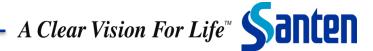
Santen Pharmaceutical Co., Ltd.

# **Investor Meeting on FY2014 Results and FY2015 Forecasts**



#### Akira Kurokawa

President & CEO May 13, 2015

#### Santen's Corporate Values

# 天機に参与する

### Tenki ni sanyo suru

By focusing our efforts on ophthalmology and related areas, Santen develops scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

# Long-term Strategic Vision, Medium-term Management Plan for FY2014-2017



#### **Long-term Strategic Vision**

# To Become a Specialized Pharmaceutical Company with a Global Presence

- Deep Understanding of True Customer Needs\*
- Distinct Advantage Against Competitors
- Global Competitiveness and Presence

<sup>\*</sup>True customer needs: Unmet medical needs of patients, consumers, doctors and healthcare professionals.

### **Long-term Growth Targets**



- Strengthen the Japan business
- Prepare for business expansion in Asia/Europe

Ranks #5 globally Overseas sales: 16% of total sales



#### **Medium-term Goal**

- Grow business in Asia/Europe and improve profitability
- Prepare for business expansion in the U.S. and other regions

Overseas sales: 30% of total sales

2020 **Santen** 

What we aim to achieve by 2020

"To become a
Specialized
Pharmaceutical
Company with a
Global Presence"

Become global #3

Overseas sales: 40%-50% of total sales



# **Basic Policy of Medium-term Management Plan** for FY2014-2017

Product development

Transform product development to realize enhanced productivity and achieve sustained growth Active investment in sustainable growth

Business expansion

Grow business in Asia/Europe and strengthen market presence by entering into new markets

Organization and talent

Develop talent and organization to realize sustained growth and strengthen the global management system



# Financial Results for FY2014 ended March 31, 2015



#### Financial Highlights for FY2014 (IFRS / Core)

(JPY billions)	FY2013	FY2014	
IFRS basis	1 12010	Actual	Var. (YoY)
Revenue	146.3	161.8	+10.6%
Operating profit	29.9	35.4	+18.4%
Profit before tax	30.4	35.9	+18.1%
Profit for the year	19.7	24.0	+21.9%
ROE	11.1%	12.0%	+0.9 pt

#### Core basis

Revenue	146.3	161.8	+10.6%
Core operating profit	30.4	39.1	+28.6%
Core profit for the year	19.8	25.9	+31.0%
Core ROE	11.2%	13.0%	+1.9 pt

### FY2014 Financial Highlights (IFRS/Core)

	EV0040	FY2014	(IFRS)
(JPY billions)	FY2013 (IFRS)	Actual	Var. %
Revenue	146.3	161.8	+10.6%
Cost of sales	-57.4	-56.4	-1.7%
SG&A	-41.6	-48.9	+17.4%
Amortization associated with products	-0.2	-4.0	-
R&D expense	-16.9	-17.5	+3.7%
Operating profit*	29.9	35.4	+18.4%
Profit before tax	30.4	35.9	+18.1%
Profit for the period	19.7	24.0	+21.9%

FY2014 Actual (J-GAAP)
161.9
-56.4
**-53.9
-
-18.1
33.5
34.3
22.6

Core operating profit	30.4	39.1	+28.6%
Core profit for the period	19.8	25.9	+31.0%
Core ROE	11.2%	13.0%	+1.9pt

Foreign exchange	FY13 Actual	FY14 Actual
US\$	JPY 100.04	JPY 110.14
Euro	JPY 133.98	JPY 139.01
CNY	JPY 16.26	JPY 17.84



<sup>\*</sup>Calculation includes other revenue and other expenses

<sup>\*\*</sup>Excludes R&D expense

### Financial Highlights for FY2014

#### Achieved sales, profit and ROE growth

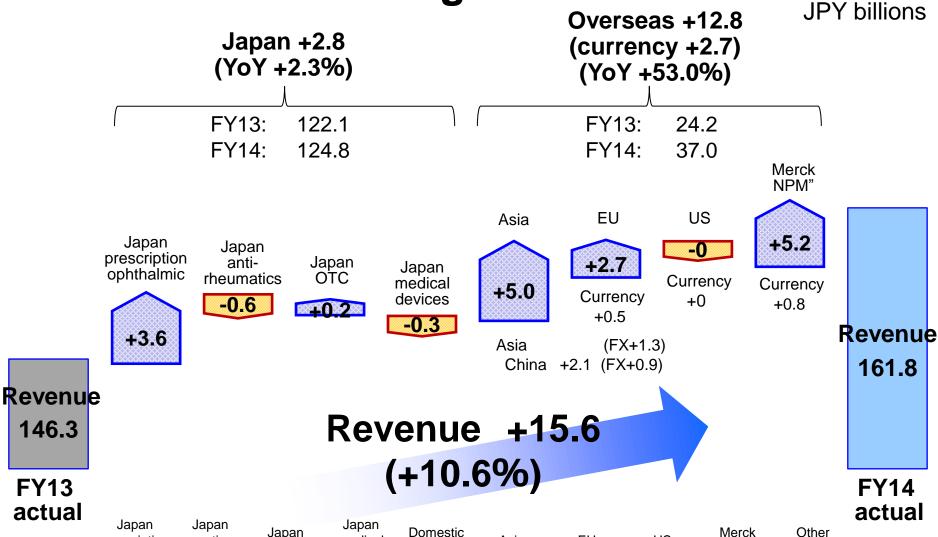
- From FY2014 financial results, Santen adopts IFRS accounting standards and Core basis performance measurement
- In Japan, despite NHI price revisions and policies aimed at promoting generic drugs, sales growth was achieved on the strong performance of new products
- Overseas, business was robust in Asian markets continuing to show marked growth, while business in Europe benefited from the Merck agreement\* and an expanding operational footprint
- Strong progress made in the integration of assets under the Merck agreement\* with contribution to results above expectations
- In Europe, severe keratitis with dry eye disease treatment, Ikervis® (generic name: Ciclosporin) received marketing approval



<sup>\*</sup>Merck agreement: Asset purchase agreement signed in May 2014 whereby Santen acquired ophthalmic products from Merck of the United States.

