Poster
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Clinical and Patient-Reported Outcomes in a Phase 3, Randomized, Open-Label Study Evaluating Axicabtagene Ciloleucel Versus Standard-of-Care Therapy in Elderly Patients With Relapsed/Refractory Large B-cell Lymphoma (ZUMA-7)

Jason R. Westin, MD, MS, FACP[1]; Frederick L. Locke, MD[2]; Michael Dickinson, MBBS, DMedSc[3]; Armin Ghobadi, MD[4]; Mahmoud Elsawy, MD, MSc[5]; Tom van Meerten, MD, PhD[6]; David B. Miklos, MD, PhD[7]; Matthew Ulrickson, MD[8]; Miguel-Angel Perales, MD[9]; Umar Farooq, MD[10]; Luciano Wannesson, MD[11]; Lori Leslie, MD[12]; Marie José Kersten, MD, PhD[13]; Caron A. Jacobson, MD, MMSc[14]; John M. Pagel, MD, PhD, DSc[15]; Gerald Wulf, MD, PhD[16]; Linqiu Du, MS[17]; Julia T. Snider, PhD[17]; Christina To, MD[17]; and Olalekan O. Oluwole, MBBS, MPH[18]

[1]The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [2]Moffitt Cancer Center, Tampa, FL, USA; [3]Peter MacCallum Cancer Centre, Royal Melbourne Hospital and the University of Melbourne, Melbourne, Victoria, Australia; [4]Washington University School of Medicine, St Louis, MO, USA; [5]Division of Hematology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; [6]University Medical Center Groningen, Groningen, The Netherlands, on behalf of HOVON/LLPC; [7]Stanford University School of Medicine, Stanford, CA, USA; [8]Banner MD Anderson Cancer Center, Gilbert, AZ, USA; [9]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [10]University of Iowa, Iowa City, IA, USA; [11]Istituto Oncologico della Svizzera Italiana, Bellinzona, Switzerland; [12]John Theurer Cancer Center, Hackensack, NJ, USA; [13]Amsterdam UMC, University of Amsterdam, Amsterdam, The Netherlands, on behalf of HOVON/LLPC; [14]Dana-Farber Cancer Institute, Boston, MA, USA; [15]Swedish Cancer Institute, Seattle, WA, USA; [16]University Medicine Göttingen, Göttingen, Germany; [17]Kite, a Gilead Company, Santa Monica, CA, USA; and [18]Vanderbilt University Cancer Center, Nashville, TN, USA

BACKGROUND

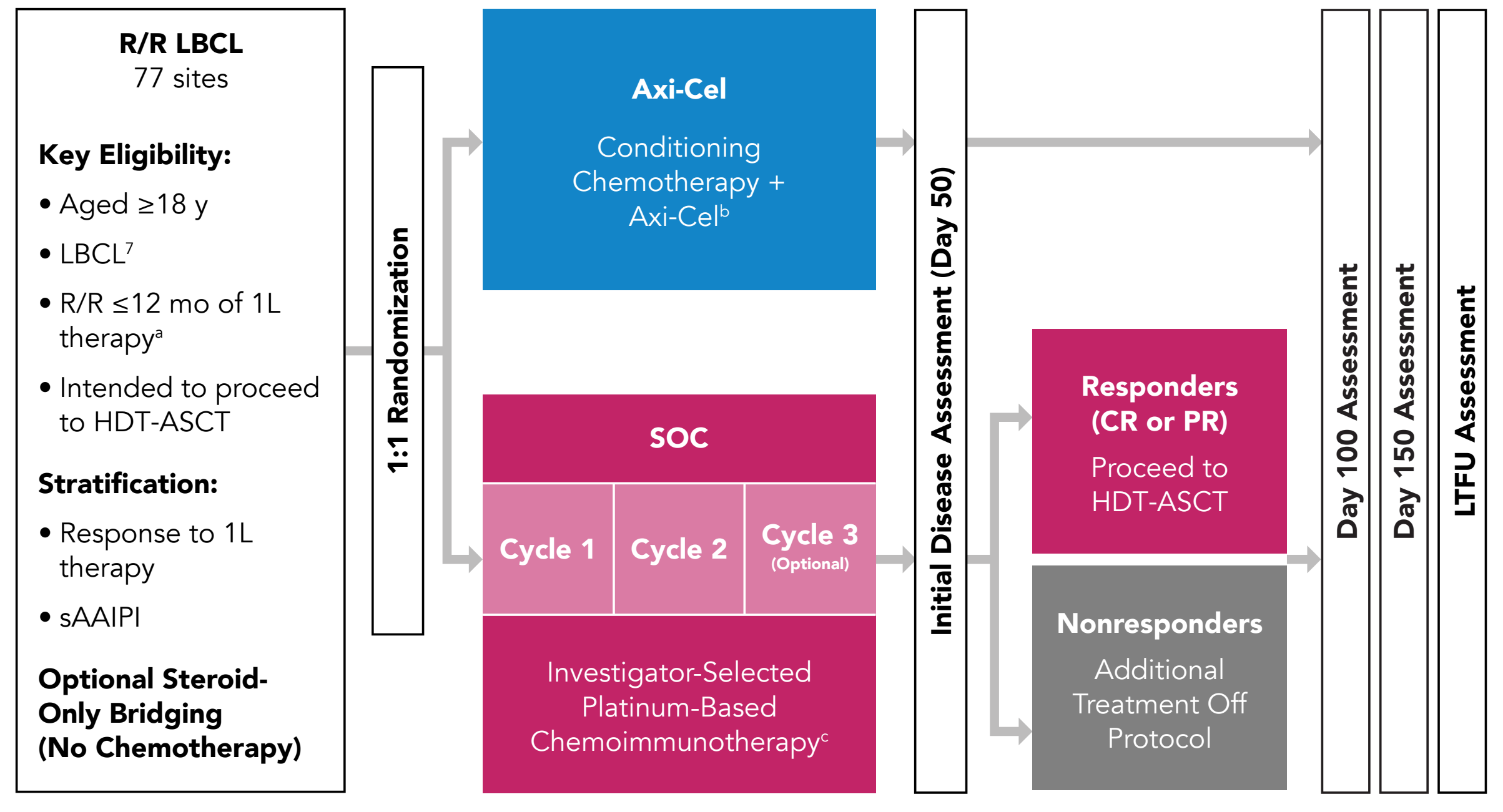
- Axicabtagene ciloleucel (axi-cel) is an autologous anti-CD19 chimeric antigen receptor T-cell therapy approved for the treatment of adult patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after ≥2 lines of systemic therapy and most recently, in the United States, for R/R LBCL within 12 months of first-line chemoimmunotherapy[1]
- The median age at LBCL diagnosis is 66 years, and age can be a determining factor in the decision to use curative therapy[2,3]
- Older patients with R/R LBCL are at risk of inferior outcomes, increased toxicity, and inability to tolerate second-line standard-of-care (SOC) treatment[3]
- In addition, second-line SOC is often associated with poor health-related quality of life (QoL)[4,5]
- ZUMA-7 (NCT03391466) is the first randomized, global, multicenter Phase 3 study of axi-cel versus SOC as second-line treatment in patients with R/R LBCL
- In ZUMA-7, axi-cel significantly improved event-free survival (EFS) compared with second-line SOC (hazard ratio [HR], 0.398, *P*<.0001; median 8.3 versus 2 months, respectively; 24-month EFS rate: 41% versus 16%, respectively; 24.9-month median follow-up)[6]

