



# Become A Social Innovator

Q1 FY2021 Financial Results  
Santen Pharmaceutical Co., Ltd.

Presentation: August 6, 2021

# Speakers

## Presentation/Q&A



**Shigeo  
Taniuchi**

President &  
Chief Executive Officer



**Kenji Morishima**

Corporate Officer,  
Head of China Product  
Development Department

## Q&A

**Kazuo Koshiji**

Senior Corporate Officer,  
Chief Financial Officer,  
Head of Finance and  
Administration Division



**Satoshi Suzuki**

Senior Corporate Officer,  
Head of Corporate  
Development Division



# Forward-looking Statements

- Materials and information provided in this announcement include so-called "forward-looking statements". The earnings forecasts and other forward-looking statements herein are based on information currently available to the Company and certain assumptions that we believe to be reasonable. The realization of these forecasts is subject to various risks and uncertainties. Please be aware that actual results could differ materially from these forward-looking statements. We assume no obligation to update the contents of this document from time to time.
- Risk factors include, but are not limited to, the following:  
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# 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.

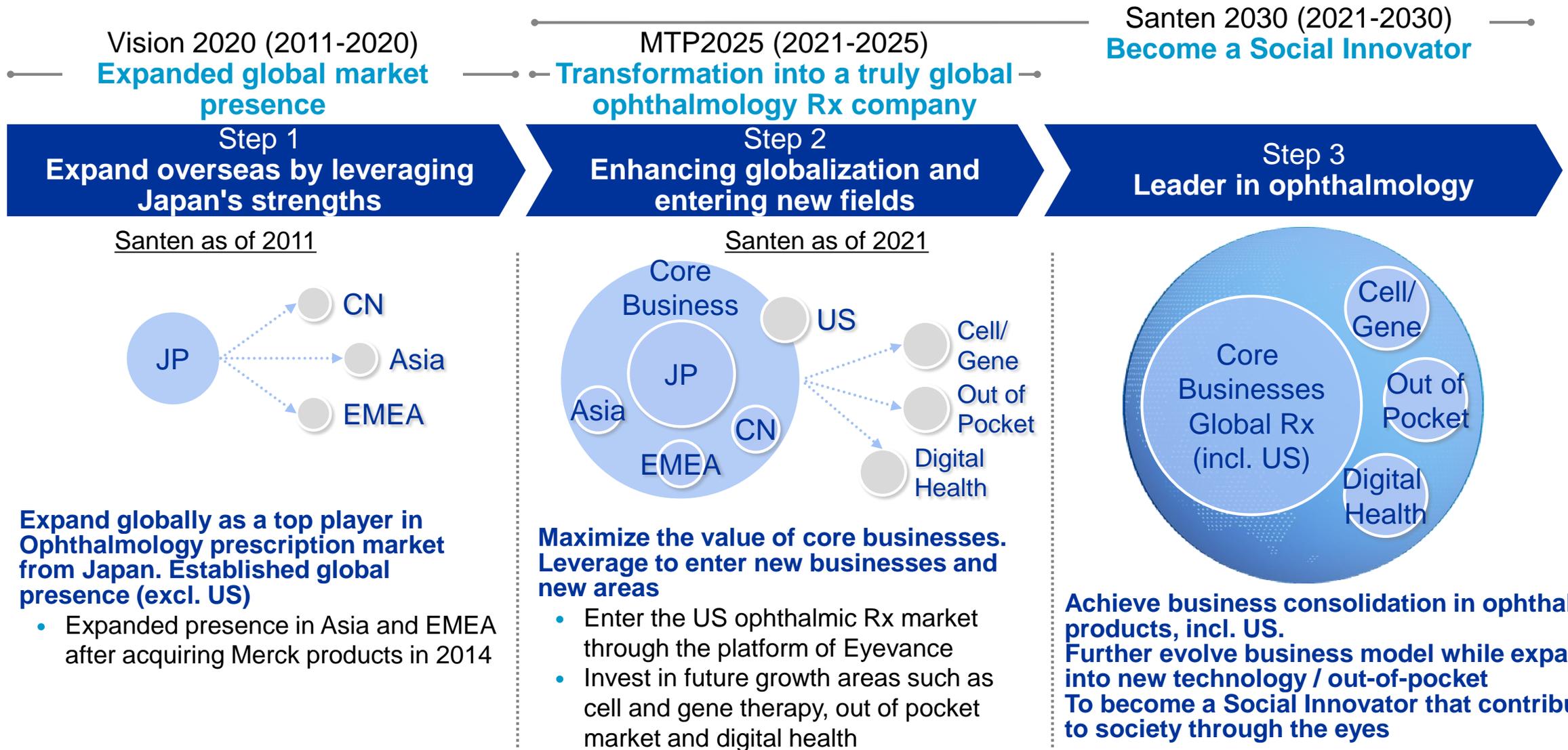
**GOAL**

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

**STRATEGY**

- A Ophthalmology**  
Innovation in Ophthalmology and Acceleration of Ecosystem Development
- B Wellness**  
Awareness and Proactive Care toward Better Eye Condition
- C Inclusion**  
Building Society that is Inclusive regardless of Visual Impairment

# Evolution from Vision 2020 to Santen 2030



# Agenda

## 1. Steady Progress Toward MTP2025

- (1) Consolidated: Great Start
- (2) Core Businesses: Progress in China
- (3) New Areas, Progress in Americas
- (4) Initiatives to Accelerate Medium-Term Plan
- (5) Global Business Platform Enhancement

## 2. Q1 FY2021 Financial Results

## 3. R&D Update

## Appendix

## MTP2025 Initiated: Implementation of Key Strategic Measures Driving Continued Growth Trend



**Profit ratio improvement in core businesses**

- Japan: **Steady revenue progress**, advancing product LCM
- China: **Strong growth trend in new channels and new products**
- EMEA, Asia: Progressing as planned despite the impact of COVID-19



**Expansion of new areas**

- Americas: **Eyevance continued to grow, Verkazia approved**, steady progress toward achieving profitability
- R&D : Progressing as scheduled



**Strengthening of foundation as a global company**

- Commenced construction of new factory in China
- CO<sub>2</sub> emission reduction targets endorsed by the **SBT**<sup>\*1</sup> initiative

\*1 : Science Based Targets

## Steady Progress in Core Businesses Across Each Region as Expected



Profit ratio  
improvement  
in core  
businesses

- Japan: Steady revenue progress, advancing product LCM
- China: Strong growth trend in new channels and new products
- EMEA, Asia: Progressing as planned despite the impact of COVID-19

\*Revenue YoY/ JPY Basis

Japan +11%\*

- ✓ Steady revenue in mainstay products
- ✓ Accelerating switch to *Alesion LX* (improved to **75%**)
- ✓ Starting clinical trial for new pipeline products  
STN1013400 (myopia)  
STN1013900 (glaucoma)

China +11%\*

- ✓ Sales growth in new channels  
**66%** of total revenue
- ✓ Drive growth with new products
  - ✓ *Tapros* **+134%**
  - ✓ *Diquas* **+886%**
- ✓ Partnering with local company that has China's largest network of eyewear stores. Starting screening across China

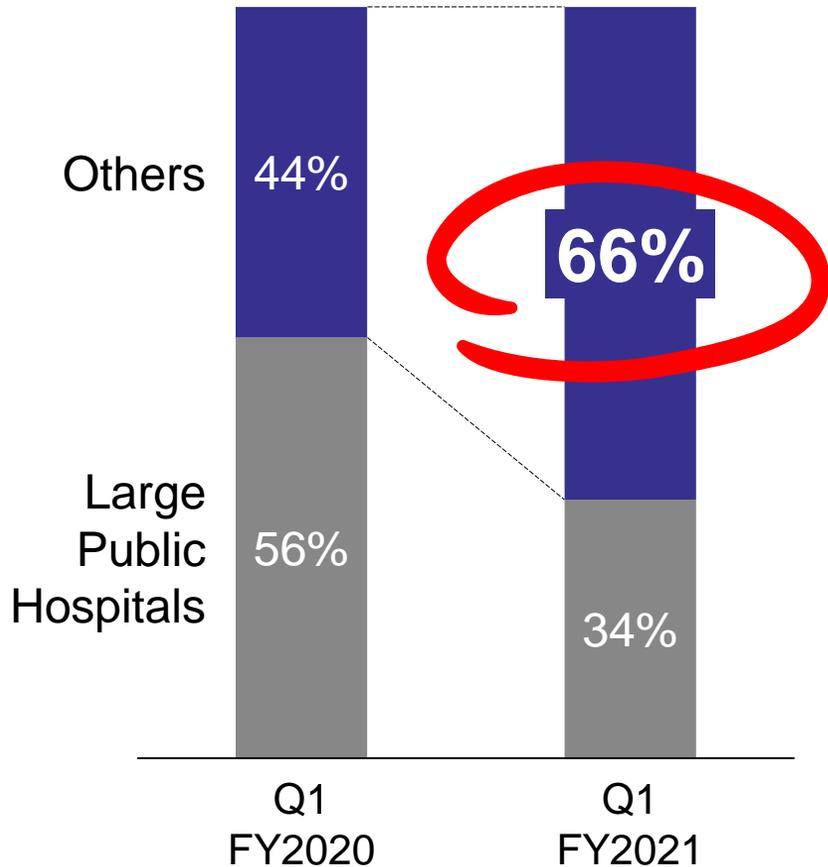
EMEA +12%\*  
Asia +16%\*

- ✓ Progressing **as planned** despite the impact of COVID-19 in EMEA and Asia
- ✓ Steady roll-out across regions of new products such as *Eybelis* and *Duressa*

