Tecartus® (brexucabtagene autoleucel)
Long-term follow-up of the ZUMA-3 Study

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Summary

Study Background[1,2]

- ZUMA-3 was a Phase 1/2, single-arm, open-label, multicenter study evaluating the safety and efficacy of Tecartus in adults with relapsed/refractory (R/R) B-cell acute lymphoblastic leukemia (B-ALL).
- The primary endpoint was the rate of overall complete remission (CR) or complete remission with incomplete hematological recovery (CRi) by central assessment. Duration of remission (DOR) and relapse-free survival (RFS), overall survival (OS), minimal residual disease (MRD) negativity rate, and allogeneic stem-cell transplant (allo-SCT) rate were assessed as secondary endpoints.
- In the primary analysis of the Phase 2 pivotal study, with a median follow-up of 16.4 months, the overall complete remission (CR+CRi) rate was 71% (95% CI, 57–82) and median OS was 18.2 months.

Long-term Follow-up[3-9]

- Follow-up analyses of the ZUMA-3 study were conducted at 2, 3, and 4 years. Efficacy outcomes, including the overall CR rate and median OS, were consistent with those from the primary analysis.
- No new-onset cytokine release syndrome (CRS), neurological event, infections, or hypogammaglobulinemia of any grade have occurred since the Phase 2 primary analysis. There was 1 new Grade 5 adverse event (AE) and 9 deaths through the 4-year follow-up.

Long-term Follow-up

Study Background [1,2]

ZUMA-3 was a Phase 1/2, single-arm, open-label, multicenter study evaluating the safety and efficacy of Tecartus, an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell

therapy, in adults with R/R B-ALL. Eligible patients were 18 years of age or older and had R/R B-ALL with morphologic disease in the bone marrow (greater than 5% blasts) at study entry. After leukapheresis and conditioning chemotherapy, patients received a single Tecartus infusion (1×10^6 CAR T cells per kg bodyweight). This study enrolled 71 patients (intent-to-treat population, ITT) from 25 sites in the USA, Canada, and Europe. Manufacturing was successful for 65 patients and 55 of these patients (modified intent-to-treat, mITT) were eventually treated.[1,2]

For full safety and efficacy information on Tecartus, please refer to the full prescribing information and the ZUMA-3 study publication.[1,2]

The primary endpoint was the rate of overall CR or CRi by central assessment. Duration of remission and relapse-free survival, OS, MRD negativity rate, and allo-SCT rate were assessed as secondary endpoints.[2]

Efficacy

Primary Analysis[2]

In the primary analysis of the Phase 2 pivotal study with a median follow-up of 16.4 months, the overall complete remission (CR+CRi) rate was 71% (95% CI, 57–82) and median OS was 18.2 months.[2]

2-Year Follow-up[3,4,5,6]

At the 2-year analysis of the ZUMA-3 study (July 23, 2021 data cut-off), the median follow-up time was 26.8 months (range, 20.7–32.6) for Phase 2 treated patients and 29.7 months (range, 20.7–58.3) for pooled Phase 1 and Phase 2 treated patients. Most patients were heavily pretreated, with a median number of 2 prior therapies and 47% having >3 prior therapies.[5,6]

The CR/CRi rate in Phase 2 treated patients was consistent with the primary analysis at 71% and a CR rate of 56%.[5,6] At the 2-year analysis, the median DOR with and without censoring patients at subsequent allo-SCT were 20 months (95% CI, 9.6–NE, with censoring) and 20.8 months (95% CI, 14.6–NE, without censoring) in Phase 2 treated patients with CR (n=31).[3,4] In patients with CR or CRi (n=39), the median DOR with and without censoring at subsequent allo-SCT was 14.6 months (95% CI, 9.4–NE) and 18.6 months (95% CI, 9.6–NE), respectively.[5,6]

The median OS was 25.4 months (95% CI, 16.2–NE) for all treated patients in both the Phase 2 (N=55) and the pooled Phase 1 and 2 (N=78) cohorts and was not yet reached in Phase 2 patients with CR. In patients with CR or CRi, the median OS was 26 months (95% CI, 21.9–NE) for Phase 2 treated patients (n=39) and 47 months (95% CI, 23.2–NE) for pooled Phase 1 and 2 treated patients (n=57).[5,6]

3-Year Follow-up[7]

