Noile-Immune Biotech

News Release

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Presentation at the American Society of Clinical Oncology (ASCO) From The Phase I Clinical Trial of CAR-T Therapy (NIB102) with Noile-Immune Biotech's PRIME Technology

NIB102, one of pipeline of Noile-Immune Biotech Inc. (hereinafter referred to as 'Noile-Immune'), is an autologous CAR-T cell therapy with PRIME (Proliferation-Inducing Migration-Enhancing) technology owned by Noile-Immune and is being developed for solid tumors targeting Glypican-3 (GPC3). In 2018, Noile-Immune granted an exclusive license to Takeda Pharmaceutical Company Limited ("Takeda") for its development and commercialization, and Takeda has been conducting Phase I clinical trial as TAK-102. The results of the clinical trial were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, U.S. from May 31, 2024. As announced on December 15, 2023, Noile-Immune received a notification from Takeda of returning the exclusive license of the development and commercialization of NIB102, and thus Noile-Immune expects taking initiative the development of NIB102.

【Summary of presentation reported by Takeda】
The phase I clinical trial was conducted to evaluate the safety of TAK-102, an IL-7- and CCL19-producing autologous CAR-T cell therapy targeting GPC3, in patients with GPC3-expressing solid tumors who were refractory or intolerant to standard therapy (NCT04405778). The trial included hepatocellular carcinoma (8 patients), liposarcoma (2 patients) and gastric carcinoma (1 patient) who were administrated from 1 x 10^7 to 5 x 10^8 cells/body of TAK-102 under dose escalation design. No Dose Limiting Toxicity (DLT) was observed at any dose, nor was Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) observed. Cytokine Release Syndromes (CRS) with higher doses of TAK-102 were observed in six patients, but each case was mild, and the tolerance of TAK-102 was confirmed. Improvements in TAK-102 cellular kinetics were observed with escalating doses, and a dose-dependent relationship was also observed for the biomarkers CCL19, IFN-γ and IL-6, with escalating doses. In one patient with hepatocellular carcinoma, demonstrating a 6-month durable anti-tumor response and tumor shrinkage, the result indicating efficacy of TAK-102 was also obtained. However, due to the evaluated sample size was limited, it is deemed necessary to caution when interpreting the results, and the results warrant further clinical studies.

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