Q1 FY2023 Financial Results

August 3, 2023

Santen Pharmaceutical Co., Ltd.

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:
  External factors such as trends in pharmaceutical administration, social and economic conditions, changes in laws and regulations, and exchange rates. Changes in the competitive environment, such as the impact of generics. Reliance on certain products and business partners, such as dependence on mainstay products, reliance on licensed products, and reliance on certain business partners for the supply of bulk drugs. Uncertainty in the development of new drugs, the possibility that R&D investment will not produce sufficient results, the success or failure of alliances with other companies, and other R&D activities. Other factors include intellectual property rights, production slowdowns and delays caused by natural disasters, product supply issues such as discontinuations and product recalls, litigation, and risks related to global business development.
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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.

Agenda

1 Financial Results

2 R&D Update

3 Appendix

1

Financial Results

Kazuo Koshiji
Chief Financial Officer &
Chief Risk Officer

Q1 FY2023 Overview

Strong start across all regions with increase in revenue and Core OP
Executing strategy for medium to long-term growth
Structural reforms progress ahead of schedule. Solid outlook on streamlining of Americas business

■ Q1 FY2023 results

- Revenue growth +10.5% YoY (JPY 72.4 billion) / 27% vs FY2023 forecast
- Core OP growth +46.6% YoY (JPY 15.5 billion) / 34% vs FY2023 forecast

■ Profitability improvement: better-than-projected progress to complete streamlining in Americas

- Contribution profit in Q1 (Americas): JPY -0.4 billion, improved JPY 0.8 billion YoY.
  Regional profit in Q1 (Americas): JPY -1.0 billion, improved JPY 1.0 billion YoY.
  Clear path to achieve approx. JPY 5.0 billion improvement on full-year basis
- Further improvement from Q2 in FY2023 Americas contribution & regional loss expected from agreed license-out and asset transfer for pharmaceutical products in Americas
- Revenue per employee in overseas: double-digit growth YoY*1

*1: Based on China, Asia and EMEA CFU employees. Excluding FX impact and one-time factors

Strong start across regions drive revenue and core OP
Delivering better-than-projected results

	Q1 FY2022 ACT	Q1 FY2023 ACT
USD (JPY)	129.16	138.01
EUR (JPY)	137.80	149.80
CNY (JPY)	19.58	19.58

(JPY billions)	Q1 FY2022 Actual	Q1 FY2022 vs Revenue	Q1 FY2023 Actual	Q1 FY2023 vs Revenue	Q1 FY2023 YoY
Revenue	65.5	-	**72.4**	**-**	**+10.5%**
Cost of sales	28.4	43%	30.0	41%	+5.5%
Gross profit	37.1	57%	**42.4**	**59%**	**+14.3%**
SG&A expenses	19.4	30%	20.7	29%	+6.3%
R&D expenses	7.1	11%	6.2	9%	-12.4%
Core operating profit	10.6	16%	**15.5**	**21%**	**+46.6%**
Non-core expenses	-	-	0.5	1%	-
Amortization on intangible assets associated with products	2.6	4%	2.3	3%	-8.8%
Other income	0.3	1%	0.3	0%	-8.9%
Other expenses	0.0	0%	0.2	0%	+388.0%
Operating profit	8.3	13%	**12.7**	**18%**	**+53.0%**
Finance income	1.4	2%	1.1	1%	-24.2%
Finance expenses	0.1	0%	0.2	0%	+37.1%
Share of loss of Investments accounted for using equity method	0.5	1%	0.8	1%	+46.5%
Profit before tax	9.1	14%	12.9	18%	+41.8%
Income tax expenses	2.4	4%	2.5	3%	+3.2%
Actual tax ratio	*26.2%*	-	*19.1%*	-	*-7.1pt*
Net profit	6.7	10%	**10.4**	**14%**	**+55.5%**
Core net profit	7.7	12%	12.8	18%	+65.2%

Gross margin

+14.3% YoY

- Revenue: +10.5% YoY, strong progress across regions with +25% YoY overseas growth including China market recovery excluding re-evaluation of *Ikervis* allowance for insurance reimbursement in EMEA (one time/ JPY +2.3 billion)
- COGS: -1.9pt of ratio YoY, resulting from region/product mix and above allowance in EMEA

Operating profit (Core basis)

+46.6% YoY

- Decrease in SG&A ratio, resulting from strict SG&A control, cost optimization and others

Operating profit (IFRS)

+53.0% YoY

- Structural reform cost: JPY 0.6 billion (non-core expenses and other expenses)

