

**Astellas Pharma Inc.**  
**FY2010 Mid-term Management Plan**  
**- Continuous Growth, then Jump ! -**

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**Masafumi Nogimori**  
**President and CEO**  
**Astellas Pharma Inc.**



## **Cautionary statement regarding forward-looking information**

**Target figures in this material are not forecasts of business results. In addition, any description relating to the future in this material is subject to known or unknown risks and uncertainties, although it is based on management's current assumptions and beliefs in light of the information currently available to it. Please be cautioned that a number of important factors could cause actual results to differ significantly from the description in the material.**

**Such risks and uncertainties include adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.**

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# Main Message of New Mid-term Plan

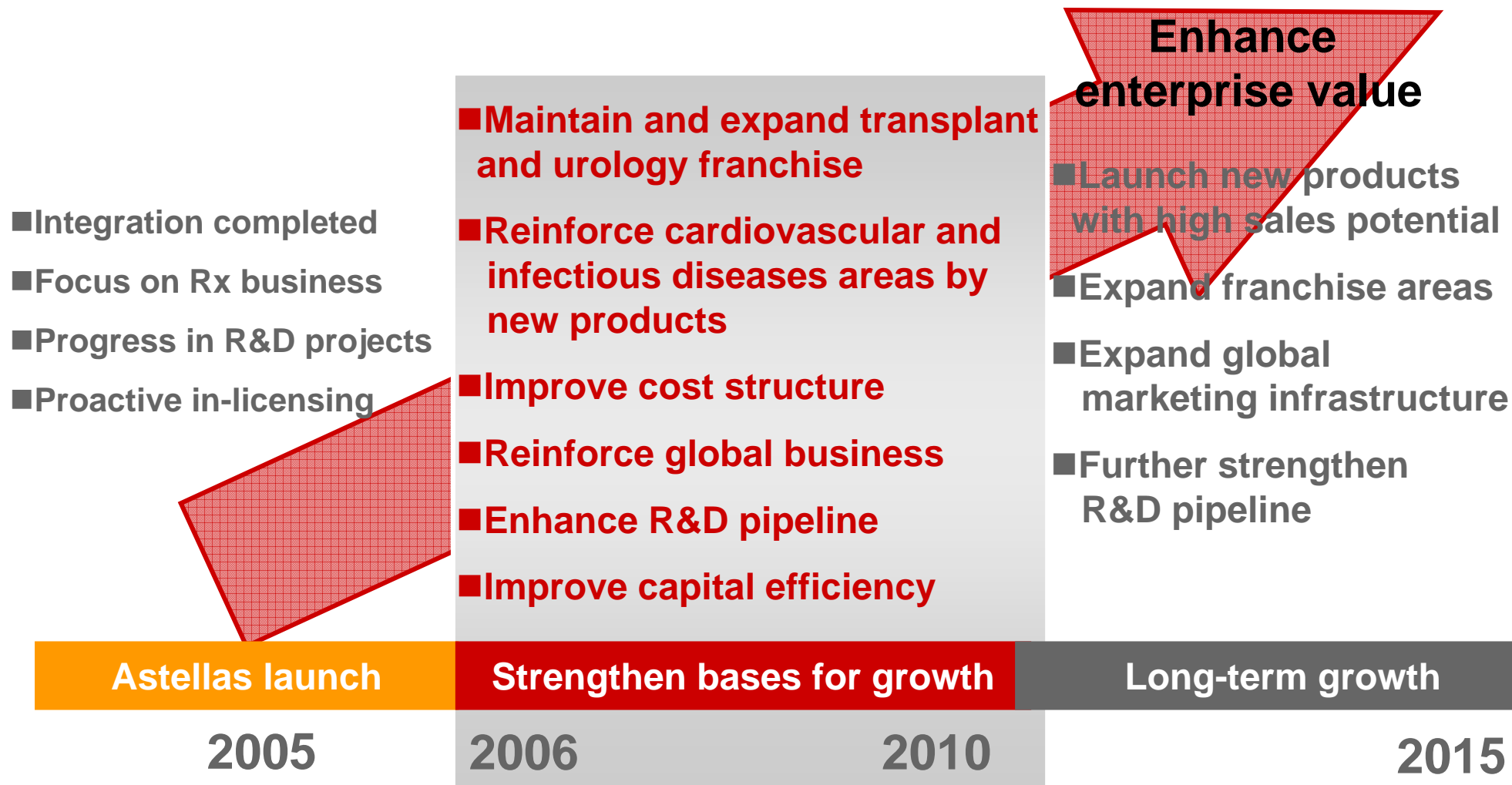
For mid- / long-term growth, we will

1. achieve a growth overcoming patent expiry of main products.
2. strengthen marketing infrastructure in Japan and aim for No.1 in the Japanese market.
3. improve cost structure and reinforce profitable bases for global business.
4. invest in R&D proactively and generate new products with high sales potential.
5. improve capital efficiency and achieve high ROE target.

**Strengthen bases for growth in order to  
meet stakeholders' expectations**

# Strengthen Bases for Growth by FY2010

**Mission: Sustainable enhancement of enterprise value**



# Overview of FY2010 Financial Targets



	FY2006 forecasts (announced on May 15)	FY2007 targets	FY2010 targets
Net sales	¥902 billion	¥960 billion	¥1,060 billion
Operating income	¥180 billion	¥250 billion	¥280 billion
R&D expenses	¥175 billion (incl. ¥40 billion in-licensing fees)	-	¥170 billion
EPS*	¥220	-	FY2006-FY2010 CAGR: mid-teens
ROE	10.7%	-	18%
DOE	3.7%	-	8%

\*Exclude the impact of extraordinary gains/losses  
Exchange rate:¥110/USD, ¥140/EUR

# Mid-term Action Plan

Issues	Action Plan
1. Continuous growth	<ul style="list-style-type: none"><li>■ Maintain transplant franchise</li><li>■ Expand urology franchise</li><li>■ Improve cost structure</li></ul>
2. Reinforcement of global business	<ul style="list-style-type: none"><li>■ Increase sales and profit in Japan, US, Europe and Asia</li></ul>
3. Improvement of capital efficiency	<ul style="list-style-type: none"><li>■ Invest in business for future growth</li><li>■ Optimize shareholders' equity by proactive return to shareholders</li></ul>
4. Enhancement of R&D pipeline (for mid- / long-term growth)	<ul style="list-style-type: none"><li>■ Accelerate clinical development of prioritized projects</li><li>■ Pursue alliance activities proactively</li><li>■ Reinforce drug discovery research in both quality and quantity</li></ul>

# 1. Continuous Growth

- Overcome patent expiry of Prograf and Harnal -



## Top-line growth

- Expand urology, infectious diseases and cardiovascular
- Maintain transplant franchise
- Launch new products

## Cost structure improvement

- Reduce manufacturing costs
- Optimize personnel
- Reduce procurement costs

## Human Resources Management

## Expand Urology, CV and Infectious Diseases / Maintain Transplant Franchise

Therapeutic area	FY2006	FY2010
Urology	¥150 billion	¥210 billion
Transplant	¥160 billion	¥170 billion
Cardiovascular	¥210 billion	¥270 billion
Infectious diseases	¥70 billion	¥100 billion

