)	NE (NE, NE)	3.87 (1.09,13.74)	0.0241	0.9903
	Other	5/34 (15)	NE (NE, NE)	0/23 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.4. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	0	5/95 (5)	28.3 (NE, NE)	13/94 (14)	NE (NE, NE)	0.24 (0.08,0.74)	0.0071	0.9719
	1	7/83 (8)	12.1 (6.0, NE)	13/74 (18)	NE (NE, NE)	0.15 (0.04,0.55)	0.0010	
Febrile neutropenia	0	4/95 (4)	28.3 (28.3, NE)	10/94 (11)	NE (NE, NE)	0.15 (0.03,0.69)	0.0051	0.8018
	1	2/83 (2)	12.1 (4.9, NE)	12/74 (16)	NE (NE, NE)	0.06 (0.01,0.46)	0.0003	
General disorders and administration site conditions	0	14/95 (15)	NE (NE, NE)	2/94 (2)	4.9 (4.9, NE)	6.70 (1.52,29.57)	0.0037	0.2184
	1	22/83 (27)	6.0 (NE, NE)	9/74 (12)	8.6 (NE, NE)	2.43 (1.08,5.46)	0.0265	
Pyrexia	0	14/95 (15)	NE (NE, NE)	1/94 (1)	NE (NE, NE)	14.09 (1.85,107.13)	0.0008	0.1724
	1	20/83 (24)	6.0 (NE, NE)	7/74 (9)	8.6 (NE, NE)	2.99 (1.20,7.46)	0.0134	
Nervous system disorders	0	12/95 (13)	NE (NE, NE)	5/94 (5)	17.9 (17.9, NE)	3.89 (1.10,13.79)	0.0232	0.4828
	1	21/83 (25)	18.0 (NE, NE)	3/74 (4)	NE (NE, NE)	6.23 (1.85,20.98)	0.0007	
Encephalopathy	0	6/95 (6)	NE (NE, NE)	0/94 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9904

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.2.4. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by ECOG status at screening (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	1	11/83 (13)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	10.00 (1.29,77.44)	0.0064	
Vascular disorders	0	11/95 (12)	NE (NE, NE)	2/94 (2)	NE (NE, NE)	5.41 (1.20,24.44)	0.0136	0.8586
	1	10/83 (12)	35.7 (35.7, NE)	1/74 (1)	NE (NE, NE)	7.21 (0.90,57.68)	0.0292	
Hypotension	0	10/95 (11)	NE (NE, NE)	2/94 (2)	NE (NE, NE)	4.86 (1.06,22.19)	0.0239	0.8758
	1	7/83 (8)	NE (NE, NE)	1/74 (1)	NE (NE, NE)	6.45 (0.79,52.39)	0.0447	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.5. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	North America	11/138 (8)	21.1 (6.0, NE)	21/120 (18)	NE (NE, NE)	0.18 (0.07,0.45)	<0.0001	0.9907
	Rest of the world	1/40 (3)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	0.20 (0.02,1.75)	0.1087	
Febrile neutropenia	North America	5/138 (4)	28.3 (12.1, NE)	17/120 (14)	NE (NE, NE)	0.07 (0.02,0.32)	<0.0001	0.5115
	Rest of the world	1/40 (3)	NE (NE, NE)	5/48 (10)	NE (NE, NE)	0.20 (0.02,1.75)	0.1087	
General disorders and administration site conditions	North America	32/138 (23)	6.0 (NE, NE)	8/120 (7)	8.6 (NE, NE)	4.16 (1.83,9.43)	0.0002	0.2296
	Rest of the world	4/40 (10)	NE (NE, NE)	3/48 (6)	4.9 (NE, NE)	1.21 (0.26,5.62)	0.8077	
Pyrexia	North America	30/138 (22)	6.0 (NE, NE)	6/120 (5)	8.6 (NE, NE)	5.53 (2.14,14.25)	<0.0001	0.3570
	Rest of the world	4/40 (10)	NE (NE, NE)	2/48 (4)	NE (NE, NE)	2.16 (0.39,11.85)	0.3621	
Nervous system disorders	North America	25/138 (18)	18.0 (NE, NE)	5/120 (4)	32.2 (NE, NE)	5.61 (1.95,16.14)	0.0003	0.5257
	Rest of the world	8/40 (20)	NE (NE, NE)	3/48 (6)	17.9 (NE, NE)	4.64 (0.99,21.86)	0.0323	
Encephalopathy	North America	13/138 (9)	NE (NE, NE)	0/120 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9914

