
Bristol Myers Squibb has obtained appropriate permissions to externally share this material with Healthcare Professionals upon request.

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

Sairah Ahmed, MD,¹ Alejandro Martín García-Sancho, MD, PhD,² Juan Luis Reguera Ortega, MD,³ Guillaume Cartron, MD, PhD,⁴ Aaron P. Rapoport, MD,⁵ Koji Izutsu, MD, PhD,⁶ Hervé Ghesquieres, MD, PhD,⁷ Hideki Goto, MD, PhD,⁸ Jeremy S. Abramson, MD, MMSc,⁹ Peter Borchmann, MD,¹⁰ Ulrich Jäger, MD,¹¹ Manali Kamdar, MD, MBBS,¹² Martin Dreyling, MD,¹³ Merav Bar, MD,¹⁴ Maria Strocchia, PharmD, PhD,¹⁴ Martina Raggi, PhD,¹⁴ Luciana Bueno, MD,¹⁴ Jessica Papuga, PhD,¹⁴ Silvia Colicino, PhD,¹⁴ Franck Morschhauser, MD, PhD¹⁵

¹MD Anderson Cancer Center, Houston, TX, USA; ²Hospital Universitario de Salamanca, IBSAL, CIBERONC, Universidad de Salamanca, Salamanca, Spain; ³Hospital Universitario Virgen del Rocío, Instituto de Biomedicina de Sevilla, Universidad de Sevilla, Seville, Spain; ⁴Montpellier University Hospital Center, Montpellier, France; ⁵University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center, Baltimore, MD, USA; ⁶National Cancer Center Hospital, Tokyo, Japan; ⁷Hôpital Lyon Sud, Lyon, France; ⁸Hokkaido University Hospital, Sapporo, Japan; ⁹Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA, USA; ¹⁰Universität zu Köln, Köln, Germany; ¹¹Medical University of Vienna, Vienna, Austria; ¹²University of Colorado Cancer Center, Aurora, CO, USA; ¹³Klinikum der Universität LMU Muenchen, Munchen, Germany; ¹⁴Bristol Myers Squibb, Boudry, Switzerland; ¹⁵Centre Hospitalier Universitaire de Lille, Groupe de Recherche sur les formes Injectables et les Technologies Associées, Lille, France

Introduction

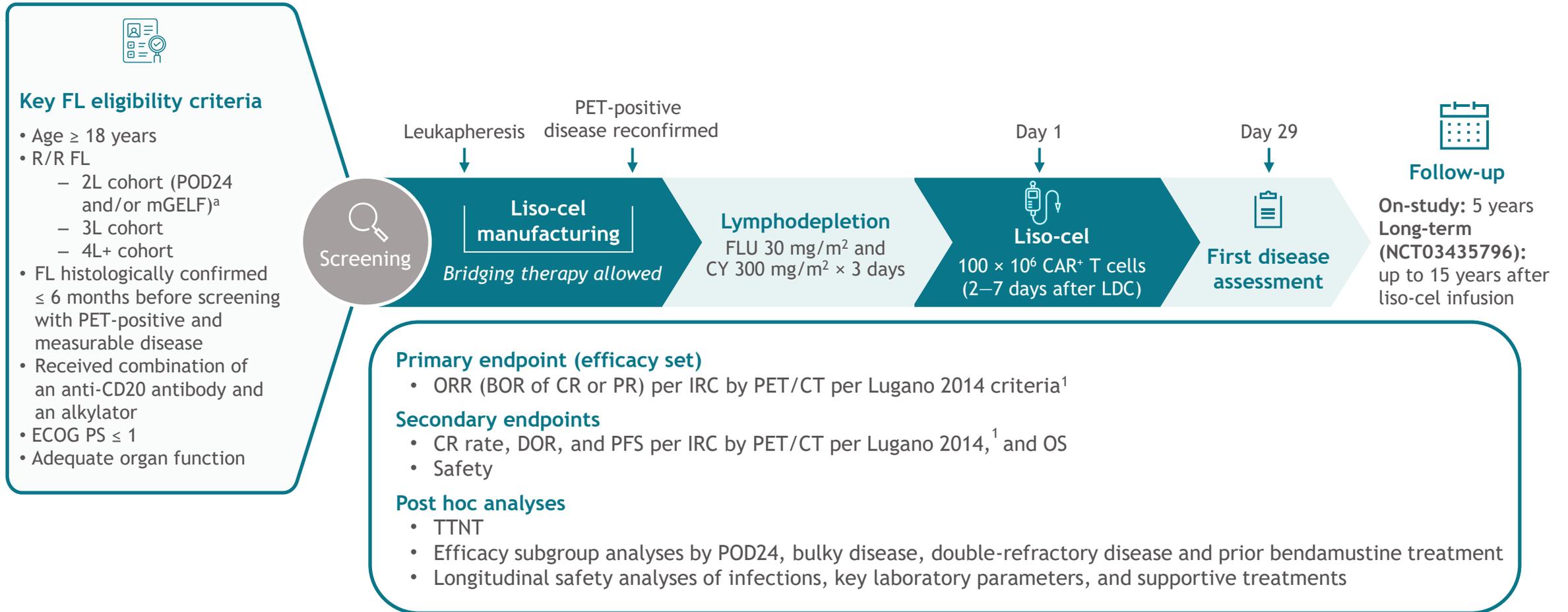
- Liso-cel, a CD19-directed CAR T cell therapy, has shown favorable efficacy with manageable safety across B-cell malignancies, including R/R LBCL, CLL/SLL, FL, MCL, and MZL^{1–7}
- In TRANSCEND FL, liso-cel showed very high response rates (ORR, 97%; CR rate, 94%) with durable efficacy outcomes at 24 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 \geq 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