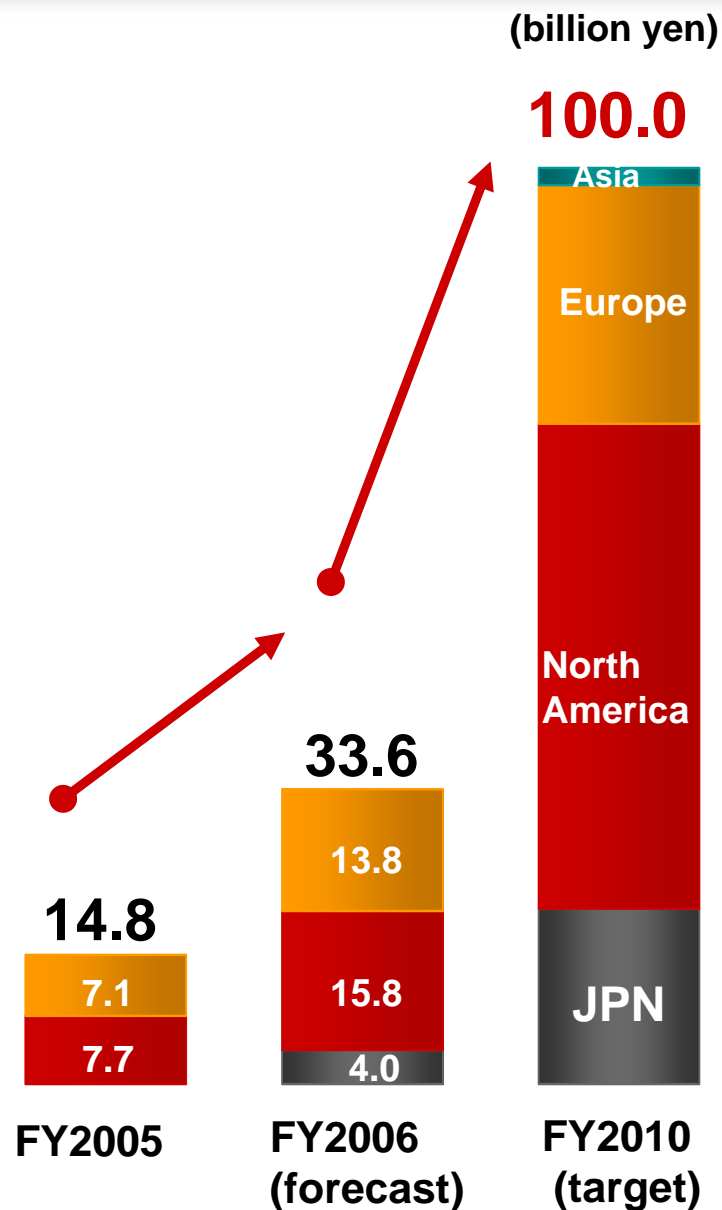
# FY2010 Sales Potential of Major Products



(billion yen)

Products	< 50	50 - 80	80 - 100	>100	>150
Vesicare				●	
Prograf					●
Harnal			●		
Funguard Mycamine	●				
Lipitor				●	
Gaster		●			
Micardis			●		

# Vesicare: FY2010 Target – ¥100 billion for Global Sales



## Growth driver

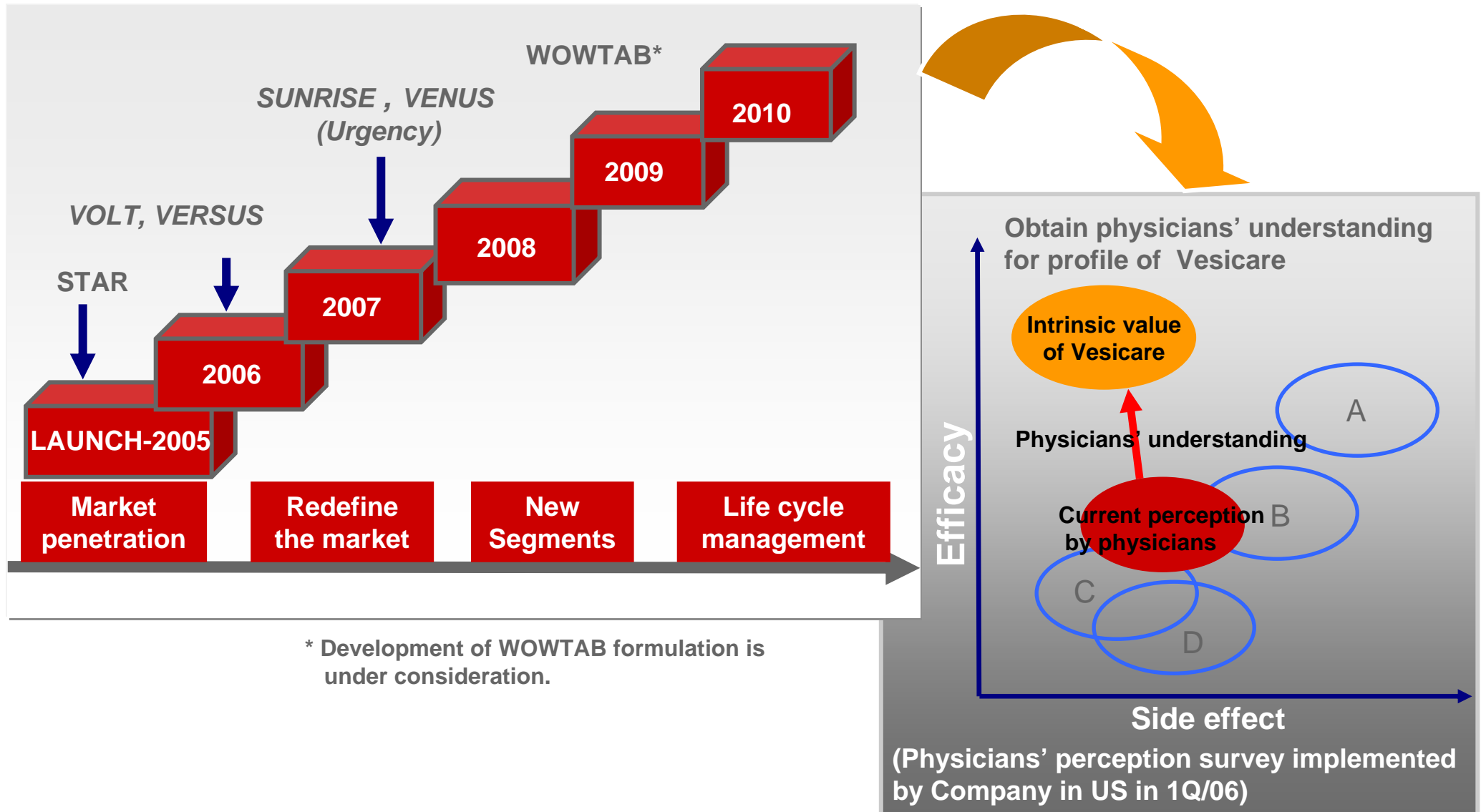
- Accumulate evidence:
  - Efficacy on incontinence and urgency
- Strengthen details to urology specialists
  - Synergy with Harnal and Eligard (in Europe)
- Co-promotion with GSK (US only)
- Induce potential patients to treatment:
  - Raise awareness through website and media
- Number of potential patients:
 

