Real-World Outcomes of Brexucabtagene Autoleucel for Relapsed or Refractory Adult B-Cell Acute Lymphoblastic Leukemia: Evidence From The CIBMTR Registry

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CIBMTR®
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The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW).

CIBMTR® & Kite, a Gilead Company Collaboration Study

Background

- Brexu-cel is an autologous anti-CD19 CAR T-cell therapy approved for the treatment of adults with R/R B-ALL (≥18 years for US and ≥26 years for EU), based on results from the pivotal Phase 1/2, multicenter, single-arm ZUMA-3 study[1,2]

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B-ALL, B-cell acute lymphocytic leukemia; brexu-cel, brexucabtagene autoleucel; CAR, chimeric antigen receptor; CR, complete remission; CRi, complete remission with incomplete hematological recovery; EU, European Union; OS, overall survival; R/R, relapsed or refractory; US, United States.

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  - Brexu-cel demonstrated high CR/CRi rates in patients with R/R ALL in both ZUMA-3 (73%) and real-world settings (91%)[3,4]
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- Here we evaluated the effectiveness and safety outcomes of brexu-cel in a broad, real-world US patient population

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Study Design and Analysis

Prospective Cohort Study	• Data were prospectively collected as part of a PASS through the **CIBMTR® registry** of adult patients with R/R[a] B-ALL treated with brexu-cel post-authorization between 2021 and 2023 • Data cutoff: **June 23, 2023** • Median follow-up: **6.1 months**

[a] Relapse is defined as the recurrence of disease after CR, meeting ≥1 of the following criteria: ≥5% BM blasts in marrow, extramedullary disease, or disease presence determined by physician upon clinical assessment. [b] CR/CRi was defined as having the following criteria for ≥4 weeks: <5% blasts in BM; normal maturation of all cellular components in BM; no extramedullary disease; ANC ≥1000/µL (CR only); platelets ≥100,000/µL (CR only); and transfusion independent. [c] Prolonged cytopenia is defined as having either prolonged Grade 4 neutropenia (failure to recover ANC ≥500/mm^3 (0.5×10^9/L) and/or sustain 3 lab values within the first 30 days after infusion) or prolonged Grade 4 thrombocytopenia (failure to recover platelet count ≥20×10^9/L within the first 30 days after infusion). 1. Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25:625-638. alloSCT, allogeneic stem cell transplant; ANC, absolute neutrophil count; ASTCT, American Society for Transplantation and Cellular Therapy; B-ALL, B-cell acute lymphocytic leukemia; BM, bone marrow; ANC, absolute neutrophil count; brexu-cel, brexucabtagene autoleucel; CIBMTR, Center for International Blood and Marrow Transplant Research; CNS, central nervous system; CR, complete remission; CRi, complete remission with incomplete hematological recovery; CRS, cytokine release syndrome; DOR, duration of remission; ICANS, immune effector cell–associated neurotoxicity syndrome; MRD, minimal residual disease; OS, overall survival; PASS, post-authorization safety study; R/R, relapsed/refractory; RFS, relapse-free survival.

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Outcomes of Interest	• **Effectiveness:** CR/CRi rate (primary), DOR, RFS, and OS • **Safety:** CRS and ICANS (per ASTCT consensus[1]), prolonged cytopenias[c]

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Statistical Analysis	• Time-to-event outcomes were analyzed using the Kaplan-Meier method • Descriptive statistics are reported • Descriptive subgroup analyses included: age (<60 and ≥60 years; <26 and ≥26 years), prior treatment (blinatumomab, yes or no; alloSCT, yes or no), disease status prior to infusion (extramedullary disease, yes or no; CNS disease, yes or no), and MRD status prior to infusion (CR/CRi[b] MRD+, CR/CRi[b] MRD-, and not in CR/CRi[b])

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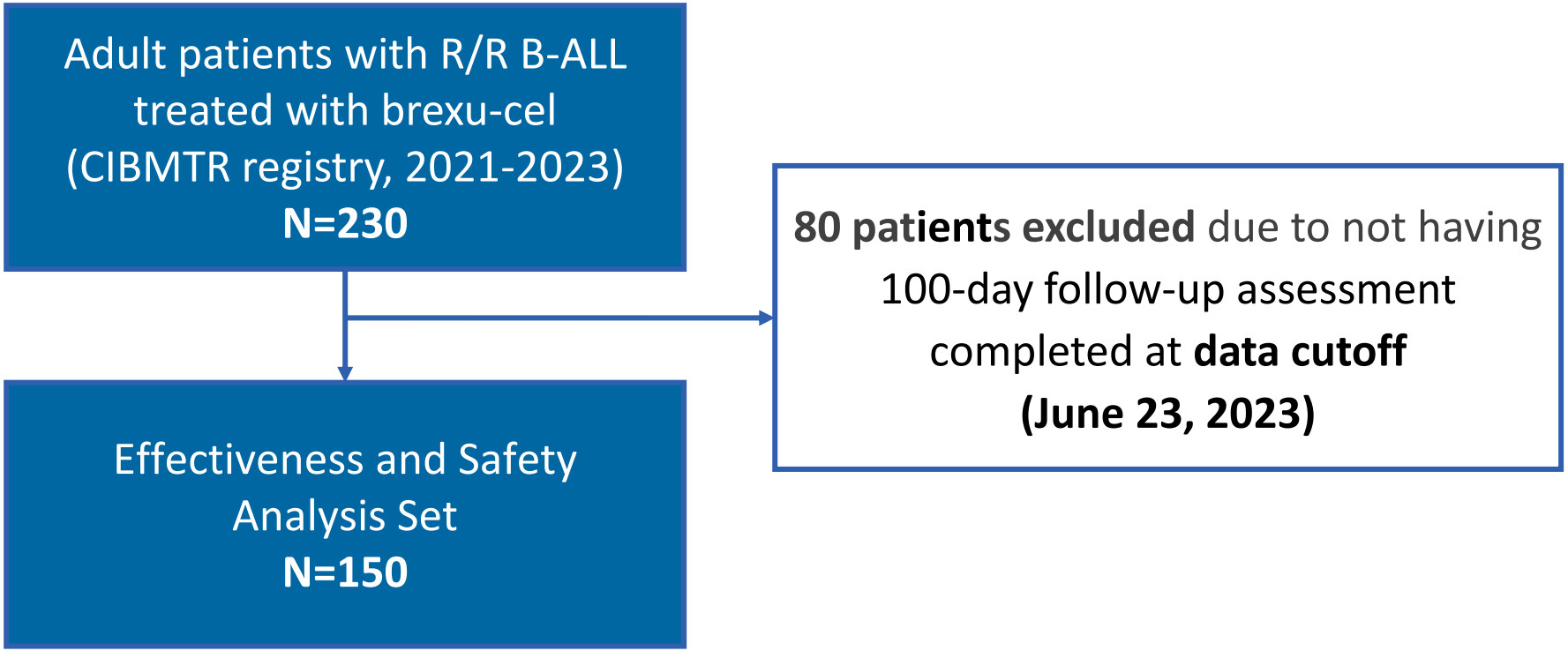