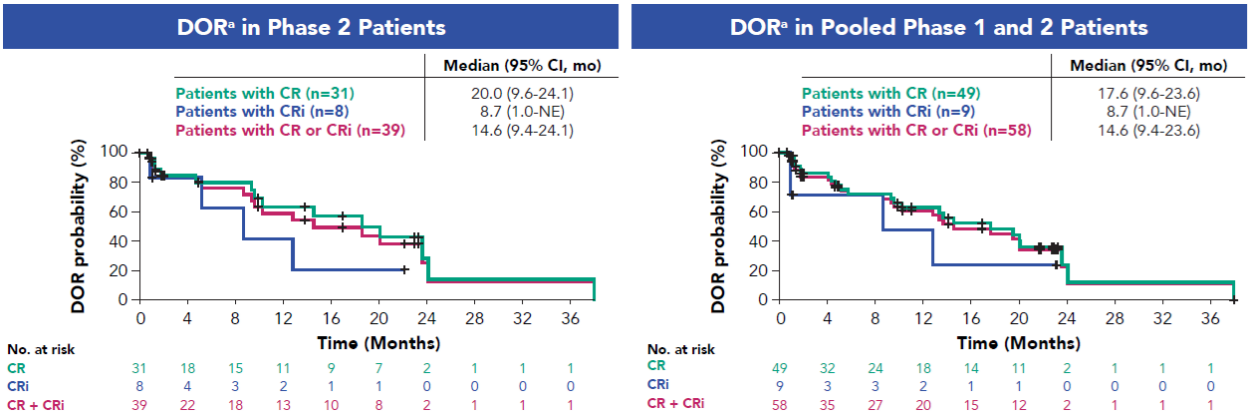
At the 3-year analysis of the ZUMA-3 study (July 23, 2022 data cut-off), the median follow-up time was 38.8 months (range, 32.7–44.6) for Phase 2 treated patients (n=55) and 41.6 months (range, 32.7–70.3) for pooled Phase 1 and Phase 2 treated patients (n=78). Most patients were heavily pretreated, with a median number of 2 prior therapies and 47% had received ≥3 prior therapies.[7]

In Phase 2 treated patients, the CR/CRi rate was consistent with the primary and 2-year analyses at 71% and a CR rate of 56%. The rate for subsequent allo-SCT also remained the

same at 20%. The median DOR was 14.6 months (95% CI, 9.4–24.1) in patients with CR or CRi (n=39) (Figure 1). The median OS was 26 months (95% CI, 16.2–NE) in all treated Phase 2 patients and 38.9 months (95% CI, 21.9–NE) in Phase 2 patients with CR or CRi (n=39). At Month 36, the OS rate was 47.1% (95% CI, 32.7%–60.2%) in the Phase 2 treated patients.[7]

In pooled Phase 1 and 2 treated patients, the CR/CRi rate, CR rate, and rate for subsequent allo-SCT were 73%, 60%, and 19%, respectively. The median DOR was 14.6 months (95% CI, 9.4–23.6) in patients with CR or CRi (n=58). The median OS was 25.6 months (95% CI, 16.2–47) in all treated pooled Phase 1 and 2 patients and 47 months (95% CI, 23.2–NE) in pooled Phase 1 and 2 treated patients with CR or CRi (n=57).[7]

Figure 1. Kaplan-Meier DOR Curves for Phase 2/Pooled Phase 1 and 2 Treated Patients[7]



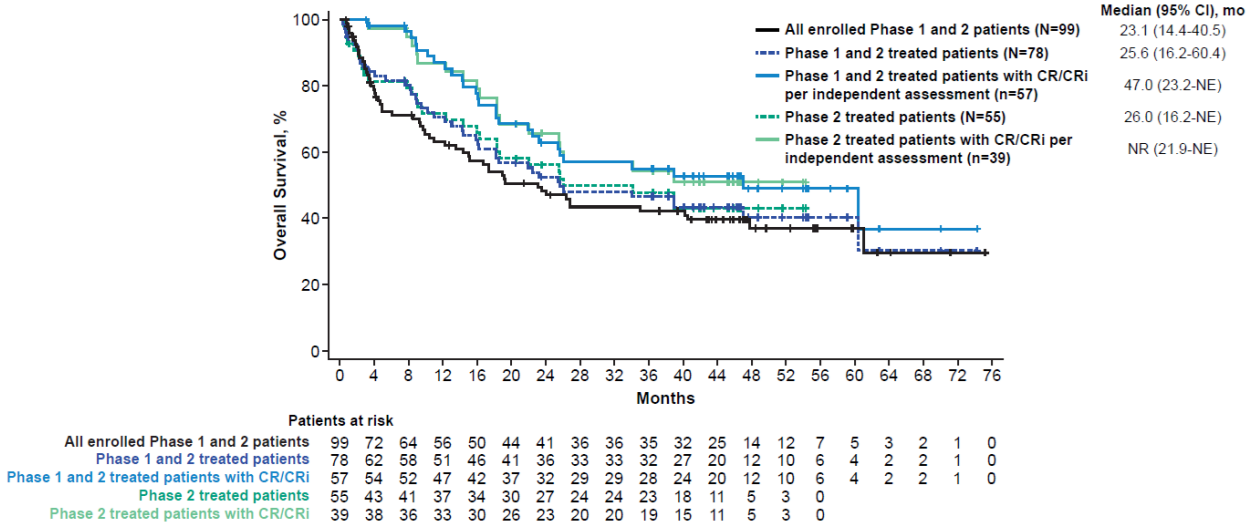
Abbreviations: CR=complete remission; CRi=complete remission with incomplete hematological recovery; DOR=duration of remission; NE=not estimable.

