

NeolmmuneTech Company Presentation

Mar 29, 2024



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Introduction

NeoImmuneTech, T-cell based immuno-therapy global leading company



NeoImmuneTech: new President & CEO





Luke Yun Suk Oh

President and CEO

Highlights

- McGill University Ph.D. (Neuroimmunology)
- 14 years of experience in biotechnology companies
 - Early development and pre-clinical projects
 - Translational science experience in small molecules and large biologic products
- 6 years of experience as a senior staff fellow at the U.S. FDA
- 2 years of experience as Vice President of Samsung Bioepis
- Founder and Chairman of the Korean-American Professional Association in Life Sciences (KAPAL) (2017-2021)
 - Over 2,000 Korean and American members
 - Leading over 20 forums, meetings, and conferences

NeoImmuneTech (president and CEO, 2024-Current)

 Overall development management for research, manufacturing, clinical trials and approvals.

Samsung Bioepis (vice president, 2021-2023)

- Leading biosimilar clinical development
- Operating 4 clinical organizations (65 people)
- Led and completed 6 clinical trials (Ph1 and Ph3)
- Led US FDA and EMA submission

U.S. Food and Drug Administration (senior staff fellow, 2016-2021)

- Center for Drug Evaluation and Research (CDER), Office of Translational Science, Division of Clinical Pharmacology
- Key Areas Immunology and Inflammation
- Participate in Sponsor meetings and discussions
- Participation in establishing several FDA Guidance and policies

Mallinckrodt Pharmaceuticals (associate director, 2012-2016)

- Development of new indications for approved product (Acthar Gel)
- Performed more than 7 collaborations and projects with academia and industry

Human Genome Sciences (senior scientist, 2008-2012)

- Leading biopharmaceutical development (translational science) - Development of new indications for Benlysta
- Early Discovery Council Member

Vertex Pharmaceuticals (research scientist, 2002-2008)

 Leading pre-clinical development of new product development projects (Proof of Concept and Safety Pharmacology)

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Founded in 2014 based in Rockville, Maryland





NT-I7; Long-acting IL-7 T cell amplifier, uniquely positioned to address unmet medical needs



Global Network for Clinical Development Combination clinical trials with Roche/Genentech,

Merck and MD Anderson, Washington University and NIH



96 Employees US: 43, KR: 52 (2024.03)

800+ patients NT-I7 injected



5 Orphan Drug Designations (GBM, ICL, PML, ARS, PDAC)

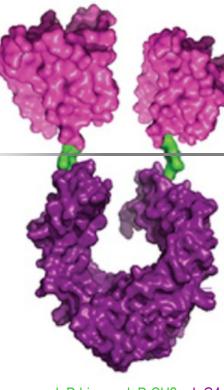


1,000 L Scale Manufacturing Scale-up FDA confirmation

*Also known as GX-I7 or rhIL-7-hyFc; NIT owns development/commercialization rights for the Americas (N,C,S) and Europe GBM: Glioblastoma Multiforme; ICL: Idiopathic CD4 Lymphopenia; PML: Progressive Multifocal Leukoencephalopathy; ARS: Acute Radiation Syndrome; PDAC: Pancreatic ductal adenocarcinoma

NT-I7, a human recombinant IL-7, enhances efficacy and safety by amplifying T cells, which play a crucial role in the body's immune system

\mathbf{NT} - $\mathbf{I7}$ (Efineptakin alfa)



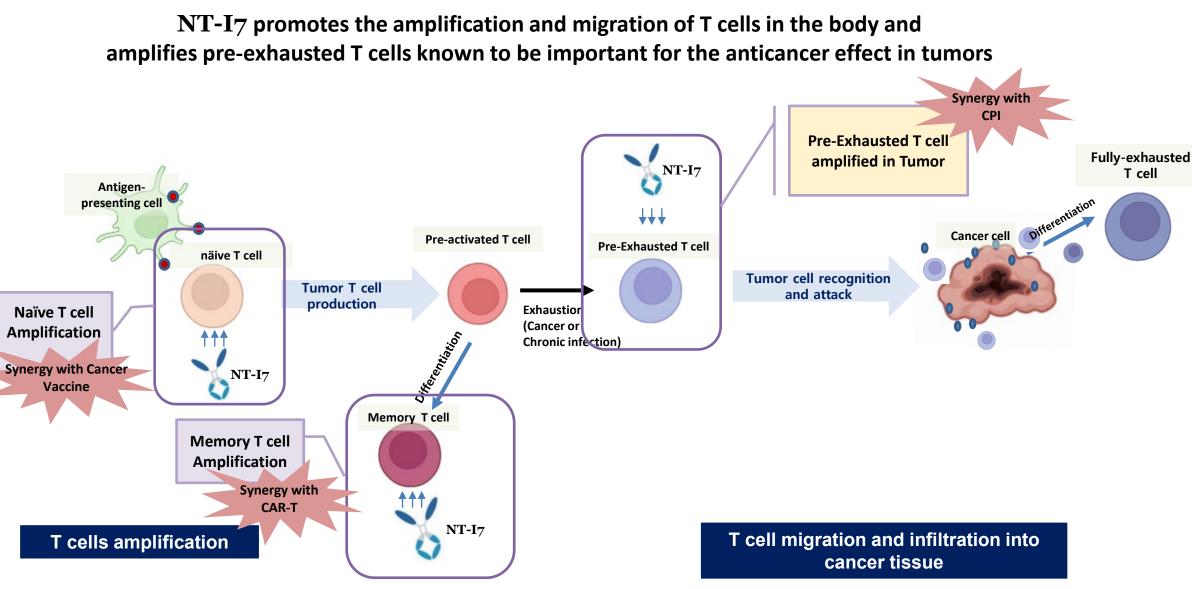
"IL-7 Engineering Patent Technology"

- High Stability
- High Productivity (100 x higher)

"hyFc Fusion Patent Technology"

- Increased Efficacy
- Increased Safety
- Half life increased by 7-fold

IgD hinge + IgD CH2 + IgG4



Blood Advances (2022) 6(23), 6093–6107 & . Journal for ImmunoTherapy of Cancer (2024) 12(3), e008001. *NIT는 2022 AACR, 2023 SITC, Nat Commun (2017) 8:15050, & Nat Immunol (2021) 22(2):229–39 에서 위 내용을 NT-I7으로 입증함 NEGIMMUNETECH

