Info Sheet for Technical description

No. 0002

Organization

* Mandatoty fields

Name of Organization*	CellSeed Inc.	
Address, City, States, Zip, Country*	15F(East Wing)Telecom Center Building 2-5-10, Aomi, Koto-ku, Tokyo 135-0064 Japan	
URL	https://www.cellseed.com/en/	
Brief Descriptions of Organization* (Approx. 100 words)	CellSeed Inc. was founded in 2001 (listed on JASDAQ in 2010) to commercialize a world's first technology of "Cell Sheet Engineering" based on temperature-responsive polymer. By using this technology, CellSeed has developed a variety of intelligent cell cultureware which are used by many researchers actively to conduct R&D activities worldwide. In Japan, three regenerative medicines utilizing our cell sheet engineering technology have been approved by the PMDA. CellSeed is also developing our own regenerative medcine of Allogeneic chondrocyte cell sheet (Clinical Trial Notification for Phase 3 submitted in September 2023) as well. In addition, CellSeed has an in-house CPC capable of manufacturing cell products for clinical use, not only for our ongoing clinical trial but also for providing CDMO service to both domestic and overseas clients.	
Contact address	Name*	Toshihiro Maeda
	Department* / Position	Board Director
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What kind of technology do you want to offer? *

- ☑ **A.** Clinical Development Pipelines → Please see **Sheet【A】**
- ☑ **B.** Regenerative Medicine-related Consumables / Instruments / Materials / CDMO Servicies etc. → Please see **Sheet【B】**
- ☐ **C.** Platform Technologies(*) that are not included in the above (Group B) → Please see **Sheet【C】**

  * Peripheral technologies that contribute to a significant improvement in productivity throughout the value chain of pharmaceuticals, from research and development to manufacturing and ultimately market launch.

If you agree to the following, please check "Yes" below. *

The technologies introduced in this 'Info Sheet' are in the public domain, as they have been published in research papers or have related patent applications.

- ☑ Yes

Do you have any collaborations/partnerships with pharmaceutical companies?

- ☐ Yes
- ☐ No

If you have already received funding from VCs or other sources, up to which stage has the investment round progressed?

- ☐ Angel / Seed (including AMED/JST grants)
- ☐ Series A
- ☐ Series B
- ☐ Series C
- ☐ Series D or further advenced stages

Do you agree to leave your presentation materials at FIRM hands and entrust us to make use of them for the purpose of promoting your partnering opportunities? *

Options*	Comments
☑ Yes ☐ No	Please kindly inform us when the presentation materials are provided to a third party through FIRM.

Filled in by*	Dandan Song
Date*	2025.08.07

Ver.1.0

Sheet【A】 Clinical Development Pipelines

Info Sheet for Technical overview

No.A-0002

* Mandatoty fields

Title*

Allogeneic Chondrocyte Cell Sheet for Knee Osteoarthritis Treatment

Development Phase*

☐ Basic Research	☐ Drug Discovery	☐ Pre-Clinical
☐ Clinical Trial (Phase I)	☐ Clinical Trial (Phase II)	☑ Clinical Trial (Phase III)
☐ Review	☐ Others	

Diesease Area*

☐ Cancer	☐ Central nervous system	☐ Ophthalmology
☑ Musculoskeletal	☐ Endocrine / Metabolism	☐ Cardiovascular
☐ Urogenital	☐ Digestive organ	☐ Blood
☐ Infection	☐ Dermatology	☐ Immunity
☐ Otolaryngology	☐ Respiratory	☐ Others

Description*

Knee osteoarthritis (OA) is a common, progressive, and multifactorial joint disease characterized by chronic pain and functional disability. It not only significantly diminishes patients' quality of life (QOL) but also accounts for a substantial portion of the national healthcare expenditure. However, no fundamental therapy has yet been established.
Aiming for radical treatment of knee OA, Dr. Masato Sato et al. at Tokai University focused on cell sheet engineering using temperature-responsive cell cultureware developed by CellSeed, initiated the research on cartilage regeneration using chondrocyte cell sheets. Since 2011, clinical research with autologous chondrocyte sheets has been conducted, and both efficacy and safety have been confirmed [1]. This therapy was subsequently approved at Tokai University Hospital as Advanced Medical Care B, and CellSeed manufactures the cell sheets for this treatment. Additionally, clinical research with allogeneic cell sheets began in 2016 at the same hospital. After completion of clinical research on 10 patients, improvements of clinical symptoms were observed without any serious adverse events [2].
Since the use of allogeneic chondrocyte sheets can avoid the invasive tissue collection and alleviate the challenges of ensuring a stable supply of cell sheets, they have the potential to treat a significantly larger number of patients. In September 2023, CellSeed submitted a Clinical Trial Notification (CTN) for a Phase 3 clinical trial of Allogeneic chondrocyte cell sheet for knee OA treatment. This product has several unique advantages such as cell-only 3D products in sheet form, extremely easy to transplant, as the cell sheet can simply be applied to the defect area without any suturing procedure. CellSeed is now conducting a Phase 3 clinical trial and plans to launch this product in Japanese market within the next few years. In parallel, we are seeking international business partners to develop and launch this innovative product in overseas markets. Our clinical-grade allogeneic chondrocyte cell bank could be expanded to overseas which would greatly accelerate development.
CellSeed is striving to provide allogeneic chondrocyte cell sheet product for patients with knee OA worldwide.
[1]Sato, M. et al., NPJ Regen Med 2019; 4:4.
[2]Hamahashi, K. et al., NPJ Regen Med 2022 Dec 16; 7(1):71.

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