Presentation Material

Financial Results for the Fiscal Year Ended July31,2025

StemRIM Inc.（Stock code：TSE4599）

Masatsune OKAJIMA, President & Chief Executive Officer
September 12,2025

Agenda

1 **Company Overview**

- Corporate Mission
- Mode of Action of “Regeneration-Inducing Medicine™”
- Business Model
- Management Indicators

2 **Progress in Research and Development**

- Highlights for the Fiscal Year Ended July 31, 2025

3 **Summary of Activities the Fiscal Year Ended July 31,2025**

- Financial Summary
- IP Strategy
- Business Development Activities

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1. Company Overview

Overcoming Refractory Diseases by "Regeneration-Inducing Medicine™"

StemRIM

Stem cell Regeneration-Inducing Medicine

StemRIM is a biotech company aiming to develop "Regeneration-Inducing Medicine™" a next generation of regenerative medicine.
"Regeneration-Inducing Medicine™" is new class of medicine that induces functional regeneration of damaged tissues or organs by maximizing the patient's innate ability of tissue repairing.

We aim for a future in which "Regeneration-Inducing Medicine™" helps patients all over the world suffering from refractory diseases.

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Mode of Action of “Regeneration-Inducing Medicine™”

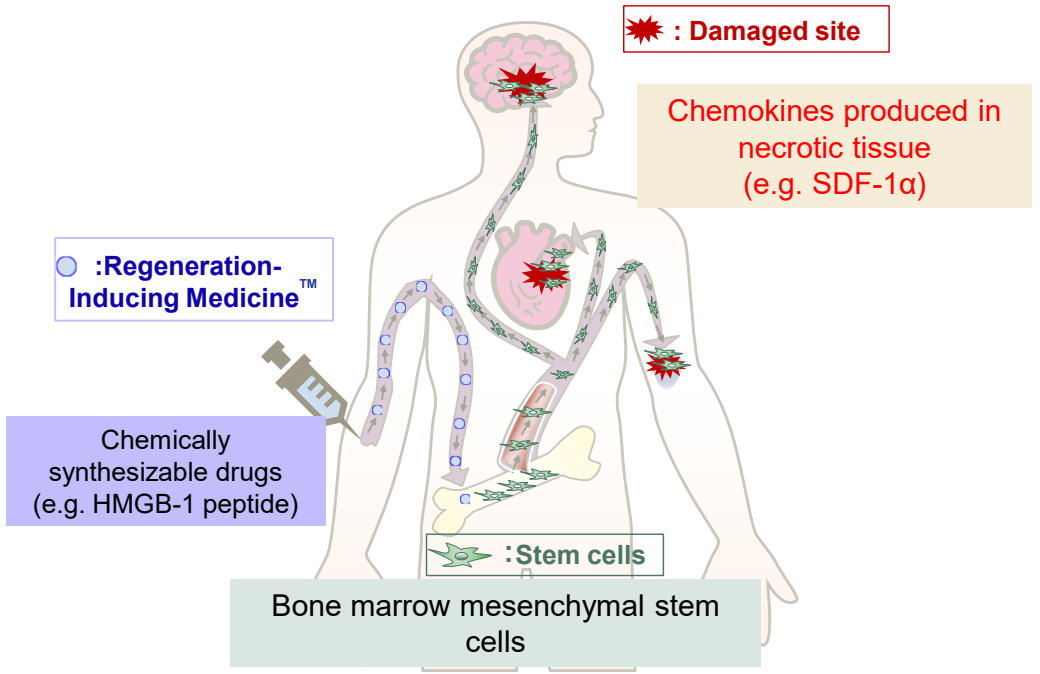
Bone marrow mesenchymal stem cells mobilized into the peripheral blood stream induce the tissue regeneration.

Administration of “Regeneration-Inducing Medicine™”

Mobilizing Stem cells from bone marrow into the blood stream

Stem cells accumulation in the damaged tissues

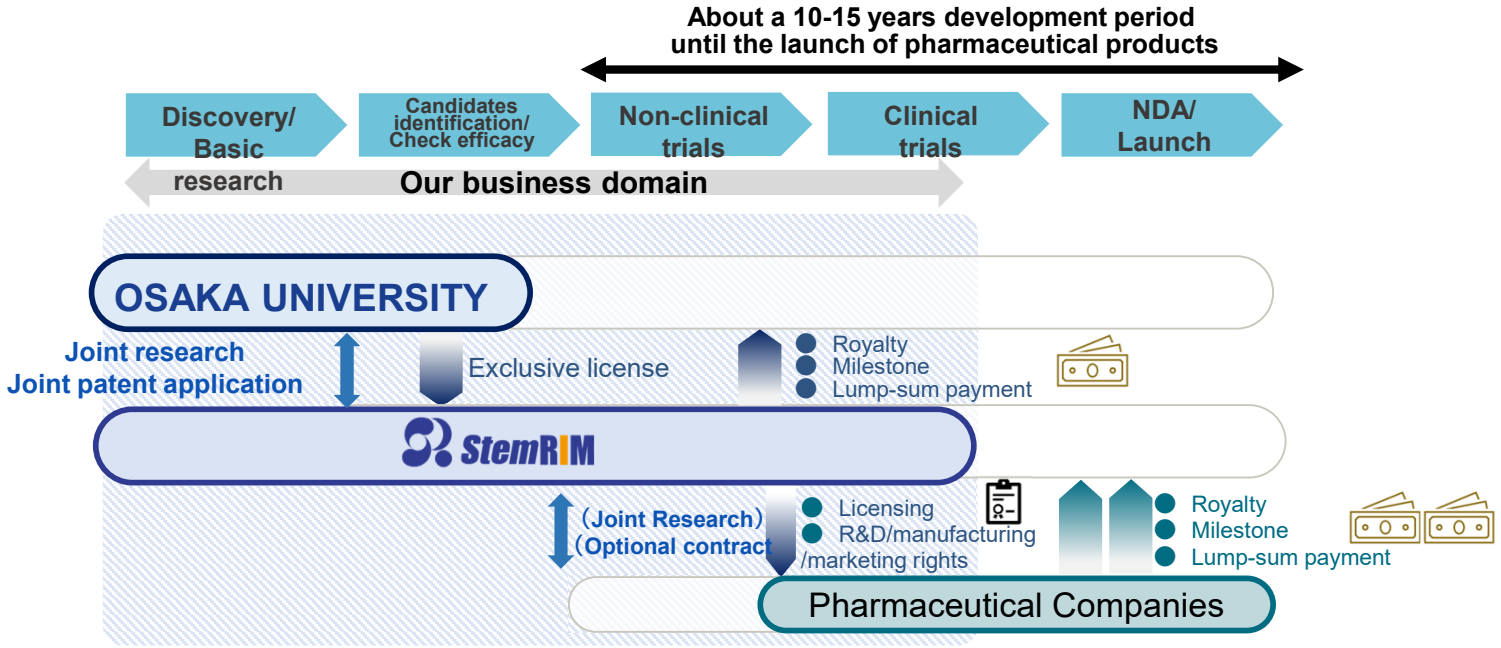
Functional tissue regeneration



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Business Model

A business model that generates income by licensing out product development, manufacturing, and marketing rights to pharmaceutical companies in Japan and overseas.



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Our Management Indicators

Annual Research and Development Expenses

1.39 billion yen

（One-year period from August 2024 to July 2025）

Cash Burn Rate for Month

117 million yen

（Results for the Fiscal Year Ended July 2025）

Sufficient funds secured for research and development activities until 2028.

Cash and Deposits

6.9 billion yen

（As of the end of July 2025 ）

Number of Clinical Development Pipelines

5

Clinical trials have been initiated in patients for epidermolysis bullosa, acute ischemic stroke, ischemic cardiomyopathy, chronic liver disease, and osteoarthritis.

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2. Progress in Research and Development

Highlights for the Fiscal Year Ended July 31 2025

Ⅰ.

Redasemtide: Global Phase 2b Trial for Acute Ischemic Stroke / Changes to Clinical Trial Protocols

Ⅱ.

