

## CellSeed Inc.

## Fiscal 2023 Earnings Results

## Presentation



Tokyo Stock Exchange Growth Code: 7776



## Company Profile

## • Financial Summary of Fiscal Year Ending

December 31, 2023

## O Progress of each business

Head office · CPC · development and manufacturing facility



Established	May, 2001
Core competence	Cell Sheet Engineering based on Temperature Responsive Polymers
Listed	Tokyo Stock Exchange Growth (7776)

#### **Head Office**

15F (East Wing) Telecom Center Building 2-5-10, Aomi, Koto-ku, Tokyo

#### **Cell Processing Center**

Telecom Center Building 6F Total Floor Area 763 m<sup>2</sup>

#### (Facility Number:FA3160008)



#### **Aomi Cell Cultureware Innovation Center**

Time 24 Building, 4-32, Aomi 2-chome, Koto-ku, Tokyo



## CellSeed Inc. Corporate Information

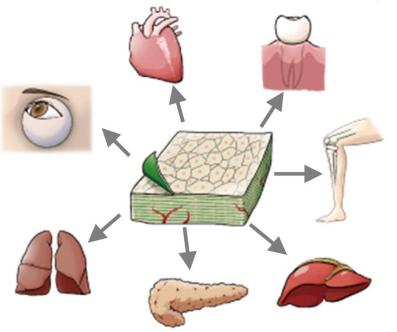


#### **Mission**

We take the initiative of contributing to global health care in the valuable and innovative field of regenerative medicine.

#### Regenerative Medical Products Business

• Commercialization of Cell Sheet Therapies



#### Regenerative Medicine Supporting Business

• Intelligent Culture Ware as Research Tools



#### **UpCell**<sup>®</sup>

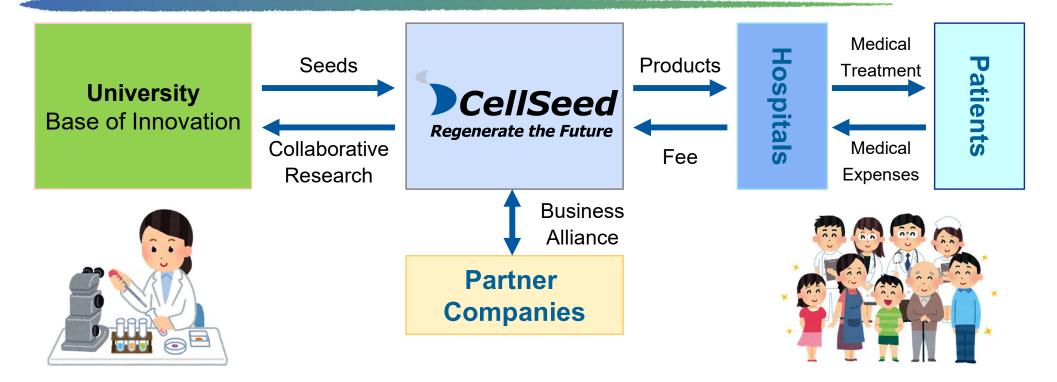
• Contract Manufacturing Services • Consulting



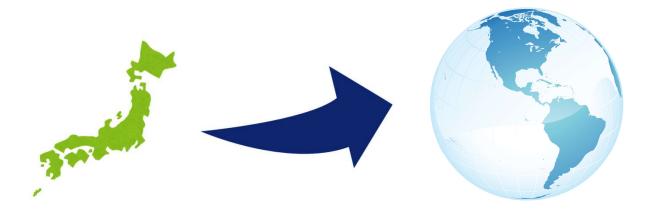
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## **Our Business Model**

