FY2023 Q3 Financial Results

Company

HEALIOS K.K. (TSE 4593)

Date

November 14, 2023

Important Note on Future Events, etc

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Contents

Key Highlights

New Healios

Inflammatory Conditions

HLCM051

1 **ARDS**

Obtained a Global License → **Market scale expanded 40-fold**

2 **Ischemic Stroke**

Announced the status of interim analysis*1 of the global clinical trial*2 → **Additional data analysis will be performed**

Global trial participation with potential partners under consideration

*1 An analysis performed by an independent statistician during the course of a clinical trial. The results can be used to revise the number of patients required.
*2 A phase III study for stroke in the U.S conducted by Athersys. (MASTERS-2 study)

Replacement Therapies

Universal Donor Cell（UDC)

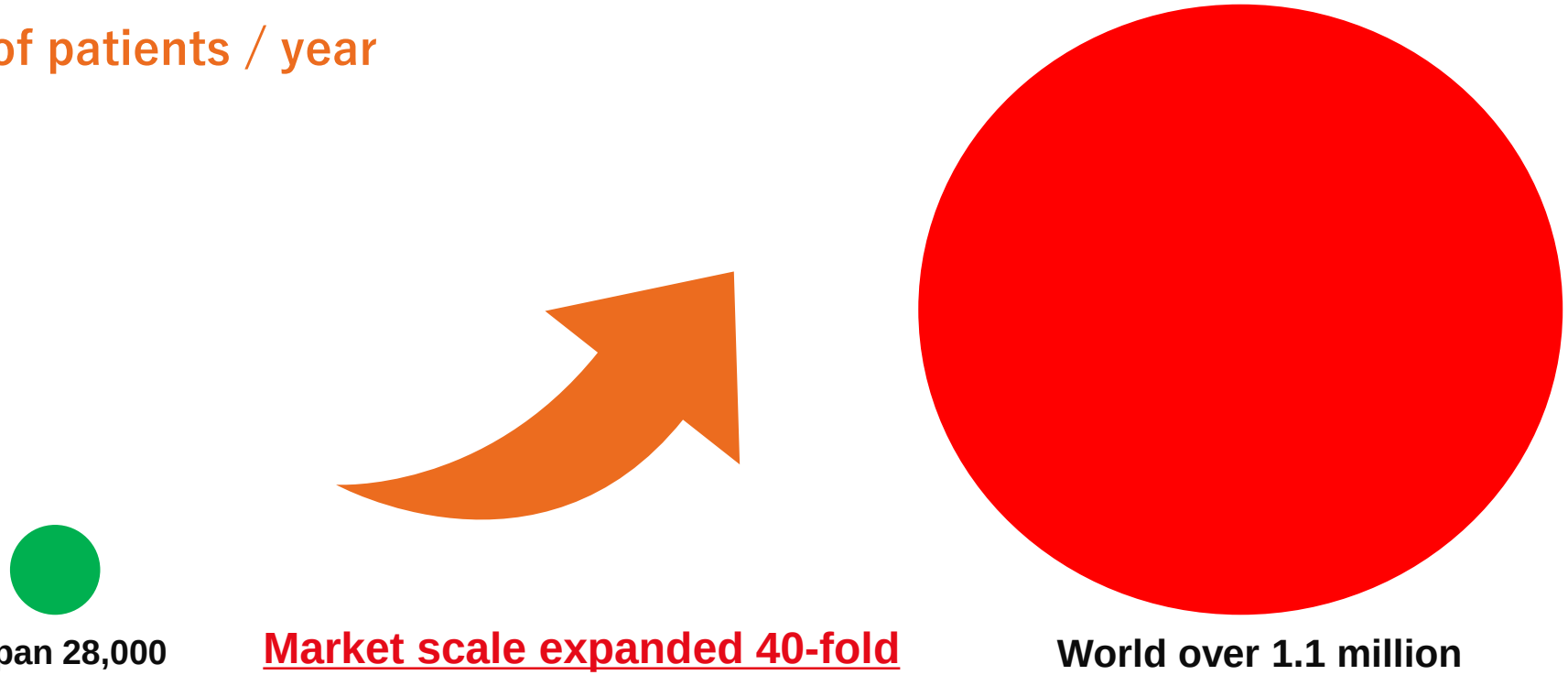
3 **Healios NA Awarded $1 million from the California Institute for Regenerative Medicine（CIRM）** → **Create next-generation UDC to target de facto standard**

HLCM051 Obtained ARDS Global License

1

New Healios

The number of patients / year



Japan 28,000

Market scale expanded 40-fold

World over 1.1 million

Outline of the License

1) The scope of the License Agreement for the development, manufacture and sale of ARDS product has been expanded from Japan to the entire world.
2) Athersys will provide our company with investigational product for use in future clinical trials conducted by our company.
3) As a result of the foregoing, Healios will pay Athersys up to $4.5 million subject to the terms of the Agreement.
4) In the future, Healios will pay development milestones and sales milestones and royalties as development and sales progress around the world.

Estimated number of ARDS patients worldwide

USA 262,000、China 670,000、Europe 133,000、Japan 28,000

(Source)
Japan: estimated by Healios based on the incidence rate of epidemiological data and the total demographical population in Japan.
USA: Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–.PMID: 28613773
Europe: Community Research and Development Information Service (CORDIS) 2020 7-9
China: Song-et-al-2014-acute-respiratory-distress-syndrome-emerging-research-in-china

Global Development Policy

Clinical Trial in Japan

Costs to be funded by ProcellCure Inc. (venture capital, grants, pharmaceutical companies).

ProcellCure Inc. plans to initiate clinical trials as agreed with regulatory authorities.

Global Clinical Trial

Discussions are planned with regulatory authorities (FDA and others) to agree on protocol and study size for the start of a global study based on the Japanese clinical trial design

Costs will be flexibly considered, including co-development with development partner pharmaceutical companies and venture capital financing.

Outline of the announcement

Athersys Inc. is conducting a clinical trial (trial name: MASTERS-2 study) in the U.S. and Europe using the same drug as HLCM051 for ischemic stroke and conducted the interim analysis of the clinical trial.

The analysis was conducted by the Independent Clinical Data Safety Monitoring Board (DSMB) based on the one-year follow-up of approximately half of the 300 patients planned in the trial.

There were no safety issues identified, however, Athersys concluded that the sample size required to achieve statistical significance is considerably larger.

Athersys intends to conduct **additional data analysis** with independent statisticians.

Healios will await the results of this analysis before taking any further action (participation in global trials).

CIRM Grant

The California Institute for Regenerative Medicine (CIRM) has awarded Healios NA, Inc. an approximately $1 million grant in support of UDC development.

CIRM → **Healios NA Inc.**

- Conduct R&D in the U.S. to realize next-generation UDC
- Grant funding is paid as milestones are achieved.

■CIRM: California Institute for Regenerative Medicine

CIRM was created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission. To meet this challenge, the team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies. With $5.5 billion in funding and more than 161 active stem cell programs in our portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality.
https://www.cirm.ca.gov

Financial Summary

Vision

To become a global biopharma company committed to transforming the lives of patients by creating, developing and commercializing cutting edge cell therapy technologies.

Healios is leading the research and development of cellular medicines focused on major causes of death and areas of unmet medical need in developed countries
—oncology: solid tumors; CNS: ischemic stroke; respiratory: ARDS—

Program Overview

Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease
Near term revenue & Commercial capabilities	**Innovative best in class programs**	

Partnering → **Carve-out**

[1]Future migration to UDC platform

Consolidated Statement of Income

Update

Healios

R&D expenses for the nine months ended September 30, 2023 were 1,531 million yen (R&D expenses of approximately 51% of the same period of the previous year). Continue to advance R&D activities while optimizing investment efficiency and expense discipline.

(Units: millions of yen)

	FY2022 Q3(YTD)	FY2023 Q3(YTD)		
			YoY variance	Main reasons for increase/decrease
Revenue	30	114	84	
Operating profit	-4,105	-2,298	1,807	Decrease in SG&A expenses ＋216 Decrease in R&D expenses +1,496
Profit	-3,957	-2,076	1,880	Increase in finance income ＋103 Decrease in finance costs +330 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	3,027	1,531	-1,496	
Number of employees	84	**63**	-21	

(Note)
* For details of the financial figures, please refer to the summary of the financial results announced today.

Supplemental Explanation of Finance Income and Finance Costs

Update

Healios

Details of finance income and finance costs

In the nine months ended September 30, 2023, we recorded finance income of ¥380 million and finance costs of ¥114 million.

Finance income was mainly due to the recording of ¥289 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund [*1] and ¥ 75 million in foreign exchange gains.

Finance costs were mainly due to the recording of ¥83 million in interest expenses on bonds [*2] and ¥29 million in interest expenses.

*1. Profit or loss transferred to equity interests held by external investors in the Saisei Fund

Profit or loss transferred to equity interests held by external investors in the Saisei Fund is the transfer amount of profits and losses of Saisei Bioventures, L.P., the consolidated subsidiary of our company, to limited partners other than our company. Saisei Bioventures, L.P. is a limited partnership established by Saisei Capital Ltd., the general partner and consolidated subsidiary of our company.

*2. Interest expenses on bonds

Of the total interest on bonds of 83 million yen posted for the nine months ended September 30, 2023, 53 million yen was charged to income using the amortized cost method. This is a non-cash expense recorded in accordance with the International Financial Reporting Standards (IFRS), which was introduced in the 1st quarter of the fiscal year ended December 2020.

Under JGAAP, convertible bond issuances were accounted for as liabilities and issue fees were accounted for as expenses. Under IFRS, however, proceeds, after deducting issue fees from convertible bond issuances, are accounted for as liabilities and equity, based on a certain standard. As a result, the difference between the face value of convertible bonds and the amount recorded as liabilities is amortized (expensed) over the period.

Consolidated Statement of Financial Position

Update

Healios

(Units: millions of yen)

	December 31, 2022	September 30, 2023		
			Variance	Main reasons for increase/decrease
Current assets	8,462 (56.3%)	10,584 (58.7%)	2,086	Increase in cash and cash equivalents +2,339 (Cash and cash equivalent balance at 9/30/23 was 9,586)
Non-current assets	6,571 (43.7%)	7,422 (41.3%)	851	Decrease in property and equipment -161 Decrease in investments accounted for using equity method -148 Increase in other financial assets +1,279
Total assets	15,033 (100.0%)	17,970 (100.0%)	2,938	
Current liabilities	3,808 (25.3%)	7,547 (42.0%)	3,739	Transfer of convertible bonds to current class +3,940
Non-current liabilities	6,842 (45.5%)	4,804 (26.7%)	-2,038	Transfer of convertible bonds to current class due to redemption within 1 year -3,887 Increase in equity interests held by external investors in Saisei Fund +1,929
Total liabilities	10.650 (70.8%)	12,351 (68.7%)	1,701	
Total equity	4,382 (29.2%)	5,619 (31.3%)	1,237	Issuance of new shares +2,976 Recording of loss -2,076
Total liabilities and equity	15,033 (100.0%)	17,970 (100.0%)	2,938	

(Note) For details of the financial figures, please refer to the summary of the financial results announced today.

Business Overview

Pipeline

Update

Healios

	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical	Comments
Inflammatory Conditions	HLCM051	Ischemic stroke	MultiStem®	Global		Phase 2/3 Planned		Preparing to start clinical trial in Japan Global clinical trial under consideration Orphan designation Developing Entity: ProcellCure Inc.
	HLCM051	ARDS	MultiStem®	Japan			Phase 2/3	Awaiting further analysis of the global clinical trial and will consider future action (participation in global trial) SAKIGAKE designation
Immuno-Oncology	HLCN061	Solid tumors	eNK	Global				Pre-IND started IND: 2025 Joint research with National Cancer Center Japan, Hiroshima University and Hyogo Medical University Developing Entity: eNK Therapeutics Inc.
	–		CAR-eNK	Global				
Replacement Therapies	HLCR011	RPE tear AMD	RPE	Japan			Phase 1/2	Scheduled to be launched in FY2025 (planned by Sumitomo Pharma) Developing Entity: Sumitomo Pharma Co., Ltd.
	–	Retinal disease	UDC-photoreceptors & RPE*	Global				
	HLCL041	Liver disease	Liver buds	Global				Carve-out plan to accelerate R&D and efficiently advance the program
	–	Diabetes	UDC-pancreatic islets	Global				

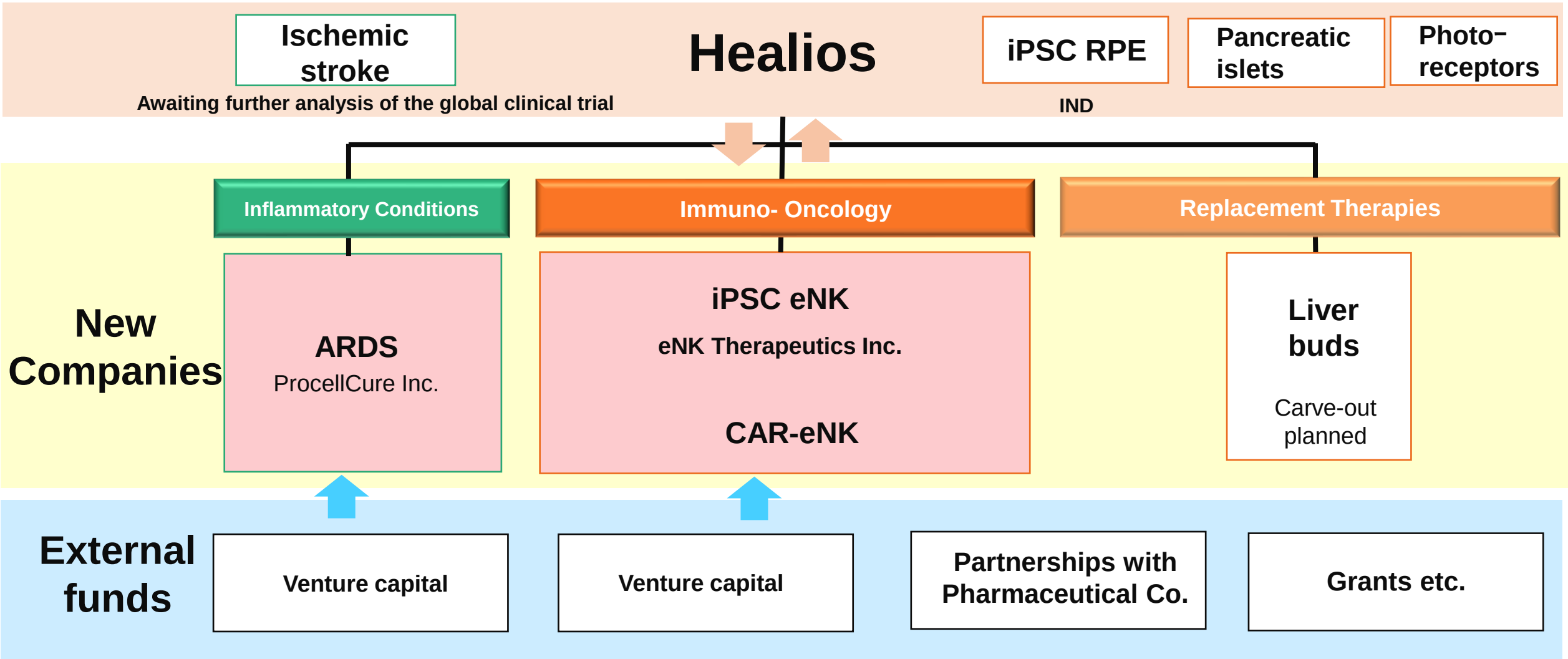
* Future migration to UDC platform

Model for promoting projects by maximizing investment efficiency

Update

Healios

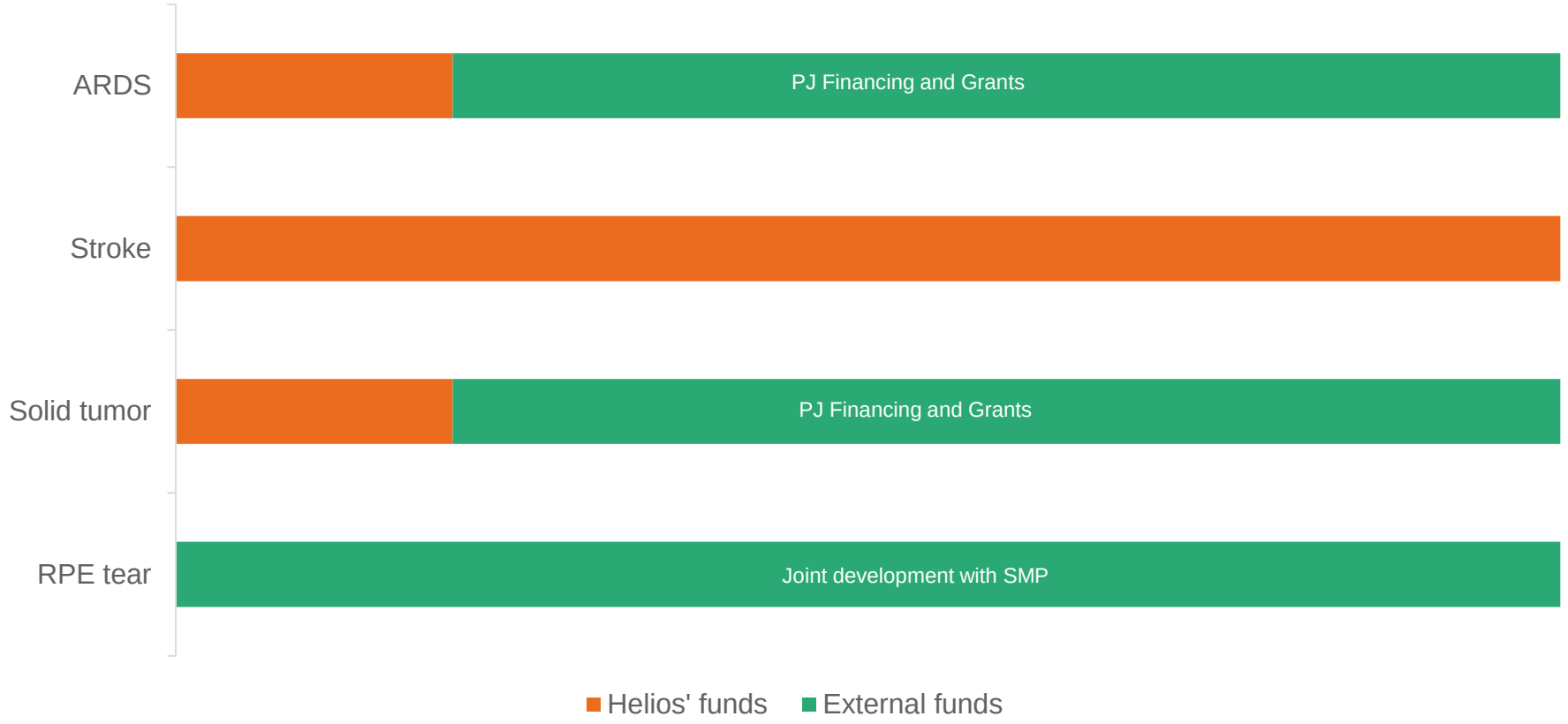
Leverage external funds and promote research and development of highly promising seeds



R&D and other funding sources

Basic policy

Promote R&D while maximizing investment efficiency and optimizing costs, using own funds and external funds such as project finance, partnering, etc.



