

## **LEVERAGING BIOPROCESS PLATFORM TECHNOLOGY FOR THE DEVELOPMENT OF A ROBUST, SCALABLE, AND ECONOMIC MANUFACTURING PROCESS OF ALLOGENEIC CAR-T CELL THERAPY PRODUCTS**

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The current autologous chimeric antigen receptor (CAR)-T cell therapy products, both commercially approved and in clinical development, have been instrumental in changing treatment paradigm to benefit cancer patients. The therapeutic success of these treatment options has, to some extent, been tempered by the challenges of consistently manufacturing patient-specific products and by the introduction of a new manufacturing model involving scaling-out and subsequent releasing 100-1000s of patient-specific lots.

Adicetbio is building on the therapeutic success of patient-specific CAR-T cell therapies by employing gamma delta (gd) T cells and engineered T-cell receptor-like tumor recognition to improve the safety and efficacy of CAR-T cell therapies against both liquid and solid tumors. Additionally, we are optimizing the manufacture allogeneic CAR gd-T cells to facilitate off-the-shelf treatment of hundreds of patients per manufacturing run. . This approach greatly simplifies the complexity of manufacturing associated with the autologous model through minimizing the variation of processing patient material and eliminating the need to support large product release testing infrastructure. Results will be presented outlining results of ongoing process development and demonstrating that, by leveraging established bioprocess platform technologies, we can efficiently engineer, expand, harvest, and cryopreserve up to  $2 \times 10^{11}$  CAR-T cells from a single healthy donor in a cGMP-compliant manner. Figure 1 outlines the CAR gd-T cell manufacturing process. This approach is scalable to both support the needs of internal development as well as clinical trials, achieving substantial economies of scale while maintaining product quality consistency.