# Strategic Briefing for the Announcement of the Next Medium-Term Plan

Mar 10, 2021 Santen Pharmaceutical Co.,Ltd.



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- Information given in this presentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
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# Agenda

### Business Growth through Innovation Initiatives

Shigeo Taniuchi President and CEO

### **Eye Diseases from the Ophthalmologist's Perspective**

Reza Haque, MD, Ph.D. Head of Ophthalmology Innovation Center

### Retinitis Pigmentosa from the Patient's Perspective

Mohamed Abdin

CSR Group, Corporate Development Division, Executive Director of Committee for Assisting and Promoting Education for Disabled in Sudan (CAPEDS), a NPO

### Growth Potential in the Ophthalmic Market

Hiroki Sakai

General Manager, Portfolio Strategy & Global Marketing Group, Corporate Development Division

### Toward the Announcement of the Medium-Term Plan

Shigeo Taniuchi President and CEO



# **Business Growth through Innovation Initiatives**







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# **Objective of This Meeting**

Jul 7, 2020Presentation of long-term vision Santen 2030Presented the vision toward 2030 and beyond

Mar 10, 2021<br/>(Today)Strategic Briefing for the Announcement of the Next Medium-Term Plan<br/>Sharing Our Growth Strategy under an execution phase to<br/>achieve our long-term vision and expected Business Scale

April 7,2021 <u>Announcement of FY2021-2025 Medium-Term Plan **MTP2025** Financial and non-financial targets, shareholder return, and business strategies to achieve these</u>



# **CORE PRINCIPLE and WORLD VISION**

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

"Exploring the secrets and mechanisms of nature in order to contribute to people's health" \*

WORLD VISION

# **Happiness with Vision**

The Happiest Life for every individual, through the Best Vision Experience

\* Santen's original interpretation of a passage from the Zhongyong (The Doctrine of the Mean) by Confucius.



# Santen 2030

### Toward 2030 and beyond

Santen's VISION

# **Become A Social Innovator**

Orchestrate and mobilize key technologies and players around the world, to deliver happiness through vision.

GOAL

Aim to reduce the loss of social and economic opportunities for people around the world due to eye conditions.

# STRATEGY

### Ophthalmology

Innovation in Ophthalmology and Acceleration of Ecosystem Development

### B Wellness

Awareness and Proactive Care toward Better Eye Condition

### Inclusion

Building Society that is Inclusive regardless of Visual Impairment



# Santen as an Imperative for Global Eye Health and its Development

We solve social issues and achieve business growth by improving and expanding our solutions



People receive **80%** of information visually

Economic loss is worth **\$410.7 bil**<sup>\*1</sup> annually due to visual impairment

Eye diseases tend to be chronic,

affecting patients' QOL throughout their lives



# **Today's Take Away**

Products having great potential, such as product for myopia and cell therapy, are to be realized after FY2025. In the next medium-term plan, aim for sales growth beyond market growth, while making investments for the growth potential beyond 2025, by solidifying a commercial base that will support this.

### New growth areas

My<mark>o</mark>pia, ptosis cell therapy, devices etc.

Strengthen core business Exceed the market growth

**MTP2025** 

FY2021-2025 Medium-Term Plan

**Core business** 

Global ophthalmology drugs

2020

2025

2030

\*1 Best case that does not take into account developmental risks, including the possibility of business development etc.

**Growth potential** 

of new areas

+ JPY 300 billion scale<sup>\*1</sup> Exceed market growth for core business

+new growth areas







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# Eye Diseases from the Ophthalmologist's Perspective



### Reza Haque, MD, Ph.D.

Head of Ophthalmology Innovation Center



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# Eye Disease in Each Life Stage

Eye disease is a lifelong challenge



Congenital disorder (retinitis pigmentosa)

**Ocular infection** 

**Refractive disorders (myopia, hyperopia, astigmatism)** 

Allergic conjunctivitis

Dry eye

Age-related diseases (retina, glaucoma, cataract, presbyopia)

# Glaucoma

No.1 cause of blindness in developed countries and still require the spread and penetration of treatment



A disease that leads to blindness, in which the optic nerve is damaged by increased intraocular pressure. The number one cause of blindness in developed countries- genetic and acquired factors exist. Treatment Option: Eye-Drop, Surgery, Laser, etc.

