

Press Conference

Astellas' Growth Strategy

November 29, 2010

Masafumi Nogimori, President & CEO

Astellas Pharma Inc.

Cautionary Statement Regarding Forward-Looking Information

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors including 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.

This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kind.

Roadmap of 2009

2008

2009

GCL

Major Milestones in 2009

- ★ Acquisition of Agensys (December, 2007)
 - ★ Complete new buildings at Tsukuba research center
 - ★ Concentrate drug discovery research function in Tsukuba
 - ★ Start operation of Beamline
 - ★ Groundbreaking for Fermentation Technology Research Building (Toyama)
 - ★ Global Development Organizational Changes
 - ★ Joint Venture with Maxygen
 - ★ Reorganization of fermentation research functions
 - ★ Creation of the Bioimaging Research Labs.
 - ★ Transfer of Fermentation and Biotechnology Labs.
 - ★ In-licensing MDV3100
 - ★ In-licensing AC220
 - ★ In-licensing Linaclotide
-
- ★ Bonoteo new launch in Japan
 - ★ Micombi new launch in Japan
 - ★ Establishment of Brazilian Affiliate
 - ★ In-licensing febuxostat (Taiwan)
 - ★ In-licensing Qutenza (EU and others)
 - ★ Agreement of Symbicort Co-pro (Japan)
 - ★ Agreement of Caduet Co-pro (Japan)
 - ★ In-licensing Sumavel™ DosePro™ (US)
 - ★ VIBATIV new launch in US

Improve ability to generate products

Strengthen Business Infrastructure

Roadmap of 2010

2009

2010

GCL

Major Milestones in 2009

Improve ability
to generate
products

★ Extending License
Agreement with Regeneron

★ In-licensing AKP002

★ In-licensing UMN Pharma's
Vaccines (Japan)

★ Acquisition of OSI

★ In-licensing Diannexin

Strengthen
Business
Infrastructure

★ In-licensing febuxostat(China/ Hong Kong)

★ Consolidating
Manufacturing Affiliates

★ Extending Micardis Family Agreement (Japan)

★ Symbicort New Launch in Japan

★ Initiating Sales Activities in Brazilian Affiliate

★ Initiating Sales Activities in Indian Affiliate

Today's Agenda :Astellas' Growth Strategy

Overcome decrease in sales and earnings from U.S. patent expiry of Prograf and Harnal and accelerate growth

Growth Strategy

**1. Efforts in
Discovery Research**

2. Efforts in Development

3. Efforts in Technology

4. Efforts in Sales & Marketing

5. Efforts in Oncology Field

**6. Efforts in
Society & Employee**

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Efforts in Discovery Research -1 : Actively Approach to Precision Medicine Drug Discovery

Astellas aims to establish a leading position in Precision Medicine by leveraging translational science and biomarker research

Past

Mass Medicine

“One-size fits all” prescription

Future

Precision Medicine

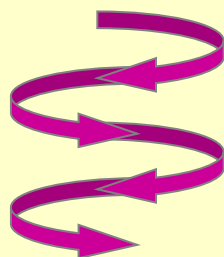
Highly effective drugs for defined patients

- **Precision Medicine:**
 - Offering highly effective therapeutic options for precisely defined patient populations based on molecular targeting and precise diagnosis
 - ▶ Higher efficacy and fewer side effects
 - ▶ Smaller-scale clinical trials targeting specific population of patients
 - ▶ Pharmacoeconomical advantages by prescribing for responders only

Efforts in Discovery Research -2 :Stimulate Collaboration between Industry and Academia

Drug discovery and medicine fusion research base aiming at next-generation immunosuppressants

Kyoto Univ.
World Class Basic Immunology
Research Platform



Astellas
Cutting-edge Drug Discovery
Technology
Prograf Development Expertise

Creating Innovative Immunosuppressants

(Overcome Immunological Intractable Diseases,
Establish Safe Transplant Medical Treatment)

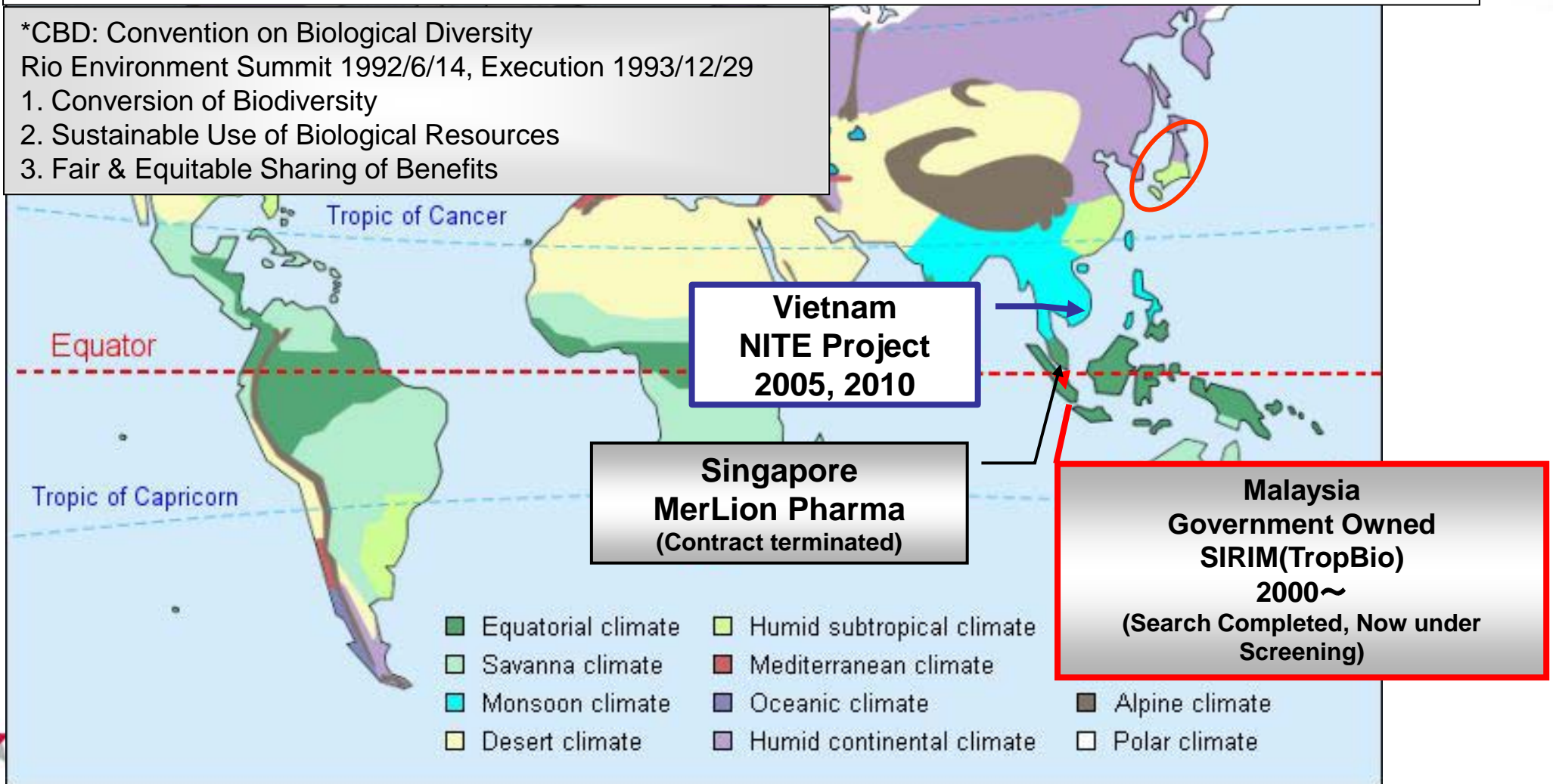
- ◆ Creating innovation at drug discovery system, as well as fostering drug discovery and medical researchers perfect for fundamental medical research, drug discover, and intellectual properties
- ◆ Discovering new drug targets (at least, 25 by end of 7th year, March 2014)
- ◆ Ultimately, aiming to propose at least 3 compounds or new medical technologies in each field of allergy, autoimmune diseases, and cancer



