

### Santen Pharmaceutical Co., Ltd. Investor Meeting

### Financial Results for the 3rd Quarter of FY2014 Financial Forecast for the FY2014

# February 3, 2015

### Kazuo Koshiji

Corporate Officer, Chief Financial Officer (CFO) Head of Finance & Administration Division



### 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

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



## Long-term Growth Targets

FY 2013

- Strengthen the domestic business
- Preparations for business expansion in Asia/Europe

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

### Medium-term Goal

FY

2017

- 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

What we aim to achieve by 2020

2020

Santen

"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

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

Organization and talents

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





### **Financial Results for 3rd Quarter of FY2014**

## Financial Highlights for Q3 FY2014

- Net Sales and Operating Profit increased by 7.2% and 3.0% year-on-year respectively in Q3 FY2014
- Operating Profit before Amortization increased by 13.4% year-on-year
- Net Profit Margin\* from Merck boosted the sales and operating profit
- Ikervis (generic name: Ciclosporin)

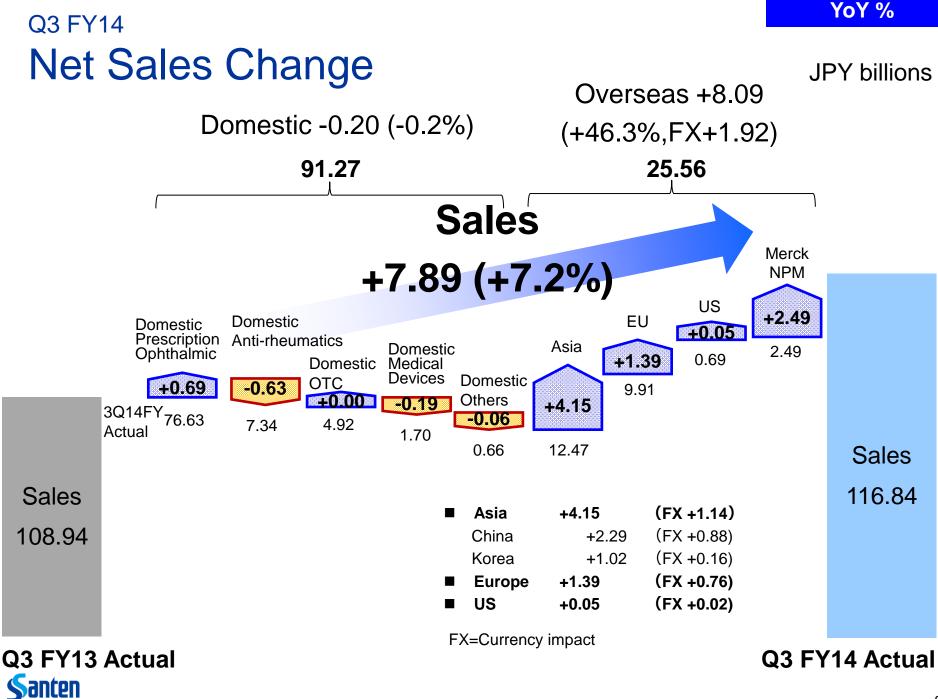
A severe dry-eye treatment under development in Europe has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in January, 2015

