Press Conference

Astellas' Current Approach Towards New Growth Stage

November 21, 2011
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Astellas Pharma Inc.

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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.

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Today's Agenda

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

1. Strengthen and optimize business platform
2. Upgrade drug generating capabilities by strengthening research, development and technical platforms
3. Advance development pipeline
4. Promote development of international human resources
5. Contribute towards a sustainable society

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Strengthen Platform with New Products/ Optimize Resource Allocation

■ Enrich portfolio with new products

Vesicare OD Tablets

Betanis Tablets

Bonoteo Tablets 50mg (Once per 4 weeks)

Prograf Additional indication for small bowel transplant

■ Optimize resource allocation

PERSEID therapeutics

Completion of acquisition in May

We support medical treatment for 6 billion people behind the scenes
EVEC, Inc

"Fully-human antibody"
License agreements

Pfizer

"Caduet Combination Tablets"
Astellas to hold distribution rights

Vical

"TransVax"
License agreements

a·cube
astellas aspiring alliance

Created a website for open innovation

TEIJIN
Human Chemistry, Human Solutions

"Febuxostat"
Expansion of licensed territory

Prosidion
Shaping medicine. Changing lives.

Sold DPP4 assets to Royalty Pharma

Abbott
A Promise for Life

"Luvox Tablets"
Transfer of distribution rights

TOA EIYO

"Pronon Tablets"
Transfer of marketing and manufacturing authorization rights

MERCK

"Vernakalant i.v."
Merck to acquire rights

sanofi aventis
Because health matters

"Targocid" "Maalox"
Transfer of distribution rights

Maruishi Pharmaceutical Co., Ltd.

"Balance Tablets, Powder"
Transfer of marketing and manufacturing authorization rights

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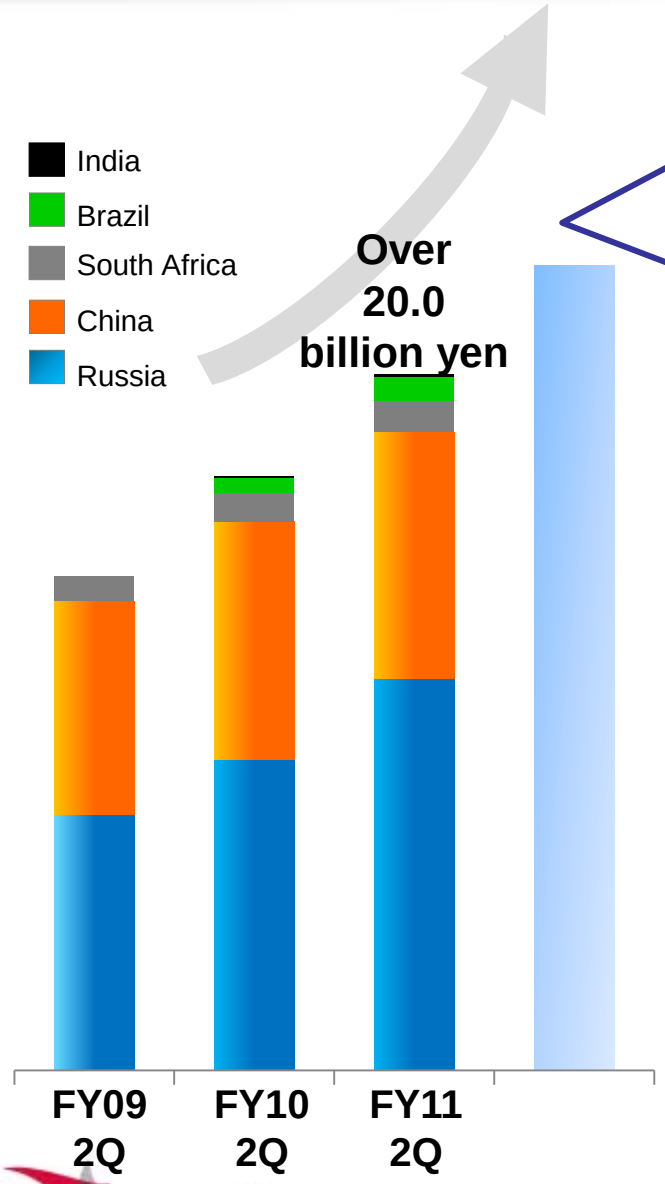
Business Expansion in Emerging Markets and Other Areas