<sup>&</sup>quot;Ikervis indication: Treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes

#### **FY14 Revenue Change**



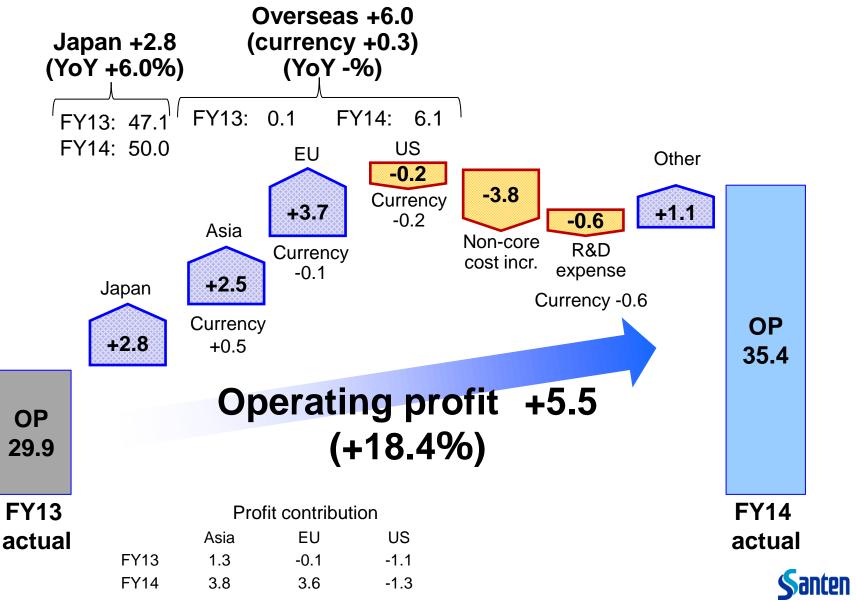
Japan Domestic Merck prescription antimedical Asia ΕIJ US OTC NPM\* others overseas ophthalmic rheumatics devices **FY13** 101.8 10.2 6.4 2.6 1.1 11.7 11.5 1.0 0 0 FY14 105.4 9.6 6.6 2.3 1.0 16.7 14.2 1.0 5.2 0

\*Net Profit Margin(NPM): Profit generated from US Merck ophthalmic products which Santen has acquired and has consigned them to Merck until the completion of transfer of the underlying marketing rights.



### **FY14 Operating Profit Change**

JPY billions



# Merck Project Current Status

### Merck Project Financial Results (IFRS)

	FY14 Actual			
(JPY billions)	Existing Business	Merck*	Total	
Revenue	152.9	8.9	161.8	
NPM	_	5.2	5.2	
Other	_	3.8	3.8	
Cost of sales	-61.0	4.6	-56.4	
SGA excluding R&D	-46.3	-2.6	-48.9	
R&D expense	-17.3	-0.2	-17.5	
Operating profit	28.4	7.0	35.4	

<sup>\*</sup>Merck: US Merck ophthalmic products which Santen has purchased in May 8, 2014.

#### **Merck Project Update**

**FY14** (ended Mar '15)

Began distribution of acquired Merck products in 11 countries

**FY15** (ending Mar '16)

Implementing transition plan for 17 countries including major markets such as Italy, Spain, United Kingdom, Portugal, Switzerland, Turkey, Russia and Korea

**FY16** (ending Mar '17)

Transition the remaining 14 countries

# Consolidated Forecasts of FY2015 ending March 31, 2016

#### Financial Forecasts for FY2015 (IFRS / Core)

(JPY billions)	FY2014	FY2015	
IFRS basis	Actual	Forecast	Var. (YoY)
Revenue	161.8	186.5	+15.2%
Operating profit	35.4	78.0	+120.5%
Profit before tax	35.9	78.5	+118.9%
Profit for the year	24.0	52.5	+118.5%
ROE	12.0%	22.5%	+10.5 pt

#### Core basis

Revenue	161.8	186.5	+15.2%
Core operating profit	39.1	40.3	+3.1%
Core profit for the year	25.9	26.9	+3.7%
Core ROE	13.0%	11.5%	-1.5 pt

#### Financial Forecasts for FY2015 (IFRS / Core)

	EV2014	FY2015	(IFRS)
(JPY billions)	FY2014 (IFRS)	Forecast	Var. %
Revenue	161.8	186.5	+15.2%
Cost of sales	-56.4	-66.4	+17.8%
SG&A	-48.9	-56.9	+16.4%
Amortization associated with products	-4.0	-6.1	+53.3%
R&D cost	-17.5	-22.9	+31.0%
Operating profit*	35.4	78.0	+120.5%
Profit before tax	35.9	78.5	+118.9%
Profit for the period	24.0	52.5	+118.5%
Core operating profit	39.1	40.3	+3.1%
Core profit for the period	25.9	26.9	+3.7%
Core ROE	13.0%	11.5%	-1.5 pt

<sup>\*</sup>Calculation includes other revenue and other expenses

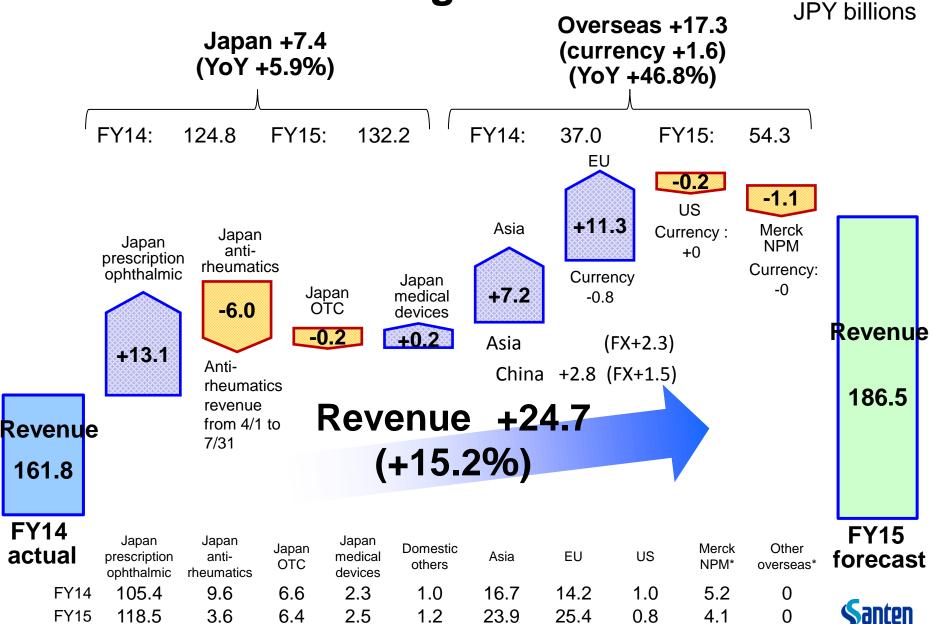
Foreign exchange	FY14 Actual	FY15 Forecast
US\$	JPY 110.14	JPY 125.00
Euro	JPY 139.01	JPY 135.00
CNY	JPY 17.84	JPY 20.00