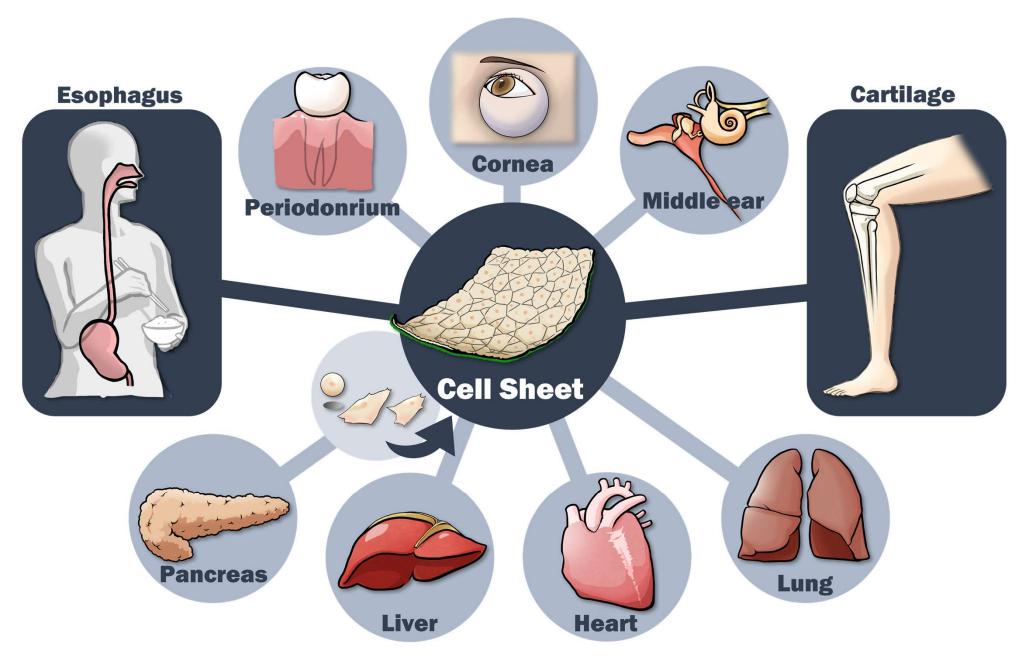




Delivering the technology developed at a university and developed at a venture to patients as soon as possible.









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## Year financial summary FY 12/2023



	First Half of the FY2023 (January 2023 - Dec 2023)			First Half of the FY2022 (January 2022 - Dec 2022)
	Amount (Millions of yen)	Change from Previous Period (Millions of yen)	Change from Previous Period (%)	Amount (Millions of yen)
Sales	190	63	50.4	126
Operating profit	-697	45	—	-743
Ordinary profit	-710	43	_	-754
Net profit	-846	-86	_	- 759



- Cell cultureware business
  - In particular, overseas sales grew considerably.
  - Achieved record-high sales.
- Commissioned regenerative medicine business
  - Tokai University entrusted us with the production of autologous cartilage cell sheets for 7 cases as Advanced Medical Care B
  - Achieved record-high sales.
- Allogeneic cartilage cell sheet
  - Submitted a clinical trial plan in September 2023.
  - Expected to start the registration of subjects in the first half of 2024.
- Business alliance activities
  - For accelerating commercialization and developing a system for selling allogeneic cartilage cell sheets, we are preparing for business alliances with some companies and conclusion of joint research contracts
  - Cancellation of the contract with MetaTech (AP) Inc.

The 24<sup>th</sup> issuance of share acquisition rights (with a provision for revising exercise price) for allocation of shares to a third party



Allocation date	June 5, 2023
Number of share acquisition rights to be issued	69,000
Allocatee	Barclays Bank
Assumed procurement amount	2,362,601,000 yen (roughly estimated net amount)
Period and conditions of exercise	About two years from June 6, 2023 to June 12, 2025. Regarding 15,000 out of 69,000 share acquisition rights, they may be exercised only after our company submits a notification on clinical trials for allogeneic cartilage cell sheets to PMDA and announces it.
Purposes of use of funds	Funds for R&D and operation

#### • Exercise during a period until the end of July 2023

37,765 out of 69,000 share acquisition rights have been exercised. (54.73% of the total number of share acquisition rights issued)



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## • Progress of each business



#### **UpCell**<sup>®</sup>

This cultureware maintains the physiological activity of cells and retains a high level of antigen proteins on the cell surface while serving as a cell culture dish for the recovery of the cell sheet.