OBJECTIVE

- To present the safety, efficacy, and patient-reported outcome (PRO) results in a preplanned subgroup analysis of ZUMA-7 patients aged ≥65 years

METHODS

Figure 1. ZUMA-7 Study Schema and Endpoints



R/R LBCL
77 sites

Key Eligibility:
- Aged ≥18 y
- LBCL[7]
- R/R ≤12 mo of 1L therapy[a]
- Intended to proceed to HDT-ASCT

Stratification:
- Response to 1L therapy
- sAAIPI

Optional Steroid-Only Bridging (No Chemotherapy)

Primary Endpoint
- EFS[d] by blinded central review

Key Secondary Endpoints
- ORR
- OS

Secondary Endpoints
- PFS
- Safety
- PROs

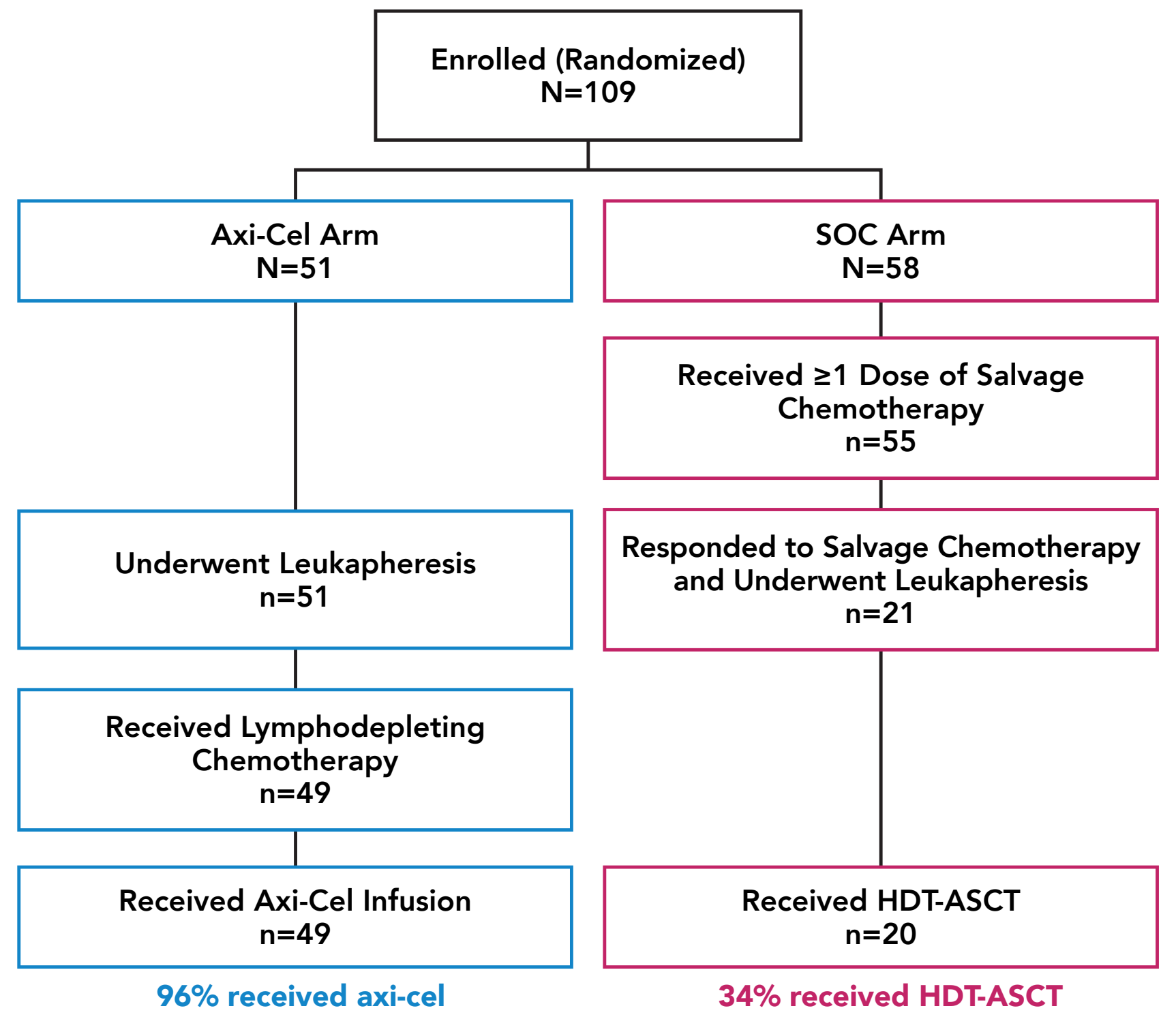
No Protocol-Specified Crossover

[a] Refractory disease was defined as no CR to 1L therapy; relapsed disease was defined as CR followed by biopsy-proven disease relapse ≤12 months from completion of 1L therapy. [b] Axi-cel patients underwent leukapheresis followed by conditioning chemotherapy with cyclophosphamide (500 mg/m²/day) and fludarabine (30 mg/m²/day) 5, 4, and 3 days before receiving a single axi-cel infusion (target intravenous dose, 2×10⁶ CAR T cells/kg). [c] Protocol-defined SOC regimens included R-GDP, R-DHAP, R-ICE, or R-ESHAP. [d] EFS was defined as time from randomization to the earliest date of disease progression per Lugano Classification,[8] commencement of new lymphoma therapy, or death from any cause.
1L, first-line; axi-cel, axicabtagene ciloleucel; CAR, chimeric antigen receptor; CR, complete response; EFS, event-free survival; HDT-ASCT, high-dose chemoimmunotherapy and autologous stem cell transplantation; LBCL, large B-cell lymphoma; LTFU, long-term follow-up; mo, month; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; PRO, patient-reported outcome; R-DHAP, rituximab, dexamethasone, cytarabine, and cisplatin; R-ESHAP, rituximab, etoposide, methylprednisolone, cytarabine, and cisplatin; R-GDP, rituximab, gemcitabine, cisplatin, and dexamethasone; R-ICE, rituximab, ifosfamide, carboplatin, and etoposide phosphate; R/R, relapsed/refractory; sAAIPI, second-line age-adjusted International Prognostic Index; SOC, standard of care; y, year.

