# Santen Pharmaceutical Co., Ltd. Financial Disclosure Meeting FY2019 Business Highlights FY2020 Forecast



#### Shigeo Taniuchi

**President & Chief Executive Officer** 

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May 11, 2020

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### **Forward-Looking Statements**

- 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.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
- The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.
- Business performance and financial conditions could be affected significantly by a substantial drop in sales of a major drug, either currently marketed or expected to be launched, due to termination of sales as a result of factors such as patent expiry and complications, product defects or unforeseen side effects. Santen Pharmaceutical also sells numerous products under sales and/or manufacturing license from other companies. Business performance could be affected significantly by changes in the terms and conditions of agreements and/or the non-renewal of agreements.
- Santen Pharmaceutical is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.



#### **Santen's Values and Mission Statement**

Values



<sup>1</sup> "Exploring the secrets and mechanisms of nature in order to contribute to people's health"

Santen's original interpretation of a passage from chapter 22 of Zhongyong (The Doctrine of the Mean) by Confucius.

We think carefully about what is essential, decide clearly what we should do, and act quickly.

Mission Statement By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.

Santen Group Measures to Combat the Impact of the COVID-19 Outbreak Our first priority is to deliver ophthalmologic drugs to patients around the world

## Respond swiftly to maintain stable business operations in state of emergency

<Major actions taken globally by the Santen Group>

- 1. Measures to secure a stable supply of our products
- 2. Measures to prevent the spread of the virus
- 3. Initiatives for the achievement of innovations in ophthalmology



\*Please visit our website for more details: https://www.santen.com/en/about/Infection19/

## **Personnel Changes and New Appointments**

Management structure revamped as of April 1 to realize the next long-term vision

Strengthen governance through separation of oversight and execution: New CEO



Chairman *Akira Kurokawa* 



President & CEO Shigeo Taniuchi

Strengthen the organization and accelerate globalization: Four new corporate officers appointed



CIO\* *Minori Hara* 



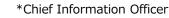
Head of Product Development Division *Peter Sallstig* 



