Noile-Immune Biotech

News Release

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

Notice of Completion of Clinical Trial Notification Submission of NIB103 Phase I Clinical Trial

Noile-Immune Biotech Inc. (hereinafter referred to as “Noile-Immune”) hereby announces that Noile-Immune submitted a Clinical Trial Notification (CTN) of NIB103 phase I clinical trial for solid cancers in Japan which Noile-Immune newly launched (hereinafter referred to as the "Trial") to the Pharmaceuticals and Medical Devices Agency (PMDA) and that the required investigation by PMDA has been completed.

As for NIB103, Takeda Pharmaceutical Company Limited (hereinafter referred to as "Takeda"), which was a licensee, had been conducting a clinical trial, but due to strategic reasons at Takeda, the rights for the development and commercialization were returned to Noile-Immune. Subsequently, Noile-Immune selected NIB103 as its top-priority pipeline (Reference 1), and has been working toward the submission of a CTN along with repeated extensive discussions with the principal investigators regarding the conduction of the clinical trial which Noile-Immune newly launched.

In addition, Noile-Immune entered into a business collaboration agreement with Takara Bio Inc. on co-development of NIB103 in Japan in September 2024, and established a manufacturing system for NIB103 in Japan. (Reference 2)

The Trial which Noile-Immune newly launched is a phase I clinical trial targeting patients with mesothelin-expressing advanced or metastatic solid cancers who have no standard treatment with clinical benefit or who are intolerant to standard treatment, and is planned to evaluate the safety and tolerability of NIB103 as the primary objectives, and the antitumor effect and cellular dynamics as secondary objectives in 12 to 30 cases. Based on the results of the Trial, Noile-Immune plans to conduct subsequent necessary clinical trials.

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.

(Reference 1) “Notice of Re-prioritization of In-house Drug Discovery Pipelines and Change in Use of Funds Raised at the Time of Listing” as of June 28, 2024

(Reference 2) “Notice of Business Collaboration with Takara Bio in the Development of NIB103” as of September 25, 2024

【NIB103】

PRIME CAR-T targeting Mesothelin

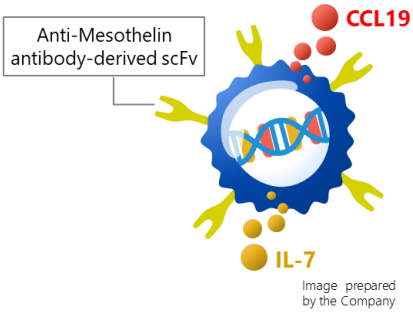

Image prepared by the Company

Estimated number of potential subjects (per year) ※1

Cancer type	Domestic deaths (Japan, US, Europe)	Mesothelin expression rate※3	Mesothelin-positive domestic deaths (Japan, US, Europe)
TNBC※2	2,562（30,219）	40%	1,025（12,088）
Colorectal cancer	59,381（353,247）	40%	23,752（141,299）
Ovarian cancer	5,302（63,714）	60%	3,181（38,228）
Pancreatic cancer	40,393（220,210）	80%	32,314（176,168）
		Total:	60,237（367,783）

※1: Estimate by the Company based on information from WHO Cancer Tomorrow (2020).
※2: Estimate by the Company based on Breast Cancer 17, 118–124 (2010), assuming triple-negative breast cancer accounts for 15% of all breast cancer cases.
※3: The expression rate is based on an analysis of clinical samples from Europe and the U.S., and does not take into account differences in expression rates due to racial differences.
Sources: Breast Cancer 17, 118–124 (2010), PloS one, 9(12), e114900, Cancer discovery, 6(2), 133–146

【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.

Contact for inquiries or additional information

2-12-10 Shiba-Daimon, Minato-ku, Tokyo 105-0012, Japan
Noile-Immune Biotech Inc.
E-mail: ir@noile-immune.com