Q2/FY2020 FINANCIAL RESULTS
ENDED SEPTEMBER 30, 2020

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President and CEO
Astellas Pharma Inc.
October 30, 2020

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.

AGENDA

I Q2/FY2020 Consolidated Financial Results and FY2020 Revised Forecasts

II Initiatives for Sustainable Growth

Q2/FY2020 FINANCIAL RESULTS

(billion yen)	Q2/FY19	Q2/FY20	Change	Change (%)	CER growth
Revenue	**650.5**	**615.5**	**-35.0**	**-5.4%**	-4.6%
Cost of sales	138.9	119.5	-19.3	-13.9%	
% of revenue	21.3%	19.4%	-1.9 ppt		
SG&A expenses	226.1	242.1	+16.1	+7.1%	
R&D expenses	105.0	111.7	+6.7	+6.4%	
Amortisation of intangible assets	11.2	11.5	+0.3	+3.1%	
Core operating profit	**168.0**	**130.3**	**-37.7**	**-22.4%**	-18.5%
<Full basis>					
Other income	7.2	4.3	-3.0	-	
Other expense	13.0	47.7	+34.7	-	
Operating profit	**162.2**	**86.9**	**-75.3**	**-46.4%**	
Profit before tax	161.6	89.1	-72.5	-44.9%	
Profit	**128.5**	**72.8**	**-55.7**	**-43.3%**	

Q2/FY2020 FINANCIAL RESULTS: REVENUE

Main products and new products continue to grow strongly

Q2/FY2020 actual

(billion yen)

XTANDI	**225.5**	**+30.5**
XOSPATA	**11.0**	**+5.2**
PADCEV	**6.0**	**+6.0**
mirabegron	**80.0**	**+1.2**
New products in Japan	**34.9**	**+7.1**

Growth of main products and new products

+50.1 billion yen

Consolidated revenue for Q2/FY2020: -35.0 billion yen, YoY

- ✓ Sales decreases from termination of sales and distribution in Japan and loss of exclusivity
- ✓ Lexiscan, Geninax, etc. negatively impacted by COVID-19

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PADCEV: Co-promotion revenue from Seagen
mirabegron (Betanis/Myrbetriq/BETMIGA)
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

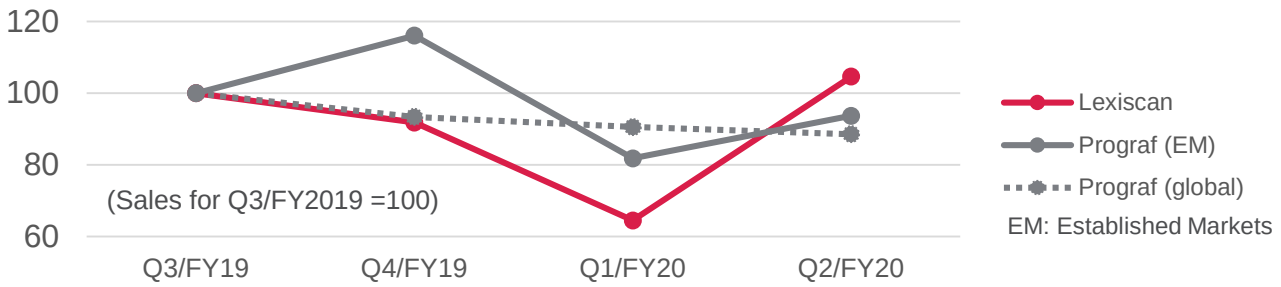
Q2/FY2020 FINANCIAL RESULTS: PROGRESS AGAINST FORECAST

- Core basis Q2/FY2020 financial results are in line with full-year forecast revised in August 2020

	Q2/FY20	FY20 FCST	Progress against FCST
Revenue	615.5 bil. yen	1,256.5 bil. yen	49.0%
Core OP	130.3 bil. yen	251.0 bil. yen	51.9%

  - ✓ Steady growth of main products such as XTANDI, XOSPATA and PADCEV
  - ✓ Sales decreases from termination of sales and distribution in Japan and LOE
  - ✓ Moderate impact of COVID-19 compared to Q1/FY2020, as expected

Quarterly sales trend



- Full basis: Booked impairment losses, not included into full-year forecast
  - ✓ Impairment losses on intangible asset due to termination of development for ASP8374 (30.5 billion yen)

LOE: Loss of exclusivity
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

FY2020 REVISED FORECAST

- No changes have been made to Core basis FY2020 forecast

(billion yen)	Q2/FY20 Actual	Forecast (Revised in Aug.)
Revenue	**615.5**	**1,256.5**
R&D expenses	111.7	233.5
Core operating profit	**130.3**	**251.0**
Core profit	**106.2**	**200.5**

Forecast: No changes

- Downward revision of Full basis profit due to impairment losses on intangible asset

(billion yen)	Q2/FY20 Actual	Forecast (Revised in Aug.)	Revised Forecast	Change
Operating profit	**86.9**	**246.5**	**210.5**	**-36.0**
Profit	**72.8**	**197.5**	**169.5**	**-28.0**

AGENDA

I Q2/FY2020 Consolidated Financial Results and FY2020 Revised Forecasts

II Initiatives for Sustainable Growth

KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q1/FY2020 Financial Results Announcement in Aug 2020)

enzalutamide

M0 CRPC

- Approved in US in Oct 2020 and filed in EU in Jun 2020 for label update to include the OS data

M1 CSPC

- Filed in EU in Jul 2019

M0 CSPC

- Phase 3 study ongoing

China

- **M0 CRPC:** Filed in Oct 2019
- **M1 CSPC:** Phase 3 study ongoing

roxadustat

Anemia associated with CKD

- **EU:** Filed in Apr 2020
- **JP:** Filed for non-dialysis in Jan 2020

Chemotherapy-induced anemia

- Phase 2 study ongoing

gilteritinib

R/R AML

- **China:** Filed in Mar 2020

Earlier-stage AML

- Phase 3 studies ongoing

zolbetuximab

Gastric & GEJ adenocarcinoma

- Phase 3 studies ongoing

Pancreatic adenocarcinoma

- Phase 2 study ongoing

fezolinetant

MR-VMS

- **US & EU:** LSLV for 12w DB period achieved in Phase 3 SKYLIGHT 2 study and enrollment completed in SKYLIGHT 1 study.
  Patient screening closed in long-term SKYLIGHT 4 study
- **Asia:** Phase 3 studies ongoing

enfortumab vedotin

mUC

- **Previously treated:**
  Met the primary endpoint (OS) in Phase 3 EV-301 study in patients, platinum and PD-1/L1 inhibitor pretreated.
  Obtained positive results (ORR) in Phase 2 EV-201 study Cohort 2 in patients, PD-1/L1 inhibitor pretreated, platinum-naïve and cis-ineligible
- **Previously untreated (first line; combo with pembrolizumab):**
  Phase 3 study ongoing
- **China:** Currently under preparation to join global studies in mUC.
  IND filed for China bridging study

MIBC (combo with pembrolizumab)

- Entered into Phase 3

Other solid tumors

- Phase 2 study ongoing

AT132 (resamirigene bilparvovec) XLMTM

- Clinical study for registration put on clinical hold by FDA, due to serious adverse events

