

November 21, 2016

Press Release

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Announcement of the Acceptance of the Third Party Allocation of New Shares by Advanced Immunotherapy, Co., Ltd. (Acquisition of the Ownership)

GreenPeptide Co., Ltd. wishes to announce that its board, at a meeting held on November 20, 2016, decided to accept the third-party allocation of new shares by Advanced Immunotherapy, Co., Ltd. (Representative President: Genjiro Miwa, HQ: Minato-ku, Tokyo, hereafter, "AIT") and acquire ownership. On the same day, we executed a capital subscription contract with AIT.

1. Purpose of accepting the third-party allocation of new shares

We currently possess two key pipelines comprising ITK-1 in prostate cancer, which was out-licensed to FUJIFILM Corporation, and GRN-1201 in melanoma, which is an overseas strategic product. In order to pursue additional growth, we are expanding new seeds and platform technology for drug discovery. As part of this effort, we have explored starting T-cell therapy research, in which the synergy with current R&D themes is high and there is high potential for cancer immunotherapy.

At AIT, we have decided to acquire the ownership of highly novel technology in the field of regenerative medicine/cell therapy using iPS technology. This company was established to commercialize the inventions, which have been made by Dr. Hiromitsu Nakauchi, Professor at the Institute of Medical Science, University of Tokyo and Professor at Stanford University, et al., in Japan and Asian countries. The company has engaged in research and development towards the first global commercialization of iPS technology-based regenerative medicine for cancer immunotherapy. The company possesses the technology to regenerate (rejuvenize) T cells using iPS technology, thereby preventing the exhaustion of T cells that attack cancer cells, which has been a challenge in cancer immunotherapy for many years. Similarly, the company possesses when iPS cell



therapy is conducted, which is also regarded as another challenge. Finally, by utilizing non-self T cells using iPS technology (use of T cells from a subject other than a patient), we expect that significant cost reduction can be achieved in cancer immunotherapy, for which treatment costs are typically very high. Furthermore, our various technologies and information related to cancer peptide vaccines and the peptide library may synergistically affect the analysis of epitopes that recognize antigen-specific T cells, which can be developed by iPS technology, and the discovery of T cells with high treatment efficacy.

Including iCELL Inc., a patent management company for various inventions by Professor Hiromitsu Nakauchi, we have agreed to make milestone payments to shareholders prior to the third-party allocation of new shares by AIT based on the progress of product development activities at AIT.

We would like to position the acquisition of AIT as a stepping-stone for expanding our development pipeline and entering the cutting-edge field of regenerative medicine/cell therapy. Moreover, we would like to become the leading company in cancer immunotherapy.

(1)	Name	Advanced Immunotherapy, Co., Ltd.					
(2)	Location	10-2, Higashi Shinbashi 1-chome, Minato-ku, Tokyo					
(3)	Title and name of representative	Genjiro Miwa, Representative Director					
(4)	Business domain	Development of cancer immunotherapy using T-iPS cells					
(5)	Capital	5,000,000 yen					
(6)	Establishment date	February 3, 2016					
(7)	Relationship with our company	There is no relationship between the capital, human resources, business relationship, and conflict of interest.					
(8)) Consolidated management performance and consolidated financial condition of						
	the company in the recent 3 years.						

2. Summary of the company acquired (Advanced Immunotherapy, Co., Ltd.)

AIT was established in February 3, 2016 and has not reached the fiscal year ending December 2016. Accordingly, some descriptions are omitted.

3. Status of the shares after acquisition

We plan to acquire 67% of the shares issued by AIT.



4. Future prospects

(1) Date of Board meeting approval	November 20, 2016		
(2) Date of contract execution	November 20, 2016		
(3) Date of share transfer	December 1, 2016 (plan)		

5. Future prospect

Acquisition of the shares will have minimum impact on business performance ending in March 2017.



About Advanced Immunotherapy, Co., Ltd.

Advanced Immunotherapy, Co., Ltd. is a biopharmaceutical venture company that develops cancer immunotherapeutics against viruses based on research findings by Professor Hiromitsu Nakauchi at the Institute of Medical Science, University of Tokyo. Professor Nakauchi established iPS cells from T cells that recognize specific antigens and, for the first time, successfully induced T cells rejuvenated functionally at a high efficiency while maintaining antigen specificity (Cell Stem Cell, 2013). Based on a series of developed technologies, he filed 2 international patents (PCT/JP2011/052260, PCT/JP2013/064291). A patent was granted in one case (US 9,206,394 B2) (Applicant: The University of Tokyo). Furthermore, by incorporating a suicide gene (induced caspase 9) which can induce apoptosis, he successfully improved the safety of iPS cell-derived T cell therapy (Stem Cell Reports, 2015). Based on these research achievements, the company acquired the exclusive right to the patent at presumed markets. The company is preparing for a clinical study to examine the treatment of virus-related tumors by antigen-specific rejuvenated T cells.