### **Consolidated Forecast of FY2015 (IFRS)**

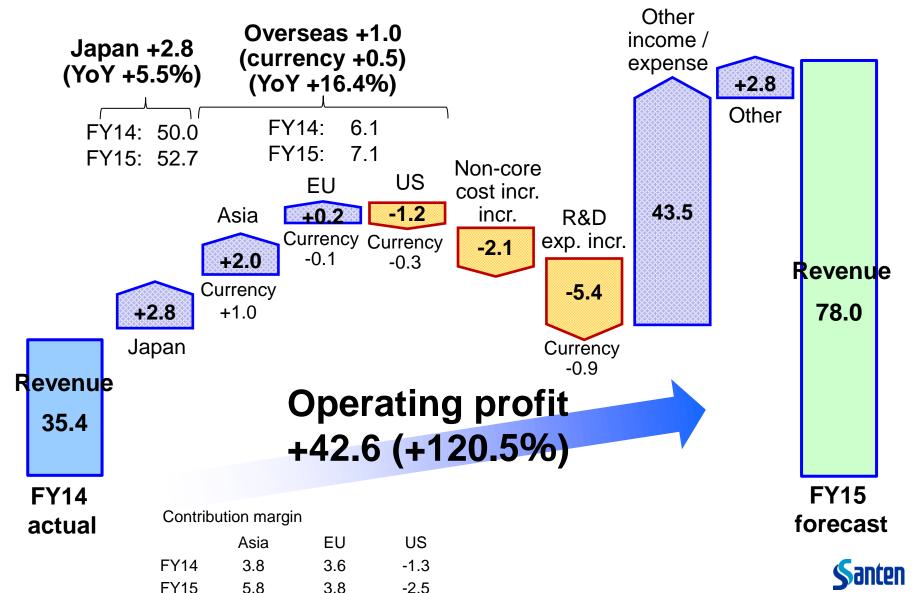
- Consolidated revenue and operating profit to grow by 15.2% and 120.5%, respectively
   Core operating profit expected to increase by 3.1%
- Operating profit includes a gain related to the succession of the company's anti-rheumatic pharmaceutical business; Core operating profit is expected to increase slightly
- In Japan, increased market penetration of new products in growing areas to offset the impact of generics
- In overseas markets, continued business growth expected in expanding Asian markets while Europe to benefit from the Merck agreement and an expanding operational footprint
- Gain expected by the end of July relating to the planned antirheumatic pharmaceutical business transaction
- 11.5% Core ROE targeted for FY15

### **FY15 Revenue Change Forecast**



#### **FY15 Operating Profit Change Forecast**

JPY billions



# Dividend for FY2015 Forecast

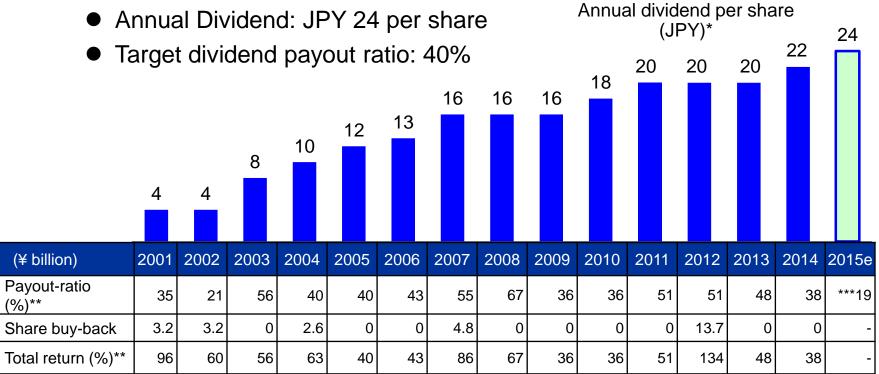


#### Dividends for FY2014 Actual and FY2015 Forecast

#### ■ FY2014

Annual Dividend: JPY 22 per share
 (pre-stock split equivalent: JPY 110 per share)

#### ■ FY2015 (Forecast)



<sup>\*</sup>The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of annual dividends per share have been adjusted in all periods for comparison purposes.

<sup>\*\*</sup>J-GAAP standards used until 2013, IFRS applied from 2014.

<sup>\*\*\*</sup>Removing the expected impact of a gain related to the succession of the company's anti-rheumatic pharmaceutical business in FY15, payout ratio is expected to be 39%.

# Reference: **Adoption of IFRS and Core Earnings Measure**

# Adoption of IFRS (International Accounting Standard) and Core Basis Indicators

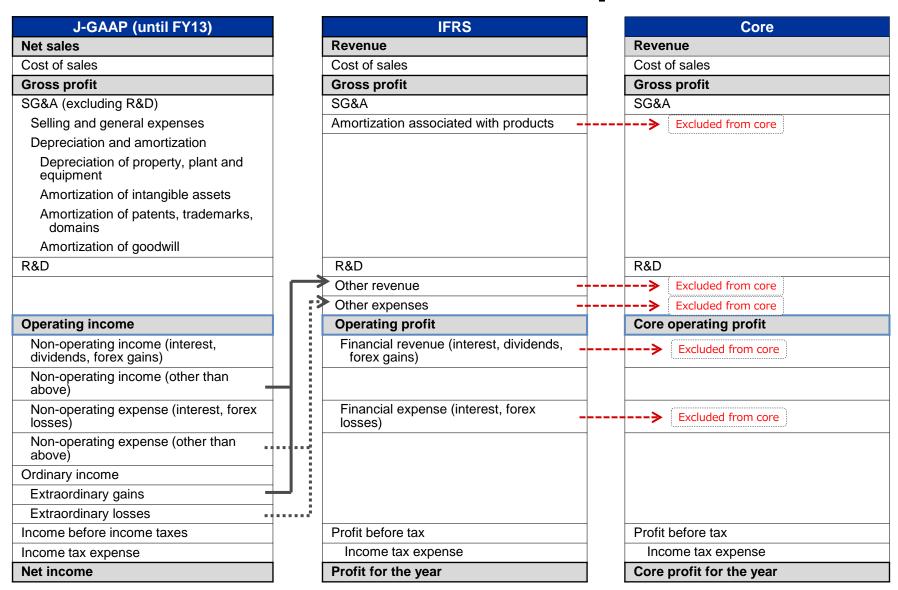
#### IFRS Adoption

- Aiming to raise comparability of financial reporting, the company utilizes IFRS international accounting standards from FY2014 onward
- The main differences between Japanese accounting standards (J-GAAP) and IFRS are as follows:
  - Revenue in IFRS corresponds to net sales in J-GAAP
  - Operating profit under IFRS differs from operating income under J-GAAP by also including non-operating income and expenses and extraordinary gains and losses (except financial revenue and expenses)