4-Year Follow-up[9]

At the 4-year analysis of the ZUMA-3 study (July 23, 2023 data cut-off), the median follow-up time was 53.6 months (range, 44.7–82.3) for pooled Phase 1 and Phase 2 treated patients (n=78).[9]

Median OS was 26 months (95% CI, 16.2–NE) in Phase 2 treated patients (n=55) and 25.6 months (95% CI, 16.2–60.4) in Phase 1 and 2 treated patients (n=78) (Figure 2). In responders (patients with CR or CRi), median OS was not reached (95% CI, 21.9–NE) in the Phase 2 treated population (n=39) and 47 months (95% CI, 23.2–NE) in the pooled Phase 1 and 2 treated population (n=57). OS rates at 48 months were generally similar across subgroups by age, prior treatment with blinatumomab or inotuzumab, and subsequent allo-SCT status.[9]

Figure 2. Overall Survival in Phase 2/Pooled Phase 1 and Phase 2 Patients[9]



Abbreviations: CR=complete remission; CRi=complete remission with incomplete hematological recovery; NE=not estimable.

A summary of efficacy findings across the primary, 2-, 3-, and 4-year analyses is provided in Table 1.[2,3,5,7,9]

Table 1. Efficacy Outcomes in Phase 2/Pooled Phase 1 and 2 Treated Patients Through to 4-Year Follow-up[2,3,5,7,9]

	N	Median follow up, mo	Overall CR rate, n (%)[a]	CR, n (%)[a]	CRi, n (%)	Median DOR, mo (95% CI)[b,c]	Median OS, mo (95% CI)
Phase 2 treated patients							
Primary analysis							
	55	16.4	39 (71)	31 (56)	8 (15)	12.8 (8.7–NE)	18.2 (15.9–NE)
2-year follow-up							
	55	26.8	39 (70.9)	31 (56.4)	8 (14.5)	14.6 (9.4–NE)	25.4 (16.2–NE)
3-year follow-up							
	55	38.8	39 (71)	31 (56)	8 (15)	14.6 (9.4–24.1)	26 (16.2–NE)
4-year follow-up							
	55	43.5	N/A	N/A	N/A	N/A	26 (16.2–NE)
Phase 1 and 2 treated patients							
2-year follow-up							
	78	29.7	57 (73.1)	47 (60.3)	10 (12.8)	18.6 (9.6–NE)	25.4 (16.2–NE)
3-year follow-up							
	78	41.6	57 (73)	47 (60)	10 (13)	14.6 (9.4–23.6)	25.6 (16.2–47)
4-year follow-up							

	N	Median follow up, mo	Overall CR rate, n (%)[a]	CR, n (%)[a]	CRi, n (%)	Median DOR, mo (95% CI)[b,c]	Median OS, mo (95% CI)
	78	46.3	N/A	N/A	N/A	N/A	25.6 (16.2–60.4)

Abbreviations: CR=complete remission; CRi=complete remission with incomplete hematological recovery; DOR=duration of remission; N/A=not available; OS=overall survival.
[a]Assessed by independent central review. Overall CR rate includes CR+CRi. [b]In patients with CR or CRi. [c]Patients censored at subsequent allo-SCT.

Safety

Long-Term Follow-up [5,7,9]

No new-onset CRS, neurological event, infections, or hypogammaglobulinemia of any grade have occurred since the Phase 2 primary analysis.[5,7,9]

One new Grade 5 adverse event occurred between the primary analysis and the 2-year data cutoff: graft-versus-host disease (Day 773) and was deemed not related to study treatment. Four additional patients died in the time between the primary analysis and the 2-year data cutoff; 1 death was attributed to progressive disease (Day 564) and 3 due to other causes (1 due to COVID-19 [Day 791] and 2 following allo-SCT [Day 554 and Day 667]).[5]

Between the 2-year and 3-year data cutoff, five additional patients died, including 2 due to progressive disease (Day 1036 and 1837), 1 due to hypoxia (Day 778), 1 due to intracranial hemorrhage (Day 1183), and 1 due to an unknown cause (Day 1184). The incidence of Grade ≥3 treatment-related AEs remained unchanged, and there were no new Grade 5 AEs.[7]

No new safety signals or deaths occurred between the 3-year and 4-year data cutoff. Treatment-emergent infection AEs in pooled Phase 1 and 2 treated patients by age, prior blinatumomab, and number of prior lines of therapy are summarized in Table 2. The rate of Grade ≥3 infections were numerically higher in younger patients, those who had received prior treatment with blinatumomab, and those who had received ≥2 lines of prior therapies.[9]

Table 2. Treatment-Emergent Infections by Key Subgroups in Pooled Phase 1 and 2 Treated Patients[9]

