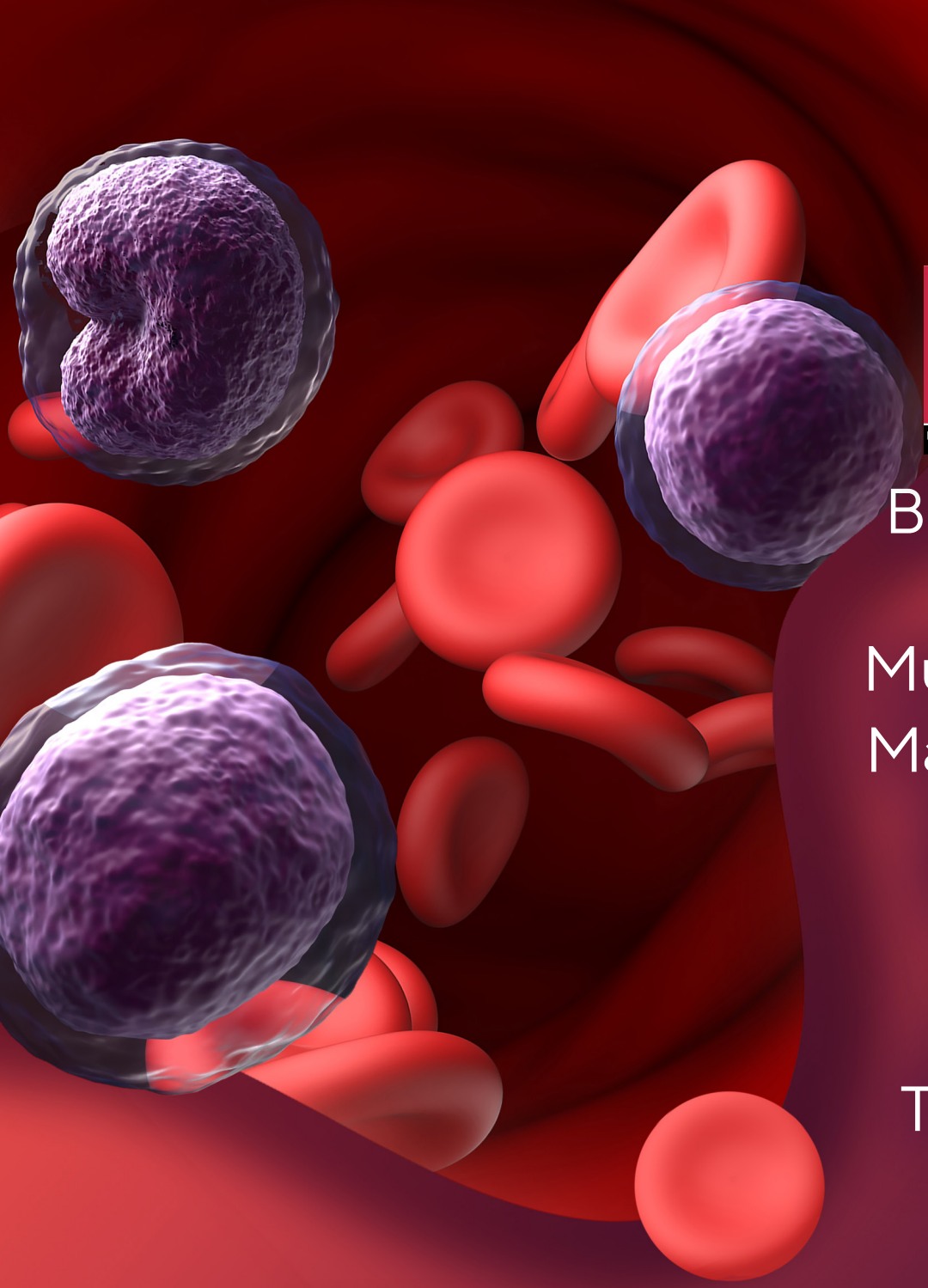

Project ECHO®

Med Learning Group - Non-Hodgkin's Lymphoma

Best Practices for the Multidisciplinary Management *of* NHL Using Antibody Therapeutics

FACULTY

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MED LEARNING GROUP

This activity is provided by Med Learning Group.
This activity is supported by an unrestricted educational grant from ADC Therapeutics America, and an educational grant from Genentech, a member of the Roche Group.

Best Practices for the Multidisciplinary Management of NHL Using Antibody Therapeutics

PROGRAM CHAIR

Mehdi Hamadani, MD
Professor of Medicine
Chief of Hematologic Malignancies
Medical College of Wisconsin
Milwaukee, WI

PROGRAM OVERVIEW

This virtually live TeleECHO educational series is designed to assist members of the multidisciplinary oncology care team in identifying approaches to the use of novel antibody therapeutics in the management of B-cell non-Hodgkin's lymphoma (NHL), particularly diffuse large B-cell lymphoma (DLBCL). This program features expert analysis of the latest clinical trial outcomes and potential adverse events associated with novel antibody therapeutics, as well as discussion of best practices for multidisciplinary management of B-cell NHL to improve long-term clinical outcomes.

TARGET AUDIENCE

This activity is designed to meet the educational needs of community-based oncologists, hematologists, nurse practitioners, pharmacists, and other members of the multidisciplinary oncology care team.

