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INFUSED WITH KNOWLEDGE — Cell Therapy Talks

Axicabtagene ciloleucel▼ curative potential in R/R DLBCL

How might we **define cure in lymphoma**?

- **Plateau after treatment cessation**[1,2]
- **Length of follow-up**[1,3]
- **Survival comparable to the general population**[1,3,a]

Axi-cel has a wealth of data supporting its **curative potential** in R/R DLBCL[4–8]

ZUMA-1 (Ph1/2;n=101)[b] — Transplant eligible population[4,5] — 3L+

5-year

- **LREFS** (exploratory analysis): 33.5% (95% CI, 24.4–42.9)
- **OS** (secondary endpoint): 42.6% (95% CI, 32.8–51.9)

Grade ≥3[c] / All grade
- CRS: 11% / 93%
- NE: 30% / 64%

Approx. **4/5** patients alive at 5 years after axi-cel **may be considered cured**

ZUMA-7 (Ph3;n=180)[d] — Transplant eligible population[6,7,e] — 2L

4-year

- **EFS** (investigator-assessed): 38.9% (HR 0.42; 95% CI, 0.33–0.55)
- **PFS**: 42% (HR 0.51; 95% CI, 0.38–0.67)
- **OS**: 54.6% (95% CI, 47.0–61.6)

Grade ≥3 / All grade
- CRS: 6% / 92%
- NE: 21% / 60%

27% decrease in risk of death with axi-cel vs. ASCT
OS at Year 4 - 54.6% axi-cel vs 46.0% SoC (HR for death, 0.73; 95% CI, 0.54–0.98; P=0.03)

ALYCANTE (Ph2;n=62)[f] — Transplant ineligible population[8] — 2L

1-year

- **EFS**: 51.2% (95% CI, 38.2–62.8)
- **OS**: 78.3% (95% CI, 64.7–87.1)

Grade ≥3[c] / All grade
- CRS: 8% / 94%
- NE: 15% / 52%

Main reasons for ASCT ineligibility
- 88.7% Age ≥65 years[g]
- 32.3% HCT-CI score ≥3[h]

Please scroll down to view clinical trial data with liso-cel

Real-world evidence supports the benefits of CAR T, even in broader populations[9–11]

US Lymphoma CAR T Consortium (n=298)[9,10,i] — 3L

5-year

- **OS**: 40.3% (95% CI, 34.2–46.4)

Grade ≥3 / All grade
- CRS: 7% / 91%
- NE: 31% / 69%

CIBMTR (n=446)[11] — 2L

1-year

OS
- All patients: 71% (95% CI, 66–76)
- ZUMA-7 eligible: 80% (95% CI, 73–85)
- ZUMA-7 ineligible: 62% (95% CI, 53–69)

Grade ≥3[c] / All grade
- CRS: 5% / 87%
- NE: 22% / 50%

Main reasons for ineligibility
ZUMA-7 (49% of patients):
- Organ impairment (34%)
- Prior malignancy (16%)
- Infection (4%)
- ECOG PS >1 (3%)

MORE THAN 11,000 PATIENTS have been treated with axi-cel in real-world settings[11]

Please scroll down to view real-world data with liso-cel

Minimise the risk of eligible patients not being considered for potentially curative treatment with timely and reliable treatment[6,12–16]

Manufacturing outcomes

Clinical trials

	Median time from randomisation to infusion	Manufacturing success rate
Axi-cel ZUMA-7	29 days (IQR, 27–34)[6]	100%[j] [6]
Liso-cel TRANSFORM	34 days (IQR, 31–36)[12]	98%[k] [12]

Real-world settings[l]

	Manufacturing success rate	Delivery	TAT	Within spec
Axi-cel	95.8%[m] (2L;n=1703)[13]	99%[n] (n=3340)[13]	17 days[13]	98% (n=99)[14]
Liso-cel	NR	NR	NR	78–93% (n=50 and n=101)[14,15]

Dana-Farber Cancer Institute[16]
Median time from CAR T service referral to CAR T-cell infusion (days)

Referral → Enrolment → Apheresis → CAR T infusion

- **Liso-cel**: 81 days (IQR, 67-91)
- **Axi-cel**: 57 days (IQR, 53-68) — **24 fewer days**

Long-term AEs require close monitoring and management, with continued collaboration between referral and treatment centres[17–21,o]

- **Prolonged cytopenias**
- **Infections**
- **Hypogamma-globulinaemia**

Manage per local guidelines

- Manage with support from referral and treating centres → **Neurological & psychological events**
- **Secondary malignancies** ← Should be reported

Proactive management strategies to help optimise patient outcomes and support curative potential[22]

- Prehabilitation to optimise health/baseline fitness before CAR T infusion[23]
- Bridging therapy to reduce tumour burden may improve efficacy and safety outcomes with CAR T[24]
- Prophylactic, early and proactive AE management strategies may reduce incidence and severity of CRS and ICANS post-CAR T infusion[22,25]

Patient eligibility for CAR T-cell therapy[6,8,26,p]

- **R/R DLBCL ≤12 months of 1L therapy** ✓
- **Age ≤70 years / Age >70 years**[q] ✓
- **ECOG PS 1 / ECOG PS 2** ✓
- **Chemo-sensitive / Chemo-refractory** ✓
- **Well-managed comorbidities and adequate organ function**[r] ✓

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TRANSCEND (Ph2/3;n=270)[s] — Transplant eligible population[27,28] — 3L+

5-year
- **DSS**: 52% (95% CI, 45.0–59.0)
- **OS**: 38% (95% CI, 32.0–45.0)