Genetic Regulation

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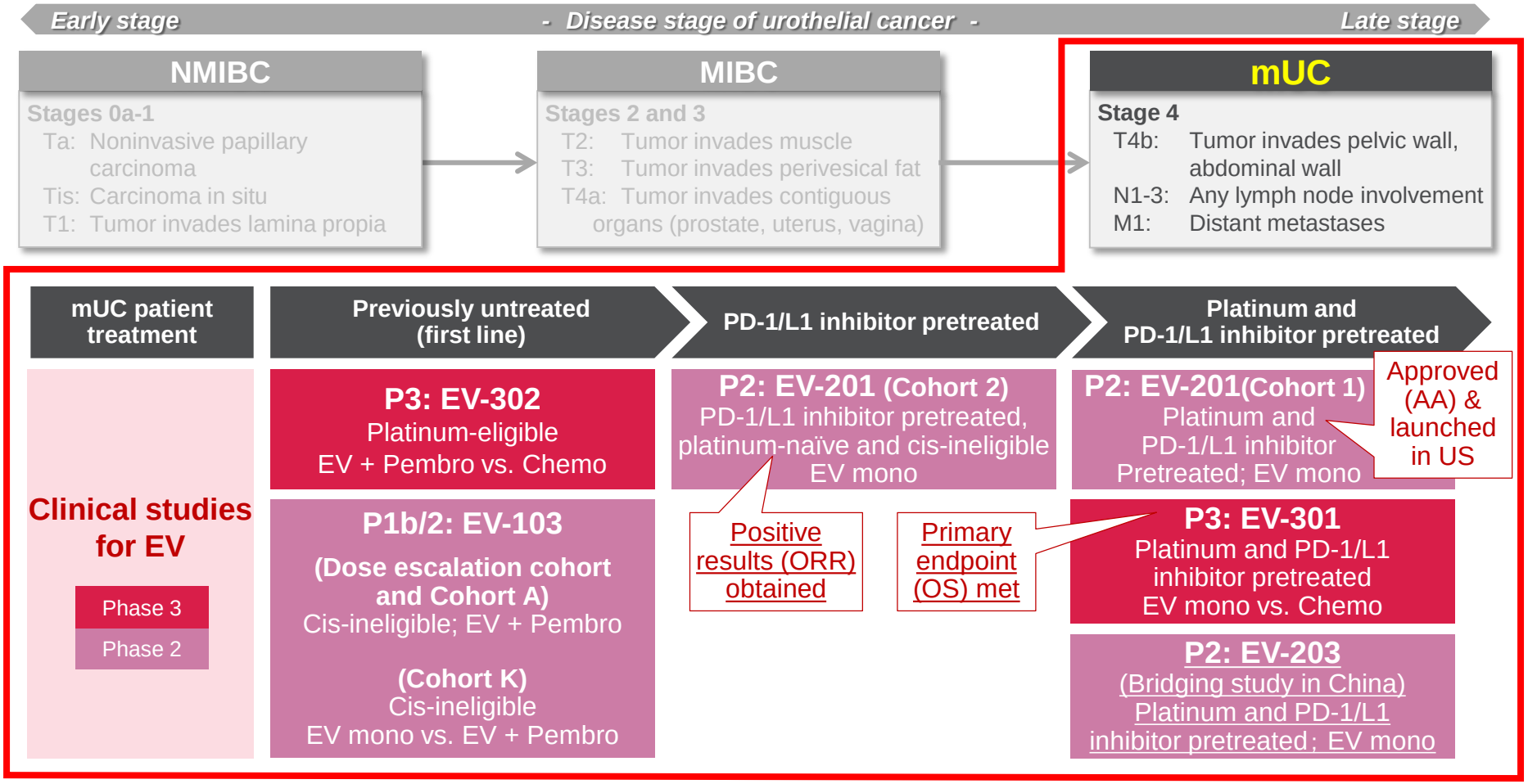
PoC: Proof of concept, M0: Non-metastatic, M1: Metastatic, CRPC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, GEJ: Gastroesophageal junction, mUC: Metastatic urothelial cancer, ORR: Objective response rate, MIBC: Muscle-invasive bladder cancer, IND: Investigational New Drug application, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptoms, LSLV: Last subject last visit, DB: Double-blinded, XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration

ENFORTUMAB VEDOTIN (EV) (1/5): OVERALL mUC PROGRAM



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Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

NMIBC: Non-muscle invasive bladder cancer, MIBC: Muscle invasive bladder cancer, mUC: Metastatic urothelial cancer, Cis: Cisplatin, mono: Monotherapy, Pembro: Pembrolizumab, Chemo: Chemotherapy, AA: Accelerated Approval, ORR: Objective response rate, OS: Overall survival

ENFORTUMAB VEDOTIN (EV) (2/5): mUC PROGRAM UPDATES

- **Global development**
  - ✓ Phase 3 EV-301 study in mUC, platinum and PD-1/L1 inhibitor pretreated:
    Met the primary endpoint of OS (HR=0.70; p=0.001) and the secondary endpoint of PFS (HR=0.61; p<0.00001), compared to chemotherapy, based on the planned interim analysis
    => *US-sBLA submission planned to convert from Accelerated Approval to Regular Approval, and global registration such as EU and Japan also planned*
  - ✓ Phase 2 EV-201 study Cohort 2 in mUC, PD-1/L1 inhibitor pretreated, platinum-naïve and cis-ineligible: Obtained positive topline results, ORR 52%
    => *US-sBLA submission planned to expand the indication in the US*
- **Development in China**
  - ✓ Previously treated - EV monotherapy:
    IND filed to conduct China bridging study (Phase 2 EV-203 study) in mUC, platinum and PD-1/L1 inhibitor pretreated, to bridge the global Phase 3 EV-301 and Phase 2 EV-201 study data for China registration
  - ✓ Previously untreated (first line) - EV + pembrolizumab combo:
    To add sites in China in the ongoing global Phase 3 EV-302 study

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mUC: Metastatic urothelial cancer, OS: Overall survival, HR: Hazard ratio, PFS: Progression free survival,
sBLA: Supplemental Biologics License Application, ORR: Objective response rate, IND: Investigational New Drug application

ENFORTUMAB VEDOTIN (EV) (3/5): MIBC TREATMENT OVERVIEW

Early stage — *Disease stage of urothelial cancer* — *Late stage*

NMIBC

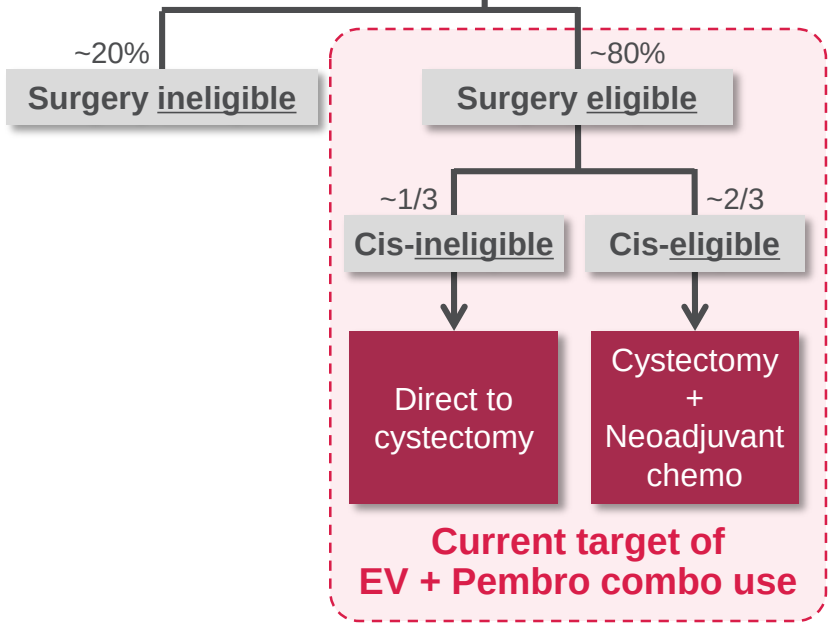
Stages 0a-1
- Ta: Noninvasive papillary carcinoma
- Tis: Carcinoma in situ
- T1: Tumor invades lamina propia

MIBC

Stages 2 and 3
- T2: Tumor invades muscle
- T3: Tumor invades perivesical fat
- T4a: Tumor invades contiguous organs (prostate, uterus, vagina)

mUC

Stage 4
- T4b: Tumor invades pelvic wall, abdominal wall
- N1-3: Any lymph node involvement
- M1: Distant metastases



MIBC treatment *

(* Approved drugs and SoC varies by region)

- Radical cystectomy (RC) plus pelvic lymph node dissection (PLND) is the established SoC
- In cis-eligible, “neoadjuvant chemo" has emerged as the preferred modality of delivering systemic therapy to nonmetastatic MIBC patients planning RC

Unmet medical needs

- Despite RC + PLND, approximately 40% die from metastatic disease within 3 years of diagnosis [1]
- Treatment options are limited to cisplatin based regimens. Patients who are cis-ineligible currently have no available systemic therapies

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1: Stein JP, *et al.*, 2001

NMIBC: Non-muscle invasive bladder cancer, MIBC: Muscle invasive bladder cancer, mUC: Metastatic urothelial cancer, Cis: Cisplatin, Chemo: Chemotherapy, SoC: Standard of care, Pembro: Pembrolizumab

ENFORTUMAB VEDOTIN (EV) (4/5): MIBC DEVELOPMENT PROGRAM

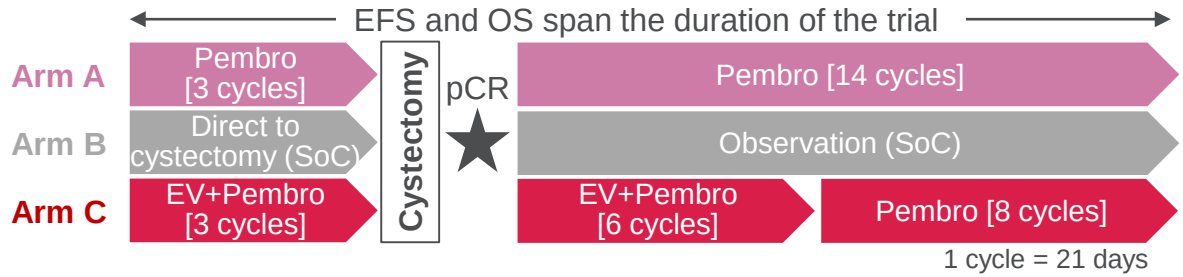
To expand the potential of EV and Pembro combo to MIBC, where high unmet medical needs still exist

