Passion for Innovation. Compassion for Patients.™



## Daiichi Sankyo Group 5-year Business Plan (Fiscal 2013 - 2017)

Friday, March 22, 2013

Joji Nakayama, President and CEO

## The Long View: Planning Background



- The rapid growth and shift of populations and economic disparity in emerging countries/regions like China, India and Africa
- Further aging of populations in developed countries
- Innovative business to generate new treatments by advanced science
- Generic business to provide quality and affordable pharmaceuticals by excellent technology
- Global reach to convey our products across world

- One of the leading companies to provide health/medical solutions globally in the coming decades
- A company to be proud of globally



## 1. Review of the Previous 3-Year Plan

#### 2nd 3-Year Plan (FY2010-2012): Overall Review



### Strong platform laid down for future growth Expansion of profitability still a key task

Enhance innovative pharmaceuticals business

Achieved

Launched New products in Japan

(Rezaltas, Inavir, Lixana, Memary, Nexium, Ranmark, etc.)

Established Global R&D: Plexxikon, RCI (Life Science Research Center in India)

....

Challenge

Olmesartan franchise and prasugrel: short of their targets

Edoxaban: NDA for AF indication in FY2013 (original target: FY2012)

Establish business composition to address diverse needs

Achieved

Established generic pharmaceutical business: Daiichi Sankyo Espha Established vaccine businesses: Kitasato Daiichi Sankyo Vaccine and Japan Vaccine

- OTC business: Launched Loxonin S
- Ranbaxy: Launched FTFs in US; growth globally

Challenge

Enhance profitability by utilizing business platform

Create synergy by collaboration with Ranbaxy Achieved

- Shifted sales of DS products in many countries (e.g. Olmesartan, Levofloxacin) to Ranbaxy affiliates
- Established new bases to cover innovative and generic businesses in Mexico and Thailand
- Signed Consent Decree with FDA. Committed to secure data integrity and comply with cGMP.

Challenge

Enhance profitability by creation of synergy

### 2nd 3-Year Plan: Quantitative Evaluation

Forex

EUR/yen

130

105.39



Yen bn

	FY2012 Target under the 2 <sup>nd</sup> MTP	FY2012 LE	Difference	Main Factors		
Net Sales	1,150	990	-160	Daiichi Sankyo	Olmesartan/Effient in US/EU	-31
					Others in US/EU	-15
					Japan Business, etc.	+12
					Forex impact	-43
				Ranbaxy	Impact from FDA issues	-52
					Forex impact	-31
COGs (/Net Sales)	343 (29.8%)	307 (31.0%)	-36 (1.2%)			
SG&A expenses (/Net Sales)	627 (54.5%)	583 (58.9%)	-44 (4.4%)	Forex impact -38		
R&D expenses (/Net Sales)	200 (17.4%)	188 (19.0%)	-12 (1.6%)			
Operating Income (/Net Sales)	180 (15.7%)	100 (10.1%)	-80 (-5.6%)			
USD/yen	90	81.26				



- 2. New 5-year Business Plan (FY2013 FY2017)
  - General Objectives
  - Core Strategies
  - Numerical Targets

## General Objectives



# Overcome Olmesartan LOE (loss of exclusivity) Set course for further growth

- 1. Achieve sustainable revenue growth and improve profitability
  - Over 5% revenue CAGR (FY2012 to FY2017)
  - Over 15% operating profit margin
  - 10% of ROE or over
  - EPS of 150 yen or over
  - Stable dividends and flexible shareholder return
  - 2. Transform into a Hybrid Business Powerhouse
    - Strengthen business in key markets (Japan, India, and USA) and emerging markets.
    - Flexible corporate structure to navigate through changing business environment

## **Core Strategies**



#### Enhance innovative product portfolio and R&D pipeline

- Maximize cash flows from Olmesartan
- Maximize sales potential for prasugrel and edoxaban
- Grow high potential products in Japan
- Enhance pipeline following launch of edoxaban
- Expand presence in biologics / biosimilar business
- Acquire external assets

#### Develop competitive businesses to address diverse local needs

- Expand business in emerging countries through Ranbaxy and the Daiichi Sankyo business in ASCA\*
- Maintain leadership in the US injectable iron market through launch of Injectafer
- Increase profitability of generic and vaccine businesses in Japan

#### Transition to a low-cost operating framework

- Establish organizational structure to address diverse needs in each region
- Establish global supply chain system for continuous cost reduction
- Strengthen revenue management at business unit and regional levels