- Disease assessments by positron emission tomography and computed tomography scan per Lugano Classification[8] occurred at specified time points from randomization (**Figure 1**)
- Primary endpoint was EFS, defined as time from randomization to the earliest date of disease progression, commencement of new lymphoma therapy, or death from any cause
- Key secondary endpoints included objective response rate (ORR) and overall survival (OS)
- Secondary endpoints included progression-free survival (PFS), safety, and PROs
- Statistical analysis of the preplanned subgroup was similar to the primary efficacy analysis
- Multivariate analyses were conducted to examine efficacy in treatment with axi-cel compared with SOC after adjusting for multiple covariates (treatment, gender, disease type, molecular subgroup, lactate dehydrogenase, tumor burden, and age)
- All reported *P* values are descriptive

RESULTS

Figure 2. Disposition of Patients Aged ≥65 Years in ZUMA-7



Enrolled (Randomized)
N=109

Axi-Cel Arm
N=51

Underwent Leukapheresis
n=51

Received Lymphodepleting Chemotherapy
n=49

Received Axi-Cel Infusion
n=49

96% received axi-cel

SOC Arm
N=58

Received ≥1 Dose of Salvage Chemotherapy
n=55

Responded to Salvage Chemotherapy and Underwent Leukapheresis
n=21

Received HDT-ASCT
n=20

34% received HDT-ASCT

Axi-cel, axicabtagene ciloleucel; HDT-ASCT; high-dose chemoimmunotherapy and autologous stem cell transplantation; SOC, standard of care.

- A total of 359 patients were enrolled in ZUMA-7 (N=180 and N=179 for axi-cel and SOC arms, respectively)
  - The subgroup analysis of patients aged ≥65 years included 109 patients (N=51 and N=58 for axi-cel and SOC arms, respectively; **Figure 2**)
- While 49/51 (96%) patients received axi-cel, only 20/58 (34%) received high-dose chemoimmunotherapy and autologous stem cell transplantation (HDT-ASCT)
- Axi-cel was successfully manufactured for all patients who underwent leukapheresis

