



# IR MEETING FOR INDIVIDUAL INVESTORS

Astellas Pharma Inc., (Securities Code 4503)



# CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice. Information about investigational compounds in development does not imply established safety or efficacy of the compounds; there is no guarantee investigational compounds will receive regulatory approval or become commercially available for the uses being investigated.

# AGENDA

I

**Introduction of Astellas**

II

Aiming for Sustainable Growth: Corporate Strategic Plan 2021 (CSP2021)  
for the period FY2021 to FY2025

III

Shareholder Return Policy

## VISION

On the Forefront of Healthcare  
Change to Turn Innovative  
Science into  
**VALUE for Patients**

We will achieve sustainable  
growth by pursuing innovative  
science to produce medical  
solutions that provide **VALUE**  
to patients

# CURRENT STATE OF THE PHARMACEUTICAL MARKET

## Classification of drugs

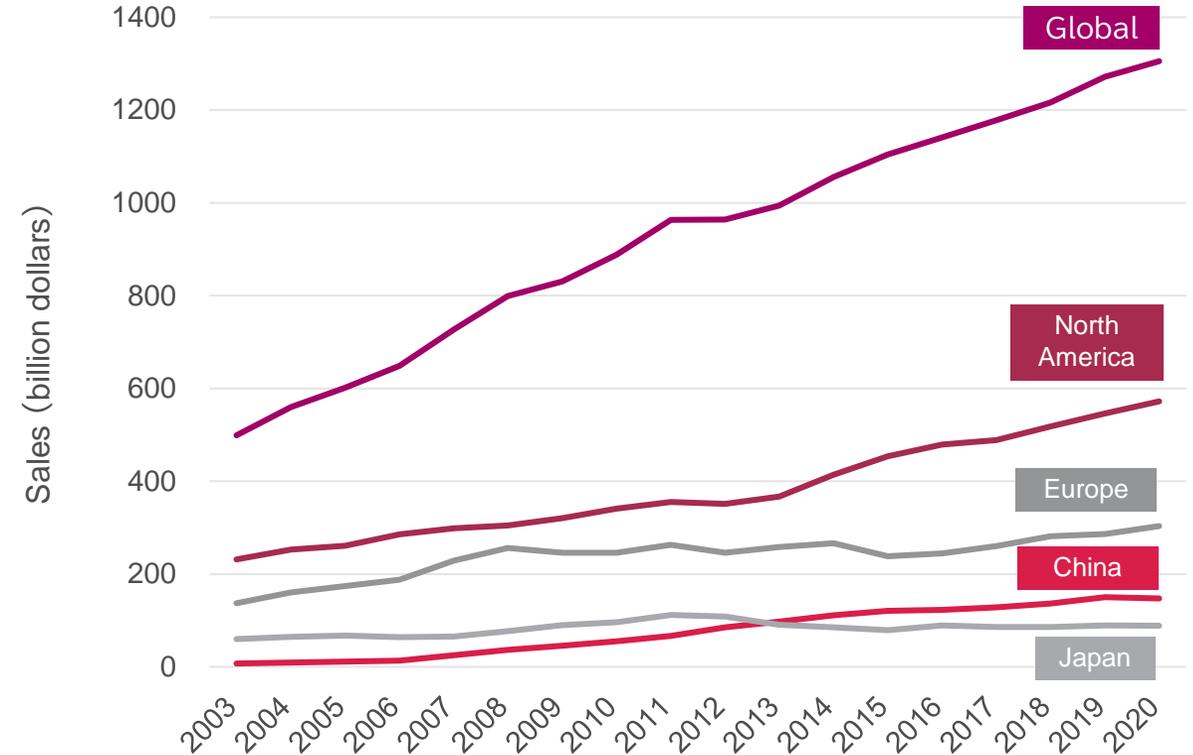


\*1 Percentage in Japanese market

Source: "Statistics of Production by Pharmaceutical Industry (2020)  
Table 1 Trends in Pharmaceutical Production Value" from the Ministry of Health,  
Labor and Welfare website (<https://www.mhlw.go.jp/topics/yakuji/2020/nenpo/>)

