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- 1. NIT-107 (IIT) CR-7 Program (Combo with Chemoradiotherapy)
 - Phase 1 (Dose Escalation) part
 - Newly diagnosed high grade gliomas
 - Combo therapy: Concurrent treatment of chemoradiation + NT-I7
- 2. NIT-110 (SIT) Check-7 Program (Combo with Checkpoint inhibitor)
 - Phase 1b (Dose Escalation) part
 - Relapsed/refractory advanced solid tumors
 - Combo therapy: Checkpoint inhibitor(Pembrolizumab) + NT-I7

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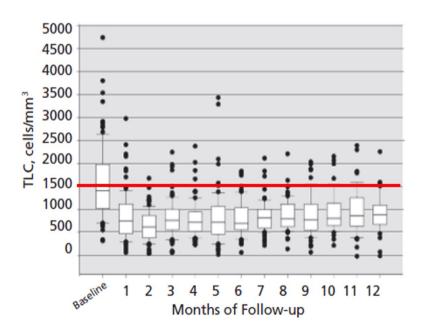


Background of Study



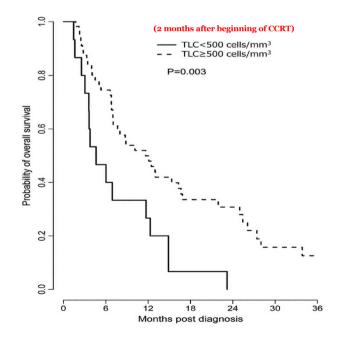
Survival of HGG Patients is strongly correlated with TLC levels. The higher TLC levels are, the higher survival rates are.

- High grade glioma (HGG) patients tend to have chronic lymphopenia after CCRT
- TLC (Total Lymphocyte Count) deficiency noted for 1 year



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

- Survival of HGG patients, highly correlated with TLC levels
- After 2 months of treatment with combo therapy,
 patients with low TLC tend to have low survival rates



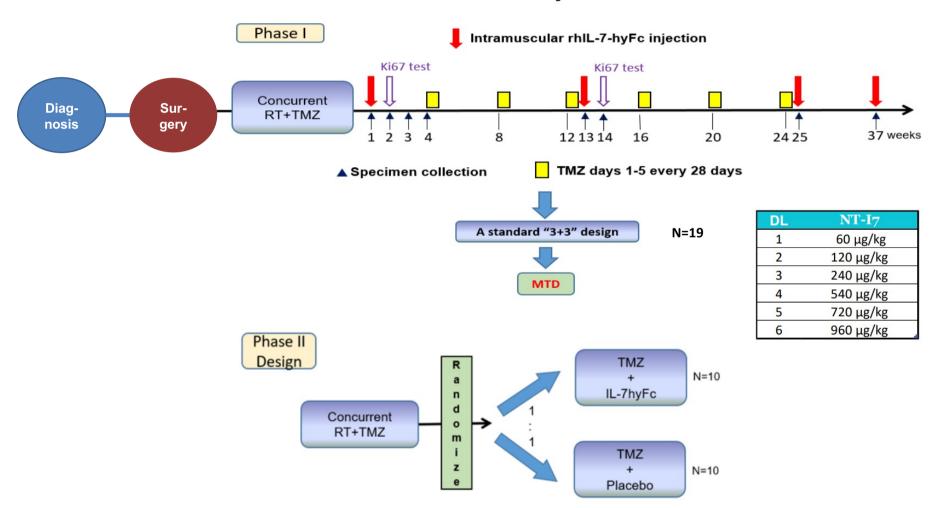
J Neurooncol. 2016 Apr;127(2):329-35.

