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# **HIGHLIGHTS IN LYMPHOMA**

## **NEW AGENTS IN DIFFUSE LARGE B-CELL LYMPHOMA AND FOLLICULAR LYMPHOMA**

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# CONFLICT OF INTEREST AND FUNDING

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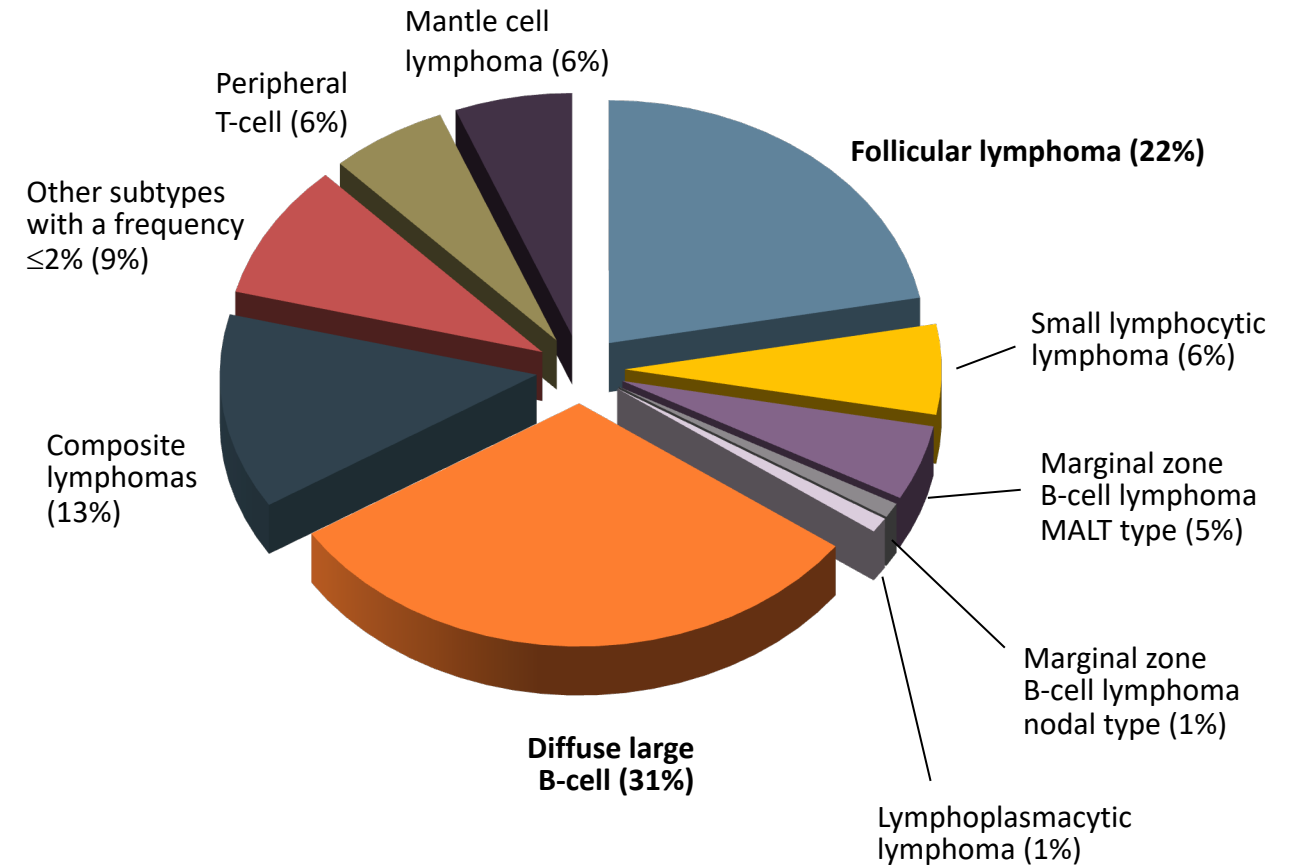
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-

- Diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) are the two most common lymphomas in the US and Western Europe
  - DLBCL and FL account for >50% of diagnosed cases of non-Hodgkin lymphoma (NHL)
- The two subtypes of NHL are on opposite ends of the clinical spectrum
  - **FL** is an **indolent, slow growing, incurable** lymphoma that does not have a standard of care induction regimen
  - **DLBCL** is **aggressive, curable** and generally treated with R-CHOP

## Frequency of NHL subtypes in adults

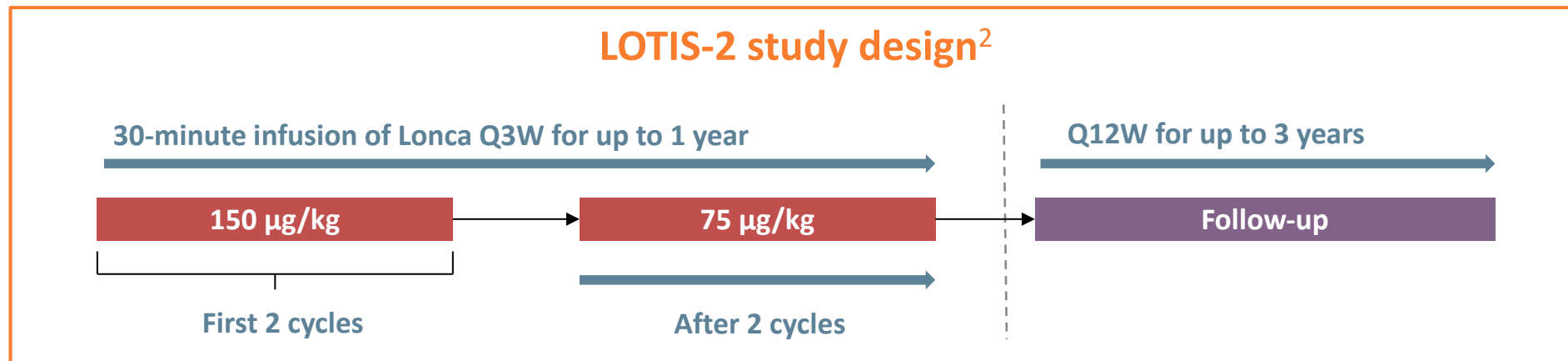


- Given the **incurable nature of FL**, there are several approved agents and numerous others in development to attempt to extend the life of those afflicted with this cancer
- **DLBCL**, while curable in some, still has a **large percentage of patients who will relapse or have primary refractory disease**
  - Second-line and beyond therapy for this population has diminishing returns, especially in refractory patients. New treatments are desperately needed for these patients
- In this slide deck some of the **recent FDA approvals** in both DLBCL and FL are reviewed as well as where they **fit in the current treatment landscape**

# LONCASTUXIMAB TESIRINE

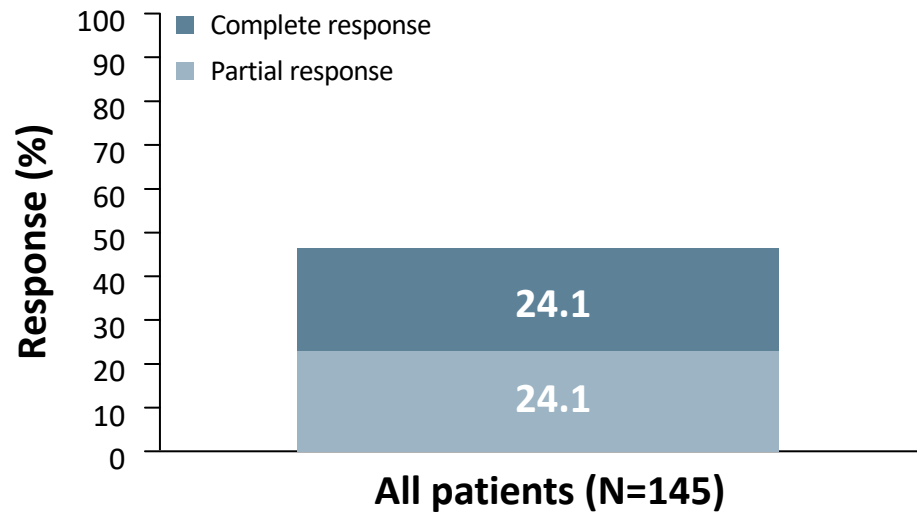
# LONCASTUXIMAB TESIRINE IN THE LOTIS-2 STUDY

- Loncastuximab tesirine (Lonca) is a **CD19 drug-antibody conjugate**<sup>1</sup>
  - The antibody is connected through a cathepsin-cleavable valine-alanine linker to a pyrrolobenzodiazepine (PBD) dimer toxin (SG3199)
  - The payload binds irreversibly to DNA to create highly potent intrastrand cross-links that block DNA strand separation preventing DNA replication. This differs from the more commonly recognized drug antibody conjugate MMAE
- LOTIS-2 is a single-arm **open-label phase 2 study** of Lonca in relapsed/refractory DLBCL after  $\geq 2$  therapies<sup>2</sup>