### *RepCell*<sup>®</sup>

In addition to the same characteristics as those of UpCell<sup>®</sup>, this cultureware allows for the recovery of cells in a single cell or small colonies using the surface grid wall.



#### *HydroCell*<sup>®</sup>

Using proprietary technology, nanosurface design, superhydrophilic polymers are fixed to the surface of this cultureware, which forms spheroids of iPS cells and cancer cells.

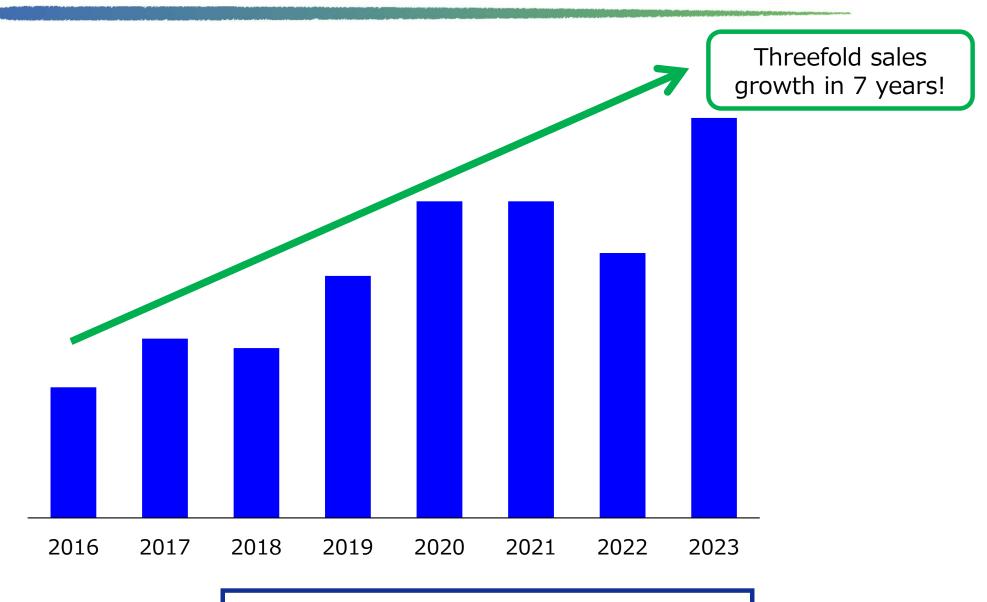


## cellZscope

This is a type of cultureware that is most suitable for research into the effect of drugs and poisons for the evaluation of cell layer barrier functions.

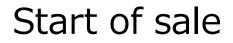


## Variation in sales of the cell cultureware business



## Achieved record-high sales

**CellSeed** Regenerate the Future





- On February 15, 2024, we released the new product VIVANT-CELL Pot with UpCell Plate.
  - Highly functional stem cells can be fractionated easily with VIVANT-CELL Pot.
    Intact cells can be collected with UpCell Plate.







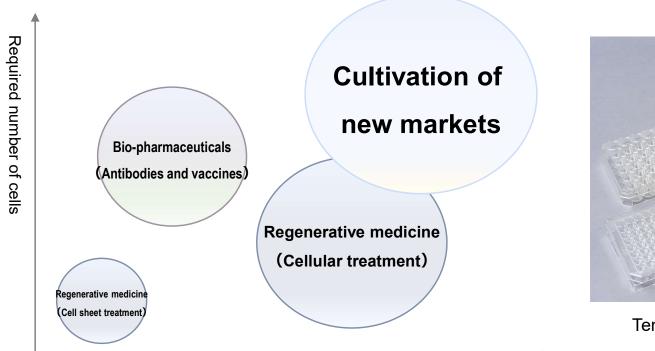
#### Need for technology to culture cells

in large quantities

- Biopharmaceutical manufacturing
- Manufacturing cells for use in immunotherapy
- Development of cellular foods such as cultured meat



