

September 14, 2021
Noile-Immune Biotech, Inc.

Announcement of Clinical Trial Notification (CTN) submission of NIB101 Phase 1 Clinical Trial for Solid Tumors in Japan

Noile-Immune Biotech Inc. announces the CTN submission of NIB101 Phase 1 Clinical Trial to the Pharmaceuticals and Medical Devices Agency (PMDA).

NIB101 is a CAR-T cell (chimeric antigen receptor-T cell) derived from autologous T cells equipped with PRIME technology and targets GM2, a type of glycolipid expressed on certain types of cancer cells.

PRIME technology was developed by Dr. Koji Tamada, a scientific founder of the company and President & CEO. The company owns exclusive license of the technology, which enhances the function of genetically modified immune cells such as CAR-T cells and activates the host's own cells.¹⁾ GM2 is known to be expressed on malignant pleural mesothelioma, small cell lung cancer, pancreatic cancer, and other cancers²⁾³⁾. These cancer types are usually aggressive cancers with a poor prognosis⁴⁾, and there are significant unmet medical needs.

This study is a phase I clinical trial, targeting patients with GM2 positive solid cancers that are refractory or intolerant of standard-of-care therapies and plans primarily to evaluate the tolerability and safety of NIB101 for approximately 42 subjects, aiming to complete the registration in the second half of 2023.

[Terminology]

T cells:

A type of lymphocyte, which expresses T cell receptor (TCR) on their surface and plays an important role in immune response against cancer.

CAR-T cells

CAR-T cells stand for chimeric antigen receptor T cells, generated by genetic modification of T cells to express an artificial chimeric antigen receptor composed of single-chain antibodies

specific for cell-surface antigens of cancer and molecular signaling domains for T cell activation.

Noile-Immune Biotech, Inc.

Noile-Immune Biotech, Inc. is a venture company derived from Yamaguchi University and National Cancer Center with the mission of contributing to the creation of a society which is able to overcome cancer. The company aims to develop new therapies for solid cancers using genetically modified immune cell therapies, mainly CAR-T cells equipped with PRIME (proliferation inducing and migration enhancing) technology.

[Citation]

- 1) Adachi K et al. Nat Biotechnol, 2018;36(4):346-351.
- 2) Miyake M et al. Cancer Res. 1988;48(21):6154-6160.
- 3) Sasaki N et al. Sci Rep. 2019;9(1):19369.
- 4) National Cancer Institute Cancer Information Service
https://ganjoho.jp/reg_stat/index.html (accessed in September, 2021)