Redasemtide: Additional Phase 2 Trial for Dystrophic Epidermolysis Bullosa / Last Patient In

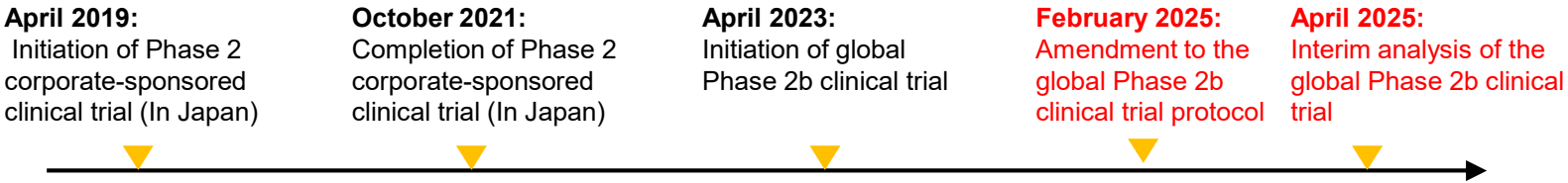
Ⅲ.

Reorganizing our Development Pipelines

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Redasemtide: Global Phase 2b Trial for AIS

I.

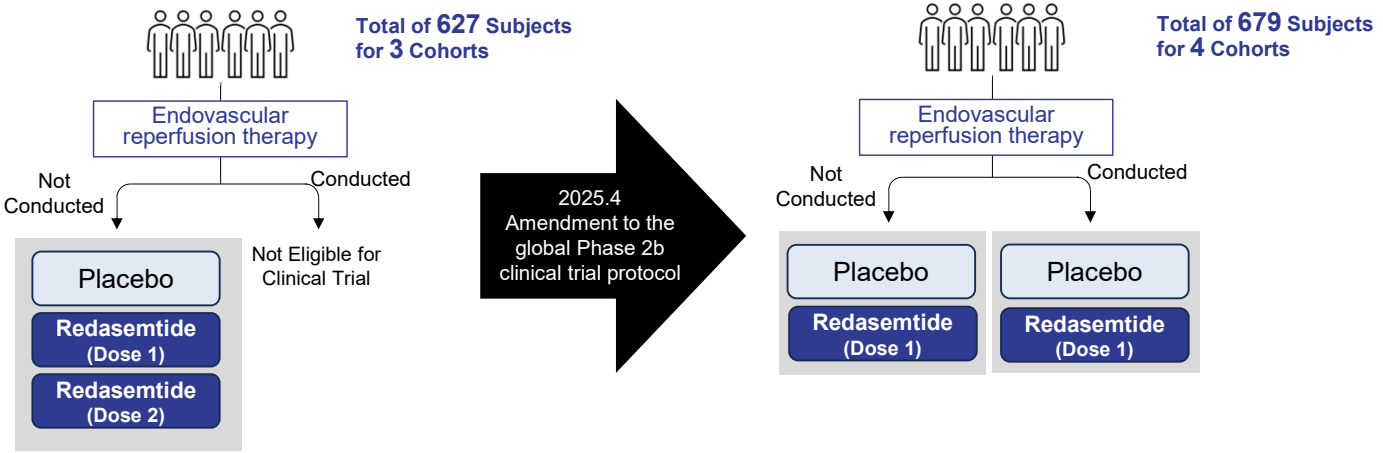


Background to the Clinical Trial Plan Change

- Advances in endovascular recanalization therapy have changed the treatment system
- Considering adding a cohort of patients who underwent endovascular recanalization therapy to respond to a wide range of patient groups
- Conduct an interim analysis and perform a “Futility Analysis” of the existing cohort.

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Ⅰ. Redasemtide: Global Phase 2b Trial for AIS



1. Addition of Clinical Trial Subjects and Case Numbers

Due to Changes in the Stroke Treatment Paradigm, a new patient group that underwent thrombolytic therapy and mechanical thrombectomy has been added. As a result, the number of enrolled cases in the clinical trial has increased.

2. Reduction in the Number of Cases Due to Discontinuation of Dose 2

For acute ischemic stroke patients ineligible for endovascular recanalization therapy, futility analysis was conducted, and based on the results, dose 2 was discontinued.

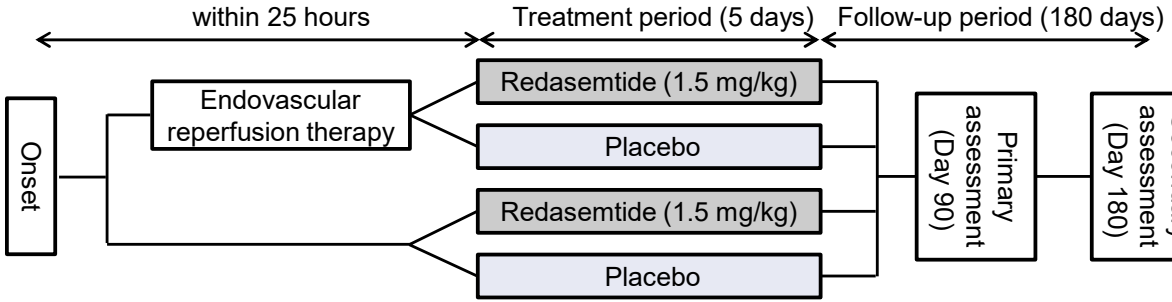
Relaxation of patient inclusion criteria, increased trial patient population, and efficient patient enrollment following discontinuation of Dose 2 are expected to prevent a significant extension of the trial period.

*jCRT：2031230083

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Ⅰ. Redasemtide: Global Phase 2b Trial for AIS

Phase 2b Trial Protocol (After interim analysis)	
Study objectives	Evaluation of the Efficacy, Safety, and Tolerability of Redasemtide in Patients with Acute Ischemic Stroke
Subject population	Patients aged 18 years or older who can receive treatment within 25 hours of stroke onset, with a baseline NIHSS* score between 8 and 22.
Study design	Multicenter, Randomized, Placebo-Controlled, Double-Blind
Intervention	Cohort A: Patients Who Did Not Received Thrombolytic Therapy and/or Mechanical Thrombectomy ・Redasemtide (1.5 mg/kg) treatment group ・Placebo group Cohort B: Patients Who Receive Thrombolytic Therapy or Mechanical Thrombectomy ・Redasemtide (1.5 mg/kg) treatment group ・Placebo group　　Total: 679 subjects
Dose	Intravenous Administration Once Daily for 90 Minutes Over 5 Days
Primary End Point	Modified Rankin Scale (mRS) at 90 Days After Initial Dosing
Region	Japan, Europe, North America, China, etc.



Future Outlook

Planned Market Launch by April 2028 ~ March 2031

*NIHSS(National Institutes of Health Stroke Scale)：Stroke Neurological Severity Rating Scale (42 points in total, the higher the score, the more severe)

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Discovery of in-vivo mechanism inducing tissue regeneration

- **Differences between normal skin and epidermolysis bullosa skin**

In normal skin (Figure A), type 7 collagen functions like an adhesive, bonding the epidermis and dermis, the superficial layers of skin. In epidermolysis bullosa congenita (Figure B), the epidermis and dermis are easily detached with the slightest irritation due to abnormal type 7 collagen.Since epidermal stem cells, which are responsible for supplying epidermal cells, reside in the epidermis, the epidermal stem cells are lost from the skin of patients with epidermolysis bullosa, and the epidermis loses its regenerative capacity.