LEARNING OBJECTIVES

- Recognize the function of novel antibody therapeutics and combinations in the management of NHL
- Evaluate contemporary clinical trial data informing the use and development of antibody therapeutics in B-cell NHL
- Assess potential adverse events associated with antibody therapeutics in NHL and best practices for management of potential adverse events in the context of the multidisciplinary oncology care team

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Medhi Hamadani, MD	Discloses that he has received consulting fees from ADC Therapeutics, Omeros, CRISPR, Bristol Myers Squibb, Kite, AbbVie, Caribou, and Genmab. Dr. Hamadani has served on the speaker's bureau for ADC Therapeutics, AstraZeneca, BeiGene, and Kite. In addition, Dr. Hamadani has conducted contracted research for ADC Therapeutics, Spectrum Pharmaceuticals, and Astellas Pharma.

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This activity is supported by an unrestricted educational grant from ADC Therapeutics America, Inc. and an educational grant from Genentech, a member of the Roche group.

AGENDA

I. Introduction

a. Epidemiology of B-cell non-Hodgkin lymphomas
   i. Relevant subtypes of NHLs (e.g., DLBCL, MCL, and FL)
b. Overview of the state of the art of with targeted therapies (e.g., CAR T-cell therapies, antibodies, checkpoint inhibitors, ADCs)
c. Considering the role of CD20 and CD3 expression in B-cell NHL
d. The role of antibody-drug conjugates, as well as bispecific antibodies for B-cell NHL

II. Developments in Therapy for B-Cell NHL

a. B-Cell Lymphomas: Where are We Now and Where Are We Going?
   i. NHL assessment
      1. Methods of assessment (e.g., immunohistochemistry, flow cytometry, karyotype, translocations, and presence or absence of gene rearrangements)
   ii. B-cell lymphoma therapies
      1. Indolent versus aggressive lymphomas
         a. Treatment strategies following initial diagnosis
         b. Treatment in the relapsed/refractory settings
   iii. Efficacy and safety of antibody therapeutics
      1. Polatuzumab vedotin (including frontline use with Pola-R-CHP based on POLARIX [NCT03274492], as well as use following 3 prior therapies with pola-BR), and results of the PolaR-ICE study, and other combination studies
      2. Tafasitamab vedotin (L-MIND study in R/R DLBCL)
      3. Loncastuximab teserine (LOTIS-2 trial and follow-up, as well as RE-MIND-2, and other ongoing results from the LOTIS clinical study program)
   iv. Basis for approval in relapsed/refractory NHL, including clinical trial outcomes
      1. Mosunetuzumab (GO29781)
      2. Epcoritamab (EPCORE NHL-1/2)
      3. Glofitamab (NP30179)
   v. Further agents in development, including clinical trial outcomes
      1. Odronextamab (ELM-1 and ELM-2)
      2. Imvotamab (ongoing phase ½ clinical trial of imvotamab as monotherapy and in combination with loncastuximab teserine)
      3. Plamotamab (phase 1 study in relapsed/refractory NHL)
      4. Bispecific T-cell engagers

III. Discussing Treatment Considerations with Patients

a. Best Practices in Discussing Therapeutic Options in Later-Line B-Cell Lymphoma Management
   i. Discussing specific therapeutic options in the management of B-cell lymphomas
      1. Recognizing potential adverse events with antibody-drug conjugates, as well as bispecific antibodies
      2. Best practices for discussing therapeutic options, infusion time, and benefits of therapy with patients
      3. Discussing clinical trial opportunities with patients with enhanced anti-CD20 therapy

IV. Conclusions/Key Takeaways

a. Opportunities and best practices for use of novel therapeutic combinations in B-cell lymphoma to overcome resistance to prior anti-CD20 therapy

Best Practices for the Multidisciplinary Management of NHL Using Antibody Therapeutics

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Milwaukee, WI

1

Disclosures

- **Mehdi Hamadani, MD**, reports that he is a consultant for ADC Therapeutics, AbbVie, Omeros, BMS, Kite, Genmab, CRISPR, Autolus, Caribou and Forte Biosciences; he also is a speaker for Sanofi, AstraZeneca, BeiGene, ADC Therapeutics, and Kite Pharma and provides contract research funding to ADC Therapeutics and Spectrum Pharmaceuticals

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- During this lecture Dr Hamadani may mention the use of medications for both US Food and Drug Administration (FDA)-approved and non-FDA-approved indications

This activity is supported by an unrestricted educational grant from ADC Therapeutics America, Inc., and an educational grant from Genentech, a member of the Roche Group.

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Learning Objectives

- Recognize the function of novel antibody therapeutics and combinations in the management of B-cell non-Hodgkin lymphoma (B-NHL)
- Evaluate contemporary clinical trial data informing the use and development of antibody therapeutics in B-NHL
- Assess potential adverse events associated with antibody therapeutics in B-NHL and best practices for the management of potential adverse events in the context of the multidisciplinary oncology care team

3

Treatment of Advanced-Stage DLBCL: R-CHOP Standard for Over 20 Years!!!