# LOTIS-2 EFFICACY RESULTS

## OVERALL RESPONSE RATE (ORR)



Lonca ORR:

**48.3%**

(95% CI: 39.9, 56.7)

Lonca CRR:

**24.1%**

(95% CI: 17.4, 31.9)

**Most responders had a response after 2 cycles; median time to first response was 41.0 days (IQR 38-44)  
Median Lonca cycles: 3.0 (IQR 2-5)**

ORR was assessed by independent reviewer

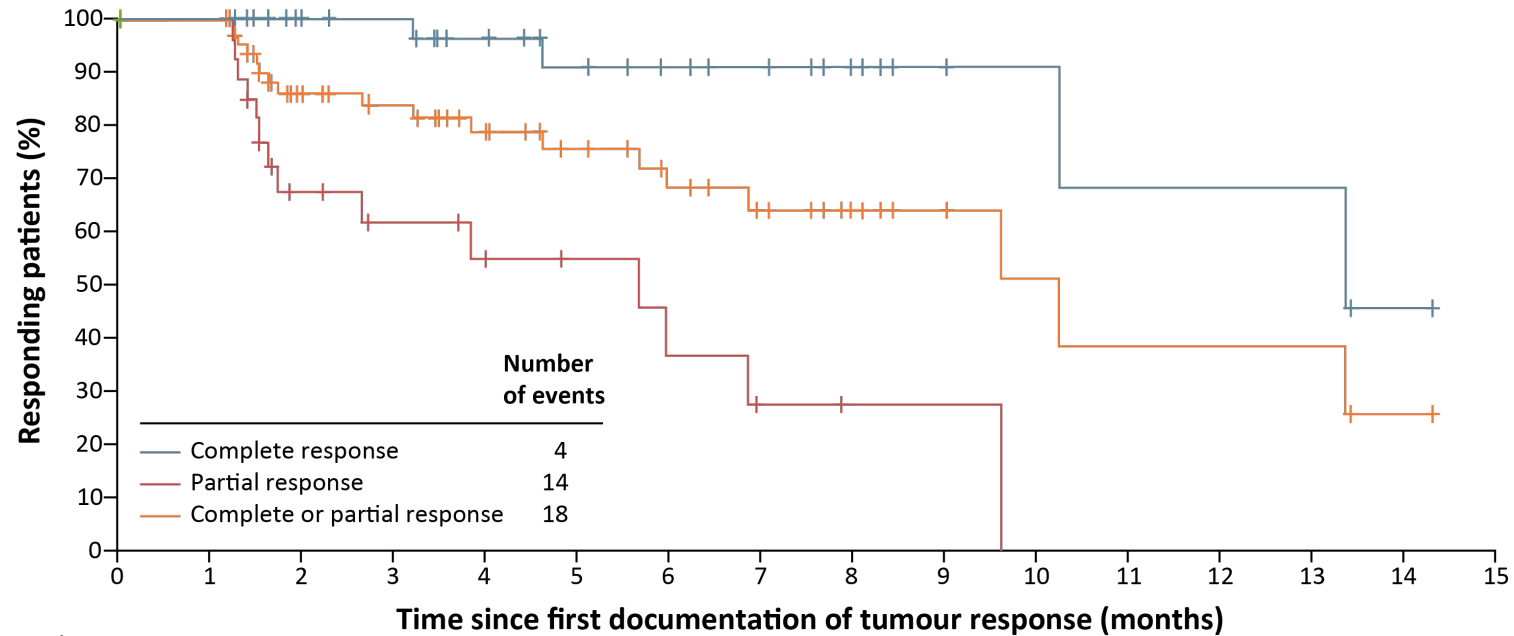
CI, confidence interval; CRR, complete response rate; IQR, interquartile range; Lonca, loncastuximab tesirine; ORR, overall response rate

Caimi PF, et al. Lancet Oncol. 2021;22(6):790-800



# LOTIS-2 EFFICACY RESULTS

## DURATION OF RESPONSE (DoR)



**Median DoR**  
**10.3 months**  
(95% CI: 6.9, NE)

**Median DoR for patients with a CR<sup>a</sup>**  
**13.4 months**  
(95% CI: 10.3, NE)

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
<b>Number at risk (number censored)</b>																
Complete response	35 (0)	34 (1)	28 (7)	26 (9)	21 (13)	17 (16)	14 (19)	12 (21)	8 (25)	5 (28)	4 (29)	3 (29)	3 (29)	3 (29)	1 (30)	0 (31)
Partial response	35 (0)	28 (7)	13 (14)	10 (16)	8 (17)	6 (19)	4 (19)	2 (20)	1 (20)	1 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)	0 (21)
Complete or partial response	70 (0)	62 (8)	41 (21)	36 (25)	29 (30)	23 (35)	18 (38)	14 (41)	9 (46)	6 (49)	4 (50)	3 (50)	3 (50)	3 (50)	1 (51)	0 (52)

**The probability of responders maintaining responses for 9 months or longer was 64%**

<sup>a</sup>mDoR for patients with a PR: 5.7 months (95% CI: 1.7-NE)

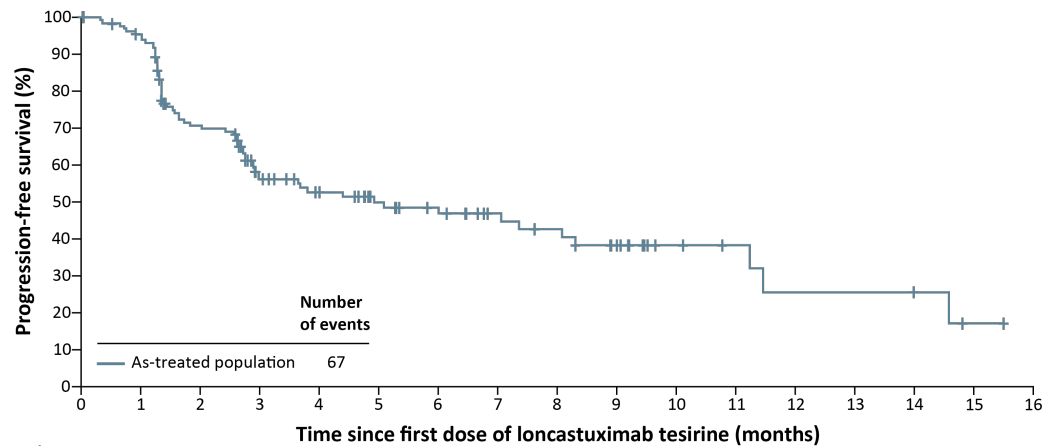
CI, confidence interval; CR complete response; (m)DoR, (median) duration of response; PR, partial response; NE, not estimable

Caimi PF, et al. Lancet Oncol. 2021;22(6):790-800

# LOTIS-2 EFFICACY RESULTS

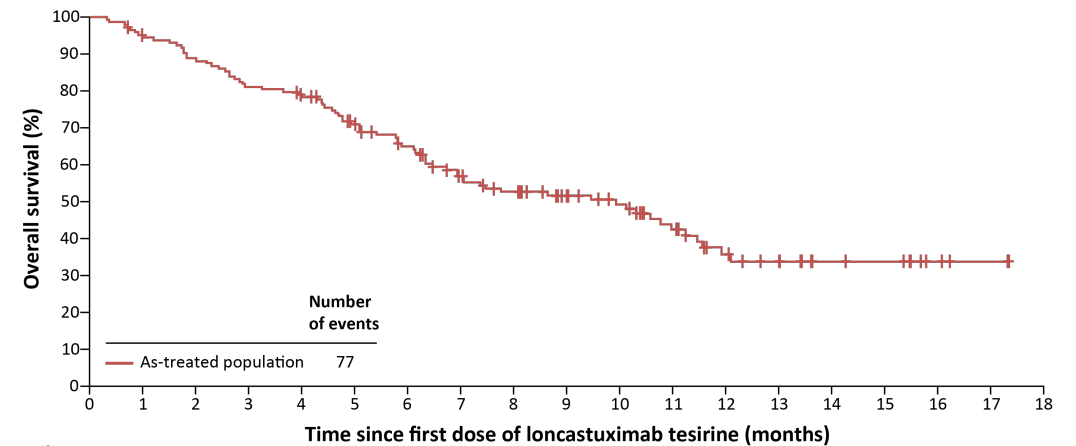
## PFS, OS, AND SUBSEQUENT TREATMENT

Median PFS: 4.9 months (95% CI: 2.9-8.3)