Rationales of EV + Pembro use for MIBC

- EV + Pembro has shown promise as a platinum free option in the EV-103 study results for first line mUC
- The combo may have potential to enhance anti-tumor activity by evoking adaptive immunity, supported by the non-clinical data

Pivotal studies in MIBC

1) Phase 3 study in *cis-<u>ineligible</u>* MIBC (KEYNOTE-905):
Perioperative EV + Pembro vs. Cystectomy alone



- Endpoints:
  - ✓ Primary (dual): EFS and pCR
  - ✓ Key secondary: OS
- n=836, randomized 1:1:1
- Arm C added to the ongoing Merck's KEYNOTE-905 study

2) Phase 3 study in *cis-<u>eligible</u>* MIBC: Under preparation (in collaboration with Seagen and Merck)

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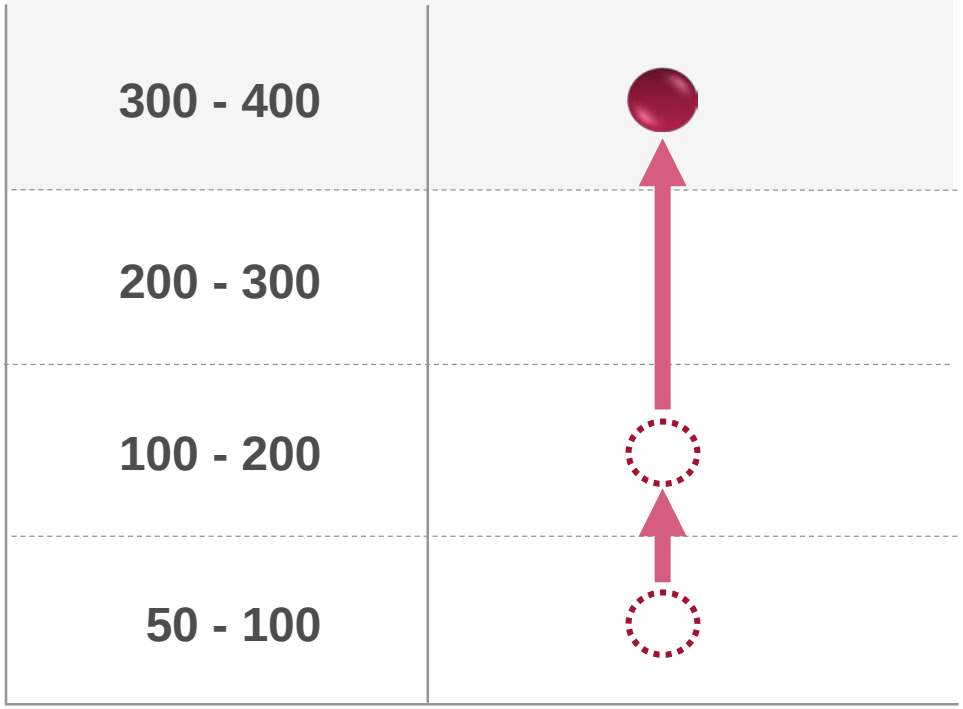
MIBC: Muscle invasive bladder cancer, Pembro: Pembrolizumab, mUC: Metastatic urothelial cancer, Cis: Cisplatin, Gem: Gemcitabine, SoC: Standard of care, EFS: Event-free survival, pCR: Pathologic complete response, OS: Overall survival

ENFORTUMAB VEDOTIN (EV) (5/5):
UPDATED POTENTIAL SALES SIZE

Significant upward revision
Potential peak sales in mUC and MIBC to be 300.0 - 400.0 billion yen

Potential sales size
(at peak, billion yen)

PADCEV
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials



Update in Oct 2020
Upward revision due to the following factors:
- ✓ Potential sales in MIBC
- ✓ Review potential sales based on actual clinical data

Update in Oct 2019
- ✓ Incorporate potential sales in First Line mUC

As of May 2018
- ✓ Potential sales in Second Line+ mUC

Note) Peak sales are expected in-market sales all of which are not booked as revenue by Astellas

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mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer

PROGRESS IN FOCUS AREA APPROACH (1/3): ASP0367 FOR PRIMARY MITOCHONDRIAL MYOPATHIES

FDA has granted Fast Track designation for the development of ASP0367 as a treatment for primary mitochondrial myopathies

Primary mitochondrial myopathies (PMM)

- A complex mitochondrial disease in which genetic mutations primarily impair the function of mitochondria, resulting in reduced muscle function, reduced endurance to exercise (i.e. exercise intolerance), increased fatigue, and muscle atrophy
- In addition, present serious and life-threatening health conditions due to multiple organ involvement
- The prevalence of mitochondrial disease is estimated at 1 in 8,000 for adults w/ clinical manifestation, and 1 in 4,300 for adults with or without clinical manifestations [1]
- No approved treatment for PMM, a disease with high unmet medical need

ASP0367/MA-0211 characteristics

- Selective PPARδ modulator, discovered by Mitobridge
- Activates a gene expression program to produce proteins essential for mitochondrial activity
  - ✓ Increase use of fatty acids as fuel to make ATP/energy
  - ✓ Produce new mitochondria
- <Nonclinical> ASP0367 increased the expression of PPARδ target genes and enhanced mitochondrial function in fibroblasts collected from patients with PMM
- <Clinical> ASP0367 showed dose-dependent increased expression of PPARδ target genes, along with safety and well-tolerated data, in Phase 1 study in healthy adults

ASP0367 development status

- Under preparation of Phase 2/3 study to start in 1Q 2021
- Also being developed as a treatment for DMD (under preparation of Phase 1b study)

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1: Gorman GS, *et al.*, 2015
FDA: Food and Drug Administration, PPARδ: Peroxisome proliferator-activated receptor delta, ATP: Adenosine triphosphate, DMD: Duchenne muscular dystrophy

PROGRESS IN FOCUS AREA APPROACH (2/3): ASP7317 FOR DRY AMD

Blindness & Regeneration

A Phase 1b/2 study amendment aimed to optimize the overall development program has been submitted for FDA's review

- Significant enrollment delay has occurred, due to:
  - ✓ More difficulty in enrollment of patients with severe vision impairment than originally expected, because of high screen failure rates in the limited number of such patients
  - ✓ COVID-19 impact, where screening and enrollment is still halted, given possible serious and potentially life-threatening complications of COVID-19 while on immunosuppression in the post-operative period
- The protocol amendment is targeted to enhance the overall development program:
  - ✓ Allow enrollment of patients with moderate vision impairment which would expand the eligible patient pool and allow for inclusion of this group in the PoC
  - ✓ Change the adjunct immunosuppressive therapy (tacrolimus and MMF) to a tacrolimus-only regimen, with a shorter duration to reduce the risks associated with immunosuppression in this elderly population
  - ✓ Decouple the PoC portion of the study to enable greater flexibility in the overall program execution, such as allowing the Phase 1b results to inform the PoC design, including selection of a primary endpoint that may reduce the required PoC sample size

The ASP7317 clinical development plan will be updated once Phase 1b/2 study amendment is finalized based on FDA feedback

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AMD: Age-related macular degeneration, FDA: Food and Drug Administration, PoC: Proof of concept, MMF: Mycophenolate mofetil