OTC: Over The Counter

## Global sales of ethical drugs\*2



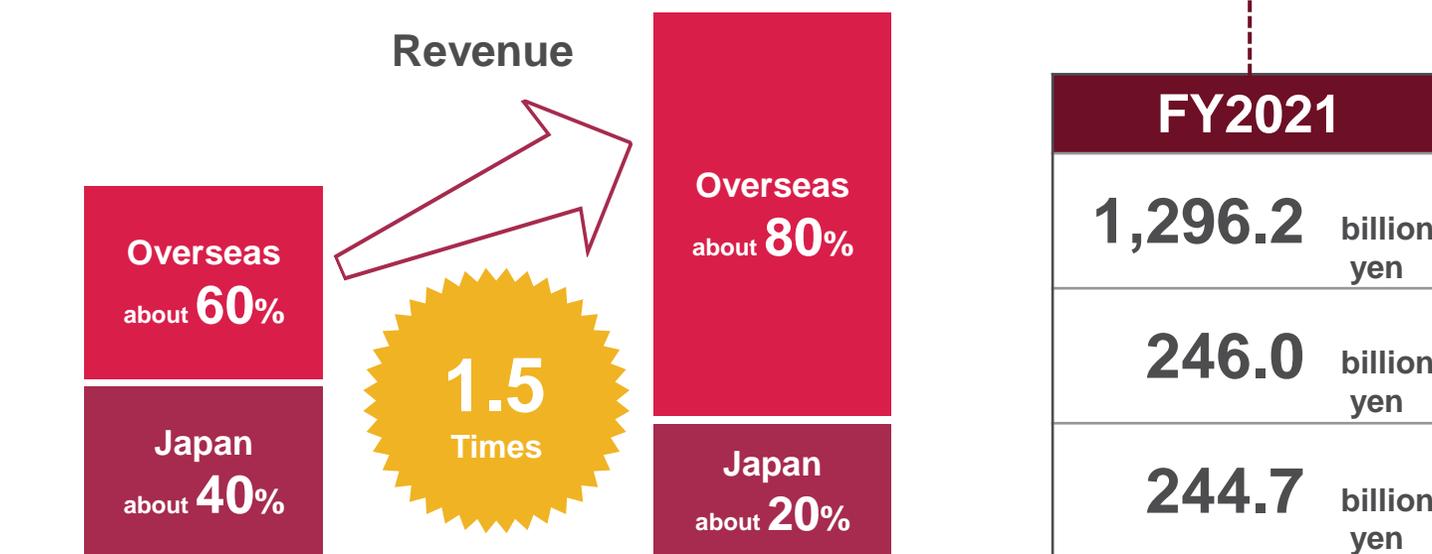
\*2 Source: Japan Pharmaceutical Manufacturers Association DATA BOOK 2022  
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Review, data period 2003 to 2020 (Reprinted with permission)



# ASTELLAS IN NUMBERS



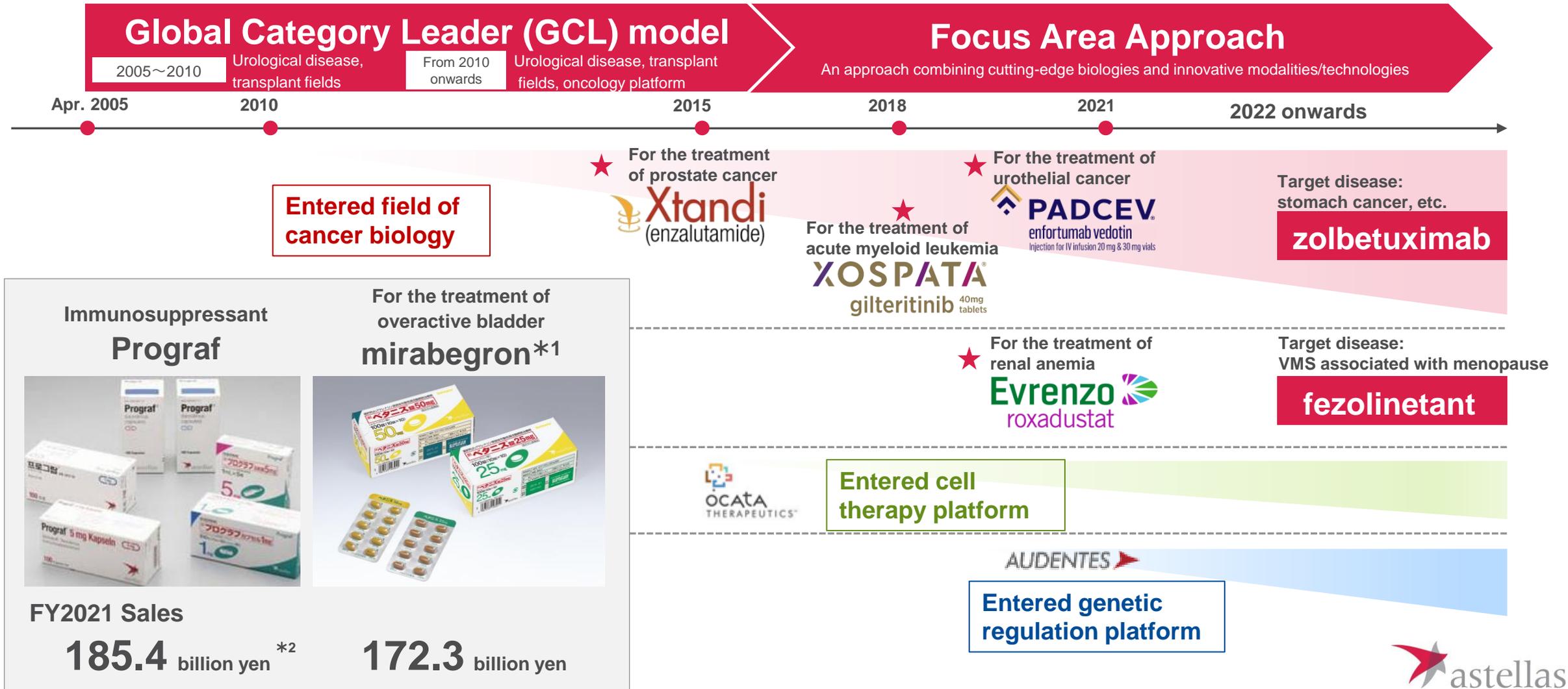
	FY2005
Revenue	<b>879.4</b> billion yen
R&D Expenses	<b>142.1</b> billion yen
Core OP*	<b>193.0</b> billion yen



