

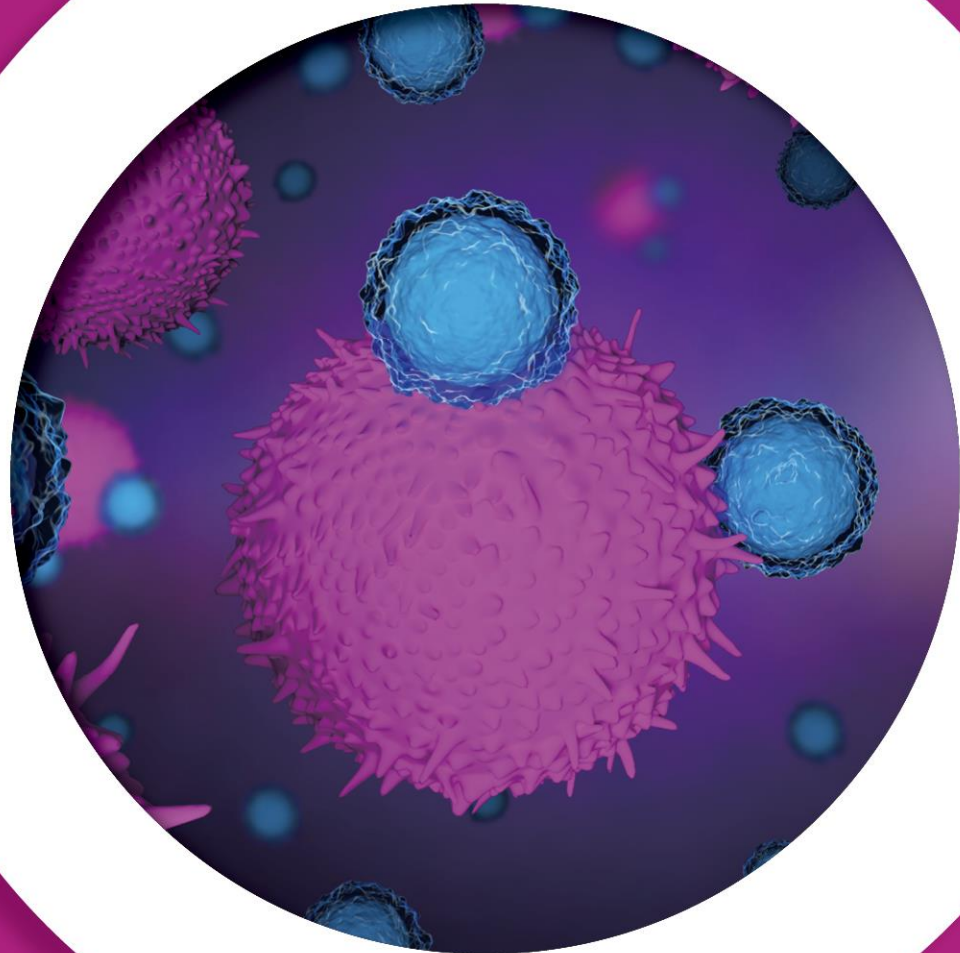
SITC 2021

Data Read-out

INVESTOR RELATIONS 2021

NEOIMMUNETECH.

IR Presentation
Nov.15, 2021



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1. Poster Presentation at SITC 2021

2. Future Development Plan

Poster Presentation at



1. NIT-107 (IIT) – CR-7 Program, [Poster #396](#)

- Phase 1 (Dose Escalation)
- Newly diagnosed high grade gliomas
- Combo therapy : Chemoradiation(TMZ,Radiation) + NT-I7

2. NIT-110 (SIT) – Check-7 Program

- Phase 2a (Dose Expansion), Relapsed/Refractory advanced solid tumors
- Combo therapy : Checkpoint inhibitor(Pembrolizumab) + NT-I7

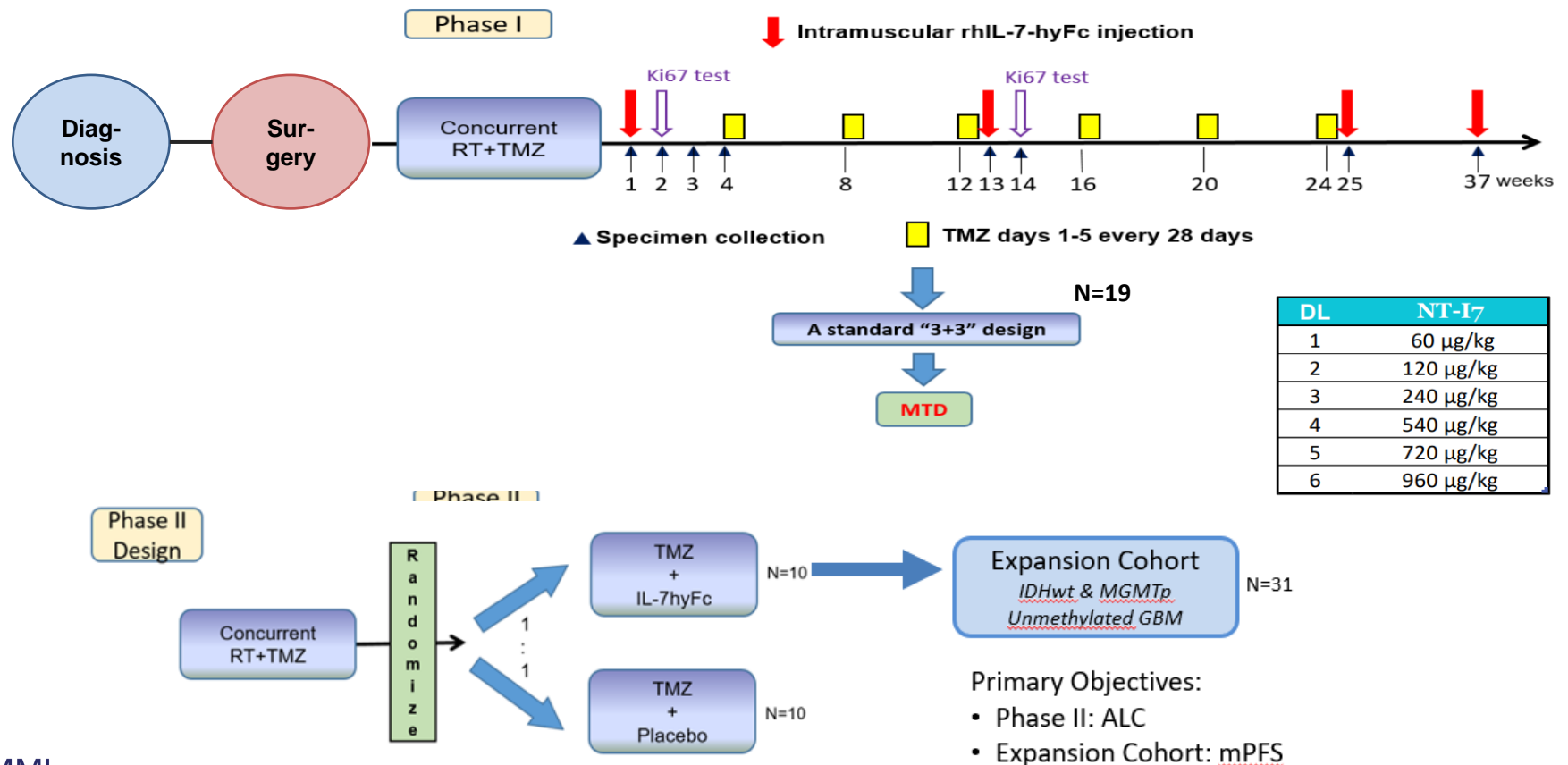
2.1 Cohort (MSS-CRC), [Poster #404](#)

2.2 Cohort (Pancreatic Cancer), [Poster #408](#)

NIT-107: Study protocol

- Targeted newly diagnosed GBM patients
- Surgery → SoC (Chemo/Radiation) + NT-I7 Injection (12weeks interval, 4 times)
- 1b/2a: Currently in Dose Escalation (1b) → Dose Expansion (2a)

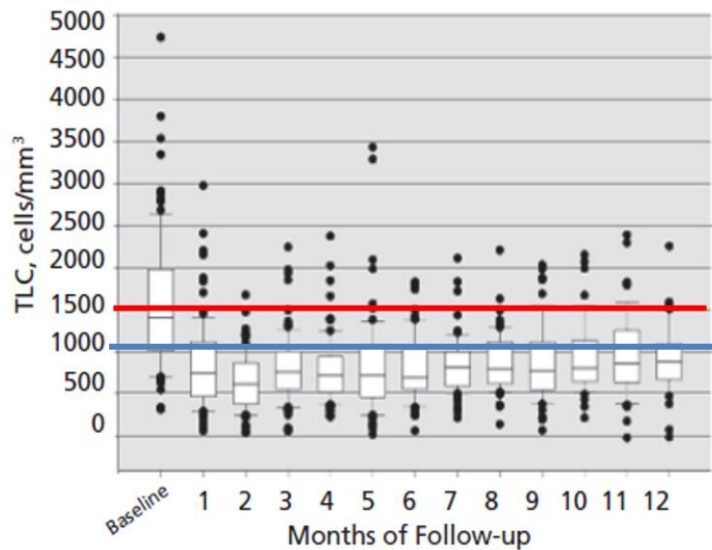
Study Schema



GBM: T cell Amplification (ALC changes)

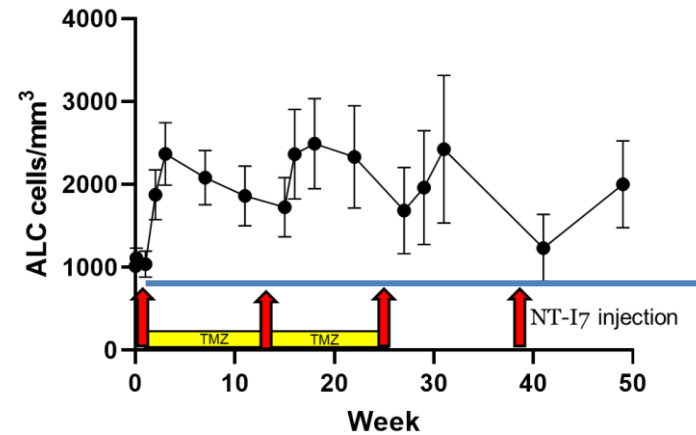
- At SoC, TLC (total lymphocyte count) stayed below 1,000/ul for 12 months
- At SoC+NT-I7 combo, ALC(absolute lymphocyte count = TLC) increased and remained high

