Nathan H. Fowler, MD | nathan.fowler@bostongene.com

Poster# **IBCL-1066**

ELARA Phase 2 Clinical Outcomes for Tisagenlecleucel in Patients With High-Risk Relapsed/Refractory Follicular Lymphoma: 4-Year Update

Catherine Thieblemont, MD[1]; Martin Dreyling, MD[2]; Michael J. Dickinson, MBBS, D Med Sci, FRACP, FRCPA[3]; Joaquin Martinez-Lopez, MD, PhD[4]; Arne Kolstad, MD, PhD[5]; Jason Butler, MBBS[6]; Monalisa Ghosh, MD[7]; Leslie L. Popplewell, MD, FACP, MPH[8]; Julio C. Chavez, MD[9]; Emmanuel Bachy, MD, PhD[10]; Koji Kato, MD, PhD[11]; Hideo Harigae, MD, PhD[12]; Marie José Kersten, MD, PhD[13]; Charalambos Andreadis, MD, MS[14]; Peter A. Riedell, MD[15]; P. Joy Ho, MBBS, FRACP, FRCPA[16]; Jose Antonio Pérez Simon, MD, PhD[17]; Andy Chen, MD, PhD[18]; Loretta J. Nastoupil, MD[19]; Bastian von Tresckow, MD[20,21]; Andrés José María Ferreri, MD[22]; Takanori Teshima, MD, PhD[23]; Piers E.M. Patten, MBChB, FRCP, FRCPath, PhD[24]; Joseph P. McGuirk, DO[25]; Fritz Offner, MD, PhD[26]; Andreas Viardot, MD, PhD[27]; Pier Luigi Zinzani, MD, PhD[28,29]; Ram Malladi, MD, PhD[30]; Aiesha Zia, MSc[31]; Rakesh Awasthi, PhD[32]; Davide Germano, PhD[31]; Roberto Javier Ramos, MD[32]; Pei Hsu, MD[31]; Stephen J. Schuster, MD[33]; **Nathan H. Fowler, MD**[34]

[1]Service d'hémato-oncologie, Hôpital Saint-Louis, Paris, France; [2]Department of Medicine III, Ludwig-Maximilians-University Hospital, Munich, Germany; [3]Sir Peter MacCallum Department of Oncology, The University of Melbourne, Melbourne, VIC, Australia; [4]Hospital Universitario 12 de Octubre, CIBER-ONC CB16/12/00369, CNIO, Madrid, Spain; [5]Oslo University Hospital, Oslo, Norway; [6]Royal Brisbane Hospital, Herston, QLD, Australia; [7]Division of Hematology/Oncology, University of Michigan, Ann Arbor, MI; [8]Department of Hematology and Hematopoietic Cell Transplantation, City of Hope, Atlanta, GA; [9]Department of Malignant Hematology, Moffitt Cancer Center, Tampa, FL; [10]Clinical Hematology, Hospices Civils de Lyon and Claude Bernard Lyon 1 University, Lyon, France; [11]Department of Hematology, Oncology, and Cardiovascular Medicine, Kyushu University Hospital, Fukuoka, Japan; [12]Department of Hematology, Tohoku University Graduate School of Medicine, Sendai, Japan; [13]Cancer Center Amsterdam, Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, Netherlands; [14]Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco, CA; [15]David and Ellа Jonas Center for Cellular Therapy, University of Chicago, Chicago, IL; [16]Royal Prince Alfred Hospital & University of Sydney, Sydney, NSW, Australia; [17]Department of Hematology, University Hospital Virgen del Rocio-IBIS, Universidad de Sevilla, Sevilla, Spain; [18]Oregon Health and Science University, Portland, OR; [19]The University of Texas MD Anderson Cancer Center, Houston, TX; [20]Department I of Internal Medicine, Medical Faculty and University Hospital Cologne, University of Cologne, Cologne, Germany; [21]Department of Hematology and Stem Cell Transplantation, West German Cancer Center (WTZ), University Hospital Essen, University of Duisburg-Essen, Essen, Germany; [22]Unit of Lymphoid Malignancies, Department of Onco-Haematology, IRCCS San Raffaele Scientific Institute, Milano, Italy; [23]Department of Hematology, Hokkaido University, Sapporo, Japan; [24]King's College London, London, United Kingdom; [25]University of Kansas Medical Center, Westwood, KS; [26]Universitair Ziekenhuis Ghent, Ghent, Belgium; [27]Department of Internal Medicine III, University Hospital of Ulm, Ulm, Germany; [28]Università di Bologna, Istituto Di Ematologia, Bologna, Italy; [29]Institute of Hematology "Seràgnoli," University of Bologna, Bologna, Italy; [30]Hospitals NHS Foundation Trust, Cambridge University, Cambridge, United Kingdom; [31]Novartis Pharma AG, Basel, Switzerland; [32]Novartis Pharmaceuticals, East Hanover, NJ; [33]Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA; [34]BostonGene, Waltham, MA