Japan:	8.1 million
US:	20 million
Europe:	25 million
- Launch in Asian countries

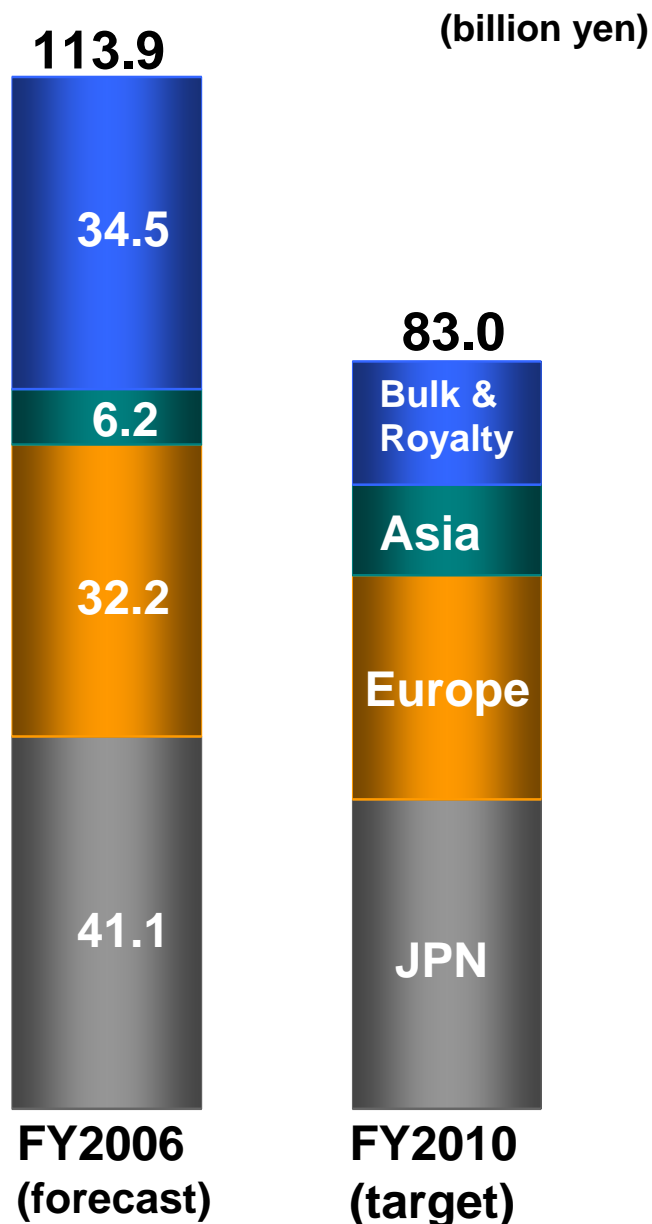
# Vesicare: Aim for the Leading Product in OAB Market



## Accumulate evidence strategically



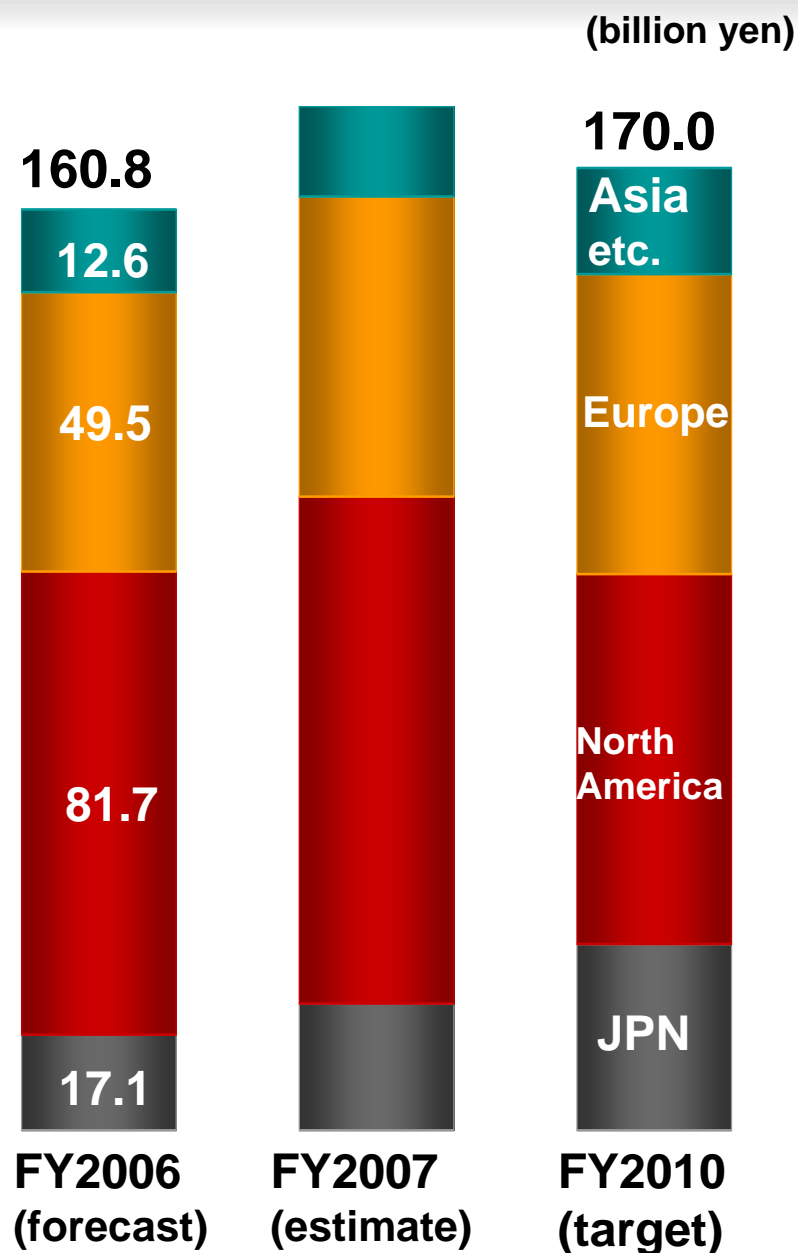
# Harnal: Sales Maximization during Product Life Cycle



## Issues in mid-term

- Japan: Maintain sales volume
  - Increase new prescriptions
  - Utilize evidence
  - Promote patient awareness
  - Strengthen relations with urologists
  - Two products detail with Vesicare
  - Additional indication for lower urinary tract syndrome
- Europe: Promote upgrade to TOCAS
- Asia: Increase sales significantly by orally disintegrating tablet and TOCAS
- Bulk & Royalty:
  - Maximize sales in US until patent expiry (October 2009)
  - =>Clinical trial for pediatric indication (market exclusivity to be extended for 6 months)

# Prograf: Maintain Transplant Franchise



## Issues in mid-term

- Cornerstone therapy in transplant area
- US / Major EU countries:  
Substance patent expiry in 2008 / 2009  
=> Maximize value of FK506MR globally
- Japan:  
Growth due to additional indications and increase of No. of transplants  
<additional indication>  
Rheumatoid arthritis, Lupus nephritis, Ulcerative colitis, Myasthenia gravis
- Growth in Asia (particularly in China)

# Prograf: Maximize FK506 modified release(FK506MR)



## Status

Filed in US, Europe and Japan  
(Approval in US: expected during FY2006)

## Patients

Primary: proactively promote use of FK506MR

Maintenance: promote a conversion from Prograf

## Accumulate evidence

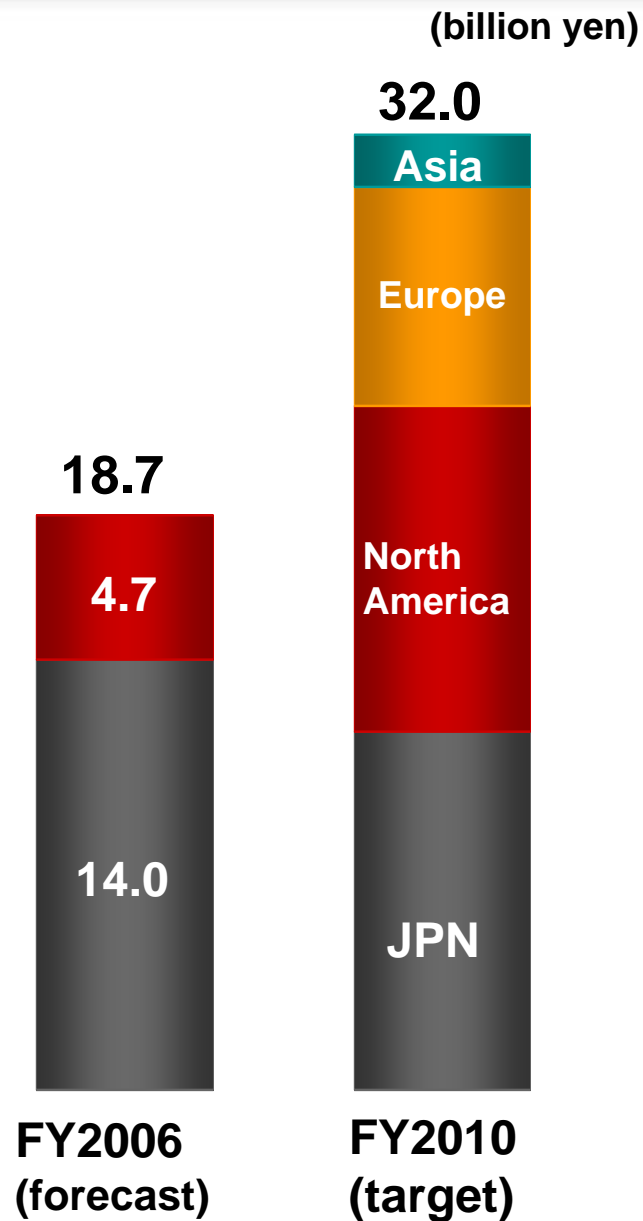
Phase-4 trials for accumulating evidence

