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3 **CAR T-cells in very elderly ( $\geq 80$  years) lymphoma patients: a DESCAR-T**  
4 **analysis**  
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## CAR T-cells in very elderly ( $\geq 80$ years) lymphoma patients: a DESCAR-T analysis

Keywords: CAR T-cells; Adoptive Cell Therapy; Lymphoma; Geriatric; Elderly patients

Over the last years, chimeric antigen receptor (CAR) T-cells have been approved for the treatment of relapsed or refractory large B-cell, mantle cell and follicular lymphoma (LBCL, MCL and FL, respectively). While clinical benefit has been demonstrated both for patients deemed eligible for intensive chemotherapy followed by autologous stem cell transplant<sup>1</sup> as well as for non-eligible patients<sup>2,3</sup>, one recurring question in routine practice is whether an absolute or physiological age limit should be considered for CAR T-cells therapy indication. Indeed, aging raises the question of the efficacy and the safety of this therapy in very old subjects.

The 4 approved CD19 CAR T-cells (tisagenlecleucel (tisa-cel), axicabtagene ciloleucel (axi-cel), lisocabatagene maraleucel (liso-cel) and brexucabtagene autoleucel (brexu-cel)) have shown different efficacy and safety profiles in trials and real-world evidence (RWE) studies<sup>1-11</sup>.

The 2 most frequent and concerning acute toxicities following CAR T infusion, that usually preclude treatment indication, are cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity (ICANS). Delayed toxicities are also common, the 2 most frequent are Immune effector cell-associated hematotoxicity (ICATH) and infection. All these toxicities can be life-threatening and lead to treatment related mortality (TRM).

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6 Trials and RWE showed no difference in efficacy and toxicity according to age<sup>12-14</sup>. Two recent  
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9 RWE studies demonstrated that axi-cel and tisa-cel therapies are feasible and provide long-  
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11 term remission in older patients compared to younger patients with R/R LBCL<sup>8,10</sup>. However, in  
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13 these studies, most of the patients were under 80 years of age (median age: 69 – 76 years). The  
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15 safety and efficacy of CAR T-cells in very elderly patients (>80 years) with R/R lymphoma  
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17 remain unclear.  
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26 In this study, we report on the outcome of 12 patients  $\geq 80$  years who received a commercial  
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28 CAR T-cell therapy for a lymphoma and were enrolled in the French DESCAR-T registry study.  
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35 All patients treated for a lymphoma in France with CAR-T cells between July 2018 and October  
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37 2023 were considered. Data export from the registry was set on September 30, 2023. Patients  
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39 with lymphoma aged 80 or older for whom a CAR-T cell therapy was ordered were selected.  
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43 The protocol was approved by national ethics committees and the data protection agency, and  
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45 the study was undertaken in accordance with the Declaration of Helsinki. DESCAR-T is  
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47 registered under the ClinicalTrials.gov identifier NCT04328298.  
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55 Of the 2,336 patients enrolled in the DESCAR-T database at data cut-off, 16 (0.7%) were older  
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57 than 80 years and 12 (0.5%) were infused. As of September 30, 2023, the median follow-up  
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3 was 7.8 months. Clinical characteristics are summarized in Table 1. The median age was 81.5  
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5 years (range, 80-87 years), 58.3% were male, and diagnose included LBCL (n=9), FL (n=2)  
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7 and MCL (n=1). As expected, patients exhibited minimal comorbidities despite their advanced  
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9 age, 8 had no comorbidity (66%) and no one had more than 1 comorbidity. All but one presented  
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11 an Eastern Cooperative Oncology Group performance status (ECOG PS)  $\leq$ 1. Tisa-cel was used  
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13 for 8 patients with LBCL and 2 patients with FL, axi-cel for 2 patients with LBCL and brexu-  
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15 cel for the only patient with MCL. [Table 1 and Figure 1 near here]  
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26 Efficacy outcomes are summarized in Table 1 and Figure 1. Among the 9 patients treated for  
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28 LBCL, 6 (66.6%) achieved a complete response (CR) as the best response, 1 a partial response  
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30 and 2 experienced disease progression. Best overall response rates (ORR) were 78% and 4  
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32 (44%) patients had ongoing response at data cutoff. Median progression-free survival (PFS)  
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34 was 2.9 months. Four (40%) patients died during follow-up, 3 from progression and 1 (11%)  
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36 from non-related mortality (concurrent illness). Median overall survival (OS) was 12.7 months.  
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43 The 2 patients with FL achieved a CR and had ongoing response at data cutoff. The patient with  
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45 MCL achieved a CR but progressed after 10 months. He was still alive at last follow-up.  
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49 Adverse events (AEs) are summarized in Table 1. The most common AE grade  $\geq$ 3 was  
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51 cytopenia, which occurred in 6 of the 12 patients. The most common grade  $\geq$ 3 cytopenia was  
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53 neutropenia, which was reported in 5 (42%) and 2 (17%) patients at 1 and 3 months,  
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55 respectively. Grade  $\geq$ 3 thrombopenia was also frequent with 5 (41%) and 1 (8%) at 1 and 3  
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3 months, respectively. All patients experienced a CRS of any grade, there was no CRS of grade  
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6  $\geq 3$ . Eight neurologic events of any grade were reported with 2 grade  $\geq 3$ . Only 1 documented  
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9 grade  $\geq 3$  infection (candidemia) has been reported. No grade 5 AEs were reported.

