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Lo último en *hematología* para *farmacia hospitalaria*

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Hospital Clínico Lozano Blesa Zaragoza

Sábado13/06/2026: UNLOCKING THE POWER OF CAR-T

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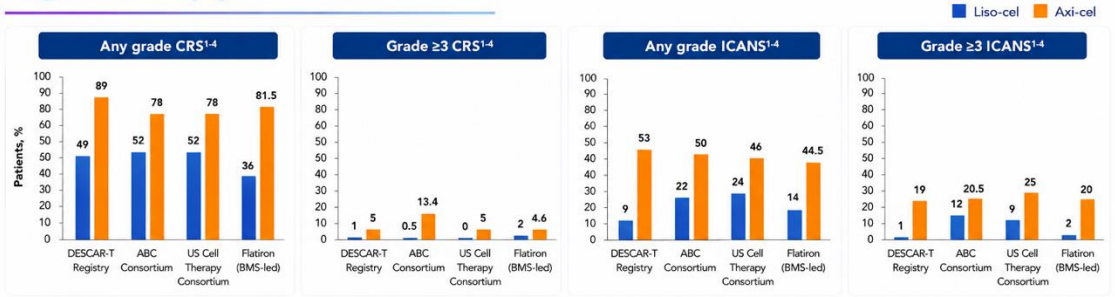
AXI-CEL, LISO-CEL-RAEs: TIEMPOS Y SEVERIDAD→RWE

Across 4 real-world analyses, liso-cel and axi-cel had a consistent safety profile, with low rates of severe CRS and ICANS



	DESCAR-T Registry Brudno et al[1]		ABC Consortium Melody et al[2]		US Cell Therapy Consortium Bachanova et al[3]		Flatiron (BMS-led) Patel S et al[4]	
	Liso-cel (n=92)	Axi-cel (n=407)	Liso-cel (n=183)	Axi-cel (n=567)	Liso-cel (n=81)	Axi-cel (n=537)	Liso-cel (n=100)	Axi-cel (n=65)
LOT	2L	2L	2L+		2L+		2L+	
Tocilizumab use, %	Not reported	Not reported	55[a]	71[a]	Not reported	Not reported	11.0[b]	16.9[b]

Table and graph format is for ease of view and does not imply comparison across trials or treatment arms.
Please see individual presentations for full study information.

[a] Tocilizumab use reported for CRS. [b]Tocilizumab use reported for ICANS (or CRS). These percentages for those who used tocilizumab only.

1. Brudno JN et al. Oral presentation at: ASH 2025, Abstract #6954. 2. Melody M et al. Oral presentation at: ASH 2025, Abstract #781.
3. Bachanova V et al. Oral presentation at: ASH 2025, Abstract #1805. 4. Patel S et al. Poster presentation at: ASH 2025, Abstract #1860.

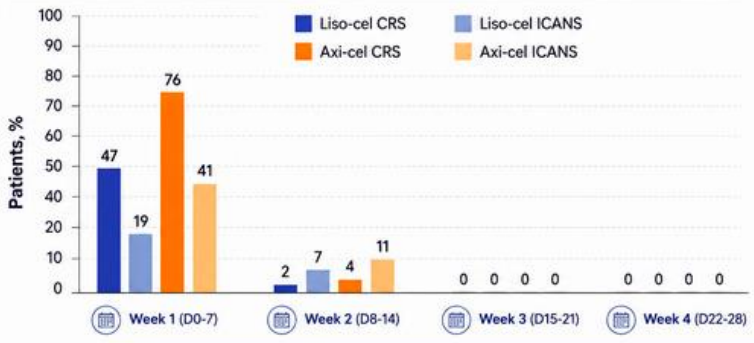
FAU Friedrich-Alexander Universität Erlangen-Nürnberg

This session is restricted to healthcare professionals only.
Satellite symposium sponsored by Bristol Myers Squibb.

5

Majority of CRS and ICANS events for CD19-directed CAR Ts occur within Days 0-14

Onset of any grade CRS and ICANS in patients with R/R LBCL treated with liso-cel (n = 101) and axi-cel (n = 216)[1,a]



Overall, grade ≥3 events were low[1]
- CRS: 7% and 3% with axi-cel and liso-cel, respectively
- ICANS: 33% and 10% with axi-cel and liso-cel, respectively

In the real-world setting, the safety profile of liso-cel continues to demonstrate lower rates of any grade CRS and ICANS compared to axi-cel[1-5]

Across studies, CRS and ICANS consistently occurred in the first 2 weeks post-infusion[1,6,7]

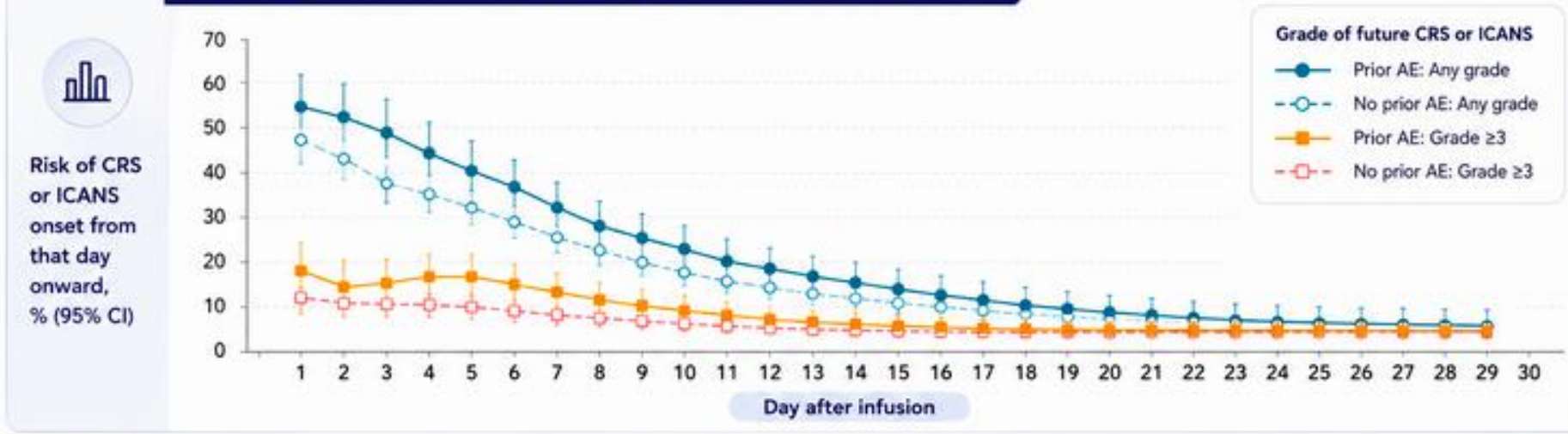
Liso cel and axi cel have not been compared in a head to head clinical trial, and direct comparisons should not be made.