^aData 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



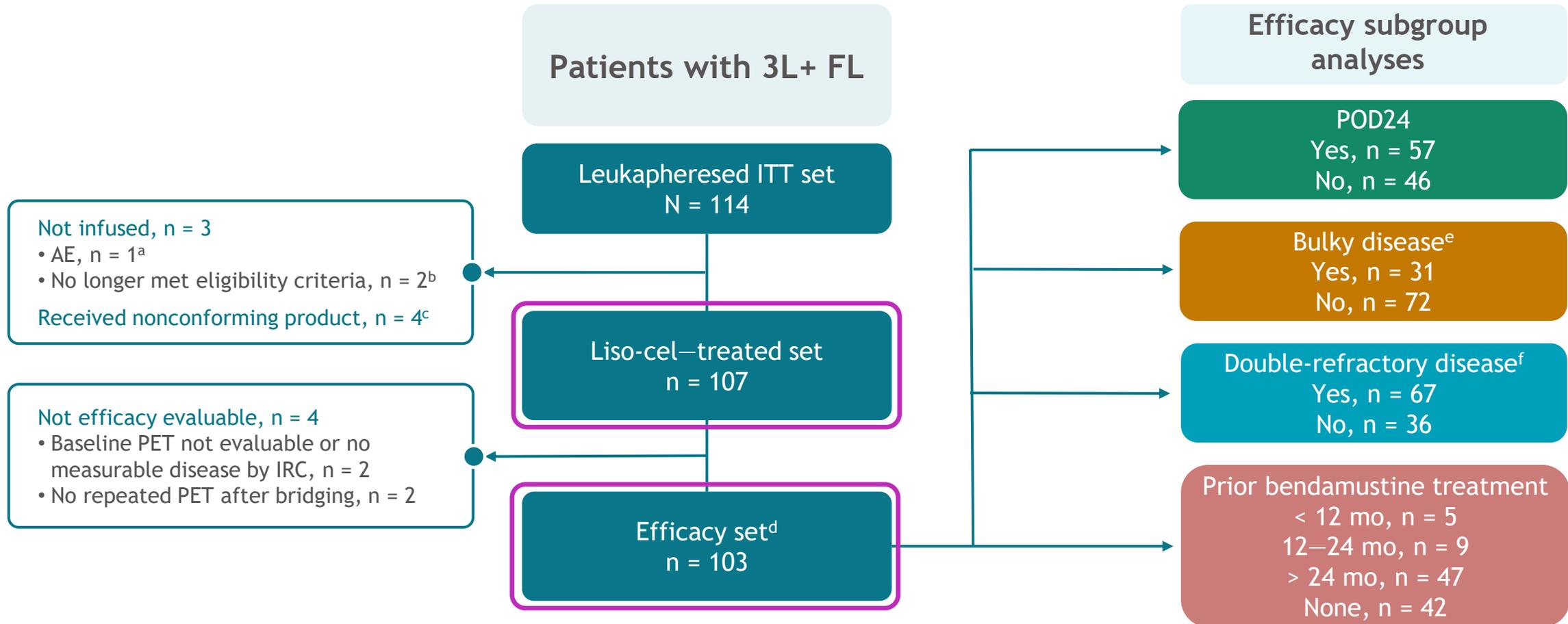
ClinicalTrials.gov identifier: NCT04245839.

^aPOD24 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 \geq 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 \geq 3 masses $>$ 3 cm]; splenomegaly; or steady progression over \geq 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 \leq 24 months from initial immunochemotherapy; TTNT, time to next treatment.

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

Patient disposition and analysis sets



^aAcute respiratory failure (enterovirus/rhinovirus pneumonia); ^bHistory of transformed FL (n = 1), PET-negative at pretreatment assessment (n = 1); ^cNonconforming 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; ^dLiso-cel–treated patients with PET/CT-positive disease per IRC before infusion; ^eAt screening based on mGELF criteria; ^fCan be met at any line of therapy that includes an anti-CD20 antibody and alkylating agent.

