

Healios

FY2018 Financial Results

February 13, 2019

HEALIOS K.K.

（TSE：4593）

https://www.healios.co.jp/en

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Healios

3 elements



strategy **mission** **governance**

algorithm

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Founding Mission Statement

(February 24, 2011)

We established the company Healios on February 24, the day when the Gregorian calendar was enacted, with the goal of developing next generation medicines, drugs and instruments.

"Delivering happiness (Gospel) to the people in the world by bringing iPSC treatments into the clinic"
This is a huge responsibility.
However, we are not afraid of this huge responsibility.

The road to the goal will be full of difficulties.
No footprints, maps, nor signs.

There is no fast track to achieve this goal, and it may take 10 or 20 years.
However, no one can stop us from starting the first step toward the goal today.
No one can stop us from assembling a team and making efforts toward the goal.
We will start with a small dot, the dots will form a line, then a line will form a large road.
This large road will be filled with the joy of patients who benefit from the iPSC treatments.
You do not need to hesitate.

Let's start.

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Mission

To foster a “Life Explosion” that enriches the lives of people around the world

Vision

By making use of the regenerative powers of iPSC therapies, we will heal and bring hope to those worldwide who are suffering.

We will create a global infrastructure to develop, manufacture and promote our therapies from within the Healios family of businesses.

We will build a biotechnology company founded on solid principles in which every individual can trust.

Values

1. **Patients**
2. **Path Finder**
3. **Jump in 60**
4. **Team Work**
5. **Look straight, Think straight, Talk straight**
6. **There is no bad weather, only bad clothing**
7. **Shining 100**
8. **Snowball**

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Governance

HEALIOS KK

Sighregen

- Joint venture with Sumitomo Dainippon Pharma
- Manufacturing & sales promotion of RPE cell products in Japan post approval

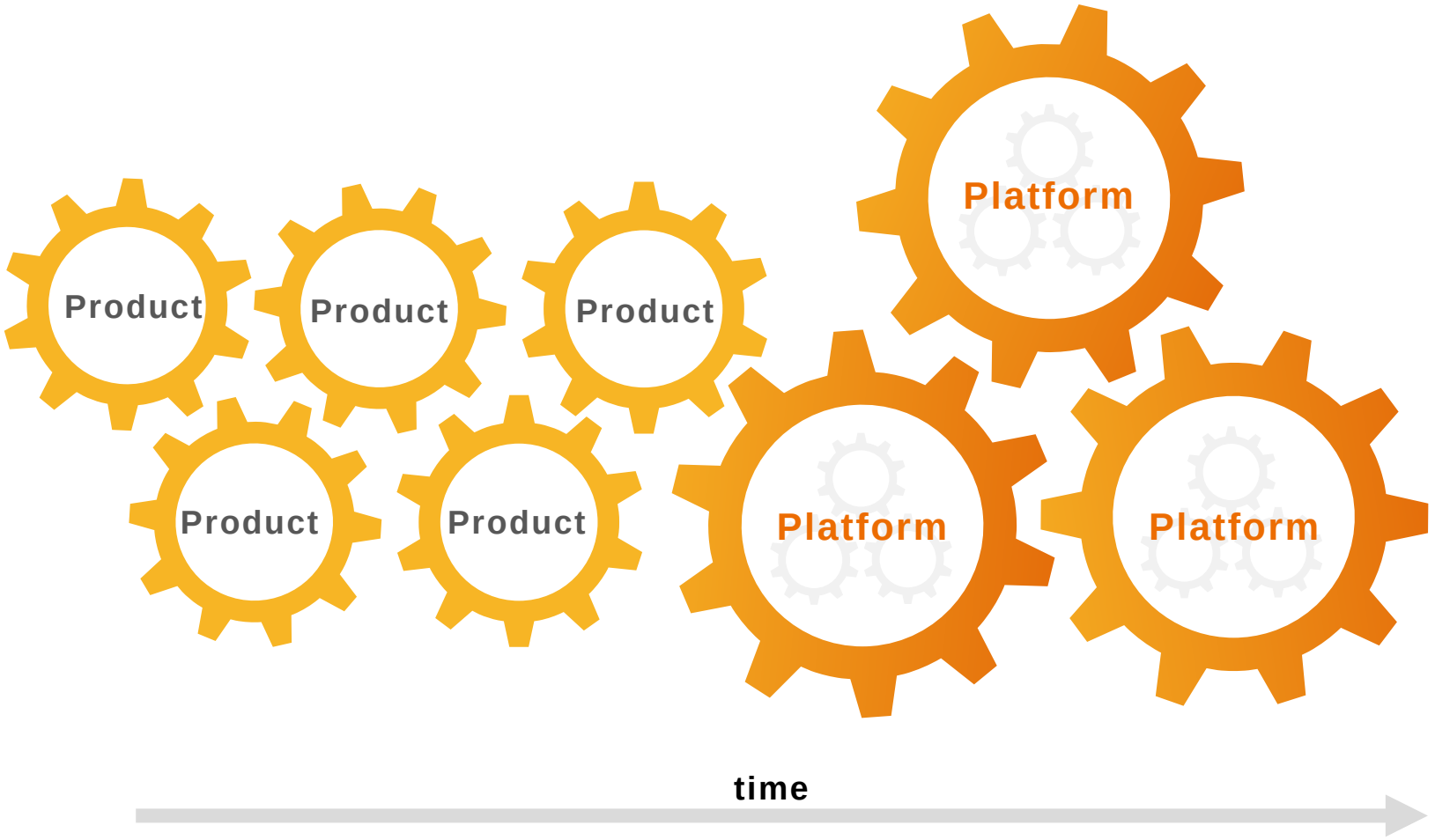
Organoid Neogenesis Laboratory (ONL)

- Established in June 2018
- Professors Hideki Taniguchi and Takanori Takebe have taken on the role of directors of ONL

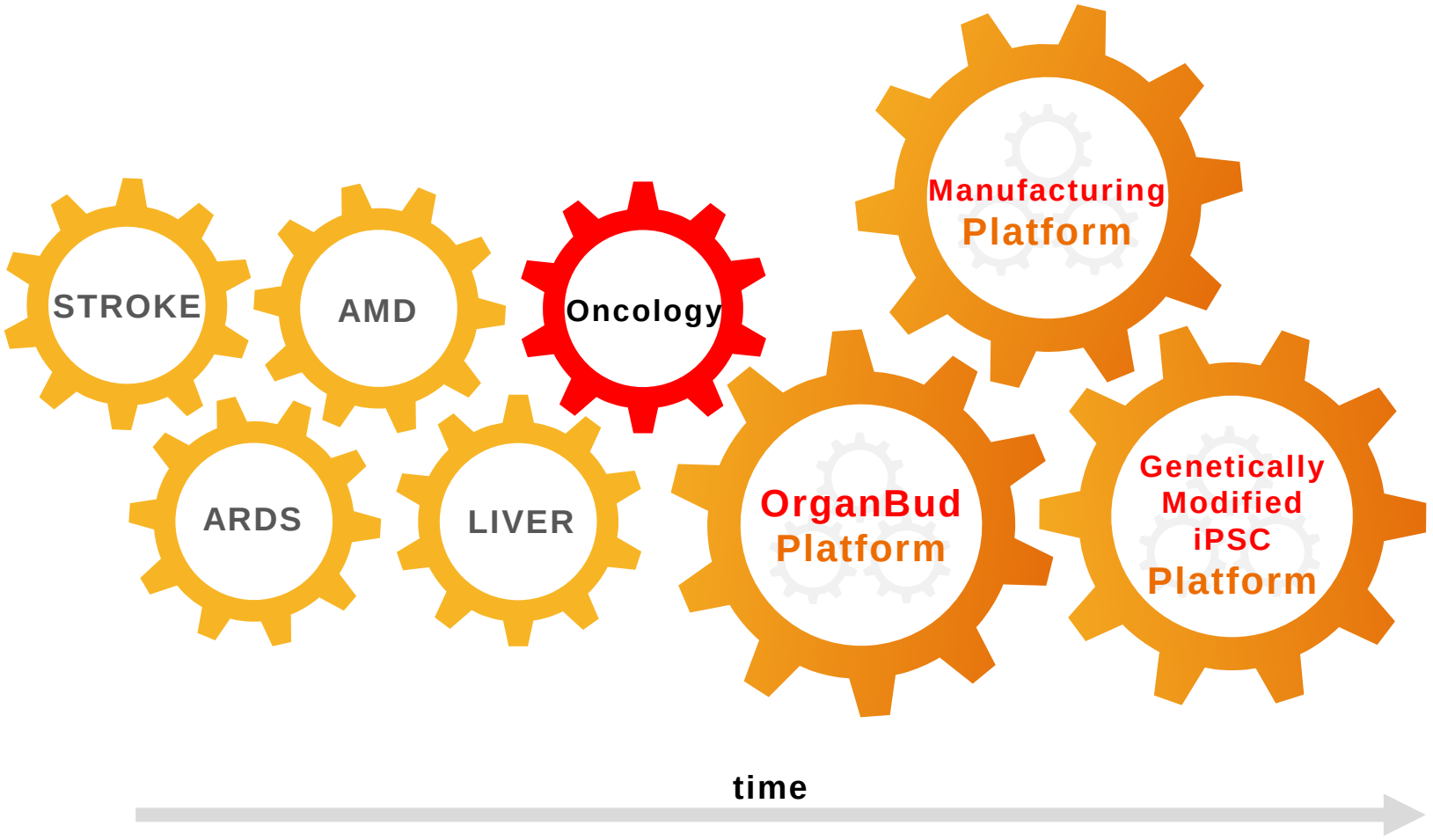
Healios NA

- Established in February 2018
- Opened a new office in Silicon Valley
- Mr. David Smith assumed the position of Chief Commercial Officer

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Athersys' Stem cell products: MultiStem®

Athersys, Inc.

Location	Cleveland, Ohio, U.S.
Listed	NASDAQ：ATHX
Products	**Stem cell products: MultiStem®**



MultiStem

- Cell therapy product based on patented technology
- Developing for "off-the-shelf" administration:
  no tissue matching needed
- Long shelf life: can be kept frozen in a stable condition for years
- Consistent safety profile
- Promotes healing and tissue repair through multiple mechanisms of action
- Not a permanent transplant: cells cleared from the body over time

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Collaboration expansion with Athersys

January 2016

- Healios acquired an exclusive license for domestic development and distribution of cell therapy products for ischemic stroke making use of the MultiStem stem cell product.

