Healios

FY2019 Q1 Financial Results

May 14, 2019

HEALIOS K.K.

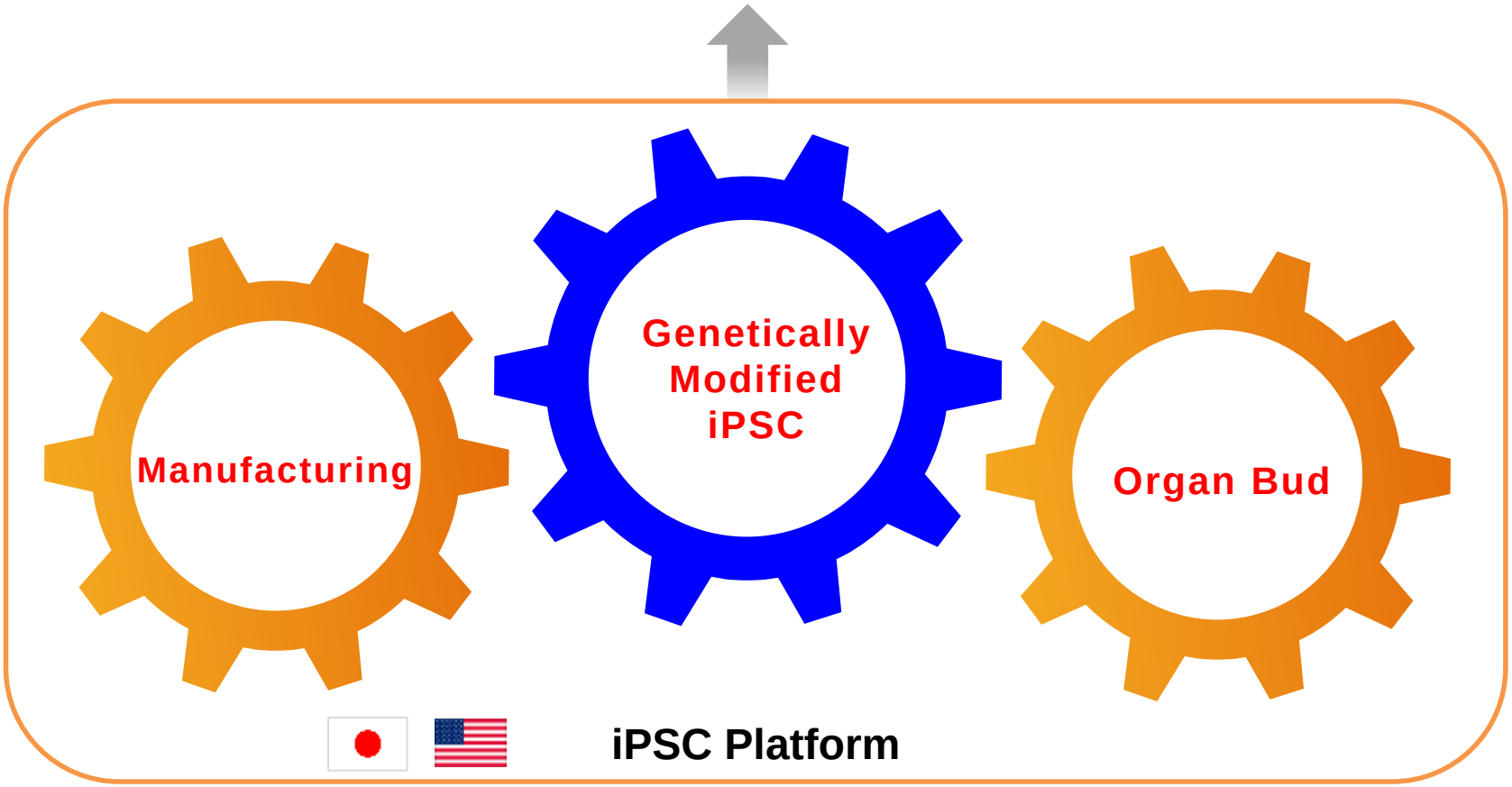
（TSE：4593）

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

Contents

Strategy

New Products: **Immuno-oncology, Liver Bud**



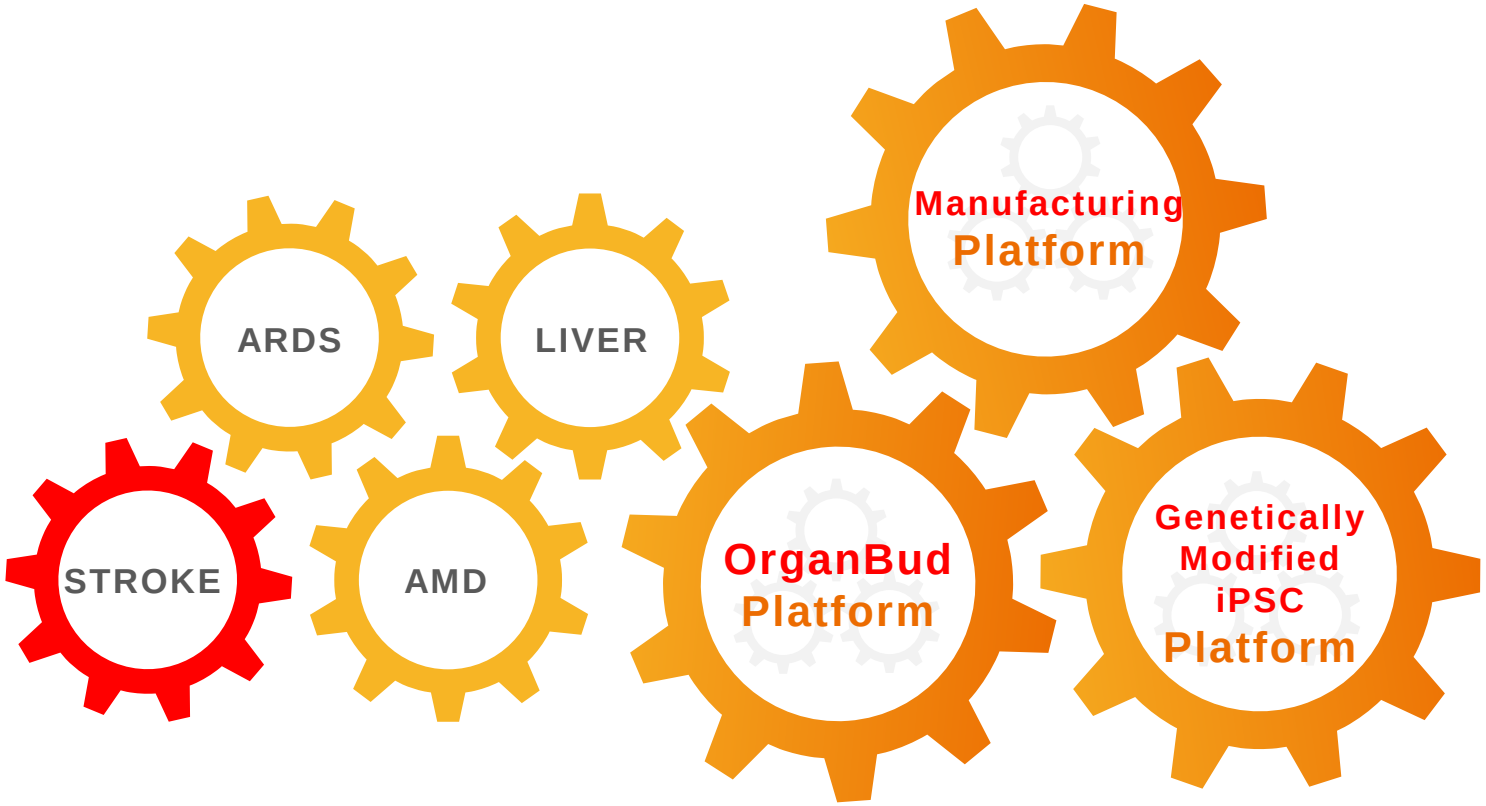
Reinvest

MultiStem
(Somatic stem cell product obtained from adult bone marrow)

Pipeline

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	→				**First patient enrolled in April 2019**
	iPSC Regenerative Medicine	**HLCR011**	Wet AMD	→				Undergoing preparation for clinical trial
		HLCL041	Metabolic Liver Disease	→				Joint research with Yokohama City University

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



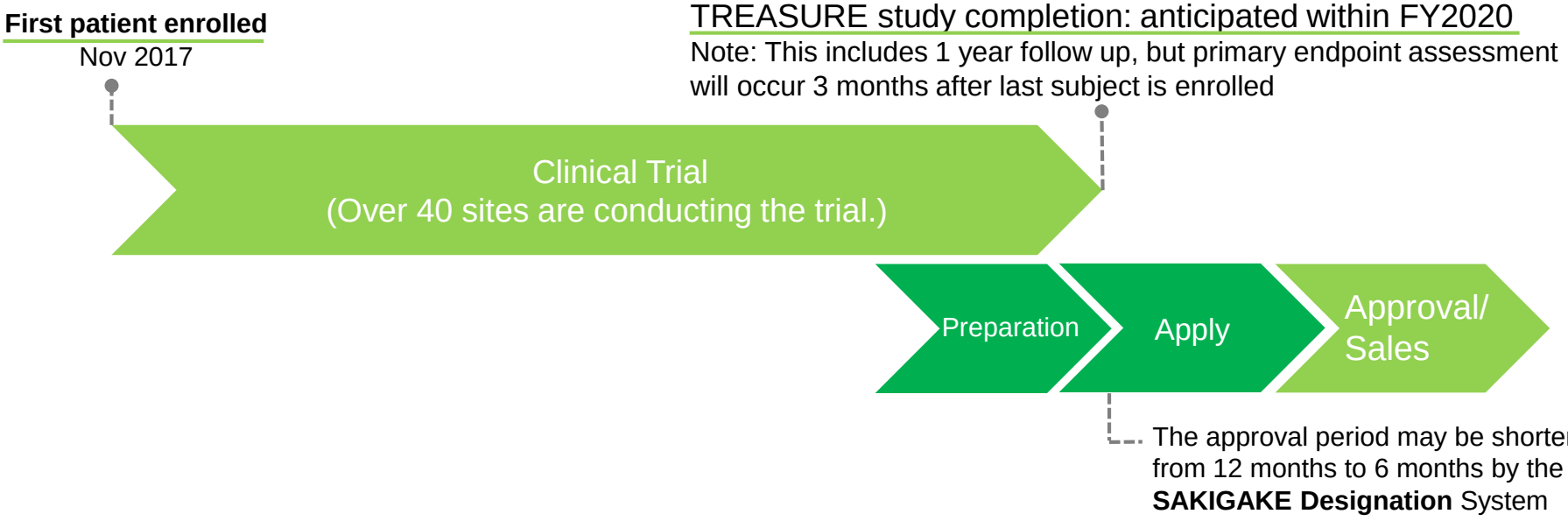
HLCM051 Stroke TREASURE Study Ongoing

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

Subjects : Ischemic stroke within 18 to 36 hours

Enrollment : 220 (HLCM051 [n=110], placebo [n=110], randomized)
Placebo-Controlled, Double-Blind