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



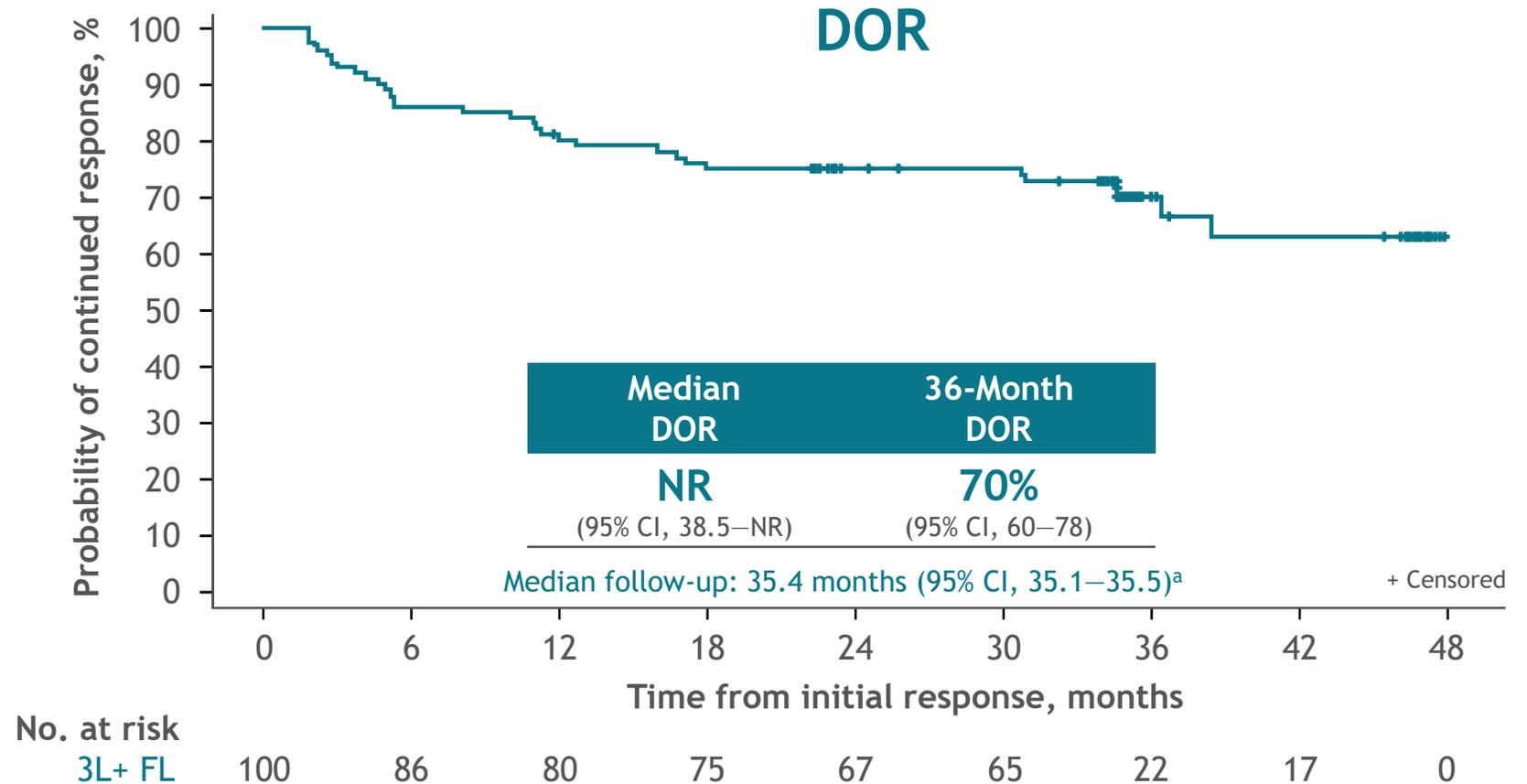
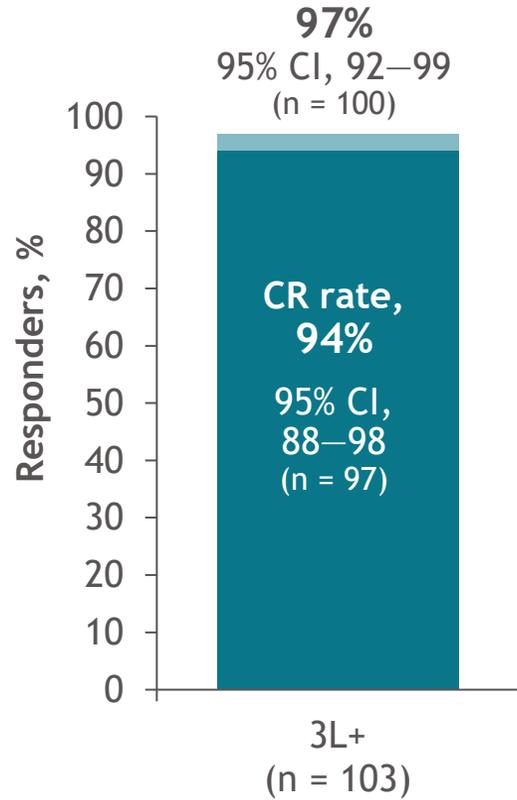
^aProportions were calculated using the number of patients evaluated for each laboratory parameter at each time period as the denominator; ^bLess than 3% CD19⁺ B cells of lymphocytes; ^cImmunoglobulin G levels < 500 mg/dL; ^dMonthly ranges (ie, Month 2–Month 3) start on the first day of the first month 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.

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)