Efforts in Discovery Research -3: Access to Genetic Resources Overseas

Searching for Microorganisms Not Living in Japan in Temperate Zone,
through Outside Research Collaborations in Tropical Zone
Complying with CBD*, Making Condition of Win-Win Relationship

*CBD: Convention on Biological Diversity
Rio Environment Summit 1992/6/14, Execution 1993/12/29
1. Conservation of Biodiversity
2. Sustainable Use of Biological Resources
3. Fair & Equitable Sharing of Benefits



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Efforts in Development -1 :Robust Pipeline

	Filed	P3	P2	P1
Urology	YM178 (OAB, JP)	YM178 (OAB, EU/USA) solifenacin/tamuslosin (EU)	YM905 (Pediatric, EU/USA)	ASP3652, ASP7035 ASP0306, AKP-002
Transplant Immunology Inflammation		YM177 (Acute pain, JP)	ASP0485 (Transplant, EU/USA) ASP9831 (Hepatitis, EU) ASP015K (Transplant, USA) ASKP1240 (Transplant, USA) Diannexin (DGF, USA)	ASKP1240 (JP) ASP015K (JP) ASP3291 ASP4058
Anti- Infective	telavancin (NP, USA) telavancin (cSSTI/NP, EU)	isavuconazole (Aspergillosis, candidemia, EU/USA)	ASP2151* (USA/JP)	telavancin (JP)
Dibabetes Cardiology Renal	YM150 (VTE, JP) RSD1235 (AF, USA)	ASP1941 (DM, JP) ASP1585 (Hyperliposphatemia, JP) YM533 (Chronic renal failure, JP/Asia)	YM150 (VTE:EU/USA, AF:EU/JP/Asia, ACS:EU) ASP1941 (EU/US) YM311 (USA), ASP1517 (USA)# PSN821 (Diabetes, obesity, USA)	YM311 (JP)# ASP1517 (JP) # ASP4178 ASP5034
CNS	ASP8825 (Restless legs syndrome, JP)			ASP0777 FK949E
Oncology	ASP3550 (1M, JP)	MDV3100 (EU/USA) elrotinib (USA) OSI-906 (Adrenocortical, USA)	OSI-906 (Ovarian, USA) OSI-027(USA) YM155 (EU/USA) AC220 (EU/USA) AGS-1C4D4 (EU/USA) ASP6183* (AGS-8M4) (USA) ASP3550 (3M, JP)	MDV3100 (JP) AGS-16M18 AGS-16M8F ASG-5ME YM155 (JP) ASP1707
Others	YM529 (1M, JP) YM443 (FD, JP)		YM060 (IBS, EU) YM060 (IBS Female, JP)	ASP0456

: In-house global
 : Local, licensed-in, new Indication, or new formulation

Efforts in Development -2: Numerous NDAs & Approvals

Approval	Vesicare OD (Japan: Oct. 2010) Overactive bladder	
	Micamlo Combination Tab. (Japan: Jul. 2010) Hypertension	
NDA	Mirabegron (Japan: Jun. 2010) Overactive bladder	
	YM443 (Japan: Sep. 2010) Functional dyspepsia	
	YM529 (Japan: Sep. 2010) Osteoporosis (Intermittent administration)	
	Darexaban (Japan: Sep. 2010) Prevention of VTE after major orthopedic surgery	
	Degarelix (Japan: Oct. 2010) Prostate cancer	
	Telavancin (EU: Oct. 2009)	*cSSTI caused by gram-positive microorganisms
	Telavancin (US: Jan. 2009)	Nosocomial Pneumonia
	Telavancin (EU: Oct. 2009)	Nosocomial Pneumonia
ASP8825 (Japan: Nov. 2009)	Restless leg syndrome	

Efforts in Development -3: New Challenge: Vaccine Development

- ▶ Astellas and UMN Pharma entered into the license agreement for UMN-0501 and UMN-0502 to co-develop and exclusively commercialize in Japan
(Memorandum of understandings: August 2010, license agreement: September 2010)

■ UMN-0501:

- A cell culture based H5N1 avian influenza vaccine manufactured through BEVS*
- Under preparation for P3 clinical trial in Japan

■ UMN-0502:

- A cell culture based seasonal influenza vaccine , containing three different antigens, manufactured through BEVS*
- Under preparation for P1/2 clinical trial in Japan.

