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POSTER ABSTRACTS

905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

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

Gabriel Brisou[1], *Guillaume Cartron*[2], *Emmanuel Bachy, MD PhD*[3], *Catherine Thieblemont, MD PhD*[4], *Cristina Castilla-Llorente, MD*[5], *Fabien Le Bras, MD*[6], *François-Xavier Gros*[7], *Michael Loschi, MD PhD*[8], *Roch Houot, MD PhD*[9], *Remy Dulery*[10], *Fabrice Jardin, MDPhD*[11], *Magalie Joris, MD*[12], *Choquet Sylvain*[13], *Franck Morschhauser, MDPhD*[14], *Stephanie Guidez*[15], *Olivier Hermine*[16], *Laurianne Drieu La Rochelle*[17], *Sylvain Carras*[18], *Blandine Guffroy, MD*[19], *Pierre Bories, MD PhD*[20], *Rene-Olivier Casasnovas, MD*[21], *Julie Abraham*[22], *Steven Le Gouill, MD PhD*[23], *Pascale Cony-Makhoul, MD*[24], *Elodie Gat*[25], *Benoit Tessoulin*[26]

[1] Institut Paoli-Calmettes, Department of Hematology, Marseille Cedex 09, France
[2] Clinical Hematology Department, Montpellier University Hospital Center, Montpellier, France
[3] Lyon-Sud Hospital Center, Pierre-Bénite, France
[4] Assistance Publique-Hôpitaux de Paris, Hôpital Saint-Louis, Hemato-oncologie, Université de Paris, Paris, France
[5] Department of Hematology, Gustave Roussy Cancer Campus, Villejuif, France
[6] Clinical Hematology, Henri-Mondor Hospital, Assistance Publique - Hôpitaux de Paris, Paris, FRA
[7] Hôpital Du Haut-Lévèque, CHU de Bordeaux, Pessac, FRA
[8] Centre Hospitalier Universitaire de Nice, Nice, France
[9] Clinical Hematology, INSERM U1236, EFS, Hopital Pontchaillou, Rennes University Hospital, Rennes, France
[10] Department of Clinical Hematology and Cellular Therapy, Saint Antoine Hospital, Assistance Publique - Hôpitaux de Paris, Sorbonne Université, Paris, France
[11] Centre Henri-Becquerel and University of Rouen, Rouen, France
[12] Service d'Hématologie Clinique, Centre Hospitalier Universitaire Amiens-Picardie, Amiens, FRA
[13] Hopital de la Pitié Salpetrière, APHP, Paris, FRA
[14] Hematology Department, Centre Hospitalier Régional Universitaire de Lille, Lille, France
[15] Hematolgy department, University Hospital of Poitiers, Poitiers, France
[16] Department of Hematology, Necker Hospital, APHP, Paris, France
[17] CHU TOURS, Tours, FRA
[18] Hematology, CHU GRENOBLE - HÔPITAL ALBERT MICHALLON, Grenoble, France
[19] Hematology department, INSTITUT DE CANCÉROLOGIE STRASBOURG EUROPE (ICANS), Strasbourg, FRA
[20] Early Phase Unit, University Cancer Institute Toulouse Oncopole, Toulouse, France
[21] CHU DE DIJON - HÔPITAL F. MITTERRAND, Dijon, FRA
[22] CHU DE LIMOGES - HÔPITAL UNIVERSITAIRE DUPUYTREN, Limoges, FRA
[23] Hematology Department, Institut Curie, Paris, France
[24] Lymphoma Academic Research Organisation (LYSARC), Pierre-Bénite, France
[25] Lymphoma Academic Research Organisation (LYSARC), Pierre Bénite, France
[26] Hematology Department, CHU Nantes, Nantes, France

Background and Significance:
Axicabtagene ciloleucel (axi-cel) has demonstrated superior efficacy as second-line therapy (2L) over standard of care chemo-immunotherapy in transplant-eligible patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL). In ZUMA-7 trial, 180 patients were randomized to receive axi-cel in 2L, achieving an estimated 4-year overall survival of 54% after a median follow-up of 47 months. In the ALYCANTE phase II study, 62 transplant-ineligible patients with R/R LBCL were treated with axi-cel as 2L, resulting in a 3-month complete metabolic response rate of 71% with a median progression free survival of 11.8 months. Here, we report the first real-world data of axi-cel as 2L for patients with early R/R LBCL treated in French centers.
Study Design and Methods:

DESCAR-T is a French nationwide registry collecting real-life data of all patients treated with approved CAR T-cell therapies (NCT04328298). All patients were informed before inclusion in the registry. The goal of the present analysis was to describe patients' characteristics, treatment course, and outcomes of all patients consecutively included in DESCART registry since July 2022, and infused with axi-cel according to the early access program supported by French authorities for patients with LBCL in early relapse (< 1 year) or refractory after a first line treatment.