- **China** Increase business bases from 5 to 8
  - -Sales in 2Q/FY11: Approx. 7.5 billion yen
  - -Continuing high growth: +10% (local currency basis)
- **Russia** Strengthened sales and marketing capabilities (Including CIS area)
  - -Sales in 2Q/FY11: Approx. €100M
  - -Continuing high growth: +28% (local currency basis)
- **Brazil** Established an affiliate in 2009
  - -Sales in 2Q/FY11: Approx. $10M
  - -Continuing high growth: +62% (local currency basis)

➢Continuous launches in emerging market and other areas

➢Thailand
-Launch of Advagraf (July)

➢Australia
-Started to sell Vesicare by Astellas (April)

➢Philippines
-Approval of Prograf for lupus nephritis (July)

➢India
-Launch of Advagraf (April)
-Approval of Vesicare (June)
-Approval of Prograf for lupus nephritis (August)

➢Taiwan
-Approval of FEBURIC (febuxostat), licensed from Teijin (May)
-Approval of Harnalidge OCAS (Harnal OCAS) (August)

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Specific Approaches to Precision Medicine Drug Discovery

Established Global Discovery Development Interface (GDDI) to facilitate implementation of a Precision Medicine strategy

＜Specific Focus Areas of GDDI＞

Biomarkers

Biomarkers to establish target engagement early and to enable patient stratification

Co-diagnostics

Early consideration for establishment (validation, qualification, production and cost) of co-diagnostics

Modeling & Simulation Techniques

Throughout all phases of R&D to inform on optimal dose, dose regimen, and study design

Translational Science Platform

To enhance predictive value for animal models and facilitate early clinical evaluation of critical efficacy and safety aspects

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Promote Multi-Track R&D Process

Industry-academia-government collaborations

Kyoto Univ.
One of the world most eminent basic immunology research

Innovative drugs for immunoregulation
(Drugs for intractable diseases and safe immunoregulation technologies for transplantation)

Riken Brain Science Institute
Cutting-edge and innovative expertise, research samples, and network

Explore, assess novel drug targets and generate new treatments for Alzheimer's Disease

Astellas
Prograf development experience

Highest levels of drug discovery research

a·cube astellas aspiring alliance

Created a website for open innovation

Website to promote collaborative research with domestic university and public research facilities

Multi-Track R&D model

Alliance with External Research

Internal Research → **Internal Development**

Alliance with other companies in early stage developments (e.g. Collaboration on Astellas' cardio-vascular compounds with Cardeus)

Alliance with other companies in late stage developments (e.g. Considering the appointment of a partner for the P3 development for Ipragliflozin)

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Bio Lead Project Formation

The Bio Lead Project was formed within Technology as an organization with functions ranging from drug substances to drug formulation, quality assurance, and regulatory affairs. The Project's platform supports CMC research up to initial production in order to quickly and continuously create products based on biotechnology and antibody drugs.

- Background & Reason
  - ✓ Turning biotechnology and antibody drugs into products is the highest priority for Technology
  - ✓ This is Astellas' first step towards development of biotechnology and antibody drugs - to make steady progress Astellas needed to form an organization with a unified sense of purpose, free of barriers between departments involved
  - ✓ This platform makes it possible to continue bringing new drugs quickly to patients that are waiting for antibodies
- Established: October 1, 2011

Tsukuba Bio Research Center Manufacturing Facility makes drug substances for development