	Age, Years		Prior Blinatumomab		Prior Lines of Therapy	
	<26 (n=15)	≥26 (n=63)	Yes (n=38)	No (n=40)	1 (n=15)	≥2 (n=63)
Any treatment-emergent infection, n (%)	6 (40)	25 (40)	19 (50)	12 (30)	3 (20)	28 (44)
Worst infection experienced was Grade ≥3, n (%)	6 (40)	17 (27)	15 (39)	8 (20)	3 (20)	20 (32)

Subgroup Analyses

2-Year Follow-up[4,5,6]

The following subgroup analyses were conducted at the 2-year follow-up:[4,5,6]

- Age (18–25, 18–39, 40–59, ≥60 years)
- Baseline bone marrow blasts (0%–5%, >5%–25%, >25%–50%, >50%–75%, >75%–100%)
- Prior number of therapy lines

- Prior blinatumomab
- Prior inotuzumab
- Prior allo-SCT
- Subsequent allo-SCT

Median OS was not reached in patients aged 18-25 or ≥60 years, or in patients with ≤5%, >25% to 50%, or >50% to 75% baseline bone marrow blasts. The estimated 24-month OS rates were similar among prespecified subgroups, though they varied among screening and baseline bone marrow blast percentage subgroups. Patients with >75% blasts had the lowest 24-month OS rate.[5]

Efficacy outcomes in each subgroup (age and bone marrow blasts) were largely consistent with the overall-treated population, though lesser benefits were observed for patients with >75% baseline bone marrow blasts (Table 3).[5]

Table 3. Efficacy Outcomes in Pooled Phase 1 and 2 Treated Patients by Age and Baseline Bone Marrow Blasts Percentage[5]

	N	Overall CR rate, n (%)[a]	CR, n (%)[a]	CRi, n (%)[a]	Median DOR, mo (95% CI)[b]	Median RFS, mo (95% CI)[b]	Median OS, mo (95% CI)
Phase 1 and 2[c]							
	78	**57 (73.1)**	**47 (60.3)**	**10 (12.8)**	**18.6 (9.6–NE)**	**11.7 (6.1–20.5)**	**25.4 (16.2–NE)**
Age, years							
18–25	15	11 (73.3)	9 (60)	2 (13.3)	14.6 (0.7–NE)	15.5 (0–NE)	23.2 (9–NE)
18–39	36	25 (69.4)	21 (58.3)	4 (11.1)	18.6 (12.8–NE)	14.2 (2.3–NE)	23.2 (14.2–NE)
40–59	27	19 (70.4)	16 (59.3)	3 (11.1)	20 (4.7–NE)	7.7 (0–22.1)	26 (8.3–NE)
Baseline BM blasts, %							
≥ 60	15	13 (86.7)	10 (66.7)	3 (20)	NR (1.8–NE)	14.4 (2.8–NE)	47 (12.2–NE)
≤5	8	6 (75)	6 (75)	0	4.9 (1.3–NE)	5.6 (0–NE)	26 (2.2–NE)
>5–25	14	12 (85.7)	10 (71.4)	2 (14.3)	23.6 (1.8–NE)	25.4 (2.8–NE)	25.4 (21.9–NE)
>25–50	12	10 (83.3)	9 (75)	1 (8.3)	18.6 (9.4–NE)	20.5 (0–NE)	NR (1.7–NE)
>50–75	14	12 (85.7)	8 (57.1)	4 (28.6)	20 (5.2–NE)	22.1 (1.8–NE)	NR (3.2–NE)
>75–100	30	17 (56.7)	14 (46.7)	3 (10)	10.3 (1.3–NE)	2.7 (0–11.7)	16.1 (9.5–NE)

Abbreviations: BM=bone marrow; CR=complete remission; CRi=complete remission with incomplete hematological recovery; DOR=duration of remission; NE=not estimable; RFS=relapse-free survival; OS=overall survival.
[a]Assessed by independent central review. Overall CR rate includes CR+CRi. [b]Patients censored at subsequent allo-SCT.
[C]Pooled analysis of Phase 1 and 2 patients who received the pivotal dose of Tecartus.

Table 4. Efficacy Outcomes in Pooled Phase 1 and 2 Treated Patients by Prior Therapies[6]

	N	Overall CR rate, n (%)[a]	Median DOR, mo (95% CI)[b]	Median RFS, mo (95% CI)[b]	Median OS, mo (95% CI)[b]
Pooled Phase 1 and 2	**78**	**57 (73)**	**18.6 (9.6–NE)**	**11.7 (6.1–20.5)**	**25.4 (16.2–NE)**
Lines of Prior Therapy					
1	15	13 (87)	4.9 (1.8–NE)	6.1 (2.8–NE)	NR (7.6–NE)
≥2	63	44 (70)	20 (10.3–NE)	11.7 (2.7–20.5)	25.4 (15.9–NE)
Prior blinatumomab					
Yes	38	24 (63)	14.6 (9.6–NE)	7.3 (0–15.5)	15.9 (8.3–25.4)
No	40	33 (83)	18.6 (5.2–NE)	11.7 (6.1–NE)	47 (18.6–NE)
Prior inotuzumab					
Yes	17	10 (59)	10.3 (1–NE)	2.2 (0–12.3)	8.8 (2.2–NE)
No	61	47 (77)	18.6 (9.4–NE)	14.2 (6.1–25.4)	47 (18.6–NE)
Prior allo-SCT					
Yes	29	22 (76)	14.6 (8.7–23.6)	12.3 (2.7–20.5)	25.4 (14.2–NE)
No	49	35 (71)	NR (5.2–NE)	10.3 (2.7–NE)	47 (10.9–NE)