<sup>\*</sup>ASCA: Internal business unit covering Asia and South, Central America

## Numerical Targets



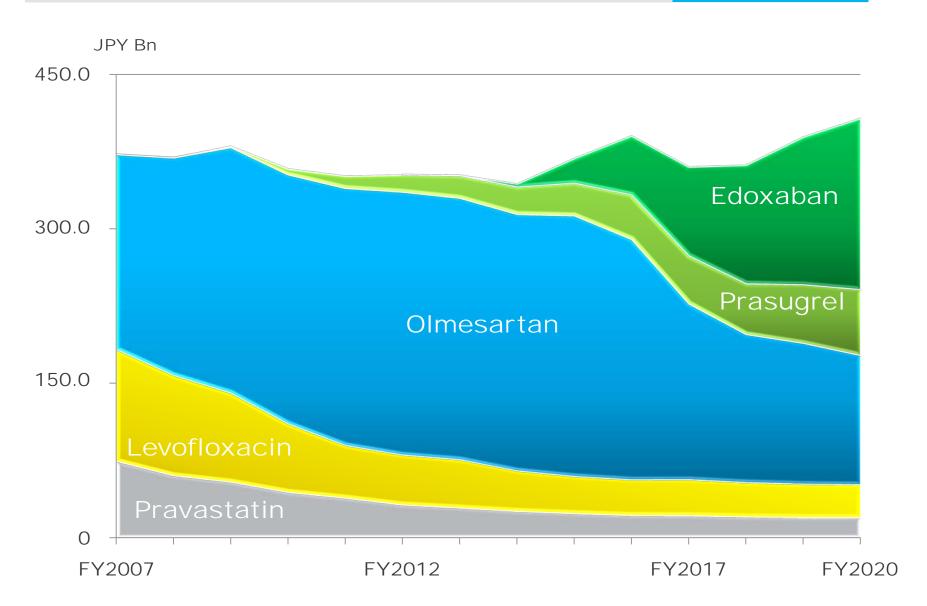
		FY2012 LE	FY2017 (Target)	
Net Sales		Yen 990 bn	Yen 1,300 bn	
COGs		31%	37%	
SG&A expenses (R&D expenses)		59% (19%)	48% (14%)	
Operating Income (/Net Sales)		Yen 100 bn (10%)	Yen 200 bn (15%)	
Profit after Tax		Yen 50 bn	Yen 110 bn	
Forex	USD/Yen		90	
	EUR/Yen		120	



## 3. Innovative Pharmaceuticals

## Sustainable Growth with Smooth Transition of Key Drivers





<sup>\*</sup>The above figures do not include partner sales

## Brand Strategy: Olmesartan



#### The best selling ARB brand globally

Japan

- "Best in class" product
  - Strong efficacy and long acting; protective effect on heart/kidneys
  - Wide range of dosing options

Global

- Lifecycle management in US/EU focusing on combination products
- Grow business in China with successful launch of Sevikar
- Enhance position in emerging markets

## Global Brand Strategy: Prasugrel



### Rapidly expand Japanese market sales Maximize global sales potential

#### Aim for standard antiplatelet therapy in Japan

- ACS-PCI\* (PRASFIT-ACS)
  - Prasugrel risk reduction 23%
  - No difference in bleeding tendency
- Elective-PCI (PRASFIT-Elective)
  - Achieved endpoints in efficacy and safety
  - NDA planned in the first half of FY2013
- Ischemic stroke (PRASTRO-I)
  - Phase 3 study comparing with clopidogrel ongoing
  - Study to be completed in FY2014