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14 Efficacy outcomes for very elderly patients are slightly lower in this series than in previous  
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17 studies based on the DESCAR-T registry for OS and PFS. In an analysis of 729 patients with  
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20 LBCL treated with tisa-cel or axi-cel, OS and PFS were 19 and 5.6 months, respectively<sup>11</sup>.  
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23 Similar survivals have been reported in another study from DESCAR-T, based on 957 patients  
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26 with LBCL where OS and PFS were 21 and 6 months, respectively<sup>15</sup>. ORR and CR appear  
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29 similar (80.4%/60.3% in Bachy et al<sup>11</sup> and 72.4%/54.3% in Lemoine et al<sup>15</sup>).

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32 Safety is consistent with previous studies regarding cytopenia, particularly grade  $\geq 3$   
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35 neutropenia that has been reported in 35% and 11% at one and three months, respectively<sup>11</sup>.  
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38 However, ICANS seems more frequent (33% of any grade and 8% of grade  $\geq 3$  in Bachy et  
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41 al)<sup>11</sup>. In our study, among the 4 patients who died, there were no death directly related to CAR  
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44 T-cells. This is in line with the results of the study from Lemoine and colleagues where no  
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47 direct correlation between age and toxicities (including increased treatment related mortality  
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49 (TRM)) were found<sup>15</sup>. The toxicity profile of patients over 80 treated with CAR T-cells, if  
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52 carefully selected, therefore seems comparable to that of younger patients.  
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3 In our study, on 12 patients, CAR T-cells appear feasible and provide a clinical benefit without  
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6 significant excess toxicity in highly selected patients (few comorbidities and good general  
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9 condition) of 80 years and older with R/R non-Hodgkin lymphoma. However, our study has  
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12 several limitations including a short follow-up, a lack of comparison with younger subjects, a  
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15 small population size and a retrospective design. An absolute age limit for CAR T-cells should  
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18 not be considered without finely examining the risk/benefit balance for a given patient and  
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21 disease. Further analyses based on a larger population and a longer follow-up will be needed to  
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24 confirm these results.