Head of North America Business *Tatsuya Kaihara* 



Head of China Business **Takayuki Yamada** 



#### Next Long-term Vision to be Announced in July





2030 Goal: Contribute to innovation in ophthalmology by breaking the boundaries for pharmaceuticals





7

Decline in patient visits to have a negative impact on revenue

Increase profits through cost control and voluntary restraint of activities

Continue to invest in long-term growth



# Topics : China Current Business Conditions Resulting from the COVID-19 Outbreak

# **Current Business Conditions in China Resulting from COVID-19**

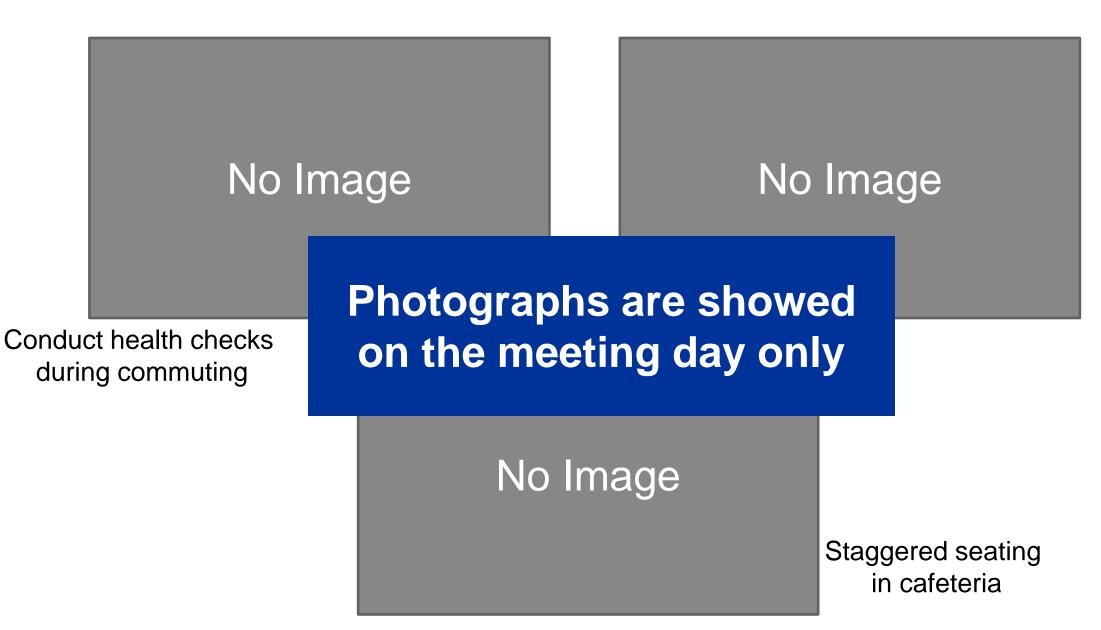


Healthcare and economic activities suspended in February and March Current conditions gradually recovering. Santen progressively resuming activities

Healthcare Activities	<ul> <li>Medical system: Ability to perform outpatient and surgical operations at about 70% of facilities</li> </ul>
	<ul> <li>Outpatient: Recovery to around 50% of normal level</li> </ul>
	<ul> <li>Ophthalmic surgery: Cataract surgery has also recovered to about 20-50% of normal levels</li> </ul>
Our Response	<ul> <li>Production: Restarted operations on February 10. Now operating normally No impact on supply</li> </ul>
	<ul> <li>Sales activities: Resumed MR visits from April 1, as appropriate for conditions at each facility</li> </ul>
	<ul> <li>Employees: Choice of telework or working in the office as appropriate</li> </ul>

(Information based on an internal survey as of the end of April)

Achieved Early Normalization Through Infectious Disease Controls (status of Suzhou Plant)





# FY2019 Financial Results Ended March 31, 2020

### FY2019 Results



### Higher sales and profits (core basis) due to growth in Japan and overseas businesses

	FY2018		FY2019			
(JPY billions)	Actual	vs Revenue	Actual	vs Revenue	YoY	
Revenue	234.0		241.6		+3%	
COGS	90.8	39%	94.8	39%	+4%	
Gross margin	143.3	61%	146.7	61%	+2%	
SG&A expenses	71.3	30%	73.4	30%	+3%	
R&D expenses	23.8	10%	23.3	10%	-2%	
Core operating profit	48.2	21%	50.0	21%	+4%	
Amortization on intangible assets associated with products	7.0	3%	9.9	4%	+42%	_
Other income	4.0	2%	0.4	0%	-90%	2
Other expenses	0.2	0%	7.0	3%		
Operating profit (IFRS)	45.1	19%	33.5	14%	-26%	
Finance income	0.9	0%	1.0	0%	+6%	
Finance expenses	2.9	1%	2.4	1%	-17%	
Profit before tax	43.1	18%	32.1	13%	-26%	
Income tax expenses	11.2	5%	10.4	4%	-7%	<hr/>
Actual tax ratio	25.9%		32.3%			
Net profit (IFRS)	31.9	14%	21.7	9%	-32%	
Core net profit	36.1	15%	35.9	15%	-1%	/
USD (JPY)	110.82		108.81			
EUR (JPY)	128.38		120.80			
CNY (JPY)	16.52		15.64			

#### **Core Basis**

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- Revenue increased in all geographic areas
- Core operating profit up on expense controls, other measures

DE-128 amortization

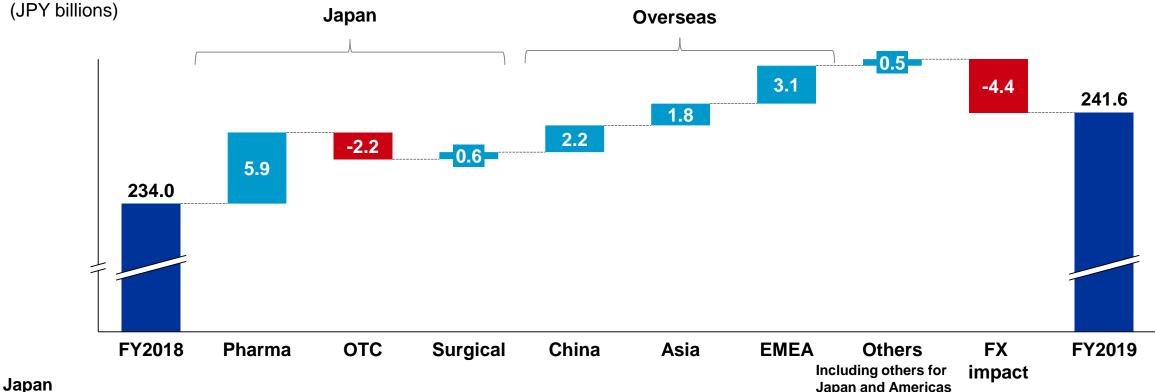
The absence of revenue from the sale of the former head office and Osaka Plant in the previous fiscal year

