

ImmuniT Research Inc.

**Maximize enterprise value through our novel
anti-cancer immunotherapy.**

Masafumi Yasukochi, Founder and CEO

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Executive Summary

CD4 T cell

Systemic CD4 immunity is a key to PD-1 blockade immunotherapy to cancer

• James P. Allison, Cell (2017)

... the fundamental understanding that CD4 help is critical for the development of robust T cell responses, as well as recent findings that CD4 T cells are critical for effective immunotherapy.

• James P. Allison, Cell (2023)

Immune checkpoint therapy – current perspectives and future directions

1 ≥ 5,500

Development of anti-cancer immunotherapy methods receiving a great deal of attention is costly, time-consuming, and often unsuccessful

- 5,500+ clinical trials of immunotherapy working on cancers
- Immunity Research has identified a key CD4 T cell factor not found in those 5,500+ clinical trials.
- Patients with higher numbers of cells of this subset are more likely to benefit from immune checkpoint inhibitors

1.5B USD

Well-positioned for \$150 Billion USD cell-therapy market

- Evidence of the T cell subset found in both of peripheral blood and tumor sites which has anti-cancer effector function, suggesting that since the subset is able to **turn the immune cell cycle** related to cancer and control the immune system, administration of these cells to patients can treat cancer

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 **3MM USD**
 **20MM USD**

Raise \$3 million USD* to accomplish below milestones:

- Protect technology with patents and speed up development
- Enabling studies, prepare clinical trials, buyout existing shareholders to deliver breakthrough growth in next 18-months
- Phase 1 & 2 clinical trials, collection of data to further accelerate studies and future drug discovery within 3-years

*If oversubscribed, raise up to \$5 million USD

Team

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Masafumi Yasukochi,

CEO: After working on R&D and marketing at Otsuka Pharmaceutical, he participated in the launch of the intellectual property department of Saitama Medical University. He founded Immunity Research as a university-launched venture company and he is familiar with IP strategy for drug discovery.



Akio Ametani, PhD,

Director of R&D Division: After earning a PhD from University of Tokyo.

With over 40+ years of researching at various universities and non-profit and for-profit research institutes, he has established a strong network of professional relationships. Highly regarded by peers both in Japan as well as overseas, he brings strong leadership, credibility, and industry connection.

Key Advisors



Hiroshi Kagamu, MD, PhD

Professor of Respiratory Medicine, Saitama Medical School: Immunology Advisor. Extensive experience in immunology research in Japan and the U.S., as well as experience as a respiratory medicine clinician.



Shigehisa Kitano, MD, PhD

General Manager of Department of Cancer Immunotherapy at Advanced Medical Development Center of Cancer Research Society Ariake Hospital : Immunology Advisor.



Shin Kawamata, MD, PhD

Dr. Kawamata in Kobe as a planned advisor, who has introduced the cell processing technology of Kymriah from Novartis and is now CEO of Cyto-Facto Inc.

Problem

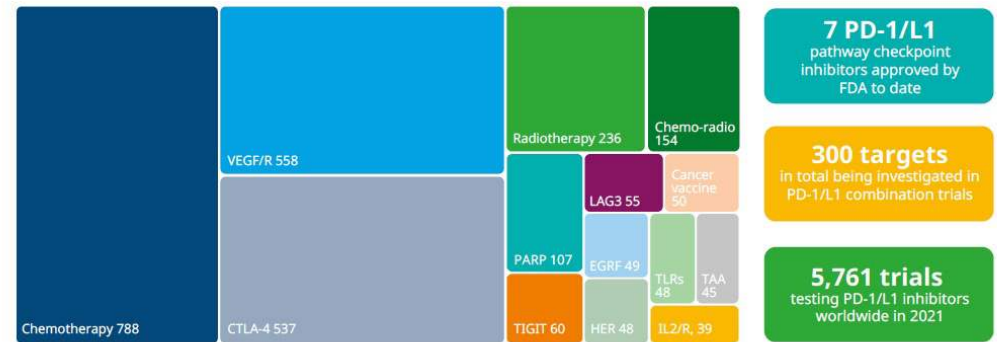
- Low rate of treatment efficacy with immune checkpoint inhibitors such as 15-20% in lung cancer patients is the major clinical problem remaining
- 5,500+ clinical trials in combination with immune checkpoint inhibitors, but many have failed, time-consuming
- Patent cliffs as major issues facing the pharmaceutical industry in immunoncology