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.5. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by Geographic Region (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Rest of the world	4/40 (10)	NE (NE, NE)	1/48 (2)	NE (NE, NE)	4.55 (0.51,40.67)	0.1369	
Vascular disorders	North America	18/138 (13)	35.7 (35.7, NE)	3/120 (3)	NE (NE, NE)	4.67 (1.36,16.05)	0.0070	0.9909
	Rest of the world	3/40 (8)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	North America	14/138 (10)	NE (NE, NE)	3/120 (3)	NE (NE, NE)	4.06 (1.16,14.15)	0.0171	0.9910
	Rest of the world	3/40 (8)	NE (NE, NE)	0/48 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.6. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	4/24 (17)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	2/56 (4)	NE (NE, NE)	7/62 (11)	NE (NE, NE)	NE (NE,NE)	NE	
Febrile neutropenia	HGBL - double hit/triple hit	1/32 (3)	NE (NE, NE)	4/24 (17)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/56 (2)	NE (NE, NE)	6/62 (10)	NE (NE, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	HGBL - double hit/triple hit	8/32 (25)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	6.12 (0.76,49.11)	0.0511	0.5921
	Double expressor lymphoma	12/56 (21)	6.0 (NE, NE)	5/62 (8)	8.6 (4.9, NE)	3.34 (1.08,10.37)	0.0265	
Pyrexia	HGBL - double hit/triple hit	8/32 (25)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9909
	Double expressor lymphoma	12/56 (21)	6.0 (NE, NE)	3/62 (5)	8.6 (NE, NE)	6.84 (1.53,30.56)	0.0035	
Nervous system disorders	HGBL - double hit/triple hit	9/32 (28)	NE (3.9, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	0.9900
	Double expressor lymphoma	7/56 (13)	NE (NE, NE)	6/62 (10)	32.2 (NE, NE)	1.51 (0.48,4.77)	0.4763	
Encephalopathy	HGBL - double hit/triple hit	4/32 (13)	NE (NE, NE)	0/24 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.6. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Double expressor lymphoma	5/56 (9)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	8/56 (14)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	HGBL - double hit/triple hit	3/32 (9)	NE (NE, NE)	1/24 (4)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	7/56 (13)	NE (NE, NE)	1/62 (2)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.7. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	HGBL - double hit/triple hit	4/40 (10)	21.5 (4.9, NE)	6/31 (19)	NE (4.1, NE)	0.25 (0.06,1.01)	0.0365	0.8215
	Double expressor lymphoma	3/44 (7)	6.0 (NE, NE)	7/33 (21)	NE (NE, NE)	0.18 (0.04,0.87)	0.0162	
Febrile neutropenia	HGBL - double hit/triple hit	1/40 (3)	NE (NE, NE)	4/31 (13)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	1/44 (2)	NE (NE, NE)	6/33 (18)	NE (NE, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	6.22 (0.78,49.81)	0.0486	0.7817
	Double expressor lymphoma	13/44 (30)	6.0 (NE, NE)	1/33 (3)	NE (NE, NE)	10.12 (1.32,77.89)	0.0057	
Pyrexia	HGBL - double hit/triple hit	8/40 (20)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	13/44 (30)	6.0 (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Nervous system disorders	HGBL - double hit/triple hit	10/40 (25)	NE (NE, NE)	1/31 (3)	17.9 (NE, NE)	> 10,000 (0.00,NE)	0.0042	0.6364
	Double expressor lymphoma	6/44 (14)	18.0 (NE, NE)	2/33 (6)	32.2 (NE, NE)	4.76 (0.57,39.54)	0.1104	
Encephalopathy	HGBL - double hit/triple hit	5/40 (13)	NE (NE, NE)	0/31 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.7. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by double hit / triple hit / double expression status per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Double expressor lymphoma	3/44 (7)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	HGBL - double hit/triple hit	3/40 (8)	35.7 (NE, NE)	1/31 (3)	NE (NE, NE)	1.34 (0.12,14.95)	0.8136	0.9915
	Double expressor lymphoma	10/44 (23)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	HGBL - double hit/triple hit	2/40 (5)	NE (NE, NE)	1/31 (3)	NE (NE, NE)	NE (NE,NE)	NE	NE
	Double expressor lymphoma	9/44 (20)	NE (NE, NE)	0/33 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.2.8. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Germinal center B-cell like	7/107 (7)	21.5 (21.1, NE)	18/100 (18)	NE (NE, NE)	0.15 (0.05,0.46)	0.0001	0.9999
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	2/18 (11)	6.0 (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Febrile neutropenia	Germinal center B-cell like	4/107 (4)	28.3 (28.3, NE)	14/100 (14)	NE (NE, NE)	0.10 (0.02,0.43)	0.0002	1.0000
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	0/18 (0)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	Germinal center B-cell like	23/107 (21)	NE (NE, NE)	9/100 (9)	8.6 (4.9, NE)	2.76 (1.23,6.17)	0.0098	0.9479
	Activated B-cell like	4/16 (25)	NE (0.8, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	6.0 (NE, NE)	1/12 (8)	NE (NE, NE)	1.78 (0.18,17.11)	0.6138	
Pyrexia	Germinal center B-cell like	21/107 (20)	NE (NE, NE)	6/100 (6)	8.6 (NE, NE)	4.10 (1.54,10.87)	0.0021	0.7941
	Activated B-cell like	4/16 (25)	NE (0.8, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240602T17:48