#### Use of Core Basis Indicators

- Core results are now used as financial indicators to better express underlying business performance by removing certain gains and expenses from IFRS results
- Items excluded from IFRS to calculate core results:
  - Amortization associated with products, other revenue and expenses, and financial revenue and expenses

### J-GAAP, IFRS and Core Comparisons





#### **Reconciliation J-GAAP to IFRS**

(JPY billions)

J-GAAP		Differ	ence	IFRS		
Net sales	161.9	(*1)	-0.1	161.8	Revenue	
Cost of sales	56.4	(*1)	-0.1	56.4	Cost of sales	
Gross profit	105.5		0	105.5	Gross profit	
				48.9	SG&A	
SG&A (excluding R&D)	53.9	(*2)	-1.0	4.0	Amortization associated with products	
R&D	18.1	(*3)	-0.6	17.5	R&D	
-	-		-	0.7	Other revenue	
-	-		-	0.5	Other expense	
Operating income	33.5		+1.9	35.4	Operating profit	
Non-operating income	4.0					
Non-operating income	1.3		-	-	-	
Non-operating expense	0.3		-	-	-	
			- -	- 0.8	- - Financial revenue	
			- - -	0.8		
			- - -		Financial revenue	
Non-operating expense -	0.3		- - - -		Financial revenue Financial expense	
Non-operating expense Ordinary income	0.3 - - 34.5		- - - - -	0.3	Financial revenue Financial expense -	
Non-operating expense Ordinary income Extraordinary gain	0.3 - - 34.5 0.2		- - - - - - +1.5	0.3	Financial revenue Financial expense -	
Non-operating expense Ordinary income Extraordinary gain Extraordinary income	0.3 - - 34.5 0.2 0.3		- - - - - - +1.5	0.3	Financial revenue Financial expense	
Non-operating expense  - Ordinary income Extraordinary gain Extraordinary income Income before income taxes	0.3 - 34.5 0.2 0.3 34.3			0.3 - - - 35.9	Financial revenue Financial expense Profit before tax	

<sup>\*1</sup> Reversal of provision for sales returns -0.1 bil yen; \*2 Impact of non-depreciable goodwill, -0.9 bil yen; \*3 Reported pipeline asset of license in payment -0.6 bil yen

Sancen

#### **Reconciliation IFRS to Core OP**

(JPY billions)	FY2014 (actual)	FY2015 (forecast)
IFRS operating profit	35.4	78.0
Non-core deduction items	-3.7	37.7
Amortization associated with products	-4.0	-6.1
Other revenue	0.7	45.0
Other expenses	-0.5	-1.2
Core operating profit	39.1	40.3

### Reference: Consolidated Results of FY2014

### **Changes in Income Statement**

		FY13 Actual	FY14			
(JPY billions)		(IFRS)	Actual (IFRS)	Var.	Major Changes	
Revenue		146.3	161.8	+10.6%		
Cost of sales	(% of revenue)	-57.4 39.2%	-56.4 34.8%	-1.7% -4.4pt	I • Product mix change ±1 1nt	
SGA excluding R&D	(% of revenue)	-41.6 28.5%	-48.9 30.2%	+17.4% +1.7pt	∙apan -3.2 •Asia -1.1 (FX-0.6)	
Amortization associated	with products (% of revenue)	-0.2 0.1%	-4.0 2.5%	- +2.3pt	<ul><li>·US/EU -1.4 (FX-0.6)</li><li>·New co1.5</li><li>·Amortization of Merck's asset -3.7</li></ul>	
R&D expenses	(% of revenue)	-16.9 11.5%	-17.5 10.8%	+3.7% -0.7pt	l '	
Other revenue		0.7	0.7	+6.3%		
Other expenses		-1.0	-0.5	-54.9%		
Operating profit		29.9	35.4	+18.4%		
	(% of revenue)	20.4%	21.9%	+1.4pt		
Financial revenue		0.9	0.8	-16.2%	[	
Financial expenses		-0.4	-0.3	-35.5%	Currency rates FY13 actual FY14 actual	
Profit before tax		30.4	35.9	+18.1%		
Income tax expense		-10.6	-11.8	+11.2%		
Profit for the year		19.7	24.0	+21.9%	CYN JPY 16.26 JPY 17.84	
ROE		11.1%	12.0%	-		
Core operating profit		30.4	39.1	+28.6%		
Core profit for the year		19.8	25.9	+31.0%		
Core ROE		11.2%	13.0%	-	Sante	

### **Revenue by Business Segment**

(JP	Y billions)	FY14 Actual					
		Japan		Overseas		Total	
		Sales	Var. %	Sales	Var. %	Sales	Var. %
Ph	armaceuticals	122.3	+2.6%	37.0	+53.1%	159.3	+11.1%
	Prescription Pharmaceuticals	115.7	+2.6%	36.9	+53.1%	152.6	+11.5%
	Ophthalmic	105.3	+3.5%	30.7	+32.1%	136.1	+8.8%
	Anti-RA	9.6	-5.9%	0.1	-31.2%	9.6	-6.1%
	Others	0.8	-9.6%	6.1	+708.8%	6.9	+330.6%
	OTC Pharmaceuticals	6.6	+3.6%	0.1	+85.5%	6.7	+4.1%
Oth	ners	2.5	-12.5%	0	-17.9%	2.6	-12.6%
	Medical Devices	2.3	-13.0%	0	-17.9%	2.3	-13.1%
	Others	0.2	-7.4%	0	-	0.2	-7.4%
Total 124.8 +2.3% 37.0 +53.0% 161.8		161.8	+10.6%				

#### **Overseas Revenue and Operating Profit**

(JPY billions)		FY2013 Actual (IFRS)	FY2014 Actual (IFRS)			
		Revenue	Revenue*	Var. %	Operating profit**	
U.S.		1.0	6.2	+507.4%	-1.3	
Europe	Europe 11.5		14.2	+23.5%	3.6	
Asia		11.7	16.7	+42.5%	3.8	
	China	8.6	10.7	+25.1%	-	
Others		0	0	-63.2%	-	
Total		24.2	37.0	+53.0%	6.1	
Overseas sales / sales		16.5%	22.9%	+6.3pt	-	

<sup>\*</sup> Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

<sup>\*\*</sup> In line with company policy accounting for operating profit, NPM is distributed by region after operationally transferred from Merck to Santen.