Program	Study	Indication	Partners	Combination	Preclinical	Phase 1	Phase 2	Phase 3	Major Institutional
NT-I7 Combina	ation thera	ру							
Checkpoint Inhibitor	NIT-110	Solid Tumors ¹⁾ TNBC, NSCLC, SCLC, PC, MSS-CRC, Ovarian		KEYTRUDA®	Phase 1b/2a				MDAnderson Gancer Center
	NIT-119	NSCLC 1L	Roche	TECENTRIQ®	Phase 2				SARAH CANNON
	NIT-120	Recurrent GBM		KEYTRUDA®	Phase 2				MAYO CLINIC
Chemo/Radio	NIT-107	Newly diagnosed GBM ²⁾		CCRT ⁵⁾	Phase 1/2				Washington University in St. Louis School of Medicine
CAR-T	NIT-112	Large B-cell Lymphoma (LBCL)		KYMRIAH ®	Phase 1b				Washington University in St. Louis School of Medicine
DNA Vaccine	NIT-124	Head & Neck squamous cell carcinoma (HNSCC/SCCHN)	Genexine	KEYTRUDA [®] , GX-188E	Phase 2				
NT-I7 Mono th	nerapy								
NT-I7 mono	NIT-113	Progressive Multifocal Leukoencephalopathy (PML) ³⁾			Pilot				NIH National Institute of Neurological Disorders and Stroke
	NIT-114	Idiopathic CD4 Lymphopenia (ICL) ⁴⁾			Phase 1/2				NAtional Institute of Allergy and Infectious Diseases
	NIT-115	Squamous cell carcinoma of head and neck (SCCHN)			Phase 1				UCSF
	NIT-A01	Acute Radiation Syndrome (ARS) ⁵⁾			Preclinical				DUKE UNIVERSITY MEDICAL CENTER

¹⁾ PC ODD (US Jan 2024) ²⁾ ODD (US Jul 2022) ³⁾ ODD (US Jun 2020) ⁴⁾ ODD (EU May 2017 US Apr 2019) ⁵⁾ ODD (US Nov 2023) Investigator-initiated trials

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Result of Major Clinical Trials

- 1. Checkpoint Inhibitors
- 2. CAR-T
- 3. Chemo/Radiation Therapy
- 4. Cancer Vaccine

In clinical trials conducted, the efficacy of T cell amplification such as ALC, TIL, and CAR-T amplification was confirmed

Study	NIT-110 (KEYTRUDA [®])		NIT-107 (Chemo/radio)	NIT-112 (CAR-T)	
Study	Solid Tumors/PDAC	Solid Tumors/MSS-CRC	GBM	NSCLC	Large B-cell Lymphoma
Clinical stage	Ph2a		Ph1 / Ph2	Ph2	Ph1b
Target patients	238/65	238/65	77	83	57
Recruited patients	203/65	203/57	41	33	13
Interim result	 ✓ Extended survival period ✓ TIL increased after one dose of NT-I7 ✓ Increased TILs associated with PD-1+response ✓ Maintains efficacy even after liver biopsy ✓ Predictive biomarker confirmation 	 ✓ Extended survival period ✓ TIL increased after one dose of NT-I7 ✓ Increased TILs associated with PD-1+response ✓ Rectum shows better response than Colon ✓ Predictive biomarker confirmation 	 ✓ Extended survival period ✓ MGMT methylation may affect efficacy 	✓ Showed better efficacy in the 1st line (NIT-119) expressing PD-L1 (when comparing all patient groups with 2nd line or higher treatment therapy for relapsed glioblastoma (NIT-110))	 ✓ Confirmation of the second rising curve of CAR-T expansion with NT-I7 administration ✓ If NT-I7 is administered in the CAR-T expansion stage (between 7 and 14 days after CAR-T administration), an amplification effect of CAR-T can be expected.
Future plans	Future plans After securing and analyzing test results, discuss future development directions with partners				

1. NIT-110: NT-I7 + CPI: TIL increase and correlation between TIL and OS

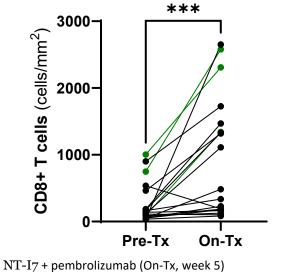
PD-1 inhibitors show low monotherapy efficacy in patients with low TIL¹⁾ levels An increase in TIL was confirmed in combination treatment with NT-I7 and PD-1 inhibitors

Increased levels of circulating CD8+ $T_{SCM}^{2)}$ at week 3 are associated with higher CD8+ T cell infiltration into the tumor at week 5

Pembrolizumab alone has failed to show consistent TIL increase, but the addition of NT-I7 favors TIL infiltration even in immunologically cold tumors

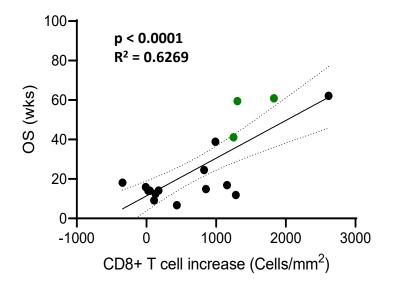
CD8+ T cell infiltration is associated with Tumor Control and OS³⁾

NT-I7 shows efficacy in infiltrating T cells



NT-I7 + pembrolizumab (On-Tx, week 5) CD8 T cell increase of 4.7X in 11/12 samples analyzed by IHC CD8 T cells: Pre-Tx = 79 cell/mm²; On-Tx = 373 cell/mm²

Increased CD8+ T cell infiltration is associated with higher OS



ESMO 2022, NIT-110

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NT-I7- in combination with pembrolizumab – showed the median Overall Survival of 9.3 months in the phase 2 study

Comparing SoC and treatments added as treatment options, the combined administration of NT-I7 + Pembrolizumab showed > 31% clinical effectiveness.

