



MAKING CELL THERAPIES ACCESSIBLE TO ALL™

FT839: A Multi-Antigen Targeting Off-the-Shelf Dual-CAR T Cell for the Treatment of Pathogenic B and T Cells in Autoimmune Diseases

ASGCT Annual Meeting

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Mark Jelcic, PhD

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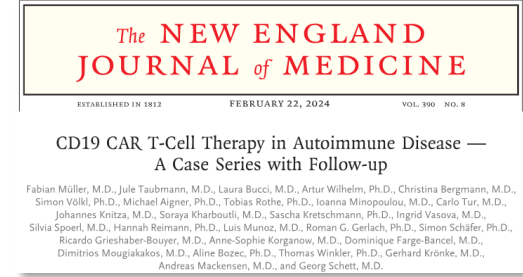
What Good Is a Cure That No One Can Access?

Autologous CAR T-cell therapy is transformative, but is unattainable for most patients

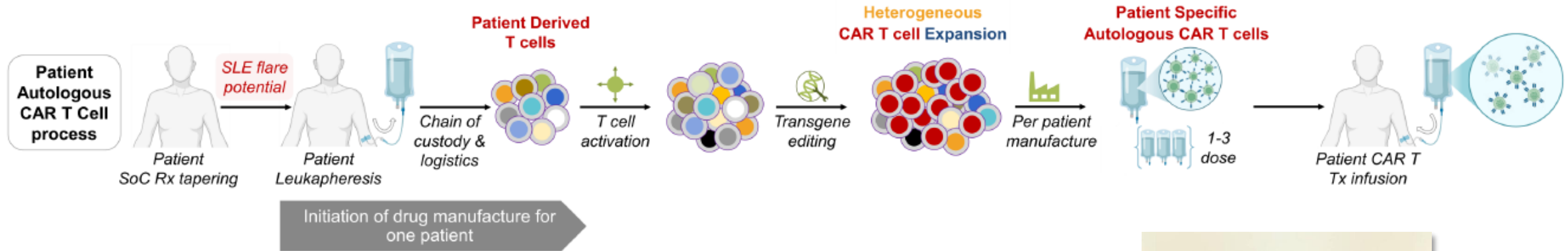
✓ “Living drugs”: CAR T cells have revolutionized how autoimmune diseases can be treated

However, Autologous CAR T-cell therapies...

- Cost ~\$400,000 - \$600,000+ per patient
- Require 4 - 8 wks of personalized medication tapering, cell collection and manufacturing
- Depend on intensive lympho-depleting pre-conditioning chemotherapy



Conventional CAR T-cell Manufacture and Treatment Paradigm



- > 80 autoimmune diseases affect up to 8% of the U.S. population¹
- Many patients have limited treatment options and progressive disease
- Limited access to novel therapeutics driven by socio-economic burden of disease



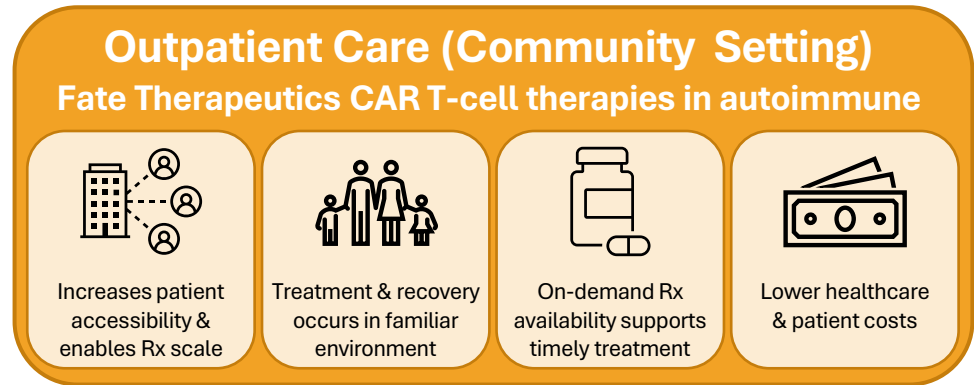
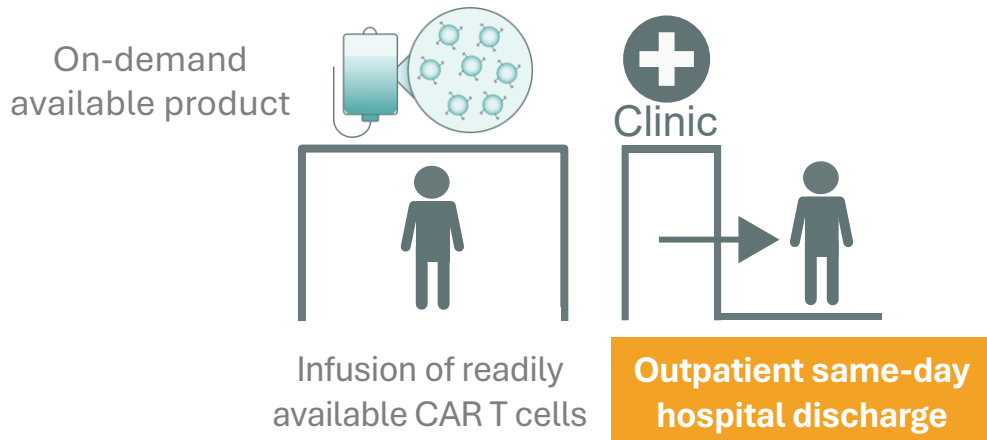
1. Abend AH, et al. *J Clin Invest.* 2024; 135, e178722

