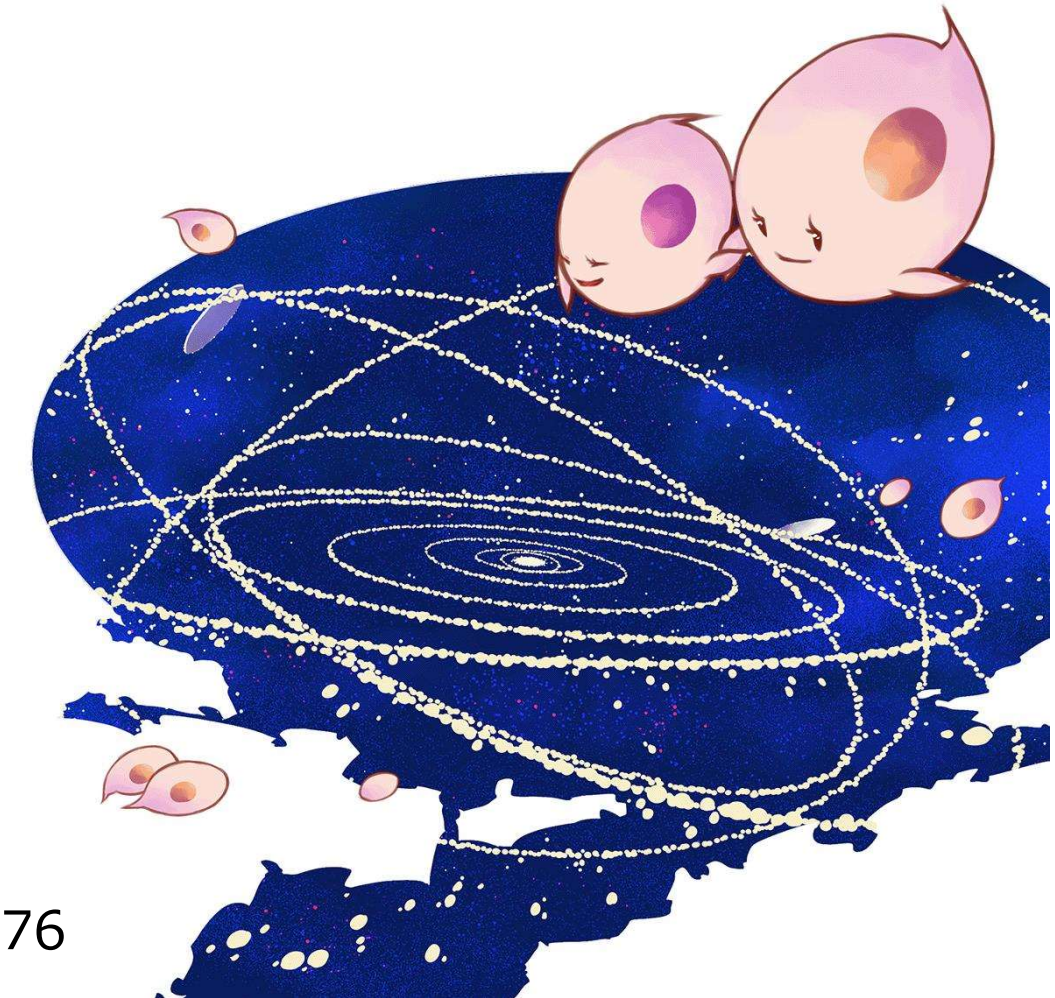
CellSeed
Regenerate the Future

CellSeed Inc.

Fiscal 2023 First-Half Earnings

Results Presentation



Tokyo Stock Exchange Growth Code:7776

Contents

- Company Profile
- Financial Summary Second Quarter of Fiscal Year Ending December 31, 2023
- 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 ㎡

（Facility Number:FA3160008）

Aomi Cell Cultureware Innovation Center

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

CellSeed Inc. Corporate Information

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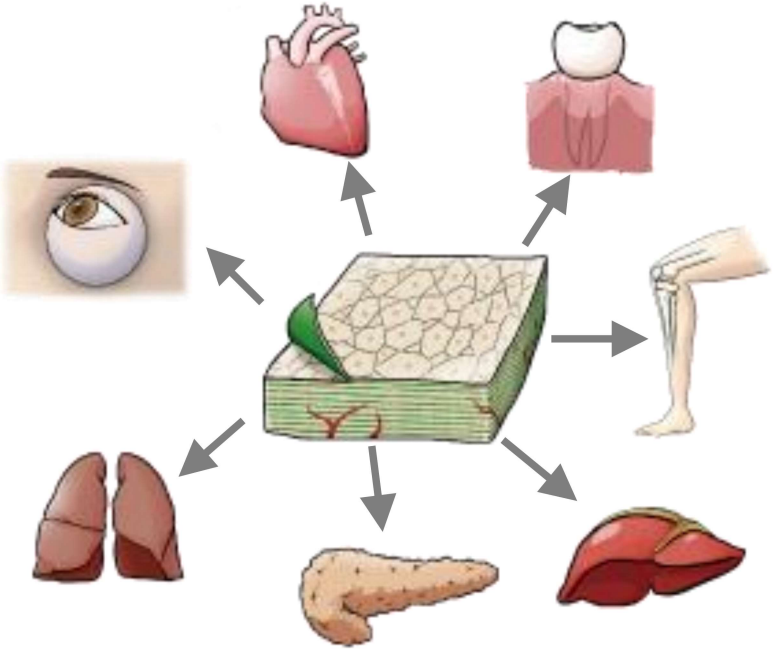
Mission

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®

- Contract Manufacturing Services・ Consulting

CPC

Our Business Model

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University
Base of Innovation