1. Can NT-I7 amplify T cells that were lowered after CCRT (Concurrent chemoradiotherapy)?

2. Can NT-I7 contribute to improved survival of patients with HGG (High Grade Glioma)?



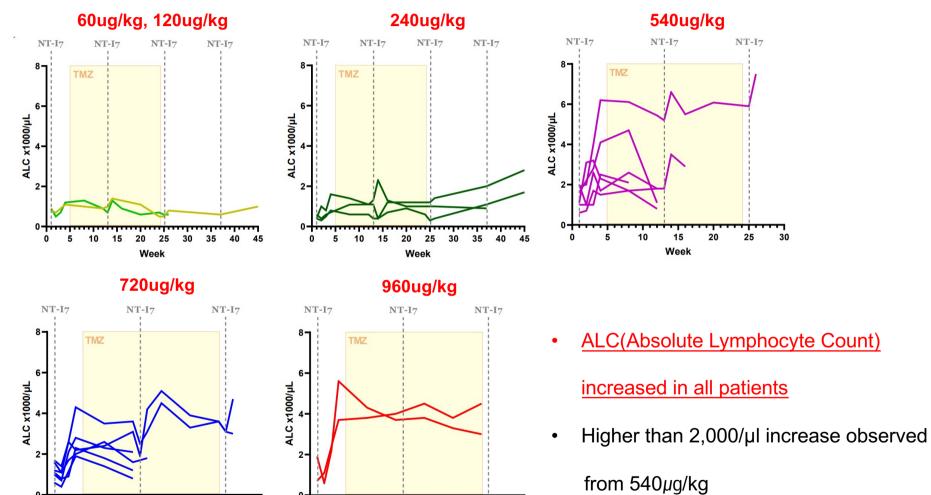
Study Schema





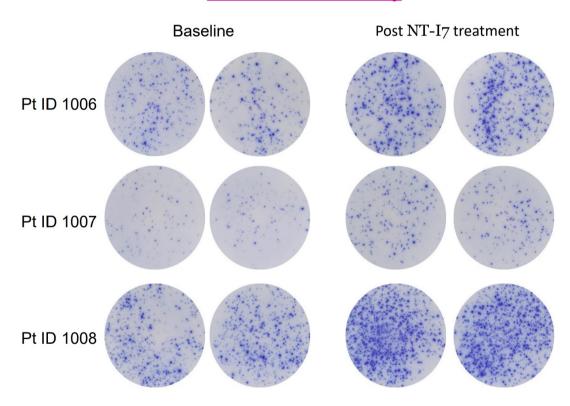
Week

Week





T cell functionality



- Evaluation of new T cells post NT-I7 injection
 - IFN-γ measured (as indication of T cell production)
- # of spots before/after treatment
- → Functioning T cell numbers increased





Adverse Event	60 μ n=1		120 բ n= ₁			ug/kg (%)	540 µ n=6		720 բ n=6	ıg/kg (%)	960 μ n=2	
	Any grade	≥Grade 3	Any grade	≥Grade 3	Any grade	≥Grade 3	Any grade	≥Grade 3	Any grade	≥Grade 3	Any grade	≥Grade 3
Injection site reaction	1 (100)	0	1 (100)	0	1 (33)	0	2 (33)	0	1 (17)	0	2 (100)	0
Pyrexia	0 (0)	0	0	0	0	0	1 (17)	0	0	0	1 (50)	0
Flu like symptoms	0	0	0	0	0	0	2 (33)	0	2 (33)	0	1 (50)	0
Rash	1 (100)	0	0	0	0	0	0	0	0	0	2 (100)	0
Fatigue	0	0	0	0	1 (33)	0	1 (17)	0	0	0	2 (100)	0
ALT increased	0	0	0	0	0	0	2 (33)	0	0	0	1 (50)	1 (50)*
AST increased	0	0	0	0	0	0	2 (33)	0	0	0	0	0
Nausea	0	0	1 (100)	0	0	0	1 (17)	0	1 (17)	0	1 (50)	0
Muscle weakness	0	0	0	0	0	0	1 (17)	1 (17)	2 (33)	0	1 (50)	0
Back pain	0	0	0	0	0	0	0	0	0	0	0	1 (50)*

 $^{^{*}}$ DLTs noted in 960 µg/kg dose level. Thus 720 µg/kg is selected as the phase 2 dose.

