# Comparative efficacy of lisocabtagene maraleucel in the PILOT study *versus* second-line chemotherapy regimens in the real world

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## **Supplementary Appendix**

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#### Supplementary methods

## Patients and study cohorts

The PILOT study enrolled patients with relapsed or refractory large B-cell lymphoma at any time after one line of chemoimmunotherapy containing an anthracycline and a CD20-targeted agent, had confirmed positron emission tomography–positive disease, were considered hematopoietic stem cell transplantation (HSCT) not intended by their physician, and met ≥1 of the following prespecified HSCT not intended criteria: age ≥70 years, Eastern Cooperative Oncology Group performance status (ECOG PS) of 2, diffusing capacity of the lung for carbon monoxide ≤60% adjusted for sex-specific hemoglobin concentration, left ventricular ejection fraction (LVEF) <50%, calculated creatinine clearance (CrCl; Cockcroft-Gault equation) <60 mL/min, and/or alanine aminotransferase/aspartate aminotransferase (ALT/AST) >2 × upper limit of normal (ULN). Patients must have had adequate organ functions measured as oxygen saturation ≥92% on room air with dyspnea of grade ≤1, LVEF ≥40%, CrCl >30 mL/min, ALT/AST ≤5 × ULN, total bilirubin <2.0 mg/dL (or <3.0 mg/dL for patients with Gilbert's syndrome or lymphomatous infiltration of the liver), and adequate bone marrow function per investigator.

The three conventional chemotherapy cohorts were derived from a harmonized dataset comprising multiple data sources collected retrospectively from COTA, Guardian Network, and clinical sites via electronic case report forms. Data sources were targeted for selection by identifying existing databases collecting longitudinal data covering clinical characteristics, treatment, and outcomes of patients with hematologic malignancies with a focus on relapsed or refractory B-cell non-Hodgkin lymphoma. The databases are of different types and owned/managed by research institutes, regional treatment networks, national research networks and epidemiologic registries. Data sources were also identified and selected among sites and centers known to treat patients with relapsed or refractory B-cell non-Hodgkin lymphoma, as

evidenced by their research outputs or trial programs, where populations of patients with relapsed or refractory B-cell non-Hodgkin lymphoma treated with standard of care were anticipated to enable chart abstractions. Data sources were grouped into clinical sites and external research data partners. Data from clinical sites were acquired by a vendor that obtains data through direct abstraction into an electronic case report form, extraction from a clinical research database or electronic medical record, or a combination thereof. Clinical sites were systematically evaluated for participation to minimize bias in site selection using the following metrics: adequate projected patient sample size, experience with observational research and data collection, speed to data access, speed to contracting and institutional review board approval, presence of preexisting relationship, and state of current data model.

#### Index dates and data cutoff dates

The index dates for the lisocabtagene maraleucel (liso-cel)–treated and leukapheresis cohorts were the day of liso-cel infusion and leukapheresis, respectively. The index date for the conventional chemotherapy cohorts was the start of second-line therapy. The data cutoff dates were September 24, 2021, for the liso-cel cohorts and December 31, 2020, for the conventional chemotherapy cohorts. The real-world data were collected from 2018 to the data cutoff date of December 31, 2020, in a retrospective manner among patients whose first large B-cell lymphoma diagnosis was in 2003 or later.

#### **Endpoint definitions**

Duration of response was defined as duration of time from first response (partial response or better) to the first documented disease progression, relapse, or death from any cause, whichever occurred first. Event-free survival was defined as time from index date to first documentation of disease progression, relapse, start of new anticancer therapy, or death due to any cause, whichever occurred first. Progression-free survival was defined as time from the index date to the first documented disease progression, relapse, death due to any cause, or end

of follow-up, whichever occurred first. Overall survival was defined as time from the index date to the first documentation of death due to any cause, or censoring, whichever occurred first.