CONCLUSIONS

- Long-term follow-up from the ELARA trial continues to demonstrate robust durable responses >4 years after tisagenlecleucel infusion, with a favorable safety profile
- Subgroup analyses suggest that most baseline high-risk disease characteristics (double-refractory disease, bulky disease, POD24, and high FLIPI) are not associated with inferior complete response rate (CRR), 4-year PFS, or 4-year OS
  - Although lower CRR, 4-year PFS, and 4-year OS rates were reported for patients with high tumor burden, these were done as an exploratory analysis and some subgroups, such as those with high tumor burden, had very limited patient numbers
- High frequencies of MRD-negative status were achieved among MRD-evaluable patients, showing that tisagenlecleucel therapy can achieve deep response in treated patients

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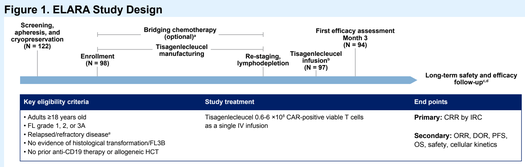
INTRODUCTION

- Previous therapies and patient-related factors should be considered when choosing treatment strategies for patients with relapsed/refractory follicular lymphoma (r/r FL)[1]
  - With increasing lines of therapy, patients with r/r FL usually have worse treatment outcomes[2]
  - Patients with high-risk disease characteristics, such as disease progression within 24 months of frontline systemic therapy (POD24), have an increased risk of less-than-optimal response to subsequent therapies (eg, rituximab plus cyclophosphamide, doxorubicin, vincristine, prednisone [R-CHOP])[3,4]
- Clinical trials with chimeric antigen receptor (CAR)-T cell therapy have shown durable responses with an acceptable safety profile among patients with r/r FL, even in patients with high-risk disease characteristics![1,5-7]
- Tisagenlecleucel, an autologous cluster of differentiation (CD)19-directed CAR-T cell therapy, is approved for the treatment of patients with r/r FL who previously received 2 or more lines of therapy[8]
- Here we present a 4-year follow-up of efficacy, safety, and pharmacokinetics of tisagenlecleucel in patients with r/r FL, with a focus on those with high-risk disease characteristics

METHODS

- ELARA study design, including eligibility criteria and key end points, can be found in **Figure 1**
- Bridging therapy was allowed and disease re-evaluation was done prior to tisagenlecleucel infusion
- Cellular kinetics were assessed by evaluation of transgene levels by quantitative polymerase chain reaction
- Minimal residual disease (MRD) levels were measured using clonoSEQ® next-generation sequencing assay done at Adaptive Biotechnologies (Seattle, WA, USA)

Figure 1. ELARA Study Design



Key eligibility criteria	Study treatment	End points
• Adults ≥18 years old • FL grade 1, 2, or 3A • Relapsed/refractory disease[e] • No evidence of histological transformation/FL3B • No prior anti-CD19 therapy or allogeneic HCT	Tisagenlecleucel 0.6-6 ×10⁸ CAR-positive viable T cells as a single IV infusion	**Primary:** CRR by IRC **Secondary:** ORR, DOR, PFS, OS, safety, cellular kinetics

CAR, chimeric antigen receptor; CD, cluster of differentiation; CRR, complete response rate; DOR, duration of response; FL, follicular lymphoma; FL3B, FL grade 3B; HCT, hematopoietic cell transplant; IRC, independent review committee; IV, intravenous; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.
[a]Disease assessment 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]Median follow-up: 53 months (range: 46-62). [e]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.