March 2018: Strategic investment / Letter of Intent

- Healios became its largest shareholder, acquiring 8.7% of Athersys' issued shares

June 2018

- Expansion of the license to develop and commercialize MultiStem

June 2018

- Our CEO Hardy Kagimoto was appointed to the Athersys Board of Directors

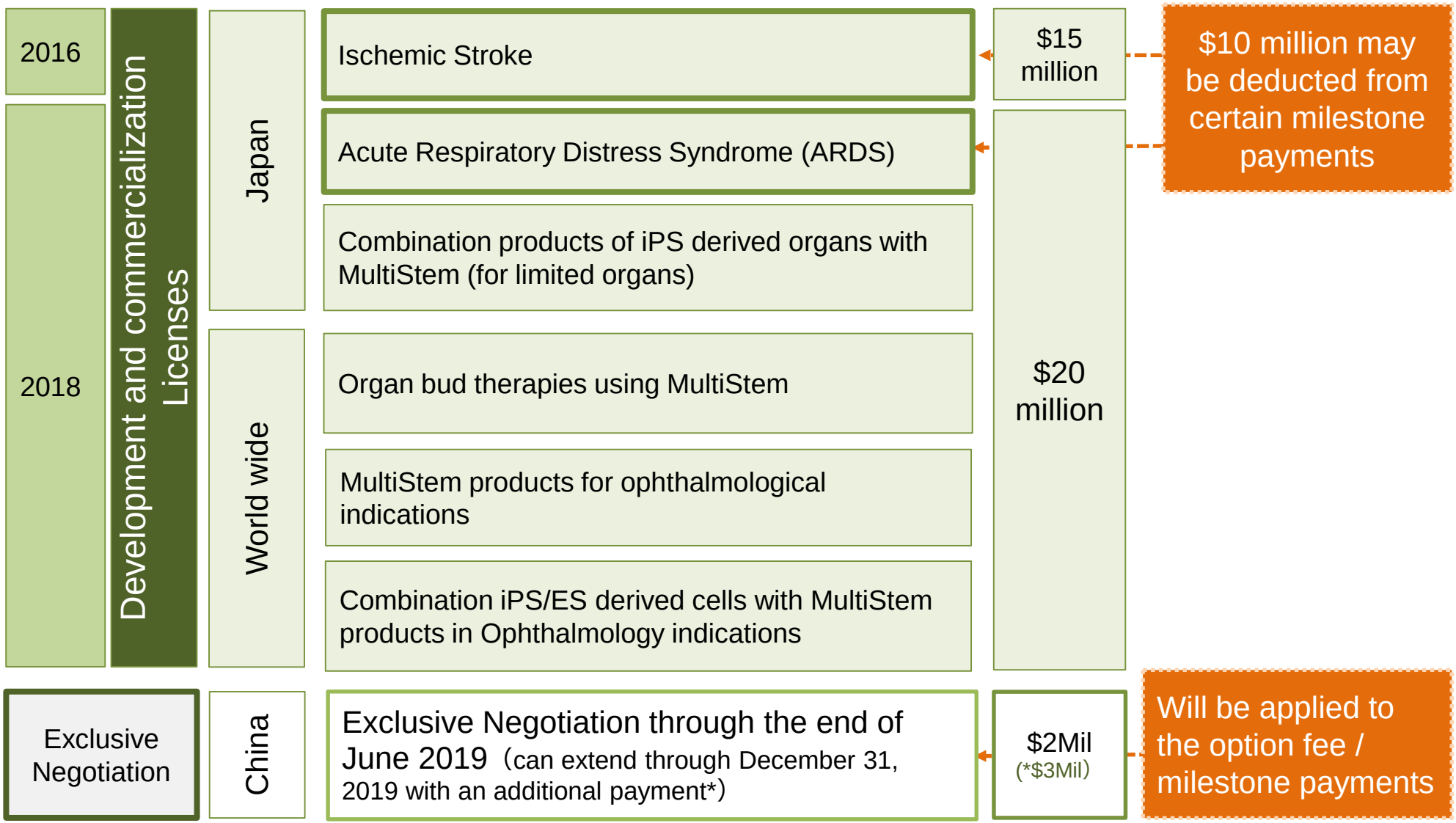


December 2018

- Extended the exclusive negotiation period about the option right to develop and commercialize MultiStem products in China

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Acquisition of MultiStem License

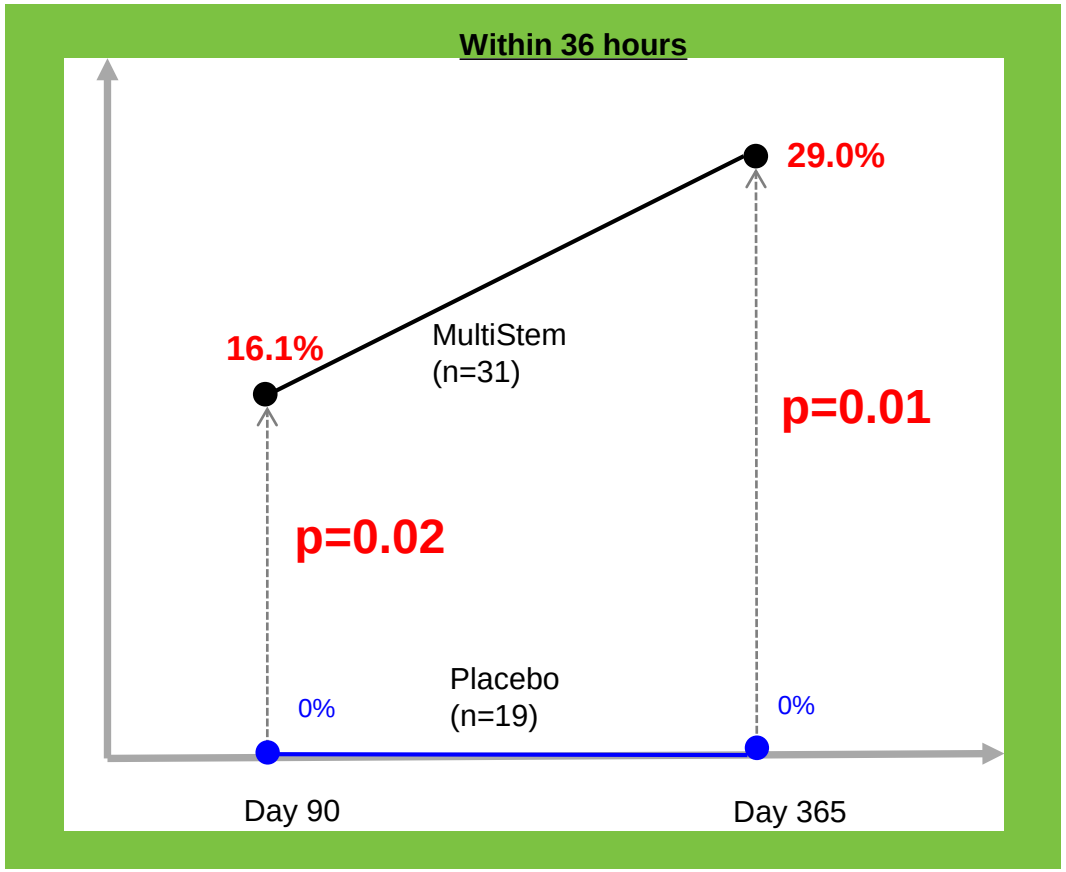


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Results of double blind study conducted by Athersys <Stroke>

The proportion of patients who achieved Excellent Outcome was **statistically significant** (compared with the placebo group) both at Day 90 and Day 365 in the group of patients who received MultiStem within 36 hours of the onset of cerebral infarction.

Analysis of the **placebo-controlled double-blind study** conducted by Athersys in the US and the UK



Subjects:
Administrated MultiStem or Placebo within 36 hours of the onset of stroke

Endpoint:
Proportion of subjects with an Excellent Outcome

<Excellent Outcome> is defined as mRS score of ≤1 (scale, 0 to 6), NIHSS score of ≤1 (scale, 0 to 42), and BI score of ≥95 (scale, 0 to 100).

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UPDATE

Results of double blind study conducted by Athersys <ARDS>

Positive Results From Athersys' Exploratory Clinical Study in US and UK
using MultiStem for the patients of ARDS (January 2019)

■ The study results provide further **confirmation of tolerability** and a **favorable safety profile** associated with MultiStem treatment.

■ Diagnosis from the **double blinded, placebo-controlled study** (MultiStem: 20 subjects, Placebo: 10 subjects) after 28 days of administration **shows an improvement trend** in the MultiStem administration group. （In more severe ARDS patients, the difference between MultiStem treatment and placebo was greater.）

	MultiStem (n=20)	Placebo （n=10）
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

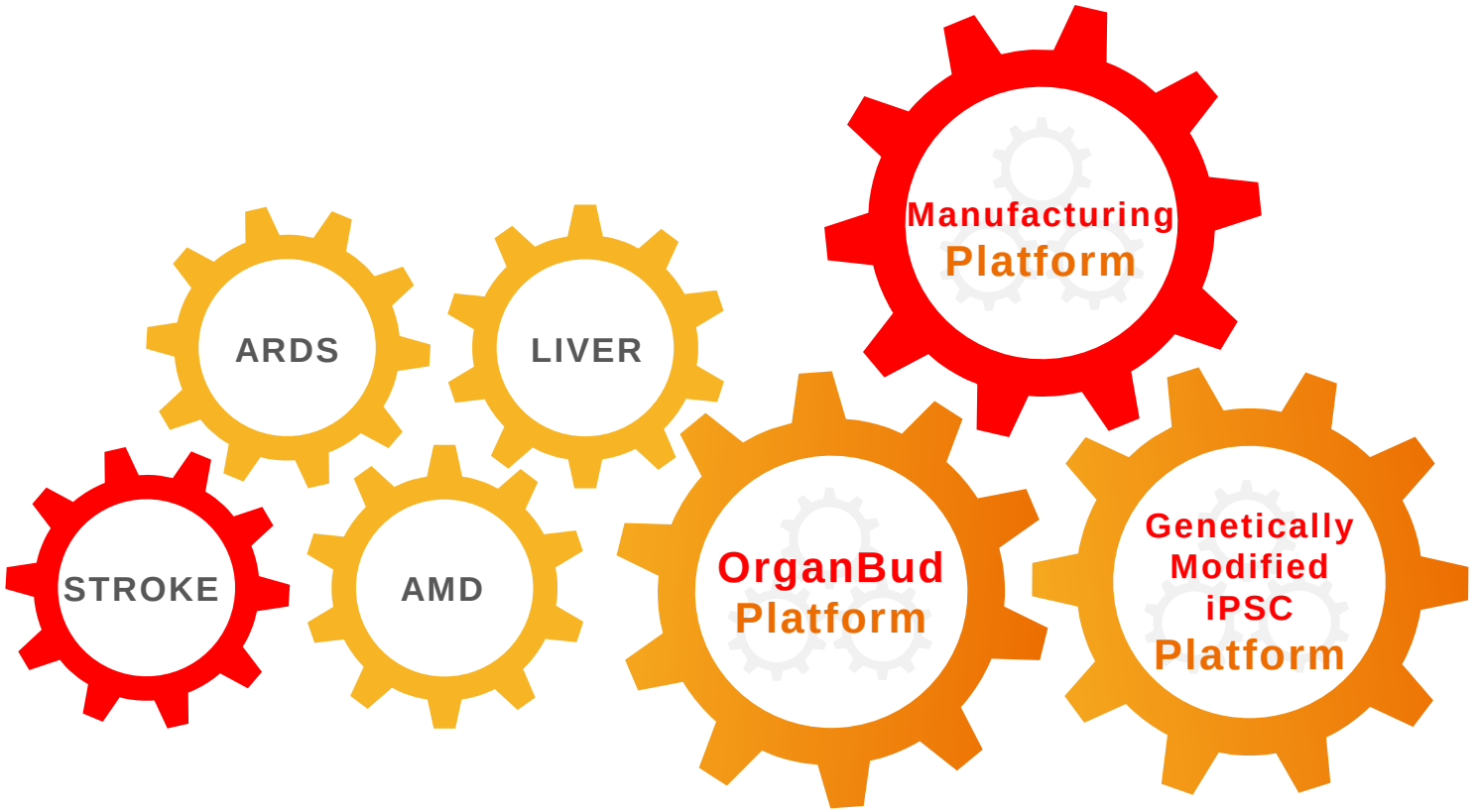
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Market	Field	Development Code	Indication	Pre-clinical test	Clinical trial	Apply-approve	On Market	Progress status
Japan	Somatic Stem Cell Regenerative Medicine	**HLCM051**	Ischemic Stroke	→				**Clinical trial ongoing**
			ARDS	→				**Undergoing preparation for administration**
	iPSC Regenerative Medicine	**HLCR011**	Wet AMD	→	⇢ Transplantation conducted under Clinical research(*1)			**Undergoing preparation for clinical trial**
		HLCL041	Metabolic Liver Disease	→				**ONL established**

Market	Field	Development Code	Indication	Pre-clinical test	Phase 1 trial	Phase 2 trial	Phase 3 trial	Apply-approve	On Market	Progress status
US EU	**iPSC Regenerative Medicine**	**HLCR012**	**Dry AMD**	→						CRADA with NEI

* 1 “Clinical research of transplantation of induced pluripotent stem cells – derived retinal pigment epithelium (RPE) cells for exudative age-related macular degeneration (AMD)” conducted by RIKEN etc.