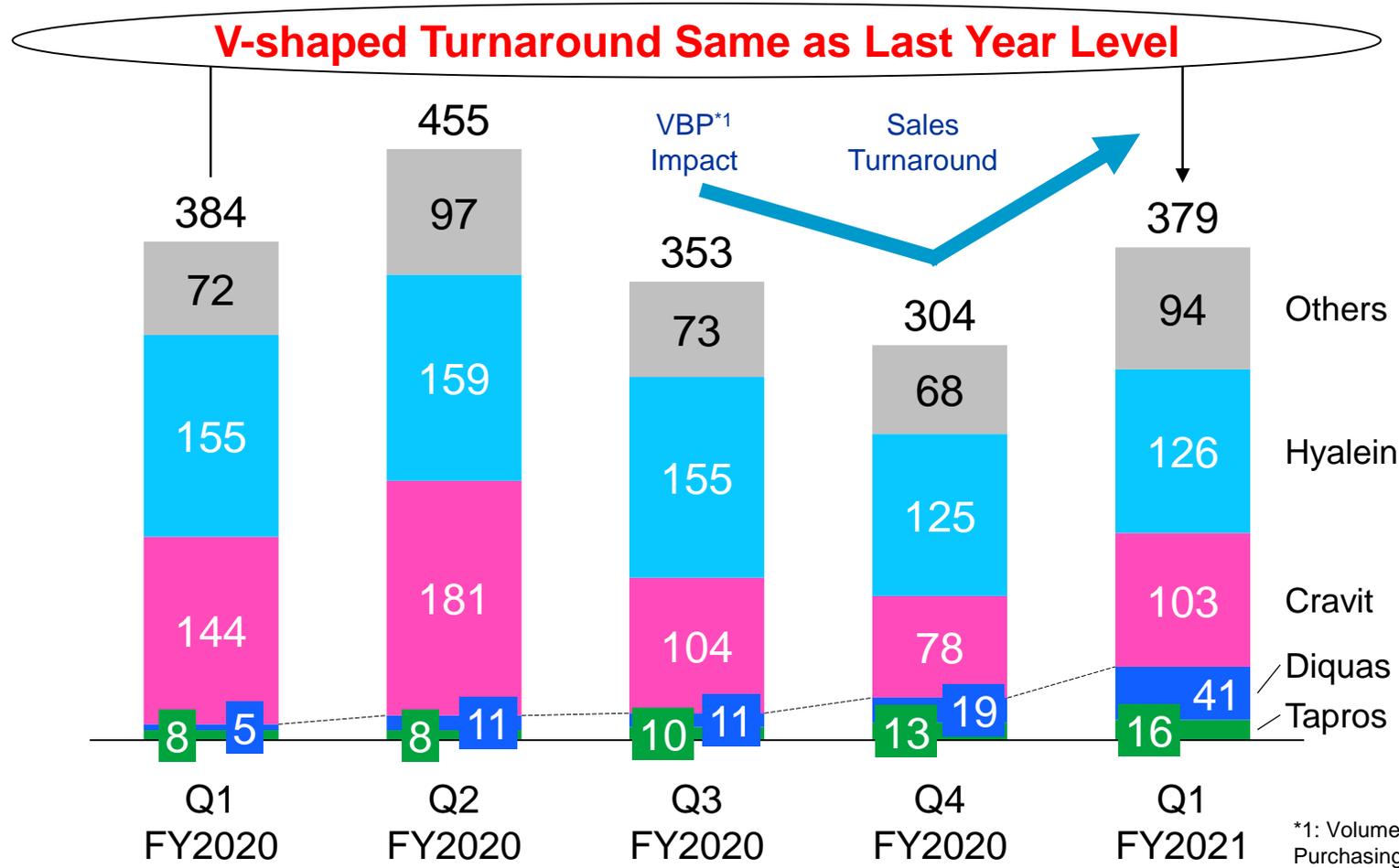
# 1. (2) Core Businesses: Progress in China (Growth Recovery)

## Maintain Growth Trajectory through Channel Shift and New Product Expansion

### Revenue by Channel



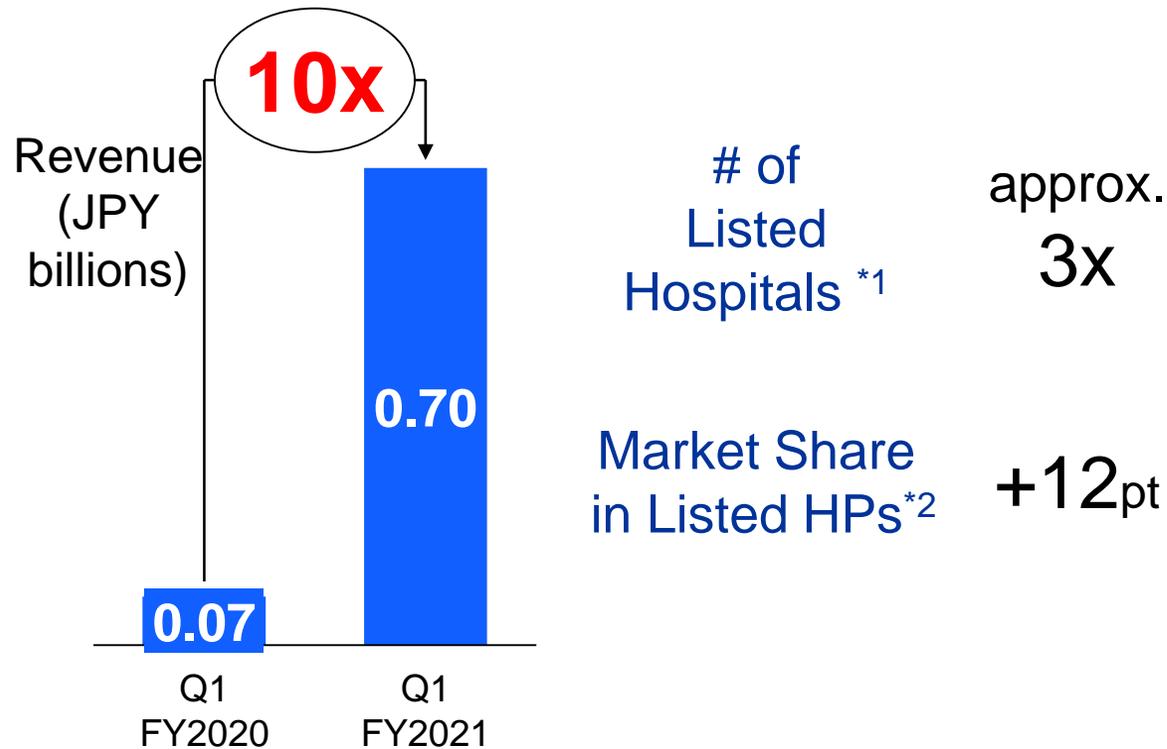
### Revenue by Product (RMB million)



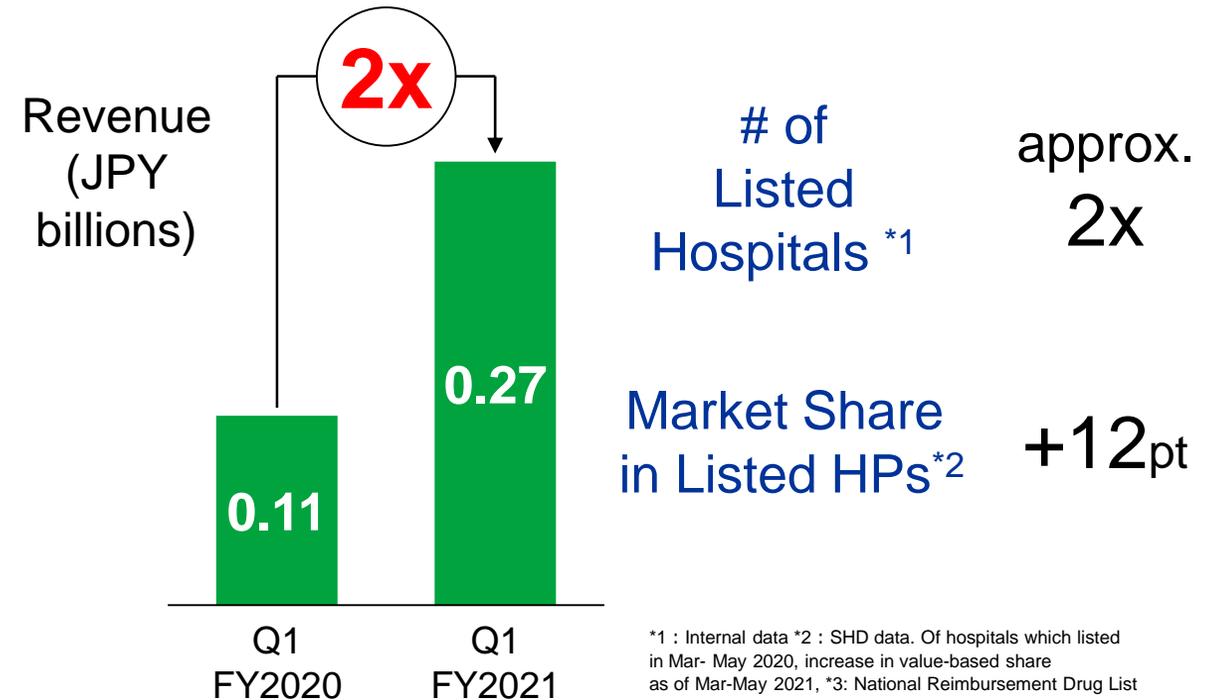
## 1. (2) Core Businesses: Progress in China (New Product Expansion)

# *Diquas* and *Tapros*, Two New Products Driving Strong Growth

***Diquas***: Highly recognized for clinical benefits and superior quality as dry eye treatment, increasing prescriptions mainly in private hospitals



***Tapros***: Acquiring new patients by leveraging strengths as the only NRDL <sup>\*3</sup> listed PG (prostaglandin) on 1st line. Sales more than doubled YoY by expanding listed hospitals and market share in each hospital across China



\*1 : Internal data \*2 : SHD data. Of hospitals which listed in Mar- May 2020, increase in value-based share as of Mar-May 2021, \*3: National Reimbursement Drug List

## 1. (2) Core Businesses: Progress in China (Developing Eye Care Ecosystem in China)

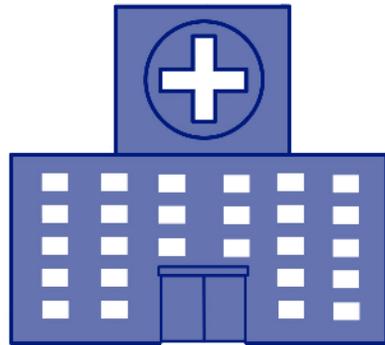
# Establishing Standard Glaucoma Medical Centers, Improving Treatment Quality for Patients

Support improved penetration of glaucoma guidelines (PG drug as 1<sup>st</sup> choice)



### Standard Glaucoma Medical Center

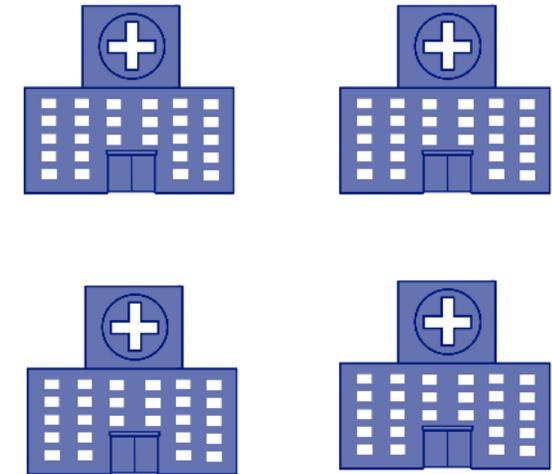
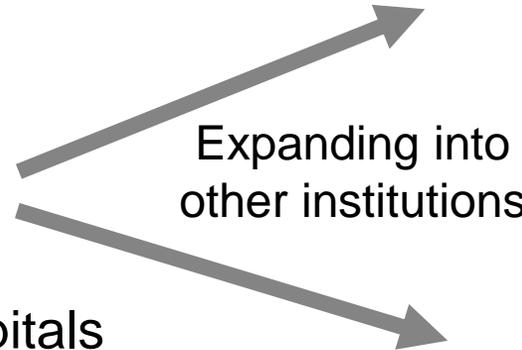
(Collaboration with Beijing Bethune Charitable Foundation)



