Q3/FY2020 FINANCIAL RESULTS
ENDED DECEMBER 31, 2020

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Executive Vice President,
Chief Strategy Officer and Chief Financial Officer
Astellas Pharma Inc.
January 29, 2021

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 Q3/FY2020 Consolidated Financial Results

II Initiatives for Sustainable Growth

Q3/FY2020 FINANCIAL RESULTS: OVERVIEW

Revenue and profit are in line with assumptions of full-year forecast

- Revenue and Core operating profit decreased, YoY
- Sales of growth drivers steadily increased
- Spending of SG&A and R&D expenses is on track
- No changes have been made to FY2020 forecast

Q3/FY2020 FINANCIAL RESULTS

(billion yen)	Q3/FY19	Q3/FY20	Change	Change (%)	FY20 FCST	Progress
Revenue	**988.5**	**940.9**	**-47.6**	**-4.8%**	**1,256.5**	**74.9%**
Cost of sales	221.6	187.7	-33.9	-15.3%		
% of revenue	22.4%	20.0%	-2.5 ppt			
SG&A expenses	353.6	363.0	+9.5	+2.7%		
R&D expenses	159.8	168.8	+9.1	+5.7%	233.5	72.3%
Amortisation of intangible assets	15.4	17.3	+1.9	+12.0%		
Core operating profit	**235.9**	**203.7**	**-32.2**	**-13.6%**	**251.0**	**81.2%**
<Full basis>						
Other income	15.1	7.0	-8.0	-		
Other expense	13.4	51.3	+38.0	-		
Operating profit	**237.7**	**159.5**	**-78.2**	**-32.9%**	**210.5**	**75.8%**
Profit before tax	239.2	164.2	-75.0	-31.3%	209.5	78.4%
Profit	**190.0**	**132.9**	**-57.1**	**-30.1%**	**169.5**	**78.4%**

Q3/FY2020 FINANCIAL RESULTS: REVENUE

Main oncology products continue to grow strongly

Q3/FY2020 actual

(billion yen)		YoY
XTANDI	**342.7**	**+44.8**
XOSPATA	**17.6**	**+7.9**
PADCEV	**9.4**	**+9.4**
mirabegron	**122.3**	**+1.3**
New products in Japan	**54.1**	**+8.7**

Xtandi (enzalutamide) 40 mg capsules
XOSPATA gilteritinib 40mg tablets
PADCEV enfortumab vedotin-ejfv Injection for IV infusion 20 mg & 30 mg vials

Total sales of 3 oncology products, YoY

+62.1 billion yen

Consolidated revenue for Q3/FY2020: -47.6 billion yen, YoY

Main decrease items

- ✓ Sales decreases due to termination of sales and distribution in Japan (-32.9) and loss of exclusivity (-42.7)
- ✓ Negatively impacted by COVID-19 mainly during Q1/FY2020

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Loss of exclusivity (LOE) products: Products with LOE in FY2019 or FY2020 (Vesicare, Tarceva, Celecox, MYCAMINE/Funguard)
Terminated products in Japan: Micardis-family, Symbicort, KM Bio products
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

Q3/FY2020 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

XTANDI	Global sales are in line with forecast. In US, progress against forecast is slightly behind due to the impact of COVID-19 (slowdown of new patient starts), but demand grew in excess of 20% YoY and continued growth is expected. In China, additional indication (M0 CRPC) approved in Nov 2020. To be listed in NRDL for M1 CRPC indication and reimbursement scheduled to start from Mar 2021
XOSPATA	Sales in US and Europe steadily expanded and global sales are exceeding forecast. Reimbursement has started in UK and Germany. Launched also in Brazil (Aug 2020) and Taiwan (Dec 2020)
PADCEV	Revenue grew steadily in the first year after launch through rapid market penetration and steady progress against forecast. We have seen strong interest from physicians by positive clinical data recently available. Captured high market share in mUC patients who have previously received a platinum and a PD-1/L1 inhibitor
Evrenzo	Additional indication in Japan (treatment of anemia of chronic kidney disease in adult patients not on dialysis) approved in Nov 2020. The restriction of 2-week administration period was lifted in Dec 2020. Steadily increasing the number of adopted facilities post approval and sales expansion is expected
mirabegron	Global sales increased slightly as demand impacted by COVID-19, but in line with forecast. In China, to be listed in NRDL and reimbursement scheduled to start from Mar 2021
New products in Japan	Sales of EVENITY (+2.6 billion yen) and Suglat-Family (+3.2 billion yen) increased, but progress against forecast is behind due to the impact of COVID-19 such as restrictions on promotion activities, reduction of hospital/clinic visits by patients, etc.