SoC

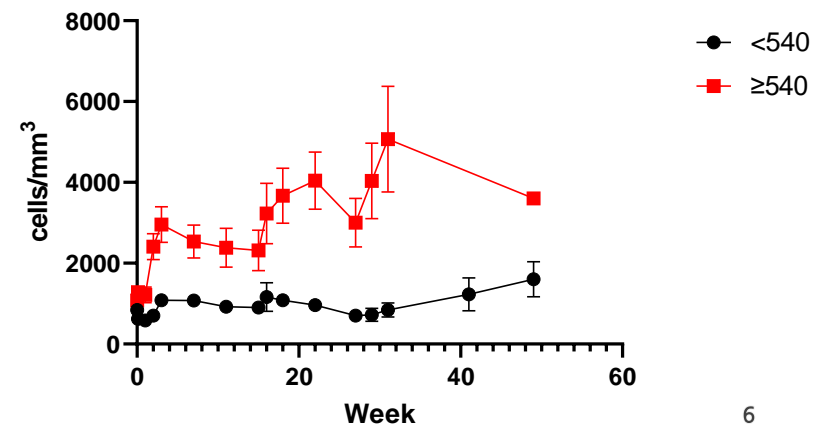


J Natl Compr Cancer Network 2015;13:1225-1231

SoC + NT-I7 Combo



ALC by dose (binary)



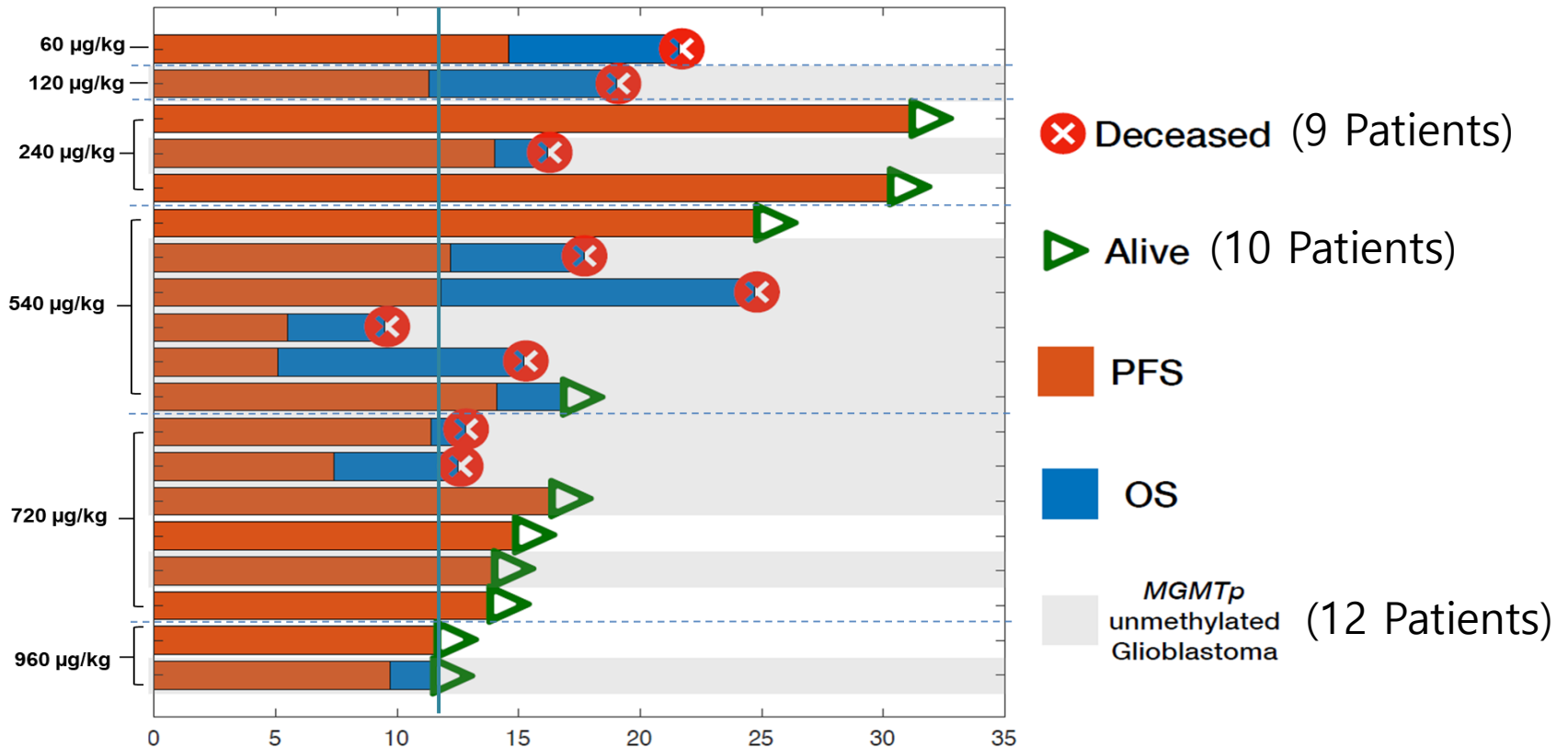
GBM: Clinical response

Survival over 1 year

SoC*
25%

VS.

SoC + NT-I7
94%



- [Glioblastoma Prognosis | Brain Tumour Survival Rates \(thebraintumourcharity.org\)](https://www.thebraintumourcharity.org/)
- <https://www.braintumourresearch.org/info-support/types-of-brain-tumour/glioblastoma-multiforme>

GBM: Interim data is positive enough

- '20~'21 Combo therapies were approved with 30~40% improvements in responses compared to SoC
- Significant clinical benefit proven even with interim data(cut-off)

	SoC (CCRT)			SoC + NT-I7	<i>As-is (cut-off)</i>
	Overall GBM	GBM with Methylated MGMT	GBM with Unmethylated MGMT	NIT-107 (as of Sep)	
Median OS	14.6 months	21.7 months	12.7 months	Over 16 months	◀ 30% ↑
Median PFS	6.9 months	10.3 months	5.3 months	Over 12 months	◀ 100% ↑
6 month PFS	53.9%	68.9%	40%		

FDA Approval	Combo Therapy	Monotherapy	Indication	Clinical Efficacy
2020. 03	Imfinzi + Chemotherapy	Chemotherapy	SCLC	OS: 13 Mon vs 10.3 Mon PFS: 5.1 Mon vs 5.4 Mon ORR: 68% vs 58%
2020.05	Opdivo + Yervoy + Chemotherapy	Chemotherapy	NSCLC 1 st line	OS: 14.1 Mon vs 10.7 Mon PFS: 6.8 Mon vs 5 Mon ORR: 38% vs 25% Response duration: 10 Mon vs 5.1 Mon
2021.03	Keytruda + Chemotherapy	Chemotherapy	Esophageal Cancer	OS: 12.4 Mon vs 9.8 Mon PFS: 6.3 Mon vs 5.3 Mon
2021.04	Opdivo + Chemotherapy	Chemotherapy	Gastric,G/E Junction Cancer, and Esophageal Adenocarcinoma	OS: 14.4 Mon vs 11.1 Mon PFS: 7.7 Mon vs 6.0 Mon

GBM: Future development plans (2022)

- **Scale-up of Ph2a with more patients**
 - SNO (Society for Neuro-Oncology) oral presentation (19 Nov.)
 - Test arm(10)+control arm(10) → Additional(30) = total 50 pts
 - Targeting unmethylated GBM pts only (Biggest unmet needs)
- **New study on 'relapsed' GBM to be initiated**
 - Based on promising NIT-107 data, a new IIT study will start
 - 1H22 IND expected
- **The next round study will be discussed & initiated**
 - Interim analysis on NIT's Ph2a data
 - I-MAB's interim data is expected for Ph2 China study on newly diagnosed GBM (160 pts)
 - Based on analysis, a next round study will be designed and initiated

Poster Presentation at



1. NIT-107 (IIT) – CR-7 Program, Poster #396

- Phase 1 (Dose Escalation)
- Newly diagnosed high grade gliomas
- Combo therapy : Chemoradiation(TMZ,Radiation) + NT-I7