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

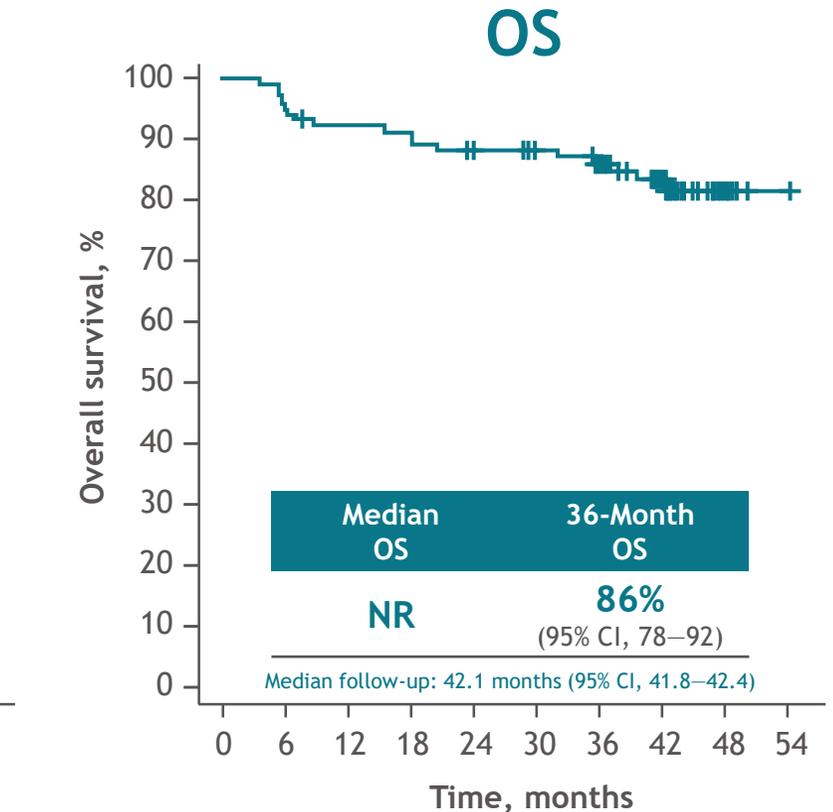
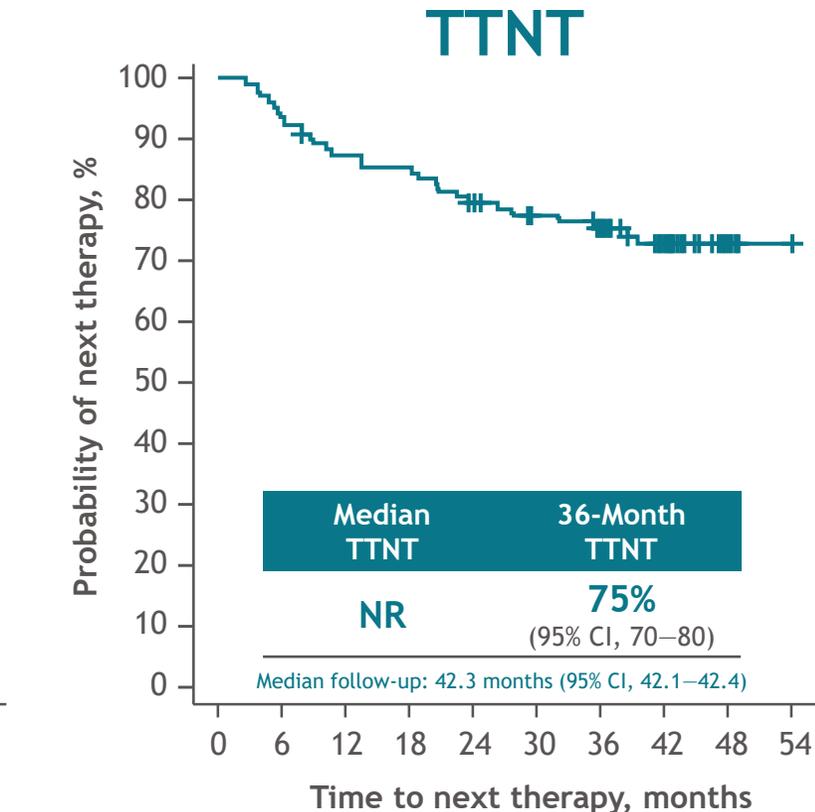
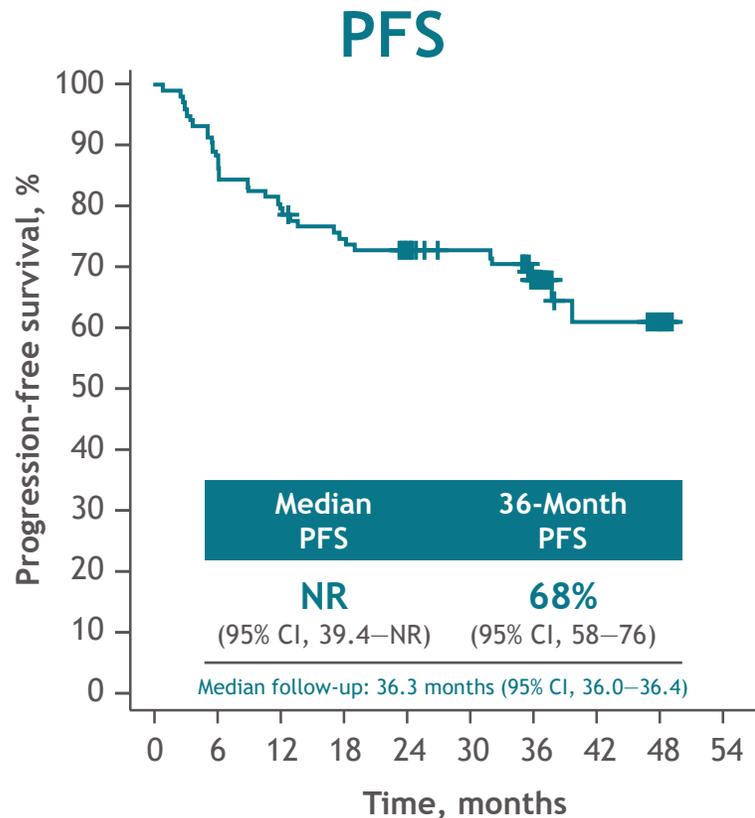
Responses were deep and durable in patients with 3L+ FL



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

^aReverse KM method was used to obtain the median follow-up and 95% CI. NR, not reached.

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



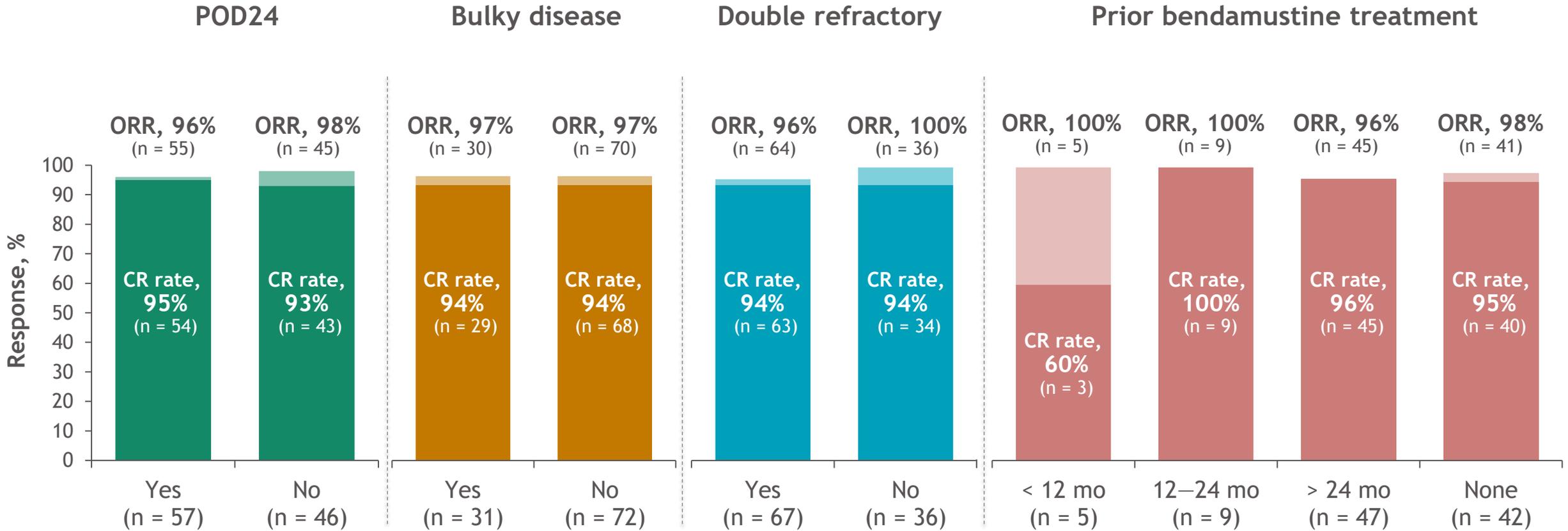
No. at risk
3L+ FL 103 91 82 76 69 65 44 17 9 0

