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Three-Year Efficacy and Longitudinal Safety of Lisocabtagene Maraleucel in Patients With Third-Line or Later Follicular Lymphoma From TRANSCEND FL

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Disclosures

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  - None
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Introduction

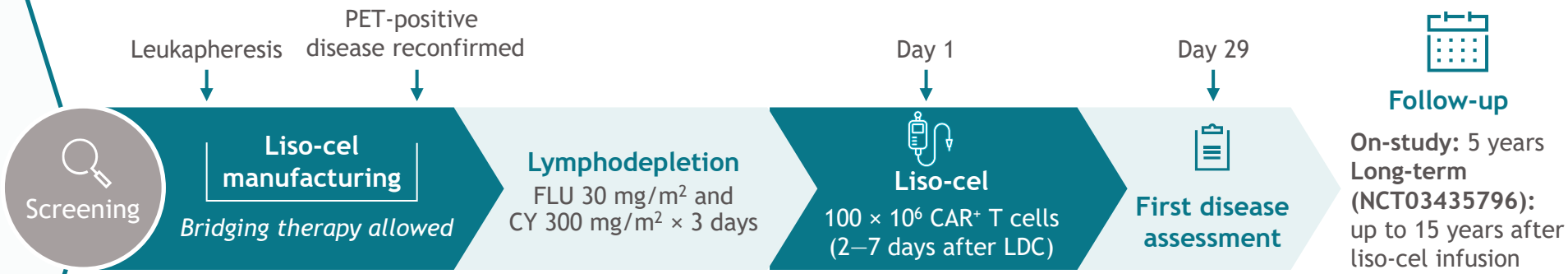
- Liso-cel, a CD19-directed CAR T cell therapy, has shown favorable efficacy with manageable safety across B-cell malignancies, including R/R LBCL, CLL/SLL, FL, MCL, and MZL[1–7]
- In TRANSCEND FL, liso-cel showed very high response rates (ORR, 97%; CR rate, 94%) with durable efficacy outcomes at 24 months (DOR, 74.6%; PFS, 72.5%; OS, 88.2%) in patients with 3L+ FL[5,8]
  - The safety profile of liso-cel remained consistent, with low rates of grade ≥ 3 CRS (1%), NEs (2%), and infections (11%) in 3L+ FL
- Here, we report 3-year follow-up efficacy and longitudinal safety for patients with 3L+ FL from TRANSCEND FL, with a median on-study follow-up of 41.5 months (range, 0.3—54.0)[a]

[a]Data cutoff date: March 31, 2025.
3L+, third line or later; CRS, cytokine release syndrome; DOR, duration of response; liso-cel, lisocabtagene maraleucel; LBCL, large B-cell lymphoma; NE, neurological events.
1. Abramson JS, et al. *Lancet* 2020;396:839—852; 2. Abramson JS, et al. *Blood* 2023;141:1675—1684; 3. Sehgal A, et al. *Lancet Oncol* 2022;23:1066—1077; 4. Siddiqi T, et al. *Lancet* 2023;402:641—654; 5. Morschhauser F, et al. *Nat Med* 2024;30:2199—2207; 6. Wang M, et al. *J Clin Oncol* 2024;42:1146—1157; 7. Palomba ML, et al. *Hematol Oncol* 2025;43(S3):e55_70093; 8. Nastoupil LJ, et al. *Blood* 2024;144(suppl 1):4387—4390.

TRANSCEND FL: phase 2, open-label, multicenter, multicohort study

Key FL eligibility criteria

- Age ≥ 18 years
- R/R FL
  - 2L cohort (POD24 and/or mGELF)[a]
  - 3L cohort
  - 4L+ cohort
- FL histologically confirmed ≤ 6 months before screening with PET-positive and measurable disease
- Received combination of an anti-CD20 antibody and an alkylator
- ECOG PS ≤ 1
- Adequate organ function



Primary endpoint (efficacy set)

- ORR (BOR of CR or PR) per IRC by PET/CT per Lugano 2014 criteria[1]

Secondary endpoints

- CR rate, DOR, and PFS per IRC by PET/CT per Lugano 2014,[1] and OS
- Safety

Post hoc analyses

- TTNT
- Efficacy subgroup analyses by POD24, bulky disease, double-refractory disease and prior bendamustine treatment
- Longitudinal safety analyses of infections, key laboratory parameters, and supportive treatments

ClinicalTrials.gov identifier: NCT04245839.

[a]POD24 was defined as progression within 24 months of diagnosis, after treatment with an anti-CD20 antibody and an alkylating agent within the first 6 months of initial FL diagnosis. Patients who did not meet criteria of POD24 had to meet ≥ 1 of the mGELF criteria (symptoms attributable to FL; threatened end-organ function, or cytopenia secondary to lymphoma or bulky disease [single mass > 7 cm, or ≥ 3 masses > 3 cm]; splenomegaly; or steady progression over ≥ 6 months).

2L, second line; 3L, third line; 4L+, fourth line or later; BOR, best overall response; CY, cyclophosphamide; FLU, fludarabine; IRC, independent review committee; LDC, lymphodepleting chemotherapy; mGELF, modified Groupe d'Etude des Lymphomes Folliculaires; POD24, progression of disease ≤ 24 months from initial immunochemotherapy; TTNT, time to next treatment.

