

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 (JASDAQ listed in 2010) to commercialize a world-first technology of "Cell Sheet Engineering" based on temperature responsive polymer. By using this technology, CellSeed have developed a variety of intelligent cell cultureware which are used by many researchers aggressively to conduct R&D activities world widely. In Japan, there are 3 regenerative medicines approved by PMDA which are using our cell sheet engineering technology. CellSeed have two pipelines of Esophageal cell sheet (in Phase 3) and Allogeneic chondrocyte cell sheet (submitting CTN for Phase 3) as well. Besides, CellSeed have in-house CPC which could manufacture cell products for clinical use, not only for our clinical trial but also providing CDMO service to domestic and abroad users.	
Contact address	Name*	Yuji Ueno
	Department* / Position	Business Development Department/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 Services 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 advanced 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
<input checked="" type="checkbox"/> Yes	Please kindly inform us when the presentation materials are provided to a third party through FIRM.
<input type="checkbox"/> No	

Filled in by*

Date*

	Dandan Song
	2023.09.15

Sheet [A] Clinical Development Pipelines**Info Sheet for Technical overview**

No. 0002

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Title***Allogeneic Chondrocyte Cell Sheet for Knee Osteoarthritis Treatment****Development Phase***

- | | | |
|---|--|--|
| <input type="checkbox"/> Basic Research | <input type="checkbox"/> Drug Discovery | <input type="checkbox"/> Pre-Clinical |
| <input type="checkbox"/> Clinical Trial (Phase I) | <input type="checkbox"/> Clinical Trial (Phase II) | <input checked="" type="checkbox"/> Clinical Trial (Phase III) |
| <input type="checkbox"/> Review | <input type="checkbox"/> Others | |

Disease Area*

- | | | |
|---|---|---|
| <input type="checkbox"/> Cancer | <input type="checkbox"/> Central nervous system | <input type="checkbox"/> Ophthalmology |
| <input checked="" type="checkbox"/> Musculoskeletal | <input type="checkbox"/> Endocrine / Metabolism | <input type="checkbox"/> Cardiovascular |
| <input type="checkbox"/> Urogenital | <input type="checkbox"/> Digestive organ | <input type="checkbox"/> Blood |
| <input type="checkbox"/> Infection | <input type="checkbox"/> Dermatology | <input type="checkbox"/> Immunity |
| <input type="checkbox"/> Otolaryngology | <input type="checkbox"/> Respiratory | <input type="checkbox"/> Others |

Description*

Knee osteoarthritis (OA) is a common progressive multifactorial joint disease and is characterized by chronic pain and functional disability. It not only significantly diminishes patients' QOL but also accounts for a substantial portion of the nation's healthcare expenditure. However, the fundamental therapy has not yet been established.

Aiming for radical treatment of knee OA, Dr. Masato Sato et al. of Tokai University focused on cell-sheet engineering using temperature-responsive cell cultureware developed by CellSeed, initiated the research of cartilage regeneration using of chondrocyte cell sheets. Since 2011, the clinical research with autologous chondrocyte sheets has been carried out and its efficacy and safety have been confirmed [1]. This therapy was approved afterwards at Tokai University Hospital as Advanced Medical Care B and we continue to manufacture 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, improvement of clinical symptoms was 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 serve a significantly larger patients. CellSeed is currently submitting CTN for 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 transplat, as the cell sheet can simply be applied to the defect area without any suturing procedure. CellSeed is preparing for its upcoming Phase 3 clinical trial and plan to launch this product on to Japanese market in several years. Concurrently, we aim to seek international business partners to develop and launch this fantastic product in overseas markets. Our clinical-grade allogeneic chondrocyte cell bank could be expanded to overseas which would greatly accelerate development.

CellSeed is trying the best to provide allogeneic chondrocyte cell sheet product to serve knee OA patients all over the world.

[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.

Filled in by*

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Date*

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