#### Global

Japan

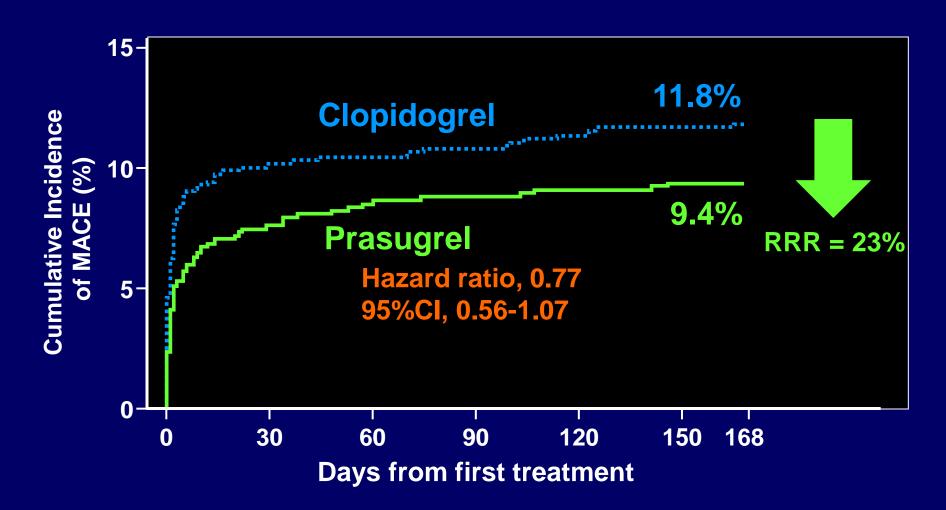
#### Focus on ACS-PCI patients with high risk of recurrence

- Obtained recommendation for "class 1b" in treatment guidelines of US (AHA/ACCF/SCAI) and EU (ESC)
- Approval in China (target: FY2013)

<sup>\*</sup> ACS: Acute Coronary Syndrome PCI: Percutaneous Coronary Intervention

# Primary Efficacy Endpoint (MACE at 24 weeks)



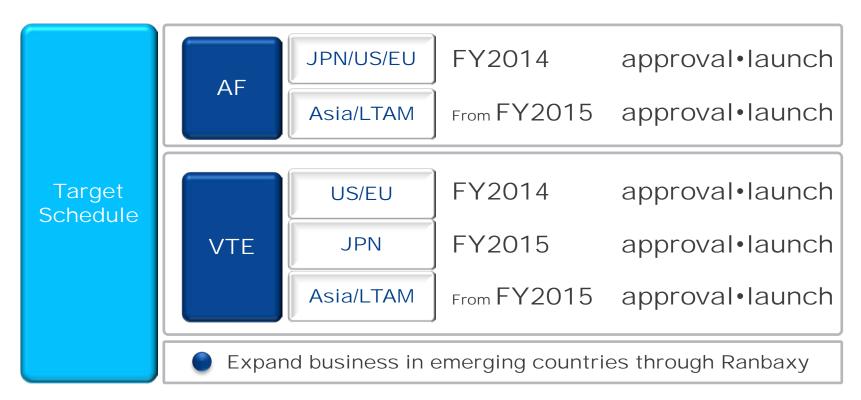


## Brand Strategy: Edoxaban



## Launch at earliest timing possible Promote as a key growth driver

Gain a competitive edge as a once daily FXa inhibitor with superior efficacy and safety profile



AF: Atrial Fibrillation

VTE: Venus Thrombo Embolism

## **R&D Strategy**



## Competitive pipelines, continuous and rapid generation of innovative pharmaceuticals

# Initiatives for innovation advancement

- Focus on first-in-class projects
- Explore venture model opportunities for development
  - Asubio, U3 Pharma, Plexxikon
  - Venture Science Laboratory (new)
- Open innovation: TaNeDS
- Enhance biologics R&D/manufacturing capabilities