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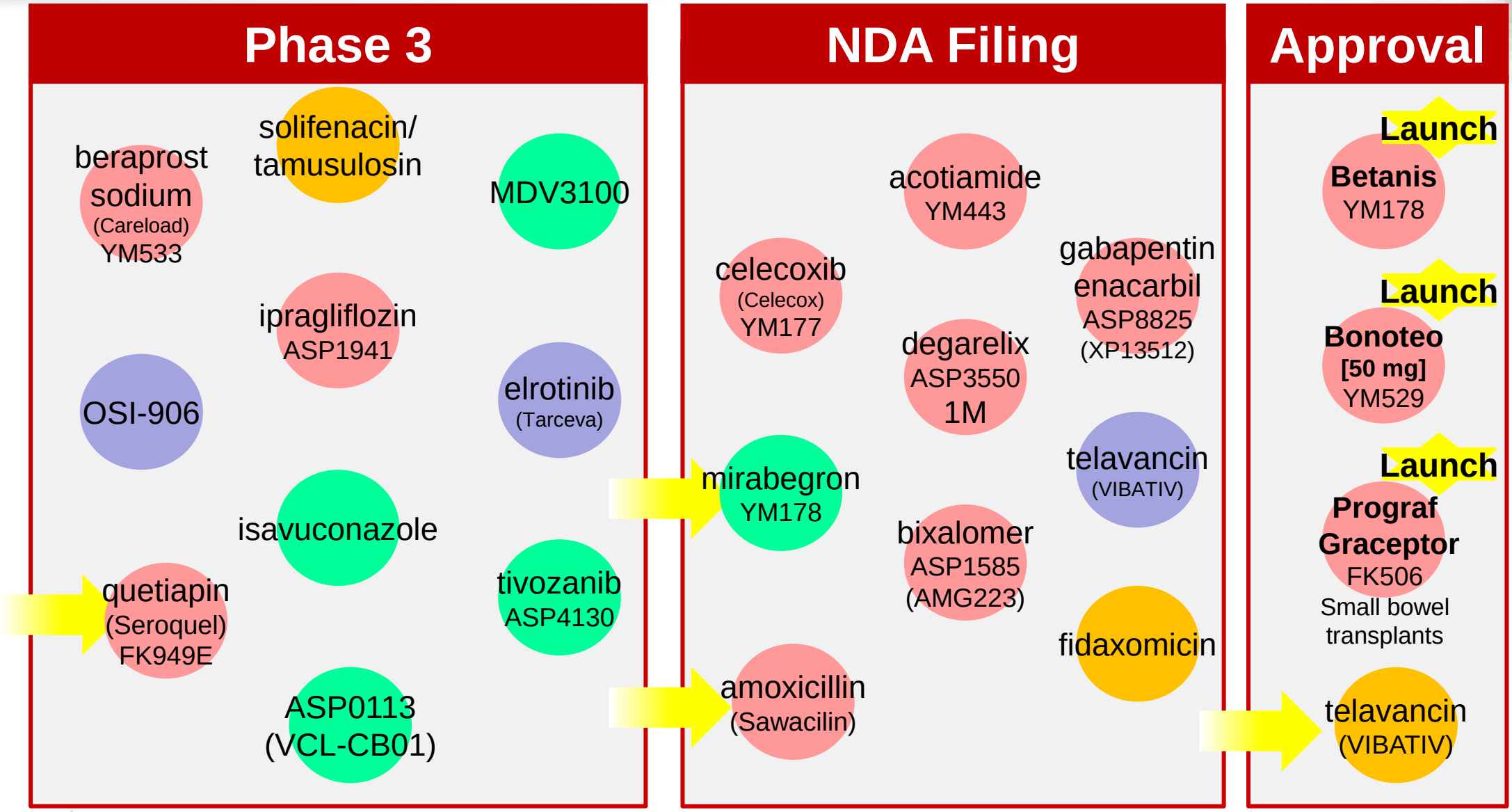
Progress of Late Phase Compounds