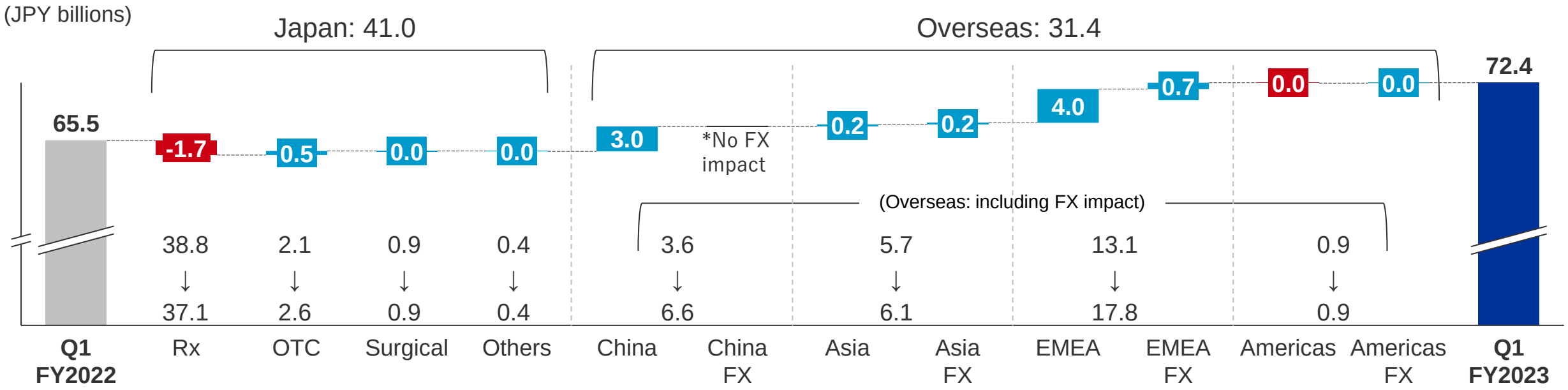
Net profit (IFRS)

+55.5% YoY

- Decrease in tax ratio caused by one-time factors (tax ratio excluding one-time factors: 21.4%)

Q1 FY2023 Sales bridge

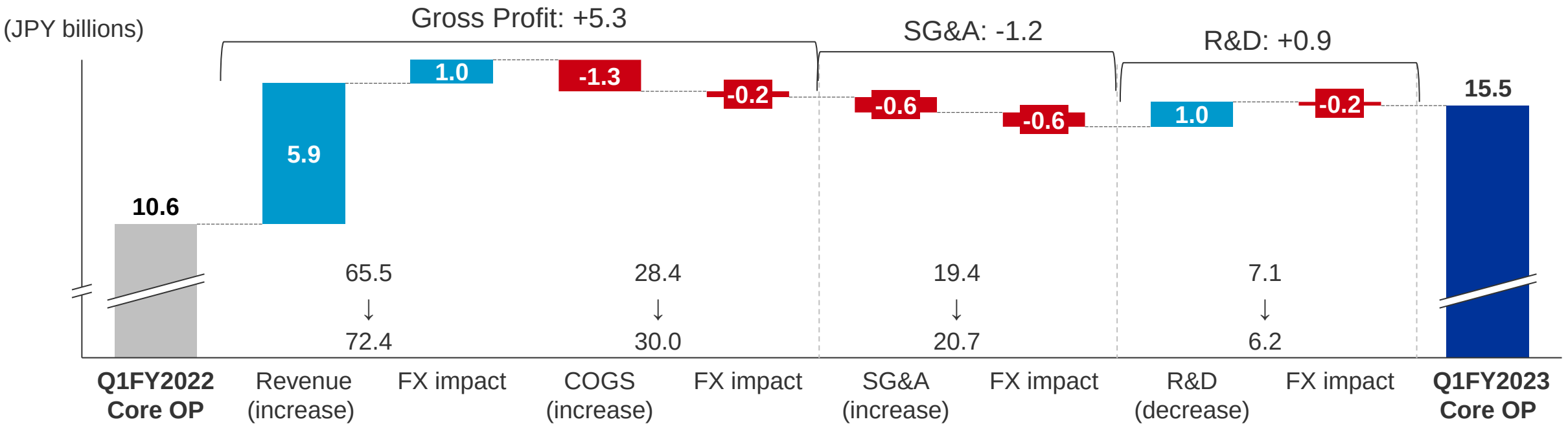
YoY Sales growth of +9.0%(excluding FX impact) from strong start across all regions including China market recovery



