Press release September, 18th, 2023

LYSA-LYSARC announces the publication in Nature Medicine of the ALYCANTE study demonstrating the clinical benefit of CAR-T cells (axicabtagene ciloleucel) as a second-line therapy in transplant-ineligible patients with large B-cell lymphoma (LBCL)

LYSA-LYSARC cooperative group is proud to announce today the publication in Nature Medicine of the full clinical results of the ALYCANTE study, showing high complete response rates and durable remissions after CAR-T cell therapy in second line for transplant-ineligible patients with relapse/refractory (R/R) LBCL. The partial results were presented at ASH 2022 and the final analysis confirms the excellent results which are highlighted in the publication in the renowned scientific journal Nature Medicine (reference below).

Final analysis from the ALYCANTE study, a multicenter, prospective, open-label Phase 2 study conducted by the LYSA group, evaluated for the first time, the efficacy and safety of axicabtagene ciloleucel (axi-cel), a CD19-directed CAR-T cell, as a second-line therapy in 62 patients with R/R LBCL who were considered ineligible for autologous stem cell transplantation (ASCT). The study met its primary endpoint, with a complete metabolic response (CMR) of 71% (95% confidence interval [CI], 58.1%–81.8%) at 3 months versus 12% expected with standard of care chemoimmunotherapy (based on historical controls). At 6 months, 59.7% of patients (n=37) remained in CMR.

"Patients with aggressive B-cell lymphomas who are refractory or relapsed early after first-line chemoimmunotherapy have a poor prognosis, especially those not eligible to high-dose chemotherapy and autologous stem cell transplantation," said Prof. Roch HOUOT, Head of Haematology Department, University Hospital of Rennes, France and coordinator of the ALYCANTE study. *"ALYCANTE is the first study to assess axicabtagene ciloleucel as second line therapy for transplant-ineligible R/R LBCL patients. The results showed high response rates and durable remissions in this hard-to-treat population. In France, these results have enabled the extension of the axi-cel early access program in second line, regardless of transplant-eligibility".*

Best objective response (OR) and complete response (CR) rates were 91.9% (n=57) and 82.3% (n=51), respectively. After a median follow-up of 12 months, median progression-free survival (PFS) from infusion was 11.8 months. Median overall survival (OS) was not reached. OS at 12 months was 78.3% (64.7-87.1%). Axi-cel showed an acceptable safety profile in this population of patients who are considered unfit for ASCT. Overall, 8.1% (n=5) and 14.5% (n=9) experienced Grade 3-4 cytokine-release syndrome or Immune Effector Cell Associated Neurotoxicity Syndrome, respectively.

About ALYCANTE study

ALYCANTE is a phase 2 study evaluating the efficacy and safety of axicabtagene ciloleucel in patients with R/R LBCL after one prior line of therapy who were unable to undergo high-dose chemotherapy and autologous stem cell transplantation and sponsored by the LYSA/LYSARC collaborative group (NCT04531046). The primary endpoint was the complete metabolic response (CMR) at 3 months from axicabtagene ciloleucel infusion. The study was funded by Kite, a Gilead Company, and carried out with axicabtagene ciloleucel CAR-Ts manufactured by Kite, a Gilead Company.

Publication reference

Houot, R., Bachy, E., Cartron, G. et al. Axicabtagene ciloleucel in large B cell lymphoma ineligible for autologous stem cell transplantation: the phase 2 ALYCANTE trial. Nat Med (2023). https://doi.org/10.1038/s41591-023-02572-5.

About the LYSA/LYSARC collaborative Group

LYSA, The Lymphoma Study Association, is a non-profit, internationally leading, academic cooperative group gathering multidisciplinary expertise in lymphoma. Its operational structure LYSARC, The Lymphoma Academic Research Organization, has all the integrated functions and platforms dedicated to pathology, biology and imaging to conduct multiple phase 1 to 4 clinical studies and registries. The LYSA has more than 500 members, researchers and medical experts, with a network of about 90 clinical research centers in France, Belgium and Portugal. The LYSA's missions are to promote clinical research, to improve prevention, care, and treatment of patients and to disseminate knowledge about all types of lymphoma.

About Large B-Cell Lymphoma (LBCL)

Large B-cell lymphoma (LBCL) is the most common sub-type of non-Hodgkin lymphoma (NHL), representing around 31% of cases. In Europe it is estimated that up to 38,000 new cases of LBCL were diagnosed in 2020. Although first-line treatment can be effective in around 60% of cases, up to half of these will relapse (return). For people who relapse, or who do not respond to first-line treatment, outcomes are often poor. Most patients with refractory (no response) LBCL have no curative options with standard treatments.

Media Contacts:

LYSA – LYSARC
Aurélie ONNIS
Head of Communication
aurelie.onnis@lysarc.org
+33 (0)6 85 33 94 72 (mobile)