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M0: Non-metastatic, M1: Metastatic, CRPC: Castration-resistant prostate cancer, NRDL: National Health Insurance Reimbursed Drug List, mUC: Metastatic urothelial cancer,
New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)

Q3/FY2020 FINANCIAL RESULTS: COST ITEMS

Spending of SG&A and R&D expenses is on track to full-year forecast

Core basis: main items for, YoY

Cost of sales
% of revenue
2.5 ppt decrease

- ✓ Decrease mainly due to changes in product mix
  (FX impact on elimination of unrealized gain: Increase in COGs ratio (+0.4 ppt))

SG&A expenses
2.7% increase

- ✓ XTANDI US co-promotion fee increased due to sales expansion
- ✓ One-off decrease in FY19 (Reversal of loss allowance: 8.2 bil. yen)
- ✓ 4.4% decrease, excluding the above

R&D expenses
5.7% increase

- ✓ Investment increase in development costs for late-stage projects including fezolinetant (Phase 3 studies ongoing)
- ✓ Audentes' R&D expenses

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FX: Foreign exchange, COGs: Cost of goods sold

AGENDA

I Q3/FY2020 Consolidated Financial Results

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KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since Q2/FY2020 Financial Results Announcement in Oct 2020)

enzalutamide

M0 CRPC

- 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:** Approved in Nov 2020
- **M1 CSPC:** Phase 3 study ongoing

gilteritinib

R/R AML

- **China:** Filed in Mar 2020 (Priority Review granted and listed in "Overseas new drugs urgently needed in clinical settings")

Earlier-stage AML

- Phase 3 studies ongoing. Phase 3 LACEWING study discontinued due to the futility based on the planned interim analysis

enfortumab vedotin

mUC

- **Previously treated:** US (sBLA), EU and JP submissions planned in Q4 FY2020. Full data of EV-301 study and EV-201 study cohort 2 to be presented at ASCO GU 2021
- **Previously untreated (first line; combo with pembrolizumab):** Phase 3 study ongoing
- **China:** IND approved for bridging study and IND accepted for EV-302 study

MIBC (combo with pembrolizumab)

- Phase 3 KEYNOTE-905 /EV-303 study in cis-ineligible ongoing, and Phase 3 KEYNOTE-B15 /EV-304 study in cis-eligible to start in Q4 FY2020

Other solid tumors

- Phase 2 study ongoing

zolbetuximab

Gastric & GEJ adenocarcinoma

- Phase 3 studies ongoing

Pancreatic adenocarcinoma

- Phase 2 study ongoing

roxadustat

Anemia associated with CKD

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

Chemotherapy-induced anemia

- Phase 2 study ongoing

fezolinetant

MR-VMS

- **US & EU:** Phase 3 studies ongoing. 12w DB period topline results for Phase 3 SKYLIGHT 2 study obtained
- **Asia:** Phase 3 studies ongoing

AT132 (resamirigene bilparvovec) XLMTM

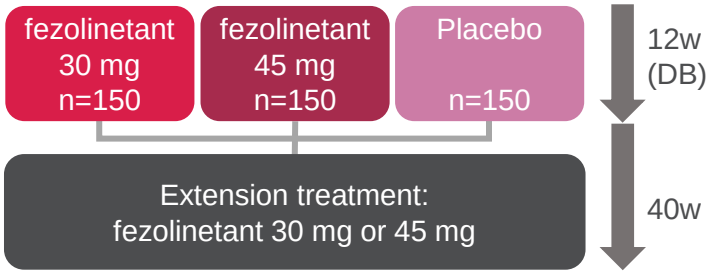
- Clinical hold lifted by FDA in Dec 2020. Clinical trial re-start activities underway. Discussions planned on the path forward toward global registration filings

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, mUC: Metastatic urothelial cancer, sBLA: Supplemental Biologics License Application, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, IND: Investigational New Drug application, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptoms, DB: Double blind, XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration

FEZOLINETANT: PHASE 3 STATUS

Three Phase 3 studies in US and EU are progressing well

Two pivotal studies (SKYLIGHT 1 and SKYLIGHT 2)



Primary endpoints:
- Mean change in frequency
- Mean change in severity

of moderate to severe VMS from baseline to Week 4 and Week 12

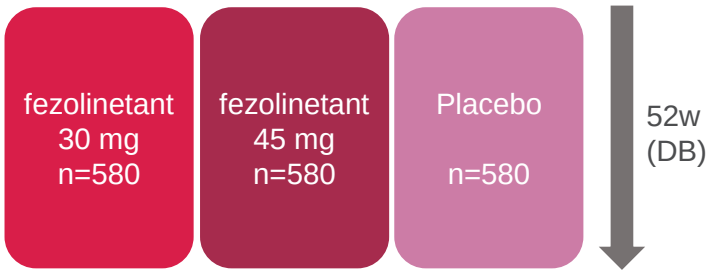
< SKYLIGHT 2 >
- Enrollment completed
- 12-week DB period topline results obtained:
  - ✓ Met the coprimary endpoints for both doses at both timepoints
  - ✓ No new safety signals of concern

=> *To continue the study for another 40 weeks to mainly evaluate long-term safety as originally planned*

< SKYLIGHT 1 >
- Enrollment completed
- LSLV for 12-week DB period achieved

=> 12-week DB period topline results available by end FY2020

Long-term safety study (SKYLIGHT 4)



Primary endpoints:
- Frequency and severity of adverse events up to Week 55
- % of participants with endometrial hyperplasia and/or endometrial cancer up to Week 52

< SKYLIGHT 4 >
- Enrollment completed

=> LSLV anticipated in Q4 FY2021

US-NDA and EU-MAA submissions planned based on the long-term data of all these 3 studies

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VMS: Vasomotor symptoms, DB: Double blind, LSLV: Last subject last visit, NDA: New Drug Application, MAA: Marketing Authorization Application

PROGRESS IN FOCUS AREA APPROACH: IMMUNO-ONCOLOGY PROGRAMS

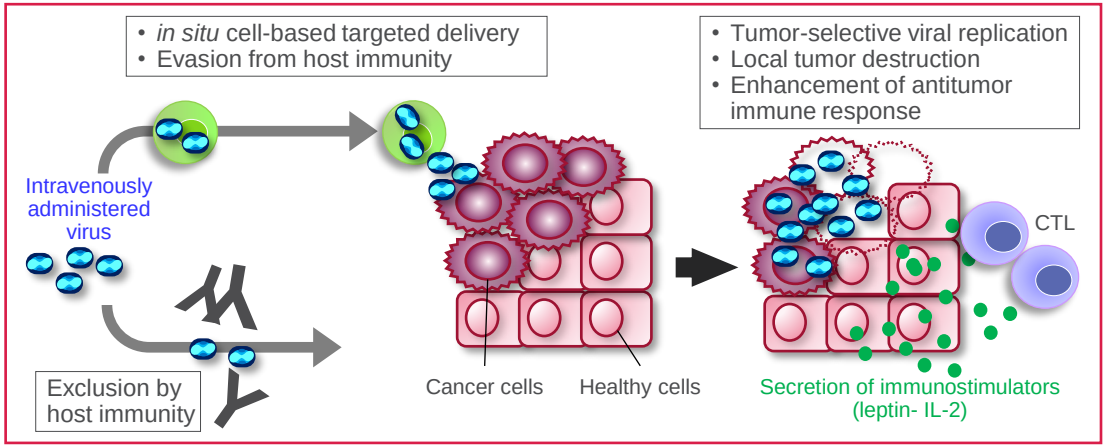
- *Partnership with KaliVir to discover and develop intravenously administered oncolytic virus*
- *Expanding aAVC platform: Phase 1 study initiation for ASP0739 & ASP7517 in solid tumors*