Fig. A

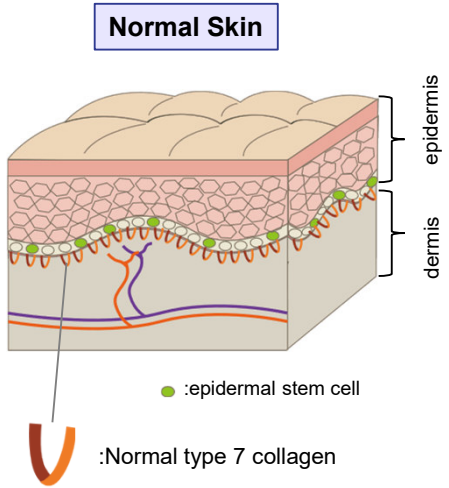
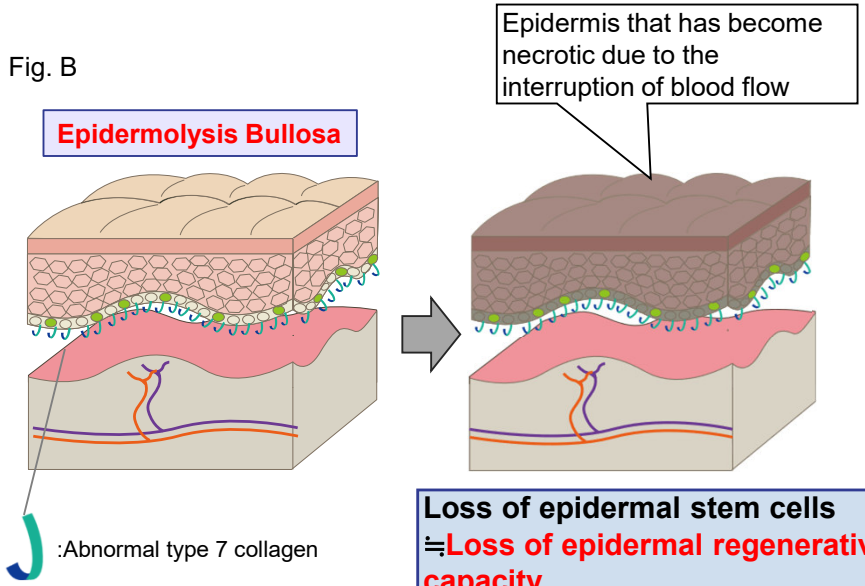


Fig. B

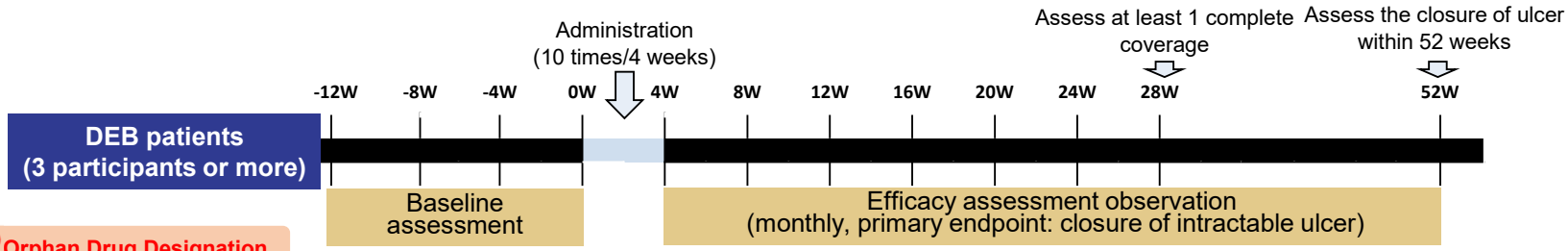


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Ⅱ. Redasemtide: Additional Phase 2 Trial for DEB

Additional Phase 2 Protocol	
Study objectives	Evaluation of efficacy and safety of Redasemtide in patients with dystrophic epidermolysis bullosa having intractable ulcers
Study design	Single arm, multicenter, open label, uncontrolled
Intervention	Redasemtide (1.0 mg/kg) group: More than 3 participants
Regimen	30-minute intravenous infusion once a day, total 10 times/4 weeks [1st week of administration: 4 times/week, 2nd-4th weeks of administration: twice/week (once every 3-4 days)]
Primary endpoint	**Closure of intractable ulcer**

Clinical Trial Timeline to Date
December 2017: Initiation of Phase 2 investigator-initiated clinical trial
September 2019: Completion of Phase 2 investigator-initiated clinical trial
March 2020: Completion of follow-up study for Phase 2 investigator-initiated clinical trial
July 2022: Initiation of additional Phase 2 clinical trial
March 2023: First patient enrolled in the additional Phase 2 clinical trial
May 2023: Orphan Drug Designation
July 2025: Final patient enrolled in the additional Phase 2 clinical trial



Orphan Drug Designation

In May 2023, the Ministry of Health, Labour and Welfare designated ledasemtid as an orphan drug for hypoparathyroidism-related epidermolysis bullosa. This designation reflects the Ministry's recognition of the development plan's validity for treating hypoparathyroidism-related epidermolysis bullosa. Eligibility for the priority review system is expected to shorten the review period, facilitating earlier approval.

Status

Planned Market Launch by March 2028

* Shionogi & Co. Ltd., 1st Quarter of Fiscal 2025 Financial Results, July 28, 2025, pp.31
** jRCT2031220378

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Ⅲ. Reorganizing our Development Piplines

Reorganization of pipeline development codes aimed at the optimal allocation of R&D resources.

Development Pipeline (Revised)

Project code	Indication	Status	Investi-gator
Redasemtide/ TRIM2 (HMGB1 cell mobilization domain peptides)	Epidermolysis Bullosa	Additional P2	Shionogi & Co., Ltd.
	Acute Ischemic Stroke	Global P2b	Shionogi & Co., Ltd.
	Ischemic Cardiomyopathy	Physician-Initiated P2	Osaka University
	Osteoarthritis of the knee	Physician-Initiated P2	Hirosaki University
	Chronic liver disease	Physician-Initiated P2	Niigata University
TRIM3 (Novel Regeneration-Inducing peptide for Systemic administration)	(Not disclosed)	—	In-house (partnership is planned)
TRIM4 (Novel Regeneration-Inducing peptide for Systemic administration)	(Not disclosed)	—	In-house (partnership is planned)
TRIM5 (Novel Regeneration-Inducing peptide for Local administration)	(Not disclosed)	—	In-house (Expansion of animal model data)
SR-GT1 (Stem cell gene therapy)	Epidermolysis Bullosa	—	In-house (partnership is planned)

Development Pipeline (Before Revision)

Project code		Development candidate	Indication
PJ1	-01	Redasemtide (HMGB1 cell mobilization domain peptides)	Epidermolysis Bullosa
	-02		Acute Ischemic Stroke
	-03		Ischemic Cardiomyopathy
	-04		Osteoarthritis of the knee
	-05		Chronic liver disease
PJ2	-01	Novel Regeneration-Inducing peptide for Systemic administration (TRIM3)	Not disclosed
	-02	Novel Regeneration-Inducing peptide for Systemic administration (TRIM4)	Not disclosed
PJ3		Novel Regeneration-Inducing peptide for Local administration (TRIM5)	Not disclosed
PJ4		Autologous cell collection device for treatment	Multiple tissue damage diseases
PJ5		Stem cell gene therapy (SR-GT1)	Epidermolysis Bullosa

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3. Summary of Activities the Fiscal Year Ended July 2025

Summary of Financial Results

- For FY 2025, there were no recognition of milestone revenues related to research progress or upfront payments from contracts. As a result, **operating revenue was none.** Since we are a drug discovery bio-venture, we have an unstable revenue structure considering our business model.

- As of the end of FY 2025, we hold **6,994 million yen** in cash and deposits.
  The estimated annual expenditure for the FY 2025 is between 1,530 million yen and 2,010 million yen (cash outflows related to R&D: 1,300 million yen to 1,700 million yen, cash outflows for general administrative expenses: 230 million to 310 million yen). At present, **we have secured sufficient funds to sustain stable R&D activities until 2028.**

(Millions of yen)

	FY 2021.7	FY 2022.7	FY 2023.7	FY 2024.7	**FY 2025.7**	Function (FY on FY)
Operating revenue	1,400	22	2,350	—	**—**	—
R&D expenses	1,523	1,421	1,567	1,453	**1,394**	-57
Total operating expenses	1,993	2,003	2,207	2,076	**1,971**	-104
Operating Income (loss)	(593)	(1,980)	142	(2,076)	**(1,971)**	+104
Ordinary Income (loss)	(583)	(1,972)	145	(2,077)	**(1,970)**	+107
Net Income (loss)	(582)	(1,948)	168	(2,022)	**(1,929)**	+92
Cash and deposit	10,172	8,880	10,217	8,410	**6,994**	