1. Cheson BD, et al. *J Clin Oncol* 2014;32:3059–3068.

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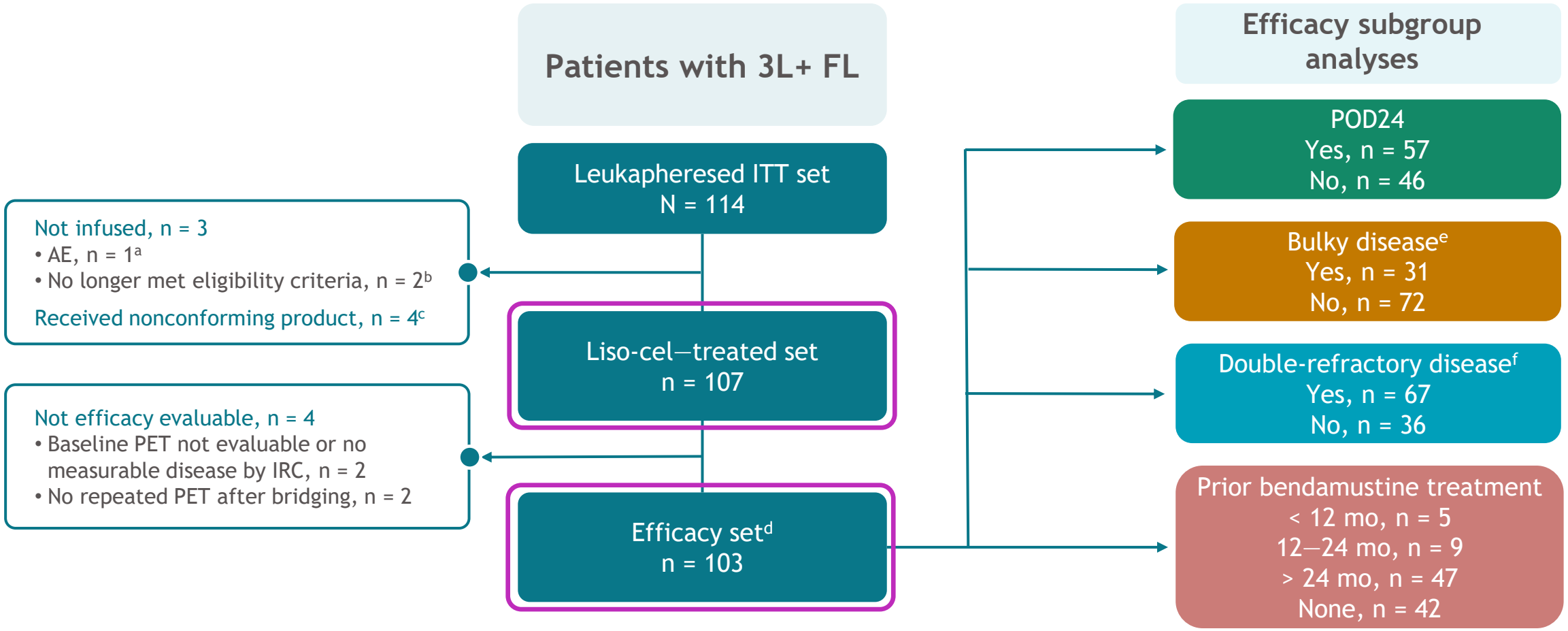
Patient disposition and analysis sets



[a]Acute respiratory failure (enterovirus/rhinovirus pneumonia); [b]History of transformed FL (n = 1), PET-negative at pretreatment assessment (n = 1); [c]Nonconforming product was defined as any product wherein one of the CD8 or CD4 cell components did not meet one of the requirements to be considered liso-cel but was considered appropriate for infusion; [d]Liso-cel–treated patients with PET/CT-positive disease per IRC before infusion; [e]At screening based on mGELF criteria; [f]Can be met at any line of therapy that includes an anti-CD20 antibody and alkylating agent.

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Longitudinal safety analyses

- Incidences of the following safety parameters were assessed:
  - Grade ≥ 3 cytopenia (neutropenia, thrombocytopenia, and anemia)[a]
  - B-cell aplasia[a,b]
  - Hypogammaglobulinemia[a,c]
  - Infections (any grade and grade ≥ 3)
  - Receipt of transfusions (RBC and platelet), immunoglobulin replacement therapy, and hematopoietic growth factors

Time periods of assessment[d]

[a]Proportions were calculated using the number of patients evaluated for each laboratory parameter at each time period as the denominator; [b]Less than 3% $CD19^+$ B cells of lymphocytes; [c]Immunoglobulin G levels < 500 mg/dL; [d]Monthly ranges (ie, Month 2—Month 3) start on the first day of the first month and end on the last day of the last month. Each patient is counted once in each time period but is counted again if having an event in another time period.
EOS, end of study; RBC, red blood cell.

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Patient demographics and baseline characteristics

	3L+ FL (n = 107)
Median (range) age, y	62 (23–80)
Met mGELF criteria at most recent relapse, n (%)	57 (53)
Bulky disease,[a] n (%)	34 (32)
Median (range) prior lines of systemic therapy	3 (2–10)
Received prior HSCT, n (%)	33 (31)
Received prior rituximab and lenalidomide, n (%)	23 (21)
Received prior bendamustine, n (%)	65 (61)
Double refractory (anti-CD20 and alkylator),[b] n (%)	69 (64)
POD24 from initial immunochemotherapy, n (%)	59 (55)
Received bridging therapy, n (%)	44 (41)

[a]Based on mGELF criteria (any nodal or extranodal tumor mass > 7 cm diameter or ≥ 3 nodal sites with > 3 cm diameter each); [b]Patients whose disease was refractory to both an anti-CD20 antibody and an alkylating agent or refractory to anti-CD20 maintenance therapy.