## Possibility of market expansion





#### Temperature-responsive cell cultureware

#### Market potential

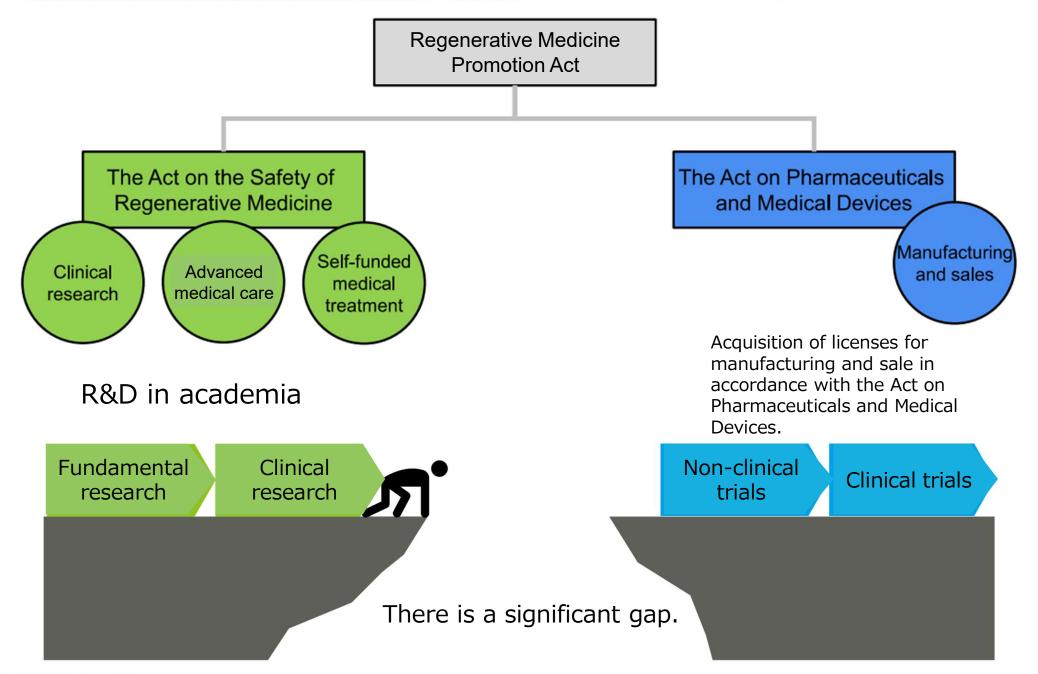
Reference info: Forecast for the global market of regenerative medicine 2025/2030/2035 (100 million yen) Tissue transplantation (cell sheets); 812/895/885 Cell transplantation (cell therapy); 13,476/24,695/36,033

Source: Survey on the market of regenerative medicine and gene therapy in fiscal 2019 Arthur D. Little Japan Final Report, P144 Reference info: Forecast for sales of bio-pharmaceutical products 2020 (100 million yen) 2020; 300,000

**Source:** Issues in the bio-pharmaceutical industry and suggestions for further development Japan Pharmaceutical Manufacturers Association, Office of Pharmaceutical Industry Research, Research Paper, No.71, P8

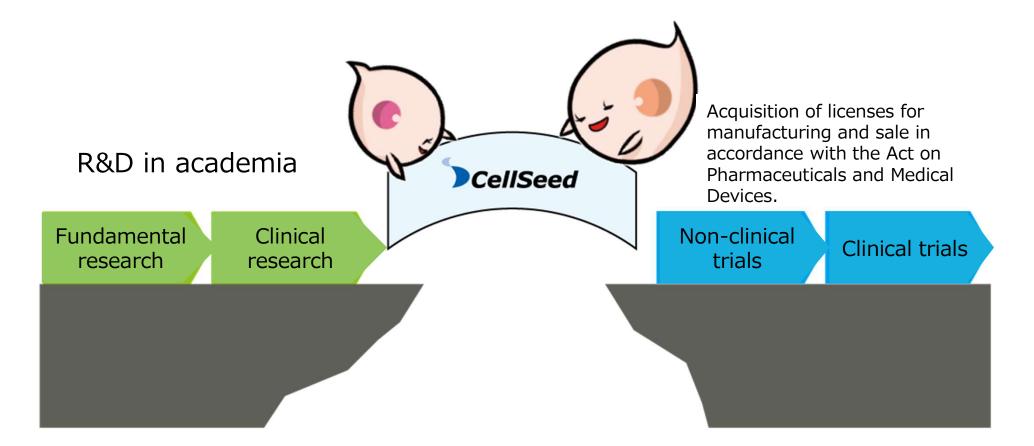
#### Regenerative medicine supporting business: Regenerative medicine consignment services







#### Serving as a bridge to deliver regenerative medicine to patients by solving problems with academia and closing the gap



CellSeed aims to contribute to the provision of regenerative medicine to patients by offering the service of undertaking regenerative medicine projects.

