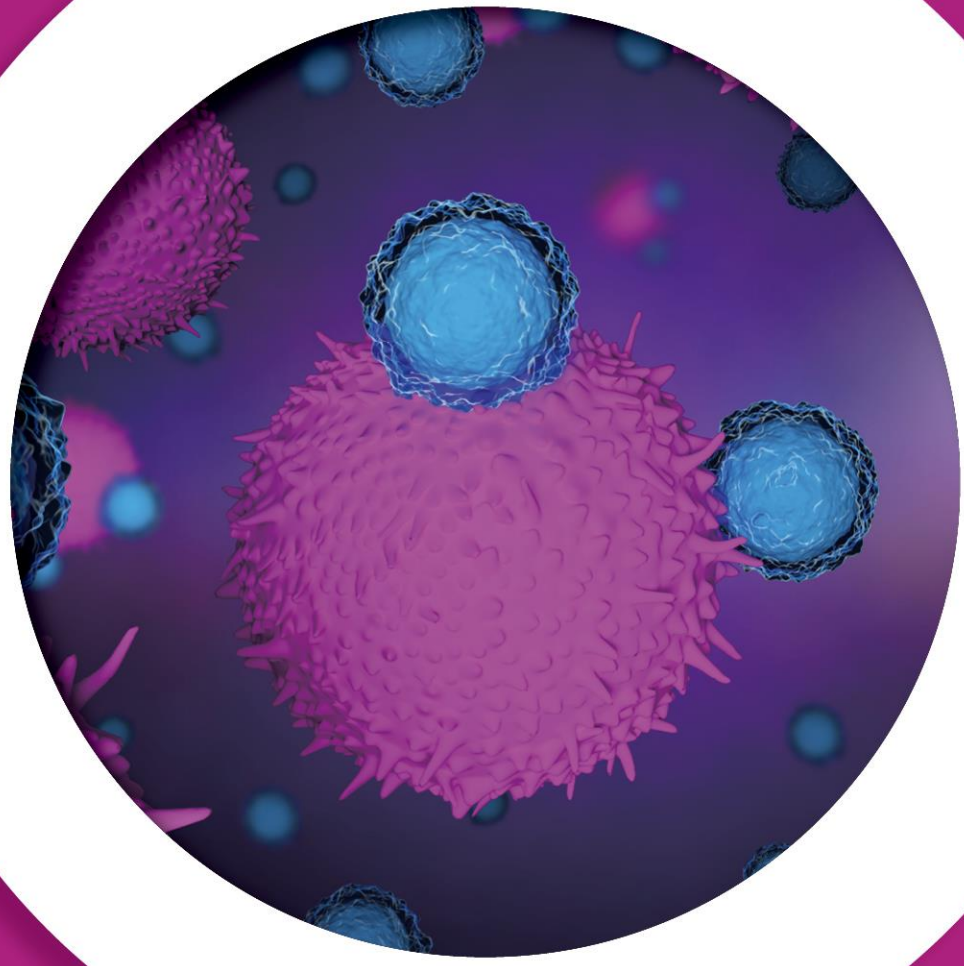
ASH 2022
Data Read-out



INVESTOR RELATIONS 2022

NEOIMMUNETECH

December 13, 2022

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Poster Presentation at

1. **NIT-112 primary data (Ph.1) Poster 4655**

   - A Phase 1b Dose Expansion Study Evaluating Safety, Preliminary Anti-Tumor Activity, and Accelerated T Cell Reconstitution with NT-I7 (Efineptakin Alfa), a Long-Acting Human IL-7, Administered Following Tisagenlecleucel in Subjects with Relapsed/Refractory Large B-Cell Lymphoma

1st data release of CAR-T combo program

1. Chemo/radiotherapy combo program (CCRT + NT-I7)
- Clinical trials started in 2018
- Data presentation at several conferences, including ASCO, SITC, and others
- [NIT-107] Ph.1b clinical trial result announced at SITC 2022

2. CPI combo program (Checkpoint inhibitor + NT-I7)
- Clinical trials started in 2019
- Data presentation at several conferences, including ASCO, SITC, and others
- [NIT-110] Ph.2a clinical interim data announced at ASCO 2022
- [NIT-110] Biomarker analysis results announced at ESMO, SITC 2022

3. CAR-T combo program (CAR-T + NT-I7)
- **Clinical trial started in Oct. 2021**
- **1st data presentation at ASH 2022**

What is CAR-T cell therapy?