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HLCM051 Outline of ischemic stroke in Japan

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.

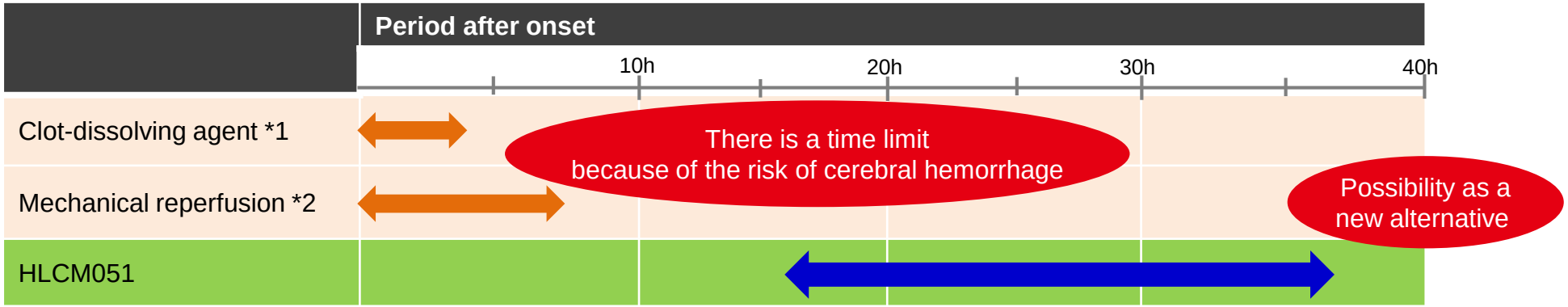
It is estimated that 37.9% of bedridden patients and 21.7% of persons who were in need of care were affected by ischemic stroke.



（Source）Athersys

Treatment in accordance with the period after onset

■ 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)



*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.

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HLCM051 Annual number of new patients with ischemic stroke in Japan

	Japan	Note
Number of patients (yearly)	**230,000 – 330,000**	Annual medical costs for ischemic stroke estimated at 1,070.7 billion yen（2009）
Severe patients（atherothrombotic and cardiogenic cerebral infarction)	**130,000**	
patients within 36 h after onset	**62,000**	

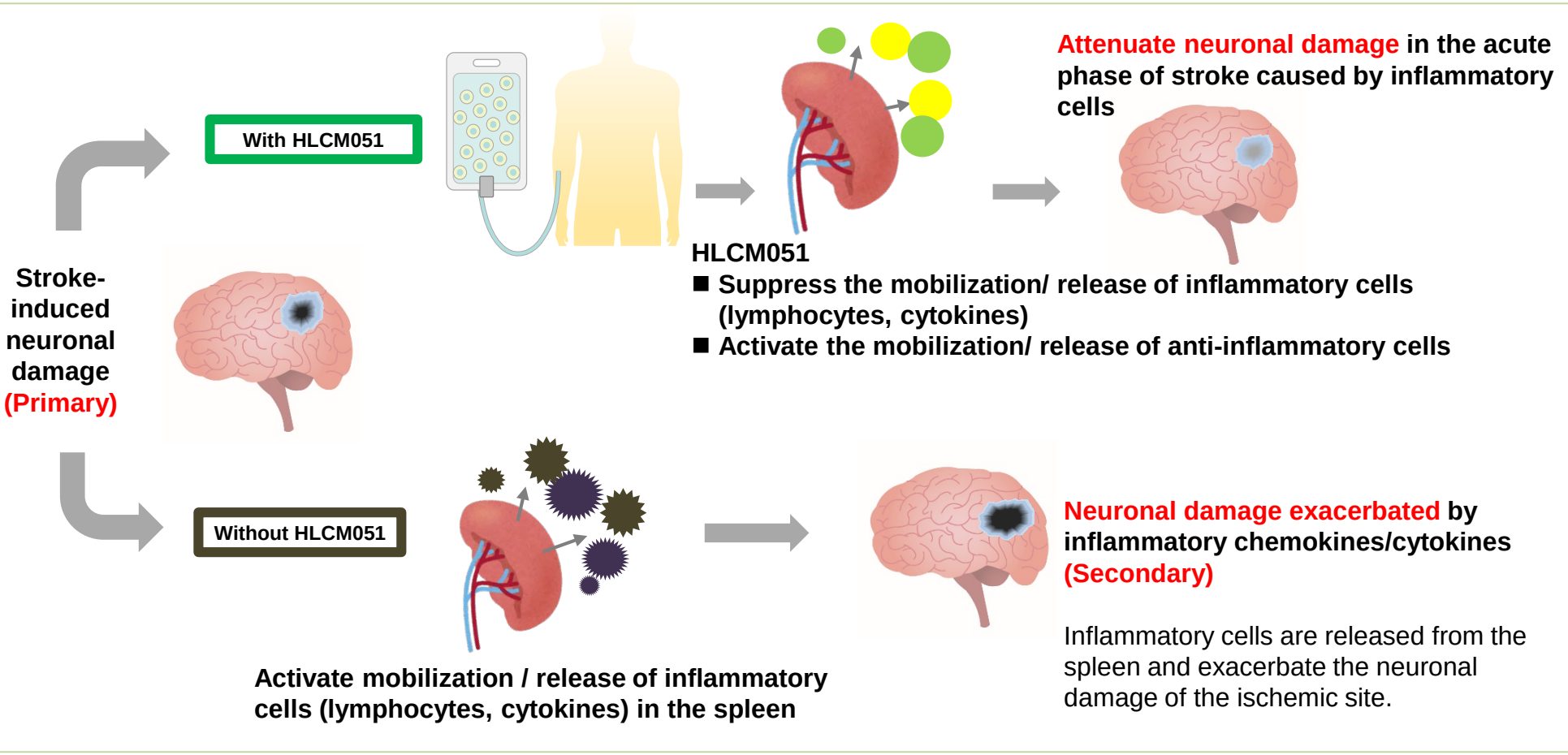
(Source) Healios estimated the annual number of new patients with ischemic stroke in Japan according to materials issued by the Fire and Disaster Management Agency, the Ministry of Internal Affairs and Communication, and the Ministry of Health, Labour and Welfare – DATAMONITOR epidemiological estimates 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.

(Note) Calculated using 2013 and 2014 fiscal year-end exchange rates.

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HLCM051 Mechanism of HLCM051 treatment

- Following intravenous administration after acute neurological injury, HLCM051 distributes to the spleen, downregulating the hyperinflammatory response.
- HLCM051 promotes a neuroprotective effect by releasing various cytokines and growth factors.



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HLCM051 TREASURE Study

Clinical trial ongoing

"Placebo-Controlled, Double-Blind, Phase 2/3 Efficacy and Safety Trial of HLCM051 (MultiStem®) in Patients With Ischemic Stroke"

Subjects	Enrollment	Primary Endpoint
Ischemic stroke within 18 to 36 hours	HLCM051 [n=110], placebo [n=110], randomized	Proportion of subjects with an excellent outcome defined by the functional assessments [Time Frame: Day 90]

- "Excellent Outcome" is defined as achieving mRs ≤1, NIHSS ≤1, and BI ≥95.
- mRS, NIHSS, and BI are the three major indices of functional assessments for stroke patients.



First patient enrolled
Nov. 2017

The approval period may be shortened from 12 months to 6 months by the **SAKIGAKE Designation** System

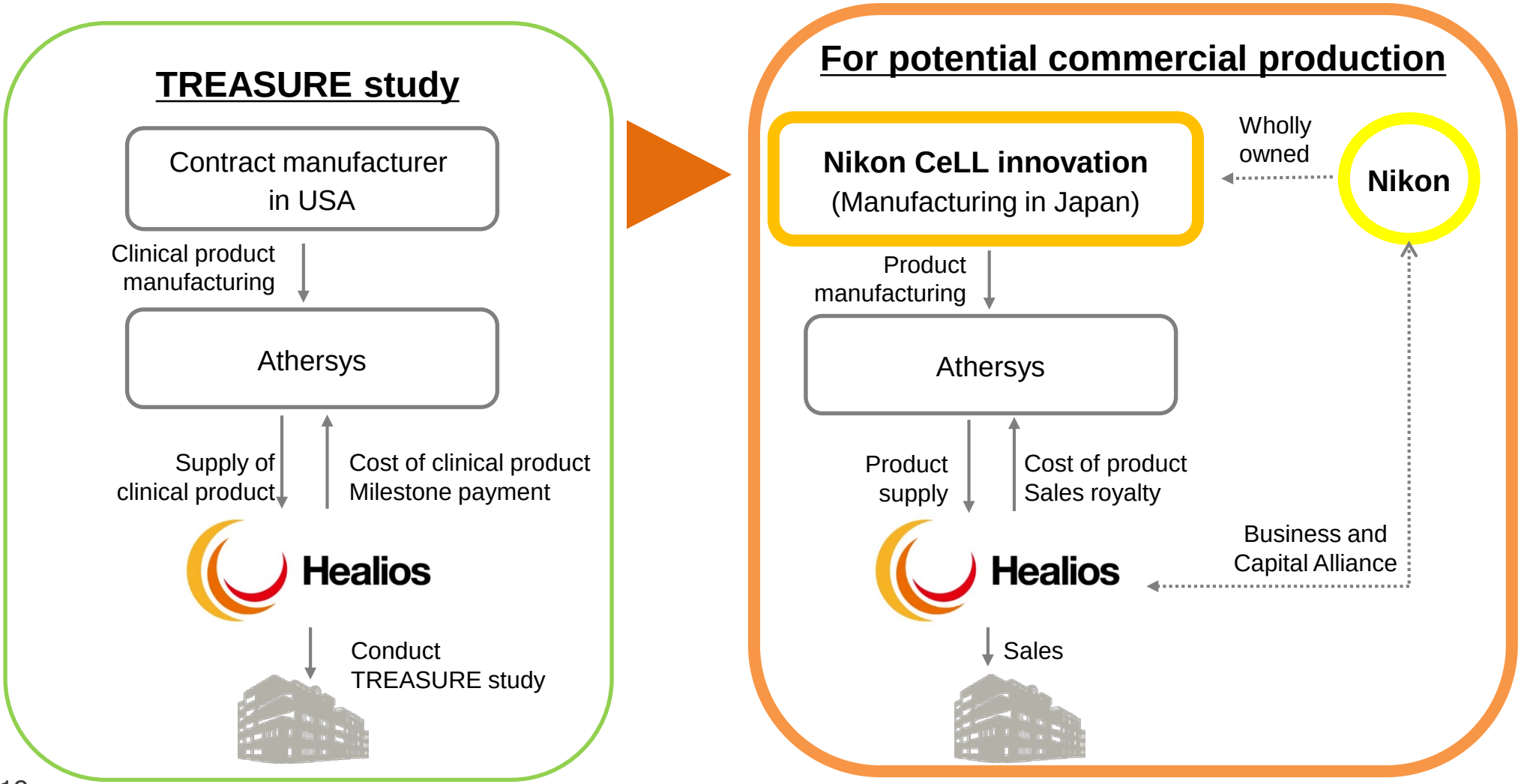
TREASURE study completion: within FY2020