Provide treatment in compliance with glaucoma guidelines

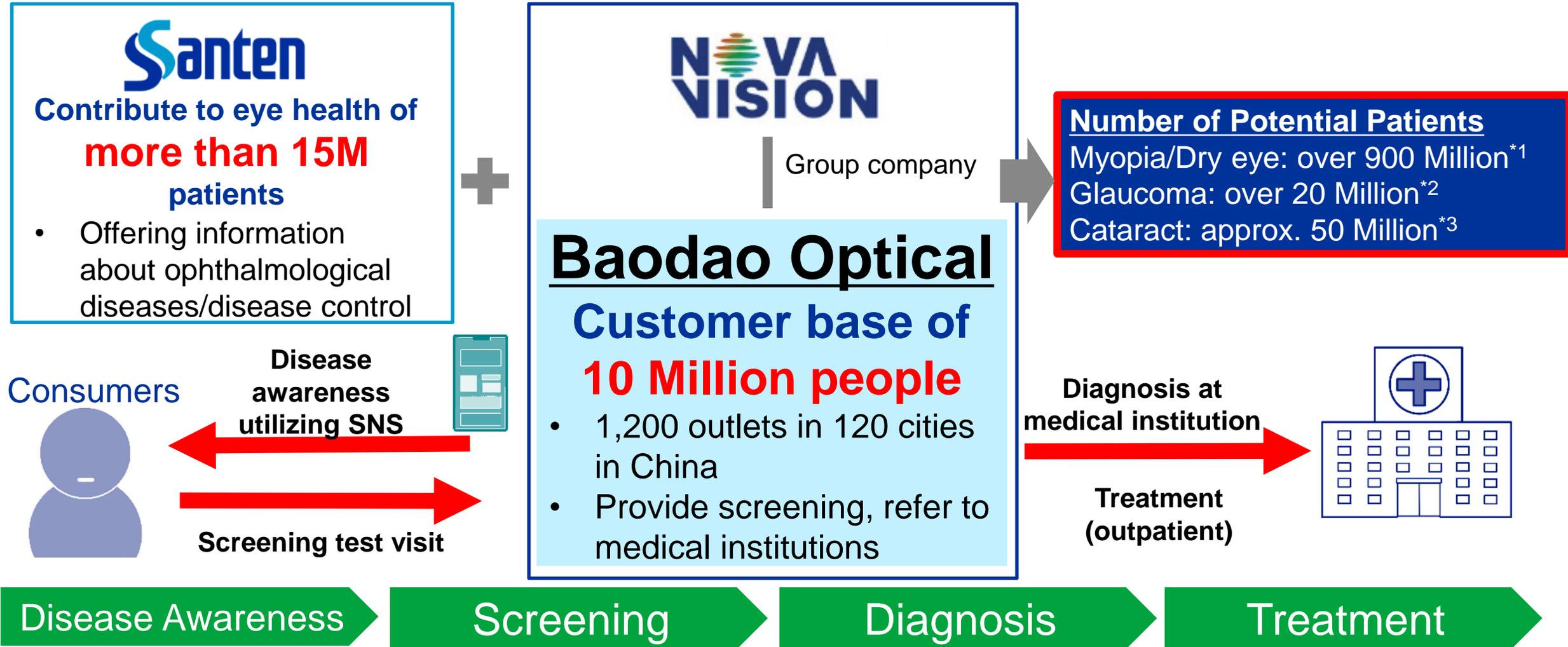
Begin with roll-out across China with main hospitals

(Eye & ENT Hospital of Fudan University, Zhongshan Ophthalmic Center, Beijing TONGREN Hospital, The Second Affiliated Hospital of Harbin Medical University, TONGJI Hospital, TONGJI Medical College of HUST)



# 1. (2) Core Businesses: Progress in China (Developing Eye Care Ecosystem in China)

## Develop Potential Market by Offering Screening Across Regions in Partnership with China's Largest Eyewear Chain



\*1/2/3: Analysis of technology, current situation, trends in Chinese ophthalmology market in 2020 <http://www.chyxx.com/industry/202006/872359.html>

## 1. (3) New Areas, Progress in Americas

# New Business Pipeline in Myopia/Ptosis Showing Steady Growth Significant Growth in Americas, a New Region for Santen



Expansion of  
new areas

- Americas: Eyevance continues to grow, *Verkazia* approved, steady progress toward achieving profitability
- R&D: Progress as scheduled

\*Revenue YoY/JPY Basis

### New Diseases

- ✓ Pipeline in new domains including myopia:  
**On track**
- ✓ Business roll-out preparation for new areas such as ptosis: Progressing
- ✓ Started preparation for study on meibomian gland malfunction (STN1010905/sirolimus)

### Americas +306%\*

- ✓ Eyevance overall: **Approx. 2 times**<sup>\*1</sup> compared to the same period in the previous fiscal year, **approx. 4 times** for Americas as a whole
- ✓ Steady increase in prescriptions for new product **Zerviate**
- ✓ Major progress toward achieving profitability with ***Verkazia* approval**

\*1 : Preliminary comparison with actual results (unaudited basis) when acquired

## 1. (3) New Areas, Progress in Americas (Direction of Americas Business)

# Products Growth of Eyevance as Platform, New Product Approvals are the Key to Achieving Profitability in Americas Business and Growth over the Medium-Term

### Short Term

#### Steady Growth Utilizing Eyevance Platform

##### Eyevance Portfolio

##### Front of the Eye (FOTE) products

- *Zerviate*
- *Tobradex ST*
- *Flarex*
- *FRESHKOTE*
- *Natacyn*

##### Eyevance Commercial Platform

- Business foundation, including commercial/product supply capability
- Sustainable system capable of standalone operation
- Coverage of **approx. 80%** of the target market based on number of MRs



### Mid-to-Long Term

#### Growth Potential

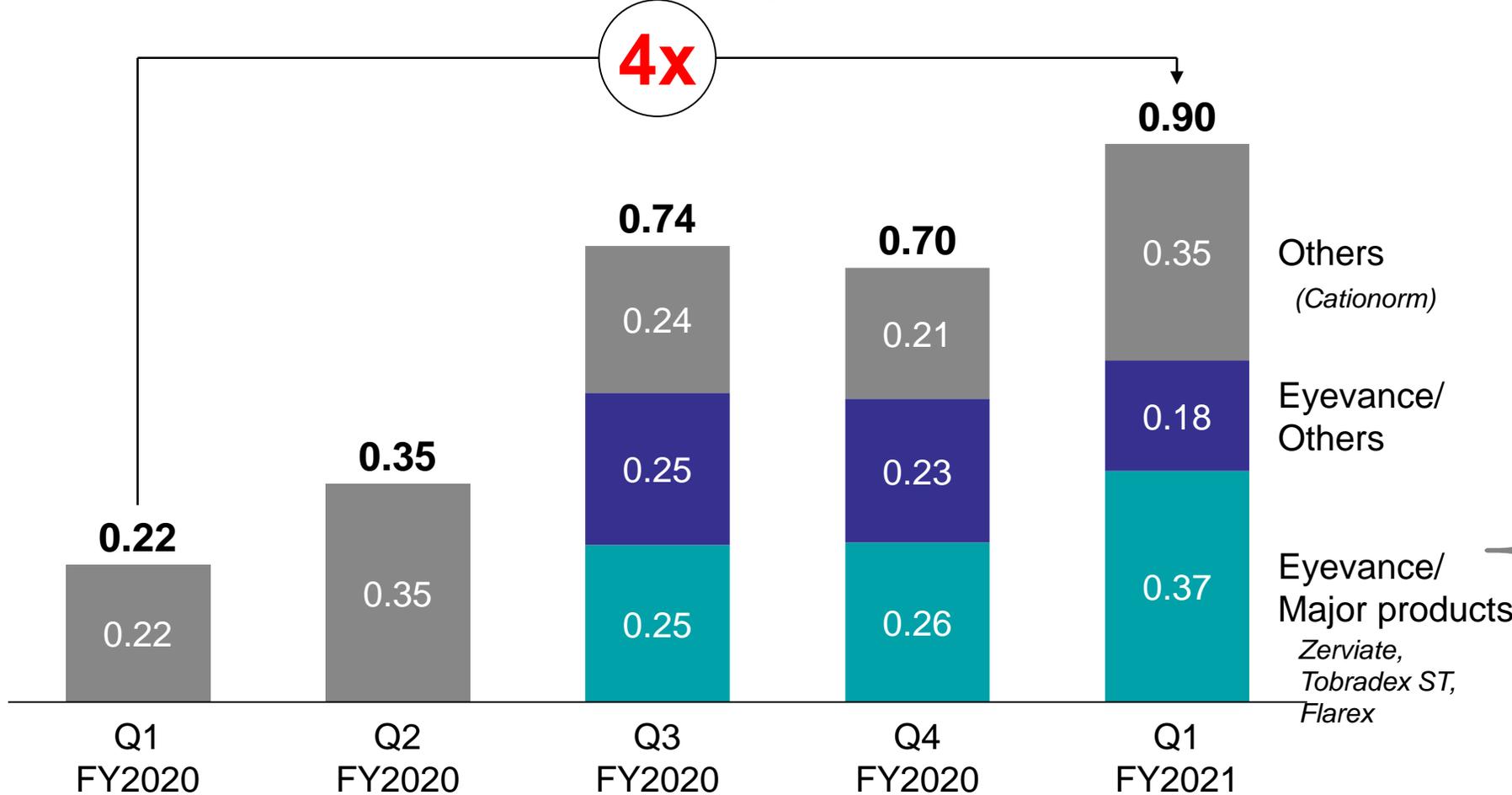
##### Pipeline as Specialized Ophthalmology Company

- ***Verkazia* (approved)**
- STN1011700
- STN1010900
- STN1012600
- (STN2000100)

# 1. (3) New Areas, Progress in Americas (Americas Sales Trend)

## Americas Business: Steady Growth Trajectory on Firm Growth of Eyevance Products

Americas Business Sales Trend (JPY billions)



Sales Volume Growth (YoY)\*1

- Zerviate (Allergy)**: approx. **5x**
- Tobradex ST (Infection/steroid)**: approx. **2x**
- Flarex (Steroid)**: approx. **2x**

