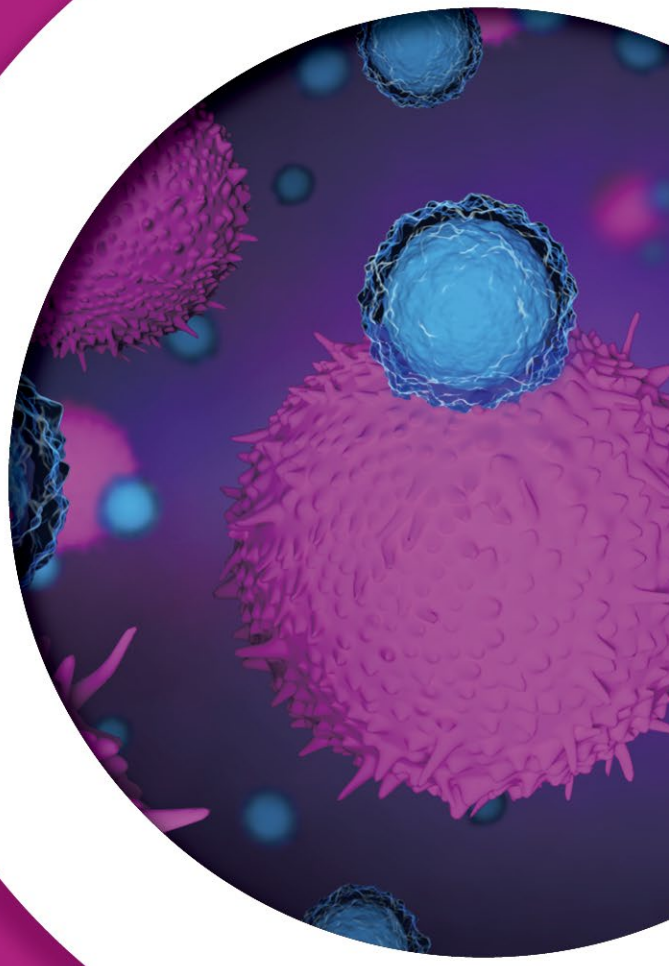
2023 NeoImmuneTech Company Presentation

New Drug Development Mid-Term Roadmap



NEOIMMUNETECH

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Agenda

Part 1. NT-I7 First Step to Commercialization

- NIT and National Institute of Allergy and Infectious Diseases (NIAID) entered into a non-clinical evaluation agreement to develop Acute Radiation Syndrome (ARS) treatment

Part 2. NT-I7 Development Status

Part 3. NT-I7 Roadmaps for Regulatory and Business Development

FAQ

Part 1.

NT-I7 First Step to Commercialization

- NIT and National Institute of Allergy and Infectious Diseases (NIAID) entered into a non-clinical evaluation agreement to develop Acute Radiation Syndrome (ARS) treatment

What is Acute Radiation Syndrome?

▪ Acute Radiation Syndrome (ARS)

- An illness affecting multiple organs following exposure to high doses of radiation. This involves destruction of rapidly dividing cells of the hematopoietic system, such as leukocytes and platelets, leading to increased susceptibility to infections
- **In preparation for a potential event involving widespread radiation exposure, the US government procures medical countermeasures for placement in the Strategic National Stockpile**

ARS medical countermeasures supported by BARDA
- Radiation/Nuclear related medicine[1)]

- Neutrophils[2)] - Neupogen® (Amgen), March 2015 approved
- Neutrophils - Neulasta® (Amgen), November 2015 approved
- Neutrophils - Leukine® (Sanofi), April 2018 approved
- Platelets - Nplate® (Amgen), January 2021 approved
- **Lymphocyte[2)] – There is no T cell amplifying treatment**

[1)] Medical countermeasures.gov. FDA APPROVALS, LICENSURES, & CLEARANCES FOR BARDA SUPPORTED PRODUCTS
[2)] A type of leukocytes

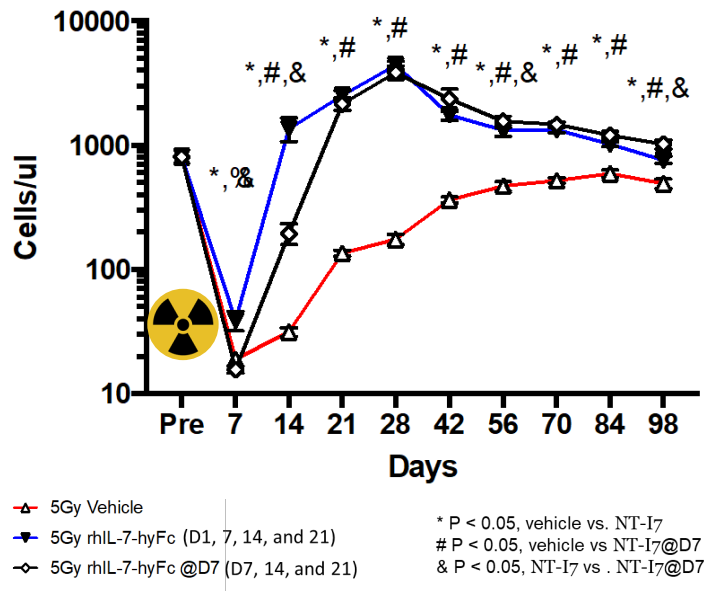
Overview of ARS agreement and anticipation

Contract Process	• **Generation of preclinical ARS data with Duke University (since 2019)** • **Meetings with multiple US government agencies including NIH/NIAID, BARDA, FDA, CDC, Department of Defense (DOD) and NASA** • **NIT executes Agreement with NIAID (Dec 2022)**
Sponsor	• National Institute of Allergy and Infectious Diseases (NIAID)
Contents	• Collaborate to execute pre-clinical studies (clinical trials on humans not possible) • **NIAID supports pre-clinical studies, NIT supplies NT-I7**
Experiment Purpose	• When exposed to radiation, there is no therapy to restore T cells • Confirm whether NT-I7 significantly decreases morbidity/mortality following radiation exposure
Expected Effect	• **Opportunity to sign a large-scale supply contract with the US government** • **Expansion of clinical development in immuno-oncology using revenue made from the ARS pipeline** • **As an approved drug for ARS, we expect the regulatory process for other indications to accelerate**

NT-I7 efficacy following irradiation

- Rapid recovery of T cells is a key requirement for improving health following radiation exposure
- In preclinical and clinical trials, NT-I7 amplifies T cell numbers following irradiation

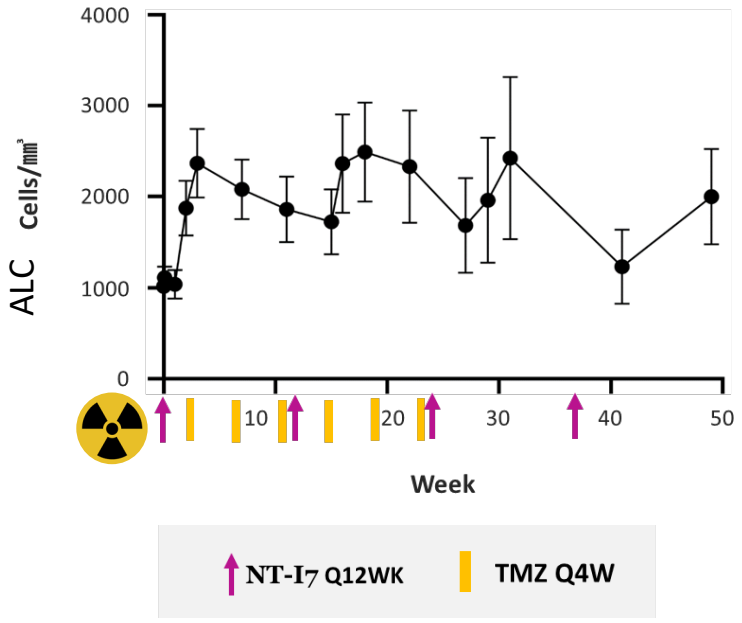
Pre-clinical study result:
CD8⁺ T cell increases in the blood



- The total-body-irradiation in a mouse model
- The control group took 2~3 months to recover
- The NT-I7 administration group fully recovered within 2-3 weeks

Radiation Injury Treatment Network 2022,
Radiation Research Society 2022

Clinical trial result:
absolute lymphocyte count increases



- Glioblastoma patients
- Rapid lymphocyte* recovery from NT-I7 administration

*T cells are a type of lymphocyte

SITC 2022, NIT-107

Case study: The HHS buying ARS treatment

- The United States purchased $290M worth of Amgen's Nplate for ARS treatment (October 2022)

Seeking Alpha

HHS buying $290M worth of Amgen drug Nplate for radiation sickness in nuclear emergency

Oct. 04, 2022 6:24 PM ET | **Amgen Inc. (AMGN)** | By: Jonathan Block, SA News Editor | 14 Comments

- HHS is purchasing $290M worth of Amgen's (NASDAQ:AMGN) Nplate (romiplostim) for acute radiation sickness due to a radiological or nuclear emergency.
- The treatment was developed by the cor
  Advanced Research and Development A
  Infectious Diseases.
- Nplate is approved for immune thromocy
  platelet counts.