## **Regenerative Medicine Supporting Business**



Development of Manufacturing Methods and Contract Manufacturing for Cell Sheet Products

- Development of cell sheet manufacturing methods
- Contract manufacturing of cell sheet products
- Quality testing of cell sheets, etc.

#### **Facility Management and Application Support**

- Support for preparing and submitting applications
- Support for document creation/consulting
- Support for operation and maintenance of facilities equipment/management system, etc.





#### **Training of Cell Culturing Technicians**

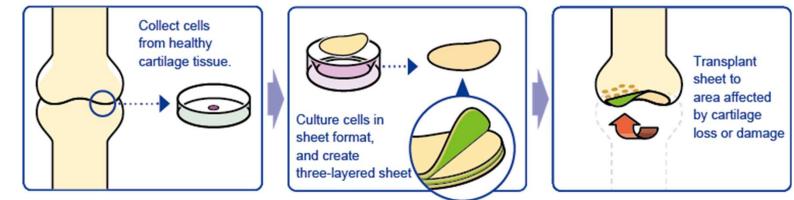
- Cell sheet culturing training
- Cell sheet harvesting training, etc.





For the regenerative medicine service, we obtained the permission to manufacture specific processed cells (facility No. FA3160008) in March 2017 and the permission to manufacture products for regenerative medicine in October 2018 and have undertaken various projects so far. We will continue the commissioned production of cell sheets, while giving top priority to quality.

- Autologous cartilage cell sheets
  - Contract manufacturing of autologous chondrocyte sheets for the Advanced Medical Care B program conducted by Tokai University.

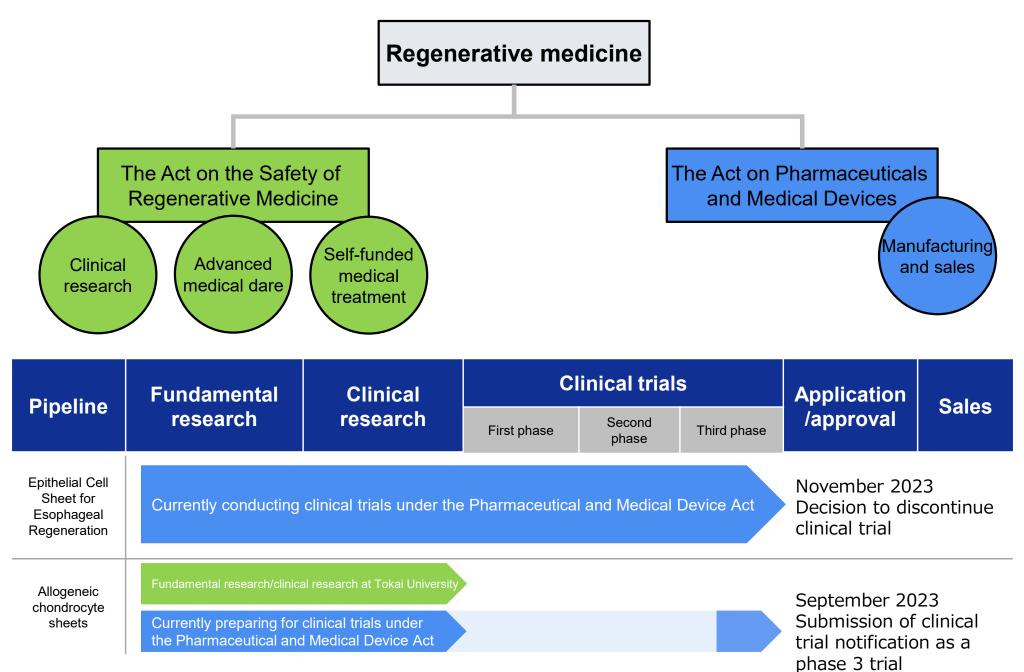


- Pediatric autologous epithelium cell sheet
  - For children after surgery for congenital esophageal atresia

\*The above are the projects that can be disclosed.