2. NIT-110 (SIT) – *Check-7 Program*

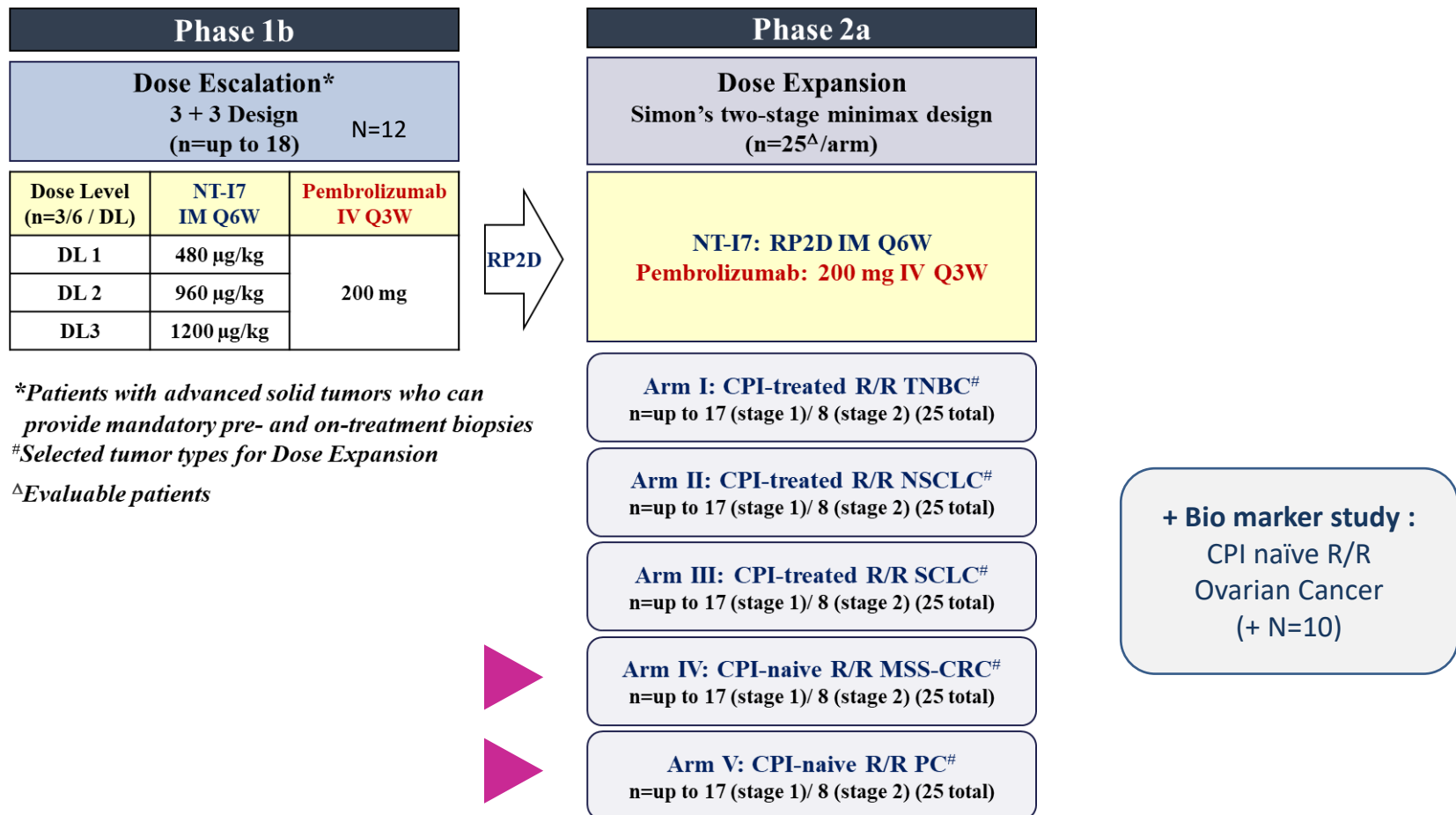
- Phase 2a (Dose Expansion), Relapsed/Refractory advanced solid tumors
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2.1 Cohort (MSS-CRC), Poster #404

2.2 Cohort (Pancreatic Cancer), Poster #408

NIT-110 Study protocol

- CPI-treated R/R solid tumor (3) + CPI-naïve R/R solid tumor (2)
- Dose escalation(1b) completed, dose expansion(2a) on-going
- High demand from patients led to earlier data read-out than expected





2.1 Cohort (MSS-CRC), Poster #404

2.2 Cohort (Pancreatic Cancer), Poster #408

MSS-CRC: Baseline characteristics and safety

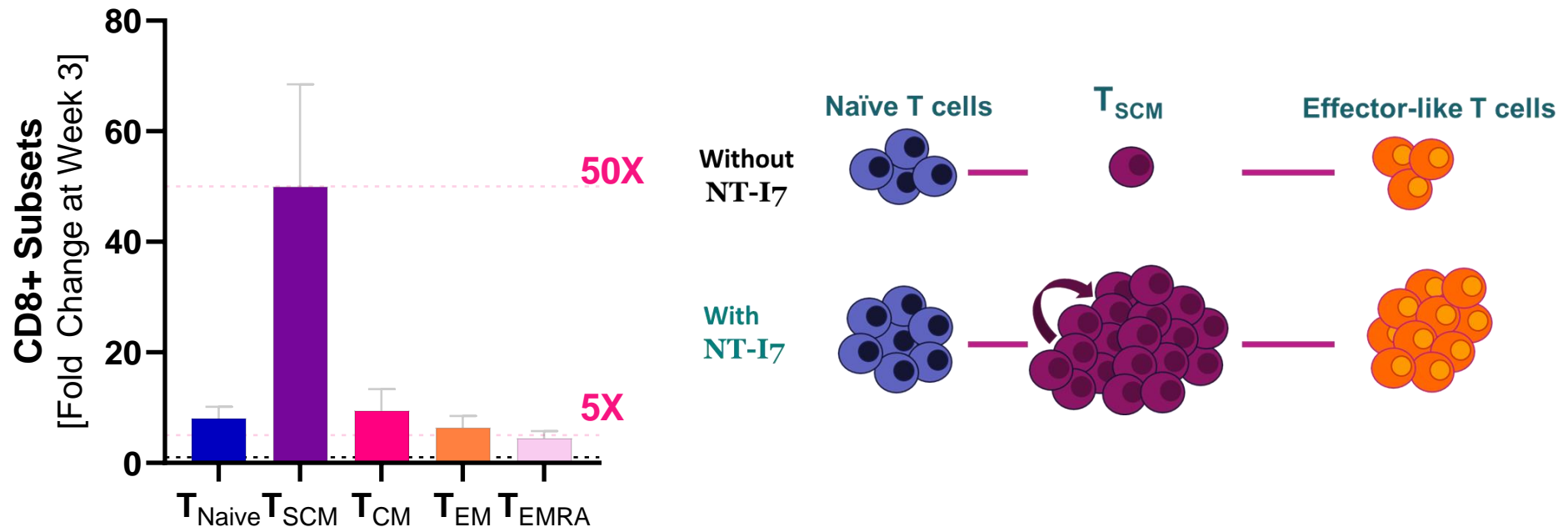
Characteristics	Categories	MSS-CRC (n = 21)
Age, year, median (range)	-	57 (37, 81)
Gender, n (%)	Male	15 (71.4)
ECOG Performance Status, n (%)	0	7 (33.3)
	1	14 (66.7)
No. of previous lines of therapy, n (%)	1	1 (4.8)
	2	2 (9.5)
	3	5 (23.8)
	>3	13 (61.9)
	Stage at diagnosis, n (%)	1
	2	3 (14.3)
	3	6 (28.6)
	4	12 (57.1)
No. of subjects with liver metastasis, n (%)	-	16 (76.2)

- Most patients received 3+ prior treatments leaving no other treatment possibilities (85%)
- At diagnosis, majority of patients were at stage 3 or 4 (85%)

n (%)	MSS-CRC (n = 21)	
Any ADR	17 (81.0)	
ADR by severity	Grade 1	6 (28.6)
	Grade 2	6 (28.6)
	Grade 3	5 (23.8)
	Grade 4-5	0 (0.0)
Most frequently reported ADR		
Fatigue	6 (28.6)	
Nausea	5 (23.8)	
Fever	4 (19.0)	
Flu-like Symptoms	3 (14.3)	
ADR resulting in drug discontinuation	2 (9.5)	

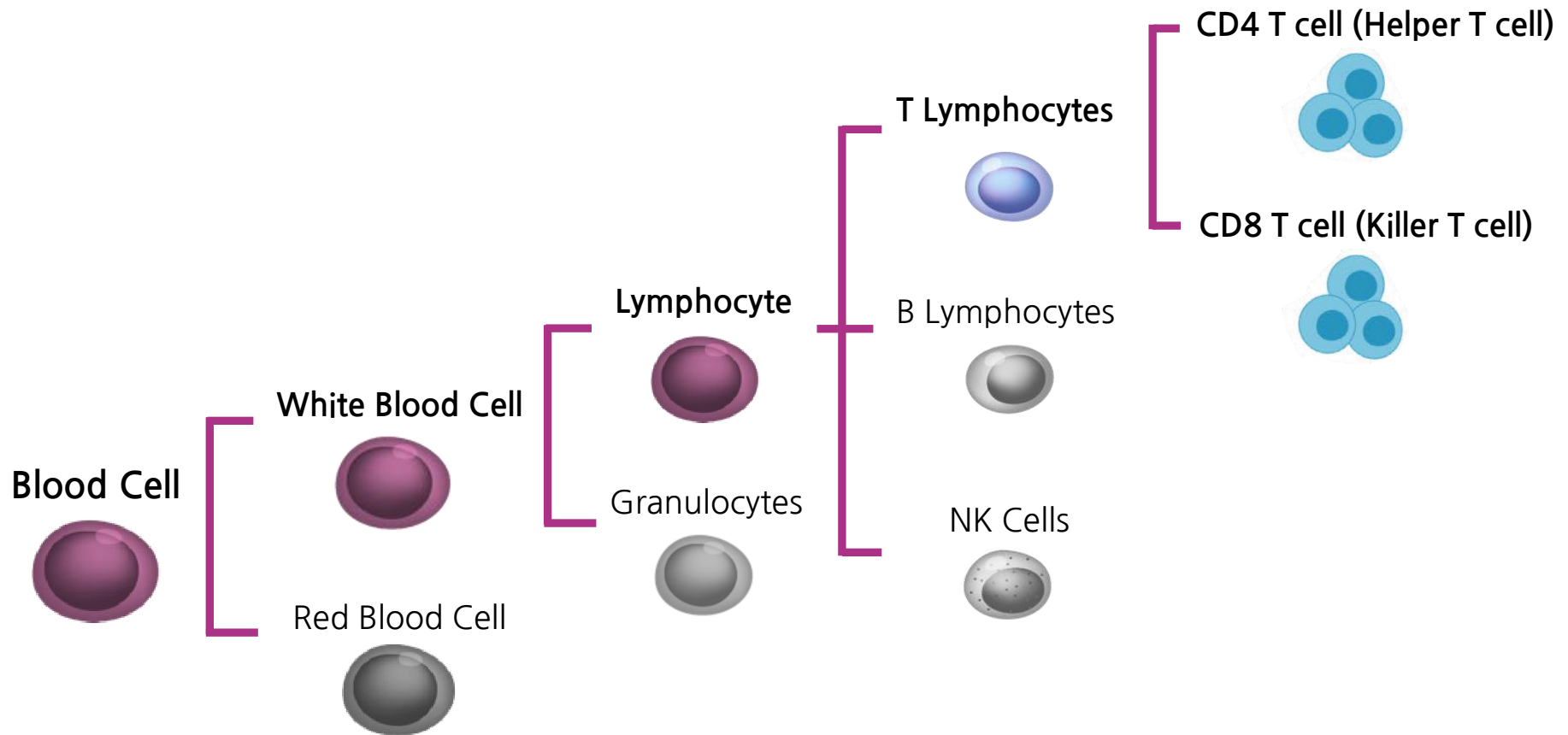
- With CPI+NT-I7 combo, no severe AEs were reported and was well tolerated (90%+)
- Two patients discontinued trial due to symptoms such as pneumonitis, etc