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Baseline Patient Characteristics

Characteristic	Patients (N=150)
Median age (range), years	42.9 (19.4-79.4)
≥26 years / ≥60 years, n (%)	139 (93) / 28 (19)
Race/Ethnicity	
Non-Hispanic White, n (%)	78 (52)
Non-Hispanic Black, n (%)	16 (11)
Non-Hispanic Asian, n (%)	9 (6)
Hispanic, n (%)	40 (27)
Not reported, n (%)	7 (5)
Cytogenic risk score of poor at diagnosis	84 (56)
Median number of prior lines of therapy, no. (range)	4 (1-13)
Prior blinatumomab, n (%)	77 (51)
Prior inotuzumab, n (%)	61 (41)
Prior alloSCT, n (%)	52 (35)

alloSCT, allogeneic stem cell transplant.

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Extramedullary disease prior to infusion, n (%)	32 (21)
CNS involvement prior to infusion, n (%)	14 (9)
MRD status prior to infusion[a,b]	
CR/CRi, MRD–	36 (24)
CR/CRi, MRD+	11 (7)
Not in CR/CRi	96 (64)
Not reported	7 (13)
% BM blast prior to infusion[a]	
≥0 to <5 / ≥5 to ≤25, n (%)	65 (43) / 14 (9)
>25 to ≤50 / >50, n (%)	7 (5) / 14 (9)
Not reported	50 (33)
Received bridging therapy, n (%)	61 (41)
ZUMA-3 ineligible, n (%)	135 (90)

[a] After previous therapy (including bridging therapy, but prior to lymphodepleting chemotherapy). [b] CR/CRi was reported separately from BM blasts prior to infusion and was defined as having the following criteria for ≥4 weeks: <5% blasts in BM; normal maturation of all cellular components in BM; no extramedullary disease; ANC ≥1000/µL (CR only); platelets ≥100,000/µL (CR only); and transfusion independent.
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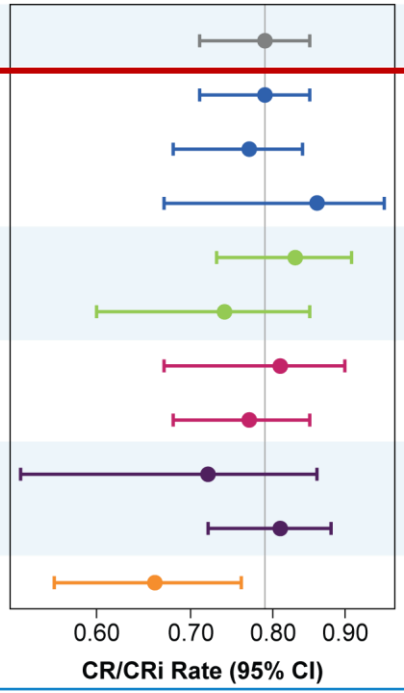
Baseline Patient Characteristics

- Most patients included in this analysis (90%) would have been ineligible for the ZUMA-3 study
- The most prevalent reasons patients would have been ineligible for ZUMA-3 included:
  - BM blasts <5% prior to infusion (43%)
  - Platelet count <50,000/µL (33%);
  - Moderate to severe pulmonary disease[a] (32%)
  - Cardiovascular/cerebrovascular/heart valve disease[a] (17%)

[a] Aligned with Hematopoietic Cell Transplantation-specific Comorbidity index criteria.
BM, bone marrow.

