Noile-Immune Biotech

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Publication of Research Article on Therapeutic Efficacy of CAR-T Cells with Noile-Immune's PRIME technology in Intractable Solid Tumors

Noile-Immune Biotech Inc. (Minato-ku, Tokyo, President and CEO : Koji Tamada, hereinafter "Noile-Immune") announced that a research article on the results of the joint research between Yamaguchi University (Yamaguchi-city, Yamaguchi, President : Yukio Tanizawa) and Noile-Immune regarding PRIME technology, which is exclusively licensed from Yamaguchi University to Noile-Immune, has been published in the electronic edition of Cancer Research Communications, an international scientific journal published by American Association for Cancer Research.

□ Paper Title：	Therapeutic efficacy of IL-7/CCL19-expressing CAR-T cells in intractable solid tumor models of glioblastoma and pancreatic cancer
□ Journal Title：	Cancer Research Communications
□ Author Name：	Keisuke Ohta, Yukimi Sakoda, Keishi Adachi, Taro Shinozaki, Masao Nakajima, Hiroyuki Yasuda, Hiroaki Nagano, Koji Tamada
□ DOI：	10.1158/2767-9764.CRC-24-0226
□ Pubmed URL：	https://pubmed.ncbi.nlm.nih.gov/39240078/
□ Outline of the paper：	・ While pancreatic cancer and glioblastoma remain resistant to conventional therapy and represent intractable solid cancers, PRIME CAR-T cells which simultaneously produce interleukin-7 (IL-7) and CCL19 demonstrated a potent therapeutic efficacy in these cancers in animal models. ・ In immunodeficient mice inoculated with tumor organoids established from tumor tissue of a pancreatic cancer patient, intravenous injection of PRIME CAR-T cells generated from peripheral blood mononuclear cells from the same patient demonstrated significantly potent therapeutic effects compared to conventional CAR-T cells without PRIME technology.

【Research background and outline】

Conventional CAR-T cell therapies against hematological malignancies have demonstrated remarkable therapeutic efficacy, which has resulted in clinical applications. However, CAR-T therapies against solid

cancers has yet to be fully developed, as only a few exceptional studies have been reported to demonstrate significant clinical efficacy for patients with solid tumor. Potential hurdles for the CAR-T cell therapy in solid cancers include the heterogeneity of tumor-associated antigens, insufficient migration and infiltration of CAR-T cells and endogenous immune cells into tumor tissues, and immunosuppressive nature of the tumor microenvironment. In collaboration with Yamaguchi University, Noile-Immune is actively engaged in cancer research of immune cell therapies using next-generation CAR-T cells equipped with PRIME technology which induces simultaneous production of interleukin-7 (IL-7) and CCL19. Through these activities, Noile-Immune is committed to the development of CAR-T therapies to overcome the hurdles in solid cancers.

The accomplishment of this joint research demonstrated the potent efficacy of CAR-T cells equipped with Noile-Immune's proprietary PRIME technology in the intractable solid tumors in mouse models, as complete rejection of tumors and prolonged mouse survival, as well as an enhanced anti-tumor cytotoxic activity, were exhibited. In addition, these results are the first to demonstrate a therapeutic efficacy of next-generation autologous CAR-T cells generated from cancer patient's peripheral blood mononuclear cells in the mouse model inoculated with tumor organoids derived from the same patient's tumor tissues.

【PRIME technology】

PRIME technology is Noile-Immune's proprietary technology which further improves immune cells, such as CAR-T cells used for anti-cancer therapy, to produce interleukin-7 (IL-7) and CCL19, and has a potential to promote the growth and survival of T cells and to stimulate the migration of T cells and dendritic cells, so as to enhance the therapeutic effects against cancer. PRIME technology was developed to create an environment conducive to attacking cancer cells efficiently by inducing accumulation of a large number of CAR-T cells and body's immune cells at the site of cancer.

For more details, please visit https://www.noile-immune.com/en/Our_Science/prime_car-t.html.

【Noile-Immune Biotech Inc.】

Noile-Immune Biotech Inc. (TSE: 4893) is a biotech company, an academia start-up, and is committed to the practical application of next-generation immunotherapy for solid cancers by utilizing PRIME CAR-T cells which incorporate Noile-Immune's proprietary PRIME technology, an innovative approach to enhance the therapeutic effects of immune cell therapy. As PRIME technology can be combined with various chimeric antigen receptors (CARs) to create novel drugs and applied to a broad range of modalities, it is expected to develop many anti-cancer therapeutic approaches in combination with other technologies in the future. Through our business activities, Noile-Immune aims to contribute to the creation of a society that can overcome cancer.

For more information, please visit https://www.noile-immune.com/en.html.

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