- Safety and tolerability was confirmed without serious AE. RP2D was decided at 720μg/kg
- ALT increase was tentative response and not serious, Back muscle pain is subjective and not serious
 AE as well
- Rationale for RP2D: Instead of additional recruiting of patients at 960μg/kg and have RP2D upgrade to 960μg/kg, for faster and effective Ph2 initiation, RP2D was decided to be 720μg/kg



Pt. ID	NT-I7 Dose (µg/kg)	Age	Sex	Diagnosis	МСМТ	IDH
1	60	58	М	GBM	Methylated	WT
2	120	32	M	GBM	Un-Methylated	WT
3	240	45	М	AO	Unknown	Mutated
4	240	46	М	GBM	Un-Methylated	WT
5	240	67	М	GBM	Methylated	WT
6	540	63	M	AO	Unknown	Mutated
7	540	67	М	GBM	Un-Methylated	WT
8	540	65	M	GBM	Un-Methylated	WT
9	540	40	F	GBM	Un-Methylated	WT
10	540	64	M	GBM	Un-Methylated	WT
11	540	25	М	GBM	Un-Methylated	WT
12	720	30	М	GBM	Un-Methylated	WT
13	720	58	F	GBM	Un-Methylated	WT
14	720	58	F	GBM	Un-Methylated	WT
15	720	58	M	GBM	Methylated	WT
16	720	78	F	GBM	Methylated	WT
17	720	66	М	GBM	Un-Methylated	WT
18	960	30	M	GBM	Methylated	Mutated
19	960	38	F	GBM	Un-Methylated	WT
	Median (Range)	58 (25-78)				

1. Diagnosis

- GBM: Glioblastoma multiforme (Negative Prognosis)
- · AO: Anaplastic oligodendroglioma (Relatively good prognosis)

2. MGMT: O6-methylguanine-DNA methyl-transferase (Enzyme)

- · Un-Methylated shows worse prognosis
- Of GBM pts, un-methylated is 71% (12/17 pts)

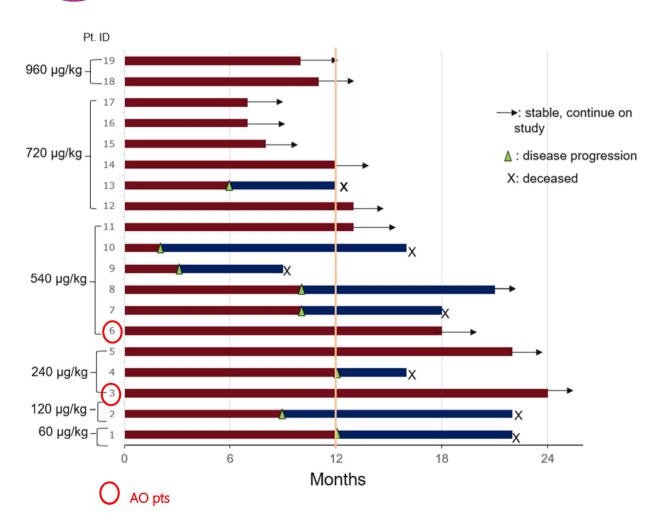
3. IDH: Isocitrate Dehydrogenase(Enzyme)

- Wild type shows worse prognosis
- Of GBM pts, WT is 94% (16/17 pts)



Survival ratio over 1 year: higher by 3-fold than SoC





- 1. Pts with over 1 year data:14
 - > GBM pts: 12 (a)
 - > Of GBM pts, survival over 1 yr :10(b)
- 2. Survival Comparison (As-is)
- NIT-107 (b/a) → 83.3%
- GBM Standard of Care * → 25%
- Phase 1 data shows survival ratio over
 1 yr is higher than that of standard of
 care by 3-fold

^{*} https://www.braintumourresearch.org/info-support/types-of-brain-tumour/glioblastoma-multiforme

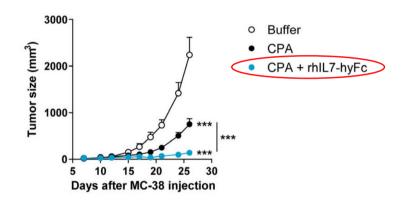
^{*} CCRT followed by adjuvant TMZ



With CCRT + NT-I7, cancer size is reduced, and survival is improved.

