



Ophthalmology: Our Singular Focus

Akira Kurokawa
President & CEO, Santen
Pharmaceutical Co., Ltd.

J.P. Morgan
Healthcare Conference
January 9, 2017

Disclosure Notice

- Information given in 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.
- This presentation includes discussions of certain Santen products marketed in certain markets and compounds in clinical trials, as well as competitors and their products and compounds in clinical trials which are given for illustrative purposes only. Such discussions may include views subject to data interpretation that may or may not be views shared by regulatory authorities in the various regions in which the Company operates.

Santen's Core Values

天機に参与する

Tenki ni sanyo suru

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.

Ophthalmology: Our Singular Focus

- Growing ophthalmology market
- Specialized in ophthalmology
- Santen's growth strategy
- Pursuing unmet medical needs in ophthalmology
- Expanding global partnership alliances

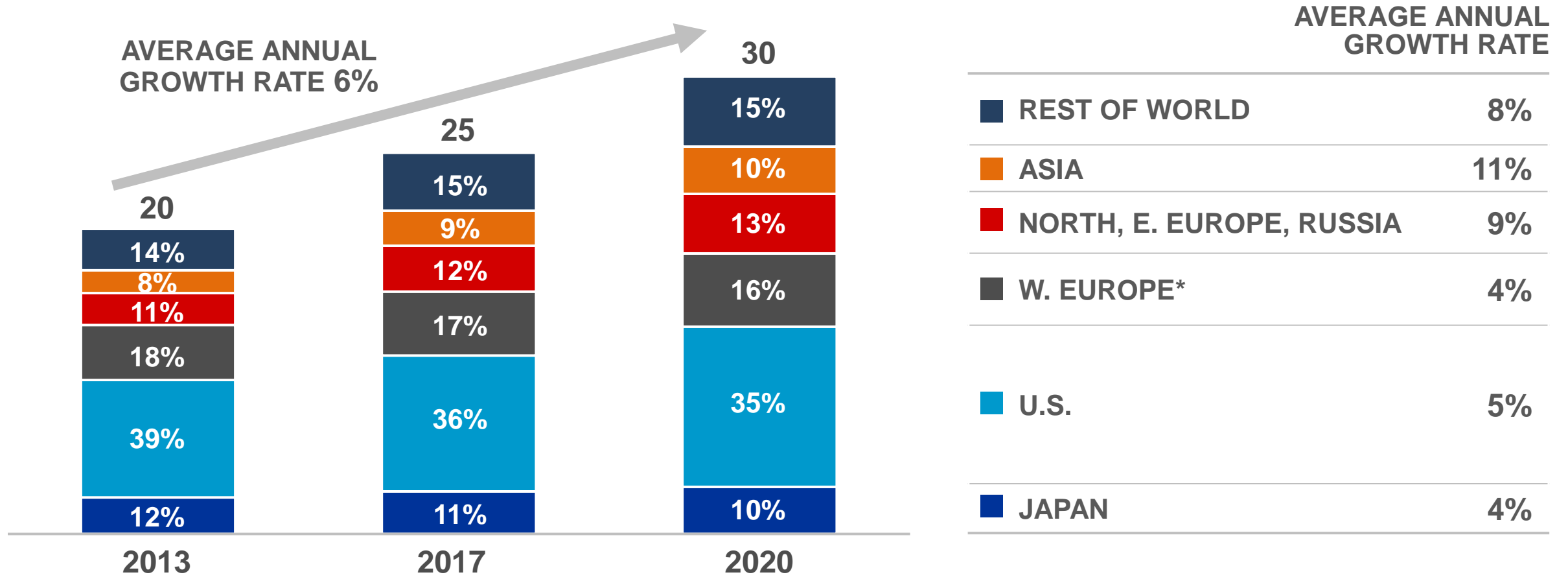
Ophthalmology: Our Singular Focus

- **Growing ophthalmology market**
- Specialized in ophthalmology
- Santen's growth strategy
- Pursuing unmet medical needs in ophthalmology
- Expanding global partnership alliances

Market Outlook: Continuing Growth Led by Emerging Markets

Global Prescription Ophthalmic Market

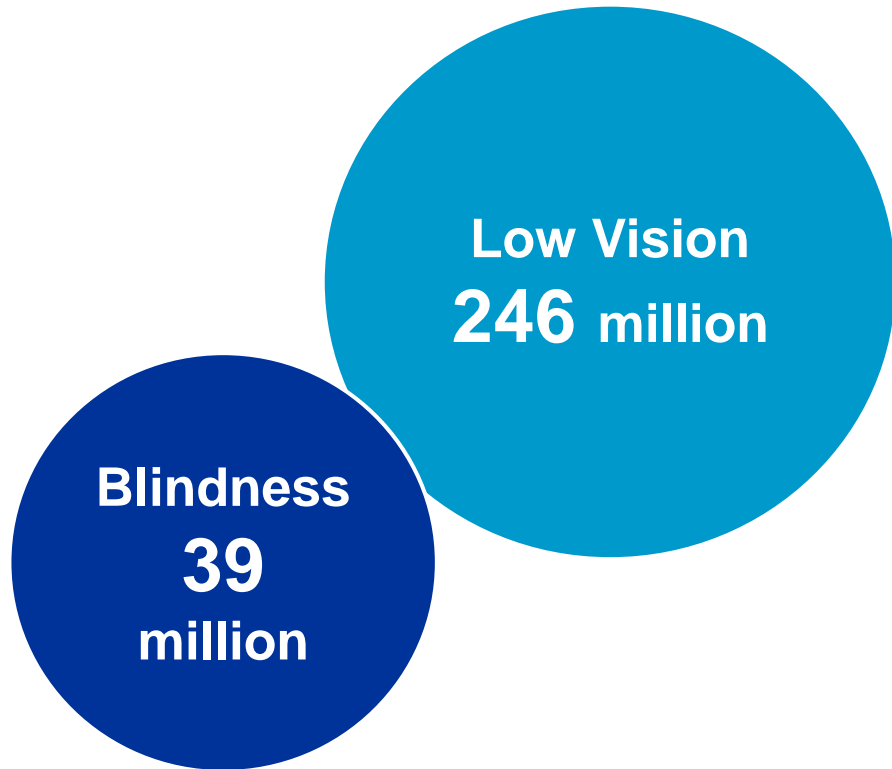
(USD billions)