RESULTS

Baseline Characteristics

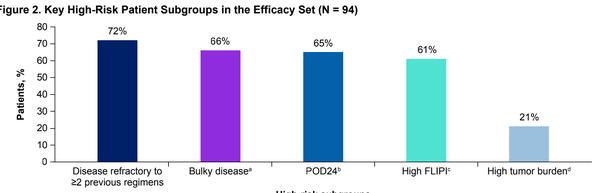
- At data cutoff (March 27, 2024), 97 patients were infused with tisagenlecleucel (last patient infused was on May 22, 2020)
  - With a median follow-up of 53 months, 94 patients were evaluable for efficacy (range: 46-62)
- Baseline and primary disease characteristics (infused set) are seen in **Table 1**
  - A quarter of infused patients were ≥65 years old, with a median age of 57 years (range: 29-73)
  - Median number of previous therapies was 4 (range: 2-13)
  - Thirty-six percent of patients had received an autologous hematopoietic cell transplant (HCT) previously
  - Seventy-eight percent of patients were refractory to the last line of therapy
- High-risk patient subgroups in the efficacy set (N = 94) can be found in **Figure 2**

Table 1. Disease History and Baseline Patient Characteristics

	Infused set (N = 97), n (%)
Median age (range), years	57.0 (29-73)
18 to <65 years	73 (75)
≥65 years	24 (25)
ECOG PS ≥1 prior to infusion	42 (43)
Stage at study entry III-IV	83 (86)
Bone marrow involvement	37 (38)
Bulky disease[a]	63 (65)
FLIPI high at study entry (≥3)	58 (60)
Median no. of prior therapies (range)	4 (2-13)
POD24[b]	61 (63)
Refractory disease to last line of therapy	76 (78)
Refractory to ≥2 regimens	69 (71)
Double refractory: anti-CD20 mAb + alkylating agent	66 (68)
Refractory to PI3K inhibitors	14 (14)
Prior autologous HCT	35 (36)

CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; FLIPI, Follicular Lymphoma International Prognostic Index; HCT, hematopoietic cell transplant; mAb, monoclonal antibody; PI3K, phosphatidylinositol-3-kinase; POD24, progression of disease within 24 months of frontline systemic therapy.
[a]Bulky disease defined as 1 lesion >7 cm or at least 3 lesions >3 cm. [b]POD24 from first anti-CD20 mAb–containing therapy or rituximab monotherapy.

Figure 2. Key High-Risk Patient Subgroups in the Efficacy Set (N = 94)



FLIPI, Follicular Lymphoma International Prognostic Index; mAb, monoclonal antibody; POD24, progression of disease within 24 months of frontline systemic therapy.
[a]Bulky disease is defined as lesions >7 cm or at least 3 lesions >3 cm. [b]POD24 from first anti-CD20 mAb–containing therapy. [c]FLIPI ≥3. [d]Total metabolic tumor volume of >510 mL.[9]

Safety

- There were no new safety signals reported since the last data cut. Adverse events (AEs) of special interest by timing post infusion are seen in **Table 2**
  - Of the patients who had cytokine release syndrome (CRS; n = 47), all first events occurred <8 weeks post infusion
    - Two patients experienced a second CRS event (late onset); one of which was in the context of a new antineoplastic therapy
  - Most cytopenias emerged in the first year post infusion
  - Rates of infections (all grade and grade ≥3) increased over time