* Retrospective review of data from the Cell Therapy Consortium registry. Evaluated data from patients with R/R LBCL who received commercial Breyanzi® or Yescarta infusion between March 2018 and May 2023.

1. Bouquegneau A et al. Oral presentation at: ASH 2024. 2. Lyman GH et al. ASH 2023. Abstract #1058. 3. CRS, cytokine release syndrome; ICANS, immune effector cell associated neurotoxicity syndrome; liso-cel, lisocabtagene maraleucel; axi-cel, axicabtagene ciloleucel; R/R, relapsed or refractory; D, Day.
4. Ahmed N et al. *Blood Adv.* 2024. doi:10.1182/bloodadvances.2023016749. 5. Zhong G et al. Oral presentation at: ASH 2025. Abstract #1127. 6. Melody M et al. Oral presentation at: ASH 2025. Abstract #781.
7. Bachanova V et al. Oral presentation at: ASH 2025, Abstract #1805. 8. Patel S et al. Poster presentation at: ASH 2025, Abstract #1806. 9. Ahmed B et al. Transplant Cell Ther. 2026; 32(1):71.e1–71.e12.
10. Orive-Maldonado V et al. EBMT 2026. Abstract #OS119-07.

Understanding the impact of prior CRS or ICANS on a patient's risk of future CRS or ICANS

Future risk[a] of CRS or ICANS stratified by prior CRS or ICANS (Days 1–30)



No. at risk																														
Prior AE	15	53	103	150	193	230	252	281	295	304	310	315	317	317	321	320	322	323	324	325	327	326	326	326	325	325	324	324	323	323
No prior AE	691	676	638	588	541	498	461	437	408	394	385	379	374	372	368	367	365	363	362	361	359	359	359	358	358	357	355	355	355	355

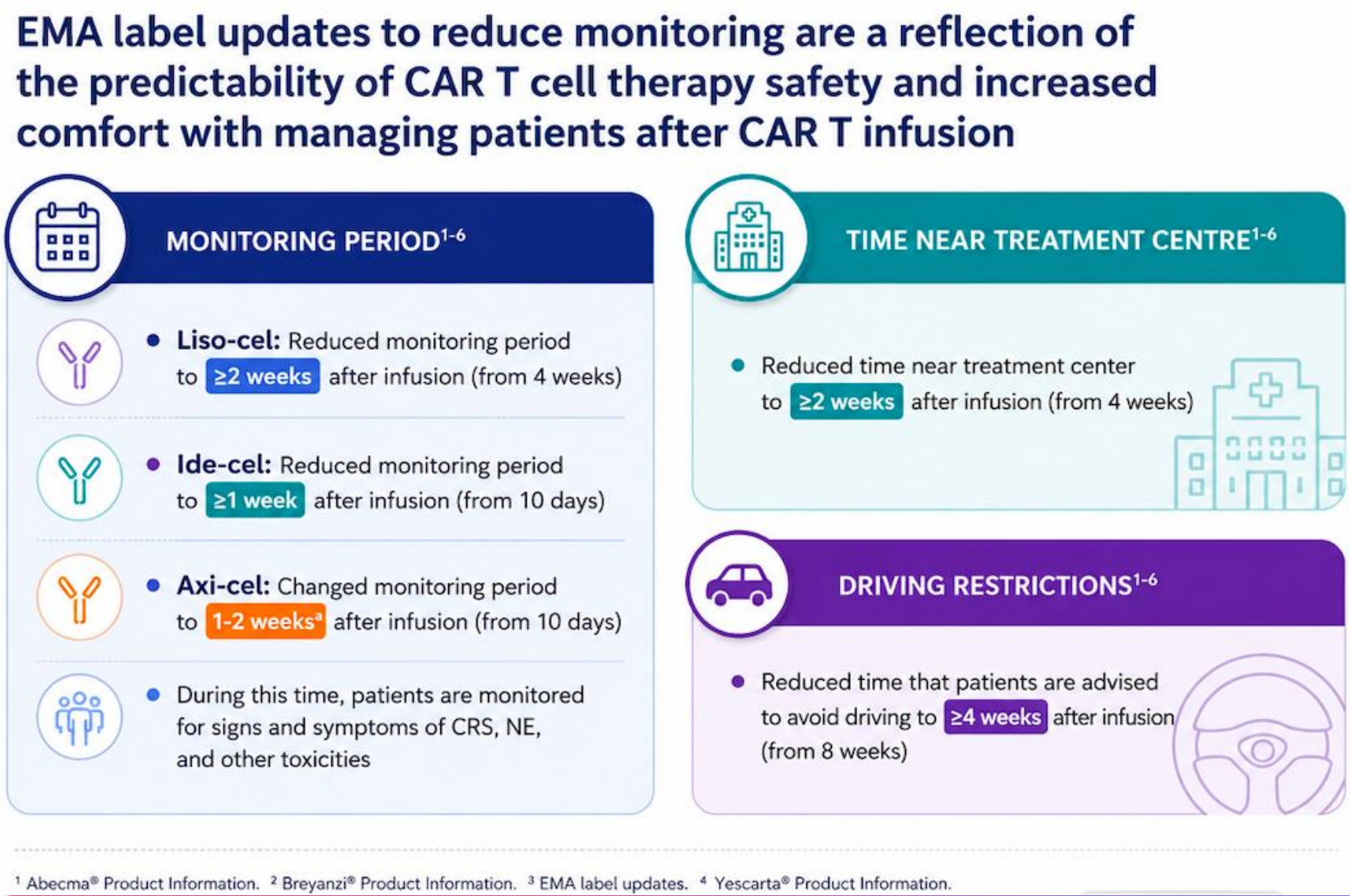
Patients without prior CRS or ICANS had numerically lower risks of new-onset CRS or ICANS

[a]Risk from that day onward.

AE, adverse event; CI, confidence interval; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

Orive-Maldonado V et al. EBMT 2026. Abstract #OS119-07.

