A rapid and cost-effective solution by GoFast chimeric antigen receptor (CAR) T-cell therapy, in patients with severe, refractory Myasthenia Gravis (MG)

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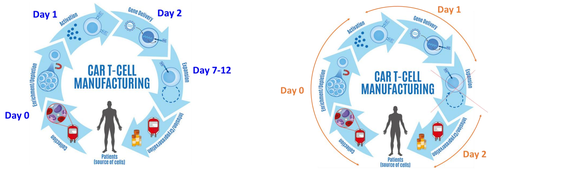
1) Introduction

Chimeric antigen receptor T-cell (CAR-T) therapy targeting B-cell and plasma cell compartments has shown promising efficacy in refractory generalized myasthenia gravis (gMG). Previously reported dual BCMA/CD19 CAR-T therapy demonstrated marked clinical improvement in heavily pretreated patients[1][2]. However, traditional manufacturing workflows (14 days) remain complex, labor-intensive, time-consuming, and high cost in GMP setting. Rapid CAR-T manufacturing has demonstrated to preserve stem cell-like phenotypes associated with self-renewal, expansion, and sustained cytotoxic function. Additionally, shortened production timeline provides added benefit of manufacturing cost reduction, while automated process minimizes operator-related variability.

[1] Zhang Y, Liu D, Zhang Z et al., Anti-BCMA/CD19 CAR T cell therapy in patients with refractory generalized myasthenia gravis: a single-arm, phase 1 trial, Lancet, Vol 90, (2025)
[2] Huang et al., BCMA/CD19 CAR T cell therapy for refractory myasthenia gravis: Proteomic signatures and single-cell transcriptomics of disease flares, Sci. Adv. 12, eaeb6424 (2026)

2) GoFast CAR-T Manufacturing



Traditional Process
1-2 weeks

GoFast™ Process In < 72 hours

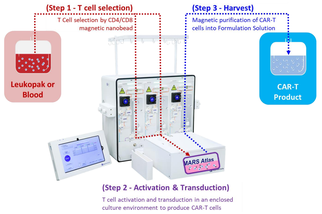


Figure 1. Development of rapid and low-cost CAR-T products represents a significant advancement in the field of cell therapy. Compared to traditional CAR-T cell manufacturing process which takes up to 14 days, the rapid GoFast™ process eliminates expansion and completes within 72 hours. With minimal cell differentiation and exhaustion, it produces CAR-T cells with **much higher potency** and **anti-tumor activity**.

3) GoFast CAR-T Phenotypes

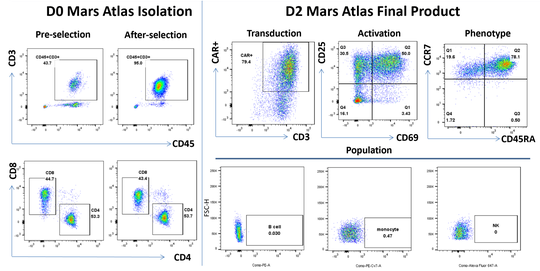
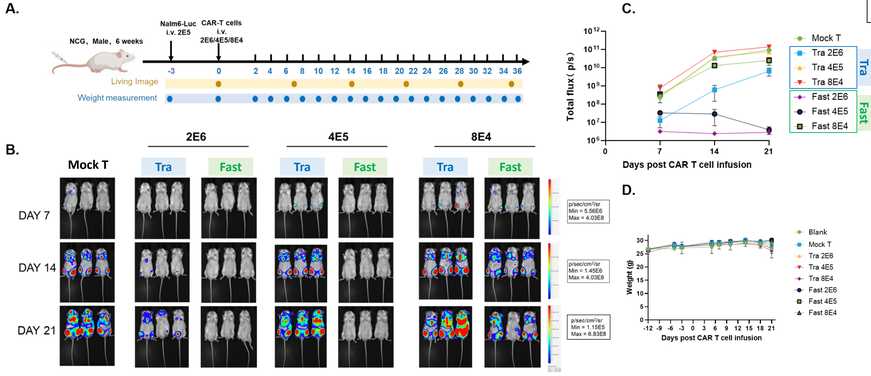


Figure 2. During manufacture, selected T cell purity exceeds 90%, with a consistent CD4+/CD8+ ratio before and after selection. At harvest, CAR-T transduction efficiency reaches ~79%. Over 50% of cells express CD25/CD69, indicating robust activation. Moreover, a high proportion of CD45RA+/CCR7+ double-positive cells reflects younger cells with better stemness. Additionally, the final product has high T cell purity, with very low percentages of NK, B, and monocytes.

4) Anti-tumor Efficacy

Figure 3. Male NCG mice aged 6–8 weeks were used. On Day (-3), each mouse was inoculated with 2×10^5 Nalm6 cells transduced with a luciferase reporter gene via tail vein injection to establish a CD19-positive xenograft tumor model. On Day (-3), each mouse also received an intraperitoneal injection of 15 mg/kg of the luciferase substrate D-luciferin. Tumor progression was monitored using a small animal in vivo imaging system under isoflurane anesthesia. On Day 0, the mice were randomly divided into 7 groups, and each group was treated via tail vein injection with the corresponding CAR-T cells, including a Mock T cell group (2×10^6 T cells, n=3), traditional BCMA/CD19 CAR-T groups (Tra), and GoFast CAR-T groups (Fast). Doses administered were 2×10^6, 4×10^5, and 8×10^4 CAR-T cells per mouse. Starting from day of CAR-T treatment initiation, in vivo imaging was performed every 7 days for a total of 21 days. The results showed that the GoFast CAR-T (Fast) group at 4×10^5 dose outperforms traditional CAR-T group at 2×10^6 dose, indicating GoFast CAR-T having a significantly superior tumor suppressive capacity over traditional CAR-T.