MSS-CRC: Tscm increased by 50-fold for first time ever in-vivo



- Tscm(stem-cell like memory T cell), the most effective anticancer T cell subset, increased by 50-fold for the first time ever in clinical trials
- Increased Tscm could be part of the mechanism of action in the immune-cold tumors so far, no other molecule/substance that can amplify Tscm by 50-fold, was reported

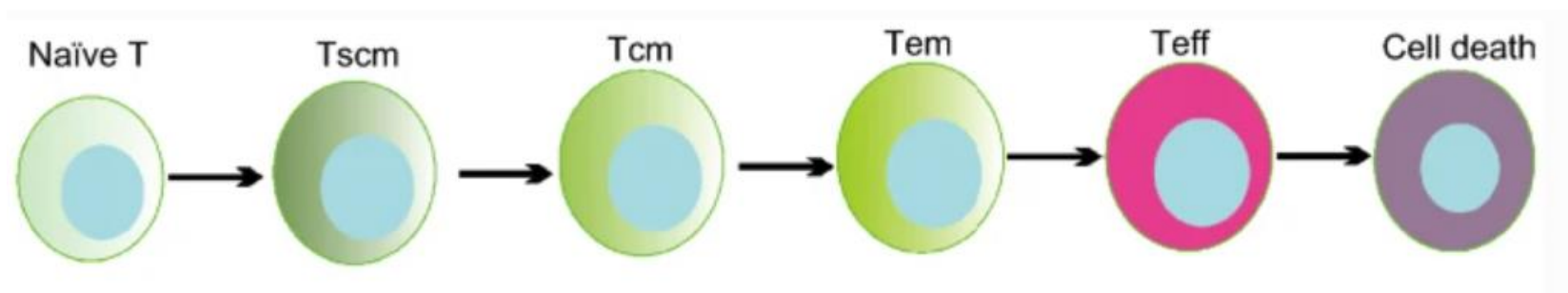
Note: What is T cell?



- Helper T cell: Army of a supporting unit that helps in the rear
- Killer T cell: Army of a combat unit that fights in the front

Note: Classification of T cells

Differentiating process of T cells



Protein & Cell 11, 549, 2020

Naïve T cell: Never met an enemy, differentiation occurs upon meeting enemies

Tscm (stem-cell like memory T): Has met the enemy, most powerful differentiation/self-renewing ability holding

Tcm (central memory T): Mainly present in lymph node/immune centers, has differentiation/proliferative ability

Tem (effector memory T): Mainly present in body organs where enemies are, has differentiation/death ability

Teff (effector T): Immediately kills an enemy when it encounters, highly active but designed to die soon*

* Activation induced cell death

Note: What is Tscm?

1. Stem-cell like memory T cell

- Discovered in 2005, possessing stem-cell characteristics
- Possesses strong self-renewing ability, rapidly differentiating into Tcm and Tem
- **Surviving over 12 to 25 years**

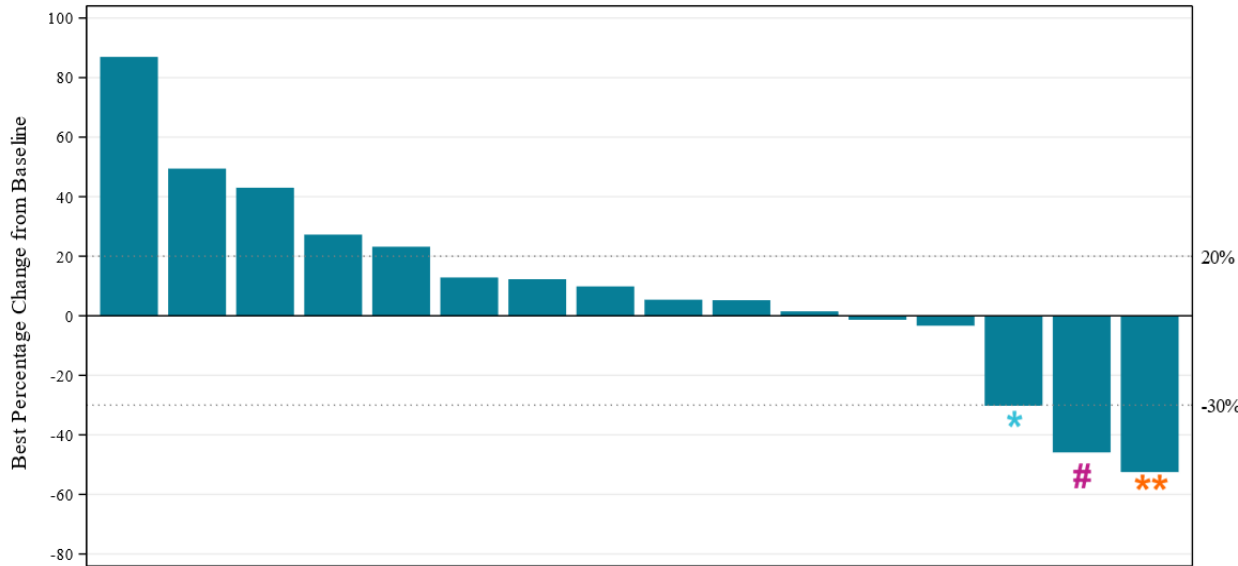
2. Tscm proliferation factor

- At in-vitro, IL-2, IL-7, IL-15 reported inducing Tscm proliferation
- In clinical setting, no study was done on IL-2 and weak inducement was studied on IL-15
- **NT-I7 is the best Tscm amplifier, over 50-fold in clinical study**

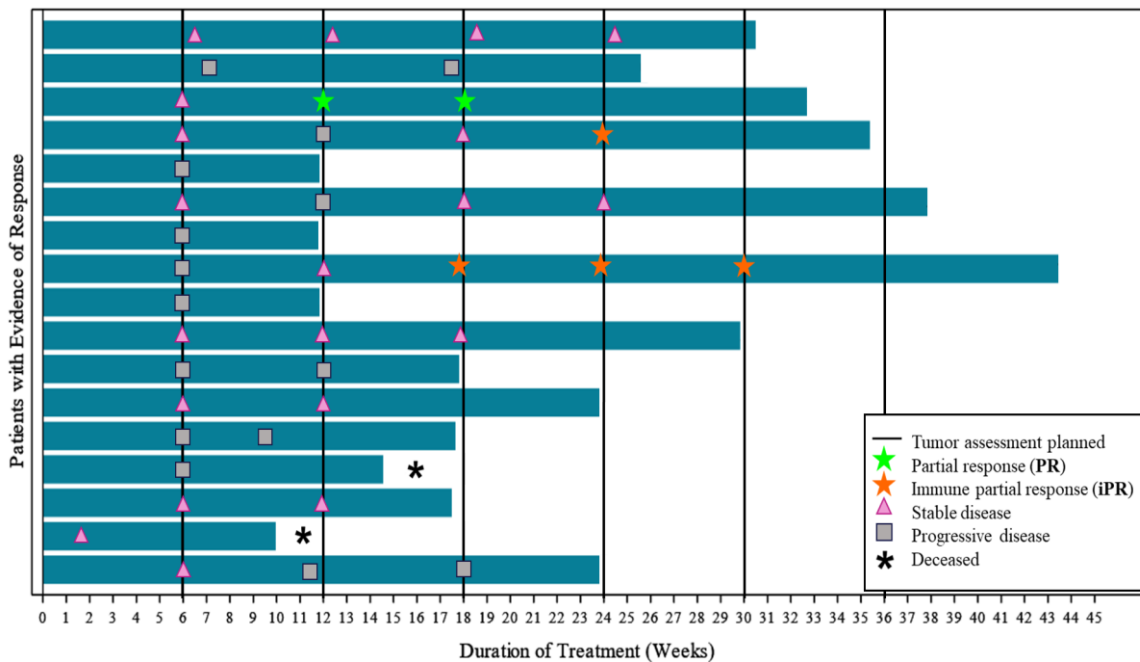
3. Tscm's clinical significance

- **Tscm is the best T cell subset in regards to anticancer effect**
- Manufacturing CAR-T, autologous T cell, TIL therapy, Tscm is the most important