Seeds

Collaborative Research

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Products

Fee

Hospitals

Medical Treatment

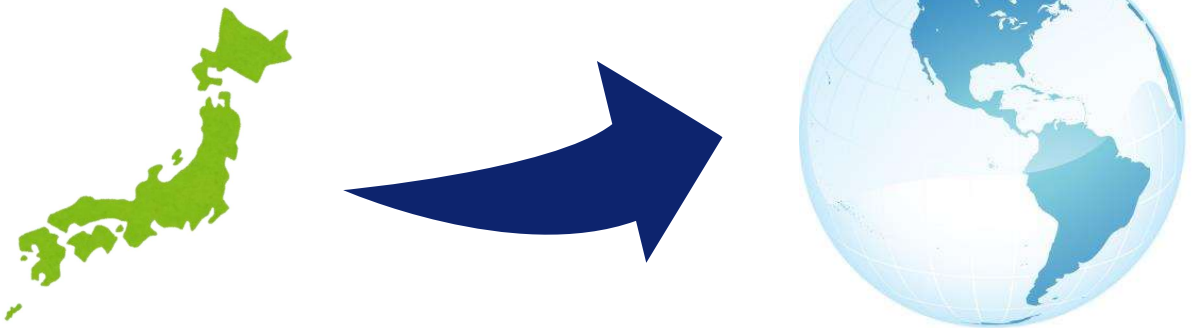
Medical Expenses

Patients

Business Alliance

Partner Companies

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



Development of Treatment Using Cell Sheet Engineering

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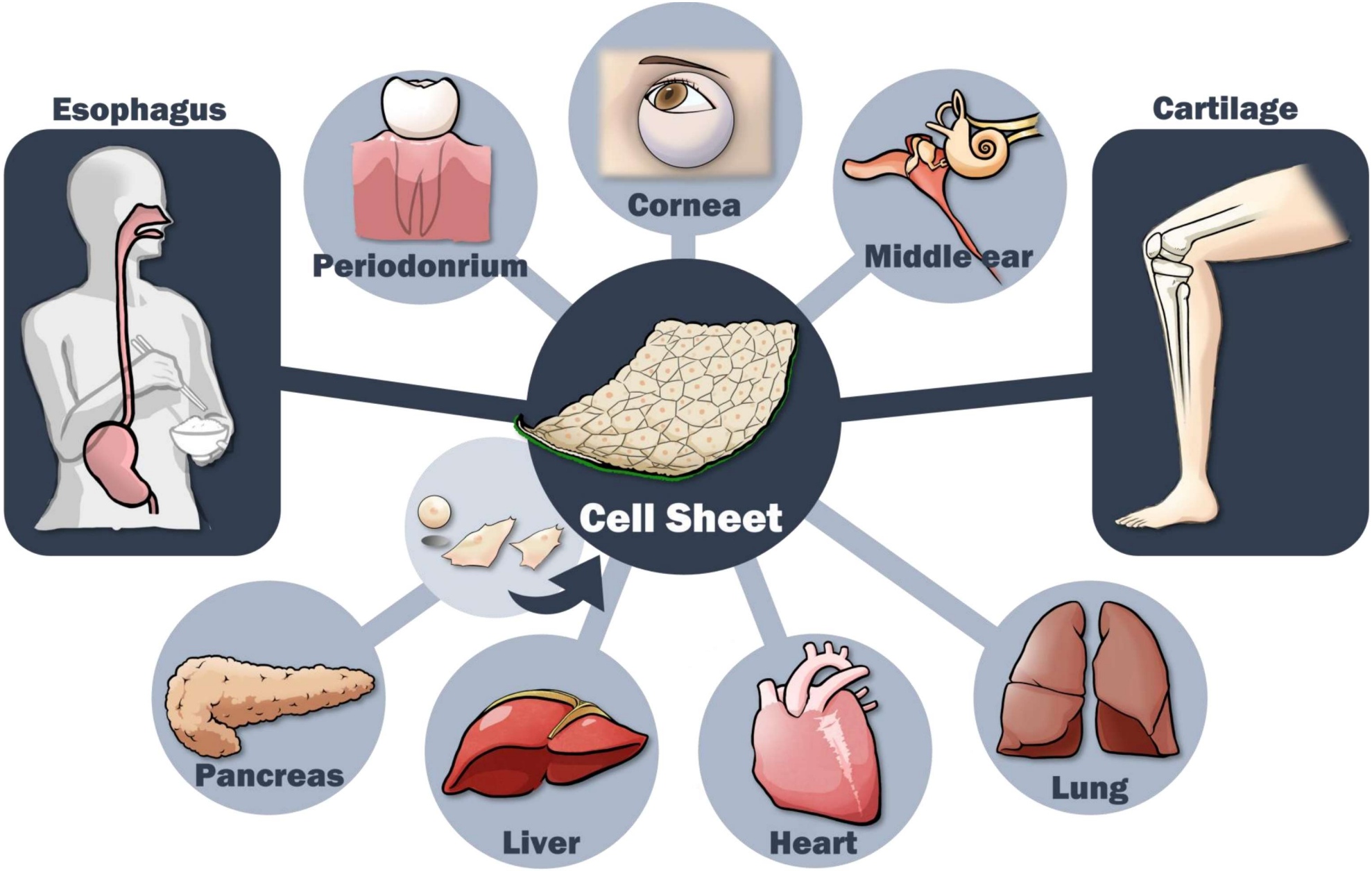

Contents

Half-year financial summary FY 12/2023

	First Half of the FY2023 (January 2023 - June 2023)			First Half of the FY2022 (January 2022 - June 2022)
	Amount (Millions of yen)	Change from Previous Period (Millions of yen)	Change from Previous Period (%)	Amount (Millions of yen)
Sales	66	-7	-10.2	74
Operating profit	-359	-10	–	-348
Ordinary profit	-366	-13	–	-352
Net profit	-363	-6	–	-357

- Enhanced the cooperation with existing distributors for sales promotion of devices and conducted active sales promotion campaigns.
- Like in the previous year, Tokai University entrusted us with the production of autologous cartilage cell sheets for Advanced Medical Care B. In the cumulative second quarter, sales came from only one case, but from the third quarter, sales are expected to come from multiple cases.
- Regarding allogeneic cartilage cell sheets, we are preparing for the submission of a clinical trial notification after consulting with PMDA.
- We are negotiating for forming business alliances and concluding contracts for collaborative development with multiple companies.