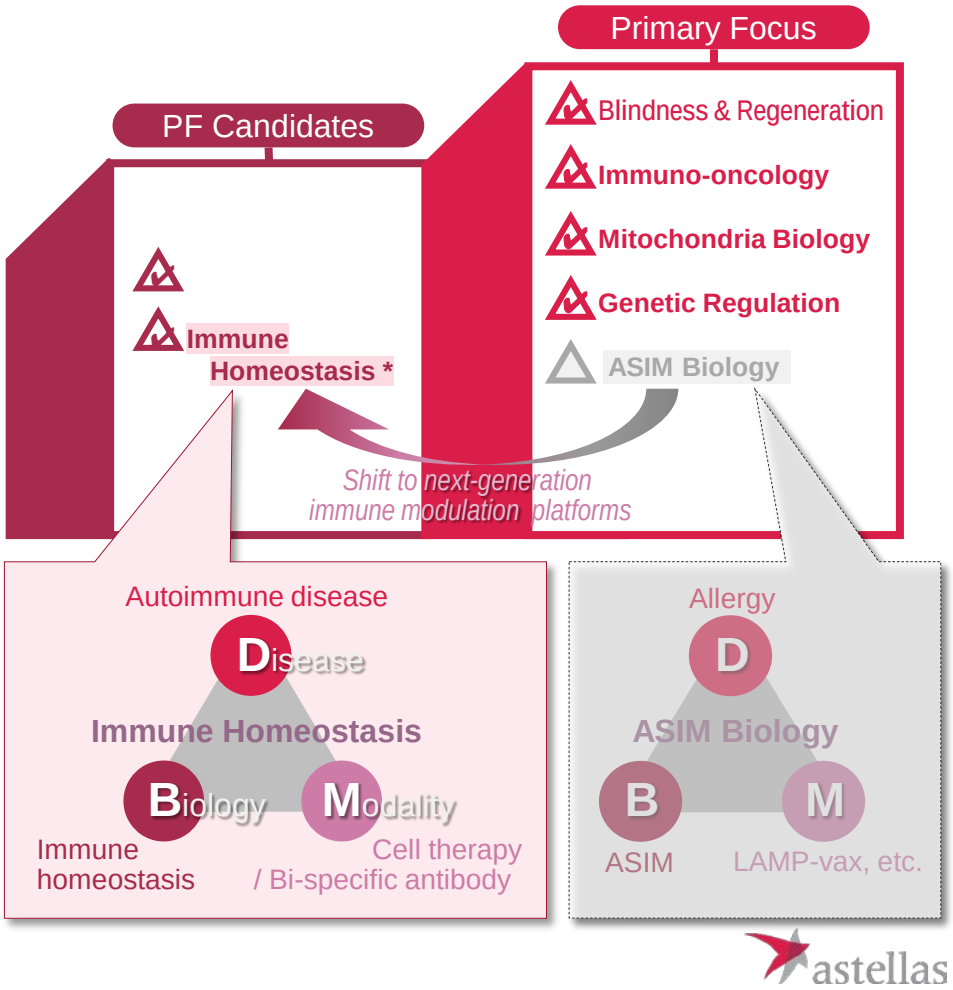
PROGRESS IN FOCUS AREA APPROACH (3/3): UPDATED PRIMARY FOCUS (PF)

Completed Primary Focus "ASIM Biology" and shift to next-generation research

- LAMP-vax, the key ASIM platform, has reached a stage of clinical validation, after completion of discovery research
  - ✓ ASP0892 for peanut allergy: Phase 1
  - ✓ ASP2390 for house dust mite-induced allergic rhinitis: Phase 1
- Exploration of next-generation immune modulation technologies led to identification of platforms with mechanisms and modalities distinct from ASIM. To deliver innovative therapeutics by utilizing endogenous homeostatic mechanism, in-house research (cell therapy) and research collaboration (Pandion Therapeutics) have been started

"ASIM Biology" completed its role as a PF to generate projects. The next generation research has been designated as a PF Candidate "Immune Homeostasis* "

- ✓ Continue the clinical studies for the ongoing 2 projects, ASP0892 and ASP2390
- ✓ Total number of PFs is 4 for now



* PF Candidate - "Multi-immune Regulation" was renamed to "Immune Homeostasis" to reflect its research concept

ASIM: Antigen-specific immuno-modulation, R&D: Research and development

KEY EVENTS EXPECTED IN FY2020

Regulatory decision	enzalutamide	M1 CSPC (EU)
		M0 CRPC (China)
		M0 CRPC, label update to include the OS data (EU)
	roxadustat	Anemia associated with chronic kidney disease, non-dialysis (JP)
Regulatory submissions *	enfortumab vedotin	mUC, platinum and PD-1/L1 inhibitor pretreated (US†, EU, JP)
		mUC, PD-1/L1 inhibitor pretreated, cis-ineligible (US‡)

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

* Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate
† Supplemental BLA submission to convert Accelerated Approval to Regular Approval
‡ Supplemental BLA submission to expand the indication

Please refer to R&D pipeline list for details including target disease

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M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, OS: Overall survival, Cis: Cisplatin, BLA: Biologics License Application

PROGRESS IN Rx+ PROGRAM: STATUS UPDATE

(Underlined: Updates since Q1/FY2020 Financial Results Announcement in Aug 2020)

Steadily progress to establish a solid ground for business acceleration

New style fitness service（Fit-eNce):

- From Sep 1st, 2020, the service was offered through fitness clubs in Kanagawa Prefecture

Smartphone exercise support application:

- Implementing medical and health research

Digital therapeutics:

- BlueStar: Under development

Image-guided precision surgery:

- ASP5354: Phase II study ongoing
  (FSFT of Phase 2 study achieved in Oct 2020)
  FDA granted Fast Track Designation

Ultra-small implantable medical devices:

- Entered into a Merger Agreement pursuant to acquire Iota Biosciences, Inc.

FSFT: First subject first treatment, FDA: Food and Drug Administration

PROGRESS IN Rx+ PROGRAM (1/2): IMAGE-GUIDED PRECISION SURGERY

FSFT of Phase 2 study achieved in October 2020

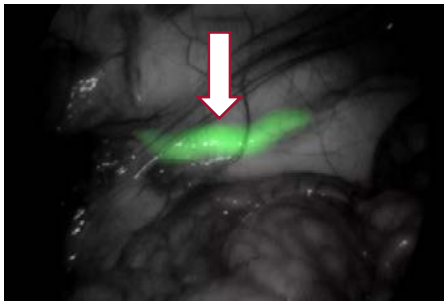
FDA granted Fast Track Designation based on nonclinical data for the development of a new imaging agent, ASP5354

Iatrogenic Ureteral Injury (IUI)

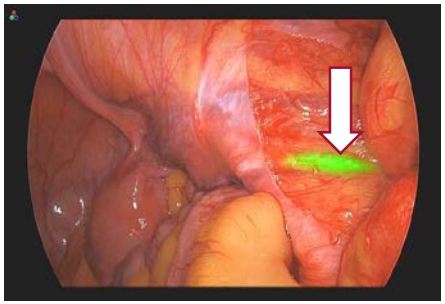
- IUI is widely recognized as a devasting complication of modern surgery. The seriousness of the IUI condition is evidenced by the findings from over 2-million U.S. surgical procedures, where IUIs were independently associated with higher mortality, morbidity, longer length of hospital stays and increased healthcare cost [1]
- The International Urological Guidelines state *"the best method to prevent iatrogenic ureteric injury is intraoperative identification of both ureters"*
- Current strategies to identify the ureters (e.g., placement of a ureter stent) carry risks for patients, including serious short-and long-term complications such as septic state, chronic renal failure, loss of renal function, etc. [2]
- There is a high unmet medical need for a novel agent such as ASP5354

ASP5354

- An imaging agent that is in development and has the potential to improve surgeon's ability in visualizing the ureter(s) in patients undergoing abdominopelvic surgery leading to minimizing the risk for IUI.
- Nonclinical and clinical data to date indicates ASP5354 has been well tolerated with no serious safety issues.
- The nonclinical (porcine model) and preliminary human findings are consistent with clear visualization in both species.



Nonclinical (in porcine)



Clinical

FDA: Food and Drug Administration, FSFT: First Subject First Treatment

1: Halabi WJ *et al.*, Dis Colon Rectum. 2014; 57:179-86
2: Chahin *et al.*, 2002; Redan & McCarus, 2009; Fanning *et al.*, 2011; Boyanet al, 2017; Nakada & Patel, 2019; Preminger, 2020.

PROGRESS IN Rx+ PROGRAM (1/2): ULTRA-SMALL IMPLANTABLE MEDICAL DEVICES

Entered into a Merger Agreement pursuant to acquire Iota Biosciences, Inc.