ACTUALIZACIONES EN FICHA TÉCNICA

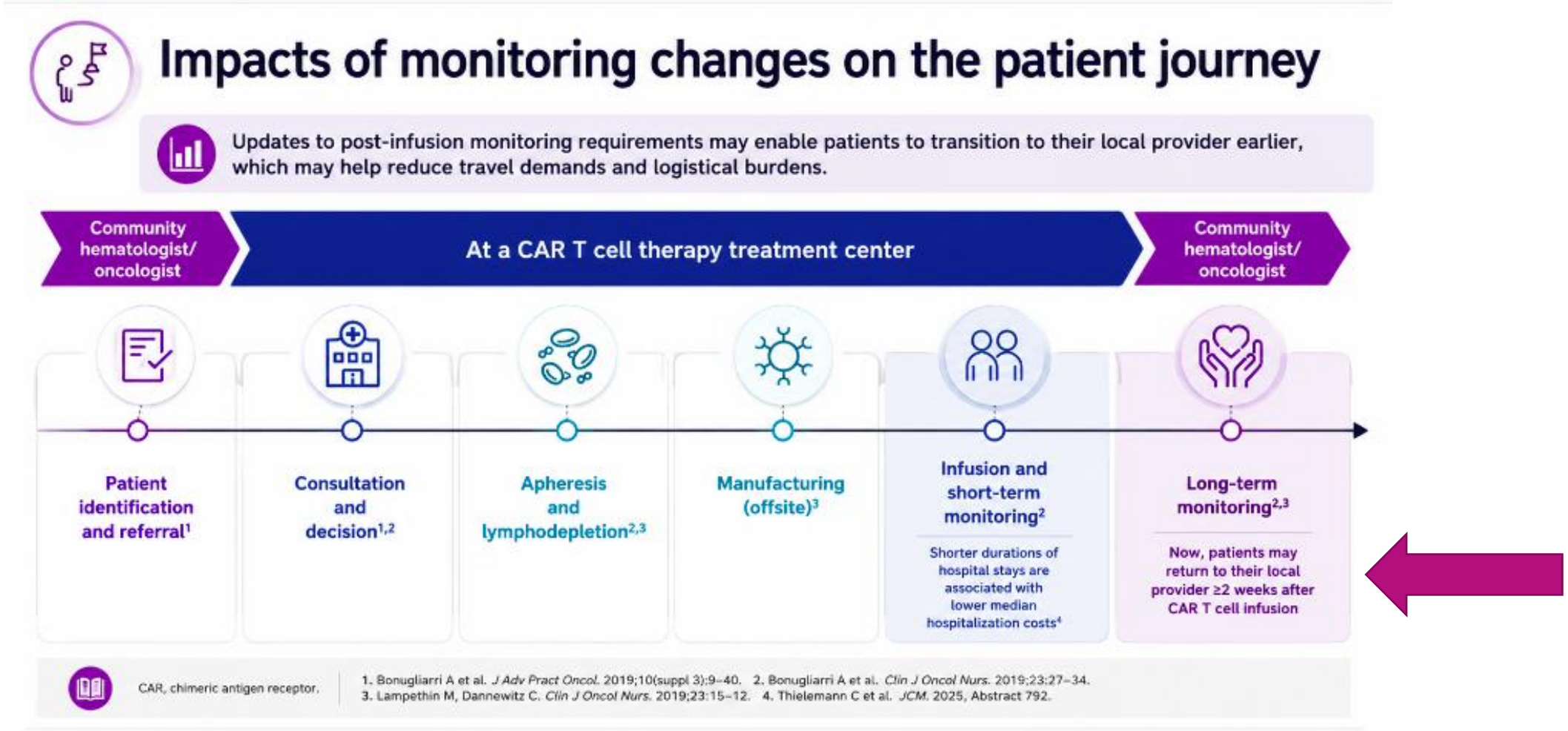


[1] Abecma® Product Information. [2] Breyanzi® Product Information. [3] EMA label updates. [4] Yescarta® Product Information.

RWE:
Datos seguridad

Relajación medidas

Impacto en la experiencia del paciente



What could an early discharge/outpatient CAR T model look like in Europe?

Case study (in BCP-ALL/MM)

In Spain, Hospital Clínic de Barcelona has adopted an "outpatient-at-home" (OATH) model for their CAR T program, where the patient remains in the outpatient setting during lymphodepletion, and then is supported by structured at-home monitoring.

Inclusion criteria:

- ✓ Stable without active toxicities
- ✓ ECOG PS ≤2
- ✓ 24-hour availability of a trained caregiver
- ✓ <30 minutes from home to hospital
- ✓ Low tumor burden

At-home timeline:

Pre-enrollment patient and caregiver health education:

- Symptom detection tools
- ICE score
- Adverse event action plan

-6 -5 -4 -3 -2 -1 0 1 2 3 14

At-home lymphodepletion:

- Fludarabine (30 mg/m²/d IV)
- Cyclophosphamide (300 mg/m²/d IV)

CAR T infusions (fractionated)

Patients monitoring:

- Twice-daily phone check-ins: Vitals & ICE score
- At-home evaluations & lab tests every 48–72 hours

24-hour support unit for managing urgent medical events

BCP-ALL, B-cell precursor acute lymphoblastic leukemia; CAR, chimeric antigen receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; ICE, immune effector cell-associated encephalopathy; IV, intravenous; MM, multiple myeloma; OATH, outpatient-at-home.

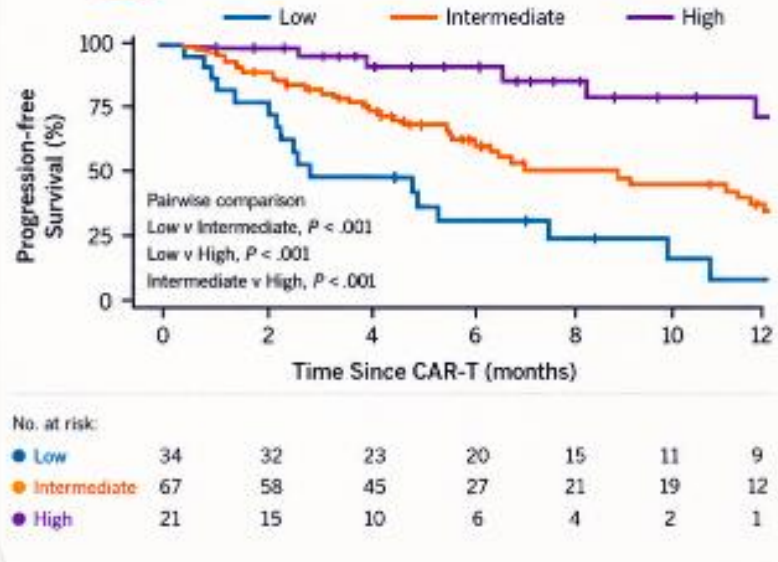
From "Expanding the Boundaries of CAR T-Cell Therapy: Implementation of an Outpatient-At-Home (OATH) Model", presented by Mufid XBM et al. at the 2024 ASH Annual Meeting. Reproduced with permission from Mufid XBM et al. Presented at ASH 2024. Abstract 6192.