FIERCE Pharma

Sign of the times? US stocks up on Amgen's radiation sickness drug Nplate

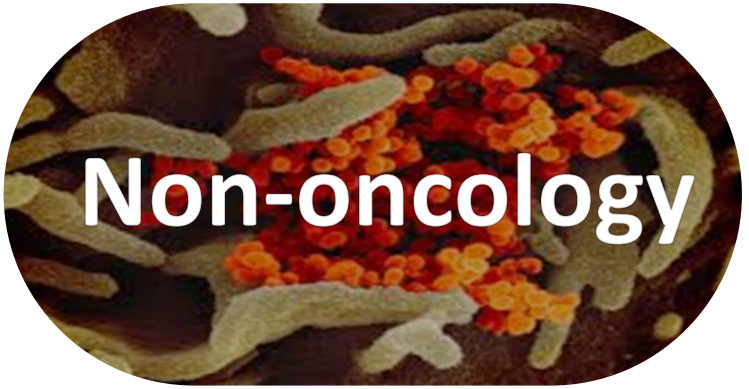
By **Fraiser Kansteiner** • Oct 5, 2022 11:09am

Wednesday, the U.S. Department of Health and Human Services (HHS) said it's throwing down $290 million to lock up an undisclosed amount of Amgen's blood disorder med Nplate, which is approved to treat blood cell injuries linked to acute radiation syndrome (ARS) in kids and adults.

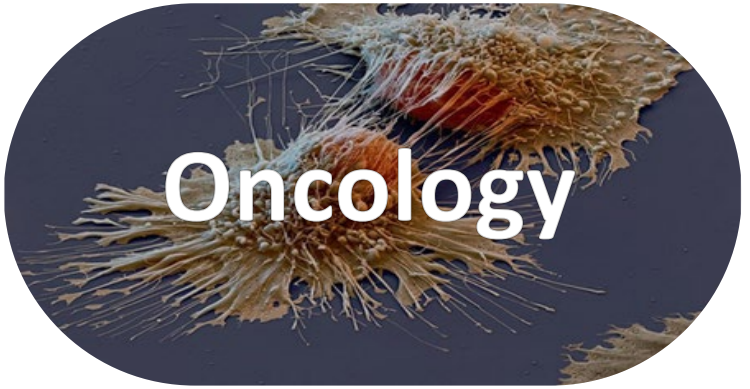
ARS development: Next steps and timeline

Step	To-do	Contract party
1st	• Pre-clinical studies using rodent models • Confirm T cell amplification	National Institute of Allergy and Infectious Diseases
2nd	• Pre-clinical studies using non-human primate models • Confirm T cell amplification and decreased morbidity/mortality • **Medical Countermeasures (MCM) FDA approval**	Biomedical Advanced Research and Development Authority
3rd	• **Contract for the Strategic National Stockpile** • Supply to the US government	The U.S. Department of Health and Human Services

Development strategy: Parallel studies



- ARS development –
  US governments
- Unique solution for lymphopenia

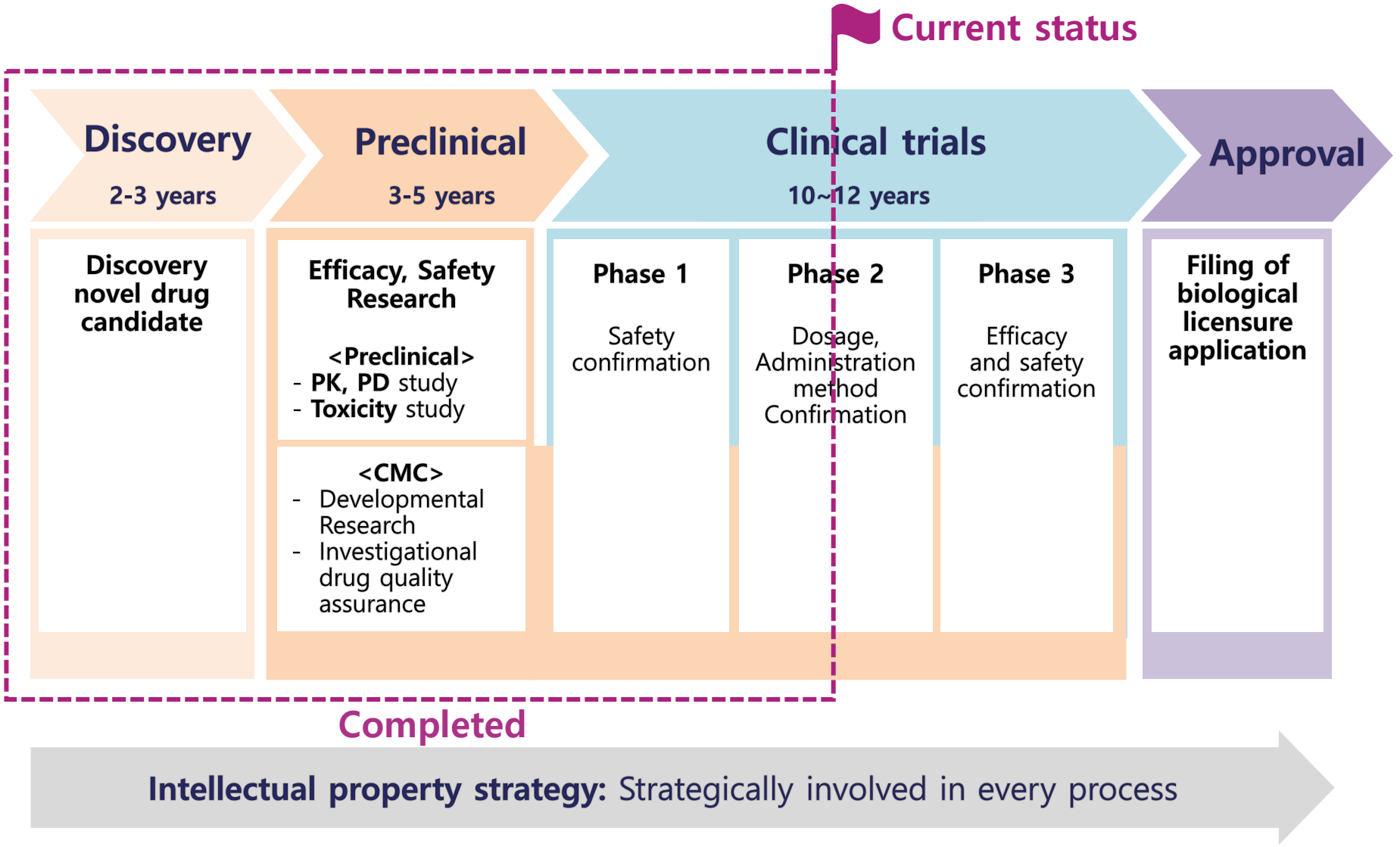


- Oncology drug development –
  Global pharma companies
- Unique position as a T cell
  amplifier

Part 2.

NT-I7 Development Status

New drug development pathway and present



Key milestones in NT-I7 development

☑	ALC increases	+3x increase (from 600+ patients)
☑	Tscm	25-50x amplification
☑	TIL	T cell amplification in cancer tissues
☑	Anticancer effect	Confirm the anticancer effect
☑	Biomarker	An increase in the response rate of a specific group
☑	ORR/OS	Confirmed in some indications
☐	Pivotal design	
☐	Pivotal trial	
☑	ODD	Orphan Drug Designation
☐	Fast track/BTD/AA	Breakthrough Therapy Designation
☐	BLA	
☐	Approval	

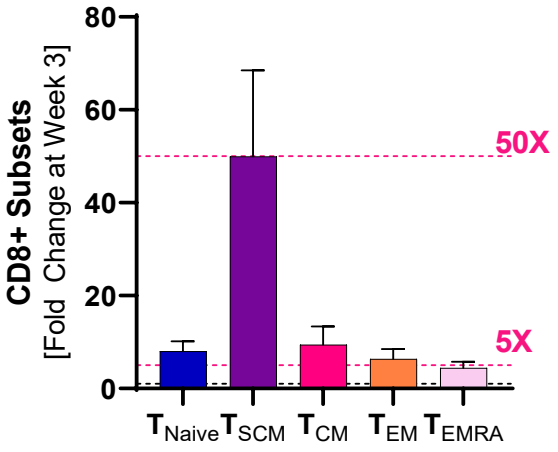
Clinical

Regulatory

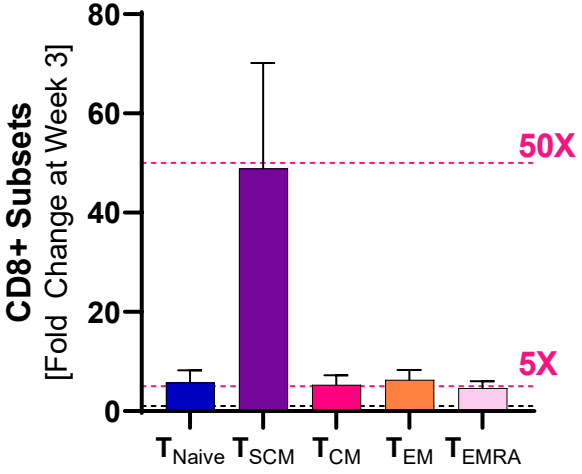
1. T cell amplification: Tscm increase

- Tscm (stem-cell like memory T cell), the most effective anticancer T cell subset, increased by 25-50-fold
- So far, no other molecule/substance that can amplify Tscm up to 25-50 fold has been reported

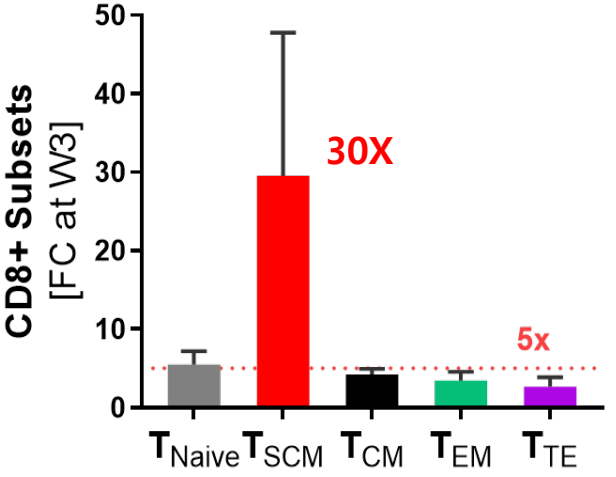
MSS-CRC[1)]