Table 2. AEs of Special Interest by Timing Post Infusion

	Infused set (N = 97), n (%)					
	≤8 weeks post infusion		>8 weeks to 1 year post infusion		>1 year post infusion	
Preferred term	**All grades**	**Grade ≥3**	**All grades**	**Grade ≥3**	**All grades**	**Grade ≥3**
Patients with at ≥1 AE	88 (90.7)	68 (70.1)	70 (72.9)	42 (43.8)	38 (45.2)	24 (28.6)
Patients with at ≥1 infection[a]	20 (20.6)	6 (6.2)	37 (38.5)	12 (12.5)	31 (36.9)	16 (19.0)
CRS	47 (48.5)	0	1 (1.0)	0	1 (1.2)	1 (1.2)
Cytopenias						
Neutropenia	33 (34.0)	32 (33.0)	21 (21.9)	18 (18.8)	5 (6.0)	5 (6.0)
Neutrophil count decreased	15 (15.5)	15 (15.5)	7 (7.3)	7 (7.3)	2 (2.4)	1 (1.2)
Anemia	23 (23.7)	13 (13.4)	7 (7.3)	5 (5.2)	4 (4.8)	3 (3.6)
Thrombocytopenia	15 (15.5)	9 (9.3)	8 (8.3)	5 (5.2)	3 (3.6)	2 (2.4)
Platelet count decreased	7 (7.2)	4 (4.1)	4 (4.2)	2 (2.1)	0	0
WBC count decreased	18 (18.6)	13 (13.4)	12 (12.5)	7 (7.3)	2 (2.4)	0
Leukopenia	7 (7.2)	3 (3.1)	3 (3.1)	3 (3.1)	1 (1.2)	0
Febrile neutropenia	10 (10.3)	10 (10.3)	2 (2.1)	2 (2.1)	2 (2.4)	2 (2.4)
Lymphocyte count decreased	10 (10.3)	8 (8.2)	2 (2.1)	0	0	0
Lymphopenia	6 (6.2)	6 (6.2)	4 (4.2)	4 (4.2)	1 (1.2)	1 (1.2)
Hypogammaglobulinemia	9 (9.3)	0	7 (7.3)	1 (1.0)	2 (2.4)	0
Patients with ≥1 serious neurological AE	10 (10.3)	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.4)	1 (1.2)

AE, adverse event; CRS, cytokine release syndrome; WBC, white blood cell.
[a]Grade ≥3 infections reported within 8 weeks of infusion included bacteremia, *Campylobacter* infection, *Escherichia* sepsis, human herpesvirus 6 encephalitis, neutropenic sepsis, pseudomonal sepsis, and staphylococcal sepsis. Grade ≥3 infections reported >8 weeks to 1 year post infusion included pneumonia, COVID-19, lower respiratory tract infection, tooth infection, coronavirus pneumonia, diverticulitis, pneumonia influenza, progressive multifocal leukoencephalopathy, pseudomonal bacteremia, and sepsis. Grade ≥3 infections reported >1 year post infusion included COVID-19, pneumonia, sinusitis, COVID-19 pneumonia, encephalitis, infection, pneumonia respiratory syncytial viral, rhinovirus infection, sepsis, skin infection, and varicella zoster virus infection.

- Second primary malignancies, defined as any new cancer occurring post infusion regardless of tisagenlecleucel relationship, were seen in 6 patients (6.2%; basal cell carcinoma [n = 2], squamous cell carcinoma [n = 2], acute myeloid leukemia [n = 1], bladder transitional cell carcinoma [n = 1], Bowen's disease [n = 1], malignant melanoma [n = 1], metastatic squamous cell carcinoma [n = 1], and myelodysplastic syndrome [n = 1])
- As of data cutoff, 19 patients have died during the study:
  - Eight due to progressive disease
  - Ten due to AEs (1 patient each; acute myeloid leukemia, bladder transitional cell carcinoma, cardiac arrest, CRS, encephalitis, gastrointestinal hemorrhage, infection, metastatic squamous cell carcinoma, pneumonia, and sepsis)
  - One from euthanasia

Efficacy

- Subgroup analyses show that most high-risk disease characteristics reported at baseline, such as double-refractory disease, bulky disease, POD24, and high Follicular Lymphoma International Prognostic Index (FLIPI), were not associated with inferior overall or complete response after infusion of tisagenlecleucel in patients with r/r FL (**Figure 3**)