#### Statistical analysis

Analysts who were blinded to outcome data behind a firewall performed initial balancing of patient baseline characteristics. Trimmed stabilized inverse probability of treatment weighting and greedy nearest neighbor matching methods were used to balance the liso-cel and conventional chemotherapy cohorts according to baseline characteristics; doubly robust procedures were used where appropriate.¹ For greedy nearest neighbor matching, a caliper width of 0.20 times the pooled estimate of the standard deviation of the logits of the propensity scores was used. Prognostic variables (based on literature and medical review) with ≤30% missing values in both liso-cel and conventional chemotherapy cohorts were included in balancing as follows: age, sex, years from initial diagnosis to index date, ECOG PS, Ann Arbor disease stage, refractory versus relapsed, duration of CR after first-line therapy, and bulky disease. The conventional chemotherapy cohort after balancing was used for the evaluation of efficacy endpoints. Statisticians and programmers were able to access outcomes data after the conventional chemotherapy cohorts were constructed.

Baseline characteristics and outcomes were summarized descriptively, and treatment patterns were analyzed descriptively at the drug level by line of therapy. A generalized linear model and/or Cox proportional hazards model was used to estimate the relative risk or hazard ratio for each outcome of interest, with accompanying 95% confidence intervals. Time-to-event comparisons were conducted using Kaplan-Meier survival or Cox proportional hazards model methods. Individual estimates and their standard errors were combined using Rubin's rules to produce an overall estimate.<sup>2</sup> All statistical analyses were conducted using SAS (previously "Statistical Analysis System") Software® version 9.4 or higher. All tests were conducted

assuming a two-tailed test of significance and alpha level set a priori at 0.05, and there was no adjustment for multiplicity. For key endpoints, comparisons between the liso-cel-leukapheresed and conventional chemotherapy cohorts were conducted as sensitivity analyses. Another sensitivity analysis excluding patients who received second-line chemotherapy regimens that are commonly received as salvage therapies before HSCT (intent-to-transplant therapy) was also conducted. The intent-to-transplant therapy (with or without rituximab) was defined per current treatment guidelines as follows: dexamethasone, cisplatin, and cytarabine; dexamethasone, cytarabine, and oxaliplatin; ifosfamide, carboplatin, and etoposide; etoposide, methylprednisolone, cytarabine, and cisplatin; and ifosfamide, mitoxantrone, and etoposide.

**Supplementary Table S1.** Additional patient demographics and baseline characteristics.

	Liso-ce	l cohorts	Conventional chemotherapy cohorts	
Characteristic	Liso-cel leukapheresed (n=74)	Liso-cel treated (n=61)	Before application of PILOT eligibility criteria* (n=601)	After application of PILOT eligibility criteria but before balancing <sup>†</sup> (n=273)
LVEF, n (%)				
<50%	3 (4)	2 (3)	5 (1)	5 (2)
≥50%	71 (96)	59 (97)	78 (13)	36 (13)
Missing	0 (0)	0 (0)	518 (86)	232 (85)
CrCl (mL/min),‡ n (%)				
<60%	16 (22)	14 (23)	24 (4)	23 (8)
≥60%	50 (68)	47 (77)	121 (20)	48 (18)
Missing	8 (11)	0 (0)	456 (76)	202 (74)
ALT, n (%)				
≤2 × ULN	74 (100)	61 (100)	317 (53)	164 (60)
>2 × ULN	0 (0)	0 (0)	9 (1)	9 (3)
Missing	0 (0)	0 (0)	275 (46)	100 (37)
AST, n (%)				
≤2 × ULN	73 (99)	60 (98)	317 (53)	160 (59)
>2 × ULN	1 (1)	1 (2)	15 (2)	15 (5)

	Liso-cel cohorts		Conventional chemotherapy cohorts	
Characteristic	Liso-cel leukapheresed (n=74)	Liso-cel treated (n=61)	Before application of PILOT eligibility criteria*	After application of PILOT eligibility criteria but before balancing <sup>†</sup>
	(11 14)		(n=601)	(n=273)
Missing	0 (0)	0 (0)	269 (45)	98 (36)
Serum LDH, n (%)				
<500 U/L	57 (77)	50 (82)	252 (42)	116 (42)
≥500 U/L	17 (23)	11 (18)	96 (16)	55 (20)
Missing	0	0	253 (42)	102 (37)

<sup>\*</sup>All patients in the conventional chemotherapy cohort with R/R LBCL after receiving therapy with an anthracycline and CD20-targeted agent.

