# DELIVERING AND CREATING VALUE FOR PATIENTS

J.P. Morgan Healthcare Conference



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## 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.



# 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

**Common Definition of** 

**VALUE\*** 



## **Outcomes**

that matter to patients

### Cost

to the healthcare system of delivering those outcomes



#### THREE STRATEGIC GOALS FOR SUSTAINABLE GROWTH





<sup>\*</sup>Key products and late-stage pipeline

#### CURRENT AND POTENTIAL GROWTH DRIVERS

If all succeed, we forecast the potential annual sales from 6 key post-POC products to reach approximately 1 trillion yen in next 10 years.

Current growth drivers







Six key post-POC programs enzalutamide

Earlier stage prostate cancer gilteritinib

Acute myeloid leukemia

enfortumab vedotin

Metastatic urothelial cancer

zolbetuximab

Gastric and gastroesophageal junction adenocarcinoma

roxadustat

Anemia associated with chronic kidney disease

fezolinetant

Menopause-related vasomotor symptoms



# STEADY PROGRESS IN ACCORDANCE WITH THE STRATEGIC PLAN

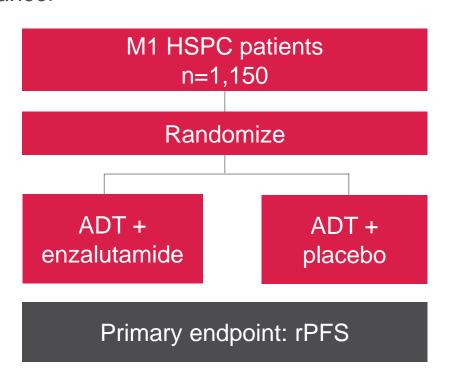
Multiple achievements after the announcement of strategic plan in May 2018

Regulatory approval	enzalutamide: gilteritinib:	Expansion to M0 CRPC in US and Europe R/R AML in Japan and US (Approval based on interim results)
Regulatory filing	roxadustat:	Anemia associated with CKD on dialysis in Japan
Data readout	enzalutamide: gilteritinib: roxadustat: fezolinetant:	P3 ARCHES study P3 ADMIRAL study Multiple global/Japanese P3 studies P2b study
Study progress	enfortumab vedotin: zolbetuximab:	Data from cohort 1 in pivotal P2 study expected in 1Q/2019 FPI achieved in P3 SPOTLIGHT study



## ENZALUTAMIDE: TOP LINE RESULTS OBTAINED FROM PHASE 3 ARCHES STUDY

Pursue further opportunity to expand the indication in earlier stage of prostate cancer



- The study met its primary endpoint, significantly improving rPFS
- The preliminary safety analysis appears consistent with the safety profile of XTANDI in previous clinical trials in CRPC.

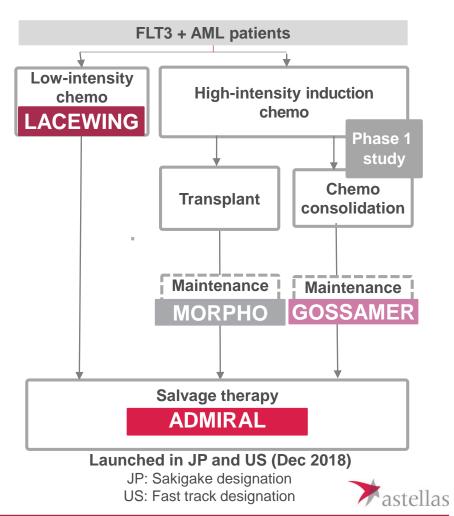




#### GILTERITINIB: LAUNCHED IN US AND JAPAN IN DEC 2018

#### First FLT3-targeting agent approved for r/r AML

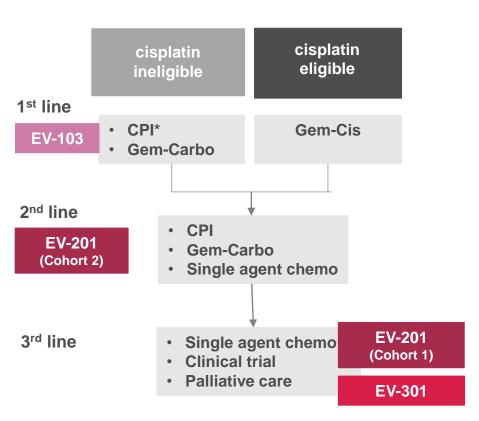
- Inhibit both FLT3-ITD mutation which is associated with poor prognosis, and FLT3-TKD mutation which is associated with treatment resistance
- Multiple ongoing studies in a wide range of disease stages
- Encouraging data in r/r AML
  - -CR/CRh of 21% in interim data of P3 ADMIRAL (US label)
  - Overall survival of 7.7 months in P1/2 CHRYSALIS
  - -Overall survival data from ADMIRAL study is available, to be presented in an upcoming meeting