MSS-CRC: Tumor burden change and time to response



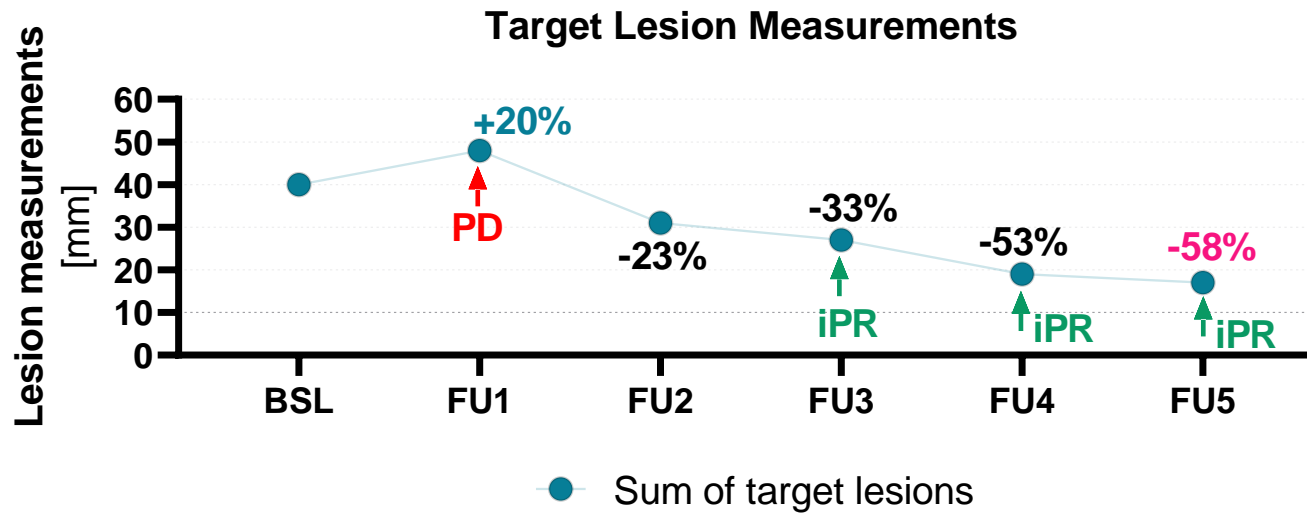
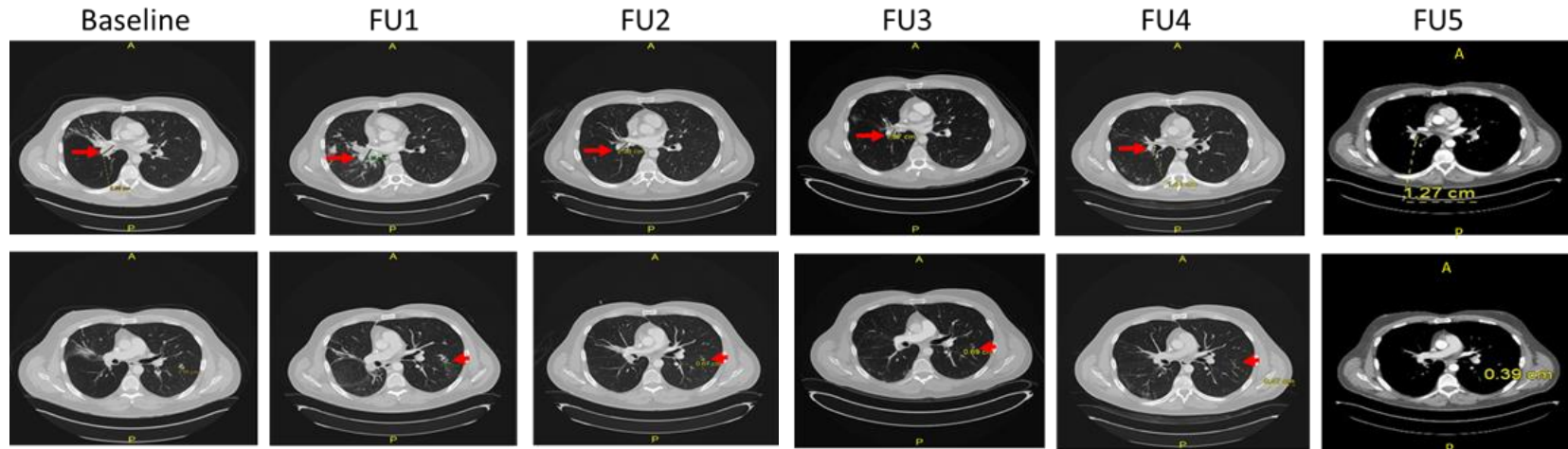
- **ORR: 18% (3/17 pts)**
 - 1 PR + 2 iPR = 3 PR
- **DCR: 59% (10/17 pts)**
 - 7 SD + 3 PR



- **Median treatment duration : 24 weeks (as of Nov.10)**
- **7/17 pts : on treatment***

* It is subject to change depending on the follow up results

MSS-CRC: Occurrence of Pseudoprogression (By iRECIST)





2.1 Cohort (MSS-CRC), Poster #404

2.2 Cohort (Pancreatic Cancer), Poster #408

PC: Baseline characteristics and safety

Characteristics	Categories	PC (n = 30)
Age, year, median (range)	-	65 (31, 81)
Gender, n (%)	Male	16 (53.3)
ECOG Performance Status, n (%)	0	10 (33.3)
	1	20 (66.7)
No. of previous lines of therapy, n (%)	1	3 (10)
	2	8 (26.7)
	3	11 (36.7)
	>3	8 (26.7)
Stage at diagnosis (%)	1	7 (23.3)
	2	5 (16.7)
	3	4 (13.3)
	4	14 (46.7)
No. of subjects with liver metastasis, n (%)	-	24 (80.0)

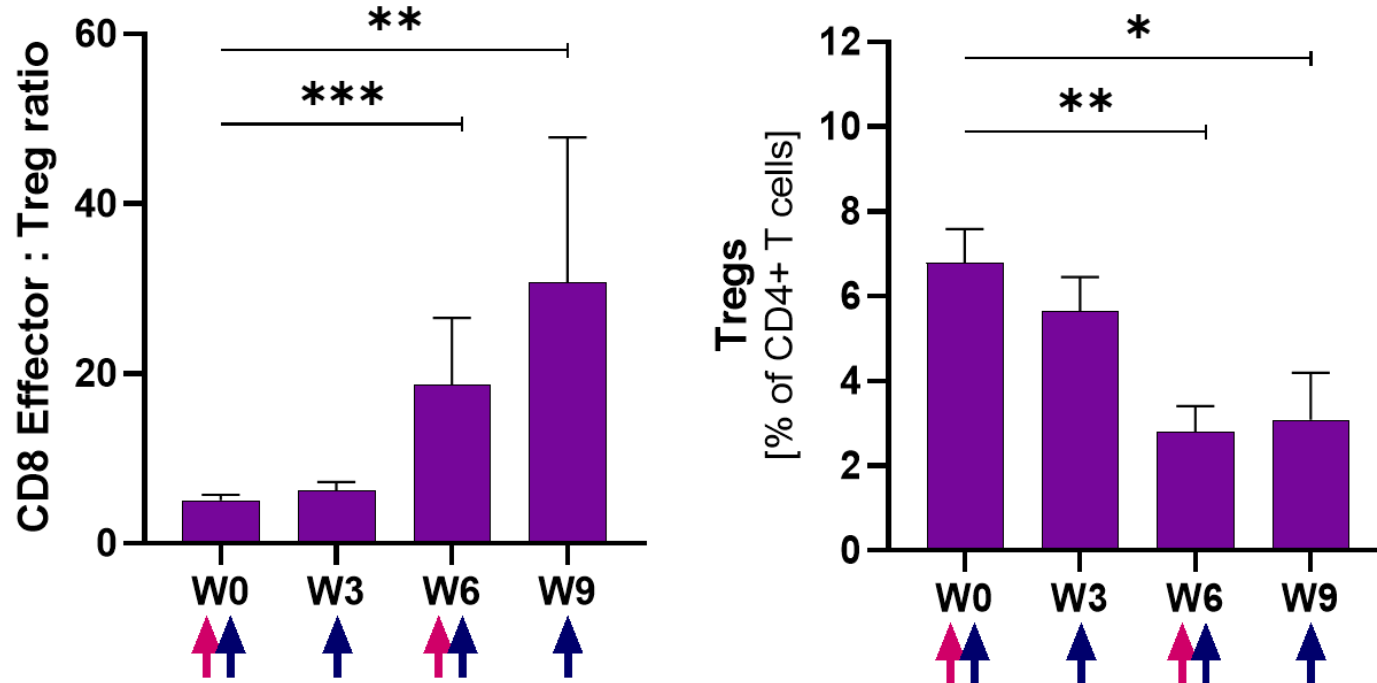
ECOG: Eastern Cooperative Oncology Group

	n (%)	PC (n = 30)
Any ADR		21 (70.0)
ADR by severity	Grade 1	9 (30.0)
	Grade 2	6 (20.0)
	Grade 3	4 (13.3)
	Grade 4-5	2 (6.7)
Most frequently reported ADR		
Fever		9 (30.0)
Fatigue		5 (16.7)
Rash		5 (16.7)
Injection Site Reaction		4 (13.3)
Chills		3 (10.0)
ADR resulting in drug discontinuation		1 (3.3)

- Most patients received 2 or more prior treatments (87%)
- Most are metastasized to the liver (80%)

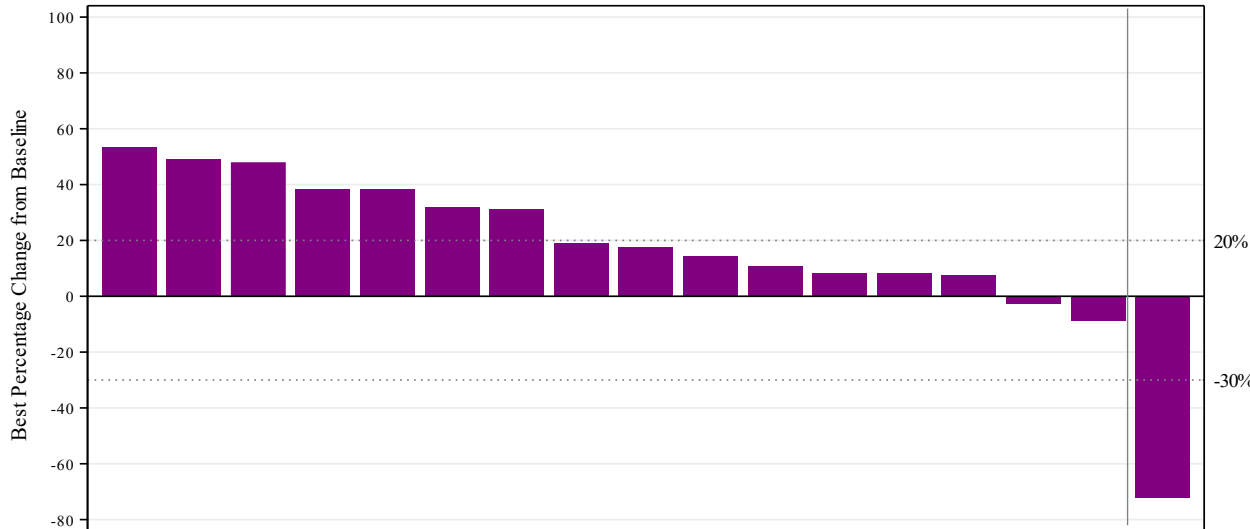
- With CPI + NT-I7 combo, no severe AEs reported and well tolerated
- One patient discontinued due to decreased platelet count