- Chimeric Antigen Receptor T cells (CAR-T) are genetically modified T cells with improved ability to fight cancer
- CAR enhances T cell's ability to recognize and attach to a specific antigen on the surface of a cancer cell

Source: Emily Whitehead Foundation

Characteristics of CAR-T Cell Therapy	
Treatment	One time only
Indication	Blood cancer
Type of cell	Autologous
Response Rate	The response to CAR-T cell therapy varies between patients
Treatment Cost	373,000-475,000 USD
Safety issue	Possibility of cytokine release syndrome (CRS)
Approved Target/Indication	- CD19: LBCL, ALL, FL - BCMA: Multiple Myeloma (MM)
Approved Drugs (two targets, six drugs)	CD19: KYMRIAH, YESCARTA, TECARTUS, BREYANZI BCMA: ABECMA, CARVYKTI

Unmet needs of CAR-T cell therapy

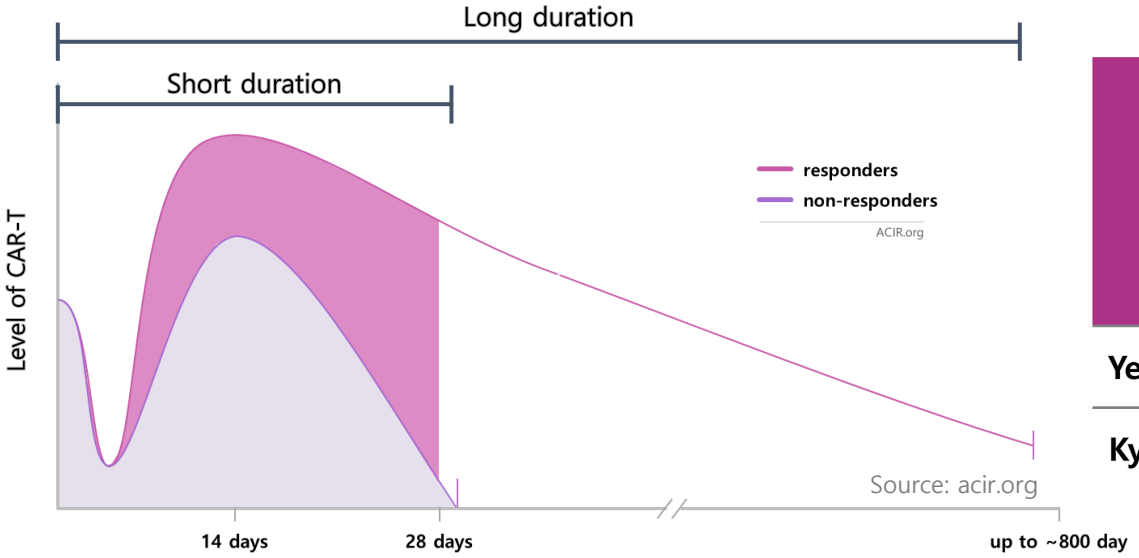
- The response to CAR-T cell therapy depends on duration of CAR-T cells in patients

  → Non-responders showed short duration of CAR-T cells and have no treatment options

  (Only one time CAR-T infusion)

- Side effects like CRS and ICANS remain huge challenges for physicians and patients treated with CAR-T cell therapy

CAR-T Amplification



Cellular kinetics of CTL019 (representative graph)

CAR-T Safety

Drug	Side Effects	
	Cytokine Release Syndrome	Neurological Toxicities
Yescarta[1)]	90%	78%
Kymriah[2)]	74%	60%

[1)] Yescarta US prescribing information 2017, rev. 2022
[2)] Kymriah US prescribing information 2018, rev. 2022