# ENFORTUMAB VEDOTIN: REGISTRATIONAL PHASE 2 STUDY ONGOING

#### The first and we believe only ADC targeting nectin-4

- Nectin-4 is a transmembrane antigen expressed in several tumors including urothelial cancer
- Using ADC to deliver a cytotoxic agent specifically to the tumor
- FDA granted Breakthrough therapy designation for metastatic urothelial cancer with prior CPI treatment
- Encouraging data of Phase 1 study (ASCO2018)
  - -ORR of 41%
  - -Interim median OS of 13.6 months



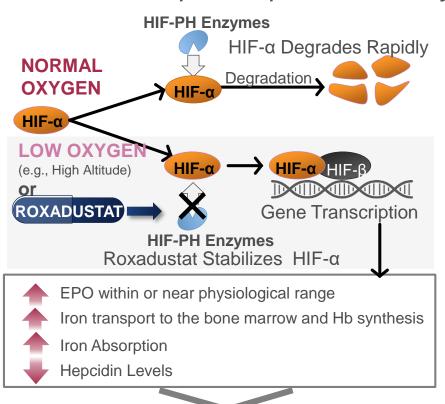
**Note)** Overall treatment flow is similar among regions even though the standard of care and approved drugs varies.

#### **SeattleGenetics**



#### ROXADUSTAT: MODE OF ACTION AND ITS CONCEPT

Potential first-in-class oral treatment for anemia associated with CKD and filed in Japan for patients in dialysis in Sep. 2018



- Potential new treatment option that is oral and reduces the need for intravenous iron
- Potential to avoid treatment burden in existing therapy
- Robust Phase 3 program to support regulatory filings and establish reimbursement in EU and Japan