## Orphan Disease Product for Indication for Vernal Keratoconjunctivitis (VKC) Leveraging Eyevance Platform to Contribute to Patient Wellbeing

### Value Offered to Patients

- Number of patients\*<sup>1</sup>: **approx. 50,000-60,000**
- **Only ciclosporin drug** indicated for VKC as orphan disease that is most often seen in young and adolescent males

### Impact on Santen Business

- Positioned to drive growth potential, contribute to **achieving profitability sooner**
- Revenue contribution: **40M USD expected at peak**
- Achieve **efficient product launch** by leveraging Eyevance platform



\*1: Santen estimation with data

## 1. (4) Initiatives to Accelerate Medium-Term Plan

# First UN/WHO Resolution on Eye Health is Strong Tail Wind for Achieving Santen 2030. Accelerating Implementation of Global Initiatives

### Objective

- Proactively support/engage in initiatives to improve ophthalmological practice and eye health, on rising awareness of eye health

**NGO**  
Lobbying  
by IAPB\*<sup>1</sup>

### UN General Assembly

- First UN agreement to tackle maintenance of eye health
- Eye health included in SDGs

### World Health Organization

Set universal goal for improving rates of vision correction/cataract surgery

**Member countries/areas**  
Set KPIs/formalize specific actions toward improving eye health including myopia

Advocating in partnership with IAPB

Promoting Be Healthy Be Mobile project

- Initiatives in each country to establish ophthalmology medical ecosystem
- In partnership with Orbis, support regions where ophthalmology medical services are not yet established

\*1: International Agency for the Prevention of Blindness



## 1. (5) Global Business Platform Enhancement

# Making Smooth Progress on Initiatives to Strengthen Global Strategy Promotion Framework



Strengthening of foundation as a global company

- Commenced construction of new factory in China
- CO<sub>2</sub> emission reduction targets endorsed by the SBT\*<sup>1</sup> initiative

### Capital Investment

- ✓ Steady progress on construction of **new building in Shiga and new plant in China** to strengthen the production base and achieve medium- to long-term growth
- ✓ New ERP under development. EMEA / US rollout

### ESG Management

- ✓ CO<sub>2</sub> reduction targets: **Endorsed by the SBT initiative**
- ✓ Specific measures for CO<sub>2</sub> reduction (Transition to bioplastics, compliant facilities for new plants, etc.)
- ✓ DE&I : Member of **30% Club Japan**, **Sign on to Women's Empowerment Principles (WEPs)**

\*1 : Science Based Targets

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## **2. Q1 FY2021 Financial Results**

## **3. R&D Update**

## **Appendix**

## 2. Q1 FY2021 Financial Results

# Great Start Toward Achieving MTP2025 Objectives

(JPY billions)	Q1 FY2020		Q1 FY2021		YoY
	Actual	vs Revenue	Actual	vs Revenue	
<b>Revenue</b>	<b>57.6</b>		<b>65.0</b>		<b>+12.9%</b>
Cost of sales	24.7	43%	26.9	41%	+8.8%
Gross margin	32.8	57%	38.1	59%	+16.0%
SG&A expenses	15.6	27%	20.4	31%	+31.5%
R&D expenses	5.6	10%	6.1	9%	+9.0%
Amortization on intangible assets associated with products	2.4	4%	2.0	3%	-16.7%
Other income	0.2	0%	0.1	0%	--
Other expenses	1.4	2%	0.0	0%	--
<b>Operating profit</b>	<b>8.0</b>	<b>14%</b>	<b>9.5</b>	<b>15%</b>	<b>+19.0%</b>
Finance income	0.5	1%	0.6	1%	+11.3%
Finance expenses	0.2	0%	0.3	0%	+48.2%
Share of loss of Investments accounted for using equity method	--	--	0.3	0%	--
Profit before tax	8.4	15%	9.6	15%	+14.3%
Income tax expenses	2.2	4%	2.2	3%	-2.3%
<i>Actual tax ratio</i>	26.7%		22.9%		
<b>Net profit</b>	<b>6.1</b>	<b>11%</b>	<b>7.4</b>	<b>11%</b>	<b>+20.3%</b>
<b>Core basis</b>					
Revenue	57.6		65.0		+12.9%
Operating profit	11.7	20%	11.7	18%	+0.5%
Net profit	8.8	15%	9.0	14%	+2.5%
USD (JPY)	107.46		109.81		
EUR (JPY)	118.69		132.05		
CNY (JPY)	15.13		17.03		

### Revenue

- Double-digit year-on-year increase in sales driven by domestic and overseas growth

**JPY65.0 billion (YoY +12.9%)**

### Operating Profit

- Double-digit growth due to a decrease of other expenses (change in fair value of the InnFocus, Inc. (U.S.) contingent consideration) from the previous fiscal year

**JPY9.5 billion (YoY +19.0%)**

### Core Operating Profit

- Profit growth on higher sales and changes in product mix, despite increase in SG&A expenses on higher co-promotion fees resulting from higher *Alesion* sales and new consolidation of Eyevance

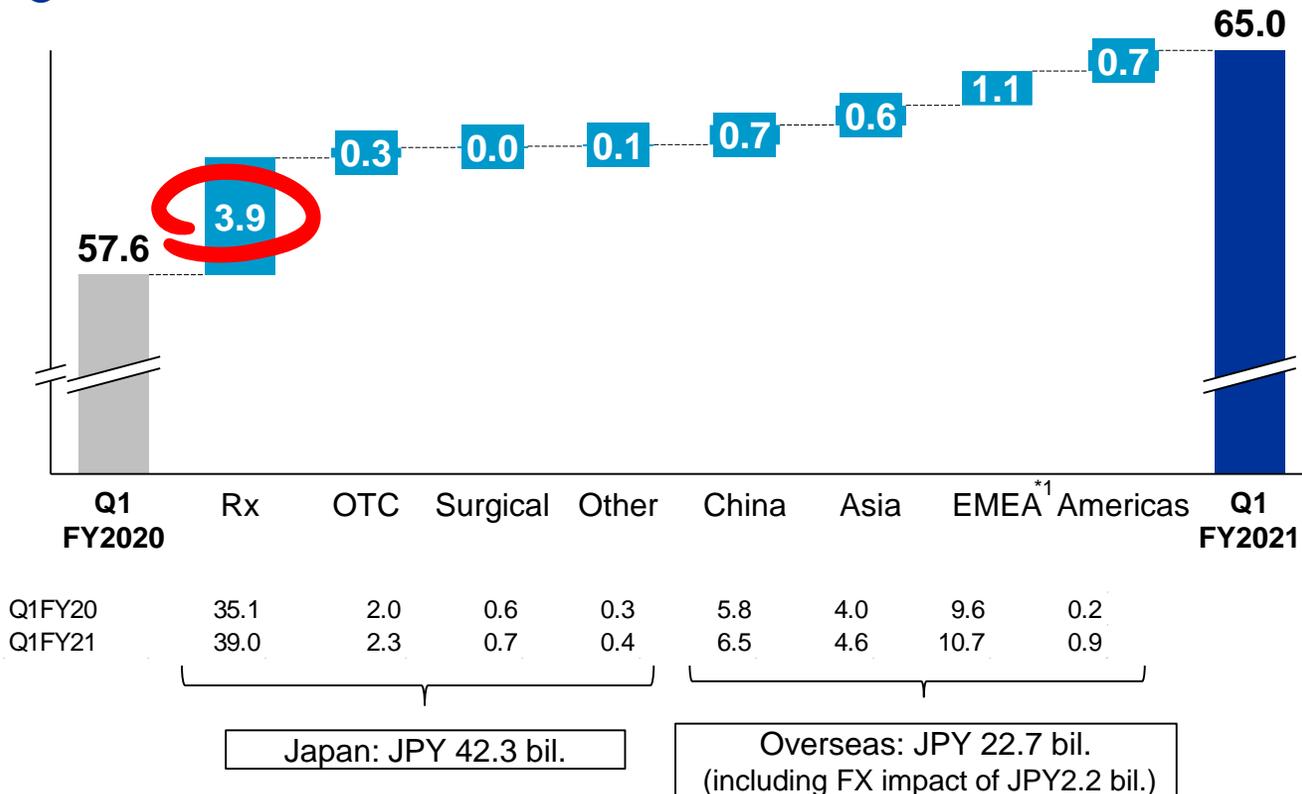
**JPY11.7 billion (YoY +0.5%)**

# Q1 FY2021: Growth Across All Businesses, Led by Solid Japan

## Increase/Decrease in Sales

(JPY billions)

Sales classified into countries or regions based on customer location



## Main Factors of Change

### Japan

- Strong Rx business revenue  
Major products such as *Alesion LX* driving revenue growth (*Alesion:LX=1:3*)
- OTC revenue increased as impact of drop in inbound demand annualized

### China

- Revenue growth in private hospital/retail channels and from new products (*Tapros/Diquas*) despite the impact of VBP<sup>\*2</sup>

### Asia

- Steady growth in Korea and Thailand, etc.
- Major products and new products to support continued growth

### EMEA

- Revenue growth despite impact of COVID-19
- Contributions from product roll-outs, including preservative-free products which respond to local needs

### Americas

- Revenue increased on contribution from Eyevence

\*1: EMEA; Europe, Middle East and Africa, \*2: Value Based Purchasing

(Reference)

# FY2021 Key Themes: Achieve Growth Recovery in China, Steadily Build US Business. Firmly Establish Foundation for Medium-to Long-Term Growth Under MTP2025



## MTP2025



<b>A</b> Profit ratio improvement in core businesses	<b>Japan</b>	<b>A</b> LCM (introduction of products and solutions based on patient needs)	<b>A B</b> Enhancement of new pipeline	<b>B</b> New areas (myopia, ptosis etc.)	
	<b>China</b>	<b>A</b> Rebuild growth drivers			
	<b>B</b> Expansion of new areas	<b>Asia/ EMEA</b>	<b>A</b> Steady growth driven by line-up expansion		
	<b>C</b> Strengthening of foundation as a global company	<b>Americas</b>	<b>B</b> Launch business led by Eyevance/Profit generation		
		<b>Consolidated</b>	<b>C</b> Establish platform (Manufacturing, IT) Strengthening product development capabilities		