To support usefulness of FK506MR

To differentiate FK506MR from Prograf

To differentiate FK506MR from cyclosporine

# Funguard / Mycamine



## Growth Driver

### ■ Japan:

- Maintain / Increase prescriptions
- Strengthen sales force for HP

### ■ US:

- Increase prescriptions under intensifying price competition
- Promote to be listed on formulary
- Co-promotion with Roche
- Additional indications

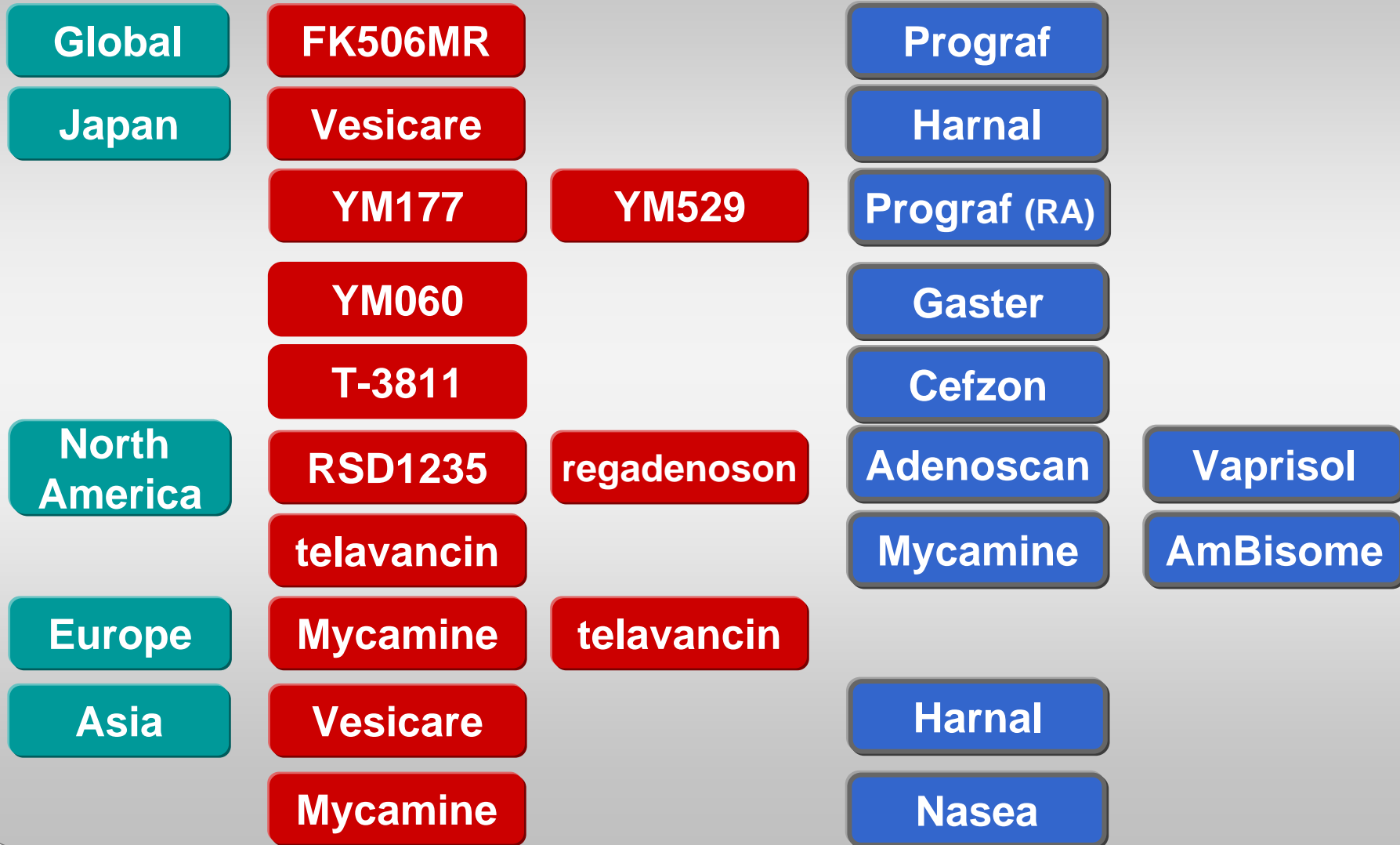
### ■ Europe: Launch in FY2007 (scheduled)

