

April 4, 2025
A-SEEDS Co., Ltd.

A-SEEDS Passes Stage-gate Review of NEDO Deep Tech Startups Support Program (DTSU) and Accelerates Global Clinical Trials of CAR-T Cell Products

A-SEEDS Co., Ltd. (Headquarters: Matsumoto, Nagano Prefecture; CEO: Shigeki Yagyu, hereinafter referred to as "the Company") is pleased to pass the stage-gate review and to continue the project in the PCA Phase (Late-Stage Commercialization Research) under the sixth call for applications of the 2024 **Deep Tech Startup Support Project (DTSU)**, administered by **the New Energy and Industrial Technology Development Organization (NEDO)**. With this selection, the Company will receive up to 1 billion yen (6.1 million dollars) in funding to accelerate its global expansion. This funding is equivalent to twice the amount raised in the most recent financing round and will serve as a powerful driver for further growth.

Project Name:

Development of Mass-Production Technology for the Clinical Implementation of Innovative CAR-T Cell Therapy

Project Overview:

The objective of this project is **to establish a scalable mass-production technology for CAR-T cell therapy using the PiggyBac transposon (PB) method, a non-viral gene editing technology, with the ultimate goal of obtaining global regulatory approvals**. To achieve this, we will undertake the following key initiatives:

- ① **Technology Transfer and Validation of Automated Manufacturing to Overseas CDMOs**
- ② **Establishment of a Manufacturing System for Clinical Trial Products in Compliance with Global Regulatory Standards**
- ③ **Execution of Overseas Clinical Trials and Out-Licensing to Global Pharmaceutical Companies**

This grant is a non-dilutive type of funding that does not involve equity dilution.

Since its founding in April 2020, A-SEEDS has been committed to addressing the challenges of clinical implementation for CAR-T cell therapy, driven by our vision:

"To deliver effective treatments to cancer patients with limited therapeutic options and create a society where more people can find hope in life."

To date, we have successfully established a clinical-grade manufacturing process and are conducting two separate Phase 1 investigator-initiated clinical trials in collaboration with Shinshu University and the National Cancer Center Hospital East.

Furthermore, preparations are underway for a Phase 1/2a company-sponsored clinical trial in Australia. Through this project, **we will transfer our automated manufacturing technology to an Australian CDMO, establish a clinical trial product manufacturing system compliant with U.S. and European regulatory standards, and conduct overseas clinical trials to validate our technology.**

Shigeki Yagyu, CEO of A-SEEDS Co., Ltd., commented:

*"The selection of A-SEEDS for NEDO's DTSU is a **strong endorsement of our technology and vision.** To achieve global clinical implementation, it is essential to establish a robust manufacturing system, conduct successful overseas clinical trials, and obtain regulatory approvals. **In March 2024, [we were selected for NEDO's DTSU](#), where we successfully developed an automated culture technology for our PB-based CAR-T cell therapy one year ahead of schedule.** This achievement enabled us to pass the stage-gate review and continue PCA phase of DTSU.

With this grant, we will maximize our efforts to accelerate overseas clinical trials and global expansion, ensuring that our CAR-T cell therapy reaches as many cancer patients as possible."*

A-SEEDS' proprietary PB-based CAR-T cell therapy offers a safer and more efficient gene-editing approach compared to conventional viral vector-based methods. This technology not only reduces manufacturing costs but also ensures high-quality and stable production, paving the way for global clinical application.

A-SEEDS is committed to developing innovative CAR-T cell therapies originating from Japan and providing new treatment options to cancer patients worldwide. By leveraging this NEDO grant, we will advance overseas clinical trials and secure global regulatory approvals, working towards a future where more people can find hope through cutting-edge therapies.

■ A-SEEDS Co., Ltd.

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Representative	Shigeki Yagyu
Establishment	April 2020
C a p i t a l	10 million yen
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