

**POSTmark**<sup>™</sup>CAR-T

Our Platform Optimized for Scale-up and Transfer (POSTmark<sup>\*\*</sup>) consists of mirrored R&D and cGMP equipment, and process to enable:

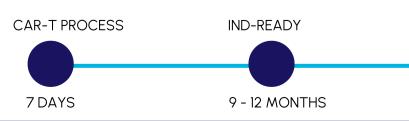
- Support for all stages of development from R&D to cGMP scale
- IND-ready in 9 -12 months
- Fast 7-day process
- Reduce time, costs and risks

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

## POSTmark<sup>®</sup>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





**ANDMARK BIO** 

## POSTmark<sup>™</sup>CAR-T Platform



## CAR - T Analytics

CAR-T			
CQA	Attribute	Test Method	Report
Identity	CAR-T	Flow Cytometry	Frequency (%)
Purity	T Cell	Flow Cytometry	Frequency (%)
	Non-T	Flow Cytometry	Frequency (%)
	Viability	Automated Cell Counters/ Flow Cytometry	Cells/mL
Potency	In-vitro Cytotoxicity	Flow Cytometry	% Cytotoxiciy
	Cytokine Production	Flow Cytometry/ELISA	% positive / Concentration
Safety	Vector Copy Number	qPCR/ddPCR	Copy/Cell
	Replication Competence	qPCR	VSVG (Copies/mL)
	Compendial (Myco, 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.



