FY2018 2Q Financial Results

August 7, 2018

HEALIOS K.K.
(TSE 4593)

Contents

1	Financial Highlights	P2
2	FY2018 2Q Business Overview	P5
3	New Somatic Stem Cell Therapy	P11
Appendix		
4	Details of Somatic Stem Cell Regenerative Medicine	P16
5	Details of iPSC Regenerative Medicine	P23
6	Expansion to 3D Organs（Liver）	P34
7	Company Overview	P39
8	Circumstances of Regenerative Medicine	P42

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1. Financial Highlights

Statement of income

(Million yen)

	FY 2017 2Q	FY 2018 2Q		
			YoY change	Main reasons for increase/decrease
Sales	27	—	▲27	
Operating income	▲935	**▲3,301**	▲2,366	Research & Development expenses increased ▲2,263
Ordinary income	▲981	**▲3,320**	▲2,338	
Net income	▲342	**▲3,323**	▲2,980	FY2017: Gain on transfer of business (▲641)

R&D expenses	626	**2,890**	2,263	Collaboration expansion with Athersys +2,160
Amortization of goodwill	33	**-**	▲33	
Number of employees	67	86	+19	-

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Balance sheet

(Million yen / %)

		December 31, 2017	June 30, 2018	Change	Main reasons for increase/decrease
	Current assets	19,288 (97.9%)	**15,269** (82.8%)	▲4,018	Cash and deposit ▲4,253 (Cash and deposit balance 14,787)
	Non-current assets	408 (2.1%)	**3,180** (17.2%)	2,772	Investment securities +2,722
Total assets		19,696 (100.0%)	**18,450** (100.0%)	▲1,246	
	Current liabilities	1,300 (6.6%)	**3,549** (19.2%)	2,248	Current portion of long-term loans payable +1,000 Accounts payable +778
	Non-current liabilities	2,232 (11.3%)	**1,754** (9.5%)	▲477	Long-term loans payable ▲586
Total liabilities		3,532 (17.9%)	**5,303** (28.7%)	1,771	
Total net assets		16,163 (82.1%)	**13,146** (71.3%)	▲3,017	Earned surplus ▲3,323
Total liabilities and net assets		19,696 (100.0%)	**18,450** (100.0%)	▲1,246	

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2. FY2018 2Q Business Overview

Pipeline

UPDATE

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Field	Development Code	Indication	Market	Progress Status
Somatic Stem Cell Regenerative Medicine	HLCM051	Ischemic Stroke	Japan	Phase 2/3 Trial
	HLCM051	ARDS	Japan	Undergoing preparation for clinical trial
iPSC Regenerative Medicine	HLCR011	Wet AMD	Japan	Undergoing preparation for clinical trial
	HLCL041	Metabolic Liver Disease	Japan	Joint research with Yokohama City University
	HLCR012	Dry AMD	US	CRADA with NEI
	HLCR012	Dry AMD	EU	Global trial under consideration based on US phase III trial

Transplantation conducted under Clinical research(*1)

* 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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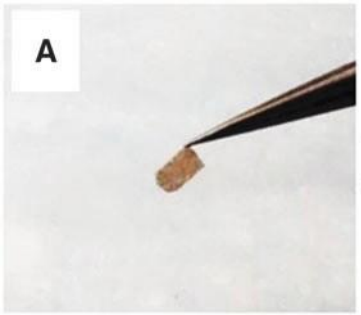
Collaborative Research and Development with NEI

UPDATE

Healios and the National Eye Institute (NEI), an institute of the National Institutes of Health (NIH), entered into a Collaborative Research and Development Agreement in May 2018.
The scope of the collaboration is the development of an allogeneic iPSC-derived RPE cell therapy for AMD.

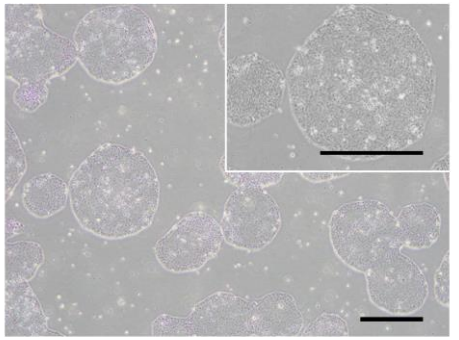
NIH National Eye Institute
Research Today...Vision Tomorrow



iPSC-RPE cells on scaffolds

Hotaling, Nathan A. et al. Journal of Ocular Pharmacology and Therapeutics. 2016, Vol. 32, No. 5
http://doi.org/10.1089/jop.2015.0157

Healios established allogeneic iPSC master cell banks (MCBs) that are expected to be applicable for global use.



Morphology of hiPSC colonies

NEI tests the quality of iPSC-RPE cell sheet that is derived from Healios' iPSC MCB using NEI's differentiation protocols

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Collaboration Expansion with Athersys

UPDATE

March 13, 2018: Strategic investment / Letter of Intent

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

June 7, 2018

- Expansion of the license to develop and commercialize MultiStem

June 18, 2018

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



Athersys inc.

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



（Source）Athersys

- 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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Contents of Letter of Intent (entered into on March 13, 2018)

Existing License

Ischemic stroke / Japan

In case of the whole expansion: $35 million

License

Japan

- Trauma
- Acute Respiratory Distress Syndrome (ARDS)

World wide

- Organ bud therapies using MultiStem
- MultiStem products for ophthalmological indications
- iPSC derived RPE products using MultiStem

Others

Option

※Payment for exercise fee is required to start development

China

- Ischemic stroke
- Acute Respiratory Distress Syndrome (ARDS)
- Trauma

Execution of $10 million in escrow

（In Japan Only）

$25 million may be deducted from certain milestone payments

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License acquired as of June 2018

UPDATE

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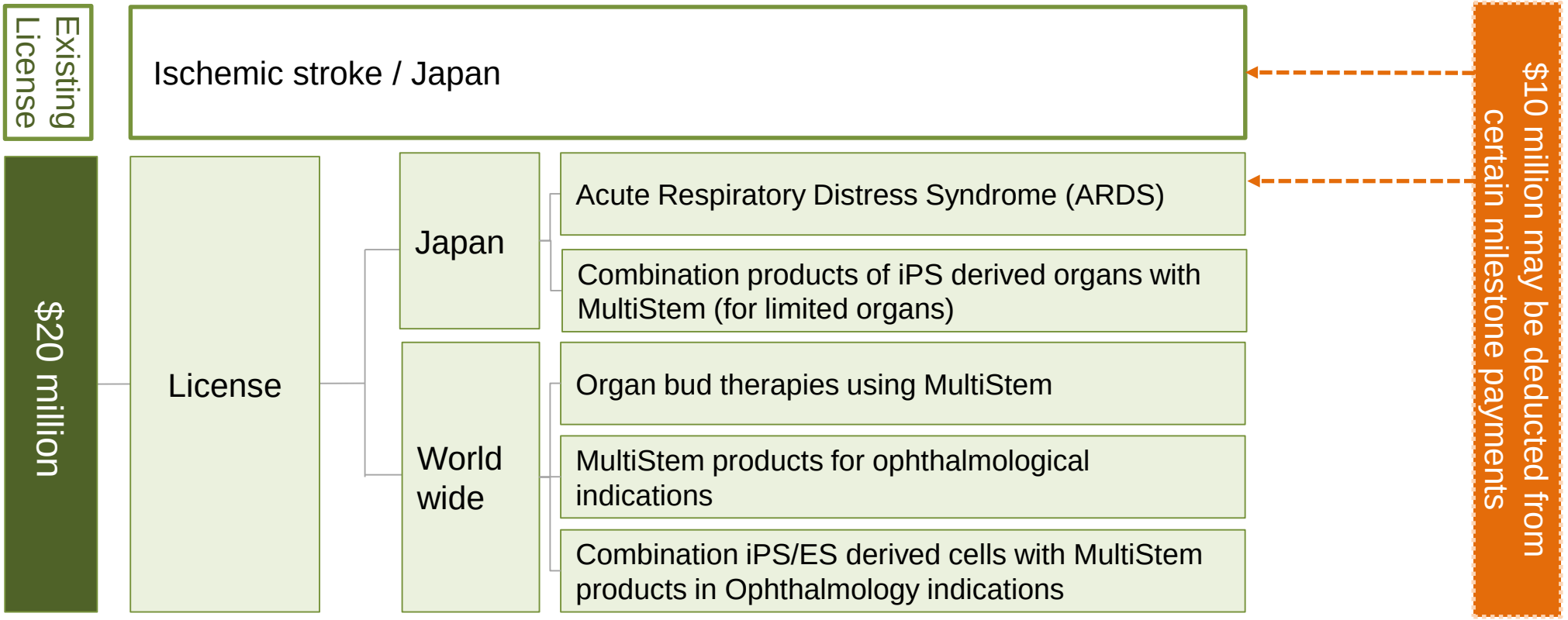