\* Based on Japanese standards. OP: Operating Profit

# HISTORY OF ASTELLAS

As of Oct. 2022



\*1 Betanis, Myrbetriq, BETMIGA \*2 Including Advagraf, Graceptor, ASTAGRAF XL  
 VMS: Vasomotor Symptoms

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# PERFORMANCE GOALS

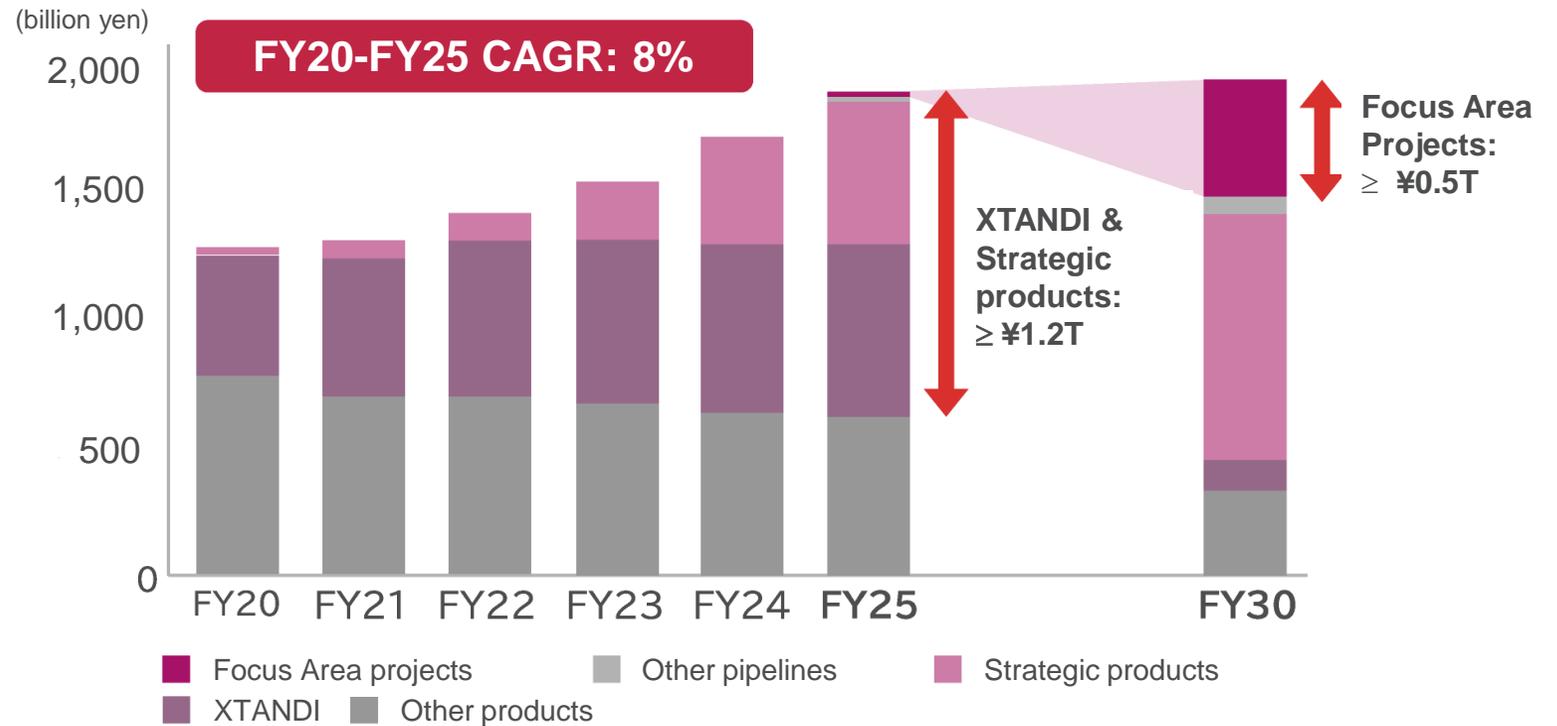
## Performance Goals of CSP2021

FY2025

- 1** XTANDI and Strategic products\* sales:  
≥ **¥1.2T in FY2025**
- 2** Focus Area projects expected sales:  
≥ **¥0.5T in FY2030**
- 3** Core OP Margin  
≥ **30% in FY2025**

