Calibr-Skaggs Institute for Innovative Medicines | Scripps Research

Reprogramming the immune system

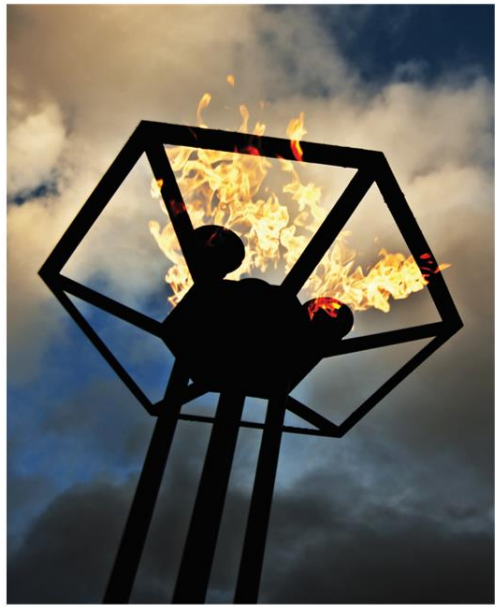
A new era of precision immunotherapy for cancer and autoimmune disease

Travis S Young
Vice President, Biologics
Calibr-Skaggs Institute for Innovative Medicines
At Scripps Research Institute

THE FRONT ROW at Scripps Research

Scripps Research | A World Leader in Biomedical Research

Some of the most brilliant minds in the world
join forces at Scripps Research:



128 active faculty
Working to advance scientific knowledge across 6 departments

THE NOBEL PRIZE

Work at Scripps Research has led to
6 Nobel prizes

The faculty currently includes
2 MacArthur Fellows

Chemists at Scripps Research have won **6 Wolf Prizes**

nature INDEX
Ranked among the **top 5** biomedical institutes in the world

Faculty earned **8 spots** on the
2023 Highly Cited Researchers list
(representing the top 1% in the world)

$ 600M+
annual research budget

15 FDA-approved drugs and vaccines have arisen from our discoveries

1,100+
U.S. patents

50+
active spin-off companies

30 memberships
in the National Academies of Sciences, Engineering and Medicine

Calibr-Skaggs Institute for Innovative Medicines | Scripps Research

Engineering Cures | A New Model for Biomedical Innovation at Scripps

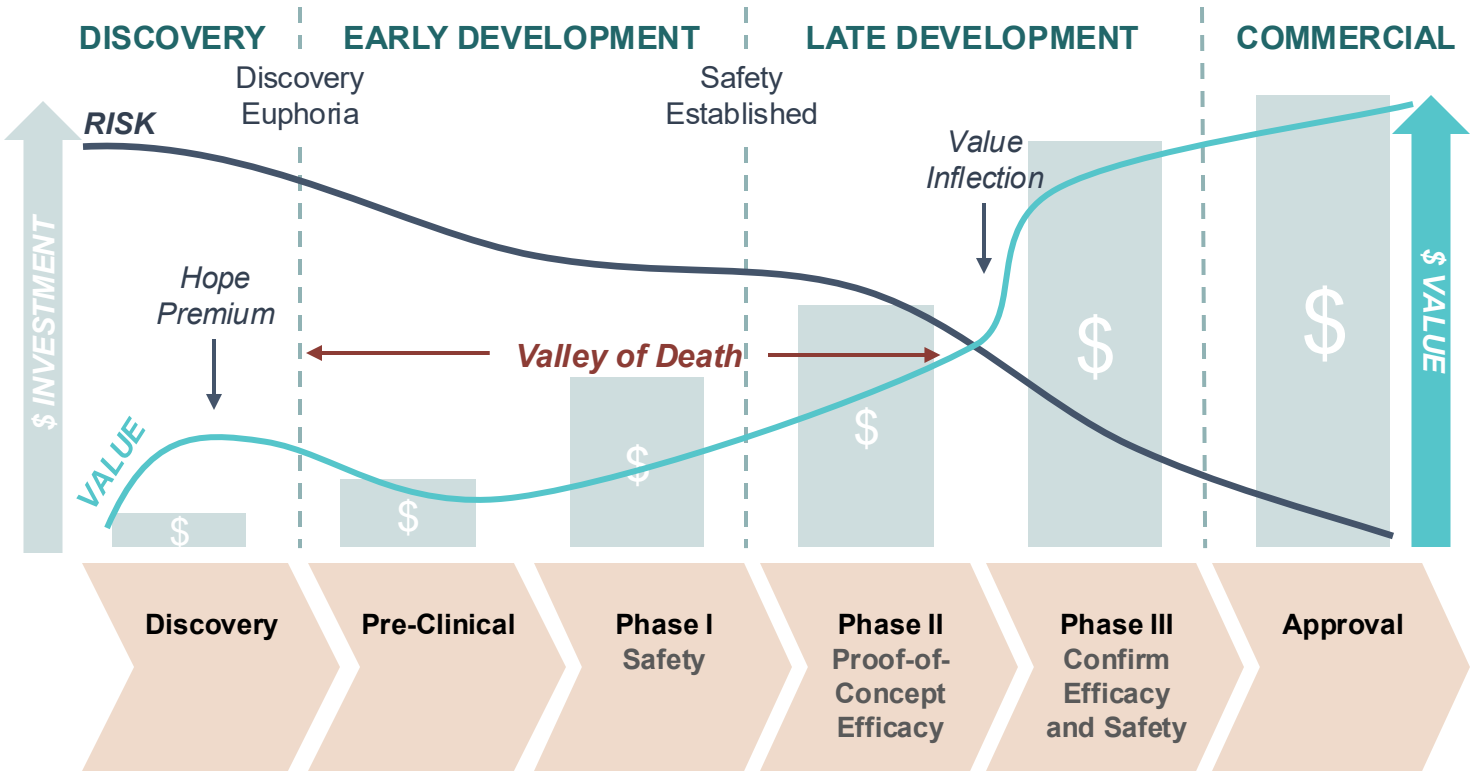
	**COVID-19 vaccines** SARS-CoV-2	2021
	**Zeposia®** Multiple sclerosis	2020
	**Trodelvy®** Multiple cancers	2020
	**Vyndaqel®** Heart disease	2019
	**Mavenclad®** Multiple sclerosis	2019
	**Takhzyro®** Hereditary angioedema	2018
	**Palynziq®** Phenylketonuria	2018
	**Bavencio®** Merkel cell carcinoma	2017
	**Unituxin®** Brain cancer	2015
	**Portrazza®** Squamous non-small cell lung cancer	2015
	**Cyramza®** Multiple cancers	2014
	**Surfaxin®** Respiratory distress syndrome	2012
	**ABthrax™** Anthrax toxin	2012
	Benlysta® Lupus	2011
	**Humira®** Autoimmune	2002
	**Leustatin®** Hairy cell leukemia	1993

Scripps Research has a 100-year history of **developing innovations,** foundational discoveries in chemistry, biology, and medicine. **Many life-changing drugs started here**, developed by scientists pursuing curiosity-driven research and **would not exist if it were not for inventions made here at Scripps**.

- **Scripps is changing the model** for nonprofit drug discovery by building an internal translational engine: The Calibr-Skaggs Institute for Innovative Medicines
- **We are leveraging this model to accelerate the development and translation** of a new type of gene and cellular therapy into patients
- **Switchable CAR-T cells**: A new therapy with the potential to treat a wide range of indications from leukemia to breast cancer, and even autoimmune conditions

The Challenge | Translating New Ideas to Patients

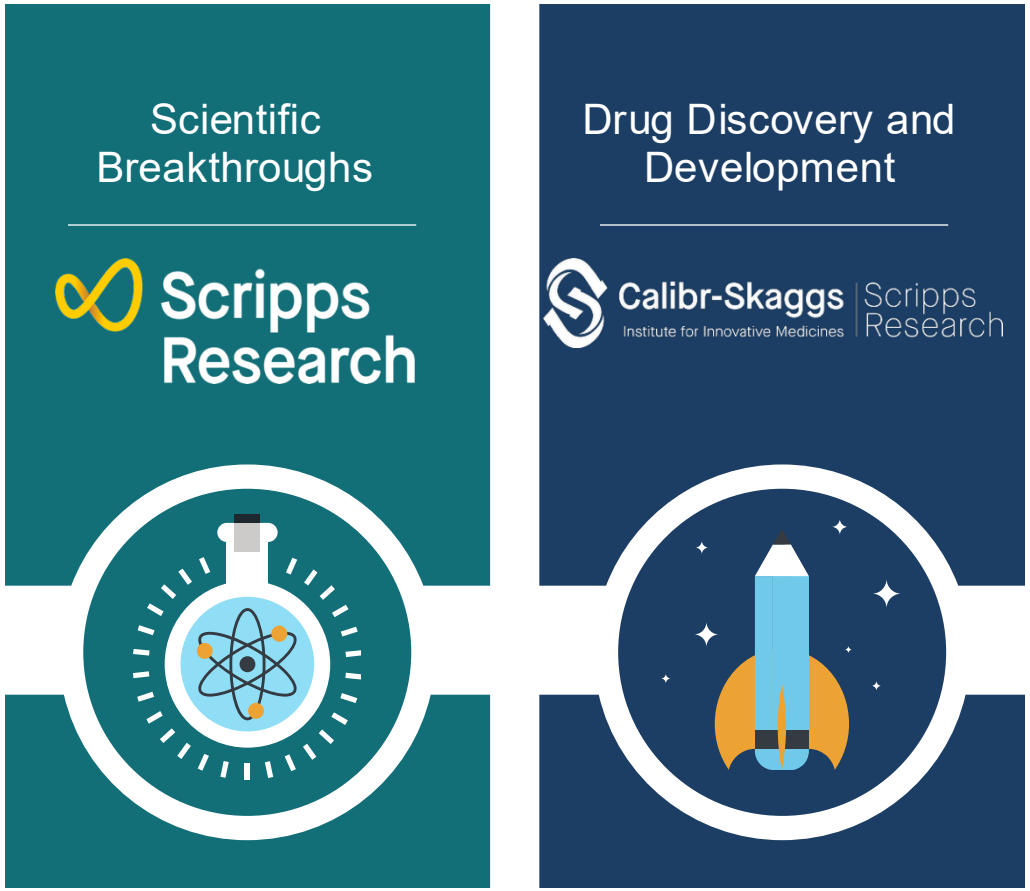
The Valley of Death in Drug Development



How do we bridge the valley of death at Scripps?

The Solution | Calibr-Skaggs Institute for Innovative Medicines

Pioneering a new vision for drug discovery in the non-profit research sector



A nonprofit research institute based on creating **a new business model for nonprofit science**

One that bridges **breakthrough findings** with the **expertise, the know-how, and the infrastructure** to translate those ideas to patients, without needing to "let go" of the science

Scientific and medical successes create funding and licensing revenues that can be reinvested in research and education to **amplify the impact of philanthropic and federal funding, and ultimately create a self-sustaining, evergreen ecosystem** for doing innovative non-profit research

Calibr-Skaggs | Institute Overview

Efficiently Translating Discoveries into Innovative Medicines

Established as an independent **501c3 nonprofit translational research center** with a focus on **preclinical drug discovery and early-stage clinical research** bridging the 'valley of death' in drug discovery and development

Calibr-Skaggs Institute for Innovative Medicines | Scripps Research

- **Based on the vision of Peter Schultz,** established in 2012 to translate new ideas into early-stage clinical trials
- Became the translational research arm of **Scripps Research in 2018**, like an **incubator** embedded within the institute
- A **conduit for new ideas to reach patients**
- As a non-profit, Calibr-Skaggs can accelerate translation of ideas **at a fraction of industry cost**
- Collaborations with foundations, pharma, and academic institutions throughout the world including the **Gates Foundation, Gilead, and AbbVie** linking early proof-of-concept with large-scale impact
- Powered by the **generosity of the Skaggs Family** with a transformational renaming gift in 2023
- 160+ full-time employees with **experienced leadership** in medicinal chemistry, pharmacology, biologics, clinical, program management, and business development

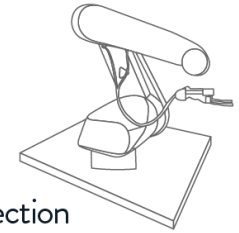
Calibr-Skaggs | State-of-the-Art Capabilities and Infrastructure

DISCOVERY

PROTEIN ENGINEERING

- Fusions of antibodies with bioactive peptides and proteins
- Semi-synthetic peptide technology
- Switchable CAR-T cell therapy

SMALL MOLECULE DISCOVERY

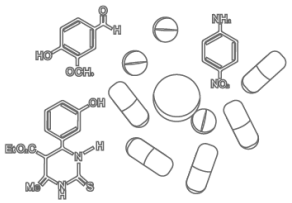


- Library of > 850,000 drug-like compounds
- Best-in-class drug repurposing collection
- State-of-the-art robotics
- Expertise in cell-based screening and mechanistic deconvolution

OPTIMIZATION

PHARMACOLOGY & SAFETY

- Dedicated core group supports rapid model development and proof-of-concept in vivo studies
- In-house/CRO support for PK/PD, in vitro safety assessment and toxicology



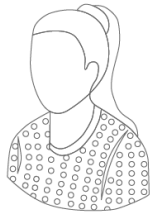
MEDICINAL CHEMISTRY

- Nimble hit-to-lead campaigns for early discovery efforts
- Lead/late-lead optimization capabilities to nominate development candidates
- Novel bio-conjugate/rational design platforms