Negotiation period has been extended to expand our collaboration beyond the scope of above listed area.

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UPDATE

3. New Somatic Stem Cell Therapy

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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Number of ARDS patients

There are approximately 12,000 ARDS patients annually in Japan.

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.

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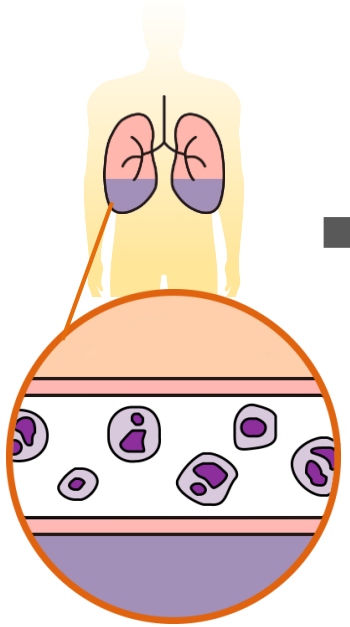
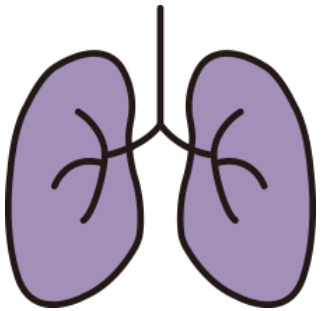
ARDS Pathological Process and HLCM051 Expected Mechanism of Action

- 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.)



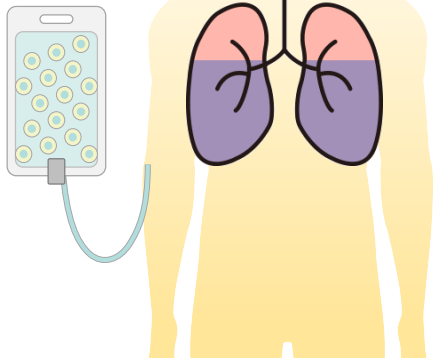
When the tissue is damaged, inflammatory cells are released in large quantities.



The inflammatory cells attack the lungs.

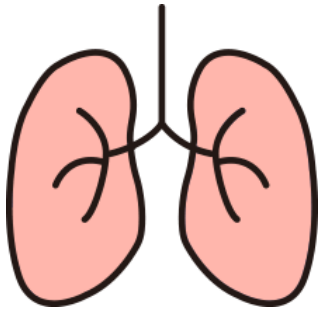
As a result, hypoxia develops and the patient falls into severe respiratory failure.

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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Development Schedule

Healios is moving forward with preparations to launch clinical trials in Japan

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

<Athersys' Development Status>
Conducting Clinical trials in Europe and the United States since January 2016 https://clinicaltrials.gov/ct2/show/NCT02611609

A Phase 1/2 Study to Assess the Safety and Efficacy of MultiStem® Therapy in Subjects With Acute Respiratory Distress Syndrome	
Estimated Enrollment	36 participants
The subject of patients	Diagnosis of moderate to severe ARDS
Follow-up period	1 year
Primary Outcome Measures	• Frequency of sustained hypoxemia or hypotension [Time Frame: 4 hours] • Suspected unexpected serious adverse reactions (SUSARs) [Time Frame: 24 hours]
Secondary Outcome Measures	Safety outcome measure: frequency of adverse events, changes in vital signs, changes in blood safety laboratories, all-cause mortality Efficacy outcome measure: ventilator-free days, ICU-free days, all-cause mortality, total length of hospital stay etc.

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4. Details of Somatic Stem Cell Regenerative Medicine

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.

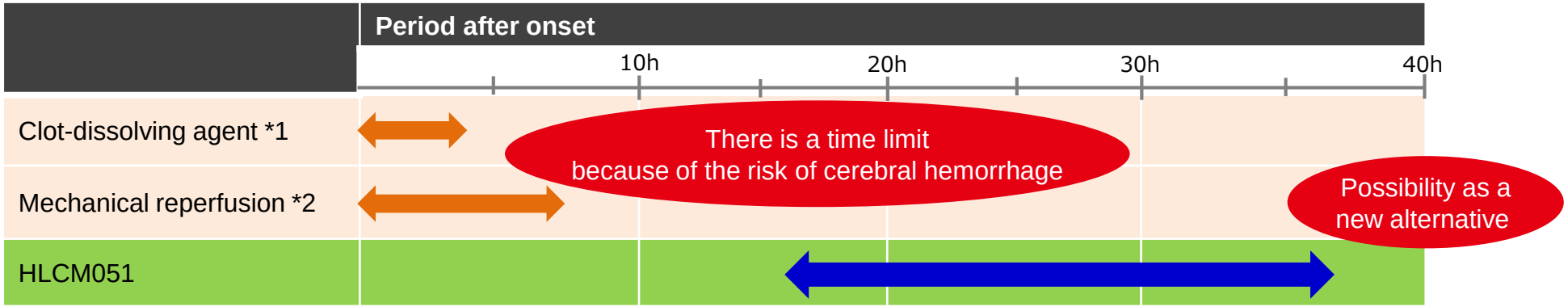
It is estimated that 37.9% of bedridden patients and 21.7% of persons who were in need of care were affected by ischemic stroke.



（Source） Athersys

Treatment in accordance with the period after onset

■ Expected development of a new therapy that can be applied in a longer treatment widow 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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Annual number of new patients with ischemic stroke in Japan