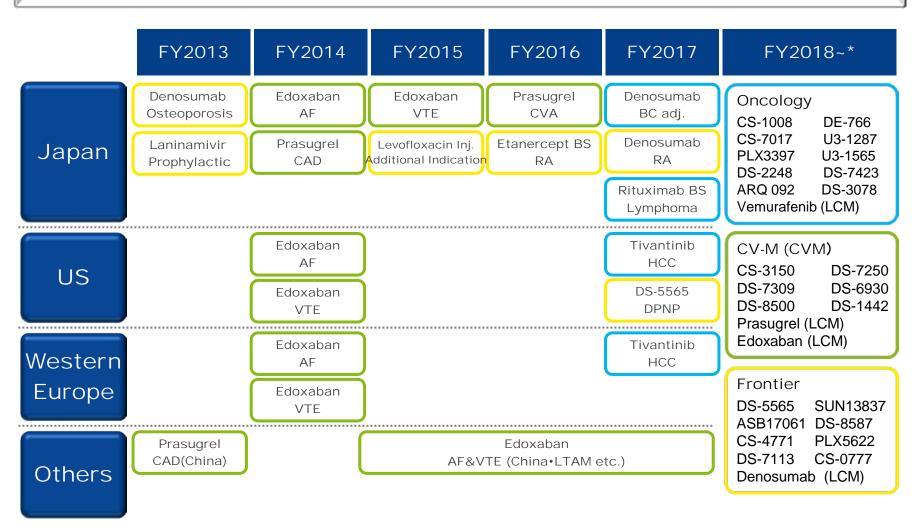
## R&D management with clear targets

- Achieve ≥ 2 new major indication launches for NME\*/BS\*\*/S-LCM\*\*\* per year\*
- Bring 4 major indications to late development stage for NME/BS/S-LCM per year
- Initiate 9 Phase 1 projects per year
- ☆ Achieve at NME\*/BS\*\*/S-LCM\*\*\*
  - \* NME: New medical entity including new biologics
  - \*\* BS: Biosimilars
  - \*\*\* S-LCM: Significant life-cycle-management project

### Pipelines: Target for Approval/Launch



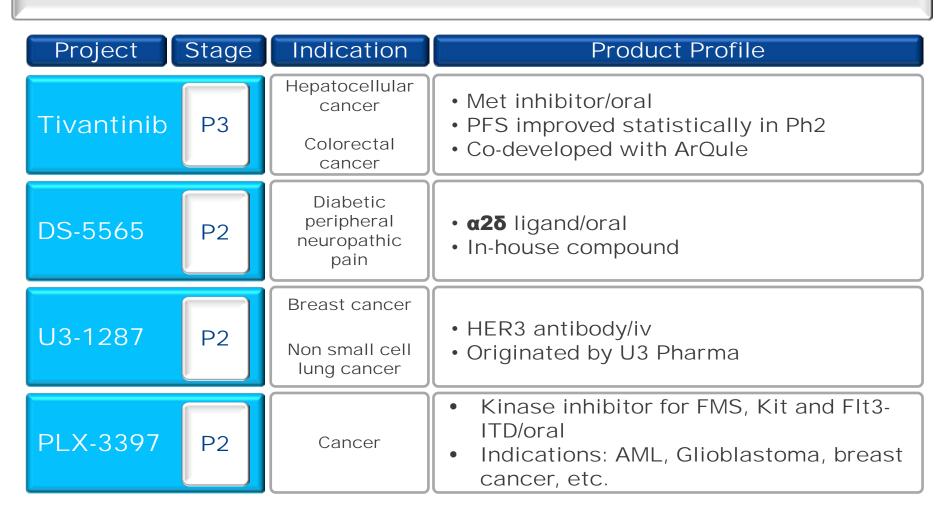
### Projects to be approved/launched



## Promising Projects Beyond FY2017



Invest in candidates to be growth drivers for the future





## 4. Ranbaxy

## Global Business Strategy



#### Sustainable growth with high quality and profitability

#### FRONT END

- Grow as a leading company in India
- Maximize FTF opportunities
   Expand Branded Derma business in US
- Global expansion of Branded Products
- Further expand reach in emerging markets

#### **BACK END**

- Implement Consent Decree by USFDA; resolution of AIP\*
- Establish organizational structure to support growth strategy

## The Hybrid Business



#### Evolution of the hybrid business model

#### **FRONT END**

- Expand Daiichi Sankyo innovative products in emerging markets through Ranbaxy network
- Expand Ranbaxy's products through Daiichi Sankyo's network
- Secure revenue/income from DS's innovative products post LOE (e.g. through AGs)

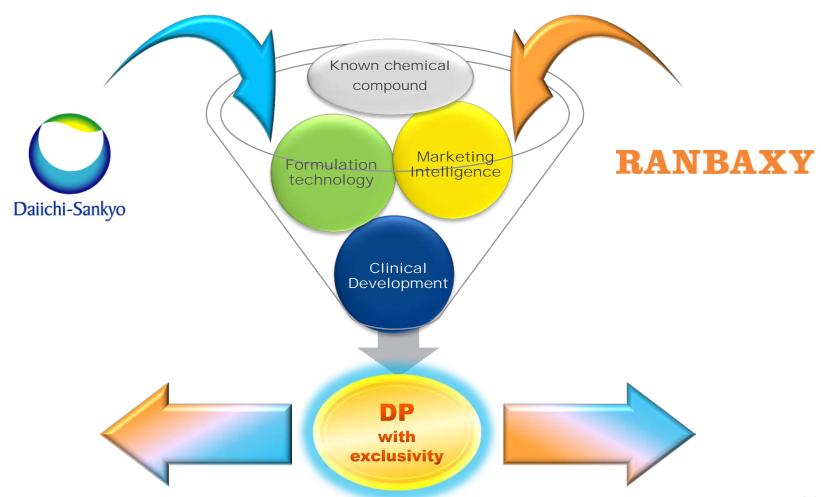
#### **BACK END**

- Cost Effective manufacturing for DS
- Quality control in collaboration with Dailchi Sankyo
- Develop value-added differentiated products