Outpatient Enabled & Community Delivered CAR T Cells

FT819: *First CAR T-cell therapy in autoimmune delivered without hospital stay*

- ✓ Successful dosing of FT819 in an outpatient setting
 - *Same-day discharge* → *No hospitalization and extended observation*
- ✓ Broad patient access
 - *Elimination of inpatient care*
 - *Reduction/elimination of conditioning chemotherapy*
 - *On-demand availability*
- ✓ Providing off-the-shelf CAR T-cell therapy in community hospital-based treatment settings reduces the burden on healthcare infrastructure, and unlocks a viable, scalable and practical therapeutic paradigm

Off-the-Shelf CAR T-cell Therapy



iPSC Platform: An 'Off-the-Shelf' Cell Therapy Solution

Mass produced, multiplex-engineered cell products for on-demand patient treatment

iPSC → **any**
cell in the body

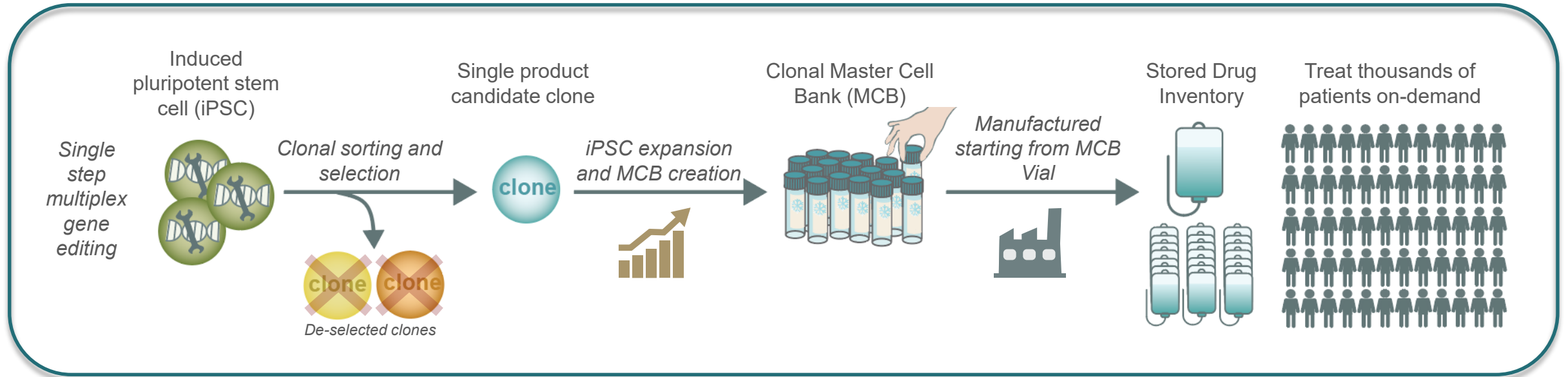
Gene editing is
a **one-time**
event completed
at iPSC stage

