Long-Term Clinical Outcomes and Correlative Efficacy Analyses in Patients with Relapsed/Refractory Follicular Lymphoma Treated with Tisagenlecleucel in the ELARA Trial


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Introduction

- FL is an indolent lymphoma subtype, however often requiring multiple lines of treatment.\(^1,2\)

- Patients with relapsed high-risk (POD24, high baseline tumor burden) have a poor prognosis, with the need for effective therapeutic options.\(^3-5\)

- Tisagenlecleucel demonstrated high response rates (ORR 86%, CRR 69%)\(^6\) and durable responses (12-month PFS rate of 67%)\(^7\) in the ELARA trial.

- Here, we present the continued durability of response, longer-term safety, and exploratory correlative biomarker analyses of patients with r/r FL treated with tisagenlecleucel after a prolonged median follow-up of 29 months.

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CAR, chimeric antigen receptor; CRR, complete response rate; FL, follicular lymphoma; NHL, non-Hodgkin lymphoma; ORR, overall response rate; PFS, progression-free survival; POD24, progression of disease within 2 years of initial chemotherapy; r/r relapsed or refractory.

ELARA Study Design

Screening, apheresis, and cryopreservation

Optional bridging chemotherapy

Enrollment

Tisagenlecleucel manufacturing

Restaging, lymphodepletion

Tisagenlecleucel infusion

First efficacy assessment
Month 3

Long-term safety and efficacy follow-up

Key eligibility criteria

Study treatment

End points

• ≥18 years of age
• FL grade 1, 2, or 3A
• Relapsed/refractory disease
• No evidence of histological transformation/FL3B
• No prior anti-CD19 therapy or allogeneic HSCT

Tisagenlecleucel dose range (single IV infusion) was 0.6-6x10^8 CAR-positive viable T cells

Primary: CRR by IRC

Secondary: ORR, DOR, PFS, OS, safety, cellular kinetics

• Bridging therapy was allowed and was followed by disease re-evaluation before tisagenlecleucel infusion
• 18% (17/97) of patients received tisagenlecleucel in the outpatient setting

CAR, chimeric antigen receptor; CD, cluster of differentiation; CRR, complete response rate; DOR, duration of response; FL, follicular lymphoma; FL3B, FL grade 3B; HSCT, hematopoietic stem cell transplant; IQR, interquartile range; IRC, independent review committee; IV, intravenous; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

a Disease was reassessed prior to infusion for all patients requiring bridging therapy.

b Infusion was conducted on an in- or outpatient basis at investigator discretion. c Every 3 months until Month 12, and every 6 months until end of study. d Refractory to ≥2nd line of systemic therapy (including an anti-CD20 antibody and alkylating agent) or relapsed within 6 months after ≥2nd line of therapy or after an autologous HSCT.

Median follow-up: 29 months (IQR 26-32)
# ELARA: Adverse Events of Special Interest

<table>
<thead>
<tr>
<th>Selected Adverse Events Anytime Post Infusion</th>
<th>Safety Analysis Set(^a) (N=97)</th>
<th>All Grade, n (%)</th>
<th>Grade ≥3, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients with at least 1 AE</td>
<td>73 (75)</td>
<td>45 (46)</td>
<td></td>
</tr>
<tr>
<td>CRS(^b,c)</td>
<td>47 (49)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hematological disorders including cytopenias</td>
<td>45 (46)</td>
<td>43 (44)</td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>23 (24)</td>
<td>23 (24)</td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>13 (13)</td>
<td>7 (7)</td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>6 (6)</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>Infections</td>
<td>16 (17)</td>
<td>9 (9)</td>
<td></td>
</tr>
<tr>
<td>Hypogammaglobulinemia</td>
<td>11 (11)</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>Serious neurological adverse events</td>
<td>8 (8)</td>
<td>2 (2)</td>
<td></td>
</tr>
<tr>
<td>ICANS</td>
<td>4 (4)</td>
<td>1 (1)</td>
<td></td>
</tr>
</tbody>
</table>

### Specific Adverse Events

- **No new safety signals** were reported in this long-term analysis.
- One patient developed HLH >1 year after receiving tisagenlecleucel.
- Rate of all-grade serious neurological events was 8% and 2% were grade ≥3.
- The 17 (18%) patients who received tisagenlecleucel in the outpatient setting required no ICU care, and one-third did not require hospitalization for AE management.
- Twenty-two patients (23%) received ≥1 new antineoplastic medication after tisagenlecleucel, mostly due to stable disease or progressive disease.

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\(^a\) All patients infused with tisagenlecleucel. \(^b\) CRS was graded using Lee scale 2014. \(^c\) Refers to first CRS episode only. \(^d\) Out of total 13 deaths (study indication=7; other=6). \(^e\) 3 were new deaths occurred during this longer-term follow-up period (PD, n=1; SAE, n=2, urothelial bladder carcinoma and post alloSCT complications). \(^f\) The patient did not have CRS during or immediately preceding HLH. The HLH fatal event occurred on Day 375 and was considered drug-related by the physician.

