Noile-Immune Biotech

News Release

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

Notice of Re-prioritization of In-house Drug Discovery Pipelines and Change in Use of Funds Raised at the Time of Listing

Noile-Immune Biotech, Inc. (hereinafter “Noile-Immune”) hereby announces that Noile-Immune has completed its re-prioritization of the development of its in-house drug discovery pipelines based on the review of the results etc. of NIB102 and NIB103 clinical trials transferred from Takeda Pharmaceutical Company Limited (hereinafter "Takeda") and, along with this, changes the in use of funds at the time of listing. Please note that the change in use of funds at the time of listing is not assumed to be a new financing at this time. As announced on December 15, 2023 and June 24, 2024, the rights for the development and commercialization of NIB102 and NIB103 have been returned from Takeda to Noile-Immune. As a consequence of the return, Noile-Immune holds NIB101, NIB102 and NIB103 in the clinical stage and NIB104 and NIB105 in the non-clinical stage as its in-house drug discovery pipelines. All of these development pipelines are Chimeric Antigen Receptor T-cell therapy (hereinafter "CAR-T therapy") with PRIME technology (Proliferation-inducing and migration-enhancing technology) owned by Noile-Immune, and target different tumor antigens to promote the developments for various solid tumors (Information on targets molecules of NIB104 and NIB105 are not disclosed).

Following the notification by Takeda regarding the return of the development and commercialization rights for NIB102 and NIB103, Noile-Immune has proceeded with the transfer of data related to the developmental activities of NIB102 and NIB103, in cooperation with Takeda. Based on the evaluation on the progresses of our in-house drug discovery pipelines and the data transferred from Takeda, Noile-Immune has made **a strategic decision to focus on initiating a new Phase I clinical trial of NIB103 with a top priority** as a pipeline developed by Noile-Immune. In the case that Noile-Immune takes over the Takeda’s clinical trial of NIB103, discussions and coordination with the regulatory authorities and outside vendors are necessary and will need significant time. Therefore, in order to resume the development of NIB103 as soon as possible and to expedite its progress, Noile-Immune has decided to initiate a new clinical trial. Noile-Immune aims to submit the Clinical Trial Application for Phase I trial as early as possible in 2025 by prioritizing the efforts to develop NIB103. With regard to the in-house drug discovery pipelines other than NIB103, Noile-Immune will promote the initiation of the clinical trials in succession through various approaches including co-development, and strive to forward NIB104 and NIB105 to clinical stages without delay. In addition, Noile-Immune will actively utilize these pipelines for accelerating our co-pipeline business.

The Phase I clinical trials of NIB102 targeting GPC3 (Glypican-3), and NIB103 targeting Mesothelin for solid tumors were conducted by Takeda (NCT04405778 and NCT05164666, respectively). As for NIB102, 11 subjects in total were administrated with the investigational drug at escalating doses. Safety and tolerability, as

well as a certain level of anti-tumor activities, of NIB102 in the early phase of clinical development were confirmed. While the clinical trial by Takeda will be ended, it is considered that further clinical investigation on efficacy and safety of NIB102 is required due to the small number of the enrolled subjects so far. These results of NIB102 study were presented by Takeda at the American Society of Clinical Oncology (ASCO) in Chicago, USA, held from May 31 to June 4, 2024 (please refer to the press release issued by Noile-Immune on June 4, 2024). As for NIB103, Phase I clinical trial was conducted in the limited number of subjects who were administrated with investigational drugs. While it is not feasible to lead to a definite interpretation of efficacy and safety at this time as the clinical trial by Takeda will be ended with the limited subject number, the tumor shrinkage considered to have obvious correlation with NIB103 was observed. On the other hand, adverse events requiring caution were also observed in NIB103 trial, suggesting that sufficient and repeated discussions on diagnostic methods and treatment policy with the responsible physicians are necessary for conducting further clinical trials of NIB103. In regard to Phase I trials of NIB102 and NIB103 conducted by Takeda, no subjects will be newly enrolled, and the follow-up monitoring of the subjects will be performed so as to meet the protocol and the related pharmaceutical regulations. Since all of these procedures will be conducted under the control of Takeda, Noile-Immune will not incur any financial burdens. In regard to NIB101 targeting GM2, which Noile-Immune has been conducting Phase I clinical trial, delays of the progress have occurred due to multiple and intermittent issues to be solved in the quality control procedures for manufacturing and quality testing of investigational drugs in the contract manufacturer, as we announced in the Notice of Revisions to Full-Year Earnings Forecast on January 25, 2024. Currently, the required activities for counter measures are being implemented, including improvement of the management system for the manufacturing, quality testing and others. However, in consideration of a substantial period required for completion of such activities, and the development costs incurred during the such period, Noile-Immune has decided to suspend the ongoing NIB101 Phase I clinical trial temporarily. Taken together with these matters, Noile-Immune decided to select and prioritize NIB103 for clinical development in our pipeline, as it is the closest and most likely to achieve the clinical Proof-of-Concept (PoC: Verification of the concept of feasibility as a therapeutic drug) in application of PRIME CAR-T therapy.

As the new strategy in pipeline development has been determined as described above, Noile-Immune has decided to change the use of funds in terms of the timing as well as the amounts which were planned at the time of the new listing. The details of the changes in the use of funds are as follows. The changed parts are underlined.

Before change

Use of funds	Amount of money	Scheduled period of appropriation
1. Development costs for NIB101	1,900 million yen	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2025
2. Costs for non-clinical trials of the pipelines after NIB104	60 million yen	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2024
3. Research expenses for generation of new pipelines	330 million yen	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2025

4. Research expenses for the new platform technologies	90 million yen	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2025
Total	2,380 million yen	

After change

Use of funds	Amount of money	Scheduled period of appropriation
1. Development costs for NIB101	530 million yen (500 million yen)	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2024
2. Development costs for NIB103 (addition)	1,600 million yen (-)	Fiscal Year ended Dec. 31, 2024 - Fiscal Year ended Dec. 31, 2026
3. Costs for non-clinical trials of the pipelines after NIB104	30 million yen (30 million yen)	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2024
4. Research expenses for generation of new pipelines	130 million yen (30 million yen)	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2026
5. Research expenses for the new platform technologies	90 million yen (20 million yen)	Fiscal Year ended Dec. 31, 2023 - Fiscal Year ended Dec. 31, 2026
Total	2,380 million yen (580 million yen)	

Amounts in parentheses ( ) are already appropriated

“Regarding CAR-T cell therapy for solid cancers, new technologies have been explored all over the world, but no robust treatment methods have been established, and thus there are no therapeutic products that have reached regulatory approval," said Koji Tamada, M.D., Ph.D., President & CEO of Noile-Immune, regarding the strategic decision this time. “NIB103, which we have selected as our prioritized in-house drug discovery pipeline this time, is CAR-T cells incorporating PRIME technology that we possess the exclusive right, in order to enhance the treatment efficacy. Clinical data showing potent therapeutic efficacy of NIB103 in solid cancer have been demonstrated, while such response was observed in the limited subject so far. We will promote the development of NIB103 as our in-house pipeline with a potential to be a breakthrough for CAR-T therapy for solid cancers, and will explore the safety and efficacy of NIB103.”

At this time, Noile-Immune does not anticipate any impact on the company’s performance for the fiscal year ending December 31, 2024 in relation to this matter. However, should any matters arise that require disclosure, we 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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