ALT: alanine aminotransferase; AST: aspartate aminotransferase; CrCl: creatinine clearance; LBCL: large B-cell lymphoma; LDH: lactate dehydrogenase; liso-cel: lisocabtagene maraleucel; LVEF: left ventricular ejection fraction; R/R: relapsed or refractory; ULN: upper limit of normal.

<sup>&</sup>lt;sup>†</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT<sup>3</sup> but before balancing to baseline characteristics with the liso-cel–treated cohort.

<sup>‡</sup>By Cockcroft-Gault equation.

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**Supplementary Table S2.** Baseline characteristics before and after balancing using trimmed stabilized inverse probability of treatment weighting.

	Before balancing			After balancing		
	Liso-cel–treated cohort (n=61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria* (n=273)	pSMD <sup>†</sup> (liso- cel-treated cohort minus conventional chemotherapy cohort after application of PILOT eligibility criteria*)	Liso-cel–treated cohort (n=61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria* (n=273)	pSMD <sup>†</sup> (liso- cel-treated cohort minus conventional chemotherapy cohort after application of PILOT eligibility criteria*)
Age, y	73.08	72.21	0.0866	72.94	72.40	0.0544
Sex (male = 1; female = 0)	0.39	0.43	-0.0714	0.41	0.42	-0.0265
R/R to 1L therapy (refractory = 1; relapsed = 0) <sup>‡</sup>	0.54	0.60	-0.1209	0.60	0.59	0.0063
Ann Arbor disease stage (III/IV = 1; I/II = 0)	0.66	0.75	-0.2116	0.68	0.73	-0.1144
ECOG PS before lymphodepleting	0.26	0.31	-0.1068	0.28	0.30	-0.0417

chemotherapy						
(≥2 = 1; <2 = 0)						
Mean duration of						
CR to 1L therapy,	16.31	10.32	0.1978	13.28	11.10	0.0767
mo						
Mean time from	2.22	1.71	0.1907	1.99	1.78	0.0849
initial diagnosis, y	2.22	1.71	0.1907	1.99	1.70	0.0049
Bulky disease	0.16	0.32	-0.3756	0.21	0.29	-0.1958
(yes = 1; no = 0)§	0.10	0.32	0.3730	0.21	0.29	0.1930

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT.3

<sup>†</sup>pSMD was obtained from the baseline characteristics in the liso-cel–treated cohort minus the baseline characteristics in the conventional chemotherapy cohorts and using stabilized weights when combining the mean and standard deviation. If a baseline characteristic had >30% missing per cohort, the characteristic was not used in the balancing except for disease stage. Disease stage had >30% missingness but was included in the balancing, as it was classified as a highly prognostic factor.

<sup>‡</sup>Disease status was refractory if a patient achieved less than a CR to last prior therapy; disease status was relapsed otherwise. §Bulky disease was defined as disease ≥10 cm for patients in the liso-cel–treated cohort and simply recorded as "yes" or "no" based on electronic medical records for patients in the conventional chemotherapy cohort.

1L: first line; CR: complete response; ECOG PS: Eastern Cooperative Oncology Group performance status; liso-cel: lisocabtagene maraleucel; pSMD: pooled standardized mean difference; R/R: relapsed or refractory.

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Supplementary Table S3. Baseline characteristics before and after balancing using greedy nearest neighbor matching.

	Before balancing			After balancing			
	Liso-cel– treated cohort (n=61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria* (n=273)	pSMD <sup>†</sup> (liso-cel– treated cohort minus conventional chemotherapy cohort after application of PILOT eligibility criteria*)	Liso-cel– treated cohort (n=56–61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria* (n=159-179)	pSMD <sup>†</sup> (liso-cel– treated cohort minus conventional chemotherapy cohort after application of PILOT eligibility criteria*)	
Age, y	73.08	72.21	0.0866	73.08	72.77	0.0429	
Sex (male = 1; female = 0)	0.39	0.43	-0.0714	0.40	0.40	-0.0002	
R/R to 1L therapy (refractory = 1; relapsed = 0) <sup>‡</sup>	0.54	0.60	-0.1209	0.55	0.57	-0.0523	
Ann Arbor disease stage (III/IV = 1; I/II = 0)	0.66	0.75	-0.2116	0.66	0.64	0.0449	
ECOG PS before lymphodepleting chemotherapy (≥2 = 1; <2 = 0)	0.26	0.31	-0.1068	0.26	0.28	-0.0456	