Japan	-3.0% YoY: Growth from mainstay products including *Diquas LX* absorbed impact from reactionary drop due to high market inventory level at end of FY2022 for *Alesion* products. Recovery trend in inbound demand for OTC products
China	+81.3% YoY (Ex. FX impact +81.3%): Market recovery from COVID-19 resurge. Strong performance from mainstay products such as *Tapros* and *Diquas* as well as major products in multi-channel segments
Asia	+7.5% YoY (Ex. FX impact +4.3%): Steady growth from mainstay products in key markets
EMEA	+36.3% YoY (Ex. FX impact +30.6%): Continued growth in glaucoma products. Strong initial sales momentum of *Rocklatan* launched last year. Including *Ikervis* one-time impact
Americas	+0.1% YoY (Ex. FX impact -5.5%): Agreed license-out and asset transfer for pharmaceutical products. In the transfer process

*Sales classified into countries or regions based on customer's location. EMEA：Europe, Middle East and Africa

Significant YoY Core OP improvement from strong sales and cost optimization



Gross profit	Net +5.3bil YoY. Increased revenue (incl. FX impact) and decrease in COGS ratio (-1.9pt YoY) from region/product mix and one-time factor
SG&A	Net -1.2bil YoY. SG&A ratio decreased from cost optimization, cost controls and others despite sales-linked-expense increases (SG&A ratio: -1.1pt YoY)
R&D	Net +0.9bil YoY. Mainly from fluctuations caused by development stage progress in each project and timing of expenses recording (R&D expenses ratio: -2.2pt YoY). No change for FY plan and policy to prioritize investment to R&D

FY2023 Outlook: No change

Revenue: JPY 273.0billion, Core OP: JPY 46.0billion, Annual dividend: JPY 32

	FY2022 ACT	FY2023 FCST
USD (JPY)	135.40	130.00
EUR (JPY)	140.97	140.00
CNY (JPY)	19.72	19.00

(JPY billions)	FY2022		FY2023		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	279.0	-	**273.0**	**-**	**-2.2%**
Cost of sales	113.0	40%	111.0	41%	-1.7%
Gross profit	166.1	60%	**162.0**	59%	**-2.5%**
SG&A expenses	93.5	34%	87.0	32%	-7.0%
R&D expenses	28.3	10%	29.0	11%	+2.5%
Core operating profit	44.2	16%	**46.0**	**17%**	**+4.0%**
Non-core expenses	2.7	1%	0.8	0%	-70.5%
Amortization on intangible assets associated with products	9.5	3%	9.4	3%	-1.2%
Other income	3.5	1%	0.6	0%	-83.0%
Other expenses	38.6	14%	4.4	2%	-88.6%
Operating profit	-3.1	-	**32.0**	**12%**	**-**
Finance income	1.2	0%	1.0	0%	-13.2%
Finance expenses	1.5	1%	0.8	0%	-46.6%
Share of loss of Investments accounted for using equity method	2.4	1%	2.4	1%	+1.6%
Profit before tax	-5.8	-	29.8	11%	-
Income tax expenses	9.2	3%	7.4	3%	-19.4%
Actual tax ratio	-	-	*25%*	-	-
Net profit	-15.0	-	**22.4**	**8%**	**-**
ROE	-		8%		
Core ROE	10.5%		12%		
Core net profit	33.2	12%	34.5	13%	+3.8%

FY2023 Outlook: factors to consider

Revenue

Japan

- Outcome & timing on market entry of generics for major products
- Sales momentum of new product (rebamipide suspension)
- Pollen-levels

Overseas

- China: sustained market recovery
- Asia/EMEA: sales trend in key markets and stable CMO supply.
- Americas: Upfront payment from license-out and asset transfer agreement

SG&A and others

- Progress in company-wide structural reform. Earlier-than-expected loss reductions in Americas