Long-term follow-up of LNH-98.5 trial

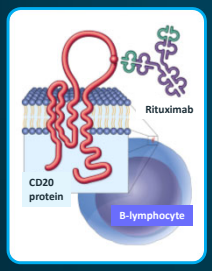
Stage II–IV DLBCL
n = 399

CHOP x 8

10-year PFS = 20.1%
10-year OS = 27.6%

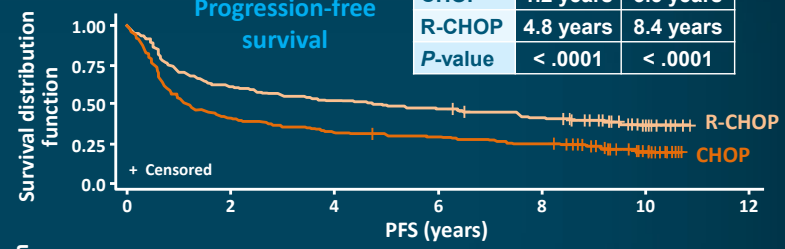
R-CHOP x 8

10-year PFS = 36.5%
10-year OS = 43.5%



CD20 molecule as expressed on B cells

	mPFS	mOS
CHOP	1.2 years	3.5 years
R-CHOP	4.8 years	8.4 years
P-value	< .0001	< .0001



m = median; OS = overall survival; PFS = progression-free survival.

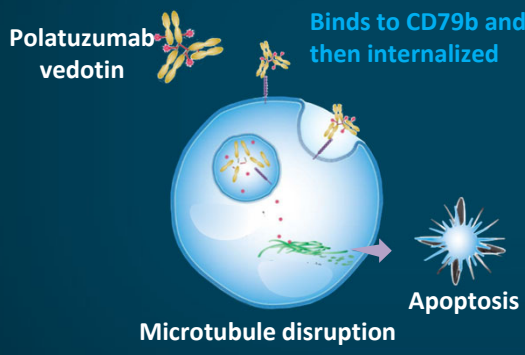
Coiffier B, et al. *N Engl J Med.* 2002;346:235-242. Coiffier B, et al. *Blood.* 2010;116:2040-2045. Pescovitz MD. *Am J Transplant.* 2006,6:859-866.

4

POLARIX: Polatuzumab Vedotin* vs Vincristine in R-CHOP

CD79B is ubiquitously expressed in B-cell NHL.

Polatuzumab vedotin is an anti-CD79b ADC, FDA-approved with bendamustine (BR) for R/R DLBCL.



Eligibility criteria
- Previously untreated DLBCL
- Aged 18 to 80 years
- IPI score 2 to 5
- ECOG PS 0 to 2

R 1:1

6 cycles: Pola-R-CHP 2 additional cycles of rituximab	6 cycles: R-CHOP 2 additional cycles of rituximab

Primary endpoint: Investigator-assessed PFS

Baseline characteristics
- Median age = 65 years
- Advanced stage = 89%
- IPI 3 to 5 = 62%
- DHL/THL = 8%
- DE = 38%

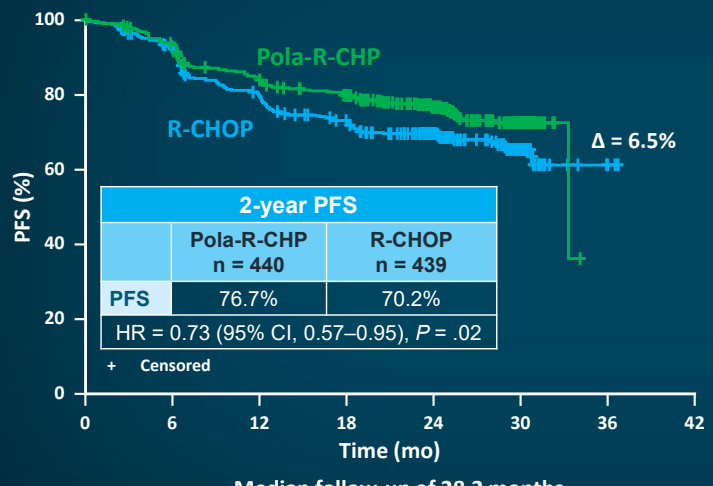
ADC = antibody-drug conjugate; DE = dual/double expresser; DHL = double-hit lymphoma; ECOG PS = Eastern Cooperative Oncology Group performance status; PFS = progression-free survival; Pola = polatuzumab; Pola-R-CHP = polatuzumab, rituximab, cyclophosphamide, doxorubicin, and prednisone; R =randomization; R/R = relapsed/refractory; THL = triple-hit lymphoma.

Tilly H, et al. *N Engl J Med*. 2022;386:351-363. Polatuzumab vedotin (Polivy®) prescribing information (PI) 2023 (www.gene.com/download/pdf/polivy_prescribing.pdf). Creative Biolabs. ADC development for NHL (www.creative-biolabs.com/adc/adc-development-for-nhl.htm). URLs accessed 2/24/2024.

*Polatuzumab is not FDA-approved for first-line DLBCL.

POLARIX—Primary Endpoint: PFS

Pola-R-CHP significantly improved PFS vs R-CHOP.