Mean duration of						
CR to 1L therapy,	16.31	10.32	0.1978	14.55	13.50	0.0348
mo						
Mean time from	2.22	1.71	0.1907	2.08	2.02	0.0226
initial diagnosis, y	2.22	1.71	0.1907	2.00	2.02	0.0220
Bulky disease	0.16	0.32	-0.3756	0.17	0.17	-0.0137
(yes = 1; no = 0)§	0.10	0.32	-0.3730	0.17	0.17	-0.0137

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT.3

<sup>†</sup>pSMD was obtained from the baseline characteristic of the liso-cel–treated cohort minus the baseline characteristic of the conventional chemotherapy cohorts and unweighted when combining the mean and standard deviation. The matched sample was constructed with greedy nearest neighbor matching of the logit of the propensity score using calipers equal to width of 0.2 of the standard deviation of the logit of the propensity score. If a baseline characteristic had >30% missing per cohort, the characteristic was not used in the balancing except for disease stage. Disease stage had >30% missingness but was included in the balancing, as it was classified as a highly prognostic factor.

<sup>‡</sup>Disease status was refractory if a patient achieved less than a CR to last prior therapy; disease status was relapsed otherwise. §Bulky disease was defined as disease ≥10 cm for patients in the liso-cel–treated cohort and simply recorded as "yes" or "no" based on electronic medical records for patients in the conventional chemotherapy cohort.

1L: first line; CR: complete response; ECOG PS: Eastern Cooperative Oncology Group performance status; liso-cel: lisocabtagene maraleucel; pSMD: pooled standardized mean difference; R/R: relapsed or refractory.

### **Supplementary Table S4.** Patient disposition.

	Leukapheresed		Conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing*		
	cohort (before liso-cel) (n=74)	Liso-cel-treated cohort (n=61)	Without 2-year follow-up limit (n=273)	With 2-year follow-up limit (n=273)	
On study, n (%)	74 (100)	61 (100)	273 (100)	273 (100)	
Discontinued from study, n (%)	41 (55)	28 (46)	165 (60)	140 (51)	
Reason for discontinuation, n (%)					
Death	26 (35)	20 (33)	165 (60)	140 (51)	
Consent withdrawal	6 (8)	6 (10)	0 (0)	0 (0)	
No longer met eligibility criteria	5 (7)	0 (0)	0 (0)	0 (0)	
Disease-related complications	1 (1)	0 (0)	0 (0)	0 (0)	
Other	3 (4)	2 (3)	0 (0)	0 (0)	

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT<sup>3</sup> but before balancing to baseline characteristics with the liso-cel-treated cohort.

Liso-cel: lisocabtagene maraleucel.

**Supplementary Table S5.** Comparative adjusted efficacy outcomes excluding patients who received intent-to-transplant therapies from the conventional chemotherapy cohort.

	Trimmed stabilized IPTW				
	Liso-cel–treated cohort (n=61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria and balancing* (n=187)			
ORR, % (95% CI)	81.1 (71.8–91.7)	49.8 (43.0–57.6)			
RR (95% CI) <i>P</i> value		(1.3–2.0) 0.0001			
CR rate, % (95% CI)	53.2 (41.6–68.2)	22.3 (17.0–29.2)			
RR (95% CI) <i>P</i> value	2.4 (1.7–3.4) <0.0001				
Median (range) time to response, mo	1.0 (0.8–2.2)	1.9 (0.1–21.0)			
Median (95% CI) DOR, mo	12.1 (1.9–22.3)	3.3 (2.2–4.3)			
HR (95% CI)  P value	·	(0.21–0.60) 0.0001			
Median (95% CI) EFS, mo	7.2 (2.7–11.7)	2.8 (2.2–3.4)			
HR (95% CI)  P value	0.42 (0.28–0.63) <0.0001				
Median (95% CI) PFS, mo	7.2 (2.7–11.7)	3.0 (2.3–3.6)			
HR (95% CI)  P value	0.45 (0.30–0.68) 0.0001				
Median (95% CI) OS, mo	NR (NR-NR)	10.8 (7.2–14.4)			
HR (95% CI) <i>P</i> value		(0.32–0.87) ).0118			

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT<sup>3</sup> balanced to baseline characteristics with the liso-cel-treated cohort.