- Acquire cutting-edge technologies applicable to multiple spheres, which Rx+ identified as focus business areas that embodies Rx+ World / Rx+ Values
- Secure commercialization rights of and accelerate advancement of multiple projects including those under the R&D Agreement since Aug 2019 and further expand the scope of applications
- Acquire innovative technology for ultra-small implantable medical devices and world-class talent
- iota powered by Astellas is to be Center of Excellence of Astellas' bioelectronics

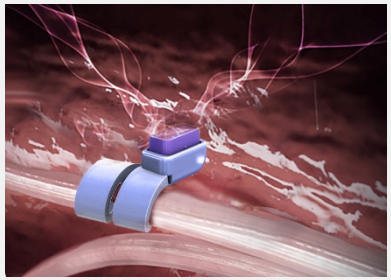
Uses ultrasound as a tool for power supply and wireless communication

iota BIOSCIENCES

Prevent disease onset and slow progression by using personal data

Expand options for people with limited access to current therapeutics

Support active living by enhancing physical and sensory function



Accurate local bio-sensing
e.g. O_2 level, pH, Pressure, Temperature

Local organ stimulation by electricity
e.g. Nerves, Muscle

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SCHEDULE

Dec 10th, 2020: R&D meeting
- Progress of Focus Area approach -

May 2021: New Corporate Strategic Plan

APPENDIX

Q2/FY2020 FINANCIAL RESULTS: COST ITEMS

Core basis: Year-on-Year comparison

Cost of sales
% of revenue
1.9 ppt decrease

- ✓ Decrease mainly due to changes in product mix
  (FX impact on elimination of unrealized gain: Increase in COGs ratio (+1.0 ppt))

SG&A expenses
7.1% increase

- ✓ XTANDI US co-promotion fee increased significantly due to sales expansion
- ✓ Decrease due to one-off reversal of loss allowance in Q2/FY19 (8.2 bil. yen)
- ✓ 1.9% decrease, excluding the above

R&D expenses
6.4% increase

- ✓ In addition to investment increase in development costs for late-stage projects, Audentes' R&D expenses increased

Q2/FY2020: REVENUE BY REGION

(billion yen)	Q2/FY19	Q2/FY20	Change (%)
Japan	183.3	144.2	-21.3%
United States	216.7	236.7	+9.2%
Established Markets	146.7	138.9	-5.4%
Greater China	29.4	29.6	+0.5%
International	63.4	56.7	-10.5%

Established Markets: Europe, Canada, Australia
Greater China: China, Hong Kong, Taiwan
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

Q2/FY2020: SALES OF MAIN PRODUCTS

(billion yen)	Q2/FY19	Q2/FY20	Change	CER growth	FY20 FCST *
XTANDI	**195.0**	**225.5**	**+15.6%**	**+16.8%**	**464.6**
XOSPATA	**5.7**	**11.0**	**+91.9%**	**+94.0%**	**23.1**
PADCEV	**-**	**6.0**	**-**	**-**	**13.0**
OAB products	**103.8**	**96.1**	**-7.4%**	**-6.5%**	**197.9**
mirabegron	78.8	80.0	+1.5%	+2.6%	167.9
Vesicare	25.1	16.2	-35.4%	-35.1%	30.0
Prograf	**96.2**	**89.6**	**-6.9%**	**-6.1%**	**182.0**

PADCEV: Co-promotion revenue from Seagen
OAB (overactive bladder) products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

* Announced in Aug 2020

FY2020 REVISED FORECAST

(billion yen)	FY20 Forecast (Revised in August)	FY20 Revised forecast	Change
Revenue	**1,256.5**		
R&D expenses	233.5		
Core operating profit	**251.0**		
Core profit	**200.5**		

No changes

<Full basis>

Operating profit	**246.5**	**210.5**	**-36.0**
Profit	**197.5**	**169.5**	**-28.0**

Q2/FY2020 ACTUAL: FX RATE

Average rate for the period

Currency	Q2/FY19	Q2/FY20	Change
USD	109 yen	107 yen	-2 yen
EUR	121 yen	121 yen	-0 yen

Change in closing rate from previous fiscal year end

Currency	Q2/FY19	Q2/FY20
USD	-3 yen	-3 yen
EUR	-7 yen	+5 yen

<Impact of exchange rate on financial results>

- 5.3 billion yen decrease in revenue, 6.5 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +1.0 ppt

FY2020 FCST: FX RATE & FX SENSITIVITY

Exchange rate (yen) Average for the period	FY20 FCST
USD	109 yen
EUR	120 yen

Forecast rates from Q2/FY2020 onwards: 110 USD/yen, 120 EUR/yen

Estimated FX sensitivity (Q2 and onward) of FY2020 revised forecasts by 1 yen appreciation *

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Revenue	Core OP	Core OP
USD	Approx. -4.3 bil. yen	Approx. -0.8 bil. yen	Approx. +0.5 bil. yen
EUR	Approx. -2.0 bil. yen	Approx. -0.8 bil. yen	Approx. +0.2 bil. yen

* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q2/FY2020 and onwards

BALANCE SHEET & CASH FLOW HIGHLIGHTS

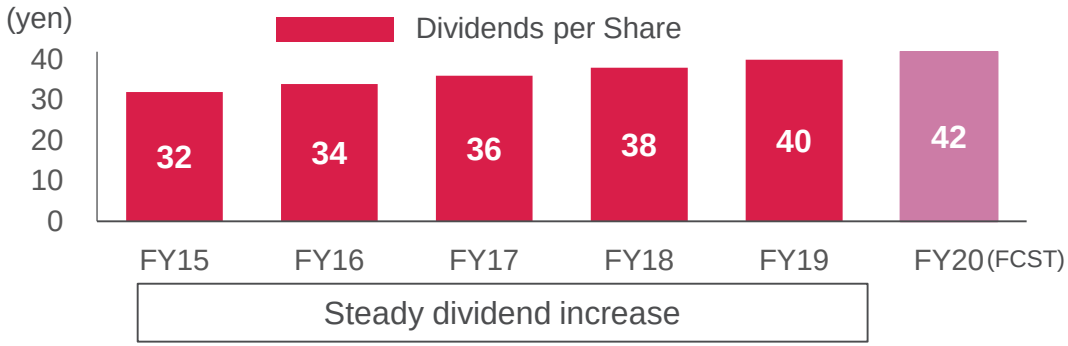
(billion yen)	FY19 end	Sep 30, 2020
Total assets	2,315.2	2,237.0
Cash and cash equivalents	318.4	286.7
Total equity attributable to owners of the parent	1,289.2	1,329.6
Equity ratio (%)	55.7%	59.4%

(billion yen)	Q2/FY19	Q2/FY20	FY19
Cash flows from operating activities	101.7	115.0	222.0
Cash flows from investing activities	-46.6	-38.3	-389.8
Free cash flows	55.1	76.7	-167.8
Cash flows from financing activities	-46.0	-109.7	181.1
Bonds and short-term borrowings	-	-142.0	326.0
Proceeds from long-term borrowings	-	80.0	-
Dividends paid	-35.8	-37.2	-73.5