EMERGING PROGNOSTIC TOOLS MAY HELP IDENTIFY OPTIMAL CAR T CANDIDATES

Multivariable modeling for early (≤5 mo) relapse/progression*

Factor	HR	95% CI	*P*	Score
EMD or PCL present	1.92	1.30 to 2.82	<.001	1
High-risk cytogenetics	1.95	1.31 to 2.92	.001	1
Ferritin > normal limit (sex-/age-adjusted)	1.59	1.07 to 2.37	.02	1
Lenalidomide refractoriness	1.69	1.02 to 2.82	.04	1
MyCARe risk				
LOW (score 0-1)	Ref	–	–	–
INT Intermediate (score 2-3)	3.27	1.87 to 5.72	<.001	–
HIGH (score 4)	7.89	4.21 to 14.79	<.001	–

PFS by risk (European cohort)



International, retrospective study of patients with RRMM treated with ide-cel or cilta-cel evaluating the MyCARe model to predict outcomes after anti-BCMA CAR T

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CI, confidence interval; EMD, extramedullary disease; HR, hazard ratio; PCL, plasma cell leukemia; PFS, progression-free survival; RRMM, relapsed/refractory multiple myeloma.

*Each risk factor received a score of 1 point, forming the MyCARe model. Scores ranged from 0 to 4, and three distinct risk groups were identified: score 0-1 (low), score 2-3 (intermediate), and a score of 4 (high risk).

Gagelmann N et al. Clin Oncol. 2024;42(14):1045-1057.

EDAD NO ES UN FACTOR LIMITANTE PARA LA ADMON DE CAR-T

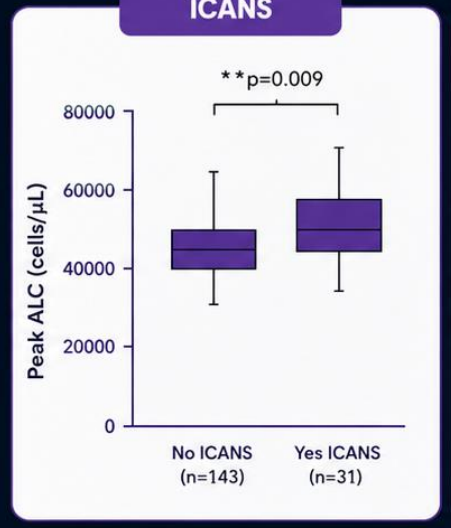
TOXICIDADES TARDÍAS…

EXPERIENCE WITH SIDE EFFECTS IN THE REAL WORLD HAS BEEN CONSISTENT WITH CLINICAL TRIALS

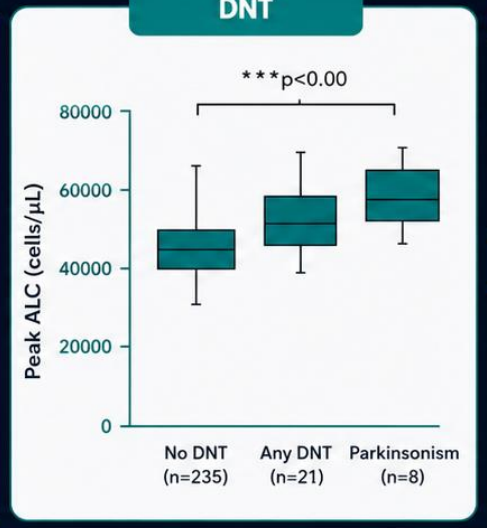
	PIVOTAL STUDIES			REAL-LIFE STUDIES	
	KarMMa (Ph.2)[1] n = 128	KarMMa-3 (Ph.3)[2] n = 250	CARTITUDE-1 (Ph 1b/2)[3] n = 97	Ide-cel French registry[4] n = 159	Cilta-cel US[5] n = 236
CRS	84% (5% gr 3-4)	88% (4% gr 3-4, 1% gr 5)	95% (4% gr 3-4, 1% gr 5)	90% (2% ≥ gr 3)	75% (4% gr 3-4, 1% gr 5)
Median time to onset of CRS, d (range)	1 (1-12)	1 (1-14)	7 (IQR: 5-8)	1 (0-16)	7 (0-14)
ICANS	18% (3% gr 3)	15% (3% gr 3-4)	17% (2% gr 3-4)	13% (4% ≥ gr 3)	14% (4% gr 3-4)
Median time to onset of ICANS, d (range)	2 (1-10)	3 (1-317)	8 (IQR: 3-6.5)	1.5 (0-7)	9 (1-51)
ONT	-	-	12% (8% gr 3-4)	0.6% (n=1)	10% (1% gr 5)
NRM	12%	13%	9%	5%	10%

US STUDY EVALUATED ASSOCIATION OF CAR T EXPANSION WITH RISK OF DELAYED NEUROTOXICITY (DNT)

ICANS



DNT



CLINICALLY ACTIONABLE ALC THRESHOLDS ASSOCIATED WITH DNT

	No DNT (n=235)	Any DNT (n=21)	Parkinsonism (n=8)
ALC>2000	56%	90%	100%
ALC>2500	48%	89%	100%
ALC>3000	38%	71%	**88%**
ALC>4000	26%	62%	75%
ALC>5000	21%	52%	75%
ALC>3000 or ALC>2500 and FC>2	41%	81%	88%

