

POSTmark™ CAR-T

Our Platform Optimized for Scale-up and Transfer (POSTmark™) consists of mirrored R&D and cGMP equipment, and process to enable:

- Support for all stages of development from R&D to cGMP scale
- IND-ready in 9 -12 months
- Fast 7-day process
- Reduce time, costs and risks

POSTmark™ was developed so that your first shot, is your best shot

POSTmark™ CAR-T At-a-Glance

- Functionally closed, rapid 7-day CAR-T process
- IND-ready in 9-12 months
- Integrated viral vector capabilities drive efficiencies and consolidated timelines
- Fresh and frozen supply chain capabilities
- cGMP manufacturing in Boston; minutes drive to world class clinical trial sites
- Support for all stages of development from Benchtop R&D to cGMP scale
- Mirrored process/analytical development and cGMP unit operations supports IND-enabling materials that can be ported into an identical cGMP-compliant workstream
- Customizable process and analytical development packages including potency assay development to commercial standards
- In house CMC Regulatory expertise and support including supporting health authority interactions, briefing books and module writing
- Our cGMP facilities, laboratories and processes have been developed and implemented to meet US FDA cGMP regulatory requirements including 21 CFR Parts 11, 210, 211, 610, and 1271; relevant US FDA Guidelines; and relevant ICH Quality Guidelines



CAR-T PROCESS



7 DAYS

IND-READY



9 - 12 MONTHS

POSTmark™ CAR-T Platform

Day 0

RECEIPT & WASH

MAGNETIC BEAD-BASED
ENRICHMENT OF T CELLS
OR T-CELL SUBSETS

ACTIVATION

Day 2

TRANSDUCTION

Days 3-7

EXPANSION

Day 7

WASH & HARVEST
FORMULATION/FILL
QC TESTING

CAR - T Analytics

| CAR-T | | | |
|----------|--|---|----------------------------|
| CQA | Attribute | Test Method | Report |
| Identity | CAR-T | Flow Cytometry | Frequency (%) |
| | T Cell | Flow Cytometry | Frequency (%) |
| Purity | Non-T | Flow Cytometry | Frequency (%) |
| | Viability | Automated Cell Counters/ Flow Cytometry | Cells/mL |
| Potency | In-vitro Cytotoxicity | Flow Cytometry | % Cytotoxicity |
| | Cytokine Production | Flow Cytometry/ELISA | % positive / Concentration |
| Safety | Vector Copy Number | qPCR/ddPCR | Copy/Cell |
| | Replication Competence | qPCR | VSVG (Copies/mL) |
| | Compendial (Myc, Sterility, Endotoxin) | Assay Specific | Detection (Pass/Fail) |

About Landmark Bio

Landmark Bio is a collective endeavor that brings together academia, industry, and hospitals to advance the development of transformative medicines. Founding members include Harvard University, Massachusetts Institute of Technology (MIT), FUJIFILM Diosynth Biotechnologies (FDB), Cytiva, and Alexandria Real Estate Equities, Inc.

Landmark Bio provides end-to-end and process development, biomanufacturing capabilities and consulting services for life sciences innovators working on novel modalities such as cell, gene, and RNA medicines, and develop innovative manufacturing technologies to enable the advancement of novel therapies.