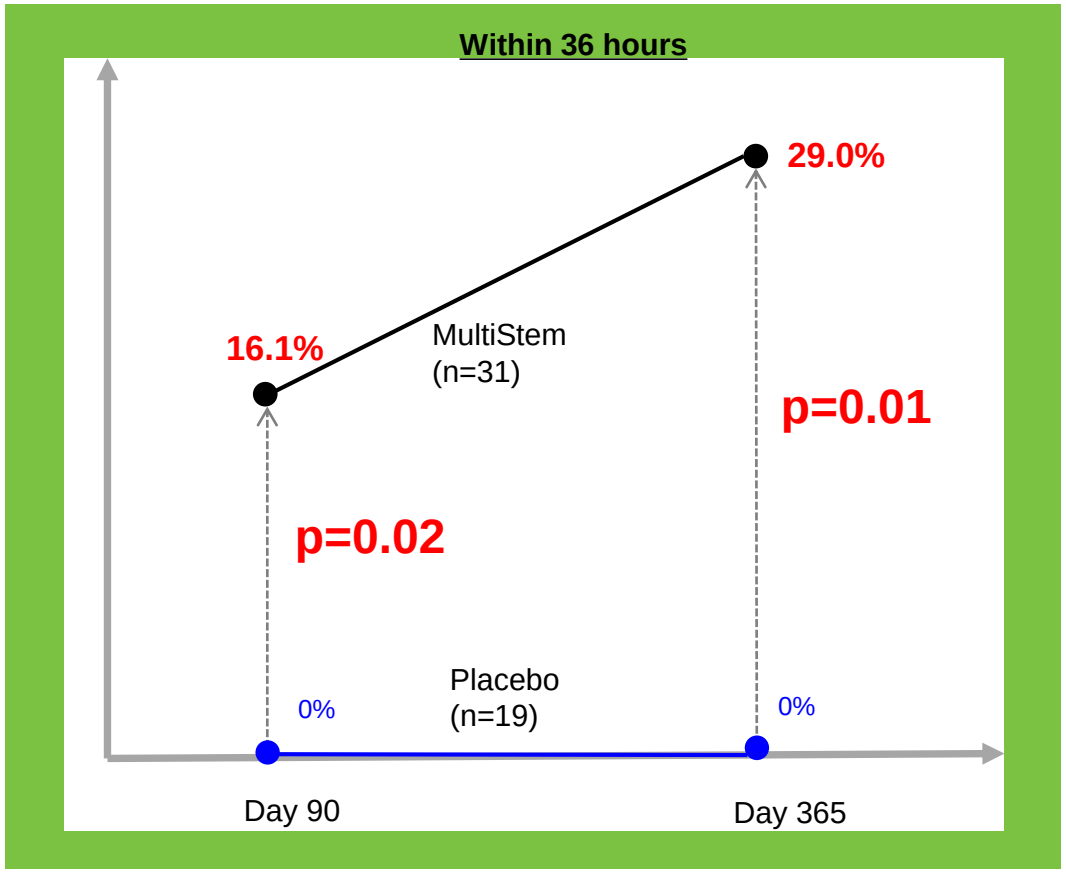
Primary Endpoint : Proportion of subjects with an **excellent outcome** defined by functional assessments
[Time Frame: Day 90]
“Excellent Outcome” is defined as achieving mRs ≤1, NIHSS ≤1, and BI ≥95.
mRS, NIHSS, and BI are the three major indices of functional assessment for stroke patients.



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:
Administered 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).

HLCM051 Stroke Outline of ischemic stroke in Japan

Ischemic stroke

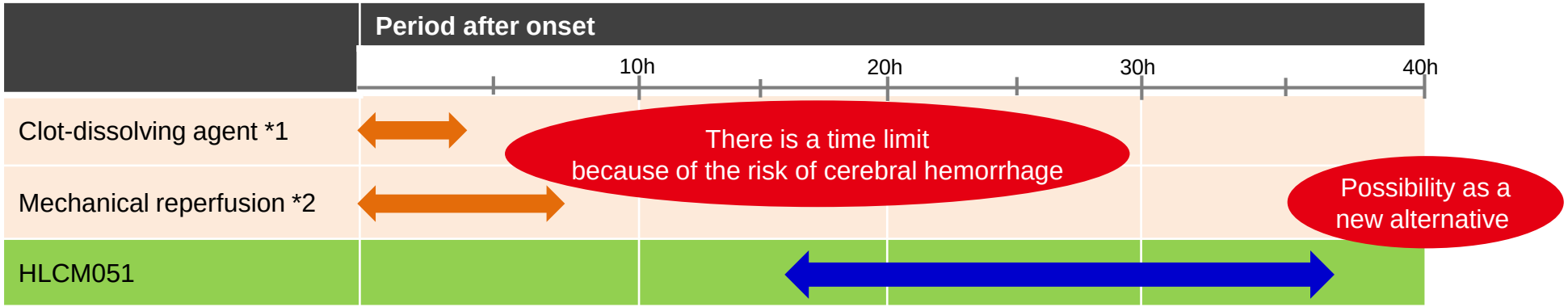
Ischemic stroke, which represents the most common form of stroke (70 - 75% of cases in Japan), is caused by a blockage of blood flow in the brain that cuts off the supply of oxygen and nutrients, resulting in tissue loss.

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.

HLCM051 Stroke Annual number of new patients with ischemic stroke in Japan

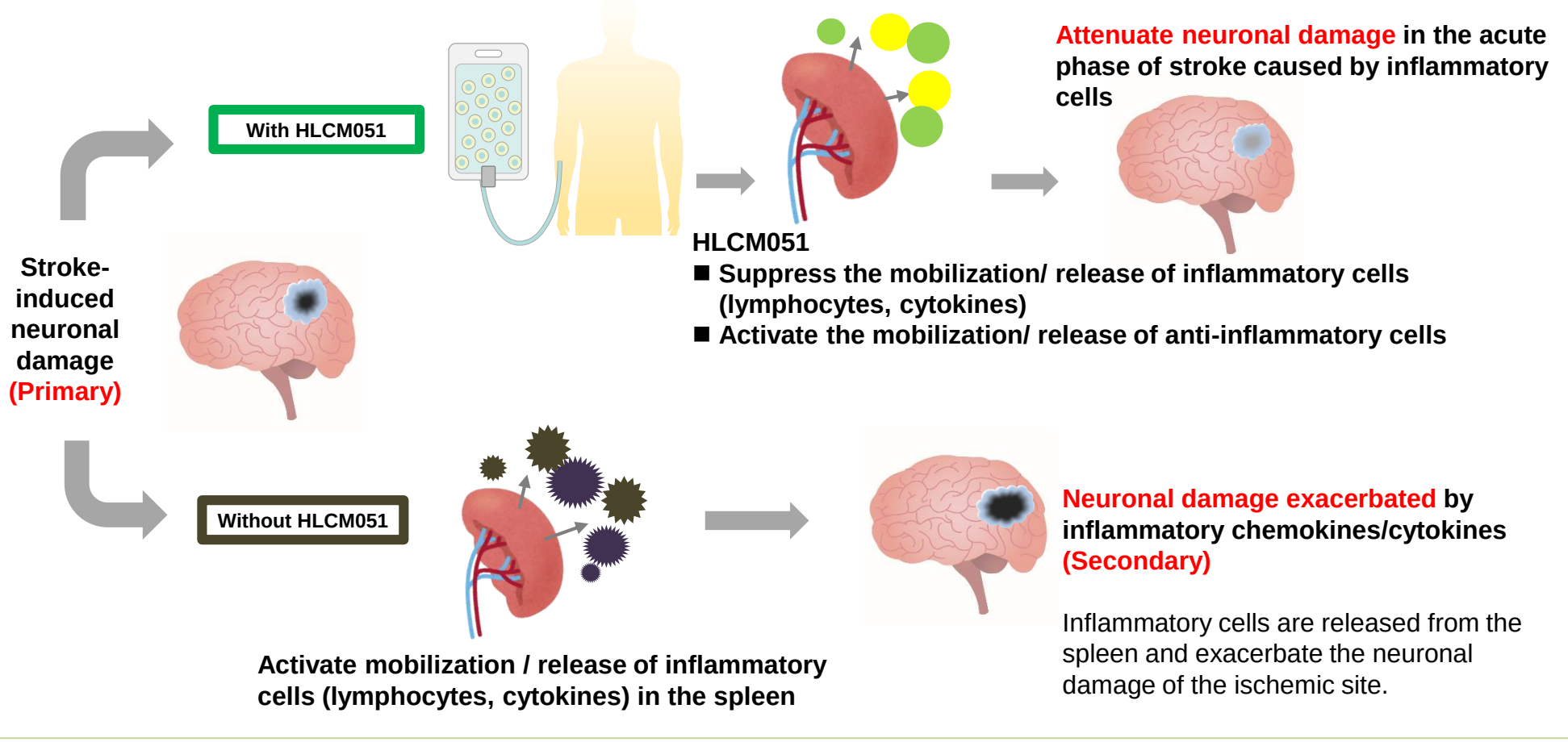
	Japan	Note
Number of patients (yearly)	**230,000 – 330,000**	Annual medical costs for ischemic stroke estimated at 1,070.7 billion yen（2009）
Severe patients（atherothrombotic and cardiogenic cerebral infarction)	**130,000**	
patients within 36 h after onset	**62,000**	