OS data CPI-naive R/R MSS-CRC (n = 27) Probability of Survival (%) 100 90-80-70-60-50-40-30-20-10-Median (mOS) weeks (95% CI) 40.3 (27.9, NE) 0-20 40 60 80 100 Time (weeks)

Comparison

Treatment	mOS	mPFS	
NT-I7 + pembrolizumab	9.3 months (40.3 wks)	18.5 months (80.3 wks)	
Lonsurf (trifluridine and tipiracil) ¹	7.1 months	2.0 months	
Stivarga (regorafenib) ²	6.4 months	2.0 months	
*Lonsurf + Avastin (bevacizumab) ³	10.8 months	5.6 months	
*Fruquintinib ⁴	7.4 months	3.7 months	

1. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/207981s008lbl.pdf;

2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/203085s007lbl.pdf;

3. 2023 ASCO GI cancers symposium;

4. ESMO 2022 ; *Upcoming treatments expected to receive FDA label

1. NIT-110: NT-I7 + CPI: PDAC phase 1/2 interim result

NT-I7 – in combination with pembrolizumab – showed the

median Overall Survival of 11.1 months in the phase 2 study

OS data

In comparison to SOC and other commonly used off-label options, NT-I7 combo provides >56% greater OS benefit.

Comparison CPI-naive R/R PDAC (n = 26) Probability of Survival (%) 00 90-80-70-60-50-40-30-20- 10-Median (mOS) weeks (95% CI) 48.3 (15.9, NE) 0-20 30 40 50 60 70 80 90 100 10 0 Time (weeks)

Treatment mOS mPFS 11.1 months 4.4 months NT-I7 + pembrolizumab (48.3 wks) (19 wks) Irinotecan + 5-FU + 6.1 months 3.1 months leucovorin¹⁾ *Gemcitabine + Nab-7.1 months 3.5 months paclitaxel²⁾ *mFOLFOX6³⁾ 3.1 months (5-FU + Leucovorin + 6.1 months Oxaliplatin)

¹⁾ https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf;

²⁾ https://pubmed.ncbi.nlm.nih.gov/35094032/;

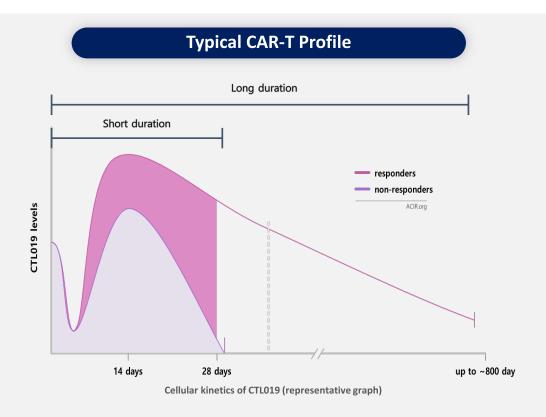
³⁾ https://pubmed.ncbi.nlm.nih.gov/27621395/; *Off-label use in 2L PAC

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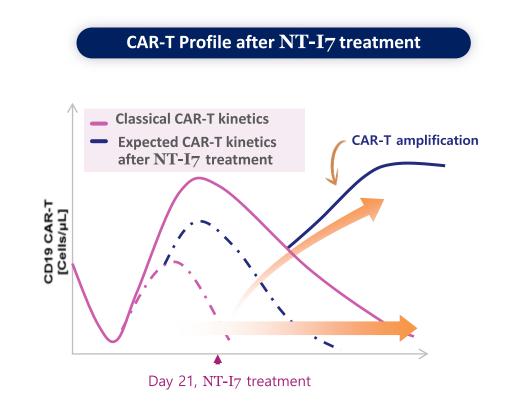
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2. NIT-112: NT-I7 + CAR-T: why combine with CAR-T?

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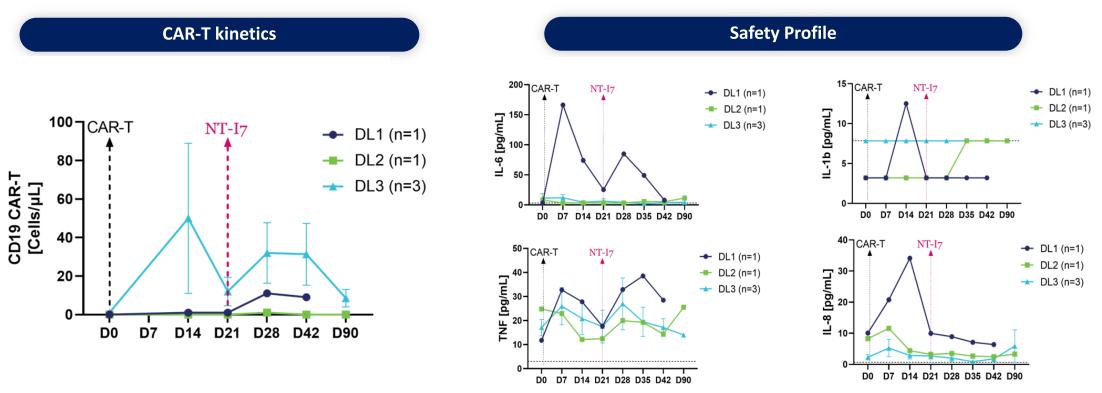


- CAR-T is a cell therapy developed as a one-time treatment.
- Responder lasts up to about 800 days after injection, while non-responder only lasts about 28 days.
- Responders have approximately twice as many CAR-T expansions than non-responders



- ALC and CAR-T level increase after NT-I7 injection
- NT-I7 re-amplifies declining CAR-T cell numbers, extending their effectiveness and offering a second chance for treatment benefit.

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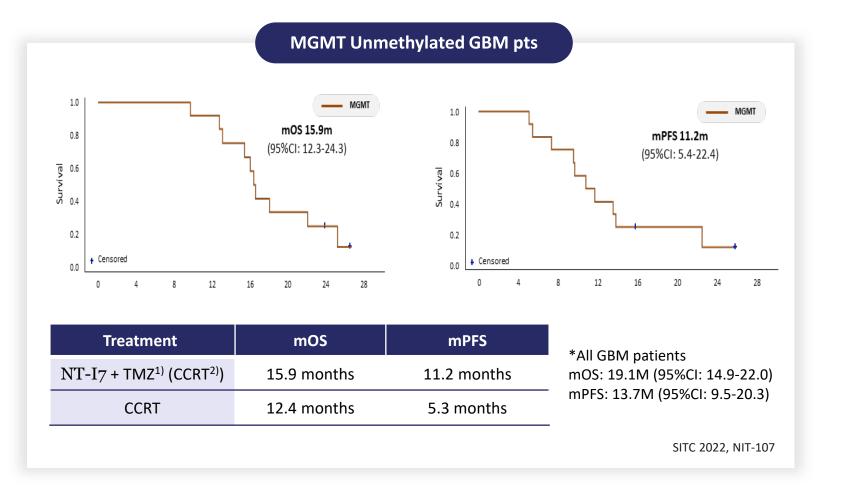
ASH 2022, NIT-112

