

Press Conference

Beyond Patent Cliff, Towards New Growth Stage with Innovative Drugs

December 12, 2012
Yoshihiko Hatanaka
President & CEO
Astellas Pharma Inc.

Cautionary Statement Regarding Forward-Looking Information

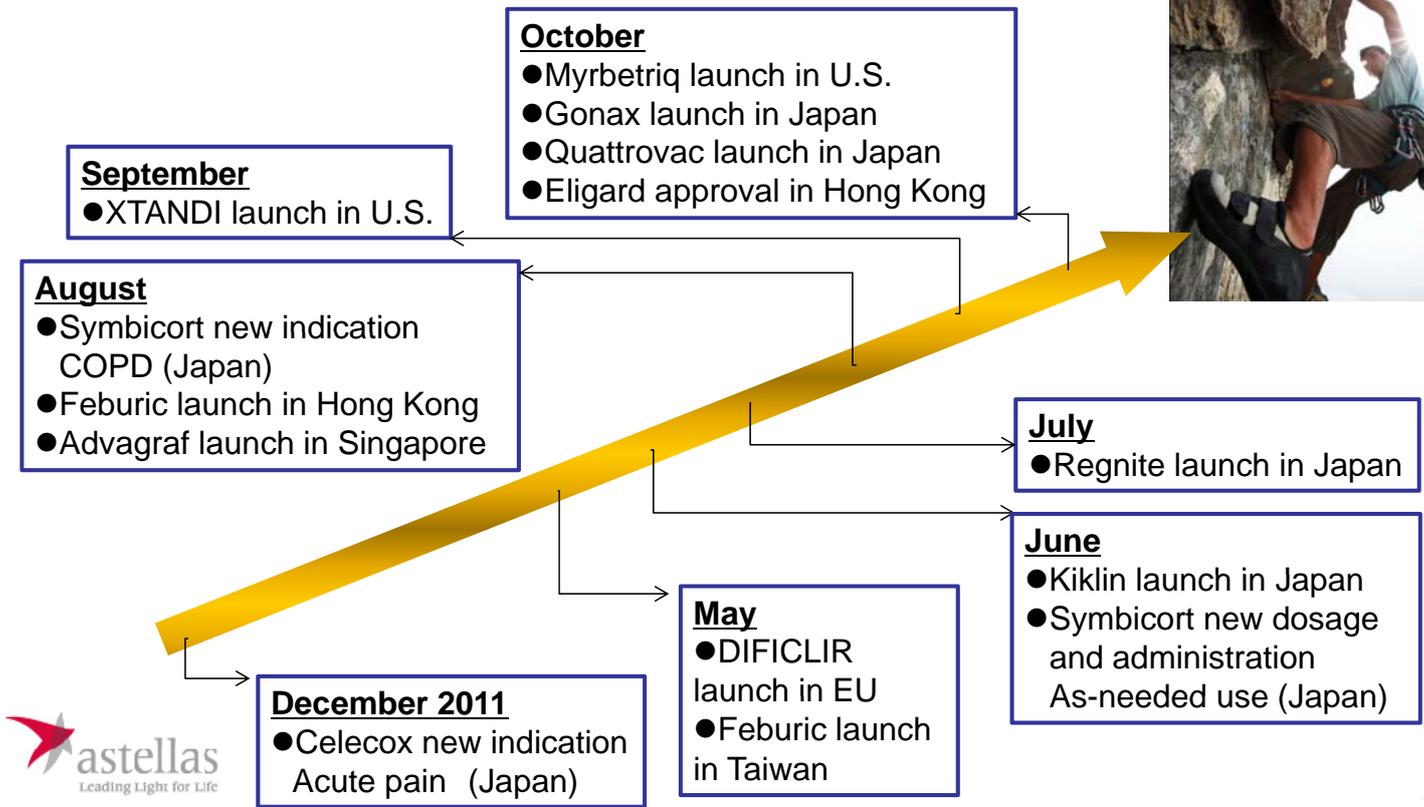
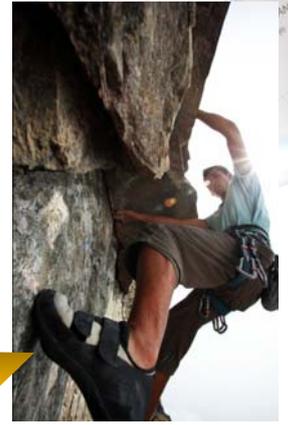
This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

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.

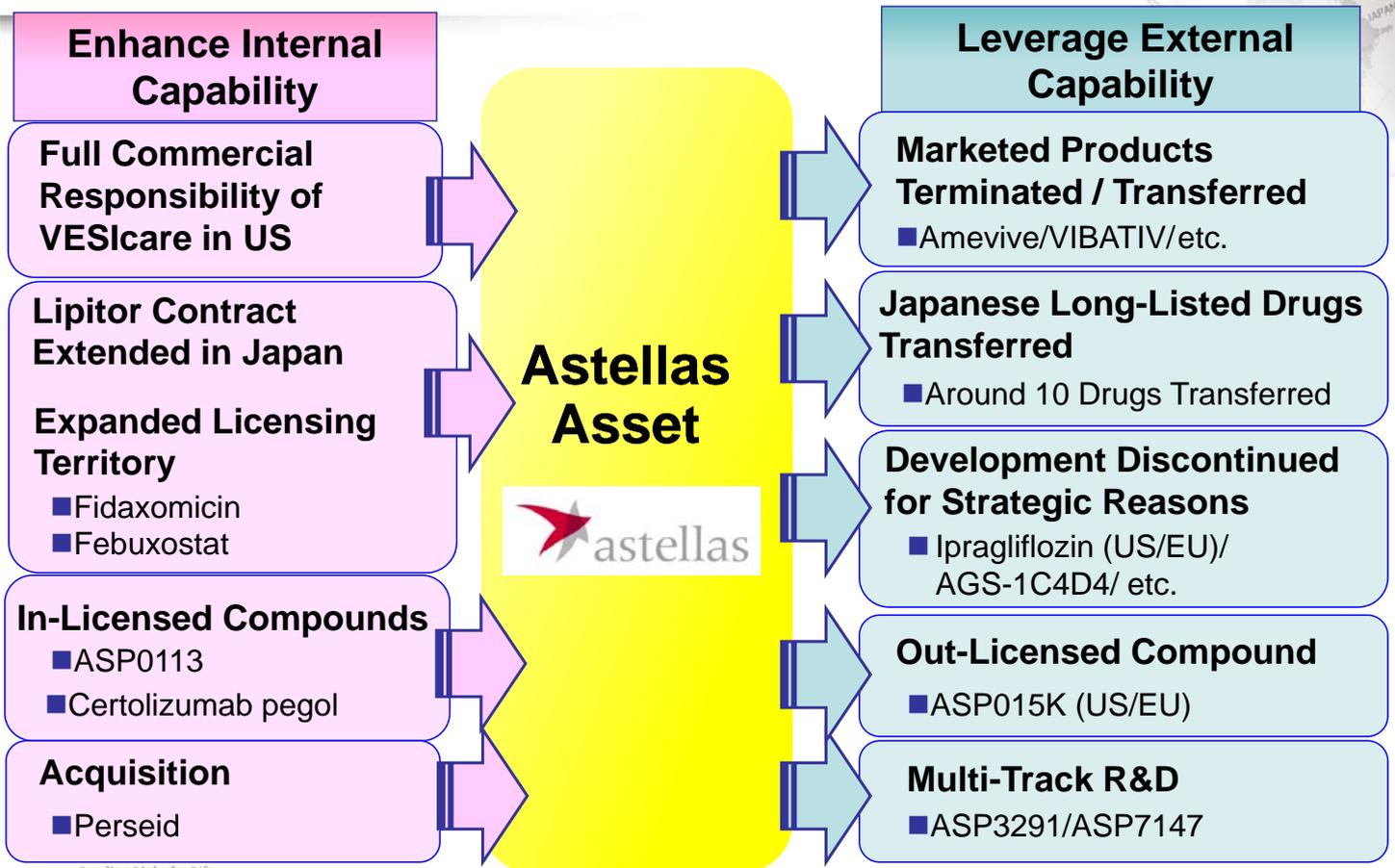
This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kind.