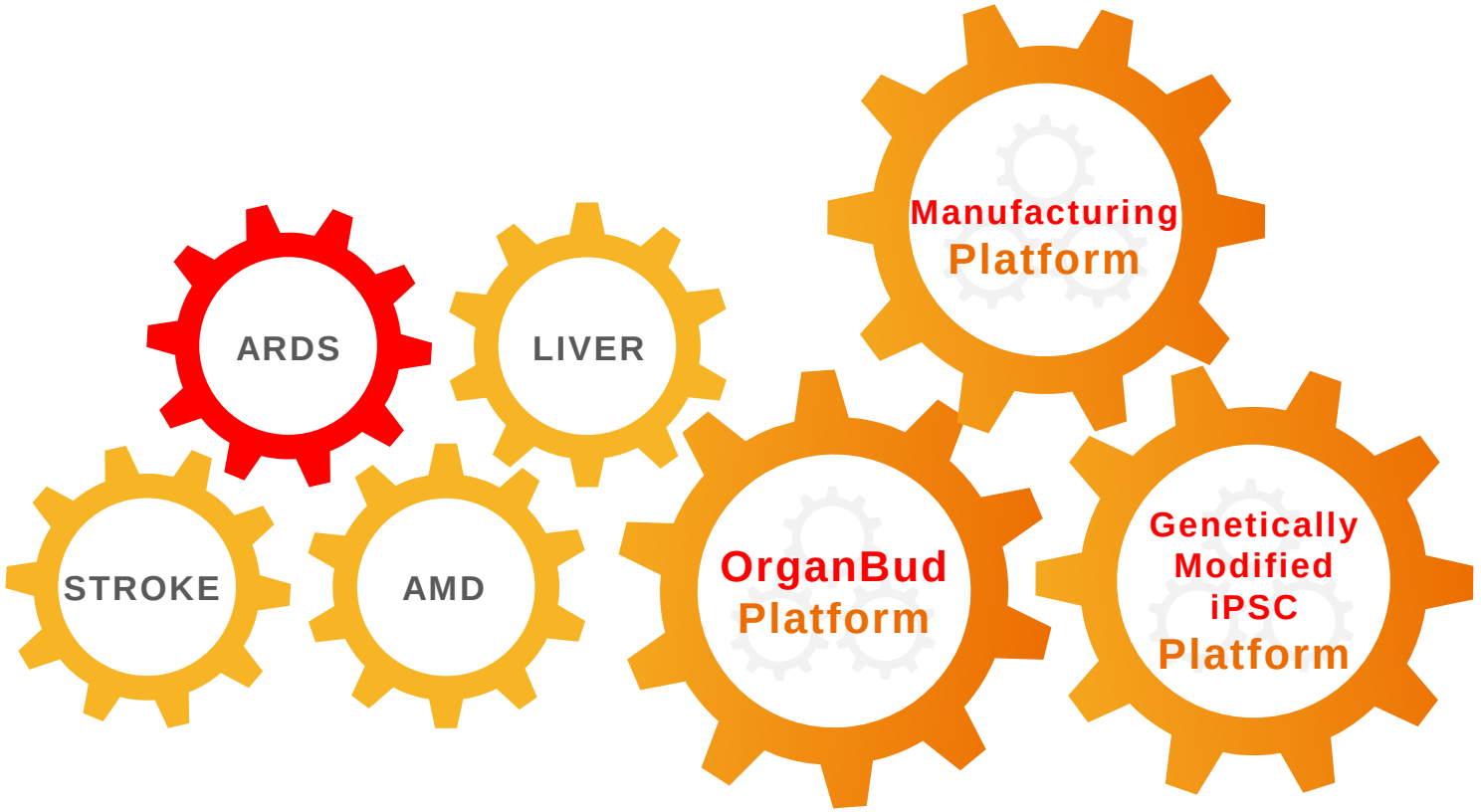
(Source) Healios estimated the annual number of new patients with ischemic stroke in Japan according to materials issued by the Fire and Disaster Management Agency, the Ministry of Internal Affairs and Communication, and the Ministry of Health, Labour and Welfare – DATAMONITOR epidemiological estimates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

HLCM051 Stroke 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.



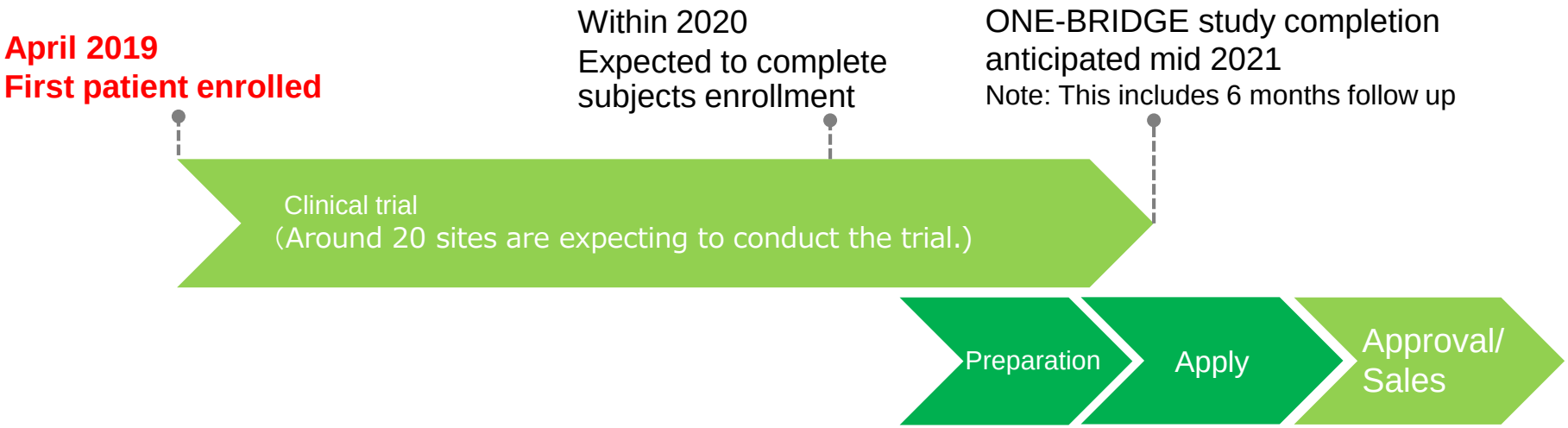


UPDATE

HLCM051 ARDS ONE-BRIDGE Study Ongoing

Efficacy and Safety Study of HLCM051 (MultiStem®)
For Pneumonic Acute Respiratory Distress Syndrome (ONE-BRIDGE)

Subjects: Patients with pneumonia induced ARDS
Enrollment: 30 (MultiStem 20, Standard therapy 10) Randomized
Open label, Standard therapy-controlled
Primary endpoint: The number of days out of 28 in which a ventilator was not used for the patient
(i.e. ventilator free days)



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

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.

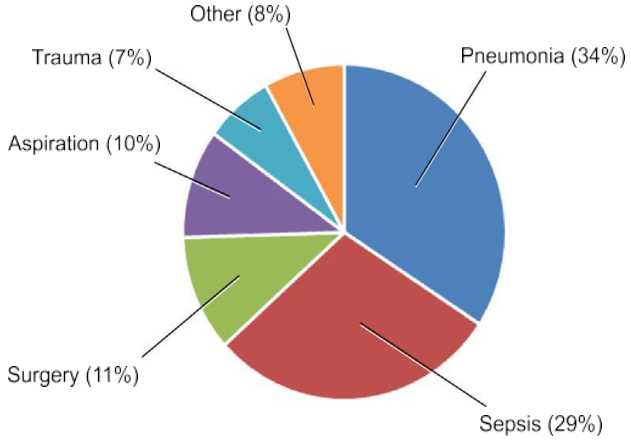
At present, there are no therapeutic drugs that can make a direct improvement to a patient's vital prognosis when ARDS develops. There is a demand for new treatments for ARDS that will lead to improvements in patients' symptoms and prognosis.

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

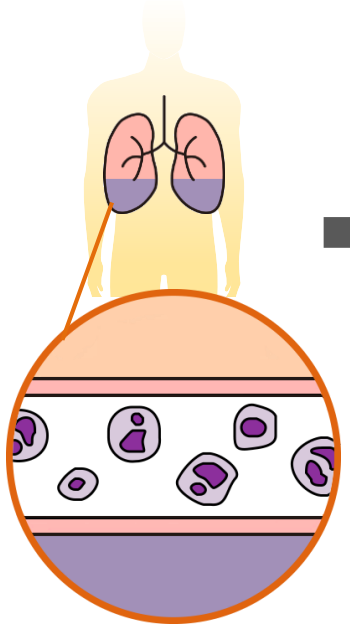
Approximately 1/3 of ARDS patients were caused by pneumonia

* 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)

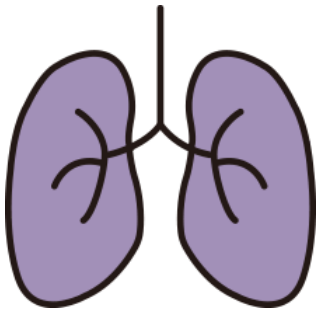
ARDS Pathological Process and HLCM051 Expected Mechanism of Action

- 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.)



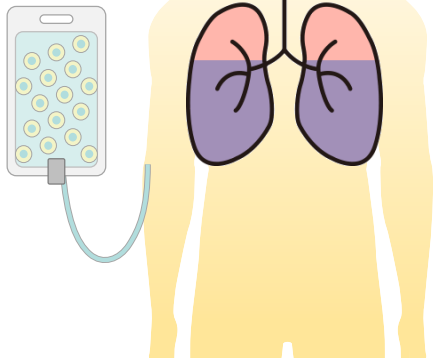
When the tissue is damaged, inflammatory cells are released in large quantities.



The inflammatory cells attack the lungs.

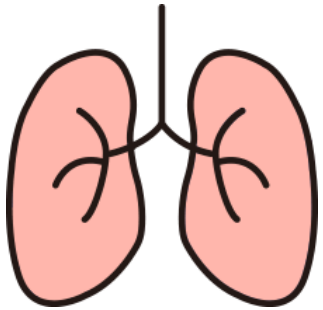
As a result, hypoxia develops and the patient falls into severe respiratory failure.