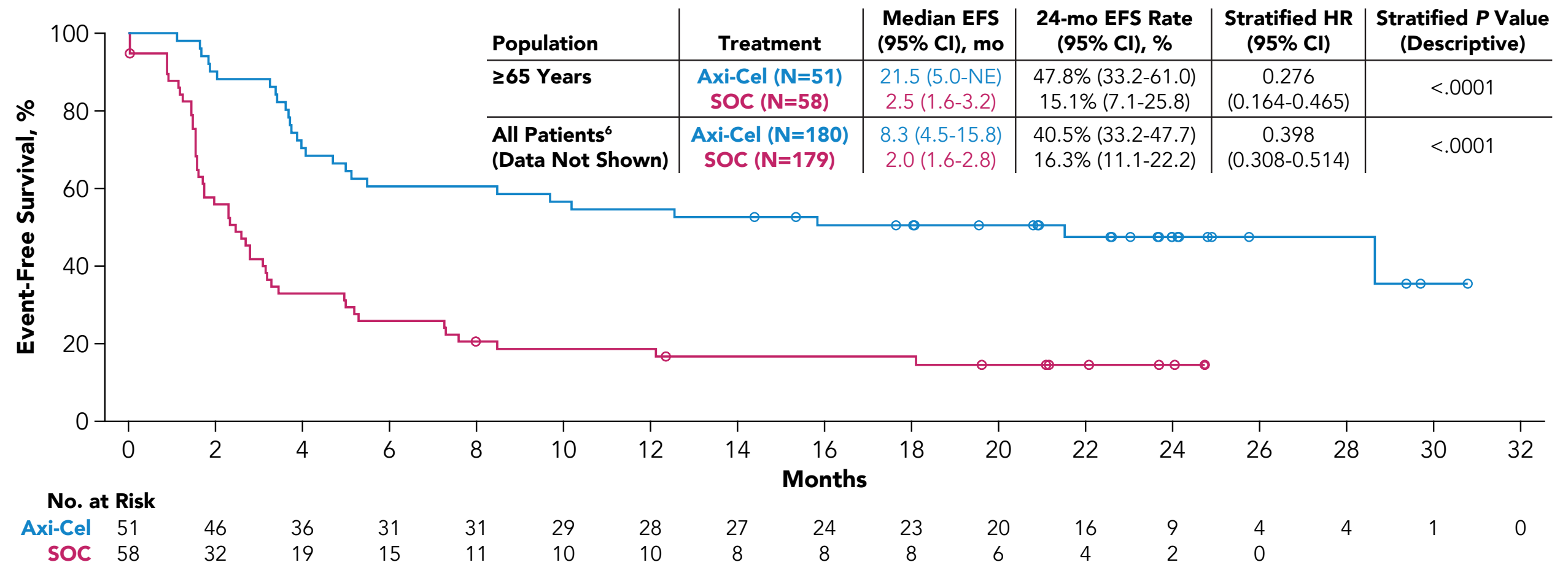
Table 1. Baseline Characteristics for Patients Aged ≥65 Years

Characteristic	Axi-Cel N=51	SOC N=58	Overall N=109
Median age (range), years	70 (65-80)	69 (65-81)	69 (65-81)
Sex, male, n (%)	28 (55)	39 (67)	67 (61)
Disease stage III-IV, n (%)	42 (82)	44 (76)	86 (79)
sAAIPI of 2-3[a], n (%)	27 (53)	18 (31)	45 (41)
Response to 1L therapy[a], n (%)			
Primary refractory	37 (73)	39 (67)	76 (70)
Relapse ≤12 months of 1L therapy	14 (27)	19 (33)	33 (30)
Disease type per investigator, n (%)			
DLBCL not specified	27 (53)	40 (69)	67 (61)
T-cell/histiocyte-rich LBCL	0 (0)	1 (2)	1 (1)
Large cell transformation from follicular lymphoma	7 (14)	9 (16)	16 (15)
HGBL with/without *MYC* and *BCL2* and/or *BCL6* rearrangement	17 (33)	8 (14)	25 (23)
Elevated LDH level[b]	31 (61)	24 (41)	55 (50)

[a] As reported by investigator at the time of randomization via Interactive Voice/Web Response System. [b] LDH level greater than upper limit of normal per local laboratory reference range.
1L, first-line; axi-cel, axicabtagene ciloleucel; DLBCL, diffuse large B-cell lymphoma; HGBL, high grade B-cell lymphoma; LBCL, large B-cell lymphoma; LDH, lactate dehydrogenase; sAAIPI, second-line age-adjusted International Prognostic Index; SOC, standard of care.

- Compared with SOC patients, more axi-cel patients had high-risk features at baseline, including second-line age-adjusted International Prognostic Index 2-3 (53% vs 31%), elevated lactate dehydrogenase (61% vs 41%), and high-grade B-cell lymphoma (including double-/triple-hit lymphoma; 33% vs 14%; **Table 1**)

Figure 3. Primary Endpoint: Event-Free Survival Per Blinded Central Review in Patients Aged ≥65 Years