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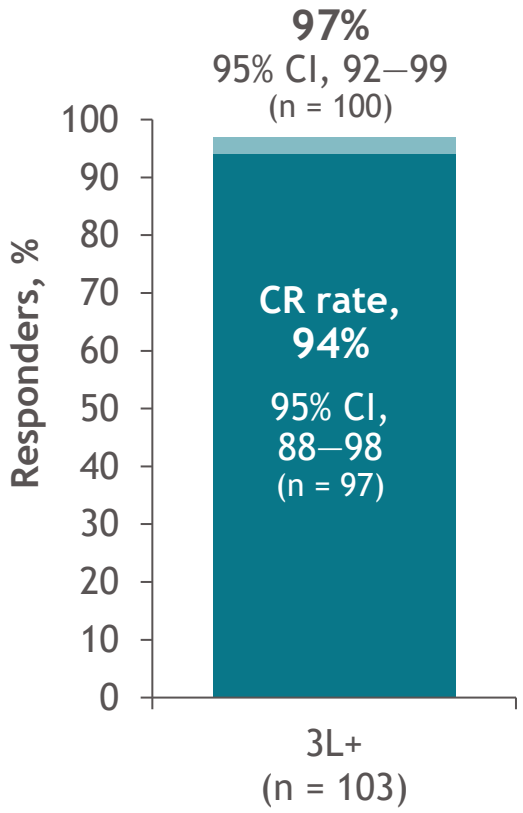
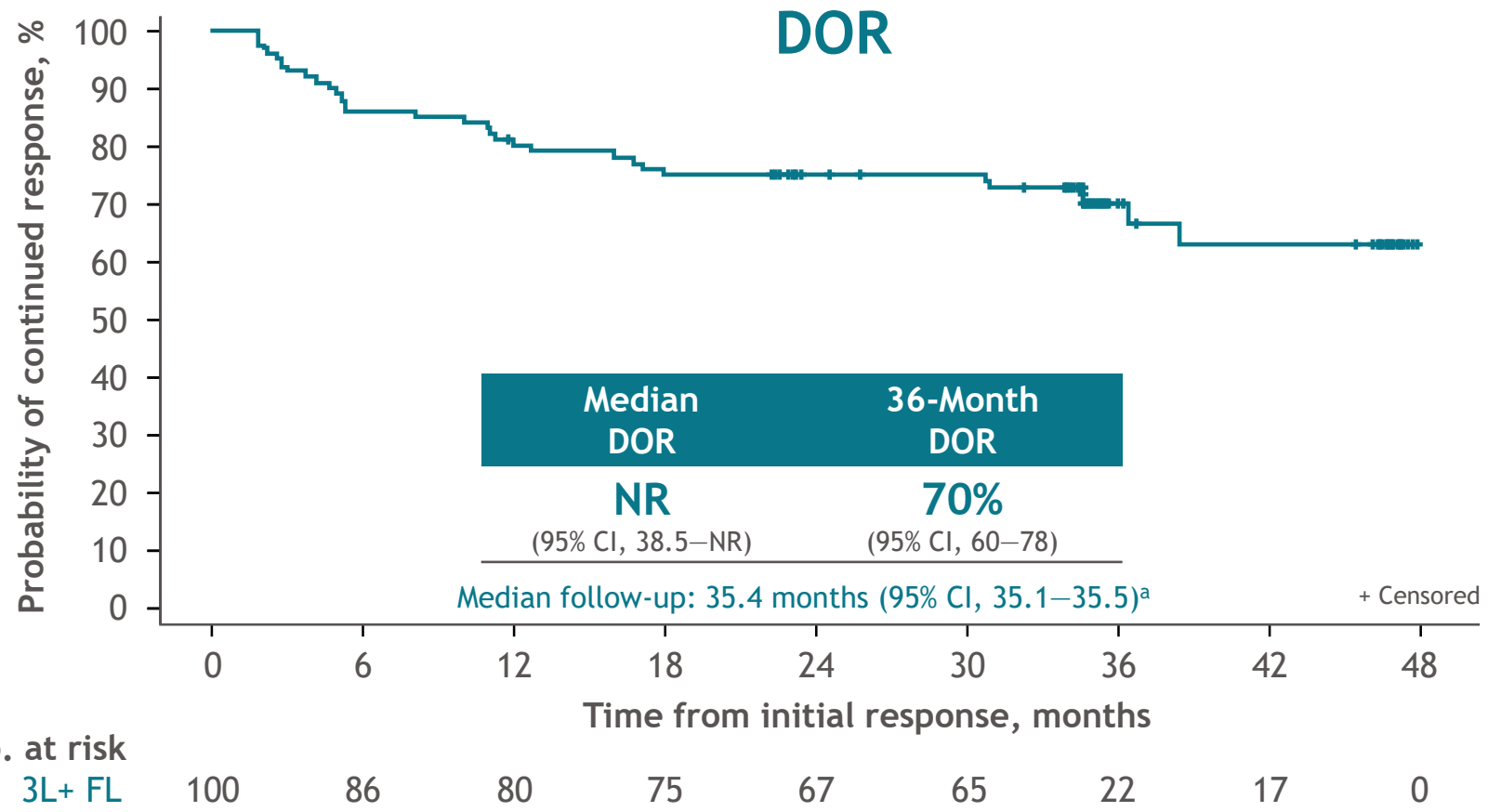
Responses were deep and durable in patients with 3L+ FL





- Median DOR continued to be not reached with longer follow-up, and 70% remained in response at 36 months

[a]Reverse KM method was used to obtain the median follow-up and 95% CI.
NR, not reached.

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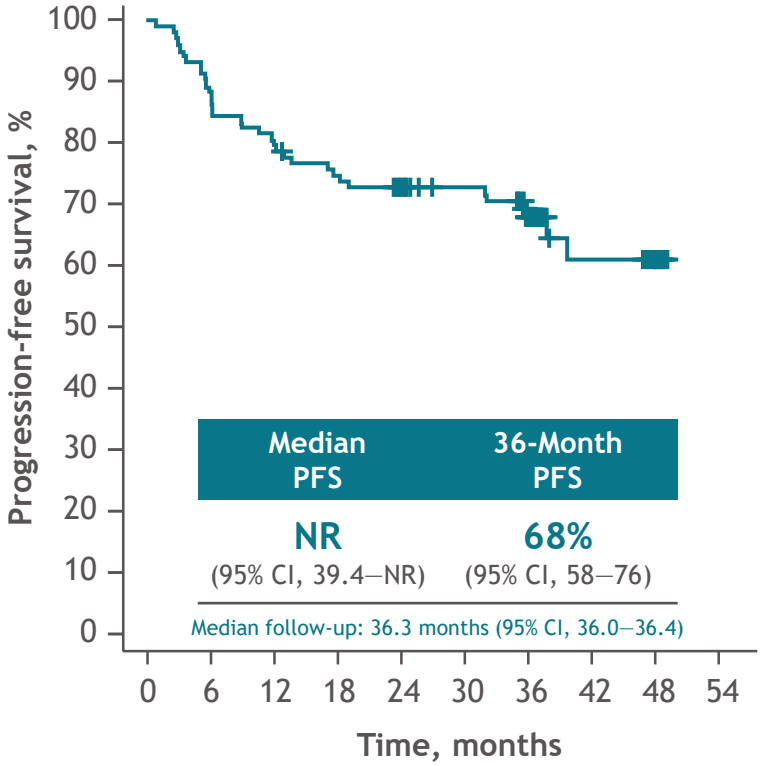
36-Month rates of PFS, TTNT, and OS were high in patients with 3L+ FL

