Abstract
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Subgroup Analyses of KTE-X19, an Anti-CD19 Chimeric Antigen Receptor T-cell Therapy, in Adult Patients With Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia in ZUMA-3

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BACKGROUND

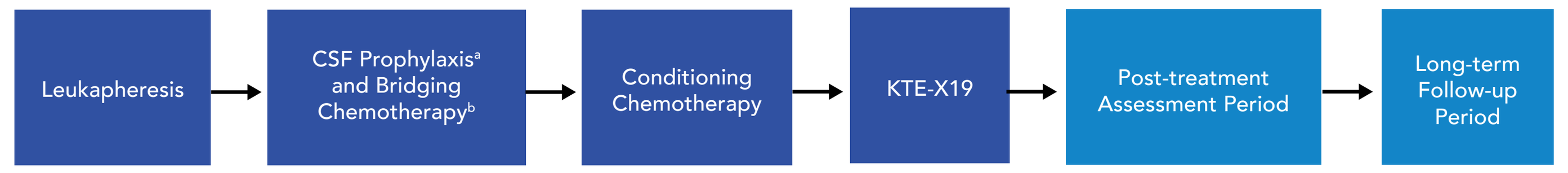
- Adult patients with relapsed or refractory (R/R) B-precursor acute lymphoblastic leukemia (B-ALL) have poor overall survival (OS; 1-year rate, 26%) after salvage therapies, and outcomes worsen with subsequent relapses[1,2]
- Although novel agents such as blinatumomab have improved outcomes in R/R B-ALL, the median OS with blinatumomab is <8 months in adult patients[3,4]
- Brexucabtagene autoleucel (KTE-X19) is an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy approved in the United States to treat adults with R/R B-ALL (based on the positive results of the ZUMA-3 study) and adults with R/R mantle cell lymphoma[5]
- In the pivotal Phase 2 portion of ZUMA-3, KTE-X19 demonstrated compelling efficacy and a manageable safety profile in heavily pretreated adults with R/R B-ALL[6]
  - At a median follow-up of 16.4 months (N=55), the overall complete remission (CR) rate (including CR with incomplete hematologic recovery [CRi]) was 71% (95% CI, 57-82) and median OS was 18.2 months
- Here, we report the outcomes of prior treatment subgroups after >2 years of follow-up in Phase 2 treated patients and in a pooled analysis of Phase 1 and 2 patients who received the pivotal dose of KTE-X19

OBJECTIVE

- To evaluate safety and efficacy outcomes in ZUMA-3 by prior number of therapy lines, prior blinatumomab, prior allogeneic stem cell transplant (alloSCT), and subsequent alloSCT in Phase 2 treated patients and in a larger pooled analysis of Phase 1 and 2 patients treated with the pivotal dose of KTE-X19 (1×10^6 CAR T cells/kg)

METHODS

Figure 1. ZUMA-3 Phase 2 Study Design[6]



Key Eligibility Criteria
- ≥18 years of age with R/R B-ALL[c] and BM blasts >5%
- Patients could have received prior blinatumomab and/or prior alloSCT

Conditioning Chemotherapy
- Fludarabine 25 mg/m^2 IV on Days −4, −3, −2 and cyclophosphamide 900 mg/m^2 IV on Day −2

KTE-X19
- 1×10^6 anti-CD19 CAR T cells/kg on Day 0

Primary Endpoint
- Overall CR rate (CR + CRi) by central assessment

Key Secondary Endpoints
- DOR
- RFS
- Subsequent alloSCT
- OS
- Safety
- CAR T-cell levels in blood (exploratory)

[a] All patients received CSF prophylaxis consisting of an intrathecal regimen according to institutional or national guidelines. [b] Bridging chemotherapy was recommended for all patients particularly those with >25% marrow blasts or >1000 blasts/µL of peripheral blood at screening, per physician's discretion. [c] R/R disease was defined as primary refractory, first relapse with remission ≤12 months, R/R after ≥2 prior lines of systemic therapy or relapsed after alloSCT.
alloSCT, allogeneic stem cell transplant; B-ALL, B-precursor acute lymphoblastic leukemia; BM, bone marrow; CAR, chimeric antigen receptor; CR, complete remission; CRi, complete remission with incomplete hematologic recovery; CSF, cerebrospinal fluid; DOR, duration of remission; IV, intravenous; OS, overall survival; RFS, relapse-free survival; R/R, relapsed/refractory.