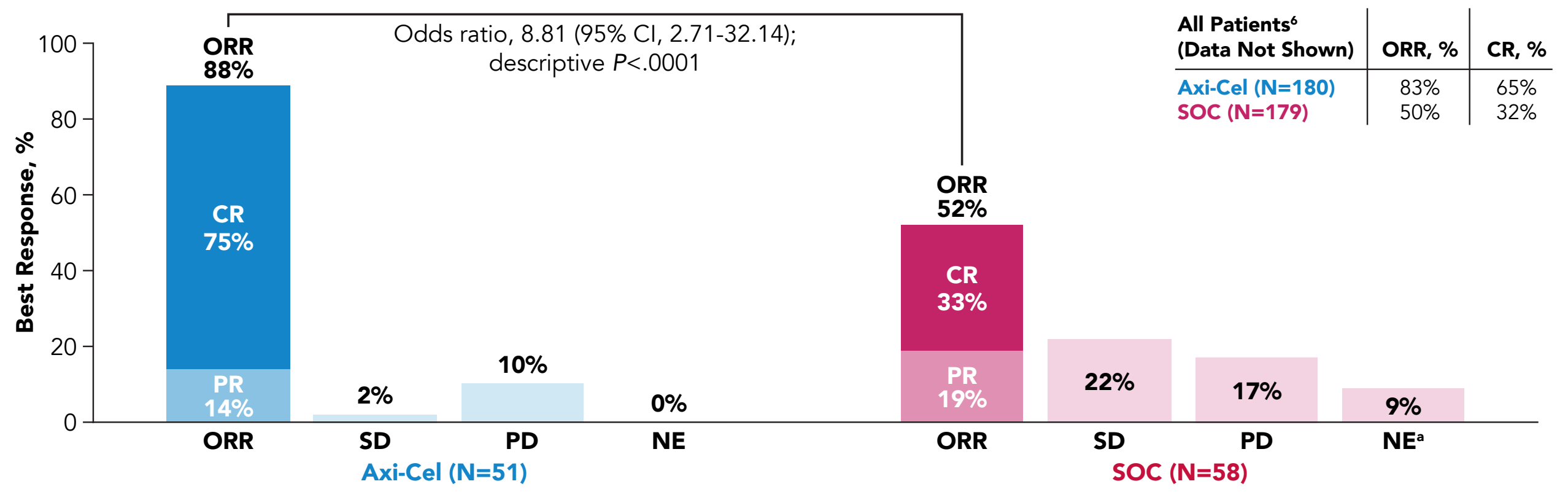
Population	Treatment	Median EFS (95% CI), mo	24-mo EFS Rate (95% CI), %	Stratified HR (95% CI)	Stratified *P* Value (Descriptive)
≥65 Years	Axi-Cel (N=51) SOC (N=58)	21.5 (5.0-NE) 2.5 (1.6-3.2)	47.8% (33.2-61.0) 15.1% (7.1-25.8)	0.276 (0.164-0.465)	<.0001
All Patients[6] (Data Not Shown)	Axi-Cel (N=180) SOC (N=179)	8.3 (4.5-15.8) 2.0 (1.6-2.8)	40.5% (33.2-47.7) 16.3% (11.1-22.2)	0.398 (0.308-0.514)	<.0001

No. at Risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
Axi-Cel	51	46	36	31	31	29	28	27	24	23	20	16	9	4	4	1	0
SOC	58	32	19	15	11	10	10	8	8	8	6	4	2	0			

Axi-cel, axicabtagene ciloleucel; EFS, event-free survival; HR, hazard ratio; mo, month; NE, not evaluable; SOC, standard of care.

- The primary endpoint of EFS showed that treatment with axi-cel was superior to SOC (HR, 0.276; descriptive *P*<.0001; **Figure 3**)
- With 24.3-months median follow-up, median EFS was longer with axi-cel versus SOC (21.5 months [95% CI, 5.0-not evaluable] vs 2.5 months [95% CI, 1.6-3.2], respectively) in patients aged 65 years or older
- Kaplan-Meier estimates of the 24-month EFS rates were higher for axi-cel than for SOC (47.8% vs 15.1%, respectively)
- Multivariate analyses showed similar EFS results when adjusting for differences in baseline characteristics (HR, 0.23; descriptive *P*<.0001)

Figure 4. Objective Response Rate in Patients Aged ≥65 Years

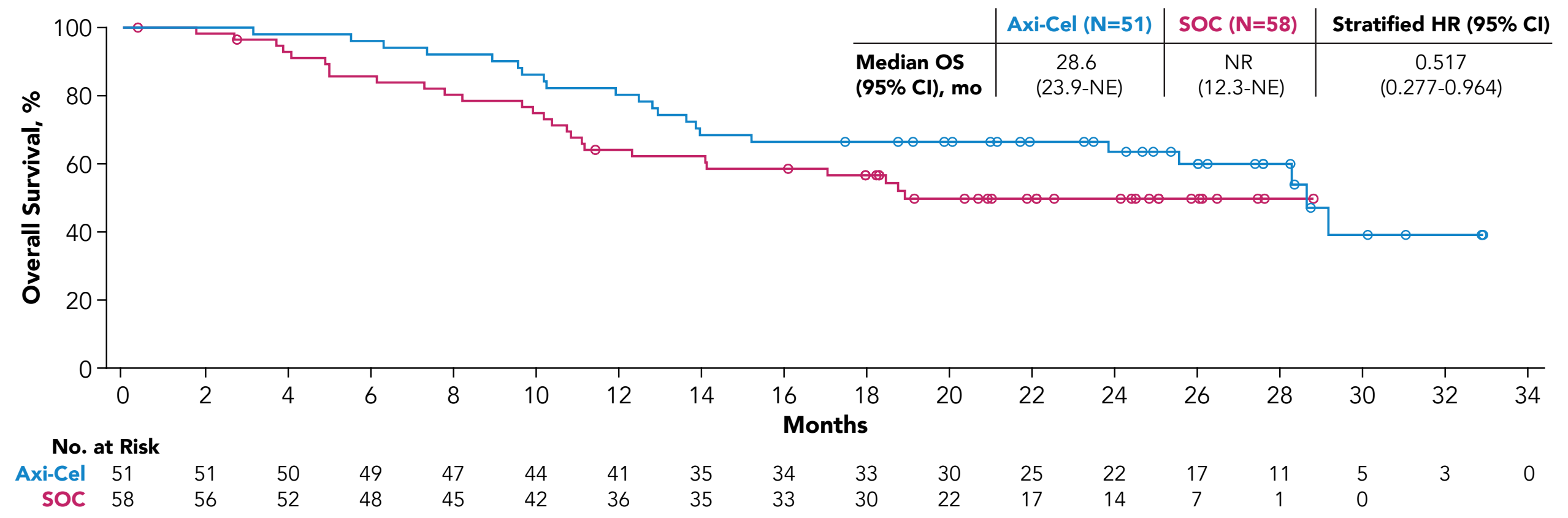


All Patients[6] (Data Not Shown)	ORR, %	CR, %
Axi-Cel (N=180)	83%	65%
SOC (N=179)	50%	32%

[a] NE: In the SOC arm, there was 1 patient with undefined disease and 4 who did not have response assessments done.
Axi-cel, axicabtagene ciloleucel; CR, complete response; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; SOC, standard of care.