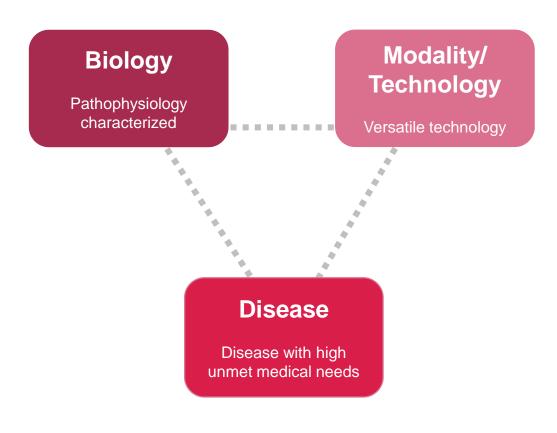
**Red Blood Cell Production** 





#### R&D STRATEGY: FOCUS AREA APPROACH

#### Focus on unique combinations of Biology and Modality/Technology



Clinical pipeline based on Focus Area approach

#### Cancer immunology

ASP8374/PTZ-201: P1 ASP1948/PTZ-329: P1 ASP1951/PTZ-522: P1

#### **ASIM**

ASP4070: P2 ASP0892: P1

#### Regeneration

ASP7317: P2

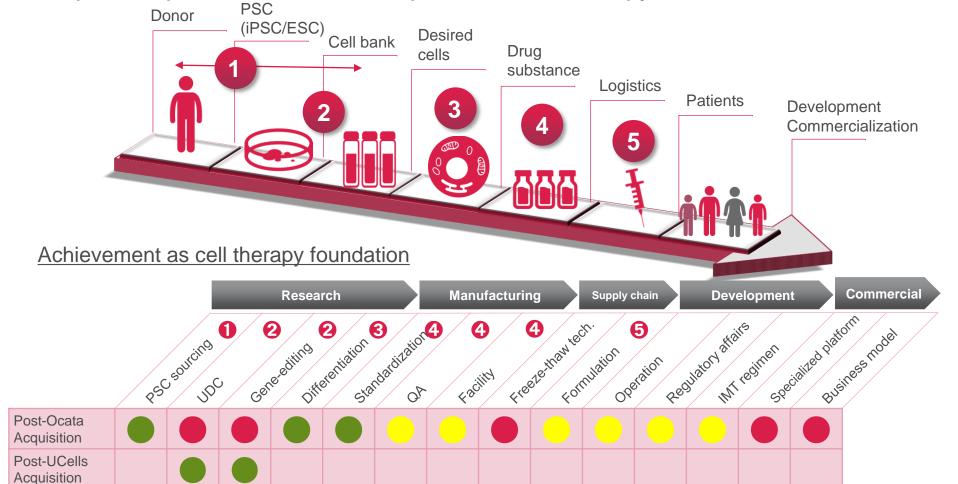
#### Mitochondria

MA-0211 MA-0217



#### ESTABLISHED CAPABILITIES IN REGENERATIVE MEDICINE

Acquired capabilities to realize the promise of cell therapy

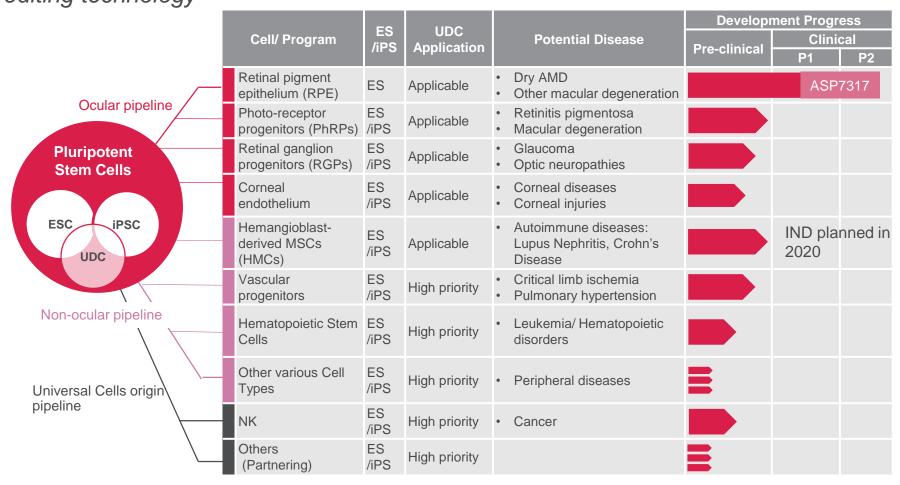


**Current AIRM** 

<sup>●:</sup> Established, ●: Underway, ●: Not Established / To be considered

## SNAPSHOT OF ASTELLAS REGENERATIVE MEDICINE PROGRAM

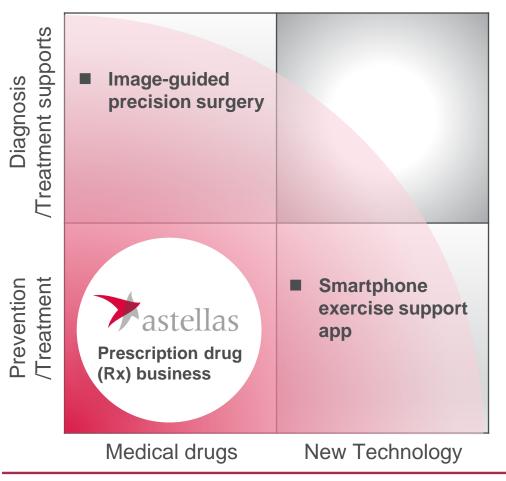
Initiated efforts in ophthalmology and expanding to other organs, using new gene editing technology



ES: Embryonic stem cell, iPS: Induced pluripotent stem cell, AMD: Age-related macular degeneration. IND: Investigational new drug application UDC: Universal donor cell (Universal Cells' proprietary to create cell therapy products that do not require human leukocyte antigen matching, potentially overcoming a huge treatment challenge by reducing the risk of rejection)

## DEVELOPING Rx+TM PROGRAMS

Steady progress and continuing to capture new business opportunities



Initiatives to build connections and networks with technology and knowledge from various fields

Rx+™ Business:
 Established US base

Astellas Rx+ Business Accelerator, LLC.

Venture Capital collaborations



strategic healthcare investment partners



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