PaC[2)]



Skin cancer[3)]



1) SITC 2021, NIT-110
2) SITC 2021, NIT-110
3) ASCO 2022, NIT-106

2. T cell amplification: TIL increase

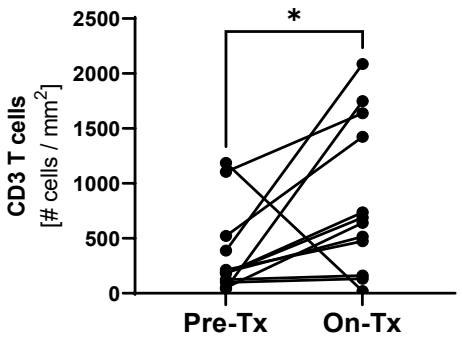
Keytruda + NT-I7 combo

- Increased CD8+ T cells (TIL*) in the tumor microenvironment in more than 80% of patients in immunologically cold indications
- After first administration, more than 5-fold increase in CD8+ T cells in more than 50% of patients

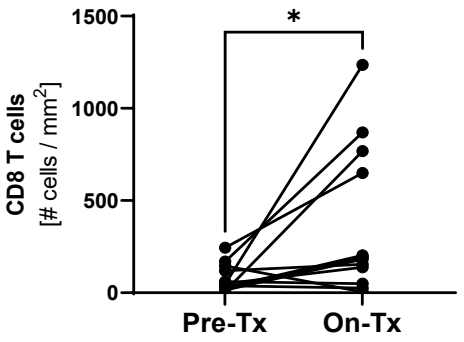
*TIL: Tumor Infiltrating Lymphocytes

Immunofluorescence

CD3 T cells

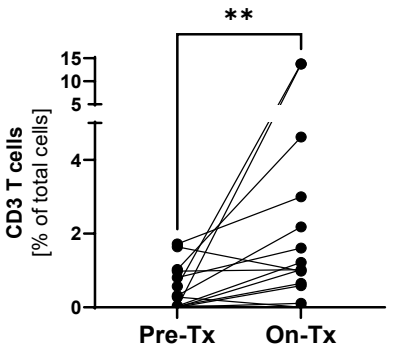


CD8 T cells

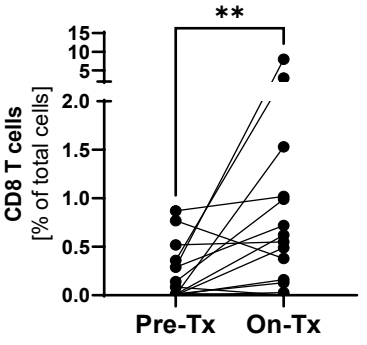


Flow cytometry

CD3 T cells



CD8 T cells

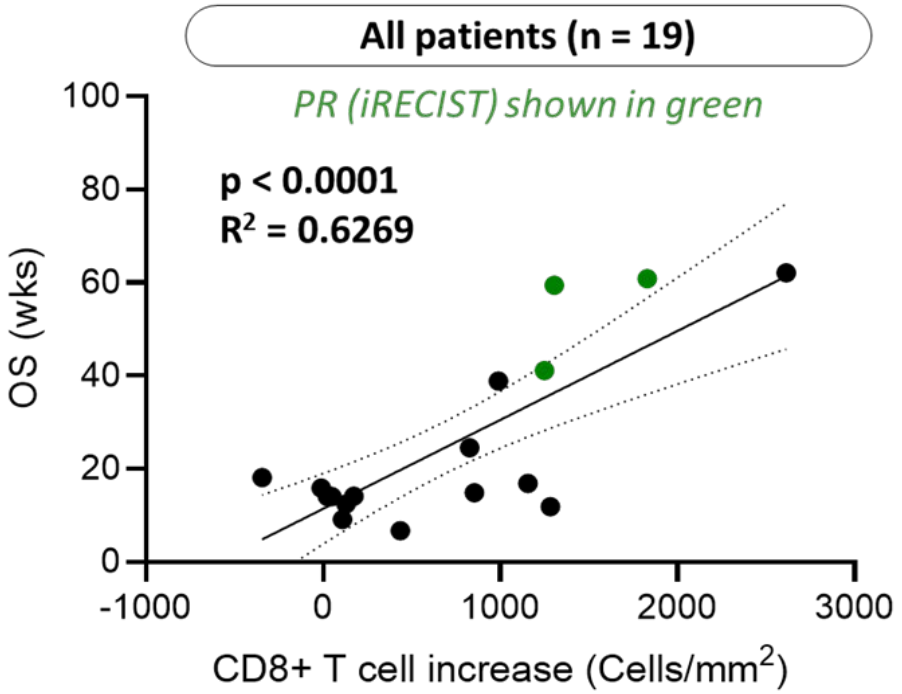


* p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001

ESMO 2022, NIT-110

3. Anticancer efficacy: Correlation with OS

- Increased CD8⁺ T cells correlate with higher overall survival

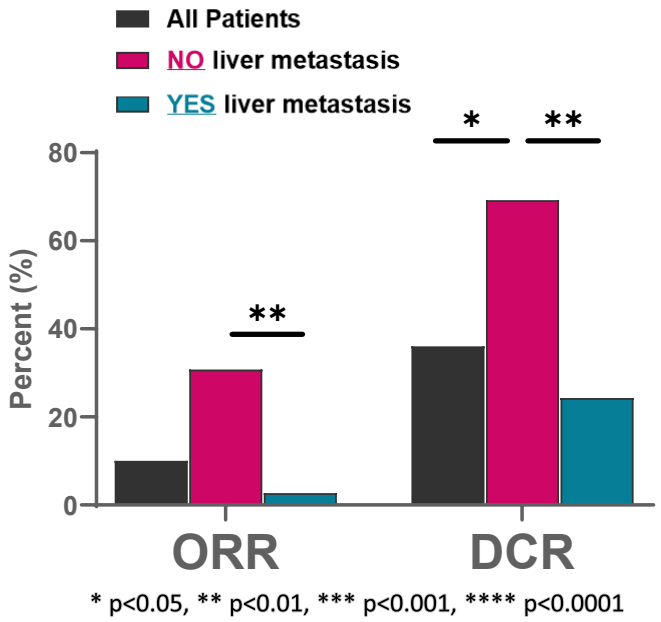


Simple linear regression, n = pts with available CD8⁺ T cell IHC data

SITC 2022, NIT-110

4. Anticancer efficacy: ORR

- ORR and DCR show significant differences depending on the presence or absence of liver metastasis[1)]
- In the absence of liver metastasis, the combined ORR of PaC and MSS-CRC was 30.8% and DCR was 69.2%.



n=50 (Pac, MSS-CRC)	ORR [% (n/total n)]		DCR [% (n/total n)]	
	RECIST v1.1	iRECIST	RECIST v1.1	iRECIST
NO liver metastasis (n=13)	**15.4% (2/13)**	**30.8% (4/13)**	**53.9% (7/13)**	**69.2% (9/13)**
YES liver metastasis (n=37)	0.0% (0/37)	2.7% (1/37)	21.6% (8/37)	24.3% (9/37)

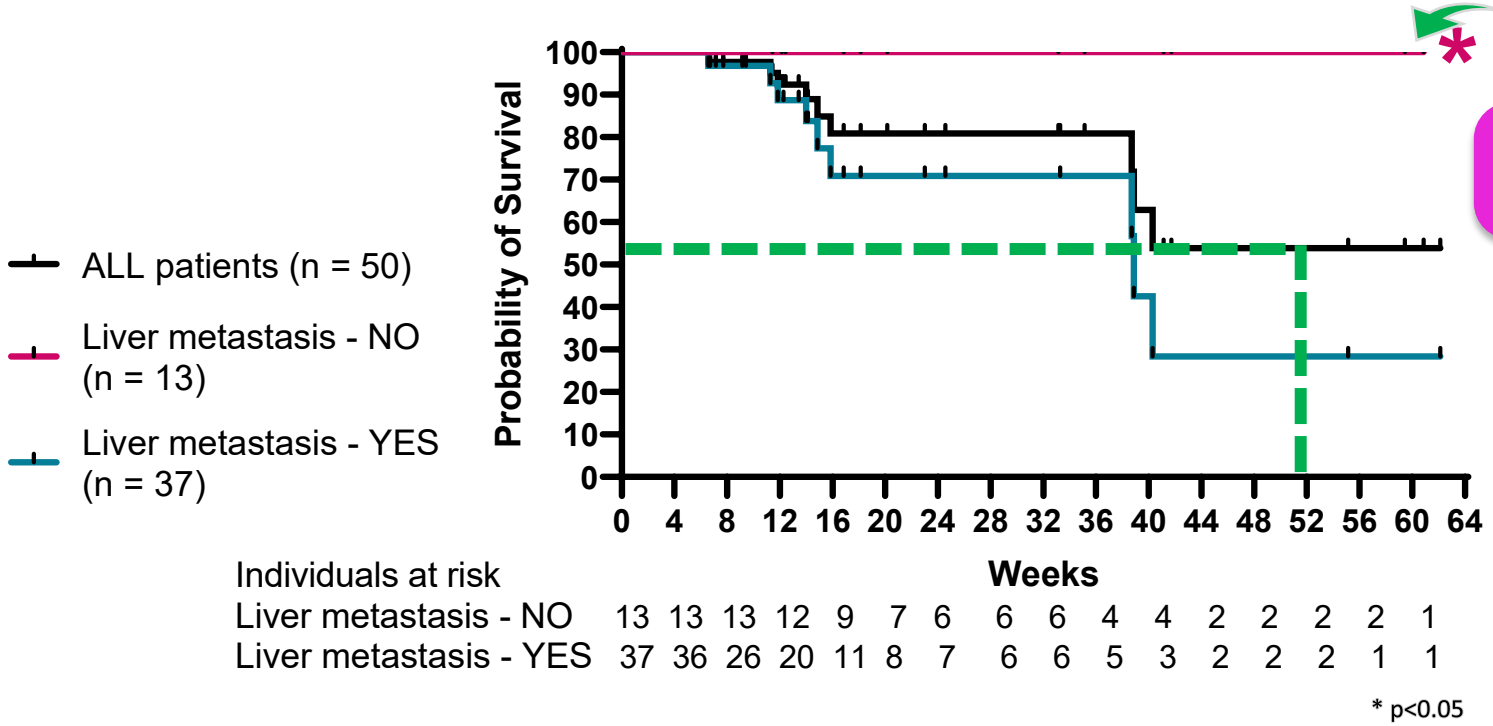
Historical ORR with anti-PD(L)1 monotherapy in these indications is 0% [2), 3)]