Impairment charges related to the discontinuation of DE-122 and impairment losses on joint venture in China

Tax rate rose due to the impact of unrecognized tax consequences on InnFocus contingent consideration and impairment losses on joint venture in China

## FY2019 Revenue

#### Group sales up on steady growth in Japan pharma and overseas business



Japan and Americas

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Prescription Pharmaceuticals: Steady growth driven by Eylea\* and Alesion LX

- OTC: Decreased due to sluggish overseas tourists' demand
- Surgical: Steady growth driven by new product LENTIS Comfort

#### **Overseas**

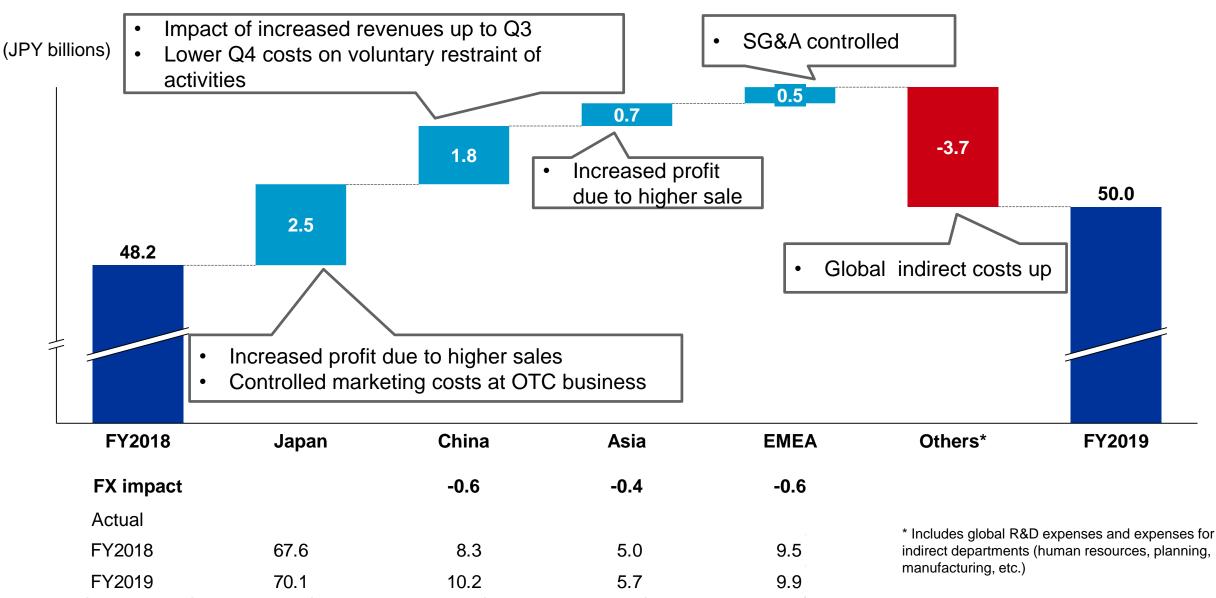
- China: Local currency sales increased 10% YoY despite the negative impact of COVID-19 in the fourth quarter. (JPY basis +4%)
- Asia: Increased 6% in JPY basis (+12% excluding FX impact) (Korea: JPY basis +4%, local currency basis +12%)
- EMEA: Increased +8% in € basis (+ 2% in JPY basis)

#### 13

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# FY2019 Operating Profit (Core Basis)

Profits up on higher sales and control of SG&A due to COVID-19 related voluntary restraint of activities





# FY2020 Forecast Ending March 31, 2021

## **FY2020 Forecast Assumptions**

Aim to increase profits through efficient cost management despite the negative impact of COVID-19