# Agenda

## **1. Steady Progress Toward MTP2025**

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## **3. R&D Update**

## **Appendix**

## Steady Pipeline Progress: Toward Achieving Medium- and Long-Term Growth

Glaucoma	<b>STN1011700</b> <i>Eybelis</i>	<b>Presented results of P3 trial in Asia</b> at Asia-Pacific Glaucoma Congress (APGC). ➤ Data of three pivotal studies for US submission including this study, to be discussed on next page.
	<b>STN1012600</b> <i>Sepetaprost</i>	<b>Achieved LPI in P2 trial</b> in US. <b>Started preparations for P2 trial</b> (exploratory study) in Europe.
	<b>STN1013900</b> <i>Rhopressa</i>	<b>Achieved LPI in one trial*<sup>1</sup> and FPI in two trials</b> in P3 in Japan.
	<b>STN2000100</b> <i>PRESEFLO MicroShunt</i>	<b>Filed in Japan. Approved</b> in Australia.* <sup>2</sup> Received rejection letter in Korea; considering refiling. (Submitting in 5 countries in Asia)
VKC	<b>STN1007603</b> <i>Verkazia</i>	<b>Approved</b> in US.
Myopia	<b>STN1012700</b> <i>Atropine</i>	<b>Presented results of P2 trial in Asia</b> at Asia-Pacific Association of Cataract & Refractive Surgery (APACRS). ➤ Top-line data explained at the Q2 FY2020 results briefing.
	<b>STN1013400</b> <i>AFDX0250BS</i>	<b>Achieved FPI in P1 trial</b> in Japan.
MGD	<b>STN1010905</b> <i>Sirolimus</i>	<b>Started preparations for P2a trial.</b>

\*1 Conducted by Aerie, \*2 Glaukos Territory

## Filed in U.S. with the Data Including Two Phase 3 Studies Demonstrating Non-inferiority Required for FDA Approval

### Same level of IOP-lowering effect to 1st line product

#### PEONY (Asia)

- ✓ **Demonstrated non-inferiority** to latanoprost

#### Spectrum-4 (US)

- ✓ **Demonstrated non-inferiority** to timolol

#### Spectrum-3 (US)

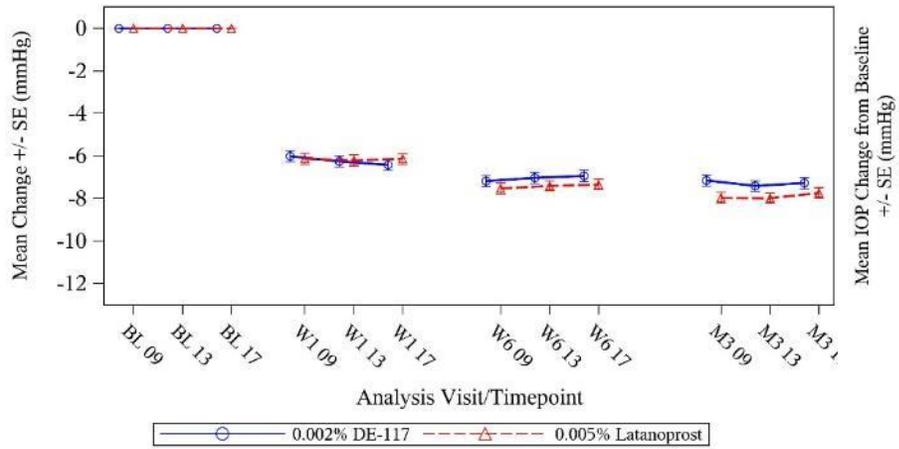
- ✓ The level of STN1011700 IOP lowering effect was **similar as that in those Spectrum-4**, although the criteria for non-inferiority to timolol maleate were not met

### No cosmetic change AEs were observed in US

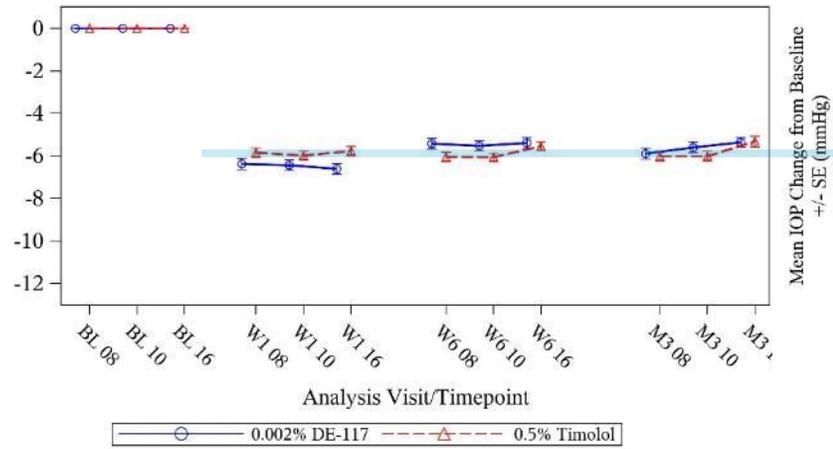
- No new safety concerns associated with administration of STN1011700 observed
- **No cosmetic change Adverse Effects (AEs) reported for eyes treated with STN1011700**
  - ⇒ Consistent with results from previous clinical and nonclinical studies (no effect of omidenepag on eyelash growth, pigmentation of iris, and deepening of upper eyelid sulcus (DUES))

# Filed in U.S. with the Data Including Two Phase 3 Studies Demonstrating Non-inferiority Required for FDA Approval

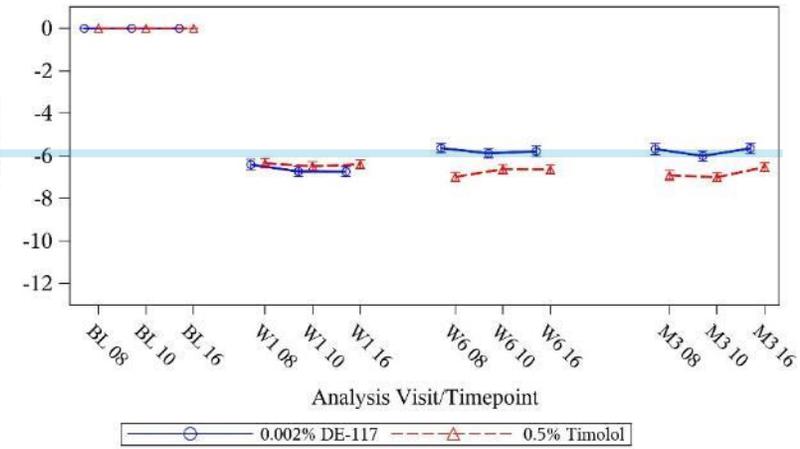
PEONY ✓



Spectrum-4 ✓



Spectrum-3



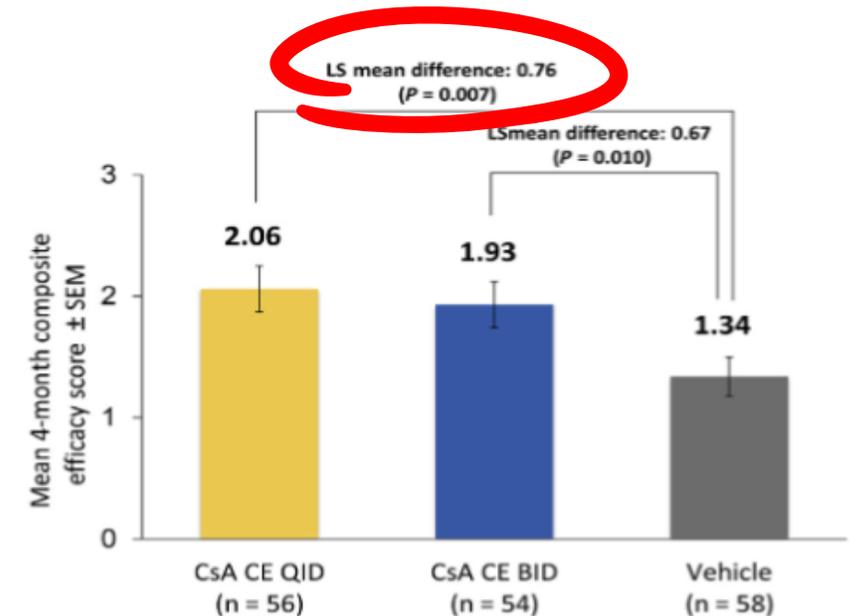
## Received Approval in U.S. Following Europe and Asia Based on Vektis Trial

### Vektis Study

Vektis was a prospective, multicenter, randomized, double-masked, vehicle-controlled phase 3 pivotal study assessing efficacy and safety of *Verkazia* in vernal keratoconjunctivitis (VKC)

**Provide new treatments for children in the United States suffering from VKC, a rare disease that significantly affects quality of life**

Mean composite efficacy score over the 4-month treatment period



**Already launched in EMEA and Asia. NDA filed in China**

## Three Pivotal Phase 3 Studies Are Ongoing in Japan Expect to Obtain the Results of Comparative Study with Ripasudil in H2 FY2021

Three pivotal P3 studies	FY20	FY21	FY22	FY23
<b>Comparative study with ripasudil</b> <ul style="list-style-type: none"> <li>➤ STN1013900 (QD) + vehicle (QD)</li> <li>➤ Ripasudil (BID)</li> </ul>		 ▲ LPI Completion scheduled for the end of 2021		
<b>Study under concomitant use of latanoprost</b> <ul style="list-style-type: none"> <li>➤ STN1013900 (QD) + latanoprost (QD)</li> <li>➤ Placebo (QD) + latanoprost (QD)</li> </ul>		 △ FPI Completion scheduled for Sep 2022		
<b>Long-term treatment study</b> <ul style="list-style-type: none"> <li>➤ STN1013900 (QD) (for low-IOL patients)</li> <li>➤ STN1013900 (QD)</li> <li>➤ STN1013900 (QD) + latanoprost (QD)</li> <li>➤ STN1013900 (QD) + timolol (BID)</li> </ul>		 △ FPI Completion scheduled for Sep 2023		

- **Filing in Asian countries** by using US Certificate of Pharmaceutical Product (CPP) is under preparation.