Note: This includes 1 year follow up, but primary endpoint assessment will occur 3 months after last subject is enrolled

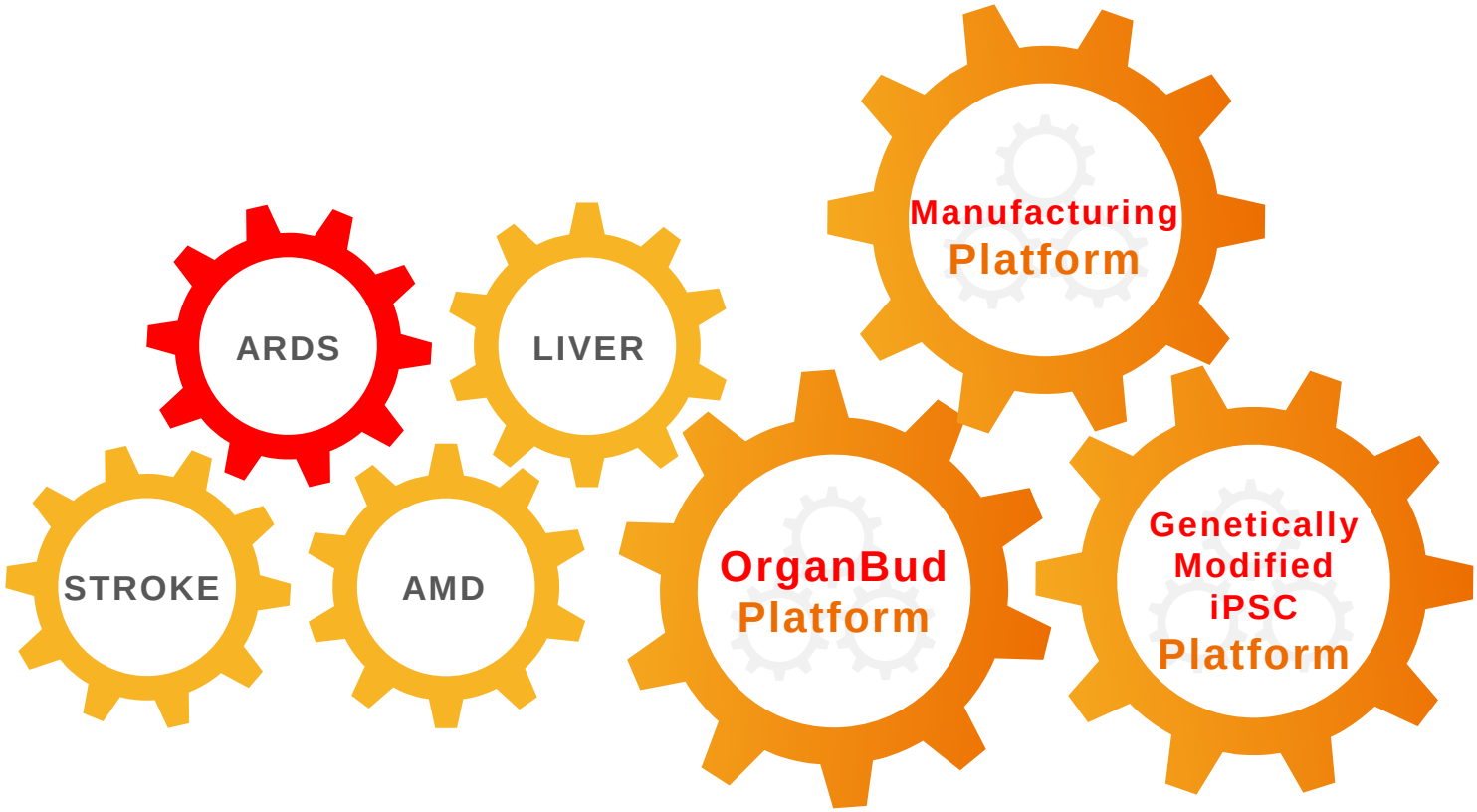
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HLCM051 Business Partners

Preparation for the commercialization of HLCM051 ongoing
at Nikon CeLL innovation



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HLCM051 ARDS Clinical trial

Study Design

✓ Open-label trial

✓ Standard therapy used as a control

Subjects : Patients with pneumonia induced ARDS
Enrollment : 30
Study Period : Approximately 2 years
Primary Endpoint : The number of days out of 28 in which a ventilator was not used for the patient (i.e. ventilator free days)

Development Schedule

Healios has started all necessary procedures, including the examinations by the Institutional Review Board of each medical institution where the trial will be conducted.

➡ **Administration of HLCM051 to the patients is expected to commence in the first half of 2019 at the earliest.**

Field	Development Code	Indication	Market	Pre-clinical test	Clinical Trial	Apply-approve	On the Market	Progress Status
Somatic Stem Cell Regenerative Medicine	HLCM051	ARDS	Japan	→				Undergoing preparation for clinical trial

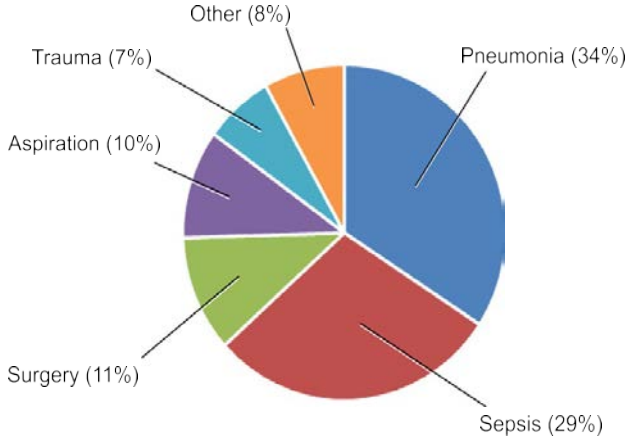
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HLCM051 ARDS Number of ARDS patients

Epidemiological data	Incidence rate	The estimated number of ARDS patients in Japan
Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries. Source: JAMA.2016; 315(8): 788-800	・0.42 cases per ICU bed ・10.4% of ICU admissions ・23.4% of patients requiring mechanical ventilation	**11,937**
Epidemiology of Acute Lung Injury (ALI)/ Acute Respiratory Distress Syndrome (ARDS) in Chiba Prefecture Source: Journal of Japanese Association for Acute Medicine 2007; 18(6): 219-228	6.1 per 100,000 persons	**7,320**

The number of ARDS patients in Japan is estimated by Healios based on the incidence rate of epidemiological data and the total demographical population in Japan.

Underlying diseases of ARDS



Source：Respiratory Investigation; 55(4): 257-263

Approximately 1/3 of ARDS patients were caused by pneumonia

* A double-blinded Phase II study by Athersys, the enrolled subjects of which were not limited by the underlying ARDS causing diseases, showed an improvement trend. (see P12)

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HLCM051 ARDS About Acute Respiratory Distress Syndrome (ARDS)

ARDS

Acute Respiratory Distress Syndrome (ARDS) is a general term for the symptoms of acute respiratory failure suddenly occurring in all seriously ill patients.
The major causes are severe pneumonia, septicemia, trauma etc.
Inflammatory cells are activated in response to these diseases or injuries, causing damage to the tissue of the lungs. As a result, water accumulates in the lungs, leading to acute respiratory failure.

Typically, ARDS is said to occur within 24 to 48 hours of the onset of the illness or injury that caused it. The mortality rate is approximately 30 to 58%*.



(Source) Athersys

(* ARDS treatment guideline 2016)

Treatment

Artificial respiration using an endotracheal tube or mask is used to treat for respiratory failure in an intensive care unit. However, it is known that prolonged use of a ventilator worsens a patient's prognosis.

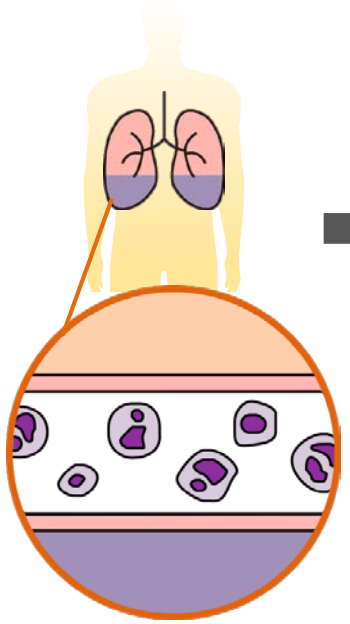
At present, there are no therapeutic drugs that can make a direct improvement to a patient's vital prognosis when ARDS develops. There is a demand for new treatments for ARDS that will lead to improvements in patients' symptoms and prognosis.

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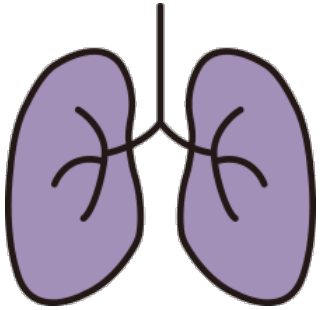
ARDS Pathological Process and HLCM051 Expected Mechanism of Action

- Following intravenous administration after ARDS, HLCM051 accumulates in the lungs and controls excessive inflammation.
- HLCM051 protects damaged tissue and promotes restoration.

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



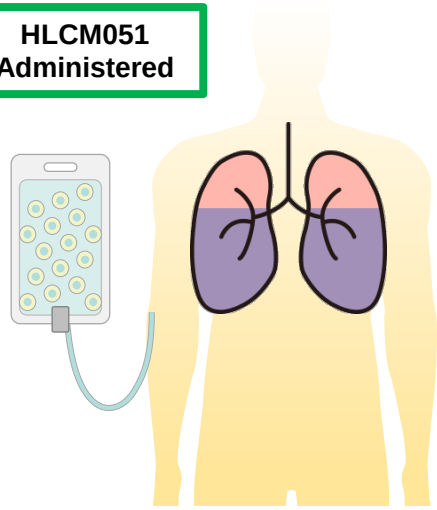
When the tissue is damaged, inflammatory cells are released in large quantities.



The inflammatory cells attack the lungs.

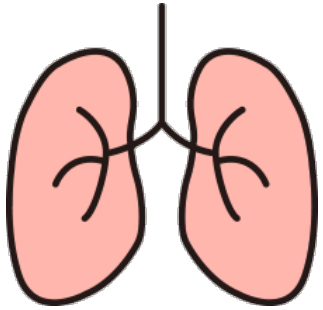
As a result, hypoxia develops and the patient falls into severe respiratory failure.