*BEVS (Baculovirus Expression Vector System):

BEVS is a technology enabling to manufacture a recombinant protein in a large scale by integrating target gene information to baculovirus vector and transmitting the vector to insect cells.

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Efforts in Technology: Strengthening Technology Development

■ Construction of Fermentation Technology Research Building (Toyama Plant of Astellas Toyama)

To ensure stable global supply of active pharmaceutical ingredients for *CTM in the development of candidate compounds obtained through fermentation based drug discovery

✓ To be constructed in the Toyama Plant

✓ Construction started in Sep,2009

Completed in Oct,2010

Plan to start operation in Apr, 2011

✓ Total construction cost:

About 6.1 billion yen



Fermentation technology research building in Toyama

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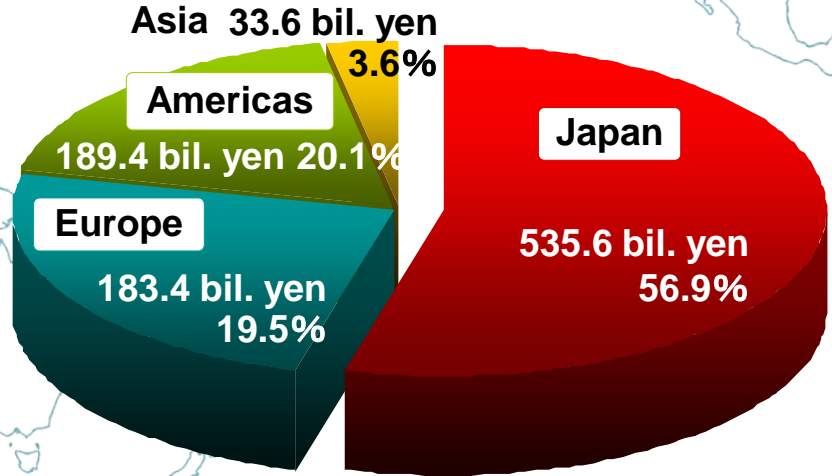
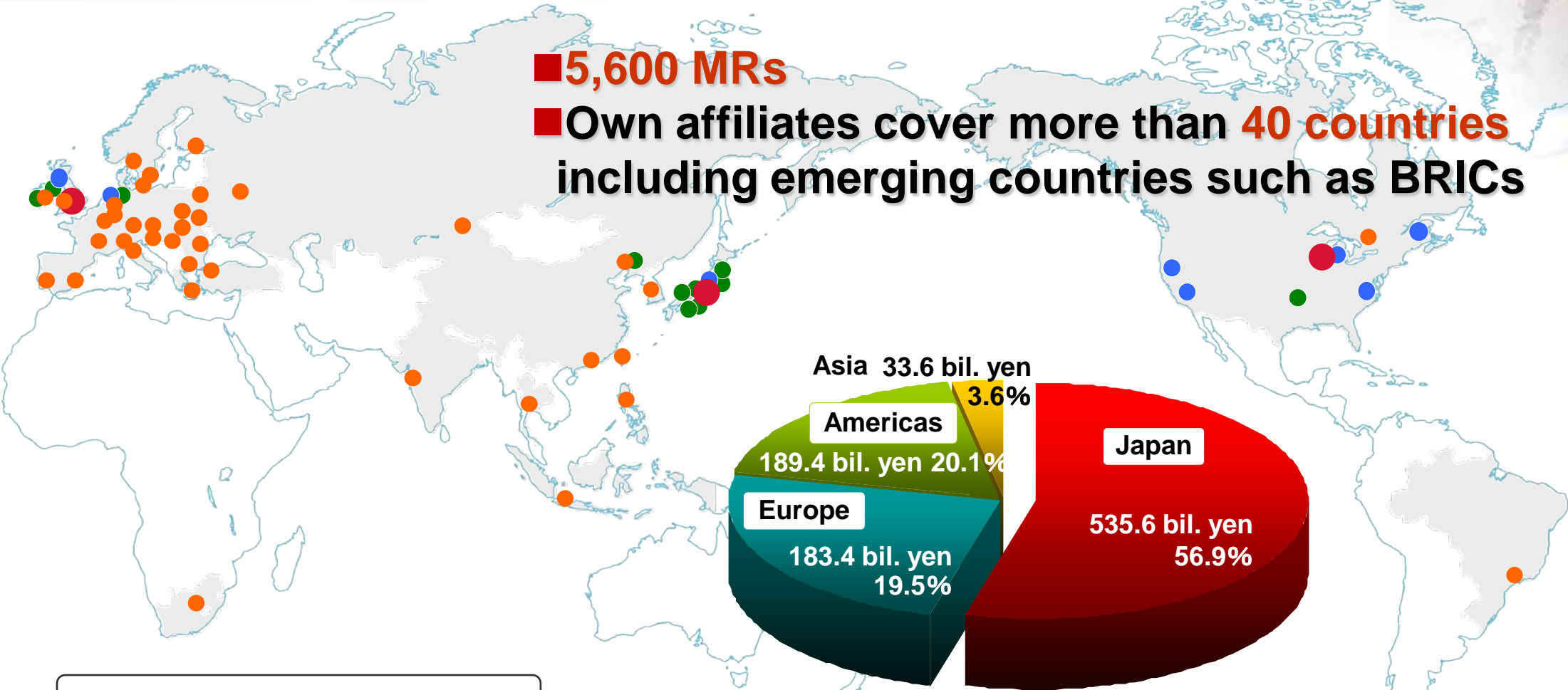
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Efforts in Sales & Marketing - 1: Well-Balanced Business Expansion in 4 Regions

■ **5,600 MRs**
 ■ **Own affiliates cover more than 40 countries including emerging countries such as BRICs**