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R&D Update

Peter Sallstig
Chief Medical Officer

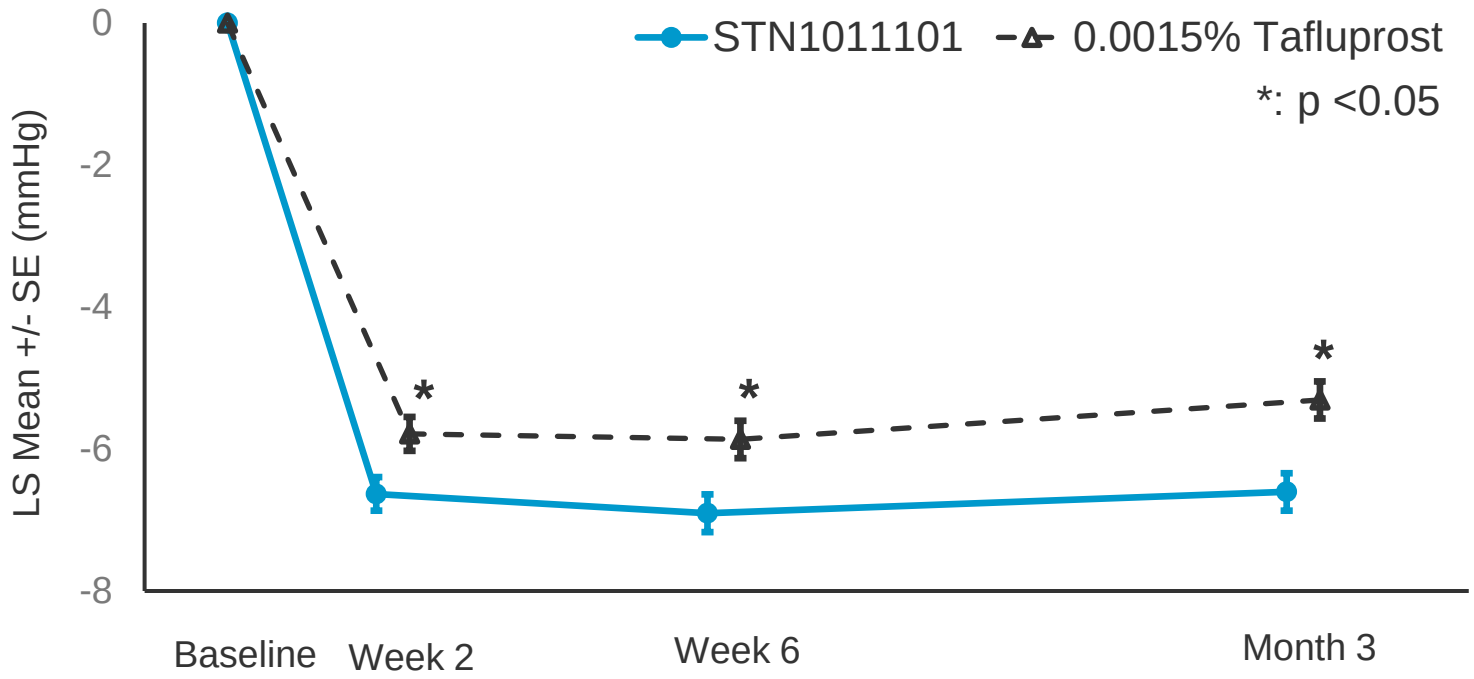
Progress in glaucoma and refractive error

Existing area	STN10**11**101 *TAPCOM / TAPTIQOM*	Glaucoma	Achieved **primary endpoint** in P3 trial in China (Filed by utilizing oversea data in December 2022)
New area	STN10**134**00 AFDX0250BS	Myopia	Achieved **FPI**[1] in P2a trial in Japan
	STN10**136**00 Ursodeoxycholic acid	Presbyopia	Achieved **LPO**[2] in P2a trial in US

1. FPI; First Patient In. 2. LPO; Last Patient Out.

Met primary endpoint in P3 trial in China. Confirmed safety and tolerance

Change from baseline of average diurnal IOP (ANCOVA analysis: Chinese information only)



- The superiority of STN10**111**01 IOP lowering effect compared to 0.015% tafluprost was confirmed (at Month 3 based on Bayesian method).
- Analysis only Chinese information showed statistically significant as well as the original EU study.
- STN10**111**01 was tolerated in Chinese population. No new safety issue was found.