Differences between the estimates and results in the second quarter of the term ending December 2023

[unit: million yen, rounded down to the nearest million]

	Sales	Operating profit	Ordinary profit	Net profit
Previously announced forecasts (announced on Feb. 14, 2023)	95	-450	-450	-455
Results (announced on Aug. 14, 2023)	66	-359	-366	-363

- **Reason for the differences**

Regarding the commissioned regenerative medicine business, the registration of patients' cases fell behind schedule, so it is expected to be concentrated in the second half of the term. Regarding the sales of devices, overseas sales fell below the initial forecast.

In terms of profit, operating profit, ordinary profit, and net profit exceeded the previous forecasts, because the cost for outsourcing development fell below the initial forecast and we curtailed R&D costs, manufacturing expenses, and SGA thoroughly.

Full-year earnings forecast for the term ending December 2023

[unit: million yen, rounded down to the nearest million]

	Sales	Operating profit	Ordinary profit	Net profit
Full year	200	-840	-840	-845

The 24th 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**

7,250 out of 69,000 share acquisition rights have been exercised. (10.51% of the total number of share acquisition rights issued)

Contents

Cell cultureware in the regenerative medicine supporting business

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Temperature-responsive cell cultureware invented by Professor Okano of Tokyo Women's Medical University in 1989 can detach cells just by lowering its temperature. This feature enabled us to collect intact cell sheets for the first time in the world. As temperature-responsive cell cultureware are sold all around the world, many researchers are actively researching and developing treatment methods using cell sheets.

UpCell®

HydroCell®

1989	Professor Okano of Tokyo Women's Medical University invented temperature-responsive cell cultureware.
2004	Released ***RepCell***® and ***HydroCell***®
2007	Released ***UpCell***®.
2010	Released cellZscope®.
2011	Released ThermoPlate®.
2015	The regenerative medicine product Heart Sheet (Terumo Corporation) approved.（***UpCell***® was adopted as its component）
2017	Released ***HydroCell***® flasks.
2019	Overseas sales via Thermo Fisher Scientific increased 200% from the previous year.
2020	The sales of devices exceeded 100 million yen for the first time.
2021	・Reached an agreement for extending the period of the sales contract with Thermo Fisher Scientific until 2025. ・Established facilities for developing and manufacturing cell cultureware.
2022	・Sales of ***UpCell***® flasks launched ・Registration of UpCell® ADVANCE to MAF of the FDA

CellSeed Temperature Sensitive Cell Cultureware Lineup

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UpCell®

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®

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

HydroCell®

Using proprietary technology, nano-surface design, super-hydrophilic 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.

12

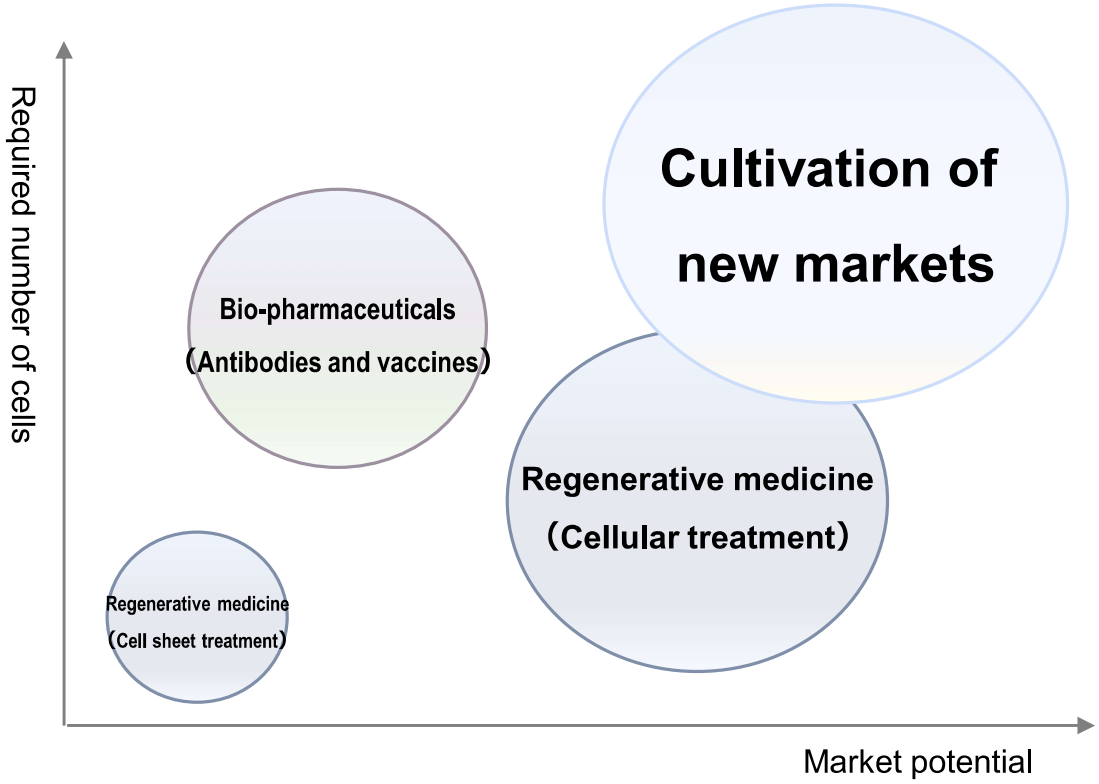
Upcoming plans for Cultureware buisiness

- Overseas sales of UpCell® flasks will start soon

- UpCell user training services will start soon
  - Training for UpCell users will be held at the Aomi Cell Culture Innovation Center.
  - We will actually give a lecture on tips for making cell sheets and detaching cell sheets.

Cultivation of new markets for cell cultureware

Recently, the production of bio-pharmaceutical products using mass-cultured cells, the immunotherapy using cells, and initiatives for solving food and environmental issues have been active. In the generally used cell collection technology, proteolytic enzymes are used, so cells are damaged when collected. Accordingly, it is difficult to keep the intrinsic functions and components of cells intact. However, by using our products, it is possible to collect cells without damaging them and utilize all functions and components of cells as they are. Therefore, our products are attracting attention, because they are expected to improve industrial efficiency and effectiveness in new markets.



