

# Anito-cel CAR-T Shows Breakthrough Results in Multiple Myeloma and What That Means for Next-Gen Manufacturing with ABBIE



Recent data presented at the 2025 American Society of Hematology (ASH) meeting and reported in medical press have confirmed that anitocabtagene autoleucel — widely known as anito-cel — is delivering remarkable results in patients with relapsed or refractory multiple myeloma. This progress represents a major milestone in cellular immunotherapy, especially for patients who have exhausted conventional treatment options.

## **Anito-cel: Deep, Durable Responses in Hard-to-Treat Patients**

Anito-cel, an investigational CAR-T therapy developed through a collaboration between Arcellx and Gilead's Kite Oncology, targets B-cell maturation antigen (BCMA) — a protein highly expressed on multiple myeloma cells. In the pivotal Phase II iMMagine-1 study of heavily pretreated patients, anito-cel showed:

- Overall response rates around ~96–97%
- Complete response rates approaching ~68–74%
- Sustained progression-free survival and overall survival at 12–18 months
- A favorable safety profile with manageable side effects, including minimal neurotoxicity.

These results are highly promising, indicating that anito-cel not only fights disease effectively but may also offer durable remissions with safety that compares favorably to existing CAR-T options.

## **CAR-T's Promise — And Its Manufacturing Bottleneck**

CAR-T cell therapies work by harvesting a patient's own T cells, genetically reprogramming them to attack cancer cells, and then reintroducing them into the body. While this approach has revolutionized treatment for several hematologic cancers, including certain lymphomas and multiple myeloma, it still faces one of the key limitations in today's clinical landscape: manufacturing speed, consistency, and cost.

Traditional CAR-T manufacturing uses viral vectors — complex, costly reagents that require specialized facilities and lengthy timelines. This often results in variable production times and high manufacturing costs, which can delay treatment and limit access.

## **How SOHM Inc.'s ABBIE Platform Could Transform CAR-T Manufacturing**

That's where platforms like ABBIE — developed by SOHM Inc. — could play a transformative role.

ABBIE is a non-viral, programmable genomic integration system that uses a Cas9-guided integrase to insert therapeutic genes precisely and efficiently, without the need for viral vectors. The platform is designed to enable controlled and stable gene insertion while avoiding the double-strand DNA breaks that can occur with conventional approaches.

### **Anito cel CAR-T**

Anitocabtagene autoleucel, widely known as anito-cel, was developed through a collaboration between Arcellx and Kite, a Gilead company, as a next-generation CAR-T therapy specifically designed for relapsed or refractory multiple myeloma. Unlike many earlier CAR-T products that rely on traditional antibody fragments to recognize cancer cells, anito-cel uses a novel, synthetic "D-Domain" binder — a compact, engineered protein that targets the B-cell maturation antigen (BCMA) present on the surface of multiple myeloma cells. This innovative binder allows high levels of CAR expression on T cells without constant activation ("tonic signaling"), potentially improving both efficacy and safety. The design promotes strong engagement with BCMA while enabling the CAR to release quickly, which may help reduce excessive inflammation during treatment. Anito-cel has advanced through Phase I and pivotal Phase II (iMMagine-1) studies and has received Fast Track, Orphan Drug, and Regenerative Medicine Advanced Therapy designations from the U.S. FDA.

Mechanistically, anito-cel works like other CAR-T therapies in that it begins with a patient's own T cells being collected and genetically engineered to express a chimeric antigen receptor that recognizes BCMA. Once infused back into the patient after preparative (lymphodepleting) chemotherapy, these modified T cells seek out and bind to myeloma cells via BCMA, become activated, expand in number, and then directly kill cancer cells. The D-Domain design enhances T-cell transduction efficiency and CAR surface density, which may contribute to rapid and deep tumor responses while helping to temper the severity of side effects often seen with CAR-T therapies.

### **Here's how ABBIE could help accelerate and improve CAR-T manufacturing:**

#### **1. Faster, More Scalable Production**

Non-viral manufacturing bypasses the need to produce lentiviral or retroviral vectors — one of the most time-consuming steps in CAR-T production. ABBIE's system can integrate CAR constructs directly using synthetic components, potentially reducing the manufacturing timeline and simplifying scale-up.

#### **2. Lower Cost of Goods**

Viral vector production is expensive and resource-intensive. By eliminating reliance on these vectors, ABBIE has the potential to shrink costs, making CAR-T therapies like anito-cel more economically feasible for broader patient populations.

#### **3. Improved Safety & Precision**

Because ABBIE uses a guided integrase approach with fewer off-target effects and without viral insertional risks, the platform could enhance the safety and predictability of CAR-T products — a benefit especially relevant for fragile patients such as those with advanced multiple myeloma.

#### 4. Platform Flexibility

Beyond a single CAR construct, ABBIE's architecture is designed to support multiple therapeutic targets and editing strategies. This means that once the platform is proven in one setting, it could be adapted rapidly to other CAR-T designs or indications — potentially speeding the pace of innovation across the cell therapy field.

#### **A Future Where CAR-T Is Faster, Cheaper, Better**

The success of anito-cel underscores how far CAR-T therapy has come in tackling complex cancers like multiple myeloma. Yet even with these advances, the full potential of cell therapy will only be realized when manufacturing hurdles are overcome.

Platforms like ABBIE may not only accelerate production timelines but could also expand accessibility and reduce costs, making life-saving CAR-T treatments more widely available.

In the rapidly evolving landscape of cancer immunotherapy, combining clinical breakthroughs like anito-cel with next-generation manufacturing platforms like ABBIE could be the key to delivering better patient outcomes faster and at scale.