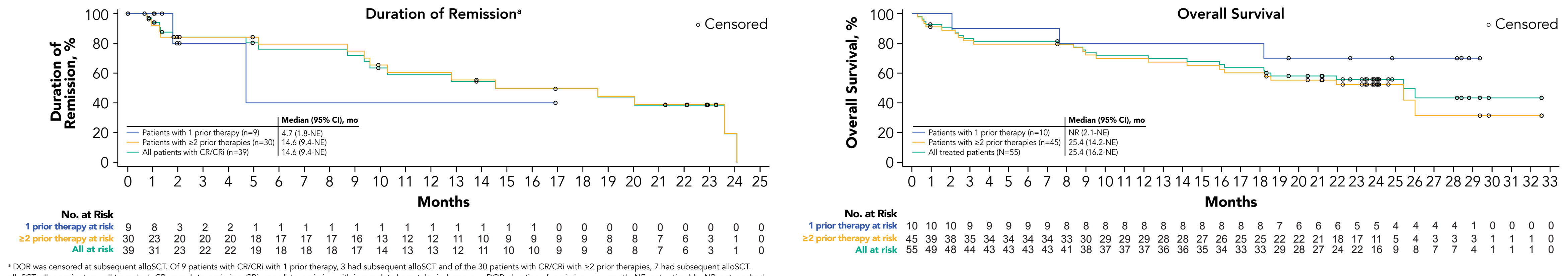
- Post hoc efficacy and safety assessments of subgroups in ZUMA-3 are reported in both Phase 2 treated patients (N=55) and in a newly conducted pooled analysis of Phase 1 and 2 patients who were treated with the pivotal dose of KTE-X19 (N=78) by
  - Prior number of therapy lines (1 prior line and ≥2 prior lines)
  - Prior blinatumomab therapy (prior blinatumomab and blinatumomab naive)
  - Prior alloSCT (prior alloSCT and no prior alloSCT)
  - Subsequent alloSCT (subsequent alloSCT and no subsequent alloSCT)
- Subsequent alloSCT was allowed per investigator discretion but was not protocol defined
- Statistical analyses
  - Efficacy outcomes were assessed by independent central review
  - Time-to-event endpoints were analyzed using the Kaplan-Meier method
  - Prespecified subgroup analyses were descriptive
- Data cutoff: July 23, 2021

RESULTS

- Median follow-up time was 26.8 months (range, 20.7-32.6) for Phase 2 treated patients (N=55) and 29.7 months (range, 20.7-58.3) for pooled Phase 1 and 2 patients (N=78)
- As previously reported, most Phase 2 patients were heavily pretreated, with a median number of 2 prior therapies and almost half (47%) having received ≥3 prior therapies[6]
- Among Phase 2 treated patients at baseline:
  - 10 patients (18%) had 1 prior line of therapy; 45 patients (82%) had ≥2 prior lines of therapy
  - 25 patients (45%) received prior blinatumomab; 30 patients (55%) were blinatumomab naive
    - 12/25 blinatumomab-exposed patients (48%) had blinatumomab as their last therapy prior to receiving KTE-X19, with a median time from blinatumomab to KTE-X19 of 4.9 months (range 2.5-45.7) in these patients
  - 23 patients (42%) received prior alloSCT; 32 patients (58%) did not
    - 5/23 previously transplanted patients (22%) had prior alloSCT as their last therapy prior to receiving KTE-X19, with a median time from alloSCT to KTE-X19 of 11.7 months (range, 9.1-45.3) in these patients
- Most baseline patient and disease characteristics were largely similar among subgroups examined

RESULTS *(Continued)*

Figure 2. Duration of Remission and Overall Survival in Phase 2 Treated Patients (N=55) by Prior Number of Therapy Lines