Temperature-responsive cell cultureware

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

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1 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.

2 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.

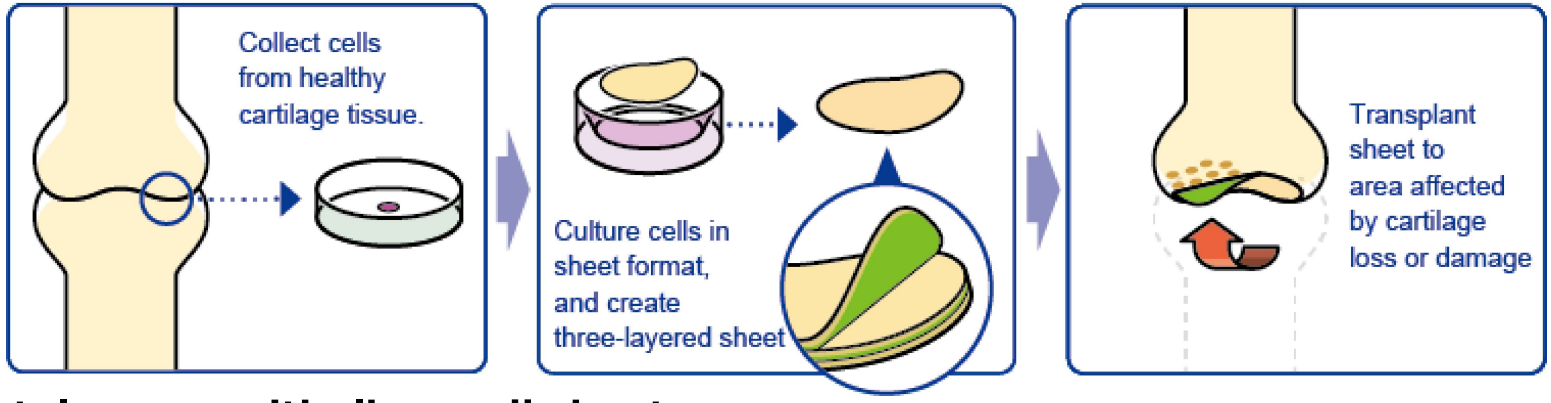
3 Training of Cell Culturing Technicians

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

Commissioned projects in our regenerative medicine service

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.

New deal of our contract services

- Contract manufacturing of autologous chondrocyte sheets for self-pay medical treatment at Ikegami General Hospital

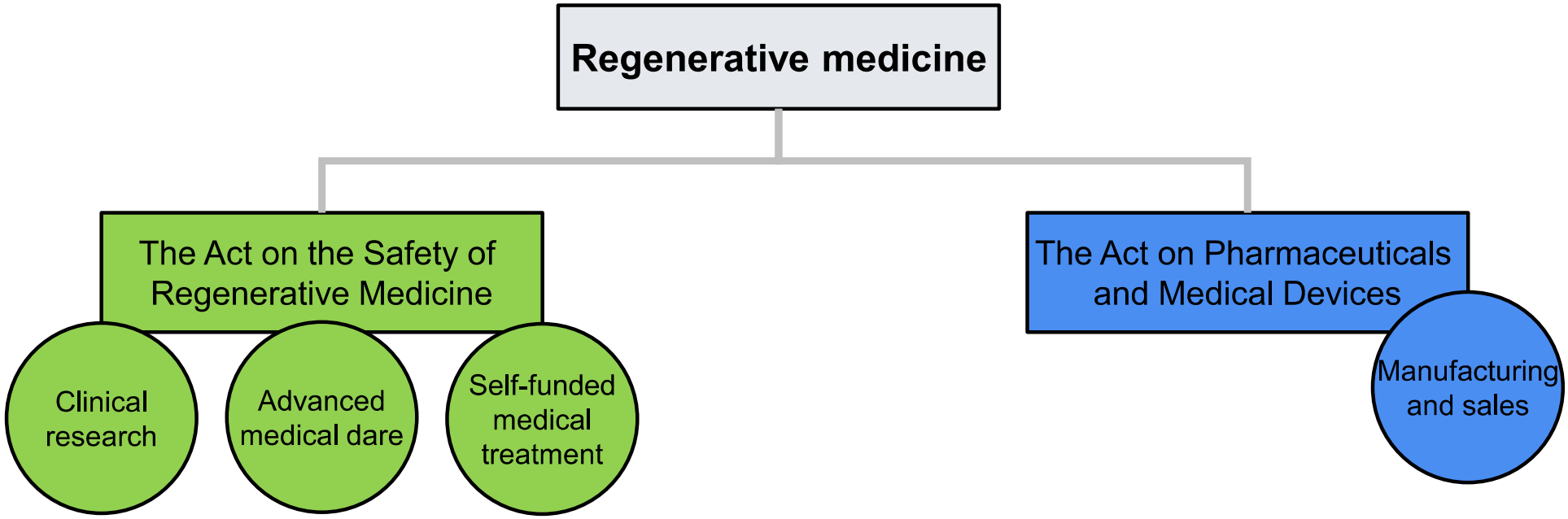
Target patients : Patients with knee cartilage due to trauma or knee OA

- Patients who are not eligible for advanced Medical Care provided by Tokai University
- Inbound from overseas

(c) Ikegami General Hospital

Look forward to expanding our contract business through contract manufacturing of cell sheets for self-pay medical treatment.