Radiation + NT-I7

Chemotherapy + NT-I7



Combo Therapy:
 IL-7; NT-I7 (GX-I7) + IR (Irradiation)

International J. of Radiation Oncology, 2020 (POSTEC)

 Combo Therapy: rhlL-7-hyFc; NT-I₇ (GX-I₇) + CPA (Cyclophosphamide)
 Clinical & Translational Immunology, 2020 (POSTEC)





- 1. Can NT-I7 amplify T cells that were lowered after CCRT (Concurrent chemoradiotherapy)? YES
 - Functioning T cells were amplified.
- 2. Can NT-I7 contribute to improved survival of patients with HGG (High Grade Glioma)? YES
 - The Ph1 data cut showed the survival ratio over 1 year is higher than that of standard of care by 3-fold.
 - However, it is a Ph1 dose escalation study based on small sample size.
 - The first patient in the Ph2(dose expansion) part was dosed in March and is in the process of getting more data for further analysis

- 1. Ph1 dose escalation showed NT-I $_7$ was safe and tolerable. RP2D was declared as $720\mu g/kg$.
- 2. Ph2 dose expansion part started, with first patient dosed in March 2021. Ph2a interim results are estimated to be released around mid-2022.
- 3. Upon finding significant data in 2022, Ph2 for fast-track approval could be initiated as an SIT.

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- Before CPI, patients with higher ALC responded better
- Before CPI, patients with higher TIL (Tumor Infiltrating Lymphocyte) responded better

Nature 2014, 515; 568-571

1. Can NT-I7 increase the ALC in the peripheral blood and TIL in the TME?

2. Can the combo therapy of NT-I₇ and a CPI improve responses of R/R solid tumor patients?

Relapsed/Refractory Advanced Solid Tumors.

Phase 1b

Dose Escalation*
3 + 3 Design
(n=up to 18) N=12

Dose Level (n=3/6 / DL)	NT-I7 IM Q6W	Pembrolizumab IV Q3W
DL 1	480 μg/kg	
DL 2	960 µg/kg	200 mg
DL3	1200 µg/kg	



^{*}Patients with advanced solid tumors who can provide mandatory pre- and on-treatment biopsies *Selected tumor types for Dose Expansion

Phase 2a

Dose Expansion
Simon's two-stage minimax design
(n=25\(^{\Delta}/\)arm)

NT-I7: RP2D IM Q6W Pembrolizumab: 200 mg IV Q3W

Arm I: CPI-treated R/R TNBC# n=up to 17 (stage 1)/ 8 (stage 2) (25 total)

Arm II: CPI-treated R/R NSCLC# n=up to 17 (stage 1)/8 (stage 2) (25 total)

Arm III: CPI-treated R/R SCLC# n=up to 17 (stage 1)/ 8 (stage 2) (25 total)

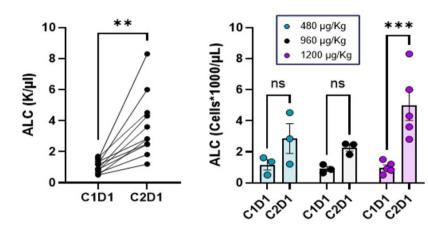
Arm IV: CPI-naive R/R MSS-CRC# n=up to 17 (stage 1)/ 8 (stage 2) (25 total)

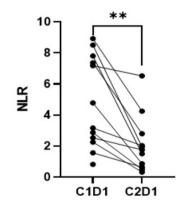
Arm V: CPI-naive R/R PC# n=up to 17 (stage 1)/ 8 (stage 2) (25 total) + Bio marker study : CPI naïve R/R

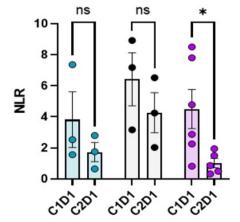
> Ovarian Cancer (+ N=10)

[∆]Evaluable patients









1. ALC (Absolute Lymphocyte Count) change

- Increased in all patients
- 1,200µg/kg group increased the most

2. NLR (Neutrophil Lymphocyte Ratio) change

- Decreased in all patients
- It is well known that high NLR is correlated with poor survival



Increase of Tumor Infiltrating Lymphocyte (TIL)