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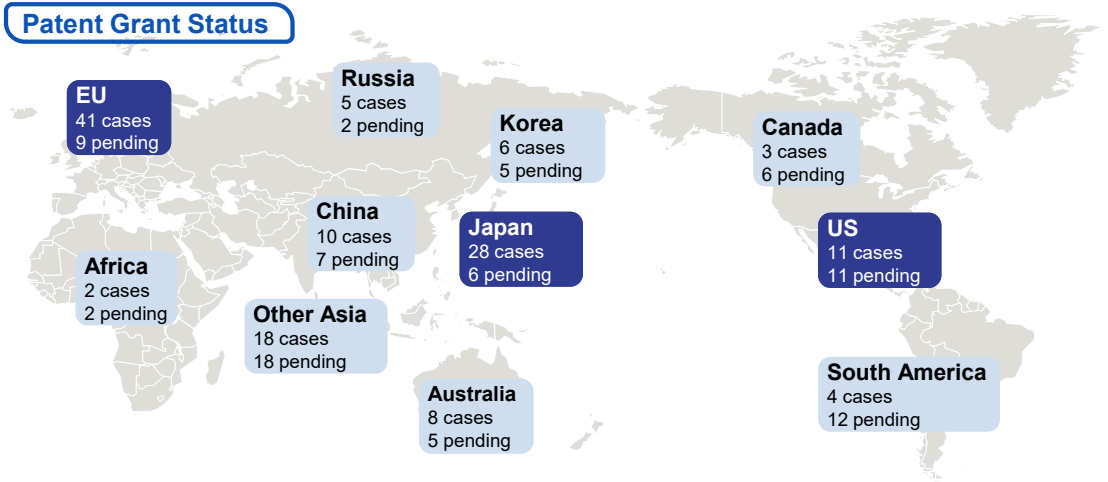
IP Strategy

Patents related to “Regeneration-Inducing Medicine™” have been granted in various countries. We are steadily promoting the intellectual property protection of our research outcomes, paving the way for global expansion.

Total Patents 134

Patent Pending 83

Patent Grant Status



Countries of Grant and Application

JPN USA CHN DEU KOR IND ESP POLE SWD RUS BEL IDN BRA MEX ZAF

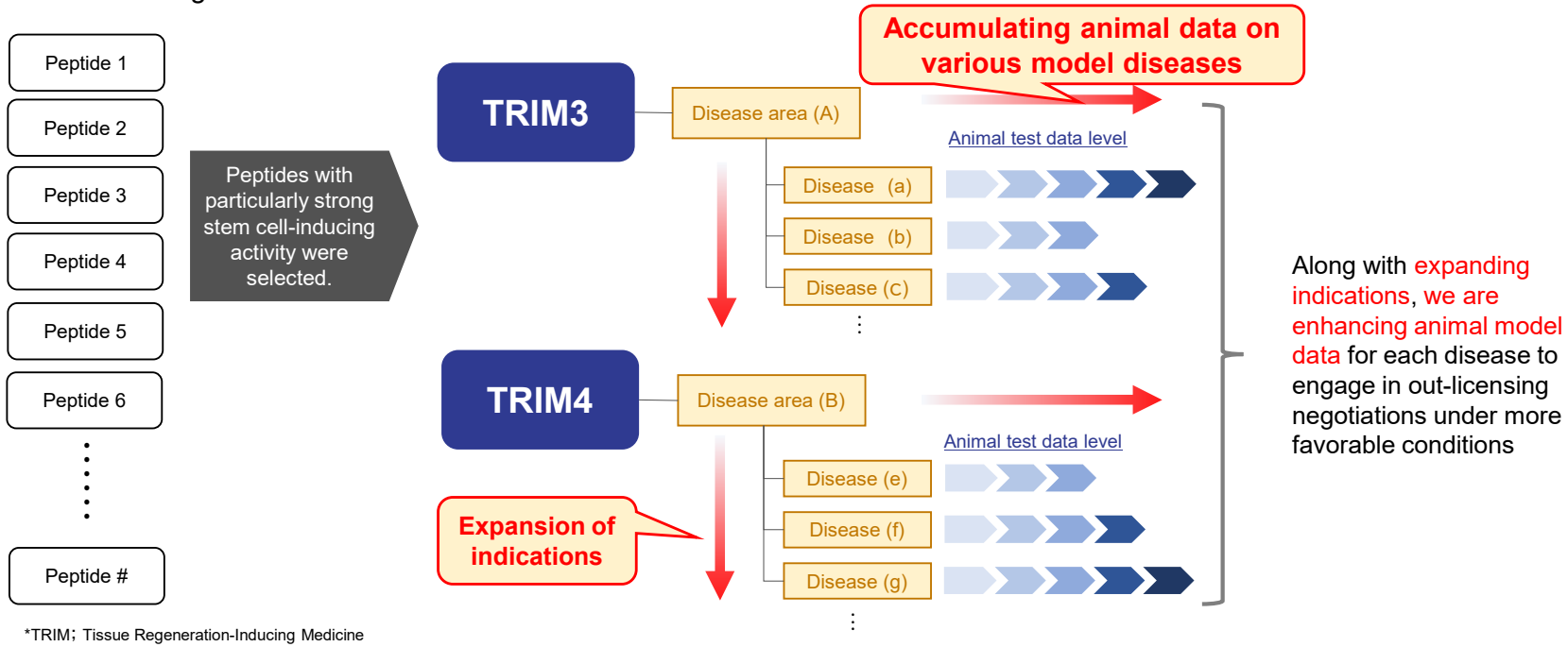
ISR HKG GBR FRA AUS CAN ITA IRL NLD CHE DNK FIN TUR SGP TWN

* As of July 2025

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TRIM3, TRIM4

We have identified several peptides that mobilize mesenchymal stem cells from the bone marrow into the bloodstream, accumulate in damaged tissues, and induce functional regeneration. Among them, two peptides with particularly prominent activity have been selected as candidates for the next-generation “Regeneration-Inducing Medicine™” : TRIM3 and TRIM4, and out-licensing activities have been initiated.



*TRIM; Tissue Regeneration-Inducing Medicine

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Business Development

Continuing from last year, out-licensing negotiations were conducted with multiple pharmaceutical companies both domestically and internationally.