- ORR was higher with axi-cel versus SOC (descriptive *P*<.0001), and complete response (CR) rate of the axi-cel arm was over double that of the SOC arm (75% vs 33%, respectively; **Figure 4**)

Figure 5. Overall Survival in Patients Aged ≥65 Years, Evaluated as an Interim Analysis



	Axi-Cel (N=51)	SOC (N=58)	Stratified HR (95% CI)
Median OS (95% CI), mo	28.6 (23.9-NE)	NR (12.3-NE)	0.517 (0.277-0.964)

No. at Risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34
Axi-Cel	51	51	50	49	47	44	41	35	34	33	30	25	22	17	11	5	3	0
SOC	58	56	52	48	45	42	36	35	33	30	22	17	14	7	1	0		

Axi-cel, axicabtagene ciloleucel; HR, hazard ratio; mo, month; NE, not evaluable; NR, not reached; OS, overall survival; SOC, standard of care.

- 57% of SOC patients received subsequent cellular immunotherapy (off protocol)
- OS, evaluated as a preplanned interim analysis, was prolonged in the axi-cel compared with the SOC arm (HR, 0.517; 95% CI, 0.277-0.964; descriptive *P*=.0175; **Figure 5**)
- The Kaplan-Meier estimate of OS at 2 years was 64% in the axi-cel arm and 51% in the SOC arm
- Preplanned sensitivity analysis suggested an OS benefit in favor of axi-cel with the Rank Preserving Structural Failure Time model[9] (HR, 0.364; 95% CI, 0.183-0.723)
- Median PFS was 21.5 months (95% CI, 5.1-NE) for the axi-cel arm and 5.0 months (95% CI, 2.8-7.3) for the SOC arm (HR, 0.384; 95% CI, 0.214-0.691; descriptive *P*<.001)

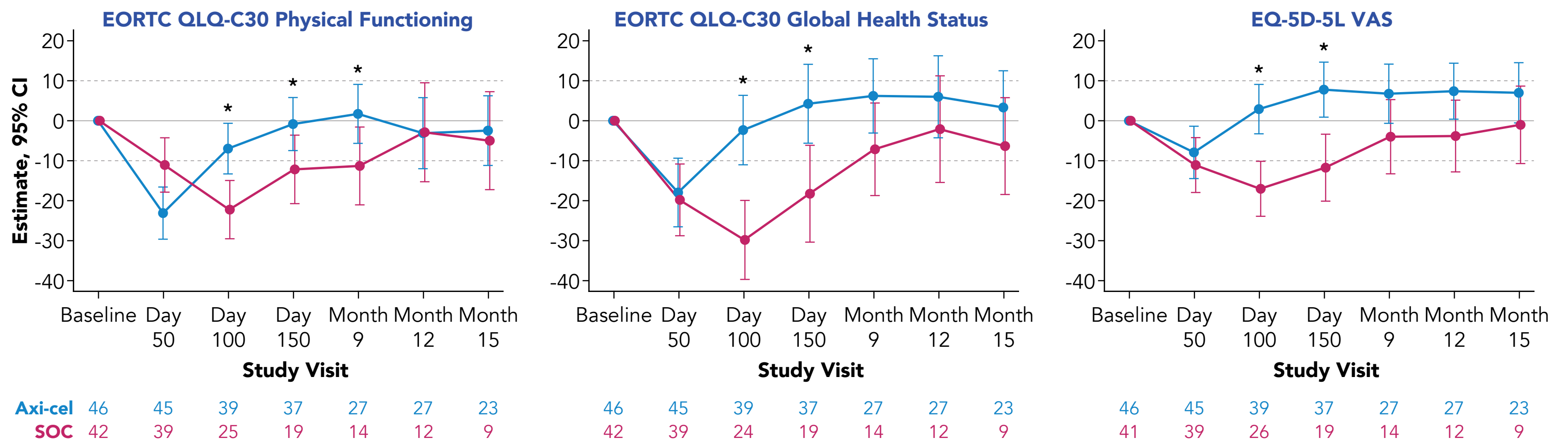
Table 2. Safety Overview in Patients Aged ≥65 Years

	Axi-Cel n=49		SOC n=55	
	Any Grade	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Any AE, n (%)[a,b]	**49 (100)**	**46 (94)**	**55 (100)**	**45 (82)**
Pyrexia	47 (96)	4 (8)	14 (25)	0 (0)
Neutropenia[c]	39 (80)	39 (80)	24 (44)	24 (44)
Nausea	23 (47)	1 (2)	37 (67)	3 (5)
Any serious AE, n (%)[d]	**29 (59)**	**25 (51)**	**26 (47)**	**23 (42)**
CRS, n (%)[e,f]	48 (98)	4 (8)	-	-
CRS management,[g] n (%)				
Tocilizumab	33 (67)		-	
Corticosteroids	14 (29)		-	
Vasopressors	3 (6)		-	
Median time to onset, days	3		-	
Median duration of events, days	8		-	
Neurologic event, n (%)[h,i]	32 (65)	13 (27)	14 (25)	1 (2)
Management with corticosteroids,[g] n (%)	22 (45)		0 (0)	
Median time to onset, days	7		26	
Median duration of events, days	9		39	
Reason for deaths, n (%)				
Progressive disease	19 (39)		20 (36)	
Grade 5 AEs during protocol-specified reporting period	1 (2)[j]		1 (2)[k]	
Definitive therapy-related mortality	0 (0)		1 (2)[k]	
Other[l]	1 (2)		5 (9)	