 $DL1 = 60 \ \mu g/kg, n=1; DL2 = 120 \ \mu g/kg, n=1; DL3 = 240 \ \mu g/kg, n=3. Mean \ \pm SEM.$

- \checkmark CAR-T cells are successfully expanded after NT-I7 administration
- Proinflammatory cytokines associated with CRS¹⁾ and ICANS²⁾ were mostly stable or did not increase levels of concern following NT-I7 administration

3. NIT-107: GBM (Lymphopenia GBM) phase 1 interim result (chemo/radio combo)

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 $NT-I_7$ + TMZ combination in unmethylated MGMT GBM³⁾ patients: mOS 15.9 months (vs. 12.4 months with SoC), mPFS 11.2 months (vs. 5.3 months with SoC)

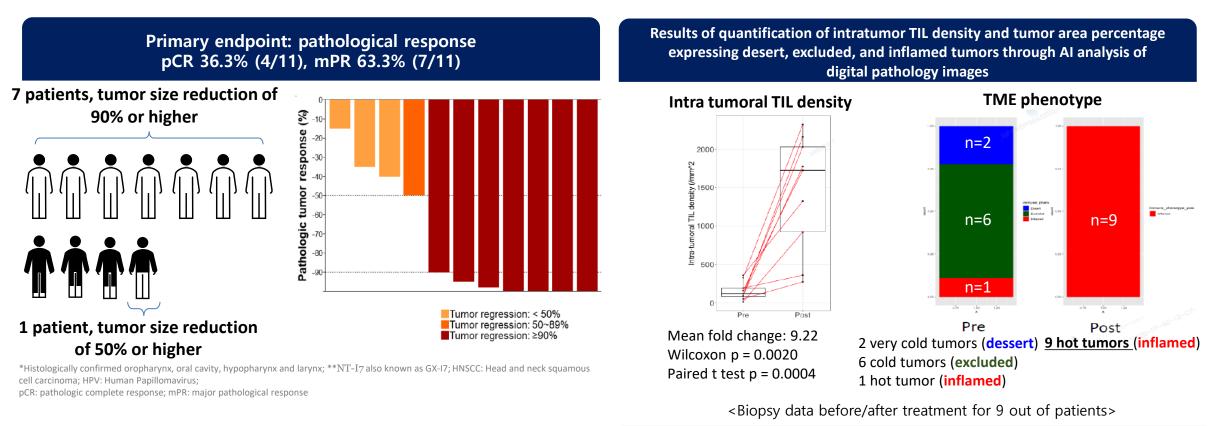
¹⁾ Temozolomide

²⁾ Concurrent chemoradiotherapy

²⁾ Methylguanine DNA Methyltransferase Glioblastoma

4. NT-I7 + Cancer Vaccine + CPI¹): result of triple combo phase 2 study in resectable HNSCC NEGIMMUNETECH

Cold Tumor with a suppressed immune response is transformed into a Hot Tumor that responds to immunotherapy, with the density of TILs increasing approximately 9-fold with the administration of NT-I7

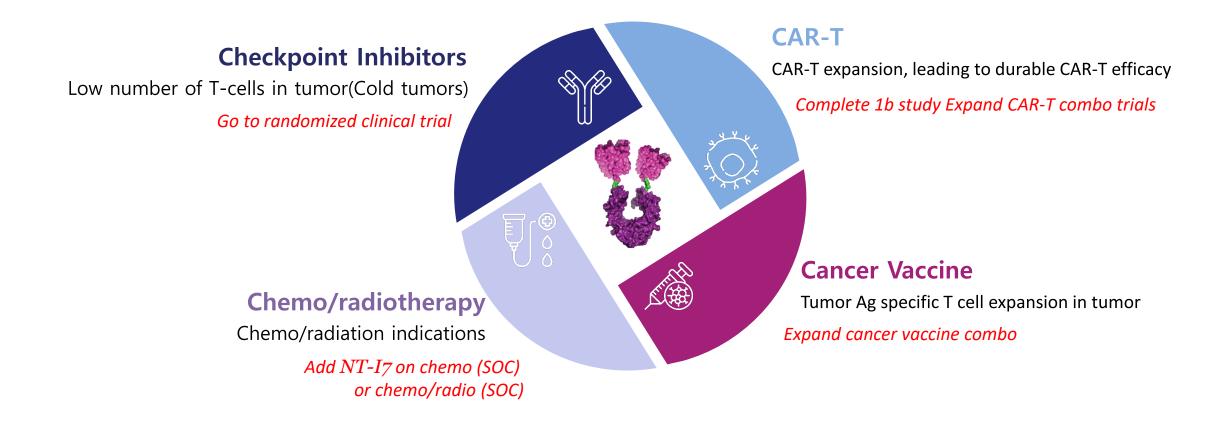


High clinical efficacy in early observation Confirm consistent response

Combination therapy increases the infiltration of lymphocytes into cancer tissue Move to the site of inflammation, which is characteristic of Hot tumor

¹⁾ Checkpoint inhibitor, ²⁾ Tumor-infiltrating lymphocyte

Addressing Key Efficacy Issues Through Combination Therapeutics



NT-I7 development status

01

02

03

04

- NIT has been focusing on four key areas, identifying shortcomings and opportunities for improvement in each
- So far, NIT has administered NT-I7 to about 350 patients, using accumulated data to identify the most suitable indications for its use.