TRANSLATION

IND-ENABLING STUDIES

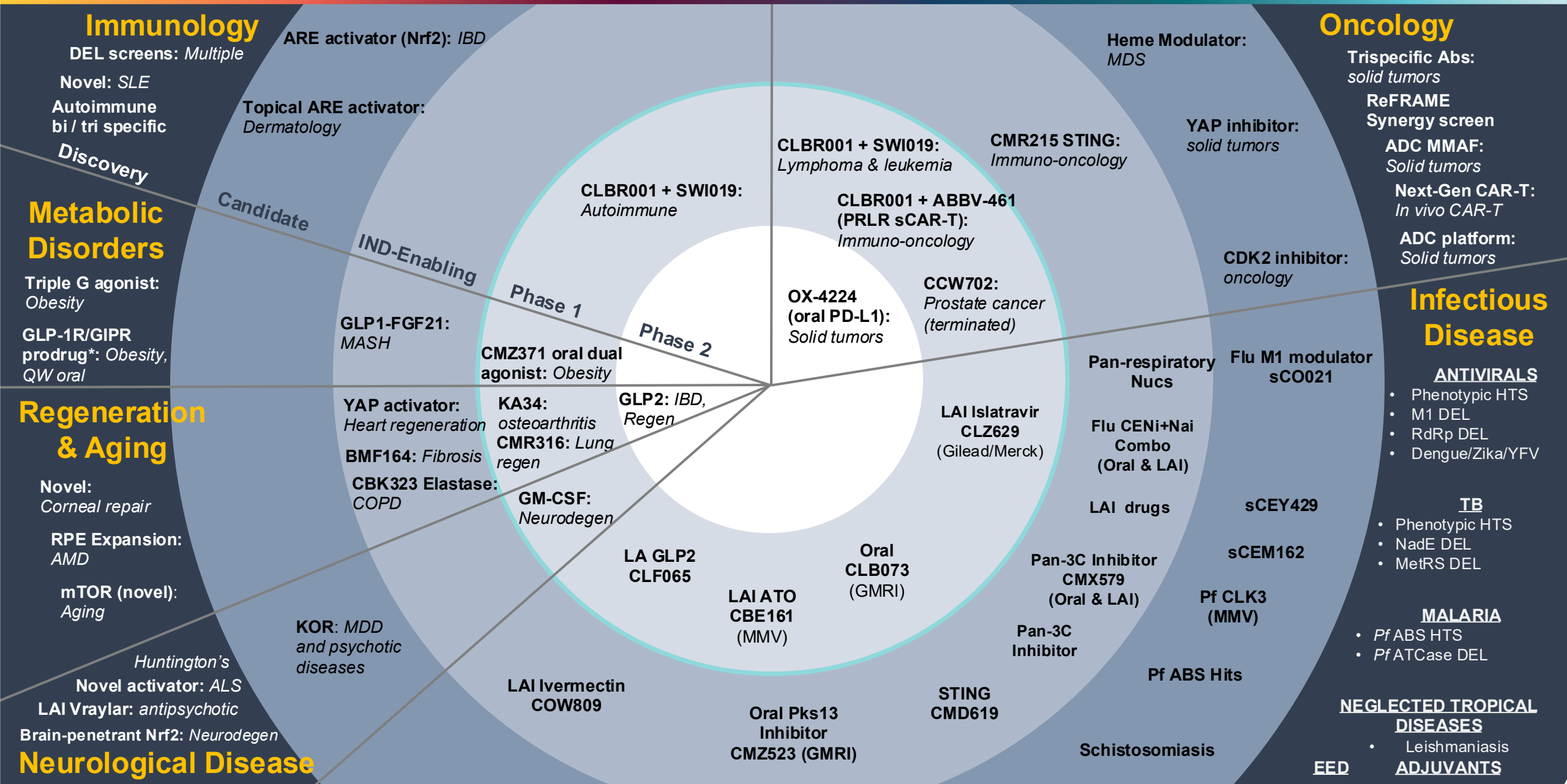
- Dedicated internal team and network of trusted contractors and consultants
- Process development and GMP manufacturing
- GLP toxicology and safety studies
- Multi-species PK and allometric scaling
- Regulatory expertise



CLINICAL SAFETY & PROOF-OF-CONCEPT

- Phase 1 safety and Phase 1b/2a proof-of-concept (PoC) studies
- Capacity to take a number of programs through early clinical studies
- Leverage non-profit clinical partners to gain unique access and speed

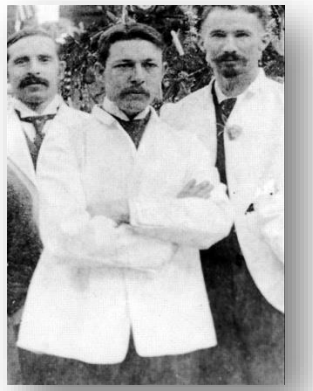
Calibr-Skaggs | A Clinical-stage Institute with a Robust Pipeline



Immunotherapy | Re-educating the Immune System to Fight Cancer

Late 1800s: Coley's Toxins

- *William Coley observes tumor regression after infections; develops "Coley's toxins" (heat-killed bacteria)*
- *Early immunotherapy concept emerges*



William B Coley Wikipedia

Early–Mid 1900s: Radiation & Chemotherapy Dominate

- *Coley's work falls out of favor as radiation and chemo become standard of care*
- *Immunotherapy largely forgotten*

1970s: BCG Immunotherapy

- *BCG approved for bladder cancer; one of the first modern immunotherapies*

Tasuku Honjo

1990s–2000s: Checkpoint Blockade Revolution

- *Breakthroughs by Jim Allison (CTLA-4) and Tasuku Honjo (PD-1)*
- *FDA approvals: Yervoy (2011), Keytruda (2014), Opdivo (2014)*
- *Nobel Prize awarded in 2018*

2010s–Today: Gene & Cell Therapy Era

Nobel Prize 2018

Jim Allison

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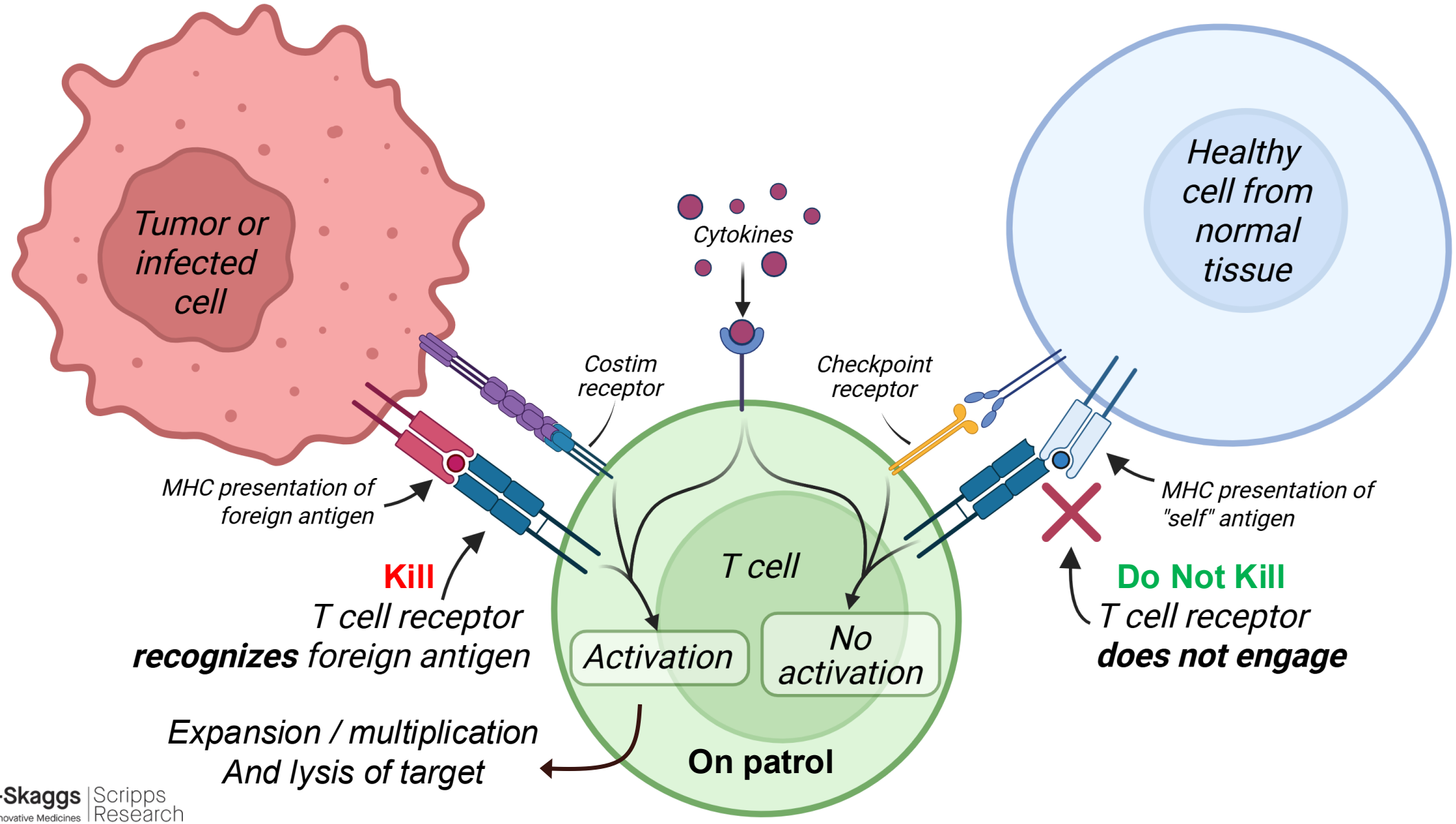
The T cell | The Immune System's Decision Engine



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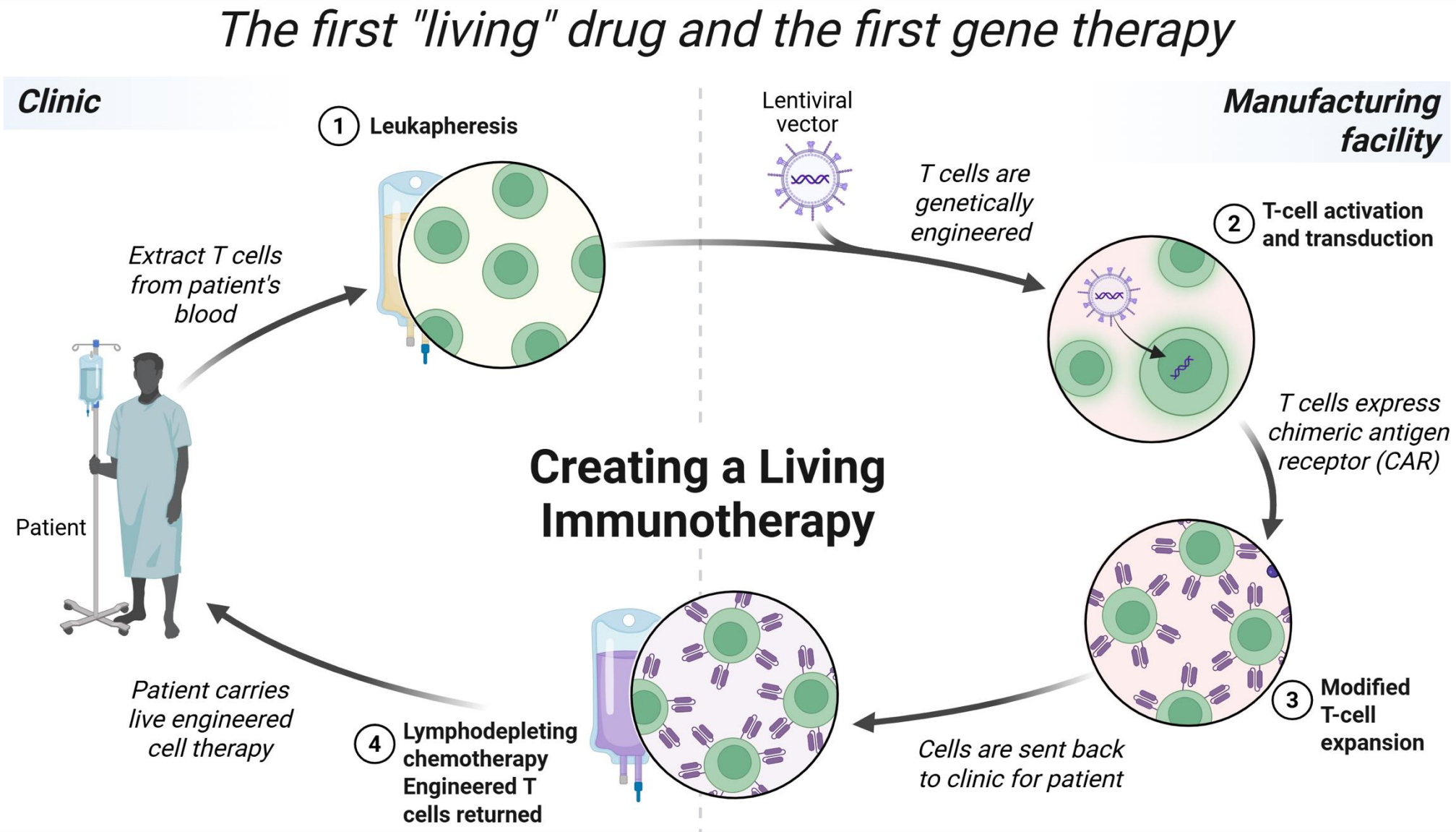
CAR-T | Chimeric Antigen Receptor (CAR) – T Cell Therapy

CAR-T | A “Living” Drug



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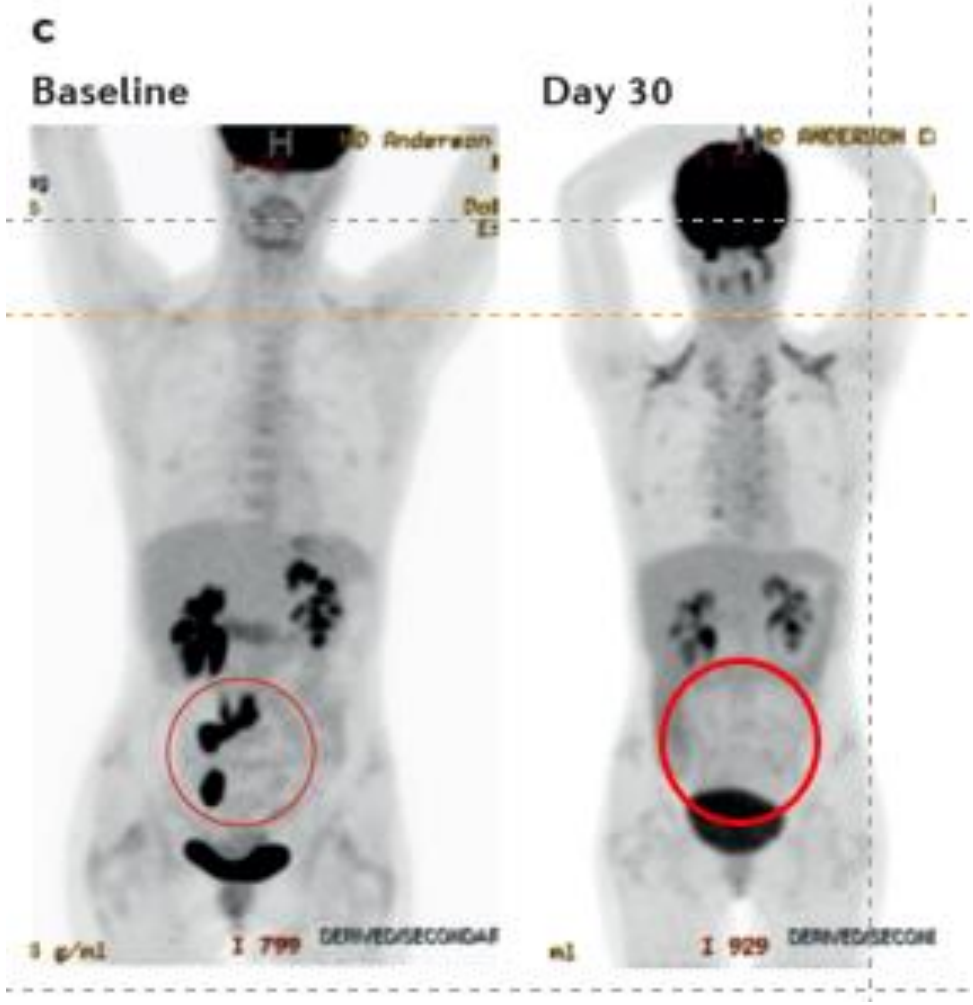
CAR-T | Transformative Efficacy for B Cell Cancers