HLCM051 Administered



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

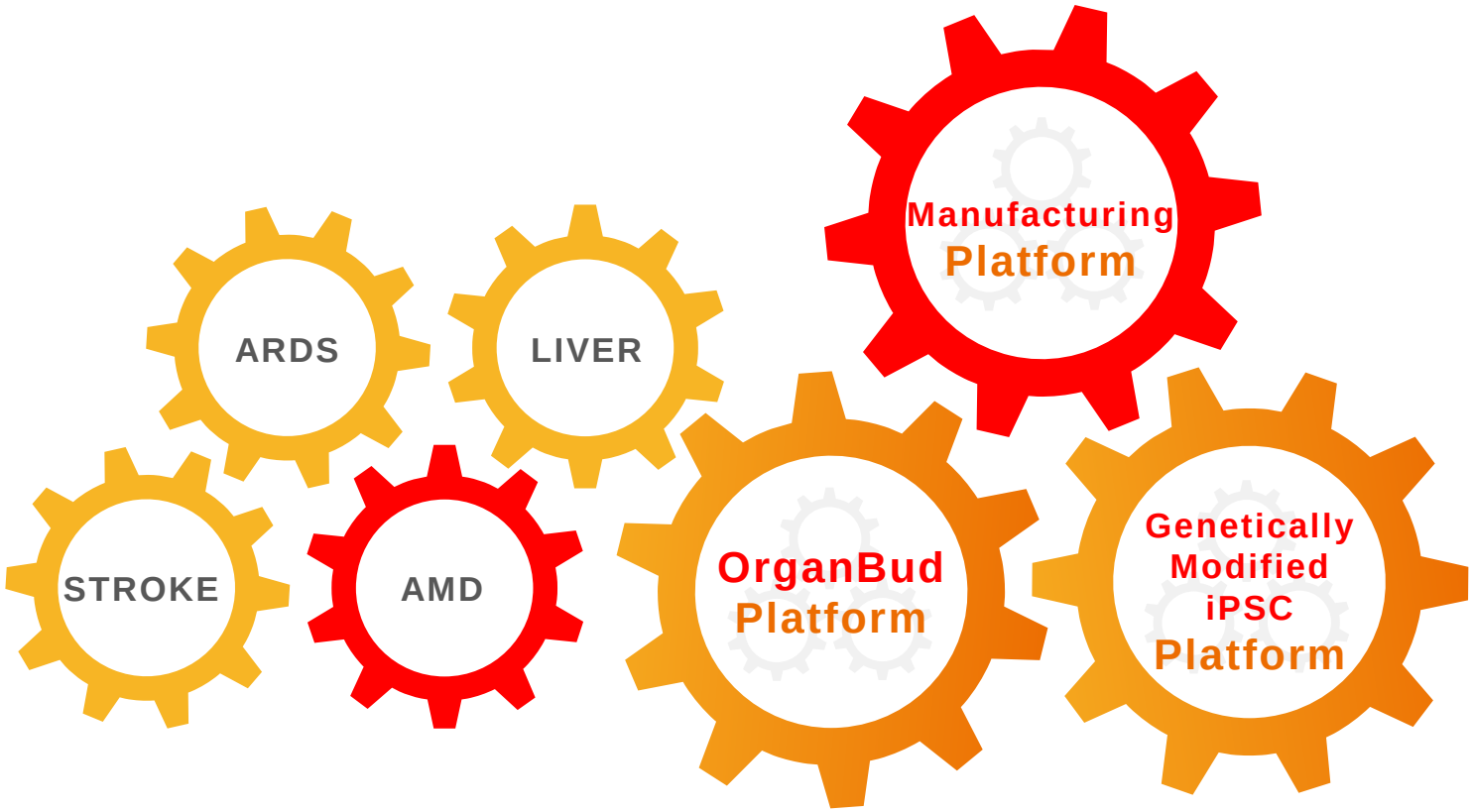
・It suppresses excessive inflammation in the lungs.
・It protects damaged tissue and facilitates healing.



Lung function improves.

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

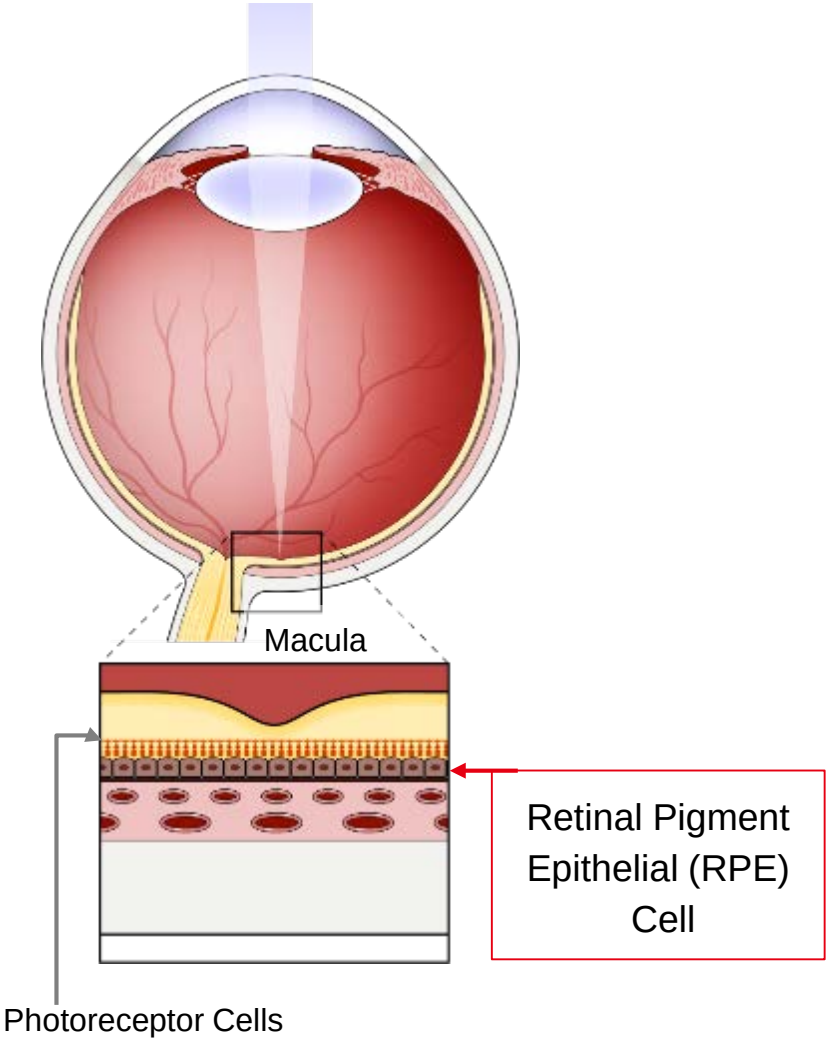
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HLCR011 AMD Explanation of AMD pathological conditions

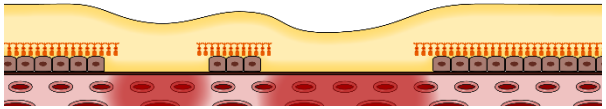
AMD causes RPE cells to degenerate, which damages function.



Regular Macular Part

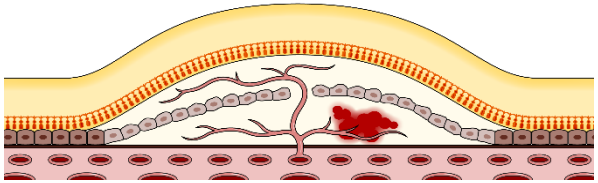
Developed Dry AMD

Immunity barrier maintained
→ Degeneration of photoreceptor→ Dry AMD



Wet AMD

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



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HLCR011 AMD Number of AMD patients

Number of both Wet and Dry patients (including mild cases)

（Thousand patients）

	America	Japan	Others
Number of AMD Patients	**10,000**	**9,230**	**13,000**
Number of AMD Patients in Serious Cases	**2,000**	**690**	**2,600-3,220**
Wet-patients in serious cases	**1,000-1,500**	**630**	**1,300-1,950**
Dry-patients in serious cases	**850-900**	**60**	**1,100-1,170**

※According to research by Hisayama Kyushu University Graduate School of Medicine in Fukuoka (based on a comprehensive study), the total number of patients in Japan is calculated, estimating the total number of first-stage age-related macular degeneration and latter stage of age-related macular degeneration based on population statistics (2007). Also, the Disease Information Center announced that the number of patients suffering serious cases is approximately 690,000. The total number of patients in the US, which the National Eye Institute reports, includes the total number of age-related macular degeneration patients in mild cases and patients with visual field defects. Also, our company calculated the total number of Dry/Wet patients based on the incidence rates presented by AMDF (2010). Our company calculated the total number of patients in Europe based on incidence rates in each grade of European population statistics （2010)

※source: Prevalence of age-related maculopathy in older Europeans: the European Eye Study (EUREYE).Source: Arch Ophthalmol. 2006 Apr;124(4):529-35

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HLCR011 AMD Market scale of anti-VEGF treatment

Sales of anti-VEGF treatment are increasing every year. No medicine for Dry AMD.

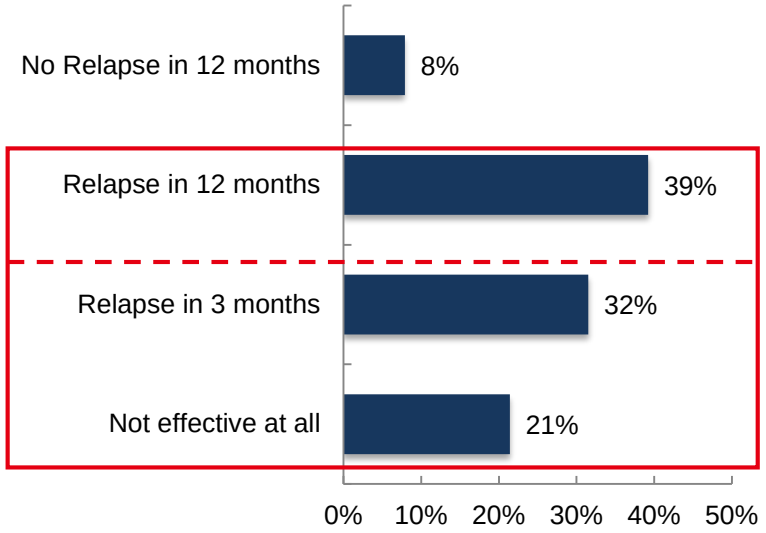
Indication	Medicine / Effect	year	America	Japan	Others	Total
Wet AMD and Other 3 diseases	Anti-VEGF treatment/ Restraint of New Blood Vessels	2015	**3.853 billion USD**	**496 million USD**	**2.661 billion USD**	**7.01 billion USD**
		2016	**4.729 billion USD**	**580 million USD**	**3.127 billion USD**	**8.436 billion USD**
		2017	**5.116 billion USD**	**632 million USD**	**3.483 billion USD**	**9.231 billion USD**
Dry AMD	**No Medicine**					

(Source) Market scale was calculated using official materials from drug companies (Roche Diagnostic, Novartis, Regeneron, Bayer HealthCare, Santen Pharmaceutical Co., Ltd). Calculated using 2015,2016,2017 fiscal year-average exchange rates. (FY2015:$1=¥121, FY2016: $1=¥110, FY2017: $1=¥112)

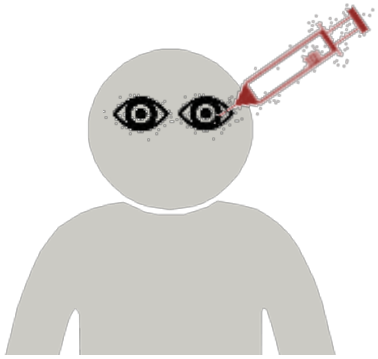
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HLCR011 AMD Treatment subjects for Wet AMD

Recurrence frequency after receiving anti-VEGF medication



92% of patients
recur within 1 year

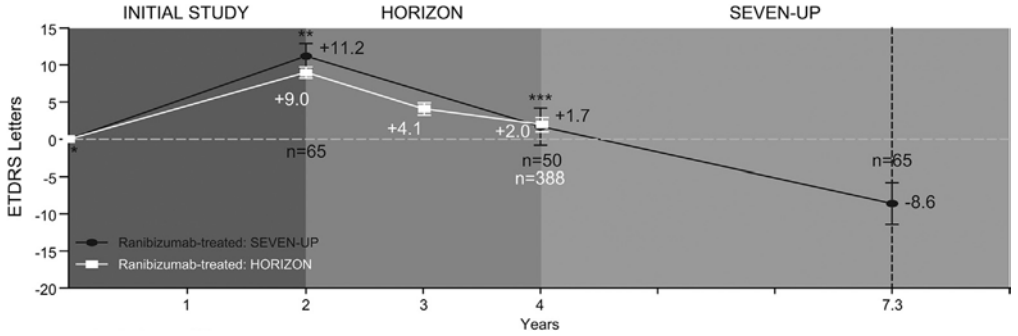


(Source) 13th Annual Meeting of The Japanese Society for Regenerative Medicine March 19th 2014, Thurs, 12:00～12:50 Approach to Clinical Application of iPS cells Institute of Physical and Chemical Research, Mandai Michiko