From the inception of its development, CMC has been designed with the aim of eventual commercialization

Drug Substance PPQ (PV) establishment phase in progress

Confirmation of ALC amplification efficacy through anticancer drug combination clinical trial

Poor efficacy of anticancer drugs in patients with low lymphocyte count

Acute Radiation Syndrome (ARS) rodent experiment conducted

Lymphocyte count recovery was confirmed in radioactive rodent experiments conducted in collaboration with Duke University

Expanding cooperation opportunities in NT-I7 development through supply investment

Mainly collaborates with technologies that require lymphocyte amplification, such as CAR-T and anti-cancer vaccines



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Development efforts need to focus on indications that require efficacy in lymphocyte count recovery

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Strategic Focus

- 1. Fast Approval
- 2. Best Outcomes
- 3. New Pipeline



a development strategy for the fastest FDA approval of NT-I7

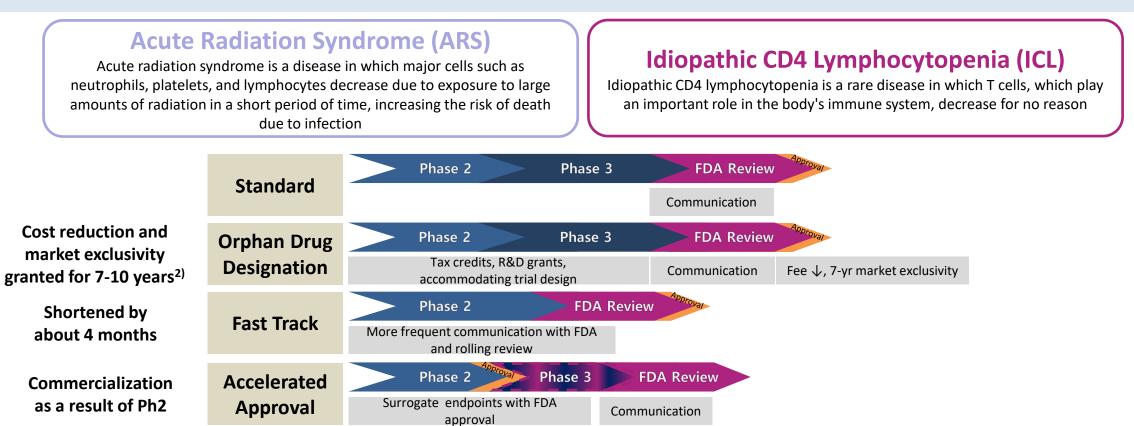
Strategic focus 1: fast approval

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NT-I7 is targeted for diseases related to lymphocytes, all of which are categorized as rare diseases

Major indications for fast approval were selected among lymphocyte-related diseases

Target BLA approval with **fast-track approval strategy**¹⁾



¹⁾ Construction of approval track strategy such as Orphan Drug Designation, Priority review and Accelerated approval. ²⁾ Once ODD is approved, the FDA grants market exclusivity for 7 years and the EMA grants market exclusivity for 10 years.

[ARS] Dual-track development strategy to accelerate development

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Progress Details

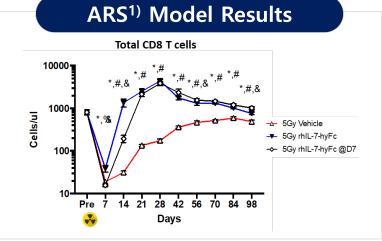
- Rodent experiments were conducted through a CRO designated by NIAID²)
 → Analysis results are undergoing QC
- Approved ARS ODD³⁾ and attended BARDA⁴⁾ Industry Day meeting and discussed strategy

Mitigation Plan

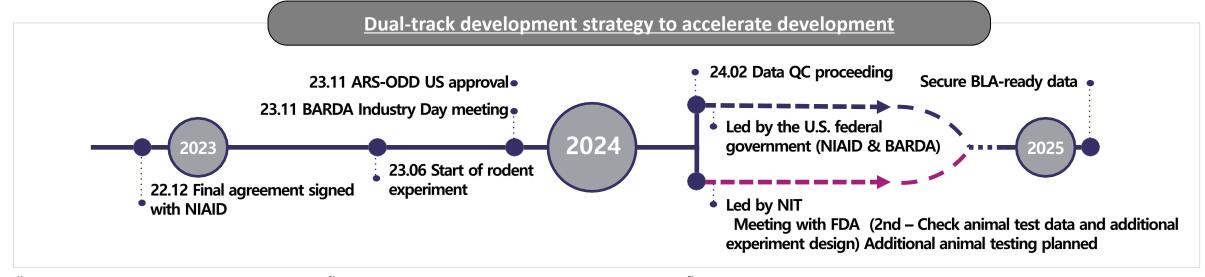
 Delayed from the schedule originally planned by the U.S. government, it is planned to proceed with a dual-track with direct operation starting from the 2nd species

→ FDA meeting scheduled at the end of April; specific plan confirmed within the 2Q

• → According to the current plan, we expect to complete animal test and obtain required documents for FDA BLA by 2025.



Rapid Injury Treatment Network 2022, Radiation Research Society 2022



³⁾ Orphan Drug Designation
 ⁴⁾ Biomedical Advanced Research and Development Authority

⁵⁾ Biologics license application

The potential of NT-I7 as the world's only treatment for Idiopathic CD4 Lymphopenia (ICL) is being validated

NT-I7 injection CD4 CD8

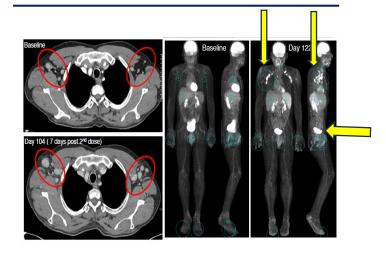
> Dotted lines: lower limit of normal T cell counts in healthy subjects



Stable remission was only noted in areas treated with laser ablation after NT-I7 treatment Confirmation of changes in CD4 and CD8 T cell distribution in ICL patients after NT-I7 administration

Days post first injection

(1st-2nd dose⁻480 µg/Kg; 3^{nt}-4th-5th dose: 720 µg/Kg) A transient drop in peripheral blood CD4/CD8 T cells immediately following NT-I7 dosing signifies a temporary redistribution of T cells to secondary lymphoid tissues



Increased size of the patient's lymph node tissue as evidence of ongoing T-cell amplification (ICIS, 2023)