# Revenue forecast: Timing of normalization varies by region

- Japan: Factor in impact in first half
- China: Expect generally recovering
- Asia: Conditions vary by country, but a moderate recovery
- EMEA: Factor in impact until around third quarter
- Core operating profit forecast: In addition to the above, incorporate the following factors
  - SG&A : Cost optimization, hiring restraint and investments on IT infrastructure for the new normal
  - R&D expense: Expect delays in some clinical trials



## FY2020 Forecast

#### Aim to increase profits through efficient cost management

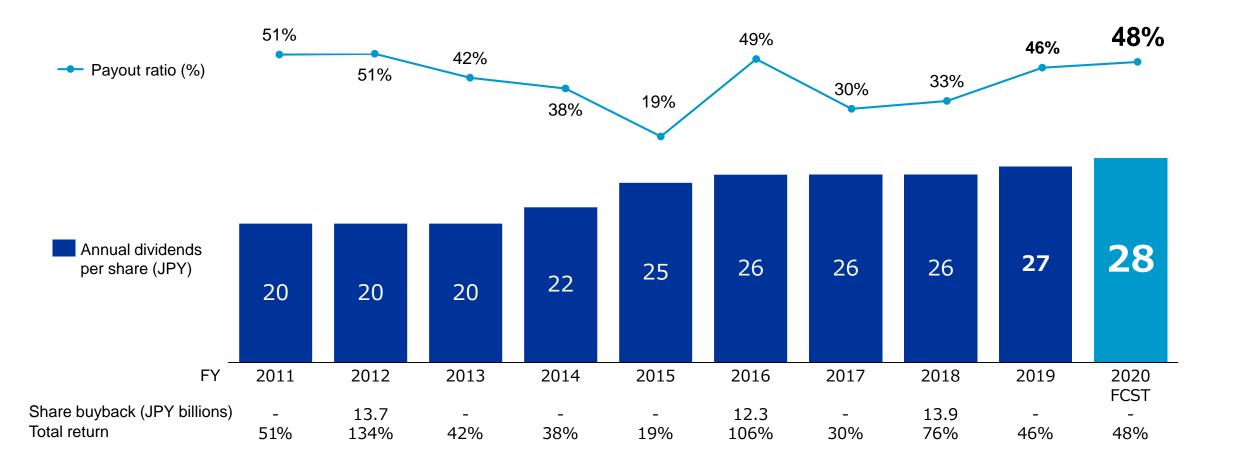
	FY20	019	FY2020		
(JPY billions)	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	241.6		235.0		-3%
COGS	94.8	39%	90.0	38%	-5%
Gross margin	146.7	61%	145.0	62%	-1%
SG&A expenses	73.4	30%	70.0	30%	-5%
R&D expenses	23.3	10%	23.0	10%	-1%
Core operating profit	50.0	21%	52.0	22%	+4%
Amortization on intangible assets associated with products	9.9	4%	9.7	4%	-2%
Other income	0.4	0%	0.9	0%	+131%
Other expenses	7.0	3%	8.2	3%	+17%
Operating profit (IFRS)	33.5	14%	35.0	15%	+4%
Finance income	1.0	0%	0.8	0%	-16%
Finance expenses	2.4	1%	1.0	0%	-58%
Investment loss by equity method			0.8	0%	
Profit before tax	32.1	13%	34.0	14%	+6%
Income tax expenses	10.4	4%	11.0	5%	+6%
Actual tax ratio	32.3%		32.4%		
Net profit (IFRS)	21.7	9%	23.0	10%	+6%
Core net profit	35.9	15%	38.7	16%	+8%
USD (JPY)	108.81		110.00		
EUR (JPY)	120.80		120.00		
CNY (JPY)	15.64		15.00		

#### **Core Basis**

- Revenue: Expect COVID-19 impact
- Core operating profit: Expect growth due to reduced activity and cost optimization

Revaluation of InnFocus contingent payment

#### **Dividend** Forecast dividend of JPY28 per share



Total return forecast for FY2020 does NOT include the potential impact from future share buybacks