## Generate Differentiated Products (DP)



Generate and convey differentiated products by utilizing the technology and network of both companies





## 5. Regional Strategy

## Growth Strategy in Major Markets



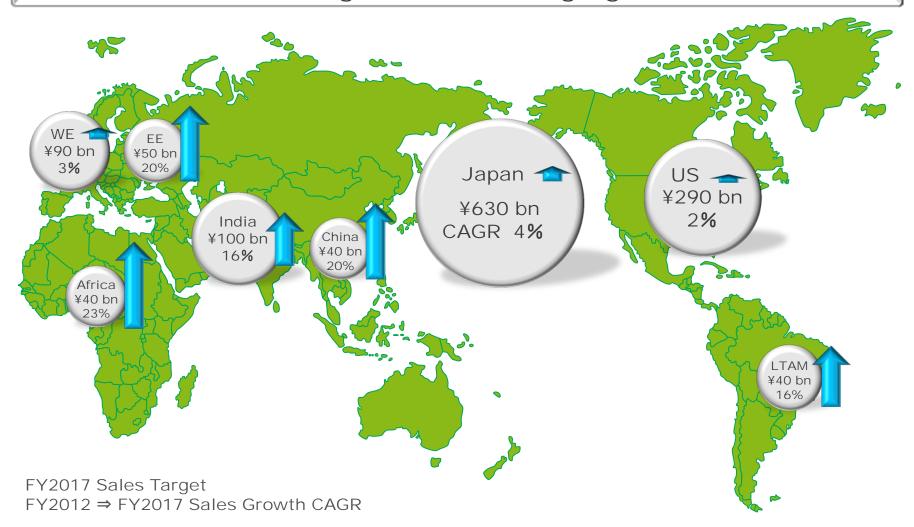
## Steady growth in developed markets Substantial sustainable growth in emerging markets



## FY2017 Regional Sales Target (image)



### Steady growth in developed markets Substantial growth in emerging markets



## Japan: Innovative Business Growth Strategy



### Key products for No.1 company in Japan

	Rey products for No. 1 company in supari						
			Strategy	Market Size (Yen bn) MAT 2013/2*			
1	Olmesaratan		Top sales in ARB market with strong efficacy and sustainability backed by Japanese data	590			
2	Memary	<b> </b>	Top share in mono/combination therapy with the unique MOA of NMDA antagonist	150			
3	Nexium		Top share as the best-in-class PPI product cooperating with AstraZeneca	220			
4	Prasugrel		Gain market share as a new standard therapy of anti- platelet for Japanese patients in heart/brain area	310**			
5	Lixiana		Standard therapy in DVT-OS, Best-in-class drug in AF and VTE	43			
	Ranmark/		Top share as the first anti-RANKL antibody in world cooperating with AstraZeneca	17			
	denosumab (osteoporosis)		Expand market share as a new therapy with good efficacy and practicality	200			
7	Tenelia/ canagliflozin	<b> </b>	Establish strong position in diabetes area cooperating with Mitsubishi Tanabe	320			

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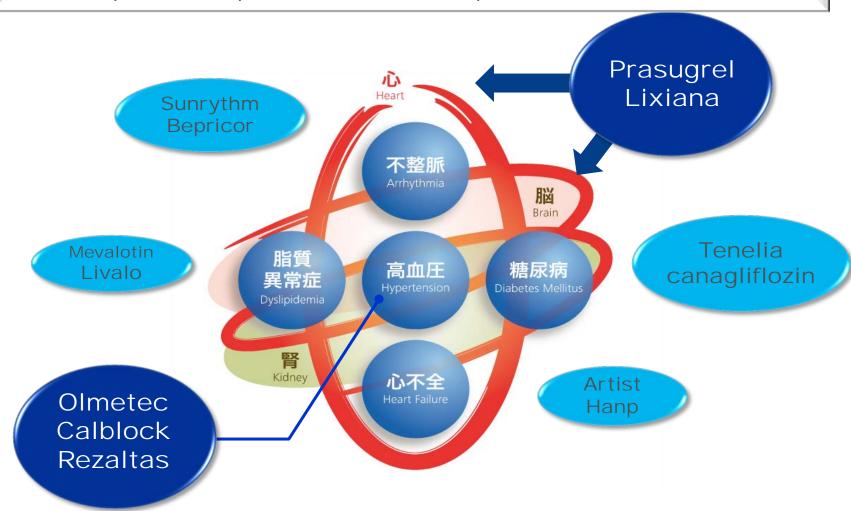
<sup>\*</sup> Moving average data