VET2-L2 from KaliVir Immunotherapeutics

- VET2-L2 is a vaccinia virus-based oncolytic virus (OV) loaded with a leptin-IL-2 fusion protein
  - ✓ that can be delivered intravenously to tumors, eliminating the need for complicated procedures of the direct intra-tumoral administration, enabling access to a broader cancer patient population
  - ✓ currently in pre-clinical stage
- Option for the second OV program

aAVC platform

- ASP0739: Second aAVC program targeting NY-ESO-1
  - ✓ To start Phase 1/2 first-in-human study in advanced solid tumors in mid FY2021
- ASP7517: First aAVC program targeting WT1
  - ✓ Phase 1/2 study in R/R AML and MDS ongoing
  - ✓ To start Phase 1/2 study in advanced solid tumors in early FY2021



Mechanism of action of VET2-L2

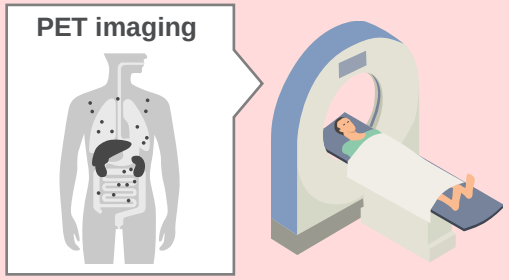
aAVC: Artificial adjuvant vector cell, IL: Interleukin, CTL: Cytotoxic T lymphocyte, NY-ESO-1: New York esophageal squamous cell carcinoma 1, WT1: Wilms Tumor 1, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome

PROGRESS IN Rx+ PROGRAM:
DEVELOPMENT OF "THERANOSTICS*"; INTEGRATION OF DIAGNOSTICS AND THERAPEUTICS

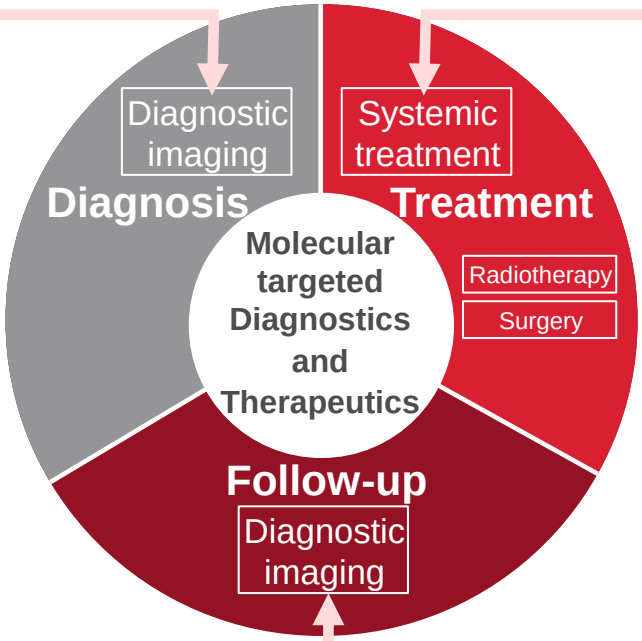
Research collaboration on targeted radiation therapy with Actinium Pharmaceuticals
Development of target-specific radioisotope diagnostics and therapeutics in parallel

- Realize personalized medicine for each patient by directly connecting diagnostic imaging to treatment
- Provide new treatment option for patients resistant to existing treatments
- Prevent recurrence and repeated resection of tumor by detecting and treating small metastasis of cancer cells with high sensitivity and accuracy

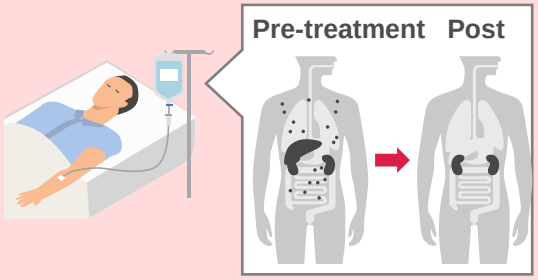
Radioisotope diagnostics



- ✓ Visualization of tumor with target-specific radioisotope diagnostics
- ✓ Diagnosis of small metastasis and tumor position / size with high sensitivity and accuracy
- ✓ Preclinical study ongoing



Targeted radiation therapy



- ✓ Treatment with target-specific radio-isotope therapeutics
- ✓ Research collaboration with Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc.