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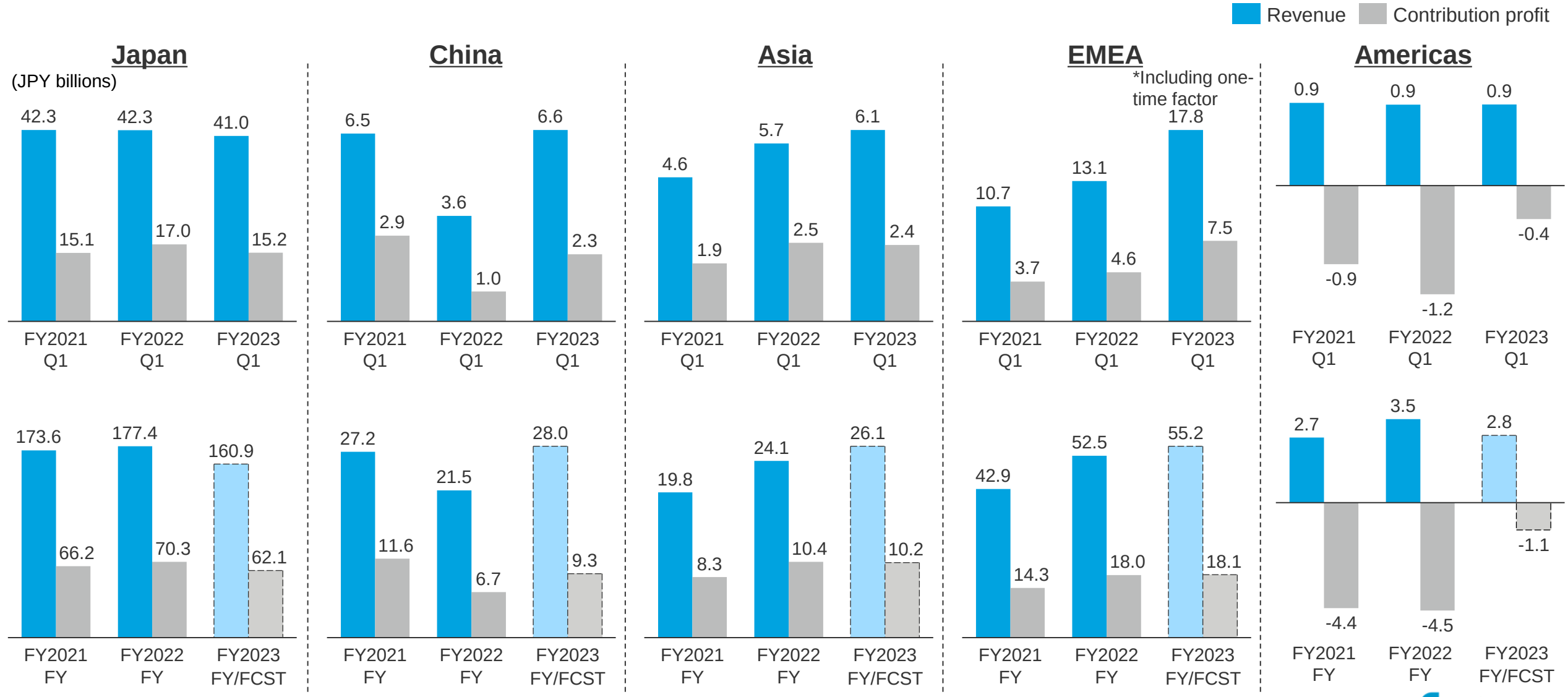
Appendix

Revenue and contribution profit by region



Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	Q1 FY2022 Actual	Q1 FY2023 Actual	vs FY2023 forecast	FY2022 Actual	FY2023 Forecast
USD	129.16	138.01	106.2%	135.40	130.00
EUR	137.80	149.80	107.0%	140.97	140.00
CNY	19.58	19.58	103.1%	19.72	19.00

Sensitivities

Impact of a 1% depreciation of the yen (vs FY2023 forecast rate)

(JPY billions)

	Total*	USD	EUR	CNY
Revenue	+1.0	+0.03	+0.50	+0.28
Core OP	+0.1	-0.11	+0.06	+0.06
OP (IFRS)	+0.0	-0.13	+0.04	+0.04

*Total: impacts from USD, EUR, CNY and other major currencies (rounding to nearest 100 million)

FX impact on Q1 FY2023 (vs Q1FY2022)

(JPY billions)

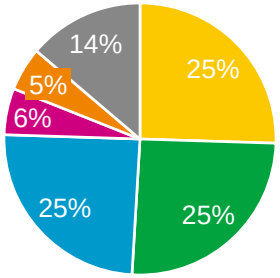
	Total
Revenue	+1.0
Core OP	-0.0
OP (IFRS)	-0.1

Q1 FY2023 revenue by region

Consolidated

(JPY billions)	Q1 FY2022 (Ref.)	Q1 FY2023
EYLEA*1	18.2	18.5
Diquas (Incl. Diquas LX)	5.1	7.1
Cosopt	6.0	6.3
Others	36.2	40.5
Total	65.5	72.4

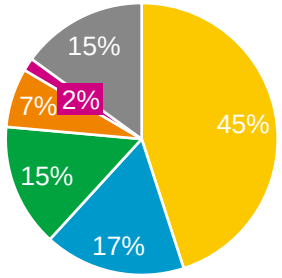
Q1 FY2023



Japan

(JPY billions)	Q1 FY2022 (Ref.)	Q1 FY2023
EYLEA*1	18.2	18.5
Diquas (Incl. Diquas LX)	3.9	5.5
Alesion*2 (Incl. Alesion LX)	4.8	2.8
Others	15.4	14.3
Total	42.3	41.0