Patient with refractory diffuse large B cell lymphoma (DLBCL)
Treated with anti-CD19 CAR-T cell therapy



Neelapu, SS, et al. *Nat Rev*. 2018 v14 p47 20

CAR-T | Emily Whitehead

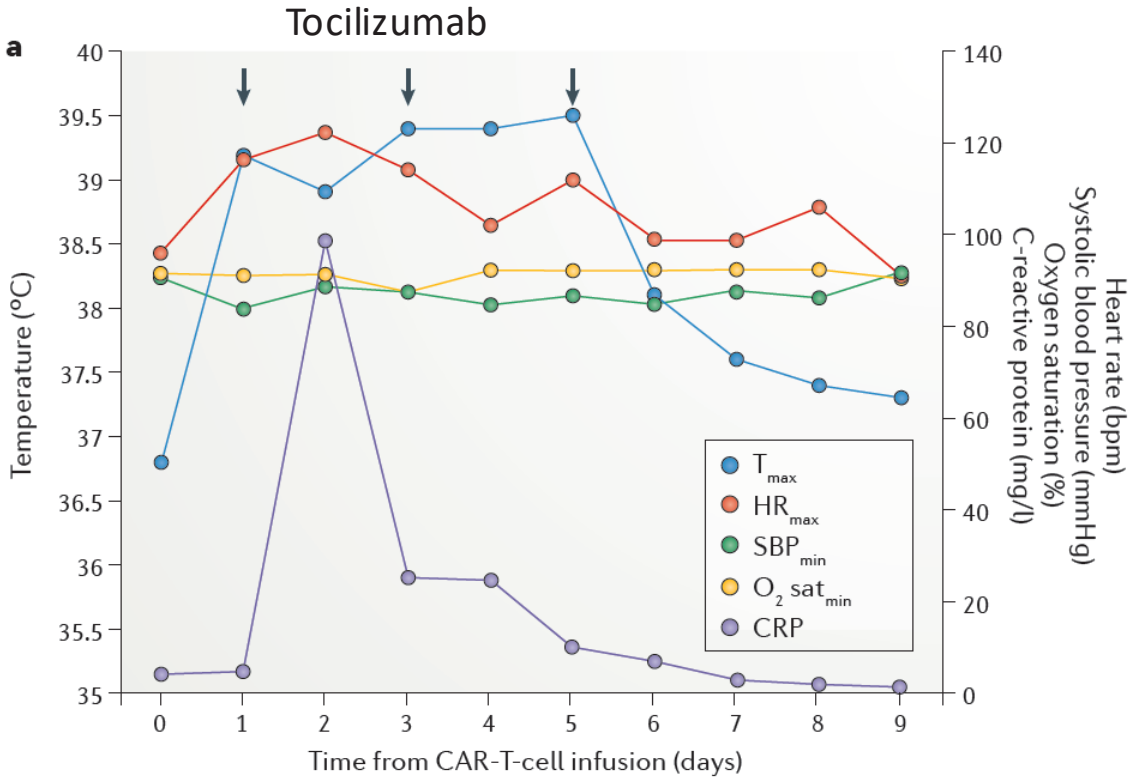
2012

acute lymphoblastic leukemia (ALL)

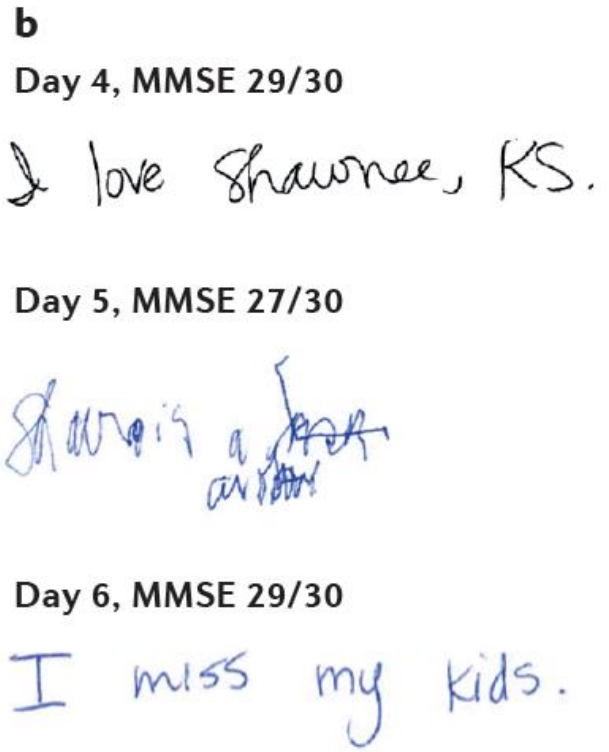
The Emily Whitehead Foundation

CAR-T | Toxicities Arising from CAR-T Cell Therapy

Cytokine Release Syndrome (CRS)



Neurotoxicity (ICANS)



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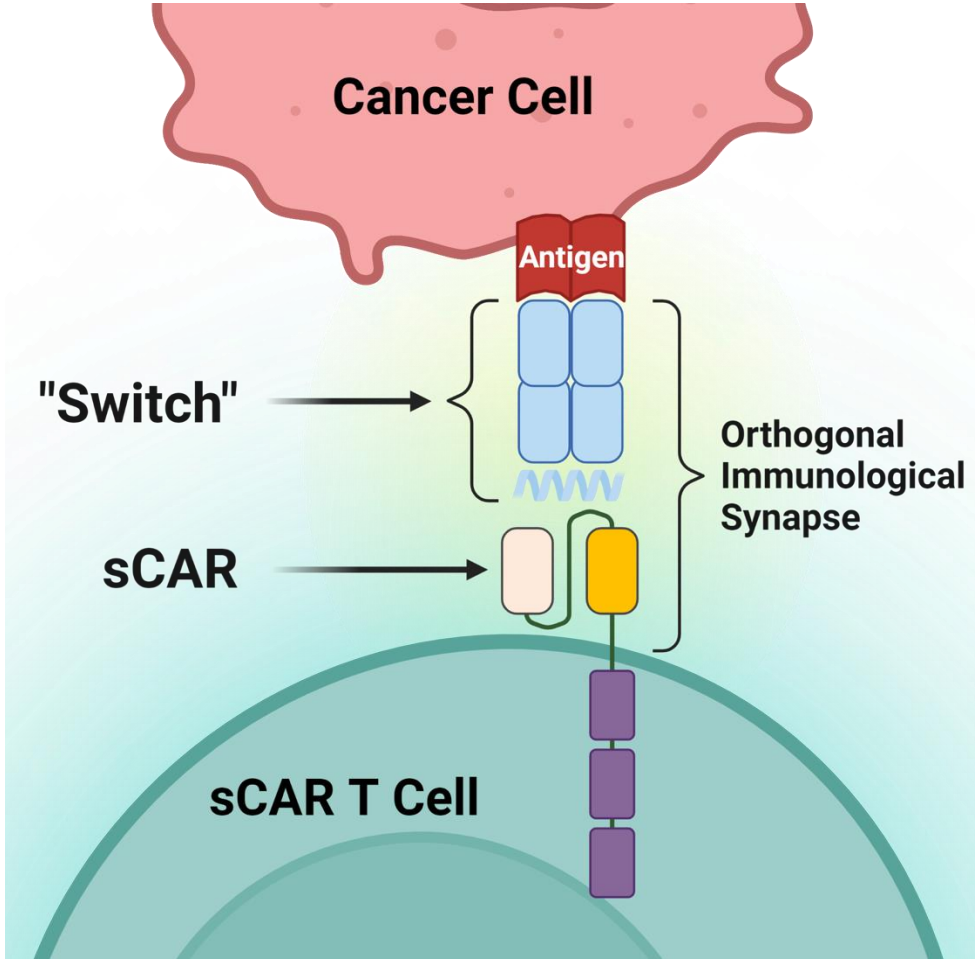
Neelapu, SS, et al. *Nat Rev*. 2018 v14 p47 20

sCAR-T | Switchable CAR-T – Core Principles

How to harness the power of CAR-T cell therapy, while addressing the challenges

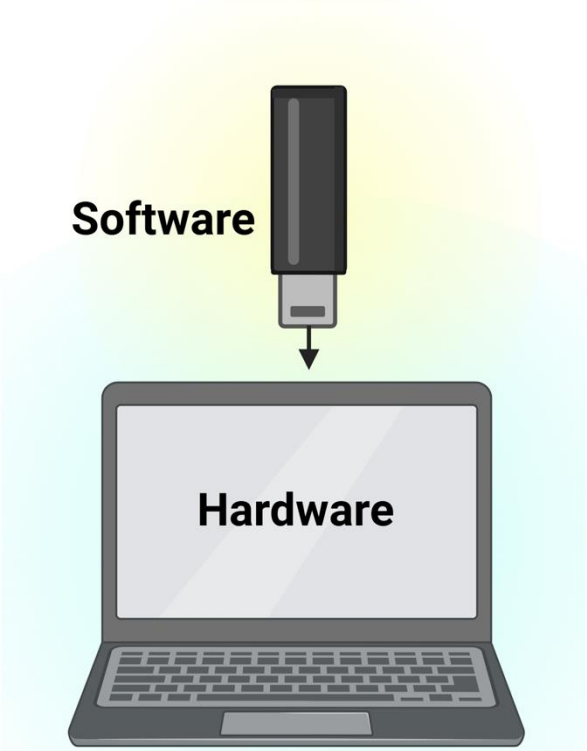
sCAR-T Core Principles

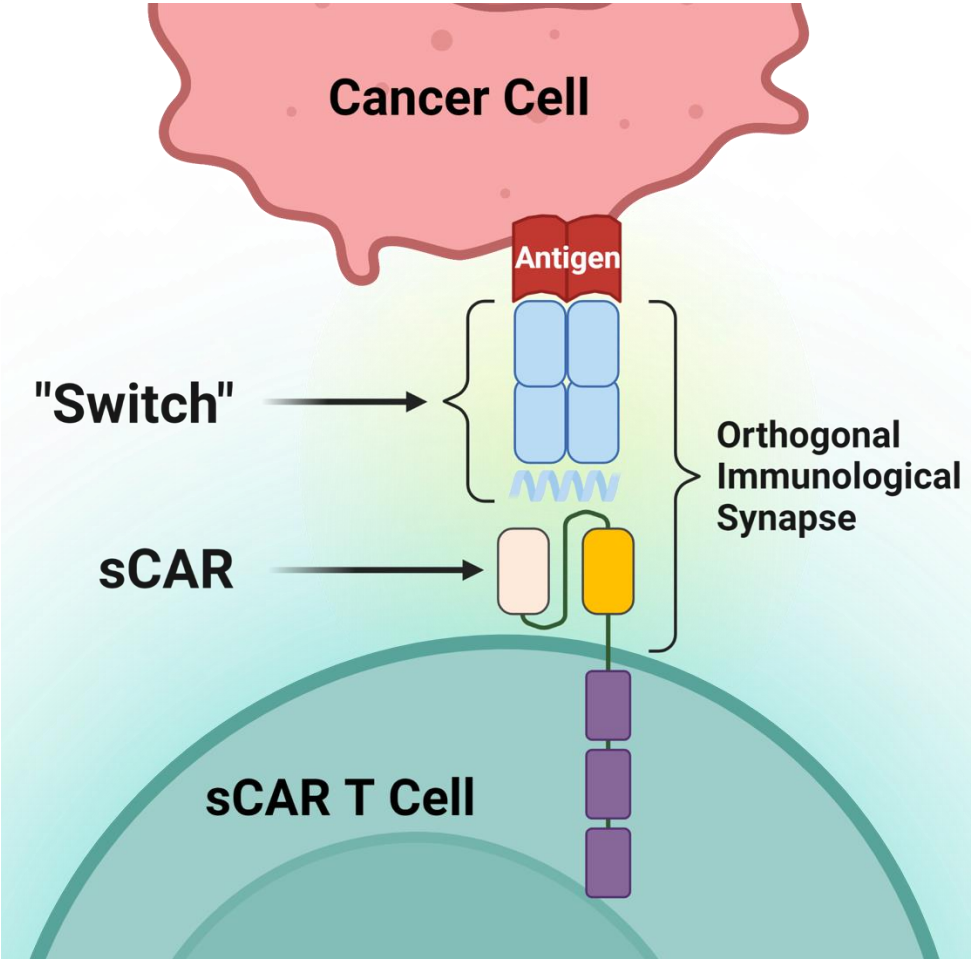
1. **Efficacy**
   Without compromising safety
2. **Safety**
   Reduce cytokine release syndrome (CRS) and neurotoxicity (ICANS)
3. **Control**
   A hardware / software-based approach
   New indication = new software
4. **Durability**
   Program cells to last longer, leading to more durable responses
5. **Universality**
   Translate success in blood cancers to solid tumors and autoimmune diseases