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* The term that combines "Therapeutics" and "Diagnostics". Treatment protocol or concept in which healthcare professionals assess lesion sites and simultaneously determine the appropriate treatment for each patient

SUSTAINABILITY: SUPPORT FOR TCFD RECOMMENDATION

Commitment to climate change issues in corporate strategy

Our approach to environment issues

- 2017	2018	2020	2021
Kerry plant: Wind turbine, Wood chip biomass boiler Hybrid cars for sales reps	**GHG reduction targets approved by SBT** Targets in 2030 covering all business activities	**Purchasing electricity from renewable energy** GHG reduction in 3 domestic facilities	**Support for TCFD recommendation** Commitment to climate change related disclosure	**CSP incorporating sustainability** To announce in May

Engagement by improved disclosure

To improve disclosure on scenario-based environmental risk/opportunity

Core elements in TCFD recommendation

- Governance
- Risk management
- Metrics and targets
- **Strategy (risk/opportunity analysis etc.)**

TCFD: Task Force on Climate-related Financial Disclosures, GHG: Greenhouse gas, SBT: Science Based Targets, CSP: Corporate Strategic Plan

SCHEDULE

Apr 27th, 2021: Financial Results for FY2020

May 26th, 2021: New Corporate Strategic Plan

APPENDIX

Q3/FY2020: REVENUE BY REGION

(billion yen)	Q3/FY19	Q3/FY20	Change (%)
Japan	276.2	221.8	-19.7%
United States	331.9	355.8	+7.2%
Established Markets	218.0	218.0	-0.0%
Greater China	44.4	43.8	-1.2%
International	102.8	87.6	-14.8%

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.

Q3/FY2020: SALES OF MAIN PRODUCTS

(billion yen)	Q3/FY19	Q3/FY20	Change	CER growth	FY20 FCST*
XTANDI	**297.9**	**342.7**	**+15.0%**	**+16.2%**	**464.6**
XOSPATA	**9.8**	**17.6**	**+80.7%**	**+83.3%**	**23.1**
PADCEV	**0.0**	**9.4**	**-**	**-**	**13.0**
OAB products	**157.2**	**147.0**	**-6.5%**	**-5.5%**	**197.9**
mirabegron	121.0	122.3	+1.0%	+2.3%	167.9
Vesicare	36.2	24.7	-31.8%	-31.7%	30.0
Prograf	**146.2**	**138.3**	**-5.4%**	**-5.3%**	**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

Q3/FY2020 ACTUAL: FX RATE

Average rate for the period

Currency	Q3/FY19	Q3/FY20	Change
USD	109 yen	106 yen	-3 yen
EUR	121 yen	122 yen	+1 yen

Change in closing rate from previous fiscal year end

Currency	Q3/FY19	Q3/FY20
USD	-1 yen	-5 yen
EUR	-2 yen	+7 yen

<Impact of exchange rate on financial results>

- 7.3 billion yen decrease in revenue, 3.6 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.4 ppt

FX: Foreign exchange, COGs: Cost of goods sold

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

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* 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

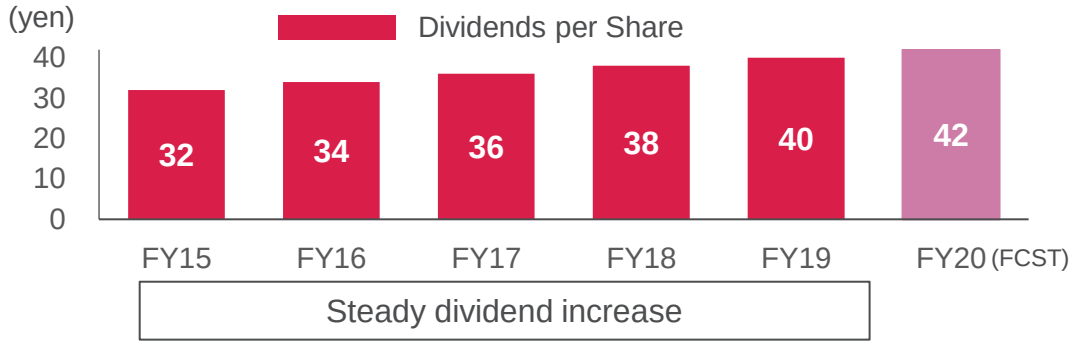
(billion yen)	FY19 end	Dec 31, 2020
Total assets	2,315.2	2,296.8
Cash and cash equivalents	318.4	306.5
Total equity attributable to owners of the parent	1,289.2	1,368.6
Equity ratio (%)	55.7%	59.6%