## **Pipeline Progress**





## Knee Osteoarthritis (OA)







30 million potential patients (Japan)

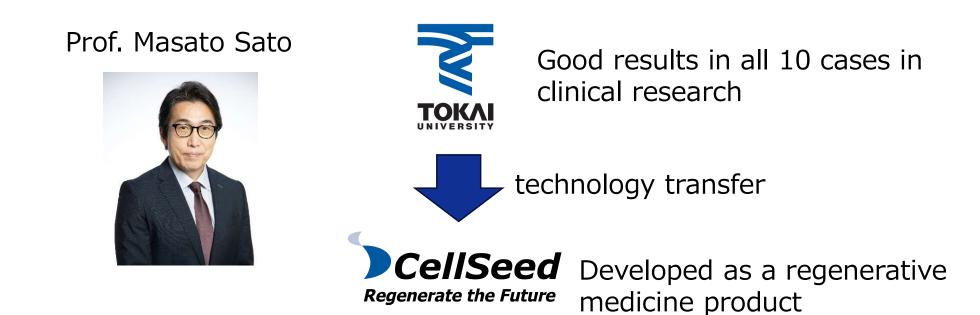
10 million patients with symptoms (Japan)

- Prevalence increases with age
- 1.5 to 2 times more women than men
- Number of patients is expected to increase due to aging of the population