BioJapan

2024.10.9～11
@ Yokohama, JPN



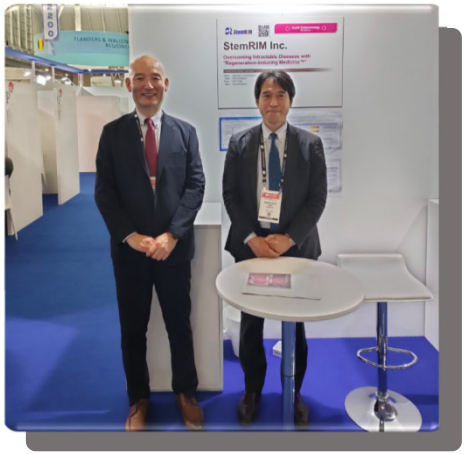
J.P.Morgan
Healthcare Conference

2025.1.13～16
@ San Francisco, CA



Bio International Convention

2025.6.15～6.21
@ Boston, MA

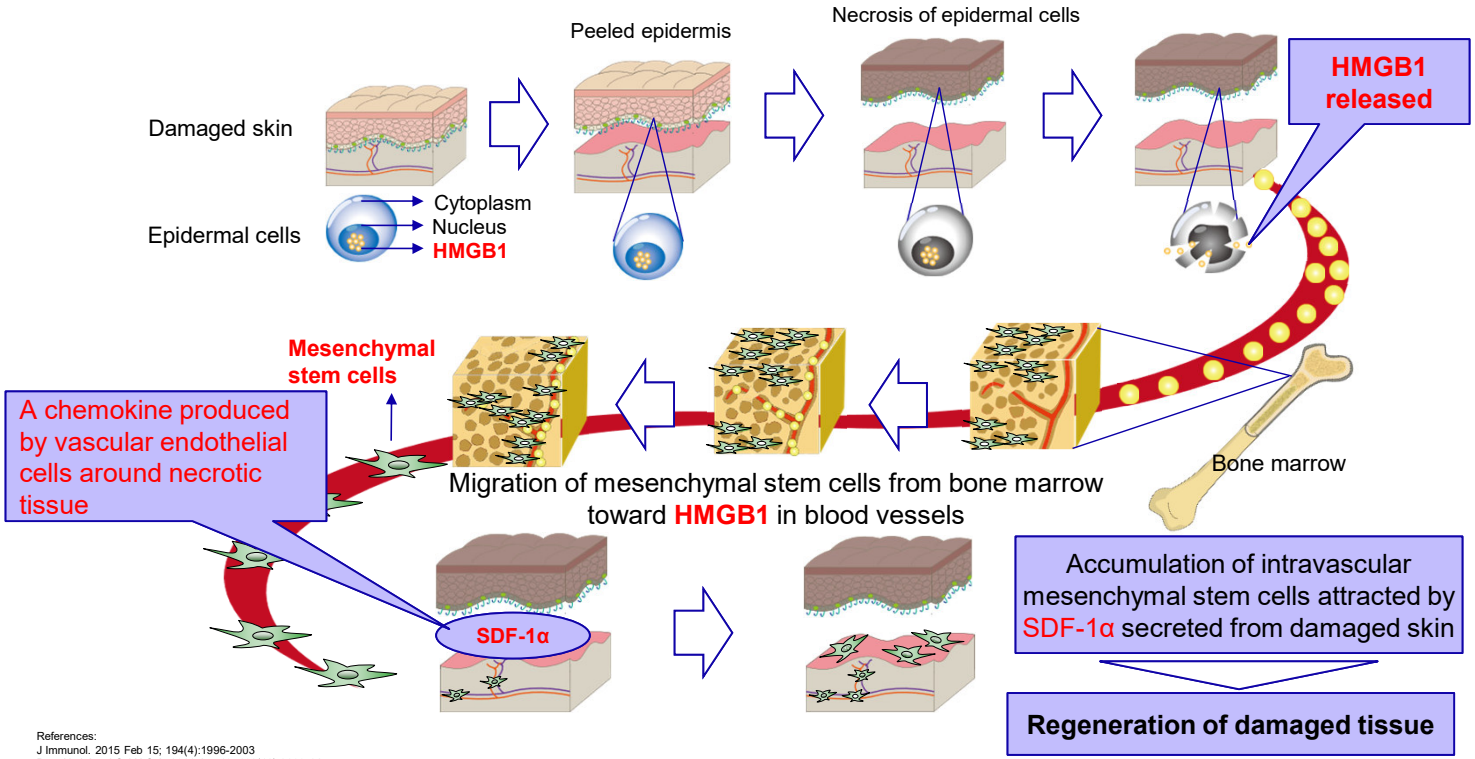


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4. Appendix

Discovery of in-vivo mechanism inducing tissue regeneration

Discovery of crosstalk mechanism between damaged skin and bone marrow mesenchymal stem cells via necrotic tissue-derived factor

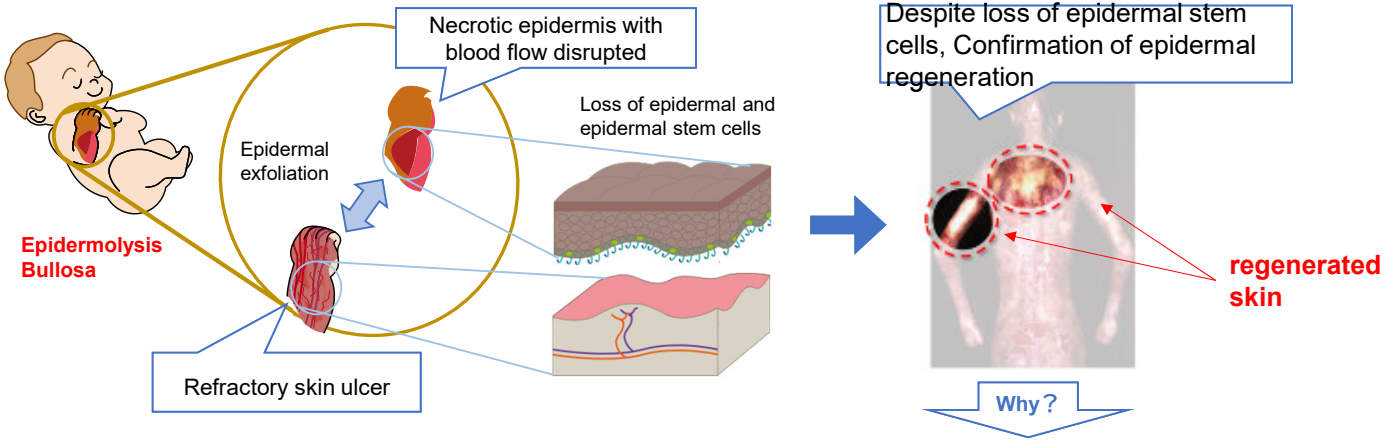


References:
J Immunol. 2015 Feb 15; 194(4):1996-2003
Proc Natl Acad Sci U S A. 2011 Apr 19; 108(16):6609-14.

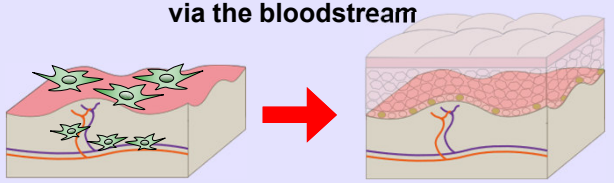
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Discovery of in-vivo mechanism inducing tissue regeneration

The beginning of the research and development on "Regeneration-Inducing Medicine™" : Hypothesis of stem cell recruitment mechanism from bone marrow to damaged skin.



Possible replenishment of stem cells via the bloodstream



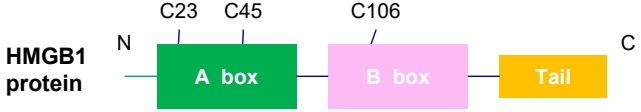
Hypothesis of stem cell recruitment mechanism via blood flow

References:
"Igaku-no-ayumi" Vol.265 No.5 463-468; 2018
Skin Diseases :41(1); 7-12,2019
Photo courtesy of Osaka University

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HMGB1 peptide drugs with improved safety

Designing highly safe, chemically synthesized peptide drug from A-Box domain of HMGB1 protein

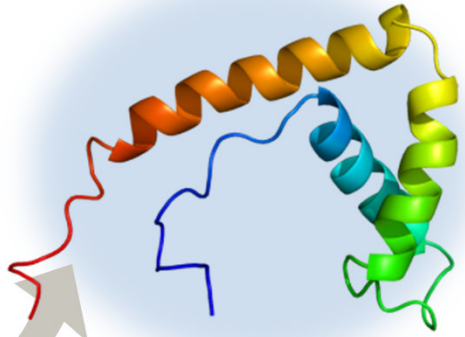


- An Important in vivo molecule that activate tissue regeneration

Identifying the function of protein domains

Prof. Katsuto Tamai
Osaka University





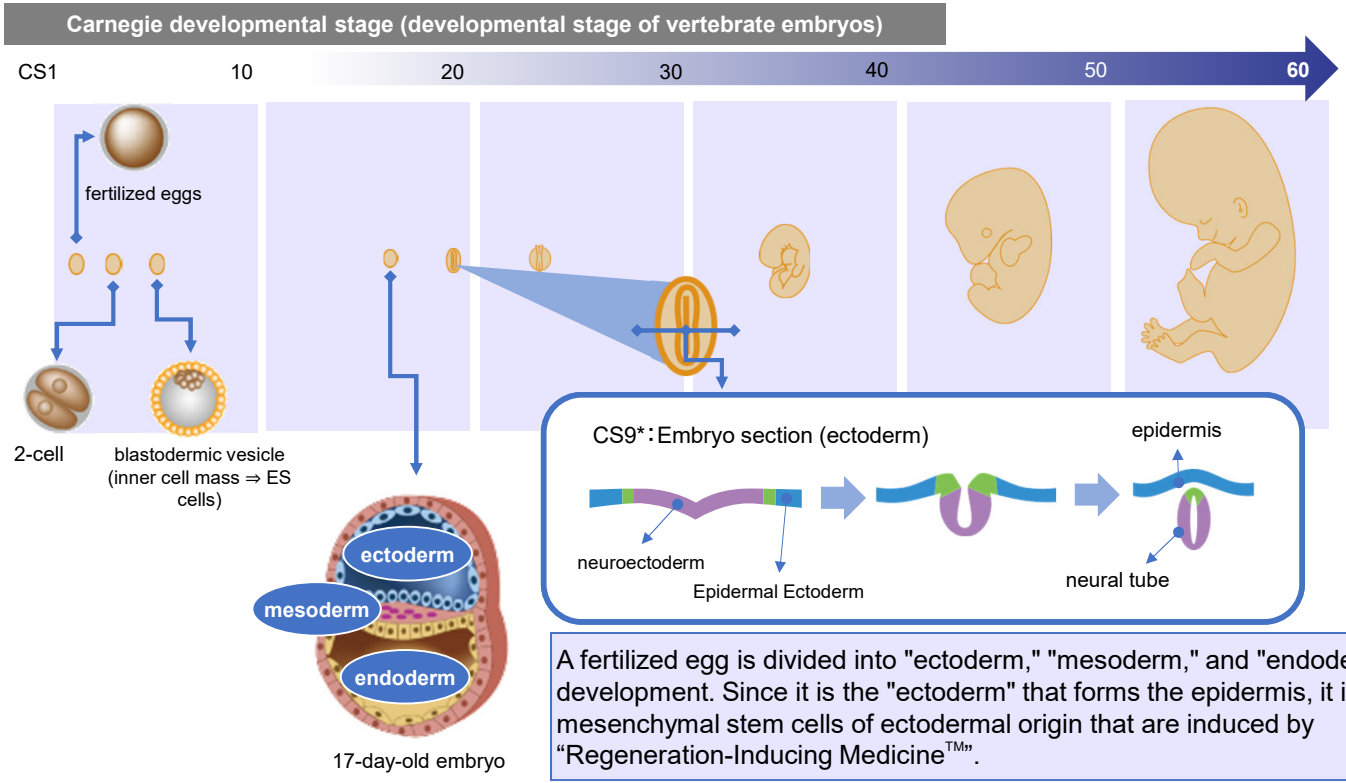
A box	Bone marrow mesenchymal stem cell activating domain, named **"KOI2-domain"**
B box	Innate immune response-activating domain that induces inflammation