Note: The bar graph above is an image and does not indicate the specific amount of R&D funds or the percentage of funding sources.

MultiStem®
Inflammatory Conditions

Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease

HLCM051 ARDS: ONE-BRIDGE Study

Update

Healios

Development plan

Inflammatory Conditions

Additional clinical trial in preparation

ARDS

- **ProcellCure Inc. is preparing to start the next clinical trial in Japan.**
- **Obtained global license and secured clinical trial product.**

August 2021
Announcement of top-line results

February 2023
After consultations with the regulator, the design of an additional study was determined.

July 2023
Regulator agreed to use of 3D bioreactor-based manufacturing method produced product.

October 2023
Obtained global license from Athersys and secured clinical trial product.

HLCM051 has been designated as an **orphan regenerative medicine product** for use in the treatment of ARDS by the Ministry of Health, Labor and Welfare. (It has received SAKIGAKE status for ischemic stroke.)

HLCM051 ARDS: Target Disease

There is demand for new treatments for ARDS that will lead to improvements in patients' symptoms and prognosis

The number of ARDS patients in the world is estimated over 1.1 million per year*1

About ARDS*2

Acute Respiratory Distress Syndrome (ARDS) is a general term for the symptoms of acute respiratory failure suddenly occurring in all seriously ill patients.

The mortality rate is approximately 30 to 58%*2.

Approximately 1/3 of ARDS cases are caused by pneumonia.

ARDS is a common cause of morbidity and mortality in severe COVID-19.

（Source）Athersys

Current Treatment

At present, there are no therapeutic drugs that can make a direct improvement to a patient's vital prognosis when ARDS develops.

The only symptomatic treatment for respiratory failure includes artificial respiration.

(source)
＊1 The number of ARDS patients is estimated by Healios adding up the statistical data of Japan, USA, Europe and China.
＊2 ARDS treatment guideline 2016

Next Clinical Trial for HLCM051 for ARDS

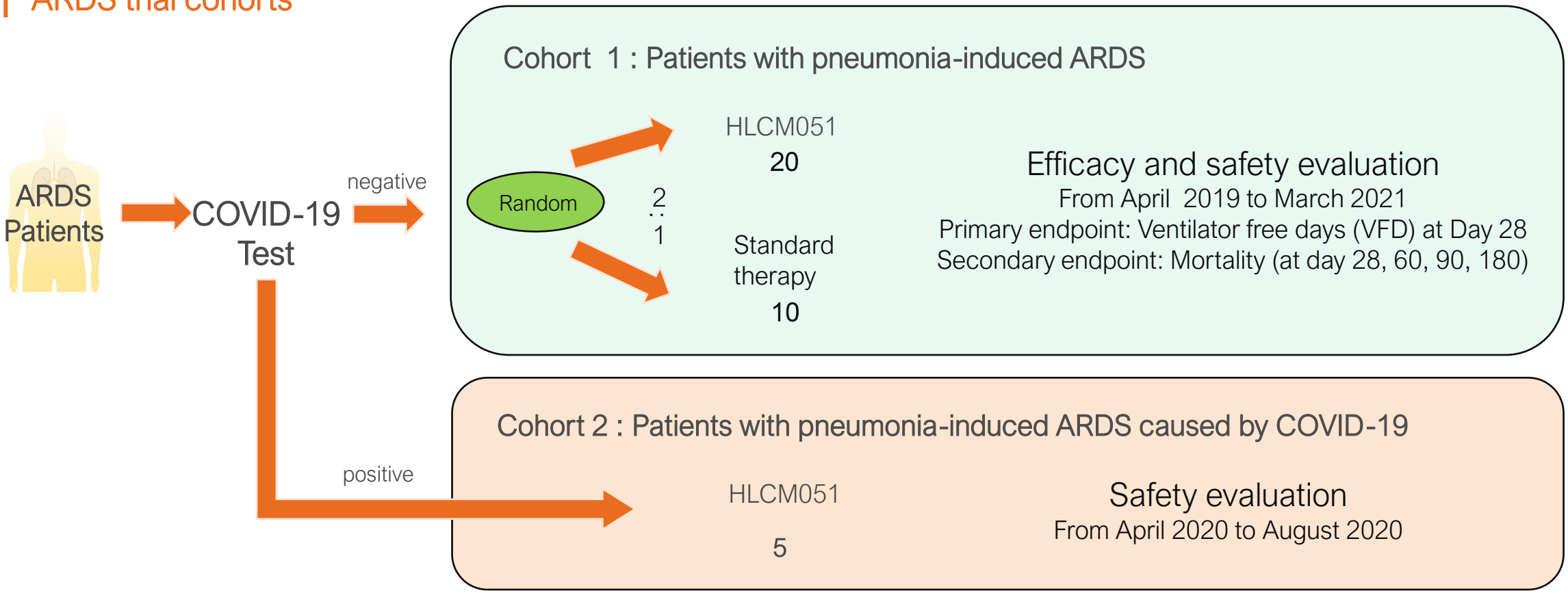
Conditions	Placebo-Controlled, Double-Blind, Randomized
Subjects	Patients with pneumonia-induced ARDS *Including patients with pneumonia-induced ARDS caused by COVID-19
Enrollment	80 (HLCM051 [n=40], placebo [n=40])
Primary Endpoint	VFD (the number of days out of 28 during which a ventilator was not used for the patient)
Secondary Endpoint (examples)	Mortality (180 days after administration)

The trial protocol will be finalized upon the submission of a future IND.

HLCM051 ARDS: ONE-BRIDGE Study

Phase II study investigating the efficacy and safety of HLCM051 in pneumonia induced ARDS patients

ARDS trial cohorts



Patient enrollment of COVID-19 pneumonia-derived cases (Cohort 2) was performed separately from the conventional clinical trial administration group (Cohort 1).

HLCM051 ARDS: ONE-BRIDGE Study Results at 180 Days Post Administration

Cohort 1

No safety concerns.

The HLCM051 treated group demonstrated a 9-day higher median VFD than the standard therapy group.

The treated group saw a 39% reduction in mortality as compared to patients treated with standard therapy.

Cohort 2

No deaths, no safety concerns.

The ventilator was withdrawn within 28 days for all five patients and in three days or less for three of these patients.

	Cohort 1	
	HLCM051	Standard therapy
Primary Endpoint		
VFD (the number of days out of 28 during which a ventilator was not used for the patient)	**20 days**	**11 days**
Secondary Endpoint		
Mortality (180 days after administration)	**26.3%**	**42.9%**

	Cohort 2
	HLCM051
Primary Endpoint	
Safety	**No safety issues**
Secondary Endpoint	
VFD	**25 days**
Mortality (180 days after administration)	**0%**

The academic paper on this clinical trial results has been published in the 'Stem Cell Research & Therapy'

HLCM051 Use of 3D bioreactor-based manufacture method

3D bioreactor-based manufacturing method

- Agreed with PMDA to use investigational product manufactured by 3D bioreactor-based method, which enables mass production, for ARDS clinical trials.
- Compared to the conventional 2D method, a large and stable supply of products can be achieved in commercial production after the product is launched.
- Cost-effectiveness and superior economics can be expected with the 3D method

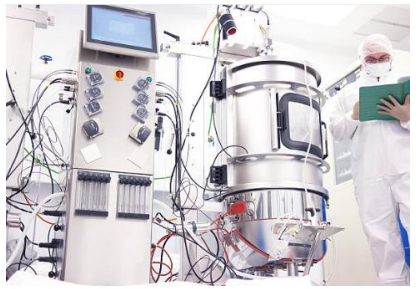
Working Cell Bank

Mass manufacturing process

2D manufacture

Adopt change

3D manufacture



Final product

Note: The above images of 2D / 3D manufacture are only images and are different from the actual instruments and operations used.

HLCM051 could be a pioneer as a 3D bioreactor-approved cell product.

Note: At the time of publication, there are no approved allogeneic cell products that have been publicly announced to be manufactured in 3D bioreactor-based method (according to our own research).

TREASURE Study: Development Status

Update

Healios

TREASURE study

Inflammatory Conditions

Ischemic stroke

- **Athersys announced interim analysis*1 results for the global clinical trial*2 on October 10. Additional data analysis will be performed.**
- **Awaiting the results of the further analysis and will consider future action (participation in global trial).**

***1 An analysis performed by an independent statistician during the course of a clinical trial. The results can be used to redefine the number of patients required.**
***2 A phase III study for stroke in the U.S conducted by Athersys. (MASTERS-2 study)**

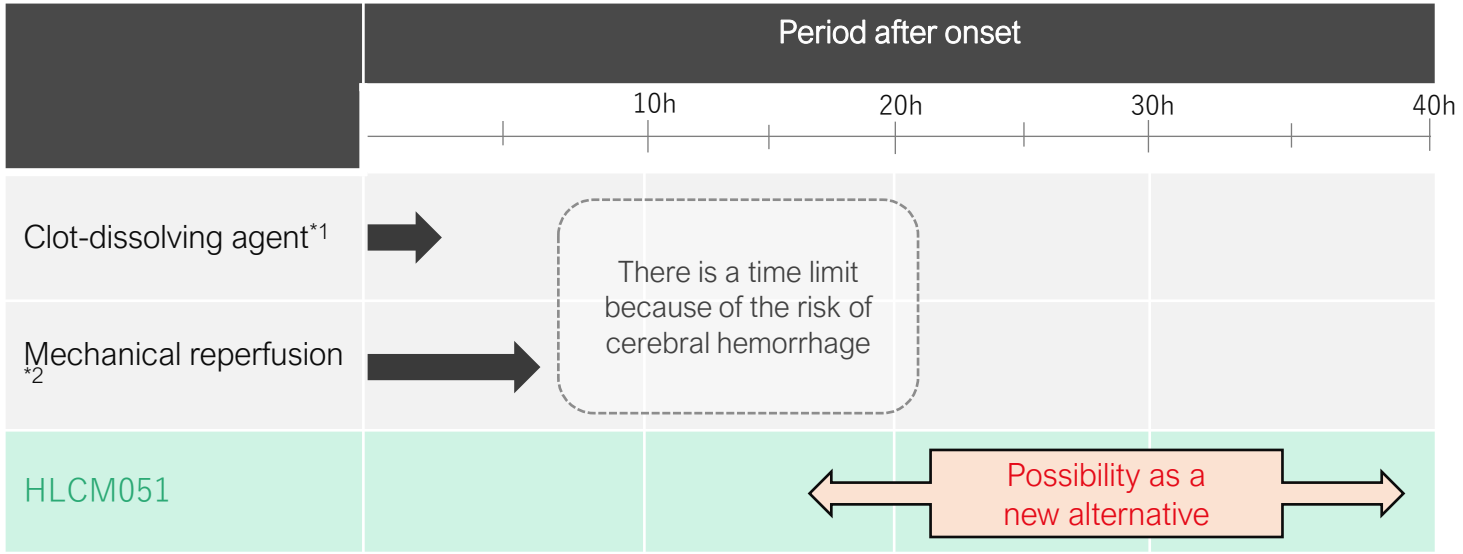
(Current)
Consultations with the regulators in Japan are planned regarding future data acquisition and application policies.

- HLCM051 is designated for SAKIGAKE Designation System

HLCM051 Stroke: Outline of Ischemic Stroke in Japan

Expected development of a new therapy that can be applied in a longer treatment window period following the onset of ischemic stroke (ability to help more patients)

Treatment in Accordance with the Period After Onset



※1 Dissolves blood clots in the brain vessels
※2 Insertion of the catheter into a blood vessel and recovery of the thrombus directly with a wire.

(Note) This material was prepared to explicitly describe the major therapeutic options for ischemic stroke and their treatment window periods after onset. Appropriate treatments are conducted according to patients' conditions and classification of their symptoms. Experimental or investigational treatments not included in the above are also performed.

Ischemic Stroke

Ischemic stroke, which represents the most common form of stroke (70 - 75% of cases in Japan), is caused by a blockage of blood flow in the brain that cuts off the supply of oxygen and nutrients, resulting in tissue loss.

(Source) Athersys

It is estimated that 37.9% of bedridden patients and 21.7% of persons who were in need of care were affected by ischemic stroke.