CR/CRi Rate for All Patients and Key Subgroups

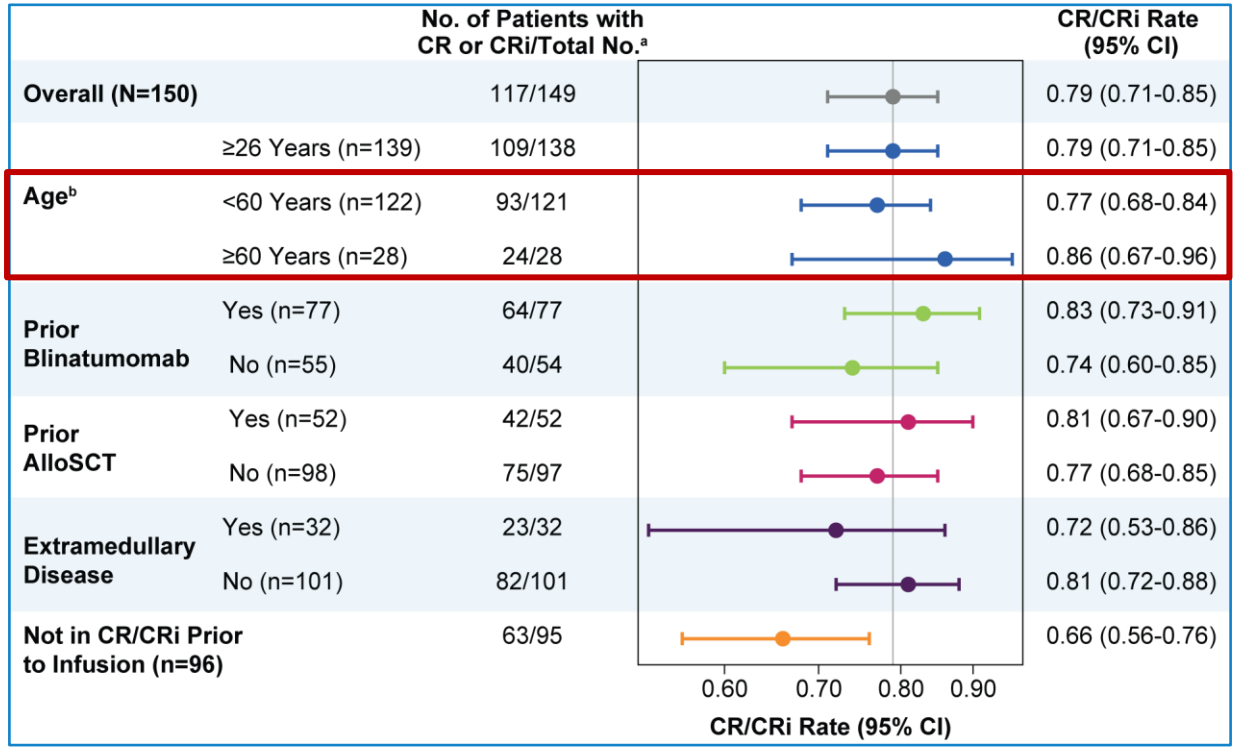
		No. of Patients with CR or CRi/Total No.[a]	CR/CRi Rate (95% CI)
Overall (N=150)		117/149	0.79 (0.71-0.85)
Age[b]	≥26 Years (n=139)	109/138	0.79 (0.71-0.85)
	<60 Years (n=122)	93/121	0.77 (0.68-0.84)
	≥60 Years (n=28)	24/28	0.86 (0.67-0.96)
Prior Blinatumomab	Yes (n=77)	64/77	0.83 (0.73-0.91)
	No (n=55)	40/54	0.74 (0.60-0.85)
Prior AlloSCT	Yes (n=52)	42/52	0.81 (0.67-0.90)
	No (n=98)	75/97	0.77 (0.68-0.85)
Extramedullary Disease	Yes (n=32)	23/32	0.72 (0.53-0.86)
	No (n=101)	82/101	0.81 (0.72-0.88)
Not in CR/CRi Prior to Infusion (n=96)		63/95	0.66 (0.56-0.76)



- The **overall CR/CRi rate in the Effectiveness and Safety Analysis Set was 79%** (66% in patients not in CR/CRi prior to infusion)
- CR/CRi rate was generally consistent across most subgroups, though a small number of patients in some subgroups limits comparison

[a] One patient in the Effectiveness and Safety Analysis Set had a missing response outcome. [b] Owing to the small number of patients aged <26 years (n=11), effectiveness outcomes are not reported for this subgroup.
alloSCT, allogeneic stem cell transplant; CR, complete remission; CRi, complete remission with incomplete hematological recovery.

CR/CRi Rate for All Patients and Key Subgroups



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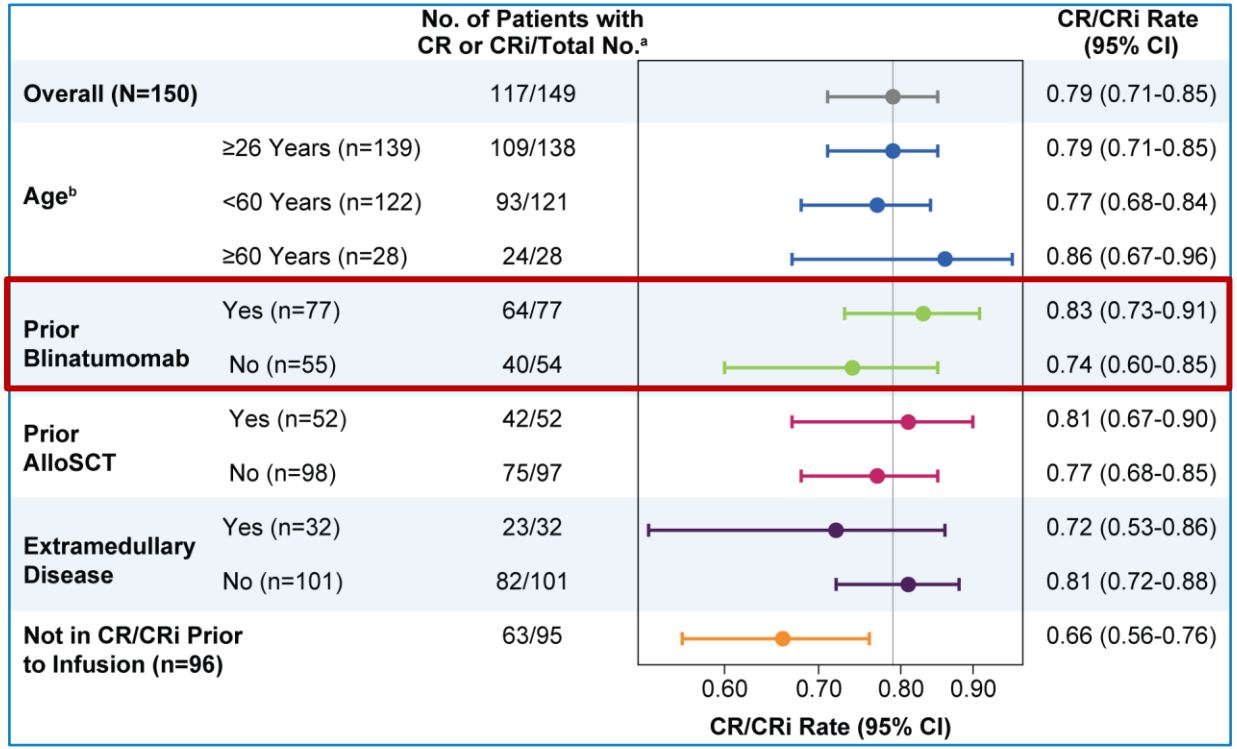