Abbreviations: CR=complete remission; DOR=duration of remission; NE=not estimable; RFS=relapse-free survival; OS=overall survival.
[a]Assessed by independent central review. Overall CR rate includes CR+CRi. [b] Patients censored at subsequent allo-SCT.

3-Year Follow-up[8]

Efficacy outcomes by age and prior blinatumomab exposure from the 3-year follow-up analysis are summarized in Table 5. Overall, rates for CR/CRi were high across the subgroups.[8]

Table 5. Efficacy Outcomes in Pooled Phase 1 and 2 Treated Patients by Age and Prior Blinatumomab Exposure[8]

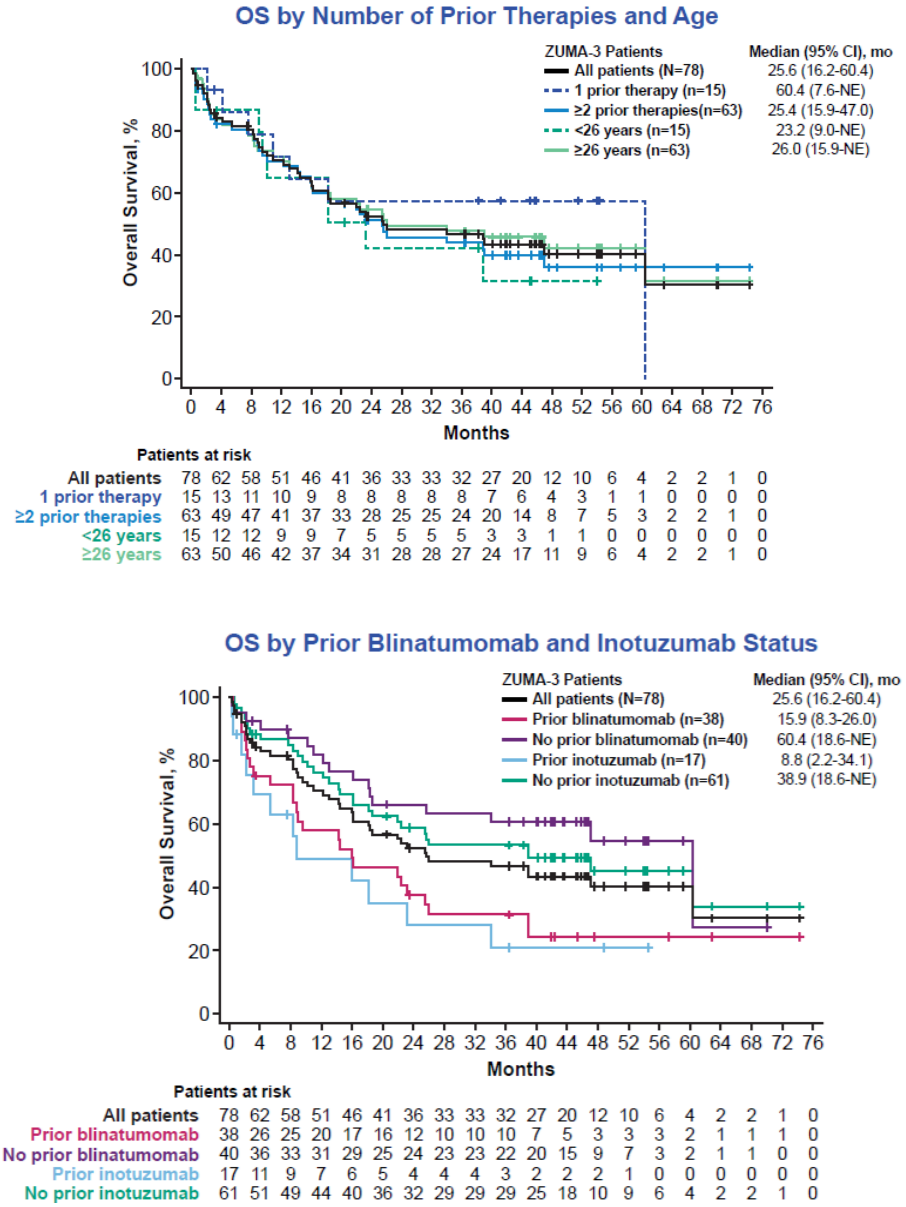
	N	Overall CR/CRi rate, n (%)	CR, n (%)	Median DOR, mo (95% CI)[b,c]	Median RFS, mo (95% CI)[b]
Pooled Phase 1 and 2[a,d]	78	57 (73)	47 (60)	18.6 (9.6–24.1)	11.7 (6.1–20.5)
Age					
<26 years	15	11 (73)	9 (60)	14.6 (0.7–NE)	15.5 (0–NE)
≥26 years	63	46 (73)	38 (60)	20 (9.4–24.1)	11.6 (5.6–22.1)
Prior blinatumomab					
Yes	38	24 (63)	18 (47)	14.6 (9.6–24.1)	7.3 (0–15.5)
No	40	33 (83)	29 (73)	18.6 (5.2–NE)	11.7 (6.1–NE)