### ■ Synergy effects with detail for telavancin in US and Europe

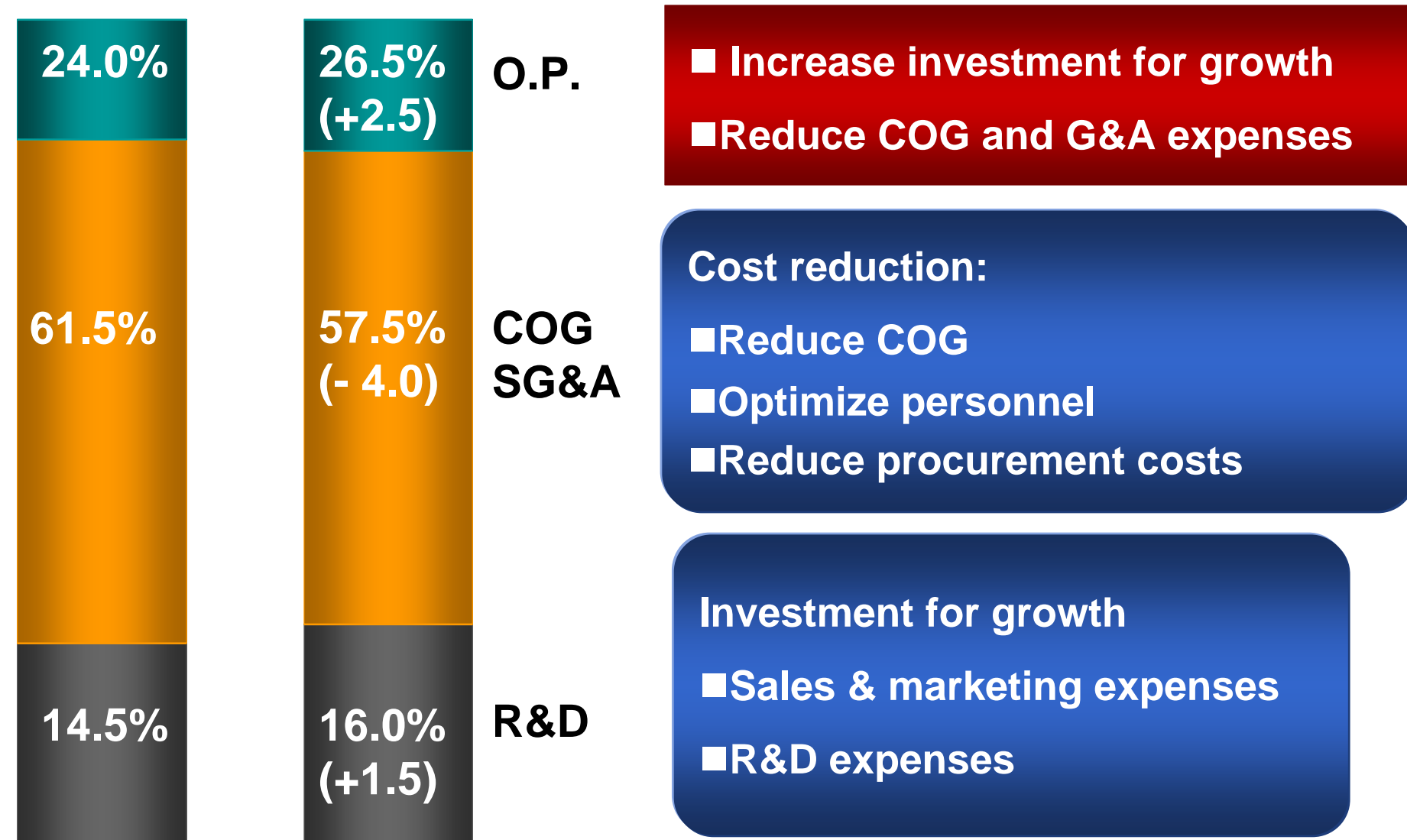
### ■ Launch in Asian countries

# New Products Launch Schedule during MTP

- Synergies between new products and main products -



# Improve Cost Structure: Investment for Growth



FY2006\*

FY2010

\*After adjustment of licensing fees for alliance with FibroGen

# Restructure Production Sites: Pursue Efficiency

## ■ Reduce manufacturing costs

=> Reduce procurement costs, Restructure production sites

## ■ Pursue efficiency by restructuring production sites / Promote outsourcing

	Japan	North America	Europe	Asia	Total
FY2006	9	2	6	1	18
FY2010	6	1	3	1	around 10

**Mid-term target**

# Human Resources Management to gain Competitive Advantage

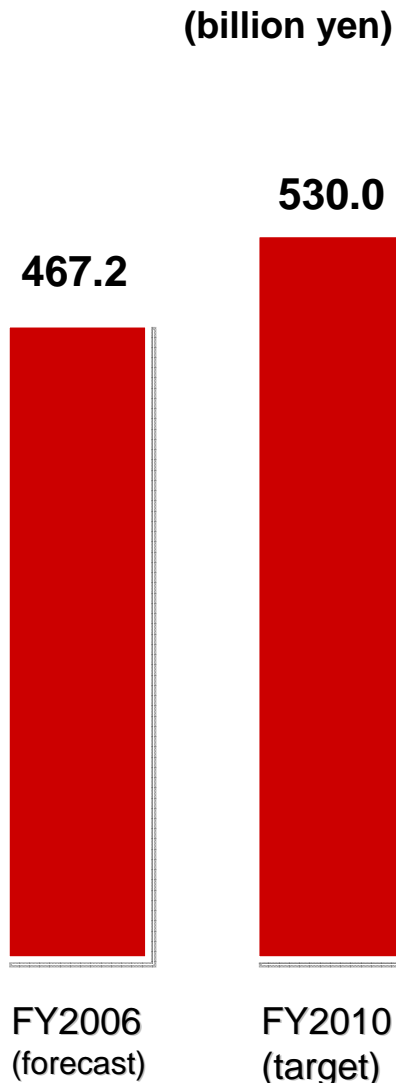
- Proactive investment in human resource to ensure competitive advantage
  - Appointment of right person for a right job
  - Performance based assessment
  - High-level support for skill development
- Achieve optimum organization through high-productivity organization structure and optimization of personnel

	April 2005	June 2006	March 2011
Rx business	14,700	14,593	13,500
Non-Rx business	800	61	0
Total	15,500	14,654	13,500

## 2. Reinforcement of Global Business



# Japan: Aim for No.1 by expanding six therapeutic areas



## Sales expansion areas

- **CV:** Lipitor: target market share 50%  
Micardis: target market share 20%
- **CNS:** Maintain No.1 in CNS area and expand sales further  
Strengthen promotion by CNS sales force  
Expand sales of Myslee, Seroquel and Luvox

## Core profit areas

- **Urology:**  
Sales increase by synergy between Harnal and Vesicare
- **GI:**  
Smooth penetration of YM060 utilizing marketing know-how established by Gaster
- **Transplant / Immunology:**  
Ensure position of leading company in transplant area
- **Infectious diseases:**  
Maintain and expand Funguard  
Successful launch and smooth penetration of T-3811

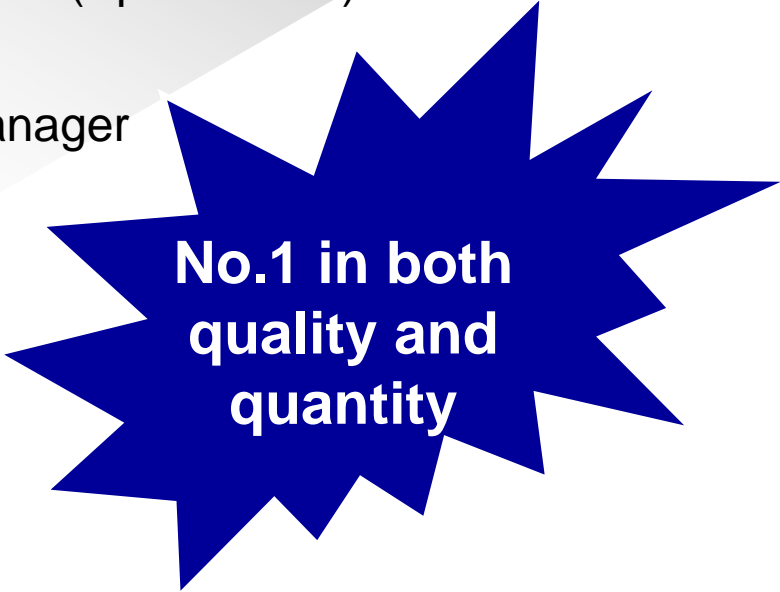
## Marketing

- Settlement of segment-based promotion system
  - => Ensure enough number of detail calls by 2,400 MRs
  - 2 line marketing system based on therapeutic areas (April 2006 ~)
- Response to customers with high specialty
  - => Promotion support by Prograf Manager/CNS Manager
  - => CNS MR

## Optimization of MR activities

- Quality
  - => SFE\* Management
  - => Renewal training system
- Efficiency
  - => Standardize management
  - => Focus on marketable segments

\*Sales force effectiveness

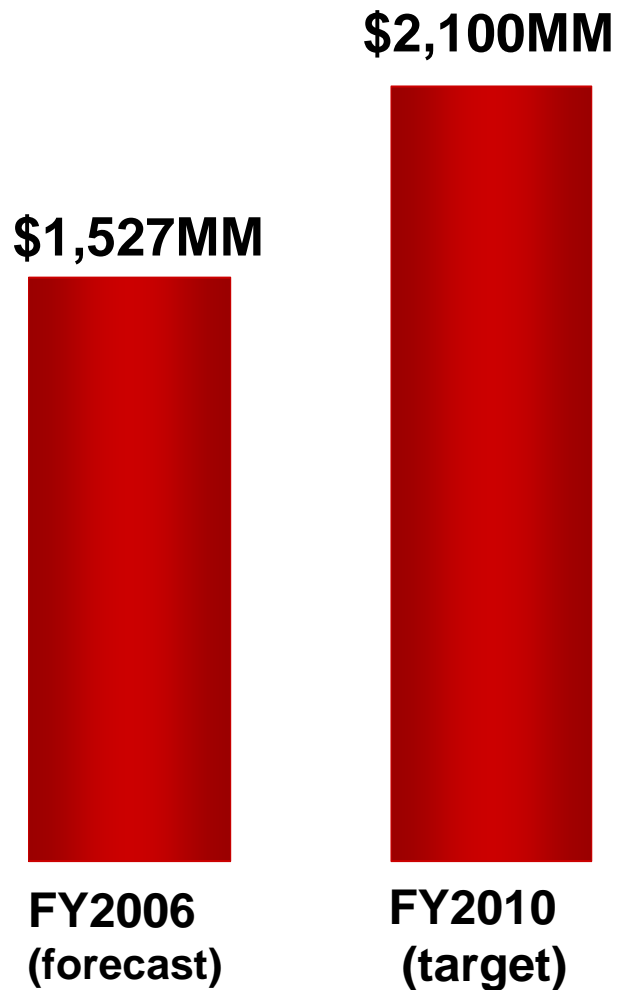


No.1 in both  
quality and  
quantity

## Support to MR activities

- Promotion support
- Area Marketing

# North America: High Growth by New Products



## Growth driver

- Enhance hospital market business / Contribution of urology business to profit\* -