Master cell
bank contains
clonally
identical
population

Master cell bank is
starting material
for CAR T-cell
manufacture

Consistent
manufacture
results in uniform
and homogenous
drug product

Off-the-shelf
drug product
supports on-
demand delivery
for broad patient
reach

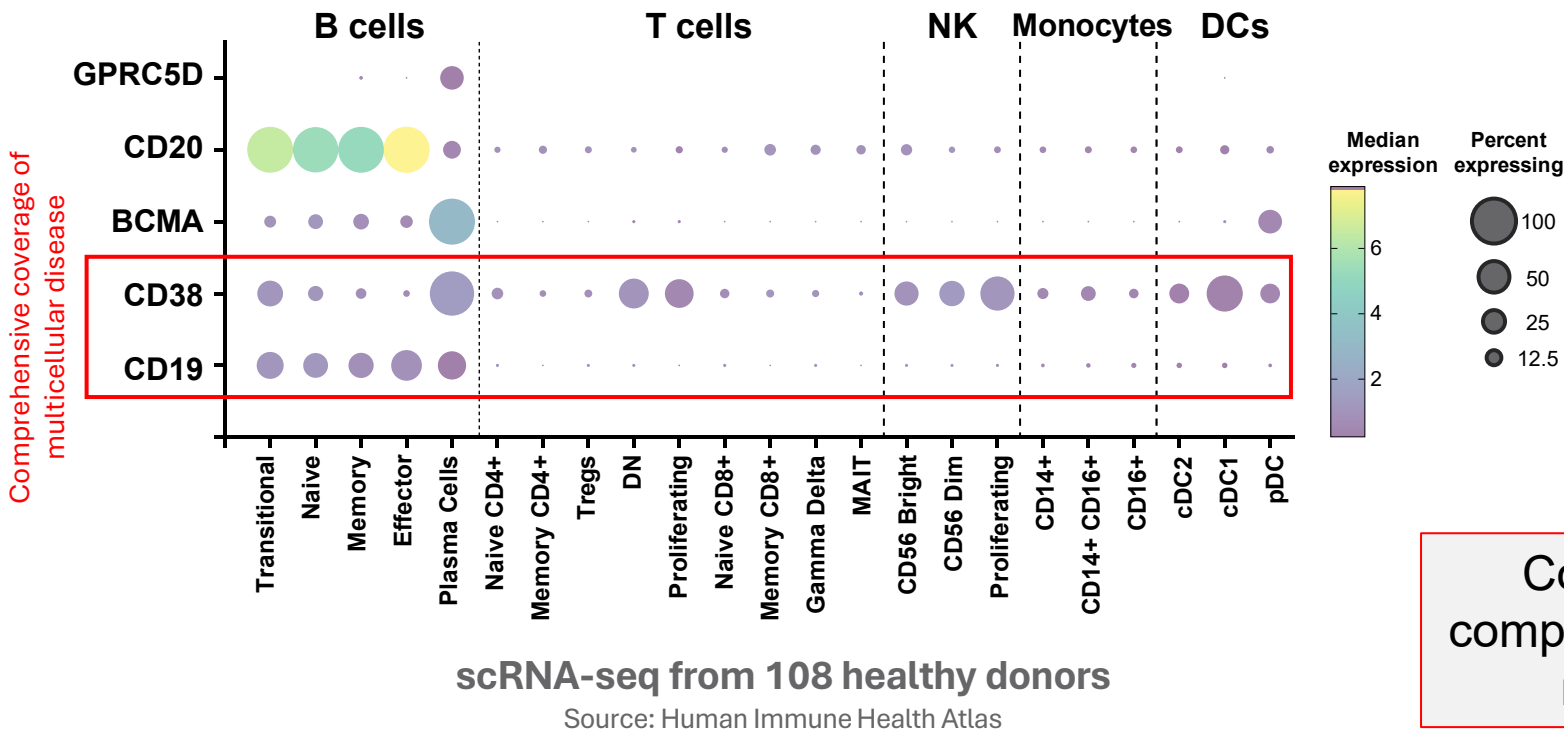


Targeting CD19 Alone is Not Enough for Eliminating Complex Multicellular Diseases

Targeting B-lineage (CD19) and activated immune cells (CD38) for a comprehensive immune reset

Autoimmune diseases are driven by multiple immune cell types

- T cells can independently sustain disease (e.g., Multiple Sclerosis & Type 1 Diabetes)
- Long-lived plasma cells are spared by CD19-targeting
- Innate immune cells drive tissue damage (e.g., Rheumatoid Arthritis)



CD38

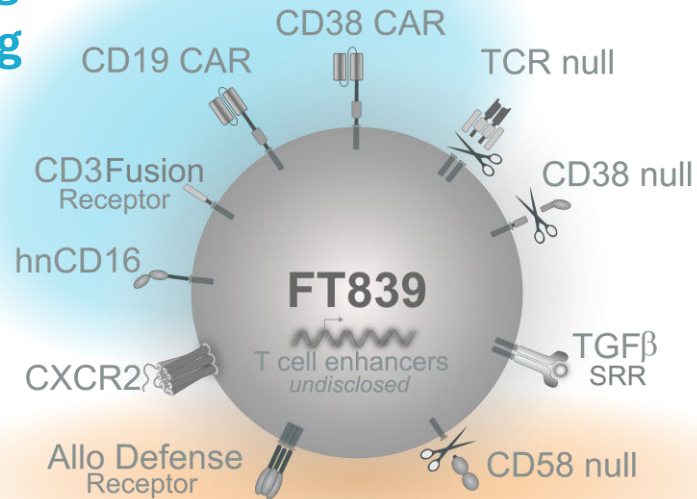
- ✓ Broad expression on activated and differentiated immune cells
 - T cells
 - Plasma cells
 - Innate immune cells
- ✓ Clinically validated target
 - *Daratumumab*
 - *Isatuximab*

Co-targeting CD19 and CD38 enables comprehensive immune cell targeting to treat multicellular autoimmune diseases

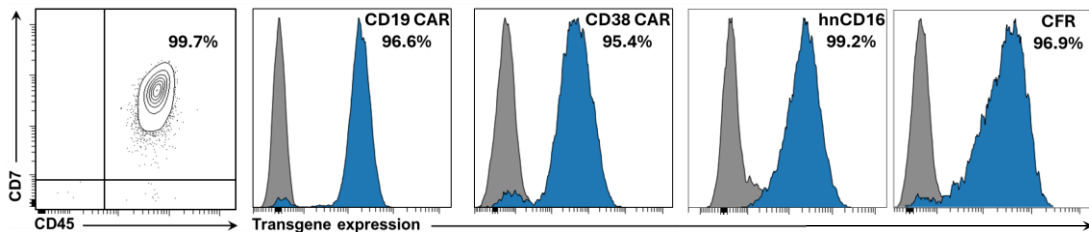
FT839: Off-the-Shelf Anti-CD19/CD38 Dual CAR T-Cell Product Candidate

ADR-armed CAR T cells target select immune cell subsets to unlock multi-disease therapy potential

Multi-Antigen Targeting



Uniquely uniform multiplexed-engineered CAR T-cell drug product



Multi-Antigen Targeting

Comprehensive targeting of pathogenic immune cells

- **CD19 CAR:** Targets B-cell lineage
- **CD38 CAR:** Targets activated immune cells including aberrant T cells
- **CD3ε Fusion Receptor (CD3FR):** Targeting in combination with T cell engagers (TCEs)
- **hnCD16:** ADCC when combined with mAbs