No. at risk
3L+ FL 103 96 89 87 80 74 68 46 11 1

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

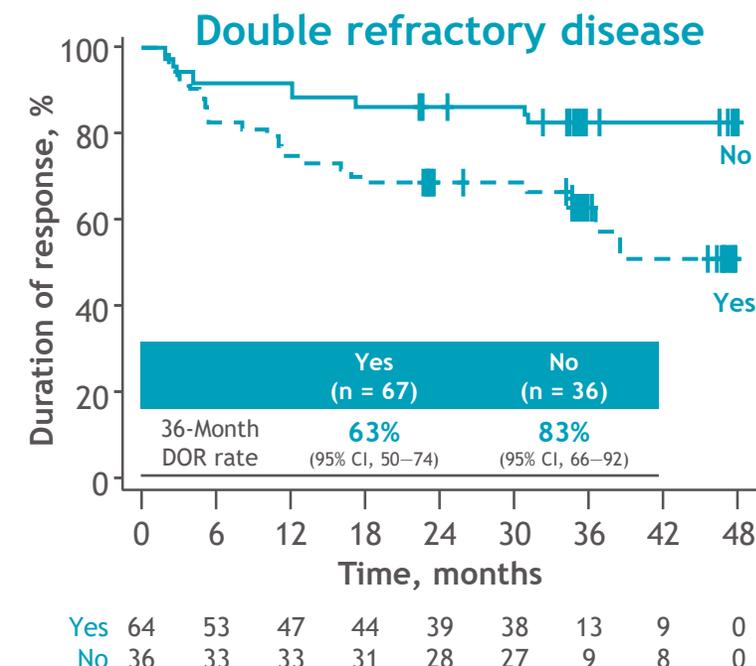
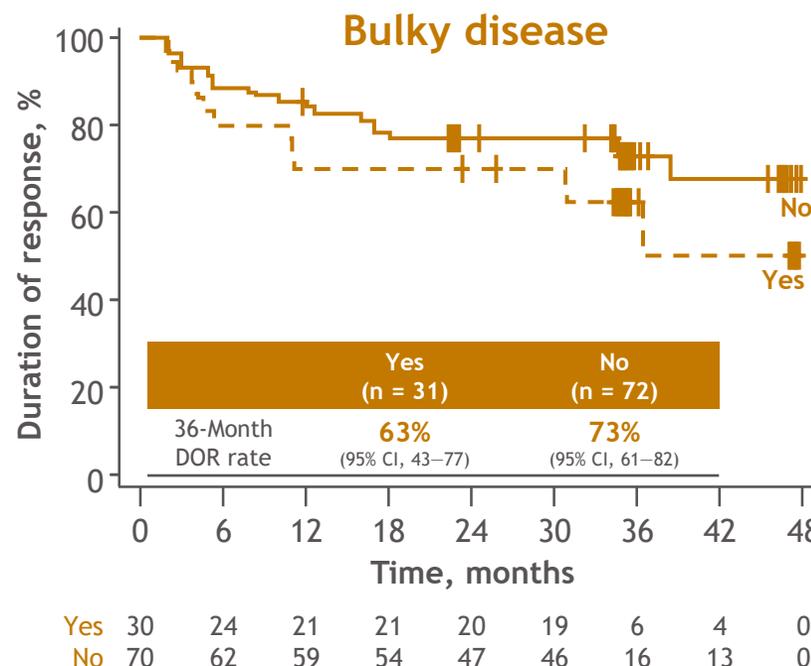
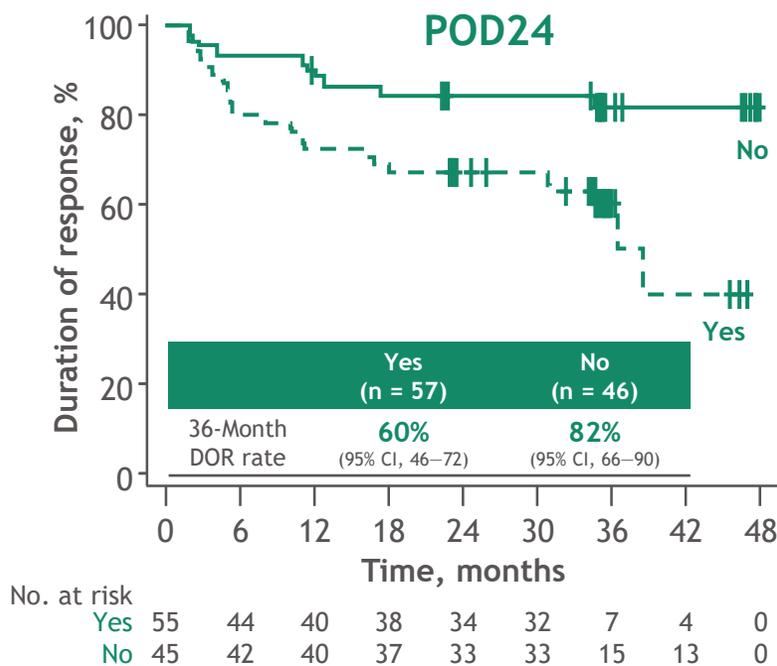
Overall response rates were > 95% across subgroups