# of Patient <sup>\*1</sup> :  $76M_{(2020)} > 95M_{(2030)}$ 

% Treated patient<sup>\*2</sup> : 10%~ 50%

%Compliance<sup>\*3</sup>: 60%

(1year continuous treatment for new patient)

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*1 World report on vision, *2 Santen analysis, *3 Japanese Journal of Ophthalmology volume 58, pages68–74, 2014
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# **Retinitis Pigmentosa**

Genetic disease, onset at a young age, and progress slowly through the patient life

✓ # of Patient : 1.5M

✓ Treatment Option: Limited

- Genetic Disease
  Autosome, sex chromosome
- ✓ Progression: Very slow

- ✓ Lower QOL than other visual impairments
  - Suffer from depression and distress
  - Needs assistance by others for daily life
  - · Less contribution to the workforce and to society





# **Pipelines of the Retinitis Pigmentosa**

Many treatment options are under development

# **Cell Therapy**

- Treated by neurotrophic factors or growth factors generated by injected cells
- Work regardless of mutation
   / possible to work just temporarily

# **Gene Therapy**

- Mutated gene will be altered to transfected normal gene
- Potentially cure all of symptoms / Limited to specific gene

# **Cell Transplantation**

- Diseased cell will be substituted by transplanted healthy cell
- Work regardless of patient condition / Need highly invasive surgery

## Pipelines in the development and the market

jCell (jCyte)

Luxturna (Spark) BIIB-112 (Biogen) A004 (MeiraGTx) CPK-850 (Novartis) QR-421a (ProQR) HORA-PDE6B (Horama) AGTC-501 (AGTC) iPS derived cell replacement (Opsis)



# Retinitis Pigmentosa from the Patient's Perspective



### **Mohamed Abdin**

CSR Group, Corporate Development Division Executive Director of Committee for Assisting and Promoting Education for Disabled in Sudan (CAPEDS), a NPO



# **Biographies**

### Born in Sudan in 1978 Retinitis pigmentosa Night blindness has slowly progressed since childhood Unable to read and write at the age of 12 Current visual acuity: light perception

- 1998 Arrival in Japan, Studied acupuncture and moxibustion at Fukui Prefectural School for the Blind and obtained a national license
- 2003 Entered Tokyo University of Foreign Studies
- 2014 Specially Appointed Assistant Professor after obtaining a Ph.D. at Tokyo University of Foreign Studies
- 2017-20 Special Visiting Professor, Department of Political Science, Faculty of Law, Gakushuin University
- 2017- Executive Director of Committee for Assisting and Promoting Education for Disabled in Sudan (CAPEDS), a NPO
- 2018- Member of the Tokyo Metropolitan Multi-Culture Symbiosis Promotion Committee
- 2020- Visiting Researcher, Center for Sustainable Development Studies, Toyo University

Oct. 2020 Joined Santen





# **Until I Understood What was Going on**



Childhood photographs (The left is my older brother, who is two years older than me.)



# "There Is No Tomorrow That I Can See Better than Today" -Burden on Life Planning-



I lost interest in going to school when my academic performance started to get behind.

My mother said

# "You have no way to live but to study"



# **Growth Potential in the Ophthalmic Market**



### Hiroki Sakai

General Manager, Portfolio Strategy & Global Marketing Group, Corporate Development Division





# Strengthening the Core Business and Acquiring New Opportunities to Realize the Growth

Core business staying as the main growth driver.

Significant growth toward 2030 pursued through new opportunities





# Maintain Solid Revenue Base by the Enhanced Core Businesses

Core businesses strengthened

by maximizing existing values and new brand releases

	Existing Global Brands	Expansion	Launch Targe	et (FY)	New Global Brands
	<b>EYBELIS</b>	US , PFUD: Asia, China	20	)22 ~	Pipelines STN1013900
Glaucom	a TAPROS	Bottle with eye drop applicator, JP	Defense from LOE 20	)23 ~	Glaucoma: ASIA, JP
		China	20	)25 ~	STN1014000 Glaucoma: ASIA, JP
Dry eye	Diquas	New Formulation 3 times / day Japan, Asia, China	Defense from LOE 20	)22 ~	STN1012600 Glaucoma: JP, US, EMEA
, ., .,.	Codeporter California: Enudades 0.1%**	PFMD: Asia	20	)22 ~	STN1010900
Allergy	Verkazia	US, China	20	)22 ~	Uveitis: US
Allergy	ALESION	(Detail not disclosed) JP	Defense from LOE 20	)24 ~	STN1010905 MGD: US,CN,ASIA, JP, EMEA

ALESION: Registreted trademarks of Boehringer Ingelheim. The pipeline listed above is only what has been agreed with external partner on the disclosure, not necessarily shows all major developed products scheduled for 2025 or before. Schedules are based on the best estimate possible assumed as of Mar 10, 2021.