#### **Summary of Balance Sheet**

(JPY billions)	As of March 31, 2014		As of March 31, 2015			
	Actual IFRS	% of Total	Actual IFRS	% of Total	Var.	
Non-current assets	84.4	35.5%	153.5	50.5%	+69.1	
Current assets	153.2	64.5%	150.7	49.5%	-2.5	
Total assets	237.6	100.0%	304.2	100.0%	+66.6	
Total equity	187.2	78.8%	211.8	69.6%	+24.6	
Non-current liabilities	11.2	4.7%	36.1	11.9%	+24.8	
Current liabilities	39.2	16.5%	56.3	18.5%	+17.2	
Total liabilities	50.4	21.2%	92.4	30.4%	+42.0	
Total equity and liabilities	237.6	100.0%	304.2	100.0%	+66.6	

Shares issued: End of March 2014: 412,915 thousand → End of March 2015: 413,266 thousand

#### **Major Changes**

- Non-current assets: Right of approval for manufacture and sale +¥59.6bil, Investment securities +¥11.4bil
- Current assets: Accounts receivable +¥7.5bil
- Equity: Retained earnings +¥16.1bil, Valuation difference on available for sale securities +¥7.8bil
- Non-current liabilities: Long term borrowing +¥25.3bil
- Current liabilities: Short term borrowing +¥11.8bil



<sup>\*</sup>The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of the number of shares issued have been adjusted in all periods for comparison purposes.

### **Summary of Cash Flows**

(JPY bil	llions)	FY13 IFRS	FY14 IFRS	Var.
	Cash flows from operating activities	26.7	25.4	-1.3
	Cash flows from investing activities	-7.8	-61.7	-53.9
	Cash flows from financial activities	-8.0	29.0	+36.9
	crease (decrease) in cash and equivalents	10.9	-7.4	-18.2
1	and cash equivalents at ning of year	60.2	72.4	+12.2
	of exchange rate changes on nd cash equivalents	1.3	0.9	-0.4
Cash a	and cash equivalents at end of	72.4	65.9	-6.5

# Capital Expenditures / Depreciation & Amortization

(15)(1,1111)	FY13	FY2014			
(JPY billions)	Actual (IFRS)	Actual (IFRS)	Var.		
Capital expenditures	3.5	5.4	+1.9		
Depreciation and amortization	2.9	*7.0	+4.1		



<sup>\*</sup>Includes JPY3.7 billion amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products

### Long-Listed, New Product Ratios to Sales

New product ratio\* increasing with consecutive successful new product launches



# Reference: Consolidated Forecast of FY2015



## **FY2015 Consolidated Forecasts**

		F`	Y2015 Fore	ecast (IFRS)		
(JPY billions)	1 <sup>st</sup> half	Var.%	2 <sup>nd</sup> half	Var.%	Full year	Var.%
Revenue	92.5	+28.6%	94.0	+4.5%	186.5	+15.2%
Cost of sales (% of revenue)	32.0 34.6%	+20.4%	34.4 36.6%	+15.5%	66.4 35.6%	+17.8% +0.8pt
SGA excluding R&D (% of revenue)	28.5 30.8%	+30.3%	28.4 30.2%	+5.1%	56.9 30.5%	+16.4% +0.3pt
Amortization associated with products (% of revenue)	3.0 3.2%	+131.2%	3.1 3.3%	+15.6%	6.1 3.3%	+53.3% +0.8pt
R&D expenses (% of revenue)	11.0 11.9%	+34.6%	11.9 12.7%	+27.9%	22.9 12.3%	+31.0% +1.5pt
Other revenue	45.0	-	-	-100.0%	45.0	-
Other expenses	1.0	-	0.2	-50.5%	1.2	+162.0%
Operating profit (% of revenue)	62.0 67.0%	+338.7%	16.0 17.0%	-24.7%	78.0 41.8%	+120.5% +20.0pt
					_	

Core operating profit (% of revenue)	21.0 22.7%	37.3%	19.3 20.5%	-18.9%	40.3 21.6%	+3.1%
( // Or revenue)	ZZ.1 /0		20.3 /0		21.076	

Foreign exchange	FY14 actual	FY15 forecast
US \$	JPY 110.14	JPY 125.00
Euro	JPY 139.01	JPY 135.00
CNY	JPY 17.84	JPY 20.00



# Revenue Forecast by Business Segment / Overseas Revenue

			FY2015 Forecast				
(JP	Y billions)	Jap	an	Over	seas	То	tal
		Sales	Var.	Sales	Var. %	Sales	Var. %
Ph	armaceuticals	129.4	5.8%	53.9	45.8%	183.3	+13.3%
	Prescription Pharmaceuticals	123.0	6.3%	53.8	45.9%	176.8	+11.0%
	Ophthalmic	118.5	+12.5%	49.1	+59.9%	167.6	+23.2%
	Anti-RA	3.6	-62.2%	0	-	3.6	-62.4%
	Others	0.9	+14.4%	4.7	-23.0%	5.6	-18.9%
	OTC Pharmaceuticals	6.4	-3.2%	0.1	-0.6%	6.5	-3.2%
Otl	ners	2.8	+11.3%	0.4	+831.0%	3.2	+25.2%
	Medical devices	2.5	+9.5%	0.1	+19.1%	2.6	+9.7%
	Others	0.3	+28.5%	0.4	-	0.7	+174.3%
Tot	al	132.2	5.9%	54.3	46.8%	186.5	15.2%

# Overseas Revenue and Operating Profit Forecast

(JPY billions)		FY2014 Actual (IFRS)		FY2015 Forecast (IFRS)		
(31 1 5111	10113)	Revenue	Revenue*	Var. %	Operating profit**	
U.S.		6.2	4.9	-20.0%	-2.5	
Europe	Э	14.2	25.4	+79.5%	3.8	
Asia		16.7	23.9	+43.4%	5.4	
	China	10.7	13.5	+26.5%	-	
Others	,	0	0	0	-	
Total		37.0	54.3	+46.8%	7.1	
Overs / sale	eas sales s	22.9%	29.1%	+6.3pt	_	

<sup>\*</sup> Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

<sup>\*\*</sup> In line with company policy accounting for operating profit, NPM is distributed by region after operationally transferred from Merck to Santen.