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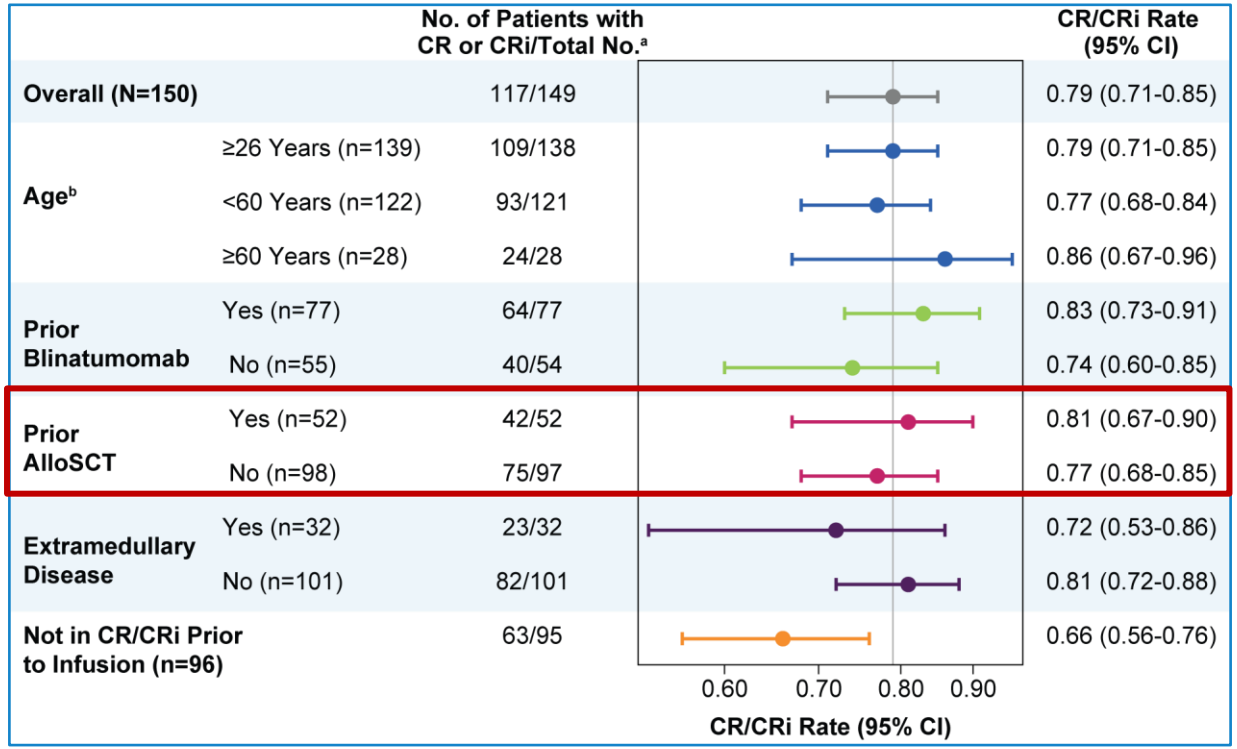

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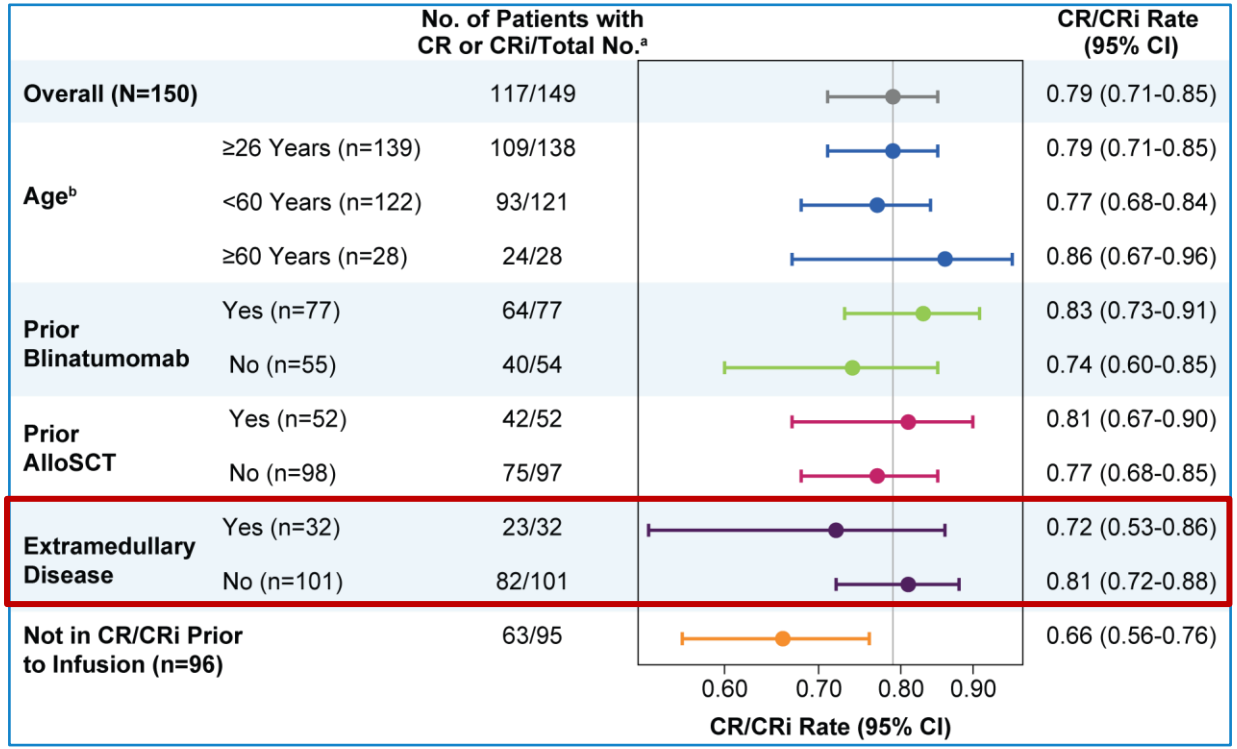
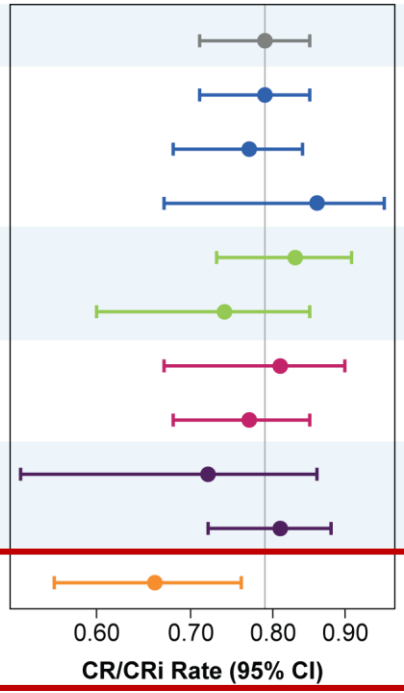