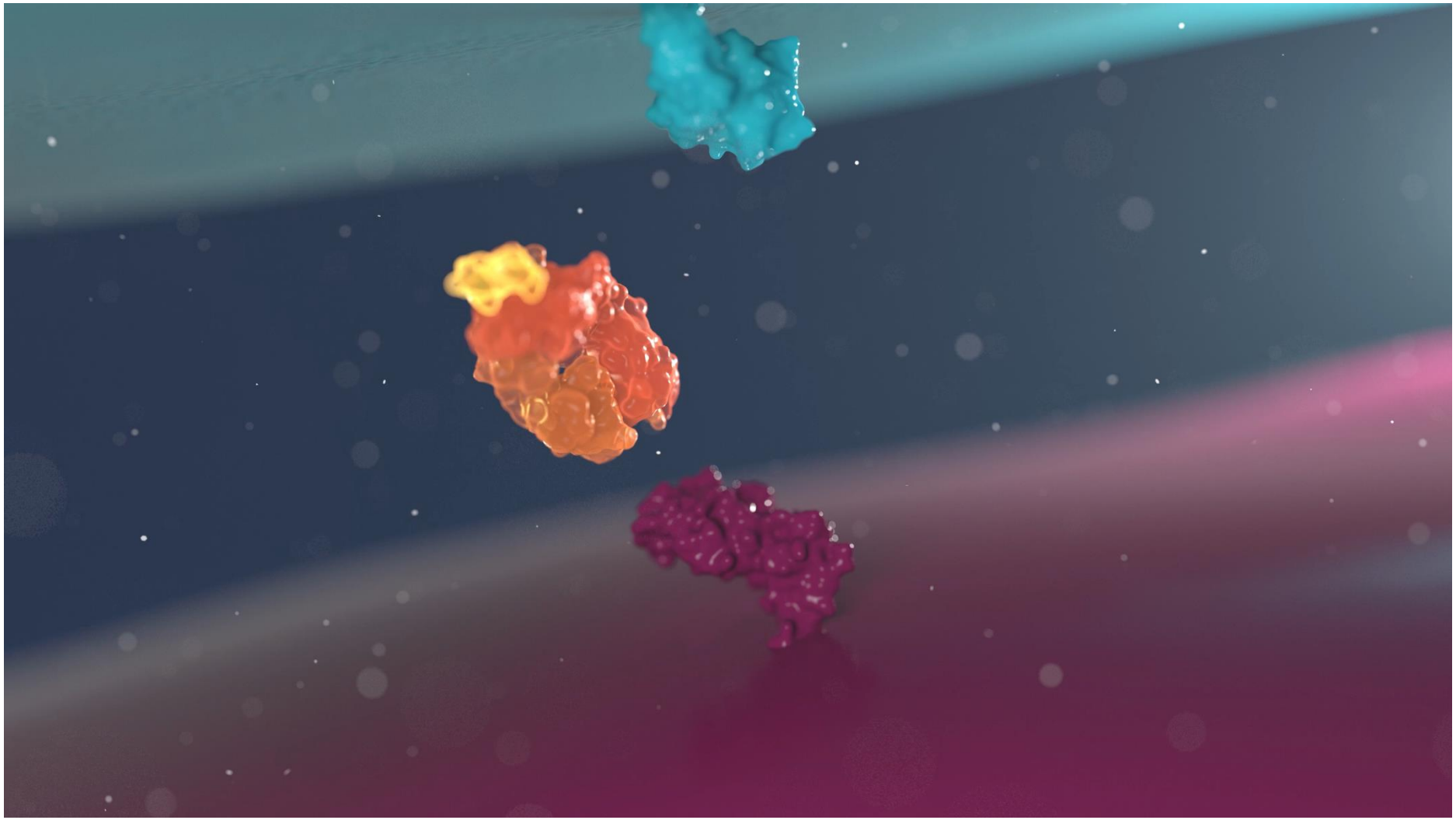
sCAR-T | A Software and Hardware-based Approach

The switch programs the CAR-T cells to target a specific antigen, much like software instructs a computer on what tasks to perform



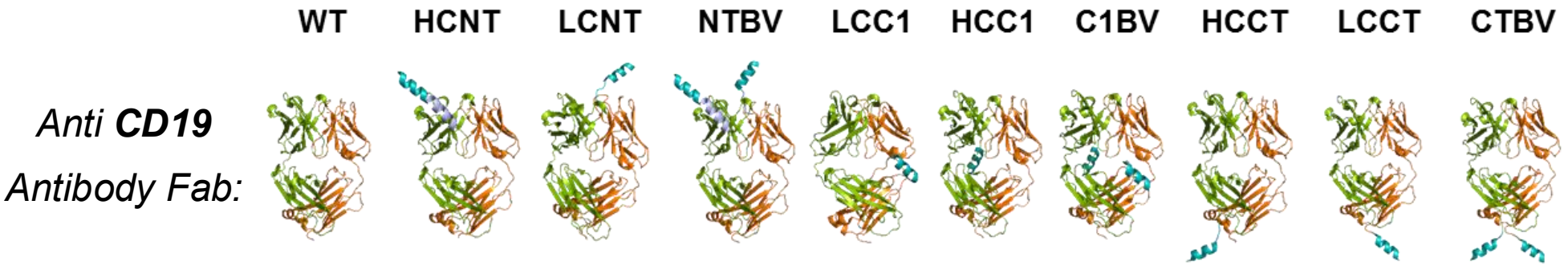


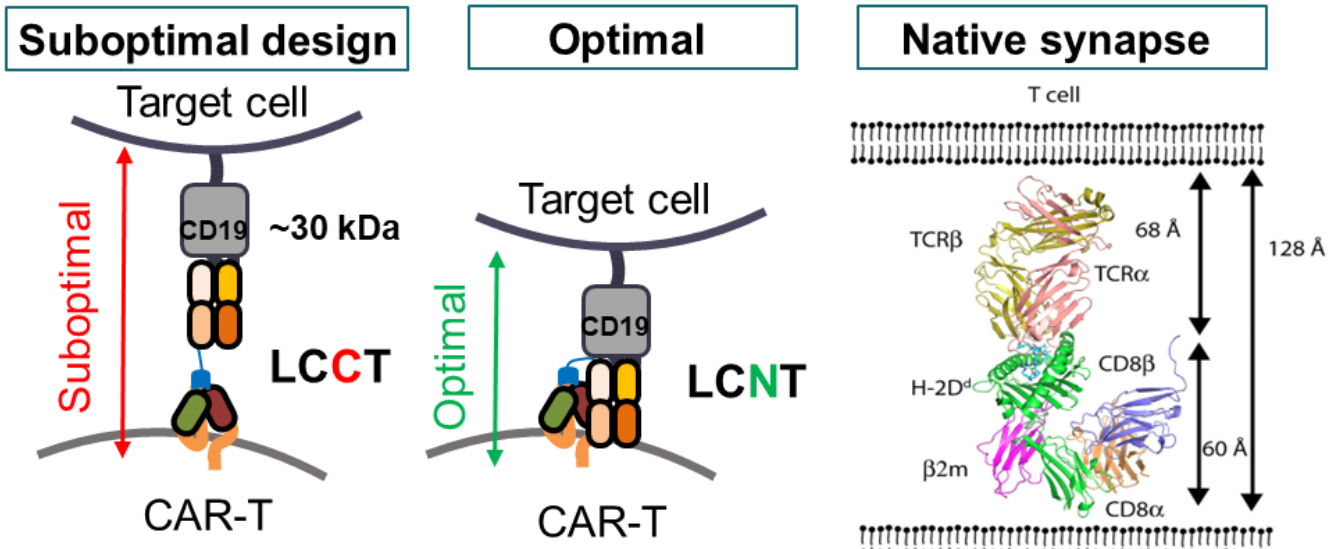
sCAR-T | How the Switch Turns “ON” the CAR-T Cell



sCAR-T | Protein Engineering for a Designer Immunological Synapse

Engineering the "switch" with structure-guided protein design to fit in the synapse





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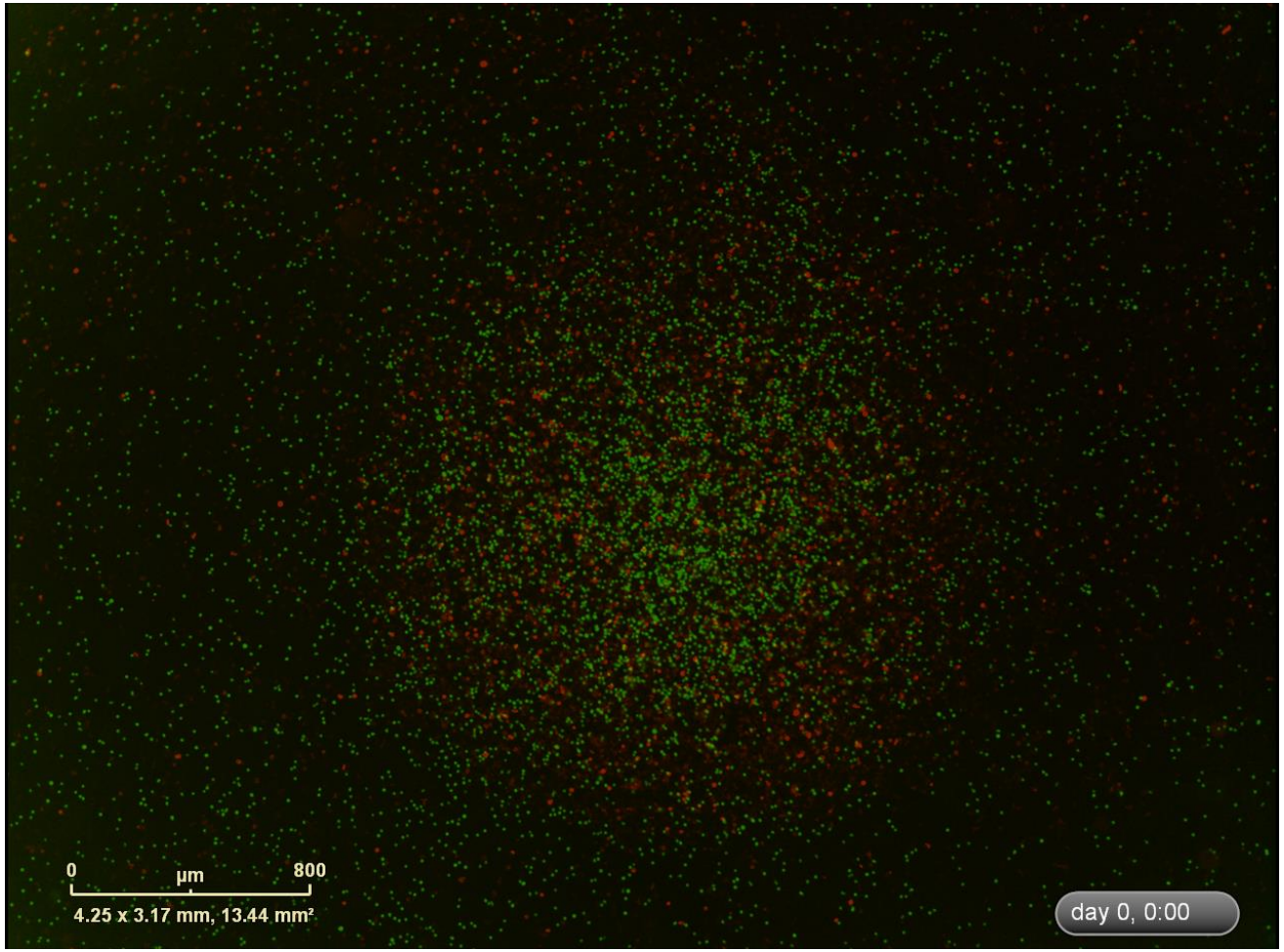
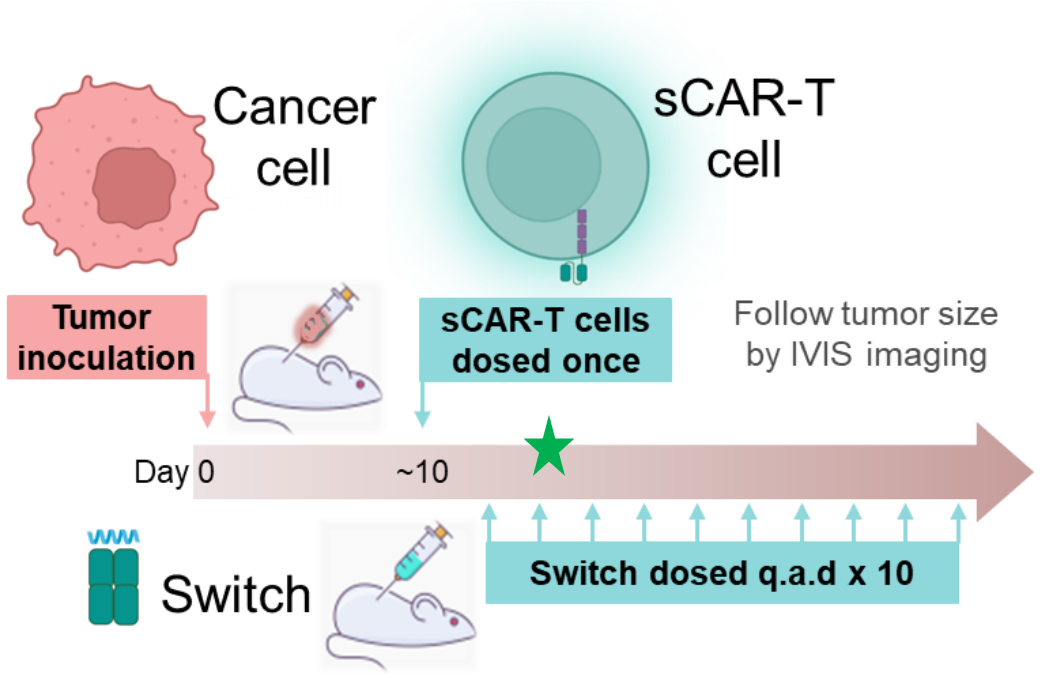
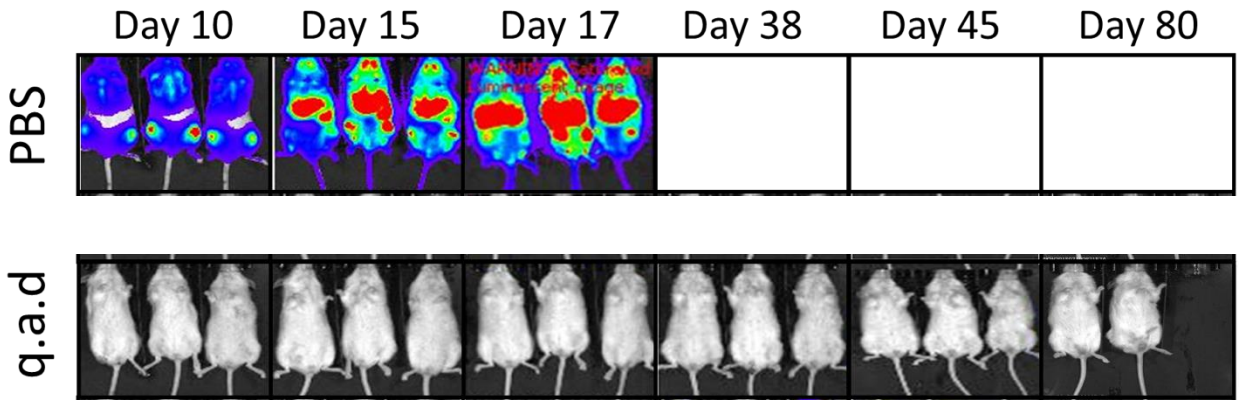
sCAR-T | Running the Software Against CD19-positive Leukemia