TREASURE Study: Overview

Trial	Placebo-Controlled, Double-Blind, Phase 2/3 Efficacy and Safety Trial of HLCM051 in Patients With Ischemic Stroke（TREASURE study）
Subjects	Ischemic stroke within 18 to 36 hours
Conditions	Placebo-Controlled, Double-Blind
Enrollment	220 (HLCM051 [n=110], placebo [n=110], randomized)
Outcome Measures (examples)	・Proportion of subjects achieving Excellent Outcome defined by functional assessments (primary endpoint at day 90) ・Global recovery (i.e., GEE) and dichotomous assessment ・Proportion of subjects with a BI score of ≥95

TREASURE Study: Results

Comparison of results between the HLCM051 group and the placebo group at 90 and 365 days

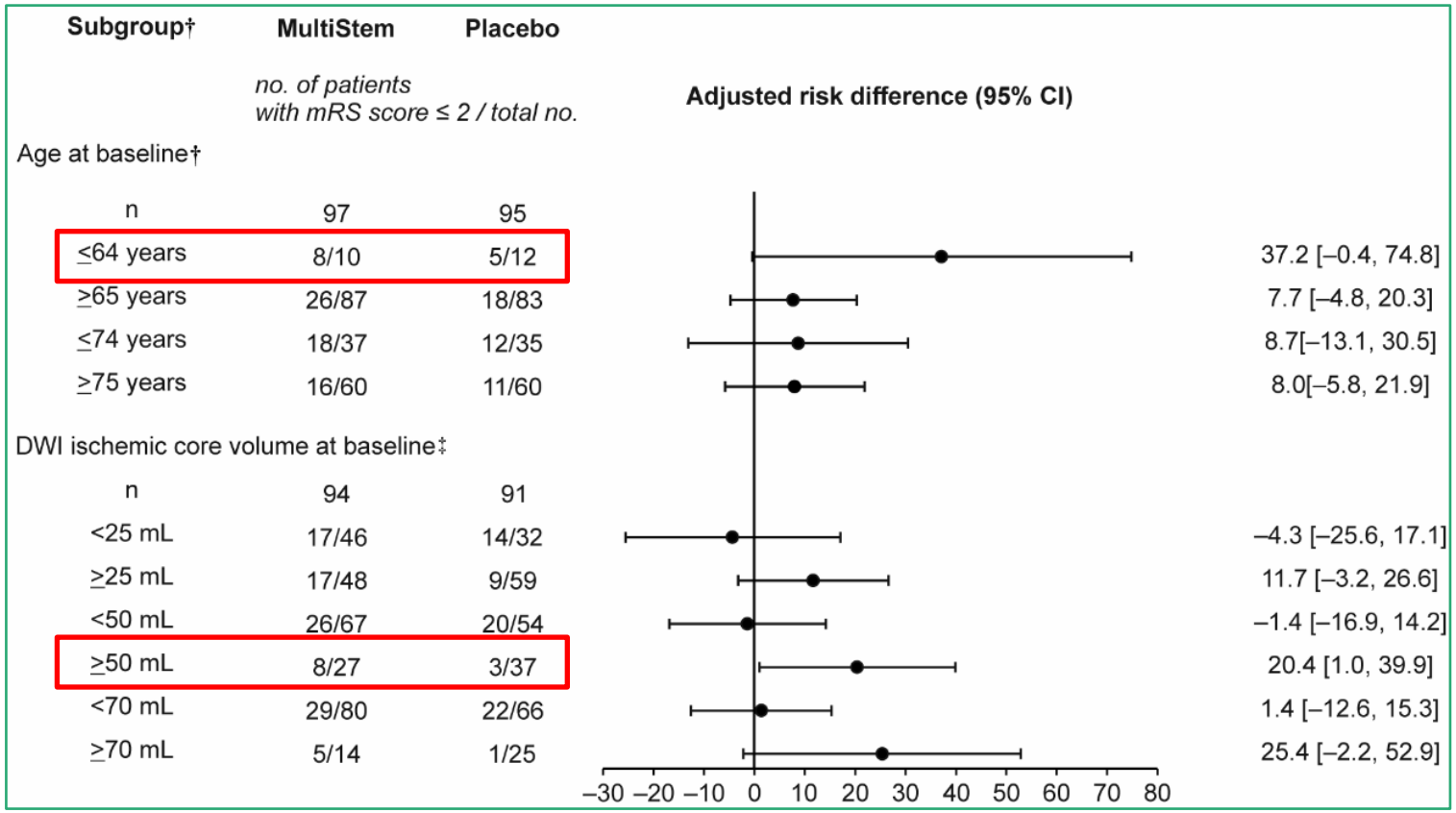
	90 days			365 days		
	HLCM051	**Placebo**	**p-value**	**HLCM051**	**Placebo**	**p-value**
Excellent Outcome*1	12 (11.5%)	10 (9.8%)	p=0.903	16 (15.4%)	11 (10.8%)	p=0.431
Global Recovery*2	20 (19.2%)	16 (15.7%)	p=0.762	29 (27.9%)	16 (15.7%)	p=0.037
BI >=95	31 (29.8%)	24 (23.5%)	p=0.437	37 (35.6%)	23 (22.5%)	p=0.045
Safety outcomes	There were no significant differences, including mortality and adverse events between the treatment and placebo groups.					

*1 Global Recovery (mRS<=2, NIHSS change >=75% and Barthel Index>=95).
*2 Excellent Outcome (mRS<=1, NIHSS<=1 and Barthel Index>=95)

＊The above data was presented at the 14th World Stroke Conference and the 40th Annual Meeting of Japan Society of Neurological Therapeutics

TREASURE Study: Subgroup Analysis Results

1. The results showed a trend toward efficacy as cerebral infarct volume increased from 25 mL to 50 mL and 75 mL. The efficacy was statistically significant, especially for volumes of 50 mL or greater.
2. Though a small sample size, patients under 64 years of age appear to achieve better results.



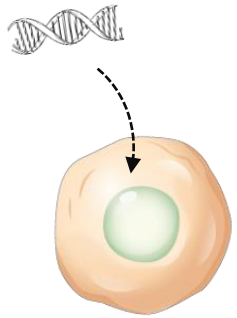
＊The subgroup analysis results were presented at the 48th Annual Meeting of the Japanese Stroke Association held on March 17, 2023.

iPSC eNK
Immuno-Oncology

Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease

eNK Program Vision: eNK Platform

Gene-edited iPSC Line



Healios' proprietary iPS cells

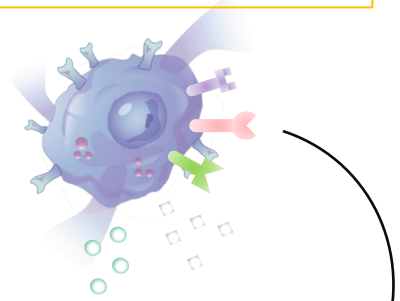
Master cell banks established for eNK cell production

eNK cells differentiation

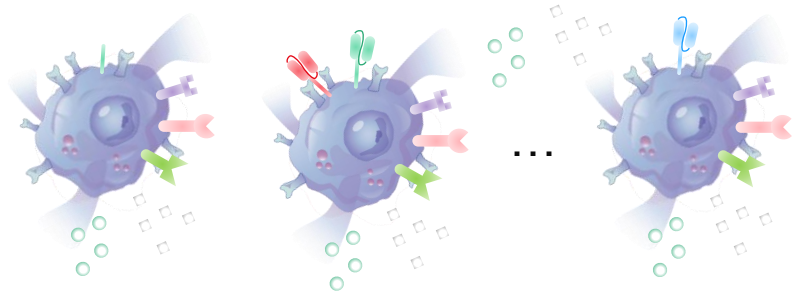
Technology Platform

Differentiation of eNK Cells with Enhanced Functionality

eNK Cells



Next Generation eNK Cells



CAR-eNK Cells *Dual CAR-eNK Cells*

Product Platform

eNK cells/CAR-eNK cells as monotherapies

+

eNK combination therapies with antibodies for ADCC*

+

eNK combination therapies with immune checkpoint inhibitors

=

Platform leading to numerous pipeline products and treatment approaches for various types of cancers

*ADCC: antibody-dependent cellular cytotoxicity
Attack activity to pathogens by an immune cell though an antibody

HLCN061: eNK Cells Enhanced Not Only with Improved Cytotoxicity and Persistence, but with Greater Migration to Tumors and Recruitment of Host Immune Cells

Healios

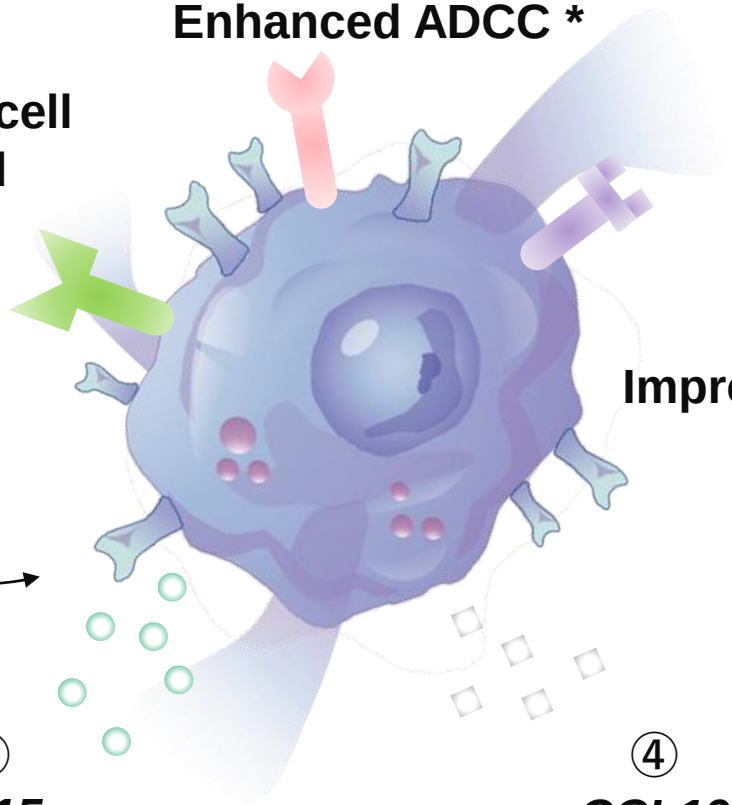
Healios' eNK Cells key features

Healios proprietary gene-edited iPS cells line

eNK cell differentiation

① ***NKG2D*** **Enhanced cancer cell recognition and cytotoxicity**

② ***CD16*** **Enhanced ADCC ***



③ ***CCR2B*** **Improved migration to solid tumors**

④ ***CCL19*** **Recruitment of host immune cells**

⑤ ***IL-15*** **Prolonged survival**

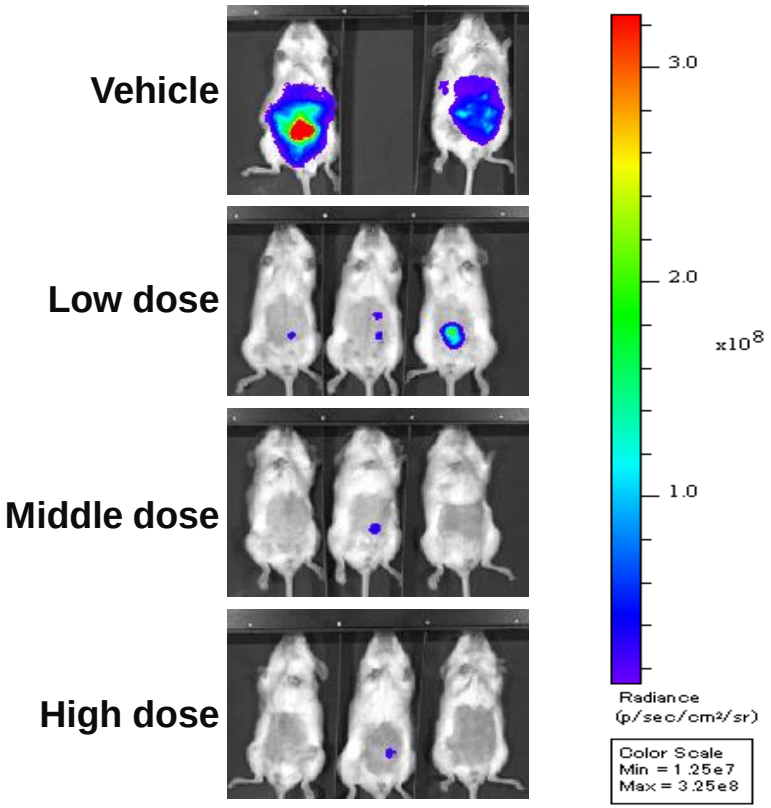
*ADCC: antibody-dependent cellular cytotoxicity
Attack activity to pathogens by an immune cell though an antibody

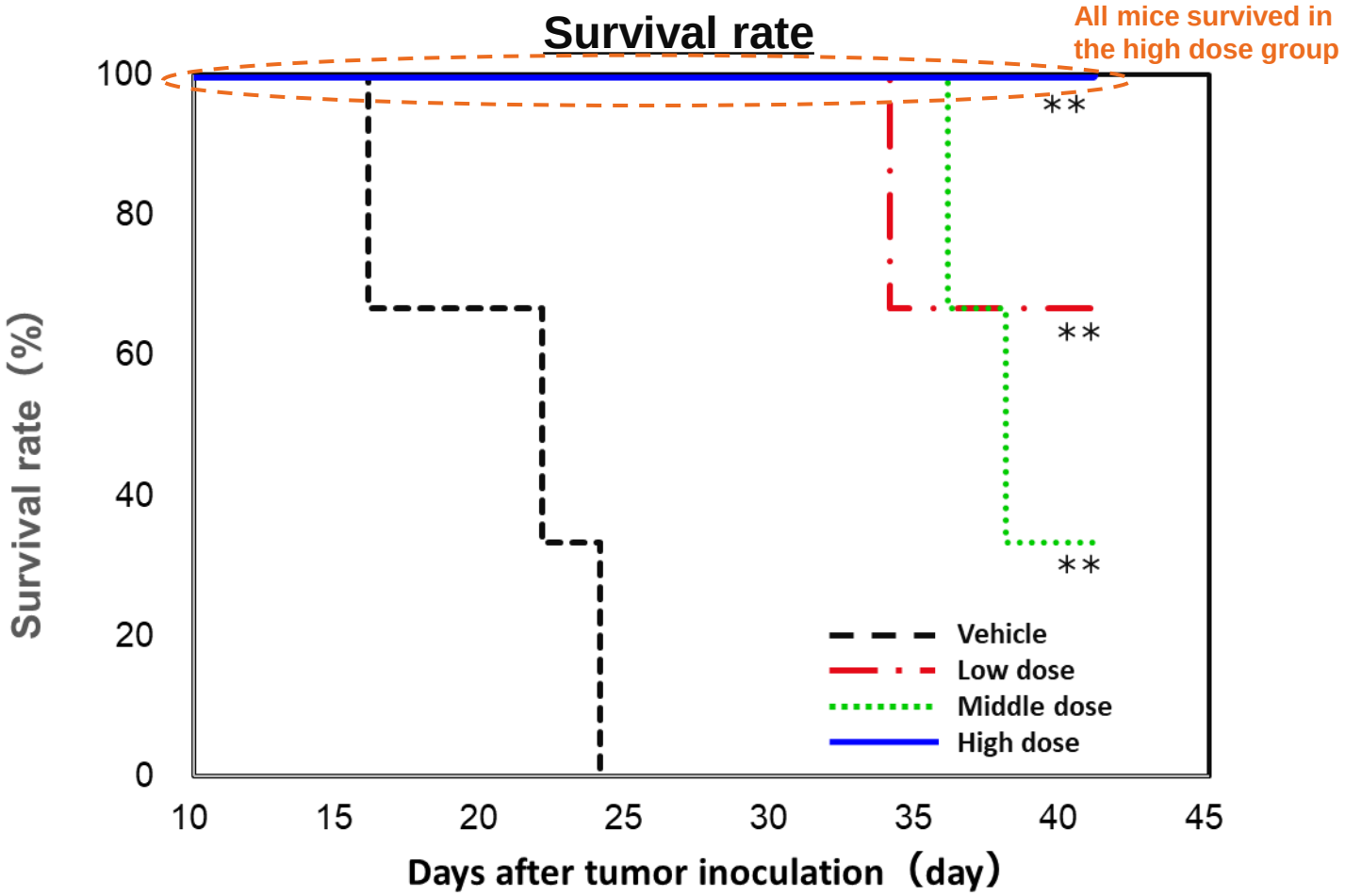
HLCN061 *in vivo:* Anti-Tumor Activity (gastric cancer peritoneal dissemination model mice)

New Healios

➢ **Prolonged survival time by administered eNK® with dose-dependent manner in gastric cancer peritoneal dissemination model mice, and all mice survived in the high dose group**

Fluorescence intensity images of cancer cells on day 20





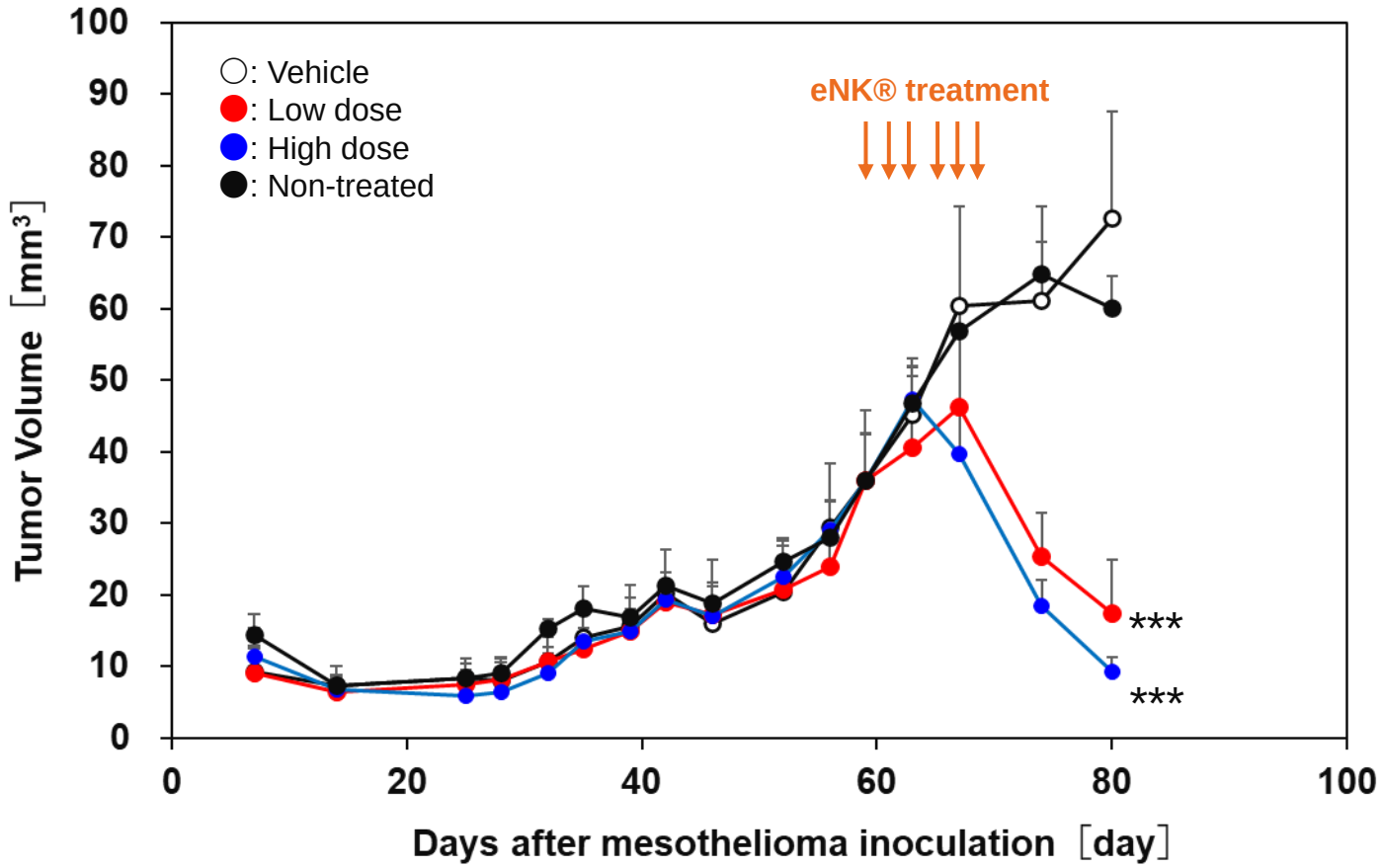
n=3

**: p<0.01 vs Vehicle, Log-rank test

HLCN061 *in vivo:* Anti-Tumor Activity (Subcutaneous mesothelioma bearing model mice)