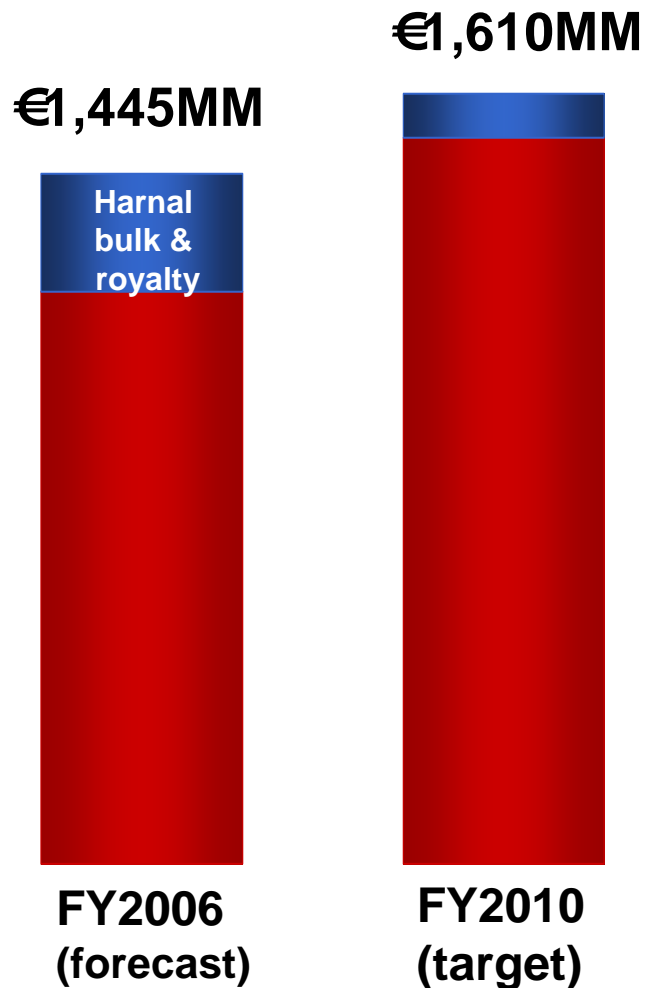
- Significant sales increase of VESIcare
- Maximize Prograf + FK506MR
- Contribution of New products in the hospital market  
Infectious diseases: Mycamine, telavancin  
Cardiovascular: Vaprisol, RSD1235, regadenoson

In Long-term

- Expand PCP marketing infrastructure along with new products launch by leveraging urology business

\* Profit earned in North America

# Europe: Stable Revenue and Profit Base



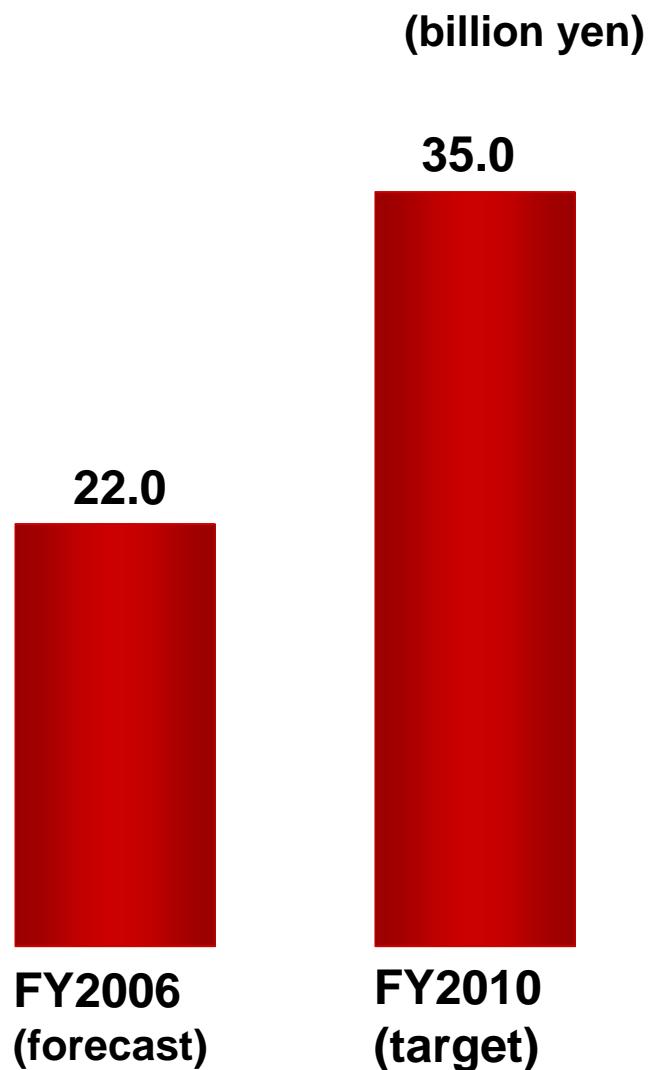
## Growth driver

- Driver: Vesicare and Eligard
- New products: Mycamine and telavancin
- Maximize Prograf + FK506MR
- Expand business in Russia  
=>offset decrease of Harnal
- Recoup investment in recently launched products
- Pursue efficiency by production sites restructuring
- Optimize personnel

In Long-term

- Launch YM311 (FG-2216) etc.

# Asia: High Growth in Expanding Markets



## Growth driver

- **Target:**  
Top10 in East Asia among foreign companies
- **Expand market share in all regions**
- **Growth driver: Prograf**  
Increase in both primary and maintenance market
- **Harnal: continuous growth**
- **Launch of Mycamine, Vesicare**

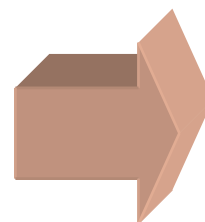
### **3. Improvement of Capital Efficiency**