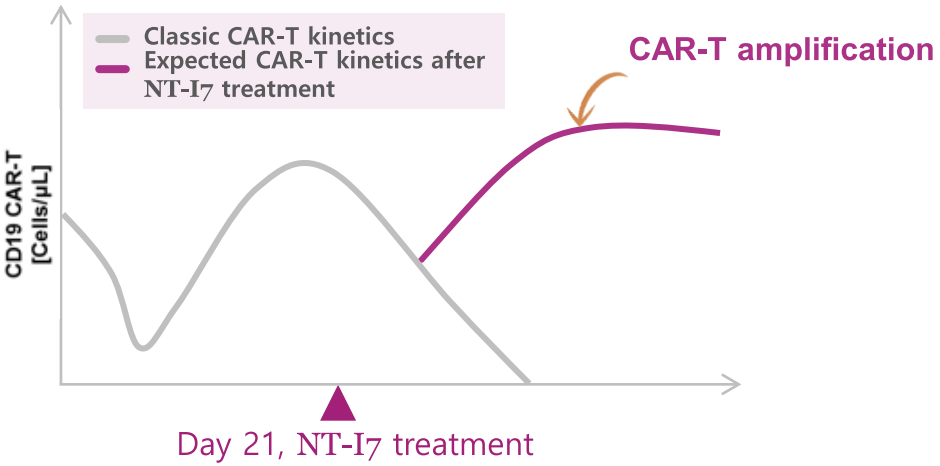
CAR-T booster, NT-I7

- Sequential administration of NT-I7 could act as a CAR-T booster
- NT-I7 can amplify the number of CAR-T cells as they start to decline, providing patients with **a second opportunity** to benefit from CAR-T treatment

NT-I7 as T cell amplifier (Clinical evidence from NIT data)

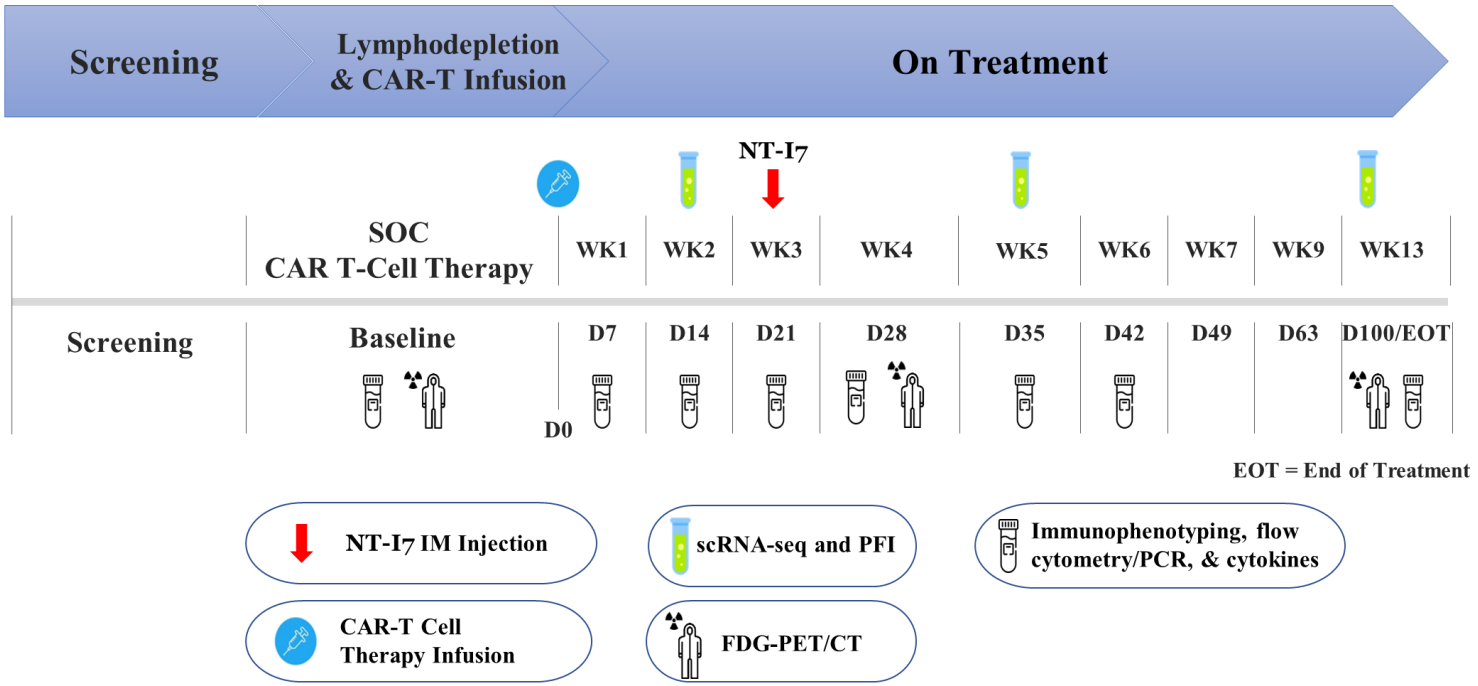
- **ALC → 3-fold increase (App. 1&2)**
- **T cells → 5-fold increase (App. 1&2)**
- **Tscm → 25 to 50-fold increase (App. 1&2)**
- **CAR-T amplification by NT-I7 (in progress)**