Abbreviations: CR=complete remission; CRi=complete remission with incomplete hematological recovery; DOR=duration of remission; NE=not estimable; RFS=relapse-free survival.
[a]Assessed by independent central review. [b]Patients censored at subsequent allo-SCT. [c]Independent review was not performed after 24 months of the last dosed patient. [d]Pooled analysis of Phase 1 and 2 patients who received the pivotal dose of brexu-cel.

4-Year Follow-up[9]

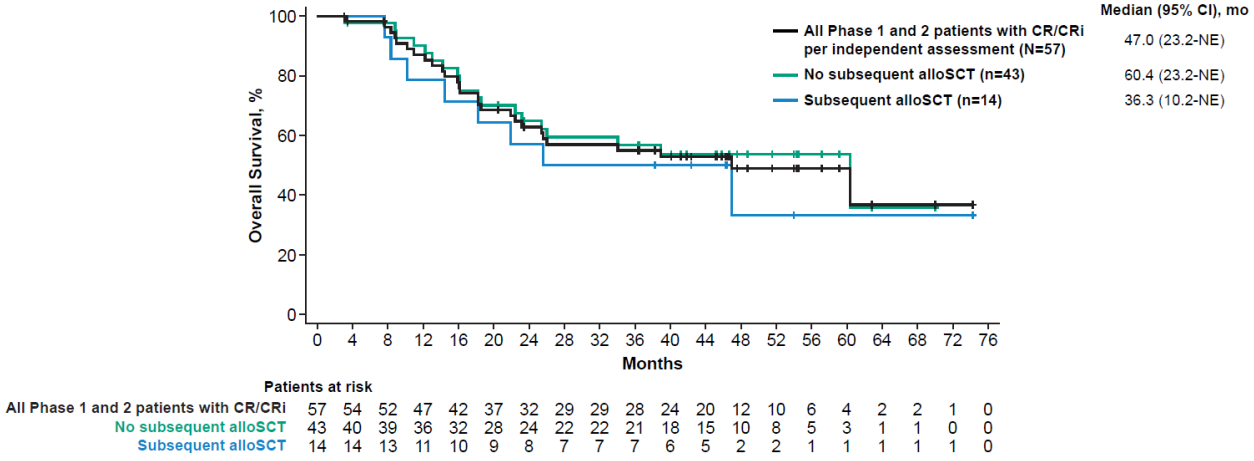
Overall survival outcomes by key subgroups (age, prior therapy, or subsequent alloSCT status) from the 4-year follow-up analysis are summarized in Figure 3, Figure 4, and Figure 5, respectively. In general, OS rates were consistent across the subgroups.[9]

Figure 3. Overall Survival in Pooled Phase 1 and 2 Treated Patients (N=78) by Key Subgroups[9]