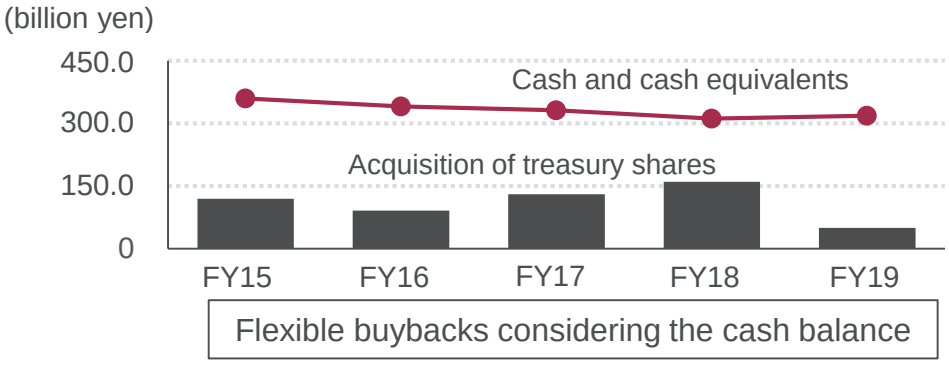
CAPITAL ALLOCATION

- *Top priority is investment for strategic business growth*

- *Dividends to be increased continuously based on mid-and long-term growth*



- *Share buybacks to be implemented in a flexible manner*



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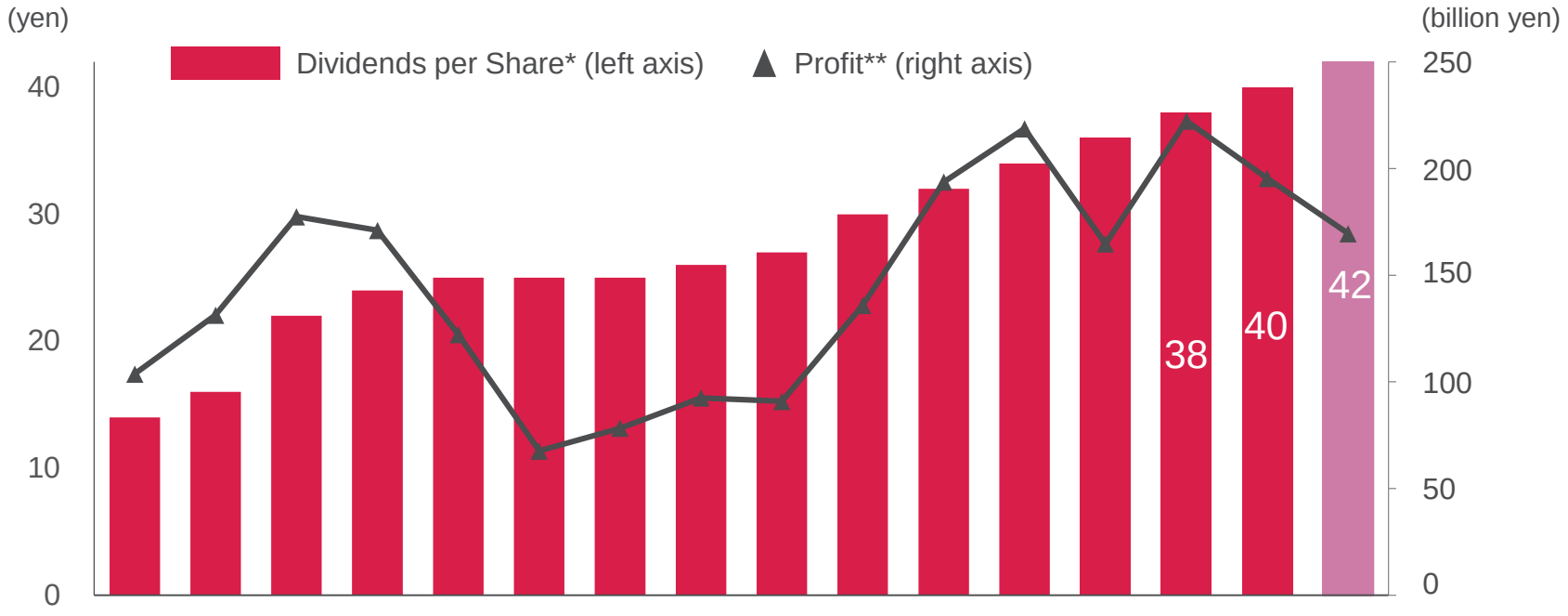
DETAILS OF SHAREHOLDER RETURNS



(billion yen)	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20 (FCST)
Total dividends	39.3	42.3	55.2	56.9	58.2	57.7	57.7	59.4	60.6	66.0	68.5	71.3	72.1	72.4	75.0	78.0
Acquisition of own share	46.2	219.9	81.8	123.4	27.0	-	-	49.4	30.0	58.2	119.3	91.4	130.0	160.0	50.0	
Total return ratio (%)	82	200	77	106	70	85	74	118	100	92	97	74	123	105	64	

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* The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of Apr 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of FY2005
** From FY2013, figures are in accordance with International Financial Reporting Standards (IFRS)

FILING OPPORTUNITIES ANNOUNCED IN STRATEGIC PLAN 2018

As of Oct 2020

✓✓✓: Approved

✓✓: Filed

✓: Data obtained, filing under preparation

FY2018

enzalutamide
M0 CRPC ✓✓✓

gilteritinib
R/R AML ✓✓✓

roxadustat
Anemia associated with CKD
Dialysis (JP) ✓✓✓

FY2019-2020

enzalutamide
M1 CSPC
(US, JP) ✓✓✓
(EU) ✓✓

enfortumab vedotin
Metastatic urothelial cancer,
Platinum and PD-1/L1
inhibitor pretreated (US) ✓✓✓

roxadustat
Anemia associated with CKD
Non-dialysis (JP) ✓✓

roxadustat
Anemia associated with CKD
Dialysis/Non-dialysis (EU) ✓✓

FY2021 or beyond

enzalutamide
M0 CSPC

zolbetuximab
Gastric and gastroesophageal junction adenocarcinoma

gilteritinib
AML (Post-HSCT maintenance)

gilteritinib
AML (Post-chemo maintenance)

gilteritinib
AML (1st line low intensity induction chemo)

gilteritinib
AML (1st line high intensity induction chemo)

fezolinetant
MR-VMS

Therapeutic area: Oncology, Urology, Nephrology, Others

Note) Subject to internal assessment, decision and regulatory consultation, as appropriate. Filing (submission) timing in the first country/region within US/EU/JP

M0: Non-metastatic, M1: Metastatic, CPRC: Castration-resistant prostate cancer, CSPC: Castration-sensitive prostate cancer,
R/R: Relapsed or refractory, AML: Acute myeloid leukemia, CKD: Chronic kidney disease, HSCT: hematopoietic stem cell transplantation,
MR-VMS: Menopause related vasomotor symptoms

ROBUST PIPELINE OF ASTELLAS

Phase 1

- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP9801
- ASP7517
- ASP0892
- ASP0367/MA-0211
- ASP2390
- ASP0598
- AT845
- ASP8062
- ASP1617

Phase 2

- zolbetuximab (Pancreatic adenocarcinoma)
- enfortumab vedotin (Other solid tumors)
- ASP7317 (Dry AMD, etc.)
- ASP1128/MA-0217 (AKI)
- ASP3772 (Pneumococcal disease)
- FX-322 (Sensorineural hearing loss)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP0367/MA-0211 (PMM)
- bleselumab (rFSGS)
- roxadustat (CIA)
- isavuconazole (Pediatric use: US)

Phase 3

- enzalutamide (M0 CSPC, M1 CSPC: China)
- gilteritinib (Earlier-stage AML, Pediatric use)
- enfortumab vedotin (mUC, MIBC)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: EU)
- fezolinetant (MR-VMS)

Filed

- enzalutamide (M1 CSPC: EU)
- enzalutamide (M0 CRPC: China)
- gilteritinib (R/R AML: China)
- roxadustat (Anemia associated with CKD, non-dialysis: JP)
- roxadustat (Anemia associated with CKD: EU)
- mirabegron (Pediatric NDO: US)

Oncology | Projects with Focus Area approach (excluding Immuno-oncology projects) | Others

Please refer to R&D pipeline list for details including target disease

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AMD: Age-related macular degeneration, AKI: Acute kidney injury, XLMTM: X-linked myotubular myopathy, PMM: Primary mitochondrial myopathies, rFSGS: Recurrence of focal segmental glomerulosclerosis, CIA: Chemotherapy-induced anemia, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, MR-VMS: Menopause-related vasomotor symptoms, CKD: Chronic kidney disease, NDO: Neurogenic detrusor

PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since Q1/FY2020 Financial Results Announcement in Aug 2020

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
	ASP0367 Primary mitochondrial myopathies	**enfortumab vedotin** Muscle-invasive bladder cancer	**mirabegron** Neurogenic detrusor in pediatric patients: US	**enzalutamide** Tablet (new formulation): US

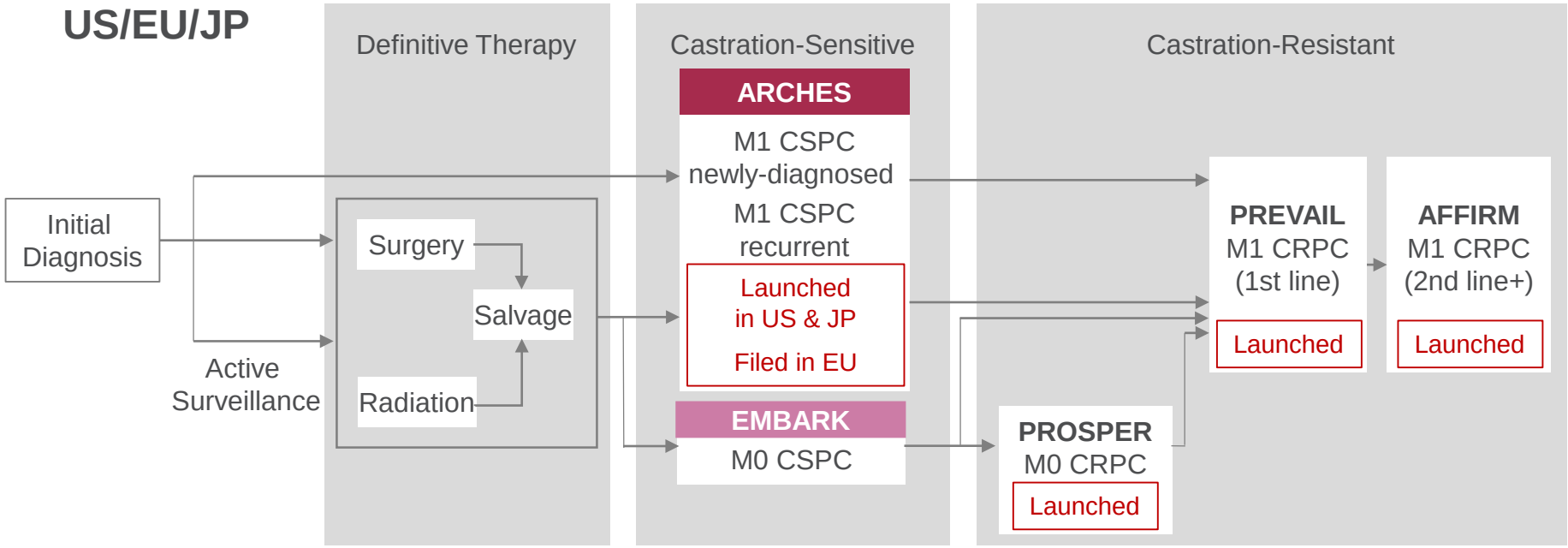
Discontinuation

ASP1650: Testicular cancer (Phase 2)
ASP8302: Underactive bladder (Phase 2)
ASP1235/AGS62P1: Acute myeloid leukemia (Phase 1)
ASP8374/PTZ-201: Cancer (Phase 1)

Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase. Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body

IND: Investigational new drug

ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR (1/2)



	P3: ARCHES	**M1 CSPC**	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019 and in JP in May 2020 Filed in EU in Jul 2019
	P3: EMBARK	**M0 CSPC**	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China

- **M1 CRPC:** Approved in Nov 2019 and launched in Mar 2020
- **M0 CRPC:** Filed in Oct 2019, based on global Phase 3 PROSPER study data
- **M1 CSPC:** FSFT of Phase 3 China-ARCHES study in Sep 2019

M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer,
ADT: Androgen deprivation therapy, FSFT: First subject first treatment

ENZALUTAMIDE (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

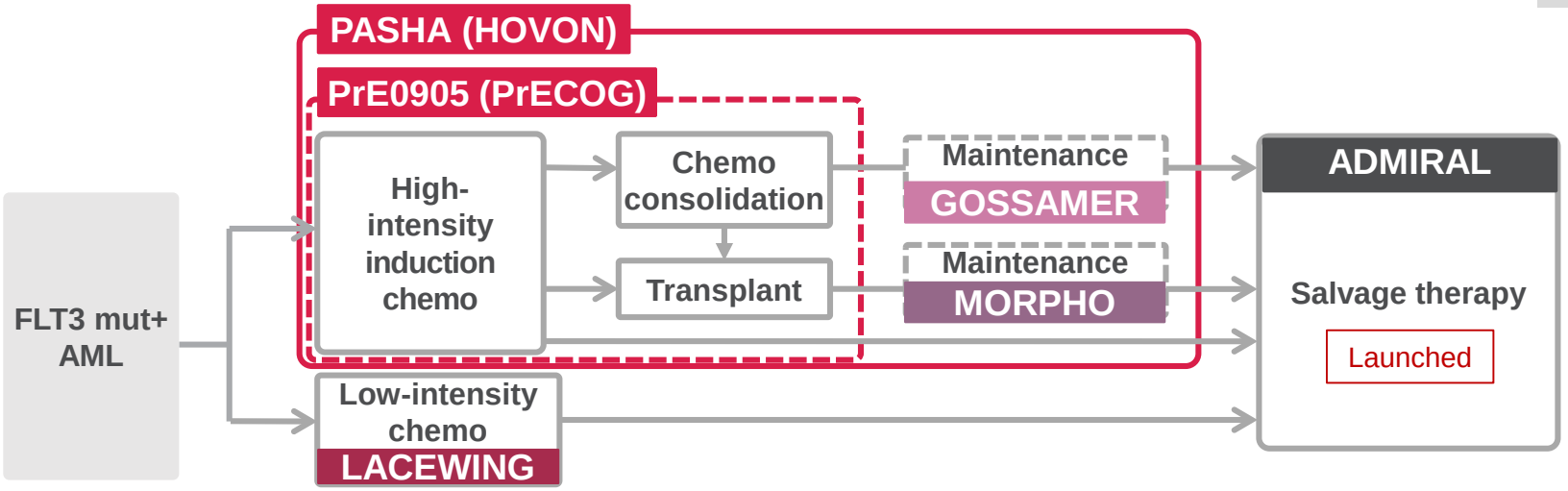
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

Disease stage	Early stage → Late stage					
	Castration-sensitive (CSPC)			Castration-resistant (CRPC)		
	M0	M1		M0	M1 (pre-chemo)	M1 (post-chemo)
Phase 3 study	**EMBARK**	**ARCHES**	**ENZAMET**	**PROSPER**	**PREVAIL**	**AFFIRM**
Control	Placebo	Placebo	Conventional NSAA	Placebo	Placebo	Placebo
Primary endpoint	MFS (Ongoing)	✔ rPFS HR 0.39	✔ OS HR 0.67	✔ MFS HR 0.29	✔ rPFS HR 0.17 ✔ OS HR 0.71*	✔ OS HR 0.63
OS	(Ongoing)	(Not reached)	✔ HR 0.67	✔ HR 0.73	✔ HR 0.77	✔ HR 0.63
DoT	(Ongoing)	(Not reached)	✔ 29.5 months	✔ 33.9 months	✔ 17.5 months	✔ 8.3 months

✔: Data obtained, *: Prespecified interim analysis

M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment

GILTERITINIB: FLT3 INHIBITOR



	Relapsed or refractory	**P3: ADMIRAL**	Monotherapy vs salvage chemo (2:1)	n=371	Launched in US, JP, and EU Filed in China in Mar 2020 (Priority Review granted)
	Newly diagnosed (intensive chemo eligible)	**P3: PASHA (HOVON)**	Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)	n=768	FSFT: Dec 2019 (Sponsor: HOVON)
		P2: PrE0905 (PrECOG)		n=179	FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)
	Newly diagnosed (intensive chemo ineligible)	**P3: LACEWING**	Combo with azacitidine vs. azacitidine alone (2:1)	n=250	FSFT: Nov 2016
	Post-HSCT maintenance	**P3: MORPHO**	Monotherapy vs. placebo (1:1)	n=346	Enrollment completed Collaborating with BMT-CTN
	Post-chemo maintenance	**P2: GOSSAMER**	Monotherapy vs. placebo (2:1)	n=98	Enrollment completed

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020
FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, FSFT: First subject first treatment, HSCT: Hematopoietic stem cell transplant, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network

ENFORTUMAB VEDOTIN (EV) : NECTIN-4 TARGETED ADC (1/3)

For urothelial cancer

	P3: EV-301	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV monotherapy vs. Chemotherapy	n=608	Met the primary endpoint (OS) in Sep 2020, based on the planned interim analysis
	P3: EV-302	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemotherapy	n=760	FSFT: Apr 2020 Removed Arm C "EV+Pembro +Platinum", due to the strength of EV+Pembro combo data in EV-103 study and the evolving first line mUC landscape
	P3: EV-303 /KEYNOTE-905	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=836	Pembro + EV arm added in Jul 2020
	P3	MIBC, Cis-eligible		Currently under preparation (in collaboration with Seagen and Merck)
	P2: EV-201	mUC, PD-1/L1 inhibitor pretreated; EV monotherapy Cohort 1: Platinum pretreated Cohort 2: Platinum naïve and cis-ineligible	n=219	Cohort 1: Approved (under the Accelerated Approval program) and launched in US in Dec 2019 Cohort 2: Obtained positive ORR in Oct 2020
	P1b/2: EV-103	Cohorts A - G and K (mUC): A-G: Combo with Pembro and other chemotherapy K: EV monotherapy vs. EV + Pembro Cohorts H & J (MIBC, Cis-ineligible, +RC, neoadjuvant): H: EV monotherapy, J: EV + Pembro	n=407	FSFT: Nov 2017
	P2: EV-203	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV monotherapy	n≈40	Currently under preparation (IND filed)

For other solid tumors

	P2: EV-202	HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric, gastroesophageal junction or esophageal cancer	n=240	FSFT: Mar 2020

