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FIRST RESULTS OF DLBCL PATIENTS TREATED WITH CAR-T CELLS AND ENROLLED IN DESCAR-T REGISTRY, A FRENCH REAL-LIFE DATABASE FOR CAR-T CELLS IN HEMATOLOGIC MALIGNANCIES.

Topic: 19. Aggressive Non-Hodgkin lymphoma - Clinical

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Background:

DESCAR-T is the French national registry for patients treated with commercial CAR-T cells (DLBCL and ALL). DESCAR-T has been designed by LYSA/LYSARC and aims to collect real-life data. DESCAR-T was approved by the French authorities in 2019 and is the reference registry for CAR-T cells reimbursement by French health authorities. Data (patients' characteristics, safety, efficacy and long-term outcome...) from time of medical decision to treat with CAR-T cells to up to 15 years after CAR-T cells infusion are registered in DESCAR-T. Several complementary registries are also linked to DESCAR-T database, such as an immune-monitoring database, a blood and tumor biobanking (so-called CeVi-CART) and an imagery platform.

Aims: Herein, we present the first analyses regarding patients' characteristics and outcome of DLBCL patients registered in DESCAR-T.

Methods: All patients with DLBCL registered in DESCAR-T were eligible for the present study. All patients gave informed consent before DESCAR-T registration.

Results: To date (Jan 2021), 14 out of 24 CAR-T cells accredited French centers have registered patients in DESCAR-T. Seven additional centers will be open for DESCAR-T in the coming months. The first patient was registered in December 2019. At the time of the present analysis, 537 DLBCL patients have been registered. CAR-T cells product has been ordered for 517 patients of whom 463 have been infused with CAR-T cells. At the time of registration in DESCAR-T, median age was 63.0 years (range, 53-70), 40.6% of patients were older than 65 years and 3.5% older than 75 years. Lymphoma subtypes were DLBCL (91%), PMBL (3%), and high-grade B-cell

lymphoma (2%). Among patients for whom CAR-T cells have been ordered (n=517), 313 (60.5%) were male, 76 (14.7%) had a PS \geq 2, 377 (72.9%) had an advanced disease (stage III or IV), and 330 (63.8%) had elevated LDH. Median number of prior lines of treatment was 3 (range, 2 – 3) and 21% of patients have been previously transplanted. Median time from CAR-T cells order to infusion was 50 days [range, 43-60]. Median time from leukapheresis to CAR-T infusion was 41.1 days (range, 36-48). Overall, 65% of patients received Axi-cel and 35% received Tisa-acel. Response was available in 419 infused patients. Best ORR was 70.2% (65.5% - 74.5%). At D30 after CAR-T cell infusion, 157 (38%) patients achieved CR and 112 (27%) achieved PR. Among the 157 patients who achieved a CR at D30, 96 (61%) remained in CR at D90. The median follow-up calculated from CAR-T cells order was 7.4 months (range, 5.8-7.9) and 6m [range, 5.5-6.2] from CAR-T infusion. The median OS calculated from time of CAR-T infusion is 12.7m [range, 10.6-NA].

Summary/Conclusion:

This first analysis from DESCAR-T registry seems to confirm CAR-T cells efficacy in real life. And be in line with previously published data. Updated results will be presented at the meeting. Overall, 537 patients with relapsed DLBCL have already been registered in DESCAR-T in 13 months and about 50 new patients are registered each month. This demonstrates that CAR-T cells therapy has become a key treatment for R/R DLBCL. In 2021, DESCAR-T will be extended to mantle cell lymphoma and multiple myeloma and treated with CAR-T cells. DESCAR-T is a new CAR-T registry to investigate CAR-T cells products in real life across all hematological malignancies.

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