HLCM051 Administered



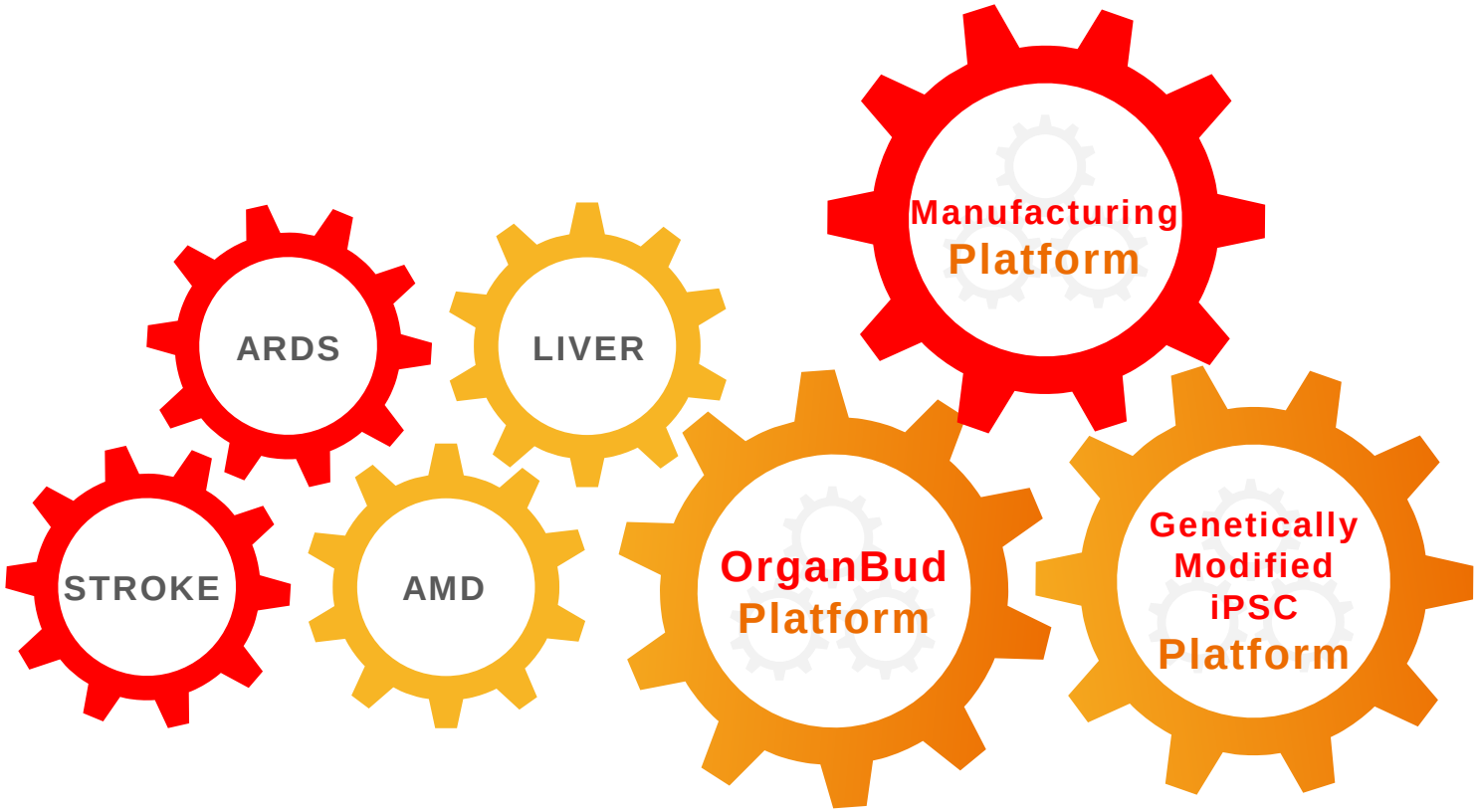
HLCM051 accumulates in the lungs as a result of intravenous administration.

・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.



Athersys' Stem Cell Products: MultiStem®

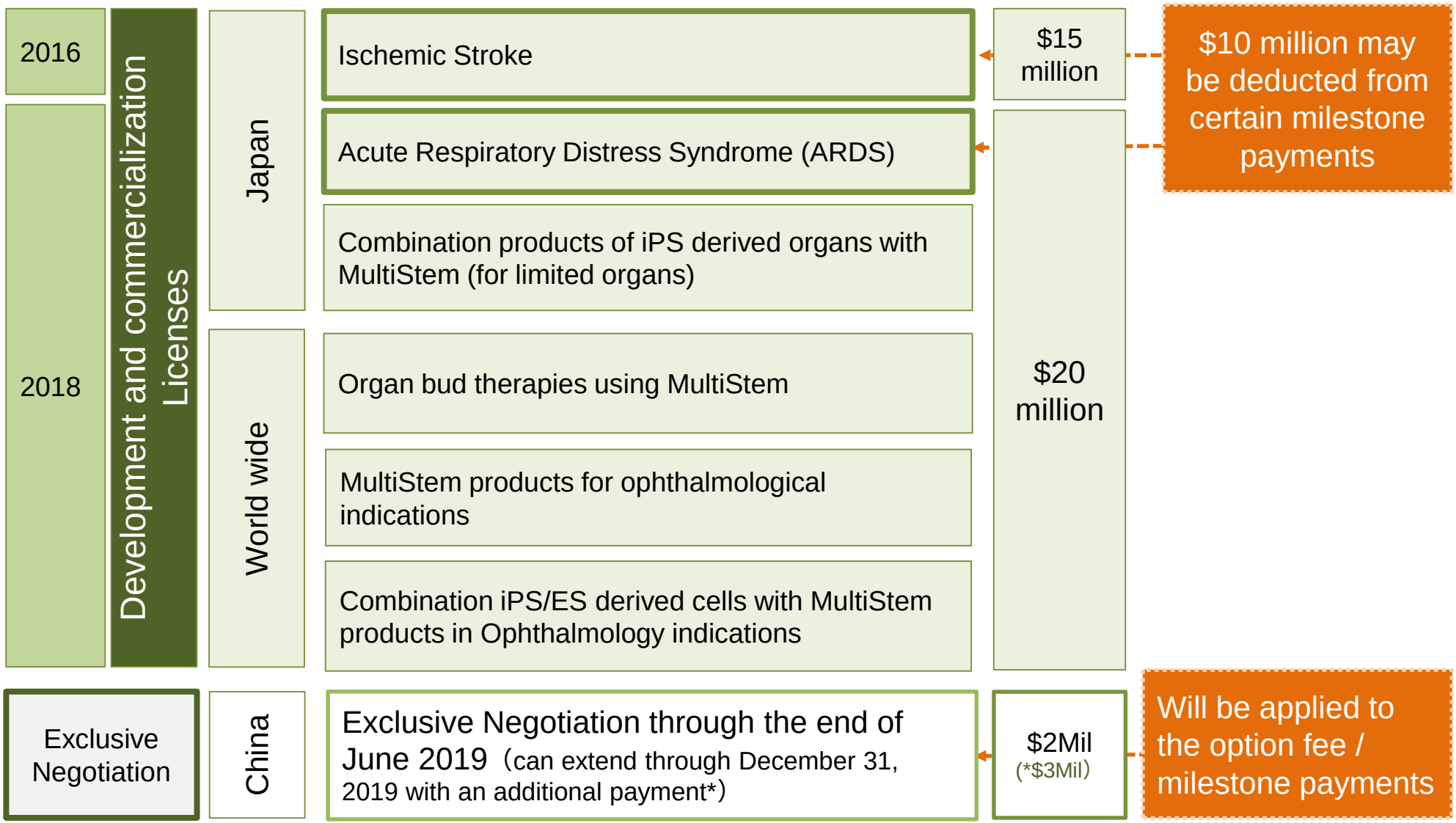
Athersys, Inc.

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

MultiStem

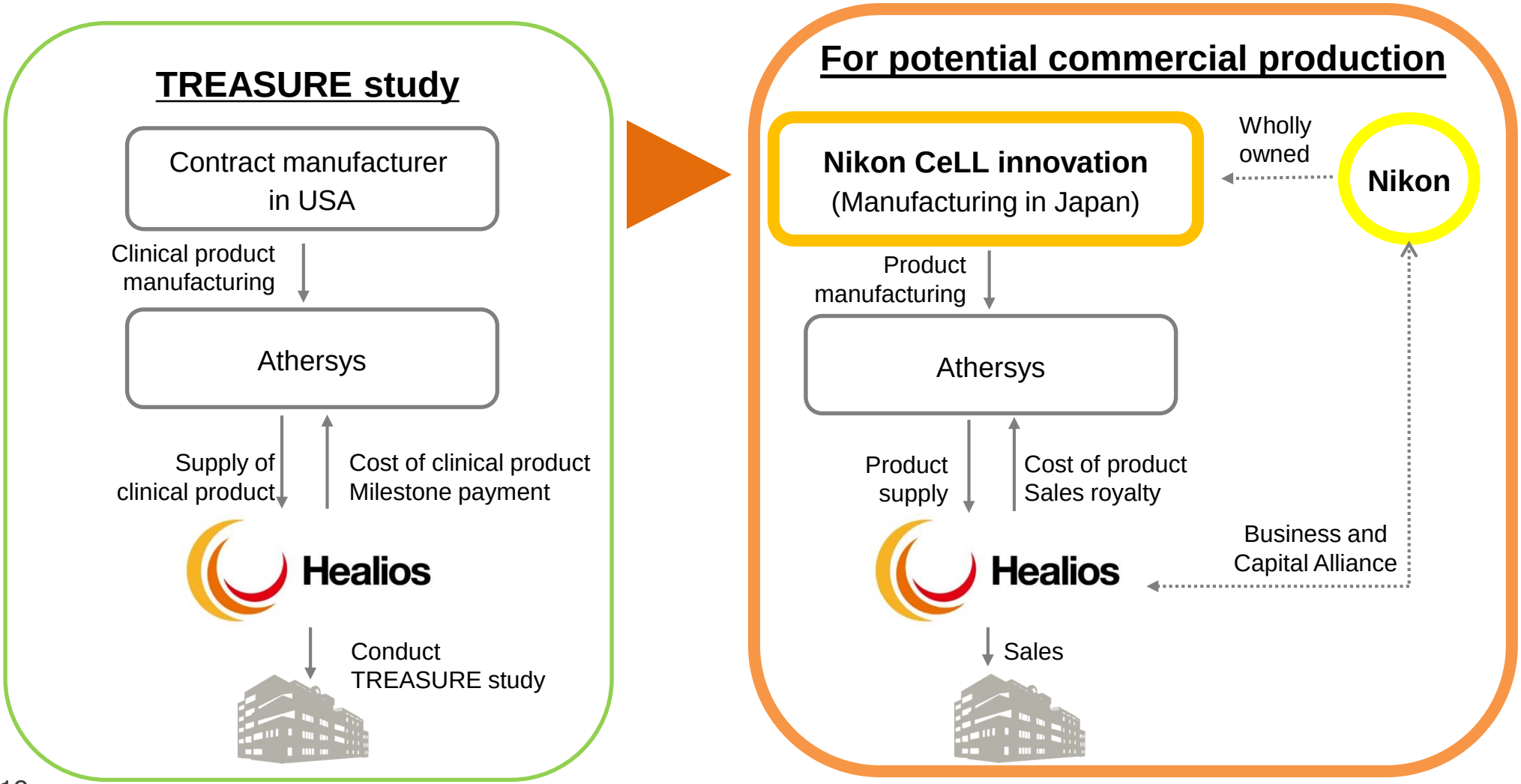
- Cell therapy product based on patented technology
- Developing for "off-the-shelf" administration:
  no tissue matching needed
- Long shelf life: can be kept frozen in a stable condition for years
- Consistent safety profile
- Promotes healing and tissue repair through multiple mechanisms of action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