1) SITC 2022, NIT-110
2) KEYNOTE-016. Le DT et al., PD-1 Blockade in Tumors with Mismatch-Repair Deficiency (2015) N Engl J Med
3) O'Reilly et al., Durvalamab with or without Tremelimumab for patients with metastatic pancreatic ductal adenocarcinoma (2019) JAMA Oncol

5. Anticancer efficacy: Survival (solid tumors)

- Among the patients without liver metastasis, the probability of survival rate through 60 weeks (approx.15 months) was 100%, which is significantly higher than in those with liver metastasis

MSS-CRC (25) + PaC (25)



SITC 2022, NIT-110

Significance of liver metastasis as a biomarker candidate

Biomarkers of immunotherapy

- Response to immunotherapy drugs applies to limited patients
- Predictive biomarkers are needed to identify patients with higher likelihood of responding to immunotherapy
- Existing predictive biomarkers: PD-L1, MSI-H

Liver metastasis as biomarkers

- Liver metastasis as a potential biomarker is still being studied
- Metastasis spreads to various organs such as the lungs, liver, bones, and brain
- In case of cytotoxic drugs, stage of the metastasis is more important than the organs affected by metastasis
- In the case of immunotherapy, recent reports indicate that efficacy is lower when the metastasis is to the liver

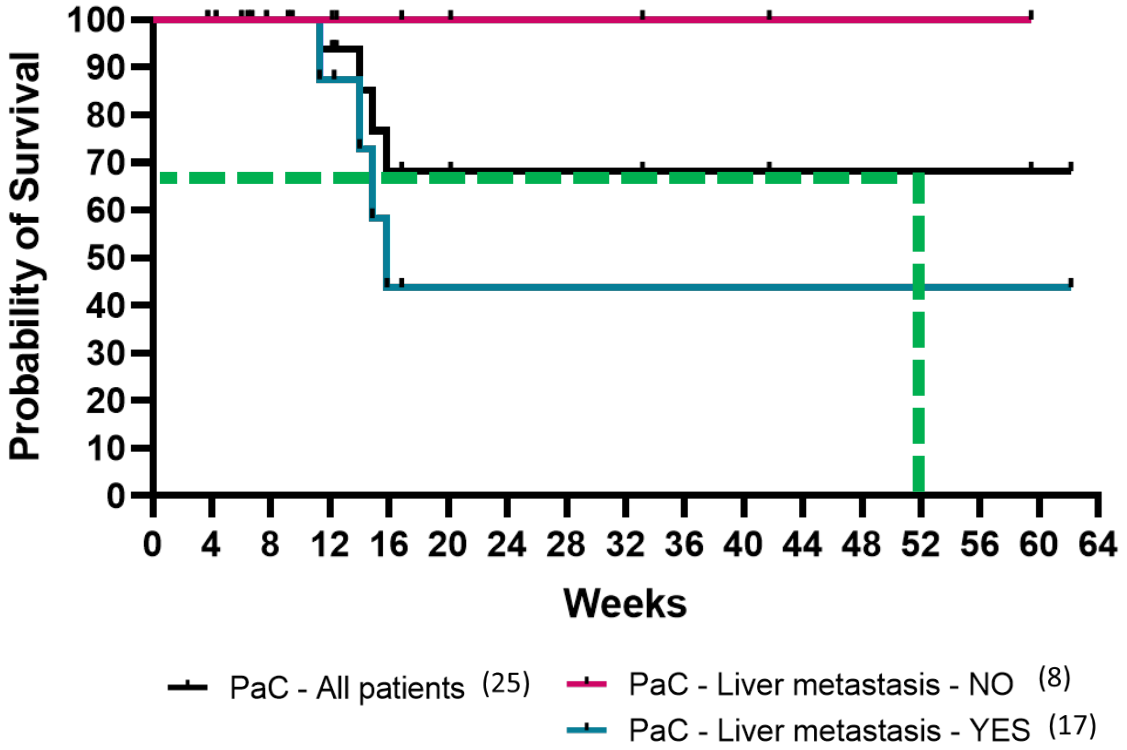
Future plans

- In the case of Keytruda + NT-I7, a significant difference is observed depending on whether there is metastasis in the liver or not.
- Plan to discuss with the FDA after obtaining additional data of predictive biomarkers as an adjunctive tool

5.1 Anticancer efficacy: Survival rate (PaC)

- In total patients with PaC, Keytruda + NT-I7 combo showed a 1-year survival rate of 65% to 70%
- mOS to be confirmed in 2023

Keytruda+NT-I7 Combo



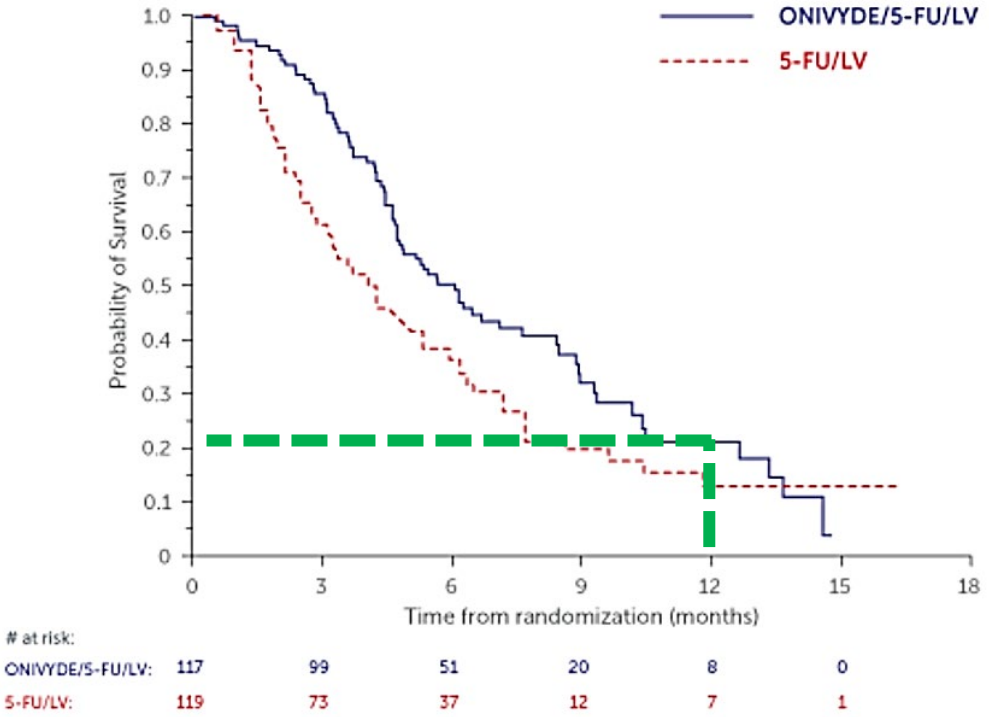
1 year survival rate 65~70%

SITC 2022, NIT-110

5.1 Anticancer efficacy: SoC comparison (PaC)

- Onivyde combination therapy, a standard for 2L+ treatment, showed a 1-year survival rate of approx. 23% (mOS 6.1 months)