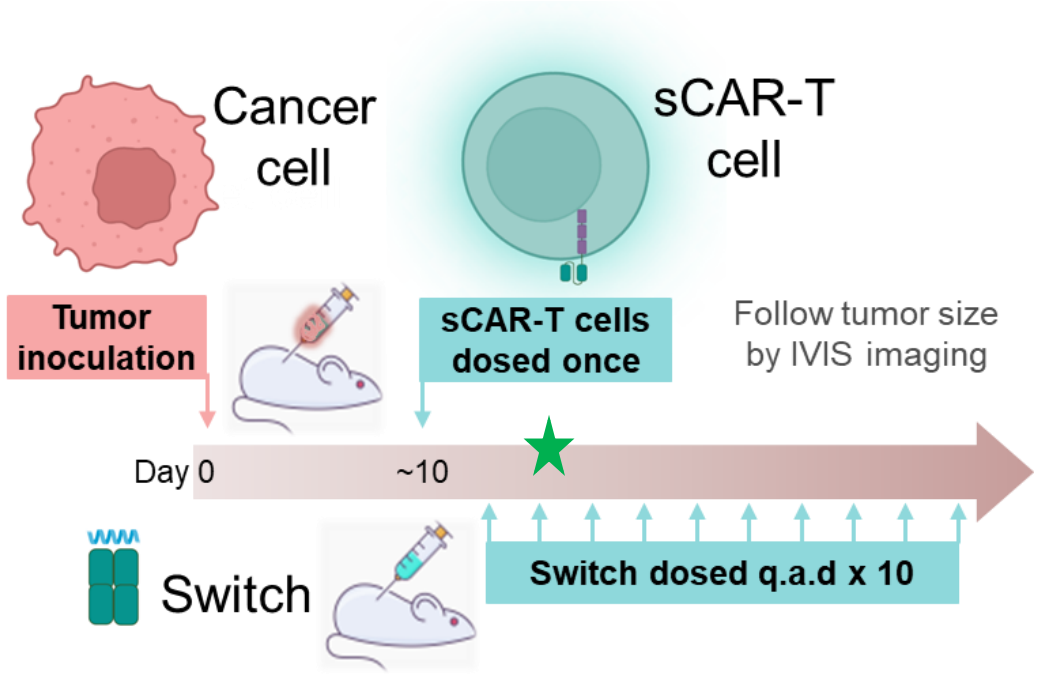
sCAR-T cells in red, cancer cells in green

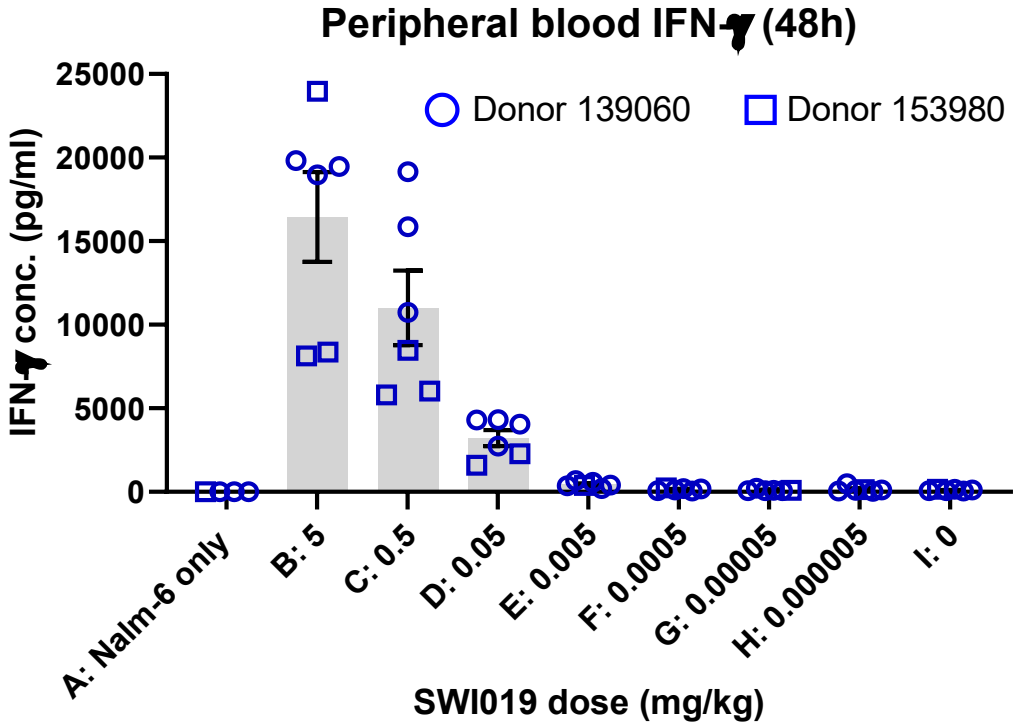
sCAR-T | Eliminating Tumors in Mice





sCAR-T | Controlling the Toxicity

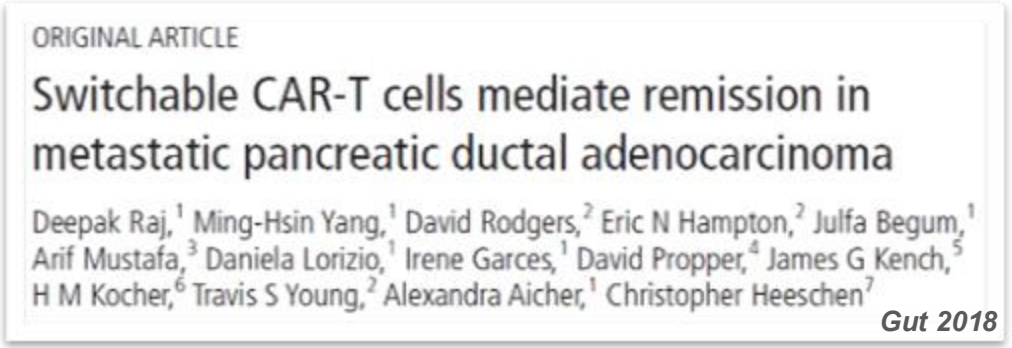




sCAR-T | Extensive Collaboration to Validate the Concept

Used internationally by labs as universal platform against liquid and solid tumors

Her2 PDAC



ORIGINAL ARTICLE

Switchable CAR-T cells mediate remission in metastatic pancreatic ductal adenocarcinoma

Deepak Raj,[1] Ming-Hsin Yang,[1] David Rodgers,[2] Eric N Hampton,[2] Julfa Begum,[1] Arif Mustafa,[3] Daniela Lorizio,[1] Irene Garces,[1] David Propper,[4] James G Kench,[5] H M Kocher,[6] Travis S Young,[2] Alexandra Aicher,[1] Christopher Heeschen[7]

Gut 2018

Her2 Breast Cancer

Cancer Immunotherapy

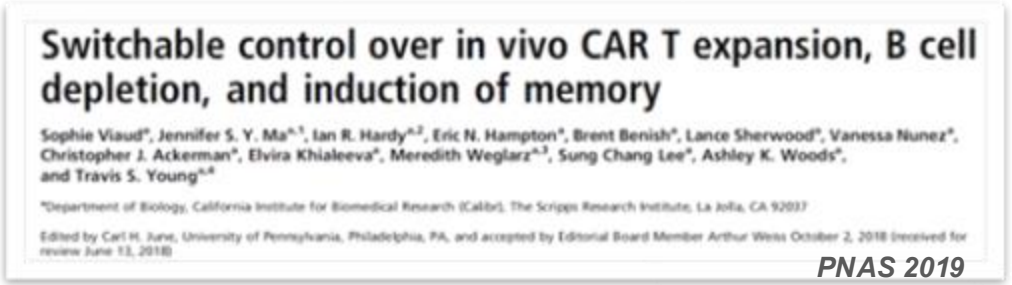
International Edition: DOI: 10.1002/anie.201601902
German Edition: DOI: 10.1002/ange.201601902

Design of Switchable Chimeric Antigen Receptor T Cells Targeting Breast Cancer

Yu Cao, David T. Rodgers, Juanjuan Du, Insha Ahmad, Eric N. Hampton, Jennifer S. Y. Ma, Magdalena Mazagova, Sei-hyun Choi, Hwa Young Yun, Han Xiao, Pengyu Yang, Xiaozhou Luo, Reyna K. V. Lim, Holly M. Pugh, Feng Wang, Stephanie A. Kazane, Timothy M. Wright, Chan Hyuk Kim, Peter G. Schultz,* and Travis S. Young**

Angew Chem Int Ed 2016

CD19 Syngeneic



Switchable control over in vivo CAR T expansion, B cell depletion, and induction of memory

Sophie Viaud[a], Jennifer S. Y. Ma[a,1], Ian R. Hardy[a,2], Eric N. Hampton[a], Brent Benish[a], Lance Sherwood[a], Vanessa Nunez[a], Christopher J. Ackerman[a], Elvira Khialeeva[a], Meredith Weglarz[a,3], Sung Chang Lee[a], Ashley K. Woods[a], and Travis S. Young[a,4]

[a]Department of Biology, California Institute for Biomedical Research (Calibr), The Scripps Research Institute, La Jolla, CA 92037

Edited by Carl H. June, University of Pennsylvania, Philadelphia, PA, and accepted by Editorial Board Member Arthur Weiss October 2, 2018 (received for review June 13, 2018)

PNAS 2019

CD19, CD20 Lymphoma

Switch-mediated activation and retargeting of CAR-T cells for B-cell malignancies

David T. Rodgers[a], Magdalena Mazagova[a], Eric N. Hampton[a], Yu Cao[b], Nitya S. Ramadoss[a,1], Ian R. Hardy[a,2], Andrew Schulman[a], Juanjuan Du[a], Feng Wang[a], Oded Singer[a,3], Jennifer Ma[a], Vanessa Nunez[a], Jiayin Shen[a,4], Ashley K. Woods[a], Timothy M. Wright[a], Peter G. Schultz[a,b,5], Chan Hyuk Kim[a,5], and Travis S. Young[a,5]

[a]Department of Biology, California Institute for Biomedical Research, La Jolla, CA 92019; and [b]Department of Chemistry and The Skaggs Institute for Chemical Biology, The Scripps Research Institute, La Jolla, CA 92037

Contributed by Peter G. Schultz, December 11, 2015 (sent for review October 23, 2015; reviewed by Carl H. June and Kevan M. Shokat)

PNAS 2016

CD19, CD22 Lymphoma Leukemia

Versatile strategy for controlling the specificity and activity of engineered T cells

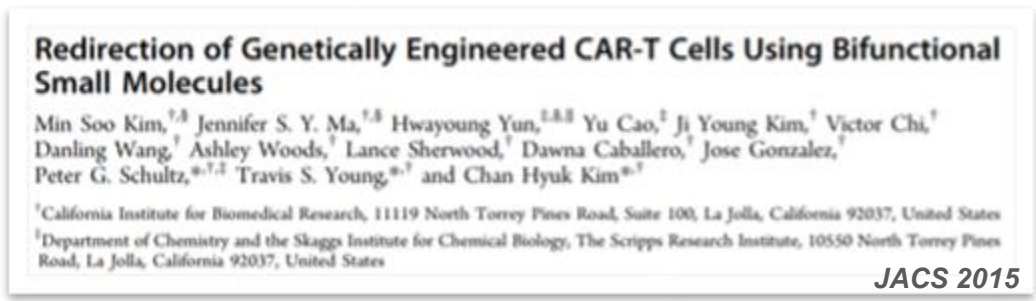
Jennifer S. Y. Ma[a,1], Ji Young Kim[a], Stephanie A. Kazane[a,2], Sei-hyun Choi[b], Hwa Young Yun[b,3], Min Soo Kim[a,4], David T. Rodgers[a], Holly M. Pugh[a], Oded Singer[a], Sophie B. Sun[a], Bryan R. Fonslow[c,d], James N. Kochenderfer[e], Timothy M. Wright[a], Peter G. Schultz[a,b,5], Travis S. Young[a,5], Chan Hyuk Kim[a,5], and Yu Cao[b,1]

[a]Department of Biology, California Institute for Biomedical Research, La Jolla, CA 92037; [b]Department of Chemistry and The Skaggs Institute for Chemical Biology, The Scripps Research Institute, La Jolla, CA 92037; [c]Department of Chemical Physiology, The Scripps Research Institute, La Jolla, CA 92037; [d]SCIEX Separations, Brea, CA 92821; and [e]Experimental Transplantation and Immunology Branch, National Institutes of Health, National Cancer Institute, Bethesda, MD 20892

Contributed by Peter G. Schultz, December 10, 2015 (sent for review October 23, 2015; reviewed by Carl H. June and Kevan M. Shokat)

PNAS 2016

PSMA Prostate Cancer



Redirection of Genetically Engineered CAR-T Cells Using Bifunctional Small Molecules

Min Soo Kim,[†,‖] Jennifer S. Y. Ma,[†,‖] Hwayoung Yun,[‡,§,‖] Yu Cao,[‡] Ji Young Kim,[†] Victor Chi,[†] Danling Wang,[†] Ashley Woods,[†] Lance Sherwood,[†] Dawna Caballero,[†] Jose Gonzalez,[†] Peter G. Schultz,[*,†,‡] Travis S. Young,[*,†] and Chan Hyuk Kim[*,†]

[†]California Institute for Biomedical Research, 11119 North Torrey Pines Road, Suite 100, La Jolla, California 92037, United States

[‡]Department of Chemistry and the Skaggs Institute for Chemical Biology, The Scripps Research Institute, 10550 North Torrey Pines Road, La Jolla, California 92037, United States

JACS 2015

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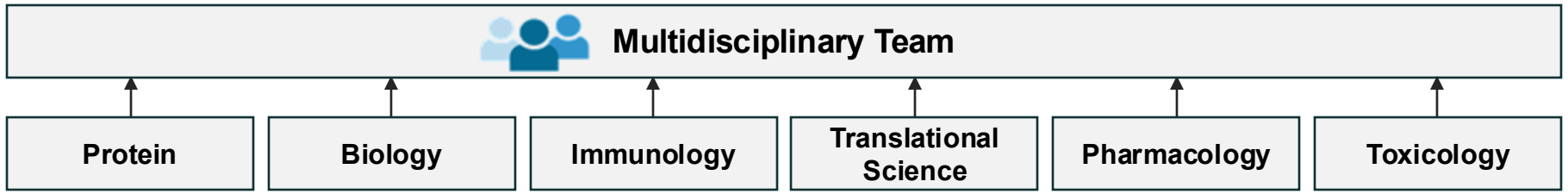
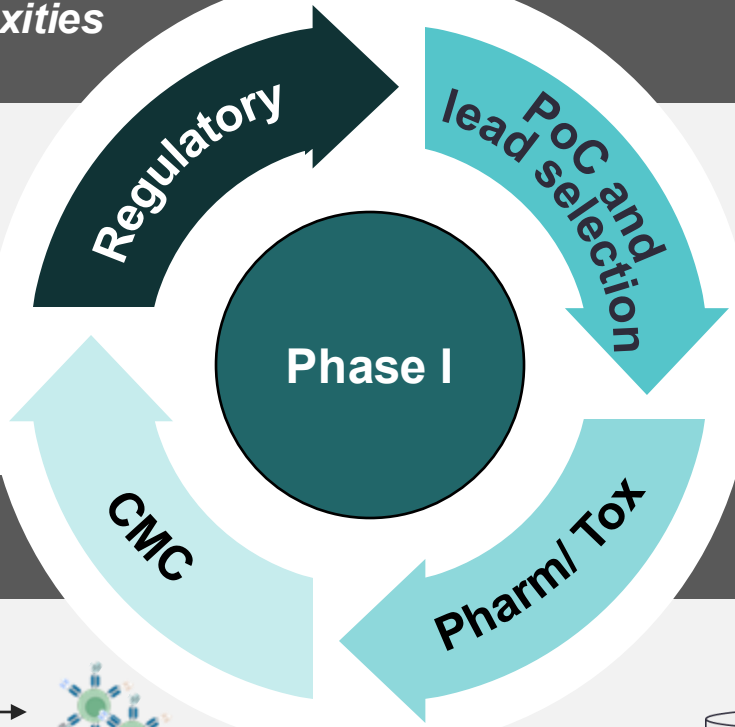
Translation | Calibr-Skaggs' Integrated Bench-to-Bedside Platform