New Healios

➢ eNK® showed rapid tumor regression effect after treatment in subcutaneous mesothelioma bearing mice



n=5 (n=3; NT),
*** : p<0.001 vs Vehicle (Dunnett's test)

HLCN061: Advanced In-House GMP Grade, 3D Manufacturing Process & Facility

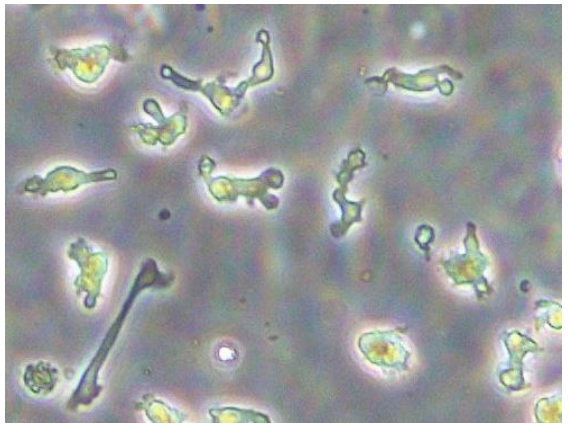
-GMP facility fully operational and being advanced in preparation for clinical trials
-In-house manufacturing enables control of the schedule and quality of clinical production

iPSC Sphere Formation → HPC Differentiation Induction → eNK Cells Differentiation Induction → eNK Cells Expansion

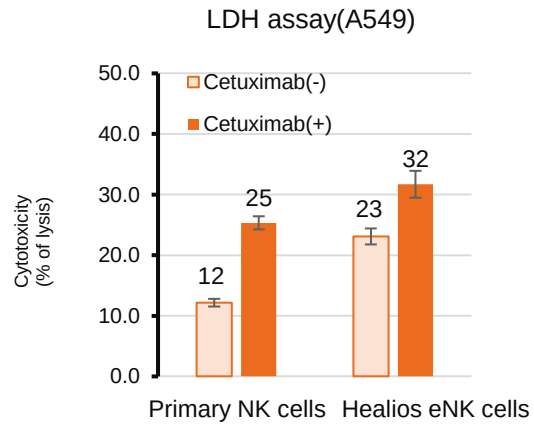
Fully-closed, feeder free, 3D perfusion bioreactor system

Cell Harvest: Concentration & Washing → Aseptic Filling and Finish → Cryopreservation → Storage

KCMI; Kobe Center for Medical Innovation
Photo by; OM Kobe (KCMI management company)



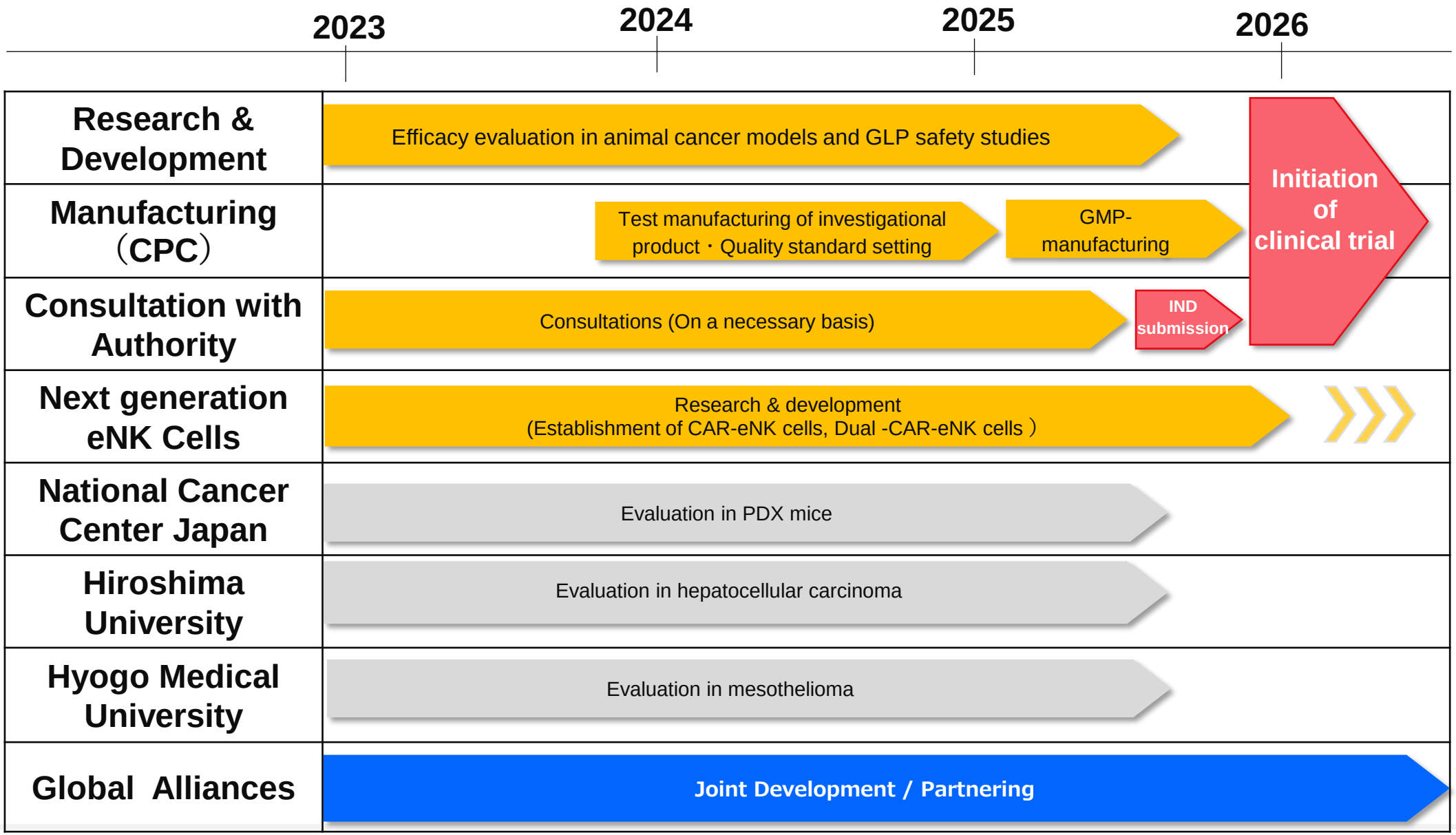
100 billion eNK cells per batch



Cryopreserved samples show high cytotoxicity post thaw

（Source）in-house data

R&D Roadmap of eNK Cells (HLCN061)



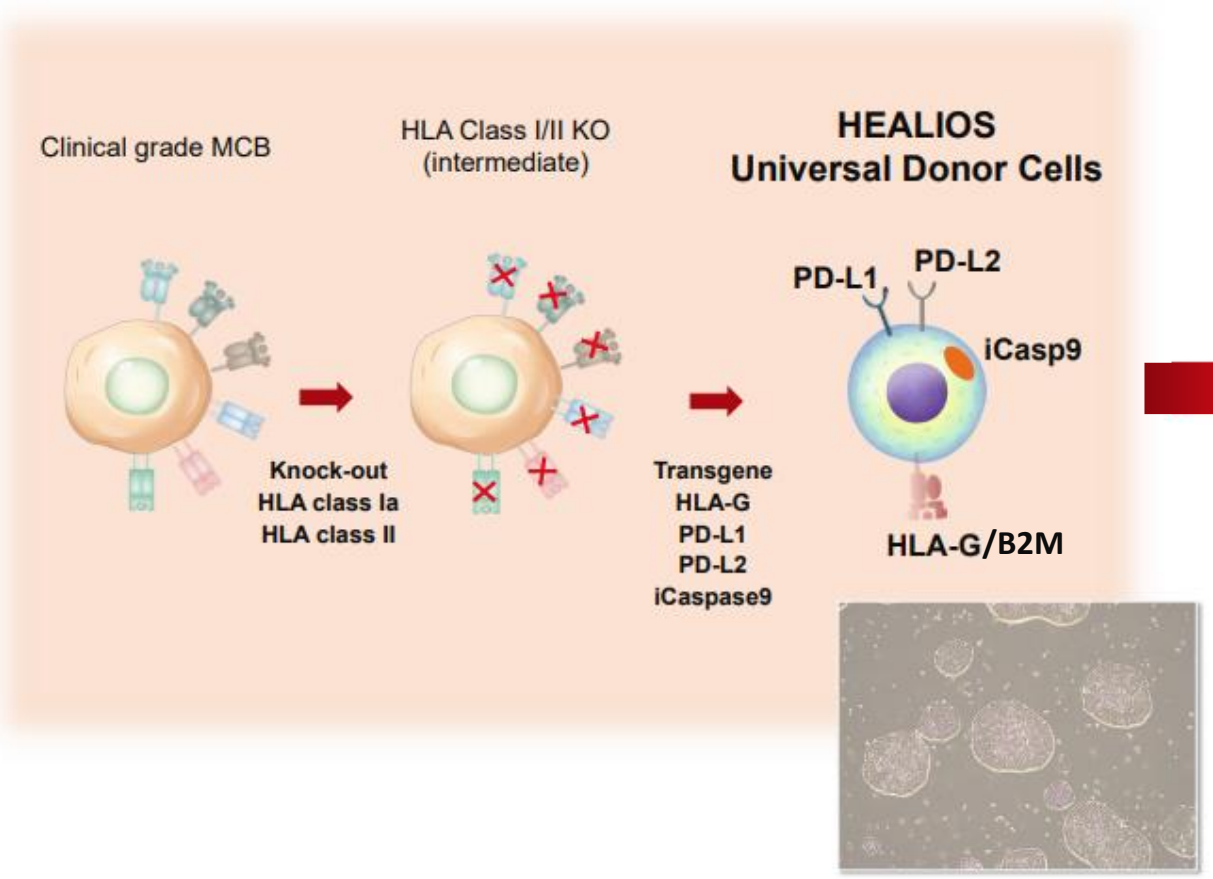
Universal Donor Cell (UDC) Replacement Therapies

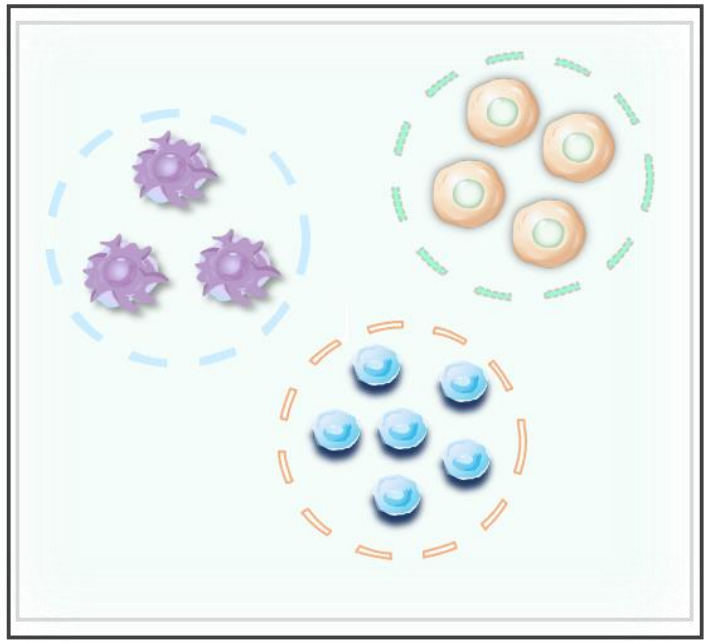
Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease

[1]Future migration to UDC platform

Hypo-immune UDC: Engineered Genetic Profile

Gene Editing Procedure for Healios UDC





- Off-the-shelf, scalable and cost-efficient
- Address broadest population with single product
- Enhanced level and duration of efficacy

(Source) in-house data

Clinical grade line and Master Cell Bank established in 2020/2021

iPSC Platform: UDC and iPS Cell Line Collaborations

September 2023, Healios provided eNK platform for a novel research study on metastatic uveal melanoma at Thomas Jefferson University in Philadelphia.

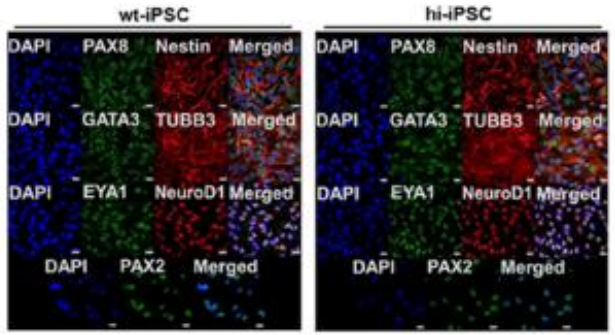
October 2023, Healios NA awarded $1 million from the California Institute for Regenerative Medicine (CIRM) in support of UDC development

Supplying UDC and iPS cells to several companies and academic institutions (more than 10 facilities) and evaluating their potential for various diseases

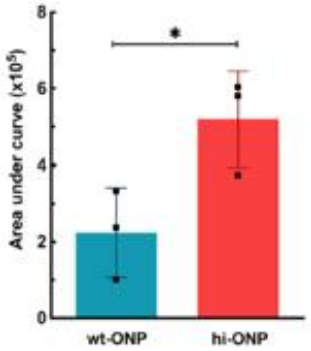
iPSC Platform: ONPs differentiated from UDCs

Healios UDC-derived otic neural progenitor cells (ONPs) demonstrate enhanced survival after transplantation into the cochlea confirmed by Northwestern University

Otic neural progenitor cells



Representative immunocytochemistry photomicrographs of iPSC-derived ONPs



Quantification of iPSC-derived ONPs 10 days following intracochlear transplantation

(Source: Northwestern University)

Left

Healios UDCs (hi-iPSCs) differentiated into late-stage ONPs as well as unedited cells (wt-iPSC) using multiple differentiation markers.

Right

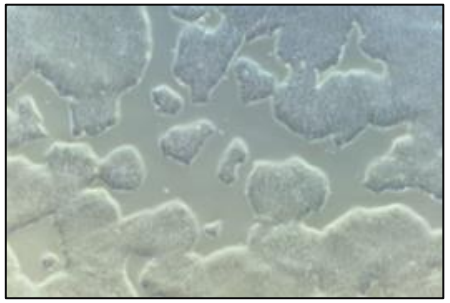
More Healios UDC-derived ONPs (hi-ONPs) than unedited parental cell-derived ONPs (wt-ONPs) were viable after transplantation. In other words, immune rejection was reduced as expected.