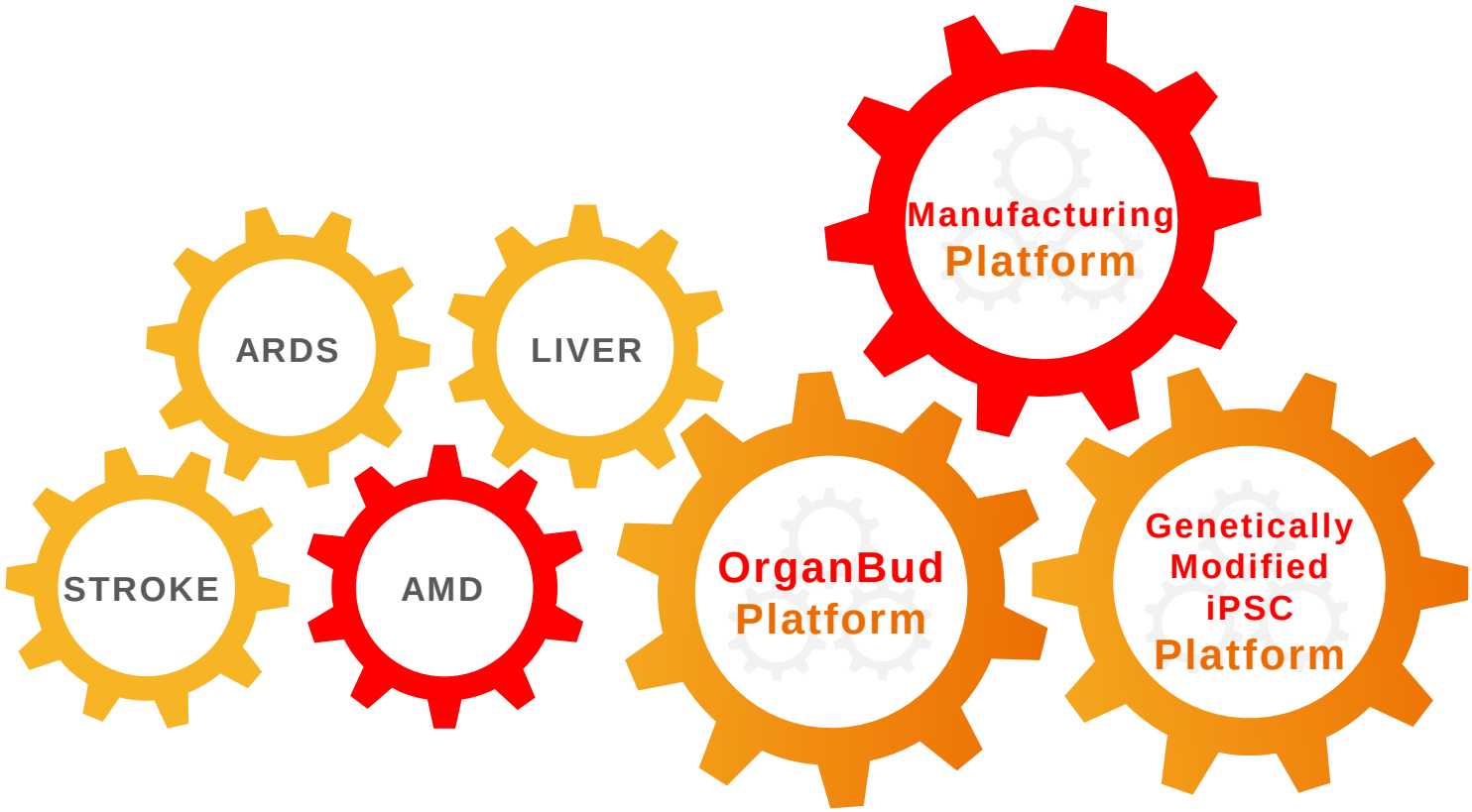
Acquisition of MultiStem License



HLCM051 Business Partners

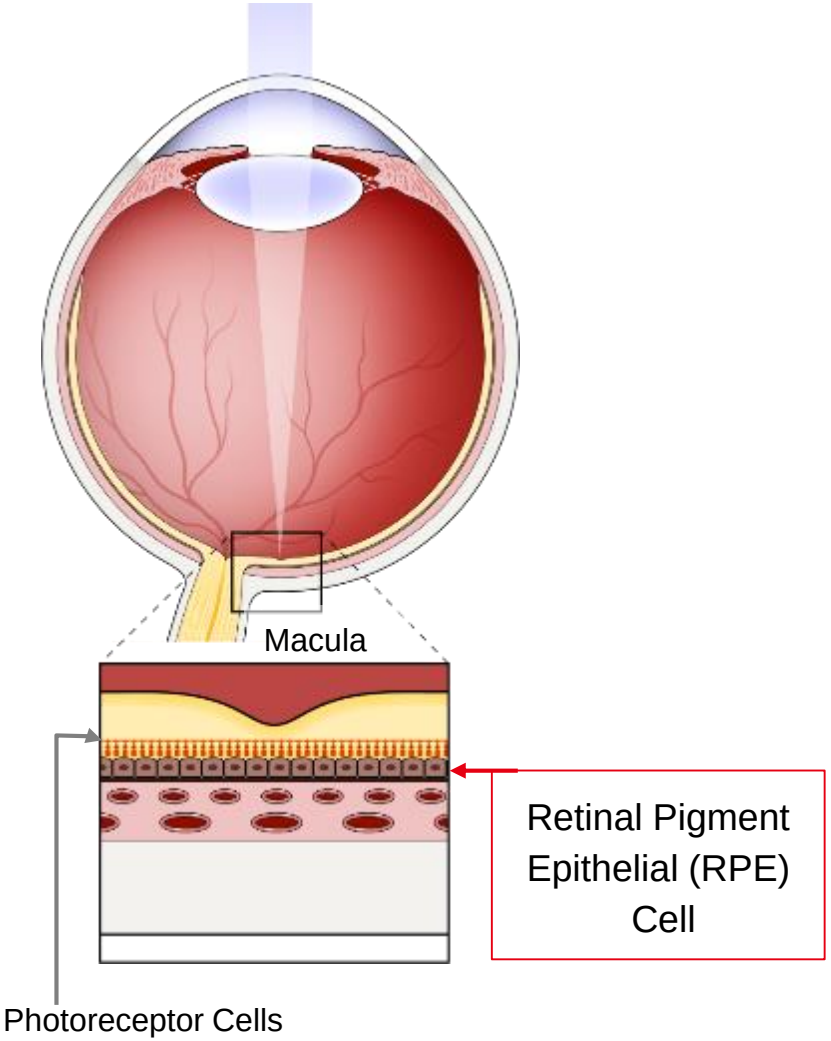
Preparation for the commercialization of HLCM051 ongoing
at Nikon CeLL innovation





HLCR011 AMD Explanation of AMD pathological conditions

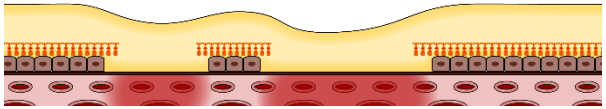
AMD causes RPE cells to degenerate, which damages function.



Regular Macular Part

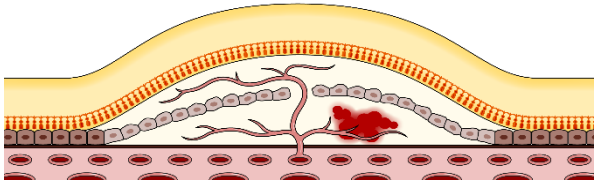
Developed Dry AMD

Immunity barrier maintained
→ Degeneration of photoreceptor→ Dry AMD



Wet AMD

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



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

HLCR011 AMD Market scale of anti-VEGF treatment

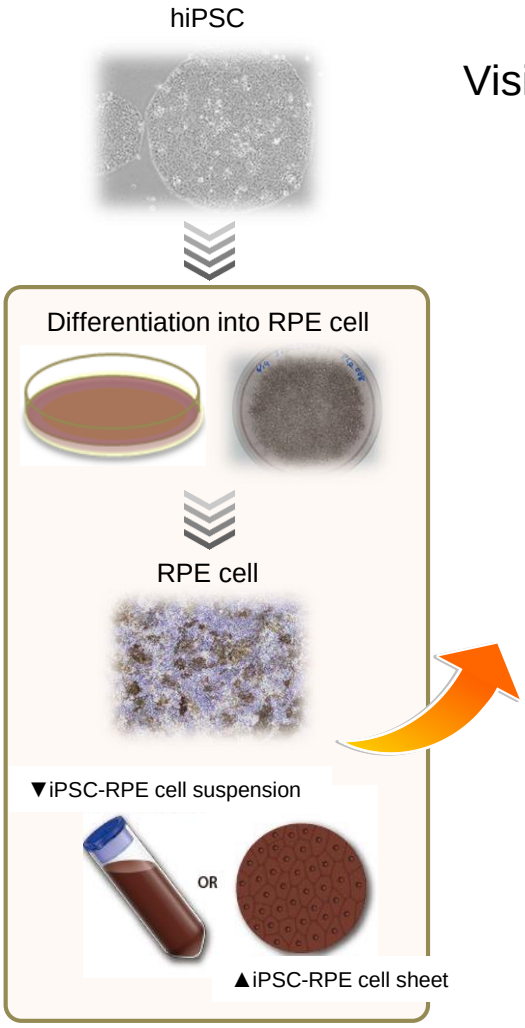
Sales of anti-VEGF treatment are increasing every year. No medicine for Dry AMD.