ONYVYDE Combo



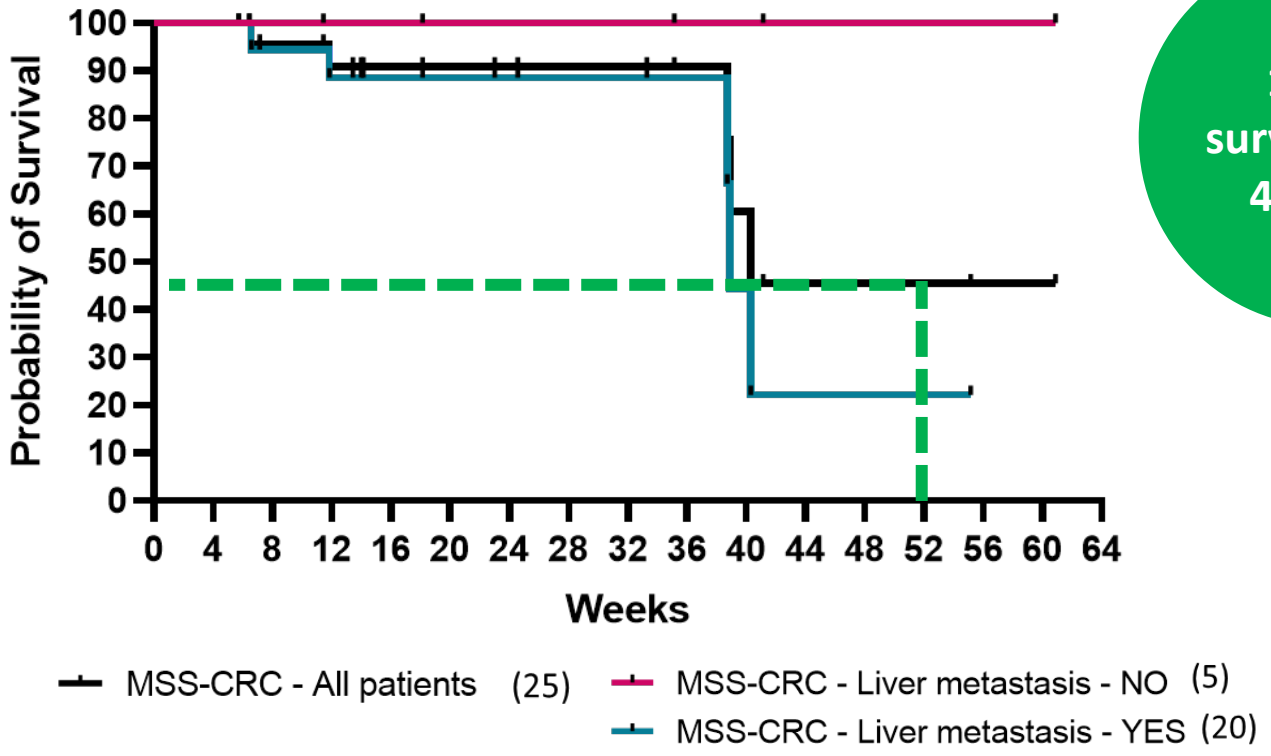
1 year survival rate approx. 23%

FDA Label

5.2 Anticancer efficacy: Survival rate (MSS-CRC)

- **In patients with MSS-CRC,** Keytruda + NT-I7 combo showed a 1-year survival rate of 40% to 50%
- mOS to be confirmed in 2023

Keytruda + NT-I7 Combo



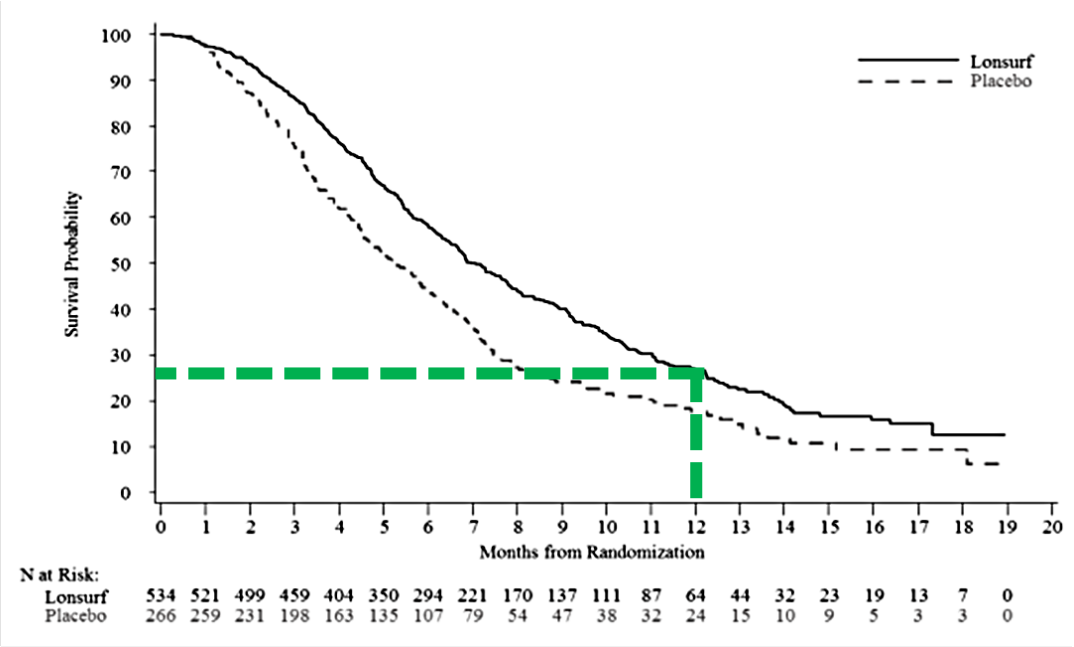
1 year survival rate 40~50%

SITC 2022, NIT-110

5.2 Anticancer efficacy: SoC comparison (MSS-CRC)

- LONSURF, a standard for 3L+ treatment, showed a 1-year survival rate of 20% to 30% (mOS 7.1 months)

LONSURF Mono-therapy



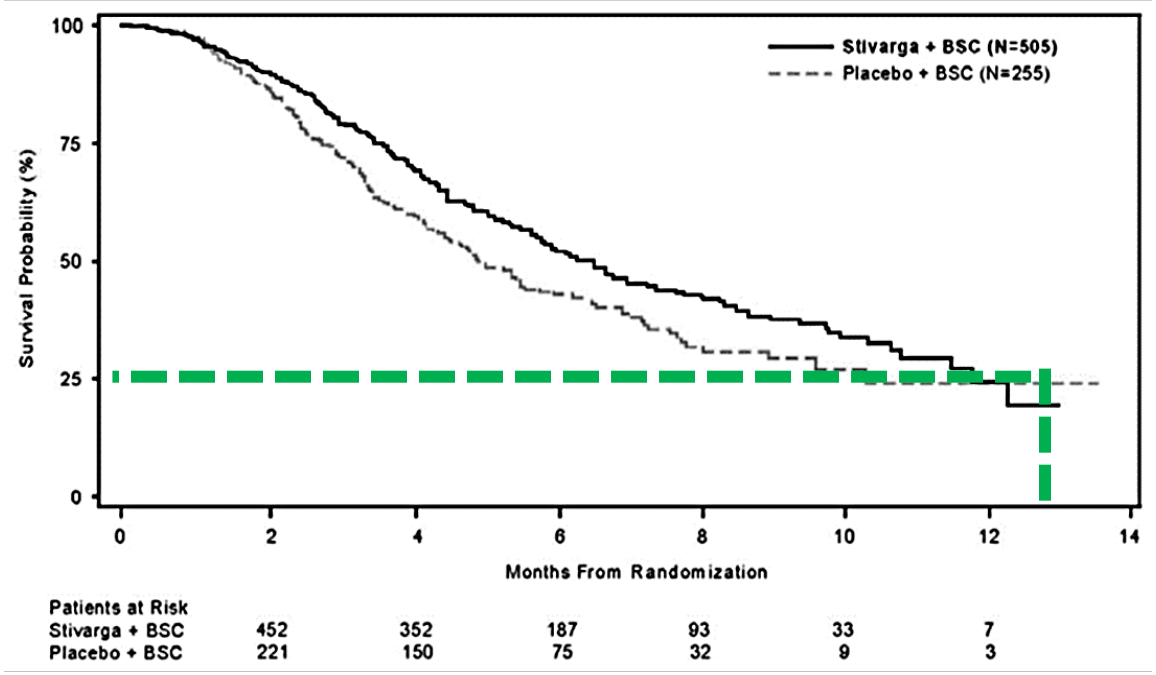
1 year survival rate approx. 27%

FDA Label

6. Anticancer efficacy: SoC comparison (MSS-CRC)

- STIVARGA, a standard for 3L+ treatment, showed a 1-year survival rate of a approx. 25% (mOS 6.4 months)

STIVARGA Mono-therapy



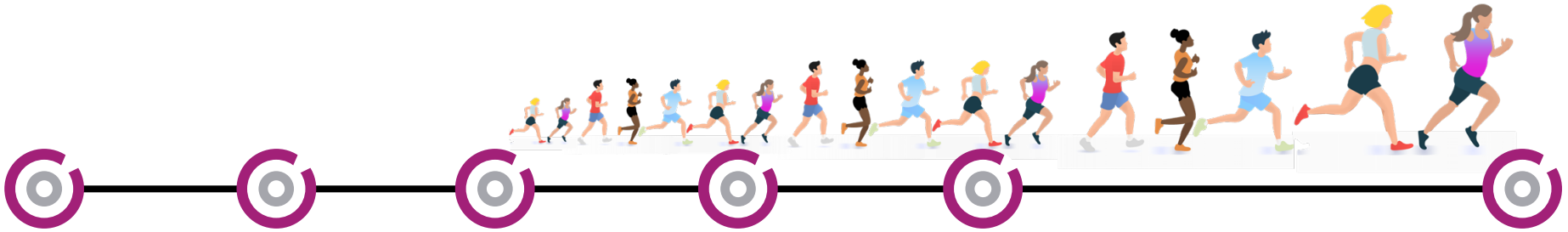
1 year survival rate approx. 25%

FDA Label

Two approaches to anticancer drug development

	Short term anticancer effect	Mid to long term anticancer effect
Authorization method	Accelerated Approval (some hard-to-treat cancers)	Approval (all cancers)
Main indicator	ORR	OS
Characteristics	Evaluate the cancer size reduction in early stage	Evaluate the overall survival over the entire treatment cycle
Appropriate mechanism	Quickly and directly destroy cancer cells (Short-term effect)	Consistently and sustainably destroy cancer cells (long-term effect)

Development of an anticancer drug is a marathon



0 5km 10km 15km 20km 42.195km

ORR **OS**

- **Language in marathon**
  Imagine that a trophy is given to a first person who passes the 5km checkpoint. The assumption would be that the first runner at the 5km checkpoint is likely to be the winner in the final. However, if you do not win the marathon (42.195 km), the trophy will be taken away.
- **Language in immunotherapy**
  An Accelerated Approval is given when the ORR goal is reached. However, a satisfied OS value is required from a phase 3 clinical trial. If phase 3 fails to statistically demonstrate an increase in OS, the therapy must be withdrawn from the market.