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Table 14.3.1.1.2.8. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Pyrexia	Unclassified	4/18 (22)	6.0 (NE, NE)	1/12 (8)	NE (NE, NE)	1.78 (0.18,17.11)	0.6138	
Nervous system disorders	Germinal center B-cell like	20/107 (19)	NE (NE, NE)	2/100 (2)	NE (NE, NE)	9.64 (2.25,41.23)	0.0002	0.4603
	Activated B-cell like	3/16 (19)	NE (1.4, NE)	1/9 (11)	NE (2.3, NE)	1.72 (0.18,16.63)	0.6341	
	Unclassified	2/18 (11)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	Germinal center B-cell like	12/107 (11)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	11.59 (1.51,89.12)	0.0028	1.0000
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	1/18 (6)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Germinal center B-cell like	12/107 (11)	35.7 (NE, NE)	1/100 (1)	NE (NE, NE)	10.34 (1.33,80.10)	0.0054	0.9999
	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	4/18 (22)	53.1 (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	Germinal center B-cell like	9/107 (8)	NE (NE, NE)	1/100 (1)	NE (NE, NE)	8.38 (1.06,66.21)	0.0156	1.0000

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240602T17:48

Table 14.3.1.1.2.8. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Hypotension	Activated B-cell like	1/16 (6)	NE (NE, NE)	0/9 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Unclassified	3/18 (17)	NE (NE, NE)	0/12 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240602T17:48