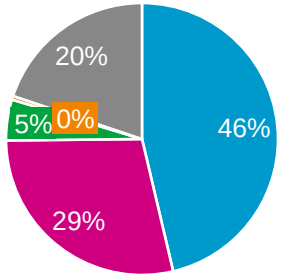
Q1 FY2023



China

(JPY billions)	Q1 FY2022 (Ref.)	Q1 FY2023
Hyalein	0.9	2.0
Cravit	0.7	1.6
Diquas	0.7	1.1
Others	1.4	1.9
Total	3.6	6.6

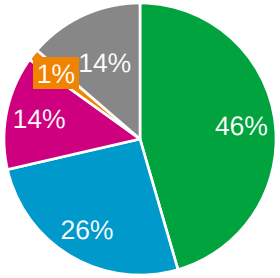
Q1 FY2023



Asia

(JPY billions)	Q1 FY2022 (Ref.)	Q1 FY2023
Cosopt	1.5	1.6
Cravit	0.5	0.6
Hyalein	0.8	0.6
Others	3.0	3.3
Total	5.7	6.1

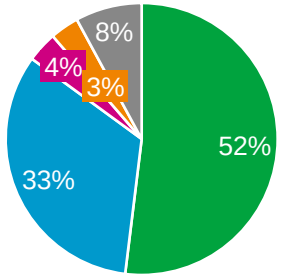
Q1 FY2023



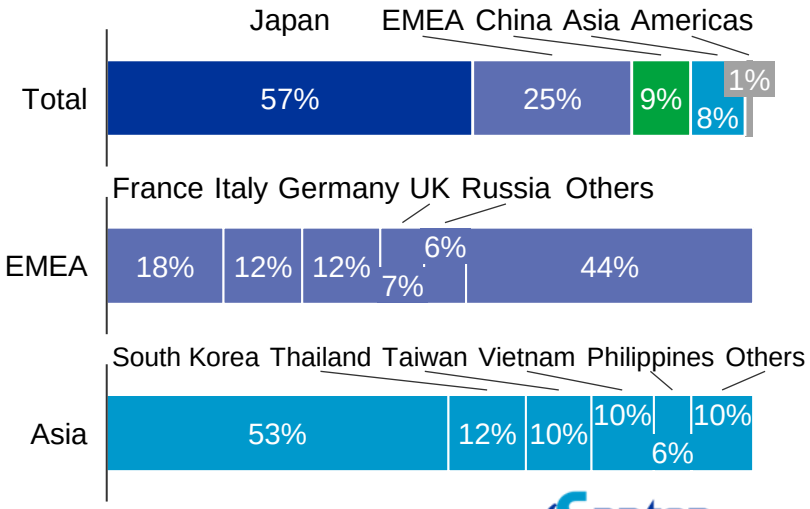
EMEA

(JPY billions)	Q1 FY2022 (Ref.)	Q1 FY2023
Ikervis	1.5	4.1
Cosopt	3.1	3.5
Tapros	2.0	2.1
Others	6.5	8.1
Total	13.1	17.8

Q1 FY2023



Revenue in each region (Q1 FY2023)



Intravitreal VEGF inhibitor | Glaucoma/Device | Dry eye | Bacterial conjunctivitis | Allergy | Others

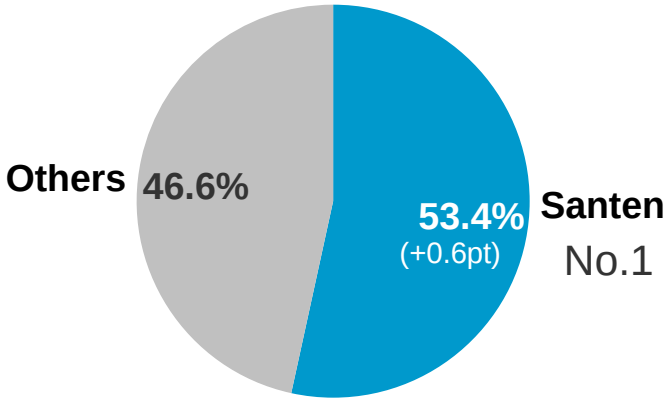
*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