Sword & Shield™

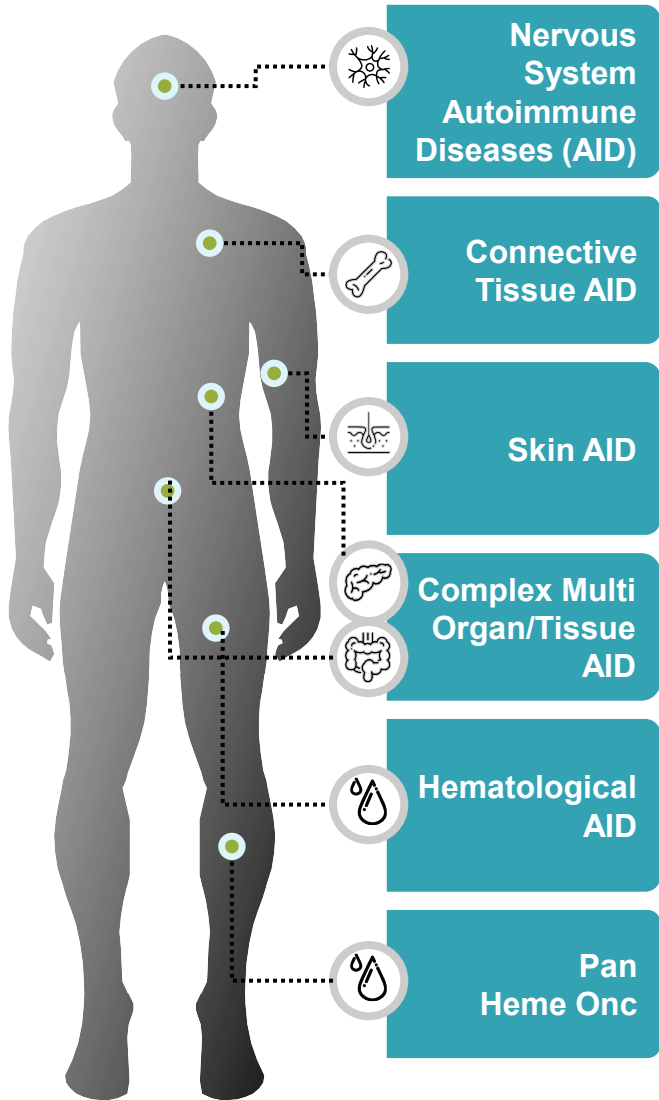
Eliminate conditioning chemotherapy

- **Sword → Allo-Defense Receptor (ADR):** Targets activated allo-reactive T-cells
- **Shield → CD58 null:** Impedes allo-reactive T cell recognition & binding

FT839 Broadly Eliminates Aberrant Immune Cell Types

CD19 and CD38 CARs selectively eliminate B lineage cells and activated T cells

Possible **FT839** Disease Indications



Multiple Sclerosis (MS)

- CD4+ T cells
- CD8+ T cells
- B cells
- Plasma cells

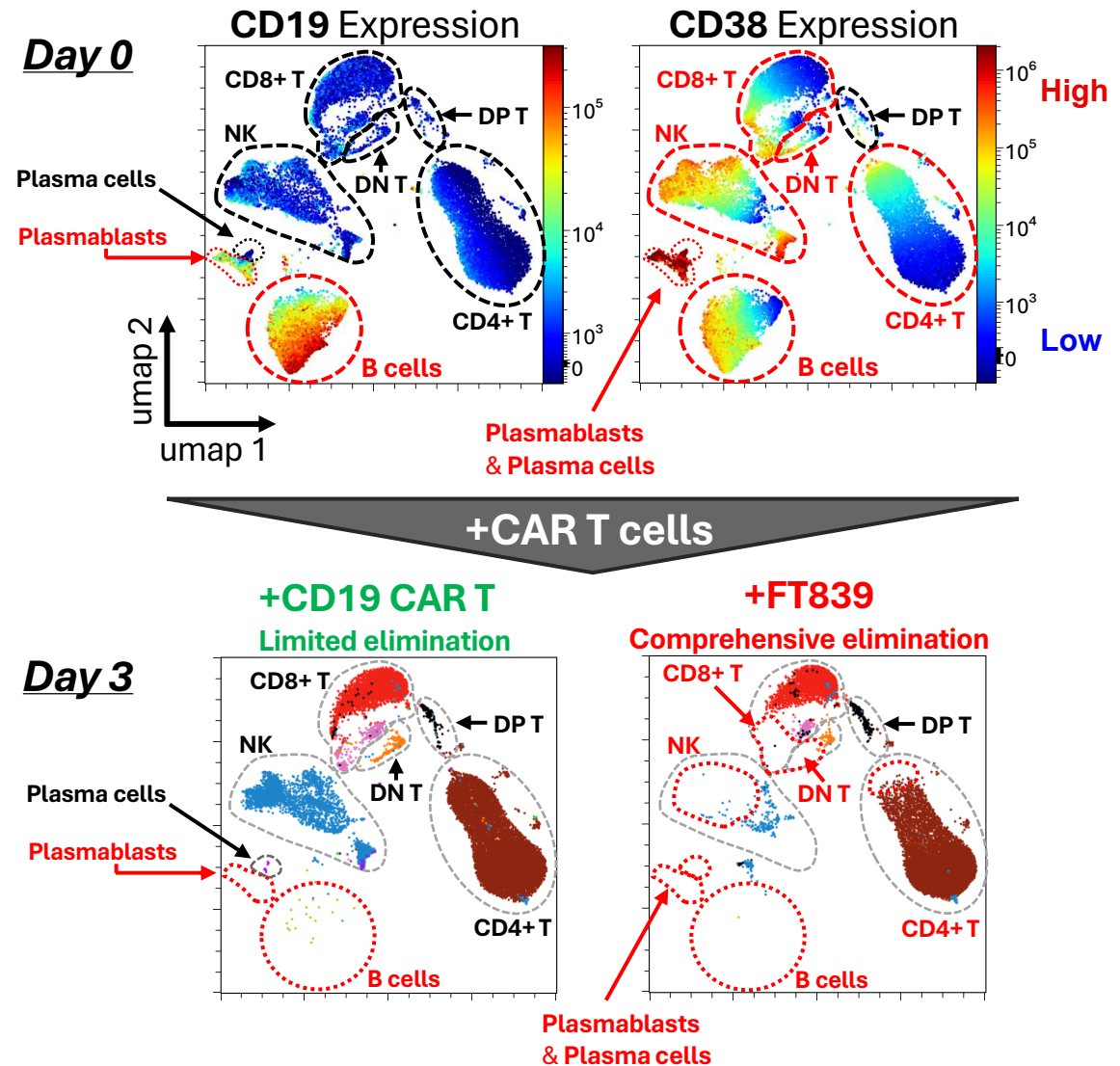
Type 1 Diabetes (T1D)

- CD8+ T cells

Rheumatoid Arthritis (RA)