Changes in vision after receiving long-term anti VEGF treatment

Seven-Year Outcomes in Ranibizumab-Treated Patients in ANCHOR, MARINA, and HORIZON *A Multicenter Cohort Study (SEVEN-UP)*

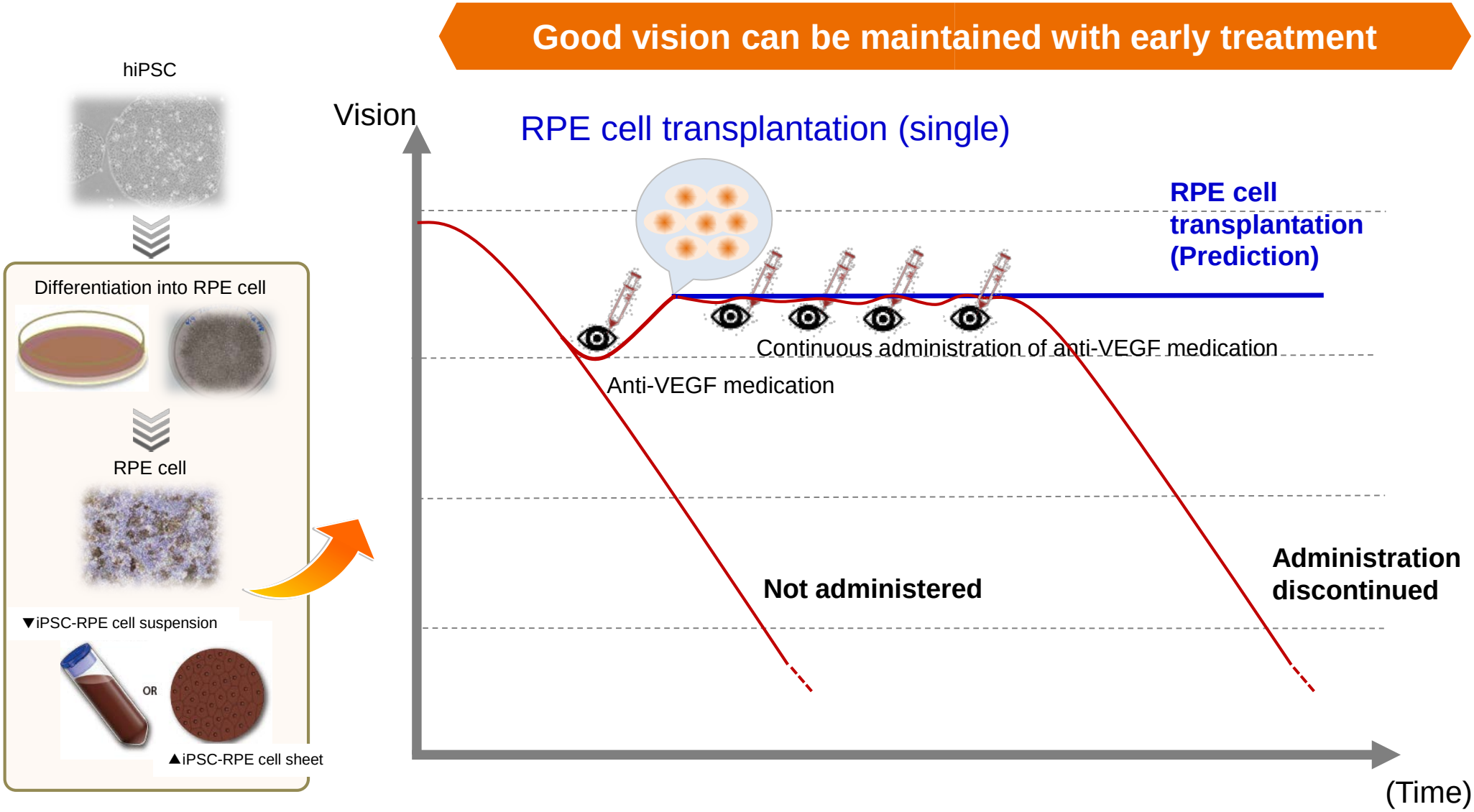
Risk for substantial visual decline remains after receiving long-term anti-VEGF medication treatment.



(Source) Rofagha S, et al. Ophthalmology 2013; 120: 2292-2299

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HLCR011 AMD Image of changes in vision with iPSC-RPE cell products treatment



* The purpose of this illustration is to promote understanding of the effects of RPE cell transplantation.
Changes in vision with the administration of anti-VEGF medication vary according to patient symptoms and administration frequency.

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HLCR011 AMD Guide to medicine price
– Approach based on the cost of existing treatment

Anti-VEGF medicine mostly continues from the beginning of treatment until death

Annual Medical Expense

Unit Price of Anti-VEGF + Treatment Price
160,000 yen

✖

Annual Recommended Medication Protocol
6 Times

=

Annual Medical Expense
1,000,000 yen

Estimate of Lifetime Medical Expense

On the Assumption of Average Life Span (Japan): 80years old (Male) / 86 years old (female)

Estimate of Lifetime Medical Expense

Continuous Treatment for **50-year old Patient Onset** ＝approx. **30years** ✖ **1.02 million yen** = **Approx. 30 million yen**

60-year old Patient Onset＝approx. **20years** ✖ **1.02 million yen** = **Approx. 20 million yen**

(source) Onset Data: National Eye Institute; Average Life Span: The Ministry of Health, Labor and Welfare; Annual Recommended Medication Protocol: Materials Presented by Institute of Physical and Chemical Research

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HLCR011 AMD Manufacturing for iPSC-derived RPE products

Sighregen (our joint venture with Sumitomo Dainippon Pharma) is establishing a manufacturing facility in "SMaRT", the Manufacturing Plant for Regenerative Medicine & Cell Therapy by Sumitomo Dainippon Pharma



Sumitomo Dainippon Pharma completed the new manufacturing plant for regenerative medicine & cell therapy "SMaRT" in Osaka in March 2018.

Sighregen rents the facility in SMaRT and is establishing the iPSC-RPE manufacturing system.



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HLCR011 AMD Status of clinical research by RIKEN etc.

"Clinical research of transplantation of allogeneic induced pluripotent stem cells – derived retinal pigment epithelium (RPE) cells for exudative age-related macular degeneration (AMD)"

March 2017:
Operation on first subject in clinical research using allogeneic iPSC-derived RPE cell suspension.
November 2017:
Operations using allogeneic iPSC-derived RPE cell suspension completed on 5 subjects. Continuing follow-up observation for one year.

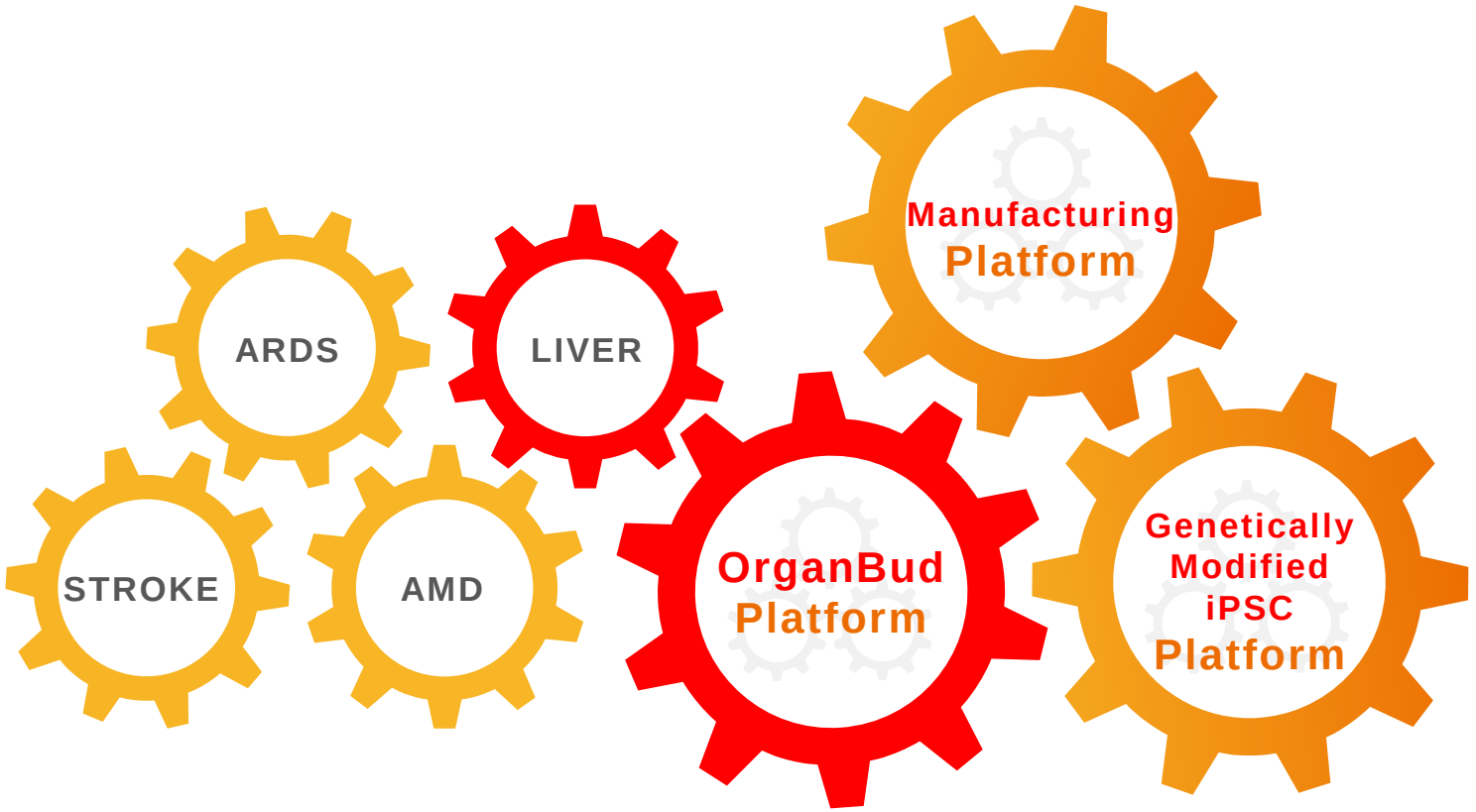
	Sheet	**Suspension**
Autologous cells	Operation on 1 subject (in 2014)	To be determined.
Allogeneic cells	To be determined	Operations on 5 subjects (in 2017)

January 2018:
In one case an epiretinal membrane, deemed to be one of the causes of retinal edema, was removed to improve symptoms during the clinical research.

Dr. Takahashi from RIKEN explained that "The adverse effect was not imminent or urgent in nature. This event will not have any impact to our clinical studies in the future."