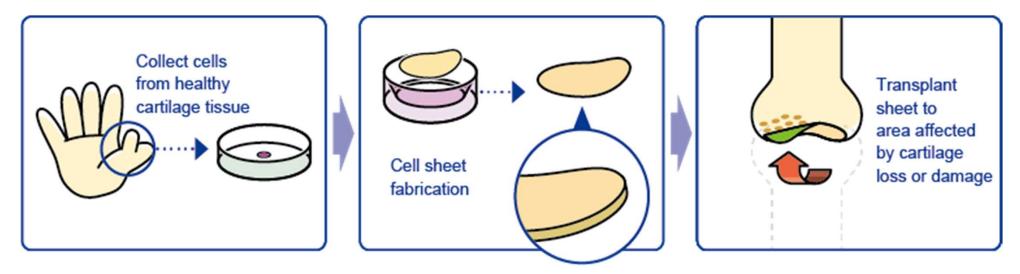
No fundamental medical therapy for OA

## Allogeneic chondrocyte sheet



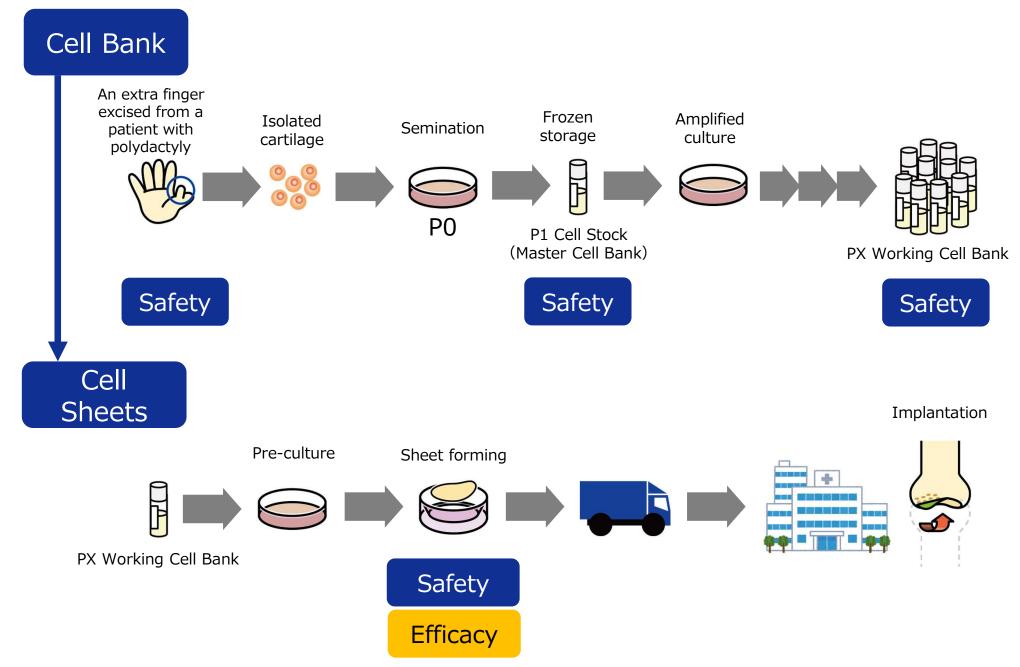


#### Allogeneic chondrocyte sheets



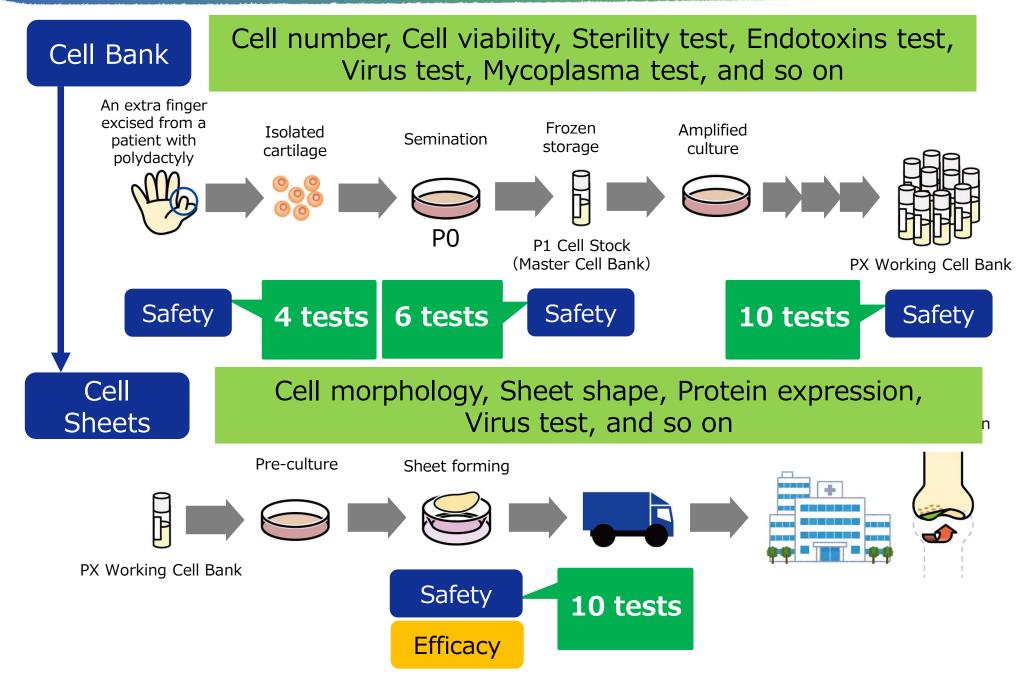
# Process of producing allogeneic cartilage cell sheets (CLS2901C)