# Improve Capital Efficiency / Increase Return to Shareholders

## Well-balanced capital policy

1. Investment in business for mid- / long-term growth
2. Proactive return to shareholders (DOE target: 8%)



## Improvement of capital efficiency

ROE  
18%

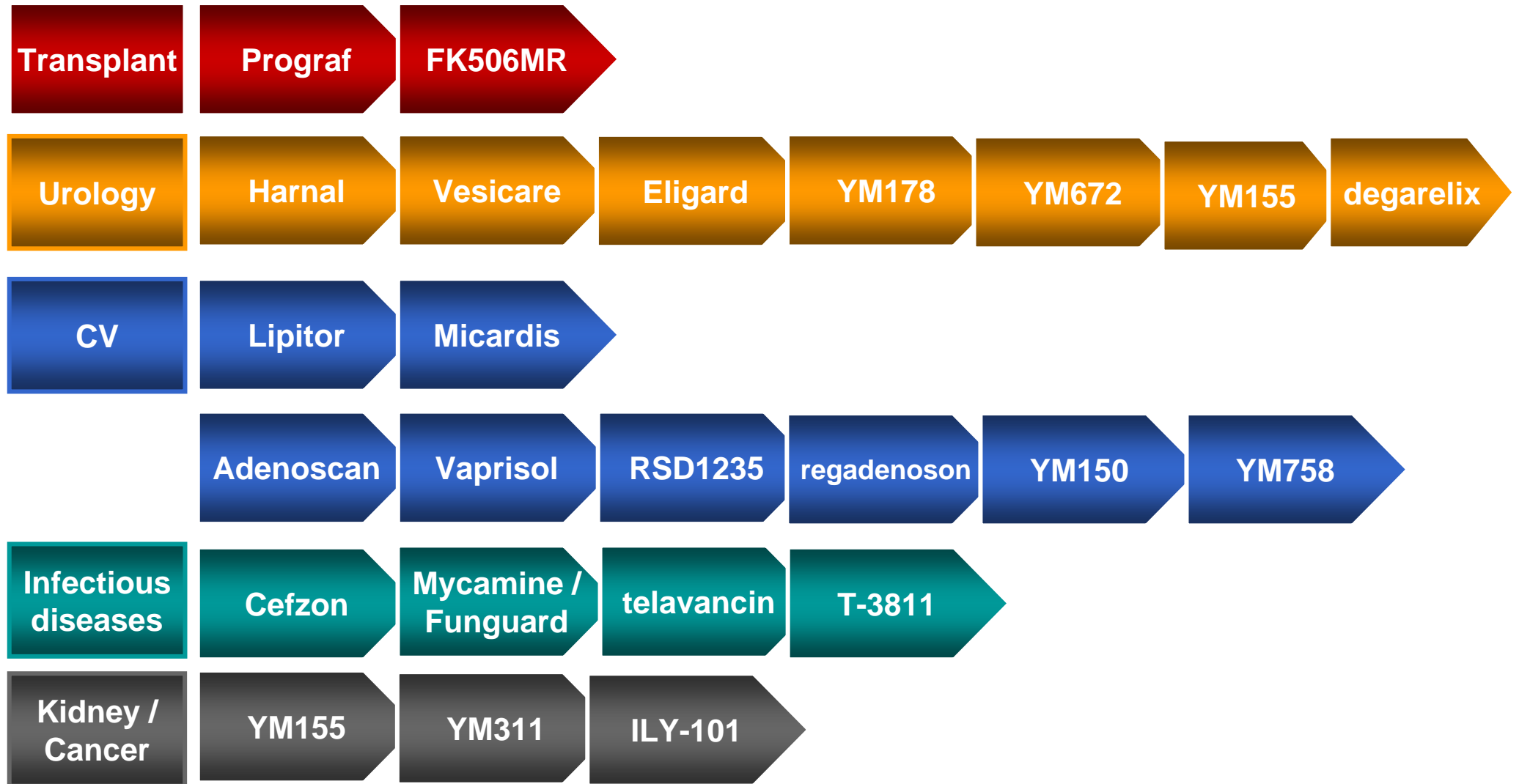
	FY2005	FY2006(plan)	Mid-term plan
ROE	8.8%	10.7%	18% by FY2010
DOE	3.3%	3.7%	8% by FY2010
Dividends	¥70/share ¥39.0 bil.	¥80/share ¥42.0 bil.	To be increased continuously
Share buyback	¥46.1 bil.	¥220.0 bil.*	To be implemented proactively and flexibly

\*Including 30 million shares at maximum, or 150 billion yen at maximum (planned to be implemented since October 06) 28

**4. Enhancement of R&D pipeline  
- for Mid-term to Long-term Growth -**



# Product Portfolio












# Expand Franchise Area

Therapeutic area	FY2006	FY2010	New products FY2011 - 2015
Urology	¥150 billion	¥210 billion	YM178 YM672 YM155 degarelix
Transplant	¥160 billion	¥170 billion	Several candidates at early stage
Cardiovascular	¥210 billion	¥270 billion	YM150 YM758
Infectious diseases	¥70 billion	¥100 billion	
Kidney / Cancer	-	-	YM155 YM311

# New Product Candidates for Long-term Growth

- Ensure the critical mass of R&D investment  
=> Maximize return by global development of in-house products
- Accelerate development by transatlantic study (YM150/YM155)
- Implement joint Japan and Asia trials (planned for YM150)

	Indication	Mechanism	Peak sales potential
YM060	diarrhea-predominant IBS	5-HT3 antagonist	
YM150	anti-thrombosis	Oral Factor Xa inhibitor	 
YM178	overactive bladder	$\beta$ 3 agonist	 
YM155	cancer	Survivin expression inhibitor	 
YM311 (FG-2216)	anemia	Oral EPO inducer	 

■ Peak sales potential

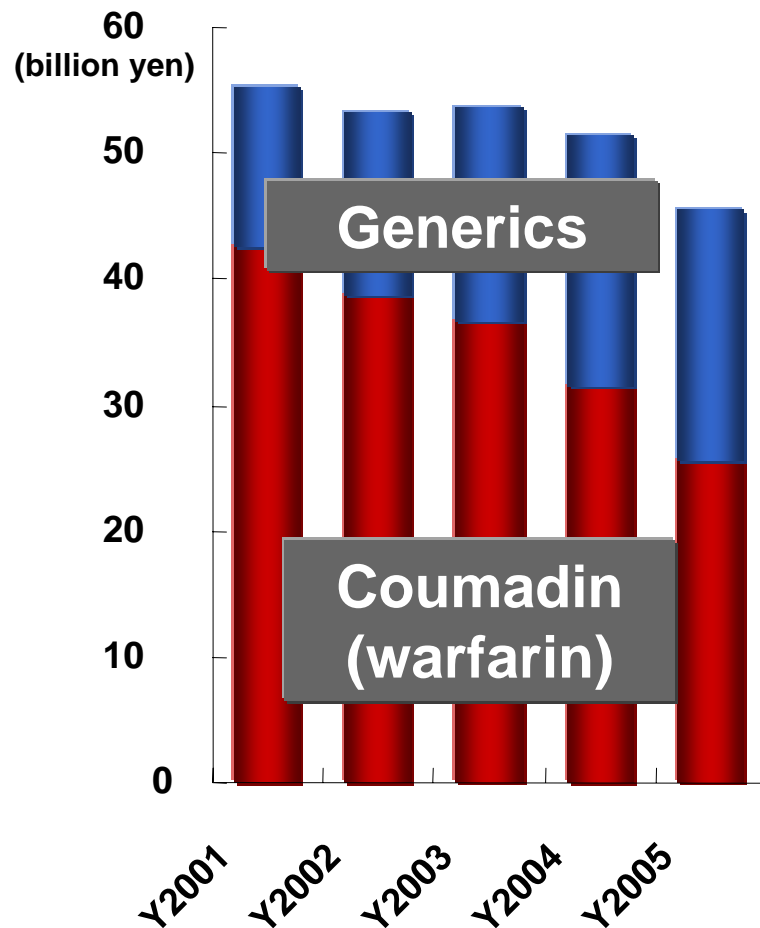
FLYING STAR:  around ¥100 billion

STAR:  around ¥50 billion

# YM150: Aim for Best-in-Class Anti-thrombosis

## Target profile:

Superior safety profile compared with other oral thrombin inhibitors or Factor Xa inhibitors under development



## High potential in US oral anti-thrombosis market

- Warfarin is the only drug approved
- Sales of generic warfarin increasing
- Number of total prescriptions steadily increasing
- Number of patients:  
VTE\* 1.5 million, AF\*\* 3.7 million

Unmet medical needs for oral drugs with low bleeding risk

\*VTE: venous thromboembolism

\*\*AF: Atrial Fibrillation

# YM155: Steppingstone to Cancer Field

- **Survivin expression inhibitor (first in class)**

- **Status: P-II**

Hormone refractory prostate cancer (HRPC)