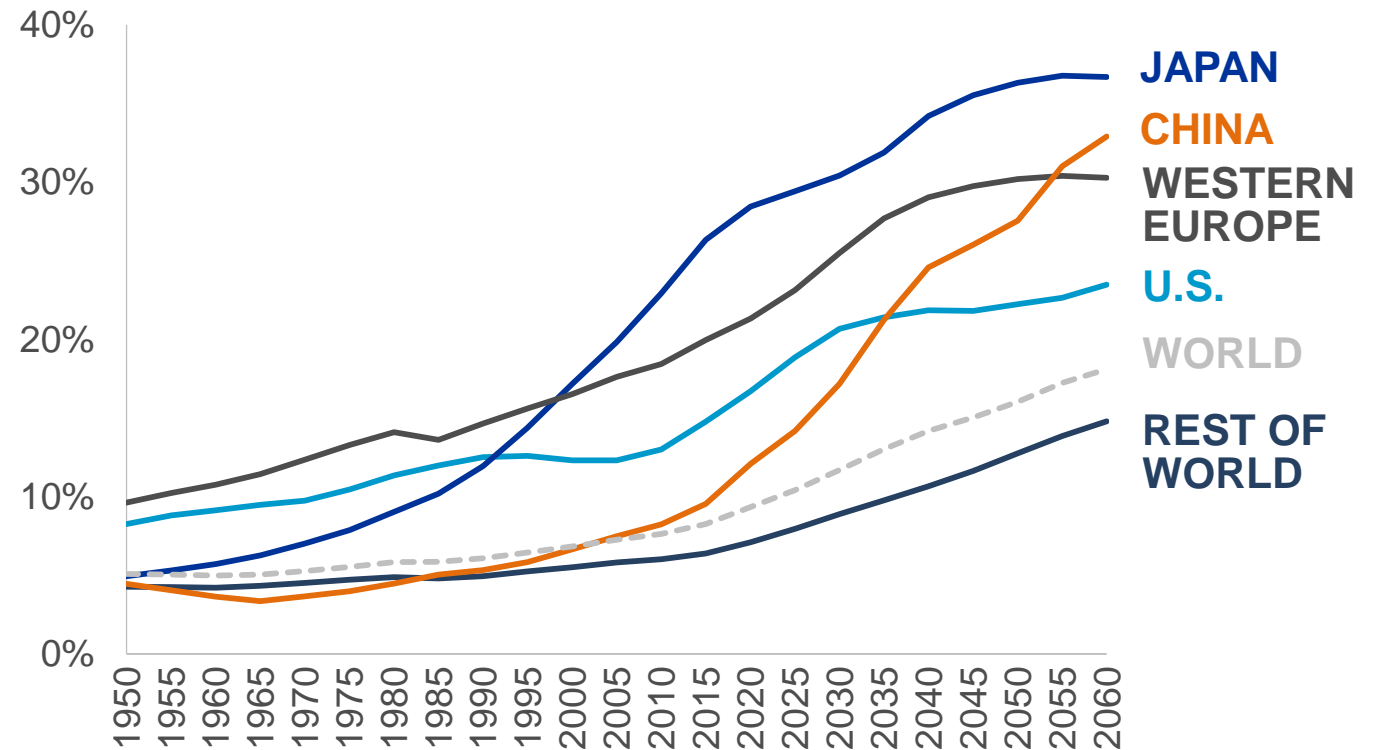
Source: Santen estimation
*UK, France, Germany, Spain, Italy