The induction of differentiation into otic neural progenitor cells and the hypo-immune benefit upon transplantation into mice were confirmed

This approach may open a new avenue for experimental and clinical sensorineural hearing loss (SNHL) treatments

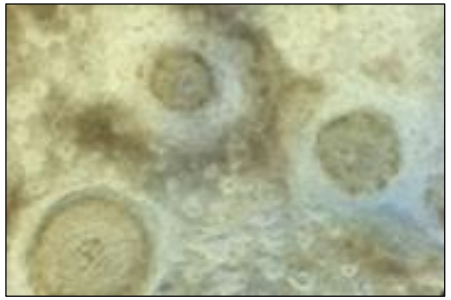
Hypo-immune UDC: Differentiation and Induction of Photoreceptor Cells

Photoreceptor cells

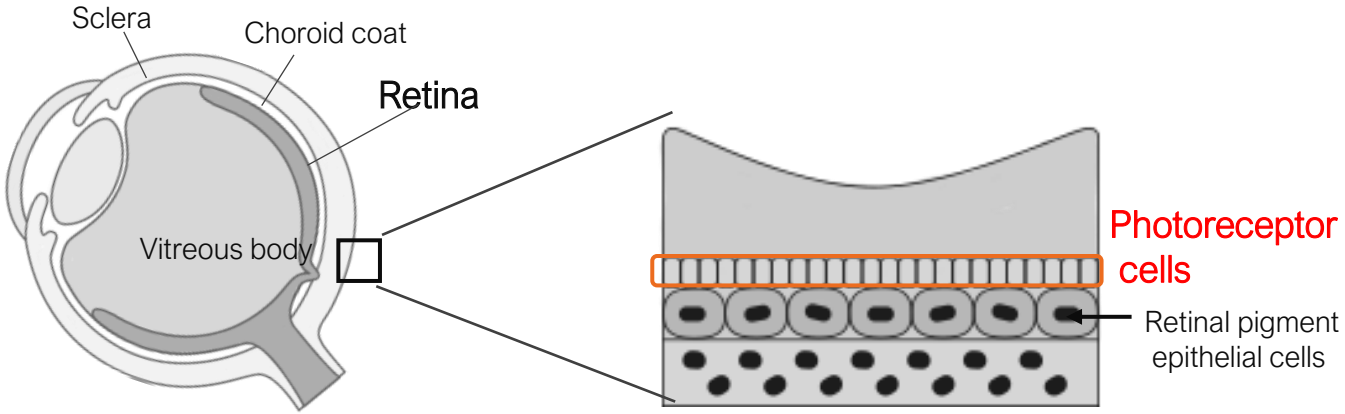


UDC

Differentiation and induction



Photoreceptor cells From UDC



Joint Research with STEMAXON

Confirmation of differentiation and culture from UDCs to photoreceptor cells* for retinal disease

-Cone cell dominant photoreceptor cell sheets with color-sensing

-Minimal contamination of unnecessary cells such as bipolar cells, which can be an obstacle to improving visual acuity

-Recovery of visual function confirmed in transplantation experiments using animal disease models

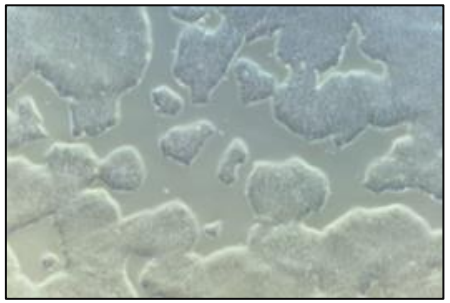
* Photoreceptor cells are one of the cells that compose the retina and are particularly responsive to light.

(Source) Joint research data

Hypo-immune UDC: Differentiation and Induction of Pancreatic β-cells

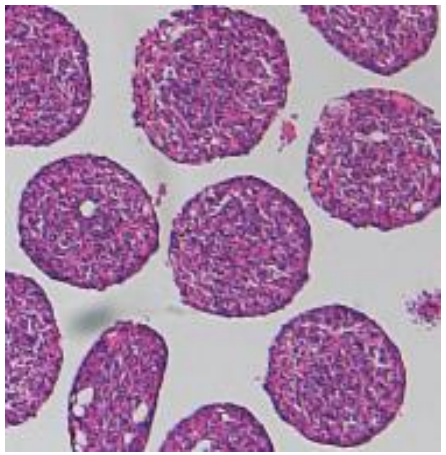
Joint research with the Department of Regenerative Medicine at the National Center for Global Health and Medicine in Tokyo

Pancreatic β-cells



UDC

Differentiation and induction



UDC-derived pancreatic β cells (HE staining)

(Photo provided by the National Center for Global Health and Medicine)

Pancreatic β-cells are a type of cell present in the islets of Langerhans within the pancreas. They produce and secrete insulin in response to blood glucose levels and serve to regulate the amount of glucose in the bloodstream.

In our joint research with the Department of Regenerative Medicine at the National Center for Global Health and Medicine in Tokyo, **we have successfully confirmed the differentiation of UDCs into pancreatic β-cells.**

Moving forward, our joint research will work on optimizing the process and verifying the efficacy and safety of these cells in animal models of diabetes. Through this achievement, we hope to develop a new more effective therapeutic approach for diabetes and further expand the value and impact of our company's iPSC platform

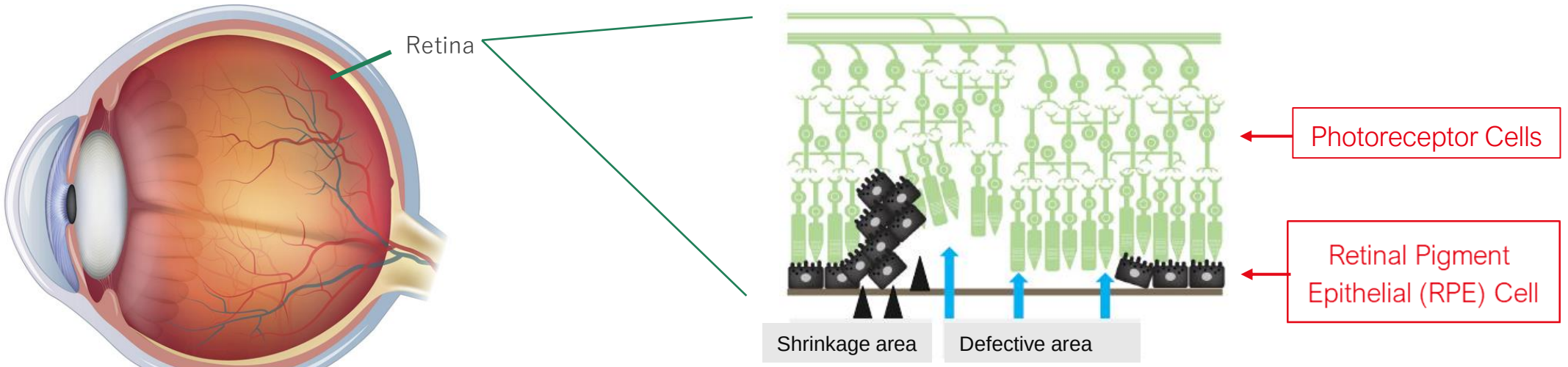
(Source) Joint research data

HLCR011 RPE Tears

An RPE (Retinal pigment epithelium) tear is a disease in which the sensory retina is detached from the RPE due to a tear in the retina (retinal tear). It causes visual field defects and vision loss.

If RPE is defective but photoreceptor function is preserved, pigment epithelial cell transplantation can restore vision.

RPE tear



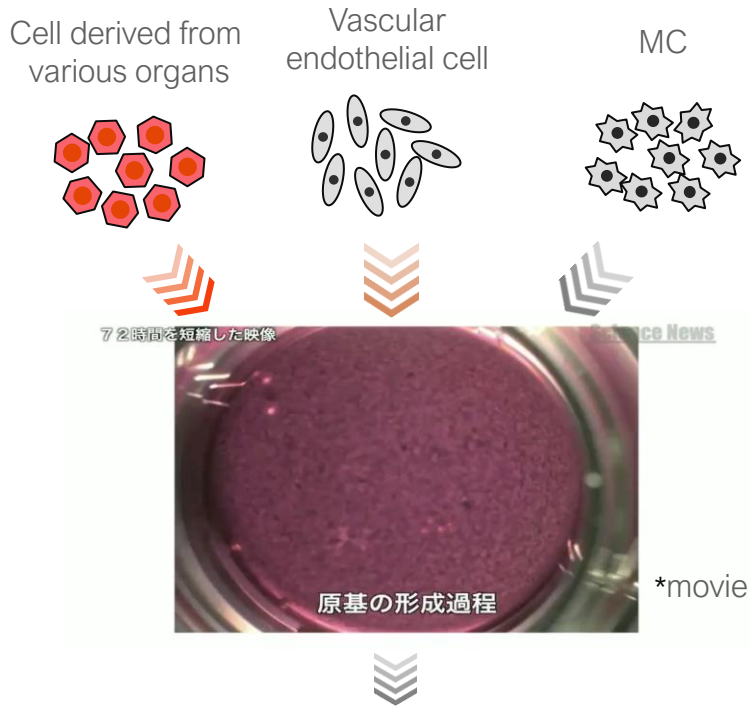
Joint Development

- In Japan, HEALIOS and Sumitomo Pharma Co., Ltd. are jointly developing a treatment using iPS cell-derived RPE cells.
- Started phase 1 / 2 study in June, 2023

HLCL041: Liver Organ Bud Platform

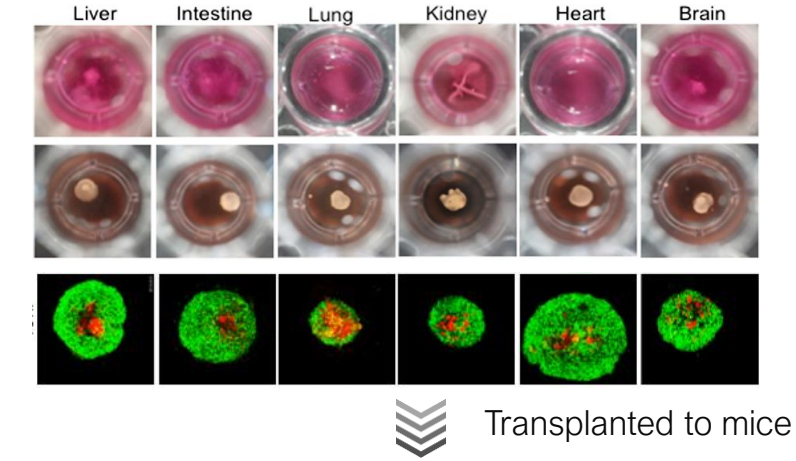
By creating an "Organ Bud" of each organ with iPS cells, we have laid the groundwork for paradigm shifting therapies to emerge for various severe diseases.

UDCs allow for the realization of organ replacement using organ buds.

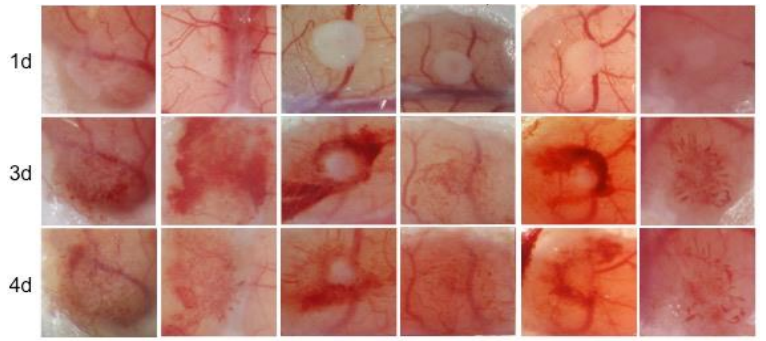


The vascularization was confirmed in vivo by transplantation to mice.

（Sours） Japan Science and Technology Agency　Science News “Diverse Approaches in Regenerative Medicine from Cell to Tissue/Organ” (Distributed October 3, 2013)
https://sciencechannel.jst.go.jp/M130001/detail/M130001005.html



Transplanted to mice



Green：Cells of each organ
Red：Vascular endothelial cell
Black：MSC

（Sours） Modified from Takebe T. et al., Cell Stem Cell, 2015

We plan to carve out the technology to efficiently accelerate R&D in collaboration with external partners such as venture capital funds.

Vision

To become a global biopharma company committed to transforming the lives of patients by creating, developing and commercializing cutting edge cell therapy technologies.

Overview of Healios

Update

About us

Company Overview

Company Name	HEALIOS K.K.
Representative	Hardy TS Kagimoto, MD, Chairman and CEO
Establishment	February 24, 2011
Paid in Capital	119 million yen (As of April 30, 2023)
Head office	Hibiya Mitsui Tower 12F, 1-1-2 Yurakucho, Chiyoda-ku ,Tokyo 100-0006, Japan
Number of Employees	63 (As of September 30, 2023)
Business	Research, development and manufacturing of cell therapy/ regenerative medicine products
Affiliated Company	Sighregen Co., Ltd. (Joint Venture with Sumitomo Dainippon Pharma Co., Ltd.)
Subsidiary	・Healios NA Inc. (Established in February 2018) ・Organoid Neogenesis Laboratory Inc. (June 2018 to promote the practical use of organ bud technology) ・Saisei Ventures LLC (January 2021, as a venture fund investment advisor) ・Saisei Capital Ltd. (January 2021 as a venture fund general partner) ・Saisei Bioventures, L.P. (January 2021 as a venture fund limited partnership) ・ProcellCure Inc. (July 2023 to promote development of ARDS) ・eNK Therapeutics Inc. (August 2023 to promote R&D of eNK cells)

Advanced Technology at Healios' Kobe Research Institute

Large number of researchers (24 Ph.D.'s as of Mar. 31) on staff and efficient, in-house implementation of everything from gene editing to process development

1. Exploratory Research
- I. Development of iPSC differentiation induction methods
- II. Functional evaluation of iPSC derived cells
- III. Functional evaluation of iPSC derived cells
- IV. Evaluation of gene-edited cells

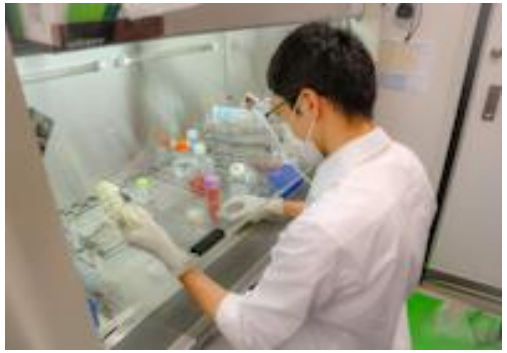
2. QC
- I. Functional evaluation of various cells
- II. Development of evaluation protocols

3. Genetic Recombination Experiments
- I. Construction of plasmids
- II. Construction of viral vectors
- III. Creation of transgenic cells

Healios' Kobe Institute Area(Photo by Kobe Urban Promotion Service Co.,Ltd.)

4. Experiments on animals
- I. Generation of disease mice models
- II. Evaluation of antitumor effects *in vivo*
- III. Evaluation of immune response *in vivo*
- IV. Evaluation: tissue section and immunostaining

5. Process Development Research
- I. Optimization of differentiation
- II. Development of mass production methods
- III. Development of freezing processes
- IV. Analysis of culture media



Healios Is Uniquely Positioned To Leverage Strong Japanese Proficiencies

Favorable External Environment In Japan

iPSCs Discovered in Japan

The Nobel Prize in Physiology or Medicine (2012) Shinya Yamanaka, M.D, Ph.D (Professor at Kyoto University)

Expedited Regulatory Framework

- Conditional and time limited authorization system
- SAKIGAKE (fast-track designation)

Precision Manufacturing in Cell Therapy

- Clinical and scale-up infrastructure for commercial purposes

Intrinsic Healios Strengths

Established Innovative R&D Expertise

- First in human iPSC technology in the world
- Proprietary hypo-immune universal donor iPSC platform technology
- Kobe Research Institute: > 30 Ph.D. holders
- Numerous high-profile R&D partnerships & JVs

Robust CMC Expertise & Foundational Alliances with Global Players

- GCTP/GMP manufacturing facility
- Automated 3D bioreactor system for eNK
- Advanced 3D organ manufacturing
- Long-standing alliances with Nikon & Sumitomo Pharma Co., Ltd.

Clinical Development Capabilities

- Completed enrolment in two major trials in 2021 including the largest Japanese cell therapy trial in history

Saisei Fund Accelerates Investment in Next-generation Therapeutics and Technologies

January 2021 Saisei Bioventures, L.P. (Saisei Fund) established by Healios

Important informational insights

Building relationships with promising companies

High return investments

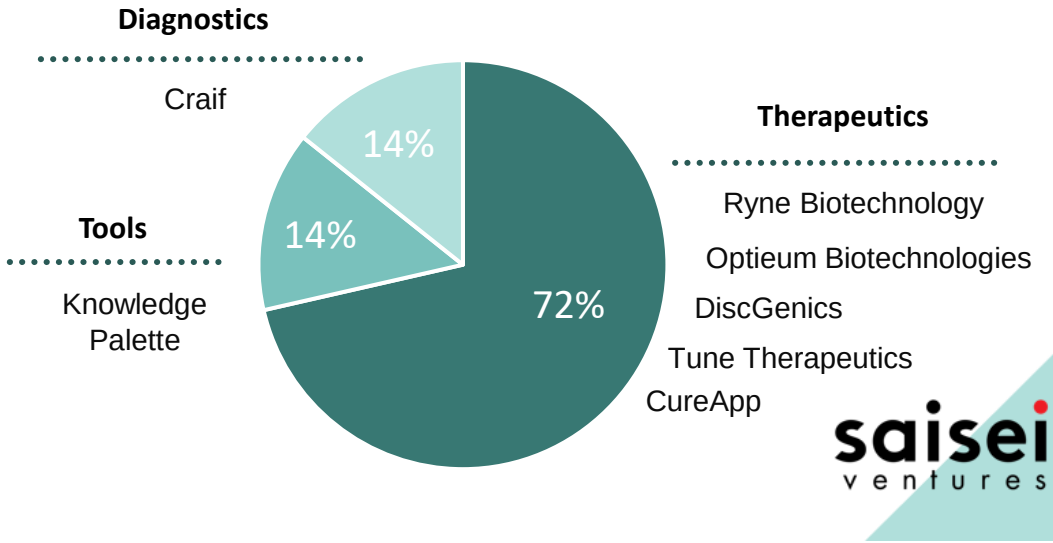
Engage deeply with regenerative medicine innovation around the world through our venture fund activities

Saisei Fund partners

Jonathan Yeh （Ph.D. MBA）
Founding Partner
Investment Committee
Board of Managers
Director of GP

Hikaru Saito （Ph.D.）
Japan representative partner
(Appointed in Jan 2023)
Formerly at Astellas Venture Management
Cell & gene specialist

Investment Portfolio



Japan Investment Corporation has made a $30 million commitment as a limited partner in the Saisei Fund, and in connection with this, Healios has decided to change its previously disclosed use of funds.