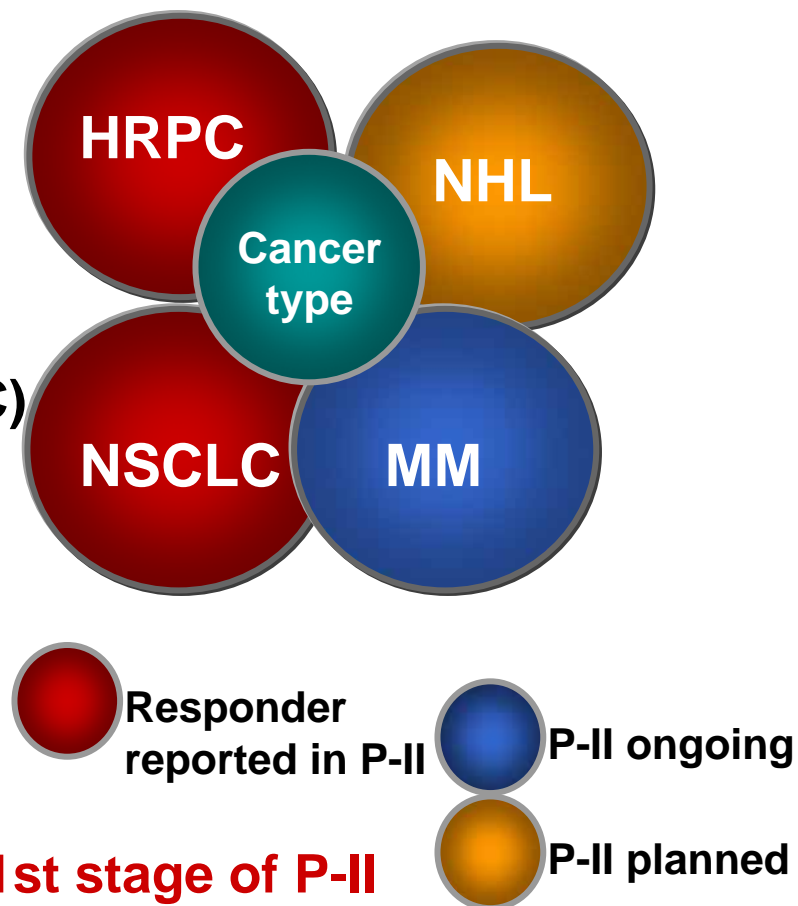
Non small cell lung cancer (NSCLC)

Metastatic melanoma (MM)

- **Progress in development:**

**Responders for HRPC/NSCLC reported at 1st stage of P-II  
Enrollment at 2nd stage initiated**

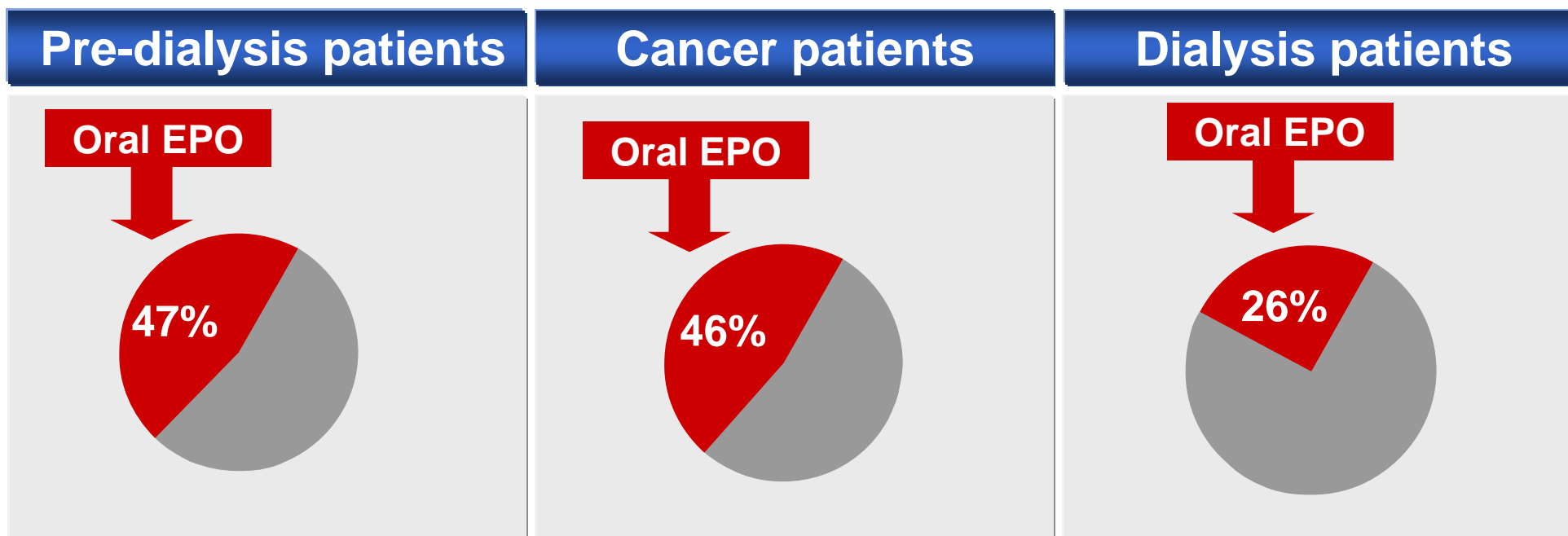
- **P-II plan for another indication:  
Non-Hodgkin's lymphoma (NHL)**



# YM311: High Expectation of Physicians for Oral EPO Inducers

“Oral EPO will be a dominant player in the future EPO market, and is expected to expand the entire EPO market.”

## Q: Future Use & Impact on Total EPO Usage



(Source: in-house report; Survey in March 2005 targeting oncologists and nephrologists who have significant current EPO prescribing in US, UK, Germany and France (N=109))

# Alliance Strategy: Further Enhancement of Product Portfolio

## Alliance concluded since April 2005

Product	Indications	Area
telavancin	cSSSI / HAP	WW*
T-3811	respiratory infections etc.	JPN
XP13512	neuropathic pain	JPN
degarelix	prostate cancer	JPN
anti-human osteopontin antibodies	rheumatoid arthritis	WW*
Amevive	psoriasis	WW*
FG-2216 FG-4592	anemia (oral EPO inducer)	JPN Europe
ILY-101	hyperphosphatemia	JPN



- Further strengthen alliance activities in this mid-term
- ✓ Enhance R&D pipeline
  - => transplant, infectious diseases and cancer etc.
  - ◆ Utilization of marketing infrastructure
  - ◆ Synergies in therapeutic area

\*WW: Worldwide

## Improve efficiency by reorganizing laboratories

- Tsukuba  
(exploratory / optimization research)
- Osaka  
(exploratory / optimization / development research)
- Tokyo (development research)
- US (immunology / urology)
- UK(CNS)
- Netherlands  
(development research)



- Tsukuba  
(exploratory / optimization research)  
\*New facility is planned.
- Osaka (development research)
- US (immunology / urology)
- Netherlands (development research)

# Drug Discovery Research: Focus on Prioritized Therapeutic Areas / Diseases

## Set up new target therapeutic area

- Unmet medical needs
  - Satisfaction level of conventional treatments
  - Treatment trend in future
- Marketability
- Research capability

## Establish new core technology

- Synthesis  
(Low molecule compounds)
- Fermentation
- Genome

+

- Antibody drugs  
=> Strengthen by alliance

## Prioritized therapeutic areas / diseases

- Urology, Immunology and Inflammatory, Diabetes, CNS/ Pain, Infectious diseases (virus), Cancer

## Beyond 2010

**Achieve No.1  
in Japanese  
market**

**Launch new products  
Strengthen global  
marketing infrastructure**

**Generate new products  
from drug discovery  
research**

**Global leadership in several diseases / therapeutic categories**

**Astellas will strive to gain the trust of stakeholders  
and thereby enhance its enterprise value.**