Target population

	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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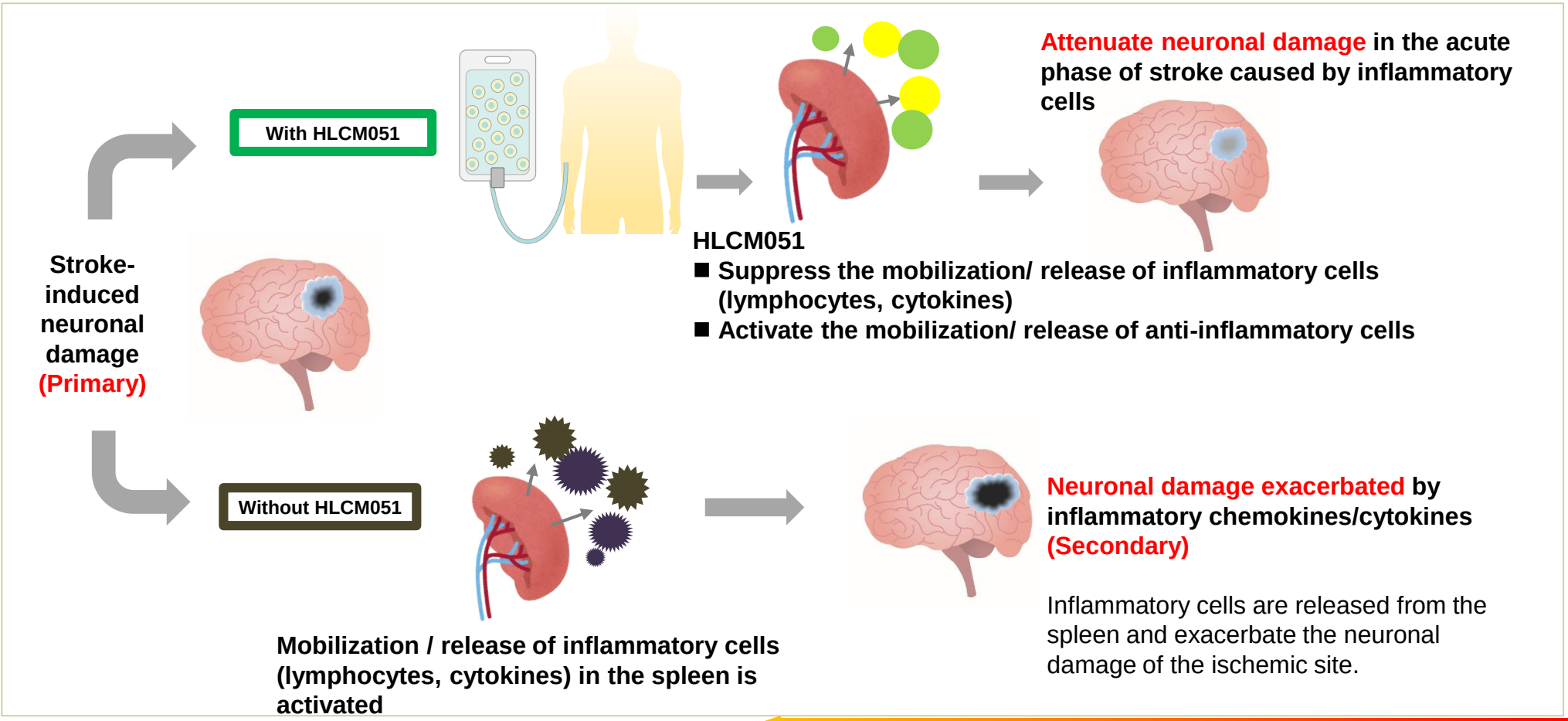
Mechanism of HLCM051 treatment

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



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Clinical trials conducted by Athersys in the US and Europe

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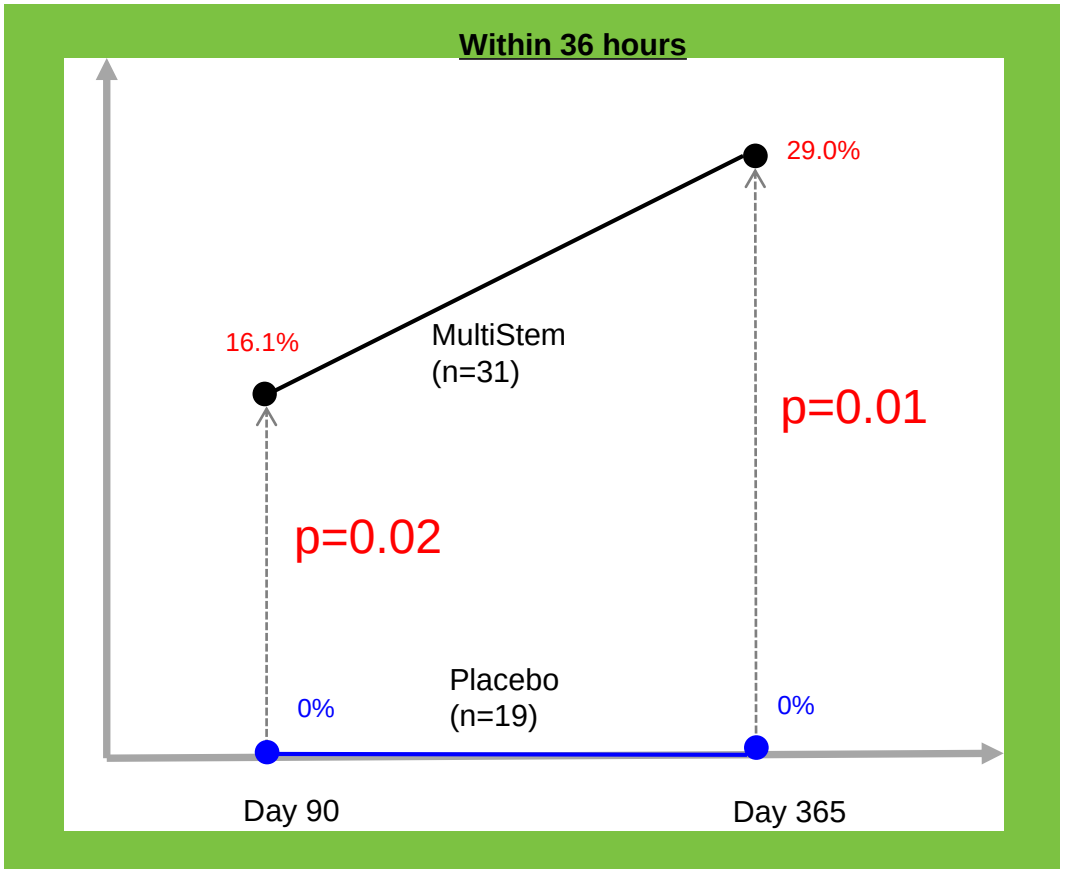
The proportion of patients who achieved Excellent Outcome was statistically significant (compared with the placebo group) both at Day 90 and Day 365 in the group of patients who received MultiStem within 36 hours of the onset of cerebral infarction.



Athersys starts conducting Phase 3 study (MASTERS-2)

*Patients will receive clinical product or placebo within 18-36 hours of stroke onset
* A total of 300 patients will be enrolled

➡ **First patient enrolled in July 2018.**

(Source) Prepared by Healios based on the data provided by Athersys.

(Note) Excellent outcome = All of the following: mRS ≤ 1, NIHSS ≤ 1, and BI ≥ 95)

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HLCM051: Clinical trial status

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

The first patient was enrolled on November 15, 2017.
Enrollment continues to make good progress.
It will take about 2 years for the inclusion of subjects as originally estimated.