Pipeline Progress



Pipeline	Fundamental research	Clinical research	Clinical trials			Application /approval	Sales
			First phase	Second phase	Third phase		
Epithelial Cell Sheet for Esophageal Regeneration	Currently conducting clinical trials under the Pharmaceutical and Medical Device Act						
Allogeneic chondrocyte sheets	Fundamental research/clinical research at Tokai University						
	Currently preparing for clinical trials under the Pharmaceutical and Medical Device Act						

Epithelial Cell Sheet for Esophageal Regeneration (CLS2702C/D)

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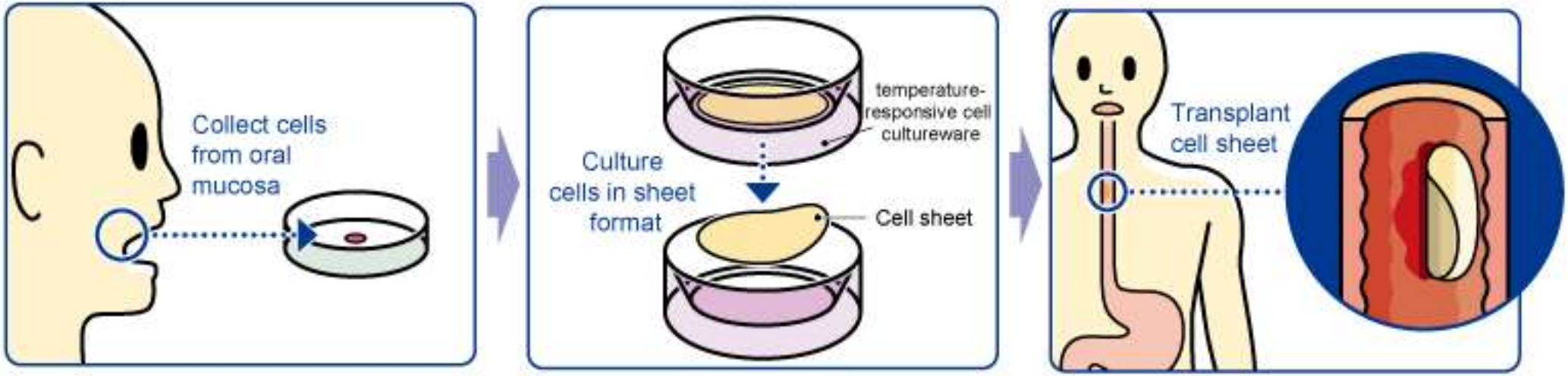
- A medical treatment developed by Tokyo Women's Medical University as a regenerative treatment for esophageal cancer (to heal esophageal wound and prevent stricture)
- Cell sheet is on a temperature-responsive cell culture ware and then transplanted into the ulcerated area in the esophagus after endoscopic surgery for esophageal cancer



Clinical Research and Clinical Trials of Esophageal Cell Sheet

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Tokyo Women's Medical University

- **Clinical Research at Universities**

2008－2014＜Japan＞

Tokyo Women's Medical Univ.	10case
Tokyo Women's Medical Univ. and Nagasaki Univ.	10case

＜Europe＞

Karolinska University Hospital	10case

Basic Development Agreement

2017.4
Business alliance agreement signed with Taiwan's MetaTech(AP) Inc.

- **Clinical Trials sponsored by CellSeed**

"SAKIGAKE Designation" in Feb. 2017

Japan ⟷ **CellSeed** *Regenerate the Future* ⟷ **Taiwan (MetaTech)** **Europe (Sweden)**

- 2016 Apr. Submitted a notification of clinical trial plan
- 2019 Mar. Completed the clinical trial in Japan
- 2020 Oct. Additional clinical trial plan notification submitted
- 2021 Feb. First medical case recorded

- 2016 Consulted with European Medicines Agency (EMA)
- 2017 Licensed out the product to MetaTech in Taiwan
- 2018 Submitted a notification of a clinical trial in Taiwan
- 2020 Suspended the clinical trial in Europe

Knee Osteoarthritis (OA)

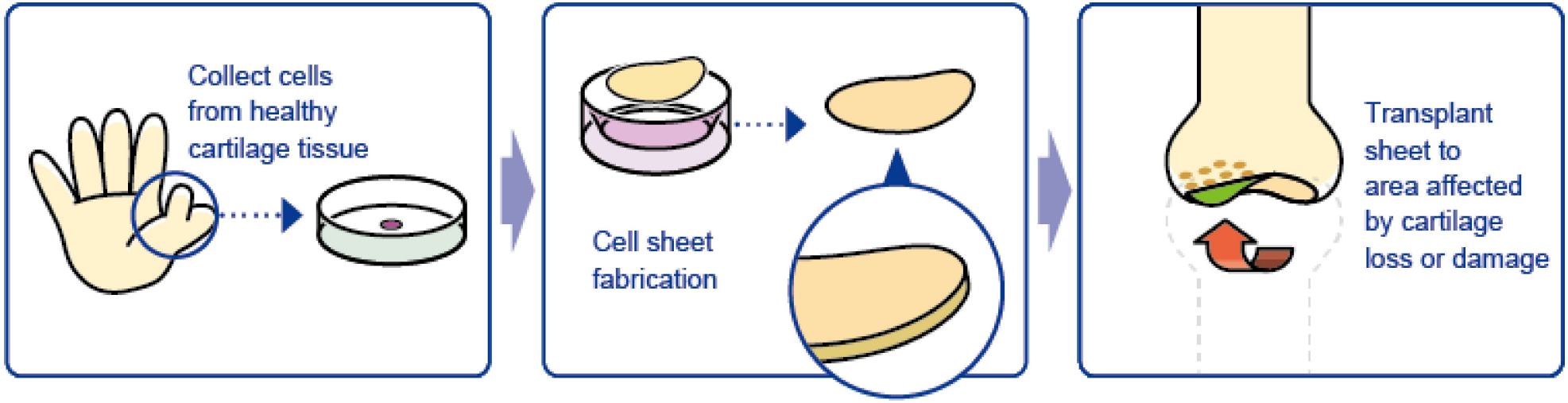
30 million potential patients (Japan)

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 sheets**



Process of producing allogeneic cartilage cell sheets (CLS2901C)