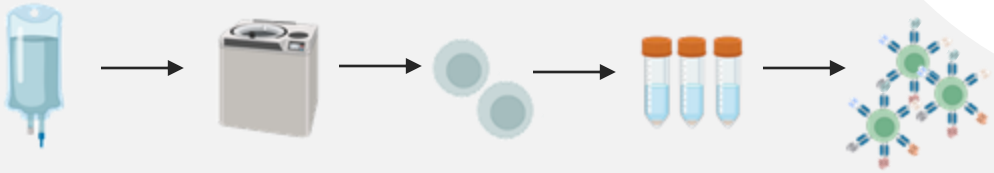
Regulatory experience navigating complexities of cell therapy

Innovative methods of determining how to accelerate first-in-human clinical designs

In vivo MABEL

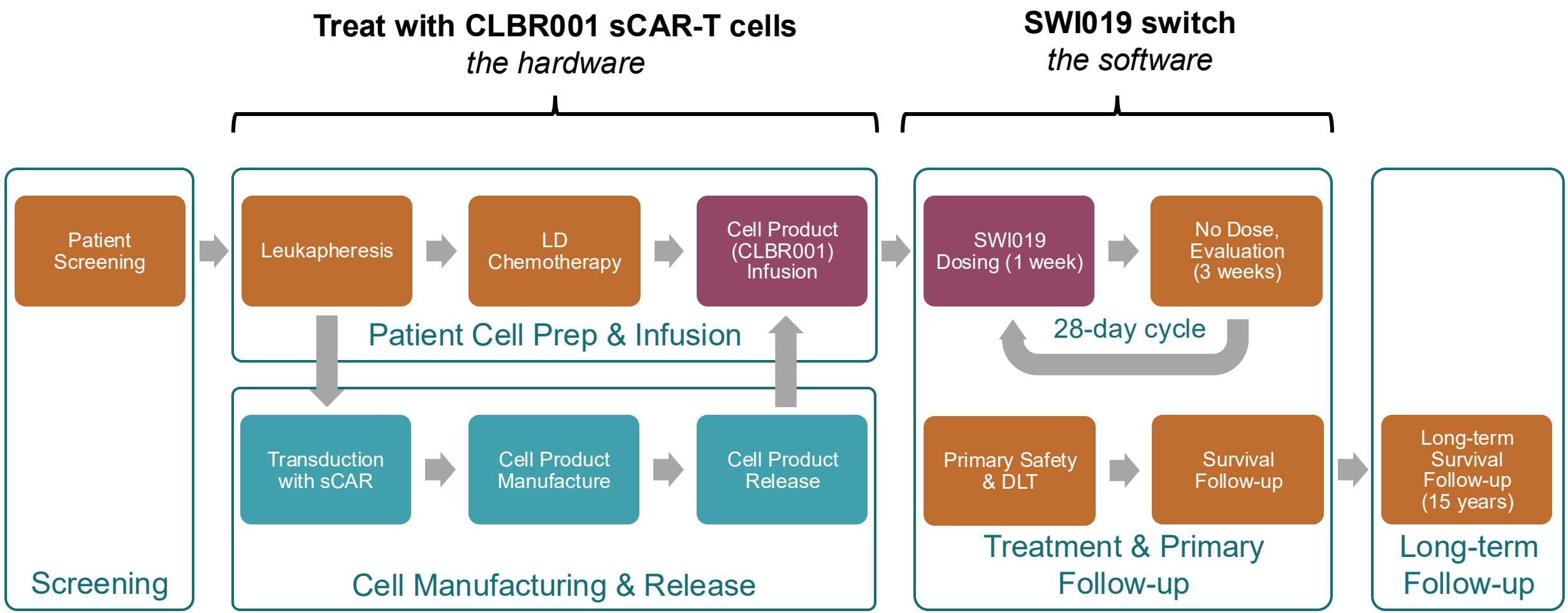


Established CMC experience developing manufacturing from the ground up



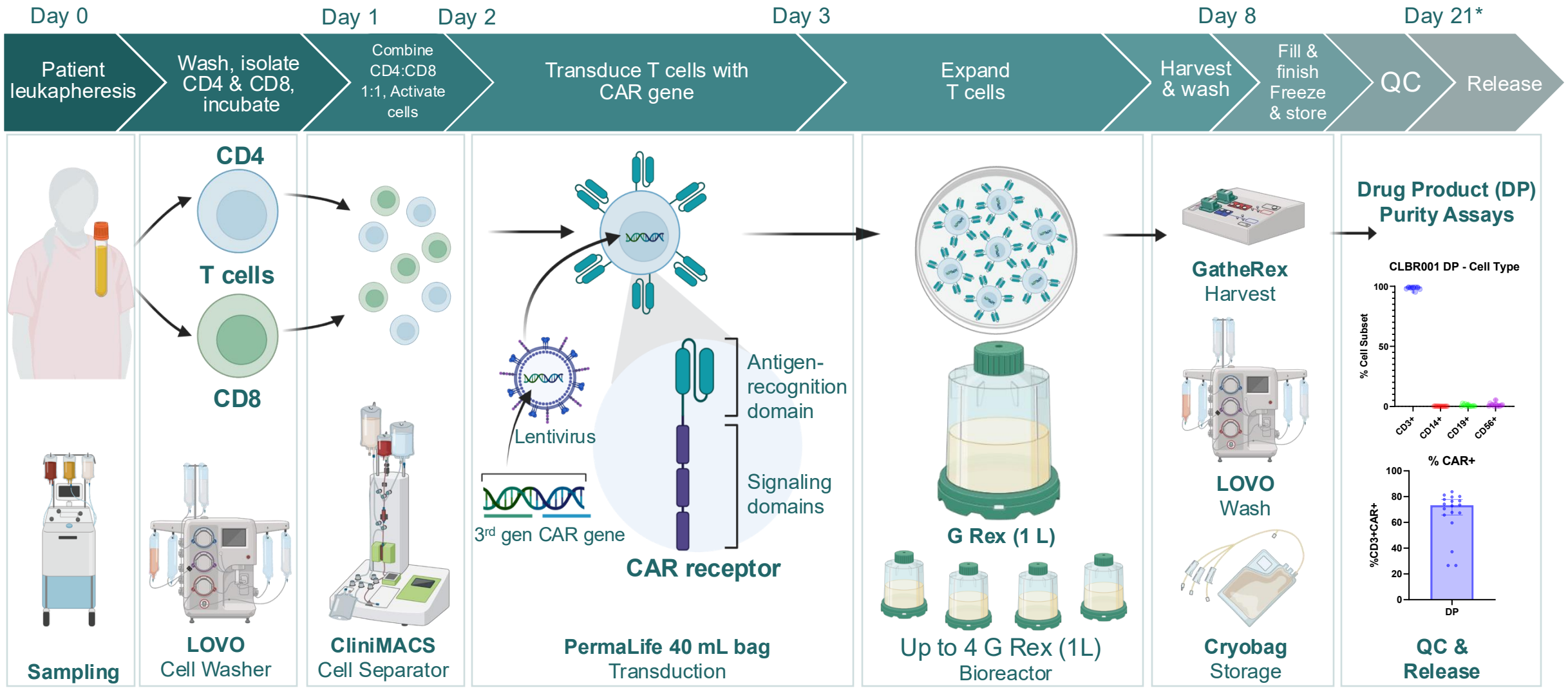
Experience in efficient toxicology designs avoids time- & cost-intensive GLP studies

Phase I, CD19 | Enrolling Patients with Leukemia and Lymphoma

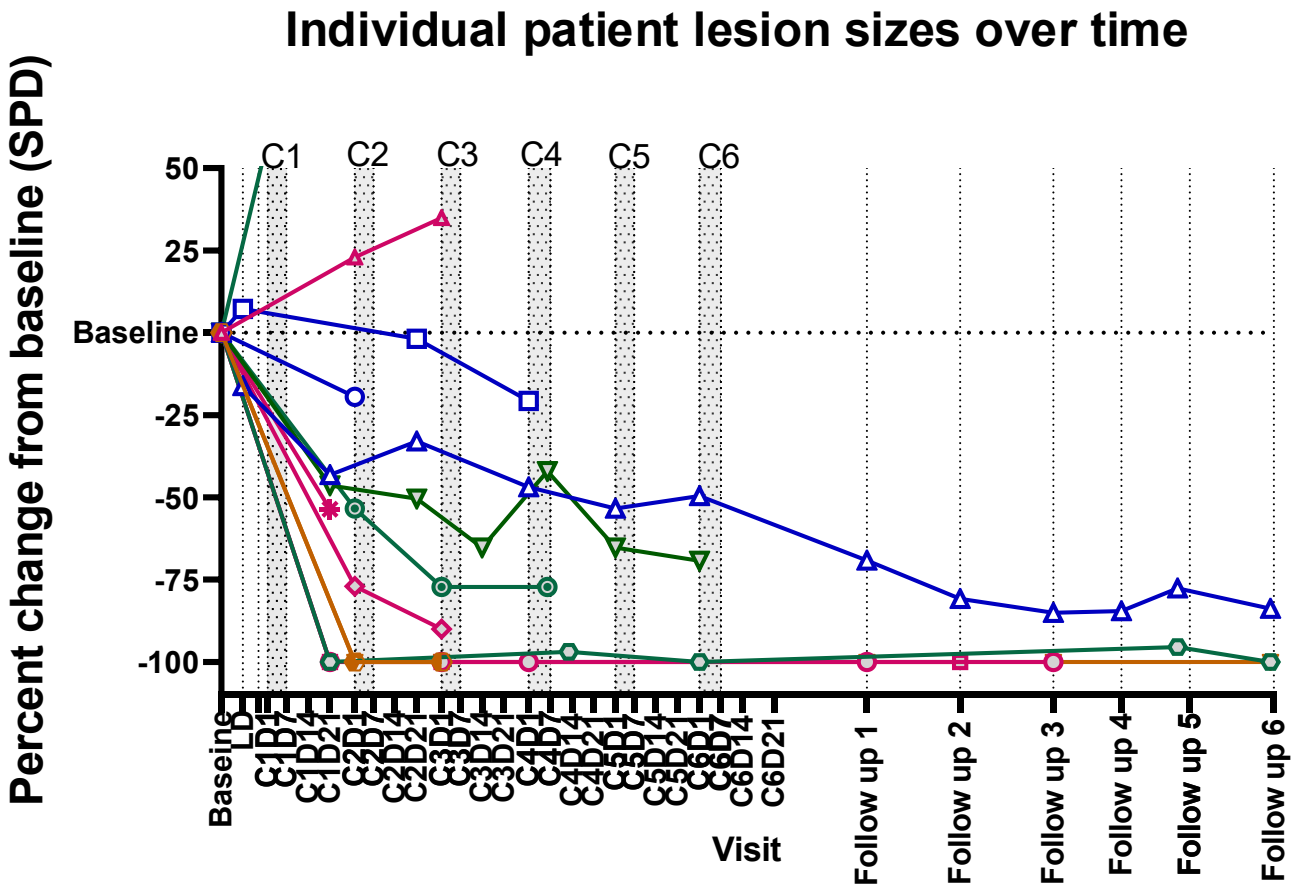


NCT04450069

Phase I, CD19 | Manufacturing an Autologous CAR-T Cell Product



Phase I, CD19 | Anti-tumor Responses in Highly Refractory Patients

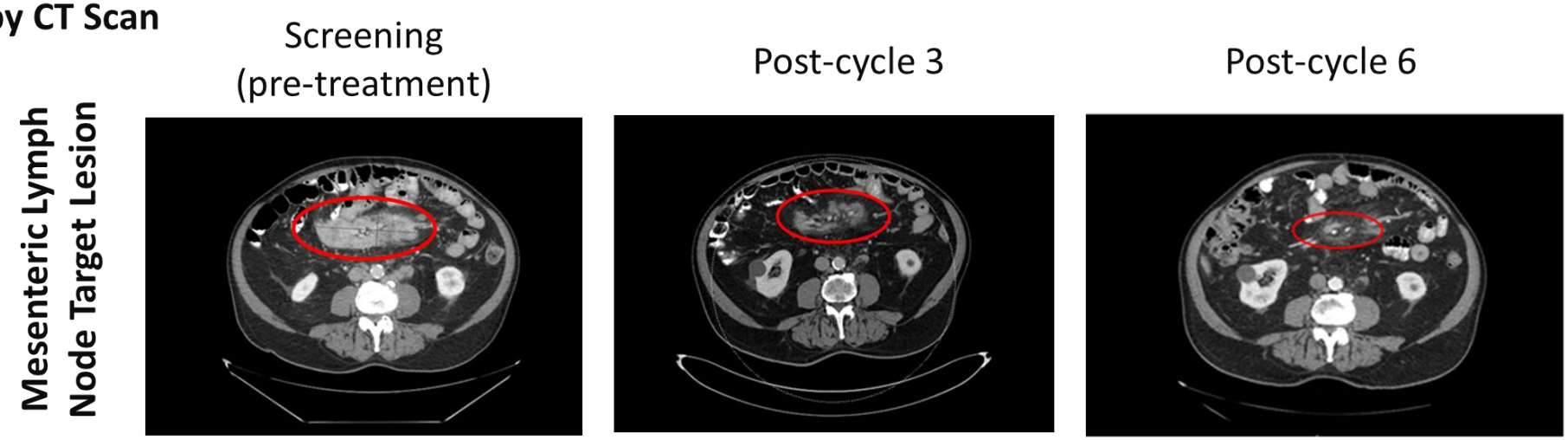


[1] 106-105-10201 CLBR001 DP was OOS (residual beads), and the product approved for use as is
Disease assessments by Lugano criteria
SPD = sum of the product of the perpendicular diameters
Disease assessment data unavailable for subjects 104-128 & 102-131 (coh 3), 104-122 (coh 4) at time of data cut; subject 107-119 deceased prior to post-treatment disease assessment

Phase I, CD19 | Case Study: Complete Response in Highly Refractory Disease

Demographics	Disease History	Treatment & Response
Enrollment # 104-102-10102	Diagnosed: 2012	Dose: 140 e6 CAR+ cells / 10 ug/kg SWI019
71 year old male	Lines of prior therapy: 6	Highest Grade CRS / ICANS: 0
Follicular Lymphoma	Bridging Therapy: none	Best Response Lugano: CR

Response by CT Scan



Subject experienced **decrease in all 5 FDG-avid target lesions**, no new target masses, no evidence of lymphoma in bone marrow by IHC

Phase I, CD19 | Comparable Efficacy, Improved Tolerability

	CBR-sCAR19-3001 CLBR001 + SWI019 *all subjects; n=18*	ZUMA-1 Yescarta Kite[1]	JULIET KYMRIAH Novartis[1]	TRANSCEND Breyanzi BMS[1]
Overall Response Rate (ORR)[2]	12/16 **(75%)**	**74%**	**52%**	**73%**
Complete Response (CR)[2]	10/16 **(63%)**	**54%**	**40%**	**53%**
CRS (Grade ≥ 3)	3/18 (17%)	10%	22%	2%
Median time to resolution CRS (any grade)	**1 day**	**8 days**	**7 days**	**5 days**
ICANS Neurotoxicity (Grade ≥ 3)	3/18 (17%)	32%	11%	10%
Median time to resolution ICANS (any grade)	**1 day**	**17 days**	**14 days**	**11 days**

[1]Source for ZUMA-1, JULIET and TRANSCEND: Westin et al 2021 https://doi.org/10.1002/ajh.26301
[2]107-119 passed away prior to end of cycle 1 imaging; 107-121 declined EOS imaging and transitioned to 3002 study, subject in CR until lost to follow up at month 18.