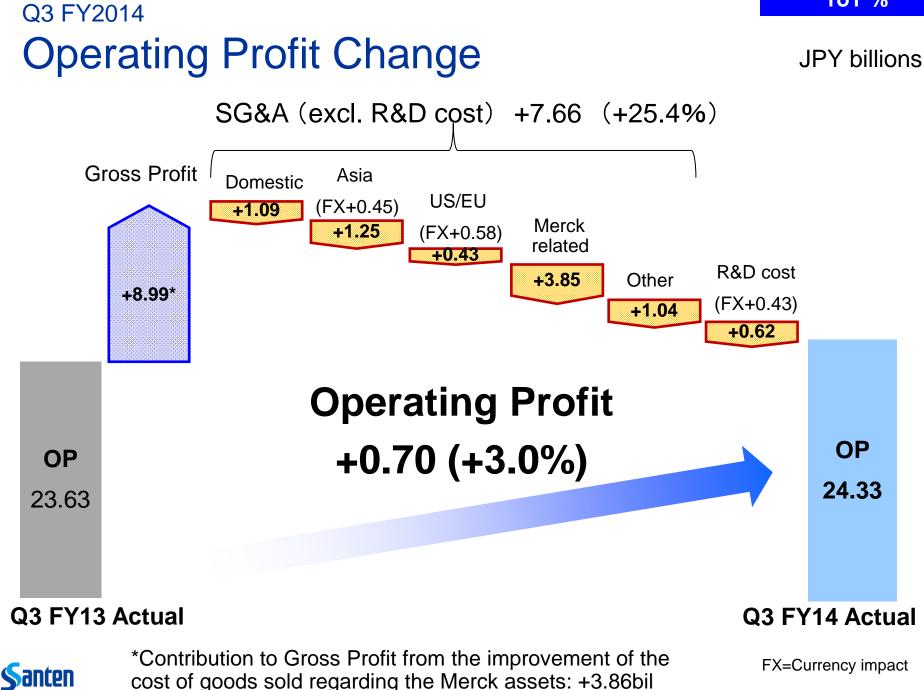
\*Net Profit Margin(NPM): Profit generated from US Merck ophthalmic products which Santen has acquired and has consigned them to Merck until the completion of transfer of the underlying marketing rights.



## Financial Highlights for Q3 FY2014

(JPY billions)		Q3 FY13 Actual	Q3 FY14 Actual	Var. %
Net Sales		108.94	116.84	+7.2%
Cost of Sales (% of net sales)		42.57 39.1%	41.47 35.5%	-2.6% -3.6pt
SGA excluding R&D (% of net sales)		30.24 27.8%	37.91 32.4%	+25.4% +4.7pt
Excluding amortization of intangible asset related Merck (% of net sales)		30.24 27.8%	35.46 30.4%	+17.3% +2.6pt
Amortization of intangible asse	related Merck	-	2.44	-
R&D Cost (% of net sales)		12.49 11.5%	13.12 11.2%	+5.0% -0.2pt
Operating Profit (% of net sales)		23.63 21.7%	24.33 20.8%	+3.0% -0.9pt
Ordinary Income		24.29	24.81	+2.1%
Net Income		15.37	16.19	+5.3%
Operating profit before amortization		26.21	29.73	+13.4%
Santen	Foreign Exchange US \$ Euro CNY	Q3 FY13 actual JPY 99.17 JPY 129.59 JPY 15.49	Q3 FY14 actual JPY 107.11 JPY 140.43 JPY 17.35	







# Merck Project Current Status

### **Merck Project** -Financial Result-

	Q3 FY14 Actual				
(JPY billions)	Existing Business	Merck*	Total		
Net Sales	112.84	3.99	116.84		
NPM	-	2.49	2.49		
Other		1.50	114.34		
Cost of Sales	45.33	-3.86	41.47		
Gross Profit	67.50	7.86	75.37		
SGA excluding R&D	34.05	3.85	37.91		
R&D Cost	13.03	0.08	13.12		
Operating Profit	20.41	3.92	24.33		

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



## **Merck Project** -Current Status-

### July, 2014

 1<sup>st</sup> closing was completed for underlying assets for Japan, Asia and a part of Europe

### September, 2014

• Completed Marketing Authorization (MA) transfer to Santen Japan

### October, 2014

- 2<sup>nd</sup> closing was completed. All the underlying assets under the agreement have been closed
- Established wholly owned subsidiaries in Italy and the UK

### December, 2014

- Established a wholly owned subsidiary in Spain
- Completed MA transfer to Santen in Sweden and Norway