ILLUSTRATIVE

NT-I7 is advantageous for OS increase

1. Amplification effect of immune-specific T cells

- Directly attack cancers by invading cancer tissues (slowly for a long time)

2. Amplification effect of non-specific immune T cells (1) – additional effect

- Indirect induction of bystander effects after invading cancer tissues
  → In previous reports, many T cells entering cancer tissues are tumor non-specific
  → Plans to analyze the quantities of all nonspecific immune T cells from our studies

3. Amplification effect of non-specific immune T cells (2) – additional effect

- Some cancer patients die from infections
  → Amplified T cells in patients can prevent/suppress infectious diseases that causes deaths

NT-I7 development: Ways to simultaneously increase ORR and OS

- There are many approved drugs that increase ORR are on the current market
- Limited candidates are available to increase OS

- Radiation treatment
- Chemical treatment
- Targeted treatment
- **T cell activator**
- **Anti-VEGF**
- Immune-checkpoint inhibitor

+

- **T cell amplifier**

The best combination therapy partner for OS improvement

ILLUSTRATIVE

Part 3.

NT-I7 Roadmaps for Regulatory and Business Development

Macro environment changes in immunotherapy

- T cell activator IL-2, which was a leading candidate for next-generation Keytruda, announced the failure of clinical development in 2022
- The importance of T-cell amplifier is highlighted on the back of limitations of other groups

2014 — **Keytruda and Opdivo approved**

2018-2022

Nektar (IL-2) L/O to BMS

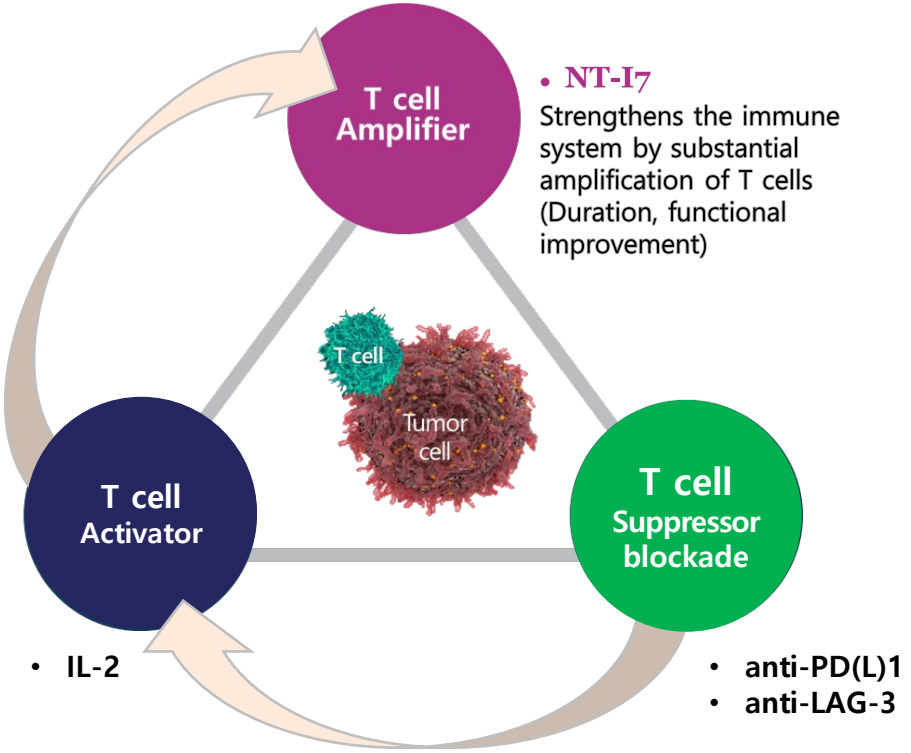
BMS and Nektar end cancer drug alliance after two more **clinical trial failures.** Mar 2022

Synthorx (IL-2) L/O to Sanofi

In wake of BEMPEG blowup, Sanofi rethinks $2.5B bet on **IL-2 after midphase efficacy falls short.** Oct 2022

2022 — **Opdualag approved (anti-Lag-3)**

2023 — **NT-I7 (T cell amplifier)**
- **Initiated development of ARS treatment**
- **Target to enter clinical trials as immunotherapy**



Prioritizing indications

1st Condition.
Is there minimal competition?

2nd Condition.
Is this the right fit to NT-I7?

3rd Condition.
Can speed up clinical trials?

Priority of the indication candidates

Top Tier

- GBM 1L
  (Glioblastoma/Brain Cancer)
- MSS-CRC +3L
  (Microsatellite Stable Colon Cancer)
- PaC +2L
  (Pancreatic Cancer)

2nd Tier

- Other CAR-T related indications

Priority indication: GBM (1L)

1st Condition.
Is there minimal competition?

- Chemo/radiation therapy after surgery is the only 1L treatment
- There have been several clinical trials, but all have failed

2nd Condition.
Is this the right fit to NT-I7?

- T-cell deficiency increases mortality. NT-I7 amplifies T cells in patients.
- SoC (Chemo/Radiation) + NT-I7 injection →PFS and OS increase

3rd Condition.
Can speed up clinical trials?

- Relatively few numbers of ongoing competitive clinical trials
- Clinical trials are actively led by PIs (such as Dr. Campian at Mayo Clinic)
- Unmethylated GBM with poor prognosis, has short survival of 13 months

Approval roadmap: GBM

1. <u>Accelerated Approval (AA)</u>
- **SOC + NT-I7**
- **PFS**

or

2. Ph.3
- **SOC vs SOC + NT-I7**
- **OS**

- Double blind randomized
- 10 (SOC + placebo) vs 10 (SOC + NT-I7)
- <u>FDA meeting planned in 2023</u>
- Final Decision with FDA: AA or BTD

1b Complete → **2a Ongoing** → **Registration trial**

2a expansion → **Registration trial**

- Dose escalation study
- RP2D confirmed
- OS increase confirmed
- ODD granted (FDA)

- Unmethylated GBM only
- 31 pts
- SOC + NT-I7 only
- Evaluation of PFS and OS

Priority indication: PaC (+2L), MSS-CRC (+3L)

1st Condition.
Is there minimal competition?

- The standard of care for both PaC and MSS-CRC is mainly chemotherapy
- 98-99% of PaC and 85-95% of CRC are MSS type with poor treatment prognosis
- There have been several clinical trials such as Keytruda, but all have failed

2nd Condition.
Is this the right fit to NT-I7?

- As representative cold tumors, low numbers of T cells are in tumor tissues
- Keytruda + NT-I7 combination shows the results of T cell amplification and OS increase

3rd Condition.
Can speed up clinical trials?

- Relatively few numbers of ongoing competitive clinical trials
- Clinical trials are actively led by PIs (such as Drs. Naing and Kim at Mayo Clinic)
- Both MSS-CRC and PaC have a survival rate of less than one year by SoC

Approval roadmap: PaC/MSS-CRC

- 6 types of solid tumors, total 135pts
- MSS-CRC 25pts, PaC 25 pts
  → OS increase confirmed
  → ORR increase confirmed
  → Liver metastasis association confirmed

1. Accelerated Approval (AA)
- Keytruda + NT-I7
- ORR/DCR/DOR
- Biomarker

or

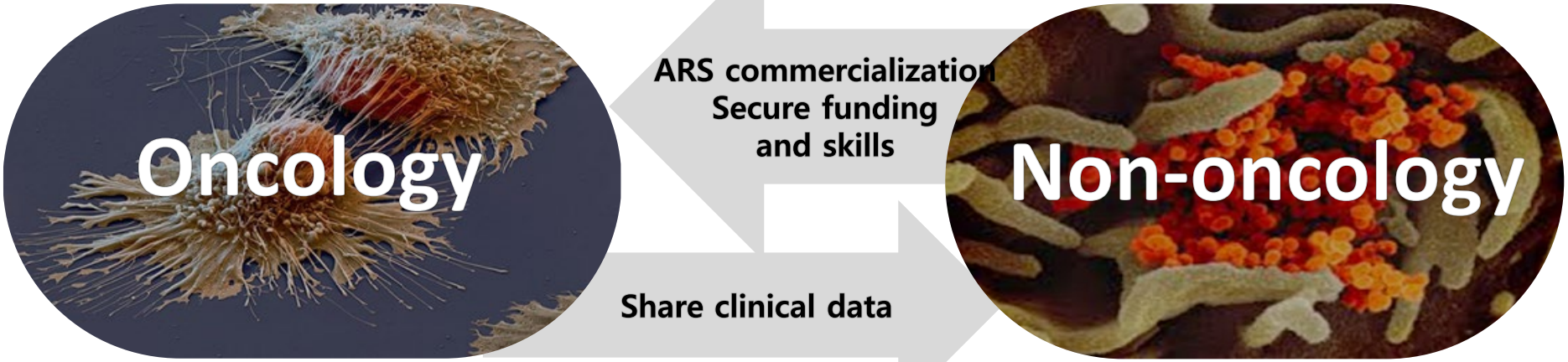
2. Ph.3
- SOC vs Keytruda + NT-I7
- OS

- Keytruda + NT-I7
- Dose escalation study
- RP2D confirmed

- Cohort expansion: addition of MSS-CRC 25pts and PaC 25 pts
  → 50 patients for each indication, total 100 patients for 2 indications
- Liver metastasis + Addition of other biomarker assay results
- ORR assessment planned, evaluation of 1-year survival rate
- FDA meeting planned in 2023
- Final decision with FDA: AA or BTD

Commercialization: Oncology & non-oncology

- Virtuous cycle structure is expected after ARS commercialization



- **Solid tumor**
- Blood cancer

Indication, combo, line of therapy, etc.