Number at risk (number censored)  
As-treated population 145 (0) 124 (15) 85 (23) 55 (37) 44 (45) 33 (54) 29 (57) 23 (62) 20 (63) 16 (65) 8 (73) 6 (75) 4 (0) 4 (75) 3 (76) 1 (77) 0 (78)

Median OS: 9.9 months (95% CI: 6.7-11.5)



Number at risk (number censored)  
As-treated population 145 (0) 136 (2) 127 (2) 116 (2) 111 (4) 95 (9) 84 (12) 68 (18) 60 (21) 49 (31) 41 (37) 29 (44) 19 (50) 15 (53) 9 (59) 8 (60) 4 (64) 2 (66) 0 (68)

### Subsequent Treatment

- **15 patients** received CD19-directed CAR-T therapy with an investigator-assessed ORR of 47% (6 CR; 1 PR)
- **9 patients** proceeded to SCT as consolidation after Lonca response

# LOTIS-2 SAFETY RESULTS

TEAEs in ≥20% of the total population				
TEAE	All patients	Age subgroup		
		All ages (N=145)	<65 years (N=65)	≥65 to <75 years (N=59)
<b>Any TEAE</b>	143 (98.6)	65 (100)	58 (98.3)	20 (95.2)
<b>Hematologic TEAEs</b>				
Neutropenia	57 (39.3)	33 (50.8)	20 (33.9)	4 (19.0)
Thrombocytopenia	48 (33.1)	28 (43.1)	17 (28.8)	3 (14.3)
Anaemia	38 (26.2)	23 (35.4)	9 (15.3)	6 (28.6)
Fatigue	40 (27.6)	21 (32.3)	15 (25.4)	4 (19.0)
Nausea	34 (23.4)	17 (26.2)	13 (22.2)	4 (19.0)
Cough	32 (22.1)	19 (29.2)	9 (15.3)	4 (19.0)
Peripheral oedema	29 (20.0)	11 (16.9)	14 (23.7)	4 (19.0)
Gamma-glutamyl transferase increased	59 (40.7)	33 (50.8)	23 (39.0)	3 (14.3)
Blood alkaline phosphatase increased	29 (20.0)	18 (27.7)	10 (16.9)	1 (4.8)

## Most common grade ≥3 TEAEs were:

- Neutropenia (37 patients; 26%)
- Thrombocytopenia (26 patients; 18%)
- GGT increased (24 patients; 17%)

## Treatment-related TEAEs leading to treatment discontinuation:

- GGT increased (15 patients; 10%)
- Peripheral oedema (4 patients; 3%)
- Localised oedema (3 patients; 2%)
- Pleural effusion (3 patients; 2%)

**No increase in toxicity was seen in patients aged ≥65 years compared with younger patients**

TEAEs were reported for the as-treated population

GGT, gamma-glutamyl transferase; TEAE, treatment-emergent adverse event

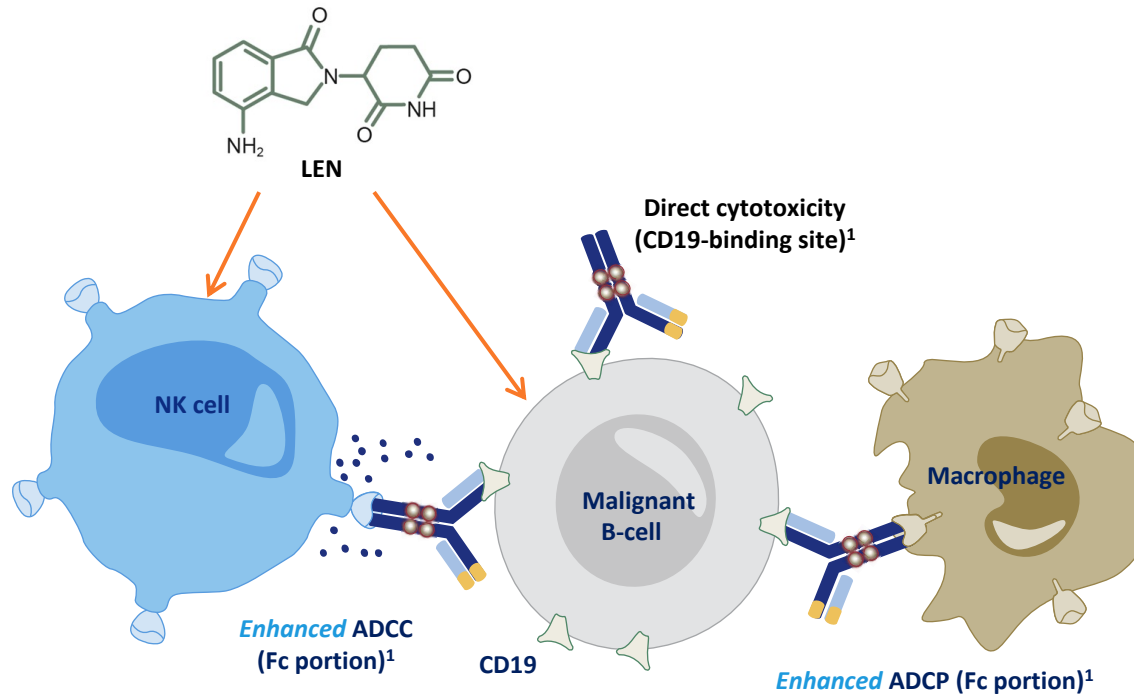
Caimi PF, et al. Lancet Oncol. 2021;22:790-800

Loncastuximab tesirine is a **CD19 drug-antibody conjugate<sup>1</sup>** that has been approved for **≥3<sup>rd</sup>-line treatment of DLBCL** based on results from LOTIS-2

In LOTIS-2 the reported ORR was 48.3% with a CR rate of 24.1%.  
The median DoR was 10.3 months<sup>2</sup>

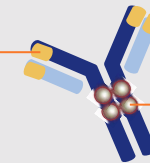
# TAFASITAMAB-CXIX + LENALIDOMIDE

# TAFASITAMAB-CXIX + LENALIDOMIDE AS AN IMMUNOLOGIC COMBINATION



## Tafasitamab-cxix (CD19-directed cytolytic mAb)<sup>1-6</sup>

Affinity-matured  
CD19-binding site



Enhanced Fc portion

- ADCC ↑
- ADCP ↑
- Direct cell death
- Phase 2a study showed single-agent activity in patients with R/R DLBCL and iNHL

## LEN<sup>4,5</sup>

- T-cell and NK-cell activation/expansion
- Direct cytotoxic and immunomodulatory effects
- Well-studied as an antilymphoma agent, alone or in combination

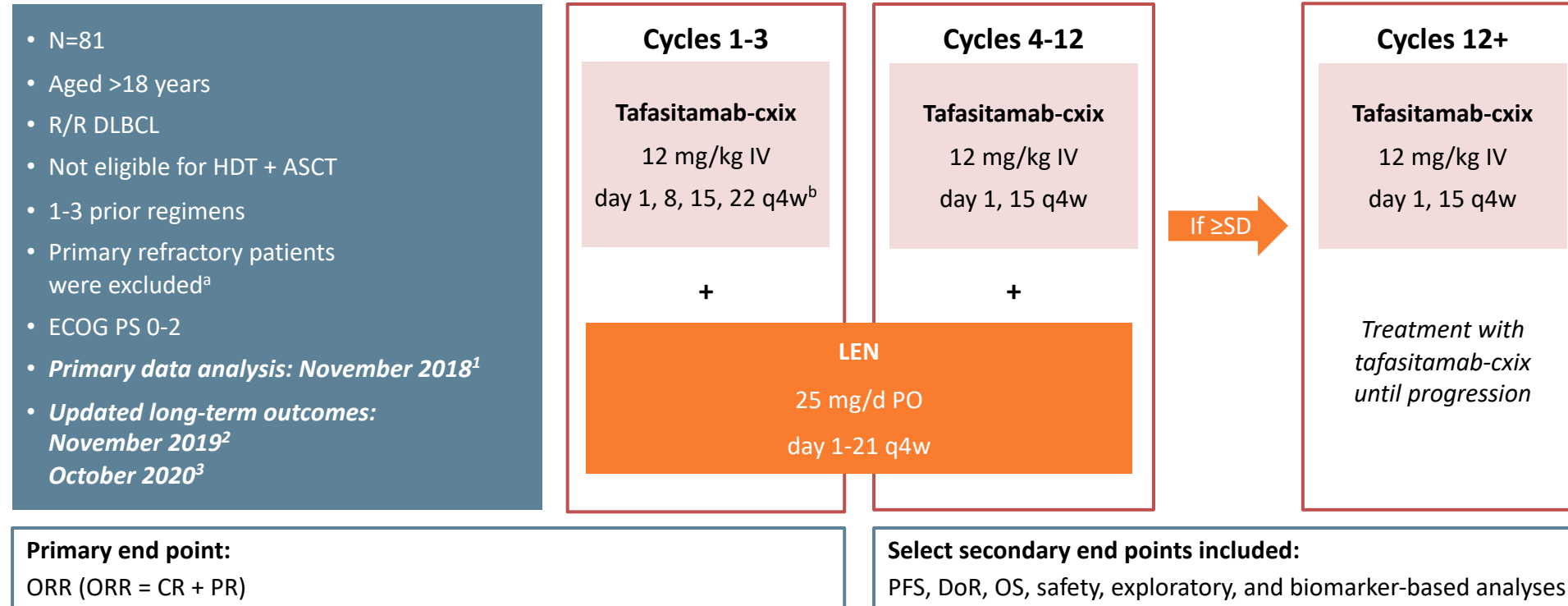
ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CD19, cluster of differentiation 19; Fc, fragment crystallisable;

iNHL, indolent non-Hodgkin lymphoma; LEN, lenalidomide; mAb, monoclonal antibody; NK, natural killer; R/R DLBCL, relapsed/refractory diffuse large B-cell lymphoma