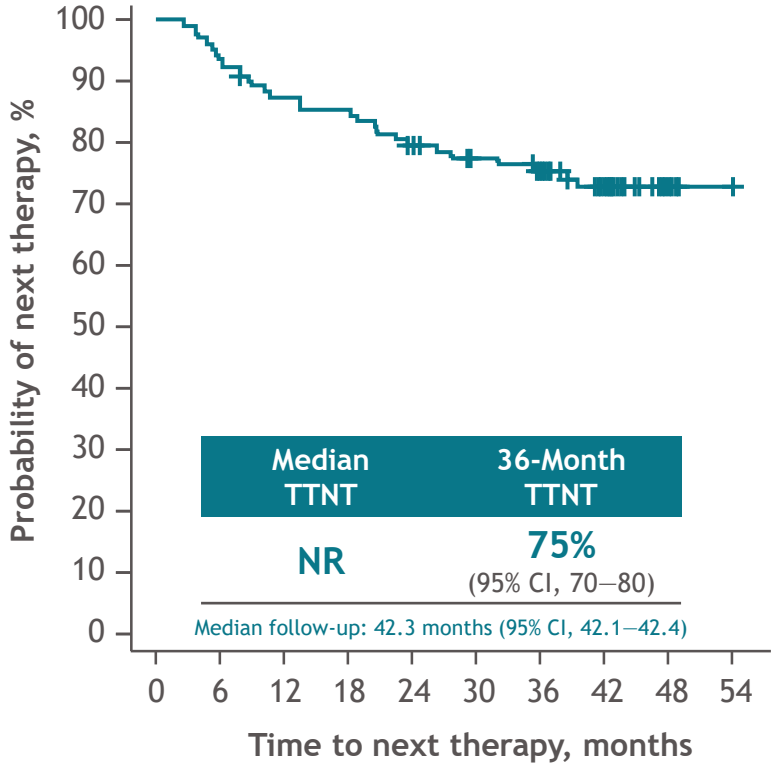
PFS



No. at risk

3L+ FL	103	91	82	76	69	65	44	17	9	0	

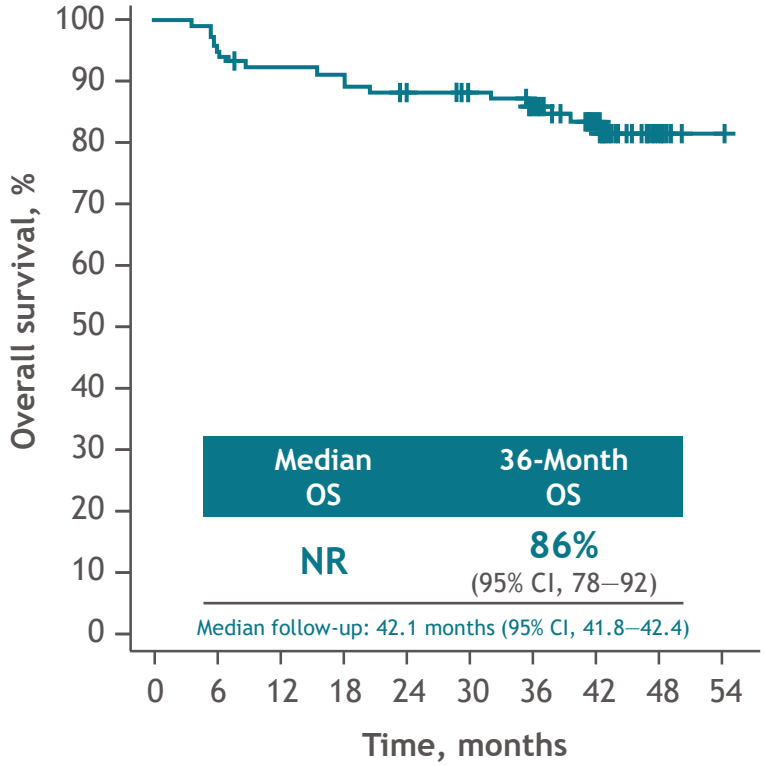
TTNT



No. at risk

3L+ FL	103	96	89	87	80	74	68	46	11	1	

OS



No. at risk

3L+ FL	103	99	94	93	89	85	78	51	12	1	

- Median PFS, TTNT, and OS all continued to be not reached with longer follow-up

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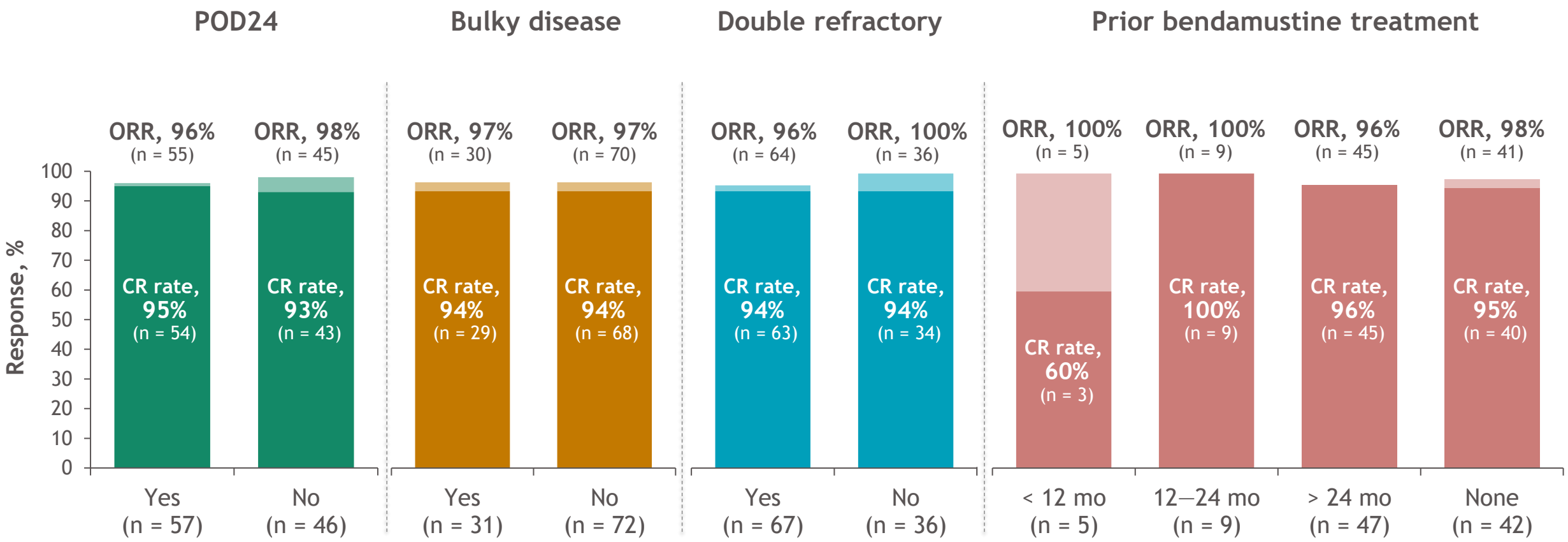
Overall response rates were > 95% across subgroups



- ORRs were very high and consistent across subgroups with most patients achieving CR