Company growth and revival through performance achievement and business strategy

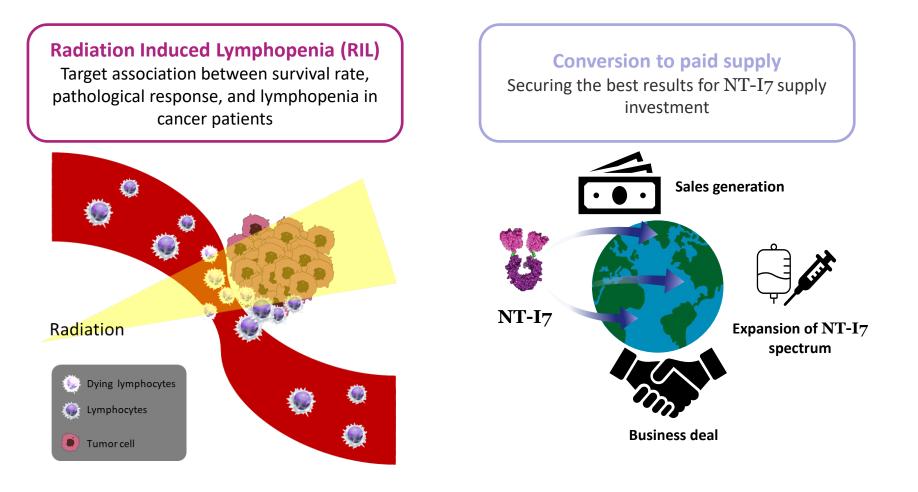
Strategic focus 2: best outcomes

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Diversifying sales opportunities by developing indications with the highest probability of success and creating

business opportunities using the experience gained through various trials and the accumulated data of NT-I $_7$

Promote company growth and revival through business planning and strategies best suited to NT-I7 development



[RIL] Lymphopenia

What is a lymphocyte?

Lymphocytes are one of the five cells of the white blood cell, which play a protective role in the immune system
against infection

What is "Lymphopenia"?

- Lymphopenia, a symptom of an abnormally low number of lymphocytes in the blood, is caused by genetic and acquired factors.
- It commonly occurs in advanced cancer, especially as a side effect of chemotherapy/radiation therapy during cancer treatment
- The most effective treatment for severe lymphopenia is NT-I7 administration.

Stages of lymphopenia and infection rate at each stage						
ALC Level	Infection Rate ²⁾					
> 1,000mm ³	n/a					
800-999/mm ³	26% higher					
500-799/mm ³	44% higher					
200-499/mm ³	76% higher					
< 200/mm ³	n/a					
	ALC Level > 1,000mm ³ 800-999/mm ³ 500-799/mm ³ 200-499/mm ³					

¹⁾ Lymphopenia grades according to WHO ²⁾ Cells. 2021 Nov; 10(11): 3177



Severe RIL G3-4 Radiation-induced lymphopenia

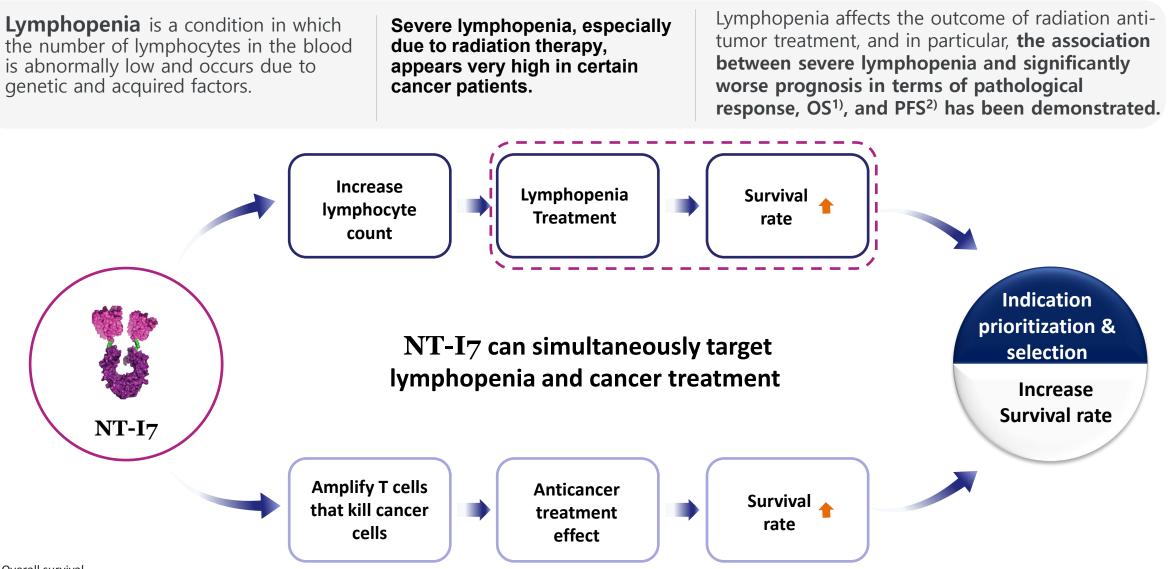
[RIL] Severe lymphopenia

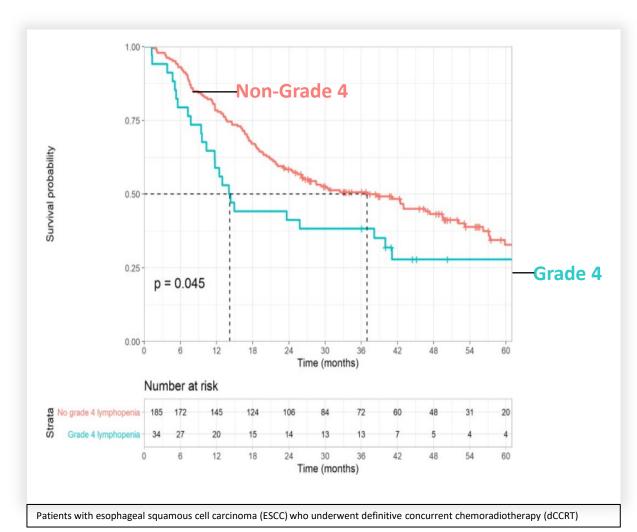
Severe RIL incidence after treatment by carcinoma type					
	Ctudy First Author Voor	Incidence Rate			
RT site	Study First Author, Year	Grade 3-4	Grade 4		
	Benitez 2019	23%			
Brain ¹⁾	Byun 2019	35%			
Brain	Mendez 2016	21%			
	Rudra 2018	25%			
	Deng 2019	91%	39%		
Esophagus ¹⁾	Zhang 2019		45%		
	Xu 2020	89%	24%		
	Vijay M Patil 2020 ²⁾	77%	13.7%		
Head and Neck	Sweet Ping Ng 2020 ³⁾	83%	25%		
Oropharynx ¹⁾	Jensen 2017		14%		
	Campian 2013	49%			
1	Zhao 2019	55%			
Lung ¹⁾	Abravan 2020	60%			
	Abravan 2020	45%			
Liver ¹⁾	Byun 2019	87%			
Liver-/	Zhang 2019	NR			
	Balmanoukian 2012	45%			
Pancreas ¹⁾	Chadha 2017	27%			
	Wild 2016	40%			
c · · 1)	Wu 2016	53%			
Cervix ¹⁾	Onal 2018	61%			
Anal canal ¹⁾	Lee 2020	42%	8%		
Bone ¹⁾	Park 2019	67%			