- Group HQ/Regional HQ
- Sales Affiliate , Promotion Base (Europe)
- R&D Site, etc.
- Production Site

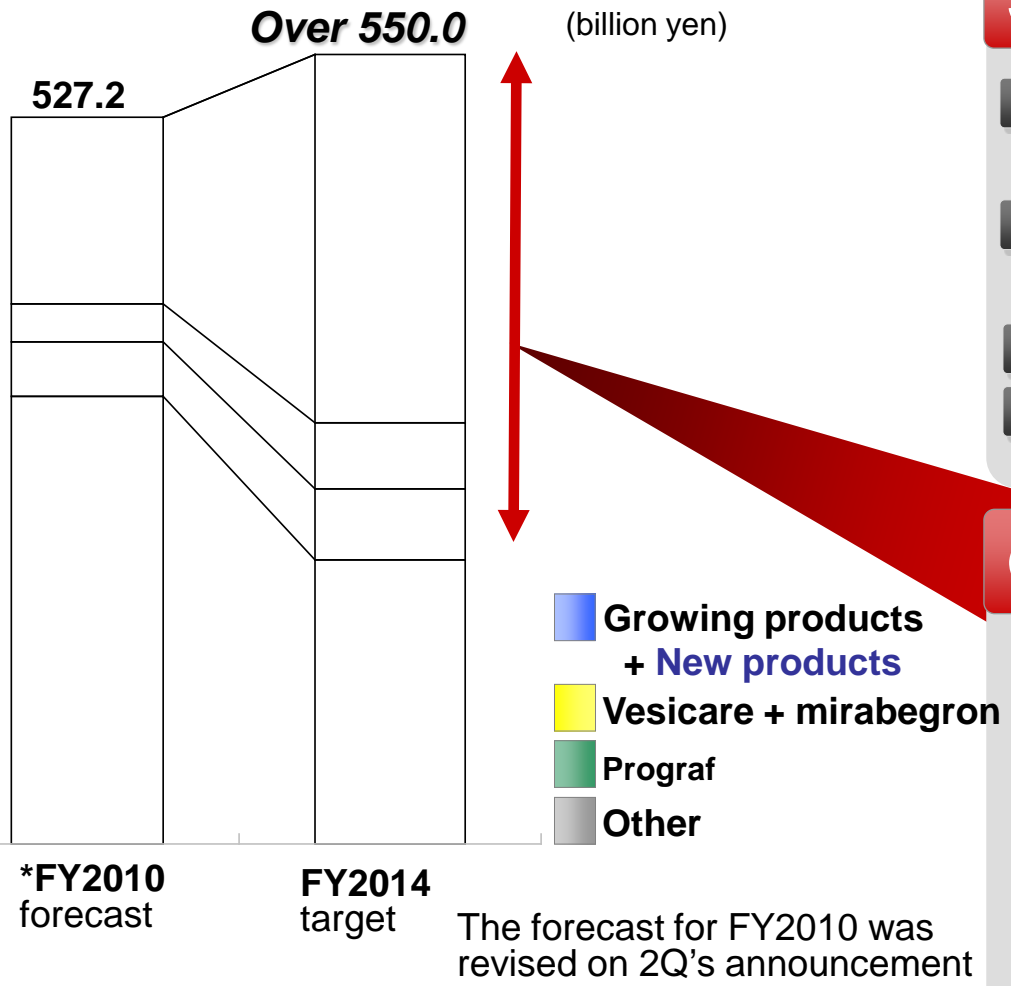
FY2010 Consolidated net sales (forecast): 942.0 bil. yen
 (calculated for each location of the sales affiliates and the promotion base, and % means the percentage of the total amount of the consolidated net sales)

Efforts in Sales & Marketing - 2: Japan: Strengths and Growth Drivers

Japan

Achieve No.1 market share in Japan during MTP14

Total Rx Sales in Japan



Strengths

- One of the biggest and best teams of MRs : approx 2,400 MRs
- Rich product lineup (Therapeutic areas and product numbers)
- Solid Sales force structure and support system
- Successful experience in marketing alliances

