

## Astellas: Strategic Plan 2015-2017

**TOKYO, May 26, 2015** – Astellas Pharma Inc. (“Astellas”; TSE: 4503, headquarters: Tokyo; President and CEO Yoshihiko Hatanaka) announced a new three-year strategic plan 2015-2017 commencing from FY2015 (“this Strategic Plan”).

### Summary of this Strategic Plan

As Astellas, we will strive to create solid and resilient continuity of growth over the mid- to long-term through the pursuit of three main strategies – “Maximizing Product Value”, “Creating Innovation” and “Pursuing Operational Excellence”. In recent years, our business environment has presented various challenges, such as the containment of healthcare costs by various countries’ governments, the increasing influence of the payer, more complicated approval requirements, and the shortening of the product lifecycle. Despite this, we believe there are many new opportunities available to us, as an ethical pharmaceutical business, to provide innovative value to patients through progress of science, the continued existence of areas of high unmet medical needs and the emergence of new modalities and drug-discovery technology.

#### <Strategy>

##### **i. Maximizing the Product Value**

- Aim to maximize the value of product driving mid-term growth, such as Betanis/Myrbetriq/BETMIGA for the treatment of over active bladder (OAB) and XTANDI for the treatment of prostate cancer.

##### **ii. Creating Innovation**

- Prioritise investment in post-POC<sup>1)</sup> projects.
- Proactively seek new opportunities such as new therapeutic areas, new technologies and new modalities in addition to existing therapeutic areas and ensure sufficient investment is allocated to them.

##### **iii. Pursuing Operational Excellence**

- In order to respond to the rapidly changing environment, we will create flexible organizations and systems and work toward higher quality and efficiency of operations.

We will explore and grasp external business opportunities through acquisition, collaboration, and in-licensing.

<sup>1)</sup> POC : Proof of Concept

### <Creating Social Values, And Corporate Governance>

- Take advantage of our strengths and partnerships, work toward solving issues with Access to Health and aim to resolve social issues for long-term sustainability and enhance our corporate reputation
- Based on expectation and request from all stakeholders, aim at further improvement of government function including transparency, objectivity and mobility

### <Financial Guidance>

ROE <sup>2)</sup>	15% or more, Maintain and improve this level after the period of this Strategic Plan
Consolidated sales	CAGR (%): Mid-single digit
Core operating profit	CAGR that exceeds sales' CAGR
R&D expenses	Higher than 17% against sales
Core EPS	CAGR that exceeds CAGR of core operating profit
DOE	6% or more

<sup>2)</sup> ROE: Full base (IFRS)

ROE: Return on equity attributable to owners of parent

DOE: Dividend on equity attributable to owners of parent

### <Profit Distribution Policy>

Astellas is working aggressively toward increasing corporate value on a continuous basis and, as a consequence, improves its return to shareholders. While putting priority on business investment to assure future growth, Astellas will strive to increase dividend payments stably and continuously, taking into consideration the factors based on mid - to long-term profit growth on a consolidated basis. Furthermore, Astellas will flexibly acquire its own shares whenever necessary to further increase capital efficiency and shareholder return.

## Supplementary explanation of <Strategy>

### i. Maximizing Product Value

New products such as Betanis , Myrbetriq, BETMIGA for the treatment of OAB and XTANDI for the treatment of prostate cancer, will drive mid-to long-term growth during this Strategic Plan and after the patent expirations of products such as Vesicare for the treatment of OAB and Tarceva, an anticancer drug.

- Urology OAB franchise:  
Drive rapid market penetration of Betanis/Myrbetriq/BETMIGA and establish its position as a new therapeutic option for OAB treatment (CAGR (%): high single-digit ).
- Oncology franchise:  
Maximize the sales of XTANDI rapidly in chemo-naive indication, and pursue long-term growth by expanding indications (CAGR (%): mid 20s).
- Other Areas:  
Transplant field: Maintain our leadership position (tacrolimus CAGR (%): minus low single-digit).  
Other fields : Pursue rapid sales uptake by prioritizing resource allocation to new products in each region

### ii. Creating innovation

#### Enhance capability to create new drugs

Through our research network, Astellas aims to create innovative medicines efficiently by prioritizing allocation of resources and incorporating external innovation while utilising the multi-track research and development process with FASTEN (FAST-Ex-NEW-standard).

In addition to this, Astellas selects disease areas for research to focus on by considering changes in unmet needs and the latest feasibility for research and development as follows.

(listed as TAs<sup>3)</sup> basis)

- Current TAs: Urology, Oncology, Immunology, Nephrology and Neuroscience
- New TAs : Muscle Diseases and Ophthalmology

Development projects and research approaches by TAs are as follows:

- Urology: Aim to maintain and enhance our leadership position in the urology by addressing new urology disorders (nocturia with nocturnal polyuria, stress urinary incontinence, etc.) that have high unmet needs to build a next generation franchise. And aim to maximize the value of the OAB franchise by pursuing development of Vesicare and Myrbetriq/BETMIGA for pediatric indication and combination therapy (EB178).
  - Oncology: Aim to create a highly competitive pipeline through pursuing additional indications of enzalutamide and promoting the development of ASP2215 (FLT3/AXL inhibitor) and ASP8273 (selective variant irreversible EGFR inhibitor). And conduct drug
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discovery research with innovative approaches such as cancer immunology and cancer metabolism in the long-term by acquiring novel targets and new modalities.

- Immunology: While promoting the development of ASP015K (JAK inhibitor), aim to produce drugs for causal therapy/cure of immuno-related disorders. Furthermore, take advantage of the AK project operated jointly with Kyoto University to explore new drug discovery targets for several immunological diseases
- Nephrology: Aim to launch Roxadustat, as the first-in-class novel mechanism for oral treatment of anemia of CKD<sup>4)</sup>, and prove the efficacy of ASP8232, which is in early development.
- Neuroscience: Aim to obtain a POC for early development stage compounds in the area of psycho-neurologic diseases and pain with high unmet needs by drugs with new mechanism of action.

TAs<sup>3)</sup>: Therapeutic Areas

CKD<sup>4)</sup>: Chronic Kidney Disease

### **New opportunities**

Astellas will explore new opportunities in new therapeutic areas, including Muscle Diseases and Ophthalmology, and drug discovery research with new technologies and modalities such as regenerative medicine and next generation vaccines. While taking advantage of collaboration with external parties, Astellas will realize long-term growth through investment in innovation.

- In new therapeutic areas, we will work on Muscle Disease and Ophthalmology as the new focus disease areas of research and explore new research areas for future focus.
- In next generation vaccines, we will develop ASP0113 to prevent cytomegalovirus infection, ASP4070/JRC-LAMP-vax targeting hay fever and vaccinations to prevent infections from respiratory syncytial virus.
- Astellas will fully accelerate the research of cell therapy as a new modality targeting diseases with high unmet medical needs, such as cardiovascular disease and cancer. We expect to start our first clinical trial on stem cell formulation within a few years.
- As new business opportunities, we will explore innovative medical solutions that utilize our strengths (for example, accurate early diagnosis techniques that utilize antibody and imaging technologies, and products that contribute to reduction of surgery time and better outcomes.).
- Astellas will explore new uses of existing drugs or terminated development assets through applying new scientific approaches and technologies.

End

### Looking ahead

- We plan to hold a briefing on the Strategic Plan for securities analysts, institutional investors and journalists on Wednesday, May 27, 2015 at 13:30 – 15:00.
  - We intend to post details of the briefing (audio) and materials used on the day on our homepage soon after the meeting is held.
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