• J-GAAP standards used until FY2013, IFRS applied from FY2014



# **Status of Research & Development**

# jCyte Partnership: Retinitis Pigmentosa

Inherited disease with no approved or effective treatments for patients

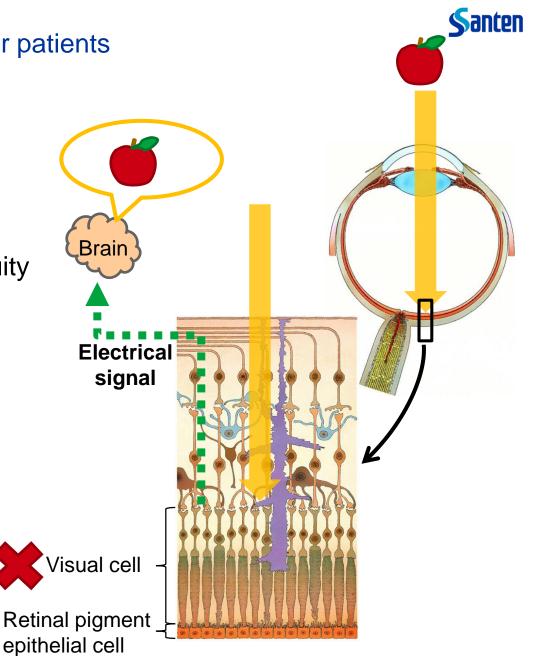
# Inherited retinal disease

- Visual cells and retinal pigment epithelial cells become disorganized
- Characteristic symptoms include night blindness, narrowing of the visual field and decreased visual acuity



- No established treatment
- 1 of 4,000 people<sup>1)</sup>

(The leading cause for congenital blindness<sup>2)</sup> and the second leading cause for visual impairment<sup>3)</sup> in Japan)



jCyte Partnership: Cell Therapy Programs for Retinitis Pigmentosa Potential to be a broadly selected as initial therapy



#### • Route of administration

Intravitreal injection

# >Unlike subretinal administration, vitreous surgery or retinotomy is not required

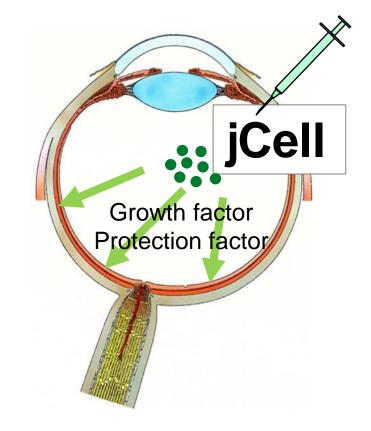
#### Expected mechanism of action

Secrete cell growth and protection factors

- $\Rightarrow$  inhibit damage to retinal nerve cells
  - $\Rightarrow$  delay disease progression

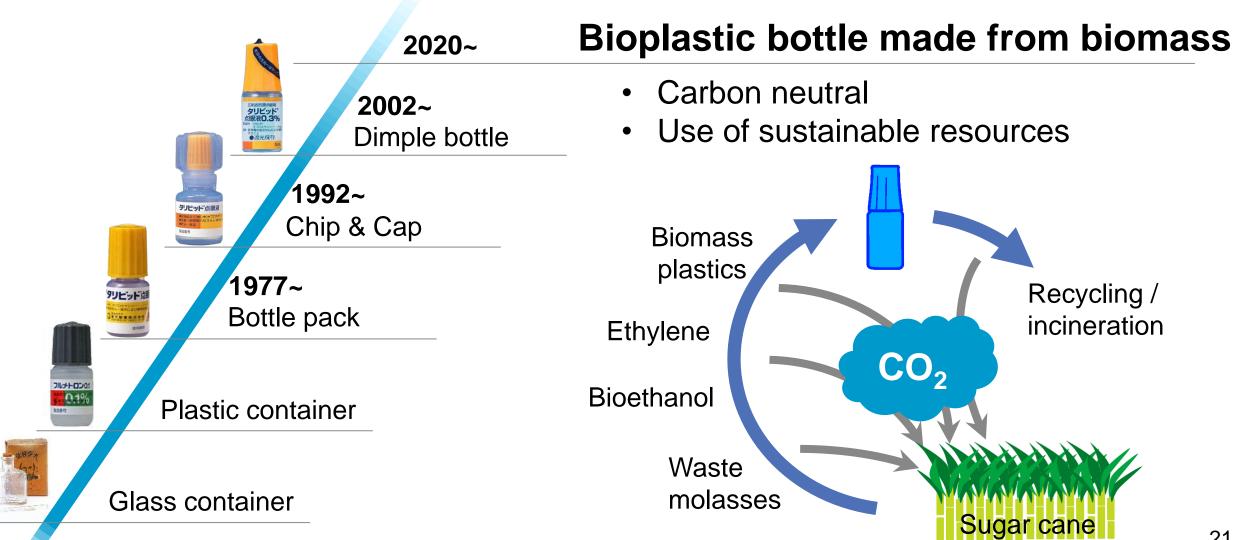
The causative genes vary, with more than 60 species of retinitis pigmentosa<sup>1)</sup>