Results:

Between July 2022 and March 2023, axi-cel was ordered and leukapheresis was performed for 85 patients. The first axi-cel infusion was performed in September 2022 and enrollment increased rapidly with 51 new patients waiting for a leukapheresis at the time of data cut-off in March 2023. No manufacturing failures occurred, at the data cut-off, 78 patients were infused with axi-cel in 22 centers, and 7 patients died before axi-cel infusion (5 because of progression, 2 from other cause). Among the 78 patients infused, 48 (61.5%) were male, median age was 60 years (range: 23-79), 35% were over 65 years old and 5% over 70 years old. Most patients had primary refractory disease (n = 58, 74.3%), a good performance status (n = 62, 79.5% ECOG 0-1), stage III-IV disease (n = 59, 75.6%) and elevated LDH (n = 48, 61.5%). The median time between leukapheresis and axi-cel infusion was 36 days, and 65 patients (83%) received bridging therapy, primarily immuno-chemotherapy (n = 57, 73%). At the time of lymphodepletion, patients had progressive (n = 35, 54%) or stable disease (n = 6, 9%), with only 23 patients (29%) responding to bridging therapy. The median follow-up since CAR-T-cells infusion was 1.1 month (range: 0-6). Safety information was reported for 65 patients: CRS occurred in 95% of patients, however only 3 patients (<5%) had a grade 3 or higher CRS. Neurotoxicity occurred in 43% of the cases, with 6 patients (9%) presenting grade 3 or higher toxicity. Furthermore, 13 patients (21%) were transferred to intensive care unit. Four patients (5%) died, 3 from lymphoma progression (missing data for the remaining patient). Among the 52 patients with at least 1 month of follow-up: the overall response and complete response rates at 1 month were 76.9% and 57.7% respectively (Figure 1).

Conclusion:

These preliminary results demonstrated that axi-cel in 2L for R/R LBCL is feasible and safe in real-life for transplant and non-transplant eligible patients. Although follow-up of our population remains short, early assessments of response are in line with those described in ZUMA-7 study. Inclusion in DESCART registry is on-going and updated results with at least 3 months of follow-up since infusion will be presented at the meeting.

Disclosures Brisou: *Novartis:* Consultancy. **Cartron:** *Janssen:* Honoraria; *Novartis:* Honoraria; *MabQi:* Consultancy; *MedxCell:* Consultancy; *Gilead:* Honoraria; *Emercell:* Consultancy; *BMS:* Consultancy, Honoraria; *AbbVie:* Consultancy, Honoraria; *Jansen, Gilead, Novartis, F. Hoffmann-La Roche Ltd, BMS, Abbvie:* Honoraria; *MedxCell, Ownards Therapeutics, MabQi, Emercell, F. Hoffmann-La Roche Ltd, BMS, Abbvie:* Consultancy; *MabQi, Ownards Therapeutics, Abbvie, Roche, Bristol Myers Squibb:* Membership on an entity's Board of Directors or advisory committees; *Ownards Therapeutics:* Consultancy; *Roche:* Consultancy, Honoraria. **Bachy:** *Incyte:* Honoraria; *Pfizer:* Honoraria, Other: Personal Fees; *Hospices Civils de Lyon Claude Bernard Lyon 1 University:* Current Employment; *Novartis:* Honoraria, Other: Personal Fees; *Takeda:* Honoraria; *Bristol Myers Squibb:* Honoraria, Other: Personal Fees, Research Funding; *Amgen:* Research Funding; *Roche:* Consultancy, Honoraria; *Kite, a Gilead Company:* Honoraria, Other: Personal Fees. **Thieblemont:** *Kyte, Gilead, Novartis, BMS, Abbvie, F. Hoffmann-La Roche Ltd, Amgen:* Honoraria; *Hospira:* Research Funding; *Gilead Sciences:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Incyte:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Novartis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Janssen:* Honoraria, Other: Travel Expenses; *Bayer:* Honoraria; *Paris University, Assistance Publique, hopitaux de Paris (APHP):* Current Employment; *AbbVie:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Amgen:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Kite:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Cellectis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses; *Roche:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses, Research Funding; *BMS/Celgene:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel Expenses, Research Funding. **Castilla-Llorente:** *Gilead/Kite:* Consultancy, Other: Travel support; *Nektar Therapeutics:* Consultancy. **Gros:** *Milteny:* Consultancy; *BMS:* Consultancy; *Gilead:* Consultancy, Other: Travel and accommodation expenses; *Novartis:* Consultancy, Other: Travel and accommodation expenses. **Loschi:** *Alexion:* Honoraria; *Sanofi:* Honoraria; *Pfizer:* Honoraria; *Novartis:* Honoraria; *MSD:* Honoraria; *Medac:* Honoraria; *Kartos:* Honoraria; *Jazz:* Honoraria; *GSK:* Honoraria; *Gilead:* Honoraria; *BMS:* Honoraria; *AstraZeneca:* Honoraria; *Sobi:* Honoraria; *Telios:* Honoraria. **Houot:** *Kite/Gilead, Novartis, Bristol-Myers Squibb/Celgene, ADC Therapeutics, Incyte, Miltenyi:* Consultancy; *Kite/Gilead, Novartis, Incyte, Janssen, MSD, Takeda, F. Hoffmann-La Roche Ltd:* Honoraria. **Dulery:** *Servier Foundation:* Research Funding; *Monahan Foundation:* Research Funding; *Philippe Foundation:* Research Funding; *DPC AP-HP:* Research Funding; *Novartis:* Honoraria; *Takeda:* Honoraria; *Kite Pharma / Gilead:* Other: Registration fees for scientific meetings and travel accommodations ; *Arthur Sachs Scholarships:* Research Funding; *Ligue Nationale contre le Cancer:* Research Funding. **Jardin:** *Janssen, Gilead, AbbVie, F. Hoffmann-La Roche Ltd, BMS, Takeda:* Honoraria. **Morschhauser:** *F. Hoffmann-La Roche Ltd, Gilead, AbbVie:* Membership on an entity's Board of Directors or advisory committees; *F. Hoffmann-La Roche Ltd, AbbVie, BMS, Genmab, Gilead, Novartis:* Consultancy. **Guidez:** *Gilead/Kite:* Honoraria; *Astra-Zeneca:* Honoraria; *Incyte:* Honoraria; *Takeda:* Honoraria. **Hermine:** *AB science:* Consultancy, Current equity holder in publicly-traded company, Current holder of