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# FY2021 Forecast: Unchanged from May 11th

(JPY billions)	FY2020		FY2021		YoY
	Actual	vs Revenue	Forecast	vs Revenue	
<b>Revenue</b>	<b>249.6</b>		<b>260.0</b>		<b>+4.2%</b>
Cost of sales	98.2	39%	101.0	39%	+2.8%
Gross margin	151.4	61%	159.0	61%	+5.0%
SG&A expenses	77.2	31%	81.0	31%	+5.0%
R&D expenses	24.1	10%	26.0	10%	+7.8%
<b>Core OP</b>	<b>50.1</b>	<b>20%</b>	<b>52.0</b>	<b>20%</b>	<b>+3.8%</b>
Non core SG&A expense	2.4	1%	0.4	0%	-83.2%
Amortization on intangible assets associated with products	9.9	4%	8.9	3%	-10.3%
Other income	16.0	6%	0.5	0%	-96.9%
Other expenses	40.9	16%	1.7	1%	-95.8%
<b>OP (IFRS basis)</b>	<b>12.9</b>	<b>5%</b>	<b>41.5</b>	<b>16%</b>	<b>+221.3%</b>
Finance income	1.3	1%	0.9	0%	-33.2%
Finance expenses	1.5	1%	0.2	0%	-86.6%
Investment loss by equity method	0.4	0%	1.2	0%	+235.5%
Profit before tax	12.4	5%	41.0	16%	+230.2%
Income tax expenses	5.8	2%	10.5	4%	+81.9%
<i>tax ratio</i>	46.5%		25.6%		
<b>Net profit (IFRS basis)</b>	<b>6.6</b>	<b>3%</b>	<b>30.5</b>	<b>12%</b>	<b>+359.0%</b>
ROE	2.2%		10%		+780.0%
Core net profit	37.5	15%	39.0	15%	+3.9%
USD (JPY)	105.95		105.00		
EUR (JPY)	123.73		125.00		
CNY (JPY)	15.61		16.50		

## Revenue

- Expect to increase year-on-year due to sales expansion in each region

**Revenue JPY260.0 billion (YoY +4%)**

## Operating profit

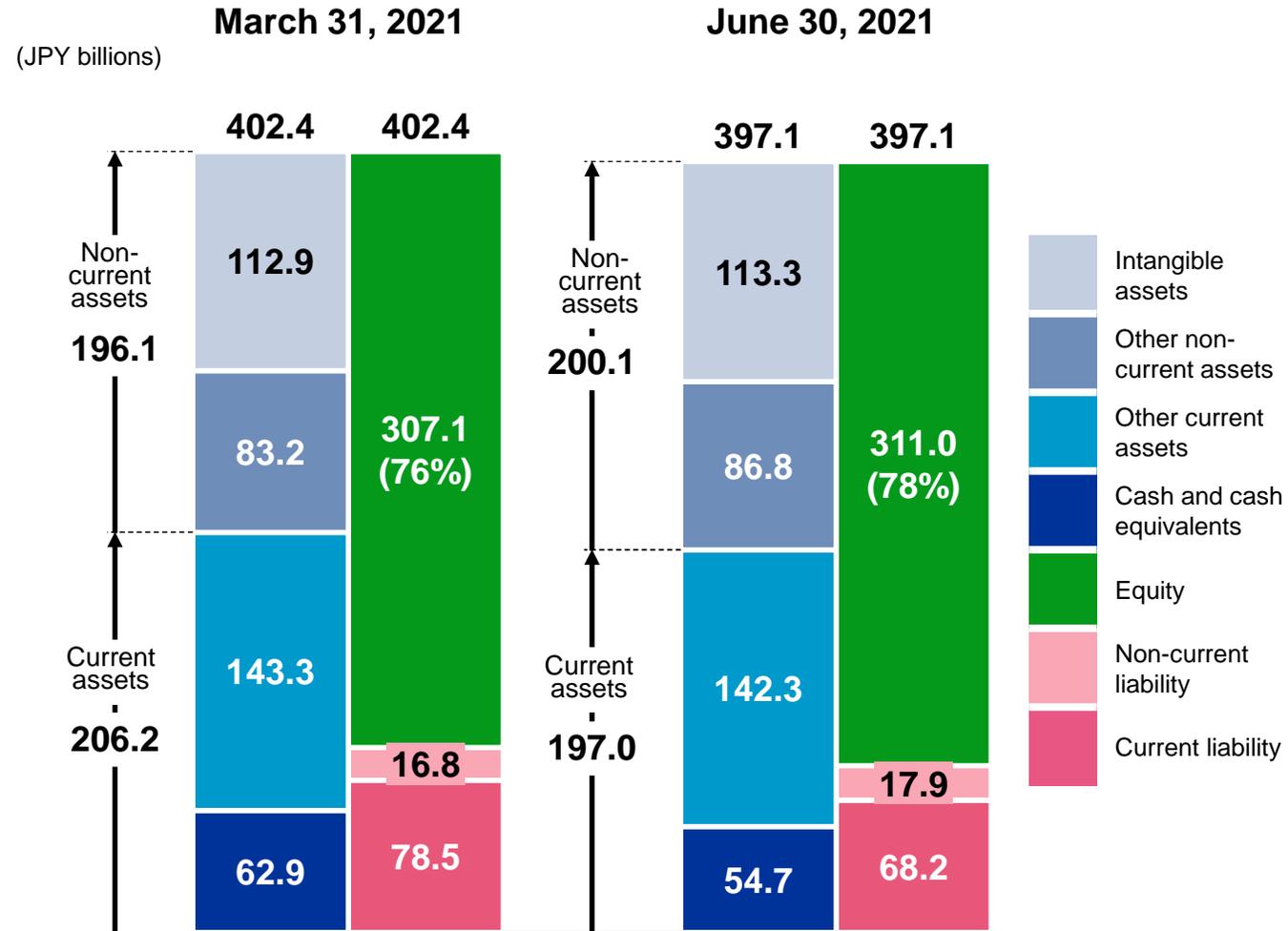
- Expect to increase profits (core) on higher sales

**Core OP JPY52.0 billion (YoY +4%)**

- Absence of impairment loss and one-off costs recorded in the previous fiscal year

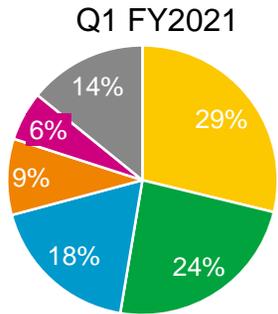
**OP (IFRS basis) JPY41.5 billion (YoY +221%)**

# Q1 FY2021 Financial Position



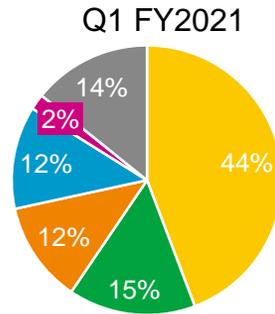
# Q1 FY2021 Revenue by Region

## Consolidated



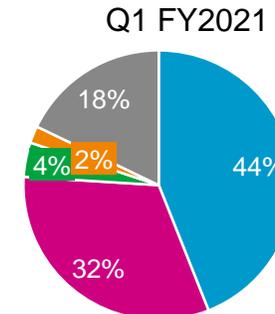
(JPY billions)	Q1 FY2021	Q1 FY2020 (Ref.)
EYLEA*	18.7	16.8
Cosopt	5.4	5.6
Alesion (Incl. Alesion LX)	5.1	3.0
Other	36.1	30.5
<b>Total</b>	<b>65.0</b>	<b>57.6</b>

## Japan



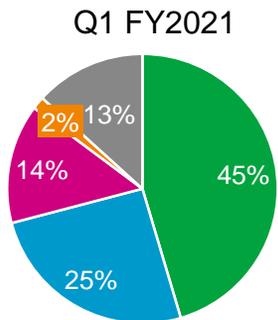
(JPY billions)	Q1 FY2021	Q1 FY2020 (Ref.)
EYLEA*	18.7	16.8
Alesion (Incl. Alesion LX)	5.0	3.0
Diquas	3.4	3.0
Diquas	15.2	15.2
<b>Total</b>	<b>42.3</b>	<b>38.0</b>

## China



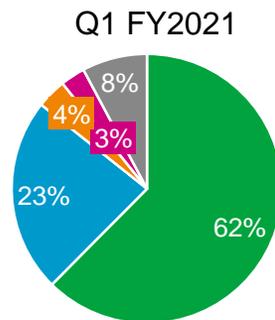
(JPY billions)	Q1 FY2021	Q1 FY2020 (Ref.)
Hyalein	2.1	2.3
Cravit	1.8	2.2
Diquas	0.7	0.1
Other	1.9	1.2
<b>Total</b>	<b>6.5</b>	<b>5.8</b>

## Asia



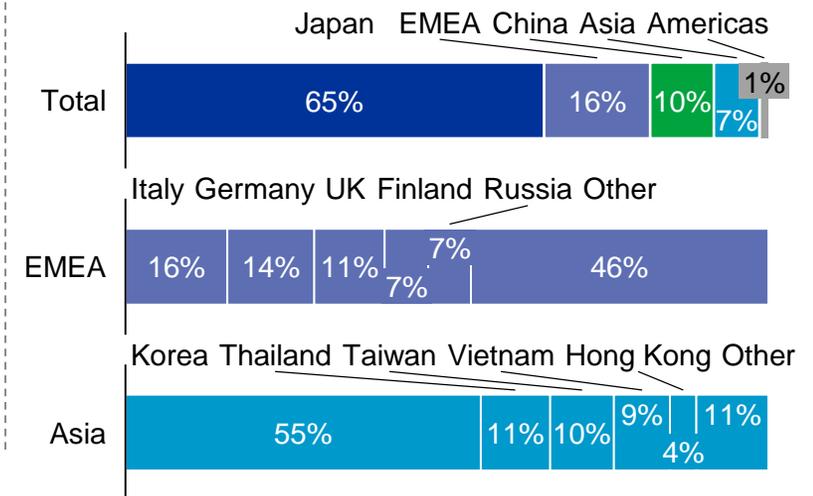
(JPY billions)	Q1 FY2021	Q1 FY2020 (Ref.)
Cosopt	1.2	1.0
Cravit	0.5	0.4
Tapros	0.5	0.5
Other	2.4	2.1
<b>Total</b>	<b>4.6</b>	<b>4.0</b>

## EMEA



(JPY billions)	Q1 FY2021	Q1 FY2020 (Ref.)
Cosopt	2.6	2.5
Tapros	1.6	1.7
Ikervis	1.4	0.7
Other	5.0	4.6
<b>Total</b>	<b>10.7</b>	<b>9.6</b>

## Revenue in each region (Q1 FY2021)



■ Intravitreal VEGF inhibitor 
 ■ Glaucoma/Device 
 ■ Dry eye 
 ■ Allergy 
 ■ Bacterial conjunctivitis 
 ■ Other

\*EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

# Current Status of Research and Development (1)

As of July 2021  
Updated information is in blue

Indication	General Name	Dev. Code	Region	Development Status
Glaucoma	<b>Omidenepag isopropyl</b> <i>EYBELIS</i>	<b>STN1011700</b> DE-117	US	Filed <i>Plan: FY2021 approval</i>
			Japan	Launched
			Asia	Launched in Korea
	Sepetaprost	<b>STN1012600</b> DE-126	US	P2 <i>Plan: FY2022 additional P2 completion</i>
			Japan	P2b (dose finding study completed)
			Europe	<i>Plan: FY2021 P2 (exploratory study) start</i>
	Implant device <i>PRESERFLO MicroShunt</i>	<b>STN2000100</b> DE-128	Japan	Filed in May 2021 <i>Plan: FY2021 approval</i>
			Europe	Launched
			Asia	Filed <i>Plan: FY2021 approval</i>

License-out to Glaukos in Americas, Australia and New Zealand in May 2021.

US: FDA is obtaining additional input from practicing glaucoma surgeons to ensure a complete evaluation of the clinical data submitted in the PMA.

Canada: Approved. Glaukos is preparing to launch.