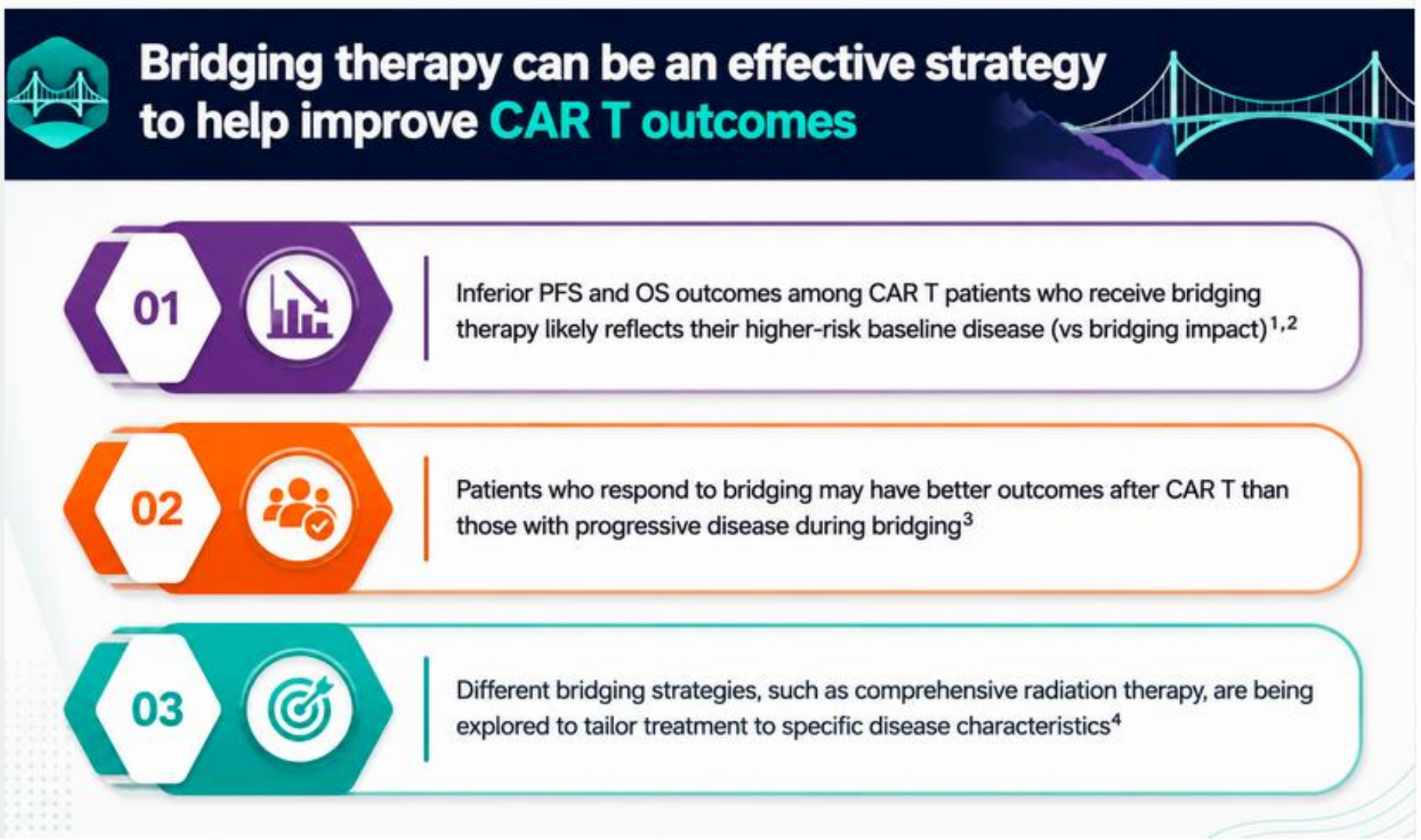
Peak ALC was higher in patients developing **ICANS** and **DNT**

ALC thresholds to stratify risk of DNT may help **risk mitigation** efforts in the clinic

ALC, absolute lymphocyte count; CAR, chimeric antigen; DNT, delayed neurotoxicity; FC, flow cytometry; ICANS, immune effector cell-associated neurotoxicity syndrome.

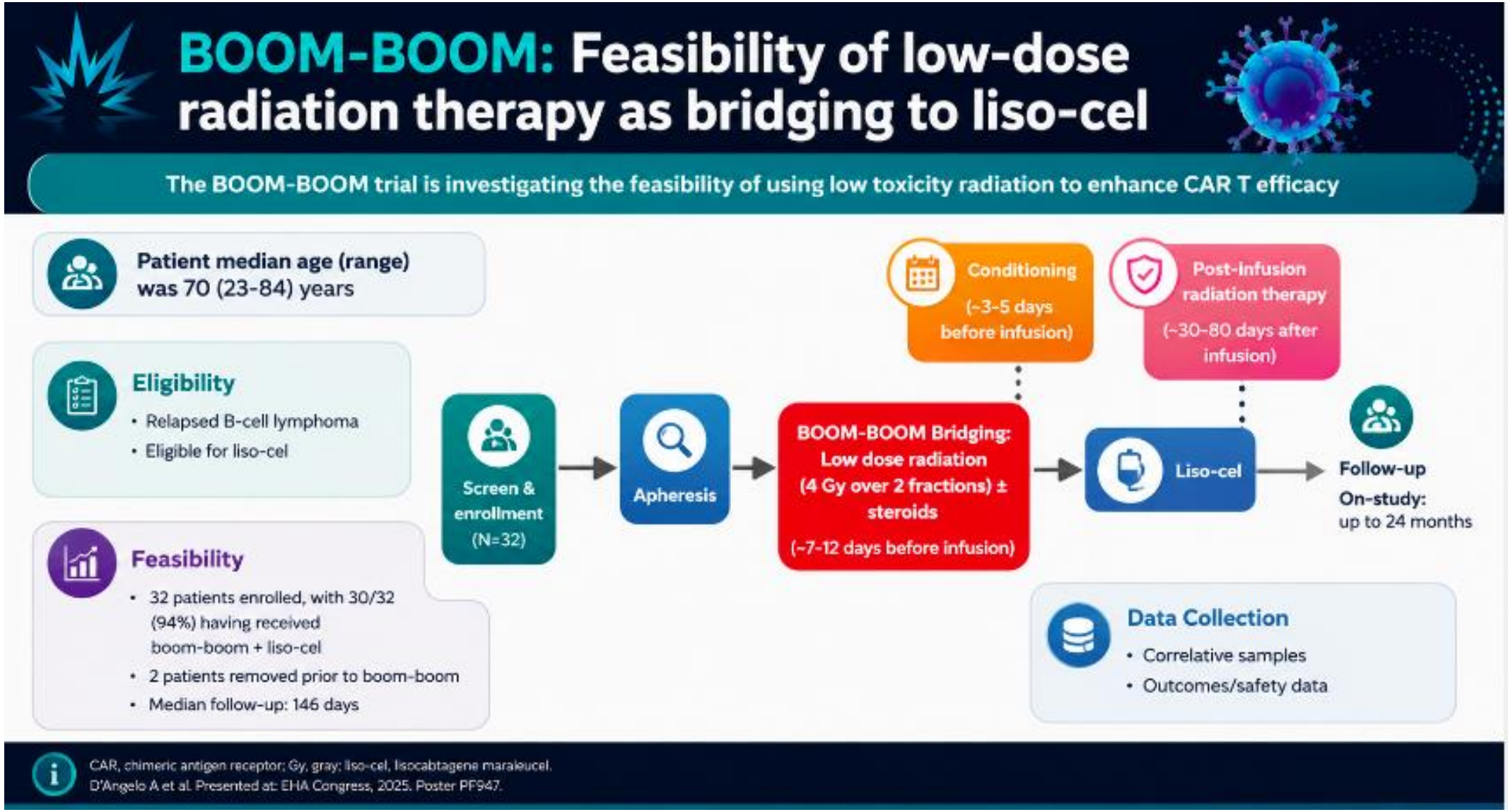
From: Pugh Jacob CAR-T Expansion & Neurotoxicity Following Ciltacabtagene Autoleucel In Multiple Myeloma' presented by Hosoya H at the 2025 ASH Annual Meeting. Reproduced with permission from the American Society of Hematology. Hosoya H et al. Presented at: ASH Annual Meetings; 2025. Abstract 96.