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Japan Europe US EU/US*

*MDV3100: EU/US/JP

Oncology Pipeline Expansion

	Project Product Name	Target cancer	Characteristics	P1	P2	P3	Filing
Small molecule	MDV3100	Prostate cancer	Second generation AR antagonist	EU/US/JP/Asia			Good P-3 interim results
	ASP4130 tivozanib	Renal cell carcinoma, Breast cancer (BC), Colorectal cancer (CRC)	Triple VEGFR tyrosine kinase inhibitor	Renal: EU/US			
				BC, CRC: EU/US		Progress	
	AC220	Acute myeloid leukemia	Potent and highly selective second generation FLT3 kinase inhibitor	EU/US			
	ASP3550 degarelix	Prostate cancer	First GnRH antagonist in Japan	1M formulation: JP			
				3M: JP			
	YM155	Breast cancer, Non-Hodgikin's lymphoma	A "First-in-class" survivin suppressant	EU/US/JP			
	ASP1707	Prostate cancer, Endometriosis					
	ASP3026	Cancer	ALK tyrosine kinase inhibitor				
	ASP9521	Prostate cancer					
OSI	Tarceva (Extension)	NSCLC (1st line for patients with EGFR mutation, adjuvant), Hepatocellular carcinoma	HER1/EGFR tyrosine kinase inhibitor	US			
	OSI-906	Adrenocortical carcinoma, Ovarian cancer, NSCLC, Hepatocellular carcinoma	IGF-1R/IR tyrosine kinase inhibitor	Adrenocortical: US			
				Ovarian etc: US			
	OSI-027	Renal cell cancer	mTOR kinase inhibitor	US			
Antibody	AGS-1C4D4	Pancreatic cancer	Novel antibody target (prostate stem cell antigen)	EU/US			
	AGS-16M8F	Renal cancer	Antibody utilizing ADC				
	ASG-5ME	Prostate cancer, Pancreatic cancer	Antibody utilizing ADC				
	AGS-22M6E	Solid tumors	Antibody utilizing ADC				

AR: Androgen Receptor, GnRH: Gonadotropin Releasing Hormone

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Executive Leadership Series

- Program to develop Astellas' global talent
- Approximately 25 senior managers participated in 1st Series
- Co-developed by Astellas and Duke Corporate Education

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Duke CORPORATE EDUCATION

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Signed United Nations Global Compact

- Astellas' CSR-based management will be further reinforced by United Nations Global Compact ("GC").
  - ✓ GC is the world's largest corporate social responsibility initiative to implement companies' sustainable growth.
  - ✓ The United Nations GC asks companies to embrace, support and enact, within their sphere of influence, a set of 10 principles in areas regarding corporate social responsibility of human rights, labour standards, the environment and anti-corruption.

Our current approach in four areas

Human rights	**Charter of Corporate Conduct** 6 Promote employee welfare.....respect all employees' human rights, character and equality. **CSR Procurement Guiding Principles** 2. Respect human rights and prohibit child labor
Labour standards	Occupational Safety and Health (OSH) Management
Environment	Undertake initiatives for reduction of greenhouse gas, efficient use of water resources, waste management, contamination prevention, preventing pollution, preserving biodiversity
Anti-corruption	Astellas Bribery Prevention Principle

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Astellas “Changing Tomorrow Day”














Europe

Asia

Japan

Americas

Changing Tomorrow Day

is a day of company-wide employee volunteer initiatives.

Astellas is committed to

sustainable development of nature, society and community.

- Group HQ/Regional HQ
- Sales Affiliate/Promotion Base (EUR)
- R&D Base
- Manufacturing Base