- The **overall CR/CRi rate in the Effectiveness and Safety Analysis Set was 79%** (66% in patients not in CR/CRi prior to infusion)
- CR/CRi rate was generally consistent across most subgroups, though a small number of patients in some subgroups limits comparison

[a] One patient in the Effectiveness and Safety Analysis Set had a missing response outcome. [b] Owing to the small number of patients aged <26 years (n=11), effectiveness outcomes are not reported for this subgroup.
alloSCT, allogeneic stem cell transplant; CR, complete remission; CRi, complete remission with incomplete hematological recovery.

CR/CRi Rate for All Patients and Key Subgroups

		No. of Patients with CR or CRi/Total No.[a]	CR/CRi Rate (95% CI)
Overall (N=150)		117/149	0.79 (0.71-0.85)
Age[b]	≥26 Years (n=139)	109/138	0.79 (0.71-0.85)
	<60 Years (n=122)	93/121	0.77 (0.68-0.84)
	≥60 Years (n=28)	24/28	0.86 (0.67-0.96)
Prior Blinatumomab	Yes (n=77)	64/77	0.83 (0.73-0.91)
	No (n=55)	40/54	0.74 (0.60-0.85)
Prior AlloSCT	Yes (n=52)	42/52	0.81 (0.67-0.90)
	No (n=98)	75/97	0.77 (0.68-0.85)
Extramedullary Disease	Yes (n=32)	23/32	0.72 (0.53-0.86)
	No (n=101)	82/101	0.81 (0.72-0.88)
Not in CR/CRi Prior to Infusion (n=96)		63/95	0.66 (0.56-0.76)



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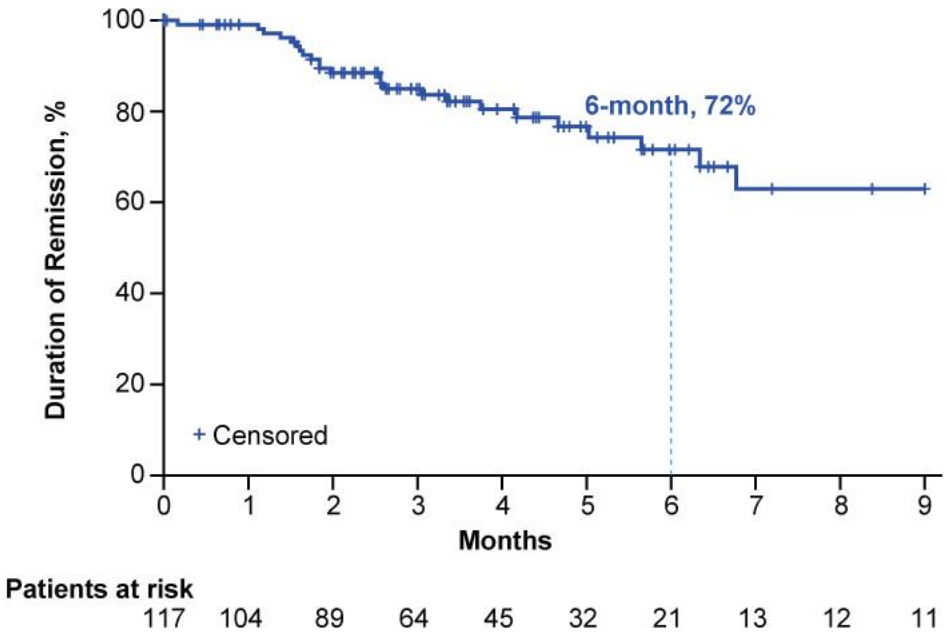
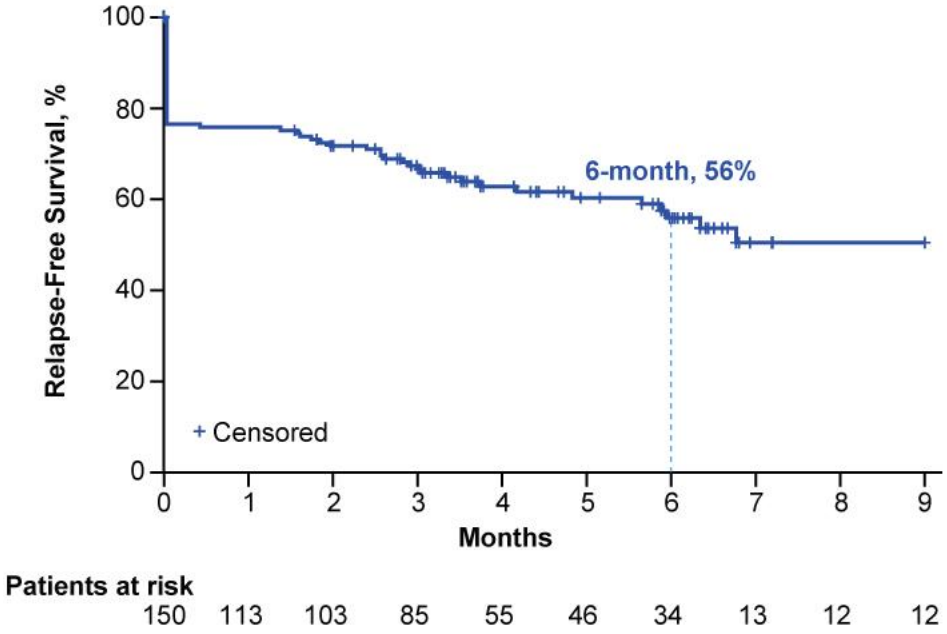
DOR[a] in the Effectiveness and Safety Analysis Set