Conceptual kinetics for CAR-T + NT-I7



NIT-112 study protocol

- Relapsed/Refractory Large B-Cell Lymphoma
- CAR-T infusion → NT-I7 injection (single injection at day 21)
- Currently in Phase 1b, dose escalation



SOC = standard of care, PCR = polymerase chain reaction, FDG-PET/CT = 18F-fluorodeoxyglucose positron emission tomography–computed tomography

Dose Level	DL1	DL2	DL3	DL4	DL5	DL6	DL7
NT-I7, μg/kg	60	120	240	360	480	600	720

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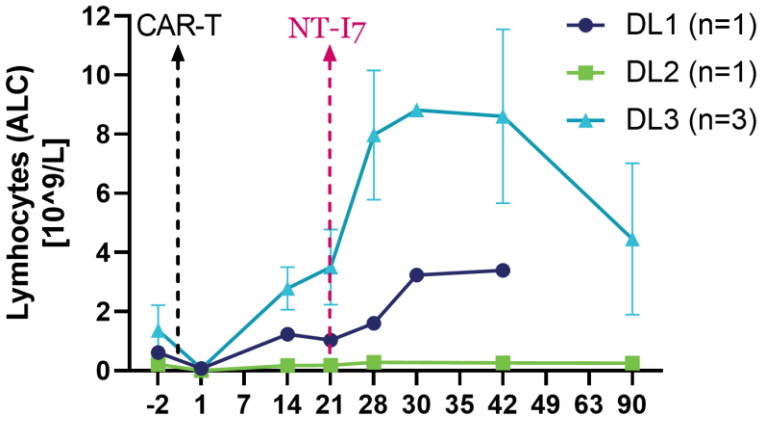
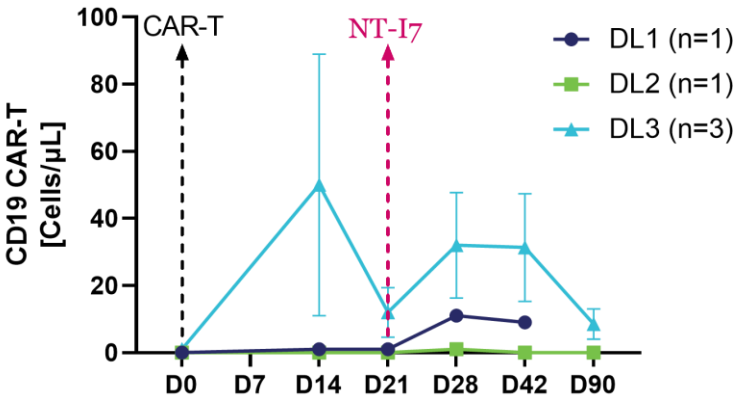
NIT-112 interim data (1)

- ALC and CAR-T levels are increased after NT-I7 infusion
- DL3 showed higher **amplification of ALC and CAR-T** than DL1 and DL2
- Dose escalation study is ongoing to find RP2D and MTD

Lymphocytes kinetics



CAR-T kinetics



NIT-112 interim data (2)