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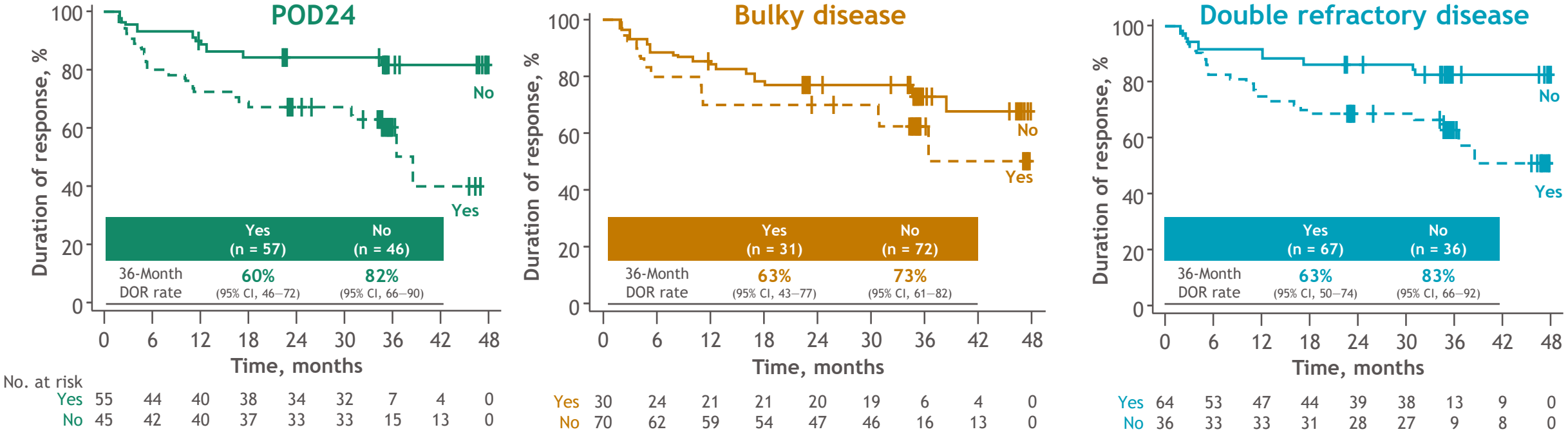
Responses were durable with high PFS rates, even in patients with high-risk disease

DOR



36-Month PFS rate

POD24 (n = 57)	No POD24 (n = 46)	Bulky disease (n = 31)	No bulky disease (n = 72)	Double refractory (n = 67)	Not double refractory (n = 36)
58% (95% CI, 43–70)	80% (95% CI, 65–89)	61% (95% CI, 41–75)	71% (95% CI, 58–80)	60% (95% CI, 47–71)	83% (95% CI, 66–92)

Median DOR was not reached across all these subgroups except patients with POD24 (38.5 months [95% CI, 31.0–NR]).

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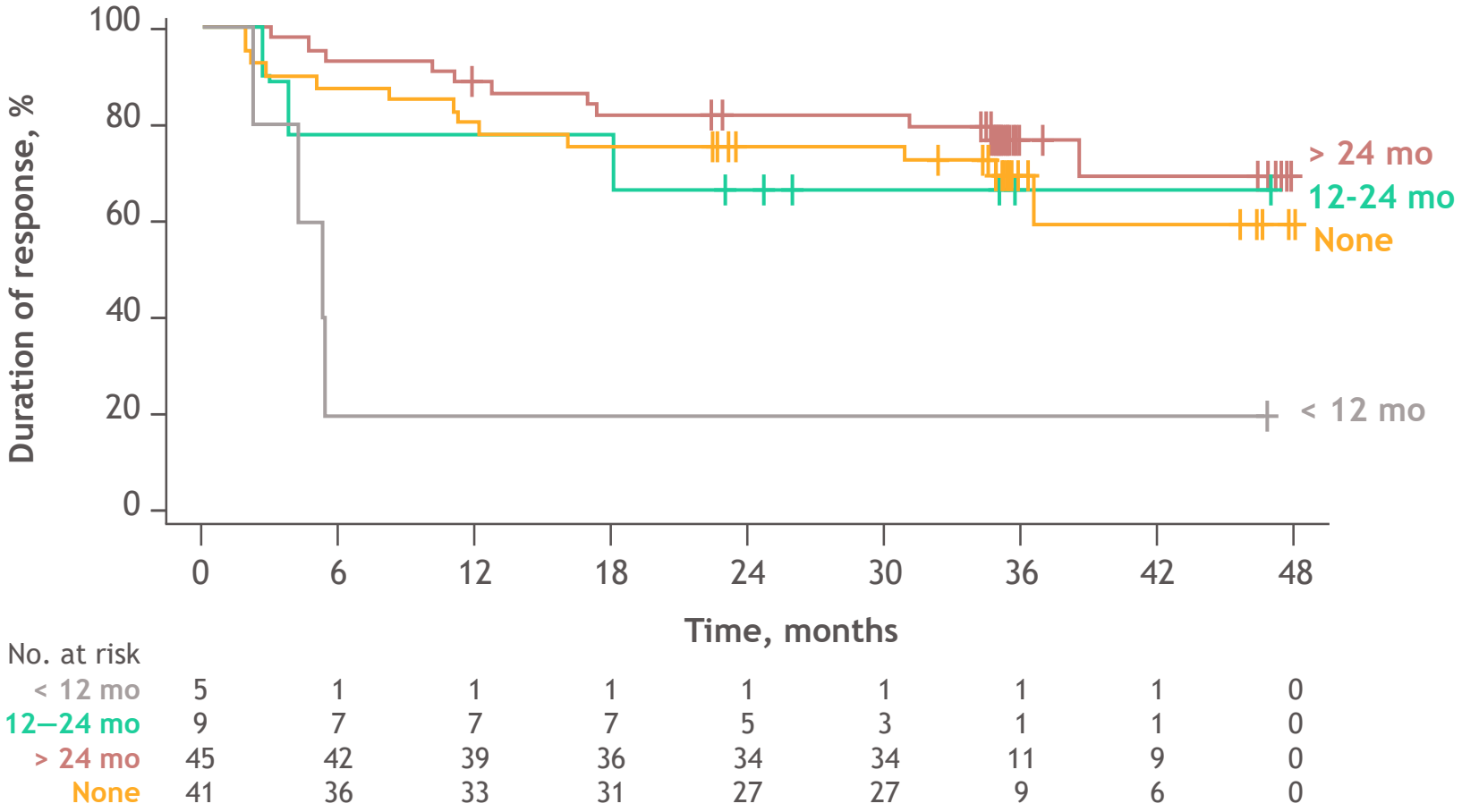
Responses were durable with high PFS rates in patients with prior bendamustine ≥ 12 months before leukapheresis

DOR



No. at risk									
< 12 mo	5	1	1	1	1	1	1	1	0
12–24 mo	9	7	7	7	5	3	1	1	0
> 24 mo	45	42	39	36	34	34	11	9	0
None	41	36	33	31	27	27	9	6	0

36-Month rates

DOR	
< 12 mo (n = 5)	20% (95% CI, 1–58)
12–24 mo (n = 9)	67% (95% CI, 28–88)
> 24 mo (n = 47)	77% (95% CI, 61.5–87)
None (n = 42)	69% (95% CI, 52–81)

PFS	
< 12 mo (n = 5)	20% (95% CI, 1–58)
12–24 mo (n = 9)	67% (95% CI, 28–88)
> 24 mo (n = 47)	74% (95% CI, 58–84)
None (n = 42)	67.5% (95% CI, 50–80)

Median DOR was not reached across all these subgroups except patients with prior bendamustine < 12 months before leukapheresis (5.2 months [95% CI, 2.2–NR]).