References:
J Intern Med. 2004 Mar ; 255(3):351-66.

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Advantages of “Regeneration-Inducing Medicine™”

Epidermis formation during human development

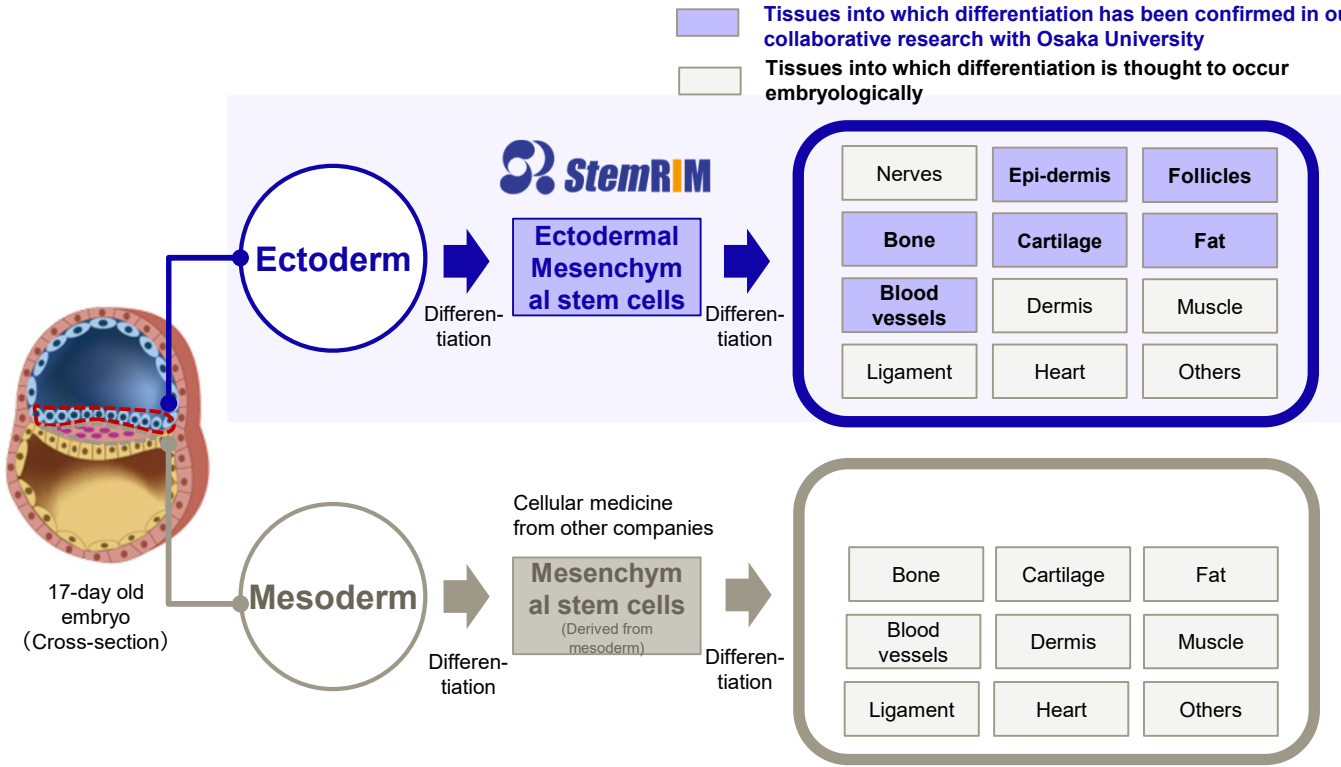


A fertilized egg is divided into "ectoderm," "mesoderm," and "endoderm" during development. Since it is the "ectoderm" that forms the epidermis, it is the mesenchymal stem cells of ectodermal origin that are induced by “Regeneration-Inducing Medicine™”.

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Advantages of “Regeneration-Inducing Medicine™”

Ectodermal mesenchymal stem cells have high pluripotency and differentiation ability to various tissues.

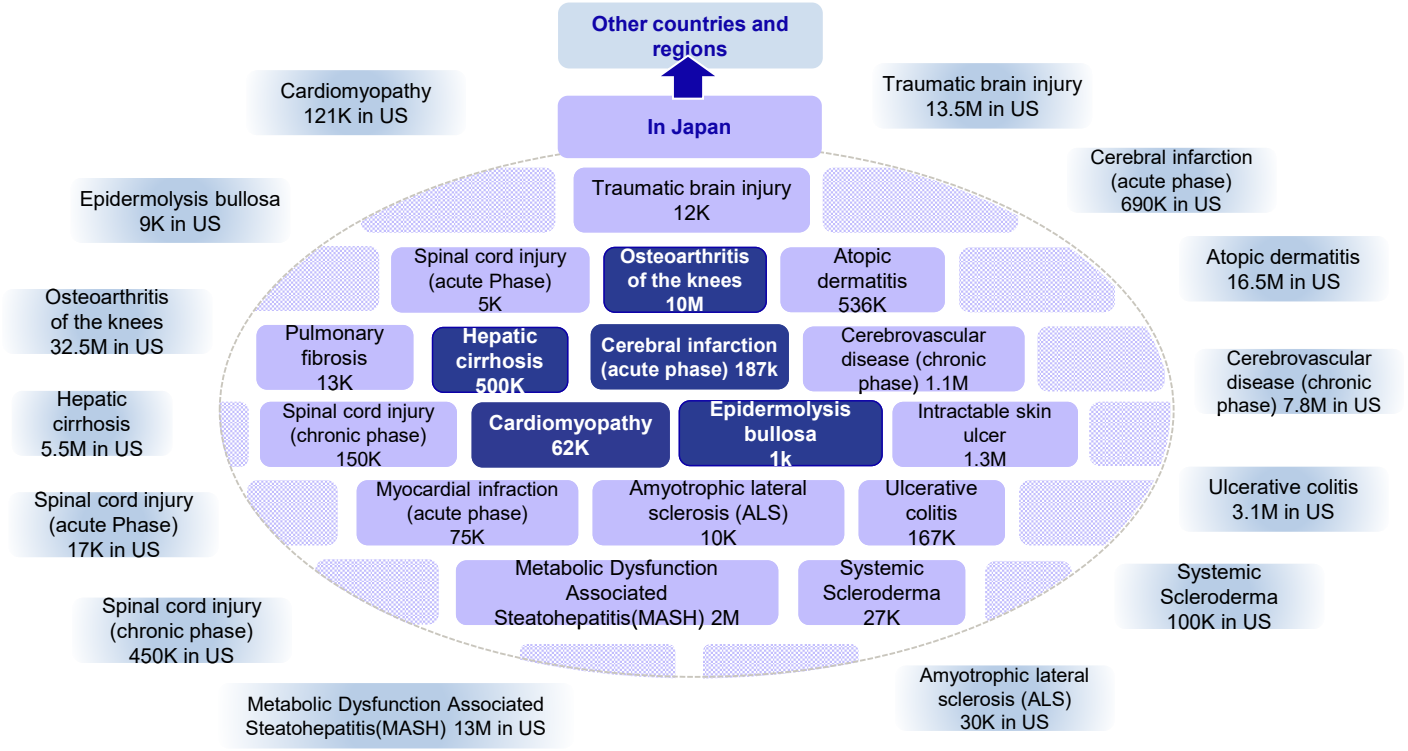


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Expanding Indications and Markets(Number of patients)