<sup>\*\*</sup>Total anti-thrombotic drug

#### Total Protection for Cardiovascular



Unmatched experience in the therapy area helps to maximize products potential for total protection in CVS



#### Generic, Vaccine, and OTC Business in Japan



#### Pursue sales growth with increased profit contribution

#### **Business Unit**

#### Strategy

#### Generic Business

- Expand the premium generics\* business
- Obtain top 3 market share for day-1 launch products
- Pursue low cost operations

#### Vaccine Business

- Establish Daiichi Sankyo as a leading vaccine company
- Enhance the manufacturing/CMC structures and improve manufacturing efficiency
- Join national plan for human influenza pandemic

#### **OTC Business**

- Increase sales and improve P&L structure
- Maximize the "Loxonin S" brand
- Expand skin care direct marketing business

<sup>\*</sup> Value added generic products to enhance safety and patient compliance through formulation and packaging technologies in addition to trust and confidence for the DS corporate brand

## Regional Strategy: US



## Three independent businesses to address diverse needs Growth through flexible operations

DSI

- Cover the LOE of Olmesartan and Welchol as much as possible with Edoxaban
- Maximize potential in Effient ACS-PCI business
- Inorganically enhance product offerings and development pipeline

Luitpold

- Maintain leadership in the injectable iron segment with Injectafer launch in FY2013
- Expand multisource business after commissioning new Pharma-Force manufacturing facility

Ranbaxy

- Successfully monetize FTFs and DS's authorized generics
- Expand branded business in dermatology

## Regional Strategy: India



## Maintain higher growth rate than Indian pharmaceutical market

#### RANBAXY

- Gain market share with strengthened MRs
- Maintain the market leader position in Anti-infectives
- Increased contribution from chronic therapies by enhancing product portfolio
- Strengthen and further expand the OTC business
- Develop and launch value added differentiated products (DP)
- Enter the biosimilars market
- Increase marketing competitiveness and improve profitability



# 6. Transition to a Low-cost Operating Framework

## Transition to a Low-cost Operating Framework



#### Theme

#### Mid-term Strategy

Establish organizational structure to address diverse needs in each region

- Optimize organizational structures in every region
- Streamline support functions
- Substantially reduce SG&A expenses (approx. 10% reduction)

Establish global supply chain system for continuous cost reduction

- Cost reduction in Olmesartan and edoxaban API through collaboration with Ranbaxy
- Establish global procurement platform to benefit from scale
- Reorganization of API manufacturing facilities in Japan
- Overall reduction Target: Over 30 bn yen (cumulative)

Strengthen revenue management

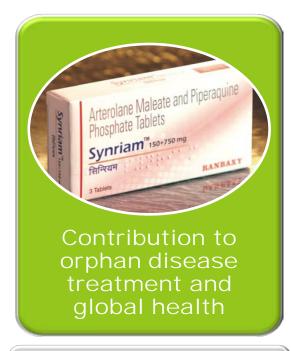
- Strengthen revenue management at businessunit/regional/product level
- Strengthen cash flow management



## 7. CSR



## Further enhance global CSR activity Contribute to healthier lives across the world





- Launch a novel Malaria drug, Synriam<sup>™</sup> in Africa
- Develop treatment for Duchenne Muscular Dystrophy



 Provide mobile medical services in rural areas of India, Cameroon and Tanzania



- Join The UN Global Compact
- Implement CSR activities according to Group Corporate Conduct Charter



## 8. Corporate Vision

## The Daiichi Sankyo Group 5 Years from Now



Succeeding in a Rapidly Changing Global Market

Global Pharma Innovator

Addressing Global Diverse Medical Needs

Accompanied With Sustainable Growth Capability

## Memo



## Memo



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