Figure 3. CRR by Subgroups

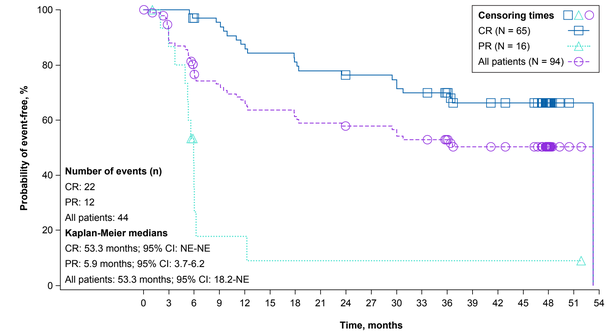
		CRR, n/N (%)	[95% CI]
All patients	All patients (N = 94)	65/94 (69.1)	[58.8-78.3]
Age	<65 years (N = 70)	46/70 (65.7)	[53.4-76.7]
	≥65 years (N = 24)	19/24 (79.2)	[57.8-92.9]
Sex	Female (N = 30)	22/30 (73.3)	[54.1-87.7]
	Male (N = 64)	43/64 (67.2)	[54.3-78.4]
Race	Asian (N = 11)	9/11 (81.8)	[8.2-97.7]
	White (N = 79)	54/79 (68.4)	[56.9-78.4]
Ethnicity	Not Hispanic or Latino (N = 87)	60/87 (69.0)	[58.1-78.5]
FLIPI at study entry	Low/Intermediate (N = 37)	29/37 (78.4)	[61.8-90.2]
	High (N = 57)	36/57 (63.2)	[49.3-75.6]
Histological grade	1-2 (N = 85)	59/85 (69.4)	[58.5-79.0]
	3A (N = 9)	6/9 (66.7)	[29.9-92.5]
Number of prior lines	≤2 lines (N = 24)	14/24 (58.3)	[36.6-77.9]
	3-4 lines (N = 43)	35/43 (81.4)	[66.6-91.6]
	>4 lines (N = 27)	16/27 (59.3)	[38.8-77.6]
PI3K inhibitor use	Pre-treated (N = 19)	15/19 (78.9)	[54.4-93.9]
	Naive (N = 75)	50/75 (66.7)	[54.8-77.1]
Prior HSCT therapy	Yes (N = 35)	22/35 (62.9)	[44.9-78.5]
	Relapsed ≤12 months (N = 14)	10/14 (71.4)	[41.9-91.6]
	Relapsed >12 months (N = 21)	12/21 (57.1)	[34.0-78.2]
	No (N = 59)	43/59 (72.9)	[59.7-83.6]
Disease status to last line	Refractory (N = 74)	52/74 (70.3)	[58.5-80.3]
	Relapsed (N = 17)	11/17 (64.7)	[38.3-85.8]
POD24	Yes (N = 61)	37/61 (60.7)	[47.3-72.9]
	No (N = 33)	28/33 (84.8)	[68.1-94.9]
Bulky disease at baseline	Yes (N = 62)	41/62 (66.1)	[53.0-77.7]
	No (N = 32)	24/32 (75.0)	[56.6-88.5]
Bridging therapy	Yes (N = 44)	29/44 (65.9)	[50.1-79.5]
	No (N = 50)	36/50 (72.0)	[57.5-83.8]
LDH at study entry	≤ULN (N = 53)	39/53 (73.6)	[59.7-84.7]
	>ULN (N = 41)	26/41 (63.4)	[46.9-77.9]
Prior R2 use	Pre-treated (N = 16)	12/16 (75.0)	[47.6-92.7]
	Naive (N = 78)	53/78 (67.9)	[56.4-78.1]
US sites	Yes (N = 26)	17/26 (65.4)	[44.3-82.8]
	No (N = 68)	48/68 (70.6)	[58.3-81.0]
Double refractory	Yes (N = 65)	44/65 (67.7)	[54.9-78.8]
	No (N = 29)	21/29 (72.4)	[52.8-87.3]
MTV at baseline	High tumor burden (N = 20)	8/20 (40.0)	[19.1-63.9]
	Low tumor burden (N = 72)	55/72 (76.4)	[64.9-85.6]



CRR, complete response rate; FLIPI, Follicular Lymphoma International Prognostic Index; HSCT, hematopoietic stem cell transplant; LDH, lactate dehydrogenase; MTV, metabolic tumor volume; PI3K, phosphatidylinositol-3-kinase; POD24, progression of disease within 24 months of frontline systemic therapy; R2, lenalidomide + rituximab; ULN, upper limit of normal.