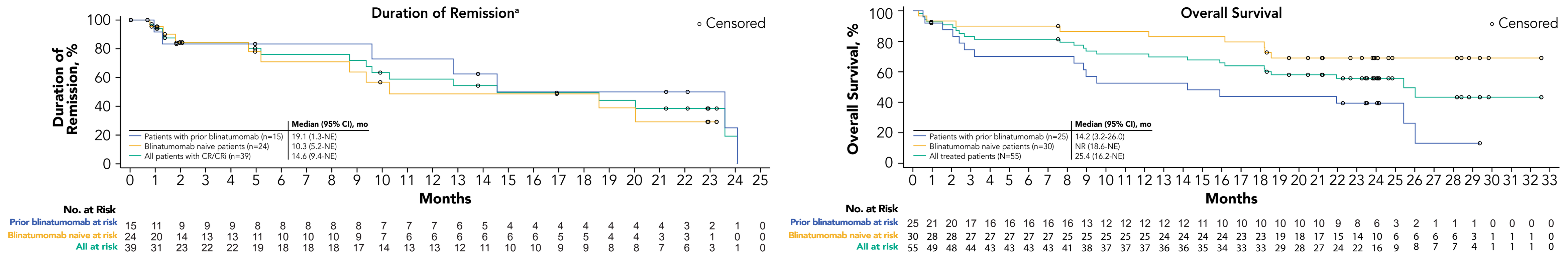


Duration of Remission[a]
Overall Survival
Censored
Duration of Remission, %
Overall Survival, %
Months
Median (95% CI), mo
Patients with 1 prior therapy (n=9) 4.7 (1.8-NE)
Patients with ≥2 prior therapies (n=30) 14.6 (9.4-NE)
All patients with CR/CRi (n=39) 14.6 (9.4-NE)
Patients with 1 prior therapy (n=10) NR (2.1-NE)
Patients with ≥2 prior therapies (n=45) 25.4 (14.2-NE)
All treated patients (N=55) 25.4 (16.2-NE)
No. at Risk
1 prior therapy at risk
≥2 prior therapy at risk
All at risk

[a] DOR was censored at subsequent alloSCT. Of 9 patients with CR/CRi with 1 prior therapy, 3 had subsequent alloSCT and of the 30 patients with CR/CRi with ≥2 prior therapies, 7 had subsequent alloSCT.
alloSCT, allogeneic stem cell transplant; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; mo, month; NE, not estimable; NR, not reached.

- Median OS was not reached in Phase 2 patients with 1 prior therapy and was 25.4 months in patients with ≥2 prior therapies (**Figure 2**)

Figure 3. Duration of Remission and Overall Survival in Phase 2 Treated Patients (N=55) by Prior Blinatumomab Exposure

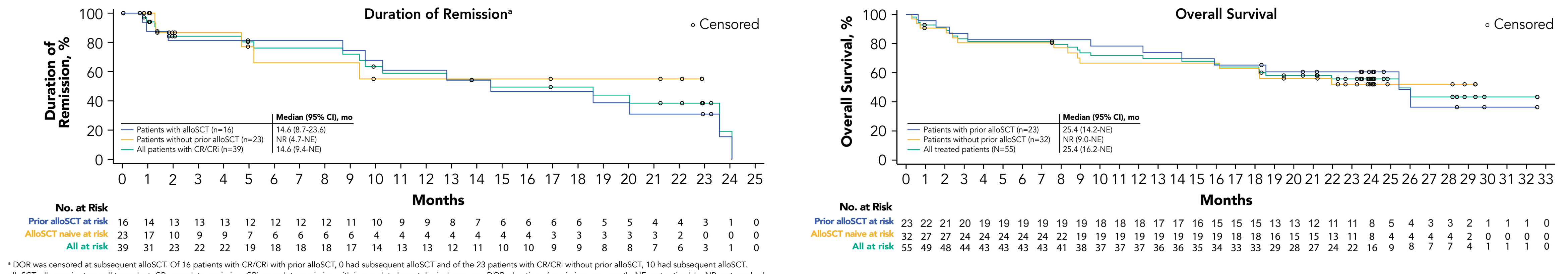


Duration of Remission[a]
Overall Survival
Censored
Duration of Remission, %
Overall Survival, %
Months
Median (95% CI), mo
Patients with prior blinatumomab (n=15) 19.1 (1.3-NE)
Blinatumomab naive patients (n=24) 10.3 (5.2-NE)
All patients with CR/CRi (n=39) 14.6 (9.4-NE)
Patients with prior blinatumomab (n=25) 14.2 (3.2-26.0)
Blinatumomab naive patients (n=30) NR (18.6-NE)
All treated patients (N=55) 25.4 (16.2-NE)
No. at Risk
Prior blinatumomab at risk
Blinatumomab naive at risk
All at risk

[a] DOR was censored at subsequent alloSCT. Of 15 patients with CR/CRi with prior blinatumomab, 3 had subsequent alloSCT and of the 24 patients with CR/CRi without prior blinatumomab, 7 had subsequent alloSCT.
alloSCT, allogeneic stem cell transplant; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; mo, month; NE, not estimable; NR, not reached.