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ONCOLOGY RESEARCH AND DEVELOPMENT ACTIVITIES

>5,500 clinical trials investigate PD-1/L1 inhibitors, 80% of which are combinations, putting huge pressure on recruitment

Exhibit 23: Number of active trials per target for top 14 targets investigated in PD-1/L1 combination trials



Source: Upadhaya S., Neftelinov S., Hodge J., Challenges and opportunities in the PD1/PDL1 inhibitor clinical trial landscape, Nature Reviews Drug Discovery, Feb 2022.

Why Now/Why ImmuniT Research?

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1. Scientific evidence of a CD4 T cell subset defined as Th7R (CXCR3-/+ CCR4- CCR6+ CD4+) in peripheral blood which has anti-cancer effector function and can be used to predict prognosis of patients treated with immune checkpoint inhibitors (see a figure), suggesting efficacy of administration of Th7R to cancer patients
2. Increasing CD62Llow CD4 T cells in patients predicted not to respond to ICI makes those patients responsive to ICI. Patients with more Th7R cells also respond well to combination therapy with anti-CTLA-4 and anti-PD-1 antibodies. **That is, the more cells of the CD4 subset, the better the response to ICI.**
3. Patents granted (in Europe) and plans to be granted in major countries
4. Established cell culture know-how
5. Established system that enables measurement

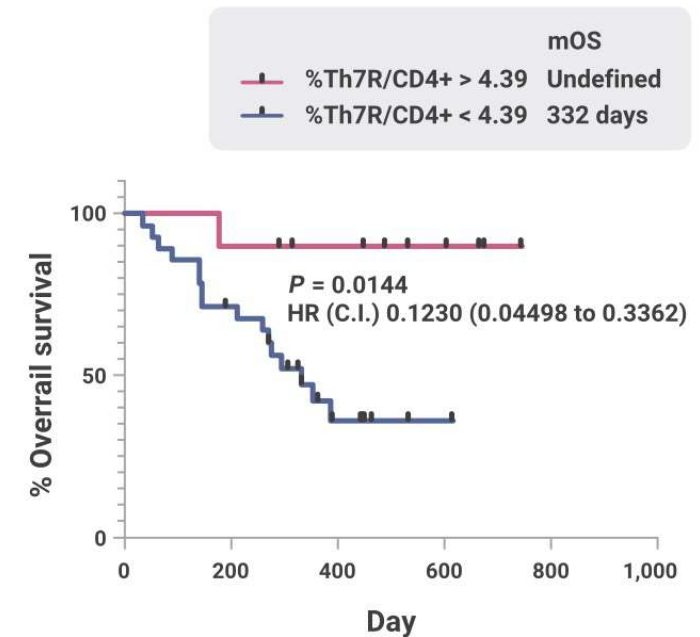
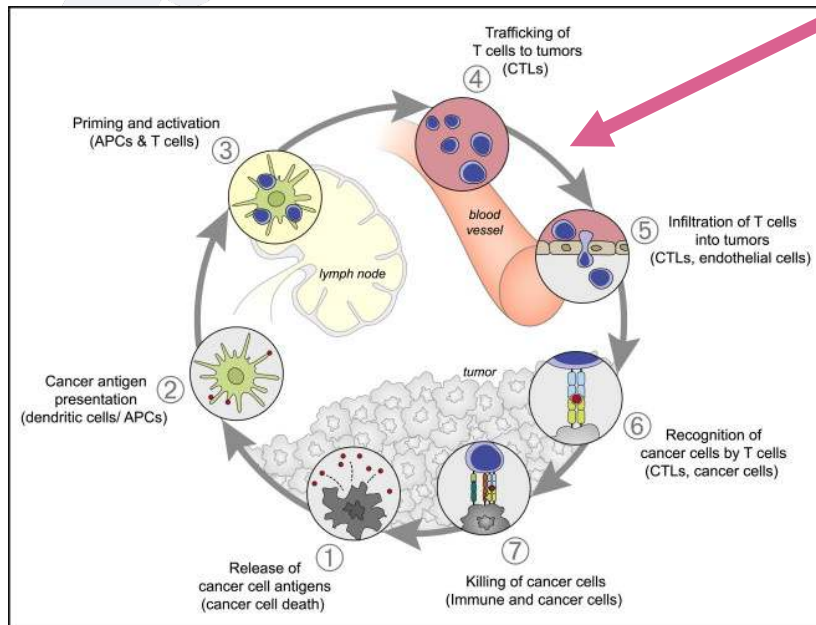