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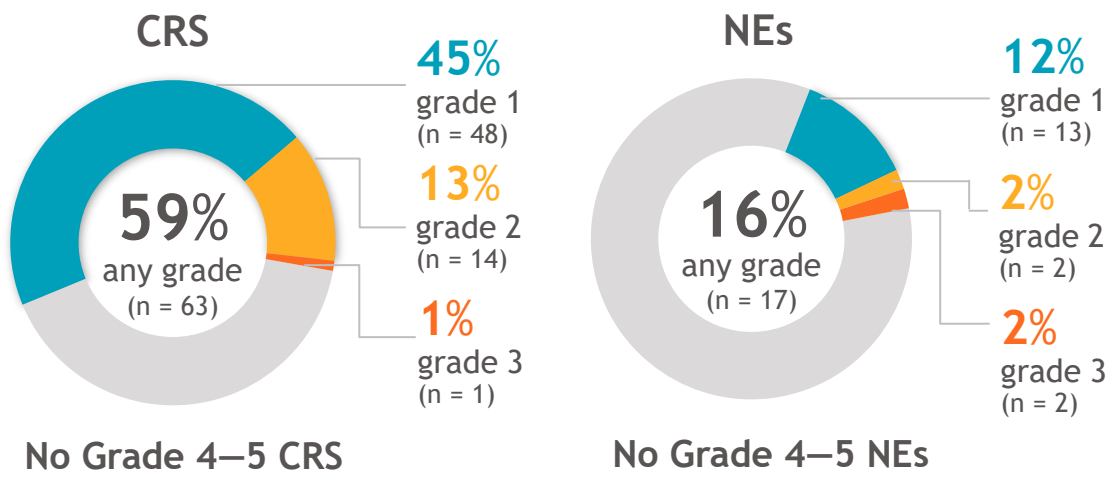
No new safety signals were observed with longer follow-up

3L+ FL (n = 107)



	3L+ FL (n = 107)
Grade ≥ 3 infection,[a] n (%)	13 (12)
TE period	7 (7)
Post-TE period	8 (7)[b]
SPM, n (%)	11 (10)
Non-hematologic	7 (7)
Hematologic	4 (4)
Grade ≥ 3 cytopenia at Day 90 visit,[c] n (%)	23 (21)
Recovered to grade ≤ 2 by Day 365, n/N (%)	18/19 (95)

- There was 1 additional patient with grade ≥ 3 infection (pneumonia) and 4 additional patients with SPMs (nonmelanoma skin cancer, melanoma, MDS, and spindle cell sarcoma [n = 1 each]) since the 2-year follow-up
- No secondary T-cell malignancies were reported

The TE period was defined as the time from liso-cel infusion through and including 90 days after administration; the post-TE period was defined as 91 days after liso-cel infusion through EOS.
[a]Some patients had events in both the TE and post-TE periods; [b]Three additional patients had grade ≥ 3 infections in the post-TE period since the 2-year follow-up: 1 patient with pneumonia without any previous grade ≥ 3 infections and 2 patients with sepsis and progressive multifocal leukoencephalopathy who had prior events in the TE period; [c]Defined as grade ≥ 3 laboratory abnormalities of neutropenia, anemia, or thrombocytopenia.
MDS, myelodysplastic syndrome; SPM, second primary malignancy; TE, treatment emergent.