# Forecast of Capital Expenditures / **Depreciation & Amortization**

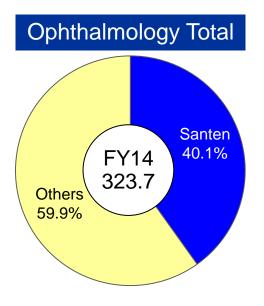
	FY14	FY2015 Forecast		
(JPY billions)	Actual (IFRS)	(IFRS)	Var.	
Capital expenditures	5.4	7.7	+2.3	
Depreciation and amortization	7.0	9.3	+2.4	

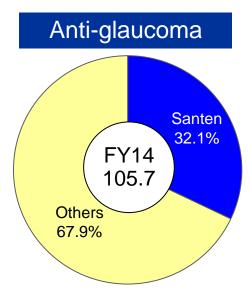
 Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products was recorded of 3.7 billion yen in FY14 and forecast to be 5.1 billion yen in FY15.

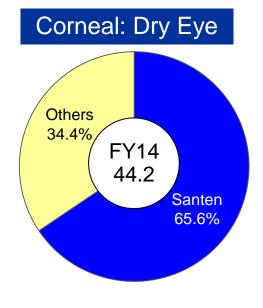
# Reference: Market Overview of Prescription Ophthalmic in Japan

# Japan: Trend & Competition in Ophthalmics (1)

Market Size: billions of yen %: Value Share







		FY13	FY14
YoY change	Market	+10.2%	+7.4%
∩ge	Santen	+23.1%	+9.3%
Santen's Share		39.4%	40.1%

FY13	FY14
+10.5%	+0.9%
+10.7%	+6.1%
30.5%	32.1%

FY14
-0.0%
-7.0%
65.6%

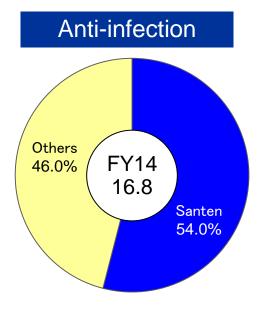
<sup>-</sup>Santen:

<sup>-</sup> Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Trusopt, Rescula, Detantol, Tapcom

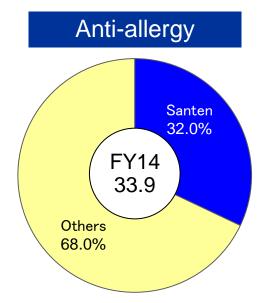
<sup>-</sup> Cornea / Dry Eye: Hyalein, Diquas

# Japan: Trend & Competition in Ophthalmics (2)

Market Size: billions of yen %: Value Share



		FY13	FY14
YoY change	Market	-3.0%	-8.2%
γ nge	Santen	-7.8%	-15.3%
Santen's Share		58.5%	54.0%

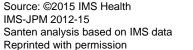


FY13	FY14
-9.7%	+21.4%
+19.7%	+83.3%
21.2%	32.0%

#### -Santen:

- Anti-infection: Cravit, Tarivid

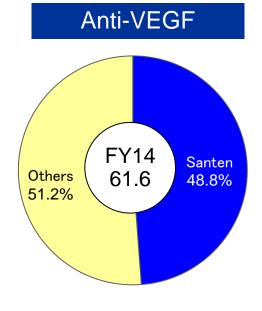
- Anti-allergy: Alesion, Livostin, Alegysal





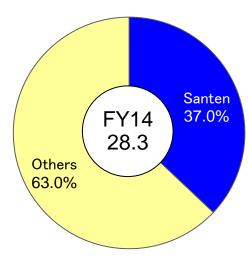
# Japan: Trend & Competition in Ophthalmics (3)

Market Size: billions of yen %: Value Share



		FY13	FY14
YoY change	Market	+52.6%	+42.6%
γ nge	Santen	-	+43.0%
Santen's Share		48.7%	48.8%

#### Anti-RA(DMARDs)

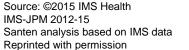


FY13	FY14
+5.5%	-1.5%
+2.0%	-5.1%
38.4%	37.0%

-Santen:

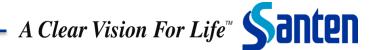
- Anti-VEGF: Eylea

- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate





# Status of Clinical Development FY2014



#### Naveed Shams, M.D., Ph.D.

Senior Corporate Officer
Chief Scientific Officer (CSO)
Head of Global Research & Development

# Status of main projects in clinical development (1)

Global

JP (Asia)

					Deve	elopme	nt Stag	е	
Disease Area	P.I   .	Compound / MOA Region	P1	P2	P3	Reg.	APV/ Launch	Changes from 3QFY14	
			JP					1 	
		Tafluprost/	EU				 	 	
	DE-111	Timolol (FDC)	KR						
		(1 00)	Asia				*		Registration in Asia
Glaucoma/ ocular	DE-118	Tafluprost	JP					I I	
hypertension	DL-110	UD	Asia						
	DE-085	Tafluprost	CN						
	DE-117	EP2 agonist	US		*		 	 	Completed P2b study
	DE-090	Lomerizine	JP					 	
Neralo-	Cyclokat	Cyclosporine	EU					*	Approved in EU
	Cyclorat	Cyclosponne	US				1	I I	
conjunctival disease	DE-089	Diquafosol	CN						
	DL-009	Diqualosoi	Asia				1		

# Status of main projects in clinical development (2)

Global JP (Asia)

				Development Stage					
Disease Area	PI	Region	P1	P2	P3	Reg.	APV/ Launch	Changes from 3QFY14	
			EU			 	*		MAA in EU
Retinal/	Retinal/ Uveal disease	Sirolimus	JP			 		 	
		US			 		 		
	DE-120	VEGF/PDGF inhib.	US			 	 	 	
Allergy	Vekacia	Cyclosporine	EU			 			

# **Major Clinical Projects Update**

# -Glaucoma / Ocular hypertension-

■ DE-085 (Glaucoma / Ocular hypertension)