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	Treated patients, n = 78	
Sex Male	48	(61.5%)
Age (years)		
Median (min; max)	60.0 (23; 79)	
Age ≥ 65 years	27	(34.6%)
ECOG		
0-1	62	(79.5%)
≥ 2	7	(9.0%)
Missing	9	(11.5%)
LDH > Normal		
No	29	(37.2%)
Yes	48	(61.5%)
Missing	1	(1.3%)
Ann Arbor Stage		
Unknown	11	(14.1%)
I-II	8	(10.3%)
III-IV	59	(75.6%)
At least one HCT-CI Comorbidity	35	(44.9%)
Bulky disease (>5cm)		
No	58	(75.3%)
Yes	13	(16.9%)
Missing	6	(7.8%)
Histology		
DLBCL	61	(78.2%)
Transformed FL	5	(6.4%)
PMBL	3	(3.8%)
HGBL	1	(1.3%)
Other#	6	(7.7%)
Missing	2	(2.6%)
Prior autologous transplant	2	(2.6%)
Primary refractory disease		
Yes	58	(74.3%)
No	17	(21.8%)
Missing	3	(3.8%)
Bridging therapy	65	(83.3%)
Disease status before CAR-T infusion		
Complete Response	6	(9.2%)
Partial Response	17	(26.2%)
Stable Disease	6	(9.2%)
Progressive Disease	35	(53.8%)
Not Evaluated	1	(1.5%)

Table 1. Characteristics of treated patients at enrollment in the axi-cel 2nd line LBCL early access program. HCT-CI: Hematopoietic Cell Transplantation-specific Comorbidity Index, DLBCL: diffuse large B cell lymphoma, FL: follicular lymphoma, PMBL: primary mediastinal B cell lymphoma, HGBL: high grade B cell lymphoma.

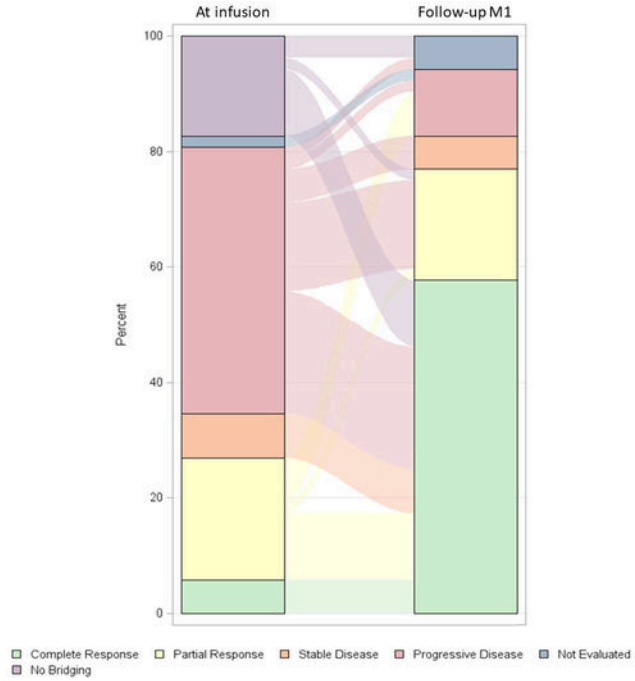

Figure 1. Sankey plot of evaluable patients 1 month (M1) after CAR-T cells infusion.

Figure 1

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