### January, 2015

• Completed MA transfer to Santen in Finland and Germany

### Q1 FY2015

• Planning to complete MA transfer in Italy and Spain





# **Consolidated Forecast of FY2014**

### **FY2014 Financial Forecast**

	FY2013	F	FY2014 F	orecast		FY2014
(JPY billions)	Actual (Japanese Standard)	Existing Business	Merck*	Total	Var. %	Fizo14 Forecast (IFRS)**
Net Sales	148.66	151.00	5.00	156.00	+4.9%	156.00
Cost of Sales	58.10	57.50	-5.50	52.00	-10.5%	52.00
(% of net sales)	39.1%	38.1%	-	33.3%	-5.8pt	33.3%
SGA excluding R&D	44.10	46.50	8.20	54.70	+24.0%	***53.80
(% of net sales)	29.7%	30.8%	-	35.1%	+5.4pt	34.5%
R&D Cost	19.04	19.00	0.30	19.30	+1.4%	19.10
(% of net sales)	12.8%	12.6%	-	12.4%	-0.4pt	12.2%
Operating Profit	27.41	28.00	2.00	30.00	+9.4%	31.10
(% of net sales)	18.4%	18.5%	40.0%	19.2%	+0.8pt	19.9%
Ordinary Income	27.92	28.50	1.50	30.00	+7.4%	31.10
Net Income	17.10	18.60	0.90	19.50	+14.0%	20.50
Operating Profit before Amortization	31.20	32.00	5.70	37.70	+20.8%	-
Cash ROE(JPY)	_	_	-	14.6%	-	-
ROE	9.9%	-	-	10.5%	+0.6pt	10.6%

\* Merck project is indicated the contribution from acquisition of Merck's ophthalmology asset which Santen contracted as of May 8th, 2014.

- \*\* [Difference between Japanese Standard forecast and IFRS]
  - Including the depreciation of intangible asset
    Reported asset of license in payment
- \*\*\* Including Merck depreciate of intangible asset, ¥3.7bil



<foreign exchange=""></foreign>	FY13 Actual	FY14 Forecast
US\$	JPY 100.04	JPY 103.00
Euro	JPY 132.98	JPY 141.00
CNY	JPY 15.93	JPY 16.90

### Dividend for 1H FY2014 Actual and FY2014 Forecast



### Dividend for 1H FY2014 Actual and FY2014 Forecast

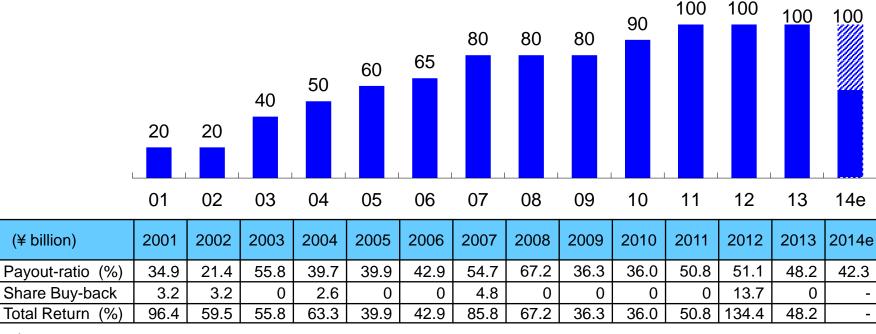
### FY2014 1<sup>st</sup> Half

FY2014 First Half Dividend : JPY 50 per share

### FY2014

- FY2014 Annual Dividend : JPY 100 per share
- Target dividend payout ratio: 40.0%

Annual dividend per share (JPY)





## Reference: Consolidated Results 3rd Quarter of FY2014

## Net Sales by Business Segment

(JF	PY billions)	Q3 FY14 Actual					
		Jap	Japan Overseas			Total	
		Sales	Var. %	Sales	Var. %	Sales	Var. %
Ph	armaceuticals	89.38	+0.0%	25.54	+46.5%	114.92	+7.6%
	Prescription Pharmaceuticals	84.46	+0.0%	25.49	+46.4%	109.95	+7.9%
	Ophthalmic	76.63	+0.9%	22.29	+31.9%	98.93	+6.6%
	Anti-RA	7.34	-8.0%	0.03	-51.8%	7.37	-8.4%
	Others	0.48	-10.9%	3.16	+631.1%	3.64	+274.6%
	OTC Pharmaceuticals	4.92	+0.0%	0.05	+83.6%	4.97	+0.5%
Ot	hers	1.89	-9.5%	0.02	-38.3%	1.91	-10.0%
	Medical Devices	1.70	-10.2%	0.02	-38.3%	1.72	-10.7%
	Others	0.18	-2.3%	-	-	0.18	-2.3%
То	tal	91.27	-0.2%	25.56	+46.3%	116.84	+7.2%