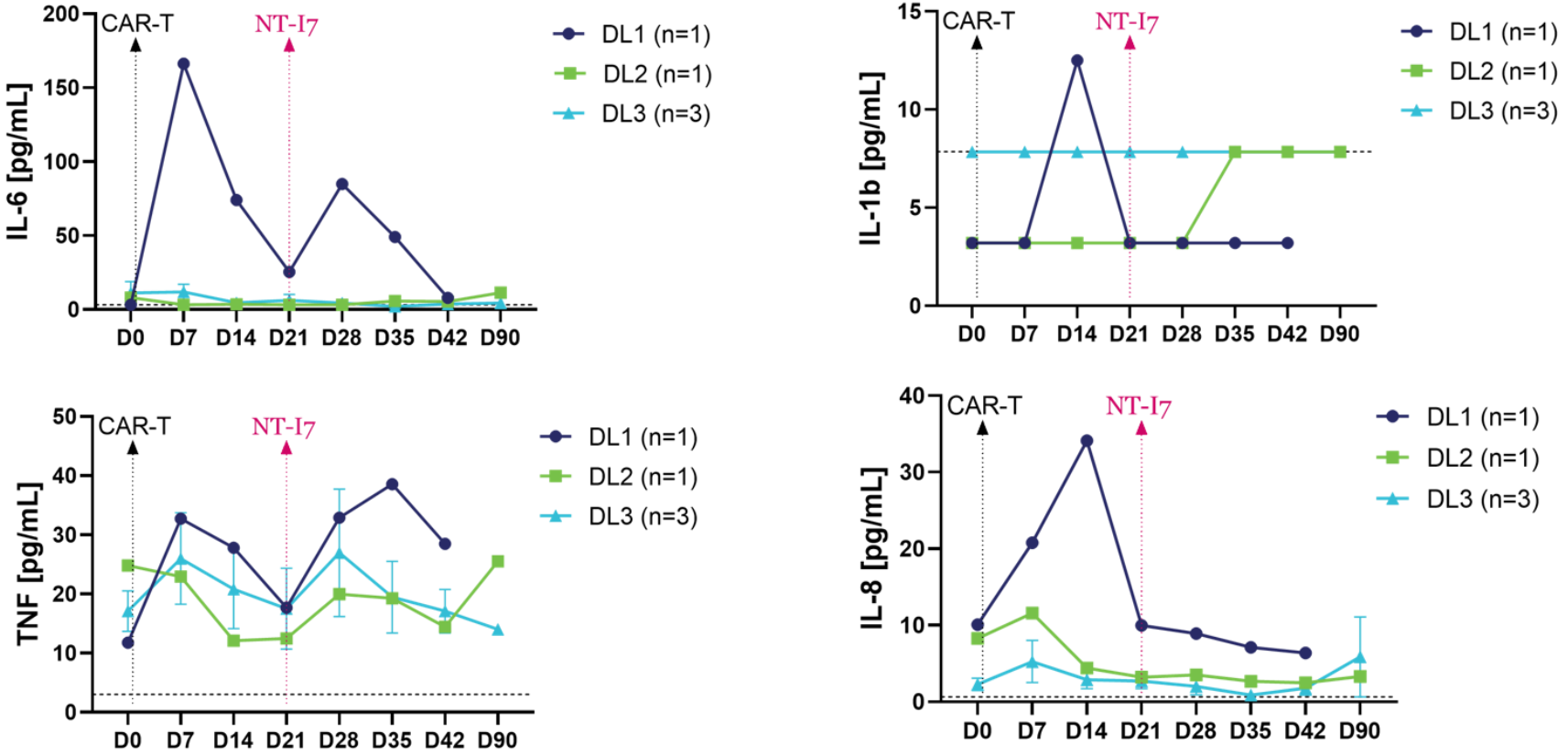
- All patients in DL1-3 completed the dose-limiting toxicity period
- Neither CRS nor ICANS were observed following NT-I7 treatment

Event Type	Events in DL1 (60 µg/kg, n=1)	Events in DL2 (120 µg/kg, n=1)	Events in DL3 (240 µg/kg , n=3)
TEAE[1)]	2	2	9
NT-I7-related TEAE Injection site reaction, Gr 1 Injection site reaction, Gr 2 Vomiting, Gr 1	 0 1 1	1	1
Immune-related TEAE Injection site reaction, Gr 1 Injection site reaction, Gr 2 Vomiting, Gr 1	 0 1 1	0	0
TEAE of special interest Injection site reaction, Gr 1 Injection site reaction, Gr 2 Vomiting, Gr 1	 0 1 1	0	0

[1)] TEAE: treatment emergent adverse event

NIT-112 interim data (3)

- Proinflammatory cytokines associated with CRS and ICANS were mostly stable or did not increase to levels of concern following NT-I7 administration



DL1 = 60 µg/kg, n=1; DL2 = 120 µg/kg, n=1; DL3 = 240 µg/kg, n=3. Mean ± SEM.

