REAL WORLD DATA OF AXICABTAGENE CILOLEUCEL AS SECOND LINE THERAPY FOR PATIENTS WITH LARGE B CELL LYMPHOMA: FIRST RESULTS OF A LYSA STUDY FROM THE FRENCH DESCAR-T REGISTRY

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INTRODUCTION

- Axicabtagene-ciloleucel (axi-cel) has demonstrated superior efficacy as 2L therapy over chemo-immunotherapy in transplant-eligible patients and promising efficacy in transplant-ineligible patients.[1,2,3]
- Axi-cel is used in France for this indication since July 2022 in the context of an early access program

AIM

Describe characteristics, treatment course, and outcomes of all patients consecutively included in DESCART registry since July 2022, to receive axi-cel as 2L treatment for R/R LBCL according to the early access program supported by French authorities.

METHOD

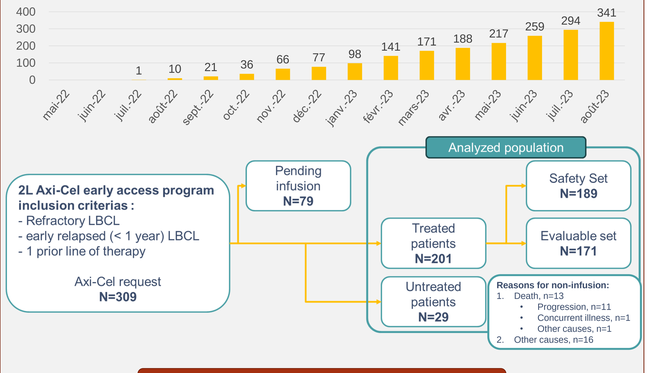
- DESCAR-T : French nationwide registry collecting real-life data of all patients treated with approved CAR T-cell therapies (NCT04328298)
- Retrospective analysis:
  - All patients included between July 2022 and 03 Aug 2023 in 2L Axi-Cel early access program
  - Database export = 01 SEP 2023

KEY MESSAGES

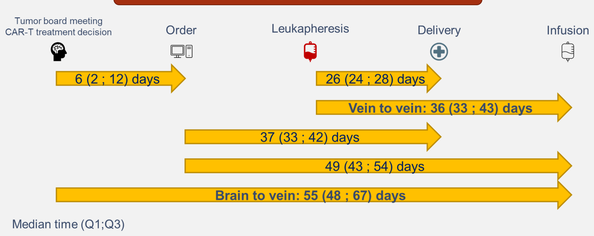
- Inclusion in DESCART registry for 2L LBCL patients is on-going with rapid accrual
- The vast majority of patients were primary refractory and received bridging chemotherapy
- Axi-cel in 2L for R/R LBCL is feasible and safe in real-life
- No new toxicity signals were observed
- Early assessments of response are in line with those described in ZUMA-7 and ALYCANTE studies
- Further follow up is needed and ongoing

RESULTS

PATIENTS



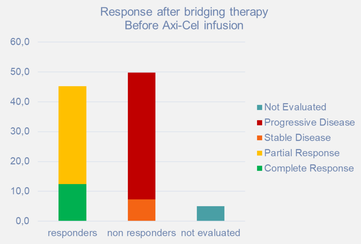
Time from decision to infusion



BRIDGING THERAPIES

Bridging therapy	**177**	**(88.1%)**
Number of bridging lines		
1	**153**	**(86.4%)**
2	19	(10.7%)
3	4	(2.3%)
4	1	(0.6%)
Type of treatment*		
Monoclonal antibody	**155**	**(87.6%)**
Anti-CD20	**153**	**(86.4%)**
Chemotherapy	**162**	**(91.5%)**
Platine-based regimen	**124**	**(70.1%)**
Radiotherapy	14	(7.9%)
IMiD	11	(6.2%)
Kinase inhibitor	14	(7.9%)
Corticosteroids	13	(7.3%)

* Several treatment possible

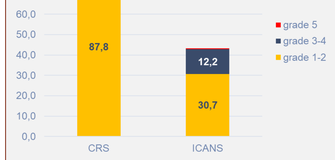


PATIENTS CHARACTERISTICS

	Treated patients N=201 (87.4%)		Untreated patients N=29 (12.6%)	
Sex Male	122	(60.7%)	16	(55.2%)
Age (years)				
Median (min; max)	61 (21; 82)		65 (34;80)	
Age >= 65 years	**77**	**(38.3%)**	**15**	**(51.7%)**
Bridging therapy	**177**	**(88.1%)**	**18**	**(62.1%)**
ECOG				
0-1	164	(81.6%)	14	(48.3%)
>=2	10	(5.0%)	3	(10.3%)
Missing	27	(13.4%)	12	(41.4%)
LDH > Normal				
No	75	(37.3%)	16	(55.2%)
Yes	122	(60.7%)	12	(41.4%)
Missing	4	(2.0%)	1	(3.4%)
Ann Arbor Stage				
I-II	30	(14.9%)	4	(13.8%)
III-IV	149	(74.1%)	20	(69.0%)
Unknown	22	(10.9%)	5	(17.2%)
Histology				
DLBCL	149	(74.1%)	22	(75.9%)
Transformed indolent	28	(13.9%)	6	(20.7%)
PMBL	6	(3.0%)	0	(0.0%)
HGBL	8	(4.0%)	1	(3.4%)
Other#	10	(5.0%)	0	(0.0%)
Primary refractory disease	**149**	**(74.1%)**	23	(79.3%)