- Median progression-free survival (PFS) was 53.3 months (95% CI: 18.2-not estimable [NE]) by independent review committee (IRC) in the overall population (**Figure 4**), with a 4-year PFS of 50.2% (95% CI: 39.2-60.3)
  - Responders (patients who had a best overall response of complete response) had a 4-year PFS of 66.1%
  - Among high-risk patient subgroups, 4-year PFS by IRC was 45.5% (POD24), 45.5% (high FLIPI), 45.2% (bulky disease), 52.8% (double-refractory), and 23.2% (high tumor burden)

Figure 4. Progression-Free Survival

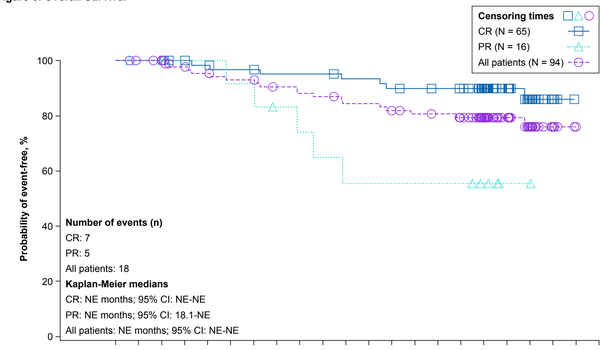


Number of patients still at risk																			
CR	65	65	62	60	55	53	51	49	47	47	45	43	40	35	34	33	14	1	0
PR	16	13	4	2	2	1	1	1	1	1	1	1	1	1	1	1	1	0	0
All patients	94	80	67	62	57	54	52	50	48	48	46	44	41	36	35	34	15	2	0

CR, complete response; NE, not estimable; PR, partial response.

- Median overall survival (OS) was not reached (**Figure 5**); 4-year OS was 79.3% (95% CI: 68.8-86.6) in efficacy-evaluable patients
  - Among high-risk patient subgroups, 4-year OS by IRC was 80.8% (POD24), 73.2% (high FLIPI), 73.0% (bulky disease), 83.7% (double-refractory), and 65.5% (high tumor burden)

Figure 5. Overall Survival

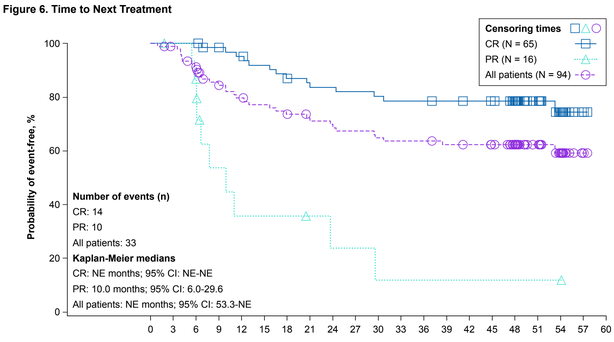


Number of patients still at risk																			
CR	65	65	65	63	61	59	59	57	57	57	55	55	53	52	51	50	40	27	17	4	0	0
PR	16	15	15	12	12	11	11	9	8	7	6	6	6	6	6	6	4	1	1	0	0	0
All patients	94	92	91	84	81	78	78	74	72	71	68	68	65	63	62	59	45	29	19	5	1	0

CR, complete response; NE, not estimable; PR, partial response.

- Median time to next treatment in the overall population and in those with complete response was not reached (**Figure 6**)

Figure 6. Time to Next Treatment



Number of patients still at risk																			
CR	65	65	65	62	59	56	53	50	50	49	48	47	47	46	45	44	36	24	15	2	0
PR	16	15	13	6	4	4	4	3	2	2	1	1	1	1	1	1	1	1	0	0	0
All patients	94	91	83	72	67	64	61	57	56	54	52	51	51	49	48	46	37	25	16	2	0

CR, complete response; NE, not estimable; PR, partial response.

- MRD data were available for 31 of 94 patients (33.0%)
  - 90.3% of evaluable patients (28/31) had MRD negativity at any time point (**Table 3**)
  - 63.6% of patients with MRD-negative status at month 6 (7/11) are ongoing without relapse
  - All 5 patients with MRD-positive status at month 6 relapsed

Table 3. MRD-Negative Rate by Timing After Tisagenlecleucel Infusion

	MRD-negative (N = 31[a]), % (n/N)
Day 28	81.5 (22/27)
Month 3	75.0 (12/16)
Month 6	68.8 (11/16)
Month 12	76.5 (13/17)
Any time	90.3 (28/31)

MRD, minimal residual disease.
[a]Patients evaluated for MRD response.

- CAR transgene persistence was observed for up to 925 days and time to last measurable concentration (T_{last}) was 210 days (range: 13-925)

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Disclosures

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