Patient ID	ORR	-	phocytes Tumor)	Lymphocytes (Stroma)		
Patient ID	UKK	Pre- Tx	On-Tx	Pre-Tx	On-Tx	
102-10101	SD	1	<1	3	20	
102-10102	SD	<1	<1	13	16	
102-10103	SD	6	20	15	20	
101-10106	PD	0	<1	2	7	

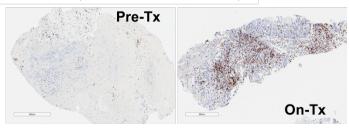
1. Tumor Biopsy before/after NT-I7 injection

- Post NT-I7 injection, TIL was up by all 4 pts
- Intratumoral & Stromal TILs(iTILs & sTIL) both increased

2. Response

- SD: all 3 showed increase
- PD: sTIL increased, absolute number is not high enough

102-10103 (Clear cell ovarian cancer)



3. Cold tumor showed more notable responses

- Ovarian cancer, a cold tumor showed a notable response
- Decided to add 10 ovarian cancer pts for biomarker study



Table 2. Summary of Adverse Events

n (%)		DL1 = 480 µg/kg (n = 3)	DL2 = 960 μg/kg (n = 3)	DL3 = 1200 µg/kg (n = 6)	Total (n = 12)
Any TEAE		3 (100)	3 (100)	6 (100)	12 (100)
ADR ADR by severity	Grade 1 Grade 2 Grade 3 Grade 4-5	0 1 (33.3) 2 (66.7) 0	0 1 (33.3) 2 (66.7) 0	0 2 (33.3) 4 (66.7) 0	0 4 (33.3) 8 (66.7) 0
Most frequently reported ADR Injection site reaction Chills Pyrexia Fatigue Oedema peripheral	3 (100) 2 (66.7) 3 (100) - 2 (66.7)	3 (100) - - 1 (33.3) 1 (33.3)	6 (100) 5 (83.3) 3 (50.0) 4 (66.7) 2 (33.3)	12 (100) 7 (58.3) 6 (50.0) 5 (41.7) 5 (41.7)	
ADR resulting in drug disconting	0	0	3 (50.0)	3 (25.0)	
DLT events		0	0	1 (16.7)	1 (8.3)

ADR: Adverse Drug Reaction; DLT: Dose Limiting Toxicity; TEAE: Treatment-Emergent Adverse Event

- Maximum tolerable dose(MTD) was not reached. NT-I₇ was tolerable up to 1,200μg/kg Q6W
- ADR (Adverse Drug Reaction) was found, but no serious AE was found
- RP2D is the highest dose of 1,200μg/kg and first Ph.2a patient was dosed in January 2021
- NT-I7 was tolerable and safe not only in mono therapy but also in combo therapy with CPI



Table 1. Baseline characteristics

Characteristics	Categories	DL1 = 480 μg/kg (n = 3)	DL2 = 960 μg/kg (n = 3)	DL3 = 1200 µg/kg (n = 6)	Total (n = 12)
Age, year, median (range)	-	58.0 (43, 64)	60.0 (59, 77)	53.0 (46, 69)	58.0 (43, 77)
Gender, n(%)	Male	2 (66.7)	1 (33.3)	3 (50.0)	6 (50.0)
ECOG Performance Status, n(%)	0 1	1 2	3	5 1	6 6
Sum of TL, mm, median (range)	-	81.0 (45, 144)	87.0 (68, 106)	102.5 (28, 127)	85.0 (28, 144)
No. of previous lines of therapy for recurrent/metastatic disease, n(%)	1-2 3-4 >4	1 (33.3) 1 (33.3) 1 (33.3)	1 (33.3) - 2 (66.7)	2 (33.3) 4 (66.7)	2 (16.7) 3 (25.0) 7 (58.3)

DL: dose level; ECOG: Eastern Cooperative Oncology Group; TL: target lesion

- All patients have relapsed or refractory advanced solid tumors.
- All patients received more than 1 prior treatment, and more than 58% of pts had 4 or more prior treatments.