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Changing tomorrow

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Annual Press Conference

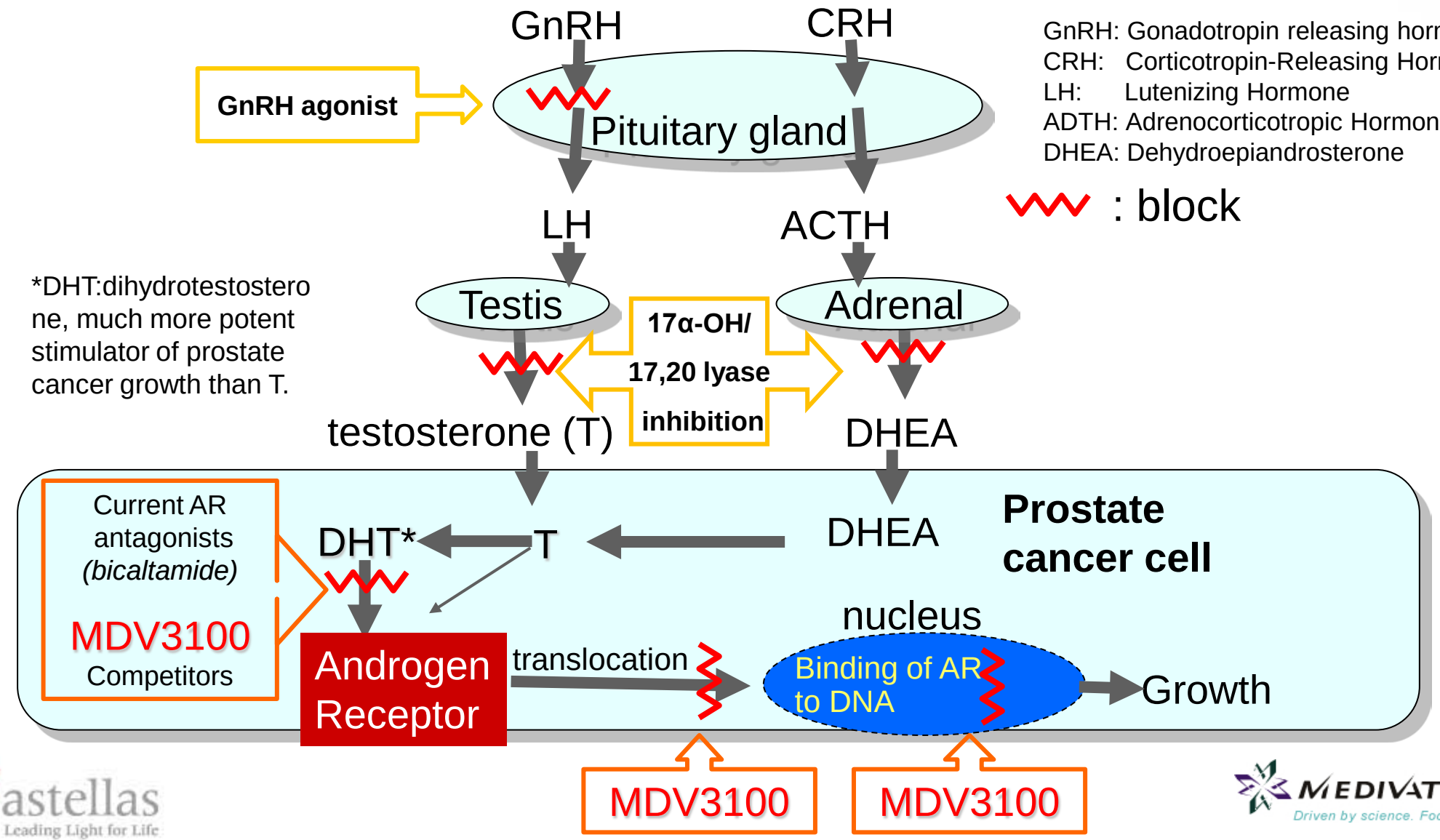
MDV3100 Interim Analysis

Steven Ryder MD, FACP
President, Astellas Pharma Global Development

November 21, 2011

MDV3100: Mechanism of Action

Androgen Receptor Signaling Inhibitor



GnRH: Gonadotropin releasing hormone
CRH: Corticotropin-Releasing Hormone
LH: Lutenizing Hormone
ADTH: Adrenocorticotropic Hormone
DHEA: Dehydroepiandrosterone

: block

*DHT:dihydrotestosterone, much more potent stimulator of prostate cancer growth than T.

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MDV3100 AFFIRM Trial Design

- Randomized Phase 3 Trial evaluating the effect of MDV3100 compared to placebo.
- 1,199 men were enrolled whose prostate cancers had advanced despite androgen deprivation and treatment with docetaxel-based chemotherapy.
- The study was monitored by an Independent Data Monitoring Committee (IDMC) who preformed a pre-specified interim analysis for safety and efficacy.

MDV3100 AFFIRM Interim Results

- Interim data analysis showed that MDV3100 produced a median survival of 18.4 months in the MDV treated group compared to 13.6 months in the placebo group; a 4.8 month increase in overall survival.
- MDV3100 also provided a 37% reduction in risk of death compared to placebo (hazard ratio = 0.631).
- Interim analysis results were highly statistically significant with a p-value of less than 0.0001.