[a] Included are the 3 most common AEs of any grade occurring in the axi-cel arm. [b] In patients aged <65 years, Grade ≥3 AEs occurred in 109 (90%) axi-cel patients and 95 (84%) SOC patients. [c] Neutropenia refers to the combined preferred terms of neutropenia and neutrophil count decreased. [d] In patients aged <65 years, Grade ≥3 serious AEs occurred in 47 (39%) axi-cel patients and 44 (39%) SOC patients. [e] CRS was graded according to Lee et al.[10] [f] In patients aged <65 years, Grade ≥3 CRS occurred in 7 (6%) axi-cel patients. [g] Toxicity management followed ZUMA-1 pivotal cohorts. [h] Neurologic events were identified per prespecified search list based on methods used in the blinatumomab registrational study.[11] [i] In patients <65 years, Grade ≥3 neurologic events occurred in 23 (19%) axi-cel patients and 0 (0%) SOC patients. [j] Due to COVID-19. [k] Due to cardiac arrest. [l] Other reasons for death included natural progression from prior subdural hematoma (n=1) in the axi-cel arm and COVID-19 (n=2), cardiopulmonary arrest (n=1), urosepsis (n=1), and sepsis (n=1) in the SOC arm.
AE, adverse event; axi-cel, axicabtagene ciloleucel; CRS, cytokine release syndrome; SOC, standard of care.

- Grade ≥3 adverse events (AEs) occurred in 46/49 (94%) axi-cel patients and 45/55 (82%) SOC patients (**Table 2**)
- Grade 5 treatment-related AEs occurred in 0 and 1 (cardiac arrest) patient in the axi-cel and SOC arms, respectively
- There were slightly higher rates of cytokine release syndrome (CRS) and neurologic events, including Grade ≥3, in patients aged ≥65 years compared with the overall ZUMA-7 population[6]
  - CRS occurred in 98% and 8% for any grade and Grade ≥3, respectively, in patients ≥65 years of age compared with 92% and 6% in the overall ZUMA-7 population
  - In the axi-cel arm, neurologic events occurred in 65% and 27% for any grade and Grade ≥3, respectively, in patients ≥65 years of age compared with 60% and 21% in the overall ZUMA-7 population

Figure 6. Change From Baseline for Prespecified PRO Endpoints in Patients Aged ≥65 Years



	Baseline	Day 50	Day 100	Day 150	Month 9	Month 12	Month 15
EORTC QLQ-C30 Physical Functioning							
Axi-cel	46	45	39	37	27	27	23
SOC	42	39	25	19	14	12	9
EORTC QLQ-C30 Global Health Status							
Axi-cel	46	45	39	37	27	27	23
SOC	42	39	24	19	14	12	9
EQ-5D-5L VAS							
Axi-cel	46	45	39	37	27	27	23
SOC	41	39	26	19	14	12	9

**P*<.05.
Axi-cel, axicabtagene ciloleucel; EORTC, European Organization for Research and Treatment of Cancer; EQ-5D-5L, EuroQoL five-dimension questionnaire using a five-level scale; PRO, patient-reported outcome; QLQ-C30, Quality of Life Questionnaire-Core 30; SOC, standard of care; VAS, visual analogue scale.

- In the QoL analysis set comprising 46 axi-cel and 42 SOC patients, there was a clinically meaningful difference in mean change of scores from baseline at Day 100 in favor of axi-cel for European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30) Global Health (*P*<.0001), Physical Functioning (*P*=.0019), and EuroQoL five-dimension questionnaire using a five-level scale (EQ-5D-5L) visual analogue scale (*P*<.0001; **Figure 6**)
  - For all 3 domains, scores favored (*P*<.05) axi-cel over SOC at Day 150
- The mean estimated scores numerically returned to or exceeded baseline scores earlier in the axi-cel arm (by Day 150) but never equaled or exceeded baseline scores by Month 15 in the SOC arm
- Additional PRO domains with mean change of scores from baseline to Day 100 in favor of axi-cel were EORTC QLQ-C30 Role Functioning, EORTC QLQ-C30 Emotional Functioning, EORTC QLQ-C30 Social Functioning, EORTC QLQ-C30 Fatigue, EORTC QLQ-C30 Dyspnea, EORTC QLQ-C30 Appetite Loss, EORTC QLQ-C30 Diarrhea, and EQ-5D-5L Index

CONCLUSIONS

- Axi-cel demonstrated superiority over second-line SOC (HDT-ASCT) in patients ≥65 years, despite the greater frequency of high-risk features in the axi-cel arm, with
  - >8-fold greater median EFS (21.5 months vs 2.5 months, respectively; descriptive *P*<.0001)
  - >3-fold greater estimated 24-month EFS rate
  - Over double the CR rate
  - Almost triple the proportion of patients receiving definitive therapy
- Axi-cel had a manageable safety profile that was consistent with previous studies and real-world data in patients of all ages[12,13]
- Compared with SOC, axi-cel also showed meaningful improvement in QoL, measured by multiple validated PRO instruments, with suggested faster recovery to pretreatment QoL
- These data demonstrate that older patients, who are frequently considered transplant-ineligible based on age, can safely receive second-line curative intent therapy
- The superior clinical outcomes and patient experience with axi-cel over SOC should help inform treatment choices in second-line R/R LBCL for patients 65 years of age or older