Strengthen Business Platform with New Products

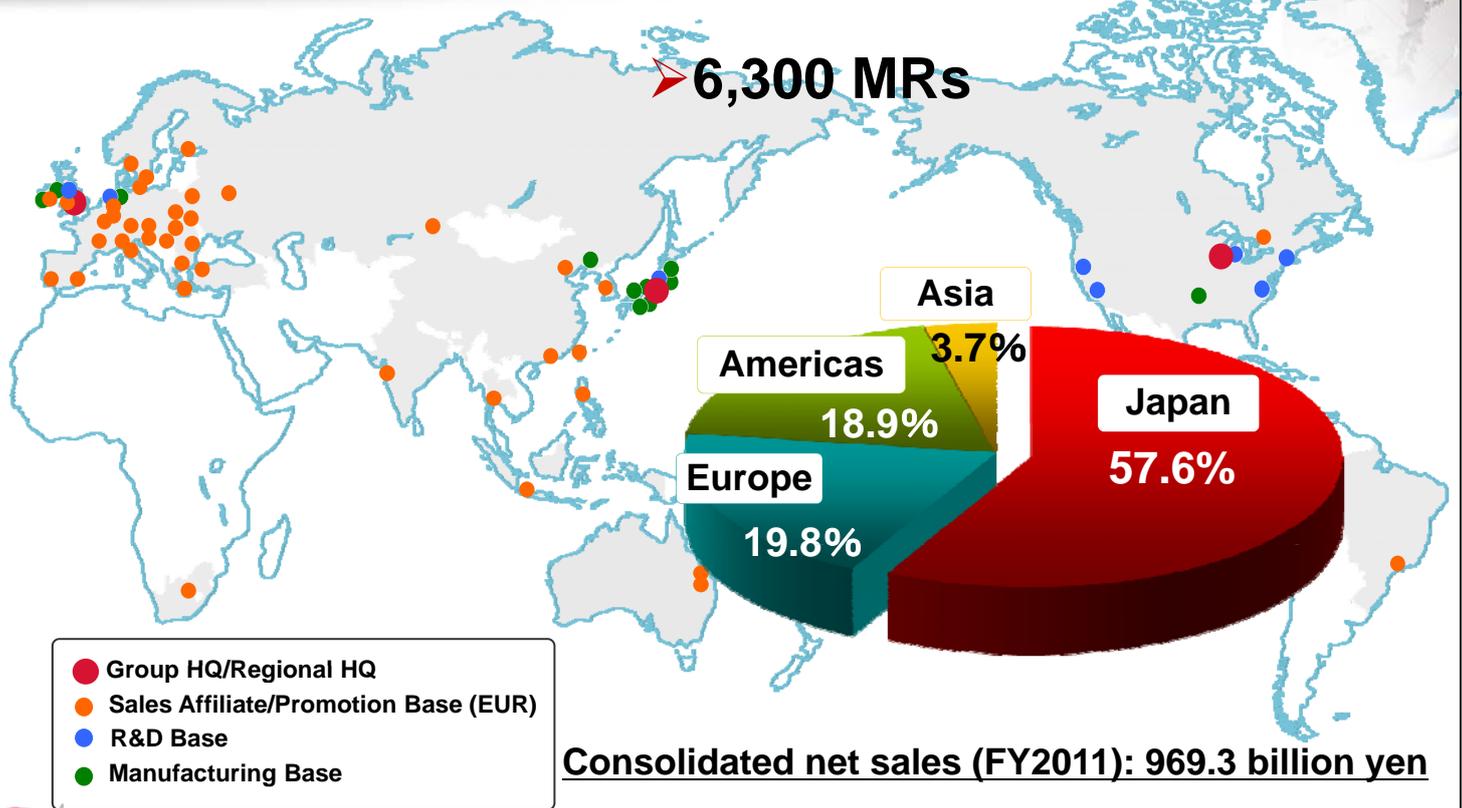
Major progress from press conference last year