First Patients enrolled In Nov 2017

TREASURE study completion: within FY2020
Note: This includes 1 year follow up, but primary endpoint assessment will occur at 3 months after last subject enrolled

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

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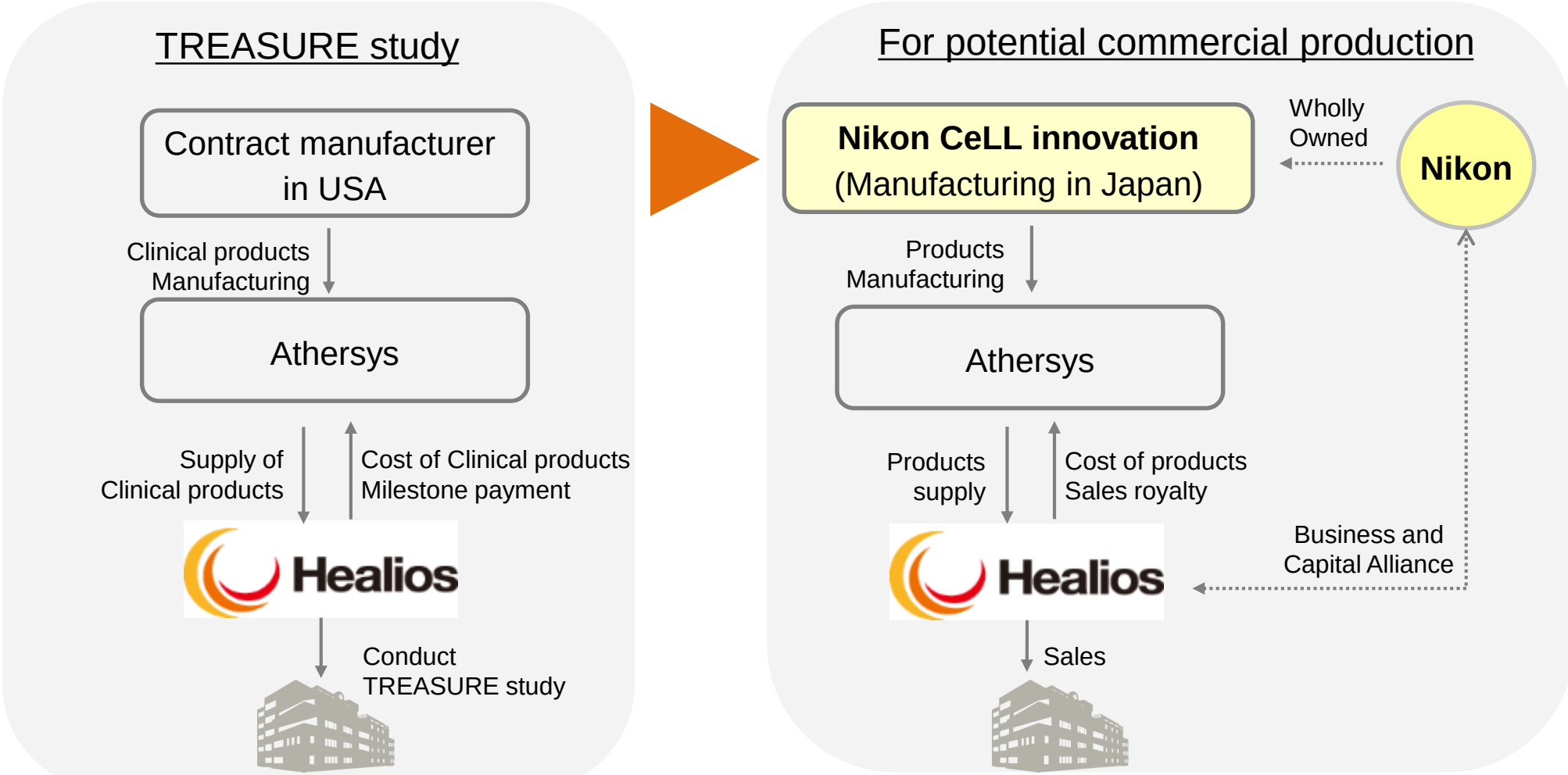
HLCM051: Business Partners

Nikon CeLL innovation executed a manufacturing service agreement with Athersys in preparation for the commercialization of HLCM051



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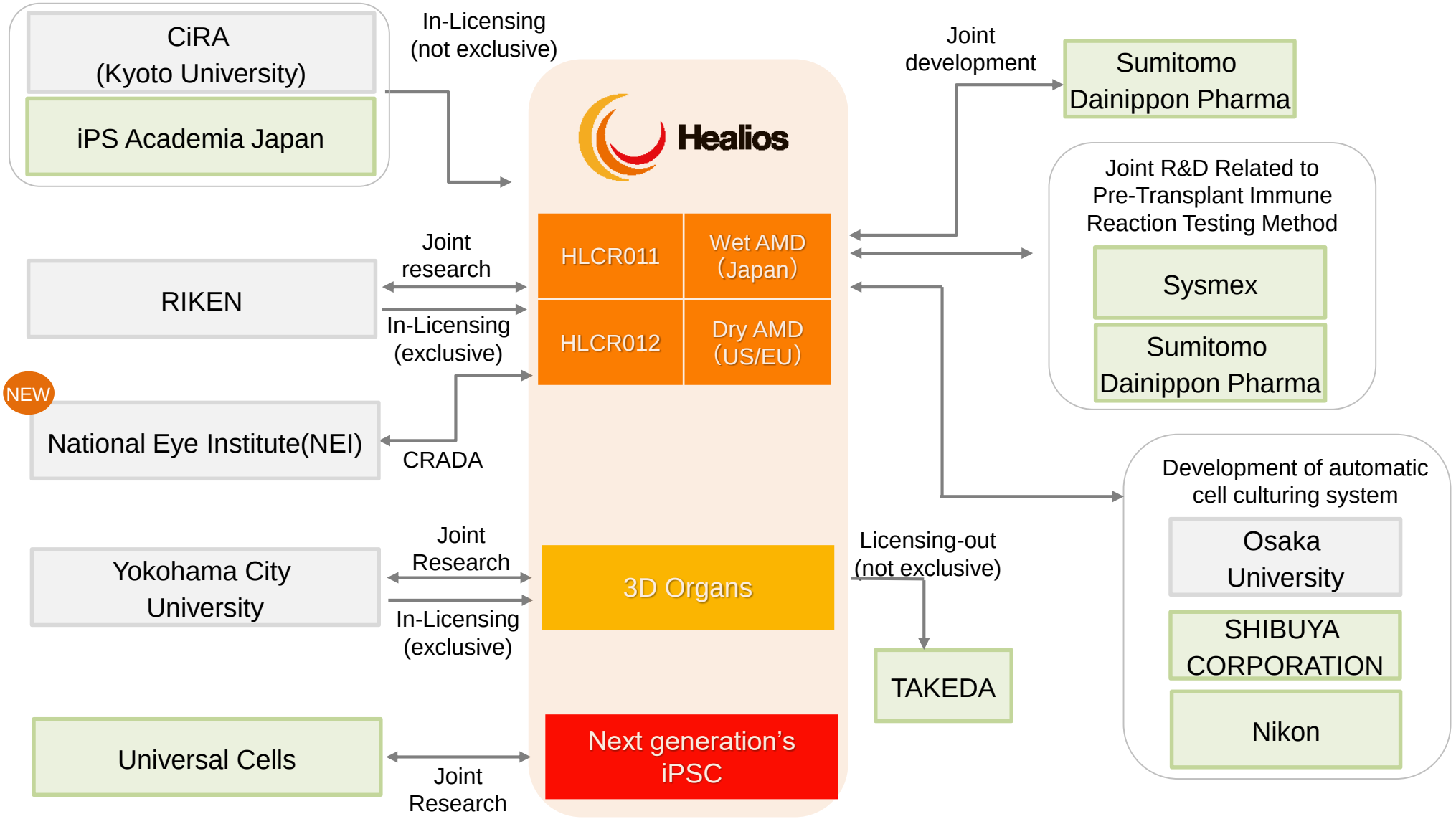
5. Details of iPSC Regenerative Medicine