¹⁾ International Journal of Radiation Oncology*Biology*Physics, vol. 111, no. 4, 2021, pp. 936–948
 ²⁾ Lymphopenia during chemoradiation—foe or friend. *Ecancermedicalscience*, 14
 ³⁾ Radiotherapy and Oncology, vol. 145, 2020, pp. 95-100

Severe RIL (sRIL)– Cancer

- Severe G3-4 lymphopenia due to radiation therapy is very high in patients with esophageal cancer (90%), head and neck cancer (80%), and liver cancer (87%).
- It is known that **the rate of Grade 4 severe lymphopenia in esophageal cancer patients (36%)** is higher than in other cancer types (average 15%).





The goal is to improve survival rate by targeting patients with severe lymphopenia

<u>Result</u>: Patients who fall into the G4 group have a lower survival rate.

mOS of G4 patient and Non-G4 patient

<u>12.7 months</u> Vs <u>**42.5 months**</u> (p = 0.045)

Clinical trials most compatible with NT-I7:

- ✓ NT-I7 already has more than 800 people clinical data showing ALC increases
- ✓ NT-I7 is capable to treat lymphopenia caused by chemo/radiation therapy
- ✓ We are preparing a preliminary meeting with the FDA to discuss specific clinical plans
- The goal is to quickly obtain the best results through efficient clinical operations

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Expectations for platform technology in the field of immuno-oncology Combination tests with various modalities

Completed supply contracts with 3 companies

Completed supply contract with a company

Currently discussing supply contracts with 2 companies

Cancer Vaccine

CAR-T

Radiotherapy

Non-cancer (New indication)

Others

Currently discussing supply contracts with 2 companies

Completed MOU with a company (Companion diagnosis)

Completed supply contract with a company Currently discussing supply contracts with other companies

2024 Goals

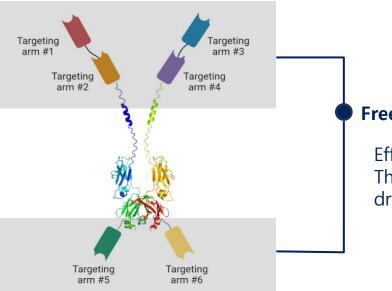
- Target to conclude two or more paid supply contracts in
 2024 (enter clinical trials)
- Preclinical trials in progress by 4 companies & securing data
- ✓ Currently actively discussing with 6 companies
- Additional discussion at the 2024 US BIO Conference



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The heterodimer hybrid Fc platform (HDHF) enhances the structural stability and immune response promotion ability of various types of multi-specific antibodies, including dual-specific antibodies

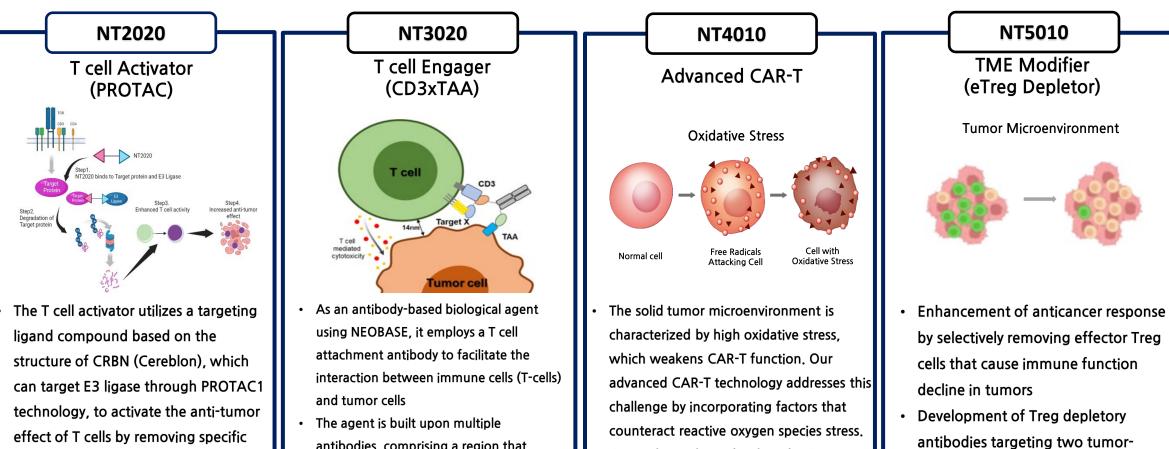
Antibody Platform Technology



Free placement of various antigen target sequences

Efficient and stable antibody development possible The rapid development of new immune-anticancer drugs possible

Immune response promotion ability and protein function enhancement platform technology Deliver new design and engineering strategies Based on world-class Fc engineering technology and T cell-based research experience, we are developing a new product that can succeed the T cell amplifier, NT-I7



Currently, we have developed a CAR-T

with target protein knockdown and are

evaluations in animal models

conducting secondary anticancer efficacy

antibodies, comprising a region that activates T cells and another region that specifically recognizes antigens expressed in cancer cells

¹⁾ Proteolysis-targeting chimeric molecule

target proteins

specific markers to reduce Tregs in

tumors

			Discovery			
Project Code	Pipeline	Indication	Target selection	Active material	Lead material	Candidate material
NT2020	T cell Activator (PROTAC)	Undisclosed				
NT3020	T cell Engager (CD3xTAA)	Solid Tumor				
NT4010	Advanced CAR-T	Solid Tumor				
NT5010	TME Modifier (eTreg Depletor)	Solid Tumor				
As of Jul 13, 2023	•			When technology n	arketing is possible	