PC: Dose dependent T cell amplification

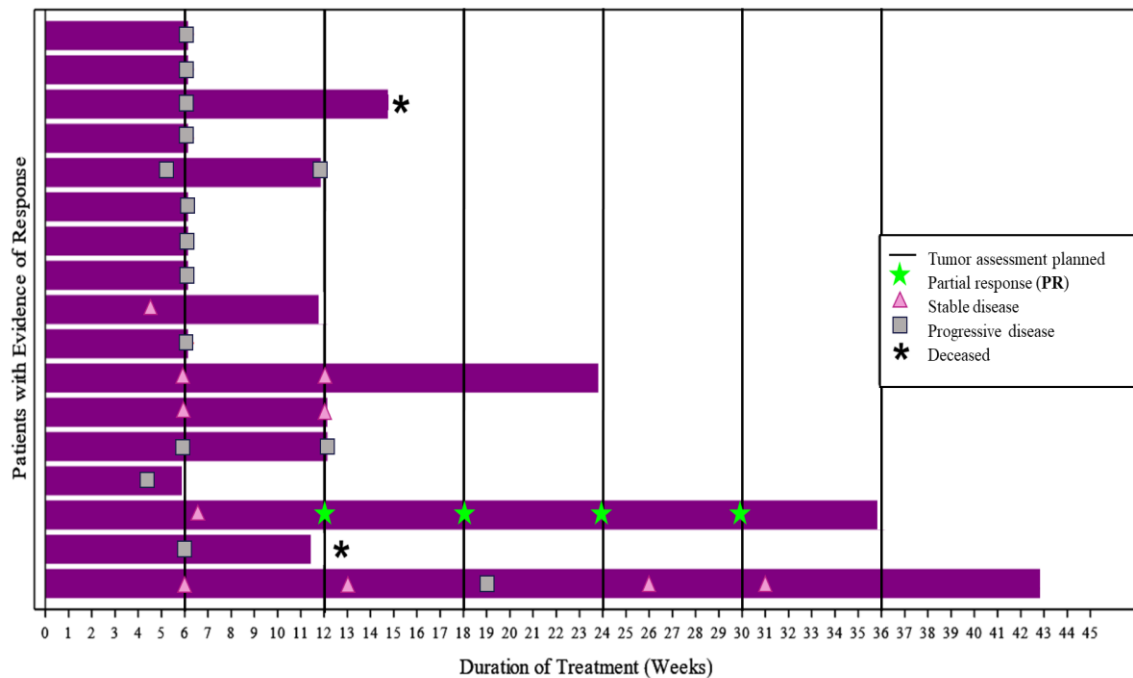


- Immune suppressing Treg was rarely amplified (VS. Biggest difference from other interleukins)
- The differential between CD8 T eff and Treg increases with dosing
- Proportion of Treg among total CD4 T cells continues to decrease with dosing

PC: Tumor burden change and time to response



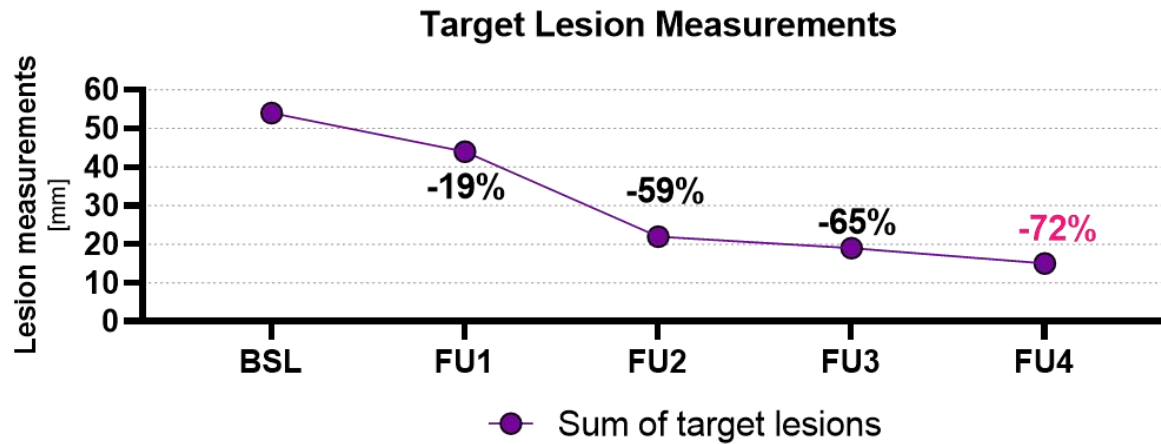
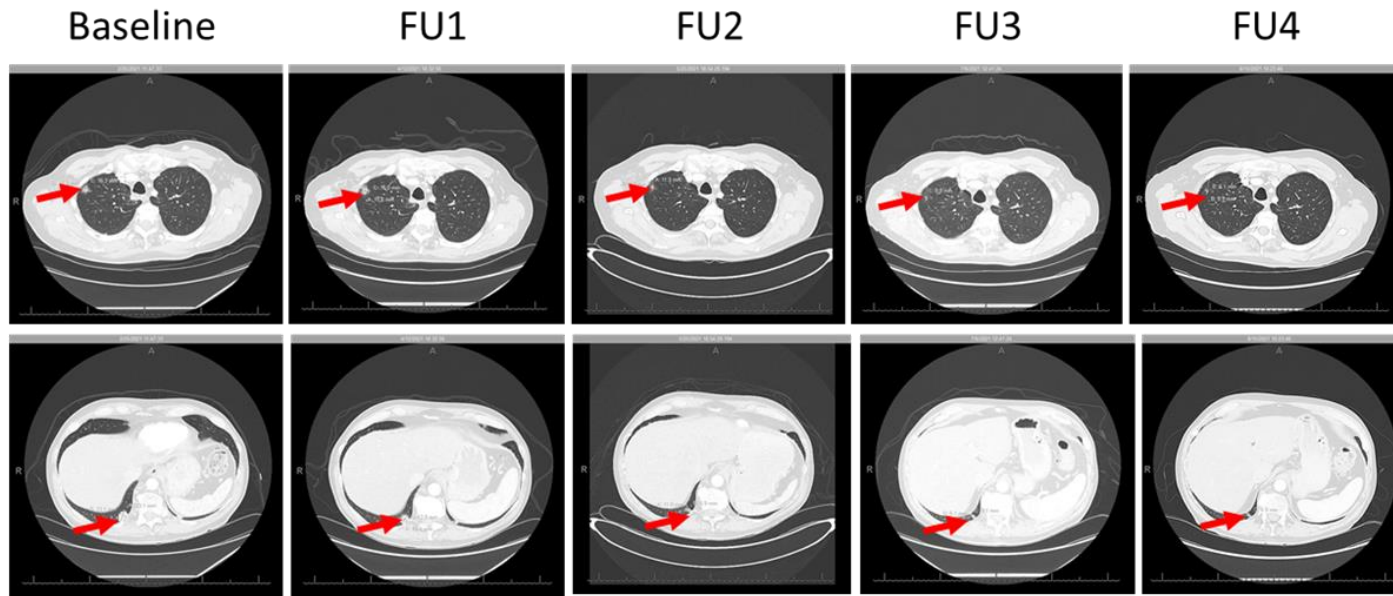
- **ORR: 6% (1/17 pts)**
- 1 PR : -72%
- **DCR: 29% (5/17 pts)**
- 4 SD + 1 PR



- **Median treatment duration : about 11.7 weeks (as of Nov.10)**
- **6/17 pts still on treatment***

* It is subject to change depending on the follow up results

PC: a PR case - sustained and notable reduction of lesion



Correlation between TIL and treatment responses

MSS - CRC

Patient ID	ORR	Lymph (%) Pre-Tx	Lymph (%) Post-Tx
4-1	iPR	2	60
4-2	PR	1	4
4-3	SD	10	0
4-4	SD	2	3
4-5	SD	1	1
4-6	PD	1	1
4-7	PD	2	5

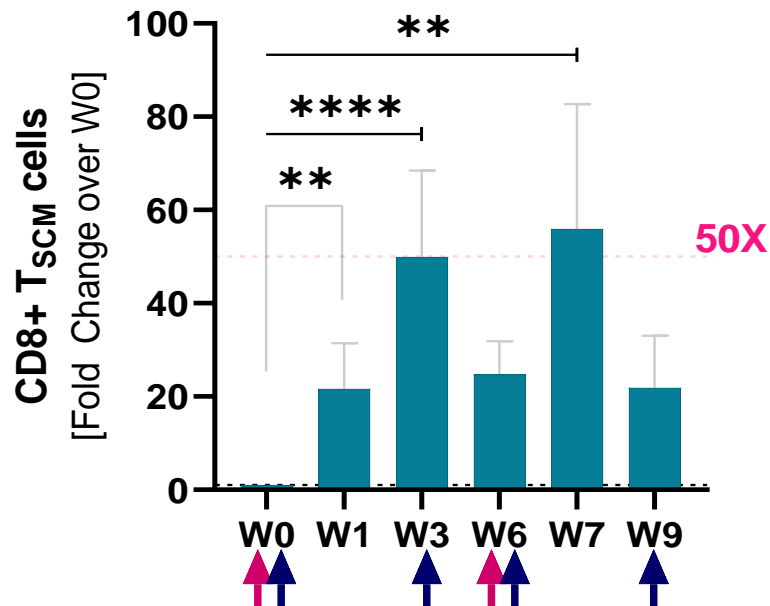
Pancreatic Cancer

Patient ID	ORR	Lymphs (%) Pre-Tx	Lymphs (%) Post-Tx
5-1	PR	20	50
5-2	SD	1	30
5-3	PD	1	1
5-4	PD	1	10
5-5	PD	3	1
5-6	PD	1	1
5-7	PD	1	1

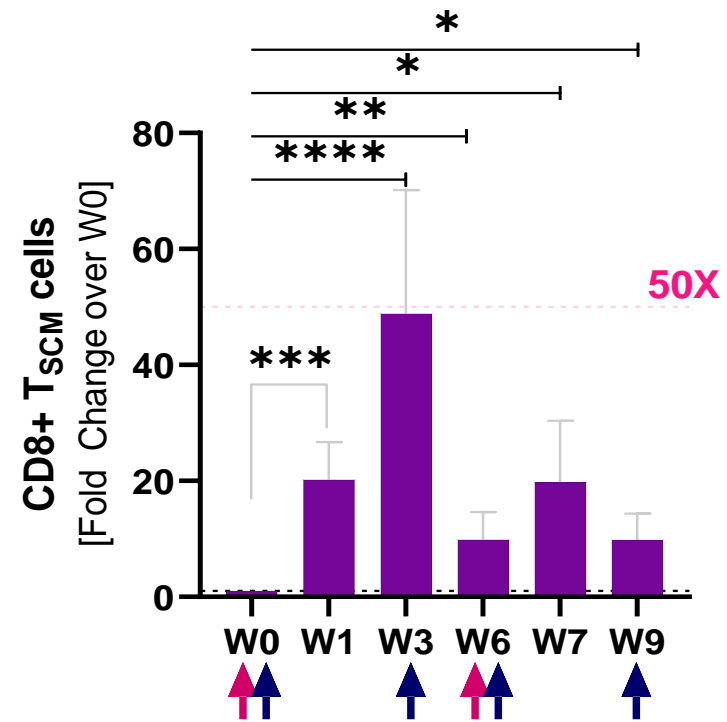
- Quantifying TIL(tumor infiltrating lymphocytes) by staining tumor tissues
- Responders(PR, SD) showed substantial increases of lymphocytes after treatment
- Non-responders(PD), no significant increase of lymphocytes seen after treatment