iPSC Regenerative Medicine field: Business Partners

UPDATE



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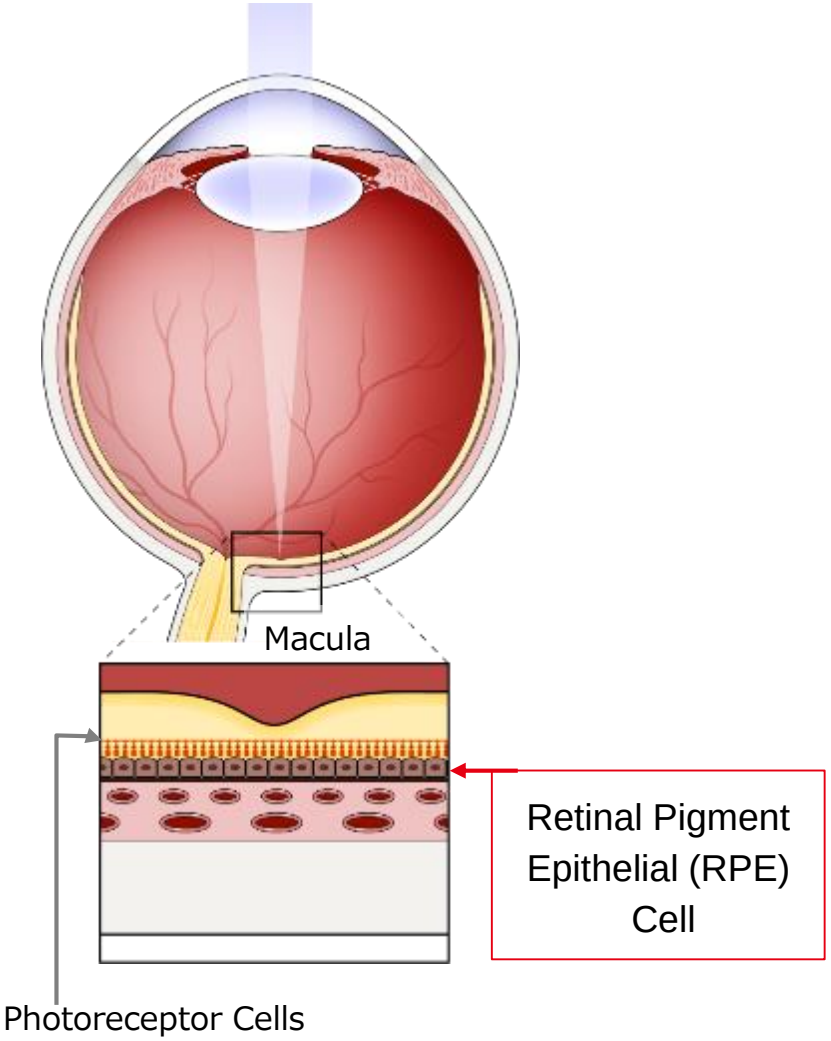
Explanation of AMD pathological condition

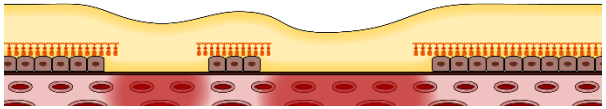
AMD causes RPE cells to degenerate, which damages function.



Regular Macular Part

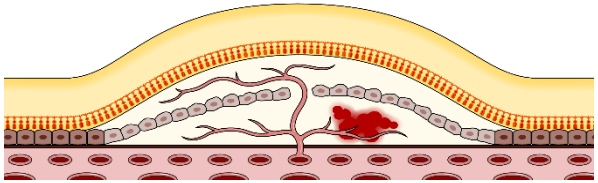
Developed Dry AMD

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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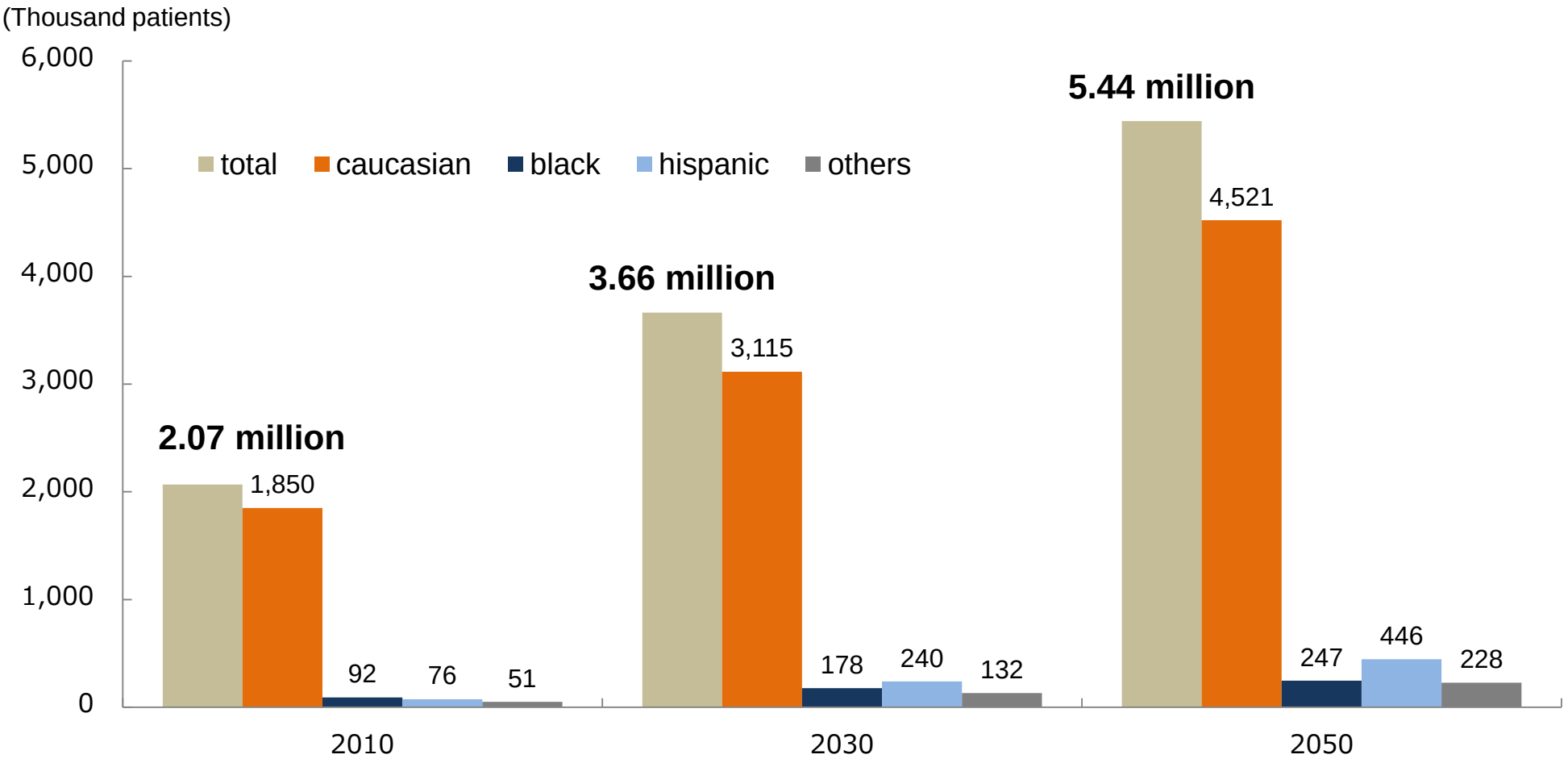
Estimated number of future serious case AMD patients in the US

Expected to increase over medium- to long-term as society ages



(source) National Eye Institute

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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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Market scale of anti-VEGF treatment