### **Oversea Sales**

	V hilliono)	Q3 FY13		Q3 FY14	
(JP	Y billions)	Actual	Actual	Var.	Var. %
U.S	S.	0.63	3.18	+2.54	+401.8%
Eui	rope	8.51	9.91	+1.39	+16.4%
Asi	а	8.31	12.47	+4.15	+50.0%
	China	5.97	8.27	+2.29	+38.5%
	Korea	1.52	2.54	+1.02	+66.8%
Oth	ners	0.01	0.00	-0.00	-79.1%
Tot	al	17.47	25.56	+8.09	+46.3%

Oversea sale/sales 16.0%	21.9%	+5.8pt	-
--------------------------	-------	--------	---



## **Summery of Balance Sheet**

	As of March 31, 2014		As of December 31, 2014		
(JPY billions)	Actual	% of Total	Actual	% of Total	Var.
Current Asset	156.00	67.5%	139.43	50.2%	-16.56
Fixed Asset	75.09	32.5%	138.58	49.8%	+63.48
Total Asset	231.10	100.0%	278.02	100.0%	+46.91
Current Liabilities	39.09	16.9%	43.22	15.5%	+4.13
Non-current Liabilities	10.80	4.7%	39.27	14.1%	+28.47
Total Liabilities	49.89	21.6%	82.50	29.7%	+32.60
Total Net Asset	181.20	<b>78.4%</b> *	195.51	70.3%*	+14.30
Total Liabilities Net Assets	231.10	100.0%	278.02	100.0%	+46.91

\*Net Worth Ratio: End of March, 2014: 78.2%  $\rightarrow$  End of December, 2014: 70.1%, Issued shares: End of March, 2014: 82,582 thousands  $\rightarrow$  End of December, 2014: 82,619 thousands

#### Major Changes

Current Asset:	Cash and deposits -¥5.20bil, Notes and accounts receivable +¥4.49bil, Securities -¥11.91bil, Products -¥2.81bil
Fixed Asset:	Right of approval for manufacture and sales +¥59.68bil, Investment securities +¥4.00bil,
Current Liabilities:	Notes and accounts payable -¥3.21bil, Short term borrowing +¥11.76bil, Income tax payable -¥5.64bil
Non-current Liabilities	: Long term borrowing +¥28.21bil
Net asset:	Earned surpluses +¥7.96bil, Valuation difference on available for sale securities+¥2.52bil,
Santen	Foreign currency translation adjustments +¥3.41bil

### **Changes in Income Statement**

	Q3 FY13	Q3	FY14	Major Changes	
(JPY billions)	Actual	Actual	Var. %	Major Changes	
Net Sales	108.94	116.84	+7.2%		
Cost of Sales (% of net sales)	42.57 39.1%		-2.6% -3.6pt	Merck -4.7pt     Product mix change +2.1pt     NHI price revision +0.4pt	
SGA excluding R&D (% of net sales)	30.24 27.8%				
Excluding amortization of intangible asset related Merck (% of net sales)	30.24 27.8%	35.46 30.4%		<ul> <li>Japan +1.09</li> <li>Asia +1.25(FX+0.45)</li> <li>US/EU +0.43(FX+0.58)</li> <li>Merck related +1.41</li> </ul>	
Amortization of intangible asset related Merck (% of net sales)	-	2.44 2.1%		Amortization of Merck's asset +2.44	
R&D Expenses (% of net sales)	12.49 11.5%	13.12 11.2%	+5.0% -0.2pt		
Operating Profit (% of net sales)	23.63 21.7%	24.33 20.8%			
Non-operating Income	0.86	0.92	+7.0%		
Non-operating Expense	0.20	0.45	+124.5%		
Ordinary Income	24.29	24.81	+2.1%		
Extraordinary Gain	0.47	0.05		I CUITENCY Rates>	
Extraordinary Loss	0.89	0.03	-96.3%	<u>3Q FY13 actual</u> <u>3Q FY14 actual</u>	
Net Income before Tax	23.87	24.83	+4.0%		
Corporate Tax	8.49	8.64			
Net Profit	15.37	16.19	+5.3%		
Operating profit before amortization (% of net sales)	26.21 24.1%				