The decision by Japan Investment Corporation to invest in Saisei Bioventures, L.P. Change in the use of funds

Potential for Future Milestone Income

May 12, 2017, 1st Quarter Financial Results Briefing (page 7)

Compounds	BBG		Transfer our business relating to an ophthalmic surgical adjuvant containing BBG250

[The transferee] D. Western Therapeutics Institute, Inc.
[Transfer price] A lump sum fee of 1.3 billion yen at the time of transfer.

There is also the possibility of receiving milestone payments in line with the progress, etc., of development and out-licensing operations.

[Business transfer due date] April 30, 2017

Expected to receive milestone payments (amount undisclosed) as progress in development is expected in the medium term.

※February 13, 2023, D. Western Therapeutics Institute, Inc. “事業計画及び成長可能性に関する事項”(page.57 Japanese only)

Healios

＜Contact information＞
IR & Finance and accounting Div.
HEALIOS K.K.

Press contact: pr@healios.jp
Investor contact: ir@healios.jp
https://www.healios.co.jp/contact/

Appendix

MultiStem®
Inflammatory Conditions

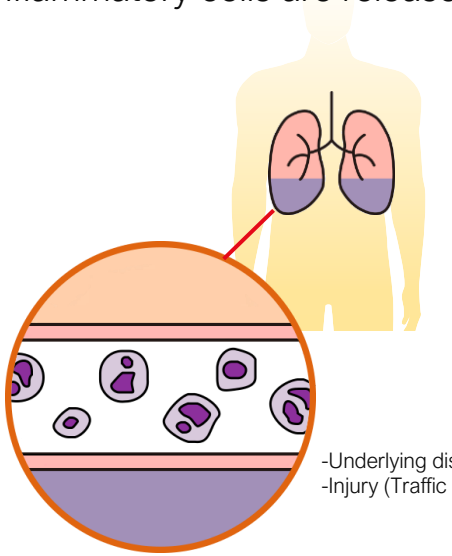
Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease

HLCM051 ARDS: Mechanism of Action

Expected effects of HLCM051(MultiStem®), bone marrow-derived somatic stem cells

- Relief of inflammation, regulation of immune function
- Promotion of angiogenesis
- Promote protection and repair of injured cells and tissues
- Improvement of lung tissue and respiratory function

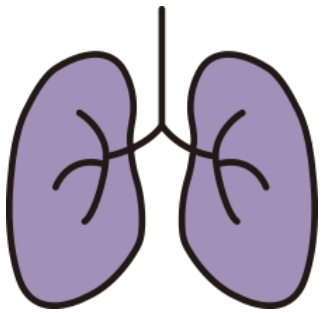
Inflammatory cells are released



-Underlying disease (pneumonia, etc.)
-Injury (Traffic accident, etc.)

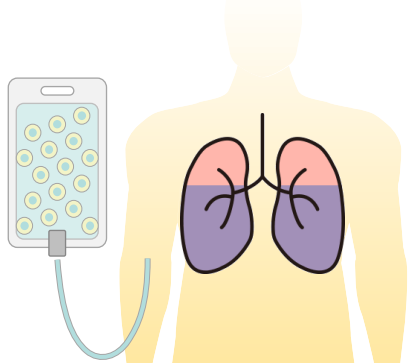
When the tissue is damaged, inflammatory cells are released in large quantities.

Inflammatory cells attack the lungs



The inflammatory cells attack the lungs. As a result, hypoxia develops and the patient falls into severe respiratory failure.

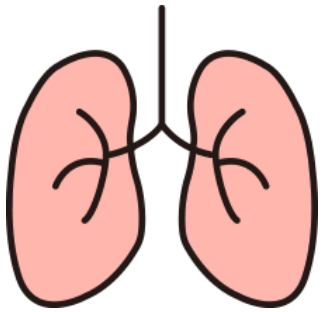
HLCM051 administered



- Suppresses excessive inflammation in the lungs.
- Protects damaged tissue and facilitates healing.

HLCM051 accumulates in the lungs as a result of intravenous administration.

Lung function improves

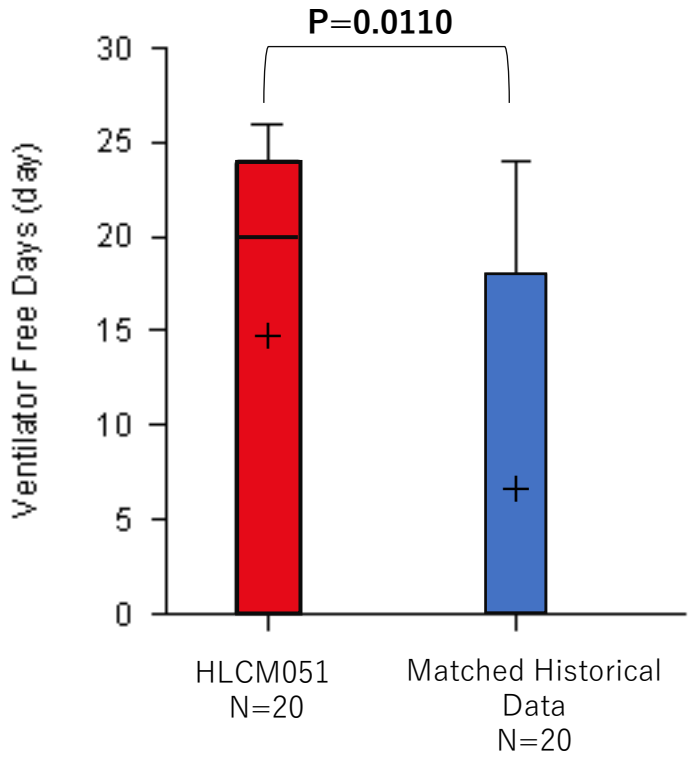


We can anticipate earlier ventilator removal and a lower mortality rate.

HLCM051 ARDS: Comparison with Historical Data

In the matched historical data comparison, the VFD was prolonged by 8.1 days (mean), and the mortality rate was 33.7% lower (reflecting a 56% decline in mortality as compared to the historical data group).

	Compared with historical data	
	HLCM051	Matched historical data
Primary Endpoint	**P=0.0110**	
VFD (the number of days out of 28 during which a ventilator was not used for the patient)	**14.8days**	**6.7 days**
Secondary Endpoint	**P=0.0536**	
Mortality (180 days after administration)	**26.3%**	**60.0%**



(Source) in-house data

Results of Double-blind Study Conducted by Athersys <ARDS>

Based on one-year follow-up summary results, an evaluation of quality-of-life suggests further potential benefits from MultiStem treatment including faster rehabilitation.

No serious adverse events were observed.

Analysis of the Double-blind study conducted by Athersys

	MultiStem	Placebo
Mortality	25%	40%
Ventilator- free (VF) days	12.9 days	9.2 days
Intensive Care Unit (ICU) free days	10.3 days	8.1 days

Post-hoc Analysis of patients in severe condition and pneumonia-induced ARDS

	MultiStem	Placebo
Mortality	20%	50%
Ventilator- free (VF) days	14.8 days	7.5 days
Intensive Care Unit (ICU) free days	12.0 days	5.0 days

In the above analysis based on data obtained 90 days after administration, the mortality rate and the number of ventilator-free days (VFD) within a 28-day post-administration period et al. tended to improve in the MultiStem group compared with the placebo group. The results of the 1-year follow-up after administration showed a similar trend.

Overview of the Analysis

Clinical trial	Exploratory clinical trial (Phase 1/2) conducted by Athersys in US and UK （MUST-ARDS study)
Subjects	ARDS patients administered MultiStem or Placebo intravenously (In Phase 2 trial, MultiStem 20, Placebo 10)
Endpoints	- Mortality - Ventilator Free days (The number of the days out of 28 in which a ventilator was not used for the patient) - ICU Free Days The number of the days out of 28 in which the patient was out of Intensive Care Unit

【Reference】

Research contents on MultiStem's mechanism of modulating the inflammatory response in critical care indications Published in Scientific Reports （Link to Athersys' Website June 30, 2021）

Report of Placebo-Controlled Clinical Trial Evaluating MultiStem Cell Therapy for ARDS Published in Intensive Care Medicine（Link to Athersys' Website November 30, 2021）

（Source）Athersys

HLCM051 can be the first available therapeutic medicine for ARDS

- Currently only artificial respiration and ECMO (Extracorporeal Membrane Oxygenation) are available as coping therapies.
- ECMO has a limited number of installations at medical institutions, requires multiple medical staff with special skills, and has a high cost of management.

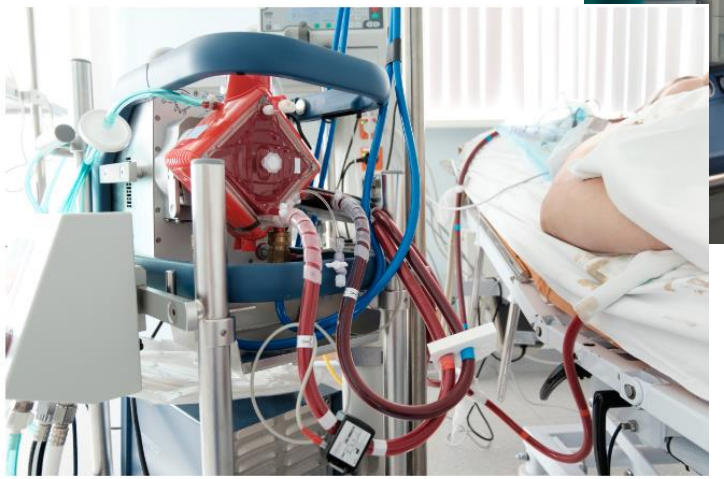
Contribution to patients ⇒ Providing new treatment
Improvement of mortality and QOL

- Improving patient lifesaving rate and QOL
- Shortening the treatment period (ICU use, length of hospital stay, etc.)

Contribution to medical ⇒ Reducing the burden on medical staff and hospitals

- Improving effective use of artificial respiration including ECMO
- Curbing medical resources per patient

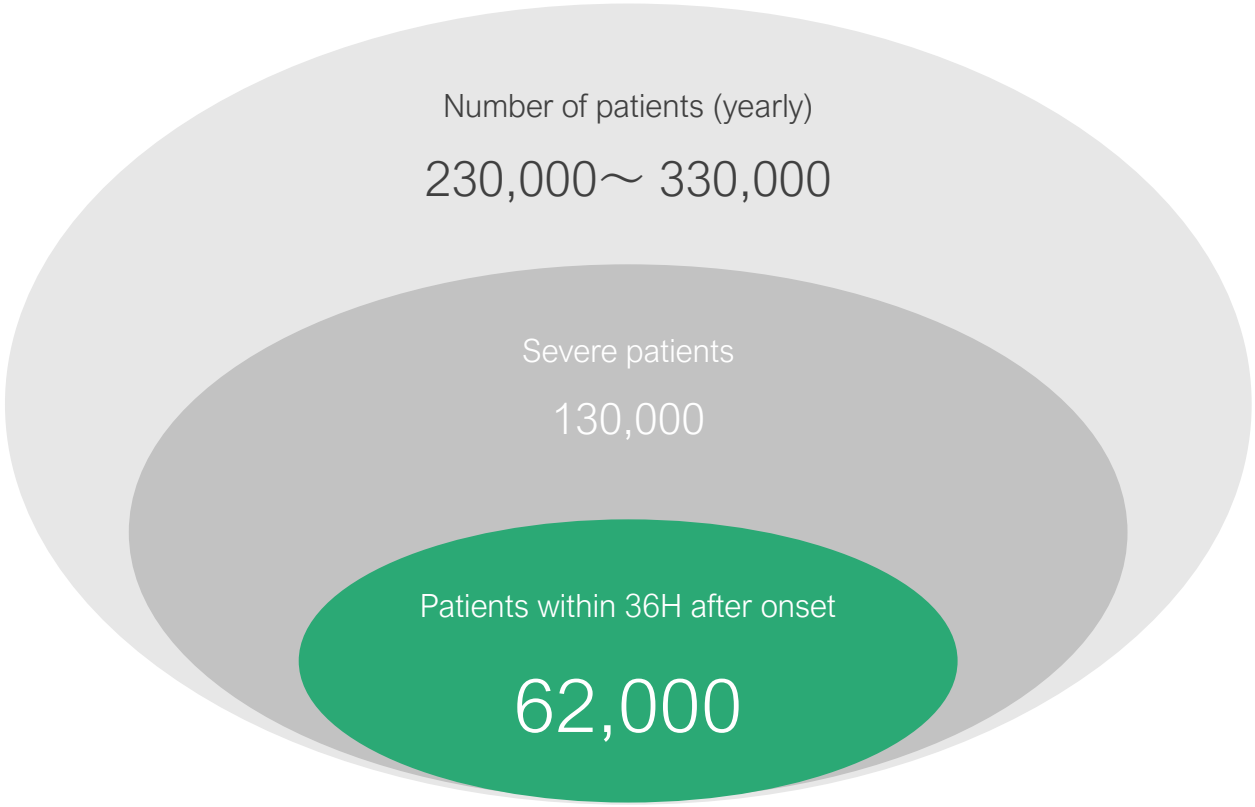
ECMO



Artificial Respiration

HLCM051 Stroke: Annual Number of New Patients with Ischemic Stroke in Japan

The number of patients in Japan targeted for HLCM051 is estimated to be 62,000 a year



Number of patients with ischemic stroke in Japan (yearly)

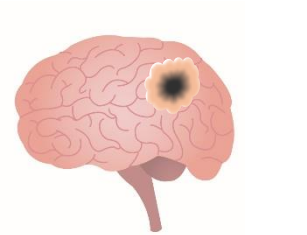
Severe patients （atherothrombotic and cardiogenic cerebral infarction)

Patients within 36 hour after onset

(Source) Healios estimated the annual number of new patients with ischemic stroke in Japan according to materials issued by the Fire and Disaster Management Agency, the Ministry of Internal Affairs and Communication, and the Ministry of Health, Labour and Welfare – DATAMONITOR epidemiological estimates also shown as upper end of range.
(Source) Healios estimated the percentage of patients who reach the hospital within 36 hours after onset at 47% according to the results of its market research.

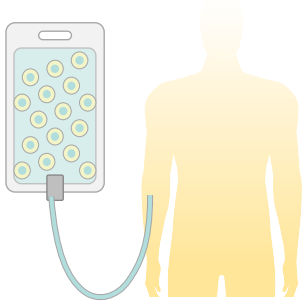
HLCM051 Stroke: Mechanism of Action

Stroke-induced neuronal damage

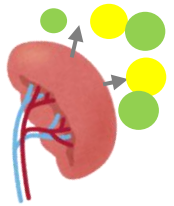


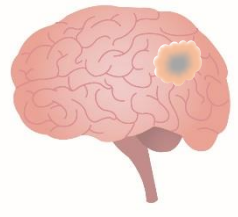
Primary Damage

With HLCM051



HLCM051
-suppress the mobilization/ release of inflammatory cells (lymphocytes, cytokines)
-activate the mobilization/ release of anti-inflammatory cells



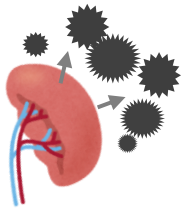


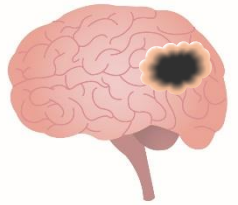
Attenuate neuronal damage in the acute phase of stroke caused by inflammatory cells

Secondary Damage mitigation

Without HLCM051

Activate mobilization / release of inflammatory cells (lymphocytes, cytokines) in the spleen





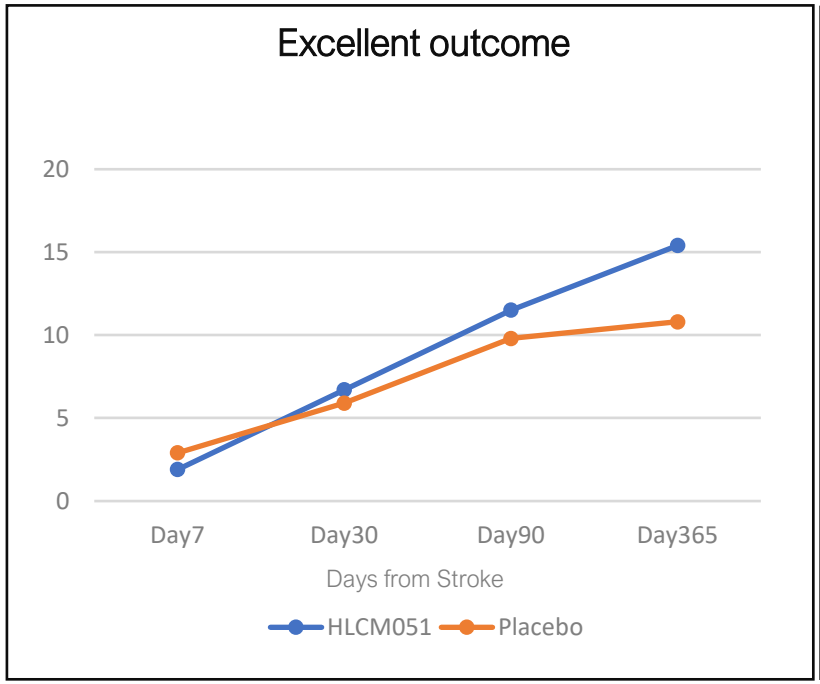
Neuronal damage exacerbated by inflammatory chemokines/cytokines
Inflammatory cells are released from the spleen and exacerbate the neuronal damage of the ischemic site.

