Noile-Immune Biotech

News Release

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Noile-Immune Biotech Inc.
https://www.noile-immune.com

Poster Presentation at the American Society of Clinical Oncology (ASCO) for Phase I Study on Safety and Efficacy of Switchable CAR-T Cell Therapy with FY001 and CART001 in Patients with Relapsed/Refractory CD20-positive B-cell Non-Hodgkin Lymphoma (EPOC1803)

Noile-Immune Biotech Inc. (hereinafter referred to as "Noile-Immune") hereby announces that the National Cancer Center Hospital East has presented the results from phase I study to evaluate the safety and efficacy of switchable CAR-T cell therapy with FITC-labeled rituximab (FY001) and FITC recognizing CAR-T cells (CART001) in patients with relapsed/refractory CD20-positive B-cell Non-Hodgkin Lymphoma (hereinafter referred to as "Trial") in a poster session (Abstract #: 7031) at the American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, U.S. from May 30 to June 3, 2025.

Noile-Immune has entered into a Letter of Commitment with the National Cancer Center and AbBio Co., Ltd. (hereinafter referred to as "AbBio") of South Korea, and under this agreement, Noile-Immune and AbBio have secured exclusive worldwide rights to access and use the comprehensive information obtained from the Trial (hereinafter referred to as "Information"). The handling of the Information and the future business plan based on the Information will be subject to continued consideration by Noile-Immune.

Background:

CD19-targeted CAR-T cell therapy has shown remarkable efficacy against relapsed/refractory B-cell non-Hodgkin lymphoma (r/r B-NHL). However, important clinical challenges persist, including relapse due to CD19 antigen loss and severe immune-related adverse events such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).

The newly developed combination therapy using FITC-labeled rituximab (FY001) and FITC-recognizing CAR-T cells (CART001) enables fine-tuning of anti-tumor activity while minimizing adverse events, as FY001 binds to CD20 on lymphoma cells and activation of CART001 occurs only through FY001. Switchable CAR-T is expected to be applicable broader r/r B-NHL cases, including elderly or frail patients. Additionally, for patients who have lost target antigen, FITC-labeled antibodies targeting different antigens can activate residual CART001, potentially exerting efficacy against relapsed lymphoma cells. For these reasons, a Phase I study was conducted to evaluate the safety and efficacy of switchable CAR-T cell therapy.

Summary of Presentation:

The switchable CAR-T demonstrated excellent tolerability and 100% response rate with long-term remission in r/r B-NHL patients.

- Six (6) participants received FY001 and CART001 treatment, in dose-limiting toxicity (DLT) evaluation (n=3) and expansion (n=3) cohorts. Participant ages ranged from 68 - 79 years, with 2 - 8 prior therapy lines; five (5) had diffuse large B-cell lymphoma and one (1) had follicular lymphoma.
- In all cases, no DLTs occurred. In observed adverse events, 1 case of Grade 4 blood creatine phosphokinase elevation (16.7%) and 1 case of Grade 3 anemia (16.7%) were observed, but none of which were determined to be causally related to FY001 or CART001. Notably, no CRS or ICANS cases were reported.
- The best overall response rate (ORR) reached 100% (95% CI: 54.1% - 100%), comprising 4 complete responses (CR) and 2 partial responses (PR). As of January 2025, 2 patients continue maintaining CR (57 and 47 months).

At this time, Noile-Immune does not anticipate any impact on the company's performance for the fiscal year ending December 31, 2025 in relation to this matter. However, should any matters arise that require disclosure, Noile-Immune will provide updates promptly.

【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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