1. Horton HM, et al. Cancer Res. 2008;68(19):8049-57; 2. Woyach JA, et al. Blood. 2014;124(24):3553-60; 3. Jurczak W, et al. Ann Oncol. 2018;29(5):1266-72; 4. Witzig TE, et al. Ann Oncol. 2015;26(8):1667-77; 5. Czuczman MS, et al. Clin Cancer Res. 2017;23(15):4127-37; 6. MONJUVI (tafasitamab-cxix) Prescribing Information. June 2021

# L-MIND STUDY DESIGN

## PHASE 2 STUDY OF TAFASITAMAB-CXIX + LEN



<sup>a</sup>Primary refractory defined as no response to or progression/relapse during or within 6 months of front-line therapy

<sup>b</sup>Loading dose on day 4 of cycle 1 only

# L-MIND RESULTS

## DURABLE ACTIVITY AFTER ≥35 MONTHS

	12-Month Analysis <sup>a</sup>	24-Month Analysis <sup>b</sup>	35-Month Analysis <sup>c</sup>
	N=80 (FAS) <sup>1</sup>	N=80 (FAS) <sup>2</sup>	N=80 (FAS) <sup>3</sup>
ORR, %	60	57.5	57.5
CR, %	42.5	40.0	40.0
PR, %	17.5	17.5	17.5
mDoR (95% CI), months	21.7 (21.7-NR)	34.6 (26.1-NR)	43.9 (26.1-NR)
mPFS (95% CI), months	12.1 (5.7-NR)	12.1 (6.3-NR)	11.6 (6.3-45.7)
mOS (95% CI), months	NR (18.3-NR)	31.6 (18.3-NR)	33.5 (18.3-NR)

The US PI includes efficacy data on a subset of patients with centrally confirmed diagnoses of DLBCL<sup>4</sup>: N=71; ORR=55%; mDoR=21.7 months after 12-month analysis

<sup>a</sup>Data cutoff: November 30, 2018

<sup>b</sup>Data cutoff: November 30, 2019

<sup>c</sup>Data cutoff: October 30, 2020

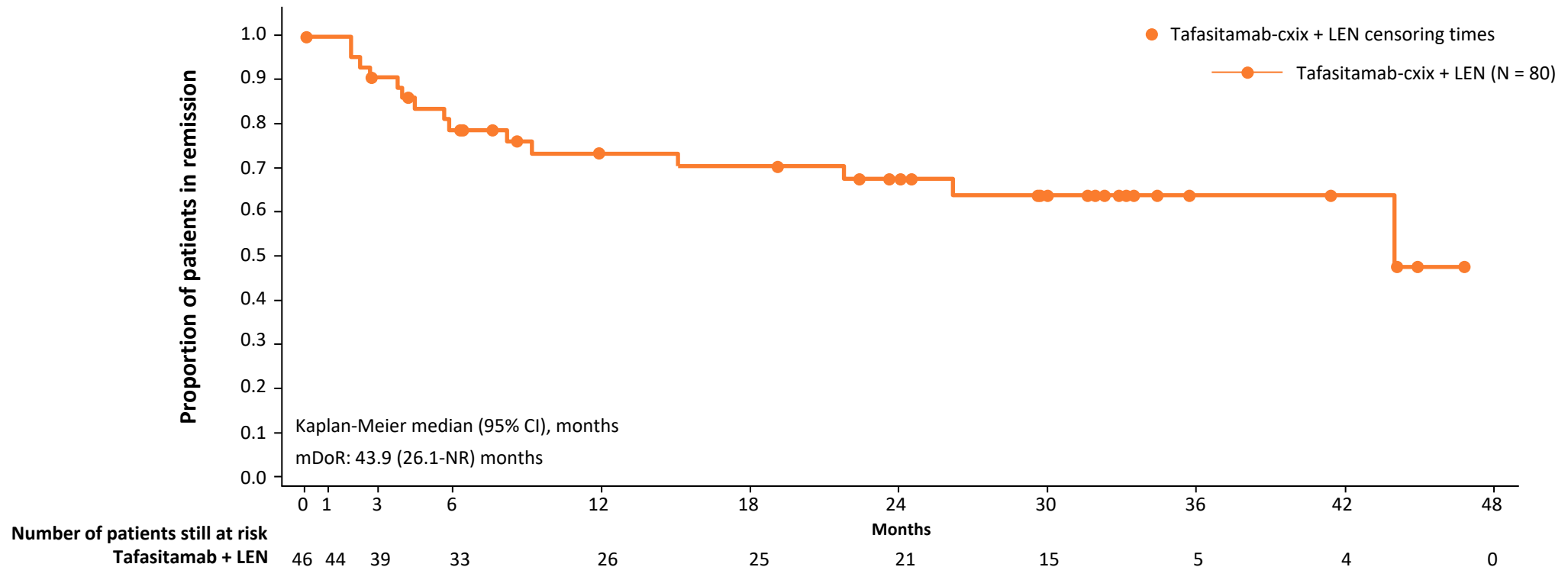
CI, confidence interval; CR, complete response; DLBCL, relapsed/refractory diffuse large B-cell lymphoma; FAS, full analysis set; LEN, lenalidomide; mDoR, median duration of response; mOS, median overall survival; mPFS, median progression-free survival; NR, not reached; ORR, overall response rate; PI, prescribing information; PR, partial response

1. Salles G, et al. Lancet Oncol. 2020;21(7):978-88; 2. Data on file, MOR208C203 EMA Analysis Tables\_21Oct2020, MorphoSys US Inc.; 3. Data on file, IA\_MOR208C203\_Toplines\_Tables\_08JAN2021, MorphoSys US Inc.; 4. MONJUVI (tafasitamab-cxix) Prescribing Information. June 2021