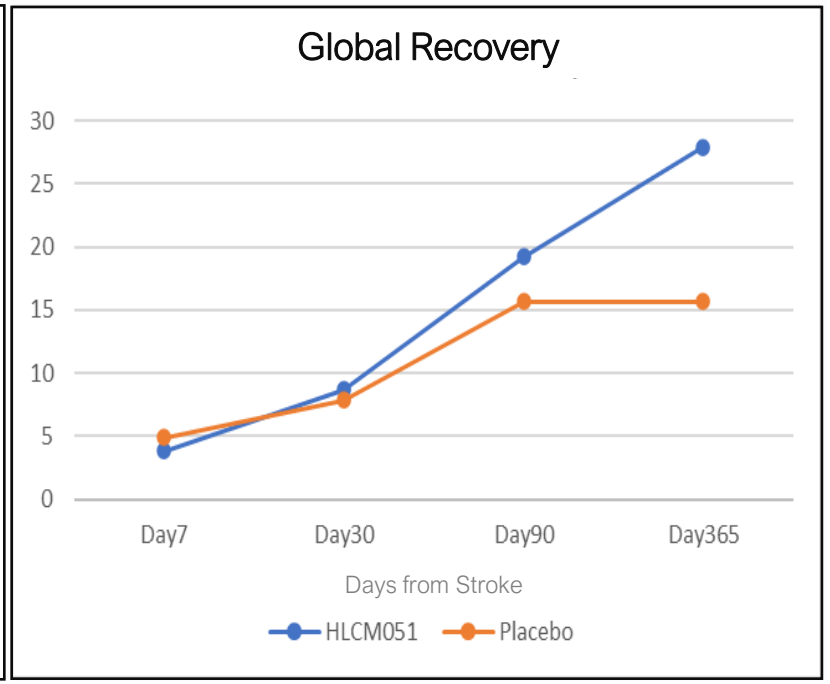
Secondary Damage

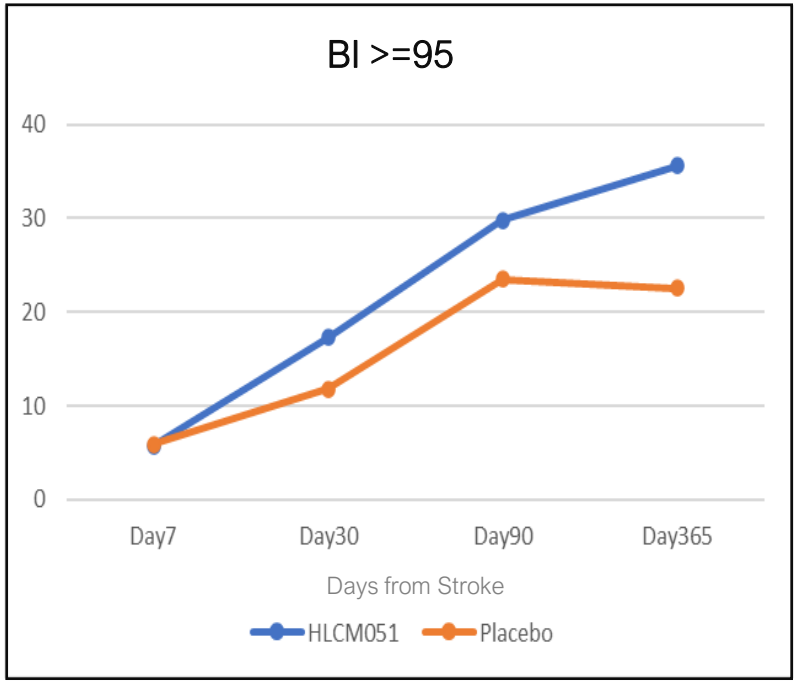
（Source） This figure was based on Stroke. 2018 May;49(5):1058-1065.Fig.2

TREASURE Study: Results

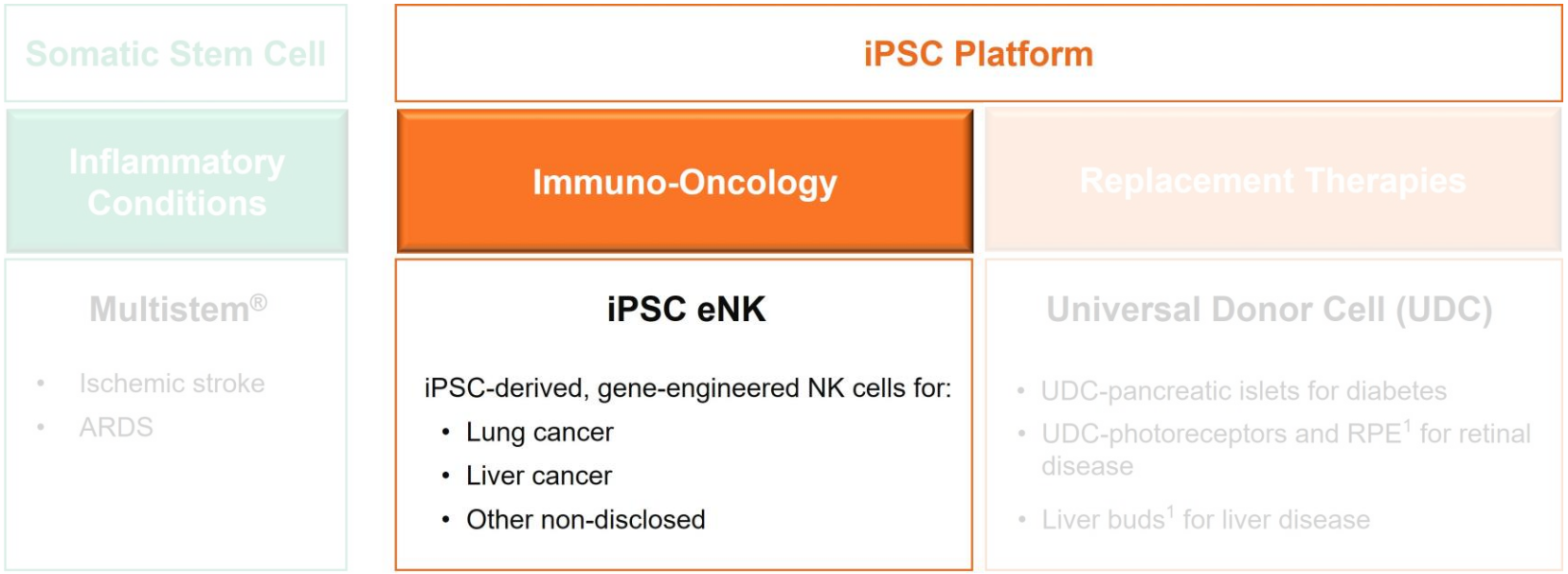
Changes in the one year improvement rate in the HLCM051 and placebo groups







iPSC eNK
Immuno-Oncology



The Promise of NK Cells as a Treatment for Solid Tumors

Key Facts about Cancer and the Unmet Need

- Solid tumors are the number one cause of death in Japan (~90% of cancer deaths)
- Cancer is the leading cause of death worldwide, accounting for nearly 10 million deaths in 2020[1]
- The economic impact of cancer is significant and increasing: The total annual economic cost of cancer in 2010 was estimated at US$ 1.16 trillion[1]

The Potential for Natural Killer (NK) Cells

- Offer tremendous promise as a new therapeutic approach to treating solid tumors.
- Innate, central role in a cell mediated defense system in humans, and attack cancer cells and virus-infected cells.
- Reported advantages over T cell-based therapies:
  - Broad mechanism to recognize tumor cells
  - Fewer adverse effects (e.g. CRS & GVHD)
  - Less exhaustion

[1]https://www.who.int/news-room/fact-sheets/detail/cancer

eNK Program Vision

Contribute to the eradication of solid tumors and other cancers by leveraging Healios' iPS cell expertise and augmenting the innate cancer killing ability of NK cells

Research & Development

- **Advanced technology at Healios' Kobe Research Institute**
  - In-house implementation from gene editing through to process development
- **Establishment of data for conducting clinical trials**
  - Generation and accumulation of efficacy and safety data

Manufacturing

- **Manufacturing Capabilities**
  - In-house production of clinical product in proprietary 3D system

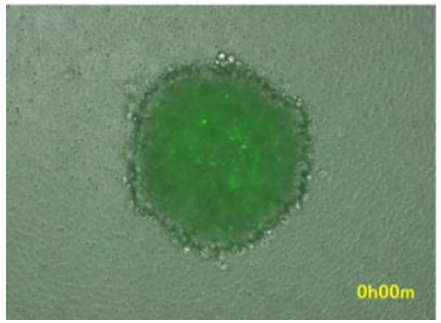
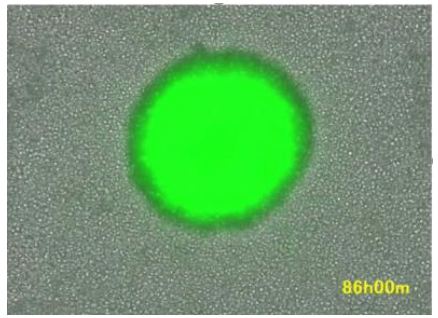
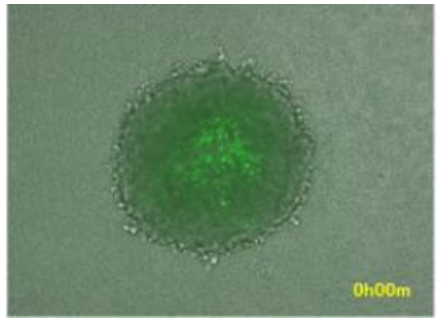
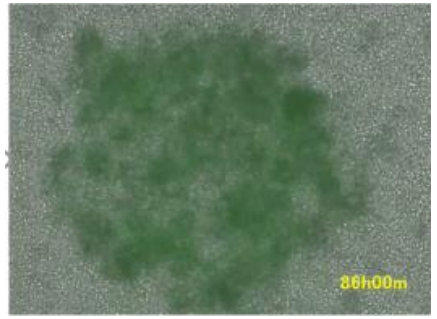
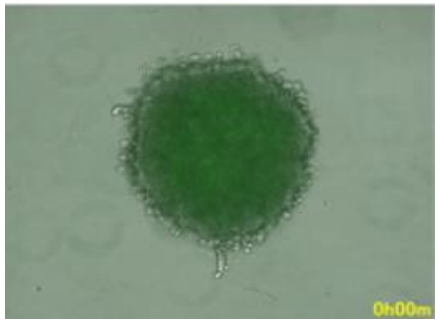
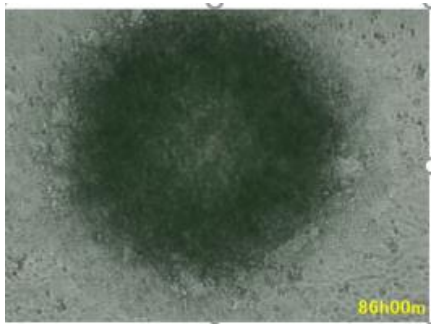
Alliances & Collaborations

- **Joint Development / Partnering**
  - Maximize the potential of the eNK cell program and platform

Accelerate activities in the above three areas

HLCN061 *In Vitro* Evidence of Anti-tumor Effect as Mono- and Combination Therapy (Lung, A549)

Bright green: apoptotic cells

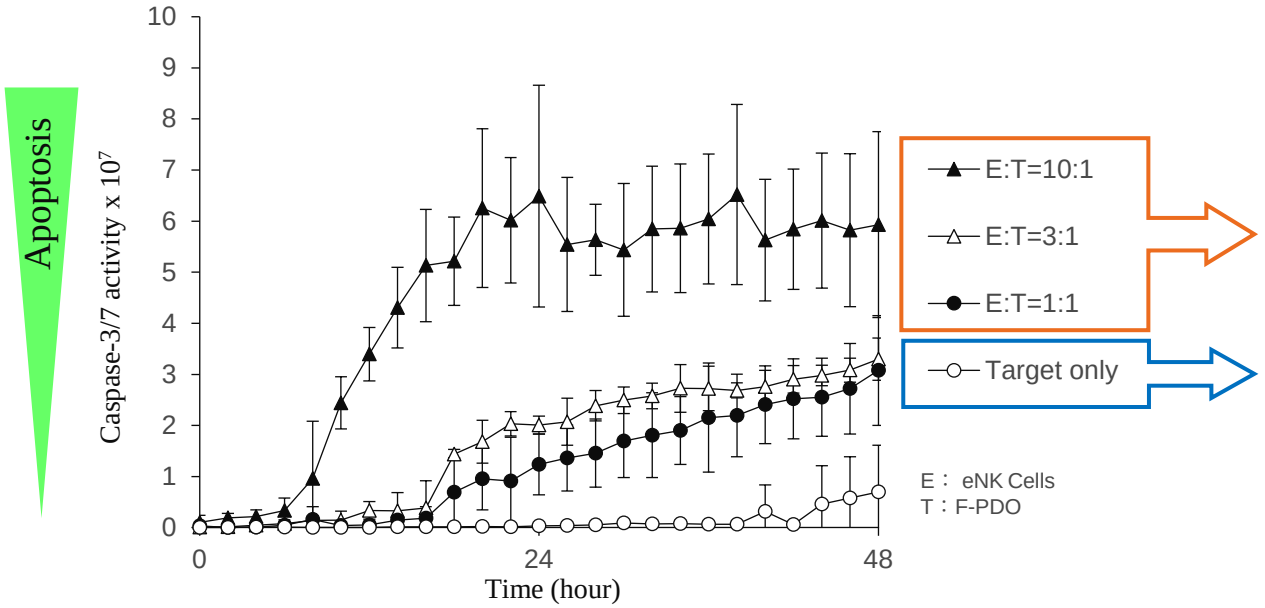
	0h	86h (3.5 days)	
eNK only			eNK cells have killed the cancer cells
eNK with anti-EGFR antibody			The lung cancer cells were efficiently killed and the lung cancer cell spheroid was destroyed.
Anti-EGFR antibody only			The cancer cells survived and the cancer cell spheroid expanded for 86 hours.

（Source）in-house data

HLCN061 *In Vitro*: Evidence of Anti-tumor Effect on Lung Cancer F-PDO®

eNK cells have demonstrated a robust anti-tumor effect on lung cancer patient-derived tumor organoids (F-PDO®)

eNK cells were co-cultured with F-PDO® in effector/tumor cell (E:T) ratios of 1:1, 3:1 and 10:1. Cytotoxic activity was determined by measuring the apoptosis (cell death) of the cancer cells by caspase-3/7 activity.



eNK Cells effective against F-PDO ®

Under conditions of co-culture with eNK cells, F-PDO®cancer cell apoptosis was observed from 8 hours (E:T=10:1) and 18 hours (E:T=3:1 and 1:1)

Under conditions of co-culture without eNK cells, the apoptosis was not observed until 42 hours.

The above graph provides data for one example. In this study, several F-PDOs were examined and generally obtained similar results.

F-PDO® :
It stands for Fukushima Patients Derived Tumor Organoid, a cell mass established at Fukushima Medical University. The F-PDO is a cell mass consisting of multiple cell types derived from patient tumor tissue. Histological and genetic analysis have confirmed that they maintain the properties of patient cancer tissue. Due to their similarity to the original cancer, the results of the effect of anti-tumor drugs in models utilizing F-PDO can be evaluated as more reflective of the clinical situation.