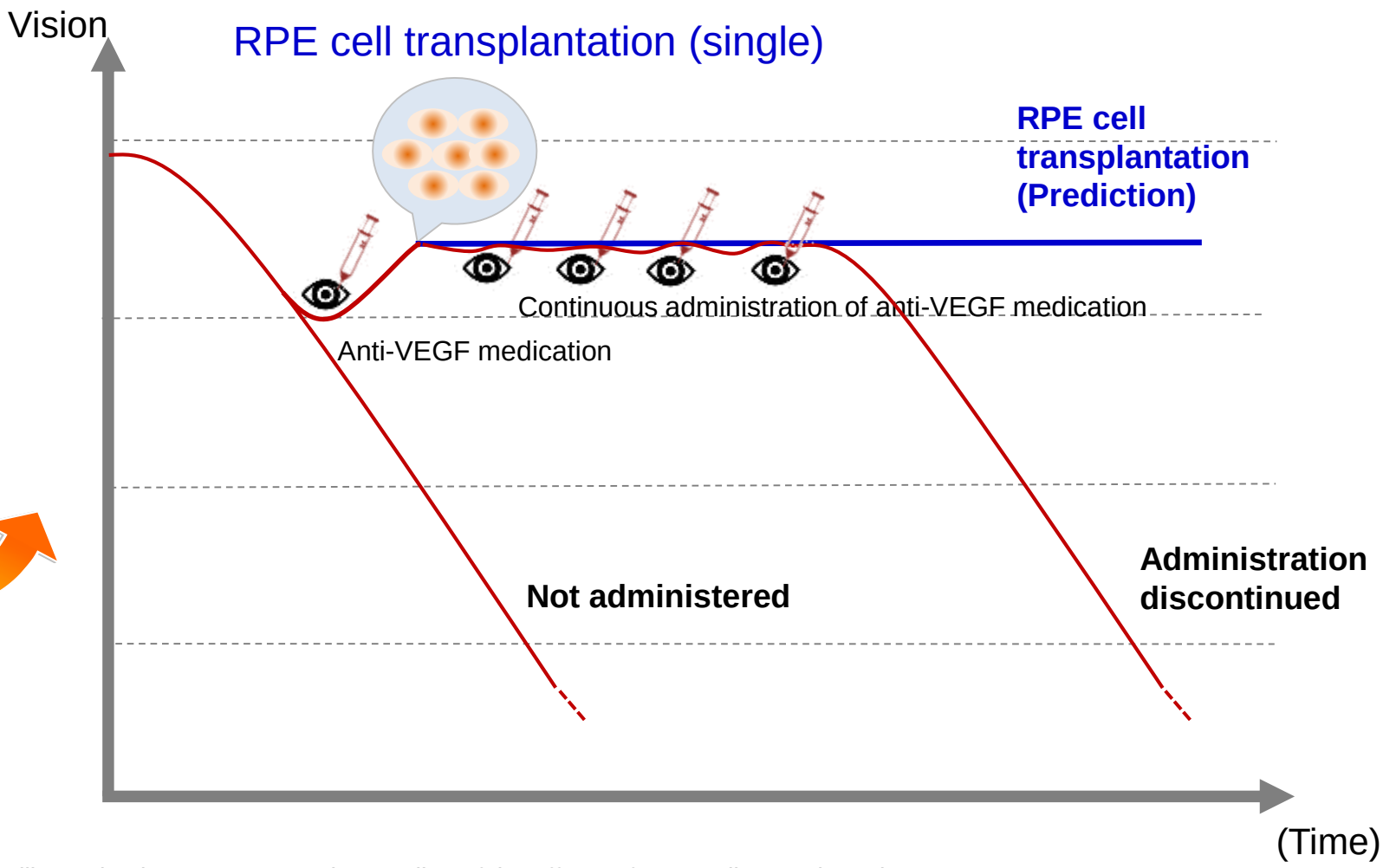
Indication	Medicine / Effect	year	America	Japan	Others	Total
Wet AMD and Other 3 diseases	Anti-VEGF treatment/ Restraint of New Blood Vessels	2015	**3.853 billion USD**	**496 million USD**	**2.661 billion USD**	**7.01 billion USD**
		2016	**4.729 billion USD**	**580 million USD**	**3.127 billion USD**	**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)

HLCR011 AMD 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.

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): 80 years old (Male) / 86 years old (female)

Estimate of Lifetime Medical Expense

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

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

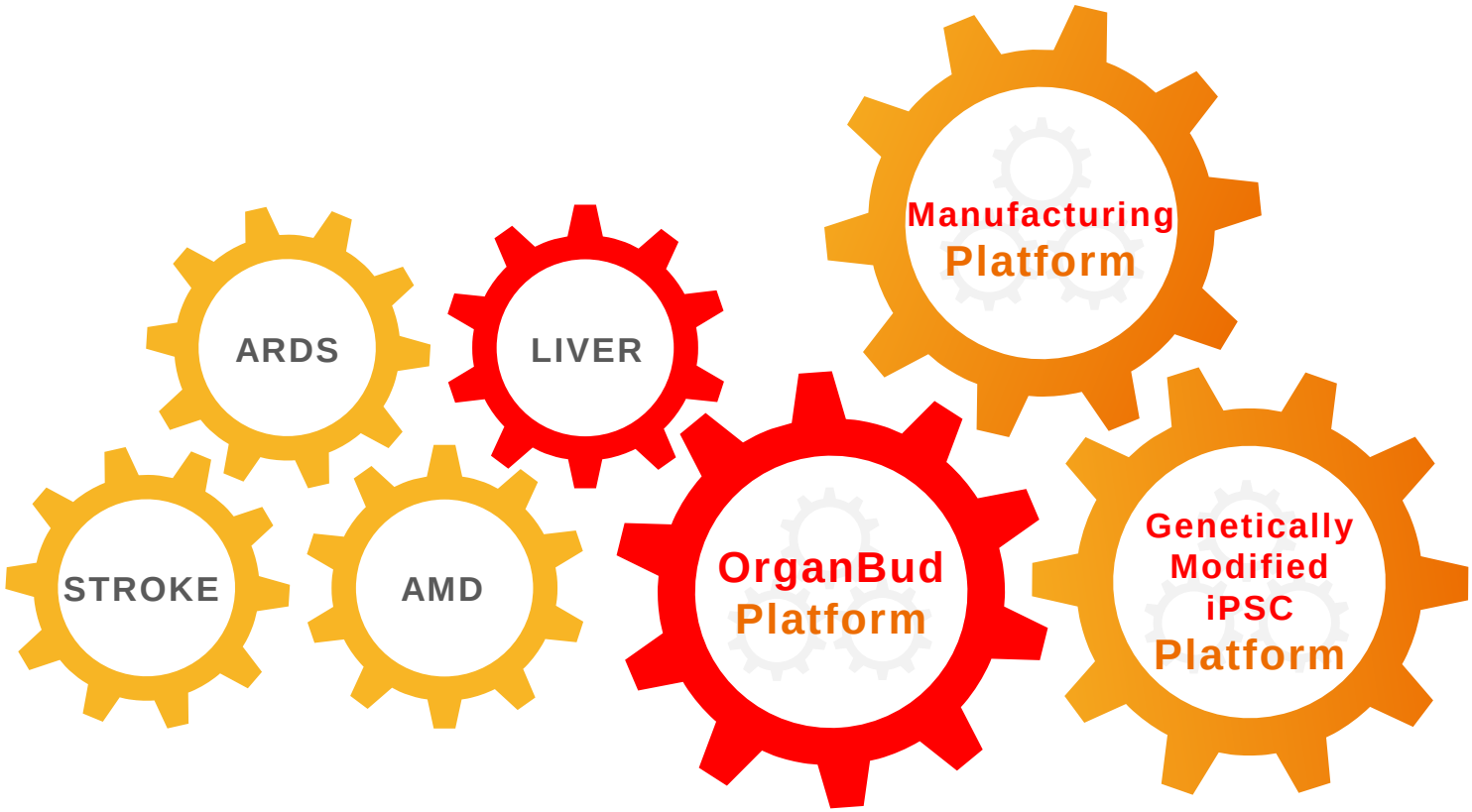
(source) Onset Data: National Eye Institute; Average Life Span: The Ministry of Health, Labor and Welfare; Annual Recommended Medication Protocol: Materials Presented by Institute of Physical and Chemical Research

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.

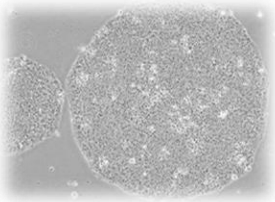
Sighregen rents the facility in SMaRT and is establishing the iPSC-RPE manufacturing system.



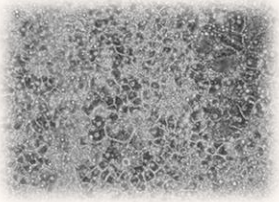
HLCL041 LIVER OrganBud Platform 3D organ generation mechanism