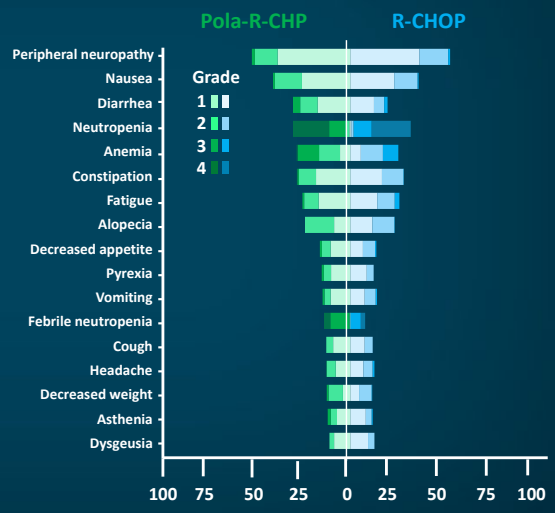
2-year PFS	Pola-R-CHP n = 440	R-CHOP n = 439
PFS	76.7%	70.2%

HR = 0.73 (95% CI, 0.57–0.95), *P* = .02

\+ Censored

Median follow-up of 28.2 months

With no excess toxicity



CI = confidence interval; HR = hazard ratio.

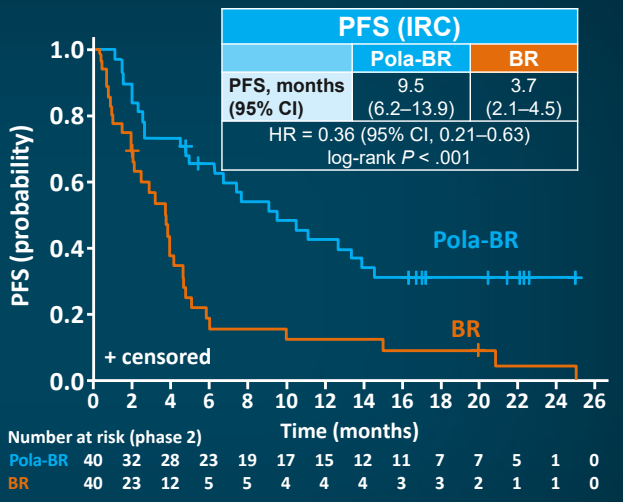
Tilly H, et al. *N Engl J Med*. 2022;386:351-363.

Randomized Phase 2 Trial of Polatuzumab-BR vs BR in R/R DLBCL

Patients received up to six 21-day cycles

Baseline characteristics	BR (n = 40)	Pola-BR (n = 40)
Median age, years	71 (30–84)	67 (33–86)
IPI ≥3, n (%)	29 (73)	22 (55)
Median prior treatment, n (range)	2 (1–5)	2 (1–7)
Prior BMT, n (%)	6 (15)	10 (25)

Response	BR (n = 40)	Pola-BR (n = 40)
ORR	17.5%	45.0%
CR	17.5%	40.0%



The primary toxicities of Pola-BR are peripheral sensory neuropathy and cytopenias.

BMT = bone marrow transplantation; IRC = independent review committee; ORR = overall response rate; Pola-BR = polatuzumab vedotin, bendamustine, and rituximab.

Sehn LH, et al. *J Clin Oncol*. 2020;38:155-165.

7

Pola-BR's Activity in Double-Hit Lymphoma

Best response to Pola-BR	All patients (N = 133)	Prior CAR-T (n = 16)	DHL/THL (n = 14)	Transformed lymphoma (n = 31)	Stand alone treatment (n = 78)	Bridge to CAR-T (n = 40)	>1 prior lines of treatment (n = 86)
CR	42 (31.6%)	3 (18.8%)	3 (21.4%)	11 (35.5%)	31 (39.7%)	7 (17.5%)	21 (24.4%)
PR	31 (23.3%)	4 (25.0%)	2 (14.3%)	10 (32.3%)	19 (24.4%)	9 (22.5%)	19 (22.1%)
SD	13 (9.8%)	3 (18.8%)	2 (14.3%)	2 (6.5%)	5 (6.4%)	6 (15.0%)	11 (12.8%)
PD	42 (31.6%)	6 (37.5%)	6 (42.9%)	7 (22.6%)	21 (26.9%)	16 (40.0%)	32 (37.2%)
Missing	5 (3.8%)	0 (0.0%)	1 (7.1%)	1 (3.2%)	2 (2.6%)	2 (5.0%)	3 (3.5%)
ORR (95% CI)	57.0% (48.0–65.7%)	43.8% (19.8–70.1%)	38.5% (13.9–68.4%)	70.0% (50.6–85.3%)	65.8% (54.0–76.3%)	42.1% (26.3–59.2%)	48.2% (37.1–59.4%)

CR = complete response; PD = progressive disease; PR = partial response; SD = stable disease.

Northend M, et al. *Blood Adv*. 2022;6:2920-2926.

8

L-MIND Phase 2 Trial of Tafasitamab/Lenalidomide in R/R DLBCL

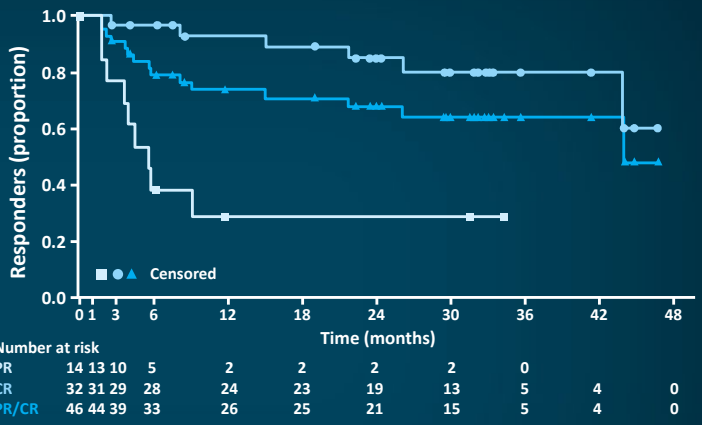
Tafasitamab: 12 mg/kg C1–3 D1, D8, D15, D22; C4+ D1 and 15, up to 12 cycles
Lenalidomide: 25 mg D1–21 (28-day cycles)