DESARROLLO DE TERAPIAS PUENTE EFICACES

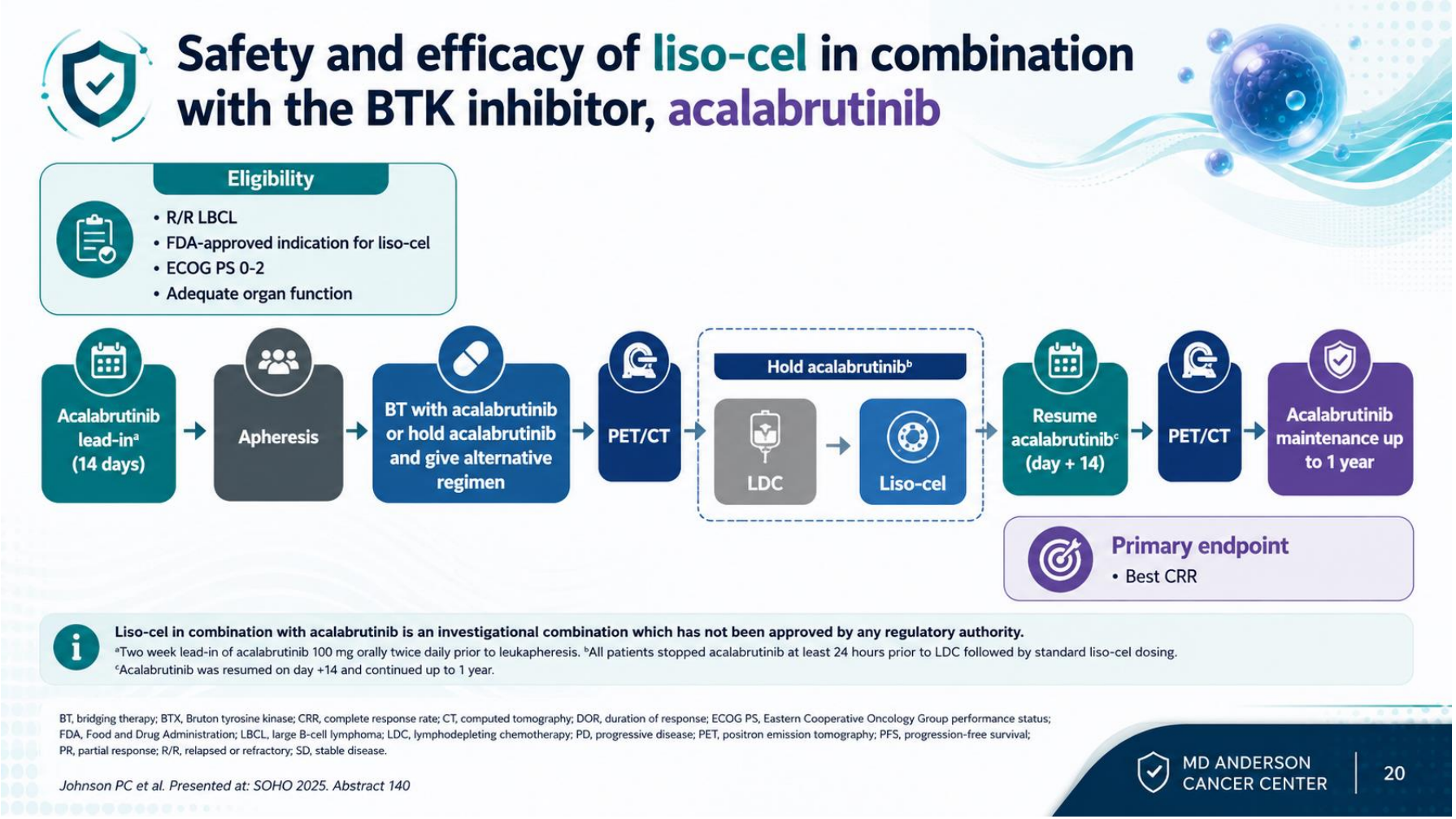


CAR, chimeric antigen receptor; OS, overall survival; PFS, progression-free survival.