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**Note:** Two patients experienced a secondary malignancy during this longer-term follow-up (squamous cell carcinoma and bladder transitional cell carcinoma); neither was considered related to study treatment. Eight patients had SARS-CoV2 infection at the time of data cutoff. Table summarizes selected adverse events anytime post infusion suspected to be related to tisagenlecleucel.

Presented at the 2022 ASH Annual Meeting and Exposition; December 10-13, 2022; New Orleans, LA, USA, and Virtual
ELARA: Tisagenlecleucel Induced Consistently High Responses in All Patients, Including, High-Risk Patient Populations

Endpoint in Efficacy Analysis Set (IRC Assessment) | % (95% CI) N=94
--- | ---
CRR | 68 (58-77)<sup>b</sup>
ORR | 86 (78-92)<sup>b</sup>

- High ORR (86%) and CRR (69%) are consistent with the primary analysis<sup>1</sup>

Baseline Disease Characteristic | All Patients n (%): N=97 | CRR % (95% CI) | ORR % (95% CI)
--- | --- | --- | ---
POD24 | 61 (63) | 59 (46-71) | 82 (70-91)
High metabolic tumor volume<sup>d</sup> | 20 (21) | 40 (19-64) | 75 (51-91)
Bulky disease<sup>e</sup> | 62 (64) | 65 (51-76) | 86 (74-93)
Double refractory | 65 (67) | 66 (53-77) | 85 (74-92)
High FLIPI (≥3) | 57 (59) | 61 (48-74) | 81 (68-90)

- High rates of durable responses were observed in most patients in high-risk disease subgroups who have poor prognosis with current non-CAR-T cell therapies

BM, bone marrow; CAR, chimeric antigen receptor; CR, complete response; CRR, CR rate; FLIPI, Follicular Lymphoma International Prognostic Index; IRC, independent review committee; ORR, overall response rate; POD24, progression of disease within 2 years of initial chemotherapy; PR, partial response; TMTV, total metabolic tumor volume.

<sup>a</sup>One patient in CR downgraded to PR due to confirmatory BM biopsy performed out of window. <sup>b</sup>The 95% exact Clopper-Pearson CIs are displayed. As the primary endpoint was met at interim analysis (<0.0001, at 1-sided 0.0025 level to reject the null hypothesis: CRR ≤15%), no formal significance testing was conducted at extended follow-up analysis. <sup>c</sup>ORR is defined as the proportion of patients with a best overall disease response of CR or PR. <sup>d</sup>TMTV >510 cm<sup>3</sup>. <sup>e</sup>Any nodal or extra nodal tumor mass that is >7 cm in diameter or involvement of at least 3 nodal sites, each with a diameter >3 cm.

ELARA: Median DOR Was Not Reached After a Median Follow-Up of 29 Months

Note: None of the patients received reinfusion of tisagenlecleucel; 1 patient received subsequent antineoplastic treatment while in remission.

CR, complete response; DOR, duration of response; IRC, independent review committee; NE, not estimable; PR, partial response.

Note: DOR is per IRC assessment. Censoring times are shown as squares.

Kaplan-Meier medians

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0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30
0 20 40 60 80 100

Probability of event-free (%)

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0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100

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Probability of event-free (%)
ELARA: Median PFS and OS Were Not Reached After a Median Follow-Up of 29 Months

**PFS**

- Kaplan-Meier medians:
  - All patients: NE months, 95% CI [18-NE]
  - CR: NE months, 95% CI [NE-NE]
  - PR: 6 months, 95% CI [5-6]

**OS**

- Kaplan-Meier medians:
  - All patients: NE months, 95% CI [35-NE]
  - CR: 35 months, 95% CI [35-NE]
  - PR: 26 months, 95% CI [24-NE]

**Event-free Probability**

- **PFS**:
  - 12-month PFS, all patients: 67 (56-76)
  - 24-month PFS, all patients: 57 (46-67)
  - 12-month PFS, patients in CR: 87 (76-93)
  - 24-month PFS, patients in CR: 75 (62-84)

- **OS**:
  - 12-month OS, all patients: 95 (88-98)
  - 24-month OS, all patients: 88 (78-93)
  - 12-month OS, patients in CR: 98 (89-100)
  - 24-month OS, patients in CR: 95 (85-98)

**Number of patients still at risk**

- **PFS**:
  - All patients (N=94): 94, 90, 78, 67, 63, 59, 57, 54, 54, 54, 49, 47, 47, 32, 19, 19, 6, 0, 0
  - CR (N=64): 64, 64, 64, 61, 60, 56, 54, 52, 52, 52, 47, 45, 45, 31, 18, 18, 5, 0, 0
  - PR (N=17): 17, 16, 13, 5, 3, 3, 3, 2, 2, 2, 2, 2, 1, 1, 1, 1, 1, 0, 0

- **OS**:
  - All patients (N=94): 94, 93, 92, 91, 84, 81, 81, 79, 78, 78, 75, 69, 55, 38, 32, 19, 9, 4, 2, 0
  - CR (N=64): 64, 64, 64, 64, 62, 60, 58, 58, 58, 56, 52, 45, 32, 27, 16, 7, 3, 1, 0
  - PR (N=17): 17, 16, 16, 16, 13, 13, 13, 13, 12, 12, 11, 9, 4, 2, 1, 1, 1, 0, 0, 0, 0

BOR: best overall response; CR: complete response; IRC: independent review committee; NE: not estimable; OS: overall survival; PFS: progression-free survival; PR: partial response.