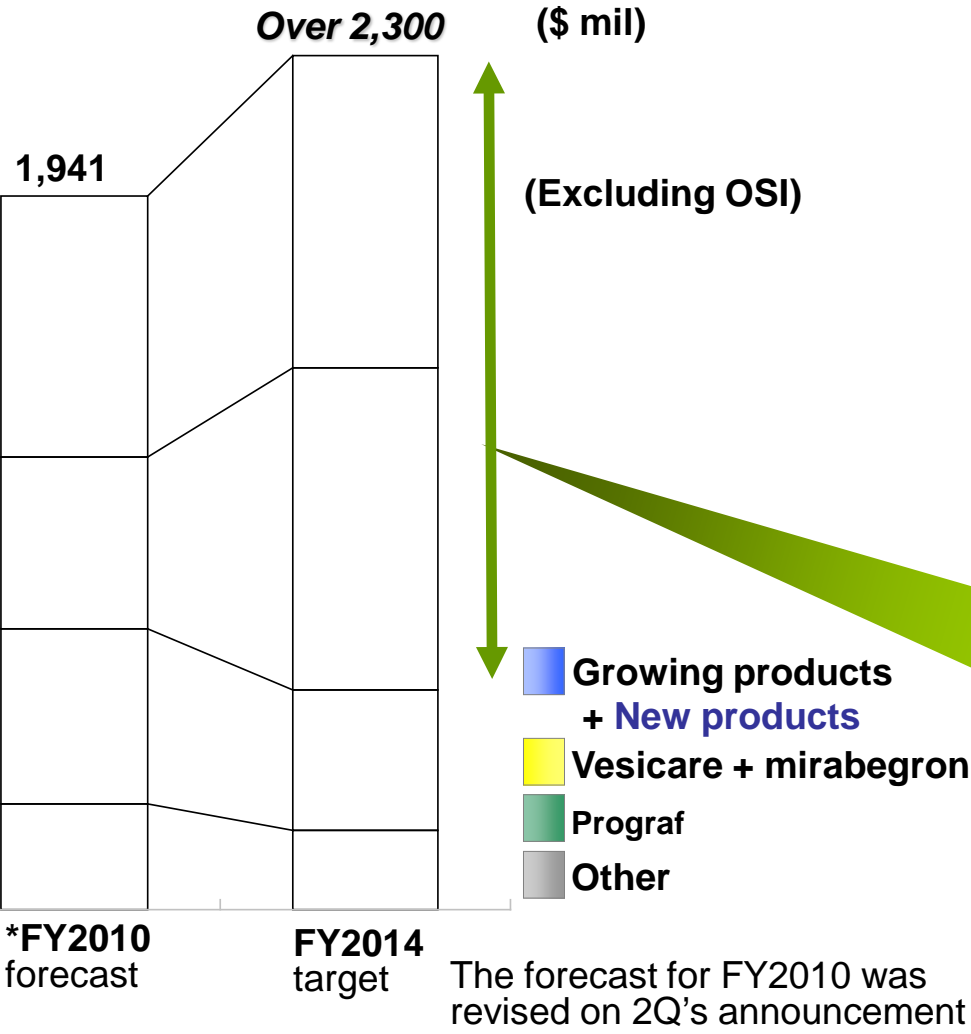
Growth Drivers in MTP14

With growing products (incl. recently launched products) + new products + Vesicare + mirabegron + Prograf, aiming more than 160.0 bil. yen revenue increase from FY2010

Efforts in Sales & Marketing - 3: Americas: Strengths and Growth Drivers

Americas

Improve and bolster existing business platform for future growth



Strengths

- US:** Business model focused on specialty areas, and slim, efficient and flexible organization
 - High-quality sales force
 - Efficient adaptation to customer needs and market trends
 - Abundant experience in strategic alliances
- Canada:** Solid sales platform centered on in-house products
- Latin America:** Sales affiliate in Brazil and business network in Latin America

Growth Drivers in MTP14

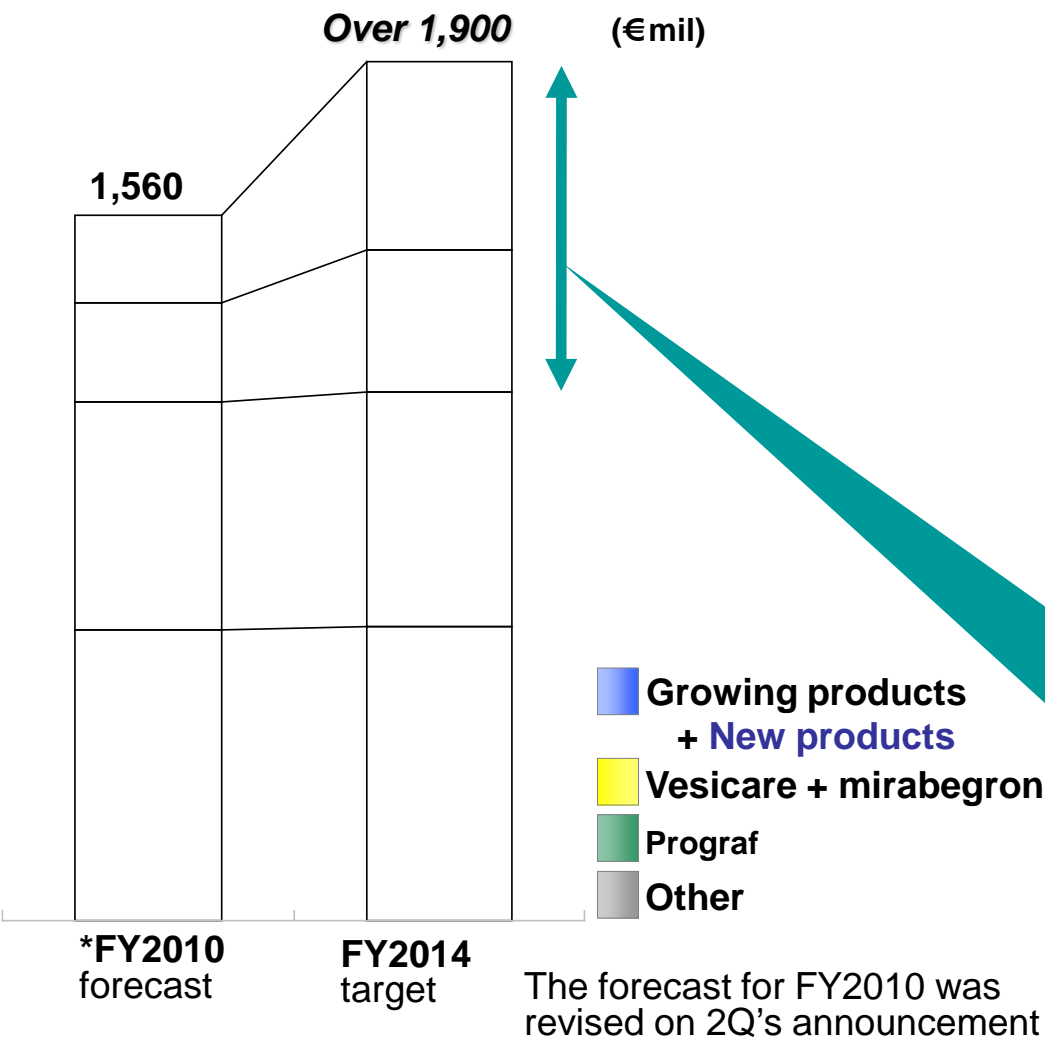
With growing products (incl. recently launched products) + new products + Vesicare + mirabegron, aiming more than \$500 mil. revenue increase from FY2010

Area expansion:
Business expansion including own sales and marketing in Latin America
Brazil: Launched Protopik and Omnic with own channel.