*2 Alesion: Trademark of alliance partner, Boehringer Ingelheim KG

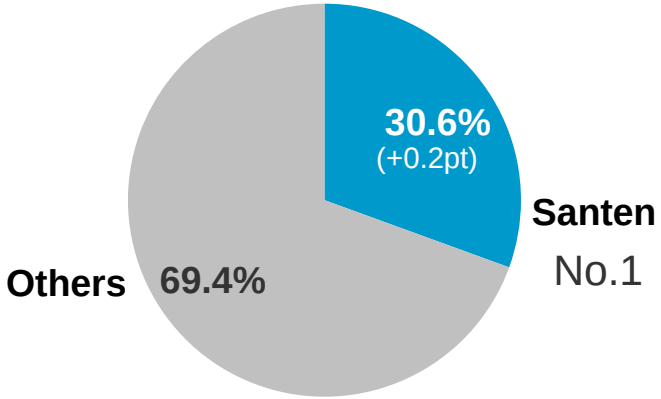
Segment: Market size
Graph: Market share (change from last year)

Prescription Ophthalmic Market in Japan （Jul.2022 - Jun.2023）

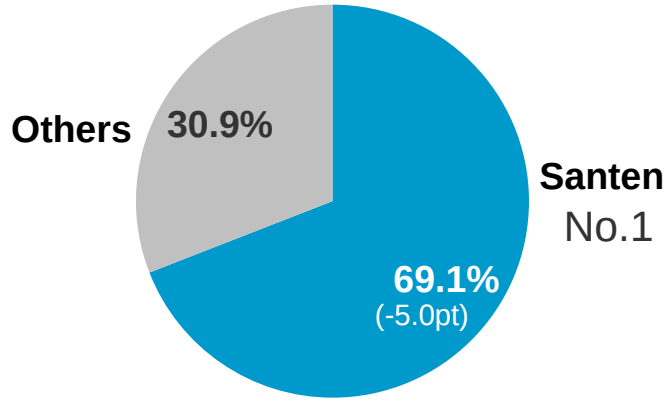
Total: JPY372.2bil



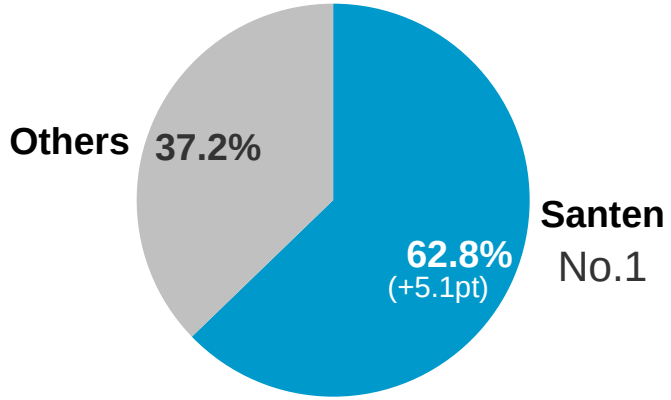
Glaucoma: JPY92.6bil



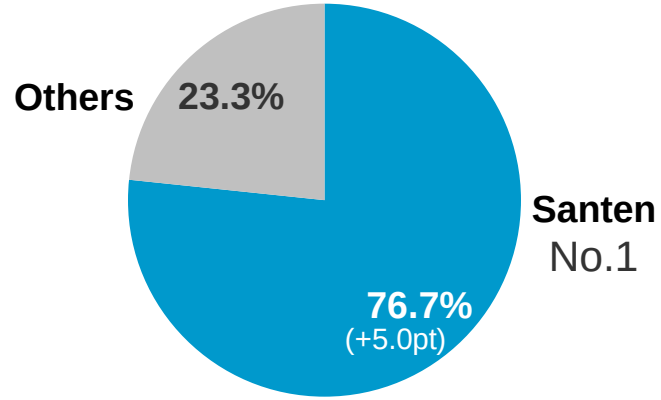
Retinal disorders*: JPY126.7bil



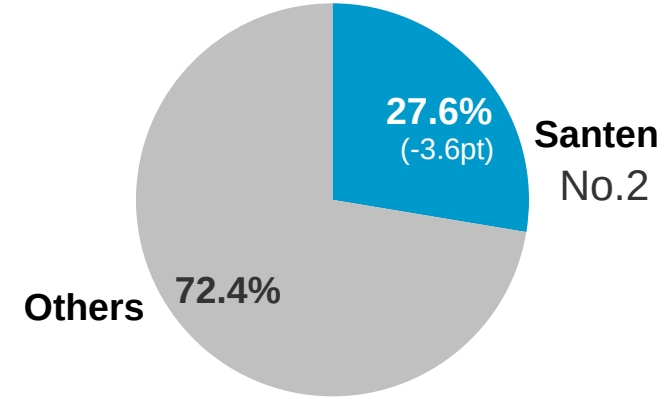
Corneal / dry eye: JPY45.9bil



Allergy: JPY51.1bil



Anti-infection: JPY6.8bil



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

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Current status of global development (1)