As of Mar 29, 2024

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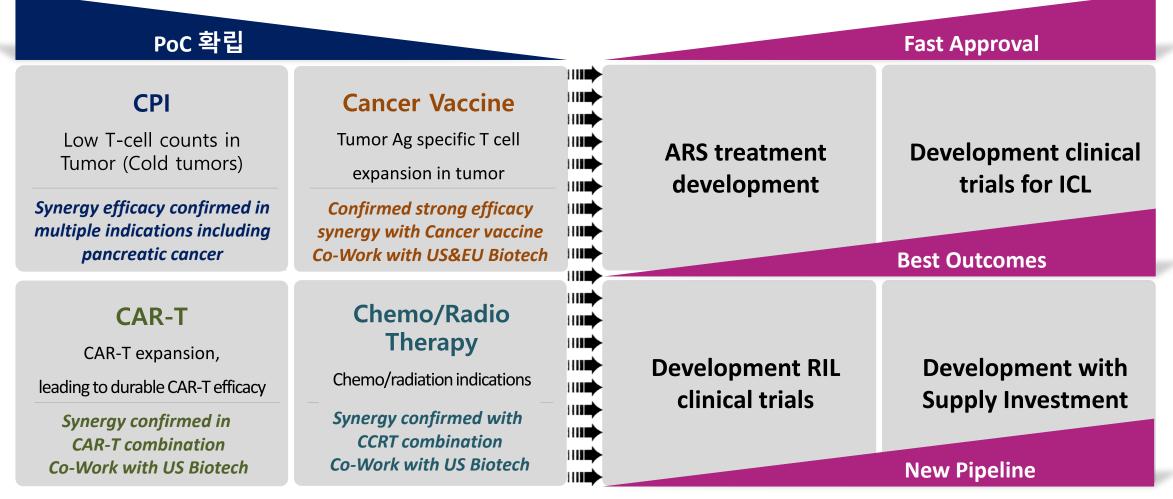
Key Message

Future direction

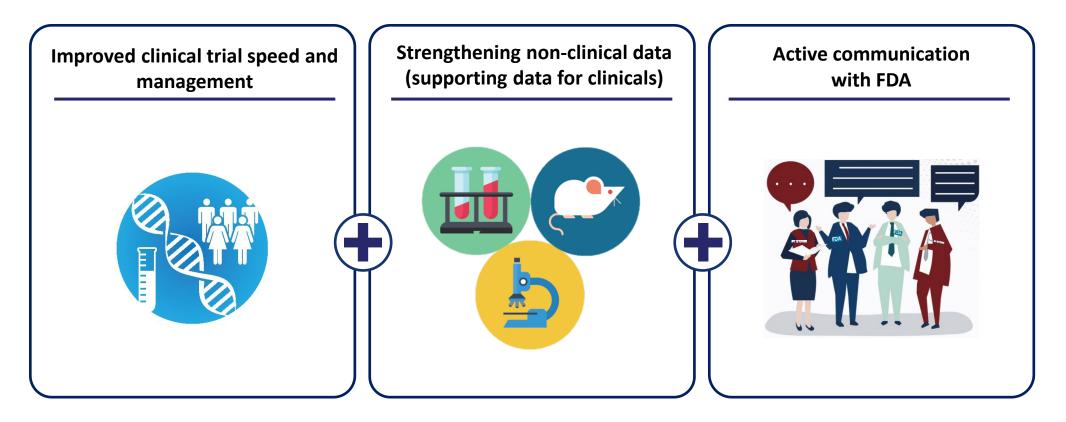
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Synergy in treatment efficacy confirmed through 14 clinical programs Redefine Business Priorities

Establishing a new Development Strategy



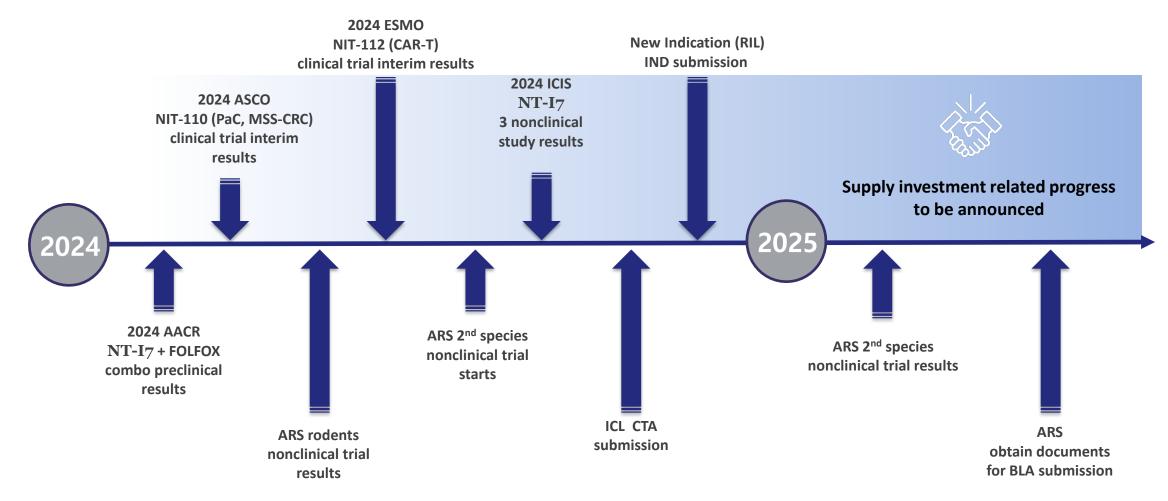
Focus more on three strategies to ensure $\mathbf{NT} extsf{-I7}$ gets approval as quickly as possible



Refining and Focusing Strategy for Fast Approval

Clinical results and ARS animal test results to be announced

Following the FDA meeting, development will be actively pursued with defined direction



- There is a possibility of change as the schedule is based on best estimates.

- It only means the expected order in which various events will occur, and the location of the arrow does not indicate the detailed timing.

Our next chapter

Ne@ImmuneTech

A pioneering pharmaceutical company dedicated to enhancing the quality of patients' lives through innovative drug development

- Drive value creation for patients and stakeholders through the development of innovative, life-transforming drugs
 - Evolve into a goal-oriented organization focused on swift approval processes and impactful outcomes
 - Enhance financial sustainability by optimizing costs and making strategic investments
 - Cultivate an organizational culture centered on genuine passion and collaborative teamwork



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