Market expansion

- **ARS**
- Infectious disease

Unmet needs are huge

and rapid regulatory review

Timing of partnership

Early-stage licensing

- Discovery - Ph.2a (Proof of concept)
- Fast ways to generate revenue
- Relatively low valuation
- More than 90% of contracts are backed out or withdrawn
- Possibility of buy & kill

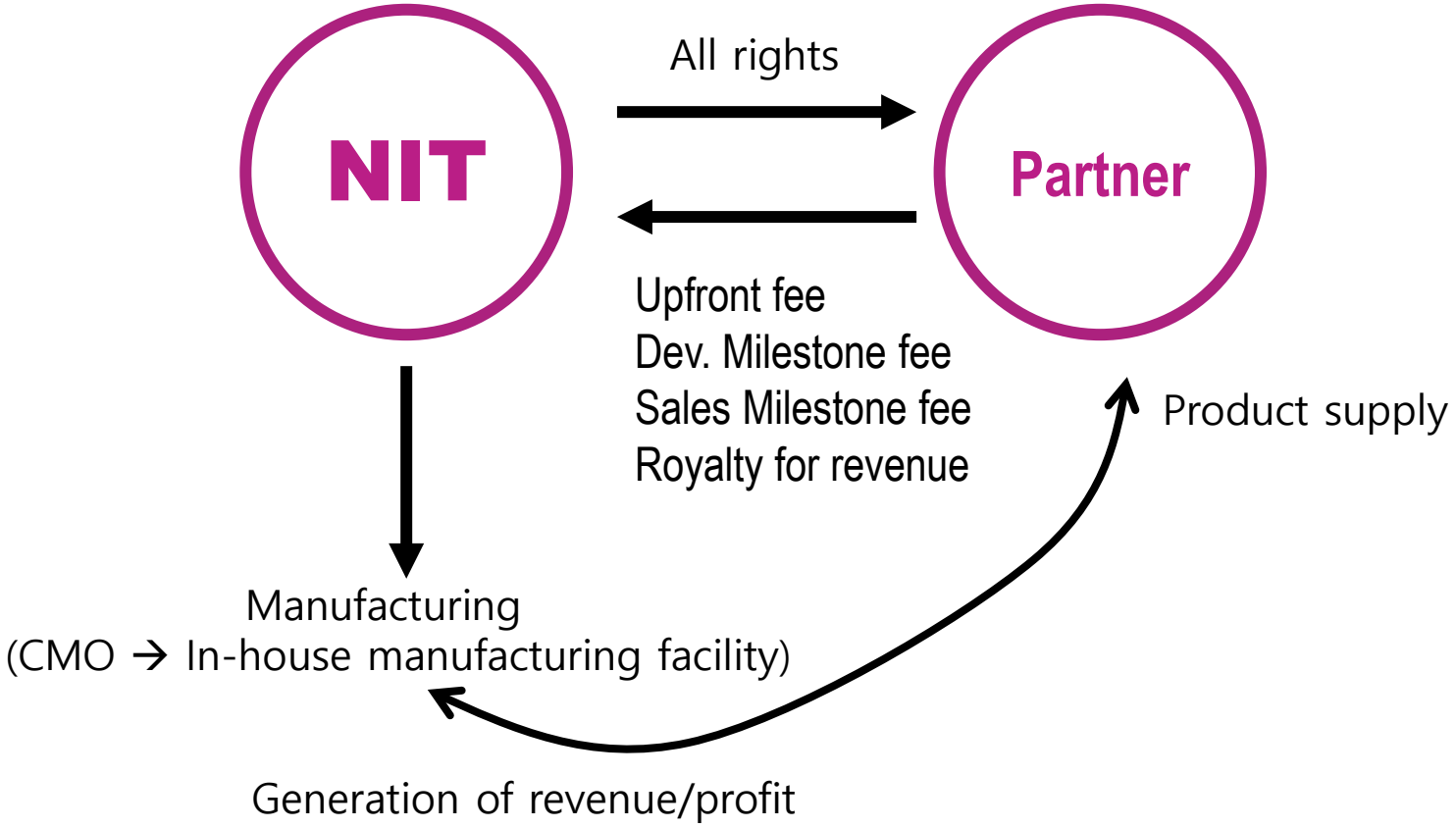
Late-stage licensing

- Ph.2 (Pivotal) - After approval
- Great ways to increase revenue
- Relatively high valuation
- More likely to continue receiving approvals and royalties
- Requires own manpower, money and time

Partnership options

1. All rights

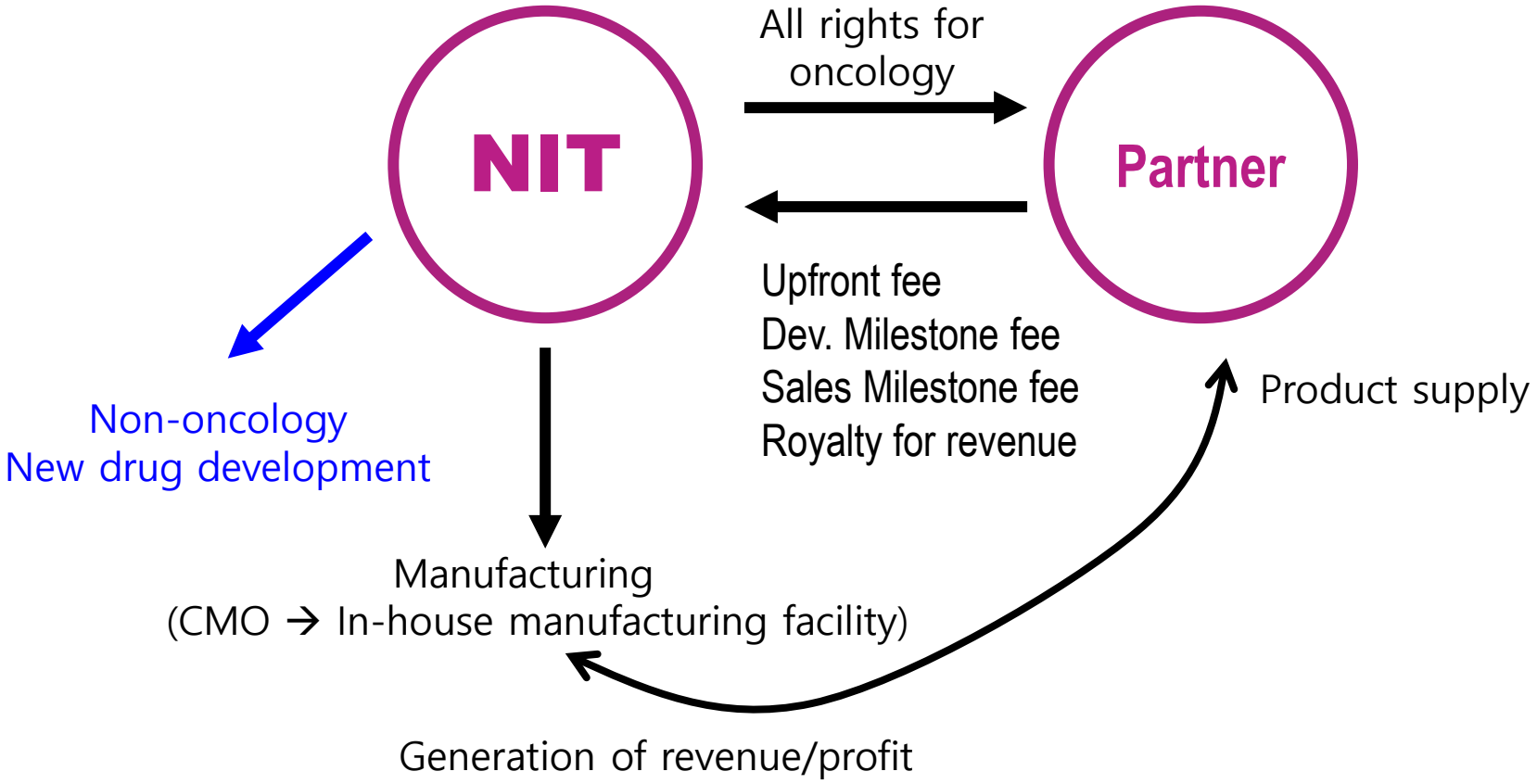
- Grant all rights (except for manufacturing rights)
- Hold manufacturing rights, development milestones and royalties per revenue