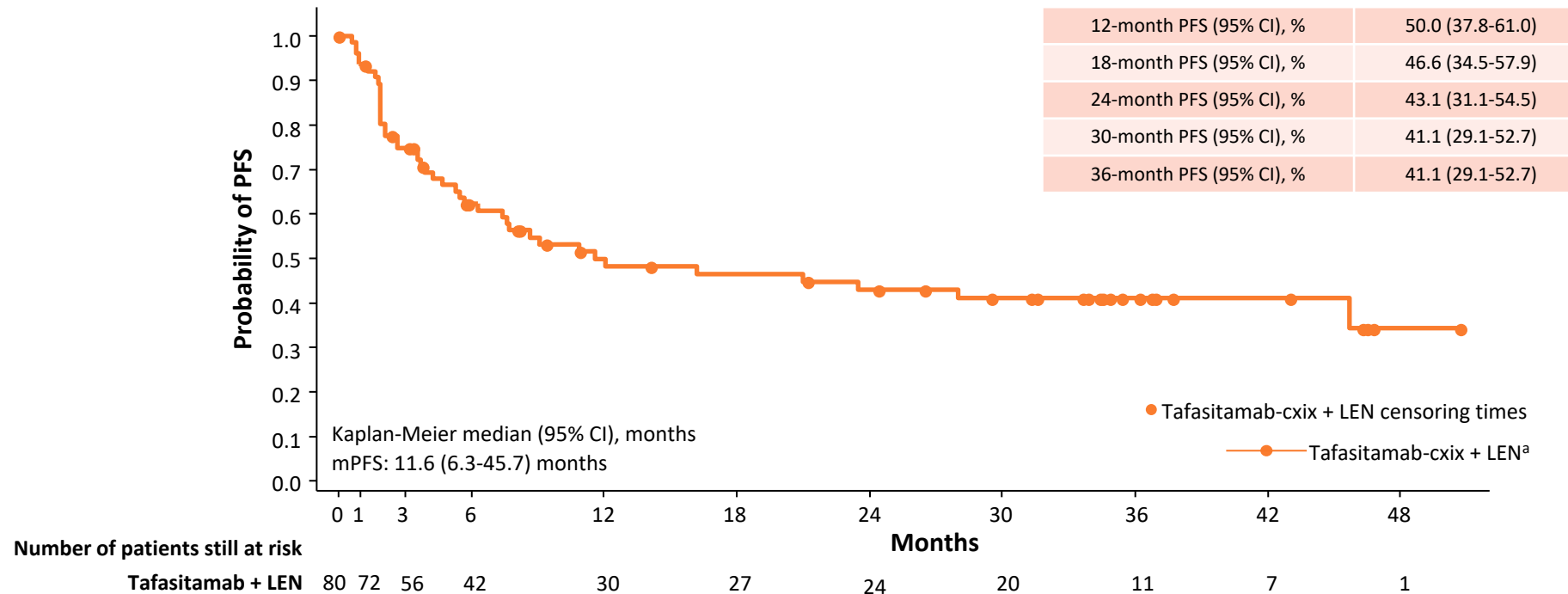
# L-MIND RESULTS

## mDoR OF 43.9 MONTHS AFTER ≥35 MONTHS OF FOLLOW-UP



# L-MIND RESULTS

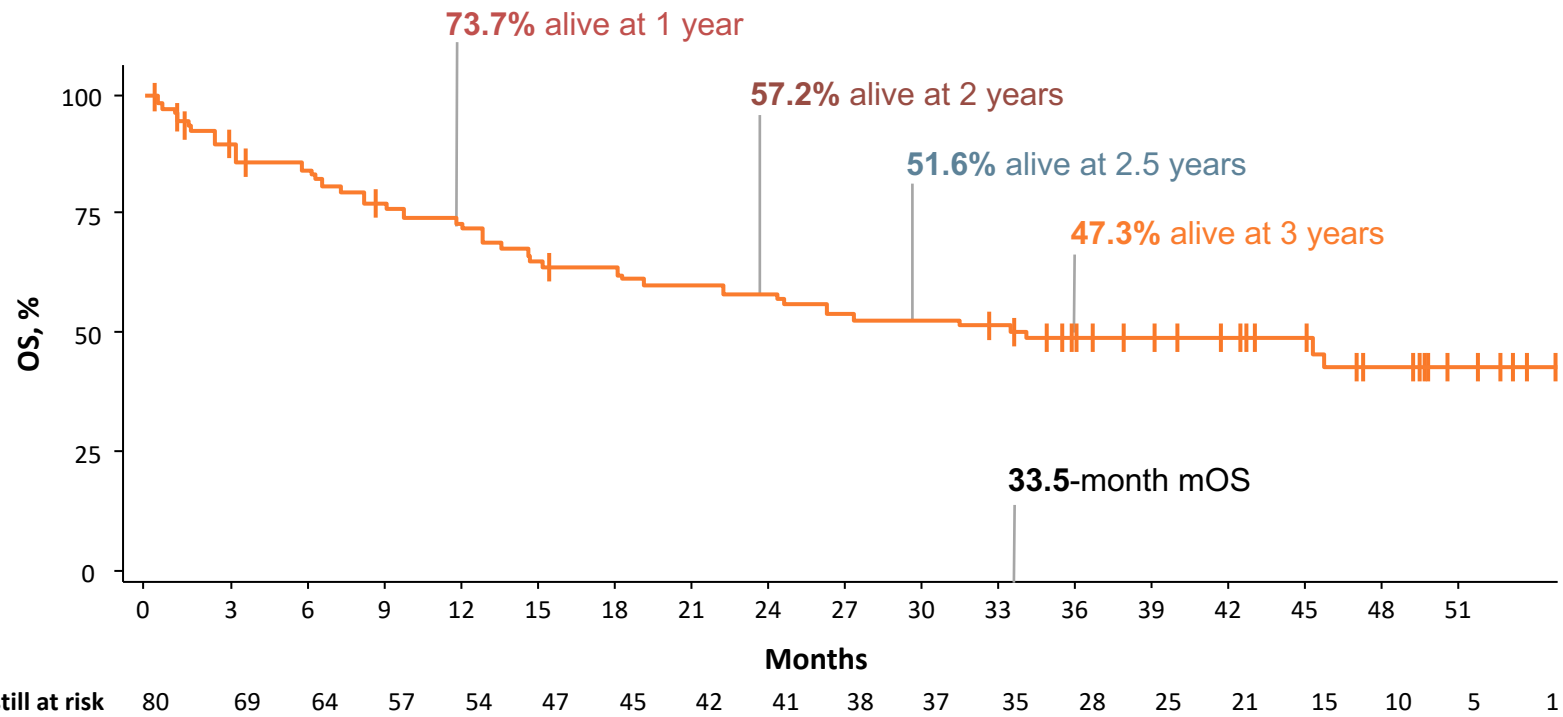
## mPFS OF 11.6 MONTHS AFTER ≥35 MONTHS OF FOLLOW-UP



Note: Data presented is exploratory. No formal conclusion can be drawn.

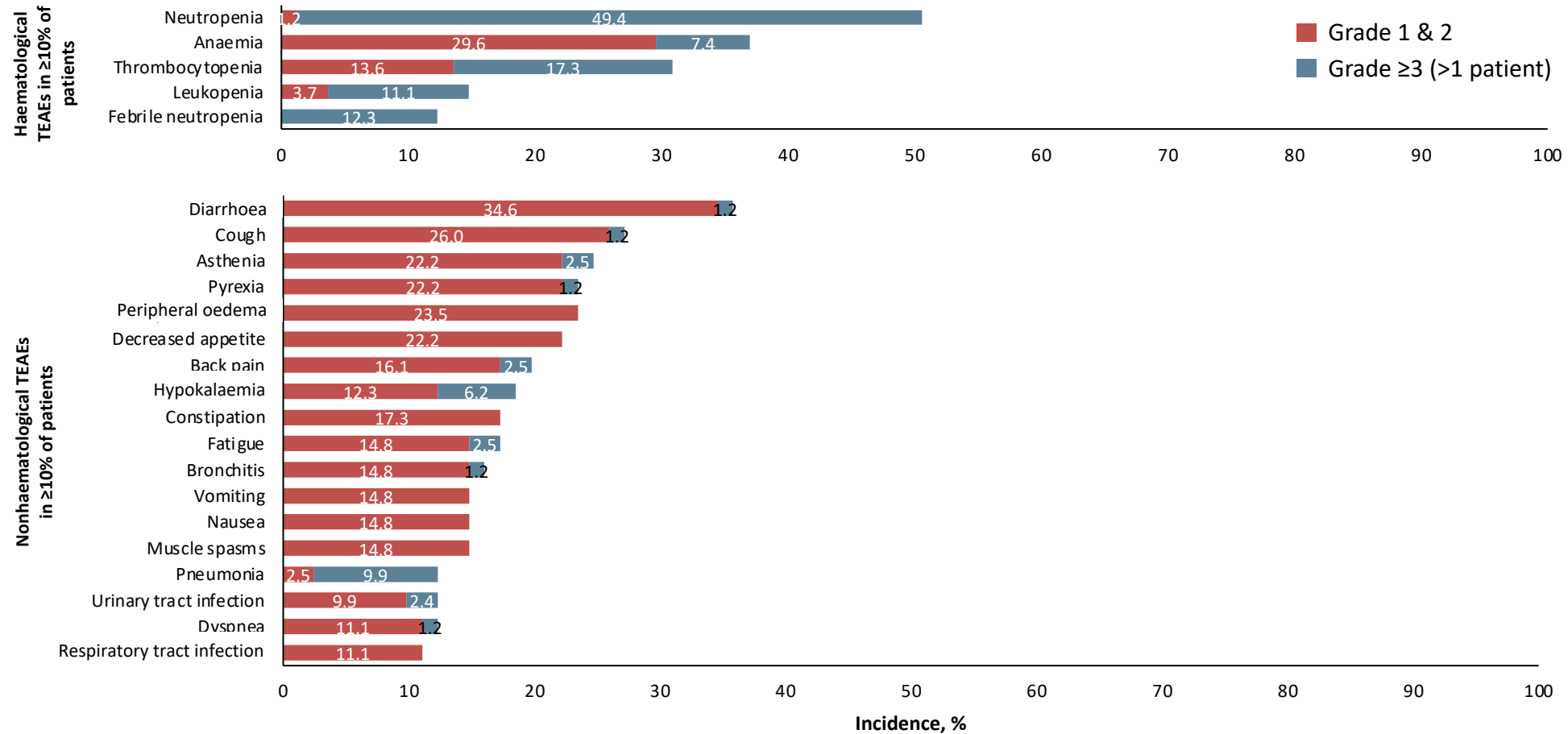
# L-MIND RESULTS

## AFTER 3 YEARS OF FOLLOW-UP, 47.3% OF ALL PATIENTS WERE ALIVE



Note: Data presented is exploratory. No formal conclusion can be drawn.