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

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

DOR

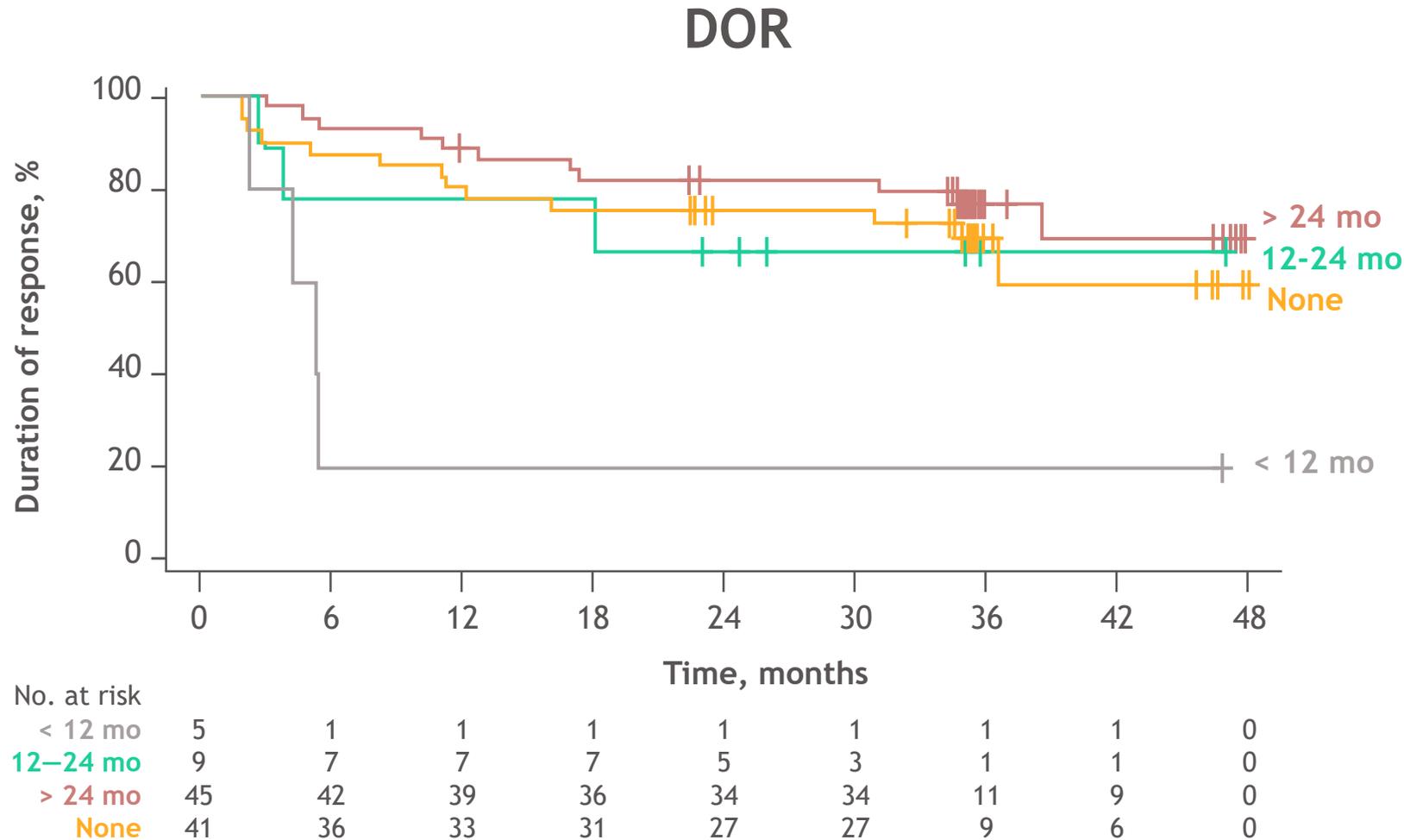


36-Month PFS rate

Subgroup	n	36-Month PFS rate	95% CI
POD24	57	58%	43–70
No POD24	46	80%	65–89
Bulky disease	31	61%	41–75
No bulky disease	72	71%	58–80
Double refractory	67	60%	47–71
Not double refractory	36	83%	66–92

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

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



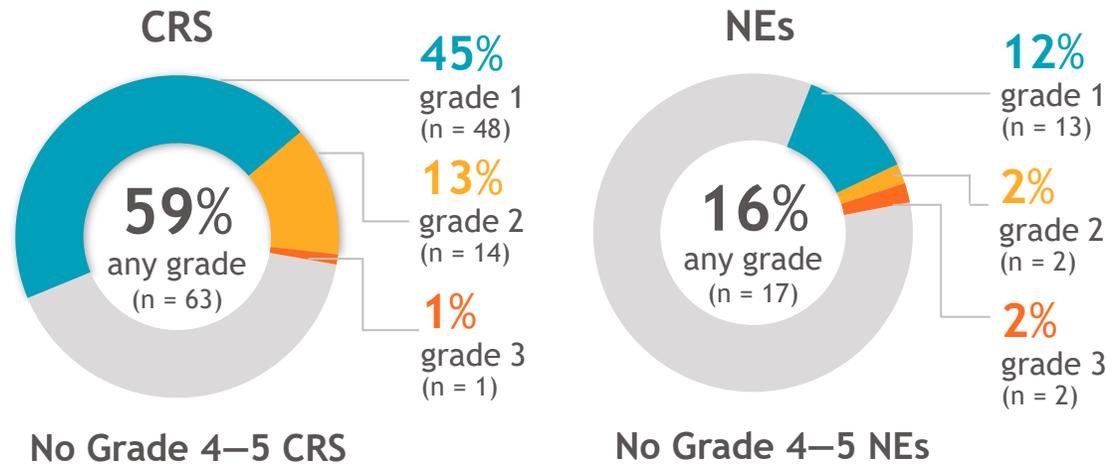
36-Month rates

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]).

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)