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

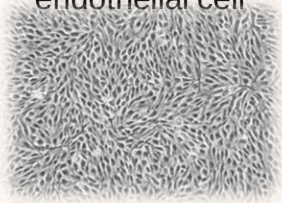
Human iPS cell



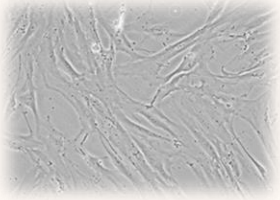
Precursor cell



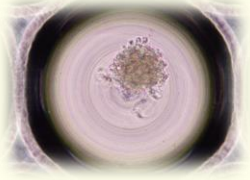
Vascular endothelial cell



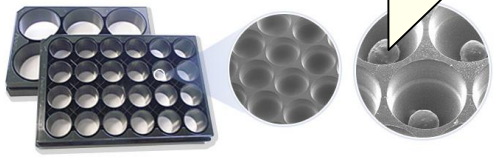
MSC



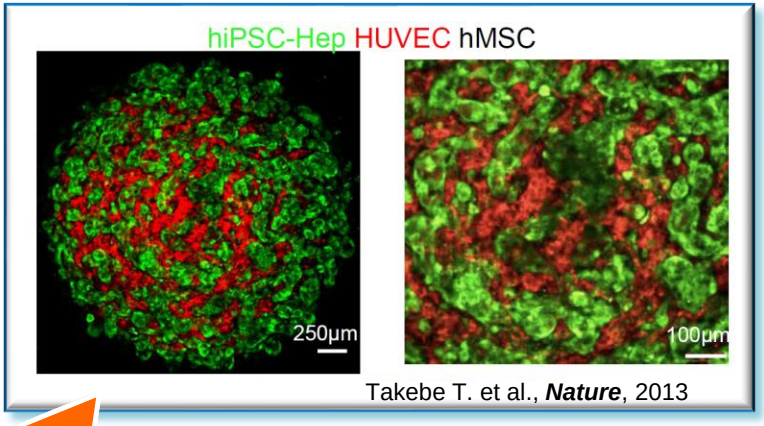
Organ bud*



Organ bud=
Origin of organ

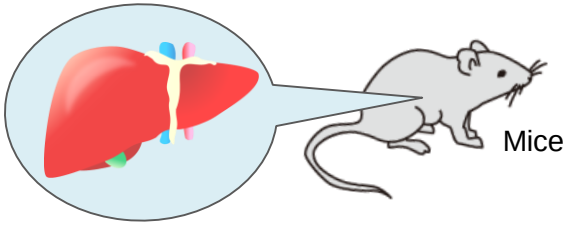


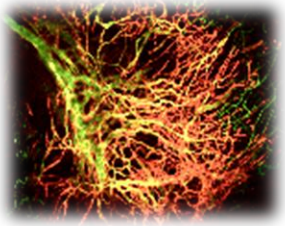
“Elplasia” from Kuraray Co., Ltd.
(http://www.elplasia.com/products/round_bottom/)



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

Cell Transplantation





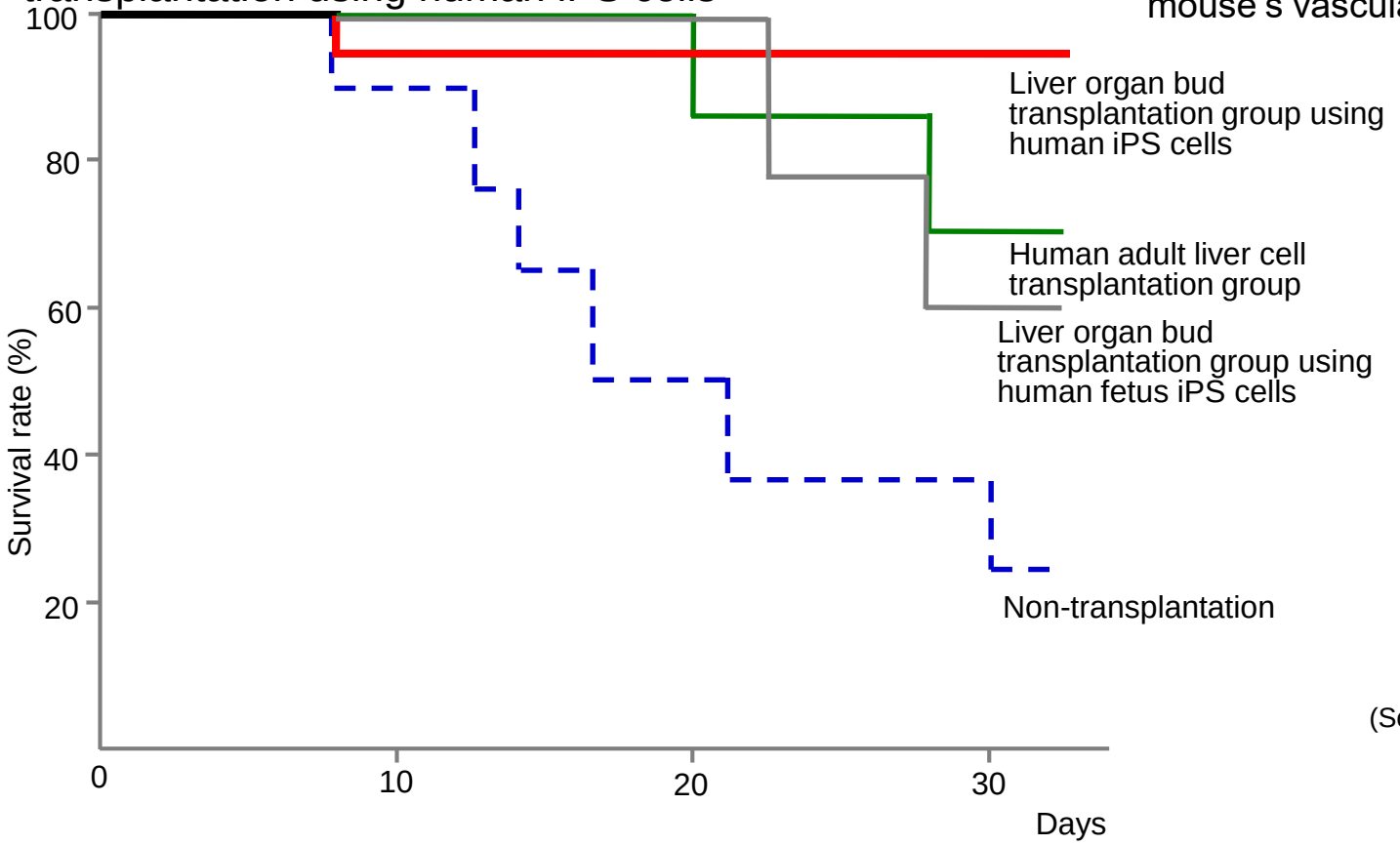
Containing blood vessels and human liver

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

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

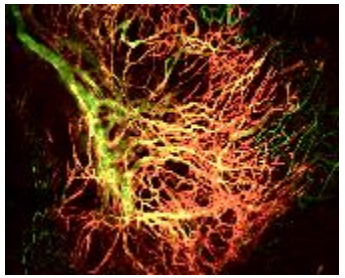
Survival rate improves significantly in transplantation experiments

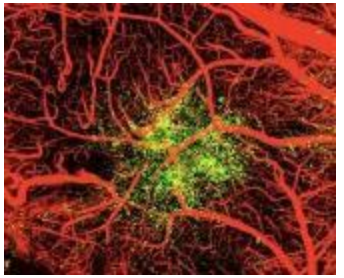
Treatment effects of liver organ bud transplantation using human iPS cells



(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)

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**

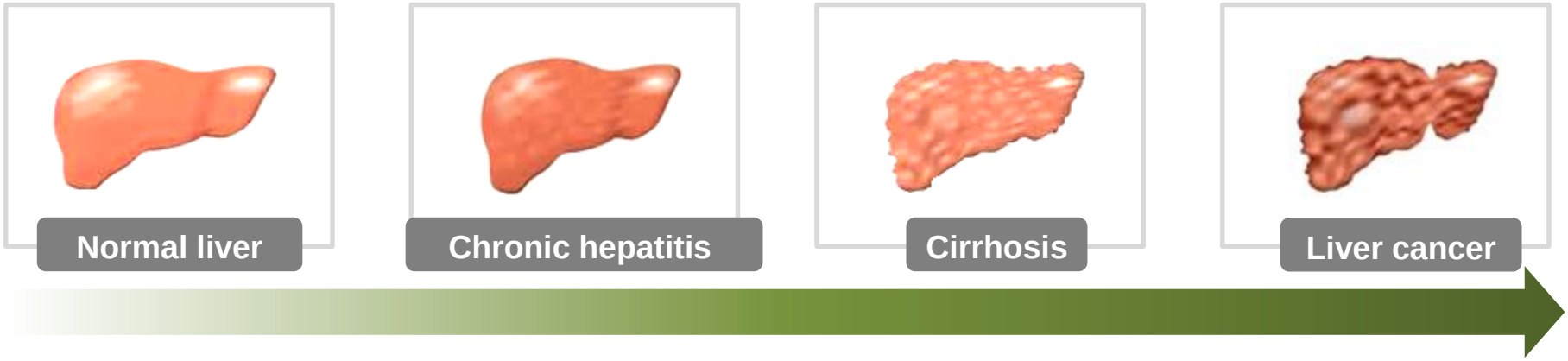
（Source）Compiled by Healios based on materials disclosed by Japanese Liver Transplantation Society, UNOS, Eurotransplan, UK Transplant, Agence de la biomédecine, and Scandia Transplant.

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



HLCL041 LIVER OrganBud Platform

Potential of application for various organs

Cell derived from various organs

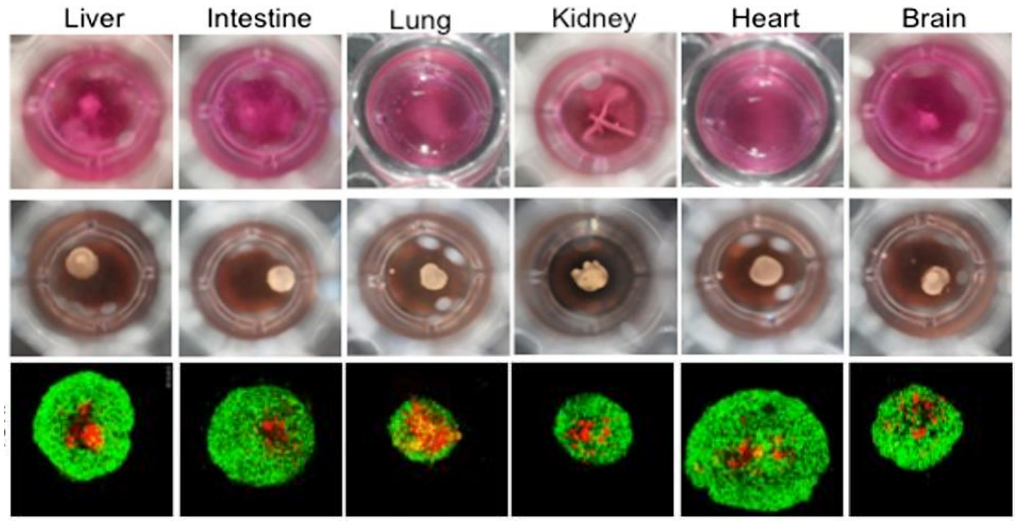
Vascular endothelial cell

MSC

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

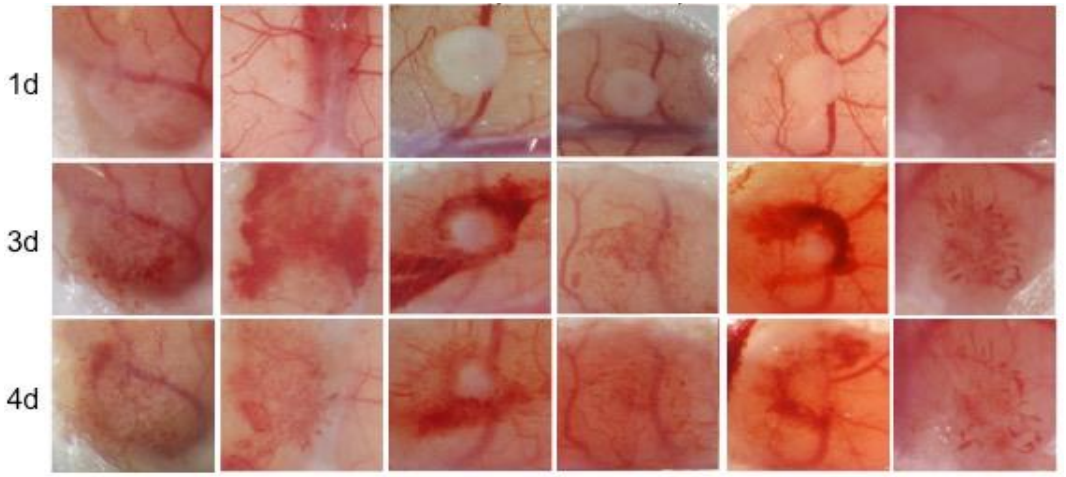
The vascularization was confirmed in vivo by transplantation to mice.