Key Messages

Preliminary results suggest that NT-I7 treatment after CAR-T (tisagenleucel) infusion can subsequently amplify CAR-T cells without inducing CRS or ICANS

1. **NT-I7 treatment following tisagenlecleucel standard of care (SOC) was safe and well-tolerated, not inducing cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS)**
2. **Administration of NT-I7 has the potential to amplify not only ALC, but also to amplify infused CAR-T cells**
3. **This study is currently enrolling to determine the RP2D**

* Data cutoff date May 30, 2022

Future development plans

Short term plans

- **Completion of dose escalation up to DL7 720 μg/kg**
- **Expansion of drugs (Kymriah → +Yescarta, Breyanzi)**

Key data to be obtained from Ph.1b:

- Safety
- PK, PD
- RP2D (optimal dose finding)

Long term plans

- **Find target indication for Ph.2**
- **Find CAR-T partners (commercialized for new CAR-T)**
- **Research expansion of other T cell based therapies**

  (TIL, TCR-T, etc.)

Target indications and potential areas to expand value of CAR-T combo therapies:

- Blood tumor and solid tumor
- Autologous and allogenic CAR-T cell combination therapies
- T cell based combination therapies in clinical trials

Major read-out plans in 2023

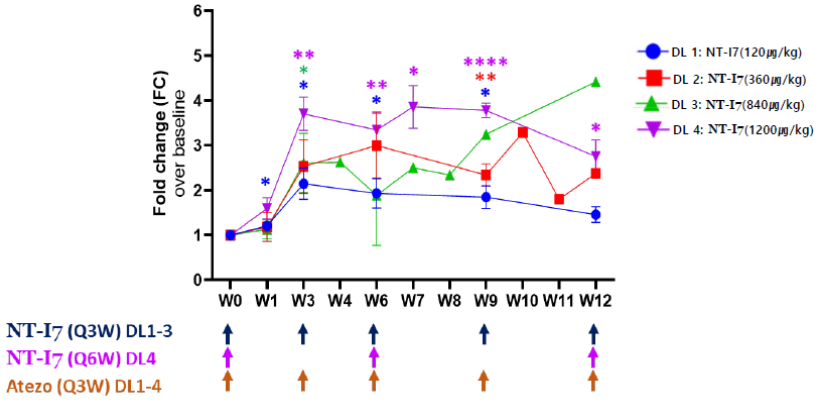
	1H 2023	2H 2023
Data Read-outs	▪ NIT-110: Solid tumor, CPI Combo Ph2a interim	▪ NIT-110: Solid tumor, CPI Combo Ph.2a final ▪ NIT-107: GBM, CCRT Combo Ph.1/2 ▪ NIT-119: 1L NSCLC, CPI Combo Ph.2 ▪ NIT-106: Skin cancer, CPI Combo Ph.2 ▪ NIT-109: Gastric cancer, CPI Combo Ph.1 ▪ NIT-112: LBCL, CAR-T Combo Ph.1b final

* Plans are subject to change

Appendix 1: NT-I7 Combo's Effectiveness (1): ALC increases

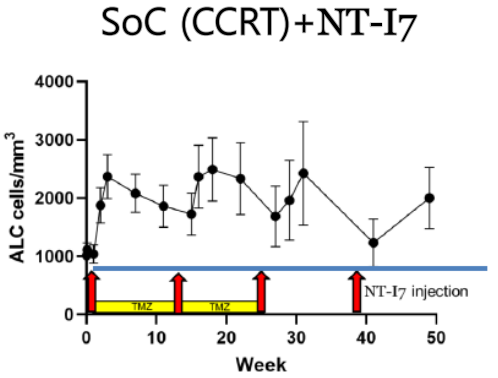
- NT-I7 combo therapy induced ALC (Absolute Lymphocyte Count) increases in subjects with GBM, R/R solid tumor, and high-risk skin cancer