As of July 2023
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Contractual territory	Dev. Code	Development Status[1]	
Glaucoma	Tafluprost / timolol maleate (combination) *TAPCOM / TAPTIQOM*	Japan, China Asia, Europe	STN10**11**101 DE-111A	China	Filed *Plan: FY2024 approval*
	Sepetaprost	WW[2]	STN10**126**00 DE-126	US	P2 (met primary endpoint)
				Japan	P3 *Plan: FY2023 P3 completion*
				Europe	P2 (exploratory study) completion, analysis in progress
	Latanoprost	WW (In-house)	STN10**130**01 DE-130A Catioprost	Europe	Filed *Plan: FY2023 approval*
				Asia	P3 (met primary endpoint)

1. Only projects where the study protocols were approved in-house are shown, 2. Worldwide

Current status of global development (2)

As of July 2023
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Glaucoma	Netarsudil mesilate *Rhopressa®/Rhokiinsa®*	Japan, China Asia, Europe	STN10**139**00 AR-13324	Japan	P3 *Plan: FY2024 P3 completion*
				Europe	Launched
				Asia	Approved *Plan: FY2023 launch*
	Netarsudil mesilate /latanoprost (combination) *Rocklatan®/Roclanda®*	Japan, China Asia, Europe	STN10**140**00 PG-324	Europe	Launched
				Asia	Approved *Plan: FY2023 launch*

STN1011700 (DE-117, generic name: omidenepag isopropyl) is sold as *Eybelis* in Japan and Asia. In U.S., Santen has received approval as *OMLONTI* and granted exclusive rights for product manufacturing and commercialization to Visiox Pharmaceuticals, Inc. (US) in July 2023.

Current status of global development (3)

As of July 2023
Updated information is in blue

Keratoconjunctival disease area including dry eye

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Vernal keratoconjunc-tivitis	Ciclosporin *Verkazia*	WW (In-house)	STN10**076**03[1] DE-076C	China	Approved *Plan: FY2023 launch*
Dry eye	Diquafosol sodium (long-lasting) *Diquas LX*	Japan, China Asia, Europe	STN10**089**03 DE-089C	Japan	Launched
				Asia	Filed *Plan: FY2023 approval*
	Olodaterol hydrochloride	WW	STN10**141**00	Japan	P1/2a *Plan: FY2023 P1/2a completion*
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	—[2]	STN10**109**04[2]	US France India	P2a *Plan: FY2025 P2a completion*
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN10**109**05	Japan	P2a (not met primary/secondary endpoints. But observed efficacy on some exploratory endpoints and detailed analysis in progress)
Allergic conjunctivitis	Epinastine HCl (ophthalmic cream)	Japan	STN10**114**02	Japan	Filed *Plan: FY2023 approval*

1. In July 2023, Santen granted Harrow Health, Inc. (US) exclusive rights in the US (launched in May 2022) and Canada (launched in November 2019) for product manufacturing and commercialization.
2. Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

Current status of global development (4)

As of July 2023
Updated information is in blue

Refractive error

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Myopia	Atropine sulfate	Japan, China Asia	STN10**127**00 DE-127	Japan	P2/3 *Plan: FY2023 P2/3 completion*
				China	P2/3 *Plan: FY2026 P2/3 completion*
				Asia	P2 (met primary endpoint)
		EMEA	STN10**127**01 SYD-101	Europe	P3 (conducted by Sydnexis Inc.) *Plan: FY2024 P3 completion*
	AFDX0250BS	WW	STN10**134**00	Japan	Started P2a in May 2023 *Plan: FY2025 P2a completion*
				China	*Plan: FY2023 P1 start*
Presbyopia	Ursodeoxycholic acid	WW (In-house)	STN10**136**00	US	P2a *Plan: FY2023 P2a completion*
				Japan	P1 (confirmed safety and tolerability)

Current status of global development (5)

As of July 2023
Updated information is in blue

Others

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	Japan, China Asia, EMEA Canada	STN10**138**00 RVL-1201	Japan	P3 *Plan: FY2024 P3 completion*
				China	*Plan: FY2023 P3 start*
				Asia	*Plan: Considering filing after FY2023*
Retinitis pigmentosa	jCell	Japan, China Asia, Europe	STN**6000100**	-	Planning P3

Protocol of P3 trial in China