- CD4+ T cells
- B cells
- Plasma cells

PBMC Co-Culture Assay



Sword & Shield – Eliminating Conditioning Chemotherapy

ADR and CD58^{KO} selectively restrict the generation and activation of alloreactive immune cells

Eliminate Reactive Immune Cells

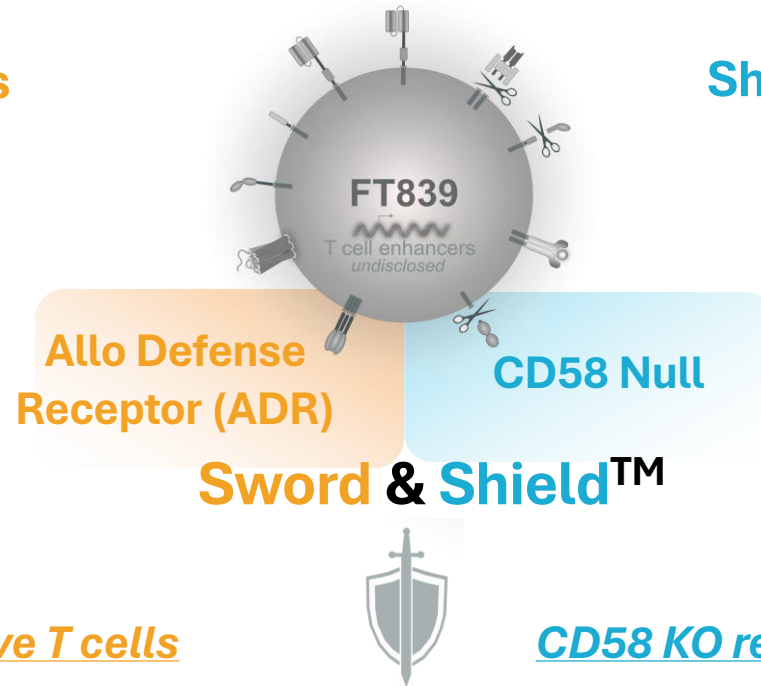

Shield Reactive Immune Cell Interactions



nature biotechnology ARTICLES
<https://doi.org/10.1038/s41587-020-0601-5>
 Check for updates

Engineered off-the-shelf therapeutic T cells resist host immune rejection

Feiyan Mo^{1,2}, Norihiro Watanabe¹, Mary K. McKenna¹, M. John Hicks³, Madhuwanti Srinivasan¹, Diogo Gomes-Silva¹, Erden Atilla¹, Tyler Smith¹, Pinar Ataca Atilla¹, Royce Ma^{1,4}, David Quach¹, Helen E. Heslop^{1,2}, Malcolm K. Brenner^{1,2} and Maksim Mamonkin^{1,2,3,4,5,6}

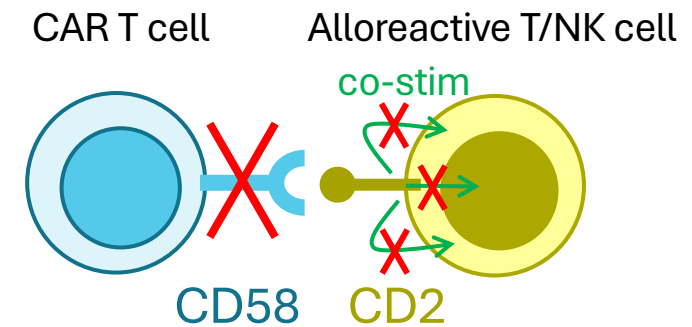
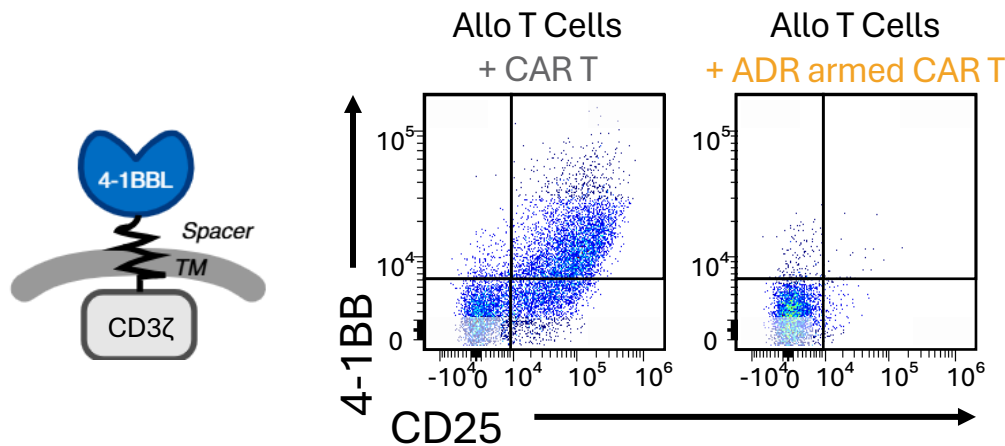
CellPress OPEN ACCESS **Cell Stem Cell**

Short article
Genetic ablation of adhesion ligands mitigates rejection of allogeneic cellular immunotherapies

Quirin Hammer,^{1,8,*} Karlo Perica,^{2,3,4,5} Rina M. Mbofung,⁶ Hanna van Ooijen,⁸ Karen E. Martin,^{7,8} Pouriya Momayyezi,¹ Erika Varady,⁹ Yijia Pan,⁵ Mark Jelcic,³ Brian Groff,³ Ramzey Abujarour,³ Silje Z. Krokeide,^{7,8} Tom Leo,⁹ Alan Williams,³ Jode P. Goodridge,⁸ Bahram Valamehr,⁵ Björn Önfelt,^{1,2} Michel Sadelain,³ and Karl-Johan Malmberg^{1,7,8,10,*}