Aim to become a company with a Market Cap valued at  
**7 trillion yen**

## Consolidated revenue forecast (Risk adjusted)



\* PADCEV, XOSPATA, zolbetuximab, EVRENZO, fezolinetant, AT132  
OP: Operating Profit

# XTANDI & STRATEGIC PRODUCTS: REVENUE

Products	FY2021 revenue (billion yen)	Global potential peak sales*1 (billion yen)
For the treatment of prostate cancer <b>XTANDI</b> 	<b>534.3</b>	<b>600 - 700</b>
Target disease: VMS associated with menopause <b>fezolinetant</b>	NDA/MAA submitted in US and EU PDUFA date in US Feb. 22, 2023	<b>300 – 500</b>
For the treatment of urothelial cancer <b>PADCEV</b> 	<b>21.7</b>	<b>300 – 400</b> <sup>*2</sup>
For the treatment of acute myeloid leukemia <b>XOSPATA</b> 	<b>34.1</b>	<b>100 – 200</b>
Target disease: stomach cancer, etc. <b>zolbetuximab</b>	P3 Plan: BLA in FY2023	<b>100 - 200</b>
For the treatment of renal anemia <b>EVRENZO</b> 	<b>2.6</b>	<b>50 - 100</b> <sup>*3</sup>



\*1 Only indications undergoing pivotal studies are included for projection (as of Oct 2022), \*2 Sales for Americas are calculated based on the sales booked by Seagen Inc. \*3 Astellas territories only; Japan, Europe, the Commonwealth of Independent States, the Middle East, South Africa, etc. VMS: Vasomotor Symptoms, NDA: New Drug Application, MAA: Marketing Authorization Application, PDUFA: Prescription Drug User Fee Act, BLA: Biologic License Application

# XTANDI & STRATEGIC PRODUCTS: REGULATORY TIMELINE

Product*	Target Filing Timing			
	FY2022	FY2023	FY2024	FY2025 or later
For the treatment of prostate cancer <b>XTANDI</b>		M0 CSPC	<div style="border: 1px solid red; padding: 5px;"> <p><b>fezolinetant</b></p> <p><b>Unmet medical needs for VMS</b>                      Since HRT was identified as posing a risk for other diseases, there has been no other alternative treatment for VMS for the past 20 years.</p> <p><b>First-in-class non-hormonal therapy (if approved)</b></p>  </div>	
Target disease: VMS associated with menopause <b>fezolinetant</b>	Moderate to severe VMS associated w/ menopause	NDA/MAA filed <b>PDUFA date in US Feb. 22, 2023</b>		
For the treatment of urothelial cancer <b>PADCEV</b>	mUC, previously untreated	sBLA filed <b>Accelerated Approval in US</b> based on EV-103 study cohort data	mUC, previously untreated(1L)	MIBC
For the treatment of acute myeloid leukemia <b>XOSPATA</b>		AML, post-HSCT maintenance		AML, newly diagnosed and HIC-eligible
Target disease: stomach cancer, etc. <b>zolbetuximab</b>		Gastric and GEJ adenocarcinoma		

\* Only indications undergoing pivotal studies are included (as of Oct. 2022). Subject to internal assessment, decision and regulatory consultation, as appropriate. Filing (submission) timing in the first country/region (either US, EU or JP)



M0 CSPC: Non-metastatic castration-sensitive prostate cancer, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplantation, HIC: High-intensity chemotherapy, mUC: Metastatic urothelial cancer, 1L: First line, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, NDA: New Drug Application, MAA: Marketing Authorization Application, PDUFA: Prescription Drug User Fee Act, sBLA: supplemental Biologic License Application, HRT: Hormone Replacement Therapy

