Noile-Immune Biotech

News Release

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Presentation at the Annual Meeting of Japan Society of Clinical Oncology (JSCO) Updated Results from First-in-Human Phase I Dose-Escalation Trial of CAR-T Cell Therapy (NIB102) with Noile-Immune's PRIME Technology

NIB102, an in-house drug discovery pipeline of Noile-Immune Biotech Inc. (hereinafter referred to as "Noile-Immune"), is CAR-T cell therapy targeting Glypican-3 (GPC3) with Noile-Immune's own innovative proprietary PRIME (Proliferation-Inducing Migration-Enhancing) technology to enhance the therapeutic effects of immune cell therapy. Noile-Immune hereby announces that the updated results from first-in-human Phase I dose-escalation trial, which Takeda Pharmaceutical Company Limited, a former licensee, had conducted as TAK-102, were presented at the 62nd Annual Meeting of Japan Society of Clinical Oncology (JSCO) at Fukuoka Convention Center from October 24 to 26, 2024.

Background:

NIB102 (TAK-102) is a GPC3-targeted Noile-Immune's autologous next-generation CAR-T cell therapy incorporating IL-7 and CCL19 and expected the persistence of CAR-T cells and expansion of memory subsets compared to those of conventional CAR-T cell therapy[1]. NIB102 (TAK-102) is also considered to be capable of overcoming the hurdles associated with a tumor microenvironment[1] including the immunosuppression as a cause of the resistance to conventional CAR-T cell therapy in solid tumors. The antitumor activity of NIB102 (TAK-102) was confirmed in a non-clinical study of a xenograft mouse model engrafted with GPC3-positive human HepG2 cells[2]. In addition, the interim results of this clinical study (data cut-off: August 22, 2022) demonstrated an encouraging safety profile of NIB102 (TAK-102) and favorable cellular kinetics at lower dose levels in four patients with advanced solid tumors[3]. In this meeting, the updated results from first-in-human Phase I dose-escalation trial of NIB102 (TAK-102) were presented orally (data cut-off: March 25, 2024) by the investigator.

References:

1. Adachi K et al. *Nat Biotechnol* 2018;36:346–51.
2. Data on file. Takeda Pharmaceuticals Company Limited.
3. Koyama T et al. *J Immunother Cancer* 2022;10:A737.

Summary of Presentation:

- NIB102 (TAK-102), next-generation CAR-T cell therapy, demonstrated a manageable safety profile, including grade 1/2 CRS.
- While further clinical investigation is required, one patient with HCC demonstrated a 6-month durable antitumor response, and some signs of antitumor activity and tumor shrinkage were observed.
- Improvements in NIB102 (TAK-102) cellular kinetics were observed with escalating doses.

- A dose-dependent relationship with NIB102 (TAK-102) was also observed for the biomarkers, CCL19, IFN-γ and IL-6, indicating increased activity with escalating doses of NIB102 (TAK-102).
- The small sample sizes require the caution when interpreting these data.
- Two patients are currently being followed up in a long-term safety study.

【NIB102】

NIB102 is a CAR-T cell therapy with Noile-Immune's proprietary PRIME technology and is an autologous PRIME CAR-T cell that uses cancer patients' own lymphocytes. NIB102 targets GPC3 (Glypican-3), which is expressed in some of hepatocellular carcinoma, stomach cancer, and NSCLCsq, and it is estimated that the potential target population is approximately 35,000 patients per year in Japan and approximately 197,000 patients per year including those overseas.

【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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