Optimize Resource Allocation in FY2011/FY2012



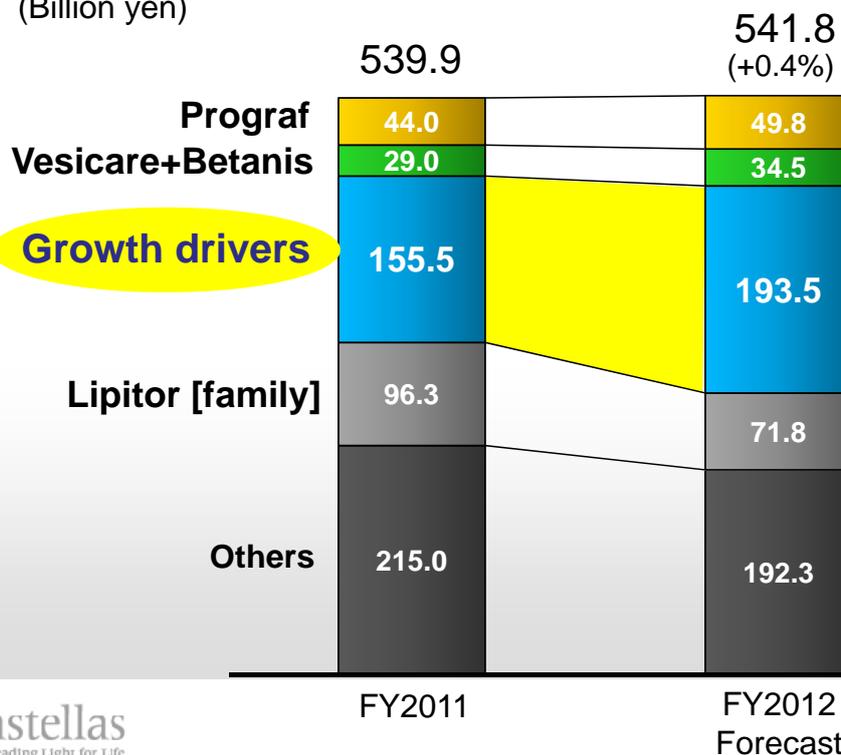
Steady Global Expansion Across 4 Regions



Japan: Multiple Products to Drive Growth

Sales in Japanese market

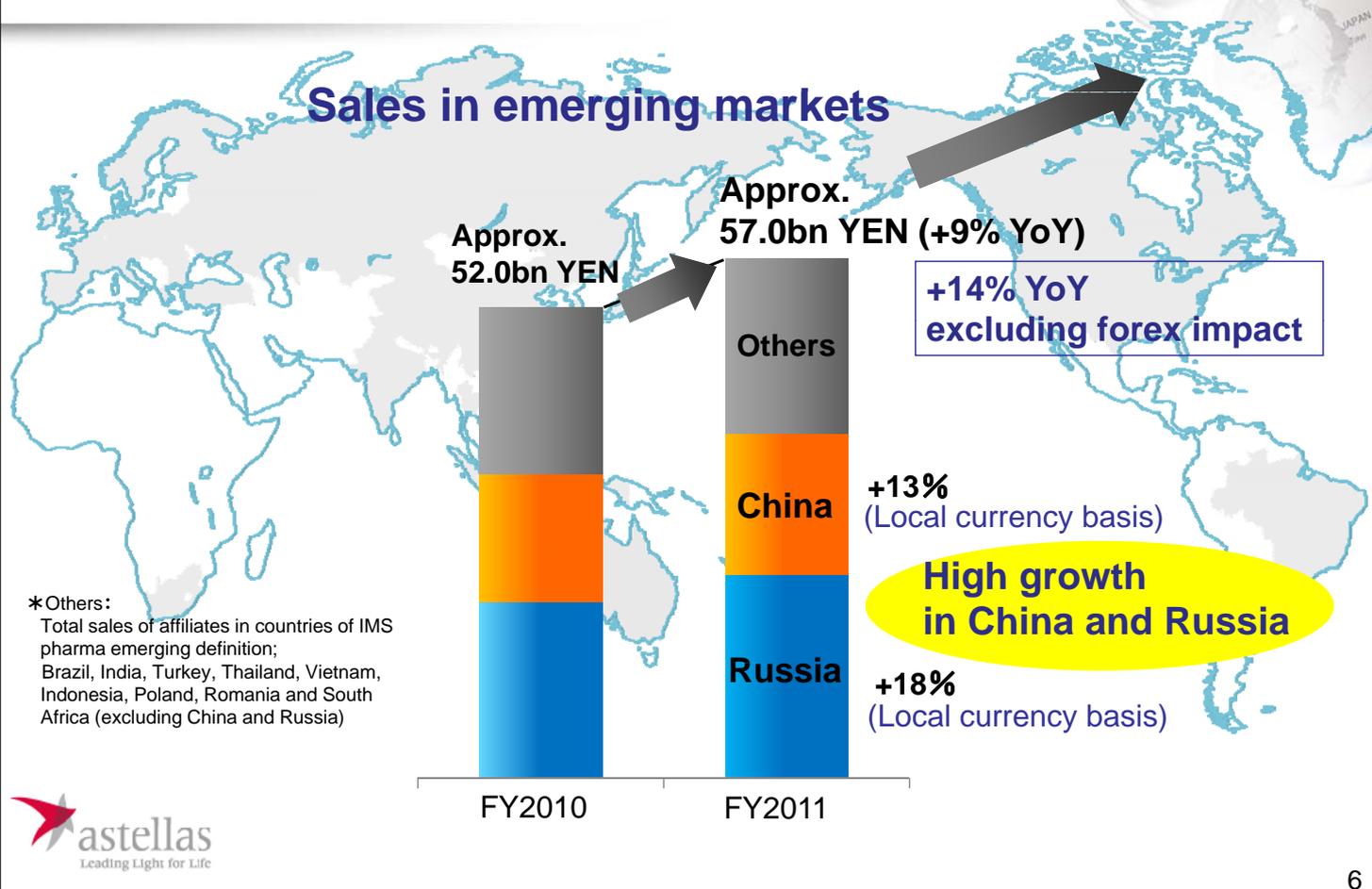
(Billion yen)



Micardis [family]
Argamate, Symbicort,
Bonoteo, Geninax, Celecox
New products launched in FY2012