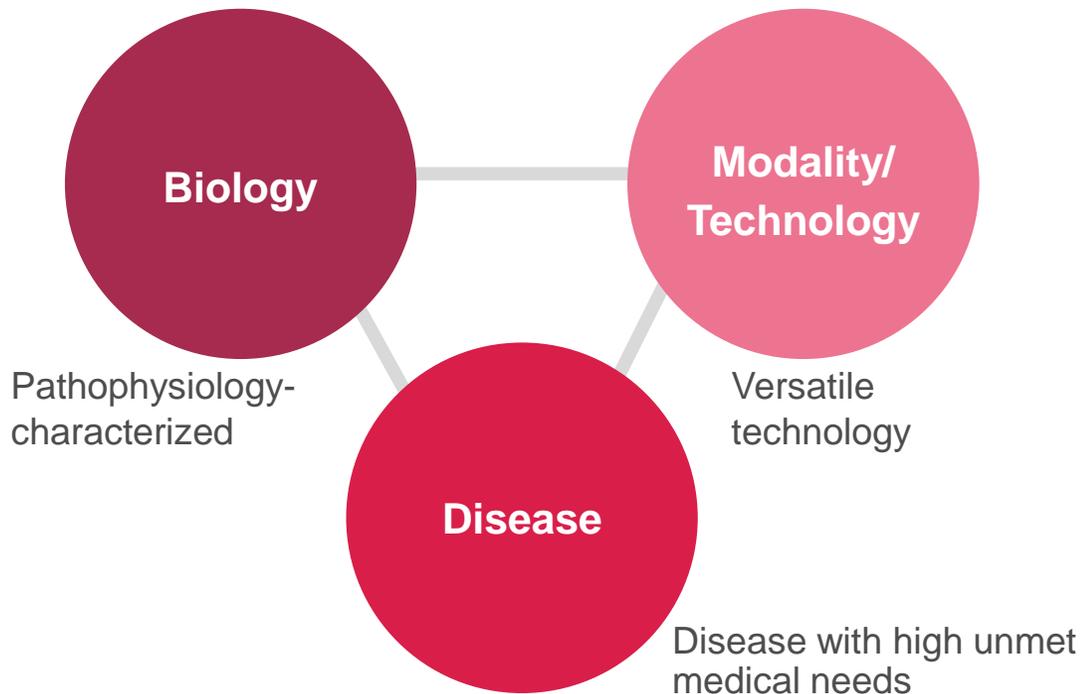
# TRANSLATE INNOVATIVE SCIENCE INTO PROVEN VALUE ASTELLAS R&D STRATEGY

## Focus Area Approach

is designed to identify drug discovery opportunities flexibly and efficiently by combining innovative biologies and modalities/ technologies to address diseases with high unmet medical needs

## Primary Focus

is a specific focal point within our Focus Area Approach where a lead and follow-on projects show a clear R&D path with expected VALUE for patients



Genetic Regulation



Immuno-Oncology



Blindness & Regeneration



Mitochondria



Targeted Protein Degradation

# CURRENT STATUS OF PROJECTS IN CLINICAL TRIAL

Primary Focus	Biology/Modality/Technology <sup>*1</sup>	No. of projects aiming for PoC by end FY25 <sup>*2</sup>
 Genetic Regulation	Gene replacement (AAV)	4
	Gene regulation (AAV)	
 Immuno-Oncology	Checkpoint	12
	Artificial adjuvant vector cell	
	Oncolytic virus (intratumoral)	
	Oncolytic virus (systemic)	
	Bispecific immune cell engager	
	Cancer cell therapy (UDC)	
 Blindness & Regeneration	Cell replacement	3
	Cell replacement (UDC)	
	Gene regulation (AAV)	
 Mitochondria	Gene regulation & mitochondrial biogenesis	4
	Mitochondrial stress	
	Mitochondrial transfer	
 Targeted Protein Degradation	Protein degradation	1
<b>Total</b>		<b>24</b>

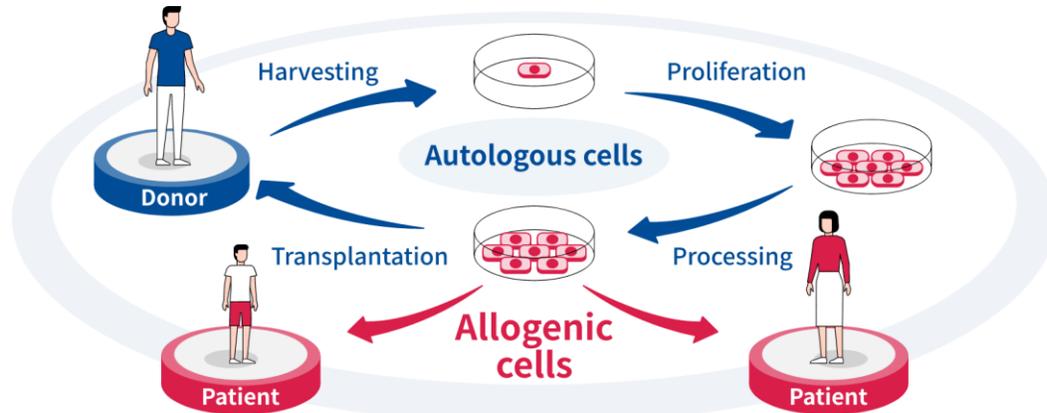


1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (as of Oct 2022)  
 PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

# FROM “DREAM” TO “REALITY”: AIM FOR CURATIVE THERAPIES OF DISEASES WITH A CLEAR RELATIONSHIP BETWEEN ETIOLOGY AND PATHOPHYSIOLOGY

