

Return of NIB102 and NIB103 from Takeda

Noile-Immune Biotech, Inc. (hereinafter “Noile-Immune”) hereby announces that Noile-Immune has recently completed discussions with Takeda Pharmaceutical Company Limited (hereinafter "Takeda") on the transfer of data on NIB102 and NIB103, our in-house drug discovery pipelines, as informed on December 15, 2023 of returning the rights for the development and commercialization of them from Takeda which was the licensee.

NIB102 and NIB103 are CAR-T cells against solid tumors, targeting GPC3 (Glypican-3) and Mesothelin respectively, and both are development pipelines incorporating Noile-Immune's own PRIME technology (Proliferation-inducing and migration-enhancing technology). For more information on NIB102 and NIB103, and PRIME technology, please see the following page. While the clinical trials of these pipelines have been conducted as Takeda's development code of TAK-102 and TAK-103 respectively, the transfer of data etc. which are transferable at this time has been completed.

As a result of the return of both pipelines, new patients will not be enrolled in the Phase I trials that were being conducted by Takeda, and these clinical trials will be monitored under Takeda's control until the end of the follow-up period after the administrations. Therefore, Noile-Immune will not incur any financial burdens related to the termination of these Phase I trials.

Publication of the data obtained so far will be considered, such as conference presentations in the future, based on the policy of Takeda and Noile-Immune. In regard to TAK-102, data on the Phase I trial was presented at the American Society of Clinical Oncology (ASCO) held from May 31 to June 4, 2024 (please refer to the press release issued by Noile-Immune on June 4, 2024).

The cancellation fees were arranged to fluctuate depending on the details of the costs incurred by Takeda for the development to date, but as a result of the calculation, any cancellation fees did not occur. With respect to NIB103, if Noile-Immune uses Takeda's own proprietary intellectual property in the future, Noile-Immune will pay Takeda royalties in low single digits after the launch.

There are no special provisions regarding the handling of the 8,119,800 shares (18.76%) of Noile-Immune's stocks held by Takeda.

Noile-Immune does not anticipate any impact on the financial results for the fiscal year ended December 31, 2024 due to this transaction.

As a result of the completion of the transfer from Takeda, Noile-Immune holds NIB101, NIB102 and NIB103 as development pipelines in the clinical stage, and NIB104 and NIB105 (target molecules of these products are not disclosed) as development pipelines in the non-clinical stage, in Noile-Immune's own in-house CAR-T

assets with PRIME technology against solid tumors. Noile-Immune will review each development pipeline, including the clinical data of NIB102 and NIB103 clinical trials, transferred from Takeda, and re-prioritize our in-house drug discovery pipelines which Noile-Immune will promote the clinical developments from now on. The details of development strategies will be announced as soon as they are determined.

【NIB-102】

NIB102 is a CAR-T cell 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.

【NIB-103】

NIB103 is a CAR-T cell with Noile-Immune's proprietary PRIME technology and is an autologous PRIME CAR-T cell that uses cancer patients' own lymphocytes. NIB103 targets mesothelin, which is expressed in some of triple negative breast cancer (TNBC), colorectal cancer, ovarian cancer, and pancreatic cancer, and it is estimated that the potential population is approximately 60,000 patients per year in Japan and approximately 367,000 patients per year including those overseas.

【PRIME technology】

PRIME technology is Noile-Immune's proprietary technology which further improves immune cells, such as CAR-T cells used for anti-cancer therapy, to produce interleukin-7 (IL-7) and CCL19, and has a potential to promote the growth and survival of T cells and to stimulate the migration of T cells and dendritic cells, so as to enhance the therapeutic effects against cancer. PRIME technology was developed to create an environment conducive to attacking cancer cells efficiently by inducing accumulation of a large number of CAR-T cells and body's immune cells at the site of cancer.

For more details, please visit https://www.noile-immune.com/en/Our_Science/prime_car-t.html.

【Noile-Immune Biotech, Inc.】

Noil 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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