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29 Disclosure of interest:

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32 R.H. reports honoraria from Kite/Gilead, Novartis, Incyte, Janssen, MSD, Takeda, Abbvie and  
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35 Roche; and consultancy at Kite/Gilead, Novartis, Bristol-Myers Squibb/Celgene, ADC  
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38 Therapeutics, Incyte, Miltenyi. N.M. reports honoraria from Kite/Gilead. E. Bachy reports  
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41 honoraria and served on advisory boards from Kite/Gilead, Bristol Myers Squibb, Novartis,  
42  
43  
44 Pfizer, Incyte, ADC Therapeutics, Roche, Takeda; Personal fees from Kite/Gilead, Bristol  
45  
46  
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48  
49  
50 reports Honoraria from Roche, BMS, Kite/Gilead. The remaining authors declare no competing  
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53 financial interests.  
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Table 1. Clinical characteristics

Patient characteristic at CAR-T Cell infusion	All (n = 12)	Anemia at M1, n (%)	
<b>Age, y</b> median (min;max)	81.5 (80;87)	Any grade Grade ≥3	8 (67%) 3 (25%)
<b>Sex, n (%)</b> Male Female	7 (58%) 5 (42%)	<b>Anemia at M3, n (%)</b> Any grade Grade ≥3	4 (33%) 0 (0%)
<b>Diagnosis</b> LBCL LF MCL	9 (75%) 2 (16.5%) 1 (8.5%)	<b>Thrombocytopenia at M1, n (%)</b> Any grade Grade ≥3	8 (67%) 5 (42%)
<b>Ann Arbor Stage, n (%)</b> I II III IV	0 2 (16.5%) 2 (16.5%) 8 (67%)	<b>Thrombocytopenia at M3, n (%)</b> Any grade Grade ≥3	5 (42%) 1 (8.5)
<b>≥3 lines of prior therapy</b>	6 (50%)	<b>ICU admission, n (%)</b> Yes No	3 (25%) 9 (75%)
<b>Comorbidities, n (%)</b> No comorbidity Solid tumor Arrhythmia Cardiac	8 (67%) 2 (17%) 1 (8.5%) 1 (8.5%)	<b>Outcomes</b>	
<b>ECOG PS, n (%)</b> 0-1 ≥2	11 (91.5%) 1 (8.5%)	<b>LBCL (9 patients)</b>	
<b>Type of CAR T-cells</b> Axicabtagene-ciloleucel Tisagenlecleucel Brexucabtagene autoleucel	2 (16.5%) 9 (75%) 1 (8.5%)	<b>Response after CAR-T at 1 month, n (%)</b> CR PR SD Progression	5 (56%) 2 (22%) 0 2 (22%)
<b>Bridging therapy</b> No bridging Response to bridging (PR or CR) No response to bridging (SD or PD)	3 (25%) 2 (17%) 7 (58%)	<b>Overall Response Rate</b>	78%
<b>Elevated LDH level at lymphodepletion, n (%)</b>	7 (58%)	<b>Complete Response Rate</b>	66%
<b>CRP</b> ≤30 mg/l >30 mg/l	10 (83%) 2 (17%)	<b>Progression free-survival (months), median</b>	2.86
<b>Toxicity</b>		<b>Overall Survival (months), median</b>	12.65
<b>CRS, n (%)</b> Any grade Grade ≥3	12 (100%) 0 (0%)	<b>Death, n (%)</b>	4 (44%)
<b>ICANS, n (%)</b> Any grade Grade ≥3	8 (67%) 2 (17%)	<b>LF (2 patients)</b>	
<b>Infection, n (%)</b> Any grade Grade ≥3	1 (8.5%) 1 (8.5%)	<b>Response after CAR-T at 1 month, n (%)</b> CR PR SD Progression	1 (50%) 1 (50%) 0 (0%) 0 (0%)
<b>Neutropenia at M1, n (%)</b> Any grade Grade ≥3	7 (58%) 5 (42%)	<b>Overall Response Rate (ORR)</b>	100%
<b>Neutropenia at M3, n (%)</b> Any grade Grade ≥3	3 (25%) 2 (17%)	<b>Complete Response Rate</b>	100%
		<b>Progression free-survival (months)</b> Patient G <sup>a</sup> Patient L <sup>a</sup>	2.86 1.18
		<b>Overall Survival (months)</b> Patient G <sup>a</sup> Patient L <sup>a</sup>	2.86 1.18
		<b>Death, n (%)</b>	0 (0%)
		<b>MCL (1 patient, Patient I*)</b>	
		<b>Response after CAR-T at 1 month</b>	PR
		<b>Best response</b>	CR
		<b>Progression free-survival (months)</b>	10.18
		<b>Overall Survival (months)</b>	15.61
		<b>Death</b>	0 (0%)