- In Phase 2 patients who were blinatumomab naive, median OS was not reached vs 14.2 months in those with prior blinatumomab exposure (**Figure 3**)

Figure 4. Duration of Remission and Overall Survival in Phase 2 Treated Patients (N=55) by Prior AlloSCT Exposure



[a] DOR was censored at subsequent alloSCT. Of 16 patients with CR/CRi with prior alloSCT, 0 had subsequent alloSCT and of the 23 patients with CR/CRi without prior alloSCT, 10 had subsequent alloSCT.
alloSCT, allogeneic stem cell transplant; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; mo, month; NE, not estimable; NR, not reached.

- After a median follow-up of 26.8 months, the median OS was not reached in Phase 2 patients without prior alloSCT and was 25.4 months for those who had received prior alloSCT (**Figure 4**)

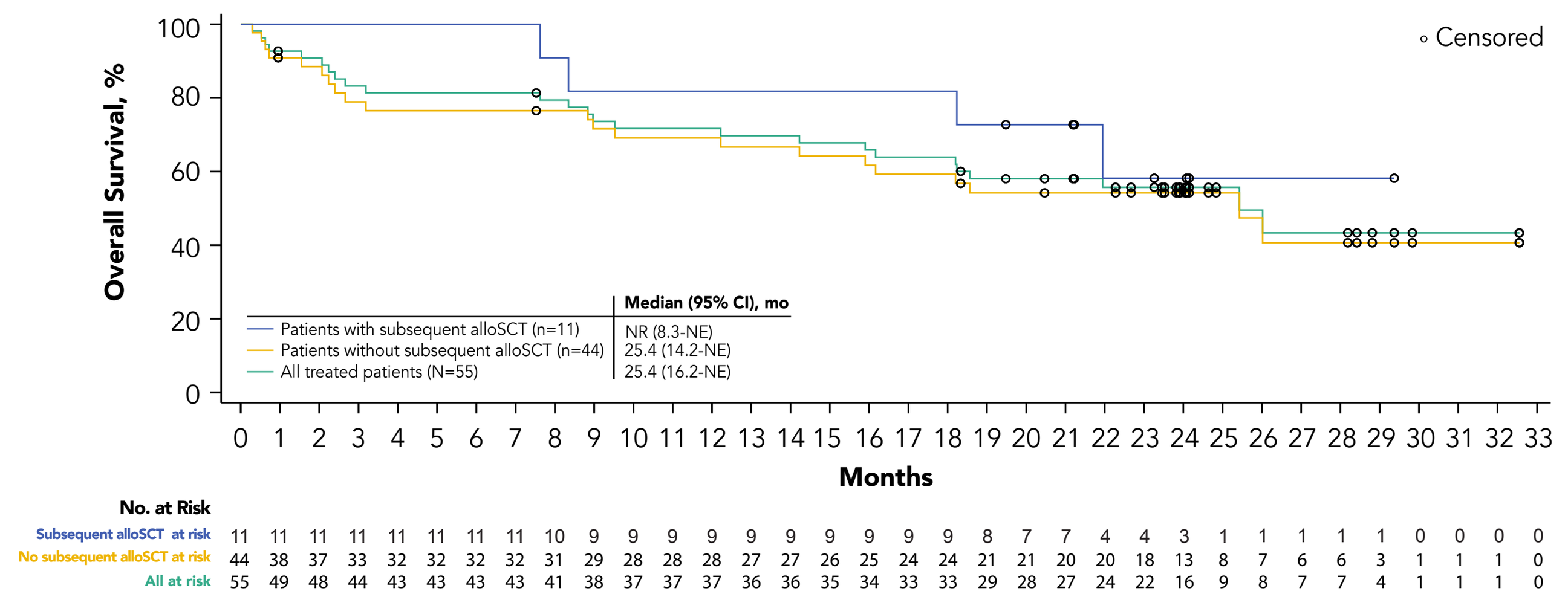
Table 1. Efficacy and Durability Outcomes in All Phase 2 Treated Patients and Pooled Phase 1 and 2 Treated Patients by Prior Therapies