Vision Problems Expected to Increase as World Populations Age

World Population Suffering
from Visual Impairment:
285 million

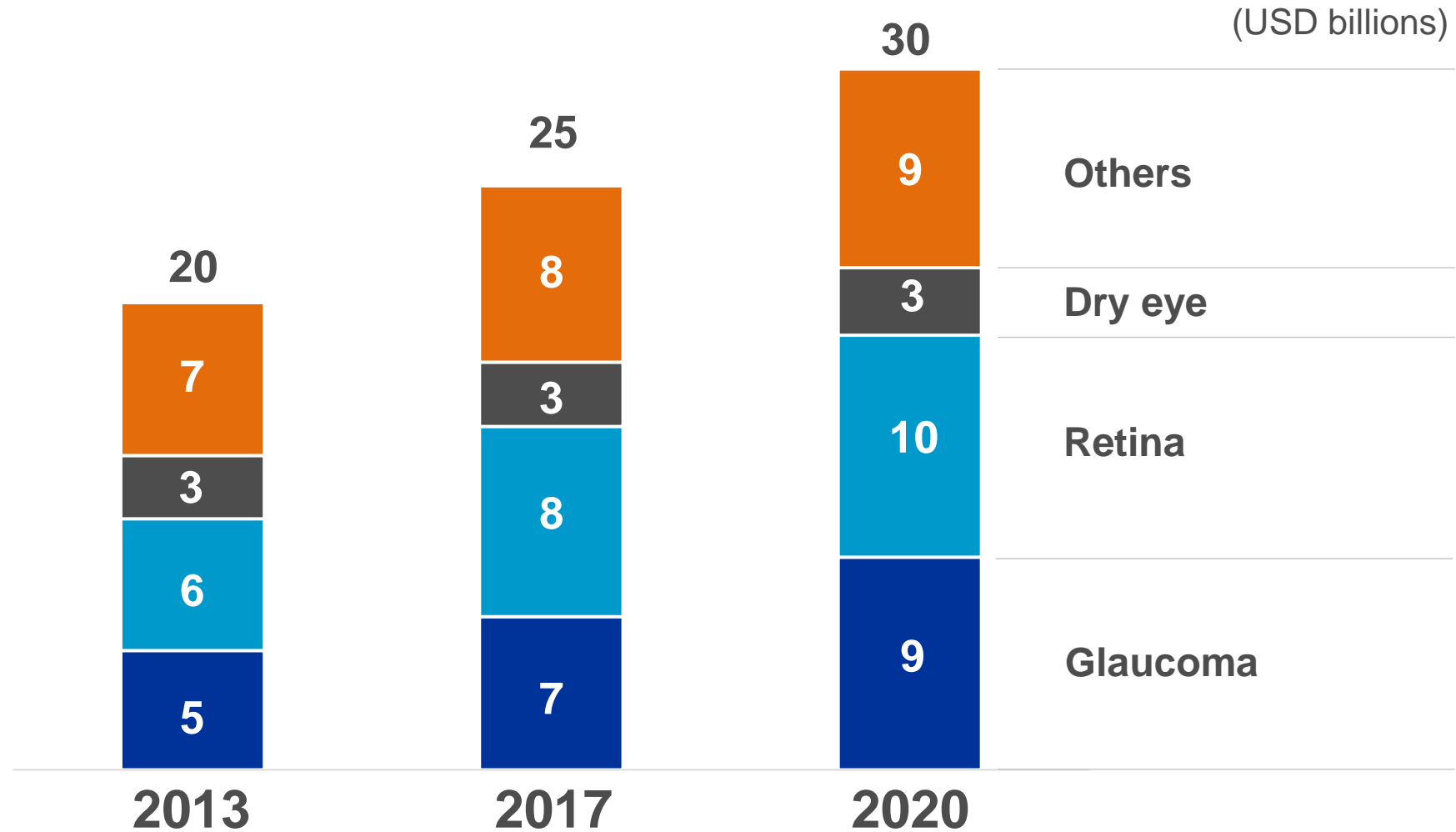


Population Aged 65+



Santen is Focused on the High Growth Areas: Dry Eye, Glaucoma and Retina

Global Market Forecast by Disease Category



Ophthalmology: Our Singular Focus

- Growing ophthalmology market
- **Specialized in ophthalmology**
- Santen's growth strategy
- Pursuing unmet medical needs in ophthalmology
- Expanding global partnership alliances

Covering All Ophthalmic Therapeutic Areas

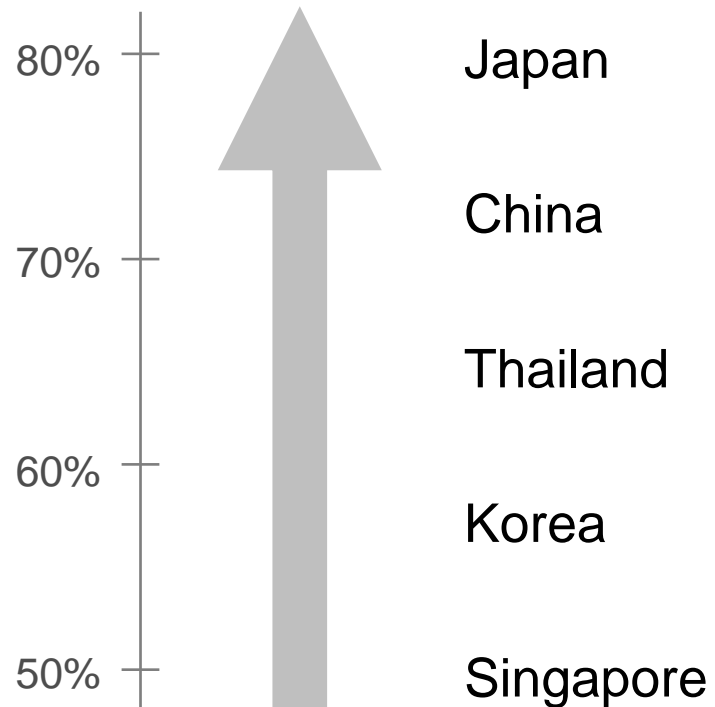
Santen provides total solutions in ophthalmic therapeutic areas to improve of quality of life

Company	Retina	Glaucoma	Dry eye	Infection	Allergy	Cataract
Santen	✓	✓	✓	✓	✓	✓
Alcon/Novartis	✓	✓	✓	✓	✓	✓
B&L/Valeant	✓	✓	✓	✓	✓	✓
Allergan	✓	✓	✓	✓	✓	
Pfizer	✓	✓				
Genentech	✓					
Regeneron/Bayer	✓					
Abbott/Solvay	✓		✓			✓
Sanofi	✓				✓	

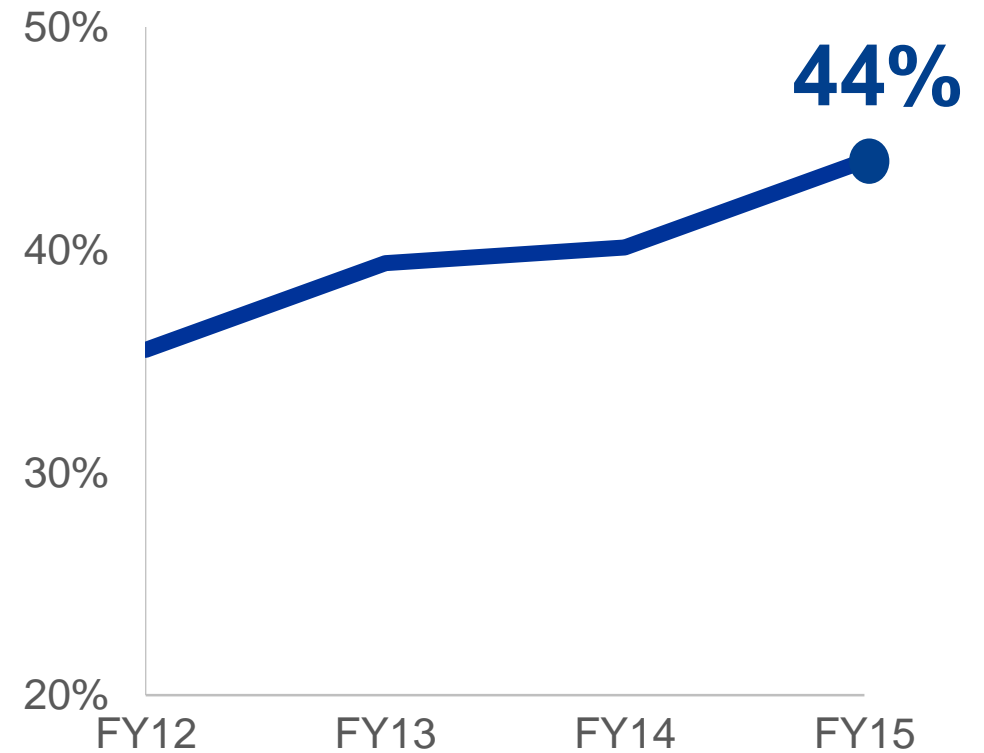
Customer Satisfaction Leadership – Santen is Transferring This Strength Beyond Asia to EMEA

Customer Satisfaction in Japan and Asia

(Percentage of Doctors Evaluating Santen as #1 or #2)