### **Summary of Cash Flows**

(JPY billions)		Q3 FY14 Actual	
Cash and cash equivalents at the beginning of 3Q FY14		72.39	
Net increase/decrease in cash and cash equivalents			
Cash flows f	rom operating activities	+13.43	
Cash flows from investing activities			
Cash flows f	rom financial activities	+31.89	
Effect of exchange rate changes on cash and cash equivalents		+1.68	
Cash and cash equiv	alents at the end of 3Q FY14	58.28	

Note: "Cash and cash equivalents" include cash equivalents thus differ from "cash and deposits" in the Balance Sheets.



# Capital Expenditures / Depreciation & Amortization

	Q3 FY13	Q3 FY14		
(JPY billions)	Actual	Actual	Var.	
Capital Expenditures	2.08	2.55	+0.47	
Depreciation and Amortization	1.83	4.57	+2.74	





# Reference: Consolidated Forecast of FY2014

## Sales Forecast by Business Segment / Overseas Sales (Japanese Standard)

				FY2014	Forecast			
(JI	PY billions)	Jap	an	Over	Overseas		Total	
		Sales	Var.	Sales	Var. %	Sales	Var. %	
Pł	narmaceuticals	121.10	+1.6%	31.56	+19.1%	152.66	+4.8%	
	Prescription Pharmaceuticals	114.79	+1.8%	31.54	+19.2%	146.33	+5.1%	
	Ophthalmic	103.77	+2.0%	28.35	+10.7%	132.12	+3.7%	
	Anti-RA	9.95	-2.0%	0.03	-61.4%	9.99	-2.5%	
	Others	1.06	+23.9%	3.15	+318.1%	4.21	+161.7%	
	OTC Pharmaceuticals	6.30	-1.7%	0.02	-36.6%	6.33	-1.9%	
01	thers	3.28	+13.3%	0.04	-6.7%	3.33	+12.9%	
	Medical Devices	2.90	+10.5%	0.04	-20.7%	2.94	+9.8%	
	Others	0.38	+40.7%	0.00	-	0.39	+43.4%	
То	otal	124.38	+1.9%	31.61	+19.1%	156.00	+4.9%	



## Oversea Sales Revised Forecast (Japanese Standard)

	FY2013 Actual	F١	2014 Foreca	ist
(JPY billions)	(Unification of Accounting Period)	Forecast	Var.	Var. %
U.S.	1.07	3.10	+2.03	+189.1%
Europe	12.29	13.64	+1.34	+11.0%
Asia	13.17	14.85	+1.68	+12.8%
China	9.79	10.06	+0.26	+2.7%
Korea	2.10	2.75	+0.65	+31.1%
Others	0.00	0.01	+0.00	+71.9%
Total	26.55	31.61	+5.06	+19.1%

Oversea sale/sales	17.9%	20.3%	+2.4pt	-
--------------------	-------	-------	--------	---



# Capital Expenditures / Depreciation & Amortization (Japanese Standard)

	FY2013 Actual	FY2014		
(JPY billions)	(Unification of Accounting Period)	Forecast	Var.	
Capital Expenditures	3.15	4.50	+1.34	
Depreciation and Amortization	2.61	6.70	+4.08	