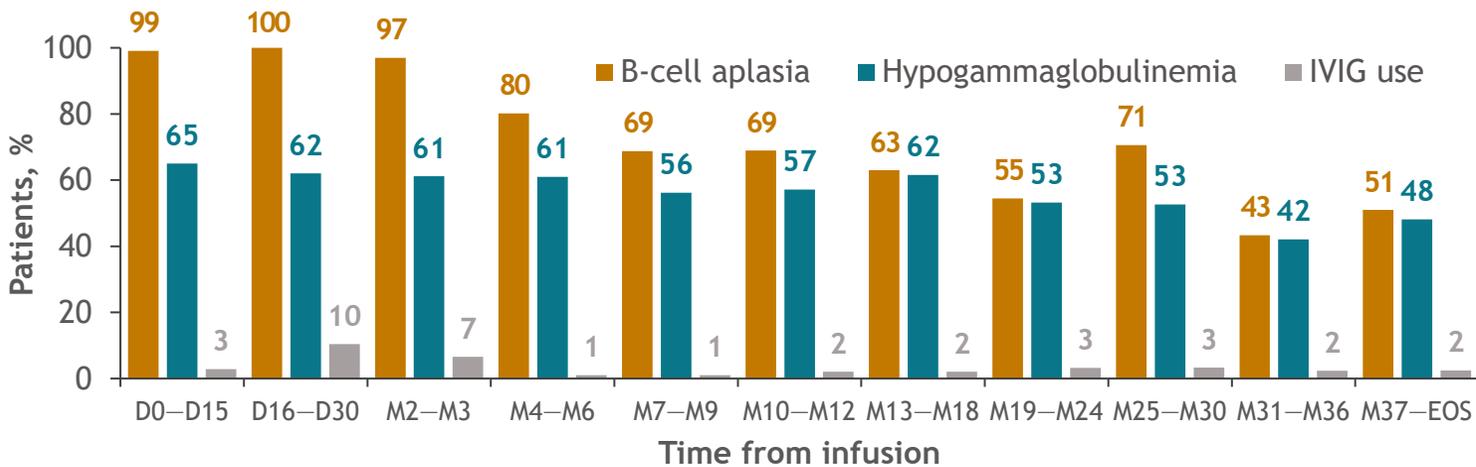
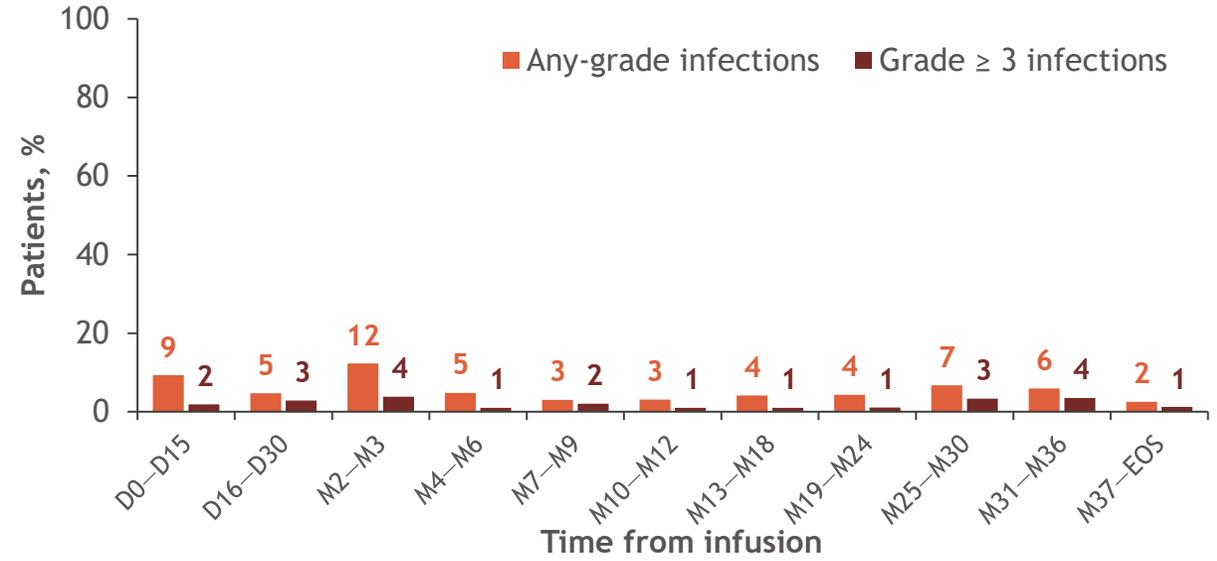
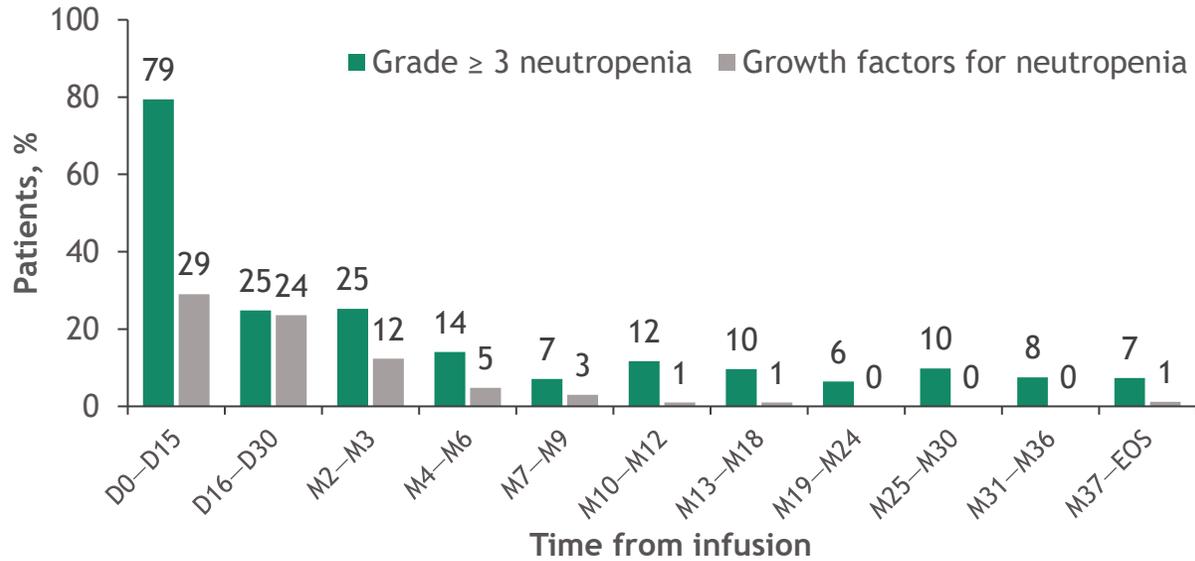
- There was 1 additional patient with grade ≥ 3 infection (pneumonia) and 4 additional patients with SPMs (nonmelanoma skin cancer, melanoma, MDS, and spindle cell sarcoma [n = 1 each]) since the 2-year follow-up
- No secondary T-cell malignancies were reported

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.

