Revista Colombiana de
Cancerología

Octubre - Diciembre / 2025

Rev Colomb Cancerol. 2025;29(4):131-134
https://doi.org/10.35509/01239015.1156

EDITORIAL

# The impact of CAR T-cell therapy on current cancer management and its outlook in Colombia

# *El impacto de la terapia celular CAR-T en el manejo actual del cáncer y su panorama en Colombia*

Juan Esteban Garcia-Robledo[1,2], Beatriz Wills[3,4,5], Gustavo Salguero[6], Virginia Abello[7], Juan Camilo Baena[2,8], Humberto Martínez-Cordero[5,9]

1 Centro de Investigación en Hematología y Oncología (CIHO), IDC Instituto de Cáncer Hemato Oncólogos, Cali, Colombia.
2 Grupo LiliCAR-T, Fundación Valle del Lili, Cali, Colombia.
3 Departamento de Oncología, Fundación Santa Fe de Bogotá, Bogotá, D. C., Colombia.
4 Facultad de Ciencias de La Salud, Universidad de los Andes, Bogotá, D. C., Colombia.
5 Grupo de Investigación Clínica y Epidemiológica del Cáncer, Instituto Nacional de Cancerología, Bogotá, D. C., Colombia.
6 Dirección General, Instituto Distrital de Ciencia, Biotecnología e Innovación en Salud (IDCBIS), Bogotá, D. C., Colombia.
7 Unidades Funcionales Clínicas de Leucemia, Linfoma y Mieloma, y de Trasplante de Progenitores Hematopoyéticos y Terapia Celular, Centro de Tratamiento e Investigación sobre Cáncer Luis Carlos Sarmiento Angulo (CTIC), Bogotá, D. C., Colombia.
8 División de Hematología y Oncología, Departamento de Medicina Interna, Fundación Valle del Lili, Cali, Colombia.
9 Unidad de Hemato-Oncología, Hospital Militar Central, Bogotá, D. C., Colombia.

Cancer treatment has experienced an unprecedented therapeutic revolution, driven by the introduction of various types of immunotherapy and advanced biotechnology. In this paradigm shift, cell therapy using T-cells that express a chimeric antigen receptor (CAR T-cell therapy) has emerged as one of the most promising and transformative approaches for treating hematologic malignancies and is increasingly being explored in solid tumors (1).

In just one decade, the concept of extracting autologous T-cells, genetically modifying them using viral vectors to express synthetic receptors capable of recognizing specific tumor antigens, expanding them *ex vivo* and reinfusing them into the patient shifted from a science fiction-like experimental approach to therapies approved by international regulatory agencies such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA). Several products approved and used today include tisagenlecleucel (anti-CD19) (2-3), axicabtagene ciloleucel (anti-CD19) (4), brexucabtagene autoleucel (anti-CD19) (5), lisocabtagene maraleucel (anti-CD19) (6), obecabtagene autoleucel (anti-CD19) (7), idecabtagene vicleucel (anti-BCMA) (8), and ciltacabtagene autoleucel (anti-BCMA) (9), which have demonstrated objective response rates and extended survival in traditionally refractory pathologies, such as relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) in both pediatric and adult patients, high-risk aggressive B-cell lymphomas, and multiple myeloma (MM).

Figure 1 presents a summary of the steps required for CAR T-cell therapy.

**Conflicts of interest**
The authors declare no conflicts of interest.

**Citation**
Garcia-Robledo J-E, Wills B, Salguero G, Abello V, Baena J-C, Martínez-Cordero H. The impact of CAR T-cell therapy on current cancer management and its outlook in Colombia. Rev Col Cancerol. 2025;29(4):131-4.
https://doi.org/10.35509/01239015.1156

**Corresponding author**
Juan Esteban Garcia-Robledo
- Centro de Investigación en Hematología y Oncología (CIHO), IDC Instituto de Cáncer Hemato Oncólogos, Cali, Colombia.
- Grupo LiliCAR-T, Fundación Valle del Lili, Cali, Colombia.

**Email:** juanegarcia@hematooncologos.com.co

**Co-corresponding author**
Humberto Martínez-Cordero
- Grupo de Investigación Clínica y Epidemiológica del Cáncer, Instituto Nacional de Cancerología, Bogotá, D. C., Colombia.
- Unidad de Hemato-Oncología, Hospital Militar Central, Bogotá, D. C., Colombia.