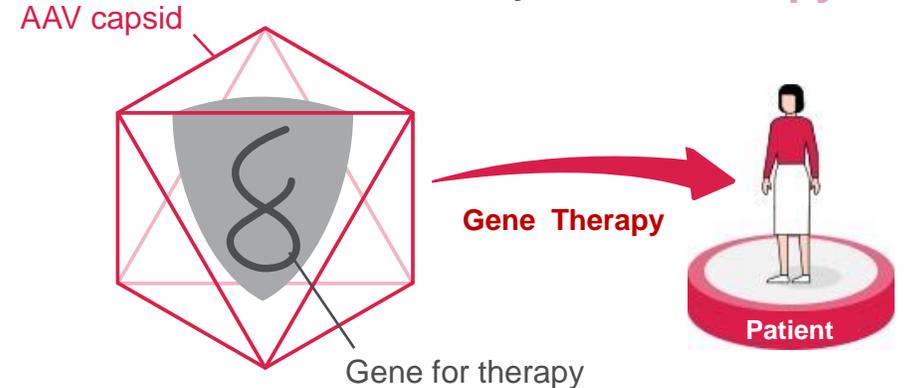
A disease caused by multiple factors, but with a clear loss of function due to the disease

## Regeneration of lost functions by **Cell Therapy**



Diseases caused by single gene deficiency/malfunction

## Replenishment of defective genes and restoration of function by **Gene Therapy**



Xyphos Biosciences  
(South San Francisco, California)



Universal Cells  
(Seattle, Washington)



Astellas Institute of Regenerative Medicine  
(Westborough, Massachusetts)



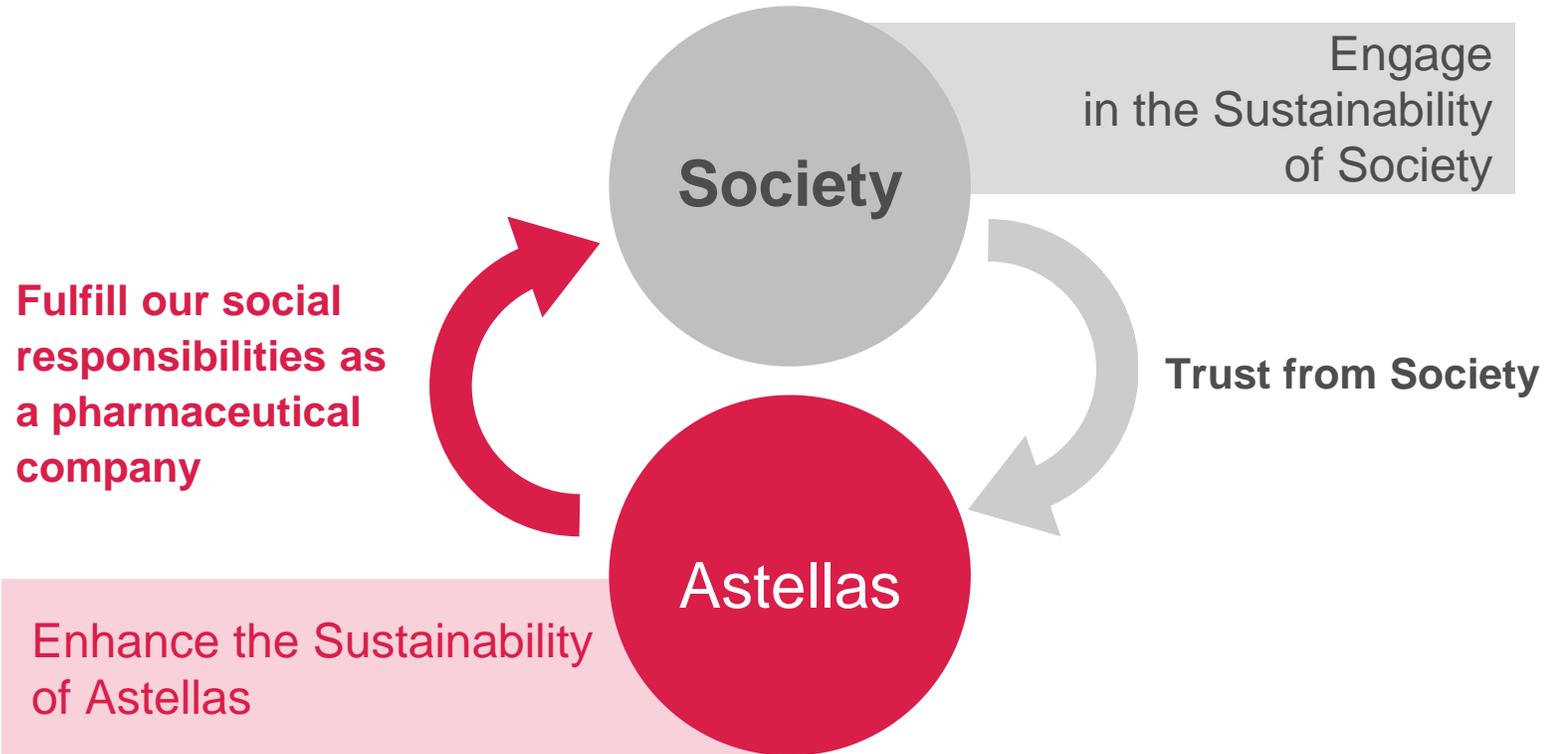
Astellas Pharma Inc.  
Tsukuba Research Center / Tsukuba Biotechnology Research Center  
(Tsukuba, Japan)