Efforts in Sales and Marketing - 4: Europe: Strengths and Growth Drivers

Europe

Expand and reinforce business further as leading Japanese pharmaceutical company in the region



Strengths

- ***No.1 in sales** among Japanese pharmaceutical companies
- Agile and lean organization
Efficient adaptation to customer needs and market trends
- Extensive geographic coverage
Most extensive geographical coverage among Japanese pharmaceutical companies: 20 sales affiliates
- Success in emerging markets
 - Russia generates the 5th largest sales among European countries
 - Recently established sales affiliate in Turkey, as well as legal entity for promotion in Romania and Bulgaria

Growth Drivers

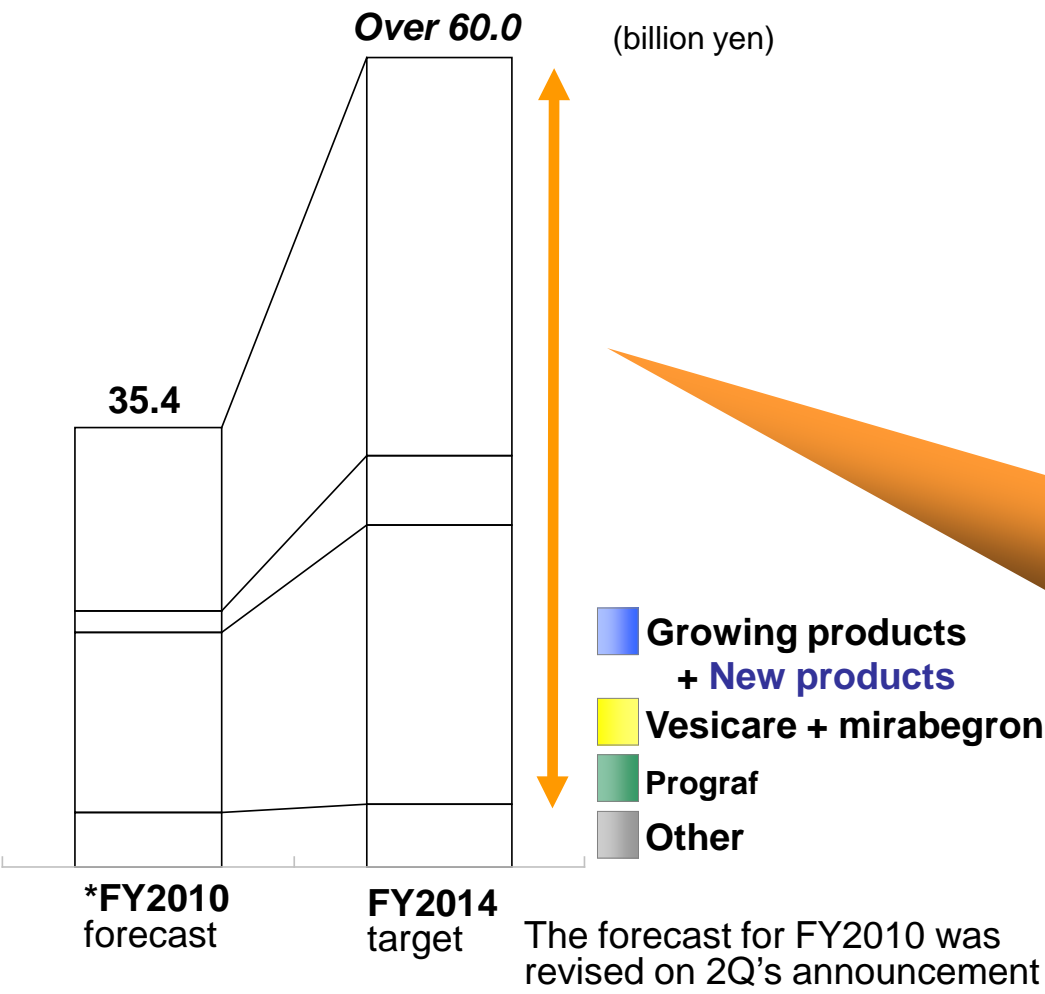
With growing products (incl. recently launched products) + new products + Vesicare + mirabegron, aiming more than €300 mil. revenue increase from FY2010

Area expansion:
Considering expanding into the Balkan Peninsula, CIS and North Africa, etc.

Efforts in Sales and Marketing - 5: Asia: Strengths and Growth Drivers

Asia

Realize dramatic growth by expanding sales in each country



Strength

- Expansion of sales network by own affiliates
 - *No.1 sales among Japanese pharmaceutical companies (6 countries except India)
 - Coverage of Asian main market (7 countries/8 affiliates)
- Business foundation with high profit structure
 - In-house products in transplantation and urology as the business core
 - Marketing strategy that accurately meets market needs in each country

Growth Drivers

As a whole Asia, aiming more than 30.0 billion yen revenue increase from FY2010

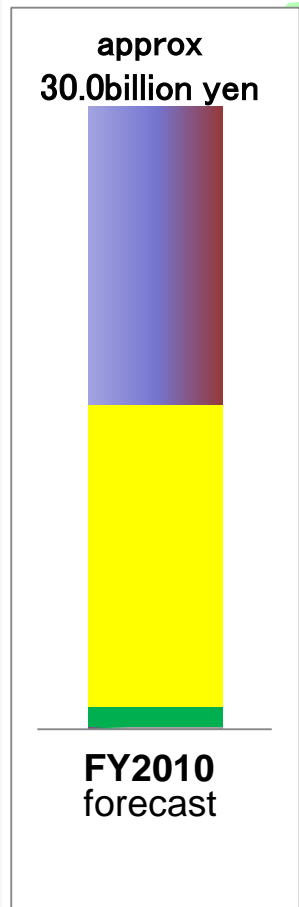
- Geographic expansion
 - Expansion of in-house sales affiliates in new territories being considered
- Most focused on China

Efforts in Sales & Marketing - 6: BRICs: Strengths and Growth Drivers

BRICs

Realize dramatic growth by expanding sales in emerging countries

- Growth Driver: China and Russia Forecast for FY2010 Approx 30.0 Billion Yen (=Sales Ratio approx 3%)
- Geographic expansion Expansion of in-house sales affiliates in new territories being considered



Brazil (Sao Paulo)
(Established: July, 2009)
-Launched Omnic and Protopic
-Plan to launch Omnic OCAS and Vesicare

India (Mumbai)
(Established: November, 2008)
-Launched Prograf on March, 2010
-Approved Advagraf in Oct, 2010.