4) Clinical Trial Results

Figure 4. Clinical Study Design

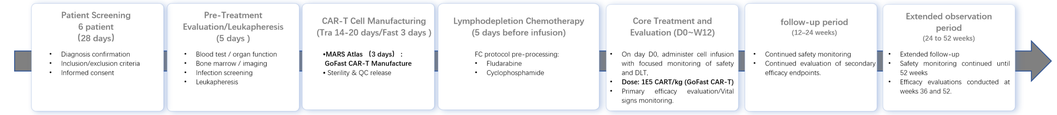
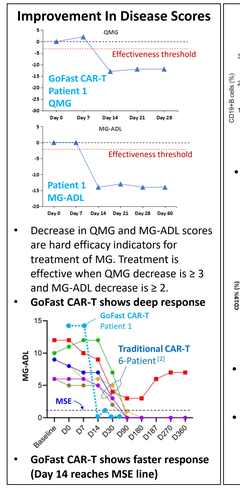
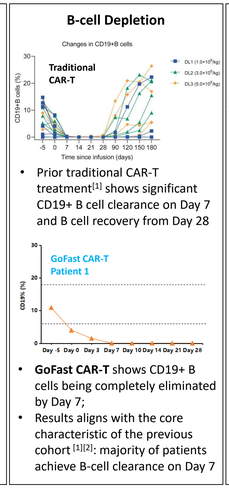
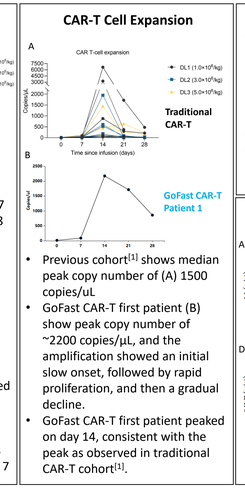
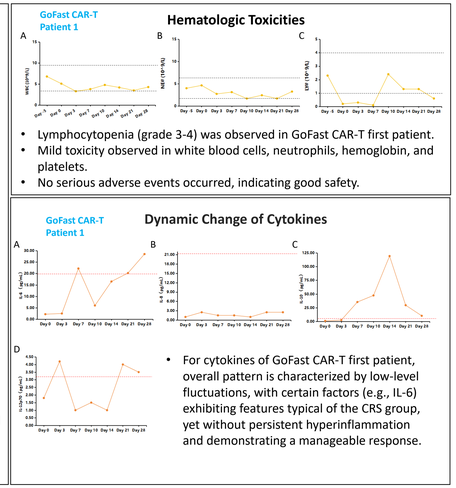


Figure 5. Results of Fast CAR-T Single-Patient Treatment (Patient #1)









5) Discussion

Depth of Response Comparison

		Approved		Investigational			
		FcRn* Inhibitor VYVGART®	Complement* Inhibitor ULTOMIRIS®	CD19 mAb* UPLIZNA®	BCMA mRNA* CAR T Descartes-08	Miv-cel* CD19 CAR T (KYSA-6, n=3)	CD19/BCMA GoFast CAR-T (n=1, Cohort=6)
Primary Endpoint		4 wks	6 months	6 months	3 months	6 months	6 months (not reached)
Depth of Response (Reduction from baseline to primary end point)	MG-ADL Reduction (Clinical Threshold ≥2)	~4.6	3.1	4.2	~4.2	8	14 (Day 60)
	QMG Reduction (Clinical Threshold ≥3)	~6.2	2.8	4.8	~3.9	7.7	12 (Day 28)
% Responders		~73%	~57%	~79%	~70%	100%	1/1
Minimal Symptom Expression (MSE) (% of patients achieving MG-ADL of 0 or 1)		40%	43%	Not reported	33%	67%	1/1

* Observations from separate clinical settings; comparisons not based on head-to-head studies. Data summarized from Kyverna Therapeutics website.

6-patient cohort still on-going

Rapid GoFast manufacture of dual BCMA/CD19 CAR-T cells using the MARS Atlas platform was feasible in all patients and produced encouraging early clinical responses with favorable safety profile in severe, refractory myasthenia gravis. These findings support the potential of a process- and platform-driven manufacturing cost reduction and facilitate broader commercial accessibility of CAR-T products.

Cost of Goods to produce GoFast CAR-T

MARS Atlas GoFast™ CAR-T Essential Kit

Per Patient : **< 72 hr** and **< $9,500 USD**

1) MARS Atlas fluidics kit including freeze-down kit (1 set)
2) GMP CD4, CD8 beads (1 set)
3) GMP T cell activation reagent (1 vial)
4) GMP complete media with ILs (200mL)
5) GMP running buffer, formulation buffer, freezing media (50mL each)
6) GMP LVV

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