Note: PFS and OS by BOR curves are per IRC assessment. Censoring times are shown as squares.

Presented at the 2022 ASH Annual Meeting and Exposition; December 10-13, 2022; New Orleans, LA, USA, and Virtual
ELARA: Median Time to Start of New Antilymphoma Therapy Was Not Reached After a Median Follow-Up of 29 Months

Eighteen patients (19%) experienced prolonged depletion of normal B cells/agammaglobulinemia post infusion and were ongoing in 11 patients at the time of data cutoff or death; none of these AEs were serious or led to fatal infections. Censoring times are shown as squares.
ELARA: Higher Baseline Tumor Burden Was Associated with Shorter PFS

**PFS by Metabolic Tumor Volume**

![Graph showing PFS by Metabolic Tumor Volume](image)

**DOR by Metabolic Tumor Volume**

![Graph showing DOR by Metabolic Tumor Volume](image)

DOR, duration of response; PFS, progression-free survival; TMTV, total metabolic tumor volume.

Note: Low risk = TMTV <510 cm$^3$ and high risk = TMTV ≥510 cm$^3$.

Presented at the 2022 ASH Annual Meeting and Exposition; December 10-13, 2022; New Orleans, LA, USA, and Virtual
ELARA: Lower Tumor-Infiltrated LAG3+ Exhausted T Cells Was Associated with Longer DOR and PFS

- In an exploratory analysis, POD24, nodal area involvement, tumor volume, and LAG3+ % among T cells in TME remained prognostic for PFS separation in multivariate Cox model

- Lower LAG3+ exhausted T cells (<3% of total T cells), representing a favorable TME, was significantly associated with longer DOR and PFS

Fluorescence Immunohistochemistry

![Fluorescence Immunohistochemistry Image](image)

AQUA, automated quantitative analysis; CD, cluster of differentiation; DAPI, 4′,6-diamidino-2-phenylindole; DOR, duration of response; LAG, lymphocyte activation gene; NK, natural killer; PD-1, programmed cell death protein 1; PFS, progression-free survival; POD24, progression of disease within 2 years of initial chemotherapy; TIM, T-cell immunoglobulin and mucin domain-3; TME, tumor microenvironment.

Note: Archival tumor biopsies were available for 67 of 97 infused patients. TME (CD19 expression, total CD3+ T cells and exhausted subsets expressing PD-1, TIM3, and LAG3, and myeloid-derived suppressor cells) was characterized by fluorescence immunohistocemistry. Fluorescent images were acquired via PhenoImagerHT (Akoya Biosciences) at ×20 using various channels, including DAPI, Opal 520, Opal 570, and Opal 620, depending on the biomarker. Images were analyzed by proprietary analysis algorithms AQUA®.

Factors included in the multivariate Cox analysis: Clinical factors; clinical lab measurements; TME characteristics; cytokines; soluble factors; blood T, B, and NK cell counts.


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ELARA: Lower Pre-LD Serum TNF-α and IL-10 Levels Correlated with Lower Tumor Volume and Prolonged PFS

- Lower TNF-α and IL-10 levels, representing less inflammatory state, were associated with prolonged PFS

TNF-α vs. Tumor Volume

TNF-α and PFS

IL-10 vs. Tumor Volume

IL-10 and PFS

FL, follicular lymphoma; IL, interleukin; LD, lymphodepleting; PD-1, programmed cell death protein 1; PFS, progression-free survival; TNF, tumor necrosis factor.

Note: R: Spearman correlation coefficient.

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Conclusions

- Median DOR, PFS, and OS were not reached in the ELARA trial after >2 years of follow-up

- Tisagenlecleucel induced high rates of durable responses in all patients including those with high-risk disease characteristics such as POD24 and high baseline tumor burden, superior to published data\textsuperscript{1-11}

- Tisagenlecleucel was found to be well-tolerated and feasible for outpatient administration

- Exploratory biomarker analyses suggest that a favorable TME (low tumor infiltration of LAG3+ exhausted T cells) and decreased inflammatory status were associated with improved clinical outcomes

- Extended follow-up of >2 years from the ELARA trial continues to demonstrate durable efficacy and a favorable safety profile following tisagenlecleucel in patients with r/r FL

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  - The principal investigators and support staff
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