Seagen

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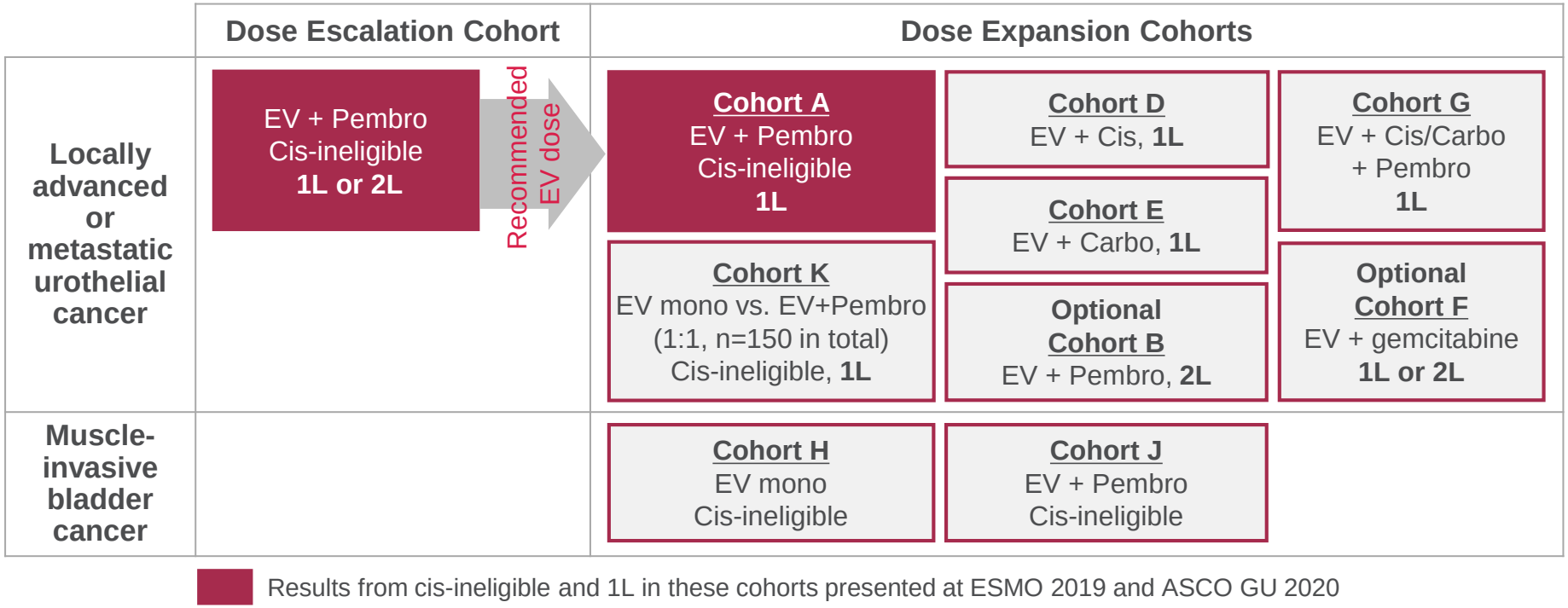
Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

mUC: Metastatic urothelial cancer, OS: Overall survival, Pembro: Pembrolizumab, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, FSFT: First subject first treatment, RC: Radical cystectomy, ORR: Objective response rate, IND: Investigational New Drug application, NSCLC: Non-small cell lung cancer, HR+: Hormone receptor positive, HER2-: HER2 negative

ENFORTUMAB VEDOTIN (EV) (2/3): PHASE 1b/2 EV-103 STUDY DESIGN



Data from Cohort K, along with other data from the EV-103 study evaluating EV combined with pembrolizumab as first-line therapy for cisplatin-ineligible patients, could potentially support registration under Accelerated Approval regulations in US

Pembro: pembrolizumab, 1L: First line, 2L: Second line, Cis: Cisplatin, Carbo: Carboplatin, mono: Monotherapy, RC: Radical cystectomy, ESMO: European Society for Medical Oncology, ASCO GU: Genitourinary Cancers Symposium of the American Society of Clinical Oncology

ENFORTUMAB VEDOTIN (3/3): NUMBER OF UC PATIENTS

Urothelial cancer (Annual)	All stages (Incidence)	MIBC	mUC		
		Post-cystectomy	Total (Incident + Newly recurrent)	Drug treated (1L)	Drug treated (2L+*)
US	79,000	20,000	19,000	15,000	8,000
EU5	118,000	32,000	29,000	27,000	12,000
JP	39,000	10,000	8,000	7,000	3,000
China	101,000	24,000	29,000	24,000	9,000

Number of drug treated patients expected to rise after new drug launch

Seagen

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Kantar Health incident and newly recurrent patients
mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer

* 2L+: Platinum and/or PD-1/L1 inhibitor pretreated

ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

Target: Claudin 18.2

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ✓ ~70% of gastric tumors; ~30% of these meet the eligibility criteria for the ongoing Phase 3 studies
  - ✓ ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

Gastric and gastroesophageal junction (GEJ) adenocarcinoma

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Gastric cancer is the third leading cause of cancer death worldwide [1]
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20% [2,3]
- Median overall survival for Stage IV gastric cancer is 10-15 months [4,5]

	Gastric and GEJ adenocarcinoma	**P3: SPOTLIGHT**	First line, combo with mFOLFOX6, vs. placebo	n=550	FSFT: Oct 2018
		P3: GLOW	First line, combo with CAPOX, vs. placebo	n=500	FSFT: Jan 2019
		P2: ILUSTRO	Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with pembrolizumab	n=112	FSFT: Sep 2018
	Pancreatic adenocarcinoma	**P2**	Combo with nab-paclitaxel and gemcitabine, vs. placebo	n=141	FSFT: May 2019

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1: WHO Cancer Fact Sheet - Globocan 2018, 2: Pennathur A, *et al*., 2013, 3: Sahin U, *et al*., 2008, 4: 2017 RDPAC survey, 5: Iizumi S, *et al*. 2018
mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

VMS has a significant negative impact on quality of life

- Physical symptoms include hot flashes and sweating/night sweats, which can impact sleep.
- Physical symptoms lead to emotional impact including embarrassment, irritability, anxiety, and sadness
- Symptoms have a negative impact on multiple aspects of everyday life [1]

Women's Health Initiative (WHI) Study [2]

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and cancer
- Since WHI's findings, no replacement for HRT with similar efficacy and no significant safety concern, resulting in huge unmet medical needs

US and EU

P3: SKYLIGHT 1	Moderate to severe MR-VMS; The first 12 weeks: DBT, 30 mg vs. 45 mg vs. placebo (1:1:1) The last 40 weeks: non-controlled, 30 mg or 45 mg		n=527	Enrollment completed
P3: SKYLIGHT 2			n=501	LSLV for 12w DB period achieved
P3: SKYLIGHT 4	MR-VMS; 52 weeks: DBT, 30 mg vs. 45 mg vs. placebo (1:1:1)		n=1,740	Patient screening closed

Asia (except for Japan)

P3: MOONLIGHT 1	Moderate to severe MR-VMS; The first 12 weeks: DBT, 30 mg vs. placebo (1:1) The last 12 weeks: non-controlled, 30 mg		n=300	FSFT: Apr 2020
P3: MOONLIGHT 3	MR-VMS; open label, 30 mg for 52 weeks		n=150	FSFT: Aug 2020

JP: Independent development plan under preparation

Underlined: Updates since Q1/FY2020 financial results announcement in Aug 2020

1: DelveInsight, Epidemiology Forecast, Jun 2018, 2: Data Source - IMS NPA (2000-2016), IMS NSP (2000-2016). (3 HTs and SSRI) NAMS 2015 Position Statement.

MR-VMS: Menopause related vasomotor symptoms, HRT: Hormone replacement therapy, DB(T): Double-blind (trial), LSLV: Last subject last visit, FSFT: First subject first treatment

AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

Characteristics of AT132

- Lead program in the gene therapy pipeline of Audentes Therapeutics, acquired by Astellas in Jan 2020
- Designed to deliver a functional copy of human MTM1 gene by AAV8 to transfect and express myotubularin in skeletal muscle cells
- Regulatory designations granted:
  - ✓ <US> RMAT, Rare Pediatric Disease, Fast Track, and Orphan Drug designations
  - ✓ <EU> PRIME and Orphan Drug designations

X-linked myotubular myopathy (XLMTM)

- Rare neuromuscular disease with X-linked, loss of function mutations in MTM1 gene
  - ✓ Approximately 1 in 40,000 to 50,000 newborn males
  - ✓ Estimated 50% mortality by 18 months
- > 80% require ventilator support
- Motor milestones substantially delayed
- No treatment available; supportive care only

ASPIRO (clinical study for registration in XLMTM patients)	vs. Delayed-treatment control Part 1: Dose escalation Cohort 1: 1 x 10^{14} vg/kg Cohort 2: 3 x 10^{14} vg/kg Part 2: Pivotal expansion (3 x 10^{14} vg/kg)	n=26	Study on clinical hold due to serious adverse events

(r)AAV: (recombinant) Adeno-associated virus, Des: Desmin promoter, hMTM1: Human myotubularin gene,
RMAT: Regenerative Medicine Advanced Therapy, PRIME: PRIority Medicines, vg/kg: Vector genomes per kilogram

ON THE FOREFRONT OF HEALTHCARE CHANGE