-Kiklin
-Regnite
-Gonax
-Quattrovac

Emerging Markets: Sales Growth Under GCL model



Improve R&D Productivity “Precision Medicine” Approach

Right drug
for
right patient

=

Drug targeting causal
molecule for disease

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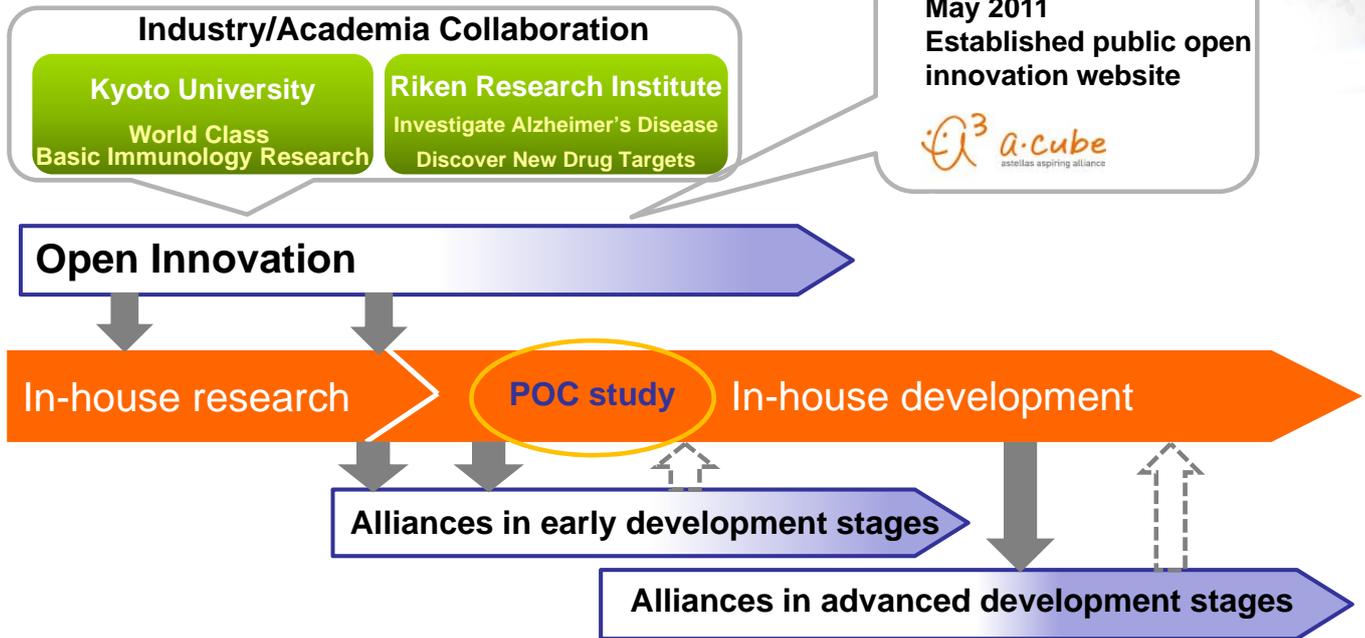
Companion diagnostic
to
identify right patients

Partnering with
diagnostics company

	Project	Target cancer	Companion Diagnostics Development ongoing	Mechanism of action	Remarks
Small molecule	Enzalutamide MDV3100	Breast cancer	✓	Androgen receptor inhibitor	
	Quizartinib AC220	Acute myeloid leukemia	✓	FLT3 kinase inhibitor	
	ASP3026	Cancer	✓	ALK tyrosine kinase inhibitor	
OSI	Erlotinib (Tarceva)	NSCLC (1st line for patients with EGFR mutation, adjuvant), : HCC, Colorectal cancer, Pediatric ependymoma	✓	HER1/EGFR tyrosine kinase inhibitor	A companion diagnostic, the cobas® EGFR Mutation Test currently under review
Antibody	AGS-16M8F/ AGS -16C3F	Renal cancer	✓	Antibody utilizing ADC (Target: ENPP3)	
	ASG-5ME	Prostate cancer, Pancreatic cancer	✓	Antibody utilizing ADC (Target: SLC44A4)	
	ASG-22ME	Solid tumors	✓	Antibody utilizing ADC (Target: Nectin-4)	