Market Share Leader in Japan



In Addition to Organic Growth, Santen Is Proceeding with Further Ophthalmology Specialization with Maximum Business Synergy

2012

Novagali Pharma acquisition

- Strengthened R&D, including Novasorb[®] formulation technology
- *IKERVIS* (now launched in several European countries)
- Supported growth in global business platform

2014

Merck ophthalmology product acquisition

- Acquired product revenue 21.6 billion yen (FY15)
- Reinforced global presence
- Accelerated EU and Asia growth
- Increased profitability
- Expanded key glaucoma franchise

2015

Anti-rheumatic (RA) pharmaceutical business divestment

7% RA
93% Op

100%
Ophthalmology

- 45b yen received to support future investment

2016

InnFocus acquisition: enhanced pipeline with *InnFocus MicroShunt* glaucoma implant device

- Santen to enter high growth glaucoma device area
- *MicroShunt* U.S. launch expected in 2020/2021
- CE marked in Europe
- Develop globally

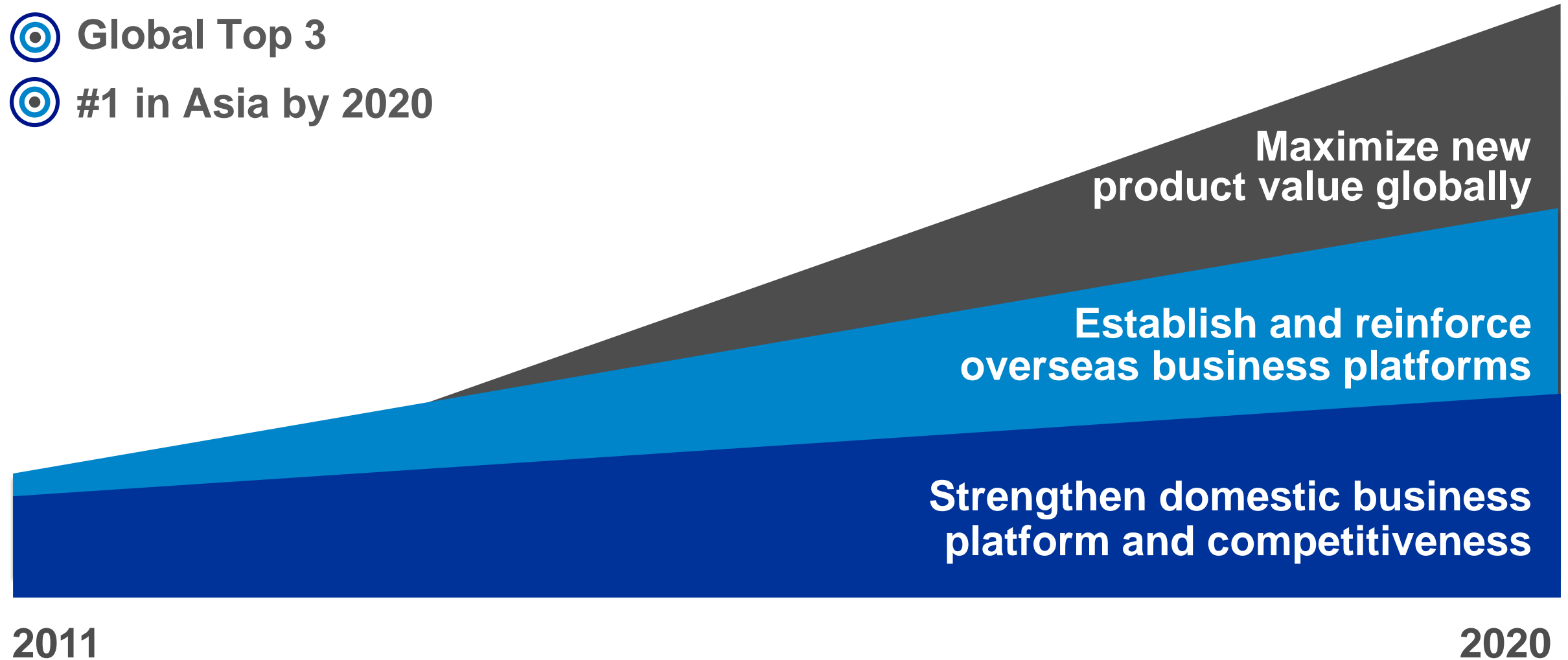
Ophthalmology: Our Singular Focus

- Growing ophthalmology market
- Specialized in ophthalmology
- **Santen's growth strategy**
- Pursuing unmet medical needs in ophthalmology
- Expanding global partnership alliances