- The median follow-up time was limited at 6.1 months
- The 6-month DOR rate in the Effectiveness and Safety Analysis Set was 72% (95% CI, 59-81)

[a] Censored at subsequent alloSCT.
alloSCT, allogeneic stem cell transplant; DOR, duration of remission.

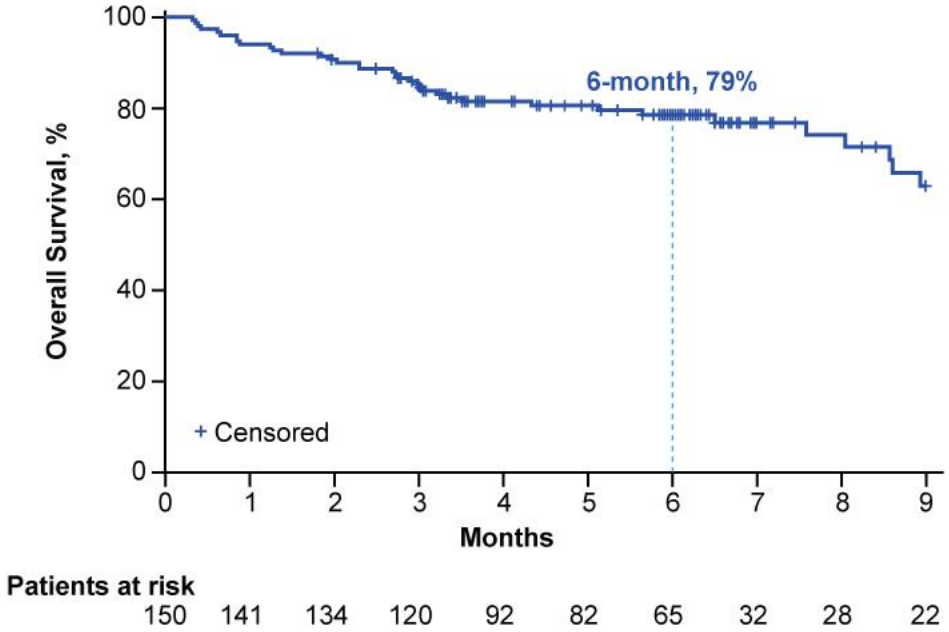
RFS[a] in the Effectiveness and Safety Analysis Set



- The 6-month RFS rate in these patients was 56% (95% CI, 46-65)

[a] Censored at subsequent alloSCT
alloSCT, allogeneic stem cell transplant; RFS, relapse-free survival.

OS in the Effectiveness and Safety Analysis Set



- The 6-month OS rate in these patients was 79% (95% CI, 71-85)

OS, overall survival.

6-Month Effectiveness Outcomes by Age and Prior Therapy

	All Patients	Age		Prior Blinatumomab[a]		Prior AlloSCT	
	N=150	<60 Years (n=122)	≥60 Years (n=28)	Yes (n=77)	No (n=55)	Yes (n=52)	No (n=98)
6-Month DOR rate (n=117),[b,c] % (95% CI)	72 (59-81)	80 (69-88)	47 (19-71)	62 (42-77)	80 (59-90)	81 (62-91)	64 (44-78)
6-Month RFS rate,[b] % (95% CI)	56 (46-65)	60 (50-68)	43 (20-64)	52 (37-65)	58 (44-70)	64 (49-76)	50 (36-62)
6-Month OS rate, % (95% CI)	79 (71-85)	80 (72-86)	71 (48-85)	77 (66-86)	82 (68-90)	79 (65-88)	78 (69-86)
Subsequent alloSCT rate among responders (n=117),[c] % (95% CI)	30 (22-39)	35 (26-46)	8 (1-27)	34 (23-47)	23 (11-38)	10 (3-23)	41 (30-53)

- 6-month DOR, OS, and RFS rates were generally consistent across prior therapy subgroups

[a] Prior blinatumomab treatment status not reported in 18 patients. [b] Censored at subsequent alloSCT. [c] Among patients who achieved CR/CRi as best response.
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	All Patients	Age		Prior Blinatumomab[a]		Prior AlloSCT	
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6-Month Effectiveness Outcomes by Age and Prior Therapy

	All Patients	Age		Prior Blinatumomab[a]		Prior AlloSCT	
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- 30% (95% CI, 22-39) of responders (n=117) went on to subsequent alloSCT with a median time to alloSCT of 102 days (range, 47-297), and this was consistent among patients with and without prior blinatumomab and patients aged <60 years