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MDV3100 Ongoing Plans

- The IDMC recommended that the study be stopped early and all patients be offered MDV3100.
- Astellas and Medivation expect to hold a pre-NDA meeting with the FDA in early 2012. We have been granted a Fast-Track designation by the FDA.
- We continue to enroll patients in other prostate cancer studies to address the efficacy of this medication in earlier stages of the disease.

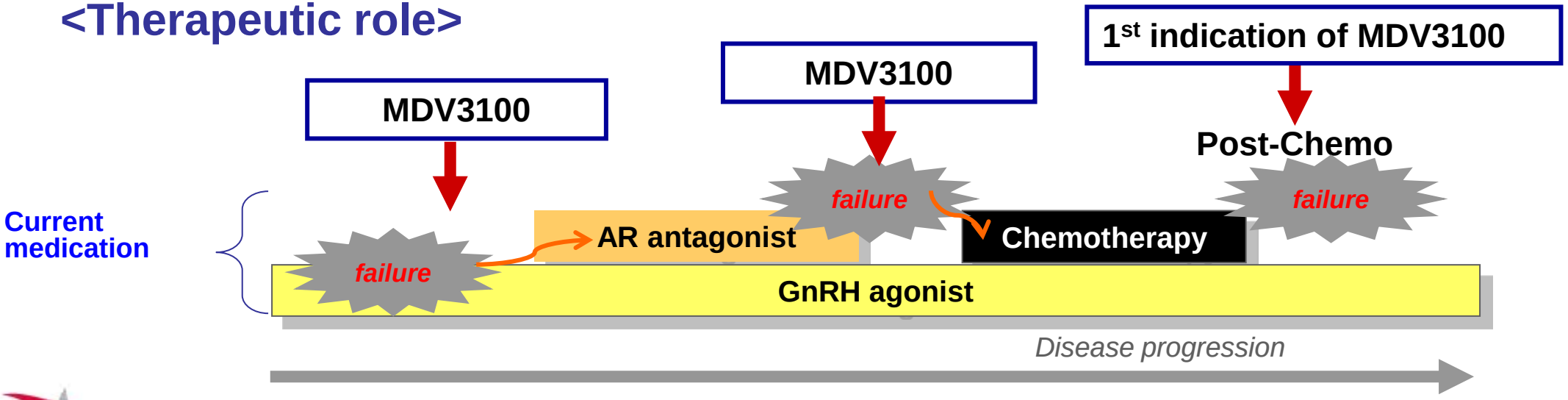
Back-up Slides

MDV3100: Target position

MDV has potential to meet unmet medical needs

- **Efficacy**
  - GnRH agonists work well initially. But prostate cancer progresses during the therapy.
  - Efficacy of current second-line hormonal agent (androgen receptor antagonist) is insufficient.
- **Safety/tolerability**
  - Low safety/tolerability of chemotherapy
- **Treatment option**
  - Very limited treatment options after chemotherapy failure

<Therapeutic role>



GnRH: Gonadotropin releasing hormone, AR: Androgen receptor

MDV3100: Development Progress

Study	Target	Design	P1	P2	P3	Filed
P3 EU/US [AFFIRM study]	Post-chemo Patients with progressive castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy	Placebo-controlled, n=1,199	Interim analysis results have just been obtained			
P3 EU/US/JP/Asia [PREVAIL study]	ADT failure Chemotherapy-naive patients with progressive metastatic prostate cancer who have failed ADT	Placebo-controlled, n=1,680	First Patient In September 2010			
P2 EU/US [TERRAIN study]	LHRH analogue failure Advanced prostate cancer patients who have progressed while on LHRH analogue therapy or following surgical castration	To compare with bicalutamide, n=370	First Patient In March 2011			
P2 EU	Hormone-naive Hormone-naive prostate cancer	Open-label, n=60	First Patient In May 2011			
P1/2 JP	Post-chemo Patients with progressive castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy	Open-label, n=46	Completed P1 part and initiated P2 part.			

ADT: Androgen deprivation therapy,
LHRH: Lutenizing hormone-releasing hormone