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.2.9. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Germinal center B-cell like	8/94 (9)	21.1 (21.1, NE)	12/78 (15)	NE (NE, NE)	0.30 (0.11,0.81)	0.0120	0.5866
	Non-germinal center B-cell like	2/47 (4)	12.1 (NE, NE)	7/49 (14)	NE (NE, NE)	0.12 (0.01,1.00)	0.0204	
Febrile neutropenia	Germinal center B-cell like	3/94 (3)	48.8 (4.9, NE)	9/78 (12)	NE (NE, NE)	0.13 (0.03,0.59)	0.0019	0.9494
	Non-germinal center B-cell like	2/47 (4)	12.1 (NE, NE)	7/49 (14)	NE (NE, NE)	0.12 (0.01,1.00)	0.0204	
General disorders and administration site conditions	Germinal center B-cell like	18/94 (19)	NE (NE, NE)	5/78 (6)	8.6 (NE, NE)	3.73 (1.26,11.02)	0.0105	0.9594
	Non-germinal center B-cell like	10/47 (21)	NE (NE, NE)	3/49 (6)	NE (NE, NE)	3.49 (0.96,12.71)	0.0438	
Pyrexia	Germinal center B-cell like	17/94 (18)	NE (NE, NE)	4/78 (5)	8.6 (NE, NE)	4.74 (1.39,16.19)	0.0060	0.7504
	Non-germinal center B-cell like	10/47 (21)	NE (NE, NE)	3/49 (6)	NE (NE, NE)	3.49 (0.96,12.71)	0.0438	
Nervous system disorders	Germinal center B-cell like	20/94 (21)	NE (NE, NE)	2/78 (3)	17.9 (NE, NE)	17.13 (2.30,127.61)	0.0001	0.0531
	Non-germinal center B-cell like	5/47 (11)	18.0 (NE, NE)	3/49 (6)	NE (NE, NE)	1.23 (0.27,5.56)	0.7912	
Encephalopathy	Germinal center B-cell like	10/94 (11)	NE (NE, NE)	0/78 (0)	NE (NE, NE)	NE (NE,NE)	NE	NE

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.2.9. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by molecular group per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	Non-germinal center B-cell like	3/47 (6)	NE (NE, NE)	0/49 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Germinal center B-cell like	11/94 (12)	35.7 (NE, NE)	1/78 (1)	NE (NE, NE)	8.25 (1.06,64.51)	0.0160	0.3156
	Non-germinal center B-cell like	6/47 (13)	53.1 (NE, NE)	2/49 (4)	NE (NE, NE)	2.36 (0.46,12.25)	0.2913	
Hypotension	Germinal center B-cell like	9/94 (10)	NE (NE, NE)	1/78 (1)	NE (NE, NE)	7.33 (0.93,57.90)	0.0264	0.3330
	Non-germinal center B-cell like	4/47 (9)	NE (NE, NE)	2/49 (4)	NE (NE, NE)	1.88 (0.34,10.34)	0.4620	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.10. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Diffuse large B-cell lymphoma	7/125 (6)	21.1 (6.0, NE)	17/119 (14)	NE (NE, NE)	0.18 (0.06,0.54)	0.0006	0.4434
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	21.5 (4.9, NE)	4/25 (16)	NE (3.3, NE)	0.37 (0.08,1.67)	0.1783	
Febrile neutropenia	Diffuse large B-cell lymphoma	4/125 (3)	28.3 (28.3, NE)	13/119 (11)	NE (NE, NE)	0.12 (0.03,0.52)	0.0008	0.8141
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/32 (3)	NE (4.9, NE)	4/25 (16)	NE (3.3, NE)	0.12 (0.01,1.10)	0.0268	
General disorders and administration site conditions	Diffuse large B-cell lymphoma	24/125 (19)	6.0 (NE, NE)	9/119 (8)	8.6 (4.9, NE)	2.81 (1.26,6.25)	0.0083	0.4362
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/32 (25)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	6.42 (0.80,51.45)	0.0439	
Pyrexia	Diffuse large B-cell lymphoma	22/125 (18)	6.0 (NE, NE)	7/119 (6)	8.6 (NE, NE)	3.49 (1.41,8.61)	0.0038	0.9900
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/32 (25)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Nervous system disorders	Diffuse large B-cell lymphoma	20/125 (16)	18.0 (NE, NE)	8/119 (7)	17.9 (17.9, NE)	2.75 (1.16,6.52)	0.0167	0.9850
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/32 (28)	NE (3.9, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Encephalopathy	Diffuse large B-cell lymphoma	10/125 (8)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	9.44 (1.21,73.78)	0.0088	0.9912