Establishing a Global Presence as a Specialized Pharmaceutical Company

🎯 Global Top 3

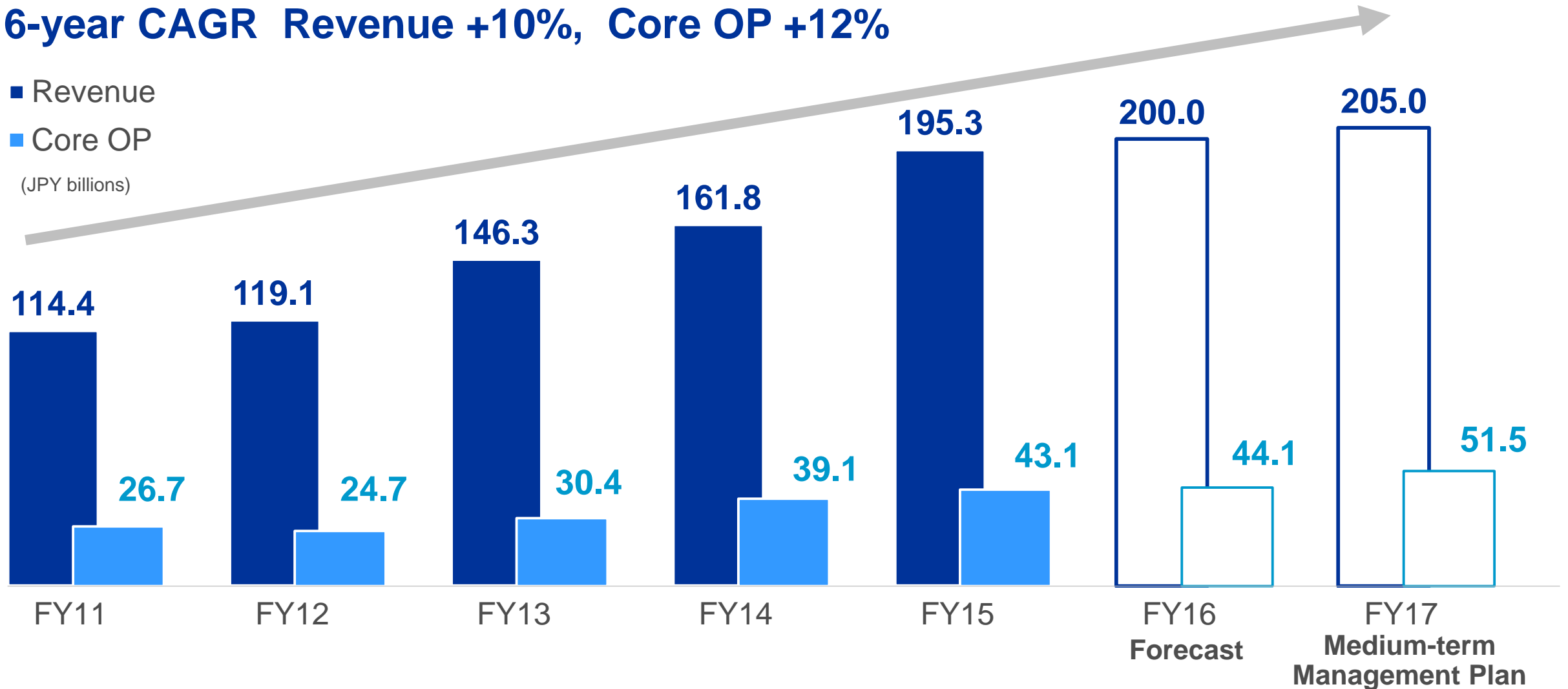
🎯 #1 in Asia by 2020



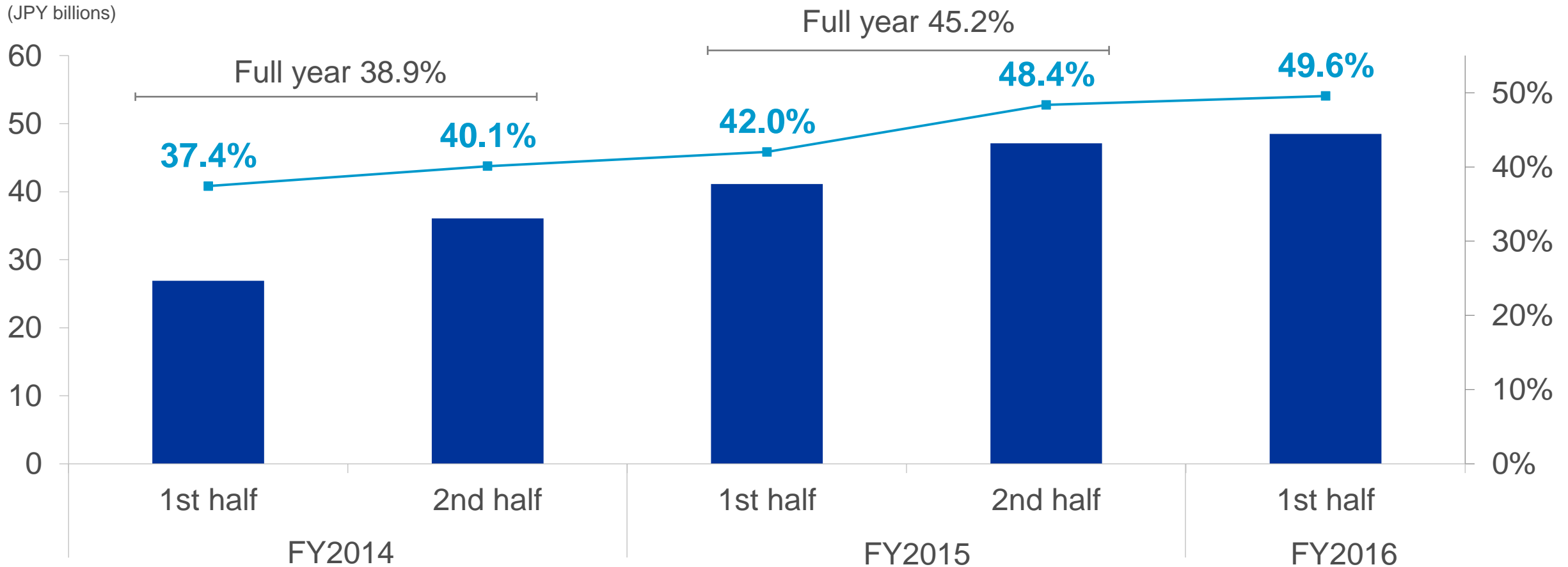
Steady Earnings Growth with Ophthalmology Specialization

6-year CAGR Revenue +10%, Core OP +12%

■ Revenue
■ Core OP
(JPY billions)



Steady Growth New Global Products As We Seek Total Ophthalmic Solutions



NEW PRODUCTS: Cosopt, Tapros, Tapcom, Diquas, Ikervis, Alesion, Eylea

Ophthalmology: Our Singular Focus

- Growing ophthalmology market
- Specialized in ophthalmology
- Santen's growth strategy
- **Pursuing unmet medical needs in ophthalmology**
- Expanding global partnership alliances

Steady Pipeline Launches Will Meet Unmet Medical Needs

Domain	Launched in FY2011-2013	To be Approved in FY2014-2017	To be Approved FY2018 Onward
Glaucoma	<i>Tapros Mini</i>	DE-111 (tafluprost/timolol combination)	DE-117 (omidinenepag isopropyl) DE-126 (sepetaprost) DE-128 (<i>MicroShunt</i>) US
Corneal and Conjunctival Disease (Dry Eye)		<i>Ikervis</i> (ciclosporin)	
Retinal Disease, Uveitis	<i>Eylea</i>		DE-109 (sirolimus injection) DE-120 (VEGF/PDGF inhibitor) DE-122 (Anti-endoglin antibody)
Other Infection, Allergy	<i>Alesion</i> <i>Cravit 1.5%</i>	<i>Vekacia</i> (ciclosporin)	