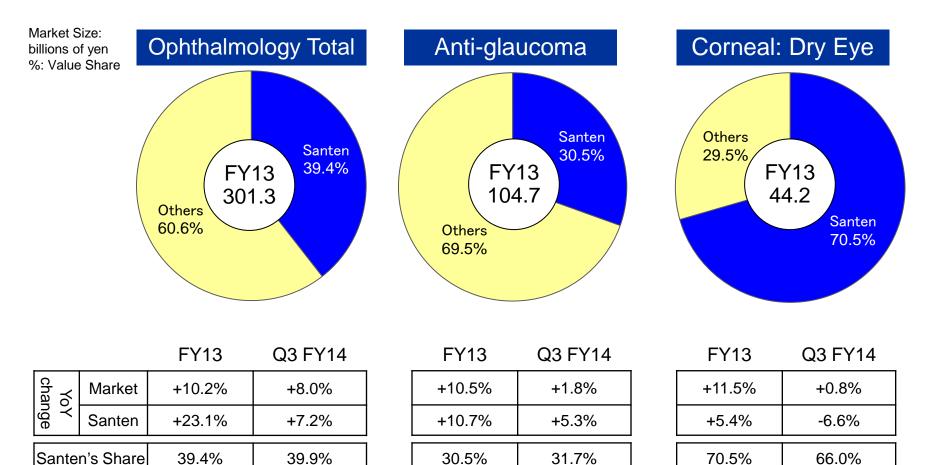




# **Reference:**

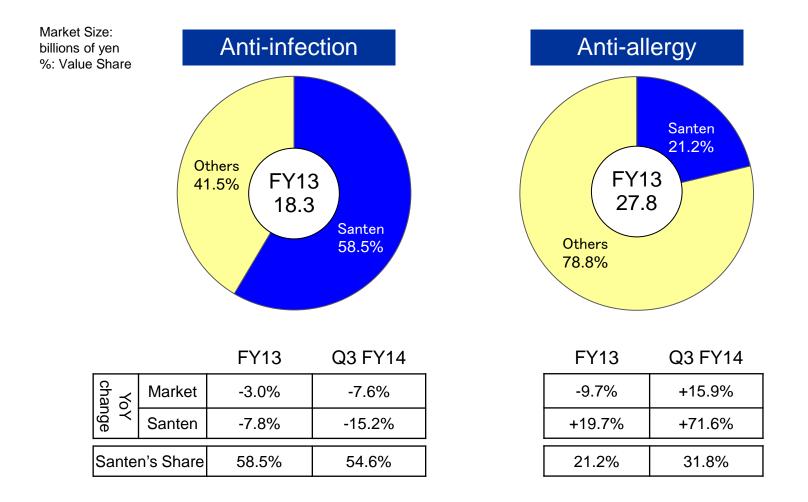
# Market Overview of Prescription Ophthalmic in Japan

# Japan: Trend & Competition in Ophthalmics (1)





# Japan: Trend & Competition in Ophthalmics (2)



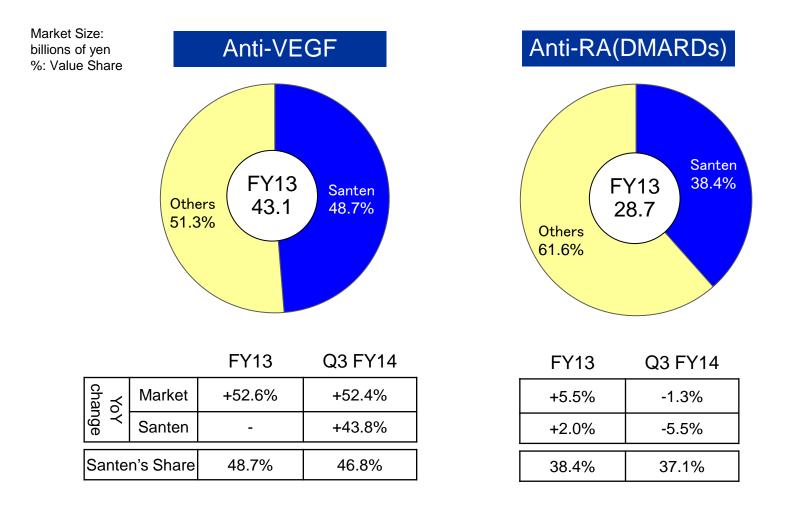
-Santen:

- Anti-infection: Cravit, Tarivid
- Anti-allergy: Alesion, Livostin, Alegysal



Source: ©2014 IMS Health IMS-JPM 2012-14 Santen analysis based on IMS data Reprinted with permission

# Japan: Trend & Competition in Ophthalmics (3)





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

Source: ©2014 IMS Health IMS-JPM 2012-14 Santen analysis based on IMS data Reprinted with permission



# Status of Clinical Development 3rd Quarter of FY2014

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

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

## Major Clinical Pipeline List (1) [by Disease]

(Red underlined: Change from 1H of FY14 Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Phas	e 2	Phase 3	NDA	Approved - Launched
Glaucoma/ Ocular		DE-1 EP2 Recepto	P2b Dr Agonist		DE-085 China Tafluprost	
Hypertension		DE-( Lomerizi			Korea DE- Taflupros	• <b>111</b> JP, <u>EU</u> st/Timolol
					Asia	- <b>118</b> JP rost UD
Corneal/ Conjunctival					China DE-089 Diquafosol Sodium	
Disease		U.S. Cyclo Ciclos			EU Cyclokat Ciclosporin	
Retina/ Uveitis	U.S. DE-120 VEGF/PDGF inh			DE-109 Sirolimus		
<b>Other</b> Infection, Allergy, RA				Vekacia Ciclosporin		



## Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from 1H of FY14 Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved • Launched
Japan		DE-090 Lomerizine HCI	DE-109 Sirolimus		DE-111 Tafluprost/Timolol
					DE-118 Tafluprost UD
North America		DE-117 P EP2 Receptor Agonis	2b DE-109 Sirolimus		
Àmerica)	DE-12 VEGF/PDGF int				
		Cyclokat Ciclosporin			
Asia (including Oceania)				DE-085 China Tafluprost	
				China DE-089 Diquafosol Sodium	
				Korea DE-111 Tafluprost/Timolol	
				DE-118 Tafluprost UD	
EU			DE-109 Sirolimus	Cyclokat Ciclosporin	DE-111 Tafluprost/Timolol
			Vekacia Ciclosporin		



## Major Clinical Projects Update

### -Glaucoma / Ocular hypertension-

### ■ **DE-085** (Glaucoma / Ocular hypertension)

Region	Developm		
	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
China	NDA Filed	NDA Filed	Generic name: Tafluprost

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

	Developm	ent Stage	
Region	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

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

	Developm		
Region	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
Japan	Launched	Approved	Generic name:
Europe	Launched (Germany)	NDA Filed	Tafluprost/ Timolol maleate
Korea	NDA Filed	—	(Combination drug)



## Major Clinical Projects Update

-Glaucoma / Ocular hypertension--Corneal disease-

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

	Developm		
Region	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
U.S.	P2b	P2b	EP2 receptor agonist

### **DE-089** (Dry eye)

	Developm		
Region	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
Asia	China: NDA filed	China: NDA filed	Generic name: Diquafosol Sodium



### Major Clinical Projects Update -Retinal Disease--Uveitis-

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

	Development Stage		
Region	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks
U.S.	P1/2a	P1/2a	VEGF/PDGF dual inhibitor

### **DE-109** (Uveitis)

Region	Development Stage			
	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks	
U.S.	P3	P3	Generic name: Sirolimus	
Japan	P3	P3		
EU	P3	P3		



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

### ■ Cyclokat (Severe Dry Eye)

Region	Development Stage			
	As of February 3, 2015	As of November 5, 2014 (Previous announcement)	Remarks	
EU	NDA filed	NDA filed	Generic Name: Ciclosporin	
U.S.	P2 Completed	P2 Completed		

#### Vekacia (Vernal Keratoconjunctivitis)

	Development Stage		
Region	As of February 3, 2015	As of November 5, 2014 (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

### **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 nonapproval 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.