Russia (Moscow)
(Established: 1994)
-Covers 13 countries including CIS
-Sales in Europe excluding Flomax Bulk & Royalty +15% (2Q FY2010 year on year)
-Russia +42%
-Poland, South Africa, Turkey +30%

China (Syenyang)
(Established: October, 1994)
-Sales Offices in Beijing and 4 other cities
-Lunched Vesicare on December, 2009
-Strengthening sales force

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Efforts in Oncology Fields -1: Reinforcement of Astellas' Oncology Business Base

2006 *Select "oncology" as a focus therapeutic area*

2010

Promote in-house research system

(Initiate antibody research headed by Molecular Medicine Research Labs.)

March 2007

MorphoSys : Phage antibody library

March 2007

Regeneron: VelocImmune[®] generating fully human monoclonal antibodies

December 2007

Integration of Agensys

Generation of fully human monoclonal antibodies

Gain target molecules in the oncology field

Therapeutic antibodies in R&D pipeline

October 2009

MDV3100(Prostate cancer)
Licensed from Medivation

December 2009

AC220(AML)
Licensed from Ambit

June 2010 Acquisition of OSI

Acquire fully integrated oncology capabilities in the U.S.

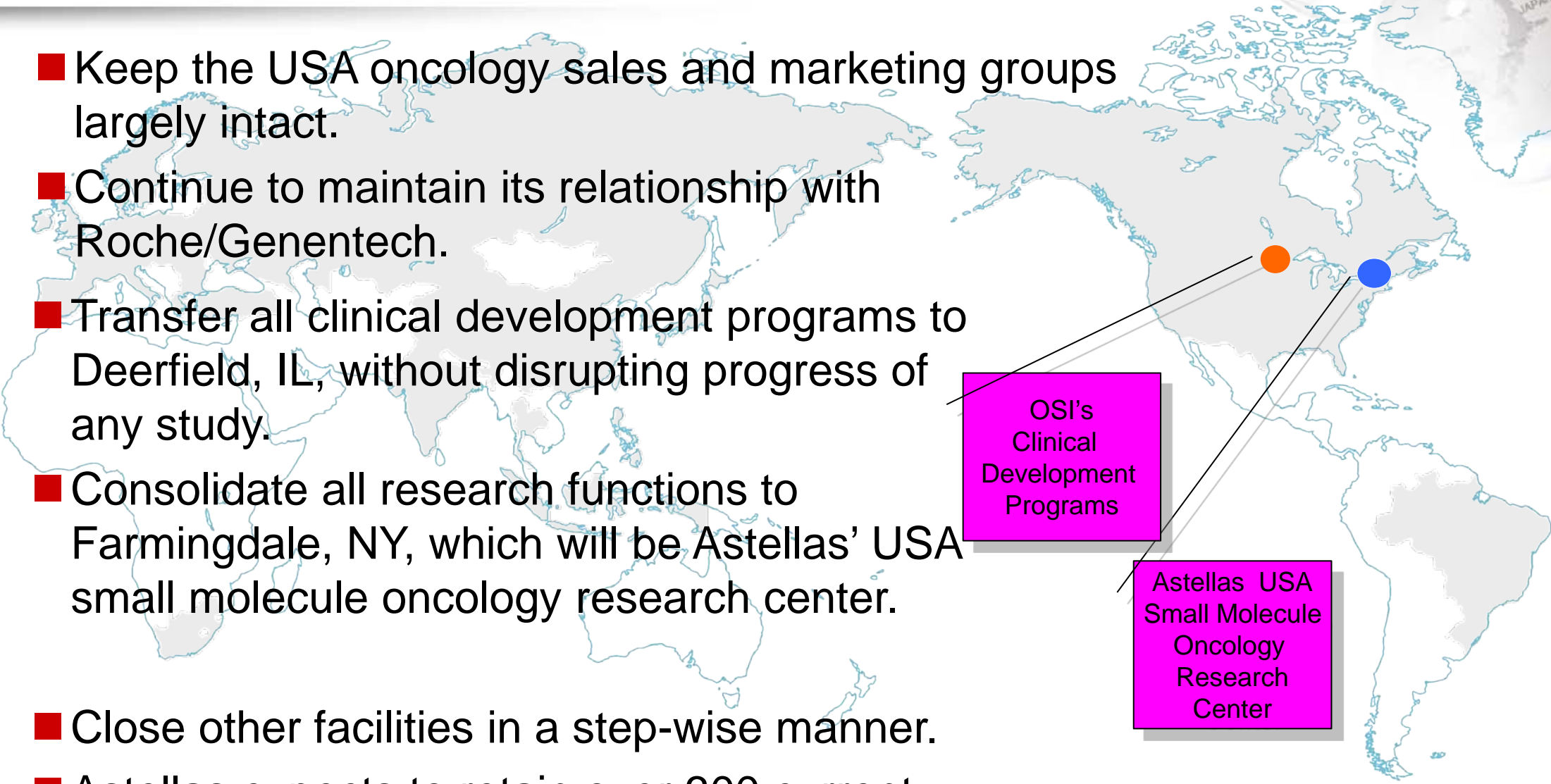
Expand clinical stage oncology pipeline

Access to small molecule discovery research platform in oncology

October 2010 Submit application of Degarelix in Japan

Efforts in Oncology Fields -2: OSI Integration

- Keep the USA oncology sales and marketing groups largely intact.
- Continue to maintain its relationship with Roche/Genentech.
- Transfer all clinical development programs to Deerfield, IL, without disrupting progress of any study.
- Consolidate all research functions to Farmingdale, NY, which will be Astellas' USA small molecule oncology research center.
- Close other facilities in a step-wise manner.
- Astellas expects to retain over 300 current OSI employees located in the USA and UK.