Baseline characteristics	N = 81
Median age, years	72 (41–86)
Primary refractory, n (%)	15 (18.5)
Median prior treatment, n (range)	2 (1–4)
Non–GCB-like, n (%)	22 (27)

Response (N = 80)			
	% or months		Months (95% CI)
ORR	57.5%	PR	5.6 (2.2–NR)
CR rate	40.0%	CR	NR (43.9–NR)
PFS	11.6 mo	PR/CR	43.9 (26.1–NR)
mDoR	43.9 mo	TTR	2.1 mo

C = cycle; D = day; DoR = duration of response; mDoR = median DoR; NR = not reached; PR = partial response; TTR = time to response.

Duell J, et al. *Haematologica*. 2021;106:2417-2426.



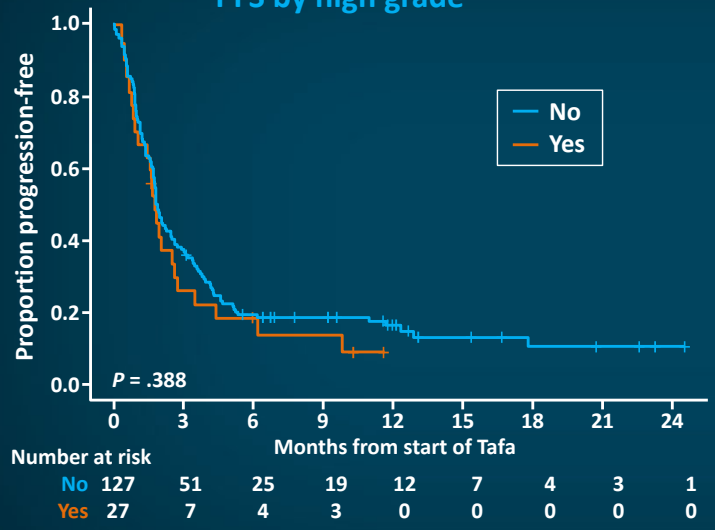
This study included second-line DLBCL and excluded patients with primary refractory and DHL.

The primary toxicities of tafasitamab/lenalidomide are cytopenias and diarrhea.

9

Real-World Evidence of Tafa-Len's Activity in HGBCL and Post CAR T-Cell

PFS by high grade



TOLA study	
DHL/THL	n = 27
ORR	18%
CR rate	15%

Response to Tafa/Len according to CAR T-cell response		
DoR after CAR T-cell	≥6 months (n = 11)	<6 months (n = 15)
ORR	36%	7%
CR	36%	7%

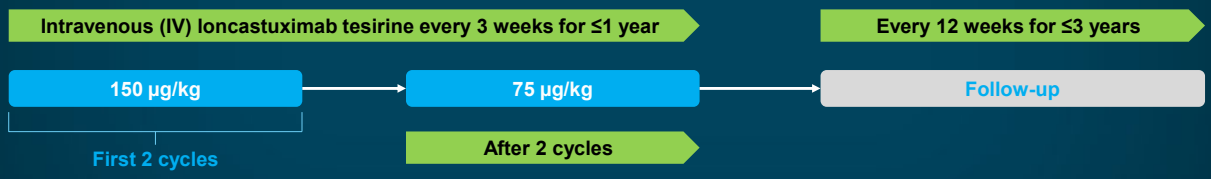
Len = lenalidomide; Tafa = tafasitamab.

Qualls D, et al. *Blood*. 2023;142(26):2327-2331.

10

LOTIS-2 Study of Loncastuximab Teserine in R/R DLBCL

- Patients with R/R DLBCL for whom salvage chemotherapy/stem cell transplantation (SCT) is unsuccessful and who have a poor prognosis and limited treatment options[1,2]
- Loncastuximab tesirine comprises a humanized anti-CD19 antibody conjugated to a potent pyrrolobenzodiazepine (PBD) dimer toxin[3]
- LOTIS-2 is a multicenter, open-label, single-arm, phase 2 study in patients aged ≥18 years with pathologically defined R/R DLBCL and ≥2 prior systemic treatments[4-6]
  - Included patients with high-risk characteristics such as double-hit, triple-hit, transformed, or primary refractory DLBCL[4]

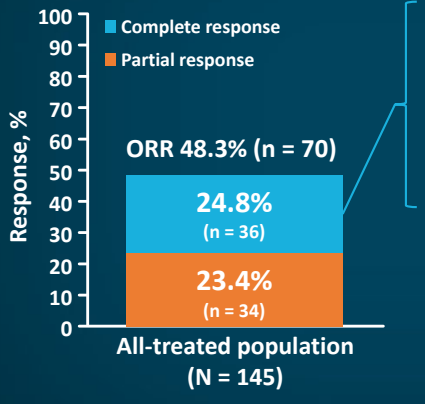


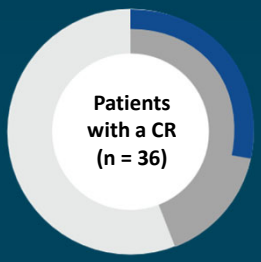
- Primary efficacy and safety data have been published (**≥6 months** since first dose)[4]
- Presented are updated results (**≥17 months** since first dose)

Study findings were previously presented as a poster at the International Conference on Malignant Lymphoma (ICML) Virtual Congress, June 18–22, 2021.