(Sources) Created by Healios
from the data at a press conference by RIKEN

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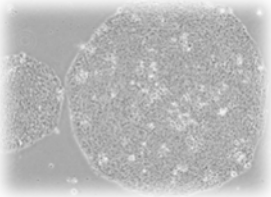


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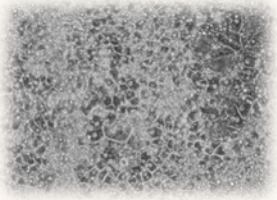
HLCL041 LIVER OrganBud Platform 3D organ generation mechanism

Generating “Organ buds” by co-culturing 3 types of cells

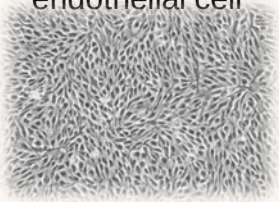
Human iPS cell



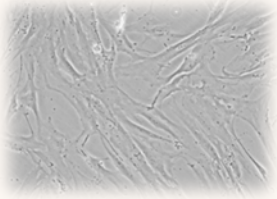
Precursor cell



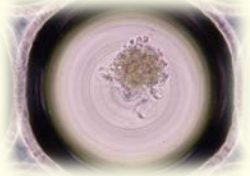
Vascular endothelial cell



MSC



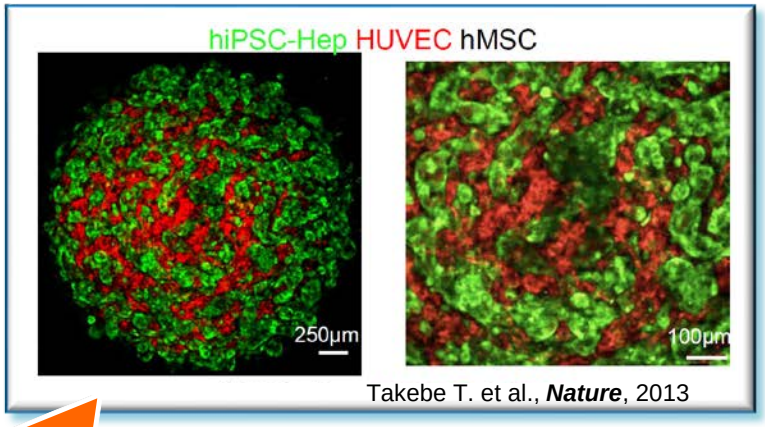
Organ bud*



Organ bud=
Origin of organ

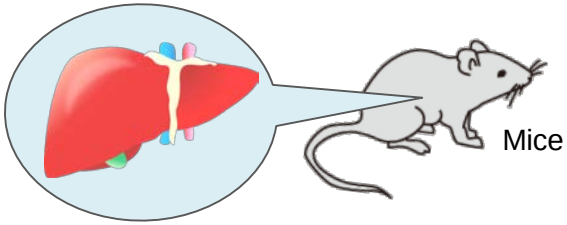


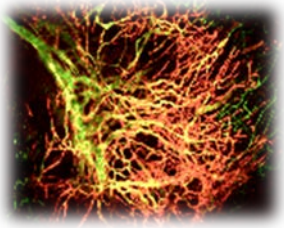
Elplasia™ from Kuraray Co., Ltd.
(http://www.elplasia.com/products/round_bottom/)



Takebe T. et al., ***Nature***, 2013

Cell Transplantation





Containing blood vessels and human liver

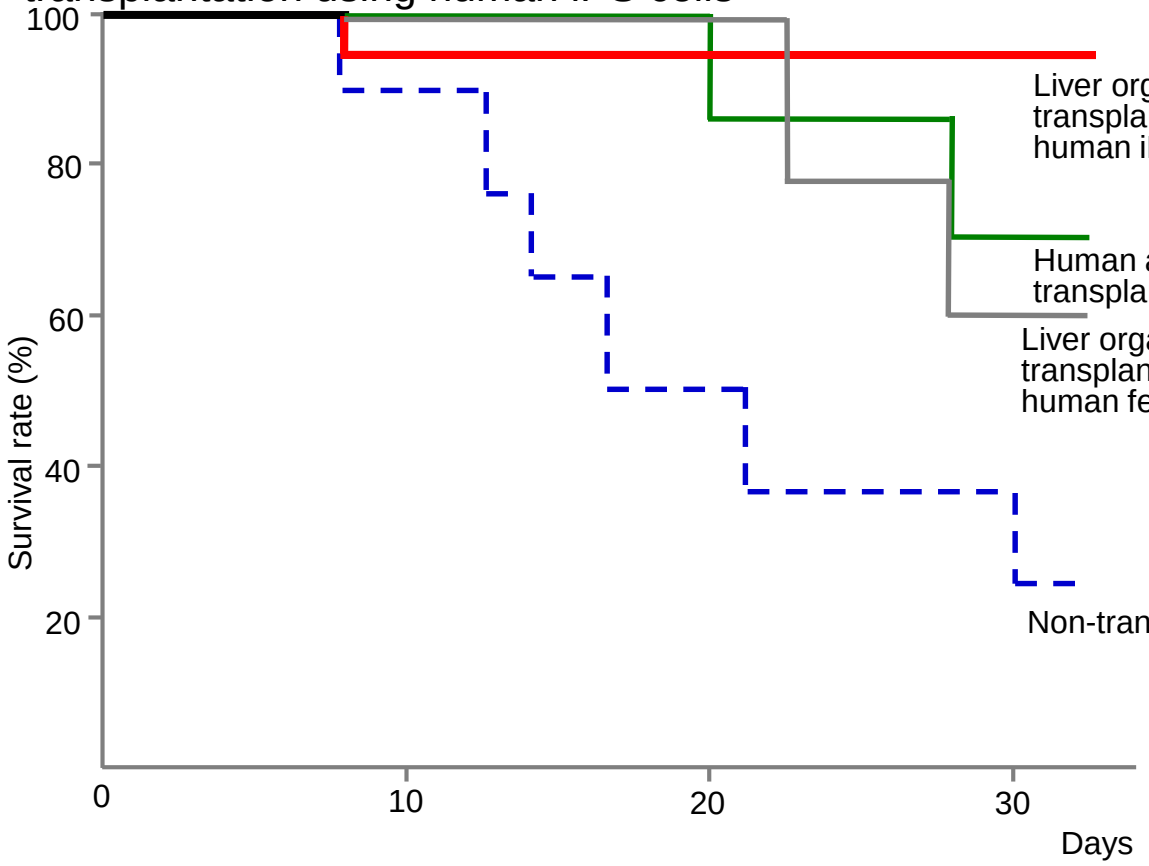
Takebe T. et al., ***Nature Protocols***, 2014

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HLCL041 LIVER OrganBud Platform Survival rate of liver failure in mouse model

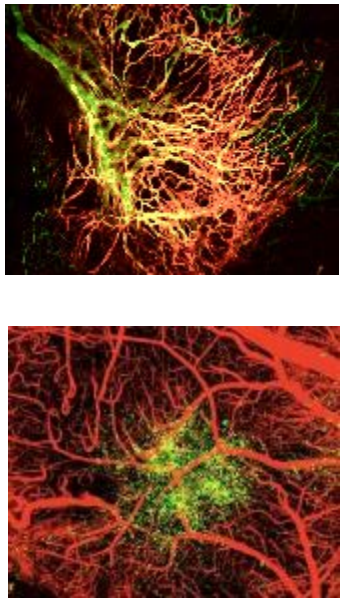
Survival rate improves significantly in transplantation experiments

Treatment effects of liver organ bud transplantation using human iPS cells



(Source) Adapted by Healios from Takebe. T, et al. Nature, 499 (7459),（2013)

Process by which organ forms from organ bud links mouse‘s vascular network autonomously



(Source) Takebe,T., et al.
Nature Protocols, 9, 396–409 (2014)

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HLCL041 LIVER OrganBud Platform Expansion of marketability

Prospecting R&D for alternative treatment for liver transplantation

	Liver transplantation			Total
	US	Japan	Europe	
Number of patients undergoing treatment (Annual)	**Approx. 6,000**	**Approx. 400**	**Approx. 4,000**	**Approx. 10,000**
Number of patients on waiting list (Annual)	**Approx. 15,000**	**Approx. 400**	**Approx. 4,000**	**Approx. 20,000**

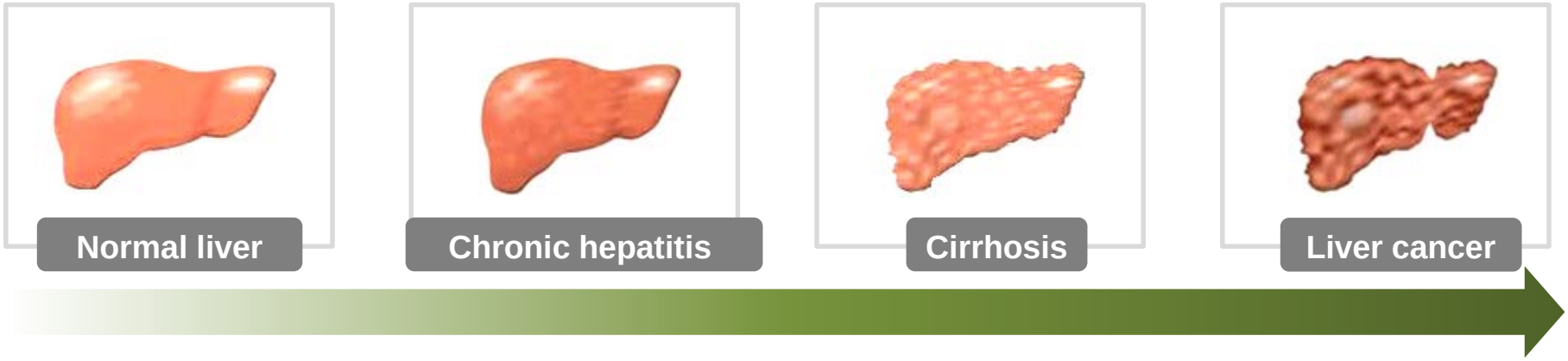
（Source）Compiled by Healios based on materials disclosed by Japanese Liver Transplantation Society, UNOS, Eurotransplan, UK Transplant, Agence de la biomédecine, and Scandia Transplant.

Liver disease drawing attention in the future is cirrhosis

Estimated patients with cirrhosis in Japan: 400,000 to 500,000. About 56,000 receive treatment at medical facilities.
Annual deaths in Japan: 17,000 patients.

（Source）Patient Survey 2011 Liver Cancer White Paper 2015

Progress of liver disease



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HLCL041 LIVER OrganBud Platform

Potential of application for various organs

Cell derived from various organs

Vascular endothelial cell

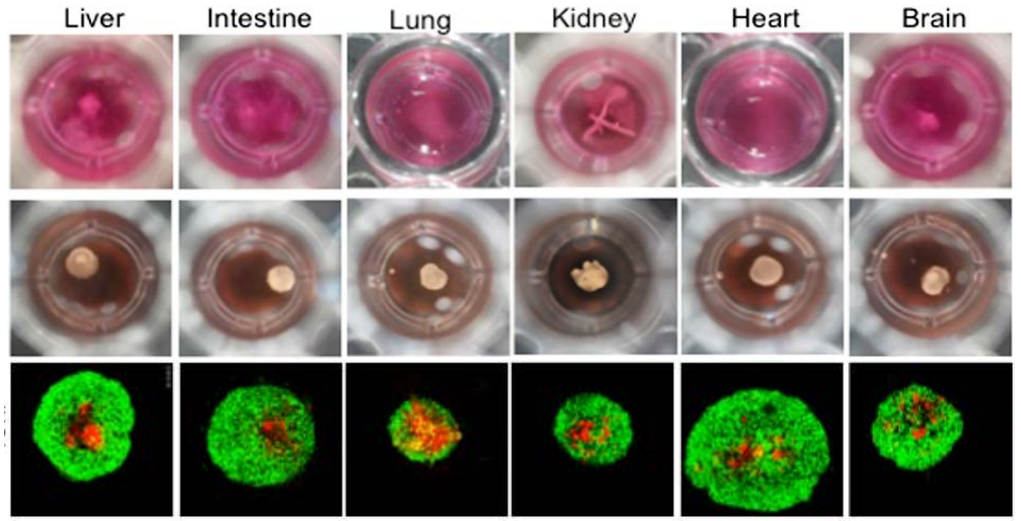
MSC



Using cells derived from various organs, vascular endothelial cells and mesenchymal stem cells, achieved construction of vascularized 3D organ buds.