Targeting all areas where mesenchymal stem cell therapy can be effective

: Clinical trial on going



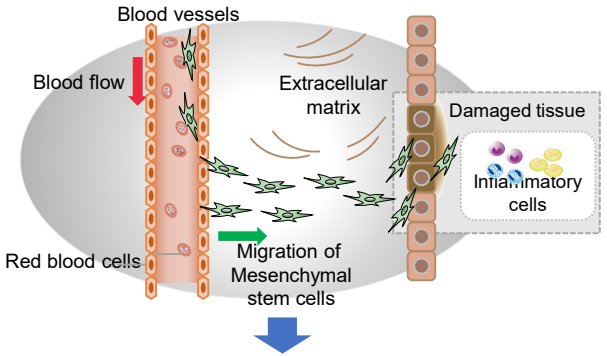
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Functions of mesenchymal stem cells

In-vivo mesenchymal stem cells have 5 distinctive capabilities

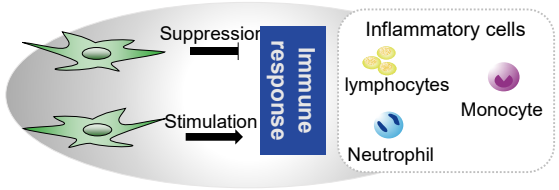
1. Cell migration ability

Mesenchymal stem cells migrate to damaged tissue via the bloodstream



2. Immunomodulatory ability

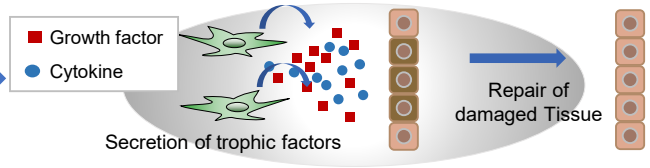
Modulates immune response and inhibits the spread of tissue damage caused by excessive inflammation



* MMP：Matrix metalloproteases

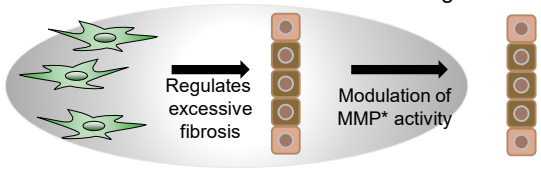
3. Trophic factor secretion ability

Promotes cell proliferation and tissue repair by secreting growth factors and cytokines to cells in damaged tissue

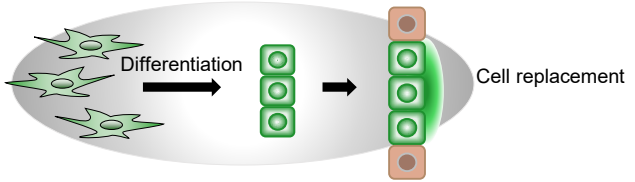


4. Fibrosis regulation ability

Regulates and inhibits excessive fibrosis of damaged tissue



5. Tissue regeneration ability

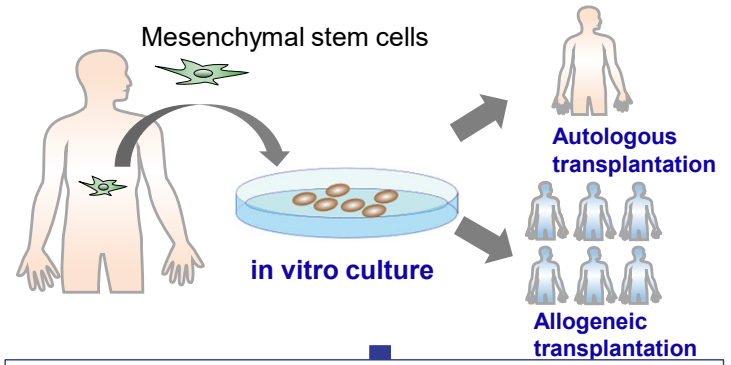


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In vitro culture reduces the functions of MSCs

"Regeneration-Inducing Medicine™" can avoid functional degradation of mesenchymal stem cells due to in vitro culture

Manufacturing process of conventional cellular medicine

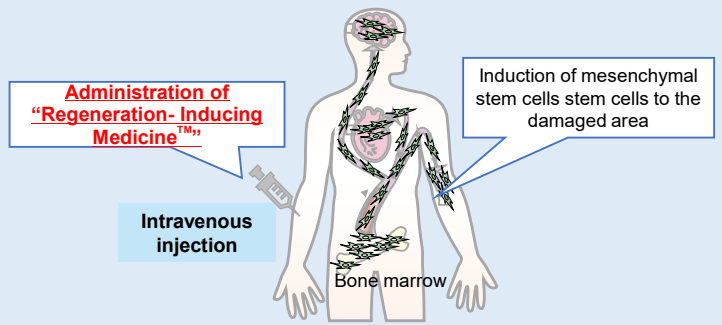


Mesenchymal stem cells lose their functions during in vitro culture

Source: Stem Cell Research & Therapy2018,9:131

~~Cell Migration ability~~ | Immuno-modulatory ability | Trophic factor Secretion ability | ~~Fibrosis regulation ability~~ | ~~Tissue Regene-ration ability~~

Induction of MSC in "Regeneration-Inducing Medicine™"



Induction of mesenchymal stem cells into damaged tissues while retaining their native functions

Cell Migration ability | Immuno-modulatory ability | Trophic factor Secretion ability | Fibrosis regulation ability | Tissue Regene-ration ability

"The effects of MSC cell therapy are limited to inflammation suppression and supply of growth factors to the remaining cells", reported by Caplan AI

「Mesenchymal Stem Cells: Time to Change the Name!」 Arnold Caplan June 2017

Source: Stem Cells Transl Med. 2017 Jun; 6(6):1445-1451. doi: 10.1002/sctm.17-0051. Epub 2017 Apr 28.

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Summary of advantages of “Regeneration-Inducing Medicine™”

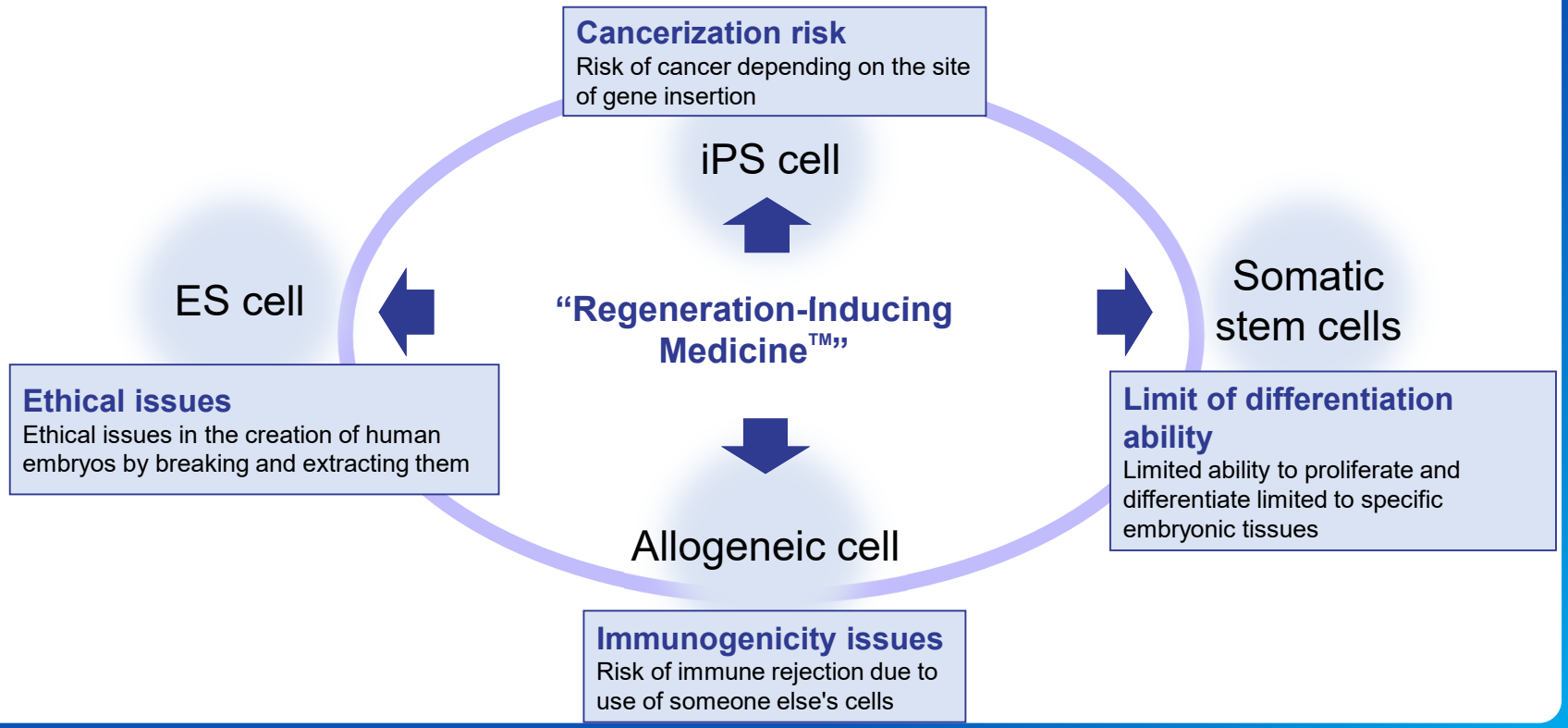
“Regeneration-Inducing Medicine™” includes advantages in both cell therapy and chemicals