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

Indication	Medicine / Effect	year	America	Japan	Others	Total
WetAMD and Other 3 diseases	Anti-VEGF treatment/ Restraint of New Blood Vessels	2015	3,853 million USD	496 million USD	2,661 million USD	7,010 million USD
		2016	4,729 million USD	580 million USD	3,127 million USD	8,436 million USD
		2017	5,116 million USD	632 million USD	3,483 million USD	9,231 million USD
DryAMD	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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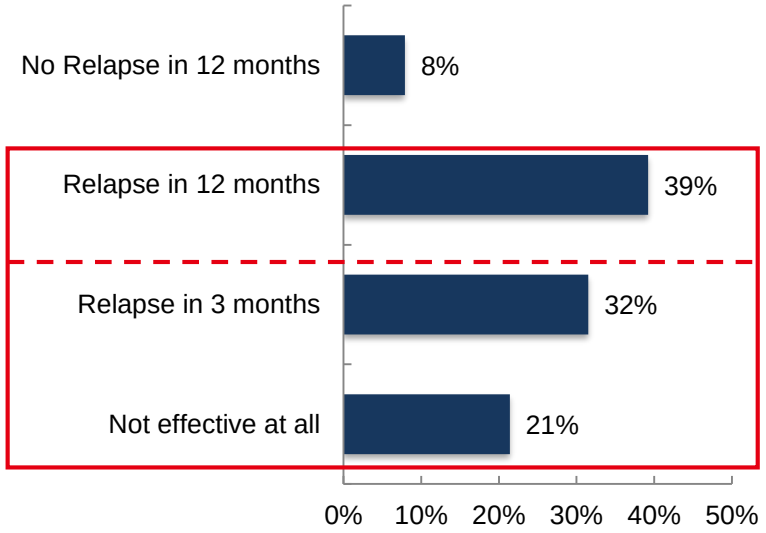
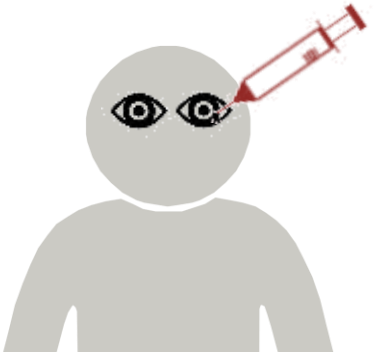
Treatment subjects for Wet AMD

Recurrence frequency after receiving anti-VEGF medication



92% of patients
recur within 1 year

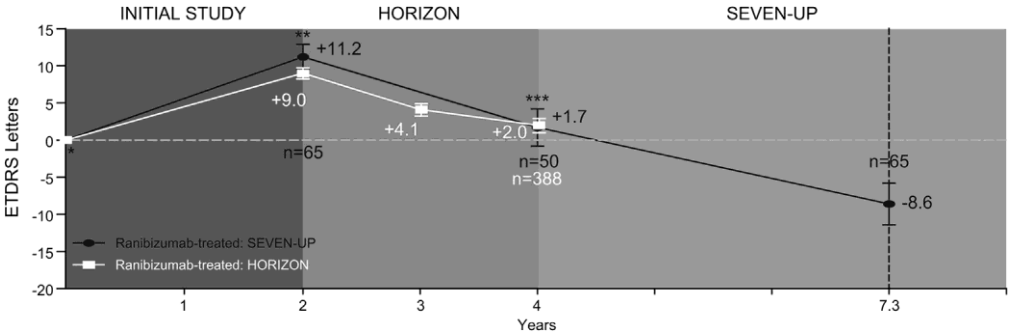


(Source) 13th Annual Meeting of The Japanese Society for Regenerative Medicine March 19th 2014, Thurs, 12:00～12:50 Approach to Clinical Application of iPS cells Institute of Physical and Chemical Research, Mandai Michiko

Changes in vision after receiving anti VEGF medication for long term

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

Receiving anti-VEGF medication for long term remains at risk for substantial visual decline



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

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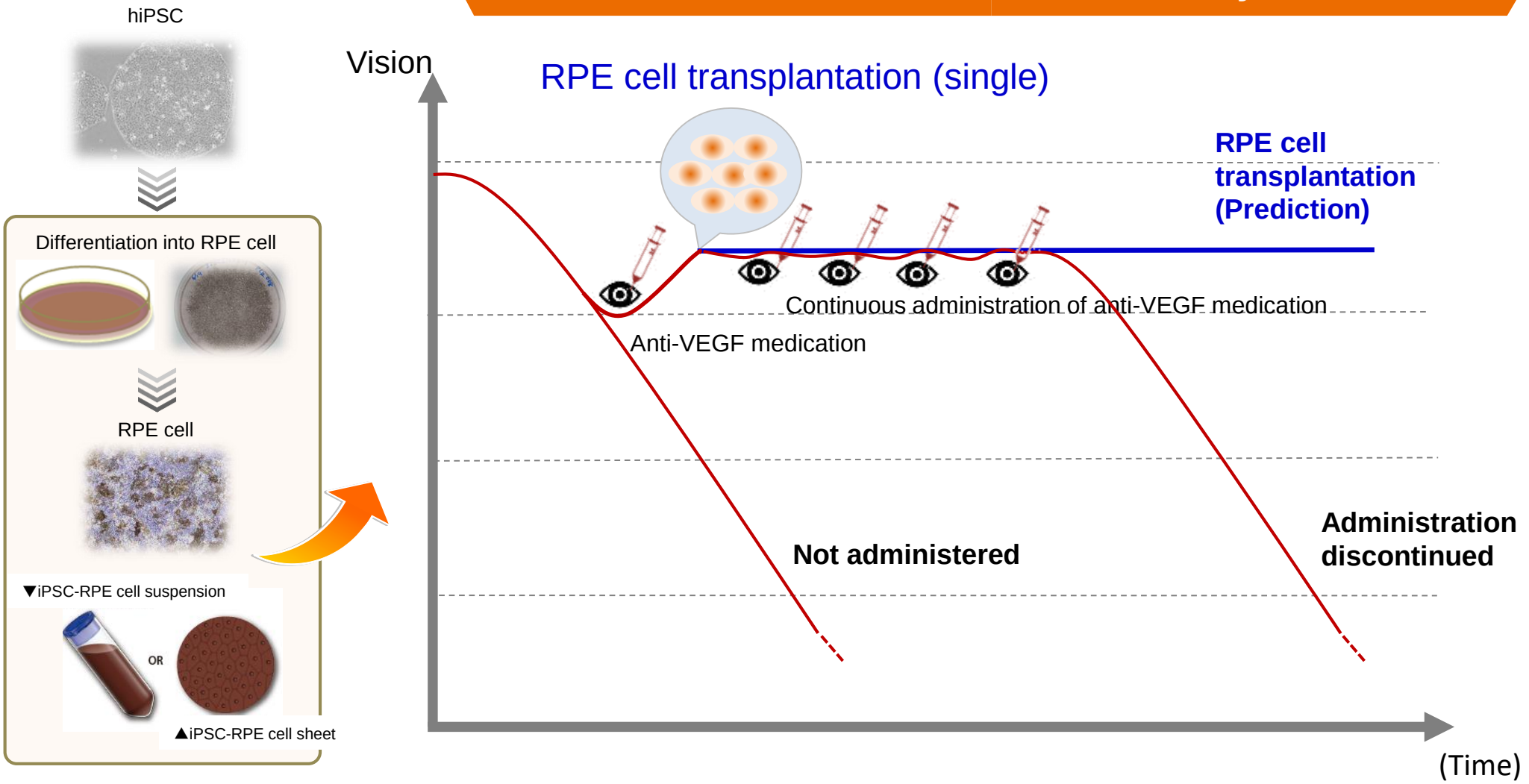
Image of changes in vision with iPSC-RPE cell products treatment

Good vision can be maintained with early 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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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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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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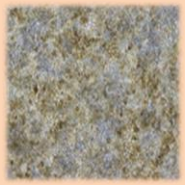
Manufacturing for iPSC-derived RPE products

iPSC Regenerative medicine

RPEs in Japan



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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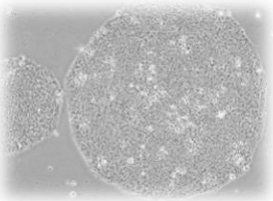
6. Expansion to 3D Organs (Liver)