	N	Overall CR rate, n (%)[a]	CR, n (%)[a]	CRi, n (%)[a]	BFBM, n (%)[a]	No response, n (%)[a]	Median DOR, mo (95% CI)[b]	Median RFS, mo (95% CI)[b]	Median OS, mo (95% CI)
Phase 2 treated	**55**	**39 (71)**	**31 (56)**	**8 (15)**	**4 (7)**	**9 (16)**	**14.6 (9.4-NE)**	**11.6 (2.7-20.5)**	**25.4 (16.2-NE)**
Lines of prior therapy									
1	10	9 (90)	8 (80)	1 (10)	1 (10)	0	4.7 (1.8-NE)	5.6 (0.0-NE)	NR (2.1-NE)
≥2	45	30 (67)	23 (51)	7 (16)	3 (7)	9 (20)	14.6 (9.4-NE)	11.0 (1.8-15.5)	25.4 (14.2-NE)
Prior blinatumomab									
Yes	25	15 (60)	10 (40)	5 (20)	2 (8)	6 (24)	19.1 (1.3-NE)	11.6 (0.0-25.4)	14.2 (3.2-26.0)
No	30	24 (80)	21 (70)	3 (10)	2 (7)	3 (10)	10.3 (5.2-NE)	11.7 (2.8-22.1)	NR (18.6-NE)
Prior alloSCT									
Yes	23	16 (70)	13 (57)	3 (13)	2 (9)	4 (17)	14.6 (8.7-23.6)	11.7 (0.0-20.5)	25.4 (14.2-NE)
No	32	23 (72)	18 (56)	5 (16)	2 (6)	5 (16)	NR (4.7-NE)	6.1 (2.2-NE)	NR (9.0-NE)
Pooled Phase 1 and 2 patients[c]	**78**	**57 (73)**	**47 (60)**	**10 (13)**	**6 (8)**	**12 (15)**	**18.6 (9.6-NE)**	**11.7 (6.1-20.5)**	**25.4 (16.2-NE)**
Lines of prior therapy									
1	15	13 (87)	12 (80)	1 (7)	1 (7)	1 (7)	4.9 (1.8-NE)	6.1 (2.8-NE)	NR (7.6-NE)
≥2	63	44 (70)	35 (56)	9 (14)	5 (8)	11 (17)	20.0 (10.3-NE)	11.7 (2.7-20.5)	25.4 (15.9-NE)
Prior blinatumomab									
Yes	38	24 (63)	18 (47)	6 (16)	4 (11)	8 (21)	14.6 (9.6-NE)	7.3 (0.0-15.5)	15.9 (8.3-25.4)
No	40	33 (83)	29 (73)	4 (10)	2 (5)	4 (10)	18.6 (5.2-NE)	11.7 (6.1-NE)	47.0 (18.6-NE)
Prior alloSCT									
Yes	29	22 (76)	17 (59)	5 (17)	2 (7)	4 (14)	14.6 (8.7-23.6)	12.3 (2.7-20.5)	25.4 (14.2-NE)
No	49	35 (71)	30 (61)	5 (10)	4 (8)	8 (16)	NR (5.2-NE)	10.3 (2.7-NE)	47.0 (10.9-NE)

[a] Assessed by independent central review. Overall CR rate includes CR + CRi. [b] Patients censored at subsequent alloSCT. [c] Pooled analysis of Phase 1 and 2 patients who received the pivotal dose of KTE-X19.
alloSCT, allogeneic stem cell transplant; BFBM, blast-free hypoplastic or aplastic bone marrow; BM, bone marrow; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; mo, month; NE, not estimable; NR, not reached; OS, overall survival; RFS, relapse-free survival.

- Response rates in each prior therapy subgroup were largely consistent with the all treated population (**Table 1**)
- Efficacy and durability outcomes in the pooled population of Phase 1 and 2 patients were similar to those observed in Phase 2 patients (**Table 1**)

Figure 5. Overall Survival in Phase 2 Treated Patients (N=55) by Subsequent AlloSCT[a]



[a] This was a single arm study with limited numbers in some subgroups. Subsequent alloSCT was allowed per investigator discretion but was not protocol defined.
alloSCT, allogeneic stem cell transplant; mo, month; NE, not estimable; NR, not reached.

