Noile-Immune Biotech

News Release

No. 24013
November 11, 2024
Noile-Immune Biotech Inc.
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Poster Presentation at the Society for Immunotherapy of Cancers (SITC) Quantitative Clinical Pharmacology and Mechanistic Modeling in a Phase I Clinical 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 in a poster session at the 39th Annual Meeting of Society for Immunotherapy of Cancers (SITC) held in Houston from November 6 to 10, 2024.

Background:

- NIB102 (TAK-102) is an investigational GPC3-targeted CAR-T therapy which produce interleukin-7 (IL-7) and CCL19 simultaneously, so as to enhance proliferation/persistence of T cells and induce infiltration of host immune cells by the effects of IL-7 and CCL19.
- An open-label, non-randomized phase I study (NCT04405778) was conducted in patients with GPC3+ solid tumors to evaluate safety and tolerability of NIB102 (TAK-102) as well as identifying recommended Phase II dose (RP2D) level.

Summary of Presentation:

- In eleven patients who have been treated with NIB102 (TAK-102), no DLT (Dose Limiting Toxicity) nor neurotoxicity was observed, and all the CRSs (Cytokine Release Syndromes) observed were manageable (mostly Grade 1), suggesting an acceptable safety profile of NIB102 (TAK-102) up to Cohort 3 dose (5×10^8 CAR-T cells/body).
- Five patients achieved SD (Stable Disease) as best response from Investigator's assessment.
- Cellular kinetics was measured by flow cytometry and qPCR (quantitative PCR), and showed improvement in exposure (Cmax/AUC) from Cohort 1 (Dose: 1×10^7 CAR-T cells/body) to Cohort 2 (Dose: 1×10^8 CAR-T cells/body) and decrease in Tmax from Cohort 2 (Dose: 1×10^8 CAR-T cells/body) to Cohort 3 (Dose: 5×10^8 CAR-T cells/body).
- As for humoral immunogenicity, anti-drug antibody (ADA) titers were measured against extracellular domain of CAR, IL-7 and CCL19. Interim data (n=11) suggested no sign of the impact of immunogenicity of NIB102 (TAK-102) on cellular kinetics and/or efficacy.
- There was dose-dependency from Cohort 1 (Dose: 1×10^7 CAR-T cells/body) to Cohort 3 (Dose: 5×10^8 CAR-T cells/body) in certain biomarkers such as peak levels of CCL19, IFN-γ and IL-6, which may point towards increased signal of NIB102 (TAK-102) activity by dose escalation.

【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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