Figure indicates that two groups with higher ratios (red) of Th7R and lower (blue) are clearly distinguished as longer and shorter survivors, respectively.
Cancer Res; 82(24) December 15, 2022

Traction

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Oncology meets immunology: the cancer-immunity cycle.



Chen and Mellman, Immunity (2013)

1. Clinical development of a novel anti-cancer immune cell therapy using Th7R

- CD4 T cells known as immune cell populations having helper activity for other immune cells, controlling systemic immunity and acting at local sites
- This CD4 T cell subset of Th7R different from Th1, Th2 and Th17
- More number of cells of Th7R found in blood of cancer patients who can respond to immune checkpoint inhibitors
- Th7R at an activated state in cancer patients
- More number of Th7R cells found in tumor sites of cancer patients who can respond to immune checkpoint inhibitors
- Th7R with common TCR found in blood and tumor sites
- Th7R cells can be in vitro expanded by our own protocol

2. Established the method of sample preparation and defining frequency of this anti-cancer CD4 T cell subset of Th7R. Licensed out to a diagnostic company.

Element technology has been developed.

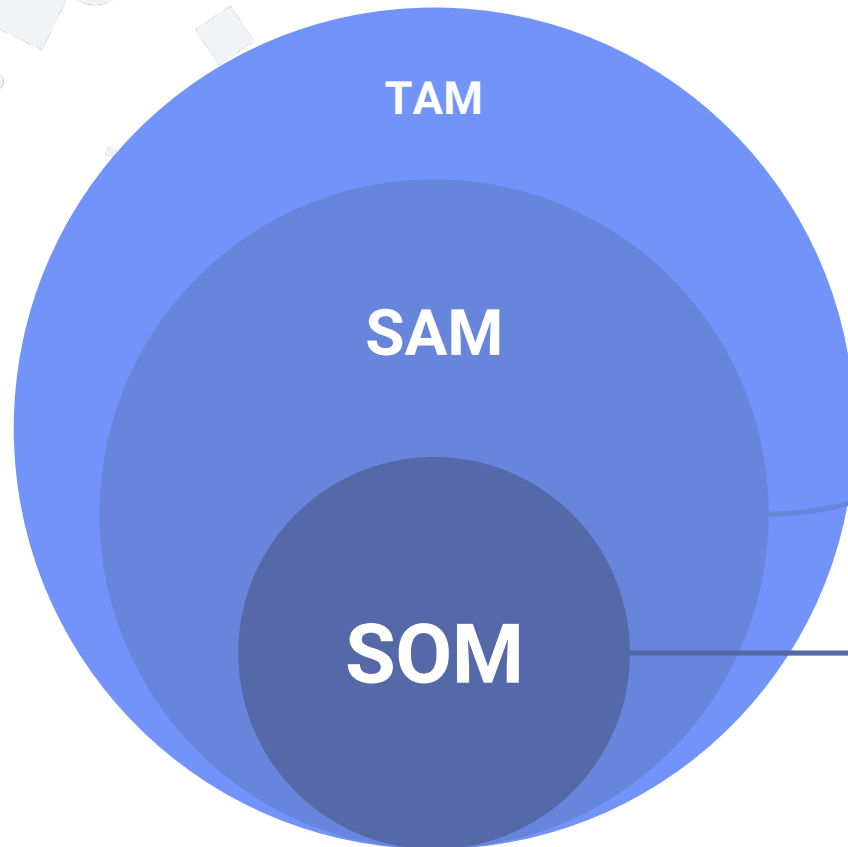
The patent has been established.