ADR eliminates 4-1BB⁺ alloreactive T cells

CD58 KO restricts stable immune synapse formation



✓ Eliminate **CD2-CD58** co-stimulation

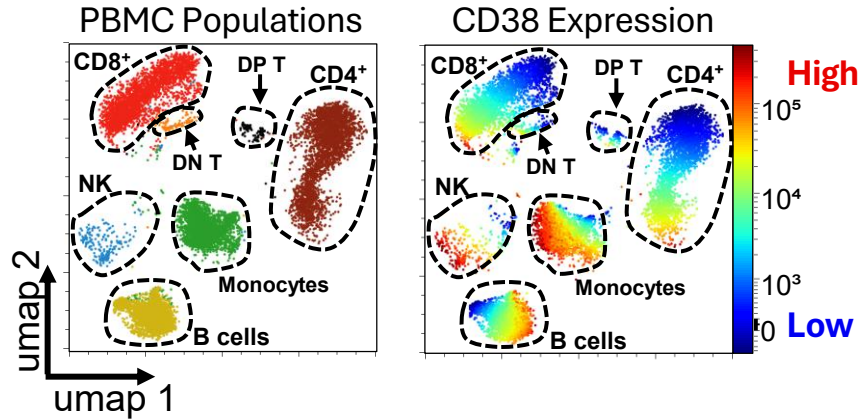
FT839 Maintains Comprehensive Disease Activity in Allo-settings

Selective depletion of B cells and activated immune cells while preventing emergence of alloreactive T cells