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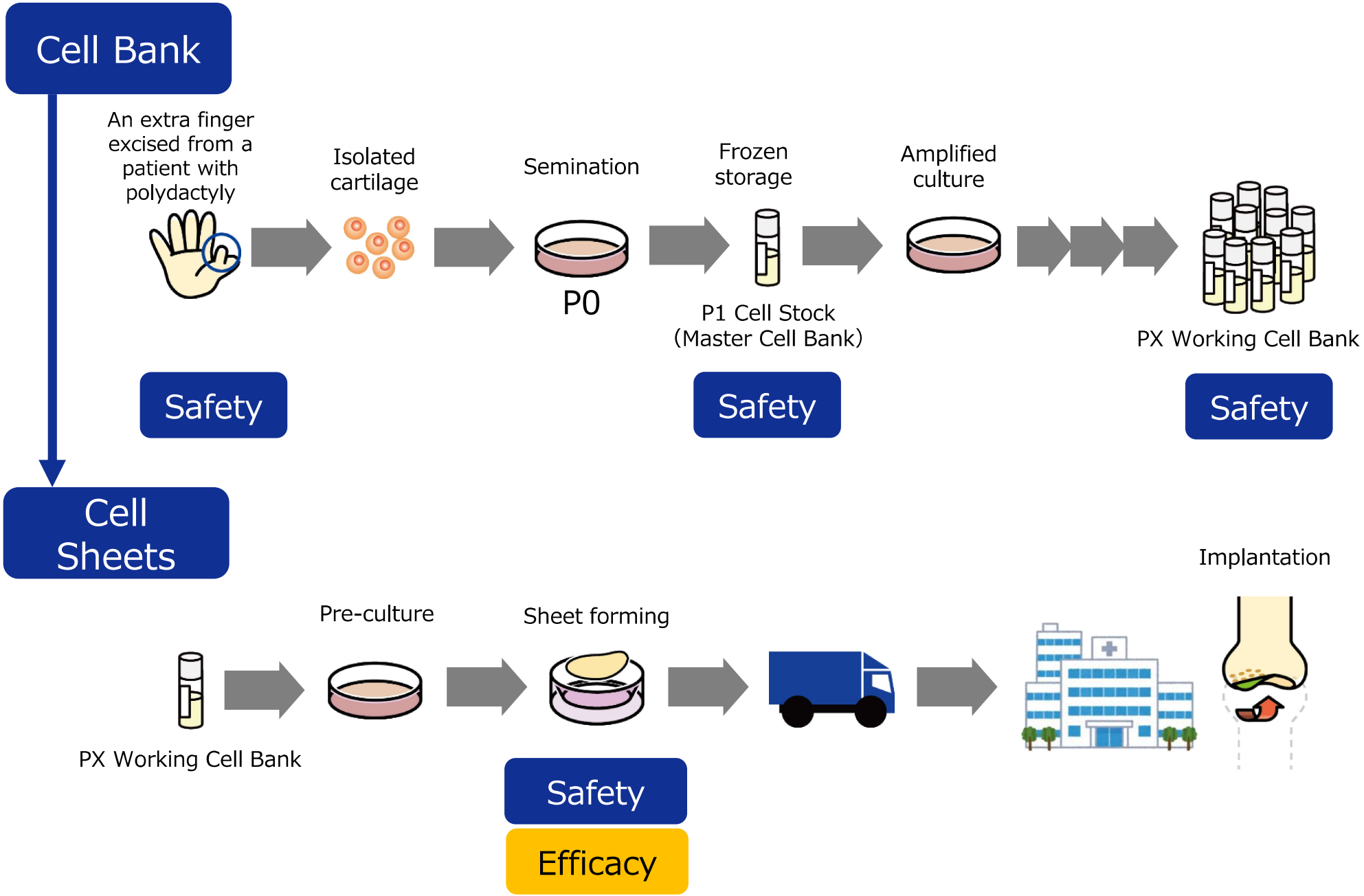

Safety testing of cell banks and cell sheets

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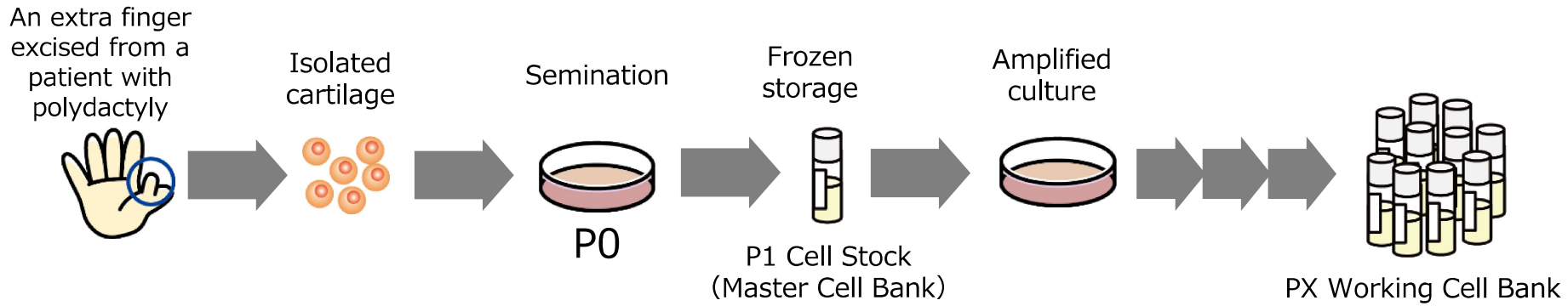
Cell Bank

Cell number, Cell viability, Sterility test, Endotoxins test, Virus test, Mycoplasma test, and so on