Astellas Gene Therapies  
(South San Francisco, California)



Astellas Gene Therapies  
(Sanford, North Carolina)



## Raison D'être

Contribute toward Improving the Health of People Around the World through the Provision of Innovative and Reliable Pharmaceutical Products

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## Mission

Sustainable Enhancement of Enterprise Value

# EXAMPLES OF ASTELLAS SUSTAINABILITY ACTIVITIES

## Aiming to improve patient access to innovative drugs



**35** countries  
**235** sites  
**over 900** cancer<sup>\*3</sup> patients

## Providing Astellas' Capabilities and Technologies

Praziquantel for Schistosomiasis  
 Contribution to the development of pediatric formulations <sup>\*1</sup>



## Environmental Initiatives

Biomass plastic for blister packages  
 (world's first, applied to limited products.)

Achieved close to zero Green House Gas emissions at the Kelly Plant, Ireland



<sup>\*1</sup> With funding from GHIT Fund and The European & Developing Countries Clinical Trials Partnership (EDCTP)  
<sup>\*2</sup> McManus, D.P., Dunne, D.W., Sacko, M. et al. Schistosomiasis. Nat Rev Dis Primers 4, 13 (2018)  
<sup>\*3</sup> acute myeloid leukemia

# INTEGRATED REPORT (FORMER ANNUAL REPORT)

Introducing,

- Astellas' initiatives for continuous VALUE creation aimed at sustainable growth.
- Astellas' medium- to long-term goals and current financial and non-financial initiatives in an easy-to-understand manner

<https://www.astellas.com/en/investors/integrated-report>



## CEO Interview

## Progress of Corporate Strategic Plan 2021

## Outside Director Interview

## Value Creation Model



Representative Director,  
President and CEO

**Kenji Yasukawa**



Representative Director,  
Executive Vice President  
Chief Strategy Officer (CStO)

**Naoki Okamura**



Chief Financial Officer (CFO)

**Minoru Kikuoka**



Outside Director,  
Audit & Supervisory  
Committee Member

**Haruko Shibumura**



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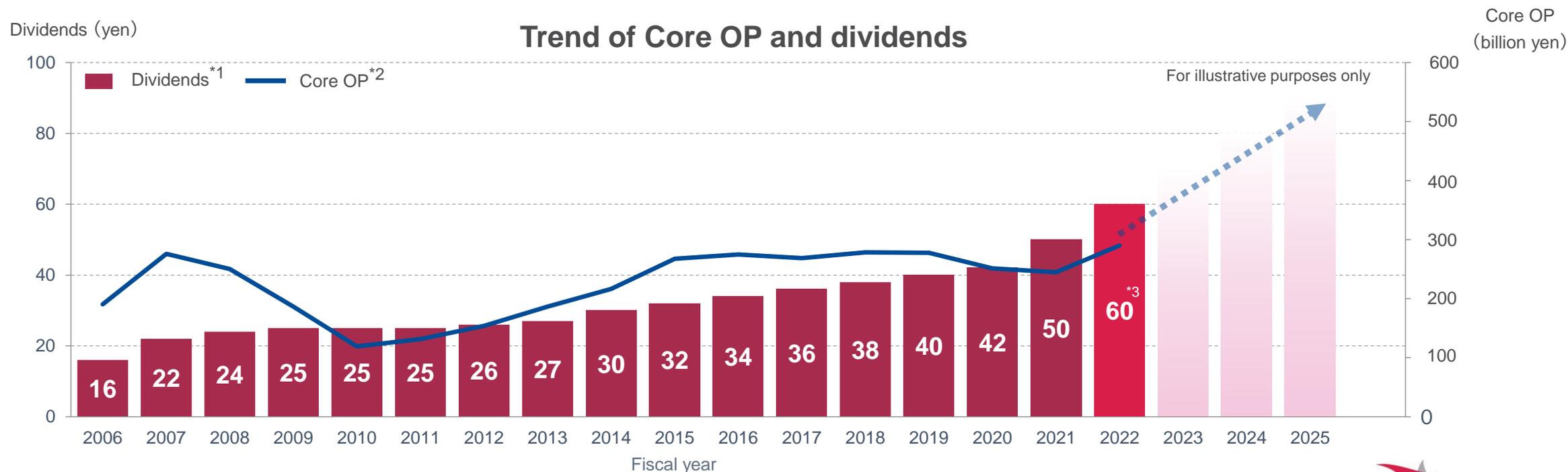
III

**Shareholder Return Policy**

# SHAREHOLDER RETURN POLICY

- Top priority is investment for business growth
- Raise dividend level aligned with profit / cashflow plan and actual performance throughout CSP2021 period
- Flexibly execute share buyback by excess cash