About GreenPeptide Co., Ltd.

GreenPeptide is a drug discovery venture company engaged in the research and development of cancer immunotherapies that make use of the body's immune system to fight cancer. Cancer immunotherapies are expected to be the 4th therapy when surgery, radiotherapy, and chemotherapy have failed.

Currently, we are mainly developing 2 peptide vaccines at clinical stage (ITK-1 for prostate cancer and FRN-1201 for melanoma). We would like to contribute to cancer treatment by developing novel world-class cancer immunotherapeutics originating from Japan.

Significance of capital and business alliance with Advanced ImmunoTherapy

Innovation in cancer immune regeneration using iPS cells —



November 21, 2016

Significance as a business strategy

- Acquire the latest cutting-edge technology in T cell therapy, an important area in cancer immunotherapy.
- Share knowledge related to the technology and clinical development of immune cell activation including cancer vaccines through current research and development programs.
- Expectations as the first clinical application of iPS cell therapy for cancer immunotherapy and anticipation of large impacts in the subsequent development.

Potential of seeds for drug discovery

Compared to current T cell therapies, higher efficacy and significant cost reduction are expected.

Therapy	CAR-T (current)	TCR-T (current)	T-iPS	T-iPS/ iC9	Remark
Securing cell counts	Restricted	Restricted	Unrestricted proliferation	Unrestricted proliferation	Number of cells that can be obtained from patients is generally limited.
Effect of T cell exhaustion	Yes	Yes	No	No	Cell exhaustion is a condition in which T cells that contact an antigen for extended time express PD-1, etc. and become susceptible to the immune inhibitory system.
Proliferation capability (duplication capability)	Low	Low	High	High	Related to maintenance of various effects <i>in vivo</i> .
Mechanisms to manage adverse reactions	None	None	None	Yes	Safeguard mechanisms to manage various adverse events.
Banking	Difficult	Difficult	Easy	Easy	Banking will expand the scope of application, such as the use of non-self.
Manufacturing costs	High	High	Low	Low	Cost reduction of T-iPS therapy is based on the use of non-self.

Promising and feasible areas of projects

Positioning of seeds in cancer immunotherapy

In current cancer immunotherapy, progress has been made in two areas, i.e., activation of antigen-specific immune cells and improvement in the cancer microenvironment (including check point inhibition). This alliance will help establish our presence in the former area in an accelerated manner.



Summary of this platform technology

For T cell therapy, "Securing sufficient number of T cells with anti-cancer activity" has been challenging. Through the use of iPS technology, an unlimited number of rejuvenated (high-activity) T cells can be supplied.



Summary of plan for managing adverse reactions

Using an apoptosis-inducing system (safeguard mechanism) programmed by caspase 9, various adverse reactions that may occur during treatment processes can be managed.



Future development strategy

Initially, development will be conducted in EB virus lymphoma, a type of virus that induces hematological cancer, to demonstrate the proof of concept. In the future, indications with a large market size including solid cancer will be developed.



Excerpt of Press Release for this technology by the University of Tokyo

- Using induced pluripotent stem cells (iPS cells), T cells, one type of immune cells, were successfully rejuvenated.
- This was the first successful re-differentiation of T cells from the re-programming of T cells into iPS cells. Moreover, it was confirmed that these T cells were younger than the original T cells.
- This may provide an innovative treatment modality for chronic infections and cancer. Moreover, T-iPS cell banking may be established to help manage various diseases. Immunotherapy may be conducted in an expedited manner in the future.

2013.1.4 Hiromitsu Nakauchi (Professor, Division of Stem Cell Therapy, Center for Stem Cell Biology and Regenerative Medicine, Institute of Medical Science, University of Tokyo)

Generation of rejuvenated antigen-specific T cells by reprogramming to pluripotency and redifferentiation. Cell Stem Cell (2013.1.4) Nishimura, et al.

- It was demonstrated that human immune cells (T cells) rejuvenated by iPS cell technology reduced tumors *in vivo* in mice.
- It was shown *in vivo* in mice that programming of a suicide gene into T cells could chemically control adverse reactions that may occur at various stages of iPS cell-based T cell therapy.
- This research output may improve the safety of iPS cell-based T cell therapy and is expected to serve as a bridge for research towards clinical application of this therapy.

2015.8.27 Hiromitsu Nakauchi (Professor, Division of Stem Cell Therapy, Center for Stem Cell Biology and Regenerative Medicine, Institute of Medical Science, University of Tokyo) Miki Ando (Division of Stem Cell Therapy, Center for Stem Cell Biology and Regenerative Medicine, Institute of Medical Science, University of Tokyo)

A Safeguard System for Induced Pluripotent Stem-Cell Derived Rejuvenated T-cell Therapy. Stem Cell Reports (2015.8.27) Ando et al.

Disclaimer

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