Australia: Approved in May 2021.

## Current Status of Research and Development (2)

As of July 2021  
Updated information is in blue

<i>Indication</i>	<i>General Name</i>	<i>Dev. Code</i>	<i>Region</i>	<i>Development Status</i>
Glaucoma	Netarsudil dimesylate <i>Rhopressa</i>	<b>STN1013900</b> AR-13324	Japan	Started P3 in November 2020 <i>Plan: FY2023 P3 completion</i>
Myopia	Atropine sulfate	<b>STN1012700</b> DE-127	Japan	P2/3 <i>Plan: FY2023 P2/3 completion</i>
			China	<i>Plan: FY2021 P1 start</i>
			Asia	P2 (met primary endpoint)
	AFDX0250BS	<b>STN1013400</b>	Japan	Started P1 in July 2021 <i>Plan : FY2021 P1 completion</i>
Vernal keratoconjunctivitis	Ciclosporin <i>Verkazia</i>	<b>STN1007603</b> DE-076C	US	Approved in June 2021 <i>Plan: Launch in FY2021</i>
			China	Filed <i>Plan: Approval in FY2021</i>
Dry eye	Diquafosol sodium (long-lasting) <i>Diquas</i>	<b>STN1008903</b> DE-089C	Japan	P3 (met primary endpoint) <i>Plan: FY2021 filing</i>
Meibomian gland dysfunction	Sirolimus (eye drop)	<b>STN1010905</b>	Japan	<i>Plan: FY2021 P2a start</i>

# Current Status of Research and Development (3)

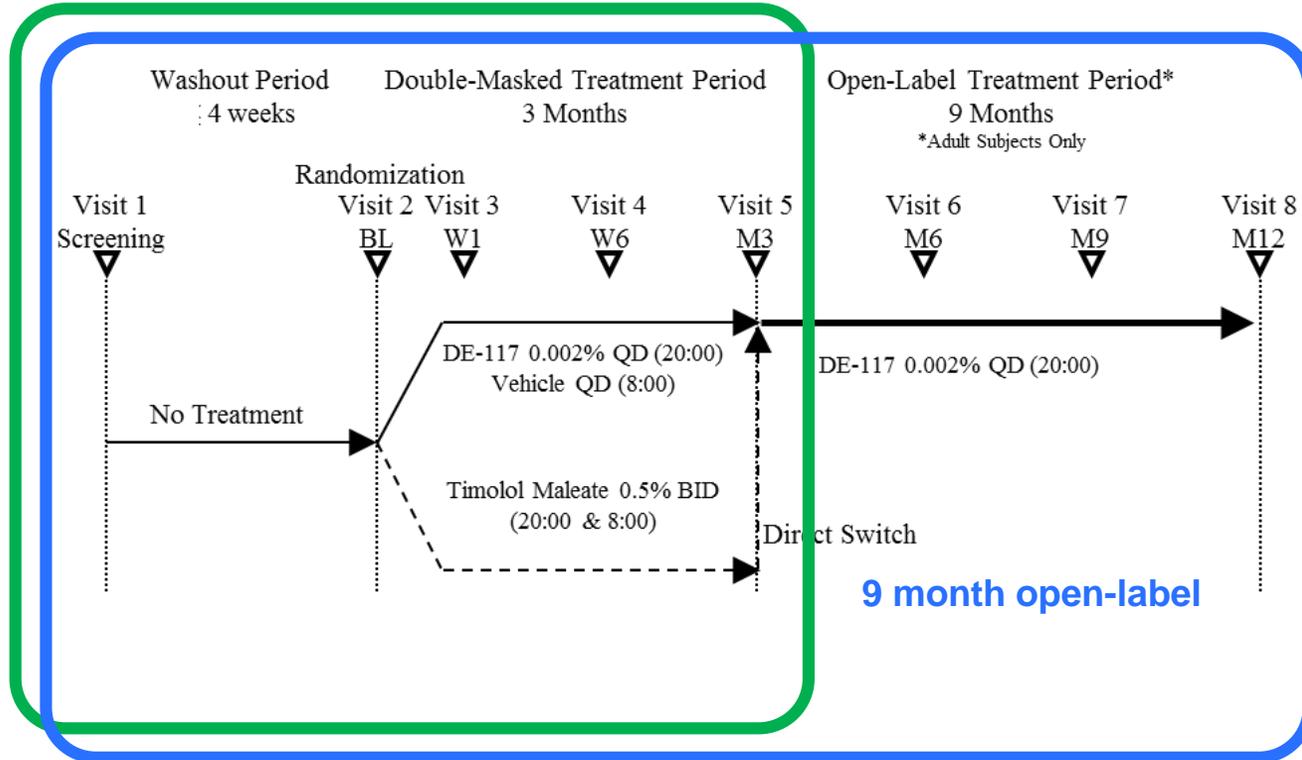
As of July 2021  
Updated information is in blue

Indication	General Name	Dev. Code	Region	Development Status
Glaucoma	Tafluprost / timolol maleate (combination) <i>TAPCOM / TAPTIQOM</i>	<b>STN1011101</b> DE-111A	China	P3 <i>Plan: FY2023 P3 completion</i>
	Latanoprost	<b>STN1013001</b> DE-130A Catioprost	Europe Asia	P3 <i>Plan: FY2021 P3 completion</i>
Uveitis	Sirolimus (intravitreal injection)	<b>STN1010900</b> DE-109	US	P3 <i>Plan: FY2022 P3 completion (FY2021 interim analysis)</i>
			Japan	P3
			EU	P3
			Asia	Filed

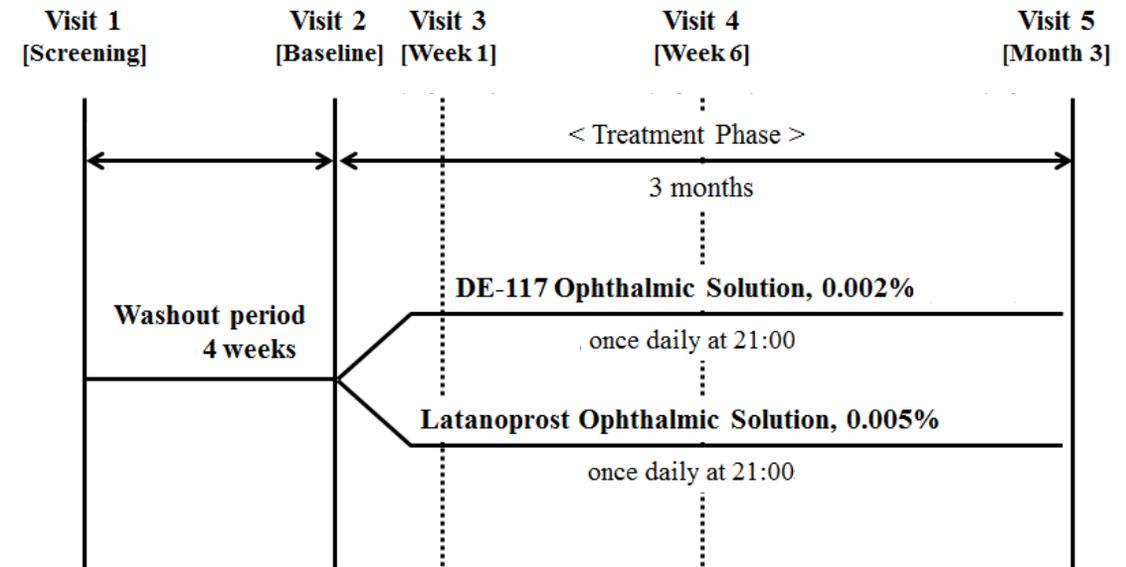
- STN1013800 (RVL-1201): The company is planning to start clinical trials for blepharoptosis in FY2021 in Japan and also considering filing in Asia with data used for US approval.  
Licensing region / Japan, China, Asia and Europe
- STN6000100 (jCell): Our partner company (jCyte) has started a phase 2 safety study (NCT04604899) for retinitis pigmentosa with an estimated completion in FY2022. jCyte and Santen have begun preparations to move the program to the phase 3 stage.  
Licensing region / Japan, China, Asia and Europe

# STN1011700: Phase 3, Randomized, Double-Masked, Active-Controlled, Parallel-Group, Multicenter Study

## Spectrum-3 & -4



## PEONY



PEONY Study has identical study design as Spectrum-3 & -4 studies for three-month double-masked treatment with latanoprost as a comparator

# STN1010905 (Sirolimus, Eye Drop): Meibomian Gland Dysfunction (MGD)

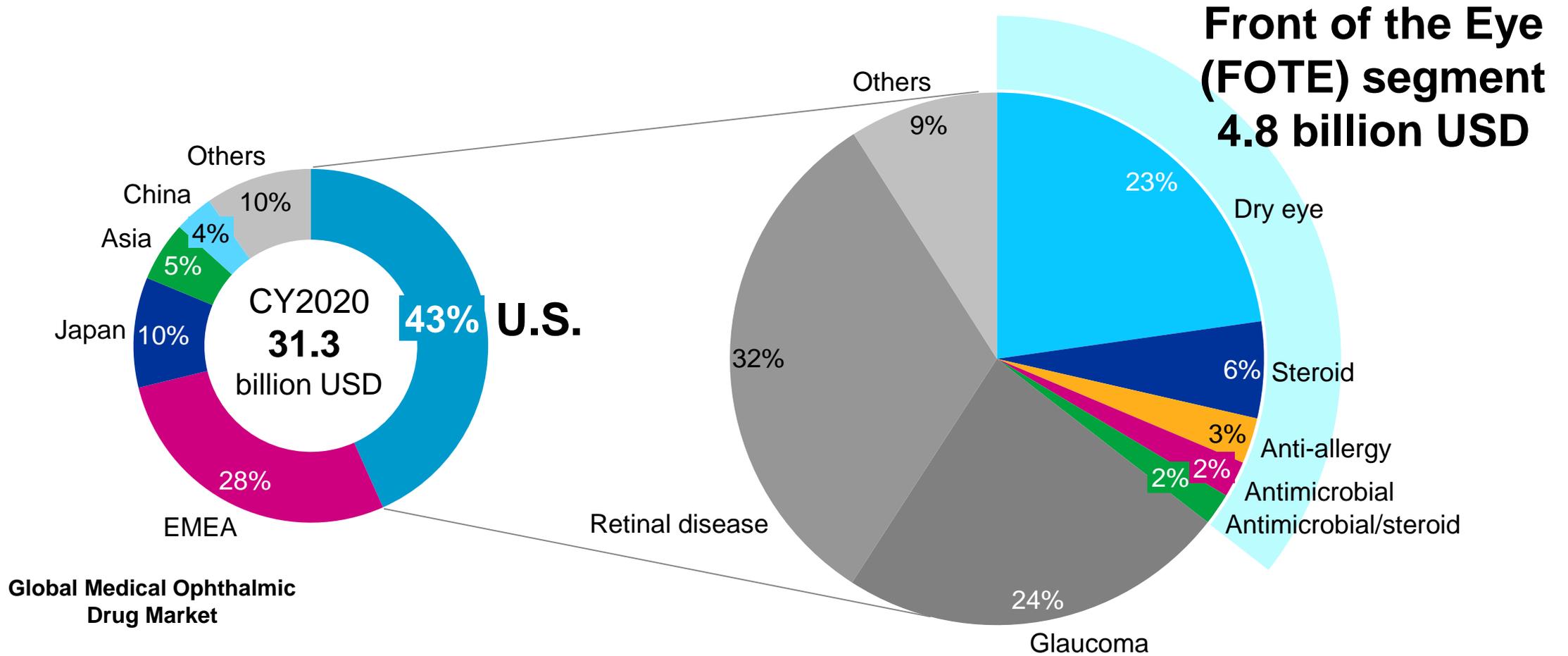
## MGD:

- Meibomian gland dysfunction (MGD) is a condition caused by functional abnormalities of the meibomian glands, due to various causes. MGD is associated with chronic ocular discomfort
- MGD is an ocular disease with a substantial patient population similar to dry eye (Hirado-Takushima study)
  - ✓ MGD prevalence: 32.9% (dry eye prevalence is also 33.4% in this study)
  - ✓ Coexistence rate of MGD and dry eye: 12.9%
- Treatment Options:  
Treatment options are lid hygiene, warm compresses applied to the eyelids, extruding secretions from MG, etc. but currently, no medication specifically approved for MGD is available.

**Expect efficacy of STN1010905 based on improvement to meibomian gland function from sirolimus**

# Huge Market Accounting for Approximately Half of the Global Market

## FOTE Segment Accounts for Approximately 40%



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## Have Products for FOTE Segment with Experience in Ophthalmic Treatment and Market Recognition. Aim to Expand Sales by Leveraging Santen's Strengths to Invest in Appropriate Commercial Strategies and Resources

	Brand Name	Indications	Product Overview	Market Size* <sup>1</sup>
Eyevance Products	 ZERVIAE <sup>®</sup> cetirizine ophthalmic solution (0.24%) <small>FORMULATED WITH HYDRELLA</small>	Allergic conjunctivitis	First and only topical eye drop of the antihistamine cetirizine used for the treatment of ocular itching occurring in allergic conjunctivitis. Launched in Apr. 2020	0.38 billion USD (Anti-allergy market)
	 TobraDex <sup>®</sup> ST (tobramycin/dexamethasone ophthalmic suspension) 0.3%/0.05%	Bacterial ocular infection with steroid-responsive inflammatory ocular conditions	Combination suspension eye drop with anti-inflammatory dexamethasone and antimicrobial tobramycin. Launched in Apr. 2020 as next-generation product of <i>TobraDex</i>	0.26 billion USD (Antimicrobial /steroid market)
	 Flarex <sup>®</sup> (fluorometholone acetate ophthalmic suspension) 0.1%	Inflammatory condition (blepharitis, conjunctivitis, keratitis, iritis, etc.)	Anti-inflammatory steroid ophthalmic solution of fluorometholone suspension. Launched in Feb. 2019	0.79 billion USD (Steroid market)
	 FRESHKOTE <sup>®</sup> Preservative Free LUBRICANT EYE DROPS	Dry eye	Polyvinyl alcohol and povidone polymer mixture with preservative-free artificial tears (OTC) that prevent dryness and inflammation of the eyes	3.1 billion USD (Dry eye market)
	 Natacyn <sup>®</sup> (natamycin ophthalmic suspension) 5%	Fungal blepharitis, conjunctivitis and keratitis	Only antifungal topical eye drop in the U.S. market	-
Santen	 Verkazia <sup>™</sup>	Vernal keratoconjunctivitis	A ciclosporin formulation with prolonged retention on the eye and improved corneal resorption through a unique technique (Cationic Nano-emulsion)	-
	 Cationorm <sup>®</sup> ACTS LIKE REAL TEARS	Dry eye	Ophthalmic solution (OTC) for dry eye containing mineral oil, supporting eye moisture replacement and evaporation prevention	3.1 billion USD (Dry eye market)

\*1 Source: Copyright © 2021 IQVIA. IQVIA MIDAS 2020.Q1-2020.Q4; Santen analysis based on IQVIA data. Reprinted with permission. Anti-allergy market: S01G; Dry eye market: S01K; Steroid market: S01B; Antimicrobial steroid market: S01C

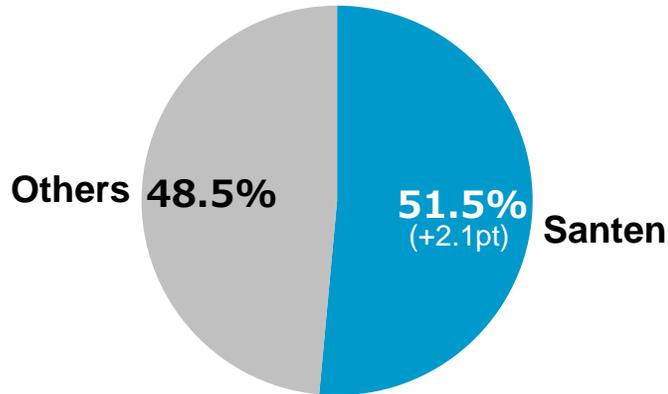
# Prescription Ophthalmic Market in Japan (Jul. 2020 - Jun. 2021)

Remain No.1 for overall market and all segments

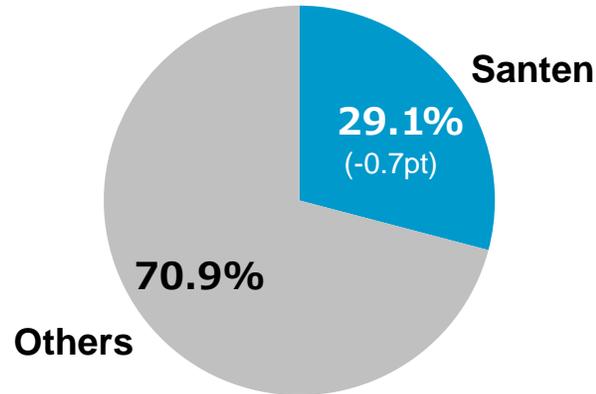
Segment: Market size

Graph: Market share (change from last year)

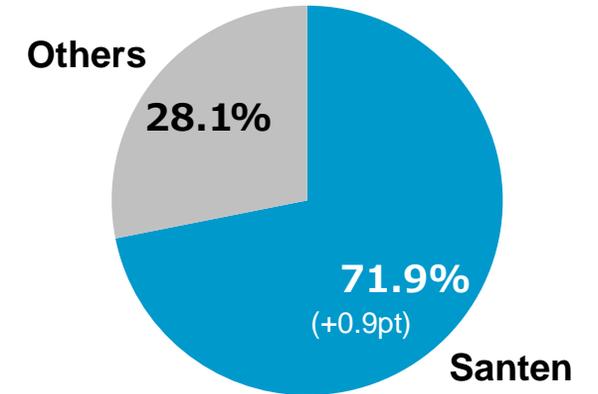
**Total: JPY383.1bil**



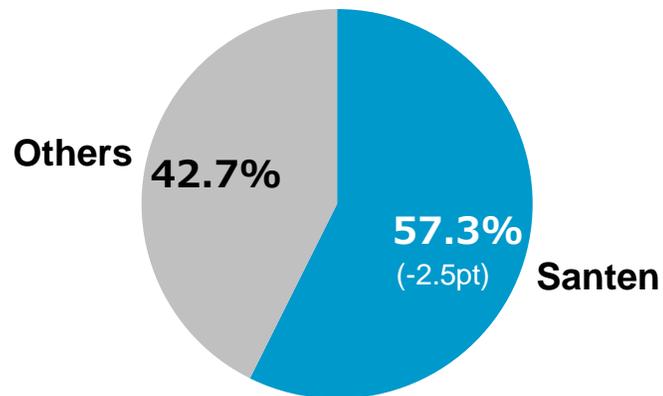
**Glaucoma: JPY104.3bil**



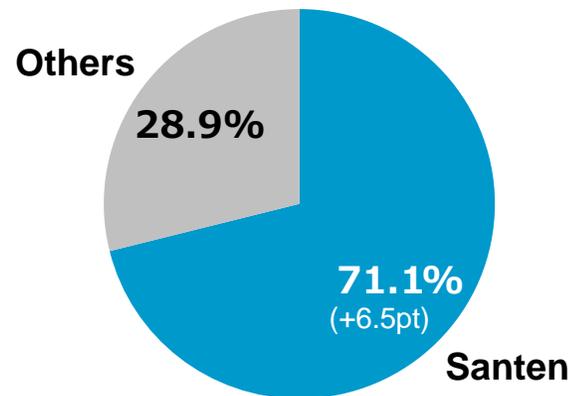
**Retinal disorders\*: JPY113.0bil**



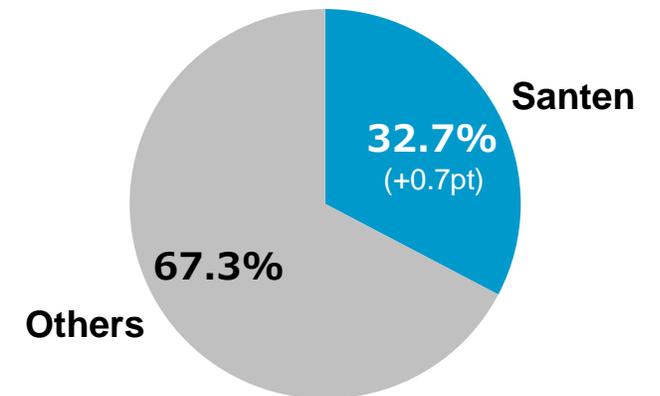
**Corneal / dry eye: JPY42.7bil**



**Allergy: JPY62.2bil**



**Anti-infection: JPY8.5bil**



\*Including co-promoted product (Anti-VEGF EYLEA) of Bayer Yakuhin, Ltd. (MAH)

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## In Addition to Financial Results Meetings, Planning to Hold R&D Day and US Strategy/ESG Meeting

Date	Event	Main Contents (Planned)
E/Sep– B/Oct (Tentative plan)	R&D Day	Development-related session centered on new areas
B/Nov	Q2 FY2021 financial results meeting	Business update Q2 FY2021 results
B/Feb	Q3 FY2021 financial results meeting	Business update Q3 FY2021 results
February-March (Tentative plan)	IR-Day	US business strategy ESG initiatives
B/May	FY2021 financial results meeting	FY2021 results FY2022 forecast

