



## The 65th ASH Annual Meeting Abstracts

## ORAL ABSTRACTS

**623.MANTLE CELL, FOLLICULAR, AND OTHER INDOLENT B CELL LYMPHOMAS: CLINICAL AND EPIDEMIOLOGICAL****Real-Word Experience of CAR T-Cells in Patients with Relapsed/Refractory Follicular Lymphoma : A Descart Registry Analysis from the Lysa**

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**Background:** Anti-CD19 CAR T-cells have revolutionized the treatment of aggressive B-cell non-Hodgkin lymphomas (NHL) by demonstrating durable responses. Although follow-up remain short, axicabtagene ciloleucel (axi-cel, ZUMA-5) and tisagenlecleucel (tisa-cel, ELARA) demonstrated promising complete response rates (CRR) of 86% and 69%, respectively, in phase II trials including relapsed or refractory (R/R) follicular lymphoma (FL). Tisa-cel and axi-cel are now approved after at least 2 lines of systemic therapy by the FDA. Few real-world evidence (RWE) data have been reported so far.

**Methods:** Patients were eligible if aged >18 years, had FL histology (grade 1-3A) and had received at least 2 previous treatment lines for tisa-cel and 3 for axi-cel according to the French early access program label. From Dec 2021 to Jan 2023, a total of 112 patients were included in early access program by 21 French centers and in DESCAR-T registry (NCT04328298), among them 87 were infused with a CAR product. At the data cut-off on March 2023, 70 had at least 1 month of follow-up (FU) with PET-CT evaluation, and thus were considered for the safety and efficacy sets (62 tisa-cel and 8 axi-cel).

**Results:** Patient and disease characteristics were as follows: 46 males (65.7%), median age 62 years (range: 34-79), 3 median prior lines of therapy (range 2-9, including bi-specific antibody in 12.9% and autoSCT in 44.3%), FLIPI 0-2 in 40.5% and 3-5 in 49.5%, bulky disease (>5cm) in 22%, and LDH > N 52.2%. POD24 after 1<sup>st</sup> systemic immunochemotherapy (IC) was reported in 44 patients (62.8%). Before CAR T-cell infusion, 58.6% of patients received a bridging therapy (20 (48.8%) chemotherapy, 25 (61%) monoclonal antibodies, 4 (9.8%) kinase inhibitors, 15 (36.6%) lenalidomide, and 3 (7.3%) radiotherapy). All patients but one received a fludarabine and cyclophosphamide-based lymphodepletion. Median time from order to infusion was 48 days (range 34-204), and 41 days (30-328) from leukapheresis to infusion.

Median FU was 7.3 months [6.4; 8.2] from product order, and 5.4 months [3.4; 6] from CAR infusion. Best ORR and CRR were 97.5 and 87.5%, respectively with 72.5% of patients in CR at 1 month with projected DOR and DOCR of 72.4% [56.8; 83.1%], and 79.7% [62.7%; 89.6%], respectively. Projected 6-months PFS, OS, were 71.8% [95% CI, 56.6%; 82.4%], 97.4% [83.2%; 99.6%],

respectively. Fifteen (21.4%) patients progressed (median time from infusion to first relapse: 3 months (range 1-10 mo). Only one patient died from lymphoma progression.

Any-grade CRS and ICANS were reported for 74.3% and 27.1% of patients, but grade 3-4 CRS/ICANS were very infrequent, 1.4% and 4.3%, respectively. No grade 5 was reported. Persisting grade 3-4 hematologic toxicities at 1 and 3 months were: neutropenia (50% and 12.3%), thrombocytopenia (18.6% and 0%), and anemia (8.6% and 0%). Medically relevant bacterial and viral infections were reported in 20% and 14.3% of patients, respectively.

**Conclusions:** Although longer FU is needed to assess disease control, RWE data from the DESCAR-T registry confirm the excellent response rates and safety profile of CAR T-cells in R/R FL after at least 2 lines of previous therapy.

**Disclosures Ysebaert:** *Beigene:* Honoraria, Research Funding, Speakers Bureau; *Roche:* Consultancy, Honoraria, Research Funding; *AstraZeneca:* Consultancy, Honoraria, Research Funding; *Janssen:* Consultancy, Honoraria, Research Funding; *BMS/Celgene:* Consultancy, Honoraria; *Abbvie:* Honoraria, Research Funding, Speakers Bureau; *Gilead/Kite:* Consultancy, Honoraria. **Houot:** *Kite/Gilead, Novartis, Incyte, Janssen, MSD, Takeda, F. Hoffmann-La Roche Ltd:* Honoraria; *Kite/Gilead, Novartis, Bristol-Myers Squibb/Celgene, ADC Therapeutics, Incyte, Miltenyi:* Consultancy. **Jardin:** *Janssen, Gilead, AbbVie, F. Hoffmann-La Roche Ltd, BMS, Takeda:* Honoraria. **Loschi:** *Abbvie:* Honoraria; *Alexion:* Honoraria; *Astra Zeneca:* Honoraria; *BMS Celgene:* Honoraria; *Gilead:* Honoraria; *GSK:* Honoraria; *Jazz:* Honoraria; *Novartis:* Honoraria; *Pfizer:* Honoraria; *Sanofi:* Honoraria; *Sobi:* Honoraria; *Takeda:* Honoraria. **Brisou:** *Novartis:* Consultancy. **Thieblemont:** *AbbVie:* Consultancy, Other: travel fees; *Amgen:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: travel fees; *Gilead Sciences:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: travel fees; *Cellectis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: travel fees; *Novartis:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Incyte:* Consultancy, Honoraria; *Roche:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: travel fees, Research Funding; *Hospira:* Research Funding; *BMS/Celgene:* Consultancy, Honoraria, Research Funding; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Beigene:* Consultancy, Membership on an entity's Board of Directors or advisory committees. **Castilla-Llorente:** *Gilead/Kite:* Consultancy, Other: Travel support; *Nektar Therapeutics:* Consultancy. **Morschhauser:** *Incyte:* Other: Advisory Board; *Genmab:* Consultancy, Other: Advisory Board; *Janssen:* Honoraria; *Celgene:* Other: Advisory Board; *BMS:* Consultancy, Other: Advisory Board; *AbbVie:* Consultancy, Other: Advisory Board; *Epizyme:* Other: Advisory Board; *Novartis:* Consultancy, Other: Advisory Board; *Gilead:* Consultancy, Other: Advisory Board; *Roche:* Consultancy, Honoraria, Other: Advisory Board. **Cartron:** *Roche:* Consultancy, Honoraria; *Novartis:* Honoraria; *MabQi:* Consultancy; *MedxCell:* Consultancy; *Janssen:* Honoraria; *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. **Bachy:** *Hospices Civils de Lyon Claude Bernard Lyon 1 University:* Current Employment; *Pfizer:* Honoraria, Other: Personal Fees; *Takeda:* Honoraria; *Novartis:* Honoraria, Other: Personal Fees; *Incyte:* Honoraria; *Bristol Myers Squibb:* Honoraria, Other: Personal Fees, Research Funding; *Amgen:* Research Funding; *Roche:* Consultancy, Honoraria; *Kite, a Gilead Company:* Honoraria, Other: Personal Fees.

<https://doi.org/10.1182/blood-2023-184653>