(billion yen)	Q3/FY19	Q3/FY20	FY19
Cash flows from operating activities	170.3	225.1	222.0
Cash flows from investing activities	-74.4	-67.7	-389.8
Free cash flows	95.9	157.4	-167.8
Cash flows from financing activities	-125.2	-171.3	181.1
Bonds and short-term borrowings	-	-161.0	326.0
Proceeds from long-term borrowings	-	80.0	-
Dividends paid	-73.5	-76.2	-73.5

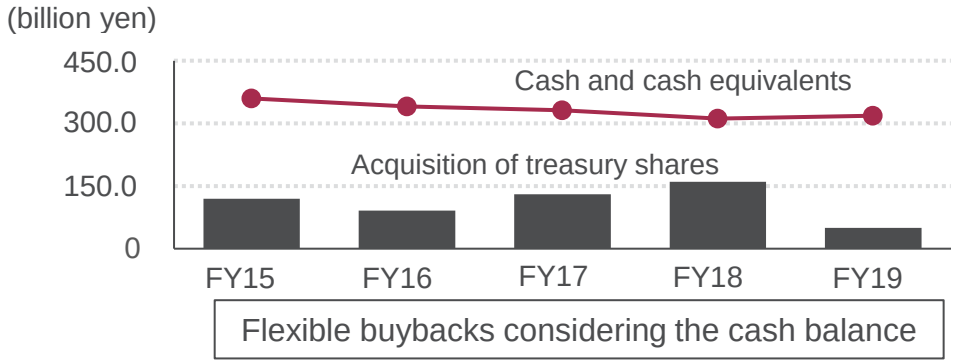
CAPITAL ALLOCATION

- *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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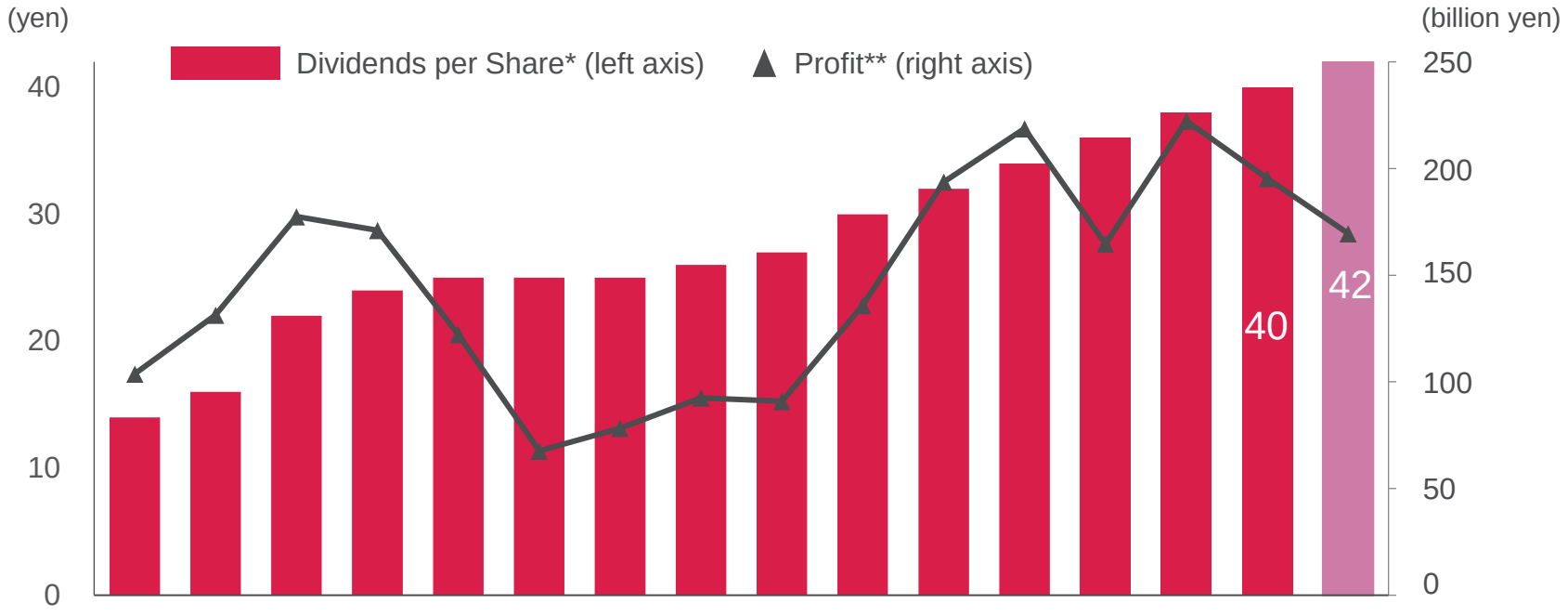
DETAILS OF SHAREHOLDER RETURNS