CI: confidence interval; CR: complete response; DOR: duration of response; EFS: event-free survival; HR: hazard ratio; IPTW: inverse probability of treatment weighting; liso-cel: lisocabtagene maraleucel; NR: not reached; ORR: overall response rate; OS: overall survival; PFS: progression-free survival; RR: relative risk.

**Supplementary Table S6.** Unadjusted comparative efficacy outcomes in the liso-cel-treated cohort versus the conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing.

Unadjusted efficacy outcomes	Liso-cel–treated cohort (n=61)	Conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing* (n=273)		
ORR, % (95% CI)	80 (68.2–89.4)	50 (44.1–56.3)		
CR rate, % (95% CI)	56 (42.4–68.5)	23 (18.5–28.9)		
Median (95% CI) EFS, mo	7.2 (3.0–22.6)	2.8 (2.3–3.2)		
HR (95% CI)	0.41	(0.28–0.58)		
P value		< 0.0001		
Median (95% CI) PFS, mo	7.2 (3.0–22.6)	2.8 (2.4–3.4)		
HR (95% CI)	0.44	(0.31–0.63)		
P value	< 0.0001			
Median (95% CI) OS, mo	NR (17.3–NR)	12.1 (9.7–15.9)		
HR (95% CI)	0.51 (0.32–0.82)			
P value	0.0051			

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT<sup>3</sup> but before balancing to baseline characteristics with the liso-cel-treated cohort.

CI: confidence interval; CR: complete response; DOR: duration of response; EFS: event-free survival; HR: hazard ratio; IPTW: inverse probability of treatment weighting; liso-cel: lisocabtagene maraleucel; NR: not reached; ORR: overall response rate; OS: overall survival; PFS: progression-free survival.

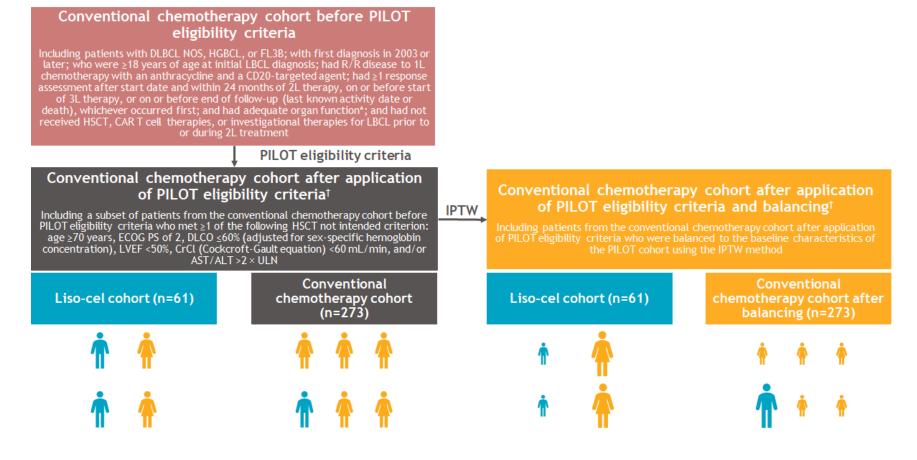
**Supplementary Table S7.** Unadjusted comparative efficacy outcomes in the liso-cel–leukapheresed cohort versus the conventional chemotherapy cohort but before balancing.

	Liso-cel–leukapheresed cohort (n=74)	Conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing* (n=273)		
ORR, % (95% CI)	66 (54.3–76.8)	50 (44.1–56.3)		
CR rate, % (95% CI)	46 (34.3–57.9)	23 (18.5–28.9)		
Median (95% CI) EFS, mo	8.1 (4.2–13.3)	2.8 (2.3–3.2)		
HR (95% CI)	0.38 (0	0.27–0.54)		
<i>P</i> value	<(	0.0001		
Median (95% CI) PFS, mo	8.1 (4.2–13.3)	2.8 (2.4–3.4)		
HR (95% CI)	0.42 (0	0.30-0.58)		
<i>P</i> value	< 0.0001			
Median (95% CI) OS, mo	NR (14.7–NR)	12.1 (9.7–15.9)		
HR (95% CI)	0.58 (0.38–0.87)			
P value	0.0093 ´			

<sup>\*</sup>A subset of the conventional chemotherapy cohort who met the prespecified eligibility criteria of PILOT³ but before balancing to baseline characteristics with the liso-cel–treated cohort.