# LONG-TERM SAFETY PROFILE AFTER ≥35 MONTHS OF FOLLOW-UP (N=81)



Tafasitamab-cxix + lenalidomide was **FDA approved in 2020** for relapsed/refractory DLBCL, ineligible for ASCT

## Place in clinical practice (expert opinion):

- It is **difficult to make true comparison to Pola-BR** given differences in study design, patient population, etc. but it would fit same patient population
  - Post-CAR-T relapse, although no data on efficacy after another C19-directed therapy
  - Patients who are ineligible for ASCT or CAR-T
  - Given lack of data about how a CD19-directed therapy might impact CAR-T, this treatment as of now should not be considered as a bridge therapy to CAR-T

# AXICABTAGENE CILOLEUCEL

# ZUMA-5 STUDY DESIGN

## MULTICENTRE, SINGLE-ARM PHASE 2 TRIAL

Patients with R/R FL (Grade 1-3a) or MZL (nodal or extranodal),  $\geq 2$  prior lines of therapy including anti-CD20 monoclonal antibody (mAb) + alkylating agent (N=146: 124 FL, 22 MZL)

### Conditioning chemotherapy

Fludarabine 30 mg/m<sup>2</sup> +  
Cyclophosphamide 500 mg/m<sup>2</sup>  
Days -5, -4, -3

### CAR-T Cells

Axi-Cel  
2 × 10<sup>6</sup> cells/kg  
Day 0

***Followed  
for safety  
up to  
15 years***

*Patients with SD but no relapse >1 year from completion of last therapy ineligible. Single-agent anti-CD20 mAb not counted as line of therapy for eligibility. Median time to delivery of axi-cel: 17 days following leukapheresis.*

- **Primary endpoint:** Objective response rate (IRRC-assessed per Lugano classification)
- **Key secondary endpoints:** CR rate (IRRC-assessed), DoR, PFS, OS, AEs, CAR T cell, and cytokine levels

# ZUMA-5

## BASELINE PATIENT CHARACTERISTICS

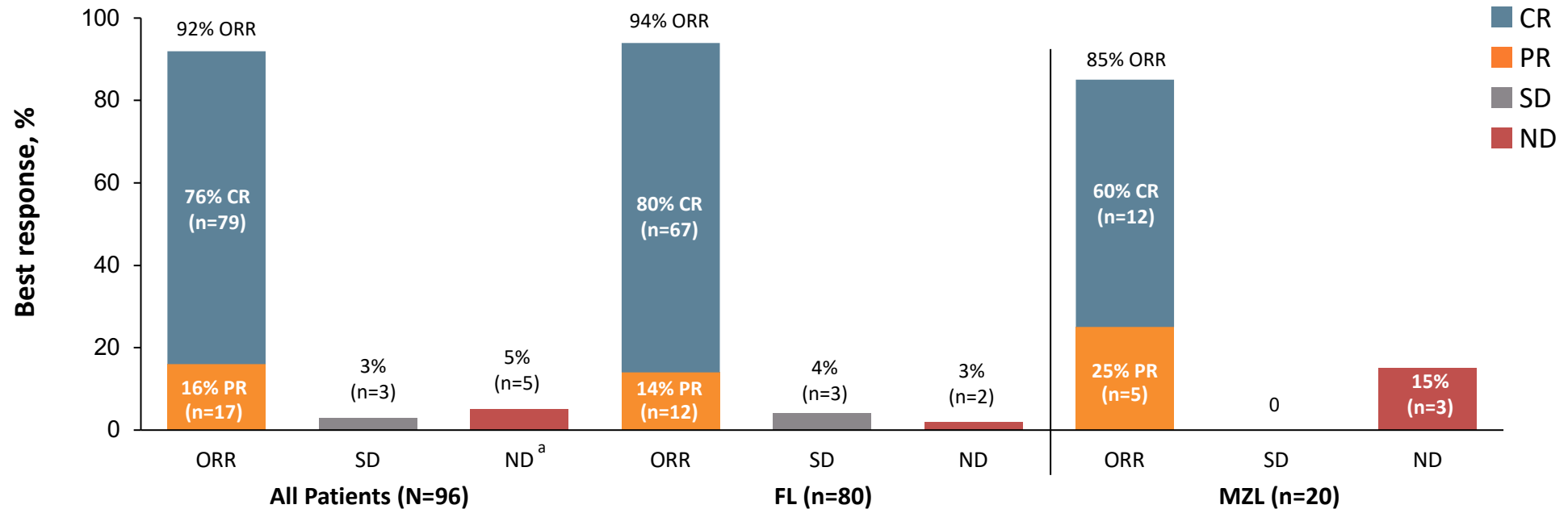
Characteristic	FL (n = 124)	MZL (n = 22)	Overall (N = 146)
Median age (range), years	60 (34 – 79)	66 (48 – 77)	61 (34 – 79)
≥ 65 years, n (%)	38 (31)	13 (59)	51 (35)
Male, n (%)	73 (59)	10 (45)	83 (57)
ECOG PS score 1, n (%)	46 (37)	9 (41)	55 (38)
Stage III-IV disease, n (%)	106 (85)	20 (91)	126 (86)
≥ 3 FLIPI, n (%)	54 (44)	14 (64)	68 (47)
High tumor bulk (GELF criteria), n (%) <sup>a</sup>	64 (52)	8 (36)	72 (49)
Median no. of prior therapies (range)	3 (1 – 10) <sup>b</sup>	3 (2 – 8)	3 (1 – 10) <sup>b</sup>
≥ 3, n (%)	78 (63)	15 (68)	93 (64)
Prior PI3Ki therapy, n (%)	34 (27)	9 (41)	43 (29)
Refractory disease, n (%) <sup>c</sup>	84 (68)	16 (73)	100 (68)
POD24 from first anti-CD20 mAb-containing therapy, n (%) <sup>d</sup>	68 (55)	11 (52)	79 (55)
Prior ASCT, n (%)	30 (24)	3 (14)	33 (23)

a Disease burden, as defined by GELF criteria: involvement of ≥ 3 nodal sites (≥ 3 cm diameter each); any nodal or extranodal tumor mass with ≥ 7 cm diameter; B symptoms; splenomegaly; pleural effusions or peritoneal ascites; cytopenias; or leukemia. b Enrollment of 3 patients with FL who had 1 prior line of therapy occurred before a protocol amendment requiring ≥ 2 prior lines of therapy. c Patients with iNHL who progressed within 6 months of completion of the most recent prior treatment. d POD24 defined as 24 months from initiation of the first line of anti-CD20-containing immunochemotherapy to progression. Percentages are based on the number of patients who ever received anti-CD20-chemotherapy combination therapy.



# ZUMA-5

## IRRC-ASSESSED OBJECTIVE RESPONSE RATE



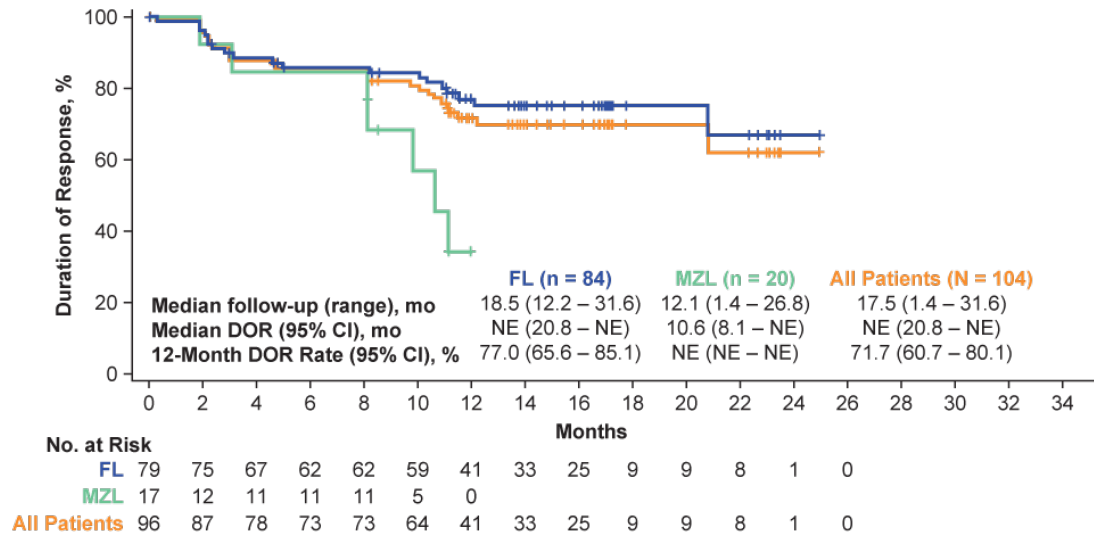
- Median **time to first response**: 1 month (range: 0.8-3.1)
- 13/25 (52%) patients with FL and **initial PR converted to CR** after a median of 2.2 months (range: 1.9-11.2)