OSI's
Clinical
Development
Programs

Astellas USA
Small Molecule
Oncology
Research
Center

Efforts in Oncology Fields -3: Strengthening Anti-Body Research & Development

Accelerating Anti-Body Development by Agensys

- Agensys' New CEO and President, Dr. Sef Kurstjens
Former Job : Allergan Inc., Senior Vice President, Chief Medical Officer and Head, Global Drug Development
: Astellas Pharma US, Inc., R&D, Senior Vice President
- Leveraging Antibody-drug conjugate technology
- Leveraging VelocImmune[®] antibody technology of Regeneron Pharmaceuticals, Inc.



Dr.Sef Kurstjens

Establishing Know-How of Antibody-Drug

- Started the transfer of Fermentation and Biotechnology Labs. →closer collaboration between manufacturing process and drug discovery research.
- The facilities to manufacture drug substances for development of antibody pharmaceuticals completed in Tsukuba Research center(Tokodai)



The facility to manufacture drug substances in Tokodai

Efforts in Oncology Fields -4: Strategy for Oncology

GOSU(Global Oncology Strategy Unit)

- Product and portfolio strategy function for oncology was consolidated into Deerfield, IL
- Global function for Astellas' oncology strategy

Oncology Portfolio Strategy—Three Approaches

1 Precision Medicine

(Selected patient population, with high efficacy)

2 Mechanisms of action with application across multiple tumor types

3 Leverage current capabilities (Urology expertise and other fields)

Current pipeline

Example

AC220

Acute myeloid leukemia

Highly selective second-generation FMS-like tyrosine kinase-3 (FLT3)

inhibitor **Best-in-class**

YM155

Non-Hodgkin's lymphoma, melanoma, breast cancer

Inhibits survivin expression

First-in-class

Prostate cancer

MDV3100

Second-generation androgen antagonist

Best-in-class



eligard®

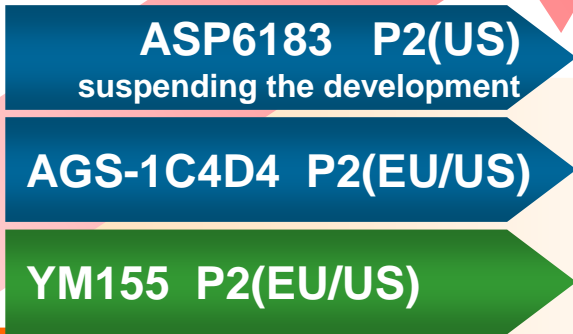
Efforts in Oncology Fields - 5: Growth in Oncology Franchise

- Expect to launch many new products from current pipeline over medium and long terms
- Strengthen pipeline through acquisition of OSI*

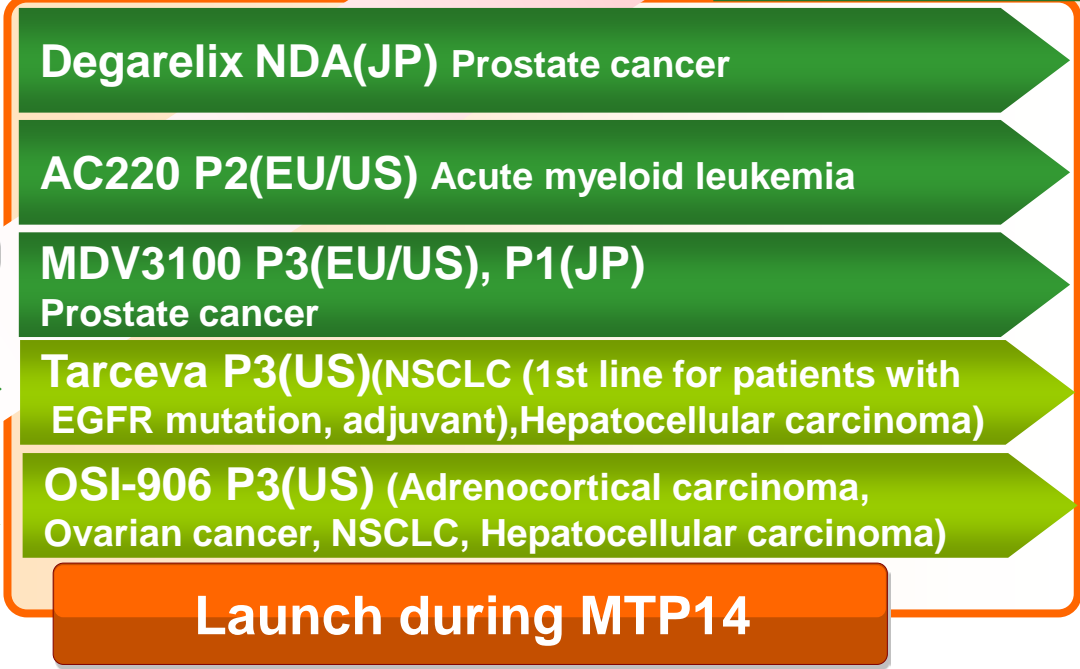
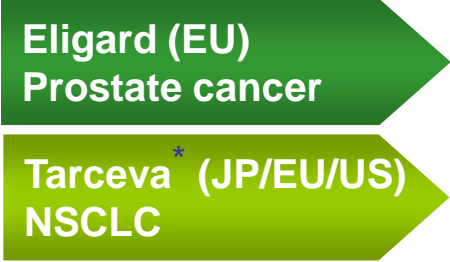


FY2014

Launch year



FY2010



Launch during MTP14

Enrich pipeline further

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Efforts in Society and Employee: Changing Tomorrow Day

Global social contribution activity on the named “Changing Tomorrow Day”

- “Changing Tomorrow Day” means the employee participation volunteer activities taken voluntarily by all of the Astellas employees worldwide in each place of business, office or group etc..
- Purport of the activity: Commemorating the fifth anniversary of Astellas, we will devote to the social contribution activity taken worldwide to demonstrate our commitment to the CSR.
- Theme of the activity: “Healthy” or ”Environment”
- Period of the activity: In principle, from Sep 1st to Oct 31th (continuing social contribution activity as an annual event)
- Feature of the activity: Volunteering with the original logoed-T shirt



Changing tomorrow

明日は変えられる。