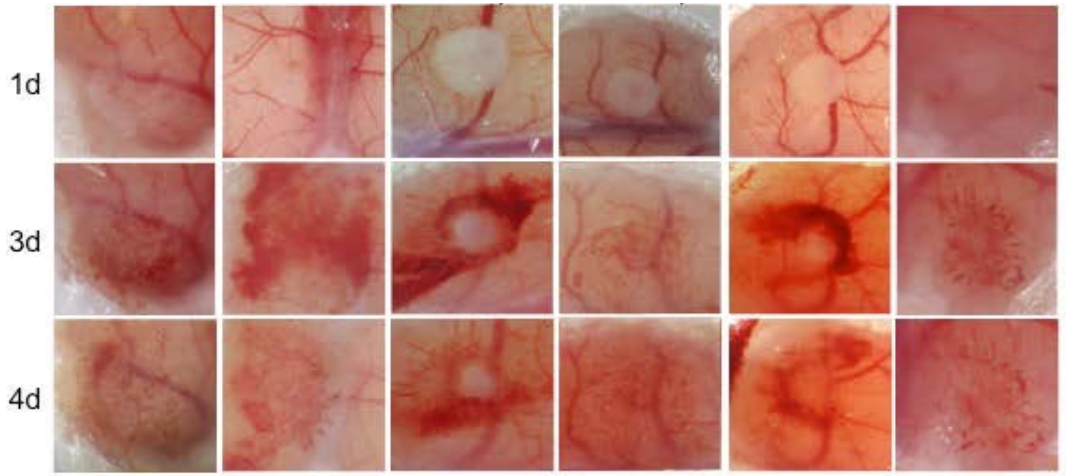
The vascularization was confirmed in vivo by transplantation to mice.

Inducing progenitor cells for each organ from iPS cells will expand the possibility of development across various organs.



Transplanted to mice

Green：Cell derived from various organs
Red：Vascular endothelial cell
Black：MSC



Modified from Takebe T. et al., ***Cell Stem Cell***, 2015

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Financial Highlights

UPDATE

Income Statement

（Units: one million US dollar）

	FY 2017	FY 2018		
			YoY variance	Main reasons for increase/decrease
Sales	0.25	—	- 0.25	
Operating income	-20.94	**-45.86**	-24.92	Mainly due to increase of R&D expenses-$23.23mn
Ordinary income	-21.53	**-46.06**	-24.53	
Net income	-15.84	**-46.16**	-30.32	Partially due to decrease in extraordinary income -$5.72mn (BBG business transfer occurred in FY2017)
R&D expenses	15.43	**38.66**	23.23	Mainly due to acquisition of MultiStem License from Athersys +$20.00mn
Amortization of goodwill	0.30	**-**	-0.30	
Number of employees	74	**93**	19	

*Adopt average exchange rate (JPY/USD) over respective fiscal years for P&L.
FY2017 112.16 yen per dollar and FY2018 110.43 yen per dollar.

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UPDATE

Balance sheet

（Units: one million US dollar）

		December 31, 2017	December 31, 2018		
				Variance	Main reasons for increase/decrease
	Current assets	170.69 (97.9%)	**111.05** (82.3%)	- 59.64	Mainly due to decrease in cash equivalents -$63.75mn (cash equivalent balance at 12/31/18 was $104.75mn)
	Non-current assets	3.61 (2.1%)	**23.91** (17.7%)	20.29	Mainly due to increase in investment securities +$18.19mn
Total assets		174.30 (100.0%)	**134.96** (100.0%)	- 39.35	
	Current liabilities	11.51 (6.6%)	**14.62** (10.8%)	3.11	Mainly due to increase in accounts payable +$2.62mn
	Non-current liabilities	19.75 (11.3%)	**23.20** (17.2%)	3.44	Mainly due to increase in long-term loans payable +$3.31mn
Total liabilities		31.26 (17.9%)	**37.82** (28.0%)	6.55	
Total net assets		143.04 (82.1%)	**97.14** (72.0%)	- 45.90	Mainly due to net loss -$46.16mn
Total liabilities and net assets		174.30 (100.0%)	**134.96** (100.0%)	- 39.35	

*Adopt spot rate (JPY/USD) at end of fiscal period for B/S.
FY2017 113.00 yen per dollar and FY2018 111.00 yen per dollar.

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Appendix

UPDATE

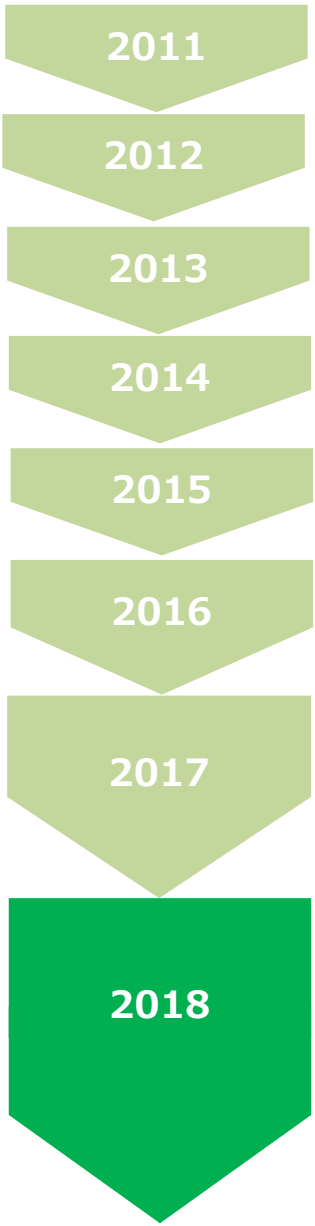
Healios overview

About Us

Company Name	HEALIOS K.K.（TSE: 4593）
Mission	To foster a “Life Explosion” that enriches the lives of people around the world
Head Office	World Trade Center Building 15F 2-4-1 Hamamatsucho Minato-ku, Tokyo Japan 105-6115
Representative	Hardy TS Kagimoto, MD, Chairman and CEO 
Paid in Capital	11,386 million yen (As of end of December, 2018)
Number of Employees	93 (As of end of December, 2018)
Research Institution	Kobe and Yokohama
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. (Established in June 2018 to promote the practical use of organ bud technology)

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Company history and societal trends



2011
- Retina Institute Japan established (currently Healios)
- ◆ Certified as RIKEN Venture

2012
- Prof. Shinya Yamanaka wins Nobel Prize in Physiology or Medicine

2013
- Act on the Safety of Regenerative Medicine, Pharmaceutical and Medical Device Act established
- ◆ Patent licensing agreement with RIKEN
- ◆ Joint development agreement with Sumitomo Dainippon Pharma

2014
- RIKEN Conducts 1st transplantation surgery in world's first clinical study using autologous iPS cells
- ■ Joint research on organ bud with Yokohama City University

2015
- RIKEN announces good follow-up results 1 year after administration in clinical study
- ✓ Listed on Tokyo Stock Exchange (MOTHERS)

2016
- ● HLCM051 Patent licensing agreement with Athersys
- ■ Collaborative research agreement with Universal Cells

2017
- RIKEN Conducts 1st transplantation surgery in world's first clinical study using allogeneic iPS cells
- ✓ Business and capital alliance agreement with Nikon
- ✓ BBG business transfer
- ● HLCM051 First patient In

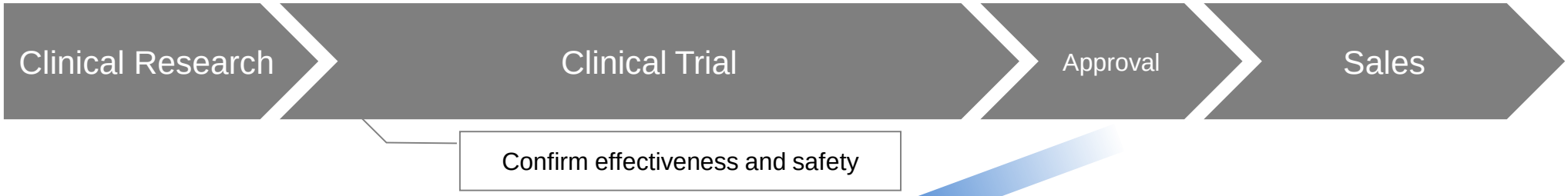
2018
- ✓ Established Healios N.A in the United States
- ■ Strategic investment in GAIA BioMedicine
- ■ Strategic Investment in Athersys
- ● Expansion of collaboration with Athersys
- ◆ Collaborative Research and Development Agreement with NEI
- ✓ Established Organoid Neogenesis Laboratory Inc.
- ● HLCM051 ARDS Clinical trial notification submitted

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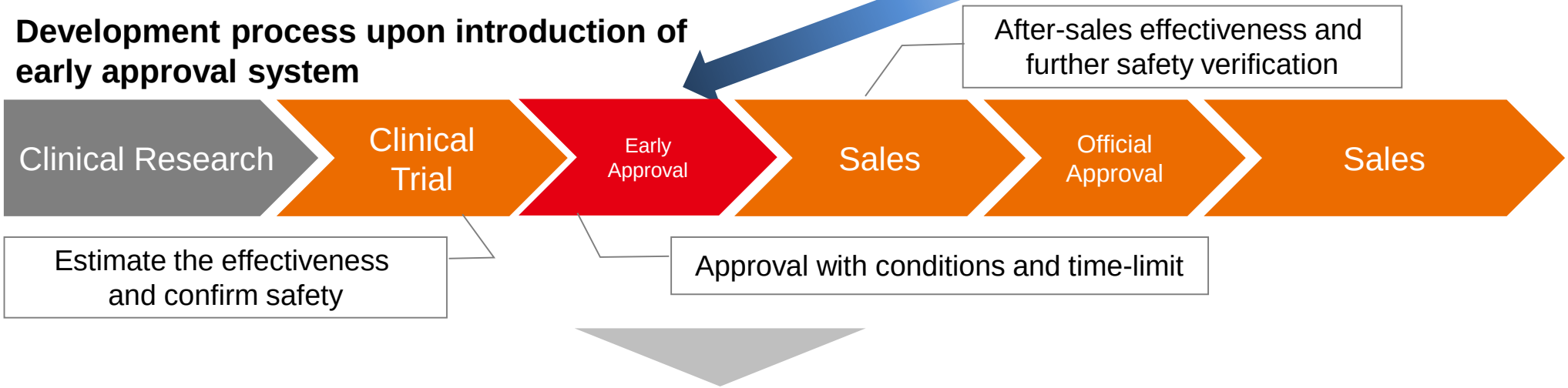
Historical relaxation of Japanese regulations

Japanese Government Revises Regulations to Put Japan at the Forefront

Traditional process of development



Development process upon introduction of early approval system



- Drastic reduction in the trial time period and number of patients with “Early Approval System”.
- Insurance is listed at ‘Early Approval’ stage.

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Important note on future events, etc.

Descriptions of future events, etc. in this document include Healios' assumptions, prospects, etc. based on information which could be acquired at the time this document was presented. For this reason, actual performance, development progress, etc. may differ from those described in this document according to the outcome of R&D in the future, the actions of regulatory authorities, etc. in the future, and uncertain/pending factors as of this point.

Also, this document contains information on regenerative medicine and medical equipment that are currently under development or already on the market. Such information is not intended for promoting, advertising or providing medical advice.

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