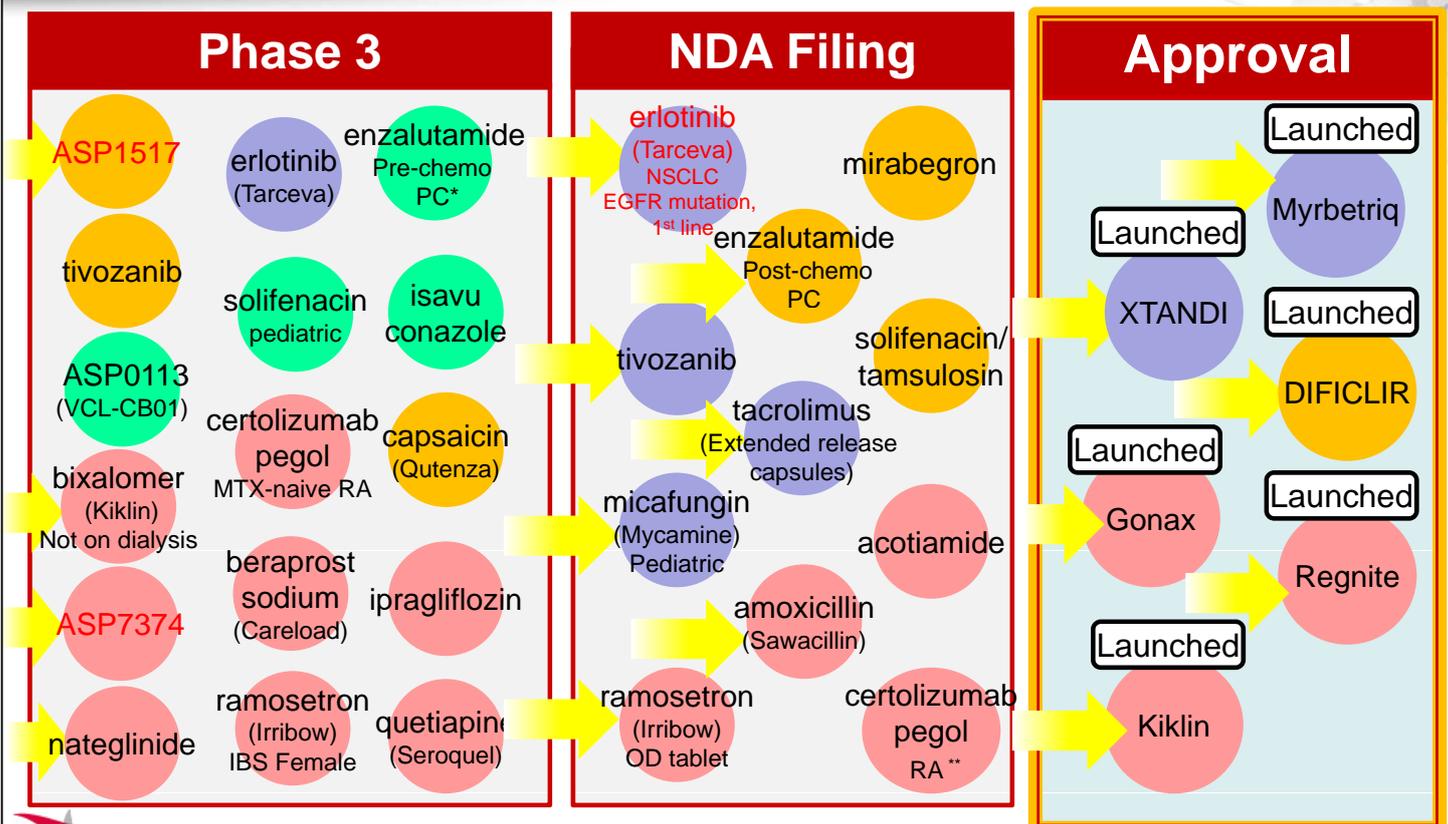
Improve R&D Productivity

“Multi-Track R&D” Approach



*POC: Proof of Concept

FY2012 Progress of Late Phase Compounds



PC: Prostate cancer, OD: Orally disintegrating, MTX: Methotrexate, RA: Rheumatoid arthritis
* EU/US/JP **RA in patients who respond insufficiently to current therapies

ASP1517: Newly Entered in P-3

- Oral formulation
- Hypoxia-inducible factor-prolyl hydroxylase inhibitor (HIF-PHI)
- Induce more complete erythropoiesis, body's natural response to hypoxic condition
 - ✓ Up-regulates erythropoietin (EPO) gene transcription to produce endogenous EPO in a physiologic range
 - ✓ Down-regulates hepcidin to enhance iron utilization
- Advantageous product characteristics over existing anemia treatment (injectable EPO receptor agonists) are expected:
 - ✓ Effective without i.v. iron supplementation
 - ✓ The ability to treat anemia without ESA-induced hypertension
 - ✓ Cholesterol lowering effect
- Over 800 subjects exposed to date
- P-2 development in preparation in Japan



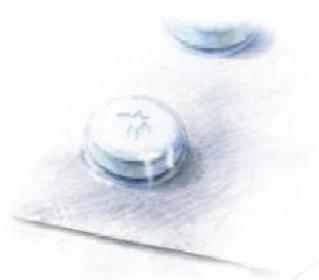
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Astellas Growth Strategy

- **Maintain and expand existing GCL franchises**
 - Urology: Maximize OAB global sales
 - Transplantation: Maximize global Prograf business
- **Develop oncology franchise rapidly as 3rd GCL**
 - Maximize existing product sales and accelerate developments
- **Maximize global sales**
 - Grow sales of multiple products in each region
 - Strengthen business in emerging markets under GCL model
- **Improve R&D productivity**
 - Reinforce "Precision Medicine" approach
 - Promote "Multi-Track R&D" approach
- **Optimize resource allocation**



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Changing tomorrow



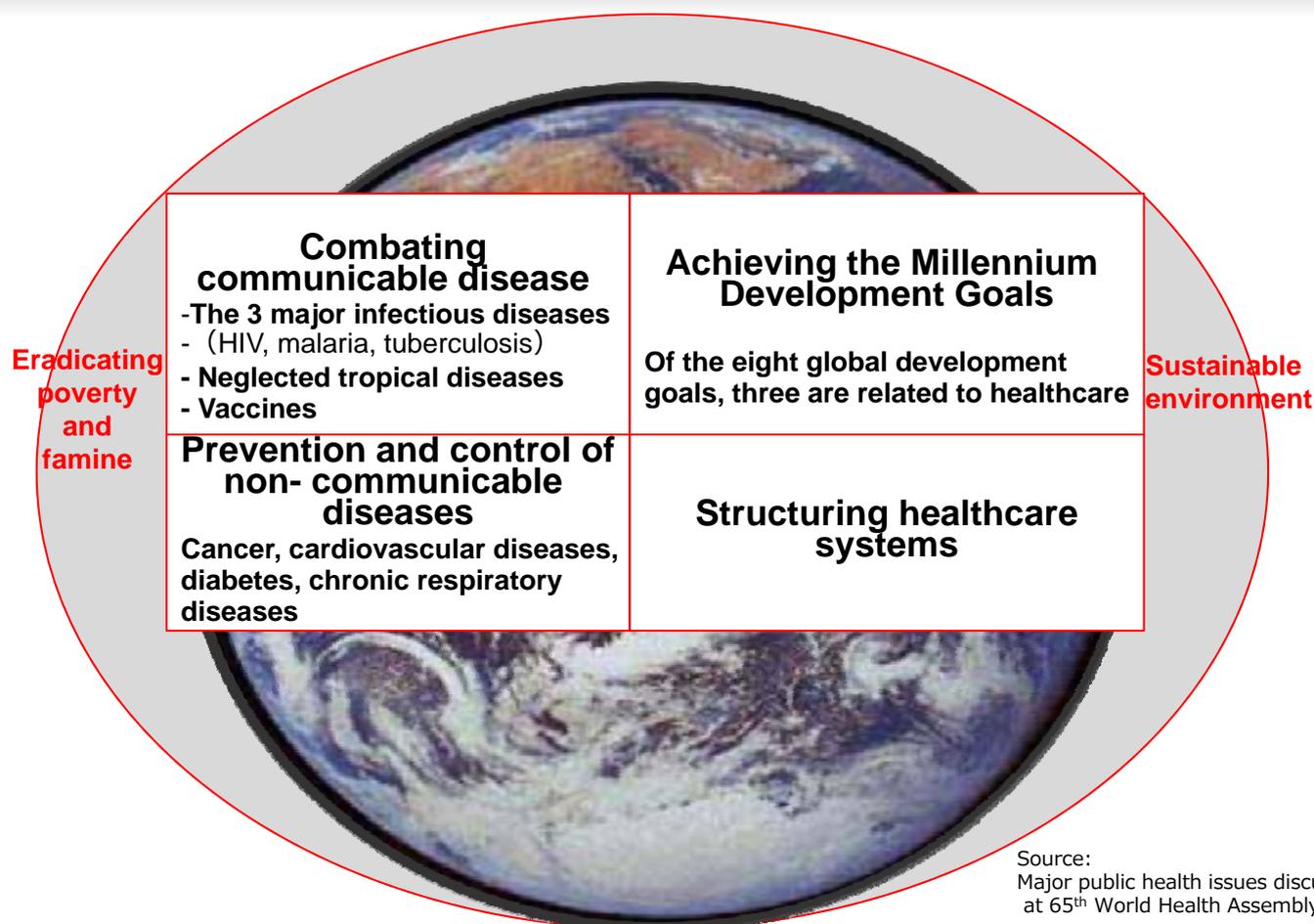
Astellas Press Conference



Momentum for Global Health ~Pharmaceutical Industry~



December 12th, 2012
Representative Director,
Chairman of the Board
Masafumi Nogimori