**Email:** rmartinez@cancer.gov.co

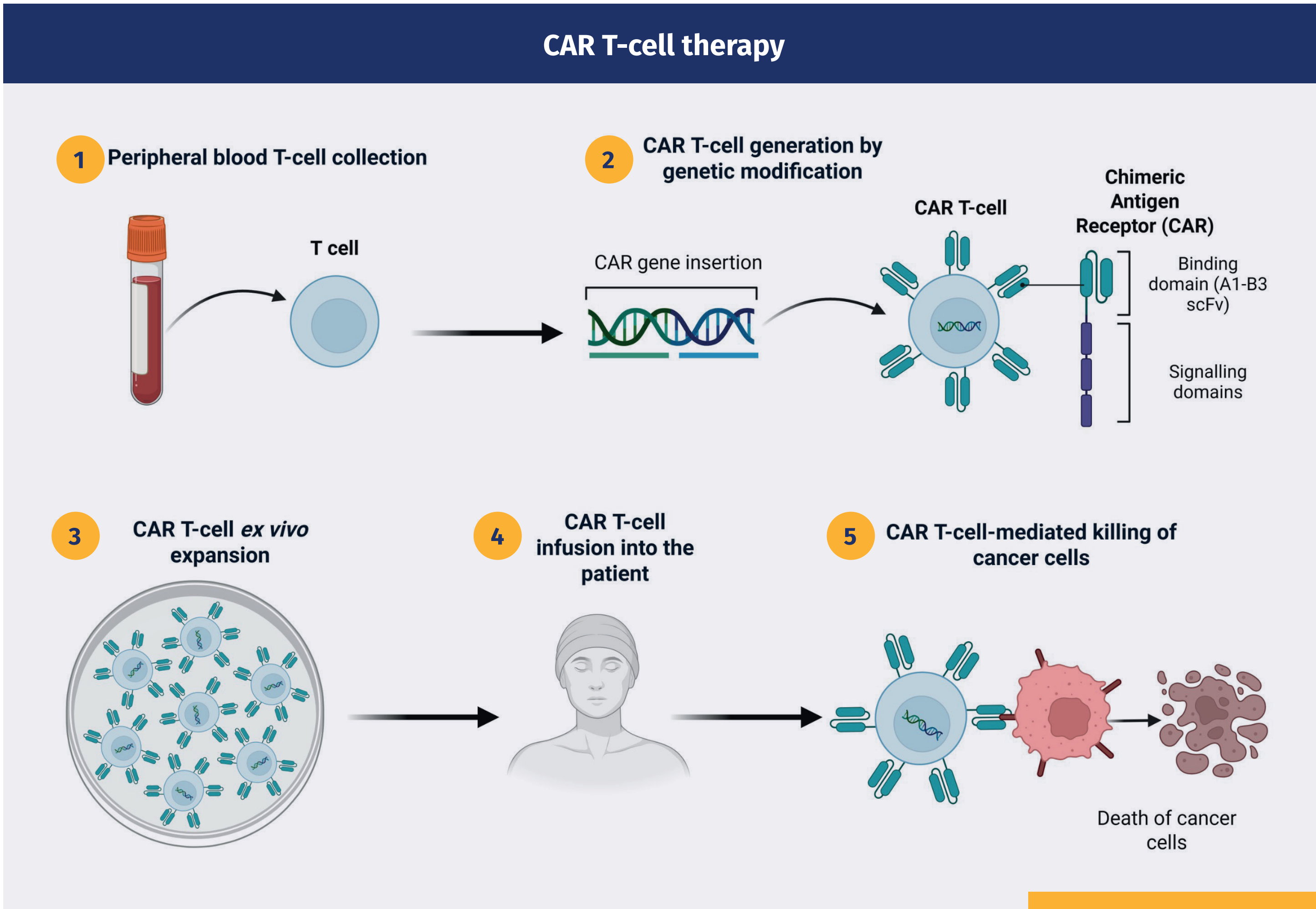


**Figure 1**. CAR T-cell manufacturing and application process. 1) Autologous T-cells are extracted and separated from peripheral blood. 2) *In vitro*, the genetic material encoding the CAR is transduced, usually using lentiviral vectors. 3) The transduced T-cells, now CAR T-cells, are expanded *ex vivo* by stimulating CD3 and CD28. 4) The expanded CAR T-cells are reinfused into the patient. 5) Circulating CAR T-cells recognize tumor cells that express CD19 and proceed to activate, expand, and execute their effector mechanisms to induce tumor destruction. Created in BioRender.com

Current data confirm CAR T-cell therapy as the primary treatment to achieve lasting remissions in patients with refractory hematologic diseases or multiple relapses after previous treatments. For example, in pivotal studies such as JULIET (3) and ZUMA-1 (4), complete response rates ranged from 40% to 54%, with median overall survival approaching two years—unprecedented figures in this clinical setting. These advances have redefined life expectancy and the prognostic outlook for many hematologic diseases, positioning CAR T-cell therapy even in early-stage treatment. However, implementing this therapy involves numerous logistical, regulatory, clinical, and financial challenges. The customized manufacturing of each product requires highly specialized production platforms and strict quality controls, with production times (vein to vein) spanning from three to six weeks (10-11).