<sup>a</sup>For the 5 patients reported as ND, 4 (1 FL; 3 MZL) had no disease at baseline and postbaseline per IRRC but were considered with disease by the investigator; 1 patient with FL died before the first disease assessment  
CR, complete response; FL, follicular lymphoma; IRRC, independent radiology review committee; MZL, marginal zone lymphoma; ND, undefined/not done; ORR, objective response rate; PR, partial response; SD, stable disease

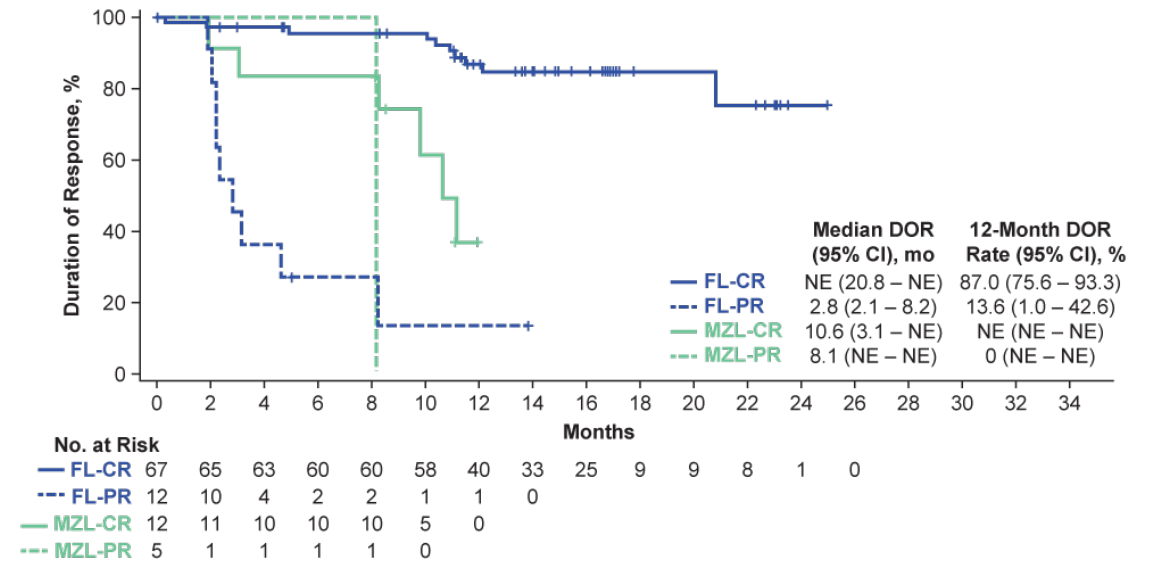
# ZUMA-5

## DURATION OF RESPONSE

### Duration of Response



### Duration of Response by Best Response



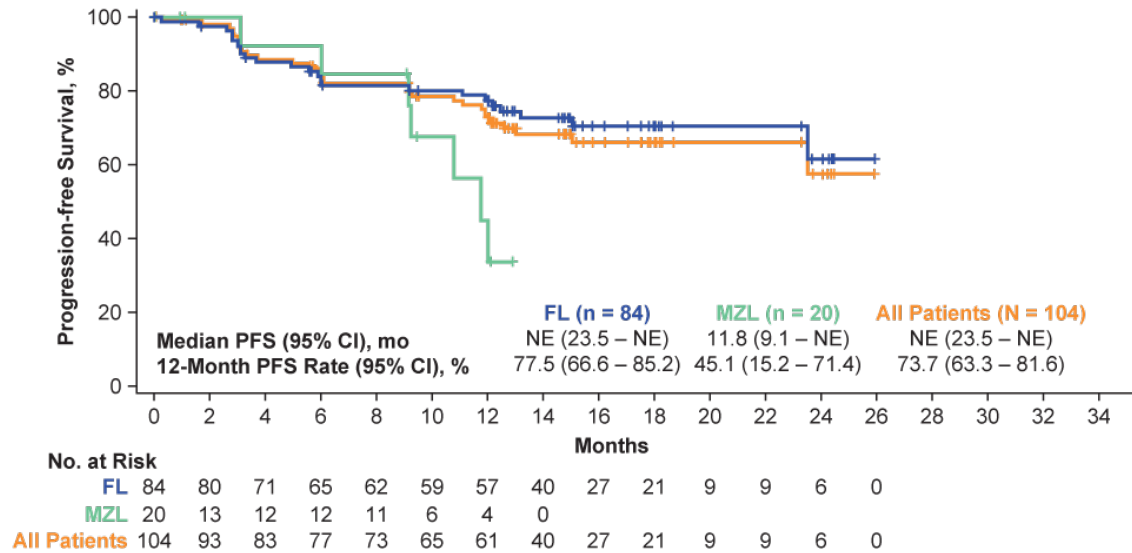
- With a median follow-up of 17.5 months, the **estimated median DoR was not reached** for all patients with iNHL; 64% of patients with FL had an ongoing response
  - 12-month DOR rate: 71.7% (95% CI, 60.7 – 80.1)
  - Responses were ongoing in 78% of patients with FL with CR and in 17% of patients with PR

CI, confidence interval; CR, complete response; DoR, duration of response; FL, follicular lymphoma; MZL, marginal zone lymphoma; NE, not estimable; NR, not reached; PR, partial response

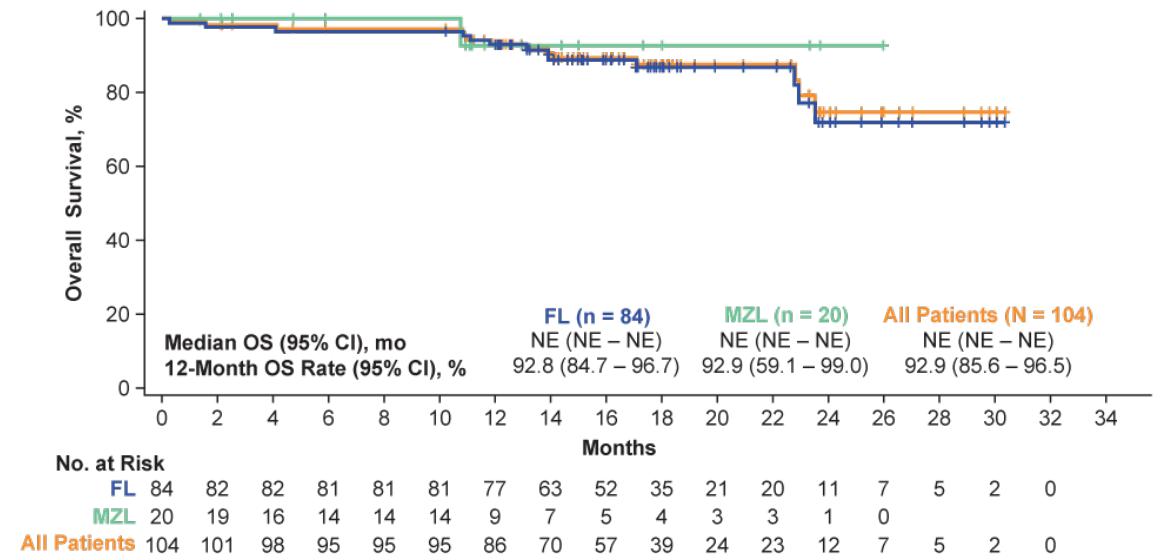
Jacobson C, et al. Oral presentation at ASH 2020. Abstract #700

# ZUMA-5 SURVIVAL

## Progression-free survival



## Overall survival



- With a median follow-up of 17.5 months, median PFS and OS were not reached
  - 12-month PFS: 73.7% (95% CI, 63.3 – 81.6) for all patients
  - 12-month OS: 92.9% (95% CI, 85.6 – 96.5) for all patients