		“Regeneration-Inducing Medicine™”	Cell therapy	Chemicals
Efficacy	Tissue regeneration	○ Applicable for large-scale tissue damage	△ Applicable for large tissue damage with large number of cells	↓ No regeneration
	Mechanism of action	○ Use in vivo native regeneration mechanism	○ Cellular physiological activity	↓ Targeting molecules often including side-effect and off-target
	Indications	○ Same compound can cover a wide range of indications	○ Same platform can cover a wide range of indications	↓ In general, targeting limited indications caused by same mechanism
Safety	Noninvasive	○ Compound mobilizes the patient’s cells in vivo and no rejection	↓ Invasive in cell collection Immune-rejection in allogenic case	○ Low noninvasive
Quality	Quality control	○ Easy quality control and stable production	↓ Cell culture includes risk of cellular change	○ Easy quality control and stable production
Other benefit	Cost	○ Normal industrial drug production	↓ CPC and cell collection and transplantation facility is required	○ Affordable and large-scale production
	Regulatory affairs	○ Same as general compound drugs	↓ No standard, and case-by-case regulation is required	○ Standardized regulation

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Summary of advantages of “Regeneration-Inducing Medicine™”

“Regeneration-Inducing Medicine™” can solve the four major problems of conventional cell therapy



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Activities of “StemRIM Institute of Regeneration-Inducing Medicine, Osaka University”

StemRIM

StemRIM Institute of Regeneration-Inducing Medicine

In June 2020, StemRIM Institute of Regeneration-Inducing Medicine, Osaka University (covering an area of 1,540 square meters) was established on the 6th and 7th floors of the Techno Alliance Building at Osaka University's Suita Campus. Professor Masayuki Endo (Department of Children’s and Women’s Health, Graduate School of medicine and Division of Health Sciences, Osaka University) was appointed as the institute's director. The team includes distinguished members such as Specially Appointed Professor Shinya Murakami (Department of Periodontology and Regenerative Dentistry, Osaka University, Graduate School of Dentistry.), Professor Masaru Ishii (Department of Immunology and Cell Biology, Graduate School of medicine and Frontier Biosciences, Osaka University), and Professor Manabu Fujimoto (Department of Integrated Medicine, Graduate School of medicine, Osaka University). Together, they aim to explore and advance the multi-faceted development of “Regeneration-Inducing Medicine™”. To date, several collaborative research projects have made significant progress.

Joint Research Projects

(number of events)

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY on FY	Notes
Division of Health Sciences	1	2	3	2	2	±0	Neonatal-Associated Diseases
Division of Biofunctional Research	—	—	—	—	—	±0	
Division of Medical Research	—	1	2	2	3	+1	Nervous System Diseases, Orthopedic-Related Diseases
Division of Dentistry	3	5	5	5	6	+!	Periodontitis-Related Diseases
Total	4	8	10	9	11	+2	



Website (Japanese):
https://stemrim-osaka-u.jp/

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Corporate Information

Corporate Name	StemRIM Inc.
Chief Executives	Masatsune Okajima (Representative Director)
Established	October 30, 2006
Business Description	Research and Development of “ Regeneration Inducing-Medicine™ ”
Shareholders’ Equity	5,861 million yen
Equity Ratio	77.9 %
Number of Employees	69

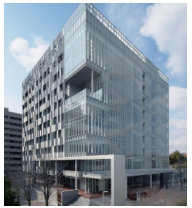
Head Office
7-7-15, Saito-Asagi, Ibaraki-City, Osaka, Japan



StemRIM Institute of Regeneration-Inducing Medicine, Osaka University
Techno-Alliance Building, 2-8, Yamadaoka, Suita-City, Osaka, Japa



Endowed Chair for Regeneration-Inducing Medicine／Joint Research Course in Stem Cell and Gene Therapy
The Center of Medical Innovation and Translational Research, 2-2, Yamadaoka, Suita-City, Osaka, Japan



As of the End of January 2025

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StemRIM Management



Masatsune Okajima, President and CEO

President and CEO, StemRIM Inc. (Oct. 2023 – Present)
President, StemRIM Inc. (March 2019 – Oct. 2023)
Vice president, Medicinova Inc. (Sep. 2006 – March 2019)
Deputy General Manager, Daiwa Securities SMBC Co., Ltd.(April 2002 – Aug. 2006)
Manager, Daiwa Securities SB Capital Markets Co., Ltd. (currently Daiwa Securities SMBC Co., Ltd.) (April 1999 – March 2002)
Sumitomo Capital Securities Co., Ltd. (Oct. 1996 – April 1999)
Sumitomo Bank, Ltd. (currently Mitsui Sumitomo Bank) (April 1991 – Oct. 1996)



Katsuto Tamai, Founder, Director and CSO

Director, StemRIM Inc. (Oct. 2022 – Present)
Guest Professor, Endowed course of Regeneration-Inducing Medicine Graduate School of Medicine/ Faculty of Medicine, Osaka University (Oct. 2023 – Present)
Professor, Endowed course of Regeneration-Inducing Medicine Graduate School of Medicine/ Faculty of Medicine, Osaka University (Oct. 2010 – Sep. 2023)
Director, StemRIM Inc. (Feb. 2007 – Aug. 2010)
Associate professor, Department of Gene Therapy, Graduate School of Medicine/ Faculty of Medicine, Osaka University (May 2003 – Sep. 2009)



Noriko Sawai, External director

Head of healthcare team, Social Innovation and Investment Foundation (Aug. 2022 – present)
Impact Officer,
Social Innovation and Investment Foundation (Feb. 2020 – July 2022)
External director, StemRIM Inc. (Oct. 2019 – Present)
DeNA Co. (June 2014 – Jan. 2020)
CSK Venture Capital Co. (April 1995 – May 2014)



Hirotada Nagai, External director

President, HyakusanSoken KK (July 2022 - Present)
External directors, StemRIM Inc. (Oct. 2020 - Present)
Auditor, Regional Fish Institute, Ltd. (May 2020 – Present)
Director, PRDM Co., Ltd. (March 2018 – Present)
Director, PorMedTec Co., Ltd. (Dec. 2017 – Present)
Director, Kyoya KK (Dec. 2017 - Present)
Pharmaceuticals and Medical Devices Agency (PMDA) (Sep. 2012 – July 2014)
Pharmaceutical and Food Safety Bureau of Ministry of Health, Labour and Welfare (April 2001 – Sep. 2017)

Yoji Kudo, External audit

Akihiro Mizukami, External audit

Yoichiro Shimada, External audit

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