- Eleven of the 55 treated patients (18%; 10 CR/CRi, 1 blast-free hypoplastic or aplastic bone marrow) in Phase 2 proceeded to subsequent alloSCT
- At data cutoff, the median OS was not reached in patients who received subsequent alloSCT and was 25.4 months in patients without subsequent alloSCT (**Figure 5**)

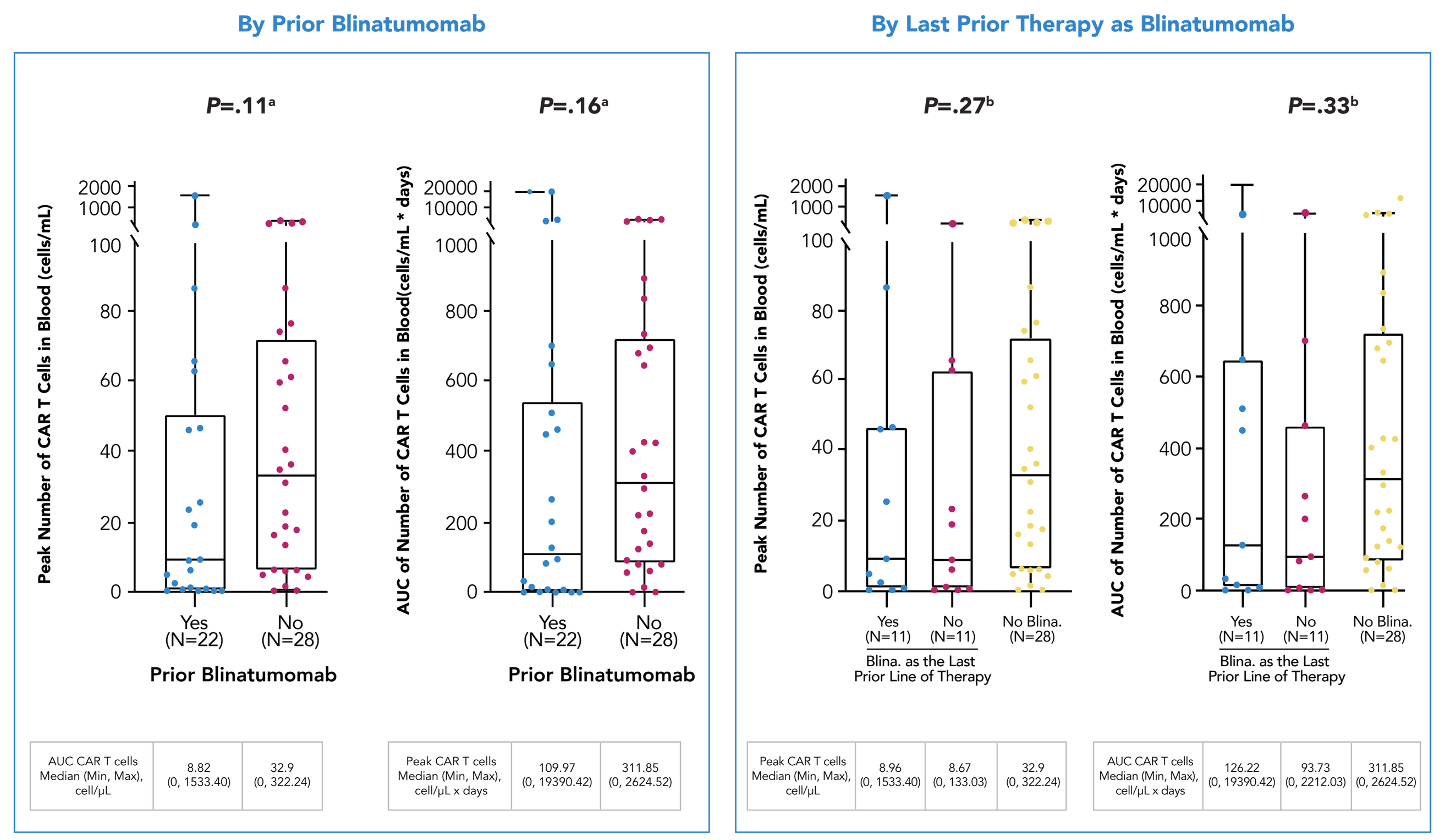
Table 2. Summary of CRS and Neurologic Events in All Phase 2 Treated Patients (N=55) by Prior Therapies