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
China	NDA Filed	NDA Filed	Generic name: Tafluprost

■ **DE-090** (Glaucoma / Ocular hypertension)

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

■ **DE-111** (Glaucoma / Ocular hypertension)

	Developm	nent Stage	
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
Japan	Launched	Launched	Generic name:
Europe	Launched	Launched	Tafluprost/
Korea	NDA Filed	NDA Filed	Timolol maleate
Asia	NDA Filed	_	(Combination drug)

# Major Clinical Projects Update Ocular hypertension-

-Glaucoma / -Corneal disease-

**DE-117** (Glaucoma / Ocular hypertension)

	Developm	Development Stage		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks	
U.S.	P2b completed	P2b	EP2 receptor agonist	

**DE-089** (Dry eye)

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
Asia	NDA filed	NDA filed	Generic name: Diquafosol Sodium

# **Major Clinical Projects Update**

-Retinal Disease--Uveitis-

■ **DE-120** (Wet Age-related Macular Degeneration (w-AMD))

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
U.S.	P1/2a	P1/2a	VEGF/PDGF dual inhibitor

#### **■ DE-109** (Uveitis)

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
U.S.	Р3	Р3	
Japan	Р3	Р3	Generic name: Sirolimus
EU	NDA Filed	P3	On Onlines

# Major Clinical Projects Update -Santen S.A.S.-

■ Cyclokat (Severe Keratitis)

	Developm		
Region	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks
EU	Approved	NDA filed	Generic Name:
U.S.	P2 completed	P2 completed	Ciclosporin

■ **Vekacia** (Vernal Keratoconjunctivitis)

	Developm	Development Stage		
	As of May 12, 2015	As of February 3, 2015 (Previous announcement)	Remarks	
EU	Р3	Р3	Generic Name: Ciclosporin	

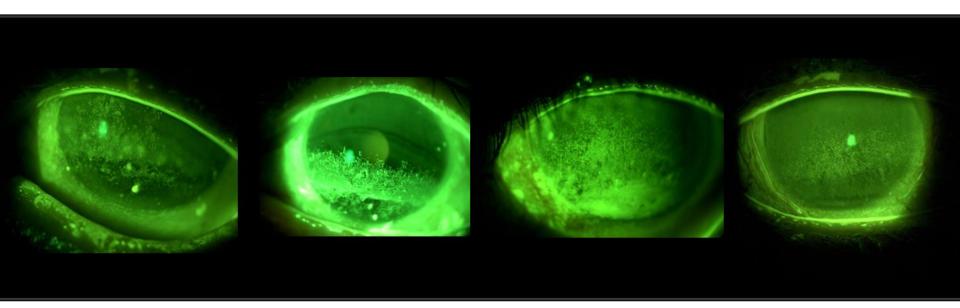
\*Project evaluations are ongoing for the products below:

Development Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ Ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject	Diabetic macular edema	U.S.	P1/2	Generic Name: Dexamethasone Palmitate

### **Ikervis**®

March 25, 2015: Santen announced approval of Ikervis (Cyclokat) for EU Marketing Authorization

Indication: Treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes



## **Ikervis** – CHMP\* conclusions

#### The benefit-risk balance was considered favourable

#### **Primary efficacy endpoint**

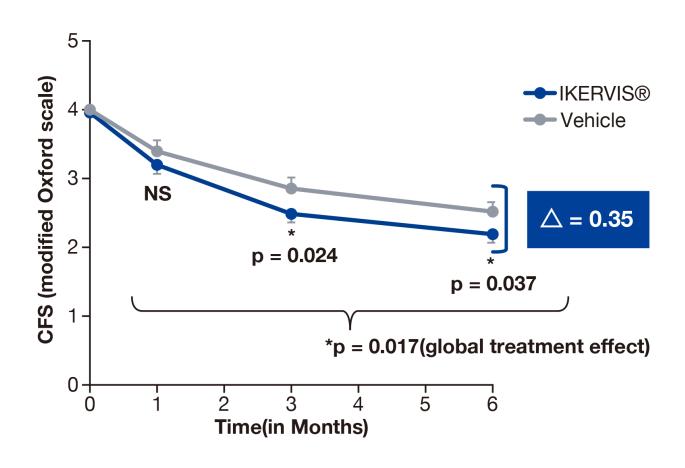
CFS-OSDI (Corneal fluorescein staining - Ocular Surface Disease Index) 50% -CFS-OSDI responder patients[%] p = 0.32640% 28.6% 30% IKERVIS® 23.1% Vehicle 20% 10% 44/154 21/91 0%-Month 6

- Although IKERVIS had not been shown to improve symptoms compared to the vehicle, there was evidence that it could improve the inflammation and damage to the cornea, i.e. keratitis.
- The improvement in corneal surface damage is clinically relevant since Ikervis may help prevent disease progression.
- Experts suggested that there might be a lag time - improvement in symptoms may occur only years after improvement in signs.



<sup>\*</sup>The Committee for Medicinal Products for Human Use (CHMP) is the committee at the European Medicines Agency that is responsible for preparing opinions on questions concerning medicines for human use.

# **Ikervis -** The mean difference in CFS\* (1/3)

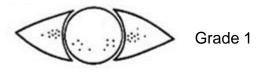


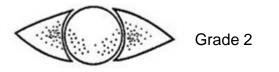


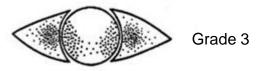
# Ikervis - The mean difference in CFS (2/3)

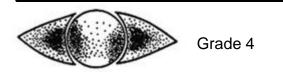
Grade 0: no staining dots

Grade 0.5









Grade 5: more than in Grade 4 picture

A difference of one grade corresponds to a multiplication of the number of dots by 3.16 (except for the difference between 0 and 1)

Grade	Nb of dots on the cornea
0	0
0.5	1
1	≤10
2	≤31
3	≤100
4	≤316
5	> 316

Switching from the mean difference to the ratio of the number of dots, the following formula was used: 3.16 (mean difference) = ratio in number of dots