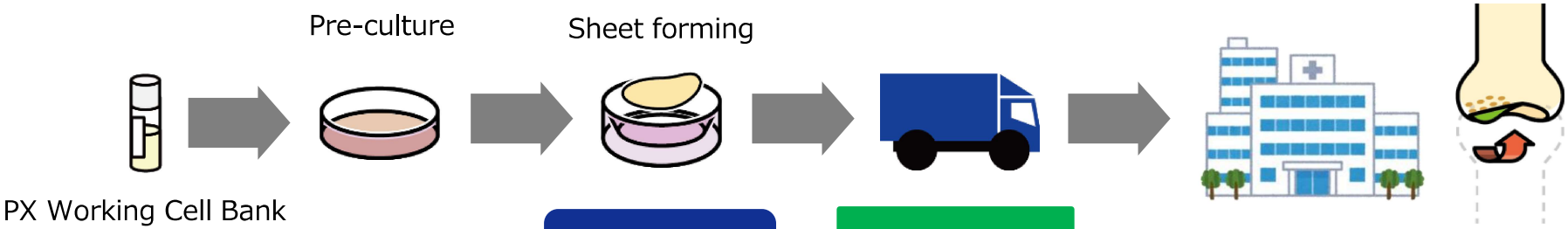


Safety — 4 tests — 6 tests — Safety

10 tests — Safety

Cell Sheets

Cell morphology, Sheet shape, Protein expression, Virus test, and so on



Safety — 10 tests

Efficacy

Safety testing of cell banks and cell sheets

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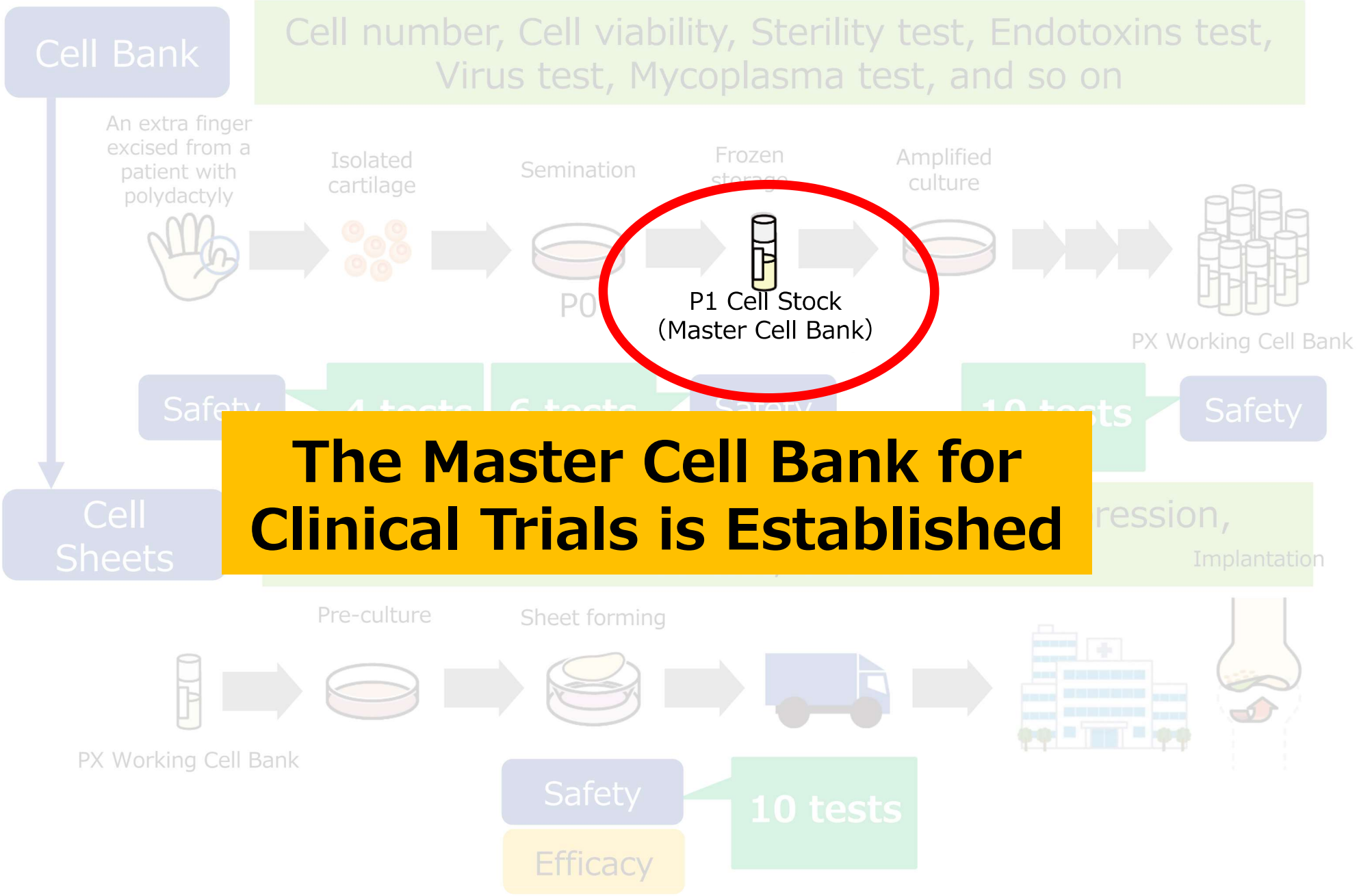