[a] Prior blinatumomab treatment status not reported in 18 patients. [b] Censored at subsequent alloSCT. [c] Among patients who achieved CR/CRi as best response.
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6-Month Effectiveness Outcomes by Disease Status

	Extramedullary Disease[a]		CNS Disease[a]		MRD Status Prior to Infusion[b]		
	Yes (n=32)	No (n=101)	Yes (n=14)	No (n=118)	CR/CRi MRD+[c] (n=11)	CR/CRi MRD–[d] (n=36)	Not in CR/CRi (n=96)
6-Month DOR rate (n=117),[e,f] % (95% CI)	85 (60-95)	70 (54-81)	80 (41-95)	71 (56-82)	64 (22-87)	66 (44-81)	75 (53-88)
6-Month RFS rate,[e] % (95% CI)	59 (39-75)	56 (44-67)	54 (23-77)	57 (46-67)	64 (22-87)	66 (45-81)	48 (37-59)
6-Month OS rate, % (95% CI)	68 (47-82)	83 (74-89)	64 (29-85)	81 (72-87)	91 (51-99)	87 (67-95)	75 (64-83)
Subsequent alloSCT rate among responders (n=117),[f] % (95% CI)	30 (13-53)	30 (21-42)	10 (<1-45)	32 (23-42)	9 (<1-41)	28 (14-45)	32 (21-45)

- 6-month DOR, OS, and RFS rates were generally consistent across disease status subgroups

[a] Prior to infusion. Disease status not reported in 17 patients. [b] Following last prior therapy and/or bridging therapy but before lymphodepleting chemotherapy. CR/CRi and MRD status were reported independently of % BM blasts prior to infusion. MRD status prior to infusion not reported in 7 patients. [c] Two patients were reported as having >5% BM blasts and 4 did not have reported BM blasts prior to infusion. [d] Eight patients did not have reported BM blasts prior to infusion. [e] Censored at subsequent alloSCT. [f] Among patients who achieved CR/CRi as best response. alloSCT, allogeneic stem cell transplant; BM, bone marrow; CNS, central nervous system; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; MRD, minimal residual disease; OS, overall survival; RFS, relapse-free survival.

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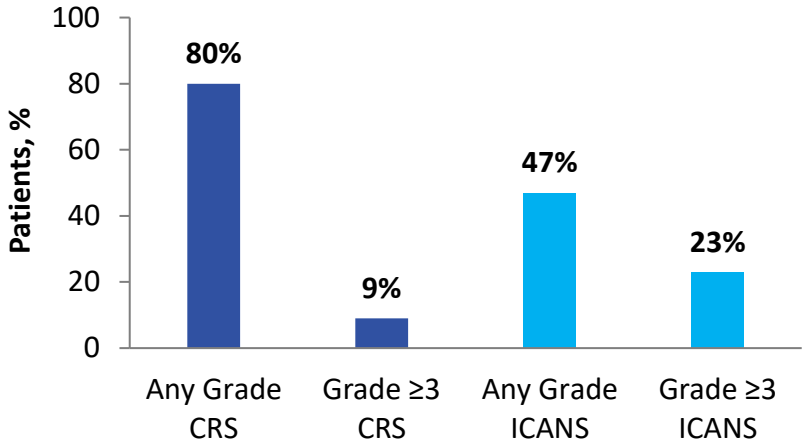
- The subsequent alloSCT rate among responders was consistent with the overall population among patients with and without extramedullary disease, patients without CNS disease, patients in CR/CRi after prior therapy who were MRD–, and patients not in CR/CRi after prior therapy

[a] Prior to infusion. Disease status not reported in 17 patients. [b] Following last prior therapy and/or bridging therapy but before lymphodepleting chemotherapy. CR/CRi and MRD status were reported independently of % BM blasts prior to infusion. MRD status prior to infusion not reported in 7 patients. [c] Two patients were reported as having >5% BM blasts and 4 did not have reported BM blasts prior to infusion. [d] Eight patients did not have reported BM blasts prior to infusion. [e] Censored at subsequent alloSCT. [f] Among patients who achieved CR/CRi as best response. alloSCT, allogeneic stem cell transplant; BM, bone marrow; CNS, central nervous system; CR, complete remission; CRi, complete remission with incomplete hematological recovery; DOR, duration of remission; MRD, minimal residual disease; OS, overall survival; RFS, relapse-free survival.

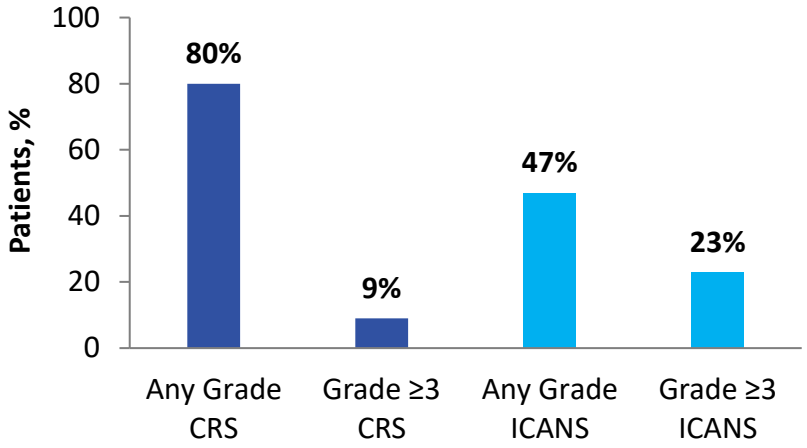
CRS and ICANS[a] in All Patients



[a] CRS and ICANS were graded per ASTCT consensus criteria.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome.