Calib Institute for

Phase I, CD19 | Greater Cell Expansion Vs Conventional CAR-T

	CBR-sCAR19-3001 CLBR001 + SWI019 *all subjects; n=18*	ZUMA-1 Yescarta Kite[1]	JULIET KYMRIAH Novartis[1]	TRANSCEND Breyanzi BMS[1]
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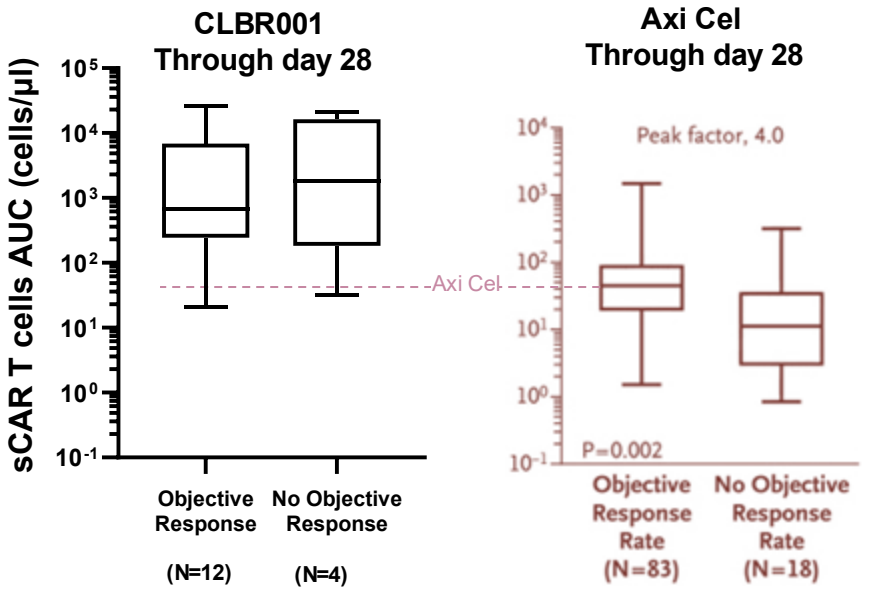

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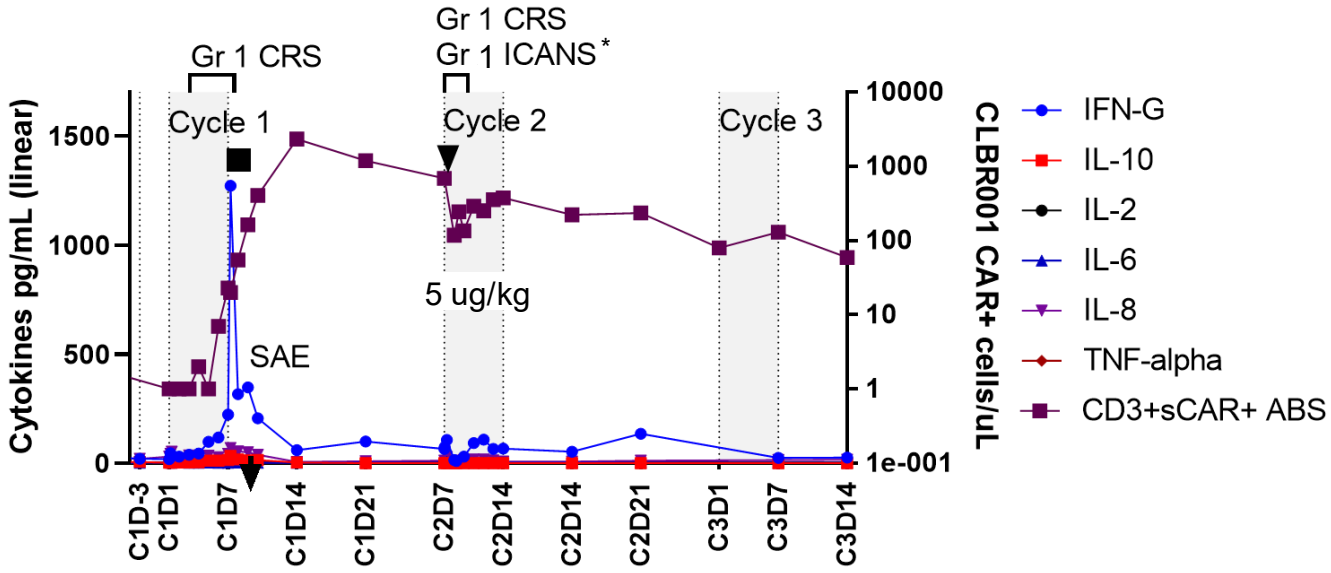
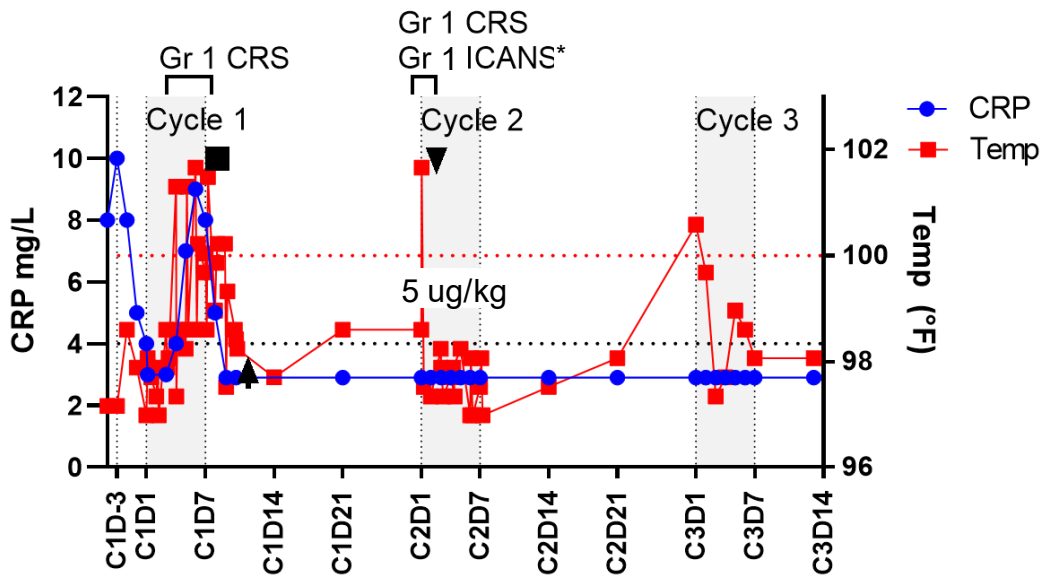
Phase I, CD19 | Case Study: Rapid Resolution of CRS / ICANS

Demographics	Disease History	Treatment & Response
Enrollment # 103-104-10104	Diagnosed: 2016	Dose: 140 e6 CAR+ cells / 10 ug/kg SWI019
70 year old female	Lines of prior therapy: 7	Highest Grade CRS / ICANS: 1
Follicular Lymphoma	Bridging Therapy: Dexamethasone	Best Response Lugano: CR

103-104-10104 Cytokines & CAR+ cell/uL



103-104-10104 CRP & Temp



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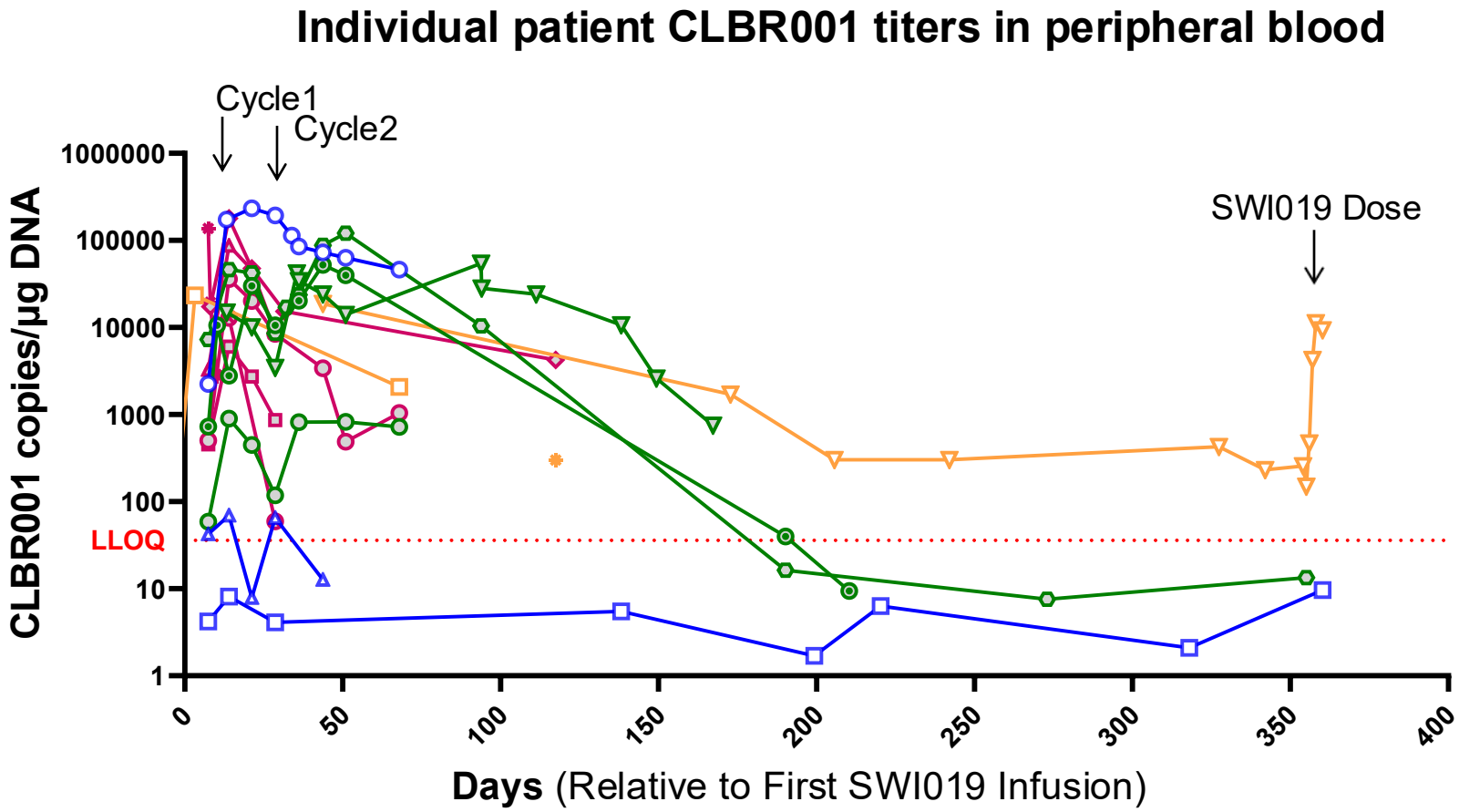
**Gr 1 ICANS updated subsequent to ASH Dec 2021 presentation*

Data presented ASH Dec 2021

CD19 Heme | CLBR001 Kinetics in Peripheral Blood



102-131-10307 not included in figure as correlative SWI019 administration data unavailable at time of data cut;
107-119 deceased prior to post-treatment disease assessment (by ddPCR, all cohorts)
Data per CBR-sCAR19-3001_ddPCR_2023.07.21

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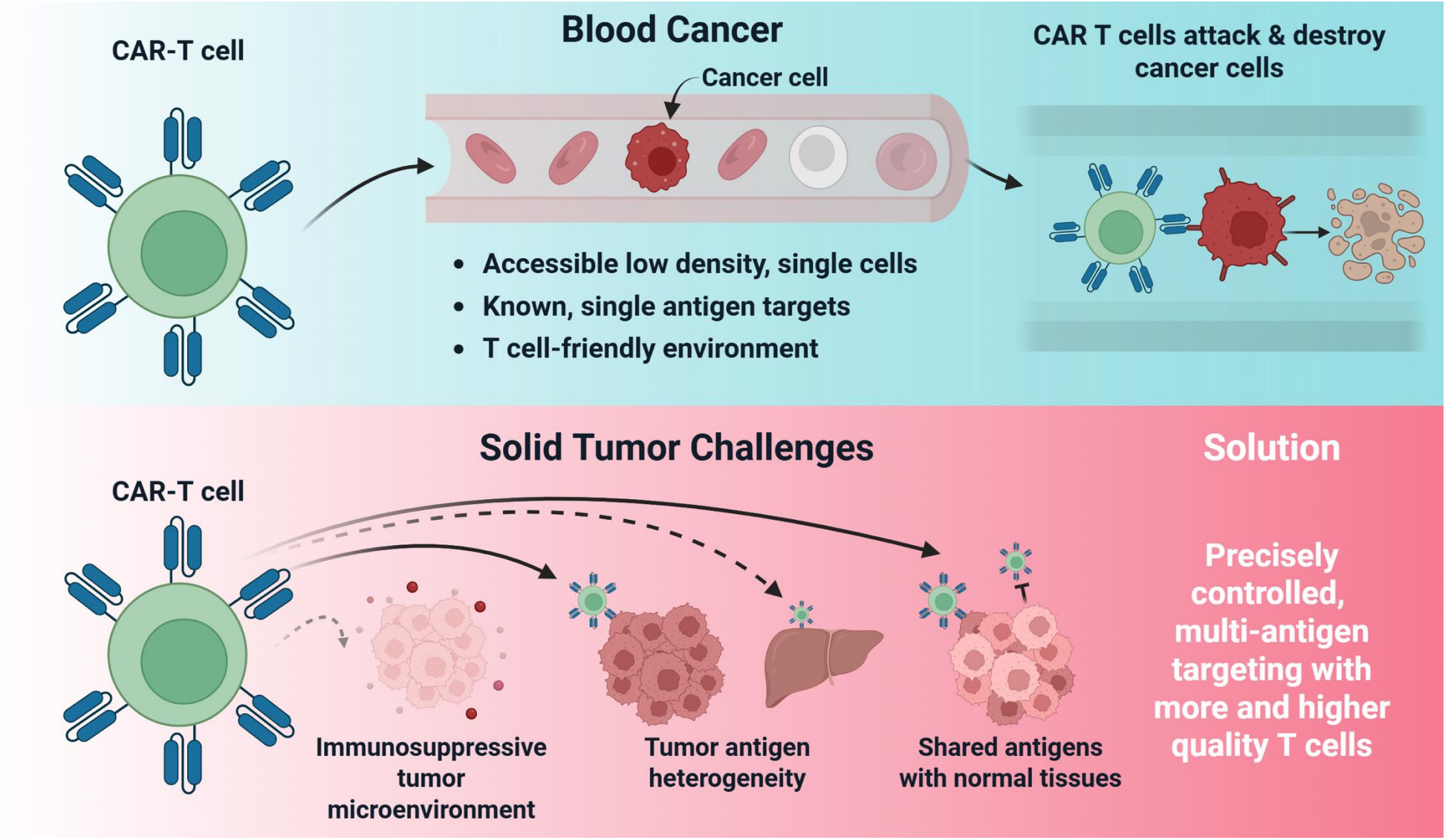
Solid Tumors | The Next Frontier, the Solid Tumor Barrier