# How to Sustain and Expand the Core Disease Areas

Continuous addition of new pipelines including LOE defenders



ALESION: Registerted trademarks of Boehringer Ingelheim



# **Glaucoma Market Potential**

Huge improvement potential in the diagnosis rate and the persistent rate. Growth potential larger than the increase in patient population



\*1 Santen estimated, \*2 World report on vision, \*3 Santen analysis based on patients' research, \*4 Japanese Journal of Ophthalmology volume 58, pages68–74, 2014



# **Growth Potential by FY25**

Glaucoma brands lead growth, expecting +80B - 100B JPY



Not all the pipelines through 2025 are listed on this slide The list is limited to those with disclosure agreements with partner companies. Schedules are based on the best estimate possible assumed as of Mar 10, 2021.



The New Growth Opportunity Huge markets exists. From orphan diseases to wellness needs

	Global Outlook		In Santen's Business*2		
Disease Area	# Patient	Market Opportunity <sup>*1</sup>	Pipeline	Launch target	Peak Revenue Potential <sup>*3</sup>
Retinitis Pigmentosa	Approx. <b>1.5 Mil.</b>		STN6000100 (jCell)	FY26~	70B JPY +
Муоріа	Approx. 2 Bil.		STN1012700 STN1013300 STN1013400	FY25~	<b>100B JPY +</b> (for all products)
Ptosis + Eyelid worries	Approx. 600 Mil. +		STN1013800	FY23~	50B JPY +

\*1 Mark defined under the contract with each partner. \*3 Non- PTS adjusted figures represent case scenarios including technical success that Santen does not currently consider probable to occur and should not be seen as a forecast or target figures.

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>1 T JPY

500B~1T JPY

<500 B JPY

# **Retinitis Pigmentosa: Market Situation**

There are many patients but very limited treatment options



### **Treatment option**

### Gene therapy

Target		Launched product / Pipeline			
Gene	Ratio in RP patient <sup>*2</sup>	Product /Pipeline*3	Company	Status	
RPE65	1%	Luxturna	Spark Therapeutics	Launched	
RPGR 3.	3.5%-12%	BIIB112	Biogen		
		AGTC-501	agtc	_	
		AAV-RPGR	MeiraGTx	Dovelopment	
USH2A	8.5%-10%	QR-421a	ProQR	R	
RHO	<1%	IONIS-RHO	ProQR		
RLBP1	<1%	CPK850	Novartis		

**Cell therapy** 

jCell MOA is agnostic to genotype	jCell	jCyte/Santen	Development
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\*1 Analysis based on Santen independent survey \*2 Santen independent analysis based on published science paper. Ref: *Retinitis pigmentosa*, T. P. Dryja, et al., Lancet, 2006; 368: 1795-1809,. \*3 Patient covered by launched product/pipeline in gene therapy is considered to be a part of RP patient, because those should be targeting a specific mechanism causing gene mutation. Cell therapy should target all RP patient.



# **Retinitis Pigmentosa: Santen's Growth Approach**

jCell launch to maximize the value and expansion of indications and other products

### Our value proposition

### jCell Therapy

- Office based procedure with a minimally-invasive intravitreal injection
- Unrestricted patient population - not targeting any specific genotype
- No

immunosuppression required



### Strategy to achieve & expand

### To achieve the goal of jCell

- Dedicated team to build new capabilities
- Close collaboration with jCyte

### To expand the business

• Indication Expansion :

Adding indications for other retinal-degenerative diseases

 Cell and Gene therapy expansion : Introducing other Gene / Cell Therapy products leveraging on jCell experience and platform



# **Myopia: Market Situation**

The number of patient continues to rise. Many governments are implementing preventive measures, seeing myopia as the issue affecting the national power.