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- All employees of Kite involved over the course of the study for their contributions
- These data were in part previously presented at the 2022 European CAR T-Cell Meeting[14]

DISCLOSURES

JRW: consultancy or advisory role for Kite, Novartis, Bristol Myers Squibb, Genentech, AstraZeneca, Janssen, Merck, ADC Therapeutics, AbbVie, Genmab, Umoja, and Iksuda; and research funding from Kite, Novartis, Bristol Myers Squibb, Genentech, MorphoSys, AstraZeneca, and ADC Therapeutics. **FLL:** consulting or advisory role with EcoR1, Emerging Therapy Solutions, Gerson Lehrman Group, Allogene, Amgen, bluebird bio, Bristol Myers Squibb/Celgene, Calibr, Iovance, Kite, Janssen, Legend Biotech, Novartis, Umoja, Cowen, Cellular Biomedicine Group, GammaDelta Therapeutics, and Wugen; research funding from Kite, Allogene, and Novartis; and patents, royalties, other intellectual property from several patents held by the institution in my name (unlicensed) in the field of cellular immunotherapy. **MD:** honoraria from Roche, Gilead, MSD, and Novartis; consultancy or advisory role for Roche, Gilead, MSD, and Novartis; speakers' bureau participation for Roche, Gilead, MSD, and Novartis; and research funding from Novartis and Roche. **AG:** consultancy or advisory role for Kite, Amgen, Atara, Wugen, and Celgene; research funding from Kite, and Amgen; and honoraria from Kite. **ME:** honoraria from Kite, Bristol Myers Squibb, Novartis, Pfizer, and Janssen; and consulting or advisory role with Kite, Bristol Myers Squibb, Novartis, Pfizer, Janssen. **TvM:** honoraria from Kite; and consultancy or advisory role for Janssen. **DBM:** consultancy or advisory role for Kite, Novartis, Juno-Celgene-Bristol Myers Squibb, Allogene, Precision BioSciences, Adicet, Pharmacyclics, Janssen, Takeda, Adaptive Biotechnologies, and Miltenyi Biotec; research funding from Kite, Novartis, Juno-Celgene-Bristol Myers Squibb, Allogene, Precision BioSciences, Adicet, and Adaptive Biotechnologies; and patents, royalties, or other intellectual property from Pharmacyclics. **MU:** advisory board: Gilead and Stemline. **MAP:** employment with Memorial Sloan Kettering Cancer Center; honoraria from AbbVie, Astellas, Bellicum, Celgene, Bristol Myers Squibb, Incyte, Karyopharm, Kite, Miltenyi Biotec, MorphoSys, Nektar Therapeutics, Novartis, Takeda, VectivBio AG, and Vor Biopharma; consultancy or advisory role for Merck, Omeros, and Orca Bio; research funding from Incyte, Kite, and Miltenyi Biotec; and other relationships with DSMB, Cidara Therapeutics, Medigene, Sellas Life Sciences, and Servier. **UF:** honoraria from Kite; consulting or advisory role with MorphoSys. **LW:** consultancy or advisory role for Novartis, MSD, Bristol Myers Squibb, AstraZeneca, and Roche; research funding from Roche; and expert testimony from AstraZeneca and Novartis. **LL:** consultancy and travel support with AbbVie, AstraZeneca, Merck, TG Therapeutics, Janssen, Epizyme, Kite, Celgene, Pharmacyclics, Bristol Myers Squibb, ADC Therapeutics, BeiGene, and Seattle Genetics; speakers' bureau participation and travel support for Kite, BeiGene, Pharmacyclics, Janssen, AstraZeneca, Seattle Genetics, TG Therapeutics, Epizyme, Karyopharm, Celgene, and Bristol Myers Squibb; Participation on a Data Safety Advisory Board with TG therapeutics, AbbVie, Pharmacyclics, Janssen, AstraZeneca, Seattle Genetics, and ADC Therapeutics. **MJK:** honoraria from Kite, Novartis, Miltenyi Biotec, Roche, and Bristol Myers Squibb/Celgene; consultancy or advisory role for Kite, Roche, Bristol Myers Squibb/Celgene, Novartis, and Miltenyi Biotec; research funding from Kite, Roche, Takeda, and Celgene; and travel support from Kite, Roche, Novartis, and Miltenyi Biotec. **CAJ:** honoraria from Kite, Celgene, Novartis, bluebird bio, Epizyme, Humanigen, Pfizer, Precision BioSciences, Nkarta, Lonza, and AbbVie; consultancy or advisory role for Kite, Celgene, Novartis, Pfizer, Humanigen, Precision BioSciences, Nkarta, bluebird bio, Lonza, Pfizer, Ispen, and AbbVie; speakers' bureau participation for Axis and Clinical Care Options; research funding from Pfizer; and travel support from Kite, Celgene, Novartis, Precision BioSciences, Lonza, Pfizer, and Humanigen. **JMP:** consultancy or advisory role for Kite, AstraZeneca, MorphoSys/Incyte, Epizyme, and Actinium. **GW:** honoraria from Gilead, Novartis, Clinigen; consulting or advisory role for Novartis; speakers' bureau for Amgen. **LD:** employment with Kite; consulting or advisory role with Agios Pharmaceuticals. **JTS:** employment with Kite; and stock or other ownership in Gilead. **CT:** employment with Kite; stock or other ownership in Gilead Sciences. **OOO:** consultancy or advisory role for Kite, Janssen, Pfizer, Novartis, and Curio Science; honoraria from Kite; and research funding from Kite.

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