## Aiming for higher level of dividends increase during CSP2021 aligned with the robust profit growth forecast



\*1 Astellas conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014. The number of shares before FY2014 has been calculated on the assumption that the stock split was conducted. \*2 Prior to FY2012, operating profit (OP) is in accordance with J-GAAP, \*3 Prediction

# STOCK PRICE

Stock Price  
(high price) (yen)

2,500

2,000

1,500

1,000



**Record-high**  
**2,205 (Jul. 27, 2022)**

**CSP2021**

Jan. 1, 2021    Apr. 1, 2021    Jul. 1, 2021    Oct. 1, 2021    Jan. 1, 2022    Apr. 1, 2022    Jul. 1, 2022    Oct. 1, 2022

## Performance Goals of CSP2021

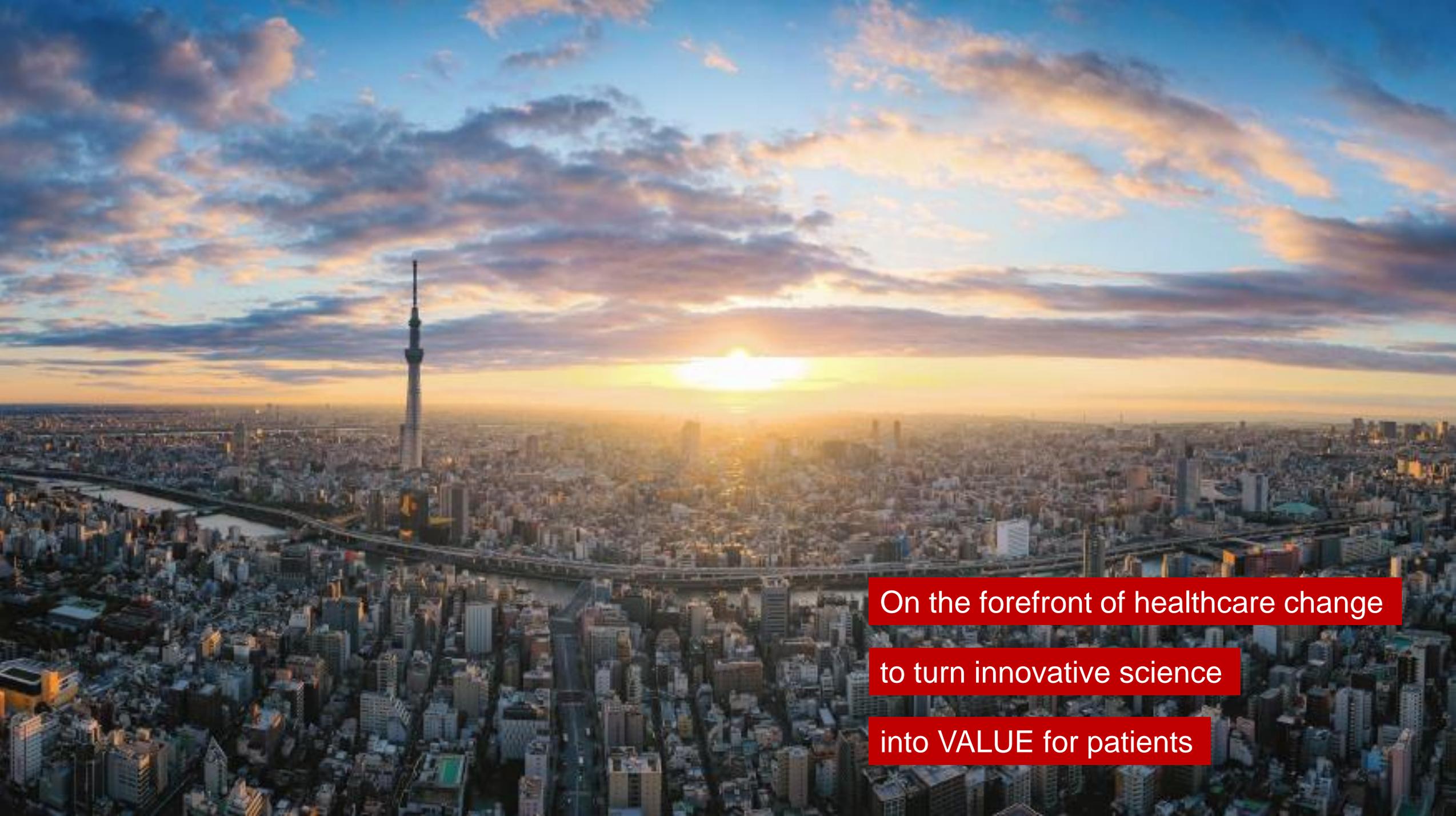
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On the forefront of healthcare change  
to turn innovative science  
into VALUE for patients

# ON THE FOREFRONT OF HEALTHCARE CHANGE