	Prior Lines of Therapy		Prior Blinatumomab		Prior AlloSCT	
	1 (n=10)	≥2 (n=45)	Yes (n=25)	No (n=30)	Yes (n=23)	No (n=32)
CRS, n (%)						
Grade 1	4 (40)	7 (16)	2 (8)	9 (30)	5 (22)	6 (19)
Grade 2	4 (40)	21 (47)	13 (52)	12 (40)	11 (48)	14 (44)
Grade ≥3	1 (10)	12 (27)	6 (24)	7 (23)	4 (17)	9 (28)
Neurologic events, n (%)						
Grade 1	2 (20)	4 (9)	2 (8)	4 (13)	2 (9)	4 (13)
Grade 2	1 (10)	12 (27)	7 (28)	6 (20)	4 (17)	9 (28)
Grade ≥3	3 (30)	11 (24)	5 (20)	9 (30)	6 (26)	8 (25)

alloSCT, allogeneic stem cell transplant; CRS, cytokine release syndrome.

- Incidences of Grade ≥3 cytokine release syndrome and neurologic events were largely similar among prior therapy subgroups (**Table 2**)

Figure 6. Peak and Area Under the Curve CAR T-cell Levels by Prior Blinatumomab in Phase 2 Treated Patients (N=55)



By Prior Blinatumomab
By Last Prior Therapy as Blinatumomab
P=.11[a]
P=.16[a]
P=.27[b]
P=.33[b]
Prior Blinatumomab
Blina. as the Last Prior Line of Therapy
AUC CAR T cells Median (Min, Max), cell/µL 8.82 (0, 1533.40) 32.9 (0, 322.24)
Peak CAR T cells Median (Min, Max), cell/µL x days 109.97 (0, 19390.42) 311.85 (0, 2624.52)
Peak CAR T cells Median (Min, Max), cell/µL 8.96 (0, 1533.40) 8.67 (0, 133.03) 32.9 (0, 322.24)
AUC CAR T cells Median (Min, Max), cell/µL x days 126.22 (0, 19390.42) 93.73 (0, 2212.03) 311.85 (0, 2624.52)

Peak is defined as maximum number of CAR T cells in blood measured after infusion. AUC_{0-28} is defined as the AUC in a plot of number of CAR T cells in blood against scheduled visit from Day 0 to Day 28.
[a] *P* value is calculated by Wilcoxon rank sum test. [b] *P* value is calculated by Kruskal-Wallis test.
AUC, area under the curve; blina., blinatumomab; CAR, chimeric antigen receptor; max, maximum; min, minimum.

- Although median peak CAR T-cell expansion appeared to trend lower (~3 fold) in patients with prior blinatumomab exposure vs those without, the differences were not statistically significant regardless of whether blinatumomab was the last prior therapy before CAR T-cell infusion, potentially due to small sample size (**Figure 6**)

CONCLUSIONS

- With longer follow-up, adult patients with R/R B-ALL continue to benefit from KTE-X19, with manageable safety, regardless of prior lines of therapy or prior exposure to blinatumomab or alloSCT
  - Survival appeared better in patients without these prior therapies and in earlier lines of therapy; however, subgroups were not matched for disease burden prior to KTE-X19 infusion and there were limited patient numbers in some subgroups
- The similar results observed in the pooled analysis of Phase 1 and 2 patients further support the subgroup outcomes described in Phase 2 patients
- Patients receiving subsequent alloSCT appeared to have longer DOR and OS compared with patients who did not receive subsequent alloSCT; however, patient numbers were limited
- CAR T-cell expansion trended lower in patients with prior blinatumomab exposure than in blinatumomab-naive patients, but the differences were not statistically significant; however, given the small sample size, the interpretation of this result is limited