1. Crump M, et al. *Blood.* 2017;130:1800-1808. 2. Gisselbrecht C, et al. *Br J Haematol.* 2018;182:633-643. 3. Zammarchi F, et al. *Blood.* 2018;131:1094-1105. 4. Caimi PF, et al. *Lancet Oncol.* 2021;22:790-800. 5. Caimi PF, et al. American Society of Hematology (ASH) 2020; Abstract 1183. 6. Caimi PF, et al. American Society of Clinical Oncology (ASCO) 2021; Abstract 7546.

Overall Response Rate and Long-Term Responses Observed in the All-Treated Population





Of the patients with a CR, **44% (16 of 36)** were event-free for ≥1 year.

Of the patients with a CR, **31% (11 of 36)** were event-free for ≥2 years.

Median (range) number of treatment cycles	
All-treated population	3.0 (1–26)
Patients with a CR	8.0 (1–26)
Patients with a CR, event-free ≥1 year[a]	12.5 (1–26)
Patients with a CR, event-free ≥2 years[a]	13.0 (1–22)

Data cutoff: September 15, 2022.

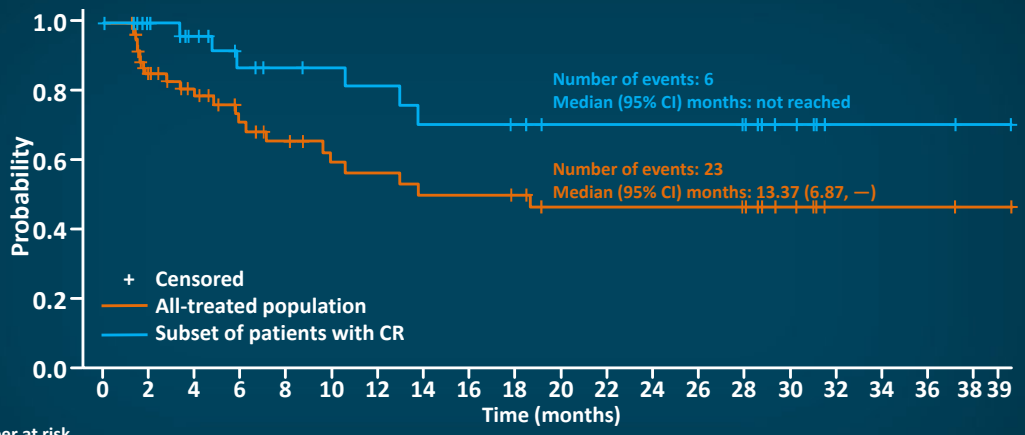
The median duration of follow-up was 7.8 months (range, 0.3–42.6 months) in the all-treated population and 35.0 months (range, 4.4–42.6 months) in patients with a CR.

[a]Event-free is defined as no progressive disease or death starting from Day 1, Cycle 1 of Lonca treatment.

CR = complete response; Lonca = loncastuximab tesirine-lpyl; ORR = overall response rate.

Caimi PF, et al. *Haematologica*. 2023. (https://doi.org/10.3324/haematol.2023.283459). Accessed 2/26/2024.

DOR: All-Treated Population and Patients With a CR



Number at risk																				
All-treated population	70	42	33	25	21	18	17	15	15	13	11	11	11	11	7	5	2	2	2	1	0
Subset of patients with CR	36	30	25	20	18	17	16	14	14	12	11	11	11	11	7	5	2	2	2	1	0

The median (range) time to response was 41 (35–247) days in the all-treated population and 42 (36–247) days for patients with a CR.

Data cutoff: September 15, 2022.

CR = complete response; DOR = duration of response.

Caimi PF, et al. *Haematologica*. 2023. (https://doi.org/10.3324/haematol.2023.283459). Accessed 2/26/2024.

13

All-Grade and Grade ≥3 Adverse Events

TEAEs, any grade in ≥30% of patients	All-treated population N = 145	Patients with a CR n = 36
Patients with any TEAE	98.6%	100%
Increased GGT	42%	50%
Neutropenia	40%	42%
Thrombocytopenia	33%	36%
Anemia	26%	36%
Peripheral edema	20%	33%
Nausea	23%	31%

TEAEs, grade ≥3 in ≥10% of patients	All-treated population N = 145	Patients with a CR n = 36
Patients with any TEAE	73.8%	75%
Neutropenia	26%	28%
Thrombocytopenia	18%	19%
Increased GGT	17%	19%
Anemia	10%	8.3%
Leukopenia	9%	14%
Hypophosphatemia	6%	11%

No new safety signals were identified during the long-term follow-up.

Data cutoff: September 15, 2022.

GGT = gamma-glutamyltransferase; TEAE = treatment emergent adverse events.