Rheumatoid Arthritis PBMCs

Sword and Shield prevents the emergence of alloreactive T cells

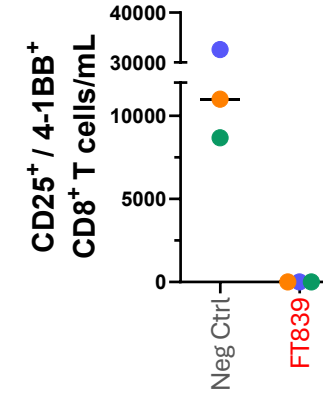
Day 0



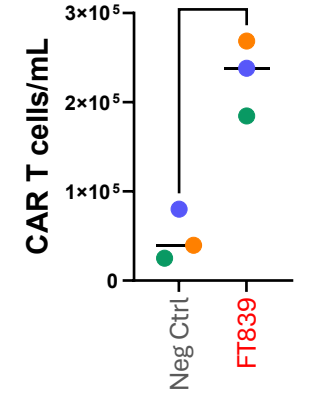
PBMC donor

- Healthy
- RA
- SLE

Alloreactive T cells



CAR T Persistence



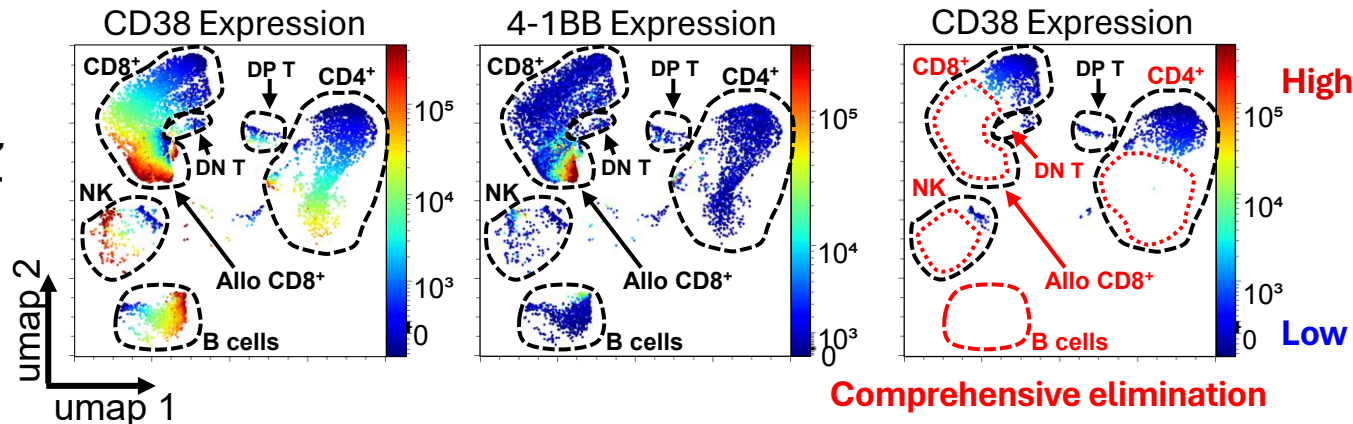
+ CAR T cells
7 days

Activated (CD38+) T cells are selectively eliminated

Day 7

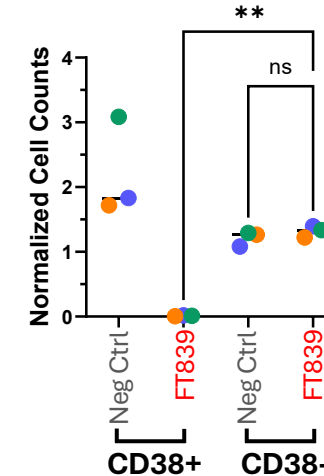
RA PBMCs + No Sword/Shield CAR T

RA PBMCs + FT839

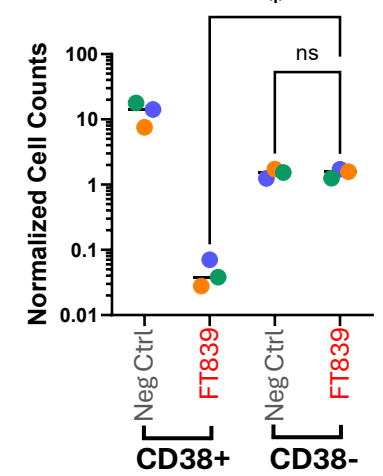


**Comprehensive elimination
maintained in allogenic setting**

CD4+ T Cells



CD8+ T Cells

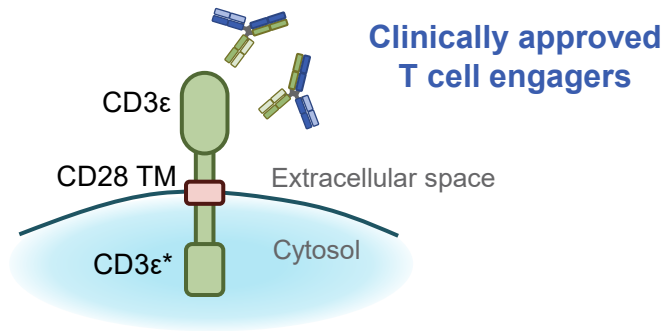


Multi-antigen Targeting in Combination with T Cell Engagers and mAbs

Customizable pairing with clinically approved biologics extends disease cell targeting capabilities

CD3FR: CD3 ϵ fusion receptor

Enables combination with TCEs without a TCR

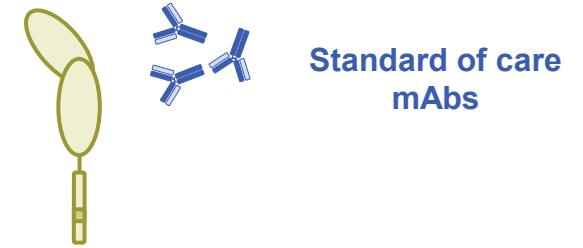


hnCD16: high affinity, non-cleavable CD16a

Enables synergistic pairing with standard-of-care mAbs

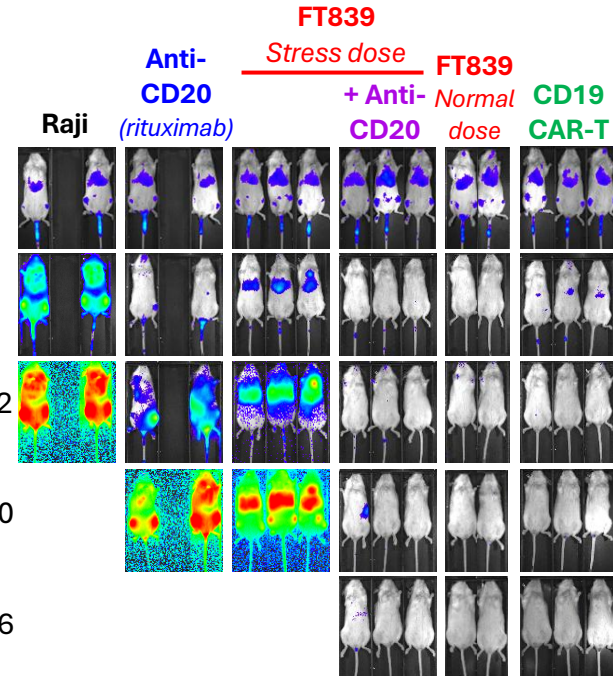
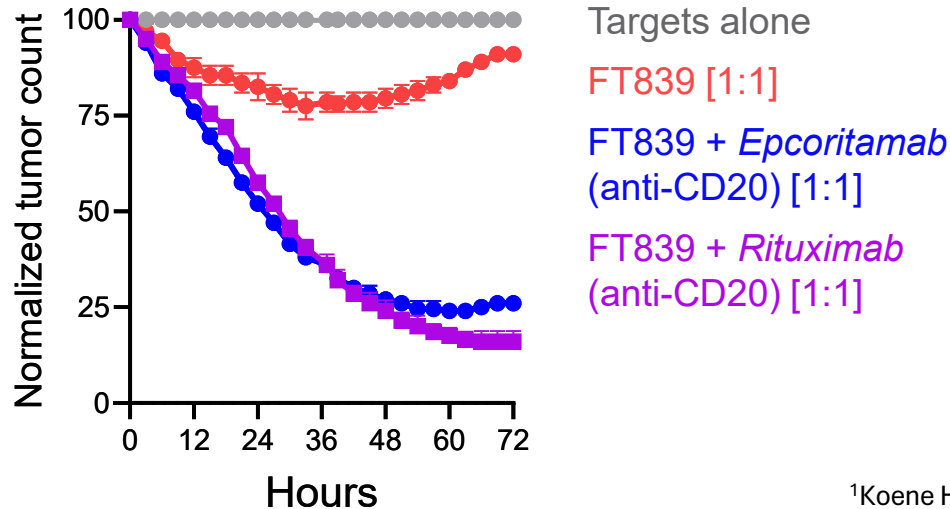
High affinity
(158V/V)¹

Non-cleavable
(ADAM17)²



Mantle Cell Lymphoma (JEKO-1)

CD19^{KO}CD38^{KO}



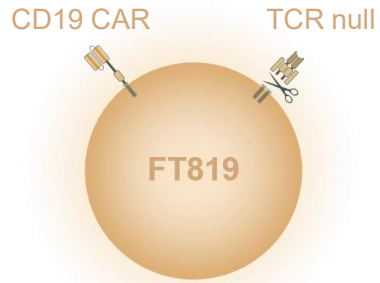
¹Koene H et al. *Blood*. 1997; 90:1109-14