Global Product

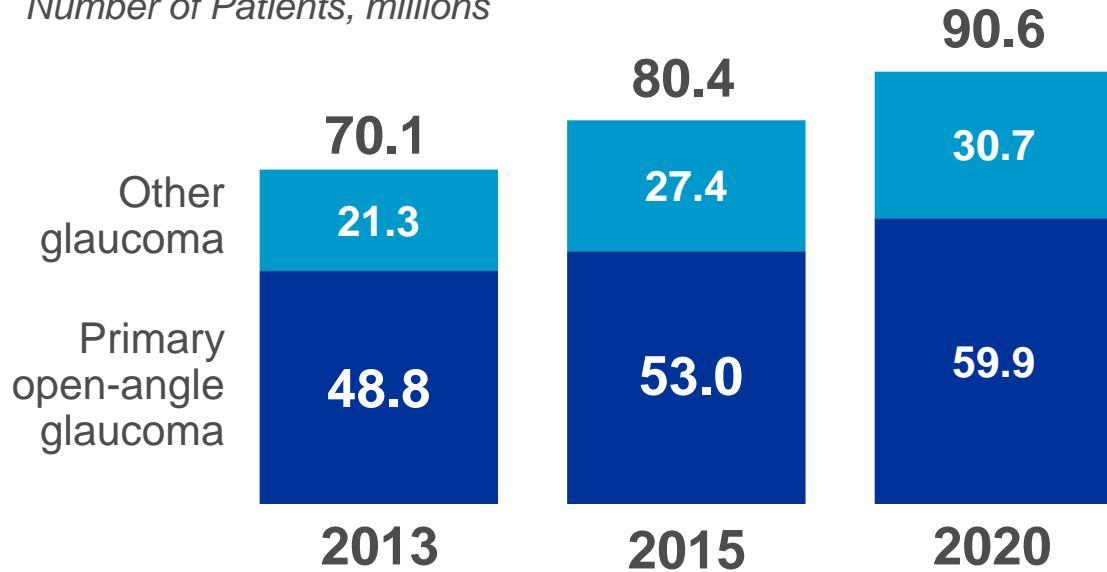
Japan (Asia) Product

Glaucoma Market is Growing

Blindness from open-angle glaucoma forecast to reach 5.9 million people globally by 2020

Global Glaucoma Patient Population

Number of Patients, millions

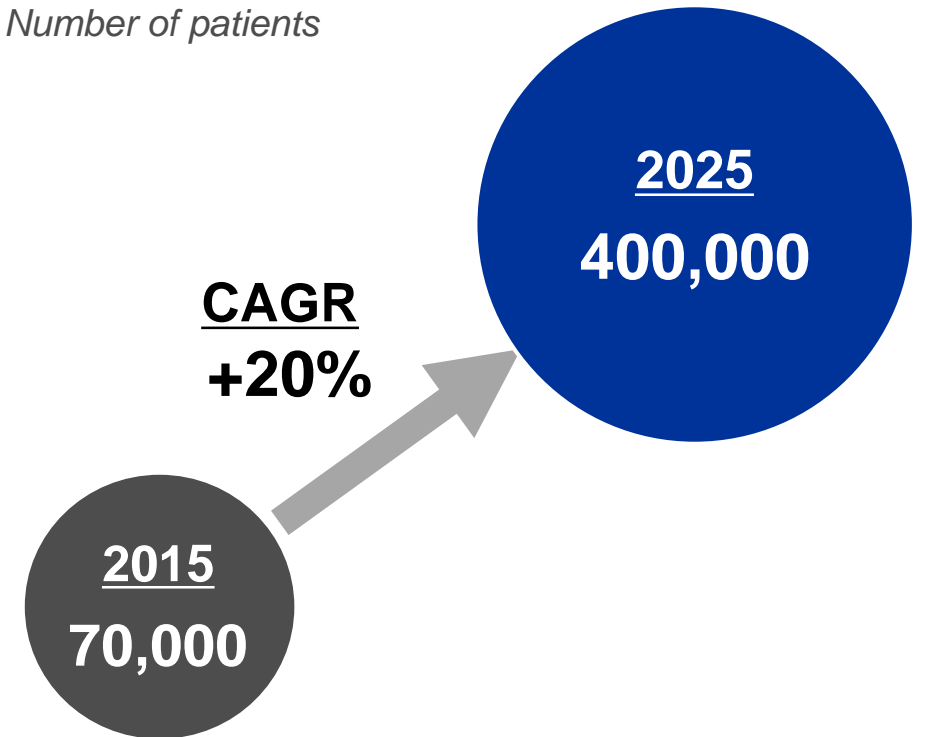


U.S. Primary Open-Angle Glaucoma

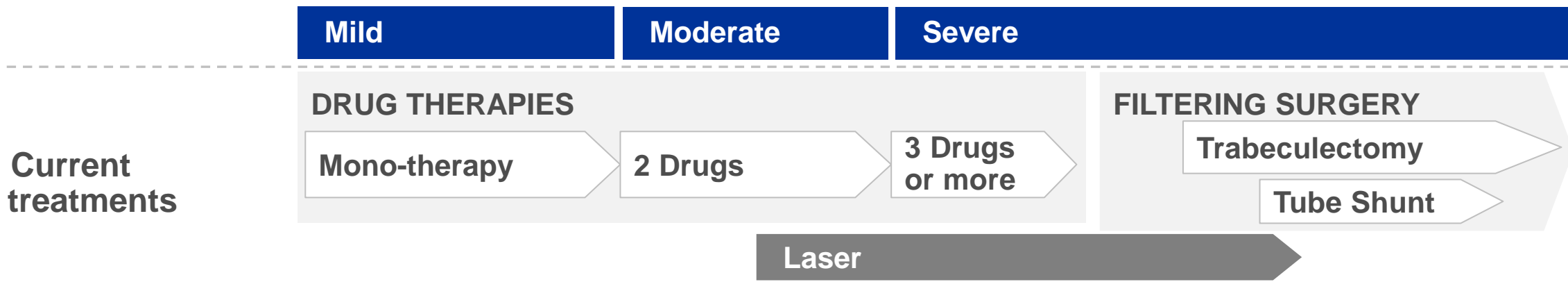
Year	2013	2015	2020
Number of Patients (millions)	3.3	3.5	3.8

U.S. Demand for Micro-Invasive Glaucoma Surgery (MIGS)