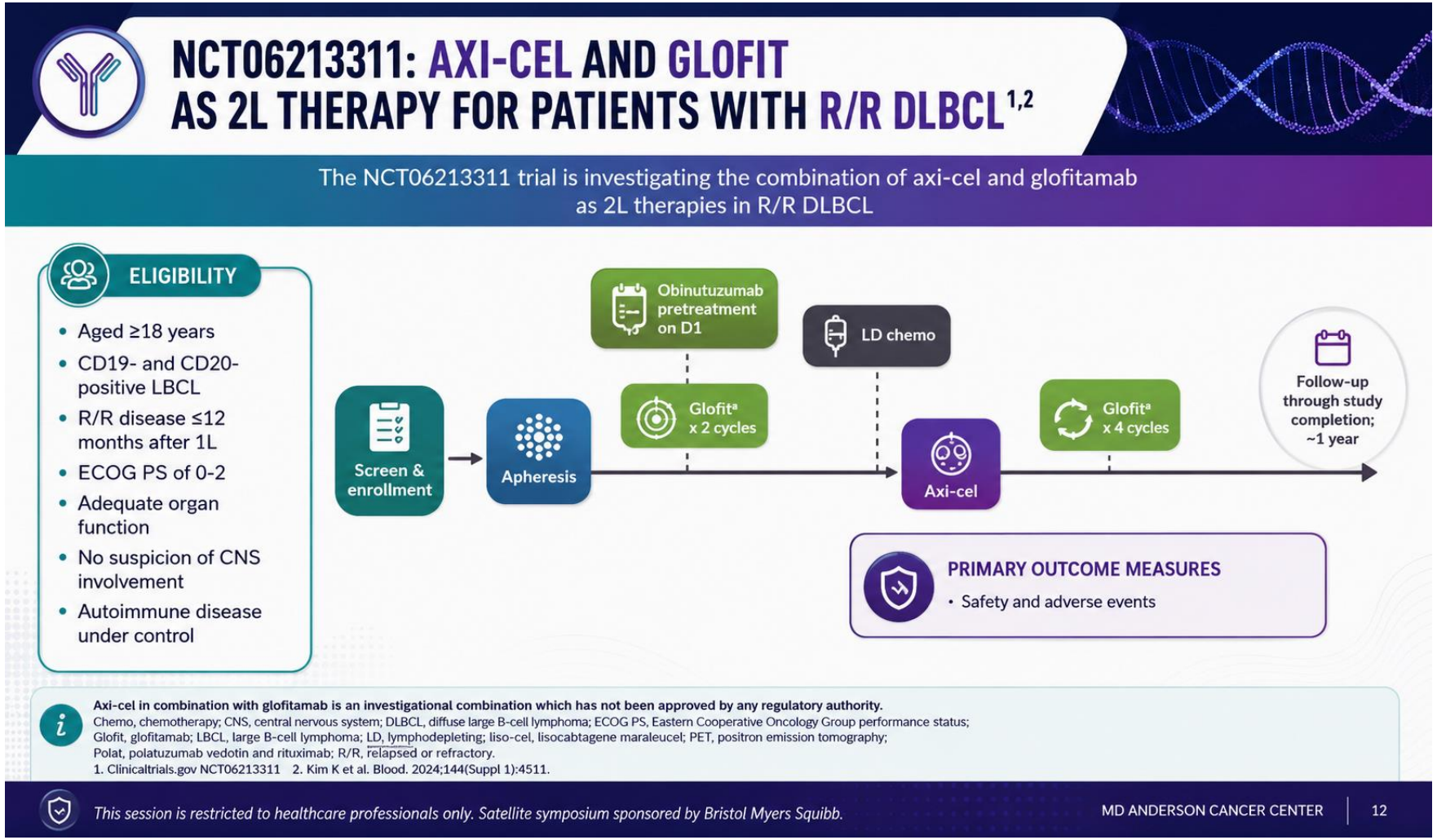
1. Pinnix CC et al. Blood Adv. 2020. 2. Jain MD et al. Blood Adv. 2024. 3. Roddie C et al. Blood Adv. 2023. 4. Saifi S et al. JAMA Oncol. 2024.


BOOM-BOOM: Feasibility of low-dose radiation therapy as bridging to liso-cel
The BOOM-BOOM trial is investigating the feasibility of using low toxicity radiation to enhance CAR T efficacy
Patient median age (range) was 70 (23-84) years
Eligibility
• Relapsed B-cell lymphoma
• Eligible for liso-cel
Feasibility
• 32 patients enrolled, with 30/32 (94%) having received boom-boom + liso-cel
• 2 patients removed prior to boom-boom
• Median follow-up: 146 days
Conditioning (~3-5 days before infusion)
Post-Infusion radiation therapy (~30-80 days after infusion)
Screen & enrollment (N=32)
Apheresis
BOOM-BOOM Bridging: Low dose radiation (4 Gy over 2 fractions) ± steroids (~7-12 days before infusion)
Liso-cel
Follow-up
On-study: up to 24 months
Data Collection
• Correlative samples
• Outcomes/safety data
CAR, chimeric antigen receptor; Gy, gray; liso-cel, lisocabtagene maraleucel.
D'Angelo A et al. Presented at: EHA Congress, 2025. Poster PF947.

¡NUEVAS COMBINACIONES!
BIESPECIFICO+iBTK acalabrutinib LDCGB



¡NUEVAS COMBINACIONES! BIESPECIFICO+CAR-T LDCGB R/R

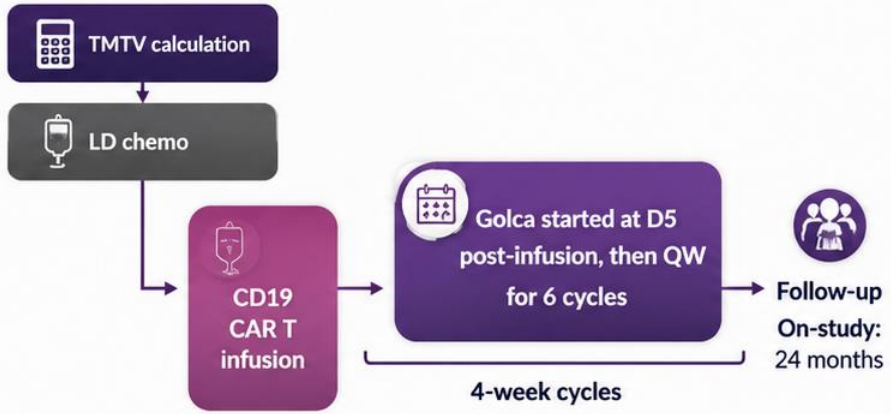


CARMOD: Golcadomide consolidation after CAR T for patients with R/R high-risk aggressive LBCL

The CARMOD trial is investigating the efficacy of the CELMoD agent golcadomide (Golca) as a post-CAR T treatment

Eligibility

- Aged ≥18 years
- ECOG PS of 0 or 1
- Aggressive LBCL (eg, DLBCL, PMBCL, tFL, MZL, HGBL, and CNS involvement[a])
- CAR T indication 2L–4L
- TMTV >80 mL by PET just before starting CAR T infusion