### Market potential & UMN

### Ratios of myopia and intense myopia patients against world population<sup>\*1</sup>



### Myopia(VA 20/40 or less)

### Measure & treatment

### Active preventive intervention by government

- Nation-wide intervention since 2008, defining myopia as the most critical eye disease
  - Restricting time spent for smart phones/PCs, homeworks, etc under the "Initiatives to reduce Myopia among Children and Adolescents"
  - Mandatory outdoor physical education 150 minutes per week or more
  - Monitoring the hours and the light strength received by children.
- National Eye center (SNEC, SERI) has developed drug for myopia, investing more than 15 billion yen

### **Development of suppressive drugs for myopia progression**

- Many companies have developed atropin (Nevakar, B&L, Xinqi, etc)
- Eye glasses and multi-focal SLC for progress suppression (Carl Zeiss, HOYA, etc)
- OK lens obtaining an indication for suppressing myopia progression (Menicon)





# Myopia: Santen's Growth Approach

Building comprehensive eco-system for myopia treatment with a managing platform





# **Ptosis: Market Situation**

Strong demand for eyelid lift-ups in addition to ptosis patient

### Market potential & UMN

Patient structure with or without ptosis at the age of 20 to 79 (global)<sup>\*1</sup>



### Current treatment & needs\*4

### Patient: 260 million

- Diagnosed, but no definitive treatment available other than surgery
- Care by cosmetics
   ca 70,000 JPY is spent per person

### Consumer: 870 million

 Significant needs of eyelid lift-ups among people not diagnosed

\*1 Santen customer survey; estimated by Santen based on various academic articles.

\*2 Ratios of people recognizing subjective symptom of eyelid lift-up difficulty with/without treatment (Santen customer survey).

\*3 Ration of people not recognizing eyelid lift-up difficulty, but answering that there is a need of eyelid lift-up or not (Santen customer survey).

\*4 prepared by a customer survey conducted in the territories where Santen has obtained the license (Japan, China, Asia, EMEA)



# **Ptosis: Santen's Growth Approach**

STN1013800 offers values both in medical and aesthetic opportunities

### Our value proposition

### UPNEEQ<sup>™</sup>(US)

### STN1013800

- ✓ Improved superior visual field
- ✓ Quick lift up for upper eyelids quickly
- Lasting effect for 6hours with one drop
- ✓ Safety was comparable to placebo



\*1 Reference of description/picture: UPNEEQ website (<u>https://ecp.upneeq.com/</u>) and brochure

### Strategy to achieve & expand

### [Medical Opportunity]

First eye-drop medical solution for ptosis patients

### [Aesthetic Opportunity]

New value for those interested in eyelid lift-ups for aesthetic purpose





# "Investments" into New Growth Area

Discovering new potential including digital devices

### **Investment list by SVI**

	Treatment	Diagnose / Monitoring, etc
Glaucoma	*	$\star \star$
Dry eye	$\star \star$	
Presbyopia	*	
Cataract	*	
RP	$\star \star \star$	
AMD	*	
others	$\star$ $\star$	*
Pharmaceuticalls (New m	nodalities)	



\*1 Joing venture company with Verily Life Sciences LLC.



# Toward the Announcement of the Medium-Term Plan







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# **Today's Take Away**

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**Growth Potential** 

of new areas

+ JPY 300 billion scale<sup>\*1</sup> Exceed market growth for core business

+new growth areas



# **Toward the New Mid-term Plan**

Enhance the corporate value by leveraging the significant growth opportunities in Ophthalmology

Solid cash flow	Mid-long term growth potential
<ul> <li>Healthy growth in existing territories (Measures for loss of exclusivity (LOE), Sales model modification in China)</li> <li>Optimization of cost structure</li> </ul>	<ul> <li>Acceleration of ophthalmic market growth</li> <li>Continuous growth of glaucoma area</li> <li>Establishment of new growth area (Myopia, Ptosis, Cell therapy)</li> </ul>

Financial Goals weighting on full ROE	Enhance shareholder return	Non-financial Goals promoting ESG management
<ul> <li>Enhance full operating profit, full ROE</li> <li>Improve the index, such as ROIC</li> <li>Balanced investment and realized revenue</li> </ul>	<ul><li>Shareholder return according to the growth of profit,</li><li>Stable dividend</li><li>Expeditious share buyback</li></ul>	<ul> <li>Set environmental related objective and implement</li> <li>Promote D&amp;I</li> </ul>

# Appendix

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# STN1012700 / DE-127

# P2 study in Asia (APPLE study, NCT03329638)

- Top line results covered in Q2 FY20 eanings release
   <u>https://www.santen.com/en/ir/document/pdf/mtg2021\_2q.pdf</u>
- Detailed report presentation rescheduled to virtual 33<sup>rd</sup> APACRS (July 30 – 31, 2021, Singapore) from Annual Meeting of Japan Myopia Society