## >Be adapted regardless of the type of causative gene



### **Commercialization of Biomass Plastic Eye Drop Container**

From the patient's perspective to mankind's perspective



### **Current Status of Research and Development**

#### Pipeline/product development (1)



#### As of April, 2020 Updated information is underlined

	Indication	Region	Status			
<b>DE-111</b> <i>TAPCOM / TAPTIQOM</i> Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 Plan: FY2020 P3 completion			
<b>DE-117</b> <i>EYBELIS</i> EP2 receptor agonist	Glaucoma / ocular hypertension	US	P3 Plan: FY2020 P3 completion			
		Japan	Launched			
		Asia	Approved Plan: FY2020 launch			
DE-126	Glaucoma /	US	P2b (dose finding study completed)			
FP/EP3 receptors dual agonist	ocular hypertension	Japan	Plan: FY2020 P2 start (exploratory study)			
<b>DE-128</b> PRESERFLO MicroShunt	Glaucoma	US	P2/3 Plan: <u>FY2020 PMA rolling submission completion</u> , FY2020 launch			
		Europe	Launched			
		Asia	<u>Filed in Mar 2020 (Korea)</u> Plan: <u>FY2020 approval</u>			
<b>DE-130A</b> Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3			
		Asia	Plan: FY2021 P3 completion			

#### **Current Status of Research and Development**

#### Pipeline/product development (2)



#### As of April, 2020 Updated information is underlined

	Indication	Region	Status		
	Uveitis	US	P3 Plan: FY2022 P3 completion		
DE-109		Japan	P3		
IVT sirolimus		Europe	P3		
		Asia	Filed		
DE-076C	Vernal kerato-conjunctivitis (VKC)	Europe	Launched		
<b>DE-070C</b> Verkazia		Asia	Approved of VKC indication extension to Ikervis		
ciclosporin		Others	Launched (Canada)		
<b>DE-114A</b> epinastine HCI (high dose)	Allergic conjunctivitis	Japan	Launched		
DE-127	Муоріа	Japan	P2/3 Plan: FY2023 P2/3 completion		
atropine sulfate		Asia	P2 (met primary endpoint)		
MD-16 Intraocular lens	Cataract	Japan	Approved Plan: FY2020 launch		

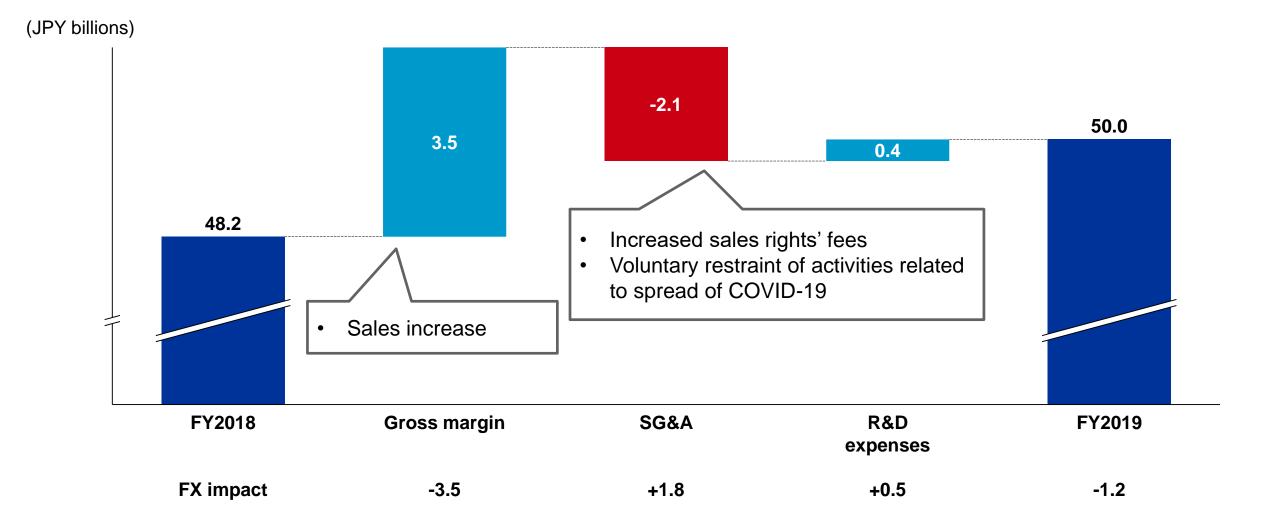
#### DE-122: Expected efficacy was not demonstrated in P2a; development discontinued in March 2020