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.10. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per central lab (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/32 (13)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Diffuse large B-cell lymphoma	16/125 (13)	35.7 (35.7, NE)	1/119 (1)	NE (NE, NE)	13.54 (1.78,102.94)	0.0010	0.2847
	HGBL with or without MYC and BCL6 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.15 (0.22,20.88)	0.4986	
Hypotension	Diffuse large B-cell lymphoma	12/125 (10)	NE (NE, NE)	1/119 (1)	NE (NE, NE)	11.55 (1.50,88.86)	0.0028	0.3370
	HGBL with or without MYC and BCL6 and/or BCL6 rearrangement	3/32 (9)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.15 (0.22,20.88)	0.4986	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.11. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	Diffuse large B-cell lymphoma not otherwise specified	7/108 (6)	21.1 (12.1, NE)	13/110 (12)	NE (NE, NE)	0.24 (0.08,0.76)	0.0084	0.9274
	Large cell transformation from follicular lymphoma	1/19 (5)	6.0 (NE, NE)	7/25 (28)	NE (3.4, NE)	0.00 (0.00,NE)	0.0099	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/43 (9)	21.5 (4.9, NE)	4/25 (16)	NE (3.3, NE)	0.30 (0.07,1.38)	0.1021	
	Other	0/8 (0)	NE (NE, NE)	2/8 (25)	NE (0.3, NE)	NE (NE,NE)	NE	
Febrile neutropenia	Diffuse large B-cell lymphoma not otherwise specified	5/108 (5)	28.3 (12.1, NE)	12/110 (11)	NE (NE, NE)	0.13 (0.03,0.59)	0.0018	0.9990
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	5/25 (20)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/43 (2)	NE (4.9, NE)	3/25 (12)	NE (3.3, NE)	0.14 (0.01,1.37)	0.0501	
	Other	0/8 (0)	NE (NE, NE)	2/8 (25)	NE (0.3, NE)	NE (NE,NE)	NE	
General disorders and administration site conditions	Diffuse large B-cell lymphoma not otherwise specified	19/108 (18)	NE (NE, NE)	9/110 (8)	8.6 (4.9, NE)	2.39 (1.04,5.46)	0.0333	0.8920
	Large cell transformation from follicular lymphoma	5/19 (26)	6.0 (NE, NE)	1/25 (4)	NE (NE, NE)	5.32 (0.59,47.57)	0.0942	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/43 (23)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.11. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
General disorders and administration site conditions	Other	2/8 (25)	NE (1.2, NE)	1/8 (13)	NE (0.3, NE)	1.72 (0.15,19.01)	0.6563	
Pyrexia	Diffuse large B-cell lymphoma not otherwise specified	17/108 (16)	NE (NE, NE)	7/110 (6)	8.6 (NE, NE)	2.90 (1.14,7.36)	0.0188	0.9856
	Large cell transformation from follicular lymphoma	5/19 (26)	6.0 (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/43 (23)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	2/8 (25)	NE (1.2, NE)	1/8 (13)	NE (0.3, NE)	1.72 (0.15,19.01)	0.6563	
Nervous system disorders	Diffuse large B-cell lymphoma not otherwise specified	20/108 (19)	18.0 (NE, NE)	4/110 (4)	32.2 (NE, NE)	7.09 (2.11,23.86)	0.0002	0.2997
	Large cell transformation from follicular lymphoma	2/19 (11)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	2.53 (0.23,27.96)	0.4312	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/43 (21)	NE (NE, NE)	1/25 (4)	17.9 (NE, NE)	> 10,000 (0.00,NE)	0.0202	
	Other	2/8 (25)	NE (1.2, NE)	2/8 (25)	NE (0.2, NE)	0.90 (0.13,6.38)	0.9122	
Encephalopathy	Diffuse large B-cell lymphoma not otherwise specified	12/108 (11)	NE (NE, NE)	0/110 (0)	NE (NE, NE)	NE (NE,NE)	NE	1.0000
	Large cell transformation from follicular lymphoma	0/19 (0)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	NE (NE,NE)	NE	