CRS and ICANS[a] in All Patients



- Among patients with 0% to <5% bone marrow blasts prior to infusion (n=65), 10 patients (15%) had Grade ≥3 ICANS (data not shown)

[a] CRS and ICANS were graded per ASTCT consensus criteria.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome.

CRS and ICANS[a] in All Patients

Parameter	All Patients (N=150)
Median time from infusion to CRS onset (range),[a,b] days	6.0 (1.0-14.0)
Median time from CRS onset to resolution (range),[a,b] days	6.0 (1.0-27.0)
Median time from infusion to ICANS onset (range),[a,b] days	8.0 (2.0-16.0)
Median time from ICANS onset to resolution (range),[a,b] days	6.0 (1.0-68.0)
Corticosteroids to treat CRS or ICANS, n (%)	75 (50)
Tocilizumab to treat CRS or ICANS, n (%)	96 (64)

- Median time to resolution for both CRS and ICANS was 6.0 days, with 94% and 80% resolved by Week 3, respectively

[a] CRS and ICANS were graded per ASTCT consensus criteria. [b] Among patients who reported any-grade CRS/ICANS at Day 100 follow-up.
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CRS and ICANS[a] in All Patients

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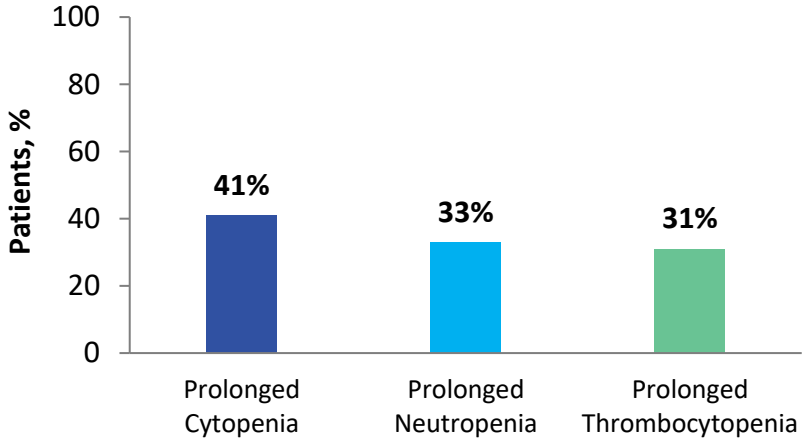
Prolonged Cytopenias[a] in All Patients



- Prolonged (present at Day 30 after infusion) Grade 4 thrombocytopenia and neutropenia occurred in 31% and 33% of patients, respectively

[a] Present at Day 30 after infusion among the 141 patients who survived Day 30. Prolonged cytopenia is defined as having either prolonged Grade 4 neutropenia (failure to recover ANC ≥500/mm^3 (0.5×10^9/L) and/or sustain 3 lab values within the first 30 days after infusion) or prolonged Grade 4 thrombocytopenia (failure to recover platelet count ≥20×10^9/L within the first 30 days after infusion).
ANC, absolute neutrophil count.

Other Adverse Events in All Patients

Adverse Events of Interest, n (%)	All Patients (N=150)
Clinically significant infections[a]	**76 (51)**
Bacterial	46 (31)
Fungal	11 (7)
Viral	34 (23)
Other	15 (10)
Deaths	**38 (25)**
Deaths ≤3 months after brexu-cel infusion, n (%)	22 (15)
Deaths ≤1 month after brexu-cel infusion, n (%)	9 (6)
Deaths >1 month and ≤3 months after brexu-cel infusion, n (%)	13 (9)

- Clinically significant infections occurred in 51% of patients, with most being bacterial or viral

[a] Any infection diagnosed after the initial infusion of brexu-cel that required treatment.
brexu-cel, brexucabtagene autoleucel.

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Other	15 (10)
Deaths	**38 (25)**
Deaths ≤3 months after brexu-cel infusion, n (%)	22 (15)
Deaths ≤1 month after brexu-cel infusion, n (%)	9 (6)
Deaths >1 month and ≤3 months after brexu-cel infusion, n (%)	13 (9)

- Clinically significant infections occurred in 51% of patients, with most being bacterial or viral

[a] Any infection diagnosed after the initial infusion of brexu-cel that required treatment.
brexu-cel, brexucabtagene autoleucel.

Other Adverse Events in All Patients

Adverse Events of Interest, n (%)	All Patients (N=150)
Clinically significant infections[a]	**76 (51)**
Bacterial	46 (31)
Fungal	11 (7)
Viral	34 (23)
Other	15 (10)
Deaths	**38 (25)**
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- Of the 38 patients who died, 22 died within 3 months of brexu-cel infusion (including 9 who died within 1 month)

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Conclusions

- This real-world study of adult patients with R/R B-ALL treated with brexu-cel demonstrated promising effectiveness outcomes, with a 79% CR/CRi rate and a 6-month OS rate of 79%

B-ALL, B-cell acute lymphocytic leukemia; brexu-cel, brexucabtagene autoleucel; CR, complete remission; CRi, complete remission with incomplete hematological recovery; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; OS, overall survival; R/R, relapsed or refractory.

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- This real-world study of adult patients with R/R B-ALL treated with brexu-cel demonstrated promising effectiveness outcomes, with a 79% CR/CRi rate and a 6-month OS rate of 79%
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- Future analyses with longer follow-up and larger sub-groups of interest are planned

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Acknowledgments

- The patients, families, friends, and caregivers
- The study investigators, coordinators, and healthcare staff at each study site
- Medical writing support was provided by Edward Sheetz, PhD, of Nexus Global Group Science, funded by Kite, a Gilead Company
- This study was funded by the National Cancer Institute (CIDR [U24 CA233032]) and Kite, a Gilead Company
- Full author disclosures are available through the virtual meeting platform

This study is a collaboration between CIBMTR® and Kite, a Gilead Company. CIBMTR® is a research collaboration between National Marrow Donor Program® and the Medical College of Wisconsin

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