The best Tscm increase observed in clinical study ever

MSS - CRC



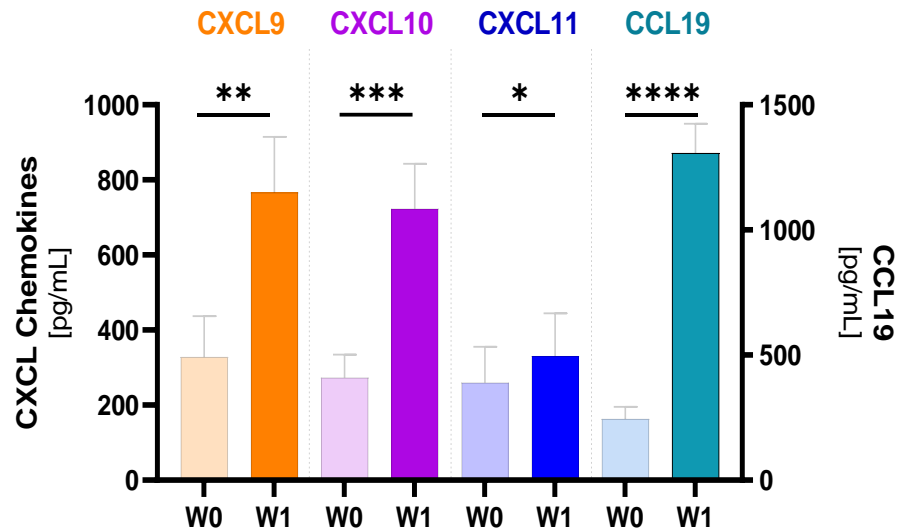
Pancreatic Cancer



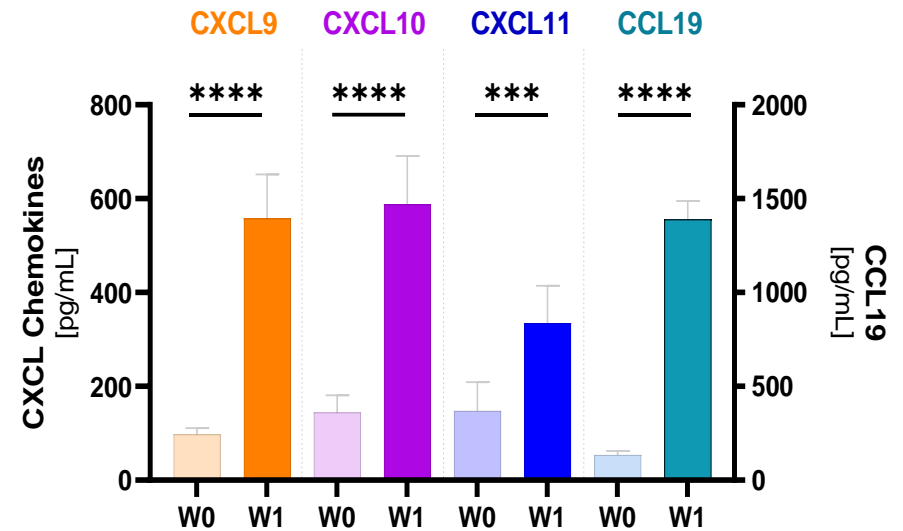
- Tscm is increased with CPI+NT-I7 combo, and not increased with CPI alone
- Tscm increase by any CPI treatment was reported

Reactivity of Chemokines

MSS - CRC



Pancreatic Cancer



- Chemokines, which are potent chemoattractants that recruit lymphocytes into the tumor, were significantly increased

NIT-110 Future Development Plans (2022)

- **Completion of Ph2a**

- Final analysis on $17+8=25$ pts on each cohort (5+1)
- Data read-out expected in 2H22
- Group1(MSS-CRC, PC) and Group2(NSCLC, SCLC, TNBC, Ovarian)

- **The following study will be initiated**

- Discuss next step study with co-development partners under combo studies
- To be used for BD discussions with major pharmas with CPIs

Key message

Potential of success of NT-I7 as a novel drug was seen

1. For first time in bio history, most powerful T cell(Tscm) amplification was demonstrated: **anticancer T cells in the blood amplified more than 50-fold**
2. Efficacy in CPI combo study: **Solid tumor patients showed notable improvements in data compared to CPI mono therapy**
3. Efficacy in CR combo study : **GBM patients showed remarkably longer survival data compared to SoC**

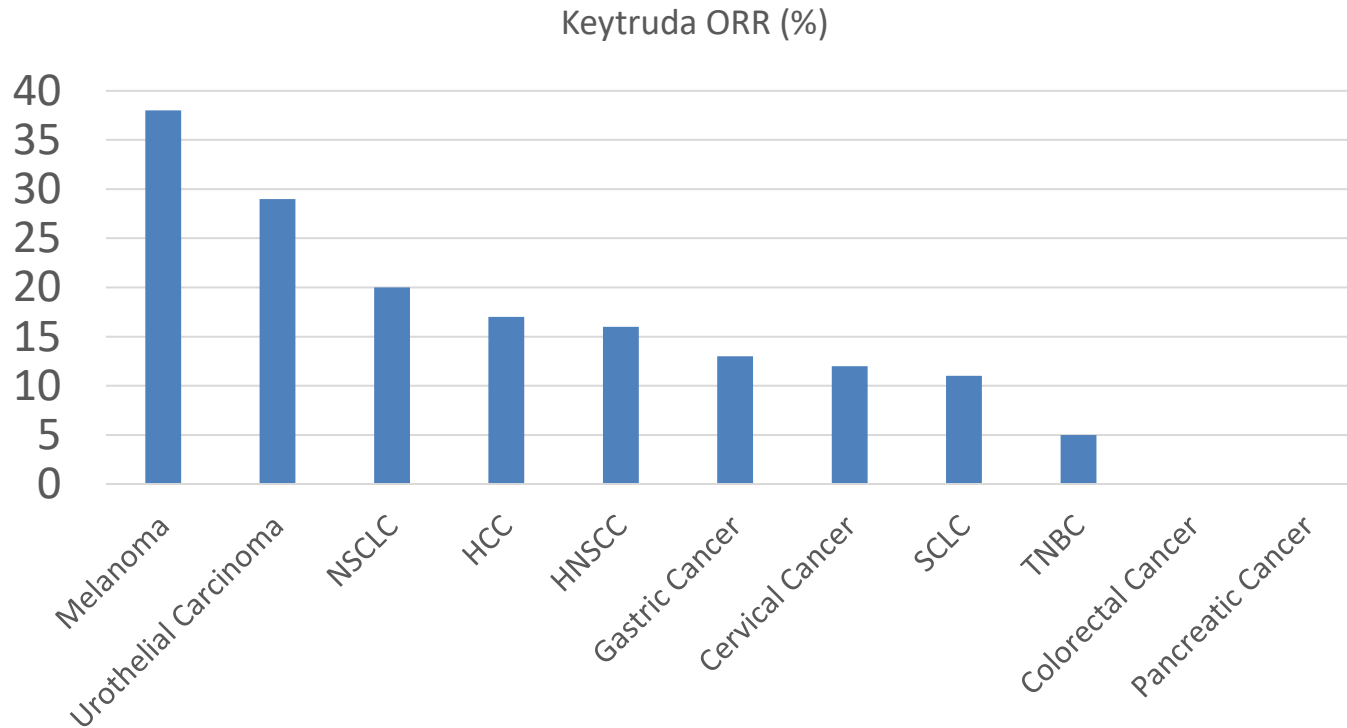
1. Poster Presentation at SITC 2021

2. Future Development Plan

Clinical strategy for regulatory strategy

- **Prioritizing indications by bigger unmet needs (Indications CPIs failed)**
 - FFIRST (GBM, MSS-CRC, PC) → BEST (NSCLC, SCLC, Gastro, TNBC)
 - MSS-CRC & PC known as immune-cold. No CPIs approved (Opportunities)
 - CPI mono provides almost no clinical benefit and chemotherapy has side effects
- **Creating new markets without competition**
 - Focusing on indications that CPIs are not approved
- **CPI+NT-I7: Increase clinical benefit without side effects**
 - This combo therapy is chemo-free and has no serious AEs
 - New treatment improves ORR and OS than CPI mono
 - Further improved responses expected by iRECIST analysis
- **Efficient drug development by sharing data across companies**
 - Ph2 GBM study is on-going in China simultaneously by IMAB

MSS-CRC & PC, hard to cure cancers

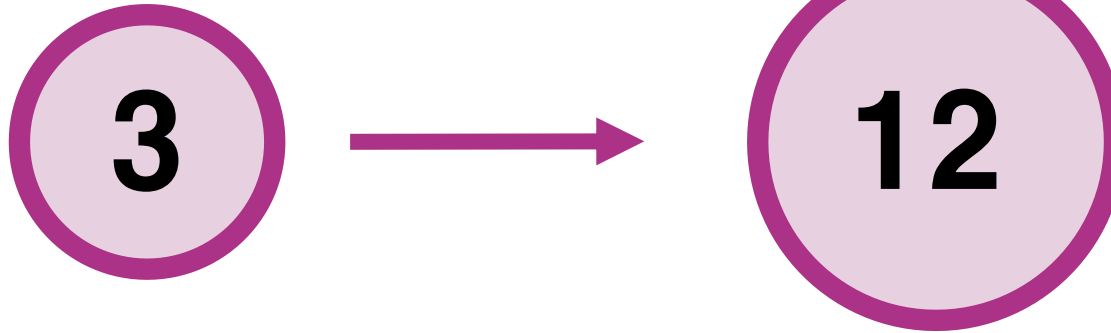


Source: NIT, KB sec Report 2021

- MSS-CRC and Pancreatic cancer are hard to cure with great market opportunity
- Keytruda mono, ORR 0%

Post 2021 SITC

- More indications will be studied in clinical trials and more data read-out to come following to SITC 2021



- GBM (NIT-107)
- MSS-CRC (NIT-110)
- PC (NIT-110)