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



Transplanted to mice

Green：
Red：Vascular endothelial cell
Black：MSC



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

Financial Highlights

UPDATE

Statement of income

（Units: one million US dollar）

	FY 2018 Q1	FY 2019 Q1		
			YoY variance	Main reasons for increase/decrease
Sales	—	—	—	
Operating income	-5.11	**-9.01**	-3.90	Mainly due to increase in R&D expenses - $3.66mn
Ordinary income	-5.10	**-9.03**	-3.93	
Net income	-5.11	**-8.14**	-3.03	Mainly due to increase in extraordinary income +$0.91mn (Milestone Revenue)
R&D expenses	3.40	**7.06**	3.66	
Number of employees	75	**98**	23	-

*Adopt average exchange rate (JPY/USD) over respective 3 month periods for P&L.
FY2018 Q1 108.22 yen per dollar and FY2019 Q1 110.21 yen per dollar.

UPDATE

Balance sheet

（Units: one million US dollar）

		December 31, 2018	March 31, 2019		
				Variance	Main reasons for increase/decrease
	Current assets	111.05 (82.3%)	**97.05** (79.4%)	-14.01	Mainly due to decrease in cash equivalents -$12.51mn (cash equivalent balance at 3/31/19 was $92.24mn)
	Non-current assets	23.91 (17.7%)	**25.13** (20.6%)	1.23	
Total assets		134.96 (100.0%)	**122.18** (100.0%)	-12.78	
	Current liabilities	14.62 (10.8%)	**9.28** (7.6%)	-5.34	Mainly due to decrease in Advances received -$3.19mn and Accounts payable -$1.86mn
	Non-current liabilities	23.20 (17.2%)	**22.94** (18.8%)	-0.25	
Total liabilities		37.82 (28.0%)	**32.22** (26.4%)	-5.60	
Total net assets		97.14 (72.0%)	**89.96** (73.6%)	-7.18	Mainly due to net loss -$8.14mn
Total liabilities and net assets		134.96 (100.0%)	**122.18** (100.0%)	-12.78	

*Adopt spot rate (JPY/USD) at end of fiscal period for B/S.
FY2018 Q4 111.00 yen per dollar and FY2019 Q1 110.99 yen per dollar.

Appendix

UPDATE

HEALIOS K.K. Leadership

Jun Narimatsu	Richard Kincaid	David Smith	Michael Alfant	Gregory Bonfiglio	Yoshinari Matsuda	Seigo Kashii
Accountant Supporting various venture companies in the field of IT/ Healthcare	President & COO, Nezu Asia Capital Management (hedge fund)	Served as VP at Lonza Corp. Extensive experience in cell manufacturing	Group Chairman & CEO, Fusion Systems, Co., Ltd. Presidents Emeriti, ACCJ	Founder & Managing Partner of Proteus, LLC. (Investment in RM ventures) Chairman of the Board of CCRM	Attorney-at-Law, Senior Management Partner of Uruma Law Offices Legal Professional Corporation	Ex-corporate auditor of Astellas Pharma

Masanori Sawada	New Mahendra Rao	Hardy TS Kagimoto	Kouichi Tamura	Michihisa Nishiyama
Executive officer, CMO (Chief Medical Officer) Administrative field	Chairperson of Scientific Advisory Board	Chairman and CEO	Executive officer, Research and Manufacturing field	Executive officer, Development field
MD, PhD, MBA	First Director of NIH Center of Regenerative Medicine	MD, Founder	Ex-Astellas US Director of Laboratories Expertise in Immunosuppressant Research	Constructed network for Tacrolimus approval and sales at Astellas in the US and Europe

UPDATE

Healios Scientific Advisory Board

We established **the Healios Scientific Advisory Board (SAB)** .

Role of Healios SAB: To deliver the best treatment not only in Japan but also for the world.
- Appropriately grasp the current position of Healios in a global context;
- Support research and development activity - encouraging speed, efficiency, and alliances;
- Provide advice from the point of view of specialists.

Chairperson of Healios SAB
Dr. Mahendra Rao

Dr. Rao is an eminent scientist in the field of stem cell biology. He has broad experience not only in the academic field but also in government, regulatory and the clinical setting. He earned his medical license at the University of Bombay (currently the University of Mumbai) in India, and completed his doctorate in neurobiology at the California Institute of Technology. Dr. Rao was appointed the Director of the U.S. National Institute of Health (NIH) Center for Regenerative Medicine when it was established in 2010, where he led the country's stem cell research. He has worked as a scientific advisor to numerous companies and foundations, and has served on advisory panels to the government of the U.S. and other countries.

Company 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	11,395 million yen (As of end of March, 2019)
Number of Employees	98 (As of end of March, 2019)
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)

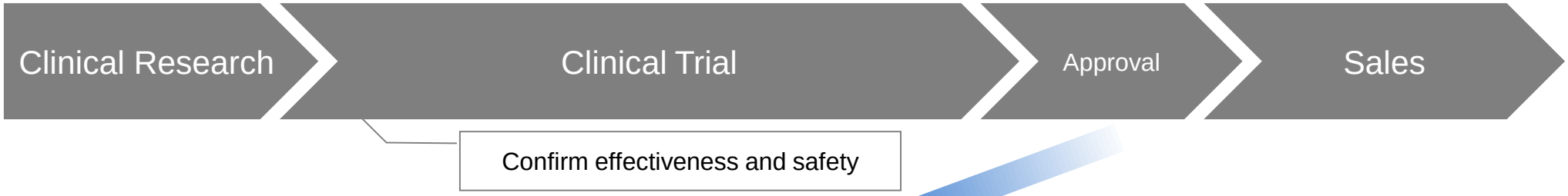
Company History

2011	Establishment of the company		
2012	Tokyo office opened		
2013		A patent licensing agreement concluded with RIKEN Joint Development Agreement with Sumitomo Dainippon Pharma Co., Ltd.	
2014		Joint research with Yokohama City University on Organ bud	
2015	Listed on Tokyo Stock Exchange (MOTHERS)		
2016			HLCM051 license agreement with Athersys, Inc.
2017	A business and capital alliance with Nikon BBG250 Business transfer		
2018	Establishment of Healios NA, Inc. in the US Establishment of Organoid Neogenesis Laboratory Inc.	CRADA with National Eye Institute	Strategic investment and collaboration expansion with Athersys Development for ARDS
2019			

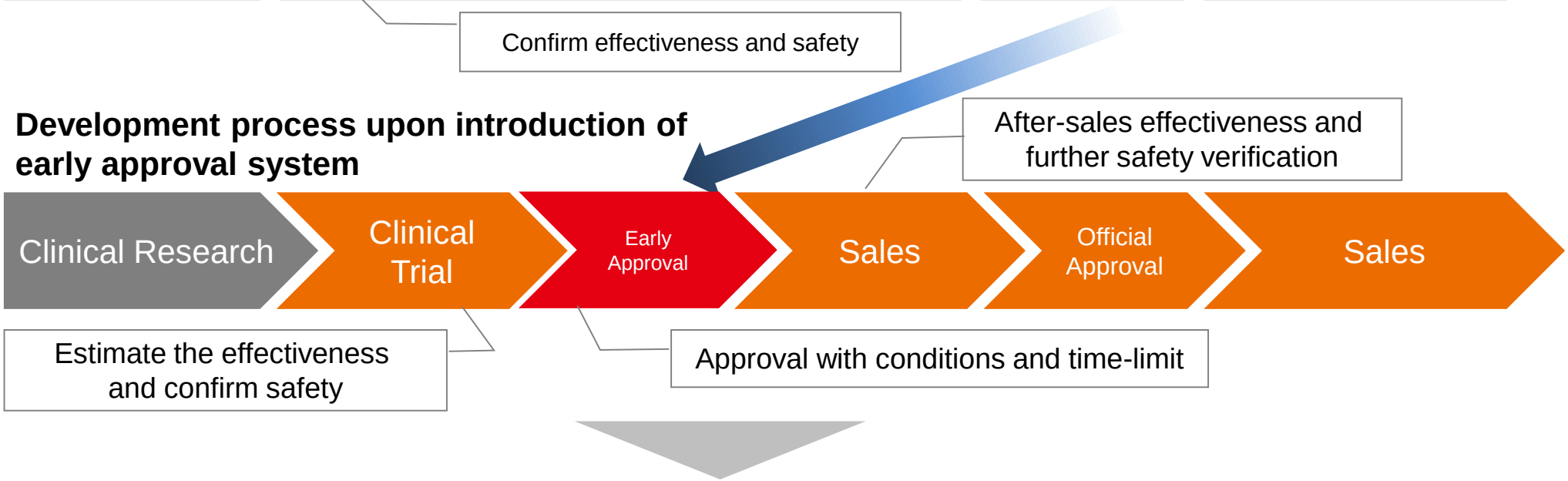
Historical relaxation of Japanese regulations

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.

Important note on future events, etc.

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