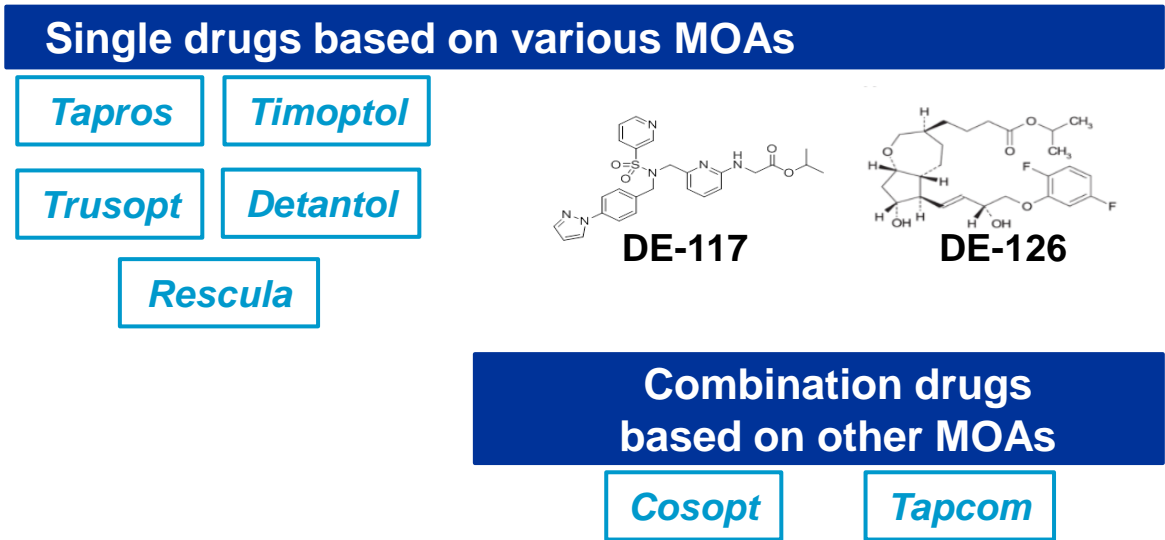
Number of patients



Santen's Glaucoma Portfolio is Positioning to Address All Stages of Glaucoma



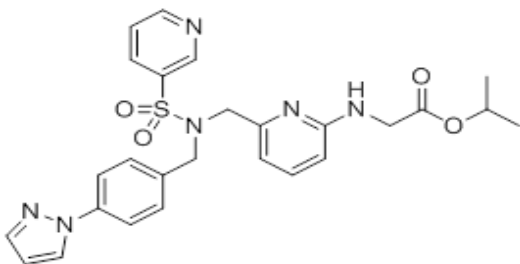
Santen's future treatment options



Santen Glaucoma Pipeline: Building A Powerful Glaucoma Treatment Franchise

DE-117

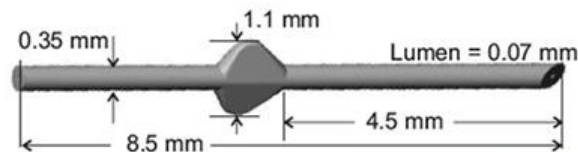
- First-in-class candidate with a novel EP2 agonist MOA
- Study on-going for non-/low-responders of gold standard glaucoma treatment, prostaglandin analogues



Mid-FY18
expected approval
(Japan)

MicroShunt (DE-128)

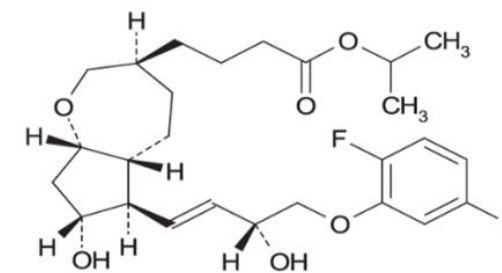
- First true replacement for trabeculectomy, “gold standard” glaucoma surgery for moderate-severe patients



FY19~FY20
expected approval
(US)

DE-126

- First-in-class candidate with a novel EP3 / FP agonist MOA.
- Expected to show a superior intraocular pressure lowering effect compared to FP receptor agonists



FY21~
expected approval

DE-128 *MicroShunt*: Less Invasive and Greater Adherence

DE-128 is being developed to address unmet needs compared to existing treatment options

Unmet needs of current treatments

- Compliance/Adherence issue of drug treatment/Lack of sustained efficacy of laser
- Invasiveness and post-op complications of trabeculectomy



MicroShunt

- One surgery to achieve mean IOP 11.1mmHg after 3 years, 49% reduction from baseline
- Procedure similar, but simplified compared to trabeculectomy
- Adverse effects observed comparable or less than other surgical procedures and devices reported in the literature

Planning, if approved, full-scale launch in the U.S. in 2020/2021

Annual peak revenue potential estimated at over \$200 million

MicroShunt (DE-128): Simple Procedure / Low Burden

Please click here for animated video of surgical procedure

(Video is 1 minute 31 seconds and contains no audio)

DE-109: Candidate for Unmet Medical Need of Uveitis

Highlight on Sirolimus Injection (DE-109)

SAKURA Phase III Program completed, topline results announced Nov 2016

Included one large pivotal trial (SAKURA 1), one supportive trial (SAKURA 2), and ongoing long-term safety extension trial (SPRING); designed to confirm dose with the optimal benefit-risk profile

NDA submission to the FDA (US) planned in fiscal Q4 (Jan–Mar); submission to EMA (Europe) later in 2017

If approved, launch in U.S. planned for first half of 2018 and peak sales potential estimated at over 10 billion yen