Primary endpoint

- CMR at 3 months

Secondary endpoints

- Efficacy (ORR, CRR, DOR, EFS, PFS, TTNT, OS)
- Safety

Lysarc
A CELMoD Company

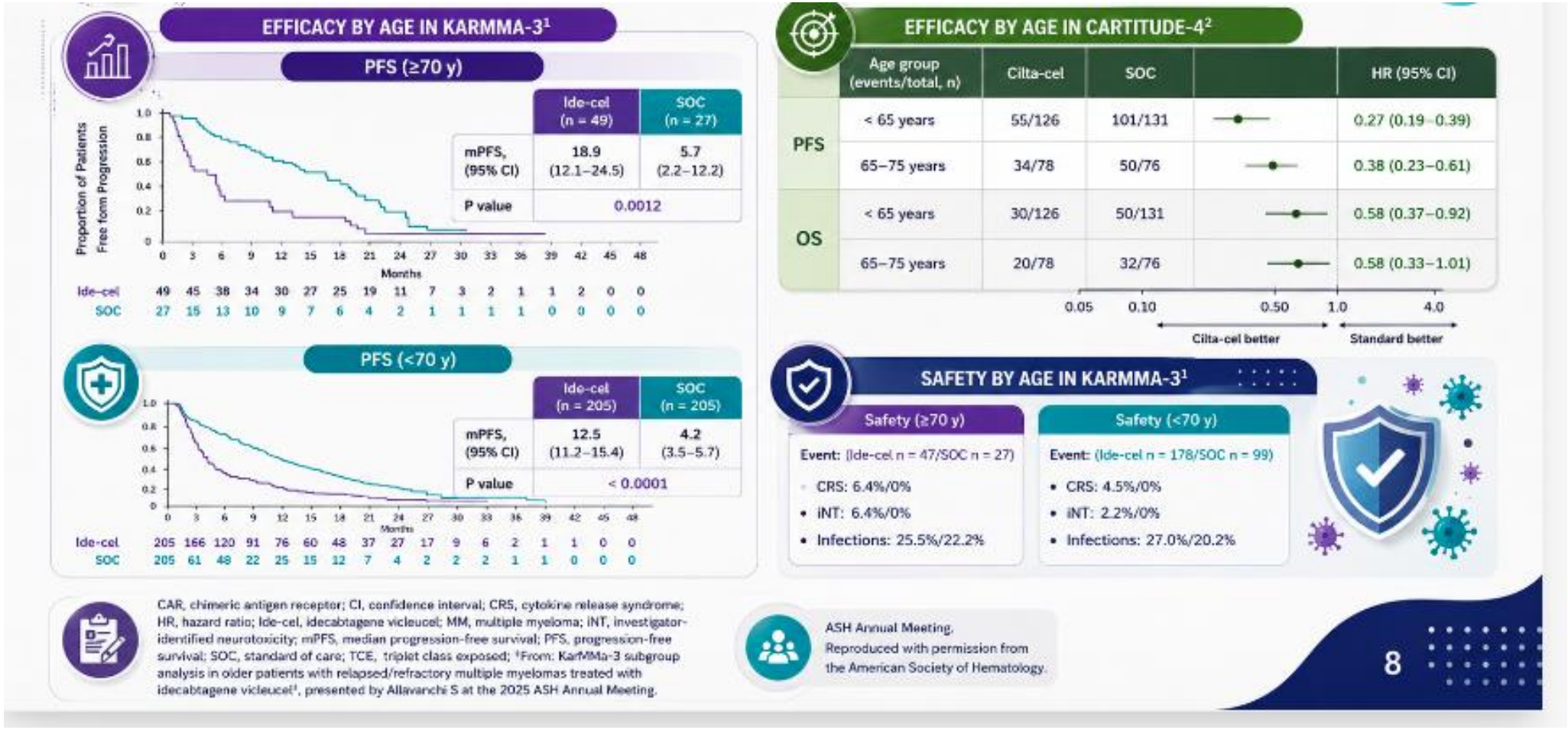
Golcadomide is an investigational combination which has not been approved by any regulatory authority.

[a]Patients with CNS involvement could be included but not patients with primary CNS lymphoma.

2L, second-line; 4L, fourth-line; CAR, chimeric antigen receptor; CELMoD, CELMoD agents; LD, lymphodepleting; days; CMR, complete metabolic response rate; CNS, central nervous system; CRR, complete response rate; D, day; DLBCL, diffuse large B-cell lymphoma; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; Golca, golcadomide; HGBL, high-grade B-cell lymphoma; LBCL, large B-cell lymphoma; LDC, lymphodepleting chemotherapy; MZL, marginal zone lymphoma; ORR, objective response rate; OS, overall survival; PET, positron emission tomography; PFS, progression-free survival; PMBCL, primary mediastinal large B-cell lymphoma; QW, weekly; tFL, follicular lymphoma; TTNT, time to next treatment; TMTV, total metabolic tumor volume.

Johnson PC et al. Presented at: SOHO 2025. Abstract 140

MM: BENEFICIOS PACIENTE MAYOR CAR-T



CAR, chimeric antigen receptor; CI, confidence interval; CRS, cytokine release syndrome; HR, hazard ratio; Ide-cel, idecabtagene vicleucel; MM, multiple myeloma; iNT, investigator-identified neurotoxicity; mPFS, median progression-free survival; PFS, progression-free survival; SOC, standard of care; TCE, triplet class exposed; [1]From: KarMMa-3 subgroup analysis in older patients with relapsed/refractory multiple myelomas treated with idecabtagene vicleucel[1], presented by Allavanchi S at the 2025 ASH Annual Meeting.

ASH Annual Meeting.
Reproduced with permission from the American Society of Hematology.

RESUMEN

- **RESUMEN**
- **01.** La terapia con células CAR T ha consolidado su posición en el paradigma de tratamiento de LDCGB y MM
- **02.** Más pacientes con linfoma y mieloma están logrando resultados no vistos hasta ahora.
- **03.** La **terapia puente puede sinergizarse** con la terapia con células CAR T para mejorar los resultados. OPTIMIZACIÓN
- **04: NUEVAS COMBINACIONES PERI-CAR-T en estudio**
- **05.** Necesitamos **herramientas** que nos permitan identificar a los *pacientes óptimos para estas terapias.*
- **06.** La edad no compromete el uso de terapias CAR T.

¡MUCHAS GRACIAS!

EHA2026 Congress