(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 Jan 2021

✓✓✓: 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

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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
- ASP0739
- ASP7317
- ASP0892
- ASP0367/MA-0211 (DMD)
- ASP2390
- ASP0598
- AT845
- ASP8062
- ASP1617

Phase 2

- zolbetuximab (Pancreatic adenocarcinoma)
- enfortumab vedotin (Other solid tumors)
- ASP1128/MA-0217 (Acute kidney injury)
- ASP3772 (Pneumococcal disease)
- FX-322 (Sensorineural hearing loss)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP0367/MA-0211 (Primary mitochondrial myopathies)
- bleselumab (rFSGS)
- roxadustat (Chemotherapy-induced anemia)
- 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)
- gilteritinib (R/R AML: China)
- roxadustat (Anemia associated with CKD: EU)
- mirabegron (Pediatric NDO: US)
- tacrolimus (Lung transplantation: 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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DMD: Duchenne muscular dystrophy, XLMTM: X-linked myotubular myopathy, rFSGS: Recurrence of focal segmental glomerulosclerosis, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive 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

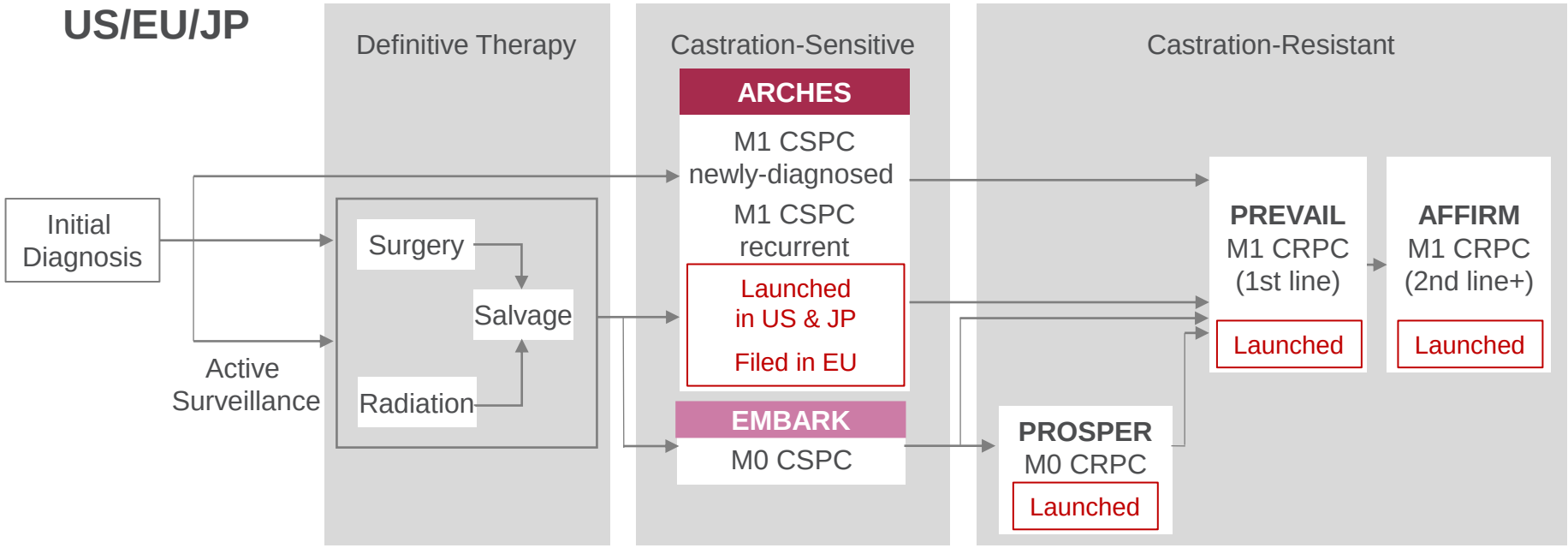
Phase 1 Entry to Approval since Q2/FY2020 Financial Results Announcement in Oct 2020