The associated adverse effects, especially cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS) (12), and toxicity in other organs and tissues, such as hematologic effects, require multidisciplinary training, critical care experience, and standardized management protocols.

In Colombia, interest in CAR T-cell therapies has increased considerably in recent years. Several high-complexity institutions have started the process of establishing centers for collecting, processing, and administering these therapies. In this context, the Collaborative Alliance for the Implementation of Advanced Therapies in Colombia (ACITAC, for its acronym in Spanish) emerged, led by the *Instituto Distrital de Ciencia, Biotecnología e Innovación en Salud* (IDCBIS). This public-private partnership, which includes the *Instituto Nacional de Cancerología* (INC) and hemato-oncologists from across the country, is conducting the first type 2 hybrid study implementing anti-CD19 CAR T-cell therapy in Colombia, called ACITAC-001.

The ACITAC-001 protocol, organized by the project's leading clinical team and developed in collaboration with the INC, has received approval from the INC's Research Ethics Committee. It also has the support of the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (Invima) and funding from the Health Research Fund Committee (FIS, for its acronym in Spanish), which includes the Ministry of Health and Social Protection and the Ministry of Science, Technology, and Innovation, amounting to over five billion Colombian pesos.

This support facilitates technology transfer and the evaluation of the lentiviral academic product ARI-0001, an anti-CD19 CAR T-cell therapy developed at the *Hospital Clínic de Barcelona* (Spain). Its recognition domain is derived from a single-chain variable fragment (scFv) from the murine clone A3-B1. Initially, ARI-0001 was tested in twelve Colombian patients with relapsed or refractory B-ALL or aggressive CD19-positive lymphomas. ARI-0001 has demonstrated outstanding efficacy and safety in these indications (13-14) and serves as a CAR T-cell therapy model worth replicating.

The main goal of the study is to demonstrate the feasibility of affordable and accessible CAR T-cell therapies through an academic model and a point-of-care test, inspired by the experience of the *Hospital Clínic de Barcelona* and implemented via a public-private partnership, where implementation sciences play a key role; therefore, a hybrid methodology was chosen.

Work is already underway at the INC, through the Cellular Immunotherapy Committee (CIC, for its acronym in Spanish) and the Center of Excellence in Multiple Myeloma (CEMMINC, for its acronym in Spanish), to expand this model to anti-BCMA CAR T-cell therapies for multiple myeloma and related diseases. The aim is to develop a decentralized and sustainable platform that makes these treatment options accessible to the largest possible number of patients who need them today (15).

Despite this, significant barriers remain regarding funding (due to very high per-patient costs), import times, regulatory approval, and the need for specialized infrastructure.

This initiative is an opportunity for Colombia in the local development of cell therapy platforms. The country has strong clinical research centers, highly trained human talent in hematology, oncology, immunology, and biotechnology, and an academic ecosystem prepared to innovate. Additionally, other national manufacturing projects for research on CAR T-cell therapies are starting to emerge, aiming to lower costs, shorten access times, and foster technological independence, alongside national research and development of new therapies. Some groups are also working on creating new transfection methods using nanotechnology (16).

In this context, it is essential to strengthen collaborative networks such as the one established by ACITAC, which brings together scientific societies, research groups, regulatory agencies, and experts from across the country. Training specialist physicians, residents, and young researchers in advanced immunotherapy must be a top priority, as they will lead the safe and effective implementation of these treatments in the future.

CAR T-cell therapy is much more than just a new drug; it represents a paradigm shift in oncology, where the patient's own cells become living medicines capable of eradicating minimal residual disease and providing extended remissions. Our responsibility as a hematology and oncology community is to establish the foundation for the ethical, sustainable, and equitable adoption of these therapies, ensuring that their benefits reach those who need them most in Colombia.