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MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

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Table 14.3.1.1.2.11. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by disease type per investigator (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/43 (12)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	Other	0/8 (0)	NE (NE, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	Diffuse large B-cell lymphoma not otherwise specified	14/108 (13)	53.1 (NE, NE)	2/110 (2)	NE (NE, NE)	6.67 (1.50,29.59)	0.0039	0.7893
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/43 (7)	35.7 (NE, NE)	1/25 (4)	NE (NE, NE)	1.00 (0.09,11.22)	0.9984	
	Other	1/8 (13)	NE (1.3, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Hypotension	Diffuse large B-cell lymphoma not otherwise specified	11/108 (10)	NE (NE, NE)	2/110 (2)	NE (NE, NE)	5.58 (1.24,25.23)	0.0117	0.7578
	Large cell transformation from follicular lymphoma	3/19 (16)	NE (NE, NE)	0/25 (0)	NE (NE, NE)	NE (NE,NE)	NE	
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/43 (5)	NE (NE, NE)	1/25 (4)	NE (NE, NE)	1.00 (0.09,11.22)	0.9984	
	Other	1/8 (13)	NE (1.3, NE)	0/8 (0)	NE (NE, NE)	NE (NE,NE)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.12. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	0 - 1	7/94 (7)	21.1 (12.1, NE)	11/93 (12)	NE (NE, NE)	0.28 (0.09,0.89)	0.0210	0.1934
	2 - 3	5/84 (6)	6.0 (4.9, NE)	15/75 (20)	NE (NE, NE)	0.12 (0.03,0.42)	0.0001	
Febrile neutropenia	0 - 1	3/94 (3)	12.1 (12.1, NE)	8/93 (9)	NE (NE, NE)	0.10 (0.01,0.77)	0.0061	0.7528
	2 - 3	3/84 (4)	28.3 (4.9, NE)	14/75 (19)	NE (NE, NE)	0.08 (0.02,0.37)	<0.0001	
General disorders and administration site conditions	0 - 1	17/94 (18)	NE (NE, NE)	6/93 (6)	8.6 (4.9, NE)	3.26 (1.20,8.84)	0.0140	0.9262
	2 - 3	19/84 (23)	6.0 (NE, NE)	5/75 (7)	NE (NE, NE)	3.40 (1.26,9.16)	0.0100	
Pyrexia	0 - 1	17/94 (18)	NE (NE, NE)	4/93 (4)	8.6 (NE, NE)	5.51 (1.61,18.83)	0.0021	0.5815
	2 - 3	17/84 (20)	6.0 (NE, NE)	4/75 (5)	NE (NE, NE)	3.81 (1.27,11.40)	0.0099	
Nervous system disorders	0 - 1	17/94 (18)	18.0 (NE, NE)	7/93 (8)	17.9 (17.9, NE)	2.80 (1.10,7.14)	0.0238	0.1371
	2 - 3	16/84 (19)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	15.32 (2.03,115.55)	0.0004	
Encephalopathy	0 - 1	5/94 (5)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	4.70 (0.55,40.25)	0.1191	0.9911