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DISCLOSURES

BDS: honoraria from Pharmacyclics, Janssen, Acrotech, Spectrum, BeiGene, and Gilead Sciences; consultancy or advisory role for Adaptive Biotechnologies, Bristol Myers Squibb/Celgene, Novartis, Pfizer, Amgen, Precision Biosciences, and Kite; research funding from Incyte, Jazz Pharmaceuticals, Gilead Sciences, and Kite; and travel support from Celgene, Novartis, Pfizer, Janssen, Seattle Genetics, Stemline Therapeutics, and Kite. **RDC:** Spouse employment with Seagen; stock or other ownership in Seagen; honoraria from Amgen, Pfizer, and Kite; consultancy or advisory role for Amgen; research funding from Pfizer, Merck, Amgen, Servier, Kite, and Vanda. **JP:** consultancy or advisory role for Kite, Novartis, and AstraZeneca; and research funding from Genentech, Amgen, and Juno. **RH:** honoraria from Bristol Myers Squibb, MSD, Gilead, Kite, Roche, Novartis, Janssen, Celgene, and ADC therapeutics; consulting or advisory role for Kite, and Gilead. **OOO:** consultancy or advisory role for Kite, Janssen, Pfizer, Novartis, and Curio Science; honoraria and research funding from Kite. **ACL:** consultancy or advisory role for Amgen, Pfizer, AbbVie, Bristol Myers Squibb; research funding from Amphivena, Astellas, Autolus, Jazz, Kadmon, Kite, and Pharmacyclics. **NB:** honoraria, consulting, or advisory role for Gilead. **TL:** consultancy or advisory role for Servier and Amgen. **MRBi:** honoraria from Kite, Incyte, Celgene, Sanofi, Novartis, Bristol Myers Squibb, and Agios; consultancy or advisory role for Novartis, Kite, CRISPR Therapeutics, Agios, Iovance, Bluebird Bio, WindMIL Therapeutics, and Arcellx; speakers' bureau participation for Kite, Agios, Incyte, Sanofi, and Bristol Myers Squibb; research funding from Kite, Novartis, CRISPR Therapeutics, Arcellx, Autolus, Immatics, Triumvira, and Tmunity; and travel support from Kite, Novartis, Bristol Myers Squibb, Agios, and Incyte. **MST:** consultancy or advisory role for Amgen, Kite, Celgene, Roche, and Regeneron; and research funding from Amgen, Kite, Roche, MacroGenics, and Regeneron. **DT:** consultancy or advisory role for EUSA, Takeda, Partner, Bristol Myers Squibb; research funding from Bristol Myers Squibb. **KMO:** consultancy or advisory role for BEAM Therapeutics. **MLA:** consultancy or advisory role for Kite, and Syndax Pharmaceuticals, Inc.; research funding from Kite (Institutional PI). **YL:** consultancy or advisory role for Kite, Janssen, Novartis, Celgene, Bluebird Bio, Juno, Legend, Sorrento, Gamida Cell, and Vineti; research funding from Kite, Janssen, Celgene, Bluebird Bio, Merck, and Takeda. **MRBa:** research funding from Kite, Takeda, Forma, AbbVie, Kura, and Ascentage. **GJS:** stock or other ownership with Amgen, Bristol Myers Squibb, and Johnson & Johnson; honoraria from Agios, Amgen, AstraZeneca, Novartis, and Ono Pharma; consulting or advisory role with Agios, Celgene, and Jazz; speakers' bureau with Kite, Celgene, Astellas, AbbVie, Incyte, Bristol Myers Squibb, Stemline, and Karyopharm; research funding from Actinium, Actuate, AbbVie, AltruBio, Arog, Astellas, AVM Biopharma, Cellectis, Celgene, Cellerant, Constellation, CTI, Forma, Cyclacel, Daiichi-Sankyo, Deciphera, Delta-fly, FujiFilm, Gamida, Gilead, Genentech/Roche, Geron, Glycomimetics, Incyte, Janssen, Karyopharm, Kite, Mateon, Medimmune, Millennium, Novartis, Onconova, Pfizer, PreCOG, Regimmune, Samus, Sellas, Sangamo, Stemline, Takeda, Tolero, and Trovagene. **MA:** stock or other ownership with CytoDyn; consultancy or advisory role for Celgene; speakers' bureau for Celgene, Bristol Myers Squibb, AbbVie, and Kite. **MCM:** consultancy or advisory role for Gilead, Janssen-Cilag, Bristol Myers Squibb, and Alnylam; speakers bureau for Medscape. **WGW:** consultancy or advisory role for Sanofi and Genzyme; research funding from GlaxoSmithKline, Novartis, AbbVie, Genentech, Karyopharm, Pharmacyclics, Acerta, Gilead, Juno, Sunesis, miRagen, Oncternal, Cyclacel, Loxo Oncology, Janssen, and Xencor. 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