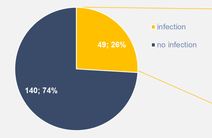
TOXICITIES

Safety Set includes all patients from the Treated set with at least one safety evaluation

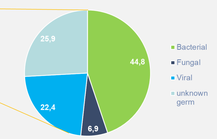


	N=189	
Cytokine release syndrome	**175**	**(92.6%)**
Grade 1-2	166	(87.8%)
Grade 3-4	**8**	**(4.2%)**
Grade 5	1	(0.5%)
Neurotoxicity	**82**	**(43.4%)**
Grade 1-2	58	(30.7%)
Grade 3-4	**23**	**(12.2%)**
Grade 5	1	(0.5%)
Patients with CRS and Neurotoxicity	**80**	**(42.3%)**
Treatment received for toxicities		
Yes	140	(80.0%)
More than one	94	(67.1%)
Intensive care unit	44	**(25.1%)**
Median number of days (min;max)	5.0 (1 ; 25)	
Pressor amines use	8	(4.6%)
Mechanical ventilation	7	(4.0%)
Tocilizumab use	**126**	**(72.0%)**
Median days of treatment (min;max)	2.0 (1 ; 7)	
Corticosteroid use	**99**	**(56.6%)**
Siltuximab use	4	(2.3%)
Anti-IL1: Anakinra	22	(12.6%)
Anticonvulsant use	30	(17.1%)

Medically significant infection observed (n; %)



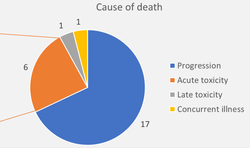
Infection type



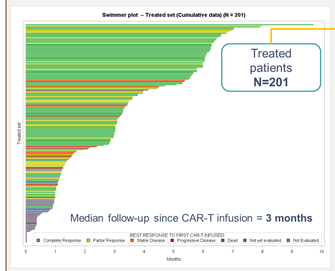
- Most of these infections occurred during the first month post infusion
- Only 6 bacterial, 1 viral and 1 fungal infections occurred later.

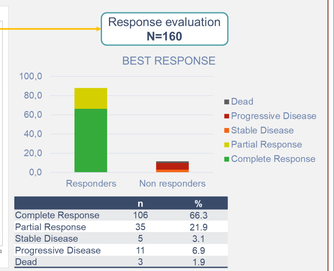
CAUSES OF DEATH

Cause of death	n
UNKNOWN	1
NEUROLOGICAL TOXICITY	1
ACUTE HEMATOTOXICITY (DEEP PANCYTOPENIA)	1
CRS	1
MULTIVISCERAL FAILURE	1
SEPTIC SHOCK	1



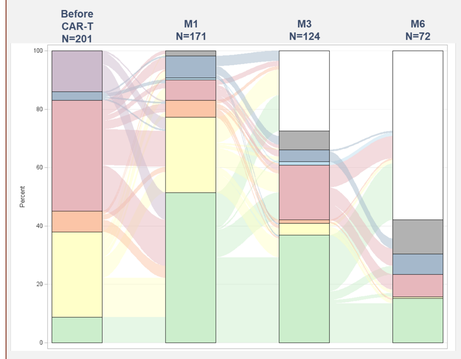
OUTCOME





	n	%
Complete Response	106	66.3
Partial Response	35	21.9
Stable Disease	5	3.1
Progressive Disease	11	6.9
Dead	3	1.9

KINETICS OF RESPONSE

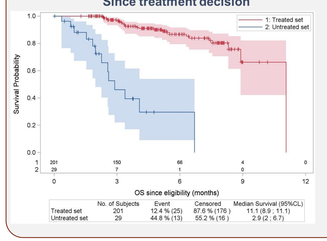


Kinetics of responses

- Complete response
- Partial response
- Stable disease
- Progressive disease
- Trt without progression
- Not evaluated
- Dead
- No bridging therapy
- Not evaluated yet

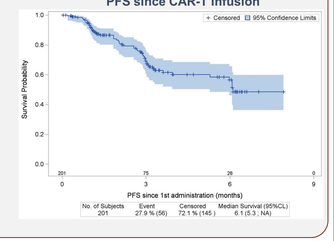
SURVIVAL

Overall survival according to treatment set
Since treatment decision



	No. of Subjects	Event	Censored	Median Survival (95%CL)
Treated set	201	12.4 % (25)	87.6 % (176)	11.1 (8.9 ; 11.1)
Untreated set	29	44.8 % (13)	55.2 % (16)	2.9 (2 ; 6.7)

PFS since CAR-T infusion



	No. of Subjects	Event	Censored	Median Survival (95%CL)
	201	27.9 % (56)	72.1 % (145)	6.1 (5.3 ; NA)

CONTACT INFORMATION

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REFERENCES

1. Locke et al. NEJM 2022
2. Houot et al. Nat Med 2023
3. Westin et al. NEJM 2023

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