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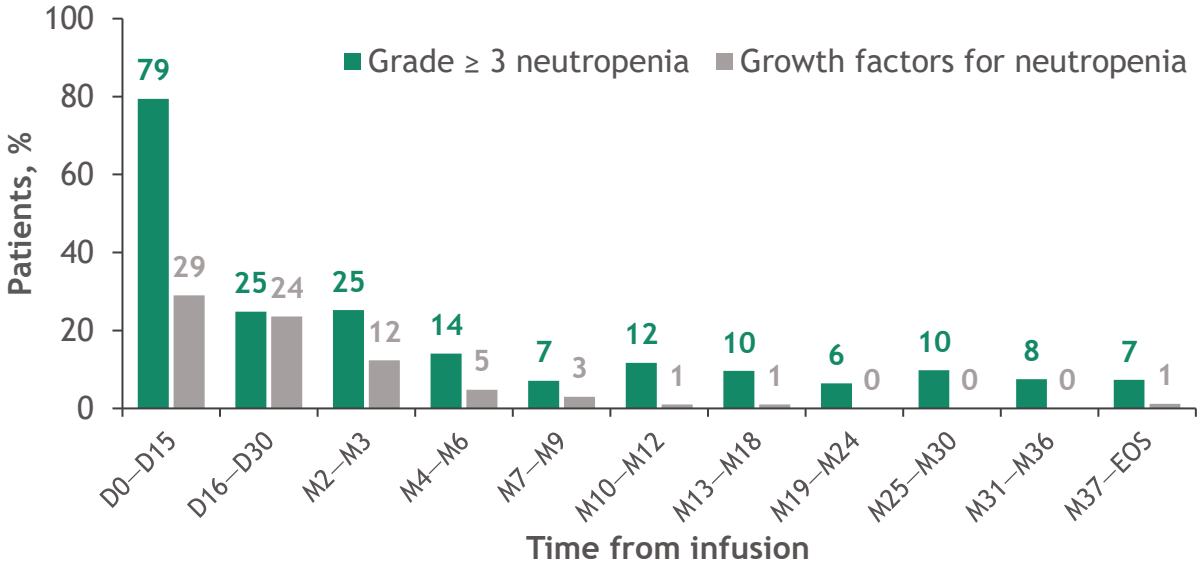
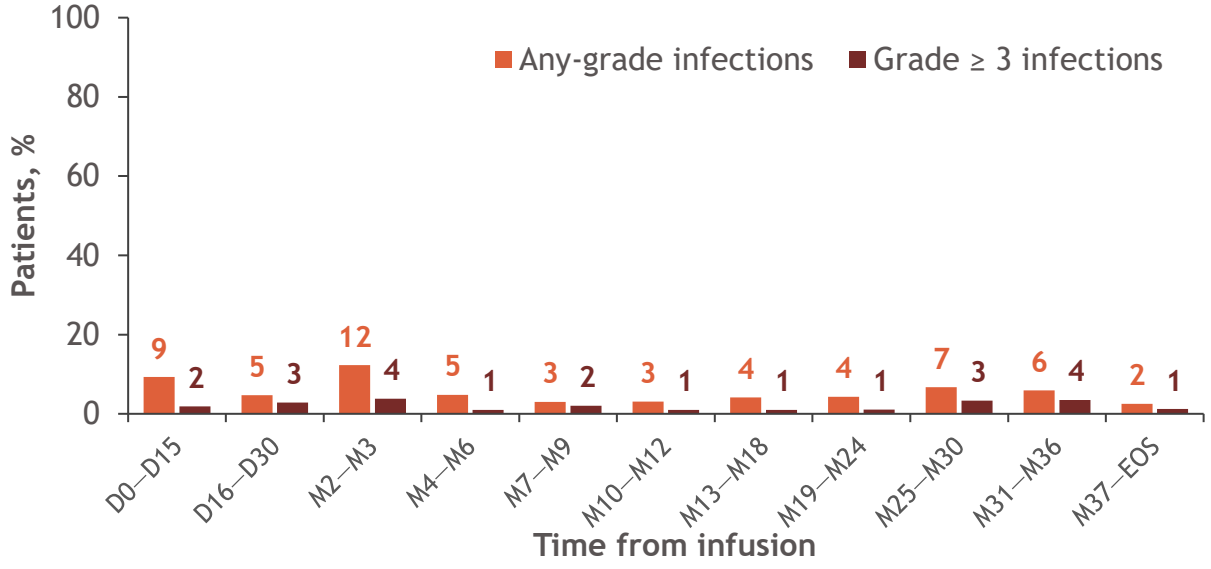
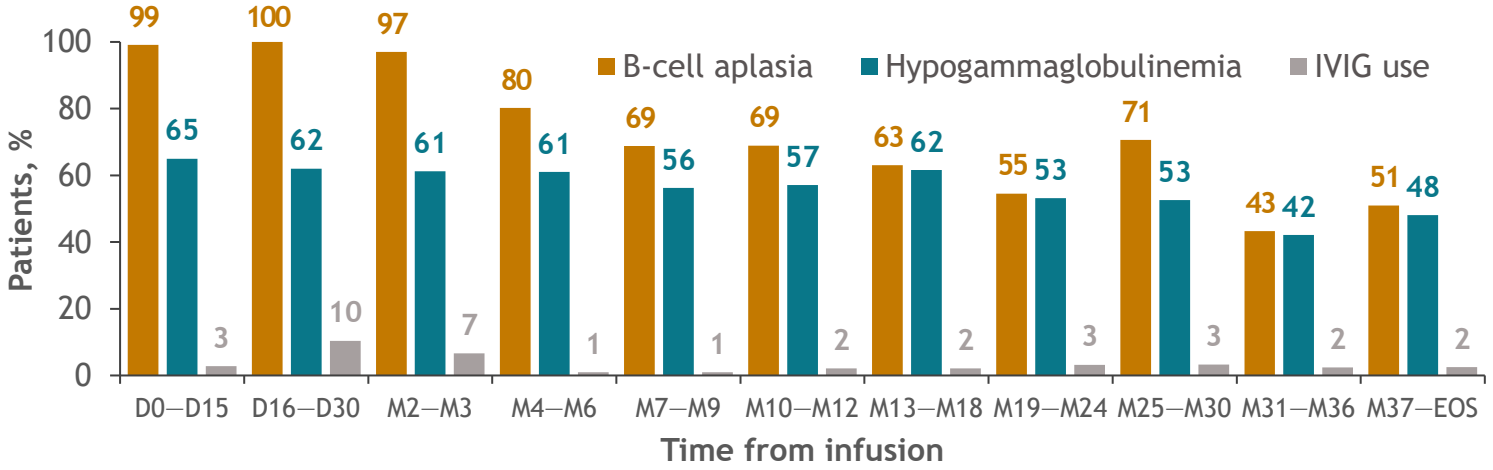
Liso-cel showed favorable long-term safety (1/2)







- Incidences of grade ≥ 3 neutropenia and use of growth factors remained consistently low from Month 4 onward
- Incidences of infections were consistently low across all time periods despite persistent B-cell aplasia or hypogammaglobulinemia in > 50% of patients at 1 year after infusion

Proportions for grade ≥ 3 neutropenia, B-cell aplasia, and hypogammaglobulinemia were calculated using the number of patients evaluated for each laboratory parameter in each time period as the denominator. From M25—M36, > 50% of patients on study had missing values for laboratory parameters. Proportions for infections and growth factor use were calculated using the number of patients on study in each time period: D0—D15, n = 107; D16—D30, n = 106; M2—M3, n = 106; M4—M6, n = 105; M7—M9, n = 100; M10—M12, n = 97; M13—M18, n = 97; M19—M24, n = 94; M25—M30, n = 90; M31—M36, n = 85; M37—EOS, n = 81. Monthly ranges start on the first day of the first month and end on the last day of the last month. Each patient is counted once in each time period but is counted again if having an event in another time period. Results are consistent when patients who started subsequent antilymphoma therapy were excluded at the initiation of subsequent therapy. D, Day; M, Month; IVIG, intravenous immunoglobulin G.