The Master Cell Bank for Clinical Trials is Established

Efficacy of allogeneic chondrocyte sheets

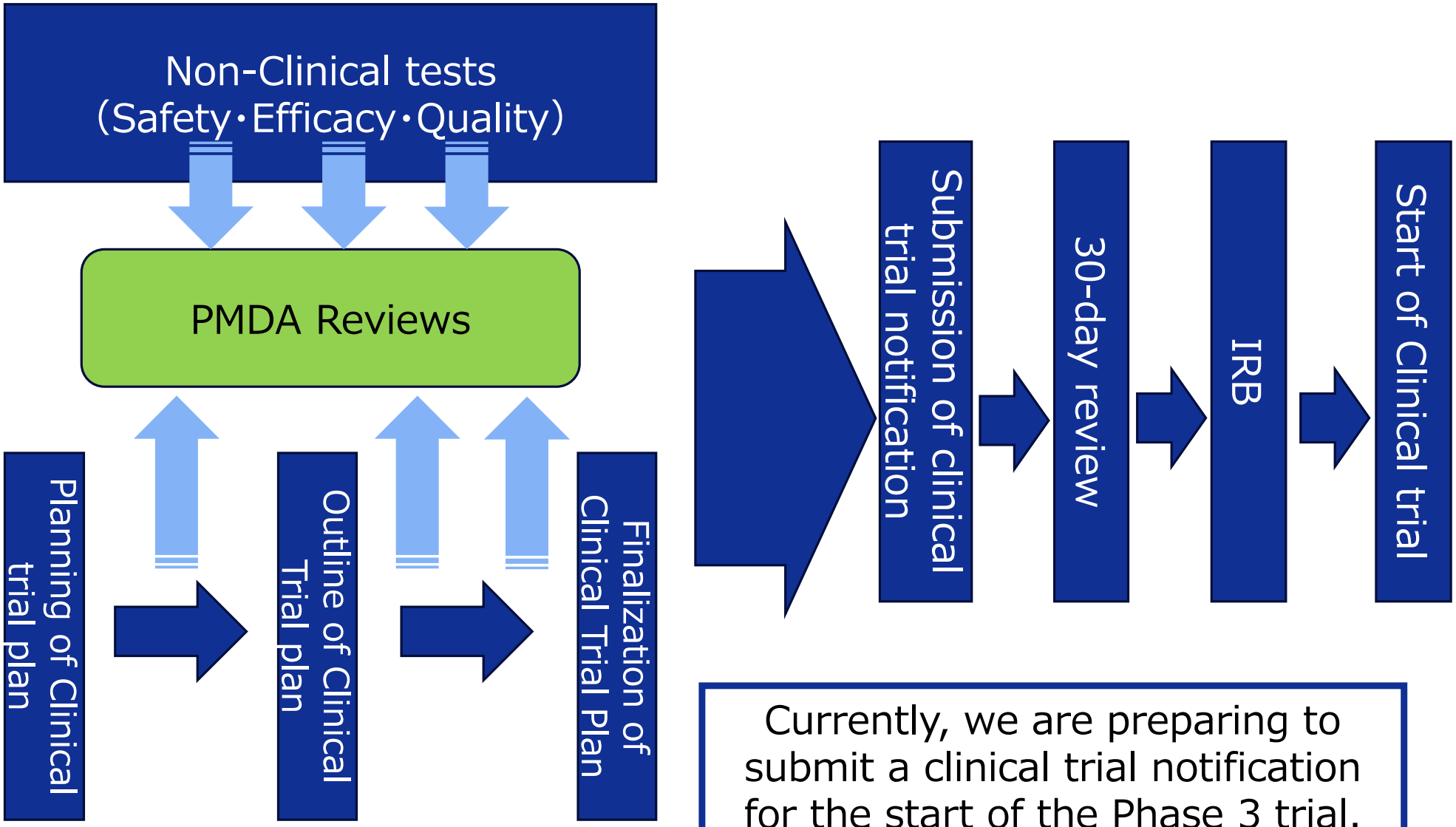
The efficacy of the cell sheets were confirmed by transplantation of the cell sheet into rat knee cartilage injury model

The results were presented at the 22nd Congress of the Japanese Society for Regenerative Medicine in March 2023.

Allogeneic chondrocyte sheets

2017 – 2019	Clinical Research at Tokai University Completed in December 2019 transplants of 10 cases
2018 – 2021	Adopted as the ancillary project of AMED Adopted as “a project for developing fundamental evaluation technologies for industrializing regenerative medicine (support for acceleration of development of regenerative medicine seeds)”; project period: Oct. 2018 to Mar. 2021
2020-	Acquired cartilage cell for commercial purposes from the National Center for Child Health and Development
2021 – 2023	Adopted as the ancillary project of AMED Adopted as “a project for developing fundamental evaluation technologies for industrializing regenerative medicine (project for promoting the industrialization of regenerative and cell medicine and gene therapy)”; project period: Aug. 2021 to Mar. 2023
2023	Preparing for submission of a clinical trial notification for the start of the Phase 3 trial

Steps for conducting clinical trial



Currently, we are preparing to submit a clinical trial notification for the start of the Phase 3 trial.

3rd Cell Sheet Engineering Innovation Forum

- Date : Friday, Nov. 24, 2023
- Venue : Miraikan Hall on the 7th floor of the National Museum of Emerging Science and Innovation, etc.
- Seating capacity : 200 people (pre-registration, first come, first served)
- Attendance fee : Free

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)

Scenes from past Cell Sheet Engineering Innovation Forums

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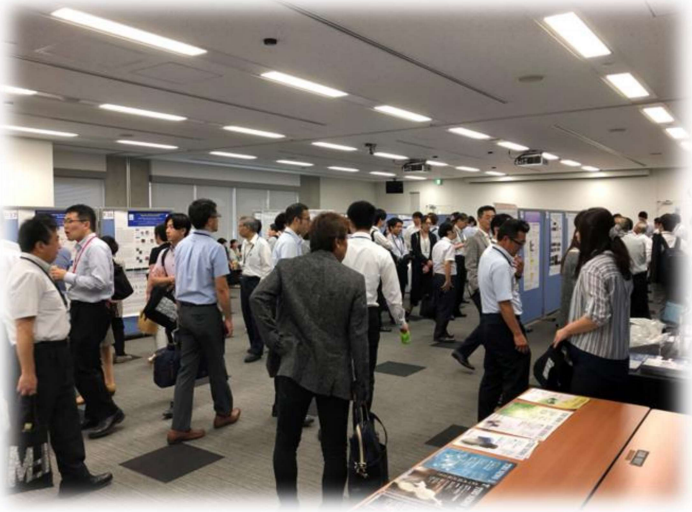

Announcements Regarding Certain Media Coverages on MetaTech(AP) Inc. in Taiwan

- Recent reports in some Taiwanese media regarding MetaTech
  - Our “cell sheet engineering” information was leaked from MetaTech
  - MetaTech is conducting research and development of allogeneic chondrocyte sheets
  - the technology involved in chondrocyte sheets has leaked out to China
- The rights granted to MetaTech by CellSeed are only for “autologous chondrocyte sheets” and “esophageal regeneration sheets” in Taiwan
- We have been demanding MetaTech should confirm the facts regarding these reporting and seek a cease and desist against the use and retrieval of the leaked information, yet MetaTech's response was that they could not explain the details
- We are continuing to investigate the facts and are consulting with our legal counsel to determine the necessary legal actions against MetaTech.

CellSeed

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