<sup>a</sup>Patients ID report in the swimming plot

ALL: Acute Lymphoblastic Leukemia; CR: Complete Response; CRS: Cytokine Release Syndrome; FL: Follicular Lymphoma; ICANS: Immune cell-associated neurologic syndrome; LBCL: Large B-Cell Lymphoma; MCL: Mantle Cell Lymphoma; MM: Multiple Myeloma; PD: Progression Disease; PR: Partial Response; SD: Stable Disease; and ULN: Upper Limit Normal.

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3 Figure 1. Patients outcome after CAR T-cell therapy  
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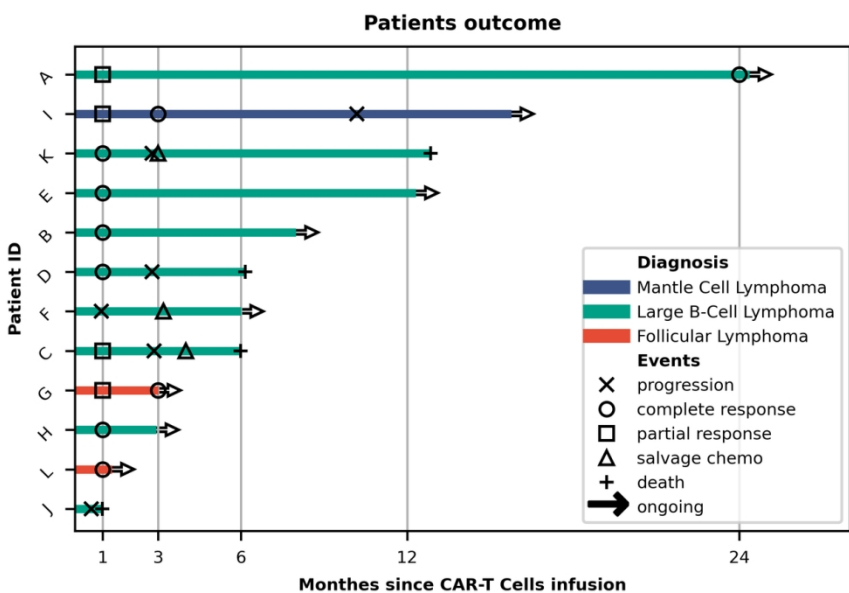


Figure 1. Patients outcome after CAR T-cell therapy

126x79mm (300 x 300 DPI)