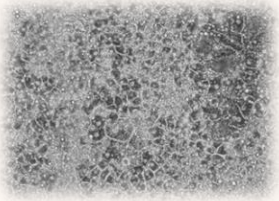
3D organ generation mechanism

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

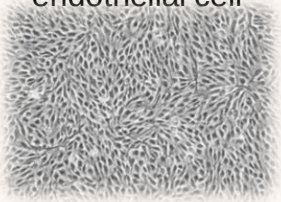
Human iPS cell



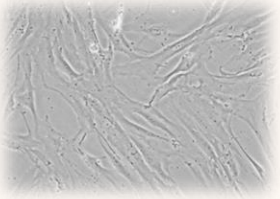
Precursor cell



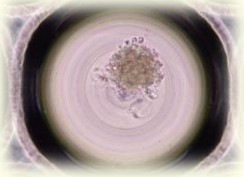
Vascular endothelial cell



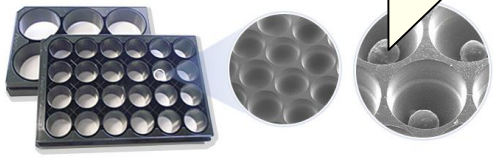
MSC



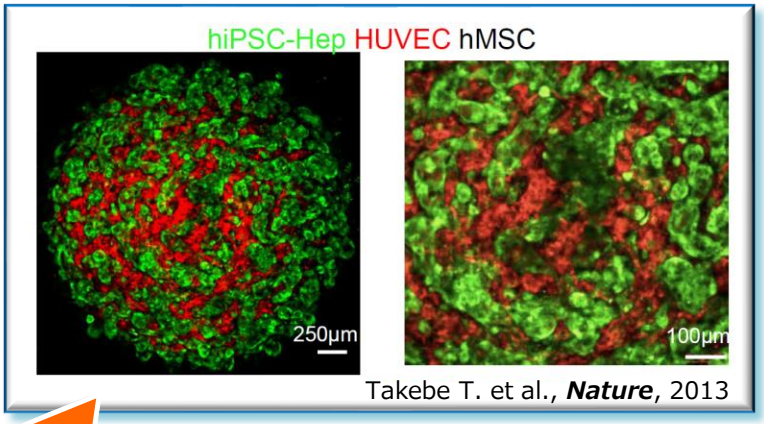
Organ bud*



Organ bud=
Origin of organ

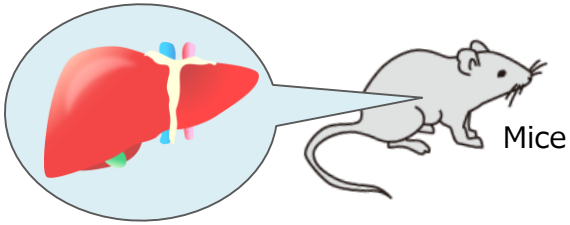


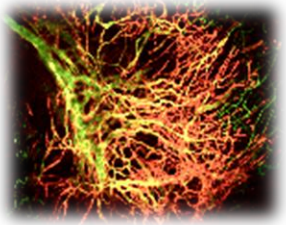
“Elplasia” from Kuraray Co., Ltd.
(http://www.elplasia.com/products/round_bottom/)



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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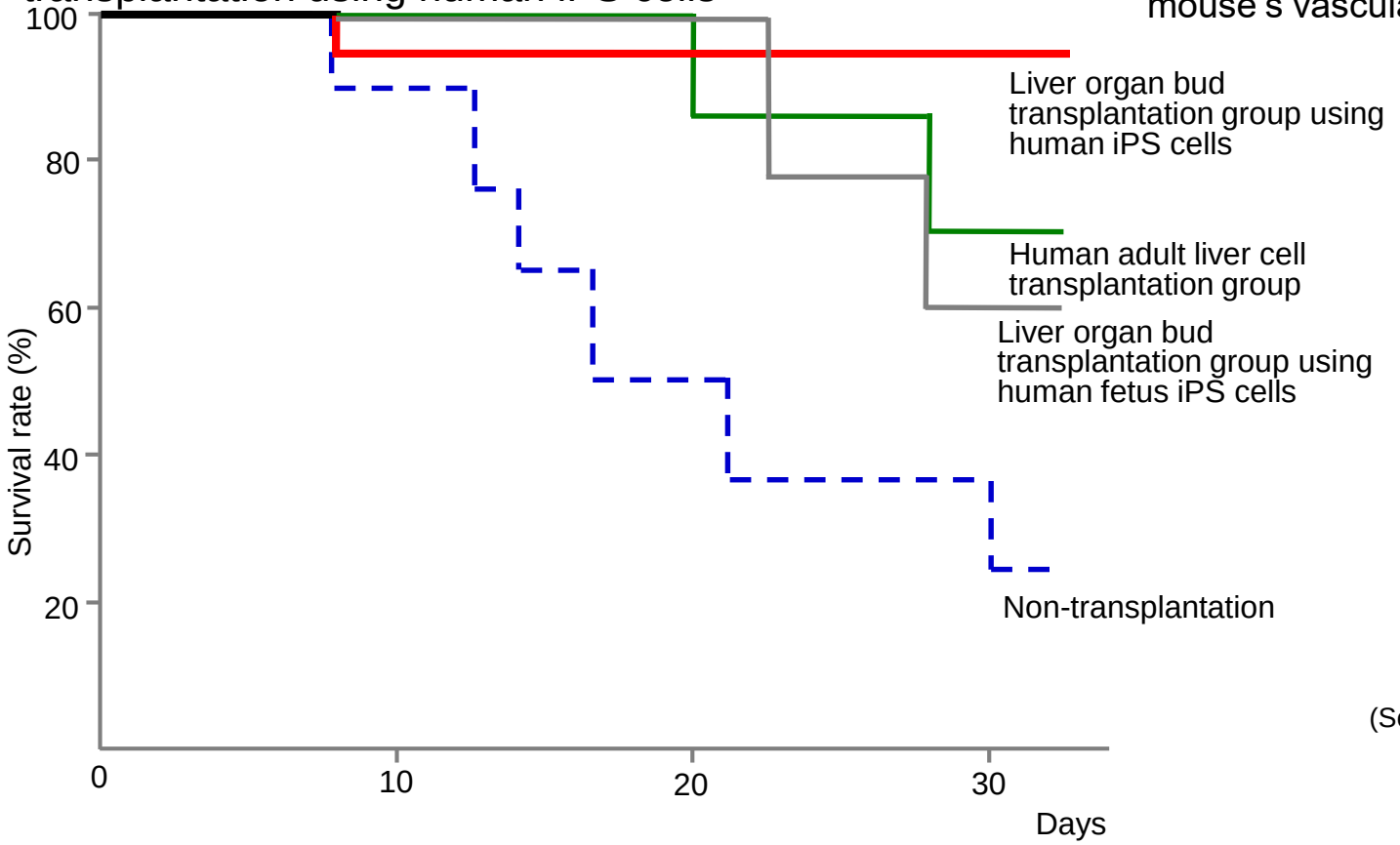
Survival rate of liver failure in mouse model

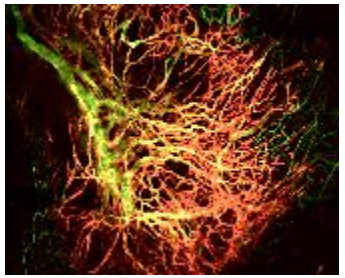
Survival rate improves significantly in transplantation experiments

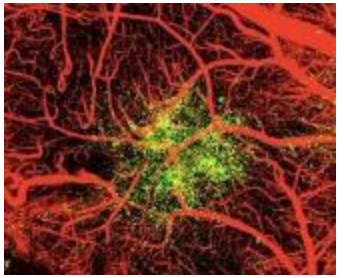
Treatment effects of liver organ bud transplantation using human iPS cells



(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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Yokohama City University planning to start clinical study in 2019

Urea cycle defect

Disease caused by congenital abnormality of enzyme functioning in metabolic pathway (urea cycle), which detoxifies ammonia in the liver and produces urea. Presently, the only definitive treatment available is liver transplantation.