## References

1. Moreno-Cortes E-F, Garcia-Robledo J-E, Booth, N, Forero J-V, Castro J-E. Optimization of third generation chimeric antigen receptor T cells targeting ROR1 for hematological malignancies. Blood. 2021;138(supl. 1):4804. https://doi.org/10.1182/blood-2021-154127

2. Maude S-L, Laetsch T, Buechner J, Rives S, Boyer M, Bittencourt H, *et al*. Tisagenlecleucel in children and young adults with B-cell lymphoblastic leukemia. N Engl J Med. 2018;378(5):439-48. https://doi.org/10.1056/nejmoa1709866

3. Schuster S, Bishop M, Tam C, Waller E, Borchmann P, McGuirk J, *et al*. Tisagenlecleucel in adult relapsed or refractory diffuse large B-cell lymphoma. N Engl J Med. 2019;380(1):45-56. https://doi.org/10.1056/nejmoa1804980

4. Neelapu S, Locke F, Bartlett N, Lekakis L, Miklos D, Jacobson C, *et al*. Axicabtagene ciloleucel CAR T-Cell therapy in refractory large B-Cell lymphoma. N Engl J Med. 2017;377(26):2531-44. https://doi.org/10.1056/nejmoa1707447

5. Wang M, Munoz J, Goy A, Locke F, Jacobson C, Hill B, *et al*. KTE-X19 CAR T-Cell therapy in relapsed or refractory mantle-cell lymphoma. N Engl J Med. 2020;382(14):1331-42. https://doi.org/10.1056/nejmoa1914347

6. Abramson J-S, Palomba M, Gordon L, Lunning M, Wang M, Arnason J, *et al*. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. Lancet. 2020;396(10254):839-52. https://doi.org/10.1016/s0140-6736(20)31366-0

7. Roddie C, Sandhu K, Tholouli E, Logan A, Shaughnessy P, Barba P, *et al*. Obecabtagene autoleucel in adults with B-cell acute lymphoblastic leukemia. N Engl J Med. 2024;391(23):2219-30. https://doi.org/10.1056/nejmoa2406526

8. Munshi N-C, Anderson L, Shah N, Madduri D, Berdeja J, Lonial S, *et al*. Idecabtagene vicleucel in relapsed and refractory multiple myeloma. N Engl J Med. 2021;384(8):705-16. https://doi.org/10.1056/nejmoa2024850

9. Berdeja J-G, Madduri D, Usmani S, Jakubowiak A, Agha M, Cohen A, *et al*. Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. Lancet. 2021;398(10297):314-24. https://doi.org/10.1016/s0140-6736(21)00933-8

10. Martinez-Cordero H, Fuentes-Lacouture C, von Glasenapp A, Peña C. The 5T's of health disparities in multiple myeloma in Latin America. Curr Opin Oncol. 2024;36(6):610-4. https://doi.org/10.1097/cco.0000000000001088

11. Shah M, Krull A, Odonnell L, de Lima M-J, Bezerra E. Promises and challenges of a decentralized CAR T-cell manufacturing model. Front Transplant. 2023;2:1238535. https://doi.org/10.3389/frtra.2023.1238535

12. Garcia-Robledo J-E, Valencia-Sanchez C, Knox M, Goodman B, Rosenthal A, Patel B, *et al*. It is in the eye of the beholder: ocular ultrasound enhanced monitoring of neurotoxicity after CAR-T cell therapy. Hematol Rep. 2022;15(1):1-8. https://doi.org/10.3390/hematolrep15010001

13. Ortíz-Maldonado V, Rives S, Castellà M, Alonso-Saladrigues A, Benítez-Ribas D, Caballero-Baños M, *et al*. CART19-BE-01: a multicenter trial of ARI-0001 cell therapy in patients with CD19+ relapsed/refractory malignancies. Mol Ther. 2021;29(2):636-44. https://doi.org/10.1016/j.ymthe.2020.09.027

14. Ortiz-Maldonado V, Martinez-Cibrian N, Del Campo G, Español-Rego M, Navarro S, Lopez-Oreja I, *et al*. Varnimcabtagene autoleucel (ARI-0001) for relapsed or refractory chronic lymphocytic leukemia (CLL) and Richter transformation (RT). Blood.2023;142(supl. 1):3483. https://doi.org/10.1182/blood-2023-182896

15. Martínez-Cordero H. From hope to reality: the road to cure from multiple myeloma centers of excellence. Rev Col Cancerol. 2023;27(2):194-7. https://doi.org/10.35509/01239015.989

16. Baena J-C, Victoria J-S, Toro-Pedroza A, Aragón C, Ortiz-Guzman J, Garcia-Robledo J-E, *et al*. Smart CAR-T nanosymbionts: archetypes and proto-models. Front Immunol. 2025;16:1635159. https://doi.org/10.3389/fimmu.2025.1635159