^aSome patients had events in both the TE and post-TE periods; ^bThree 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; ^cDefined as grade ≥ 3 laboratory abnormalities of neutropenia, anemia, or thrombocytopenia.

MDS, myelodysplastic syndrome; SPM, second primary malignancy; TE, treatment emergent.

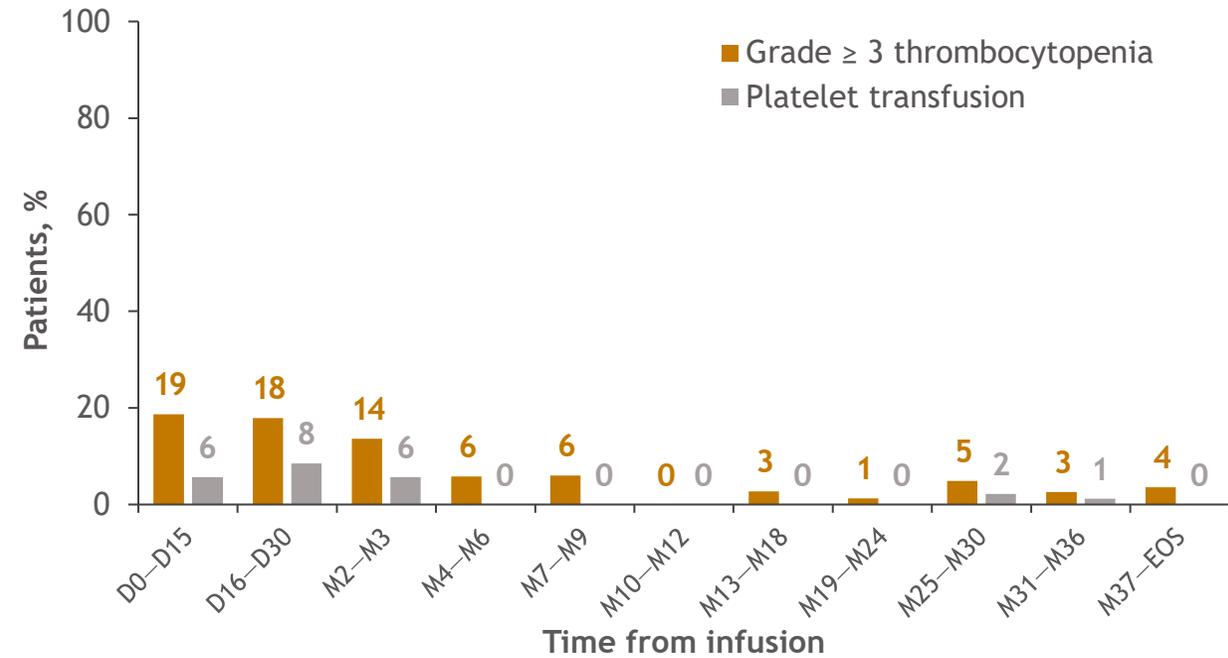
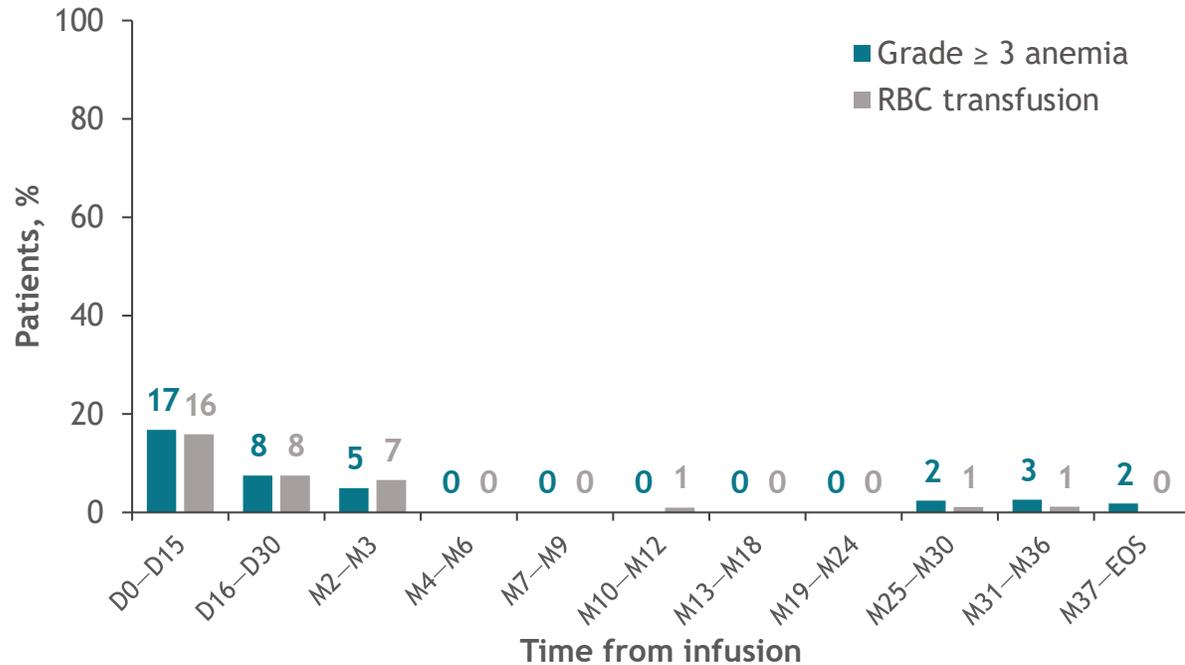
Liso-cel showed favorable long-term safety (1/2)



- Incidences of grade \geq 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 \geq 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.

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. ^aNo patient received thrombopoietic growth factors for thrombocytopenia.

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 \geq 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

Acknowledgments

- We would like to thank the patients, caregivers, investigators, and study personnel
- This study was funded by Celgene, a Bristol-Myers Squibb Company
- All authors contributed to and approved the presentation; writing and editorial assistance were provided by Allison Green, PhD, CMPP, of The Lockwood Group (Stamford, CT, USA), funded by Bristol Myers Squibb