Partnership options

2. All rights for immunotherapy indications

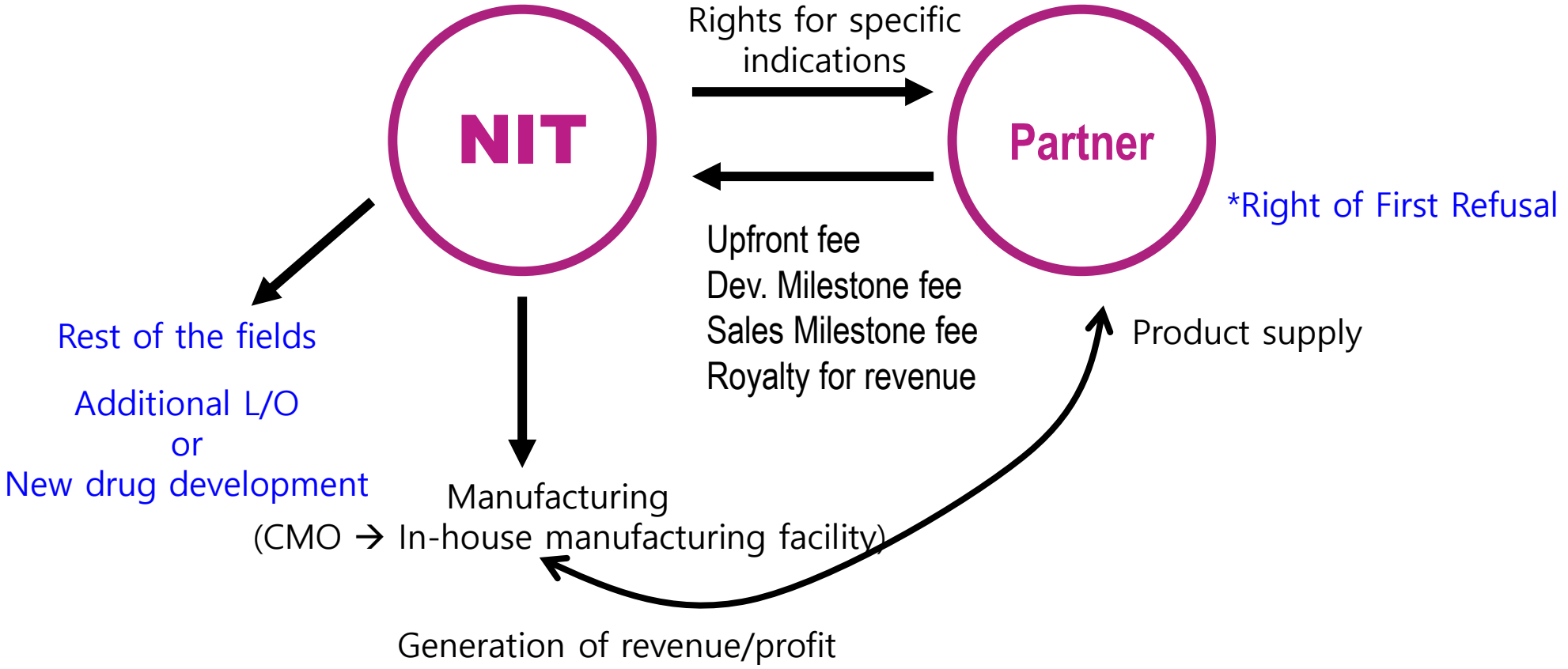
- Hold non-oncology rights (except for manufacturing rights)
- Revenue from product supply and development milestones and royalties per revenue + revenue from non-oncology rights revenue



Partnership options

3. Partnerships with specific combination product

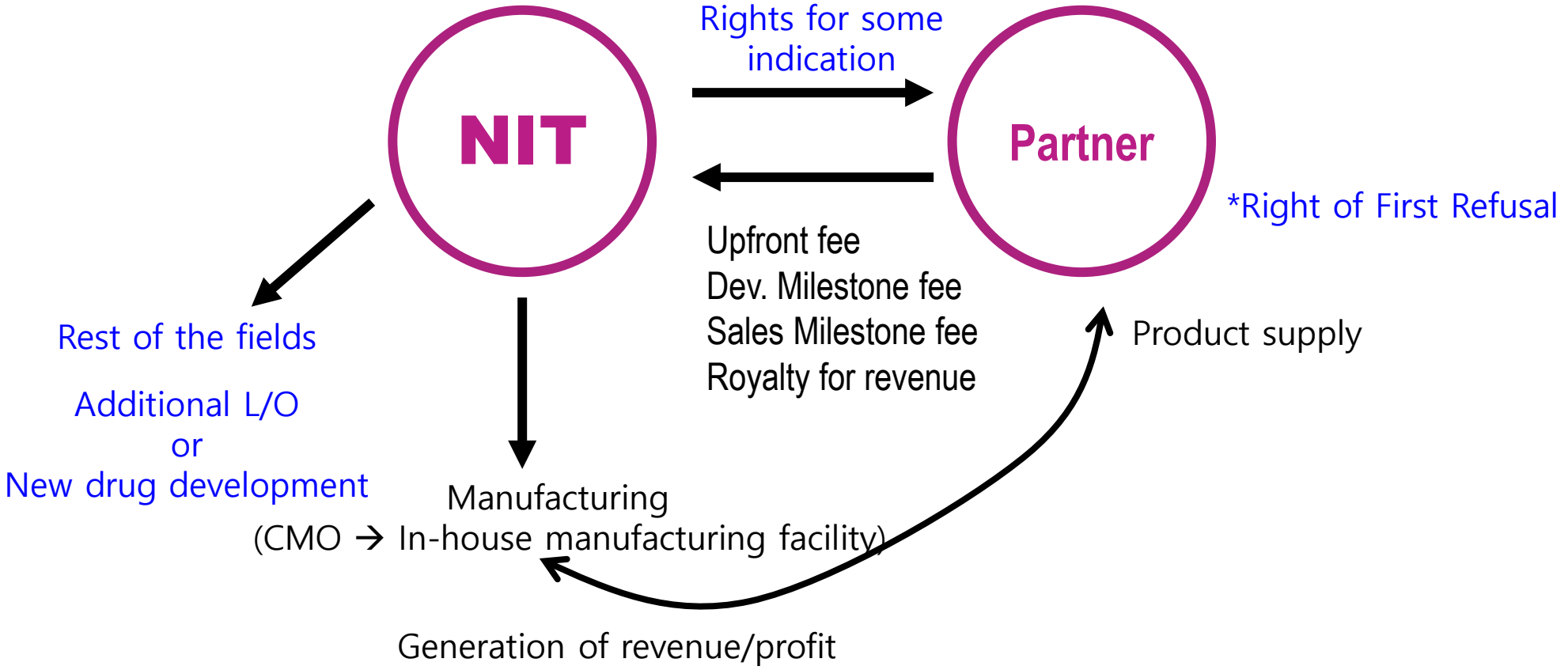
- Exclusive agreement for CPI or CAR-T
- Revenue from product supply and development milestones and royalties per revenue + revenue generation from held rights



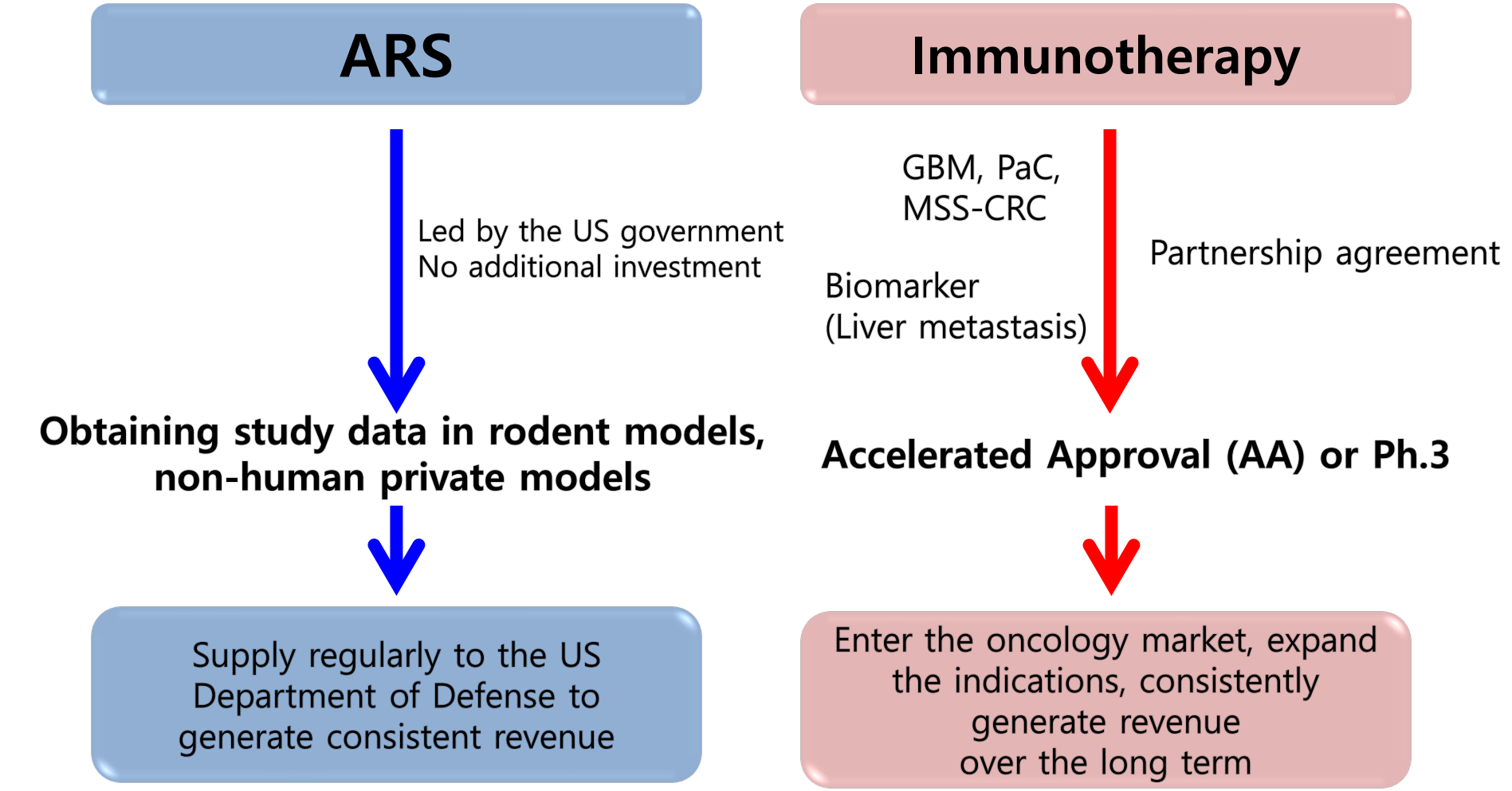
Partnership options

4. Rights for specific indications

- Grant development and commercialization rights for some indications
- Revenue from product supply and development milestones and royalties per revenue + revenue generation from held rights



Overview of commercialization strategy



Upcoming major events in 2023

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

* Plans are subject to change

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THANK YOU

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