CI: confidence interval; CR: complete response; DOR: duration of response; EFS: event-free survival; HR: hazard ratio; IPTW: inverse probability of treatment weighting; liso-cel: lisocabtagene maraleucel; NR: not reached; ORR: overall response rate; OS: overall survival; PFS: progression-free survival.

#### Supplementary Figure S1. Real-world cohorts.

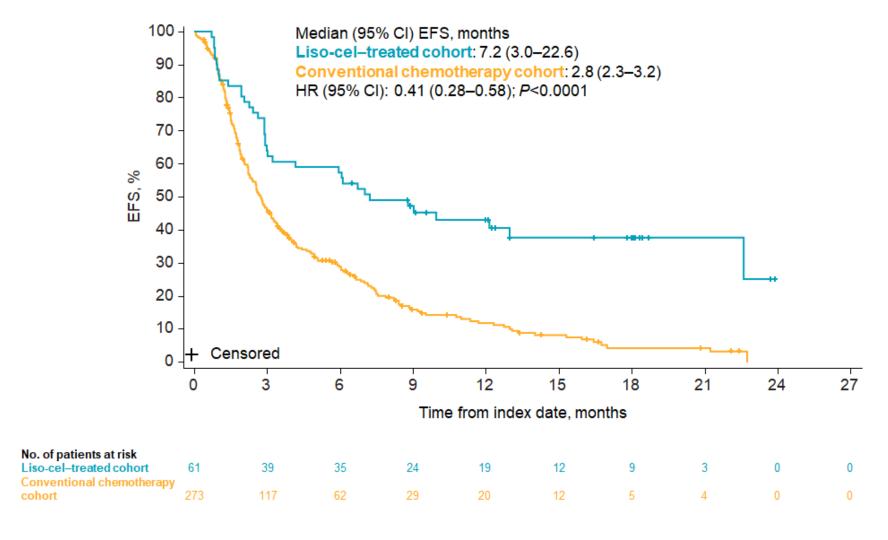


The size of the figure icons in the conventional chemotherapy cohort after application of PILOT eligibility criteria and balancing reflects the relative contribution of those patients' data toward the cohort as a whole after balancing to the baseline characteristics of the PILOT cohort using the IPTW method. \*LVEF ≥40%, CrCl >30 mL/min, AST/ALT ≤5 × ULN, total bilirubin <2.0 mg/dL (or <3.0 mg/dL for patients with Gilbert's syndrome or lymphomatous infiltration of the liver). †Adjusted efficacy outcomes were reported in the conventional chemotherapy cohort after balancing, a subset of conventional chemotherapy cohort before balancing who were