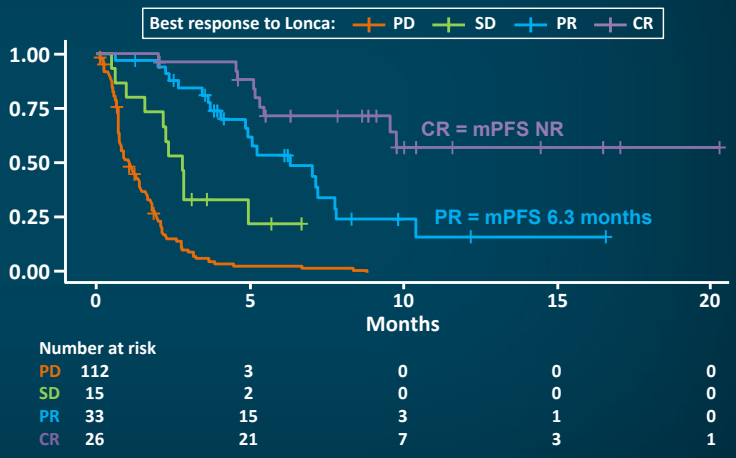
Caimi PF, et al. *Haematologica*. 2023. (https://doi.org/10.3324/haematol.2023.283459). Accessed 2/26/2024.

14

Real-World Data for Loncastuximab

N = 187	ORR (%)	CR (%)
Overall study population	**32**	**14**
CD19 status		
Positive	32	14
Negative	26	21
Bulky disease (N = 32)	16	0
Prior CAR T-cell		
Yes (N = 112)	30	15
No	35	12
Number of prior therapies		
<4	33	14
4+	30	13
Age >75 years		
Yes	32	14
No	26	21

PFS by response to Lonca



Ayers E, et al. ASH 2023; Abstract 312.

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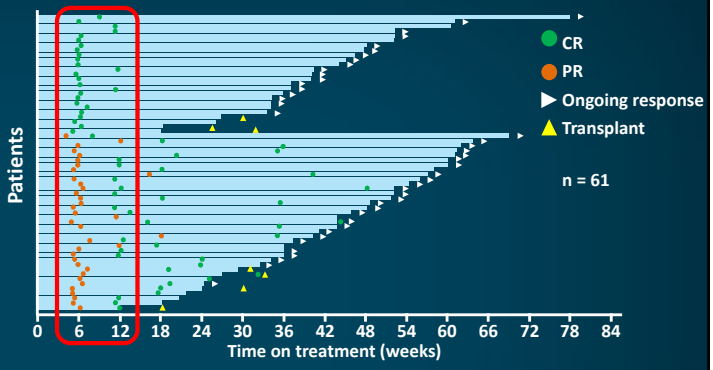
Epcoritamab in R/R LBCL: EPCORE NHL-1 LBCL Expansion Cohort

Step-up dosing protocol

Patient group	n	ORR, %	CR, %
All LBCL	157	63	39
• **<65 years of age**	80	56	35
• **65 to <75 years**	48	69	40
• **>75 years**	29	72	48
• **De novo DLBCL**	97	61	37
• **tDLBCL**	40	68	45
• **Primary refractory**	96	55	30
• **CAR T-cell therapy naïve**	96	69	42
• **CAR T-cell therapy exposed**	61	54	34
• **CAR T-cell therapy refractory**	46	46	28
• **2 prior lines**	46	65	35
• **3 prior lines**	50	64	40
• **4 prior lines**	61	61	41

Received FDA approval on May 19, 2023, for R/R DLBCL after 2 prior therapy lines



CRS parameter	LBCL (N = 157)
CRS events, n (%)	78 (49.7)
Grade 1 to 2	74 (47.1)
Grade 3	4 (2.5)
Median time to resolution from first full dose, days	2
Treated with tocilizumab, n (%)	22 (14.0)
ICANS Grade 1 to 2	5.7%
ICANS Grade 3 or more	1 (0.6)

ICANS = Immune effector cell-associated neurotoxicity syndrome.
Thieblemont C, et al. *J Clin Oncol.* 2022;41:2238-2247.

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Glofitamab Monotherapy at RP2D Induces Durable Complete Responses

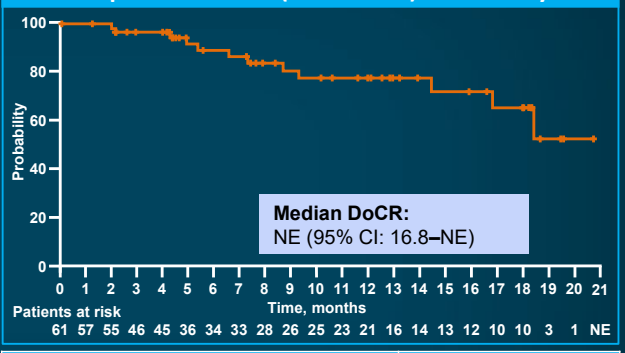
Heavily pretreated, highly refractory population

Pivotal phase 2 results presented at ASCO 2022

- DLBCL NOS, HGBCL, trFL or PMBCL; ≥2 prior therapies
- Glofitamab 2.5/10/30 mg (N = 155)
- Efficacy
  - CR rate: 39.4% (61/155)
  - ORR: 51.6% (80/155)

Received FDA approval on June 15, 2023, for R/R DLBCL after 2 prior therapy lines

Pivotal phase 2 cohort (ASCO 2022) – DoCR* by IRC



	N = 61
Median DoCR follow-up, months (range)	10.6 (0–21)
12-months DoCR, % (95% CI)	**77.6 (64.3–90.8)**
CRs ongoing at CCOD, n (%)	49 (80.3)

Clinical cutoff date: March 14, 2022. *Time from the initial occurrence of a CR until PD or death due to any cause, whichever occurs first.