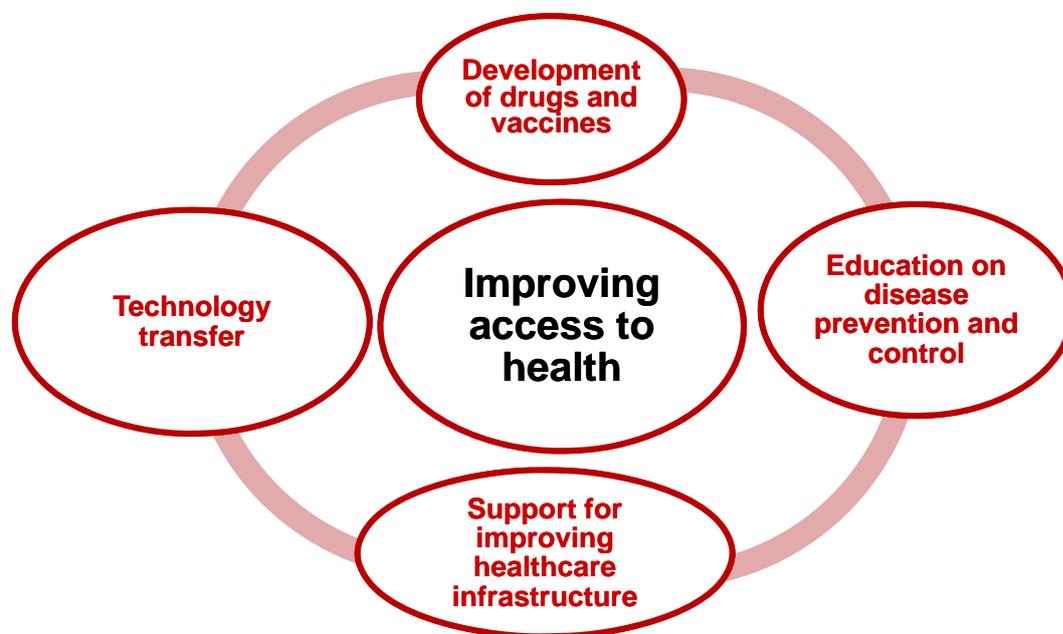
European, US pharmaceutical companies actively engaged in access to health initiatives

Approaches to contribute to access to health	Details
R&D	<ul style="list-style-type: none"> Research and development of innovative products and formulations, additional pediatric indications, etc (using Private Development Partnerships)
Flexible pricing	<ul style="list-style-type: none"> Affordable price setting for least developed countries and areas
Intellectual property (IP)	<ul style="list-style-type: none"> Implement the patent system in a flexible manner, considering non-application of IP rights in certain countries and flexibility of associated conditions
Technology transfer	<ul style="list-style-type: none"> Support capacity building, know-how transfer, education/training on product manufacturing and quality control
Product donations/ Philanthropy	<ul style="list-style-type: none"> Donation of products Philanthropic activities to structure healthcare systems

“Many developing countries do not yet have sufficient access to medical care. Improving healthcare in these areas must be a top priority.”

Source:

“JPMA's (Japan Pharmaceutical Manufacturers Association) Contribution to Global Health”



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Astellas Press Conference

Access to Health: A New Initiative for NTDs (NTDs: Neglected Tropical Diseases)

Changing tomorrow

December 12th, 2012
Senior Corporate Executive
Vice President, External Relations
Masaru Imahori

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Our contribution to Access to Health

Development of drugs and vaccines

- We are always working to develop innovative new drugs, especially in therapeutic areas with a high level of unmet medical needs.



Support for improving healthcare infrastructure

- We donated a birth center and health clinic in Indonesia from FY2009 to 2011 through NPO People's Hope Japan, offering 24-hour health care to reduce child mortality rate and improve maternal health.



Education on disease prevention and control

- The Astellas Europe Foundation has been supporting the Tanzania Malaria Prevention Project by the NGO Save the Children since 2010.

Technology transfer

- We have supported local drug discovery research in Malaysia by providing training for microorganism isolation culture and screening
- From April 2011 to March 2012, we have contributed to the WHO-TDR Clinical R&D Fellowship Program by having a Fellow



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Access to Health Mission Statement

Astellas' raison d'être is to **contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceuticals products.** Guided by this business philosophy, **our main efforts towards "Access to Health" lie in discovering, developing and providing innovative medicines for patients. Astellas also endeavors to advance "Access to Health" by engaging in initiatives in countries where adequate medical care is needed.** In order to develop our activities, we will continue to work with and maintain close dialogue with multiple public health stakeholders.