→Animal experiments and clinical trials are required.

Market Size and Opportunity

(Top-down approach)

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**Immune Checkpoint Inhibitors
market size
Over \$150Bn by 2030**

**\$50Bn in major markets such
as US, Europe, Japan, etc.**

\$1.5Bn
**Assume 3% of the market
for SAM**



Th7R Cell Therapy Market Forecast

(Bottom-up approach)

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Number of the patients

NSCLC		Kidney		Melanoma	
Number of new patients in the U.S. (2022)	236,740	Number of new patients in the U.S. (2022)	79,000	Number of new patients in the U.S. (2022)	99,789
Number of new patients per year for NSCLC	189,392				
Total number of patients in the U.S.	568,176	Total number of patients in the U.S.	316,000	Total number of patients in the U.S.	399,156
Total number of patients across Japan, U.S. and Europe	1,136,352	Total number of patients across Japan, U.S. and Europe	632,000	Total number of patients across U.S. and Europe	598,734
Patients with advanced/relapsed disease for whom anti-PD-1/PD-L1/CTLA-4 antibodies are indicated	227,270	Patients with unresectable/metastatic disease for whom anti-PD-1/PD-L1/CTLA-4 antibodies are indicated	126,400	Patients with unresectable/metastatic disease for whom anti-PD-1/PD-L1/CTLA-4 antibodies are indicated	119,747
Target Patients	4,545	Target Patients	2,528	Target Patients	2,395

Assumption		Assumption		Assumption	
Assume NSCLC is 80% of total new patients	80%				
Based on the 5-year survival rate of 23% for lung cancer (Source: NCI Cancer Stat Fact), the total number of patients is assumed to be about 3 times the number of new patients per year.	3	Based on the 5-year survival rate of 76.5% for renal cancer (Source: NCI Cancer Stat Fact), the total number of patients is assumed to be about 4 times the number of new patients per year.	4	Based on a 5-year survival rate of 93.7% for melanoma patients (Source: NCI Cancer Stat Fact), the total number of patients is assumed to be about 4 times the number of new patients per year.	4
Assuming twice this number of patients in Japan, the U.S., and Europe as a whole.	2	Assuming twice this number of patients in Japan, the U.S., and Europe as a whole.	2	Assumes 1.5 times this number of patients in the U.S. and Europe as a whole (ignoring Japan since the number of patients is small)	1.5
Assumes 20% of patients with advanced/relapsed disease who are candidates for anti-PD-1/PD-L1/CTLA-4 antibodies	20%	Assume 20% of patients with unresectable/metastatic disease indicated for anti-PD-1/PD-L1/CTLA-4 antibodies	20%	Assumes 20% of patients with unresectable/metastatic disease for whom anti-PD-1/PD-L1/CTLA-4 antibodies are indicated	20%
Assuming that 2% of them receive the treatment in question	2%	Assuming that 2% of them receive the treatment in question	2%	Assuming that 2% of them receive the treatment in question	2%

NHI drug price

Our own calculation based on the US NHI price

Keytruda : \$175,000/ Year

Opdivo : \$157,200/ Year

Yervoy : \$256,000/ Year

Based on the above, set the annual drug price (1 course/ Year/pt)

for Th7R cell therapy at **\$175,000**.

The market size of Th7R cell therapy in US, Europe, and Japan.

$$(4,500 + 2,500 + 2,400) \times \$175,000$$

\$1.65 Bn USD / Year



Seek investment

ImmuniT Research Inc.

- **Investment amount :** \$3MM USD
- **Investment type :** Issue shares or SAFE
- **Pre-money :** TBD
- **Post-money :** TBD
- **Use of funds :** Set-up US entity with signed investor contract
Animal testing

- **Complete animal testing within 3-years, target further growth with strategic partners at over \$100MM USD valuation (IRR 33%+)**

**Note: If oversubscribed, raise up to \$5 million USD
Subject to shareholder's approval.**

