DESCAR-T: a French nationwide registry for patients treated by chimeric antigen receptor t (CAR-T) cells

Co-funded by the Health Programme of the European Union

TYPE	STATUS	LAST UPDATE	
	Fully implemented Ongoing program	June 2021	FRANCE ● NATIONAL Diagnostic & treatment CAR-T cells innovative cellular immunotherapy

PROBLEM & OBJECTIVE

PROBLEM Immunotherapy using T cells genetically engineered to express a chimeric antigen receptor (CAR-T cell) is rapidly emerging as a promising new treatment for hematological malignancies including lymphoma. CAR-T cells have benefited from an accelerated approval procedure in many countries. In December 2018, French health authorities issued conditional approvals for two CAR-T specialties 2018, with the requirement that data are collected about safety and efficacy in a real-life tool.

OBJECTIVE The main objective of the DESCAR-T registry is to describe overall survival of patients eligible for CAR-T. Secondary objectives include (i) describing overall survival of patients treated with CAR-T; (ii) evaluating CAR-T efficacy in real-life settings; and (iii) describing the short-term and long-term safety profile of CAR-T in real-life.

CONTACT

Florence Broussais
Medical director
florence.broussais@lysarc.org

LYSARC
Centre Hospitalier Lyon Sud
Bâtiment 2D
165 Chemin du Grand Revoyet
69495 Pierre Bénite Cedex France
experts-recherche-lymphome.org

KEY COMPONENTS / STEPS

After HAS approved the DESCAR-T protocol in June 2019, LYSARC initiated the DESCAR-T registry.

- An electronic case report form was created to collect data on demographics, clinical characteristics, treatment pre- and post- CAR-T, toxicities, relapses, vital status.
- Data are extracted from medical records, after receiving informed consent from patients.
- Authorization was obtained from the National Commission for data protection and freedom of information (CNIL) to collect the unique social security number, in order to facilitate long term follow-up of vital status of patients.
- All French centres qualified for CAR-T infusion were contacted and offered to join the registry, with the first centre opening in December 2019.
- As of April 2021, 23 hospitals are actively participating in the DESCAR-T registry, with the objective to activate all French sites qualified for CAR-T.
- As of April 29th, 2021, 748 patients have been included in DESCAR-T.
- A collaboration has been implemented with medical information departments in hospitals so that they can use data extracted from DESCAR-T registry as a basis for CAR-T and hospital stay reimbursement.
- New CAR-T specialties for additional indications (e.g., mantle cell lymphoma, myeloma) are expected to be authorized in 2021 and 2022 and will be included in DESCAR-T.

KEY CONTEXTUAL FACTORS

- To avoid multiple data collection sources, the National Health Authority (HAS) recommended the creation of a national independent data collection tool to follow-up patients treated with CAR-T in France.
- Six collaborating groups and scientific societies (Lymphoma Study Association (LYSA), Group for Research on Adult Acute Lymphoblastic Leukemia (GRAAL), French Myeloma Intergroup (IFM), French Innovative Leukemia Organization (FILO), French Society of Endoscopic Surgery (SFCE), and Francophone Society of bone marrow transplant and cell therapy (SFGM-TC)) expressed their interest to create a registry and mandated the Lymphoma Academic Research Organisation (LYSARC) to design and build the nationwide registry, named DESCAR-T, which was approved by the HAS in June 2019.
- LYSARC is the sponsor of DESCAR-T and in charge of implementation.
- The collaborating groups and scientific societies are members of the DESCAR-T Scientific Committee and give strategic scientific guidance.

MAIN IMPACTS / ADDED VALUE

- One of the strengths of the DESCAR-T is its dual objective, specifically meeting regulatory requirements for CAR-T cell evaluation of efficacy and safety in real-life for regulatory bodies, as well as meeting scientific requirements to improve scientific knowledge around CAR-T cells.
- Thanks to DESCAR-T, the scientific community is better able to understand real-life use of CAR-T cells in France, which patients benefit most from this treatment, and what are the risk factors for post-CAR-T cell relapse.
- Ultimately, the main benefit will be improved treatments for patients suffering from an advanced hematologic malignancy.

LESSONS LEARNED

- First challenge – governance: With the number and diversity of stakeholders (health authorities, industrial partners, cooperating groups) as well as requirements (scientific, regulatory and reimbursement) and data entry challenges in centres (e.g., avoiding duplicate data entry), one of the keys was to establish the overall approach to governance with representatives and missions for each stakeholder.
- Second challenge – data quality: Real-life data collection presents specific challenges that need ad hoc tools to be created, and very strong relationships with centers. The pre-existing hospitals network of collaborating groups, with their mutual history and trust, was crucial in ensuring the proper implementation of DESCAR-T.
- Third challenge – financial sustainability: Industry partners are currently supporting all costs of the registry, but a sustainable long-term financial model has not yet been guaranteed.

REFERENCES & DOCUMENTATION

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- Avis du 5 décembre 2018 de la COMMISSION DE LA TRANSPARENCE concernant YESCARTA® (indication concernée : «YESCARTA est indiqué pour le traitement des patients adultes atteints de lymphome diffus à grandes cellules B (LDGCB) et de lymphome médiastinal primitif à grandes cellules B (LMPGCB) réfractaire ou en rechute, après au moins deux lignes de traitement systémique. »).
- Avis du 12 décembre 2018 de la COMMISSION DE LA TRANSPARENCE concernant KYMRIAH® (indication concernée : «Traitement des adultes atteints de lymphome diffus à grandes cellules B (LDGCB) en rechute ou réfractaire après la deuxième ligne ou plus d'un traitement systémique»).
- Avis du 12 décembre 2018 de la COMMISSION DE LA TRANSPARENCE concernant KYMRIAH® (indication concernée : Traitement des enfants et jeunes adultes jusqu'à 25 ans atteints de leucémie aigüe lymphoblastique (LAL) à cellules B réfractaire, en rechute après greffe ou après la deuxième rechute ou plus. »).

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This publication was funded by the European Union's Health Programme (2014-2020)