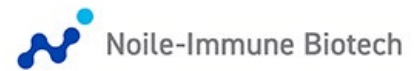
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Chugai Pharmaceutical Co., Ltd.
Noile-Immune Biotech Inc.

Chugai and Noile-Immune Biotech Enter into a License Agreement for Noile-Immune's PRIME CAR-T Technology

- Chugai and Noile-Immune enter into a license agreement for Noile-Immune's PRIME CAR-T technology
- Chugai and Noile-Immune aim to make CAR-T cell therapy available for patients with solid tumors by utilizing PRIME technology and Chugai's drug discovery technology

TOKYO, August 22, 2022 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) and [Noile-Immune Biotech Inc.](#) announced that the companies entered into a license agreement for Noile-Immune's proprietary PRIME (Proliferation-Inducing and Migration-Enhancing) CAR-T technology.

In recent years, cancer immunotherapy has been widely recognized as a new approach to cancer treatment by enhancing the immune system to attack cancer cells. Chimeric antigen receptor T cell (CAR-T cell) therapy is a type of cancer immunotherapy, in which a patient's immune cells (T cells) are collected, transfected with a gene for an artificial chimeric antigen receptor (CAR), which recognizes a cancer antigen, expanded in large numbers and returned to the patient's body. The therapy is currently used as a new treatment for hematologic cancers. Noile-Immune's PRIME technology is expected to open up the possibility of CAR-T cell therapy not only for hematologic cancers but also for solid tumors. PRIME technology is a platform designed to enhance the function of immune cells through the expression of the cytokine^{*1} IL-7 and the chemokine^{*2} CCL19 from CAR-T cells, exerting anti-tumor effects.^{1,2} Preclinical studies (mouse, *in vivo*) have shown that the PRIME technology increases the expression of IL-7 and CCL19 and boosts the proliferation and migration into solid tumors of both CAR-T cells as well as the patient's own immune cells.

^{*1} Cytokine is a bioactive substance secreted from cells, and mainly controls the proliferative activity, function, survival, etc. of immune cells.

^{*2} Chemokine is a type of a bioactive substance that control the migration of immune cells, including white blood cells, into tissues.

The agreement is based on the evaluation results for PRIME technology under the previous technology assessment agreement between Chugai and Noile-Immune in June 2020. Under the newly executed license agreement, Noile-Immune grants Chugai the rights to use PRIME technology for the creation and research of PRIME CAR-T cells, as well as the rights to develop, manufacture and commercialize PRIME CAR-T cell products for certain targets. Chugai will pay Noile-Immune an upfront payment and technology transfer fees. Also, Chugai may potentially pay over ¥20 billion in total if predetermined development or sales milestones are achieved. If Chugai successfully launch a product using PRIME technology, it will also pay royalties on sales in addition to the aforementioned sales milestones.

“Chugai is focusing efforts to establish new modalities following small molecules, antibodies and mid-size molecules under its multi-modality drug discovery strategy. We will challenge ourselves to make an innovative modality available for solid tumors by combining Noile-Immune’s PRIME technology and Chugai’s scientific and technical capabilities,” said Dr. Osamu Okuda, Chugai’s President and CEO.

“I am very pleased that the evaluation for our PRIME technology, which was initiated in 2020, resulted in this license agreement. We hope that this agreement will accelerate the development of safe and effective cancer immunotherapies for solid tumors, deliver new treatment options to patients suffering from cancer worldwide as soon as possible, and lead to the creation of a society that can overcome cancer,” said Koji Tamada, M.D., Ph.D, Noile-Immune’s President & CEO and scientific founder.

About Chugai

Chugai Pharmaceutical Co., Ltd., headquartered in Tokyo, is a research-based pharmaceutical company with world-class drug discovery capabilities, including proprietary antibody engineering technologies. Chugai is committed to creating innovative pharmaceutical products that may satisfy unmet medical needs. Chugai is listed on the Prime Market of the Tokyo Stock Exchange. While maintaining autonomy and management independence, Chugai is an important member of the Roche Group. Additional information is available at <https://www.chugai-pharm.co.jp/english/>.

About Noile-Immune

Noile-Immune Biotech Inc., established as a university start-up, aims to contribute to the arrival of an era when we can overcome cancer through the next-generation cancer immunotherapies, centering on PRIME technology. For more information, please refer to <https://www.noile-immune.com/en.html>.

About CAR-T Cell

CAR-T cell stands for Chimeric Antigen Receptor T cell, in which T cells are transfected with an artificial chimeric antigen receptor. The receptor is designed by combining a single-chain antibody specific to an antigen on cancer cells and signaling domains involved in T cell activation.

About PRIME Technology

PRIME technology is the one that enhance not only functions of gene-modified immune cells such as CAR-T cells, but also activities of a patient’s own immune systems. Noile-Immune has an exclusive right to implement PRIME technology.

Reference

1. Nobuyuki Miyasaka and Atsushi Miyajima, Cytokine – state of arts, *Journal of Clinical and Experimental Medicine*, additional edition October 2004, Ishiyaku Publishers, Inc.
2. Adachi K et al, *Nat Biotechnol*, 2018;36(4):346-351.

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