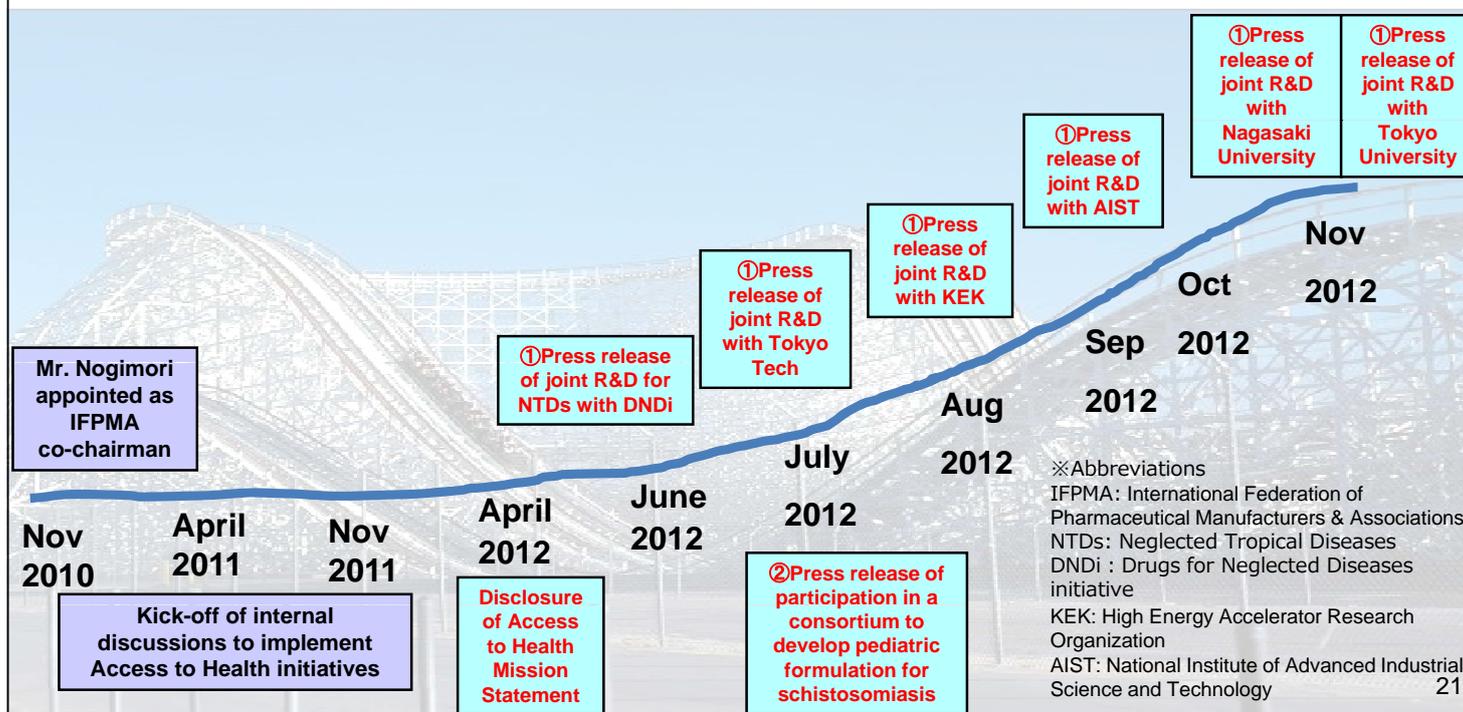
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We will improve Access to Health by

- utilizing our own strengths and assets (product, technology, know-how)
- collaborate with optimal partners

New “Access to Health” initiatives

- ① Collaborative drug discovery research for anti-protozoan compounds for NTDs
- ② Contribution to development of a pediatric formulation for treatment of schistosomiasis



New initiatives

1. New drug discovery research for anti-protozoan compounds for NTDs

⇒Utilizing our know-how and assets in drug discovery research

2. Contribution to development of a pediatric formulation for treatment of schistosomiasis

⇒Utilizing our cutting-edge pharmaceutical technology

New initiatives

1. New drug discovery research for anti-protozoan compounds for NTDs

⇒Utilizing our know-how and assets in drug discovery research

2. Contribution to development of a pediatric formulation for treatment of schistosomiasis

⇒Utilizing our cutting-edge pharmaceutical technology

Feature①

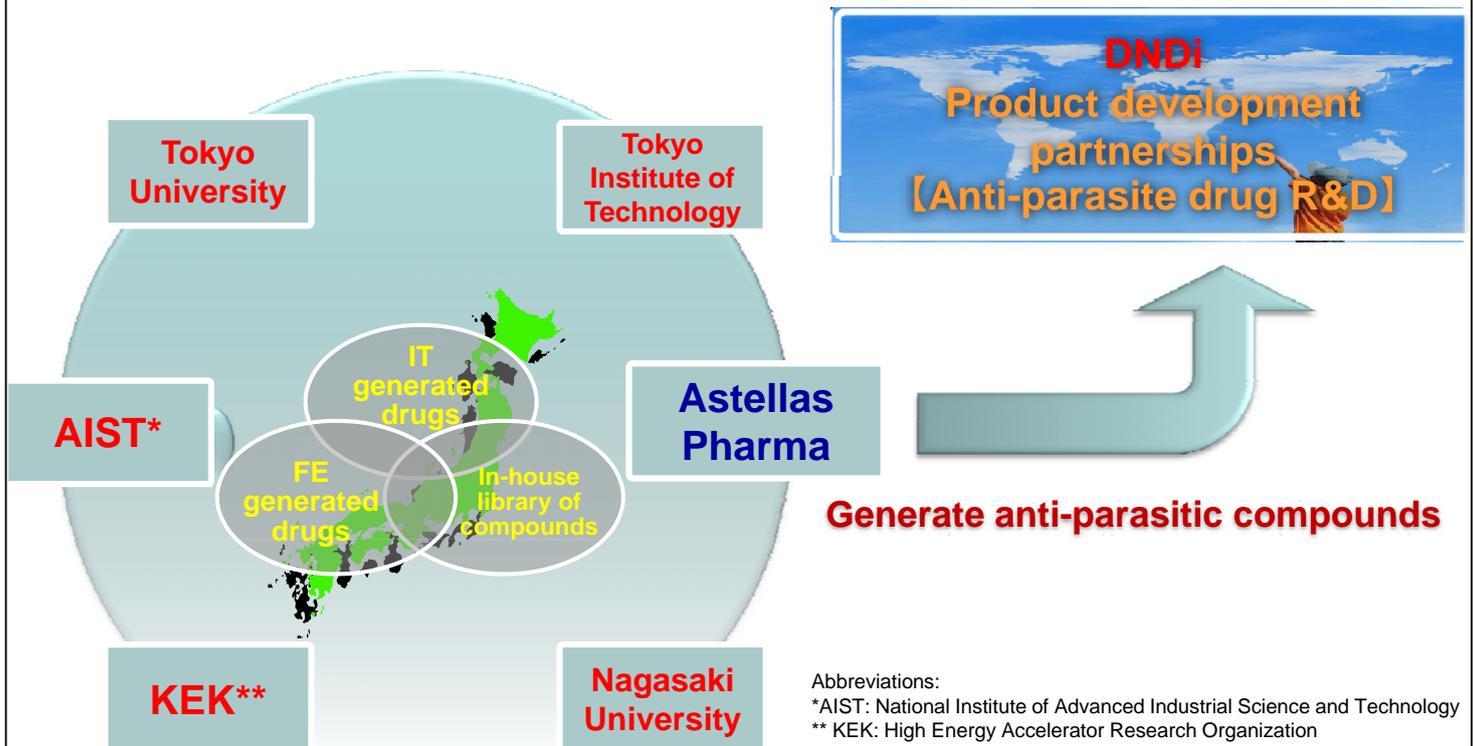
Select 3 NTDs with highly unmet medical needs
(Leishmaniasis, Chagas disease, and Sleeping sickness)