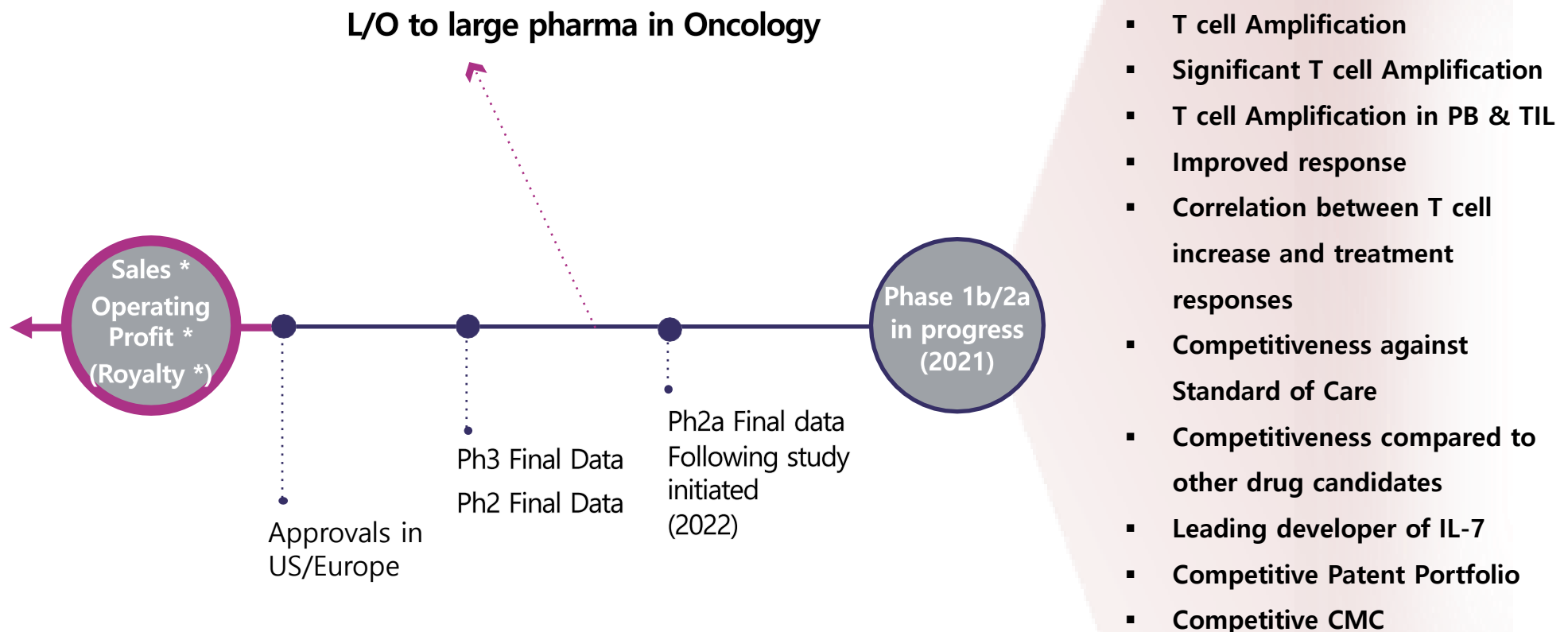
- NSCLC (NIT-110)
- SCLC (NIT-110)
- TNBC (NIT-110)
- Ovarian (NIT-110)
- 3 Skin Cancers (NIT-106)
- 3 Gastro related cancers (NIT-109)
- NSCLC, 1L (NIT-119)
- Blood Cancer (NIT-112)

Business strategy

- **Focus on the first approval (GBM, MSS-CRC, PC)**
 - L/O, optional L/O, co-development, etc (Open possibilities)
 - 1st approval → Triggering other indications approvals in a row
 - Ph2 GBM study is on-going in China simultaneously by I-MAB
 - Core strategy for quality deals (e.g., Immunomedics)
- **L/O for CPI combo only**
 - CPI market expected to grow up to 100 billion USD by 2030
 - Areas with great growth potential by more mono & combo approvals
 - Possible L/O only for CPI combo (e.g., Nektar's IL-2 case)
- **L/O for all oncology**
 - many other I-O drugs or drug candidates besides PD-(L)1
 - Potential combo partners (e.g., anti-TIGIT, IL-2, Cancer vaccine, etc)
 - NT-I7 can be best positioned with unique mechanism even for triple combo

Business Goal : Global L/O

- Immunotherapy market is expected to grow up to 100 billion USD by 2030
- "NT-I7", the best partner of PD-(L)1, aims to be commercialized into the global markets as the next-generation immunotherapy



Core competitiveness of NeoImmuneTech

■ One of a kind?

- Only company developing T cell amplifier in the global market (US/Europe)

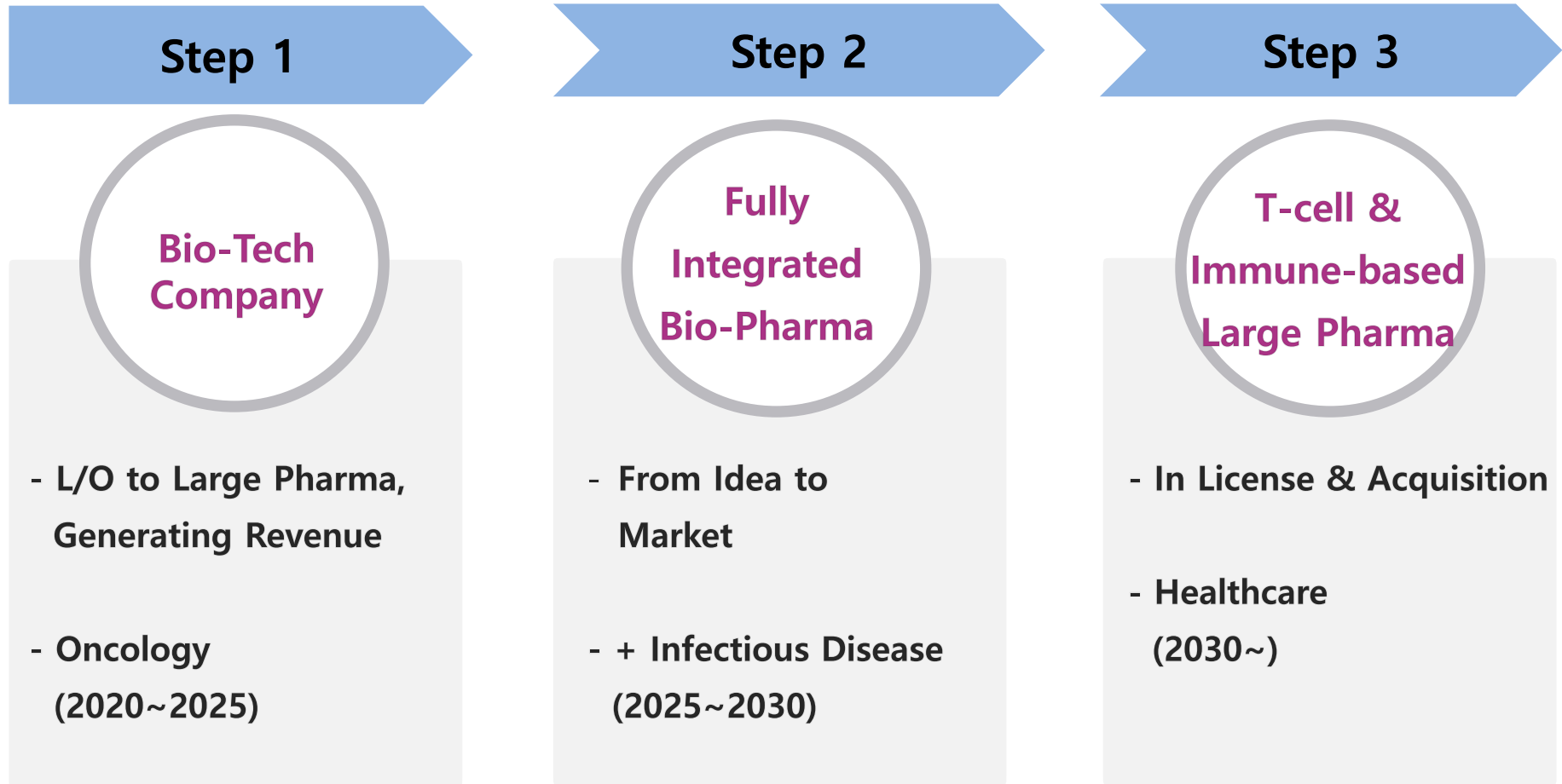
■ Globally competitive?

- Targeting global markets (80%), not the Korean market (1%)
- Possesses patented technology/assets that increases the best anticancer T cells by 50-fold
- Best T cell amplifier needed by many different pharmaceuticals

■ Commercially attractive?

- Best partner of CPI that will reach 100 billion USD soon
- Protein treatment drug capable of mass production in factories
- Possible to create new market as an only treatment option in certain indications

Growth vision



Upcoming major events for 2022

	1H 22	2H 22
Trial Starts, etc.	<ul style="list-style-type: none"> ✓ NIT-109: Gastric/GEJ/EA CPI Combo <i>Ph2 part</i> ✓ NIT-106: Skin Cancer CPI Combo <i>Ph2 part</i> ✓ NIT-120: Recurrent Glioblastoma CPI Combo for neoadjuvant therapy 	<ul style="list-style-type: none"> ✓ NIT-114: ICL ✓ NIT-105: Elderly with Bladder, Breast, and Colorectal Cancer Survivors <i>Ph1b part</i>
Data Read-Outs	<ul style="list-style-type: none"> ✓ NIT-106: Skin Cancer CPI Combo <i>DE Phase</i> ✓ NIT-110: Basket Study CPI Combo <i>Interim Analysis: Cohort 1 (TNBC), 2(NSCLC), 3 (SCLC)</i> ✓ NIT-112: CAR-T Combo <i>Preliminary Safety</i> 	<ul style="list-style-type: none"> ✓ NIT-107: GBM Chemo Combo <i>Interim Analysis</i> ✓ NIT-109: Gastric/GEJ/EA CPI Combo <i>DE Phase</i> ✓ NIT-110: Basket Study CPI combo <i>Final Analysis</i> ✓ NIT-119: 1L NSCLC CPI Combo <i>Interim Analysis</i>

- All plans are subject to change

THANK YOU !

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