²Jing Y et al. *PLoS One*. 2015; 10, e0121788

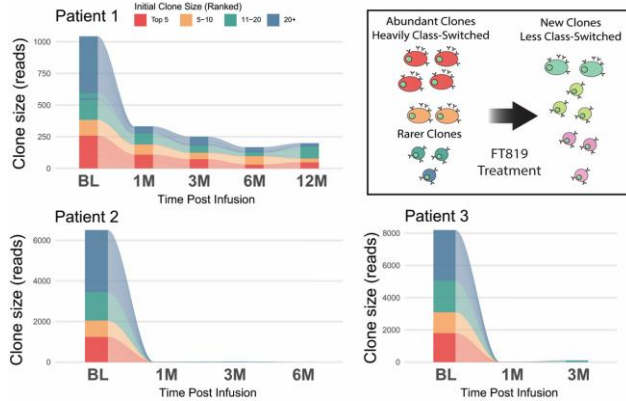
Delivering Off-the-Shelf CAR T Cells to Patients Without Conditioning Chemotherapy in Autoimmune, Hematological Malignancies and Solid Tumor Settings

FT819 in Autoimmune Disease

CD19-targeting CAR T cells combined with SOC therapy



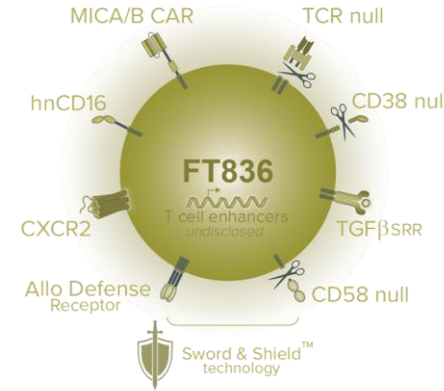
FT819 w/o conditioning eliminates major B cell clones



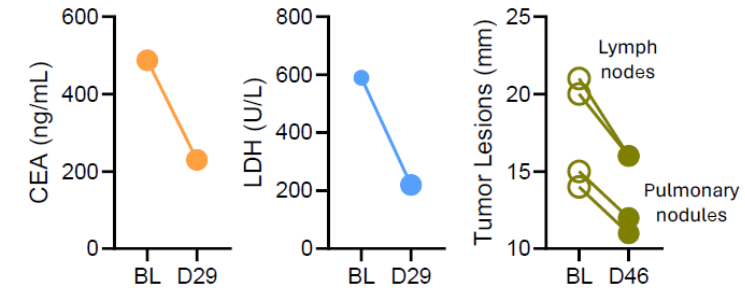
NCT06308978
Greene et al. ASGCT 2026

FT836 armed with Sword and Shield in Solid Tumors

MICA/B-targeting CAR T cells without lympho-conditioning



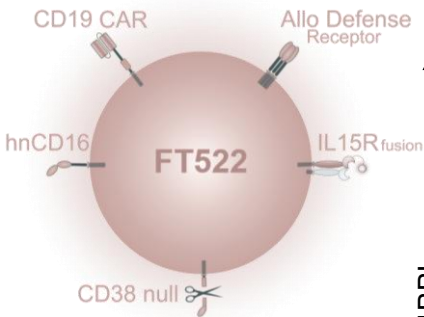
Disease response in heavily pretreated metastatic colorectal carcinoma (CRC) patient



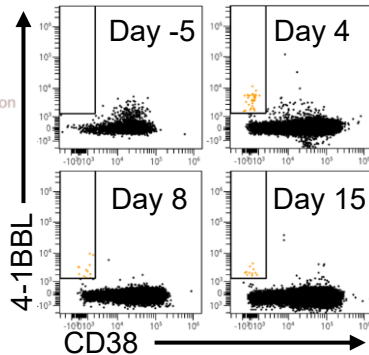
NCT072161051
Shirinbak et al. ASGCT 2026

FT522 armed with ADR in Lymphoma

CD19-targeting CAR NK cells without lympho-conditioning



Functional persistence of FT522 resulting in B cell depletion and clinical efficacy



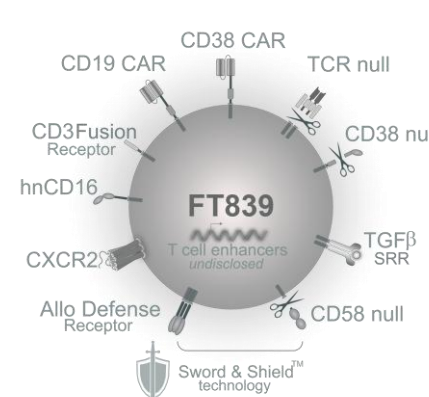
Clinical outcomes:

- Favorable emerging tolerability profile with no CRS or ICANS of any grade was observed
- Responses were observed following FT522 treatment both with and without conditioning and across B cell lymphoma histology, including durable responses in LBCL

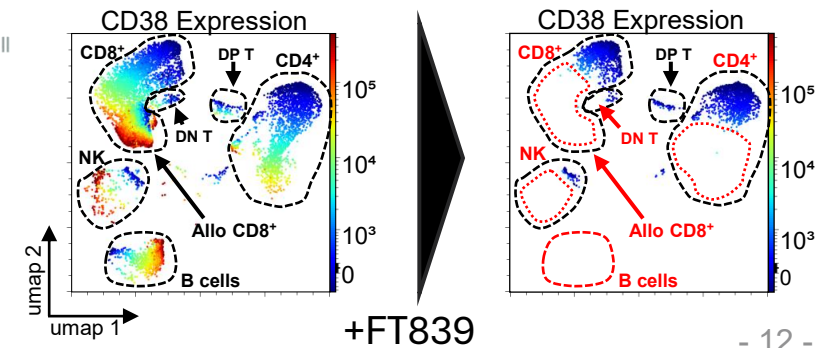
NCT05950334
Bachanova et al. ICML 2025

FT839 armed with Sword and Shield in Autoimmune

CD19- and CD38-targeting CAR T cells without lympho-conditioning



Broadly eliminating pathogenic immune cells while preventing the emergence of alloreactive cells



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- Karl-Johan Malmberg



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- Bruce Walcheck



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