Previous data of pts diagnosed with same indications



Indication (NIT-110, number of subjects)	Checkpoint inhibitor (Keynote Studies)					
indication (NT 110, number of subjects)	ORR	PFS	OS	Source		
Malignant Melanoma (1)	26%	6m PFS, 45%	13.4 months	KEYNOTE-001		
MSS-CRC (4)	0%	5m PFS, 11%	5 months	KEYNOTE-016		
Esophageal cancer (2)	11.6%	6m PFS, 14.1%	5.8 months	KEYNOTE-059		
Ovarian Cancer (1)	9.9%	6m PFS, 22% Median PFS 2.1m	17.6 months	KEYNOTE-100		
Metastatic Pancreatic Cancer (MSI-H) (1)	18.2%	6m PFS, N/D Median PFS 2.1m	4 months	KEYNOTE-158		
Metastatic Breast Cancer (1)	12%	6m PFS, 16.7%	8.6 months	KEYNOTE-028		
Soft-tissue sarcoma (1)	18%	3m PFS, 55%	11.4 months	SARC028		

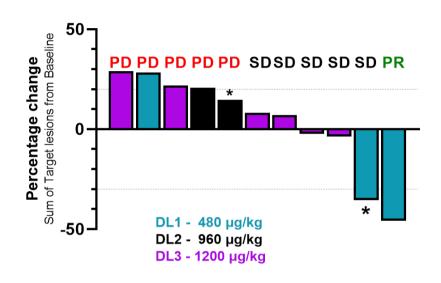
- All 12 pts showed fast progression → negative prognosis
- Post Keytruda mono therapy, all cancer types showed low ORR except melanoma. Particularly,
 PFS and OS were very short
 - → Fast cancer progression up to decease
- Listed indications leave big medical unmet needs for PFS and OS





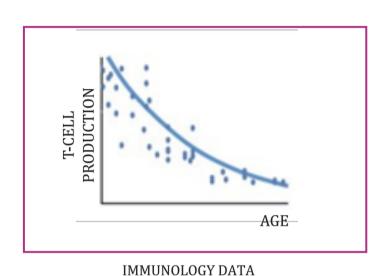
Anticancer activities that suppress progression

SubjectID	Dose Level	Best Overall Response	Best Overall Change
101-1001	480 μg/kg	Partial response (PR)	- 45.8%
101-1002	480 μg/kg	Progressive Disease (PD)	+ 28.4%
101-1003	480 μg/kg	Stable Disease (SD)	- 35.6%
101-1004	960 µg/kg	Progressive Disease (PD)	+ 20.7%
101-1005	960 µg/kg	Progressive Disease (PD)	N/D
101-1006	960 µg/kg	Progressive Disease (PD)	+ 14.7%
102-1001	1200 µg/kg	Stable Disease (SD)	+ 7.0%
102-1002	1200 µg/kg	Stable Disease (SD)	- 2.4%
102-1003	1200 µg/kg	Stable Disease (SD)	+ 8.2%
102-1004	1200 µg/kg	Progressive Disease (PD)	+ 21.8%
102-1005	1200 µg/kg	Stable Disease (SD)	- 3.6%
102-1006	1200 µg/kg	Progressive Disease (PD)	+ 28.9%



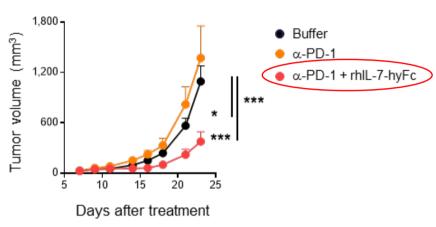
- * Pt had reduction in initial lesion, but cancer found in another lesion; SD -> PD, PR -> SD
- Of the 11 evaluated, 6 pts showed controlled progression (DCR: 55%)
 - > 1) a malignant melanoma patient responded very fast to the combo therapy, in spite of the two failed prior treatments with Nivolumab (aPD1) and Ipilimumab (aCTLA4)
- Of the 5 SD pts, 4 pts remained in SD for more than 6 weeks
- Increased <u>mPFS can be estimated</u>





Source: Protein Cell (2018), NIT analysis

Thymectomy Mouse Model



Clinical & Translational Immunology, 2020 (POSTEC)