Solid Tumors | Breast Cancer Trial

Phase 1, Open-Label, Dose-Escalation Study Evaluating CLBR001, an Engineered Autologous T Cell Product, and ABBV-461, an Antibody-Based Biologic, in Subjects with Locally Advanced or Metastatic Breast Cancer

abbvie

Prolactin receptor (PRLR)

Eligible Patients

Locally advanced or metastatic Luminal A, B, or TNBC

- Refractory/ relapsed following standard of care & ineligible for or refused other treatment options

Goals

- **Efficacy**: Demonstrate increased sCAR-T expansion (compared with conventional CAR-T) overcomes immunosuppressive tumor microenvironment leading to durable responses
- **Safety**: Demonstrate the switch-based control can avoid adverse effects associated with solid tumor targets

Locations

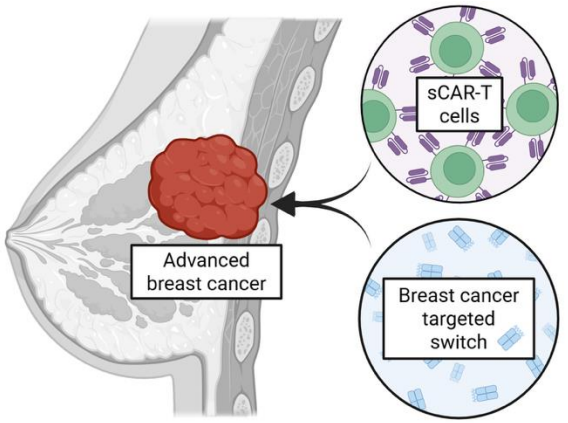
Indiana University
Indianapolis, Indiana

Roswell Park Cancer Institute
Buffalo, New York

University of Virginia
Charlottesville, Virginia

Trial Information

For more information, visit:
clinicaltrials.gov
NCT#: NCT06878248



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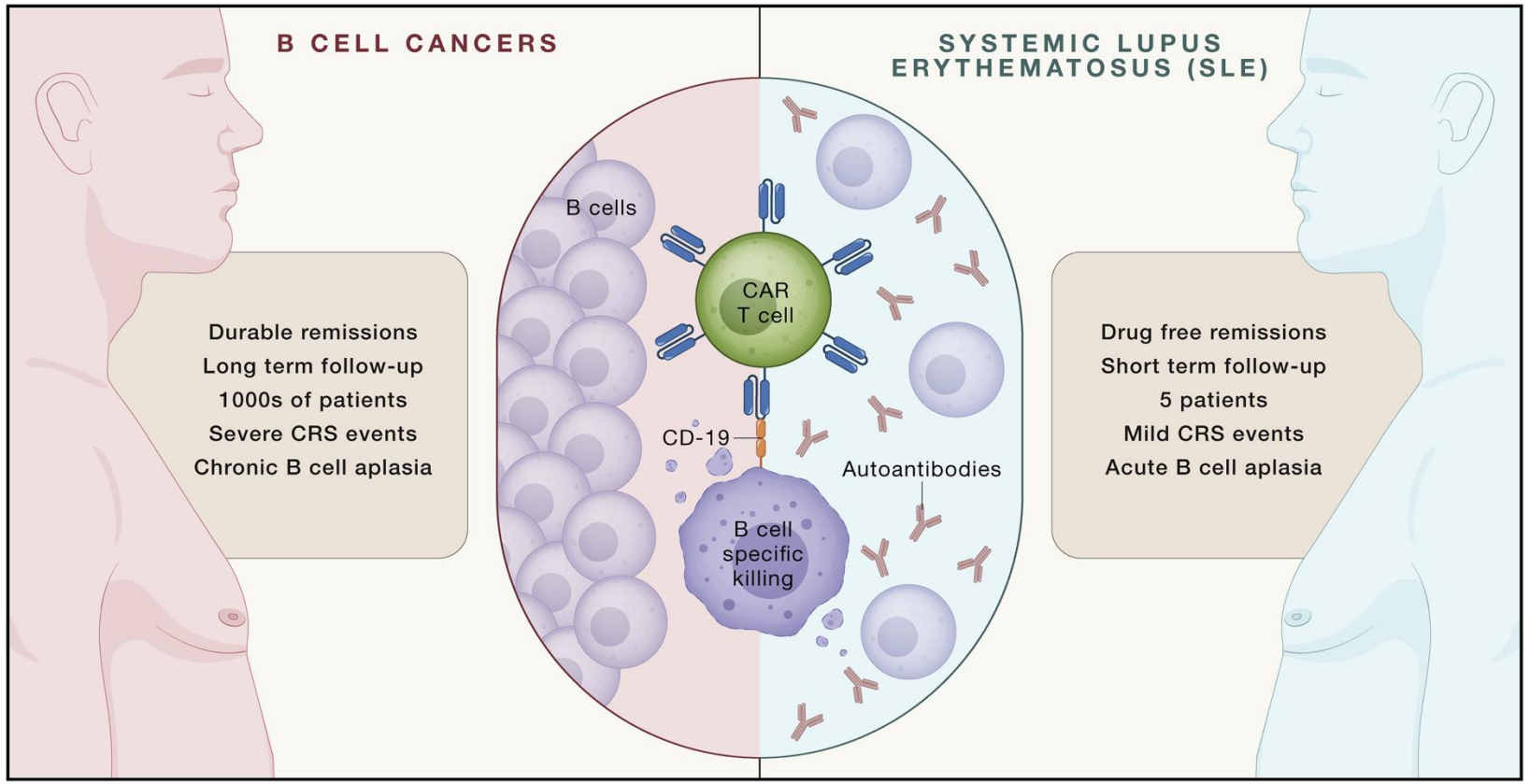
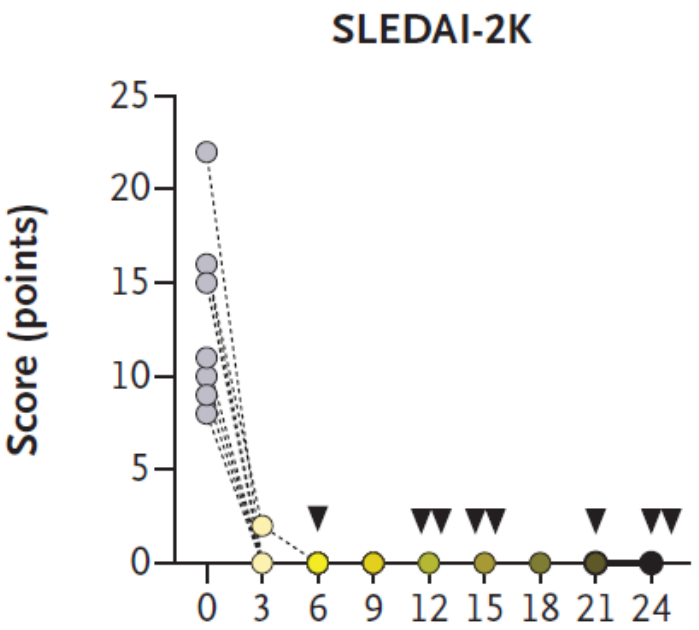
Autoimmune Diseases | Turning CAR-T Cells Around



Adapted from Cell, Volume 185, Issue 24, P4471-4473, November 23, 2022

Lupus patients (SLE)



Müller F et al. N Engl J Med2024;390:687-700

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Autoimmune Diseases | Phase I Clinical Trial

A Phase 1b Study Evaluating the Safety and Efficacy of CLBR001 and SWI019 with or without Lymphodepletion in Subjects with Autoimmune Disorders Including SLE, Systemic Sclerosis, Idiopathic Inflammatory Myositis, or Rheumatoid Arthritis

abbvie

CD19-Targeted Switch

Eligible Patients

Moderate to severe systemic lupus erythematosus or SLE, systemic sclerosis, idiopathic inflammatory myositis, or rheumatoid arthritis

- Patients must have failed at least two prior immunosuppressive treatments

Goals

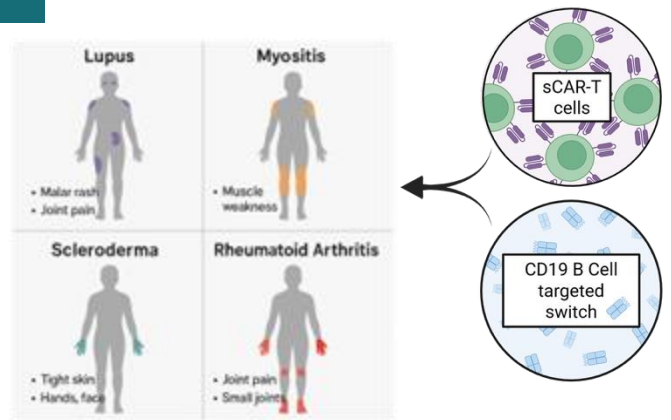
- **Avoid lymphodepletion**: Demonstrate complete remission of disease without the use of lymphodepleting chemotherapy
- **Safety**: Demonstrate the switch-based control can avoid adverse effects associated with conventional CAR-T cell therapies and allow repopulation of B cells post therapy

Locations

Augusta University
Augusta, Georgia
Duke University
Durham, North Carolina
Methodist University
Fayetteville, North Carolina
Indiana University
Bloomington, Indiana

Trial Information

For more information, visit:
clinicaltrials.gov
NCT#: NCT06913608



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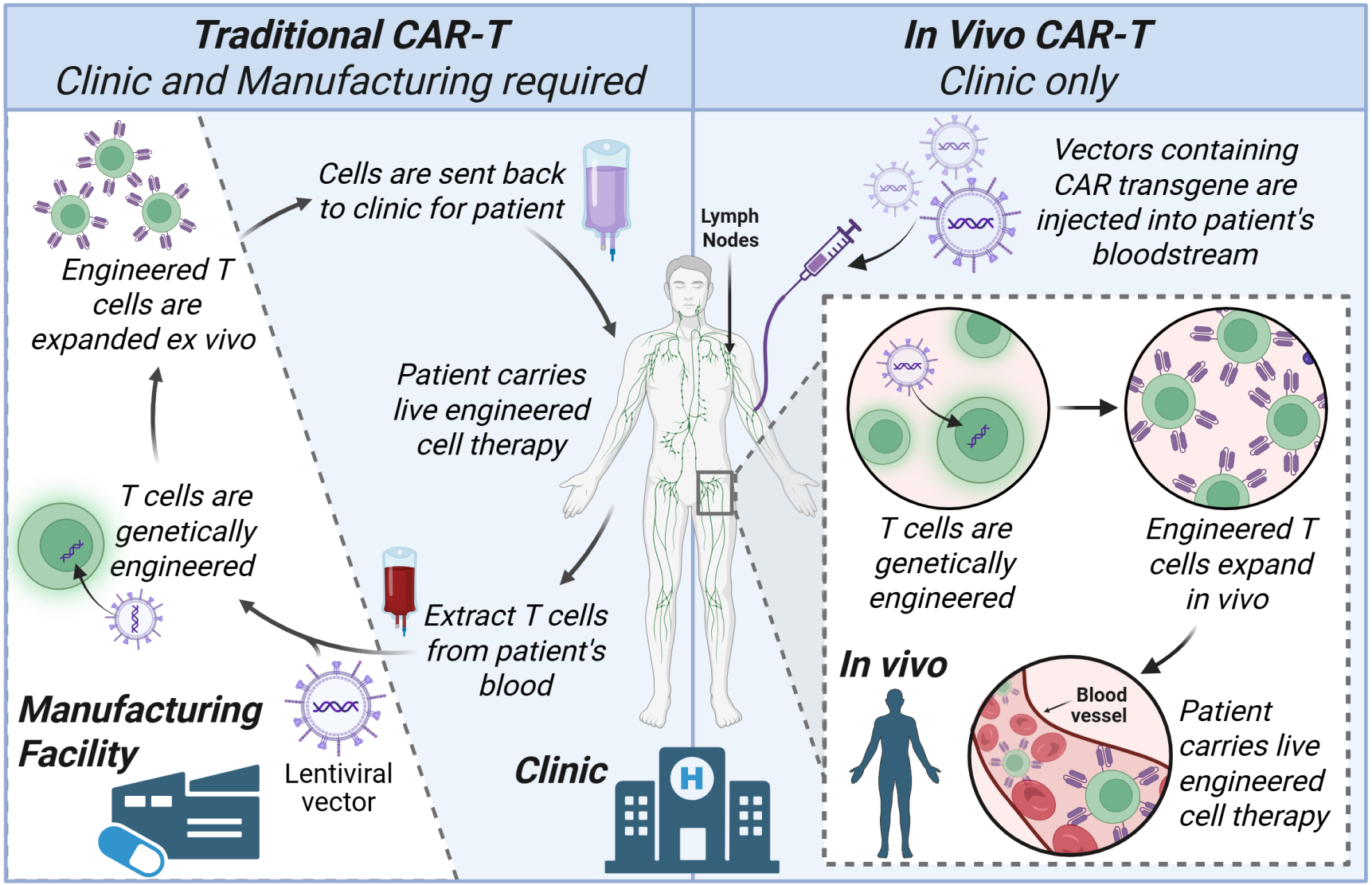
What's Next | *In Vivo* CAR Delivery



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