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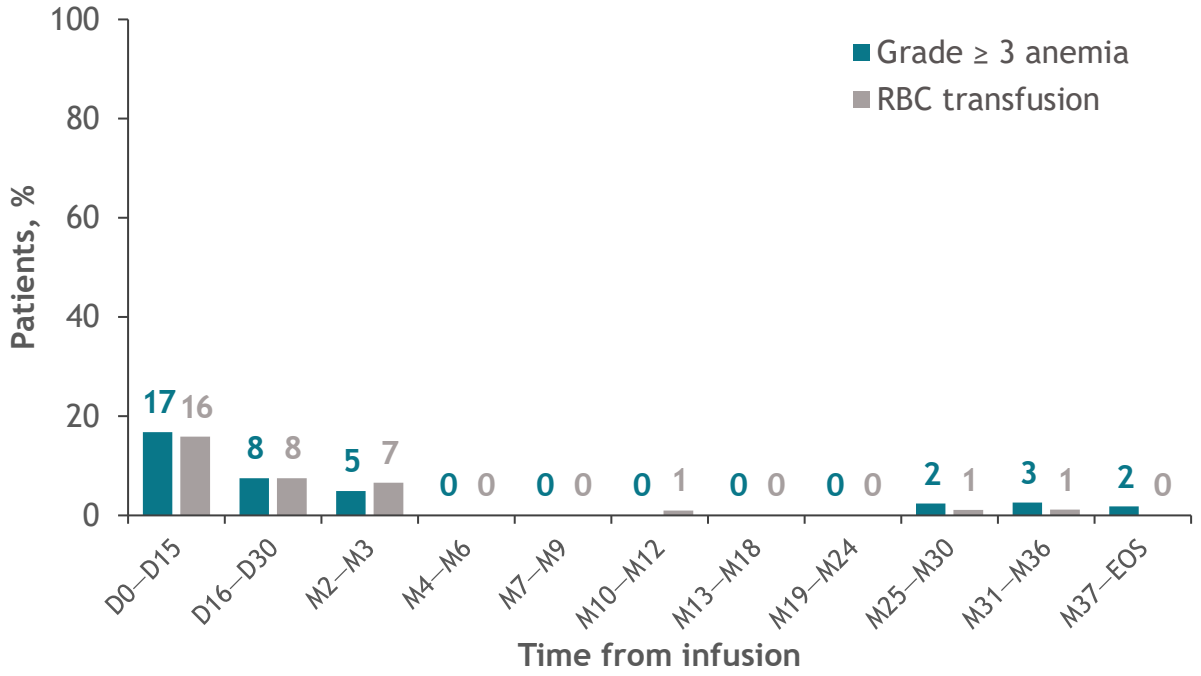
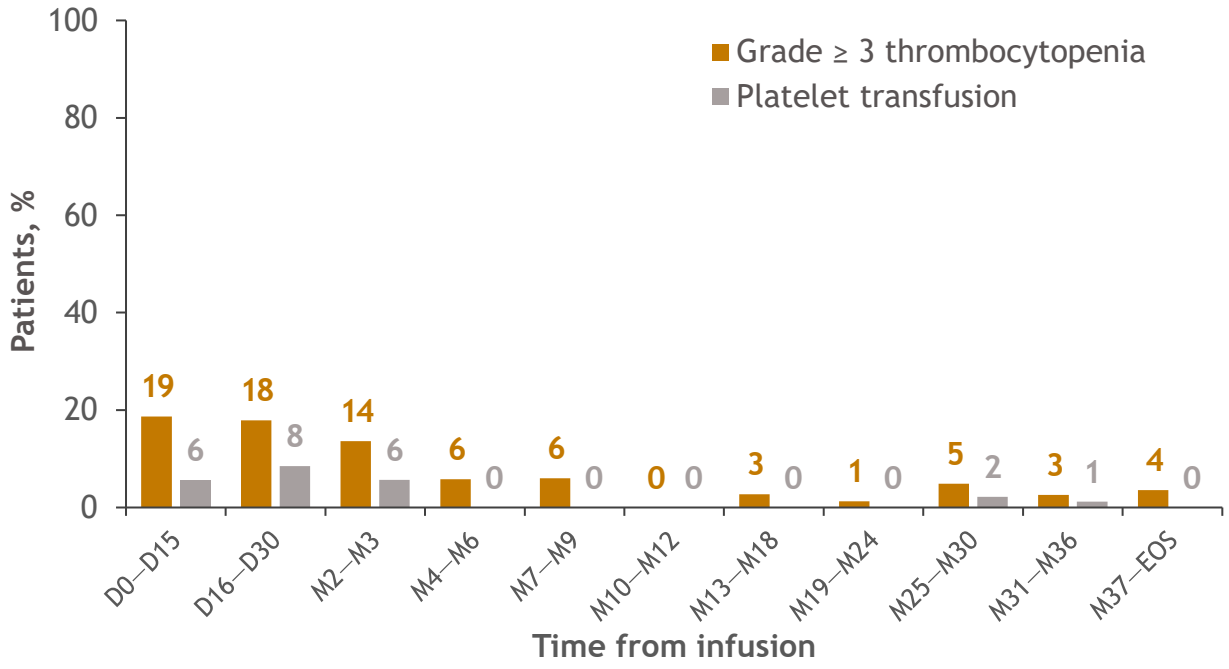
Liso-cel showed favorable long-term safety (2/2)





Use of growth factors, transfusions, and IVIG therapy, n (%)	3L+ FL (n = 107)
Growth factors for neutropenia	54 (50)
Erythropoiesis stimulating agents	5 (5)
RBC transfusions for anemia	24 (22)
Platelet transfusions[a]	16 (15)
IVIG therapy	29 (27)

- Use of RBC and platelet transfusions was < 10% starting from Day 16 and remained low at 1%—2% from Month 4 onwards

Proportions for grade ≥ 3 anemia and grade ≥ 3 thrombocytopenia were calculated using the number of patients evaluated for each laboratory parameter in each time period as the denominator. From M25—M36, > 50% of patients on study had missing values for laboratory parameters. Proportions for transfusion use were calculated using the number of patients on study in each time period: D0—D15, n = 107; D16—D30, n = 106; M2—M3, n = 106; M4—M6, n = 105; M7—M9, n = 100; M10—M12, n = 97; M13—M18, n = 97; M19—M24, n = 94; M25—M30, n = 90; M31—M36, n = 85; M37—EOS, n = 81. Monthly ranges start on the first day of the first month and end on the last day of the last month. Each patient is counted once in each time period but is counted again if having an event in another time period. Results are consistent when patients who started subsequent antilymphoma therapy were excluded at the initiation of subsequent therapy. [a]No patient received thrombopoietic growth factors for thrombocytopenia.

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Summary

- After 3 years of follow-up, a single infusion of liso-cel continued to show high rates of deep (CR rate, 94%) and durable responses (36-month DOR, 70%) with sustained survival (36-month OS, 86%) in patients with 3L+ R/R FL
  - Liso-cel demonstrated consistently high efficacy across subgroups with ORR of 96%—100% and 3-year ongoing response rates of 60%—83%, even among patients with high-risk characteristics (POD24, bulky disease, double-refractory disease)
  - Patients who received bendamustine ≥ 12 months before leukapheresis had durable responses and high 3-year PFS rates, similar to the overall population and consistent with patients without prior bendamustine exposure
- Longitudinal safety analyses demonstrate a favorable long-term safety profile with liso-cel in patients with 3L+ FL
  - Low infections, high rates of hematologic recovery, and modest supportive care needs reinforce the feasibility of outpatient management and the potential for low health care resource utilization with liso-cel in clinical practice
- Three-year follow-up from TRANSCEND FL confirm the high efficacy and sustained favorable safety with a single infusion of liso-cel, positioning it as a key therapeutic option for 3L+ R/R FL

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