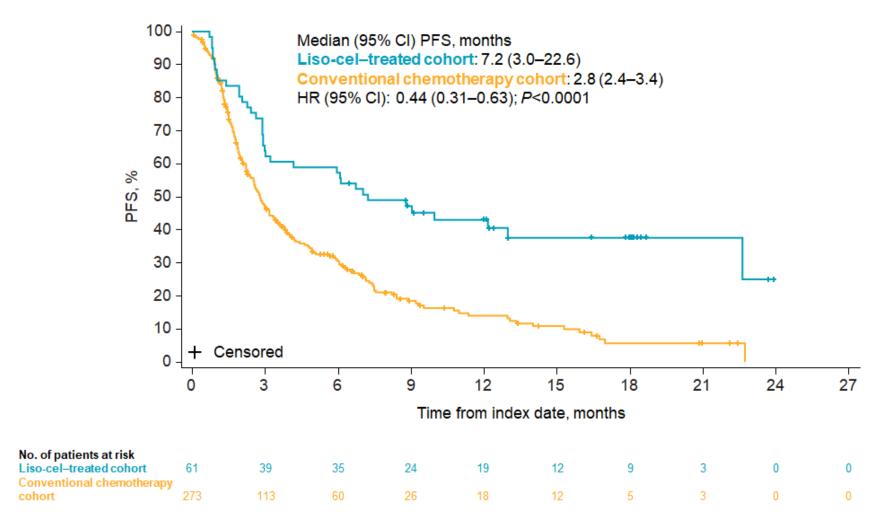
matched with the liso-cel population using IPTW; patient demographics, baseline characteristics, and treatment patterns were reported in the conventional chemotherapy cohort before balancing. 1L: first line; 2L: second line; 3L: third line; ALT: alanine aminotransferase; AST: aspartate aminotransferase; CAR: chimeric antigen receptor; CrCl: creatinine clearance; DLBCL: diffuse large B-cell lymphoma; DLCO: diffusing capacity of the lung for carbon monoxide; ECOG PS: Eastern Cooperative Oncology Group performance status; FL3B: follicular lymphoma grade 3B; HGBCL: high-grade B-cell lymphoma; HSCT: hematopoietic stem cell transplantation; IPTW: inverse probability of treatment weighting; LBCL: large B-cell lymphoma; liso-cel: lisocabtagene maraleucel; LVEF: left ventricular ejection fraction; NOS: not otherwise specified; R/R: relapsed or refractory; ULN: upper limit of normal.

Supplementary Figure S2. Unadjusted comparative efficacy outcomes in the liso-cel-treated cohort versus the conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing.