# ZUMA-5

## TREATMENT-EMERGENT ADVERSE EVENTS

AE, n (%) <sup>a</sup>	FL (n = 124)	MZL (n = 22)	Overall (N = 146)
<b>Any AE</b>	123 (99)	22 (100)	145 (99)
Pyrexia	103 (83)	20 (91)	123 (84)
Neutropenia <sup>b</sup>	79 (64)	15 (68)	94 (64)
Hypotension	59 (48)	13 (59)	72 (49)
Headache	54 (44)	11 (50)	65 (45)
Fatigue	51 (41)	13 (59)	64 (44)
Nausea	45 (36)	13 (59)	58 (40)
Anemia	44 (35)	11 (50)	55 (38)
Sinus tachycardia	41 (33)	7 (32)	48 (33)
Tremor	36 (29)	9 (41)	45 (31)
Chills	33 (27)	9 (41)	42 (29)
Constipation	35 (28)	6 (27)	41 (28)
Diarrhea	33 (27)	8 (36)	41 (28)
Decreased appetite	28 (23)	8 (36)	36 (25)

- Grade  $\geq 3$  AEs occurred in 126 patients (86%)
  - The most common Grade  $\geq 3$  AEs were cytopenias (70%) and infections (16%)
- Grade 5 AEs occurred in 3 patients
  - Related to axi-cel: multisystem organ failure in the context of CRS (n = 1, Day 7)
  - Unrelated to axi-cel: aortic dissection (n = 1, Day 399); coccidioidomycosis infection (n = 1, Day 327)

<sup>a</sup>Treatment-emergent AEs shown are those that occurred in  $\geq 25\%$  of patients;

<sup>b</sup>Neutropenia includes preferred terms of neutropenia, neutrophil count decreased, and febrile neutropenia

AE, adverse event; axi-cel, axicabtagene ciloleucel; CRS, cytokine release syndrome; FL, follicular lymphoma; MZL, marginal zone lymphoma  
Jacobson C, et al. Oral presentation at ASH 2020. Abstract #700

# ZUMA-5

## CYTOKINE-RELEASE SYNDROME

Parameter	FL (n = 124)	MZL (n = 22)	Overall (N = 146)
<b>CRS, n (%)<sup>a</sup></b>	97 (78)	22 (100)	119 (82)
Grade ≥ 3	8 (6)	2 (9)	10 (7)
<b>Most common symptoms of any grade, n/n (%)</b>			
Pyrexia	94/97 (97)	20/22 (91)	114/119 (96)
Hypotension	39/97 (40)	10/22 (45)	49/119 (41)
<b>AE management, n (%)</b>			
Tocilizumab	56 (45)	15 (68)	71 (49)
Corticosteroids	19 (15)	6 (27)	25 (17)
<b>Median time to onset (range), days</b>	4 (1 – 15)	4 (1 – 9)	4 (1 – 15)
<b>Median duration of events (range), days</b>	6 (1 – 27)	6 (2 – 14)	6 (1 – 27)
<b>Patients with resolved events, n/n (%)</b>	96/97 (99) <sup>b</sup>	22/22 (100)	118/119 (99) <sup>b</sup>

<sup>a</sup>CRS was graded per Lee DW, et al. Blood. 2014;124:188-195. Individual symptoms of CRS were graded per National Cancer Institute's Common Terminology Criteria for Adverse Events version 4.03. <sup>b</sup>One patient with FL died of multisystem organ failure in the context of CRS (Day 7) prior to the resolution of CRS.

AE, adverse event; FL, follicular lymphoma; MZL, marginal zone lymphoma  
Jacobson C, et al. Oral presentation at ASH 2020. Abstract #700

# ZUMA-5

## NEUROLOGIC EVENTS

Parameter	FL (n = 124)	MZL (n = 22)	Overall (N = 146)
<b>Neurologic events, n (%)<sup>a</sup></b>	70 (56)	17 (77)	87 (60)
Grade ≥ 3	19 (15)	9 (41)	28 (19)
<b>Most common events of any grade, n/n (%)</b>			
Tremor	36/70 (51)	9/17 (53)	45/87 (52)
Confusional state	28/70 (40)	7/17 (41)	35/87 (40)
<b>AE management, n (%)</b>			
Corticosteroids	38 (31)	14 (64)	52 (36)
Tocilizumab	7 (6)	2 (9)	9 (6)
<b>Median time to onset (range), days</b>	7 (1 – 177)	7 (3 – 19)	7 (1 – 177)
<b>Median duration of events (range), days</b>	14 (1 – 452)	10 (2 – 81)	14 (1 – 452)
<b>Patients with resolved events, n/n (%)</b>	67/70 (96)	14/17 (82)	81/87 (93)

<sup>a</sup> Neurologic events were graded per National Cancer Institute's Common Terminology Criteria for Adverse Events version 4.03.

Axi-cel is a chimeric antigen receptor T-cell therapy that demonstrated **high rates of durable responses**

- ORR of 93% in patients with iNHL (95% in FL) and a CR rate of 80% (81% in FL)
- With a median follow-up of 15.3 months, responses were ongoing in 68% of patients with FL (80% of patients who achieved a CR)

The **safety profile was manageable** and appeared favourable in patients with FL compared with that previously reported in DLBCL

- No Grade 5 neurologic events occurred; 1 Grade 5 CRS event occurred

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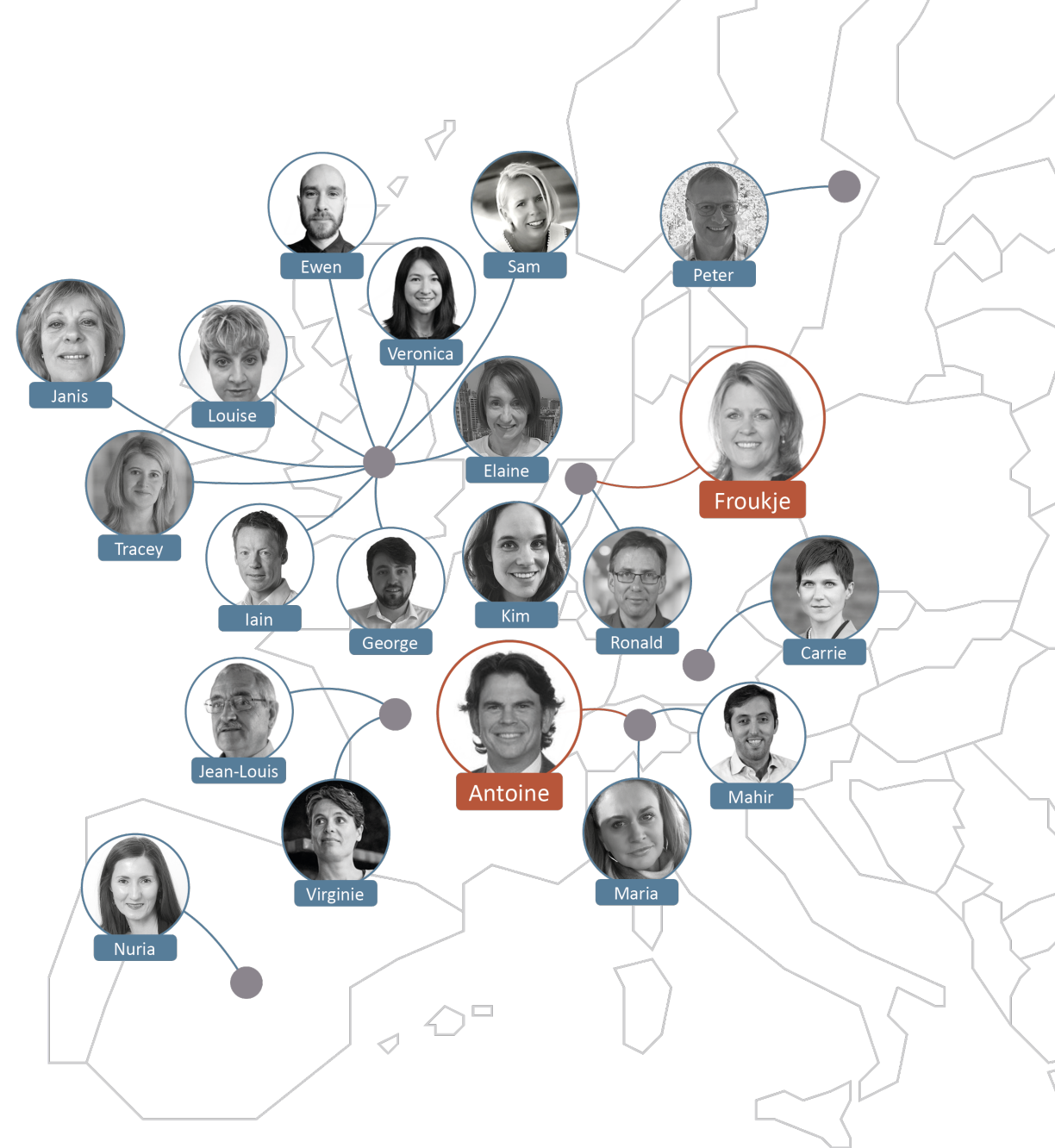
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