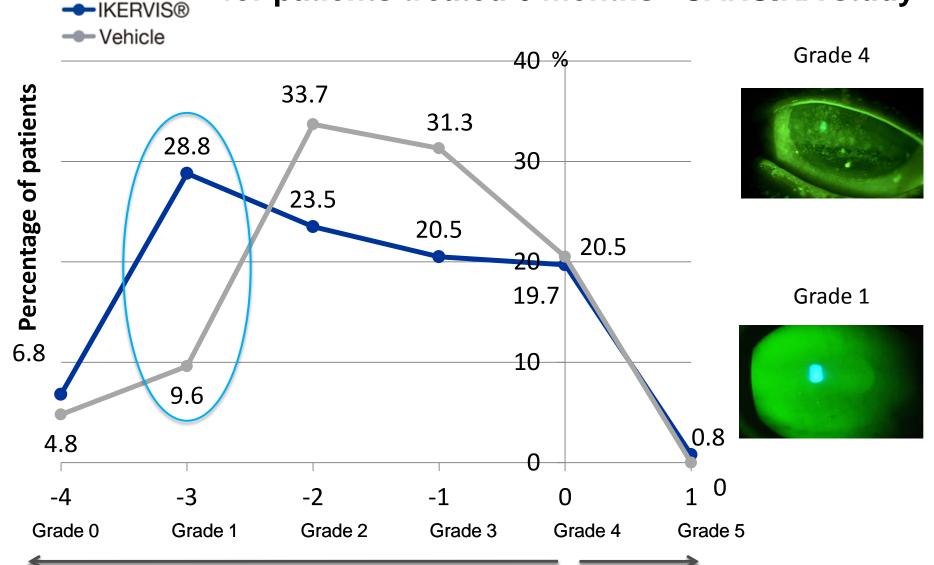
$$3.16^{0.35} \neq 1.5 = \frac{nb \ of \ dots \ in \ Vehicle \ group}{nb \ of \ dots \ in \ Ikervis \ group}$$



## Ikervis - The mean difference in CFS (3/3)

- 0.35 represents a ratio of 1.5 in the damaged surface area (in the vehicle group vs. Ikervis group)
- This ratio means that at 6 months, the vehicle group still has 50% more dots on average than the Ikervis group

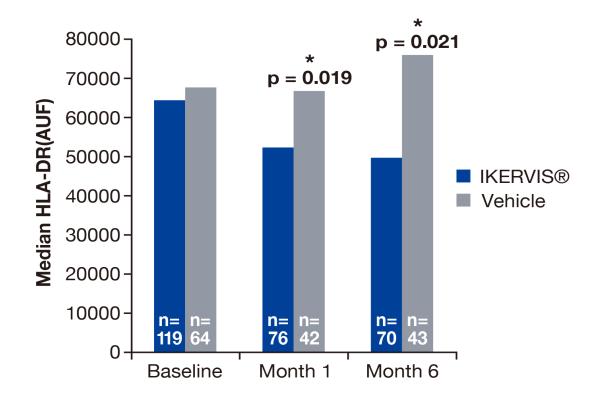
# **Ikervis -** Corneal staining (CFS): change from baseline for patients treated 6 months - SANSIKA study





# **Ikervis -** HLA-DR\* – SANSIKA study Secondary endpoint – Planned analysis

IKERVIS has a long-term (6 months), statistically significant effect on inflammation as assessed by the HLA-DR biomarker



\*HLA-DR: human leukocyte antigen-DR, a MHC class II cell surface receptor commonly used as inflammation marker



#### **Ikervis - Overview of adverse events**

#### Summary of the safety profile

In clinical studies including patients who received either Ikervis or the vehicle (control), administration was conducted at least once a day in both eyes, for up to one year. The most common adverse reactions, which were usually transitory and occurred during instillation, were:

eyelid erythema (1.7%)

- eye pain (19%)
  lacrimation (6.2%)
  eye irritation (17.8%)
  ocular hyperaemia (5.5%)

#### Table of undesirable effects in SmPC (Summary of Product Characteristics)

SOC	Frequency	PT	
Infections and infestations	≥ 1/1,000 to < 1/100	Keratitis bacterial, herpes zoster ophthalmic	
Eye disorders	≥ 1/100 to < 1/10	Erythema of eyelid, lacrimation increased, ocular hyperaemia, vision blurred, eyelid oedema, conjunctival hyperaemia, eye irritation, eye pain	
	≥ 1/1,000 to < 1/100	Conjunctival oedema, lacrimal disorder, eye discharge, eye pruritus, conjunctival irritation, conjunctivitis, foreign body sensation in eyes, deposit eye, keratitis, blepharitis, corneal decompensation, chalazion, corneal infiltrates, corneal scar, eyelid pruritus, iridocyclitis	
General disorders and administration site conditions	≥ 1/10	Instillation site pain	
	≥ 1/100 to < 1/10	Instillation site irritation, instillation site erythema, instillation site lacrimation	
	≥ 1/1,000 to < 1/100	Instillation site reaction, instillation site discomfort, instillation site pruritus, instillation site foreign body sensation	

#### (for reference)

# **Ikervis - Trial Design**

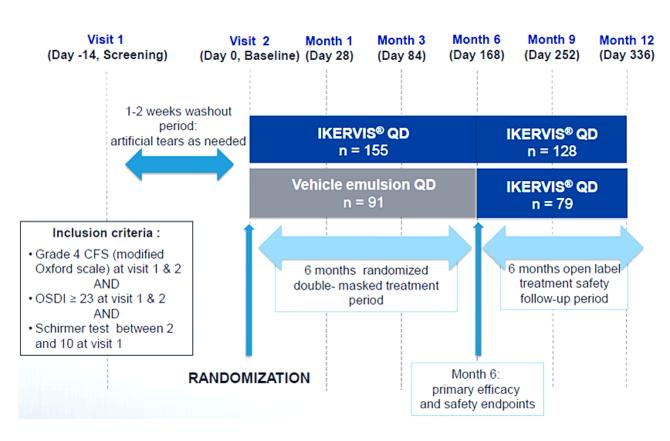
#### Phase 3 SANSIKA trial design

Multicentre Randomised Double-masked 2 parallel arm Vehicle-controlled

# Primary efficacy endpoint:

CFS-OSDI composite responder rate at month 6 where responder simultaneously:

- Improves ≥2 grades from baseline in CFS¹, and
- Improves ≥30% from baseline in OSDI (i.e. % change ≤-30%)



<sup>&</sup>lt;sup>1</sup> Based on the modified Oxford scale (i.e. change in CFS ≤-2),

#### **Forward-Looking Statements**

- Information given in this announcement and accompanying documentation 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 and event were to adversely affect supply capabilities for related final products.

# A Clear Vision For Life™