- As we age, the Thymus shrinks and produces less T cells
- With a lower number of T cells, there is a higher chance of cancer developing and a lower response to a checkpoint inhibitor
- To build a similar clinical setting, adult mice with Thymectomy were used
- In this model, CPI (aPD1) mono therapy did not show significant anticancer activity
- But in the combo treatment cohort (CPI + NT-I7), suppression of cancer progression was observed



- 1. Can NT-I7 increase the ALC and TIL? YES
 - T cells were increased in all patients with NT-I7
 - Neutrophil-lymphocyte ratio (NLR) was decreased in all patients
 - All pts with evaluable tumor biopsies showed increase TILs (4 pts)

2. Can NT-I7+ CPI (aPD1, pembrolizumab) contribute to improve responses in

R/R advanced solid tumor? YES

- It was only limited number of patient-based Ph.1b dose escalation study
- Ph.2a part started in Jan.2021 to get more data for further analysis including OS and PFS.



- 1. Ph.1b demonstrated that the combo therapy(NT-I₇ 1200 μg/kg IM Q6W + pembrolizumab 200 mg IV Q3W) was safe and tolerable. RP2D was determined to be 1,200μg/kg
- 2. Some patients who failed in the prior treatments showed PR and SD.
- 3. <u>In Ph.2a with 5 solid tumor types, cold tumors (CPI not approved for) such as MSS-CRC and</u> Pancreatic cancer are in fast progress.
 - It is estimated that <u>interim data release on selected tumor types in the Ph.2a could be</u> available 4Q21 at the earliest.
- In 2022, indication related strategy for accelerated approval can be initiated

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Clinical Trial Development Plan (USA)

Program	Study	Combo Trial	Indications	2020	2021	2022	2023	2024+	Data Releas e
CR-7	NIT-104 NIT-107	CCRT	Glioblastoma, GBM	Ph1			Ph2		2021 ASCO
CAR-7	NIT-112	CAR-T (Novartis ⁴)	Relapsed or refractory large B-cell lymphoma, DLBCL	ma, Ph1b/2a			Ph	2	
	NIT-106	CPI (Roche)	3 Skin caners ¹		Ph1b/2a		Ph	2	2021 SITC(E)
Check-7 (Me NIT-110 (Me NIT-110 (C) NIT-110 (C)	CPI (Merck)	5 Solid cancers ²		Ph1b/2a		Ph	2	2021 ASCO/ SITC (E)	
	NIT-109	CPI (BMS)	3 Gastro cancers ³			P	h2		
	CPI (Roche)	NSCLC (1L)		Ph2		Ph	3		
VAX-7	NIT-105	-	Infectious disease for elderly subjects		Ph1b		Ph	2	
	NIT-116 NIT-118	-	COVID-19		Ph1	P	Ph2	Ph3	
Mono-7	NIT-114	-	Idiopathic CD4 lymphopenia, ICL		Ph	1/2a	P	h2	
NIT-113 -		-	Progressive multifocal leukoencephalopathy, PMI		h1	Ph			

Note) 1. Melanoma, Merkel Cell Carcinoma (MCC), Cutaneous Squamous Cell Carcinoma (cSCC). 2. Triple Negative Breast Cancer (TNBC), Non-small Cell Lung Cancer (NSCLC), Small Cell Lung Cancer (SCLC), Pancreatic Cancer, Colorectal. 3. Gastric Cancer, Gastro-Esophageal Junction Cancer, GEJ, Esophageal Adenocarcinoma, EAC. 4. Combined therapy is going on without collaboration agreement

^{*} Clinical plan and data presentation schedule may be changed depending on internal and external environment



2H2021

1H2022

Trial Starts	 ✓ NIT-112: CAR-T combo trial ✓ NIT-119: 1st Line NSCLC CPI combo ✓ NIT-106: Skin Cancer CPI combo (Ph2 part) 	✓ NIT-109: Gastric/GEJ/EA CPI Combo (Ph2 part)
Data Read-Outs	 ✓ NIT-106 - Skin Cancer CPI combo (DE phase) ✓ NIT-110 - Basket Study CPI combo (Certain Tumor Types - Ph2a part) 	✓ NIT-110 - Basket Study CPI combo (Additional Tumor Types, Ph2a part)

- Multi journal publications are under review and in preparation
- All schedules are subject to change



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