# Appendix

### FY2019 Core Operating Profit (Breakdown)

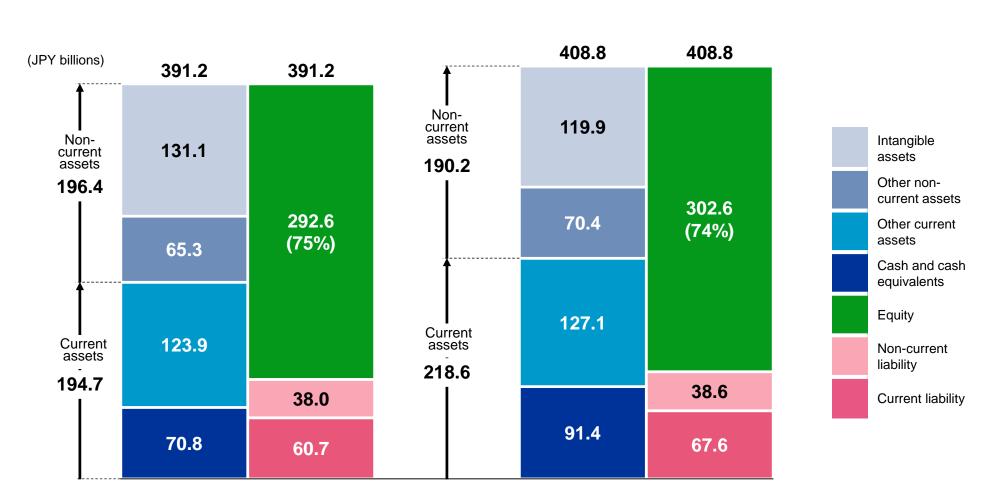
Profit growth due to the effect of increased sales which offsets SG&A increase



#### 25

#### **FY2019** Financial Position

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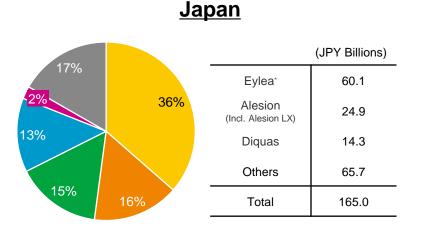


March 31, 2019

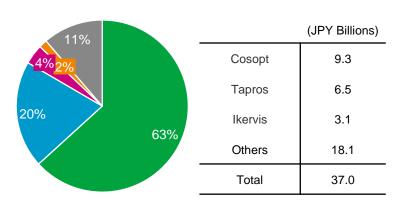
March 31, 2020

### FY2019 Revenue by Region





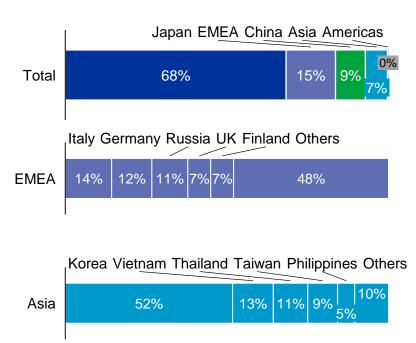
Eylea\*: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)



Asia

**EMEA** 

#### **Revenue in each region**



#### <u>China</u>