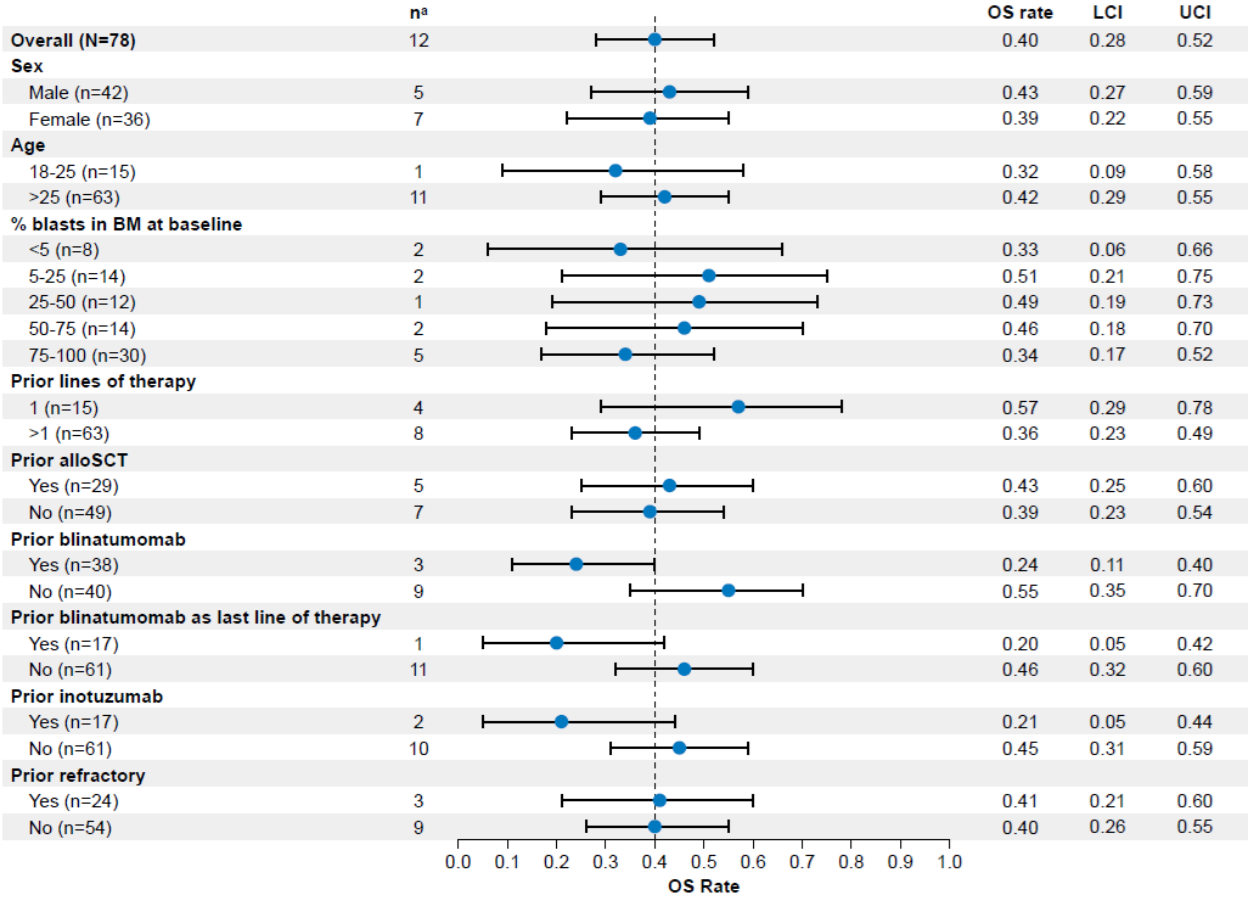
Abbreviations: NE=not estimable; OS=overall survival.

Figure 4. Overall Survival in Pooled Phase 1 and 2 Responders (n=57) Per Independent Assessment by Subsequent AlloSCT Status[9]



Abbreviations: alloSCT=allogeneic stem cell transplantation; CR=complete remission; CRi=complete remission with incomplete hematologic recovery; NE=not estimable.

Figure 5. Overall Survival Rates at 48 Months in Pooled Phase 1 and 2 Treated Patients (N=78) by Key Subgroups[9]



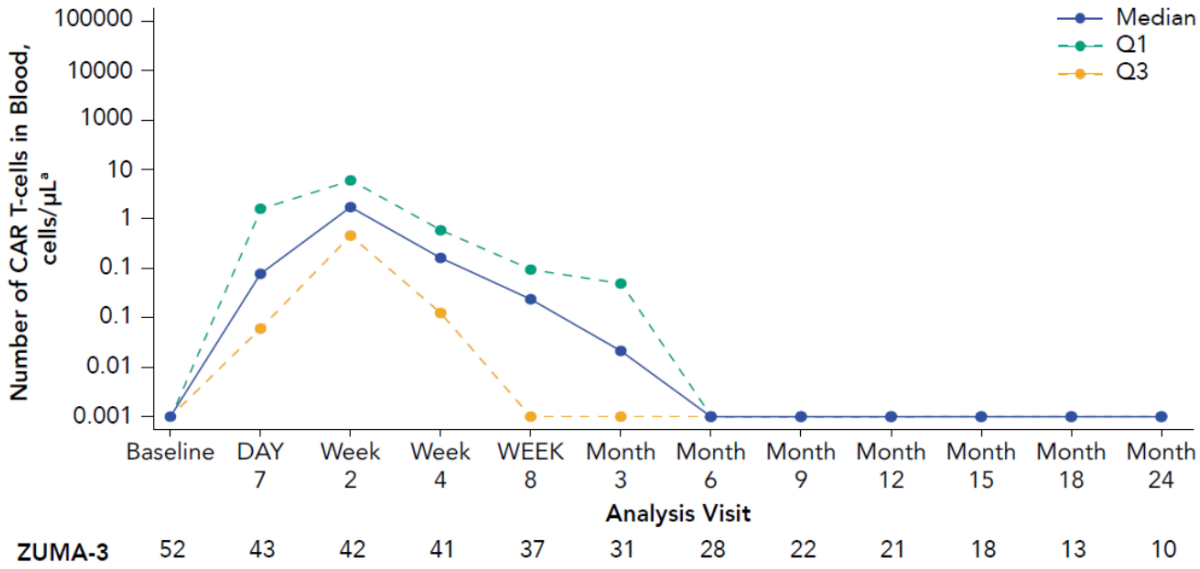
Abbreviations: alloSCT=allogeneic stem cell transplantation; BM=bone marrow; LCI=lower confidence interval; OS=overall survival; UCI=upper confidence interval. [a]Number of patients at risk at Month 48.