DE-109: Candidate for Unmet Medical Need of Uveitis

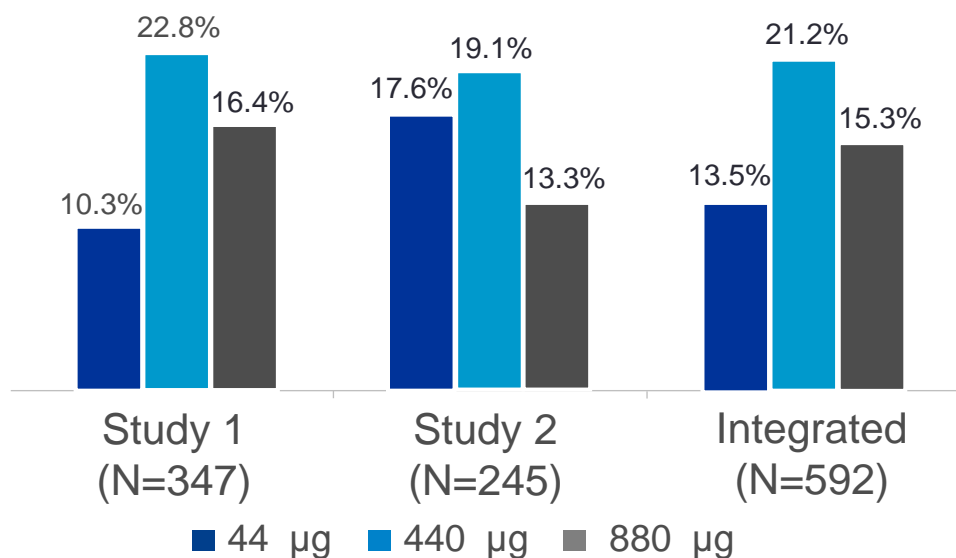
SAKURA Program Supports Benefit-Risk Profile of Sirolimus Injection, with 440 µg as Optimal Dose for Treatment of Non-Infectious Uveitis of Posterior Segment

VH 0 Response, Intent to Treat (ITT) Population P-value (440 µg vs. 44 µg)

P = 0.010

P = 0.783

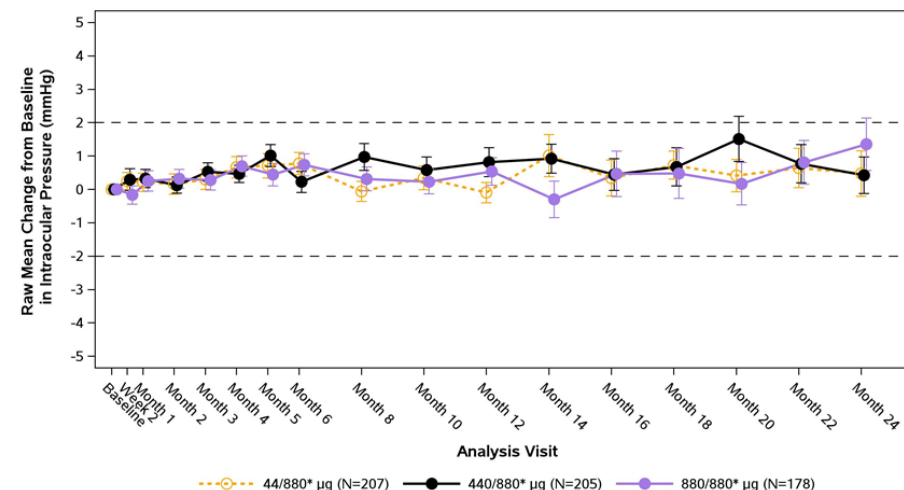
P = 0.038



Reduction or Elimination of Corticosteroids (≤5 mg/day)

Tapering of Corticosteroid for Intent-to-Taper Patients	44 µg N=32	440 µg N=46	880 µg N=32
Baseline mean dose, mg/day	24.2	26.2	20.74
Tapering success (n)	(22) 68.8%	(32) 69.6%	(22) 68.8%
Tapering success and VH 0/0.5+ (n)	(9) 40.9%	(20) 62.5%	(10) 45.5%

Minimal Impact on IOP post Sirolimus Intravitreal Injection



Pipeline Development: To Quickly Deliver Important Ophthalmic Treatment Solutions

DE-117	Q2/Q3 FY2017 Filing in Japan	
DE-126	FY2016 P2b Start	
DE-109 <i>(OPSIRIA)</i>	Jan-Mar 2017 Filing in US	Jan-Jun 2018 Launch in US
	Calendar 2017 Re-filing in EU (After filing in US)	
DE-120	FY2016 P2a Completion	
DE-122	FY2017 P1/2 Completion	
DE-128 <i>(MicroShunt)</i>	Calendar 2018-2019 P2/3 Completion	Calendar 2020-2021 Launch in US

Ophthalmology: Our Singular Focus

- Growing ophthalmology market
- Specialized in ophthalmology
- Santen's growth strategy
- Pursuing unmet medical needs in ophthalmology
- **Expanding global partnership alliances**

To Meet Unmet Medical Needs, Expanding Global Partnership Alliances

Santen is working closely with excellent companies, institutes, and academia



In Conclusion, Santen Is...

- ✓ Specialized in ophthalmology
 - ✓ Pursuing unmet medical needs
 - ✓ Building high customer satisfaction with customer-oriented strategy
 - ✓ Steadily growing earnings driven by global new products
 - ✓ Enjoying high market share in Japan and continuing to grow in Europe and Asia
- ✓ Preparing for business expansion in the U.S and other regions
 - ✓ Developing treatments for all stages of glaucoma in our substantial and high-growth franchise
 - ✓ Expecting to file drug candidates DE-117 and DE-109 to government agencies in 2017
 - ✓ Building partnerships with leading companies and institutions worldwide

Santen

A Clear Vision For Life[®]

For Reference: SAKURA Development Program

Sirolimus injection study Assessing double-masKed Uveitis tReAtment (SAKURA)

Phase 3, Multicenter, Randomized, Double-Masked Study Assessing the Safety and Efficacy of Intravitreal Injections of DE-109 (Sirolimus Injection, 3 Doses) for Treatment of Non-infectious Uveitis of the Posterior Segment

Objective	To evaluate the safety and efficacy of sirolimus injection of 440 µg and 880 µg sirolimus vs. active comparator (44 µg) for the treatment of non-infectious uveitis of the posterior segment	
Principal Eligibility Criteria	<ul style="list-style-type: none">• Diagnosis of active NIU of the posterior segment• VH score >1+ (study eye, modified SUN scale)• BCVA: ≥19 ETDRS letters or 20/400 (study eye); Vision ≥20/200 (fellow eye)	
Study Design	Randomized in 1:1:1 ratio to receive 44 µg (active control), 440 µg, or 880 µg by intravitreal injection for 2 months for a total of three doses; safety follow up for up to 24 months	
Primary Endpoint	Vitreous Haze Score = 0 at Month 5	
Clinical Sites	Largest global clinical program in NIU-PS: 103 sites in 15 countries across the US, EMEA, India, Latin America, and Japan	
	STUDY 1	STUDY 2
Patients (N)	347	245
Timing	Subjects enrolled through March 31, 2013, completed October 2013	Subjects enrolled on or after April 1, 2013, completed October 2016