eTable 1. Clinical characteristics

Patient characteristic at CAR-T Cell infusion	Patient A	Patient B	Patient C	Patient D	Patient E
Age, y	80	82	82	87	82
Sex	Female	Male	Male	Female	Female
Diagnosis	LBCL	LBCL	LBCL	LBCL	LBCL
Ann Arbor Stage	II	III	IV	IV	IV
Number of prior treatment lines	5	2	2	5	2
Comorbidities	No	Solid tumour	Solid tumour	Arrhythmia	No
Performance Status (ECOG scale)	1	0	1	1	1
Type of CAR-T	Tisagenlecleucel	Axicabtagene-ciloleucel	Tisagenlecleucel	Tisagenlecleucel	Tisagenlecleucel
Bridging therapy	R-Ifosfamide-VP16	Obinutuzumab-Lenalidomide	No	R-miniCHOP	R-Ifosfamide-VP16
Response to bridging therapy	PR	CR	NA	Not evaluated	PD
CRP (mg/l) at lymphodepletion	10	14	66	6	2
Ratio LDH/ULN at lymphodepletion	1.112	1.060	1.259	1.418	0.973
<b>Toxicity</b>					
CRS (max grade)*	2	2	1	1	2
ICANS (max grade)*	1	3	0	1	3
Infection, grade $\geq 3$	No	No	No	No	No
Neutropenia grade at M1	0	0	0	3	2
Neutropenia grade at M3	0	0	0	0	2
Anemia grade at M1	0	3	0	3	2
Anemia grade at M3	0	1	0	2	2
Thrombocytopenia grade at M1	0	3	0	2	2
Thrombocytopenia grade at M3	0	1	0	1	1
ICU admission	No	Yes	No	No	No
<b>Outcomes</b>					
Response after CAR-T at 1 month	PR	CR	PR	CR	CR
Best response	CR	CR	PR	CR	CR
Progression free-survival (months)	24.21	7.83	2.86	2.79	12.16
Overall Survival (months)	24.21	7.83	5.78	5.95	12.16
Death	No	No	Yes	Yes	No
Cause of death			NRM	Progression	

37 CEP, Cyclophosphamide, Etoposide, Prednisone; CR, Complete Response; CRS, Cytokine Release Syndrome; ICANS, Immune effector-cell associated neurotoxicity

38<sup>a</sup> Patient died in the first month.

39<sup>b</sup> Patient with a follow-up less than 3 months.

	Patient F	Patient G	Patient H	Patient I	Patient J	Patient K	Patient L
1	80	80	81	83	81	80	83
2	Male	Female	Female	Male	Male	Male	Male
3	LBCL	FL	LBCL	MCL	LBCL	LBCL	FL
4	IV	III	IV	IV	IV	IV	II
5	2	3	6	4	2	2	3
6	No	No	No	Cardiac	No	No	No
7	1	1	0	1	1	3	1
8	Tisagenlecleucel	Tisagenlecleucel	Tisagenlecleucel	Brexucabtagene autoleucel	Tisagenlecleucel	Axicabtagene ciloleucel	Tisagenlecleucel
9	Ifosfamide-VP16	R-Ifosfamide-VP16	R-Ifosfamide-VP16	Liposomal doxorubicin - CEP	No	R-Ifosfamide-VP16	No
10	PD	PD	PD	PD	NA	PD	NA
11	4	9	1	2	4	103	3
12	0.777	1.041	0.855	0.653	1.129	3.911	0.924
13							
14	1	1	1	1	1	2	2
15	1	0	0	0	2	2	2
16	No	No	No	No	Candidemia	No	No
17	3	4	0	3	NA <sup>a</sup>	2	4
18	3	4	0	0	NA <sup>a</sup>	0	NA <sup>b</sup>
19	2	3	0	1	NA <sup>a</sup>	1	1
20	0	2	0	0	NA <sup>a</sup>	0	NA <sup>b</sup>
21	3	4	0	1	NA <sup>a</sup>	4	4
22	2	4	0	0	NA <sup>a</sup>	0	NA <sup>b</sup>
23	No	No	No	No	No	Yes	Yes
24							
25	PD	PR	CR	PR	NA	CR	CR
26	PD	CR	CR	CR	PD	CR	CR
27	0.95	2.86	2.79	10.18	0.59	2.79	1.18
28	5.95	2.86	2.79	15.61	0.79	12.65	1.18
29	No	No	No	No	Yes	Yes	No
30					Progression	Progression	

city syndrome; FL, Follicular Lymphoma; LBCL, Large B-Cell Lymphoma; MCL, Mantle Cell Lymphoma; NRM, Non-Related Mortality; PD, Progression Disease; PR, Partial