CAR T-Cell Levels

2-Year Follow-up[5]

As previously reported, median time to peak CAR T-cell levels in blood after Tecartus infusion in Phase 2 was 15 days (Figure 6). CAR T-cell levels were undetectable in 79% of evaluable patients (22/28) by Month 6 and in all evaluable patients (n=10), including ongoing responders, by Month 24.[5]

Figure 6. Median CAR T-Cell Levels Over Time in Phase 2 Treated Patients[5]



Abbreviation: Q=quartile.
[a]Detected by polymerase chain reaction.

3-Year Follow-up[7]

At the data cutoff in pooled Phase 1 and 2 treated patients, median (range) peak CAR T-cell levels were 63 (21.9–84) cells/µL in patients with ongoing CR/CRi response, 23.3 (2.2–322.2) cells/µL in patients who had relapsed, and 2.5 (0–183.5) cells/µL in patients who were non-responders. Median (range) $AUC_{0\text{-}28}$ of CAR T-cell levels were 698.1 (185.8–1122.6) cells/µL x days in patients with ongoing CR/CRi response, 263.1 (15.3–2624.5) cells/µL x days in patients who had relapsed, and 32.1 (0–642.3) cells/µL x days in patients who were non-responders.[7]

References

1. TECARTUS® (brexucabtagene autoleucel) [US Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc. 2024.
2. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;398(10299):491-502. doi: 10.1016/S0140-6736(21)01222-8
3. Shah BD, Ghobadi A, Oluwole OO, et al. Two-year follow-up of KTE-X19, an anti-CD19 chimeric antigen receptor T-cell therapy, in adult patients with relapsed/refractory B-cell acute

lymphoblastic leukemia in ZUMA-3. Poster presentation at American Society of Clinical Oncology (ASCO) Annual meeting; June 2-6, 2022; Chicago, IL.
4. Shah BD, Cassaday RD, Park JH, et al. Subgroup analyses of KTE-X19, an anti-CD19 chimeric antigen receptor T-cell therapy, in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia in ZUMA-3. Poster presentation at European Hematology Association Annual meeting; June 9-12, 2022; Vienna, Austria.
5. Shah BD, Ghobadi A, Oluwole OO, et al. Two-year follow-up of KTE-X19 in patients with relapsed or refractory adult B-cell acute lymphoblastic leukemia in ZUMA-3 and its contextualization with SCHOLAR-3, an external historical control study. *J Hematol Oncol*. 2022;15(1):170. doi: 10.1186/s13045-022-01379-0 and Supplementary appendix.
6. Shah BD, Cassaday RD, Park JH, et al. Impact of prior therapies and subsequent transplantation on outcomes in adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia treated with brexucabtagene autoleucel in ZUMA-3. *J Immunother Cancer*. 2023;11(8):e007118. doi: 10.1136/jitc-2023-007118 and Supplementary appendix.
7. Hadjivassileva T, Shah BD, Ghobadi A, et al. Three-year follow-up of brexucabtagene autoleucel, an anti-CD19 chimeric antigen receptor T-cell therapy, in adults with relapsed/refractory B-cell acute lymphoblastic leukemia in ZUMA-3. Poster presented at the 5th European CAR T-cell Meeting; February 9-11, 2023; Rotterdam, the Netherlands.
8. Shah BD, Cassaday RD, Park JH, et al. Impact of age, prior therapies, and subsequent transplant on long-term outcomes of adults with relapsed or refractory B-cell acute lymphoblastic leukemia (R/R B-ALL) treated with brexucabtagene autoleucel (brexu-cel) in ZUMA-3. Poster presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-5, 2023; Chicago, Illinois.
9. Oluwole OO, Ghobadi A, Cassaday RD, et al. Long-term survival outcomes of patients with relapsed or refractory B-cell acute lymphoblastic leukemia treated with brexucabtagene autoleucel in ZUMA-3. Poster presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, Illinois.

Abbreviations

AE=adverse event
allo-SCT=allogeneic stem cell transplant
AUC=area under the curve
B-ALL= acute B lymphoblastic leukemia
BM=bone marrow
CAR=chimeric antigen receptor
CR=complete remission
CRi=complete remission with incomplete hematological recovery
CRS=cytokine release syndrome
DOR=duration of response
ITT=intention-to-treat
mITT=modified intention-to-treat
MRD=minimal residual disease
N/A=not available
NE=not estimable
NR=not reached
OS=overall survival
Q=quartile
RFS=relapse-free survival
R/R=relapsed/refractory
SAE=serious adverse event
US=United States

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Please report all adverse events to:

Kite ☎ 1-844-454-KITE (1-844-454-5483)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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