



July 18, 2024
A-SEEDS Co., Ltd.

A-SEEDS Co., Ltd. Receives Award from the Japan Agency for Medical Research and Development (AMED) for the Competitive Funding Program to Conduct All-Japan R&D and International Expansion of CAR-T Cell Therapy Commercialization (non-dilutive funding)

A-SEEDS Co., Ltd. (located in Matsumoto, Nagano Prefecture; CEO: Shigeki Yagyu, hereinafter referred to as "the Company"), is delighted to announce our selection as a research and development collaborator for “the Project for Fundamental Technology Development for the Industrialization of Regenerative Medicine and Gene Therapy”, the Japan Agency for Medical Research and Development (AMED) with Professor Yozo Nakazawa of Shinshu University serving as the principal investigator. This award supports our continued efforts to advance the clinical application of CAR-T cell therapy, with the goal of offering this innovative treatment to cancer patients who currently have limited therapeutic options.

Project Name:

Streamlining CAR T cell therapy logistics with Japanese innovations from academic clinical trials to global commercialization through optimized production and a practical trial framework

Project Overview:

In this project, **academia and 14 domestic companies including the company form a consortium to advance research and development and clinical trials for the CAR-T cell therapy.** This initiative aims to **establish an ecosystem to produce internationally competitive domestic CAR-T therapies and facilitate their global expansion.** We also aim to **transfer the manufacturing to CDMOs and QC CROs and establish a clinical trial manufacturing system aimed at conducting overseas trials and obtaining regulatory approval.** This grant is **non-dilutive funding**, meaning it does **not cause any stock dilution.**

Since its establishment in April 2020, A-SEEDS Co., Ltd. has been committed to addressing the challenges of clinical application for CAR-T cell therapy. Our mission is to provide effective treatments for cancer patients with few alternatives, striving to offer new hope to as many patients as possible. We have developed a manufacturing process for clinical-grade CAR-T cell therapy utilizing the PiggyBac transposon system (PB method) and have initiated Phase 1 trials in

partnership with Shinshu University and the National Cancer Center Hospital East. We are currently making preparations for the clinical trial scheduled to commence in Australia next year.

In order to make CAR-T cell therapy, produced via the PB method, **a viable clinical option, it is essential to establish a manufacturing system for clinical trials and a mass production system for CAR-T cell products** using the PB method. We aim to **transfer the manufacturing previously conducted in the clinical trials to CDMOs and QC CROs**. This will address challenges in clinical trial manufacturing, optimize manufacturing processes and quality control methods for commercialization, and **establish a clinical trial manufacturing system aimed at conducting overseas trials and obtaining regulatory approval**. By improving the efficacy of our CAR-T cell products and leveraging the outcomes of this project as a competitive edge, we aspire **to pioneer the world's first mass-production technology for CAR-T cell therapy using the PB method, thereby positioning our nation at the forefront of CAR-T cell therapy development and obtaining regulatory approvals in Japan and overseas**.

■ A-SEEDS Co., Ltd.

A-SEEDS, an innovative biotech company sprouted from Shinshu University, is dedicated to pioneering advanced treatments for life-threatening cancers. Harnessing the potential of non-viral genetic engineering, our cutting-edge immune cell therapy opens up new horizons of hope for patients seeking effective and transformative solutions.

Company name	A-SEEDS Co., Ltd.
Location	3-1-1 CSMIT, Asahi, Matsumoto, Nagano,
Representative	Shigeki Yagyu
Establishment	April 2020
Capital	36 million yen
Home page URL	https://www.a-seeds.co.jp/en-home

■ Contact Info.

A-SEEDS Co., Ltd.

Kiyohito Tani

Tel: 0263-31-5882

E-mail: kiyohito.tani@a-seeds.co.jp