Feature②

Open innovation drug discovery approach

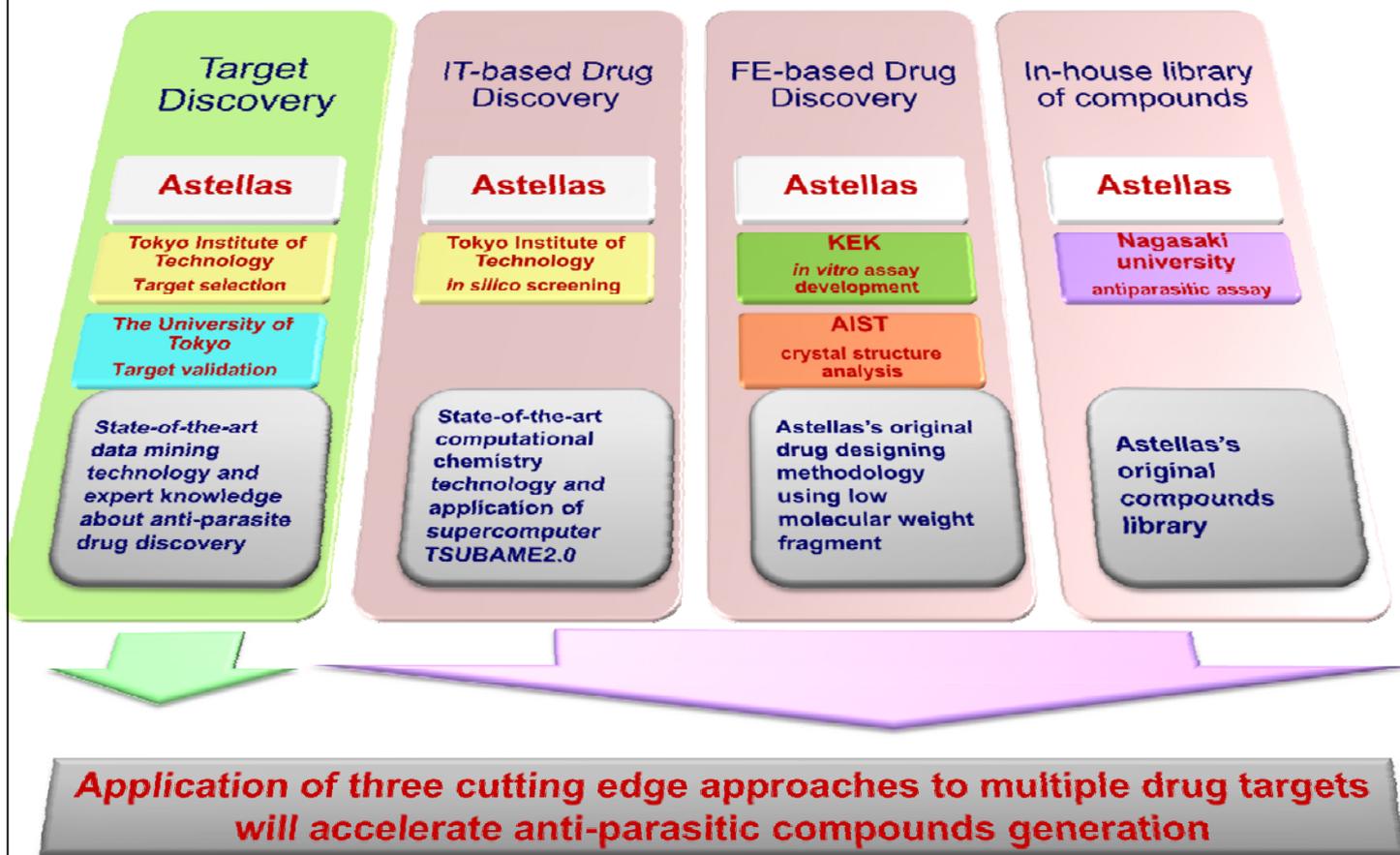
Overview of NTDs drug discovery collaboration

In cooperation with 5 research organizations in Japan through a public-private partnership, we will take three types of ultramodern approaches relating to new drug discovery



Target discovery and three cutting-edge approaches

New drug discovery research for NTDs



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Next steps

New drug discovery research for NTDs

We aim to contribute to the discovery of anti-parasite compounds for NTDs through continuous R&D activities

- Initiate evaluation of in-house compounds at the Swiss Tropical and Public Health Institute, a partner of DNDi
- Timely share information and research results within the collaborative drug discovery framework

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1. New drug discovery research for anti-protozoan compounds for NTDs

⇒ Utilizing our know-how and assets in drug discovery research

2. Contribution to development of a pediatric formulation for treatment of schistosomiasis

⇒ Utilizing our cutting-edge pharmaceutical technology

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The current difficulties of treatment of schistosomiasis

Pediatric formulation development for schistosomiasis

➤ Schistosomiasis –one of the most prevalent neglected diseases

- estimated approximately 200 million infected people
- mostly prevalent in African region
- high prevalence of infection in children



➤ A clear unmet medical need for a pediatric suitable formulation

- standard care with Praziquantel is only available for adults and older children and there is no pediatric formulation that can be used in the very young children age group
- very young children cannot swallow due large tablet size (1050mg, 23x8.5mm)
- strong bitter taste of active ingredients leads to low compliance for patients

Current drug



Access to Health

News Release

July 2, 2012

New public-private partnership to develop a treatment for schistosomiasis-infected preschool children

- **Astellas' contribution by utilizing our innovative pharmaceutical technologies**
- **Several formulations are under evaluation to consider the following points**
 - ✓ suitable formulation and size which infants (>3 months) can swallow
 - ✓ reduction of bitter taste
 - ✓ dosage adjustment
 - ✓ stability in hot and humid climates (ex: African region)
 - ✓ manufacturability
 - ✓ speedy development is preferred

The value of “Access To Health” initiative



- We endeavor to fulfill our **social mission as a pharmaceutical company** to contribute to the health of people worldwide
- **We believe that the Access to Health initiative brings a synergistic effect on our business activities from a long-term perspective**, such as establishing a new drug discovery model through partnerships with academia, as well as strengthening our relationships with various stakeholders involved in global health and building relationships with government and local partners in developing countries.



Astellas will continue our challenge to solve global health issues through our Access to Health initiatives



Changing tomorrow

