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In-Vivo CAR-T Therapies: A New Horizon in Market Access for Autoimmune Disease and Beyond

By ***Oznur Seyhun*** *30 July 2025* *0* *95*

The field of advanced cell and gene therapies is evolving rapidly—and nowhere is this more evident than in the growing interest around **in-vivo CAR-T therapies**. Traditionally viewed through the lens of oncology, these therapies are now **expanding into autoimmune diseases and fibrotic conditions**, signaling a profound shift not just in clinical science, but in the market access landscape.

A new white paper from Novotech, *In-Vivo CAR Therapies – Global Research and Development Landscape (2025)*, outlines the transformative impact of this next-generation modality—and what stakeholders in pricing, reimbursement, and policy must prepare for.

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Streamlining the CAR-T Paradigm: A Market Access Milestone

Ex-vivo CAR-T therapies have delivered impressive outcomes for certain cancers, but they come with steep logistical and financial barriers: individualized manufacturing, long lead times, and six-figure price tags. These challenges have limited scalability and placed pressure on health systems, payers, and policymakers alike.

(LNPs), and mRNA platforms to engineer T cells directly inside the body, these therapies **eliminate the need for centralized cell manufacturing**, potentially lowering cost, reducing turnaround time, and improving access across diverse care settings—including in community hospitals and emerging markets.

From Oncology to Autoimmunity: Broadening Indications, Expanding Markets

According to Novotech's report, in-vivo CAR-T therapies are now being developed for **autoimmune conditions like systemic lupus erythematosus (SLE), multiple sclerosis, and type 1 diabetes**—diseases with **high global burden**, chronic treatment costs, and substantial unmet need. This opens new doors for payers and health technology assessment (HTA) bodies to reconsider how cell therapies can be valued and reimbursed **beyond oncology.**

If durable remission can be achieved without long-term immunosuppression, **lifetime treatment costs could be significantly reduced**, shifting the value proposition in favor of early intervention. This would represent a **critical inflection point** for payers who have struggled to reconcile short-term budget impact with long-term societal and health system value.

Regulatory and Commercial Considerations: Ready for Scale?

The white paper also dives into regulatory dynamics shaping the in-vivo CAR-T space. While frameworks for ex-vivo therapies are relatively mature, **in-vivo approaches challenge traditional regulatory models**, particularly around manufacturing control, safety monitoring, and long-term follow-up. Health authorities are beginning to adapt, but harmonization and clarity will be essential for consistent global access.

On the commercial side, **biotech sponsors and CROs are now optimizing in-vivo CAR-T platforms for scalability**, with Novotech leading clinical development efforts across Asia-Pacific, North America, and Europe. With more than **100 ATMP studies completed** and the **world's first in-vivo CAR-T trial** under its belt, Novotech is positioned to help bring these programs to market quickly and efficiently.

Access Implications: What Stakeholders Should Watch

1. **Shift to One-Time Treatments**: In-vivo CAR-T may follow the pricing model of gene therapies—large up-front costs with long-term benefit. Outcomes-based agreements may be essential to align payer expectations.
2. **Infrastructure Simplification**: Eliminating the need for cell collection and reengineering could reduce treatment center exclusivity, enabling broader geographical access.
3. **New Burden of Proof**: Clinical trials must demonstrate not only efficacy and safety but **real-world durability, cost-offset potential, and population-wide applicability**—all key metrics for market access.
4. **Indication Sequencing**: Success in autoimmune conditions could justify earlier interventions and redefine treatment pathways, especially in countries where biologics already strain budgets.

Conclusion: Preparing for the Next Chapter in Cell Therapy

The promise of in-vivo CAR-T therapies is not just scientific—it is economic, logistical, and structural. With clinical programs expanding across oncology, autoimmunity, and fibrosis, the need for thoughtful market access strategies has never been greater.

Novotech's white paper offers a valuable foundation for stakeholders seeking to understand how delivery innovations, regulatory shifts, and global trial momentum are converging to **reshape the economics of cell therapy**.

To access the full report or connect with Novotech experts for deeper insights, contact: mediacontact@novotech-cro.com

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