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.12. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per CRF (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Encephalopathy	2 - 3	12/84 (14)	NE (NE, NE)	0/75 (0)	NE (NE, NE)	NE (NE,NE)	NE	
Vascular disorders	0 - 1	9/94 (10)	53.1 (NE, NE)	2/93 (2)	NE (NE, NE)	3.65 (0.77,17.21)	0.0802	0.4145
	2 - 3	12/84 (14)	35.7 (NE, NE)	1/75 (1)	NE (NE, NE)	10.55 (1.36,81.72)	0.0049	
Hypotension	0 - 1	8/94 (9)	NE (NE, NE)	2/93 (2)	NE (NE, NE)	3.65 (0.77,17.21)	0.0802	0.5547
	2 - 3	9/84 (11)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	8.65 (1.10,68.28)	0.0136	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CI, confidence interval; HR, hazard ratio; NE, not estimable; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the leukapheresis in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Log-rank test was used to calcuated unstratified P-value (2-sided); Cox model was used to calculate interaction P-value (2-sided).
Note: System organ classes and preferred terms are sorted by alphabetical order.
Note: AEs are coded using MedDRA version 25.1.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.

Data Source: ADSLGBA, ADBASE, ADTTEAE Program Name: t_teae_sg_ser.sas Output Generated: 20240411T17:11

Table 14.3.1.1.2.13. Analysis of Time to the First Serious Treatment-emergent Adverse Events by System Organ Class and Preferred Term with event is >=5% in at least one study arm by second-line age-adjusted IPI score per IXRS (Modified Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Median time to AE (mons) 95% CIs	Standard of Care n/N (%)	Median time to AE (mons) 95% CIs	Unstratified HR (95% CI)	Unstratified P-value	P-value for Interaction
Blood and lymphatic system disorders	0 - 1	8/98 (8)	21.1 (12.1, NE)	14/93 (15)	NE (NE, NE)	0.21 (0.07,0.63)	0.0022	0.7588
	2 - 3	4/80 (5)	6.0 (4.9, NE)	12/75 (16)	NE (NE, NE)	0.17 (0.05,0.63)	0.0027	
Febrile neutropenia	0 - 1	4/98 (4)	28.3 (12.1, NE)	10/93 (11)	NE (NE, NE)	0.07 (0.01,0.56)	0.0010	0.7177
	2 - 3	2/80 (3)	NE (4.9, NE)	12/75 (16)	NE (NE, NE)	0.11 (0.03,0.52)	0.0008	
General disorders and administration site conditions	0 - 1	17/98 (17)	NE (NE, NE)	6/93 (6)	8.6 (4.9, NE)	3.08 (1.13,8.35)	0.0201	0.9485
	2 - 3	19/80 (24)	6.0 (NE, NE)	5/75 (7)	NE (NE, NE)	3.59 (1.33,9.67)	0.0068	
Pyrexia	0 - 1	17/98 (17)	NE (NE, NE)	4/93 (4)	8.6 (NE, NE)	5.25 (1.54,17.93)	0.0031	0.6672
	2 - 3	17/80 (21)	6.0 (NE, NE)	4/75 (5)	NE (NE, NE)	4.02 (1.34,12.02)	0.0070	
Nervous system disorders	0 - 1	17/98 (17)	18.0 (NE, NE)	7/93 (8)	17.9 (17.9, NE)	2.69 (1.06,6.86)	0.0306	0.1152
	2 - 3	16/80 (20)	NE (NE, NE)	1/75 (1)	NE (NE, NE)	16.24 (2.15,122.49)	0.0002	
Encephalopathy	0 - 1	5/98 (5)	NE (NE, NE)	1/93 (1)	NE (NE, NE)	4.52 (0.53,38.66)	0.1310	0.9917

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Keine Subgruppenanalyse der häufigen SUE nach SOC/PT weist einen statistisch signifikanten Interaktionsterm auf, womit keine Kaplan-Meier Plots darzustellen sind.