Skin cancer



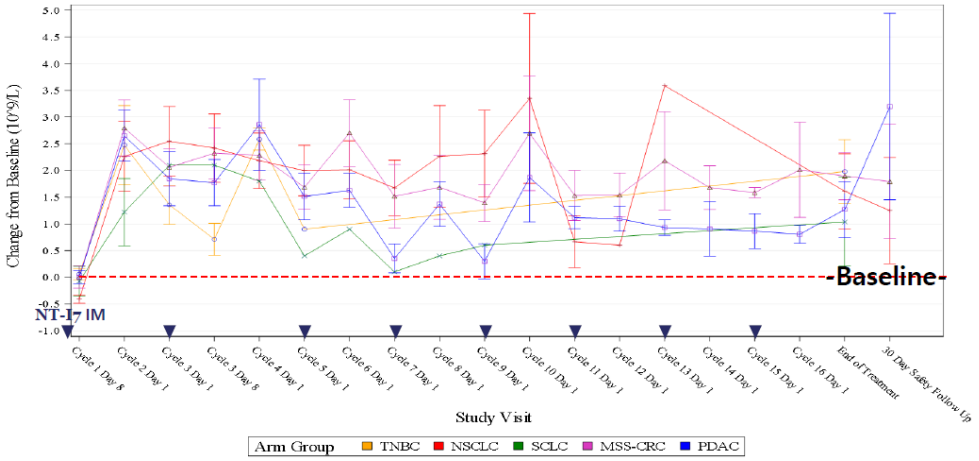
*ASCO 2022, NIT-106

GBM



*SITC 2021, NIT-107

Advanced solid tumor

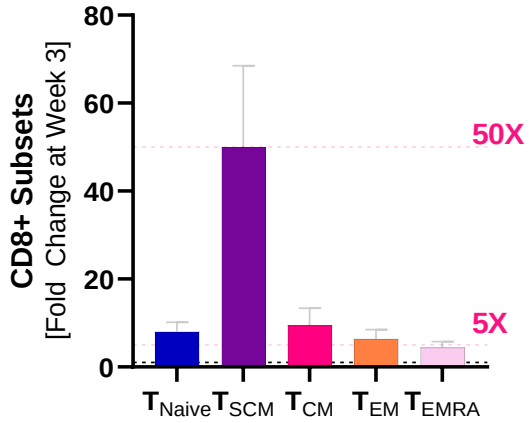


*ASCO 2022, NIT-110

Appendix 2: NT-I7 Combo's Effectiveness (2): Tscm increases

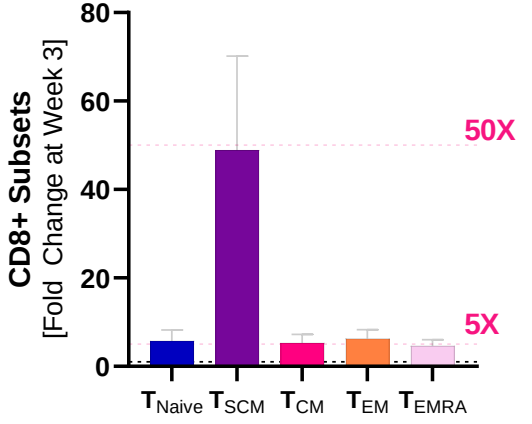
- Tscm (stem-cell memory T cells), the most effective anticancer T cell subset, increased in general by 25 to 50-fold
- No other product has reported a significant increase of Tscm to this level of potency.

MSS-CRC



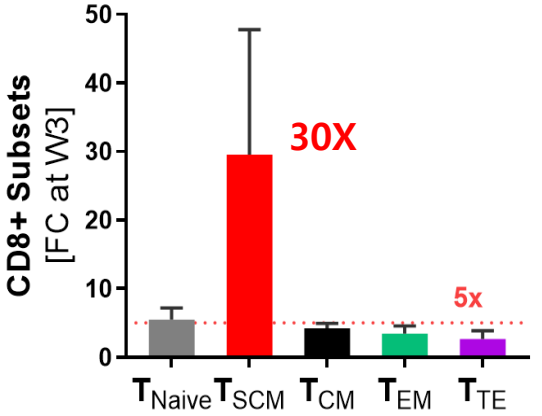
*SITC 2021, NIT-110

PC



*SITC 2021, NIT-110

Skin cancer



*ASCO 2022, NIT-106

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THANK YOU

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