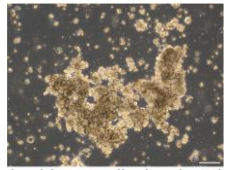
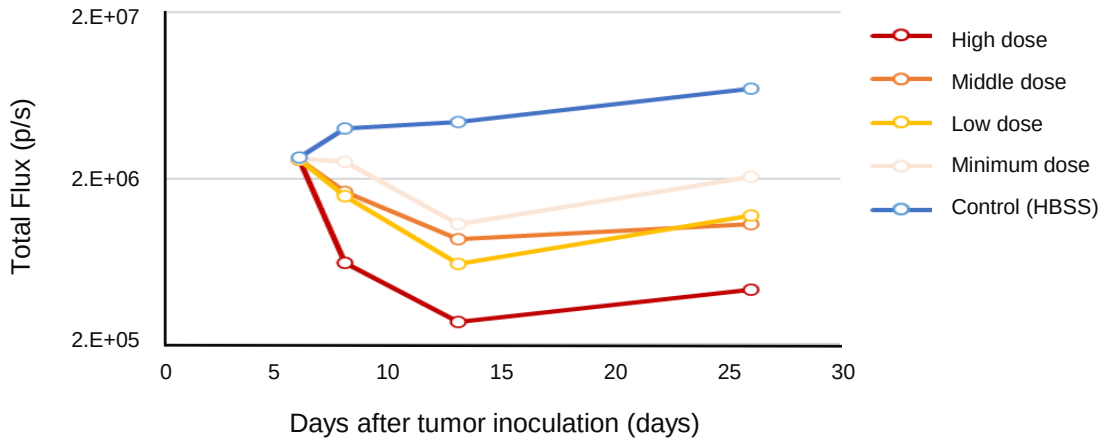


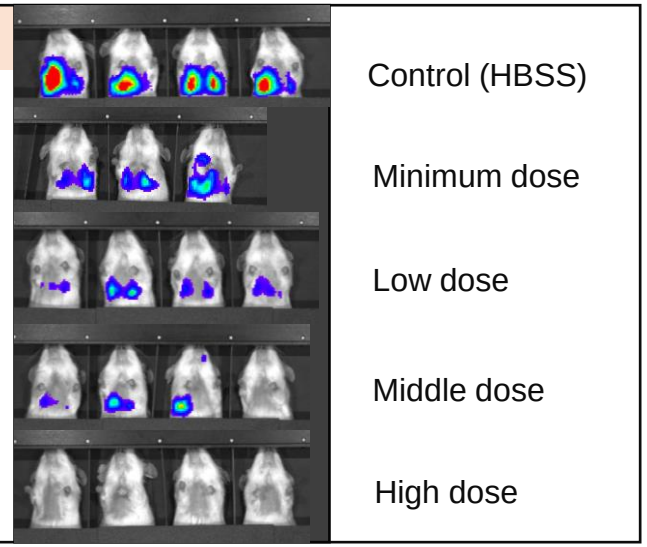
Photo by Fukushima Medical University

＊This examination was commissioned by Healios to the Fukushima Translational Research Foundation and conducted at FUJIFILM Wako Bio Solutions Corporation.

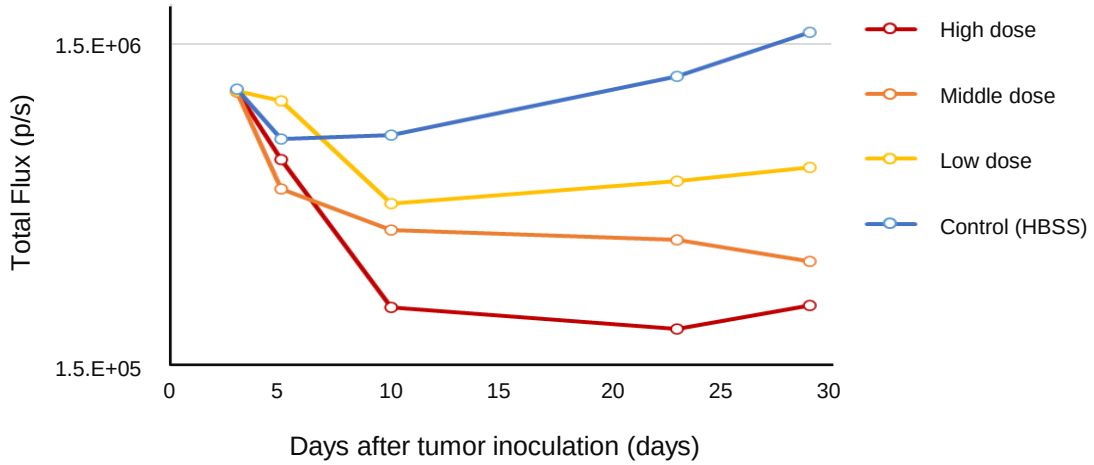
HLCN061 In Vivo: Healios' eNK Cells Show Robust Anti-Tumor Activity Against Lung Cancers

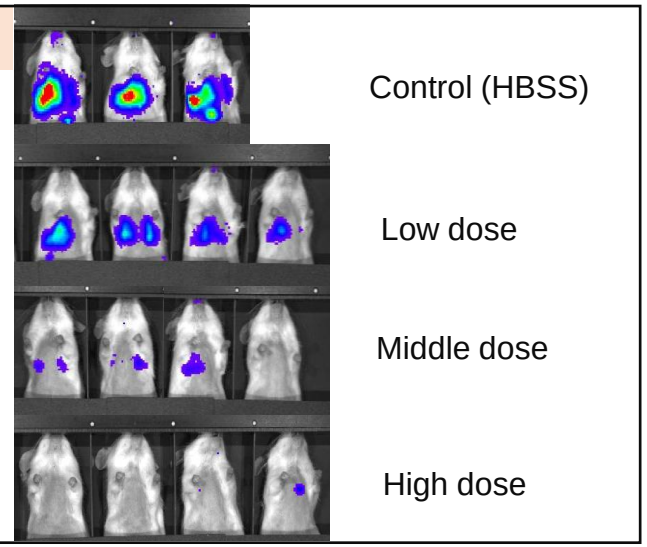
HCC827-Luc





H1975-Luc





（Source）in-house data

Maximize the potential of the eNK cell program and platform

We are pursuing partnerships with pharmaceutical companies, to access financial and other resources as well as to leverage technological synergies.

We aim to accelerate our research and development to deliver new immuno-oncology therapies using eNK cells to patients as soon as possible.

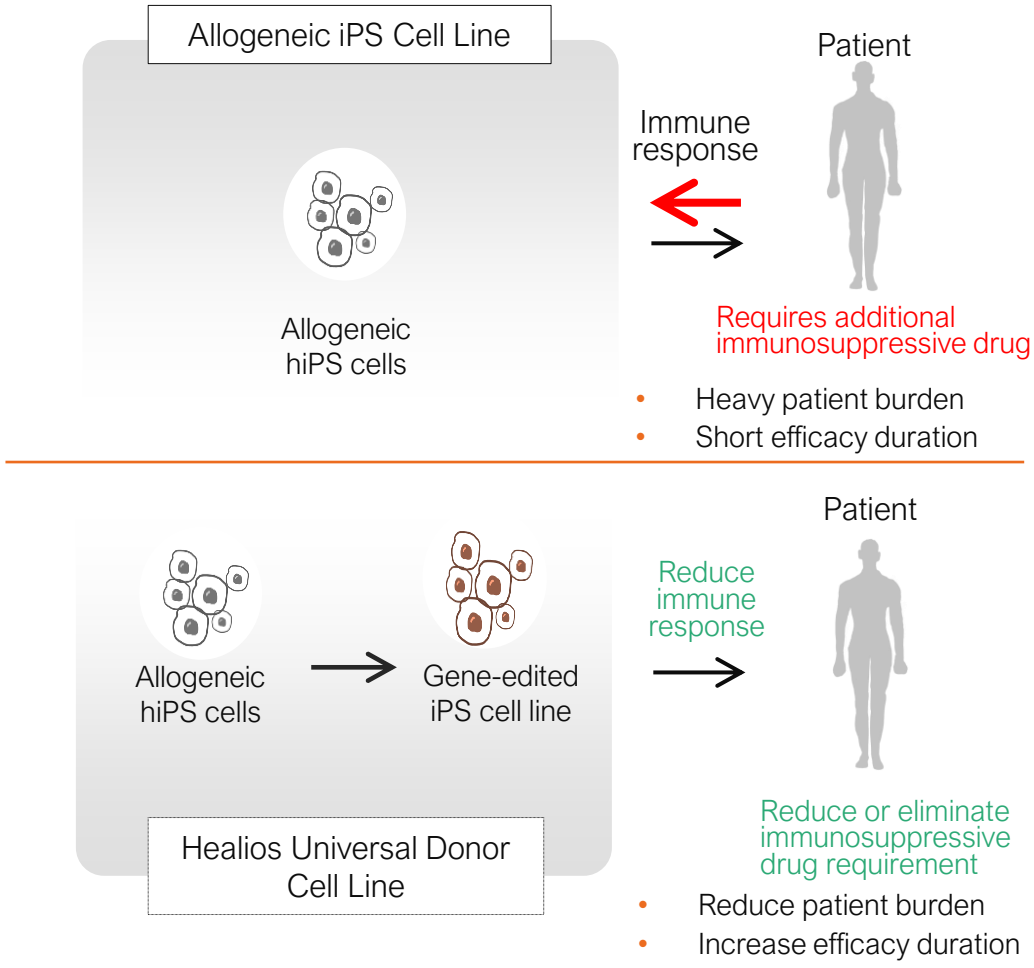
Universal Donor Cell (UDC) Replacement Therapies

Somatic Stem Cell	iPSC Platform	
Inflammatory Conditions	**Immuno-Oncology**	**Replacement Therapies**
Multistem® • Ischemic stroke • ARDS	**iPSC eNK** iPSC-derived, gene-engineered NK cells for: • Lung cancer • Liver cancer • Other non-disclosed	**Universal Donor Cell (UDC)** • UDC-pancreatic islets for diabetes • UDC-photoreceptors and RPE[1] for retinal disease • Liver buds[1] for liver disease

[1]Future migration to UDC platform

Hypo-immune Universal Donor Cell (UDC) Platform

World-leading engineered “universal” iPSC platform: “UDC”

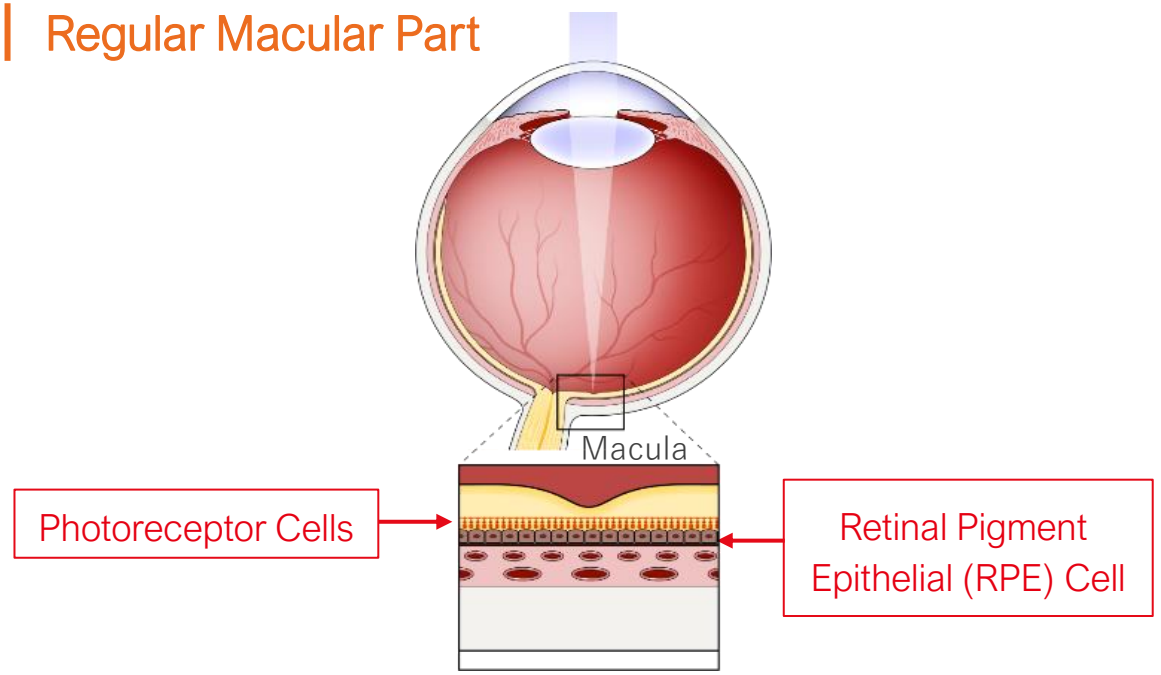


Targeted cell programming through gene-editing

- In October 2020, Healios established a clinical grade universal donor IPS cell line that can be clinically applied to humans in each of Japan, the United States and Europe.
- Master Cell Bank established in 2021
- Healios has led the development of high-quality, universal donor iPS cells in accordance with global standards.
- Consultations with the FDA and PMDA led to no concerns in relation to clinical use of UDC derived therapeutics.
- The UDC line differentiates readily into various in-house made cells (e.g. NK cells, liver progenitor cells, vascular endothelial cells, etc.).

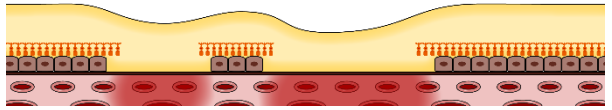
Age-related Macular Degeneration (AMD) causes Retinal Pigment Epithelial (RPE) cells to degenerate, which damages function

Regular Macular Part



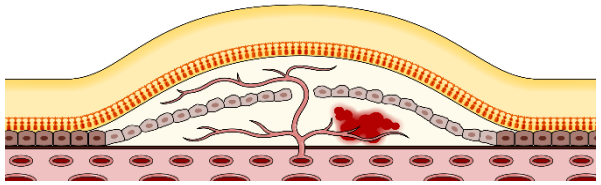
Developed Dry-AMD

Immunity barrier maintained
→ Degeneration of photoreceptor→ Dry AMD



Wet AMD

Destruction of immunity barrier → Invasion of immune cells
→ Inflammation → Wet AMD



Joint Development

In Japan, HEALIOS and Sumitomo Pharma Co., Ltd. are jointly developing a treatment using iPS cell-derived RPE cells.

After confirming the efficacy of the treatment in RPE tears, Sumitomo Pharma will consider expanding the indication to include AMD.

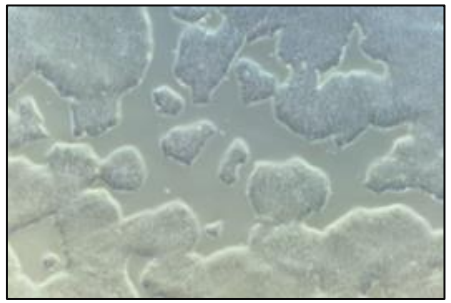
HLCR011 Outline of clinical study in RPE tears

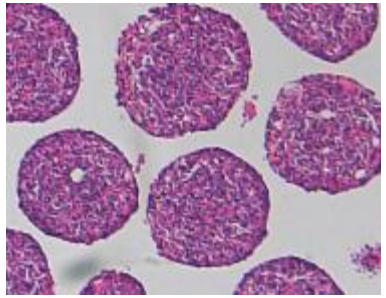
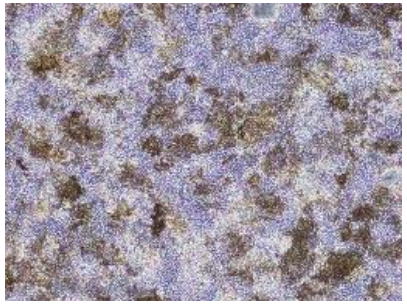
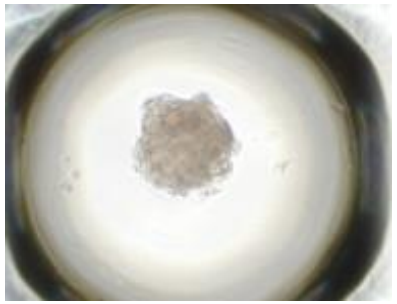
Test product	HLCR011: iPS cell-derived retinal pigment epithelial (RPE) cells suspension
Development stage	Phase 1/2
Subjects	Patients with retinal pigment epithelium tears
Design for the clinical study (target number of cases)	Part 1: Unmasked, uncontrolled (one HLA-mismatched subject) Part 2: Unmasked, randomized (treatment/observation groups, 10 subjects/group, total 20 subjects)
Primary endpoint	Safety of subretinal administration of HLCR011 in patients with RPE tears (number and ratio of subjects with observed adverse events)
Secondary endpoint (efficacy)	Visual function evaluation

The clinical study is a multicenter, unmasked, randomized study. Sumitomo Pharma is now selecting clinical study sites. Subjects will be enrolled immediately after the completion of the preparation, including conclusion of contracts with the clinical study sites.

Hypo-immune UDC: Examples Of Cell Therapies

Universal Donor Cells (UDC)



Photoreceptor cells	Pancreatic β cells	RPE cells	Liver buds
			

Successfully differentiated from UDCs

Future migration to UDC platform

（Source）in-house data and Joint research data


Healios