* Even patients with minor conditions require treatment combining food treatment and medication to lower ammonia levels throughout their lives.

Estimated market size of metabolic liver disease in newborns

	US	Japan	Europe	Total
Number of patients (yearly)	**Approx. 160**	**Approx. 30**	**Approx. 230**	**Approx. 420**
Treatment costs (annual) Enzyme replacement therapy	**30 million yen – 50 million yen**			
Estimated annual market scale	**5 - 8 billion yen**	**1 - 1.5 billion yen**	**6 - 11.5 billion yen**	**12 - 21 billion yen**

∗ Number of patients and market size are estimated by Healios based on number of newborns and incidence rate.

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Expansion of Marketability
(Alternative treatment for replacing liver transplantation)

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**

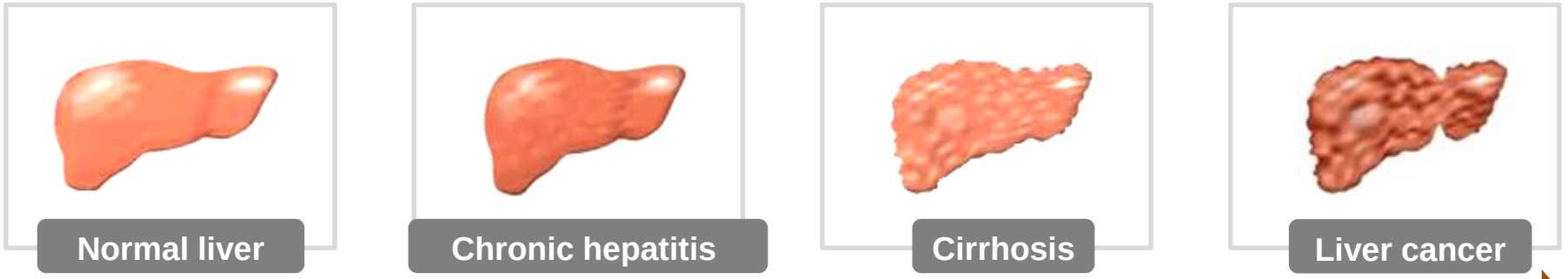
（Source） Compiled by Healios based on materials disclosed by Japanese Liver Transplantation Society, UNOS, Eurotransplan, UK Transplant, Agence de la biomédecine, and Scandia Transplant.

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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7. Company Overview

Healios Overview

UPDATE

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
Paid in Capital	11,386 million yen (As of end of June, 2018)
Number of Employees	86 (As of end of June, 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)

Our Experienced Executive officers

Chairman and CEO Hardy TS Kagimoto, MD		■ Succeeded in Developing BBG250 and Realized Sales in Europe
CMO (Chief Medical Officer)	Masanori Sawada, MD, PhD, MBA	■ Osaka University Invited Associate Professor
In charge of Research and Manufacturing/ Head of Kobe Research Lab.	Kouichi Tamura, PhD	■ Astellas US Director of Laboratories ■ Well-acquainted with Immunosuppressant Research
In charge of Development	Michihisa Nishiyama	■ Constructed network for Tacrolimus approval and sales at Astellas in the US and Europe
In charge of Administrative field	Ken Ishikawa	■ Striving to strengthen organizational capabilities

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Company History and Societal Trends

UPDATE

Healios

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 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.

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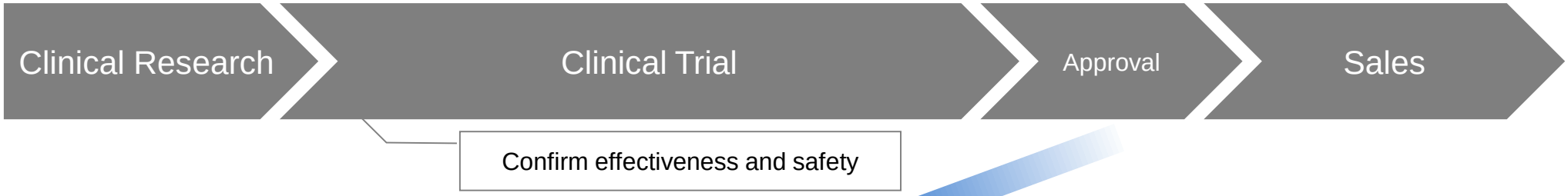
8. Circumstances of Regenerative Medicine

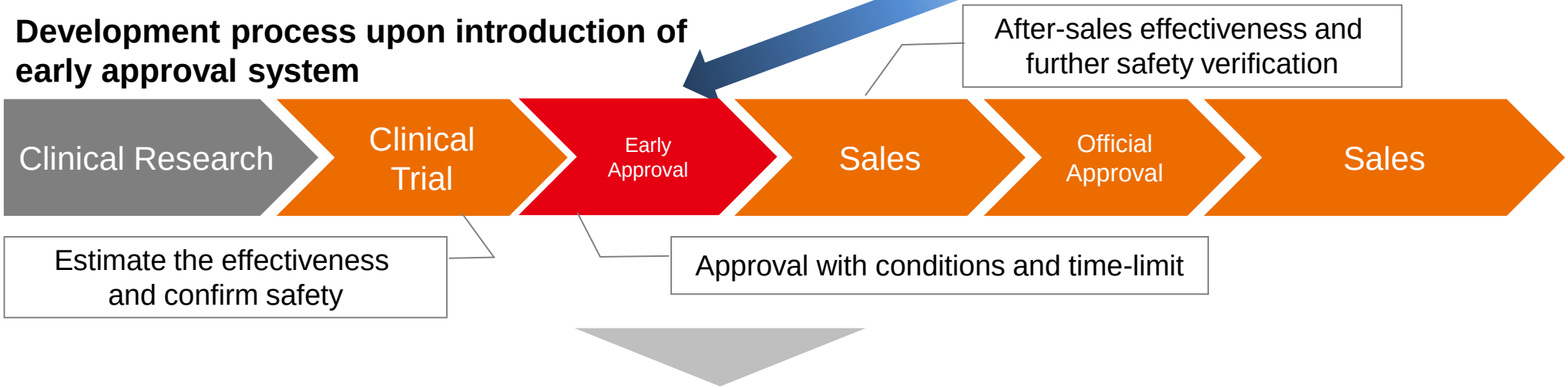
Historical Alleviation of Regulations

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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Rapid impact of modified regulations

Approval of regenerative medicine products, September 2015

Product Name	Temcell® HS Injection	Heart Sheet
Company	JCR Pharmaceuticals	Terumo
Indications	Acute GVHD after hematopoietic stem cell transplantation	Severe heart failure due to ischemic heart disease
Price	13.9 million yen	14.76 million yen
Important Point	First allogeneic cell-based regenerative product	First conditional approval

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

Price calculation method prospects

Cost accounting system

* The price of new drugs is basically calculated according to the prices of official articles with similar efficacy (price determination by comparable drug). However, if there are no appropriate similar official articles, required costs are added in the calculation of prices (cost accounting system).

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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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