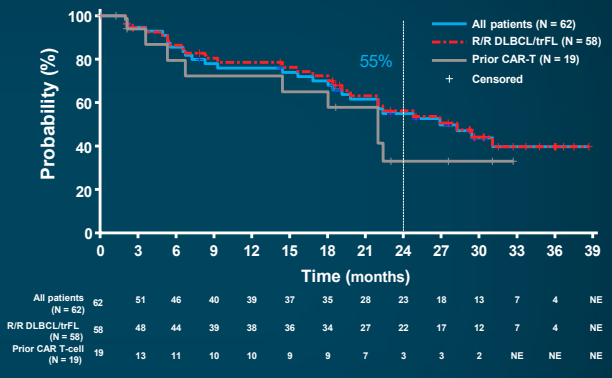
CCOD = clinical cutoff date; CI = confidence interval; CRS = cytokine release syndrome; DoCR = duration of complete response; IRC = independent review committee; PD = progressive disease; PMBCL = primary mediastinal large B-cell lymphoma; RP2D = recommended phase 2 dose; trFL = transformed follicular lymphoma.

Dickinson MJ, et al. ASCO 2022; Abstract 7500. Dickinson M, et al. *N Engl J Med*. 2022;387:2220-2231.

Response Rates and DoCR: Update Follow-Up ASH 2023

	All patients (N = 155)*	R/R DLBCL/trFL (N = 132)†‡	Prior CAR T-cell (N = 52)†
ORR, n (%) [95% CI]	80 (52)	74 (56)	26 (50)
	[43.5–59.7]	[47.2–64.7]	[35.8–64.2]
CR rate, n (%) [95% CI]	62 (40)	58 (44)	19 (37)
	[32.2–48.2]	[35.3–52.8]	[23.6–51.0]
Median DoCR, months (95% CI)	26.9	28.3	22.0
	(19.8–NR)	(19.8–NR)	(6.7–NR)
24-month DoCR, % (95% CI)	55.0	56.2	33.1
	(41.1–68.8)	(41.9–70.4)	(7.2–59.0)
Median CR follow-up, months (range)	29.6	29.6	23.0
	(0–39)	(0–39)	(0–33)
Ongoing CRs, n/N (%)	34/62 (55)	32/58 (55)	10/19 (53)

DoCR by IRC



- Median time on study: 32.1 months (range: 0–43)

With 32 months median follow-up, glofitamab showed high response rates and durable remissions across subgroups.

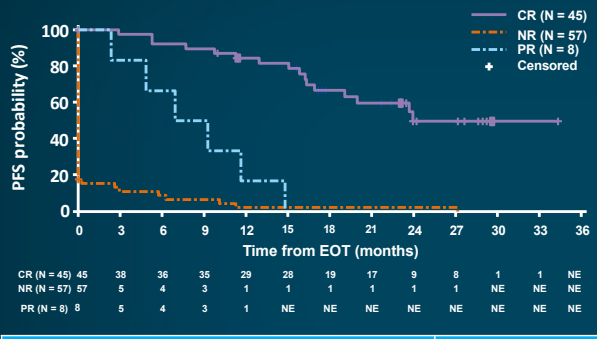
*Intent-to-treat population (DLBCL, trFL, HGBCL, and PMBCL). †Patients in this subgroup had similar baseline characteristics to the overall population. ‡Primary efficacy population reported in the glofitamab USPI, all patients received at least 1 dose of glofitamab.

CI = confidence interval; NE = not estimable; NR = not reached; USPI = United States prescribing information.

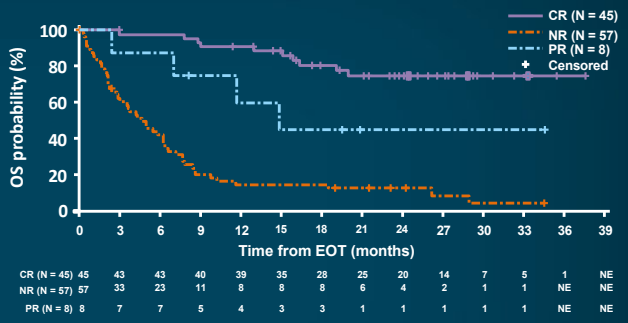
Glofitamab-gxbm (Columvi™) PI 2023 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761309s000lbl.pdf). Accessed 2/24/2024; Hutchins M et al. ASH 2023; Abstract 433.

Landmark Analysis by Response at EOT

PFS



OS



Landmark PFS from EOT in patients with CR at EOT*	N = 45
Median PFS, months (95% CI)	24.0 (19.1–NE)
18-month PFS rate, % (95% CI)	66.6 (51.0–82.2)

Landmark OS from EOT in patients with CR at EOT*	N = 45
Median OS, months (95% CI)	NE (NE)
18-month OS rate, % (95% CI)	80.7 (68.6–92.8)

The majority of patients with a CR at EOT remained progression-free and alive at 18 months after EOT.

*KM estimates.

EOT = end-of-treatment.

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