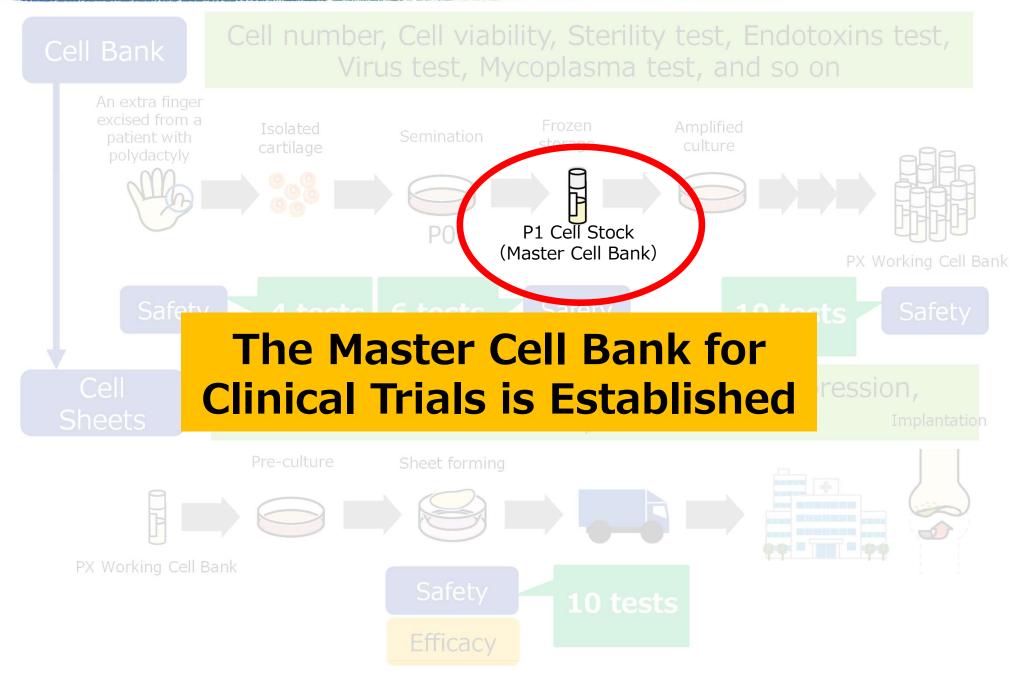
## Safety testing of cell banks and cell sheets





## Safety testing of cell banks and cell sheets

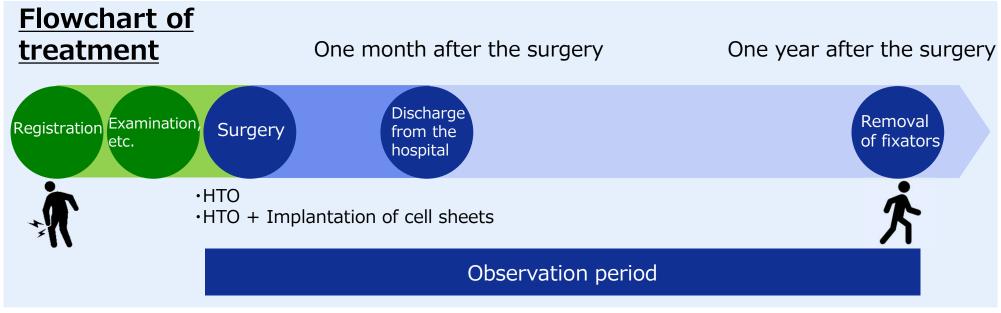




## Phase-3 test for allogeneic cartilage cell sheets



Test design:	Multicenter, single-blinded, randomized, parallel-group trial
Target number of cases:	96
Subjects:	Patients with knee osteoarthritis subject to low tibial osteotomy
Major items to be evaluated:	Patients' reports (evaluation method in which patients judge symptoms and quality of life by themselves without intervention of medical doctors and others)
Facilities where the test will be conducted:	A total of 5 facilities, including Tokai University Hospital (planned)



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• Date : Friday, Nov. 24, 2023

• Venue

: Miraikan Hall on the 7th floor of the National Museum of Emerging Science and Innovation, etc.

## **Lecturers**

#### **Prof. Masato Sato**

(Professor of Department of Orthopaedics, School of Medicine, Tokai University)

#### Prof. Haruko Takeyama

(Professor of Department of Life Science and Medical Bioscience, School of Advanced Science and Engineering, Faculty of Science and Engineering, Waseda University)

## Dr. Masahiro Ando

(Second-tier researcher of Research Organization for Nano & Life Innovation, Waseda University)

#### Dr. Masahito Kawabori

(Lecturer of Department of Neurosurgery, Graduate School of Medicine, Hokkaido University)

## Prof. Tatsuya Shimizu

(Professor and Director of Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University)







The 4th Cell Sheet Engineering Innovation Forum will be held in 2025



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