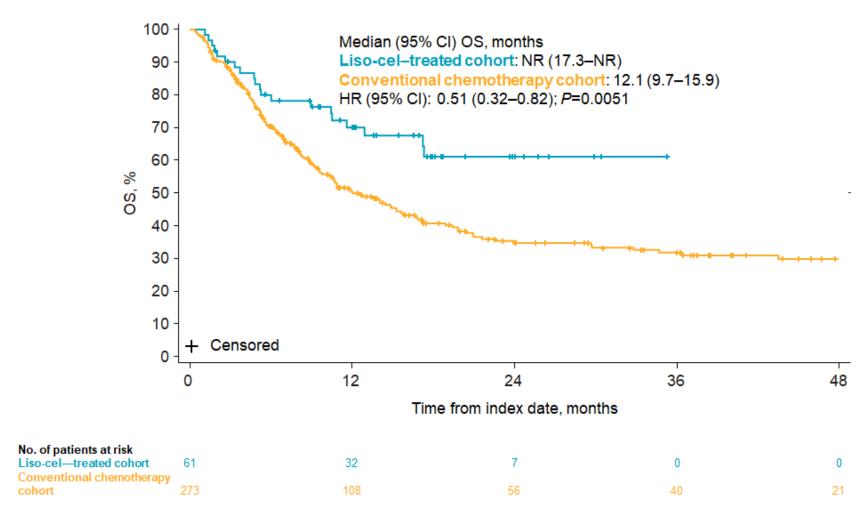
Α



В



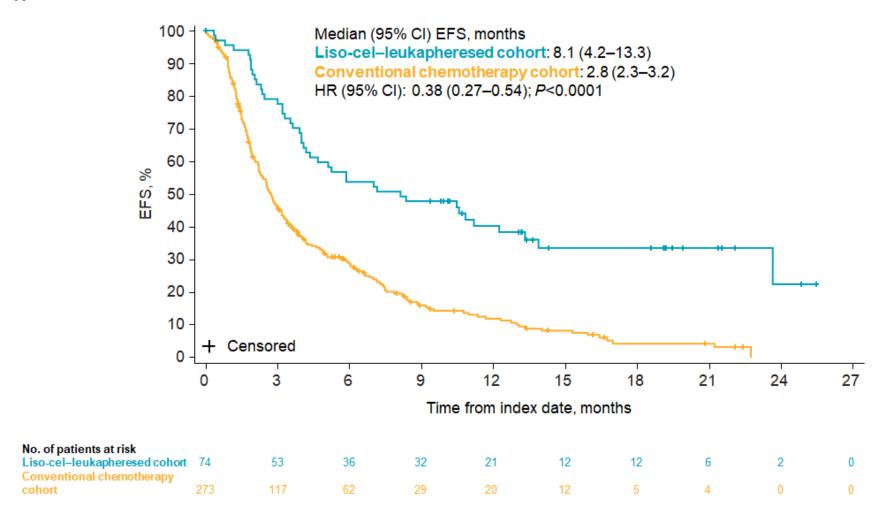
С



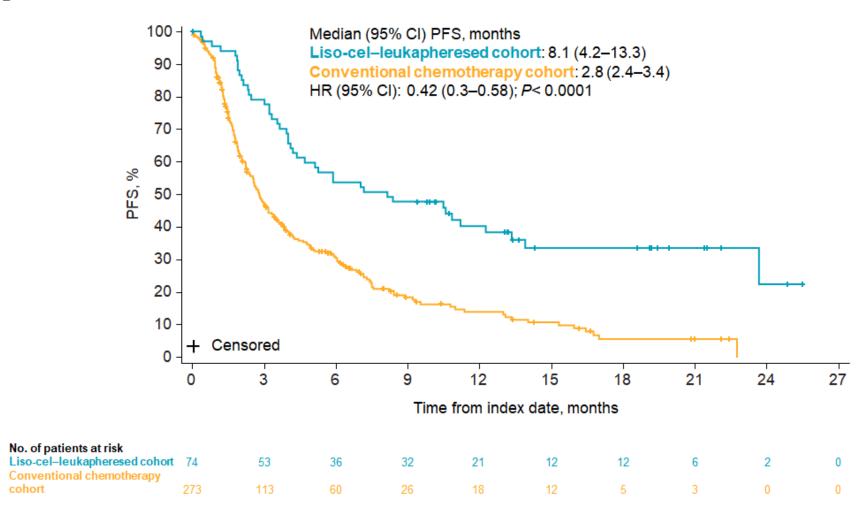
(A) EFS, (B) PFS, and (C) OS in the liso-cel-treated cohort versus conventional chemotherapy cohort. CI: confidence interval; EFS: event-free survival; liso-cel: lisocabtagene maraleucel; NR: not reached; OS: overall survival; PFS: progression-free survival.

Supplementary Figure S3. Unadjusted comparative efficacy outcomes in the liso-cel-leukapheresed cohort versus the conventional chemotherapy cohort after application of PILOT eligibility criteria but before balancing.

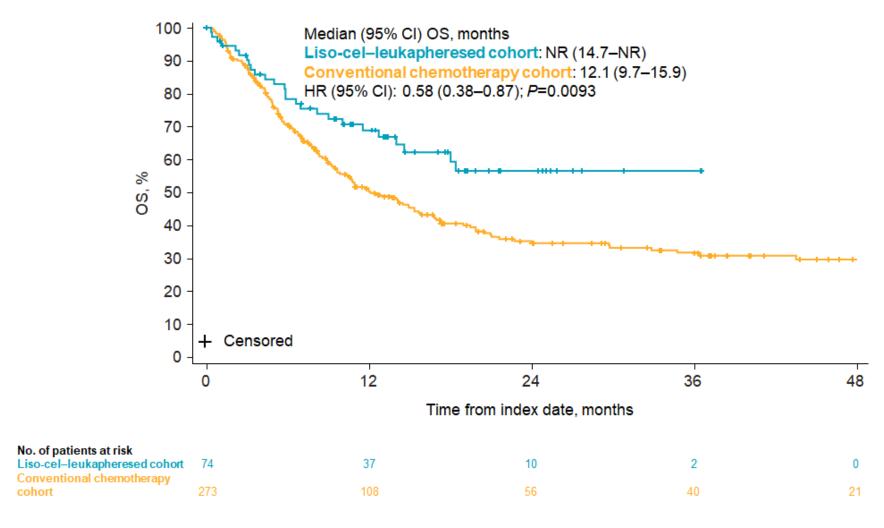
Α



В



С



(A) EFS, (B) PFS, and (C) OS in the liso-cel-leukapheresed cohort vs conventional chemotherapy cohort. CI, confidence interval; EFS, event-free survival; liso-cel, lisocabtagene maraleucel; NR, not reached; OS, overall survival; PFS, progression-free survival.

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