Grade ≥3 / All grade
- CRS: 2% / 42%
- NE: 10% / 30%

TRANSFORM (Ph3;n=92)[t] — Transplant eligible population[29] — 2L

3-year
- **EFS**: 46% (95% CI, 35.2–56.5)
- **PFS**: 51% (95% CI, 39.9–62.0)
- **OS**: 63% (95% CI, 52.7–72.9)

Grade ≥3 / All grade
- CRS: 2% / 49%
- NE: 4% / 11%

PILOT (Ph2;n=61)[u] — Transplant ineligible population[30,31] — 2L

1-year
- **EFS**: 43% (95% CI, 30.2–55.3)
- **OS**: 70% (95% CI, 56.1–80.3)

Grade ≥3 / All grade
- CRS: 2% / 38%
- NE: 5% / 31%

RW (n=157)[32] — 2L

0.5-year

OS
- All patients: 87% (95% CI, 80.0–92.0)
- TRANSFORM eligible[v]: 90% (95% CI, 76.0–96.0)
- TRANSFORM ineligible: 85% (95% CI, 76.0–91.0)

Grade ≥3 / All grade
- CRS: <1% / 45%
- NE: 6% / 20%

Main reasons for ineligibility
TRANSFORM (67% of patients):
- Age ≥75 years (42%)
- Severity of comorbitities
- ECOG PS >1 (5%)

Disclaimer
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- ▶ Axicabtagene ciloleucel is indicated for the treatment of adult patients with R/R DLBCL and PMBCL, after two or more lines of systemic therapy
- ▶ Axicabtagene ciloleucel is indicated for the treatment of adult patients with DLBCL and HGBL that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy
- ▶ Axicabtagene ciloleucel is indicated for the treatment of adult patients with R/R FL after three or more lines of systemic therapy
- ▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Footnotes
[a]Based on extrapolations from data derived from first-line treatment settings; [b]ZUMA-1 was a multicentre, single-arm study assessing axi-cel in patients with R/R LBCL (primary endpoint: investigator-assessed ORR [83%; 95% CI, 74–90]); data presented are secondary endpoints; [c]Beyond 1 month; [d]Randomised, multicentre trial of axi-cel vs SoC (chemo + HDCT ± ASCT) in patients with R/R LBCL (primary endpoint: mEFS by central review [8.3 months vs SOC 2.0 months]); data presented are secondary endpoints; [e]SoC 2L treatment in the curative setting for patients with R/R LBCL is high-dose chemotherapy with ASCT if the disease is responsive to salvage chemoimmunotherapy; [f]Single-arm study assessing axi-cel in patients with high-risk R/R LBCL deemed ineligible for ASCT (primary endpoint: CMR at 3 months [71%; 95% CI, 58.1–81.8%]); data presented are secondary endpoints; [g]There is limited experience with axi-cel in patients ≥ 75 years of age. Generally, safety profile and efficacy were similar between patients ≥ 65 years and patients < 65 years of age treated with axi-cel; [h]Patients with active central nervous system (CNS) disorder or inadequate renal, hepatic, pulmonary, or cardiac function are likely to be more vulnerable to the consequences of the adverse reactions and require special attention; [i]275 patients received axi-cel infusion; [j]For patients who underwent leukapheresis; [k]One patient underwent leukapheresis but did not receive CAR T cells and one patient received non-conforming product; [l]These data are from a retrospective analysis conducted at a single treatment centre (Dana-Farber Cancer Institute) and may not reflect the experience of other centres; [m]Among patients in 2L (n/N=1631/1703); [n]For all patients in 2023; [o]AEs shown are not exhaustive considerations post CAR T; please refer to product SmPCs for more information; [p]Please refer to your local reimbursement criteria; [q]There is limited experience in patients ≥75 years of age[33]; [r]Patients with inadequate renal, hepatic, pulmonary or cardiac function are likely to be more vulnerable to the consequences of adverse reactions and require special attention[33]; [s]Multicentre study assessing liso-cel in patients with R/R LBCL (primary endpoints: safety and ORR by independent review [73%; 95% CI, 66.8–78.0]); efficacy data presented are from the LTFU study; [t]Multicentre study assesing liso-cel vs SoC in transplant-eligible patients with primary refractory or early relapsed LBCL (primary endpoint: EFS data presented - 45.8% liso-cel, 19.1% SoC; HR 0.375 [95% CI, 0.259–0.542]); PFS and OS data presented are secondary endpoints; [u]Single-arm study assessing liso-cel in patients with R/R LBCL who were deemed ineligible for ASCT (primary endpoint: ORR [80%; 95% CI, 68.2–89.4]); data presented are secondary endpoints; [v]Patient subgroup includes those who have unknown eligibility status.

Abbreviations
1L, first line; 2L, second line; 3L, third line; 3L+, third line or later; AE, adverse event; ASCT, autologous stem-cell transplant; CAR T, chimeric antigen T-cell; CI, confidence interval; CIBMTR, Center for International Blood and Marrow Transplant Research; CRS, cytokine release syndrome; DLBCL, diffuse large B-cell lymphoma; DSS, disease-specific survival; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; HCT-CI, haematopoietic cell transplantation-specific comorbidity index; HR, hazard ratio; ICANS, immune effector cell-associated neurotoxicity syndrome; IQR, interquartile range; LREFS, lymphoma-related event-free survival; LTFU, long-term follow-up; NE, neurological event; NR, not reported; OS, overall survival; PFS, progression-free survival; R/R, relapsed/refractory; RW, real-world; SoC, standard of care; TAT, turnaround time.

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