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
ASP0739 Cancer			**tacrolimus** Prevention of rejection after lung transplantation: US	**enzalutamide** Nonmetastatic castration-resistant prostate cancer: China **roxadustat** Anemia associated with chronic kidney disease in patients not on dialysis: JP

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:** Approved in Nov 2020
- **M1 CSPC:** Enrollment completed in Phase 3 China-ARCHES study

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy

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

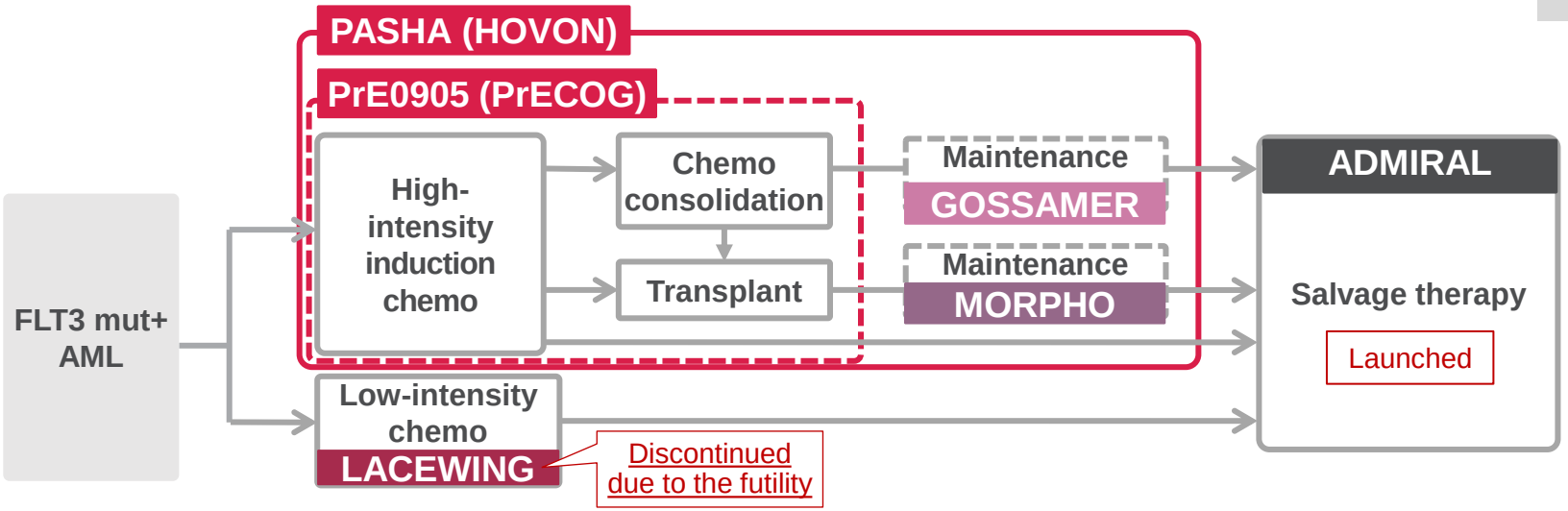
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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 and listed in "Overseas new drugs urgently needed in clinical settings")
	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=146	Discontinued due to the futility based on the planned interim analysis
	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 Q2/FY2020 financial results announcement in Oct 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 (1/5)

For urothelial cancer

P3: EV-301	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	Met the primary endpoint (OS) in Sep 2020, based on the planned interim analysis (full data to be presented at ASCO GU 2021)
P3: EV-302	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=760	FSFT: Apr 2020
P3: EV-303 /KEYNOTE-905	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=836	Enrollment ongoing in Pembro + EV arm
P3: EV-304 /KEYNOTE-B15	MIBC, Cis-eligible; EV+Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	To start in Q4 FY2020
P2: EV-201	mUC, PD-1/L1 inhibitor pretreated; EV mono 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 (full data to be presented at ASCO GU 2021)
P1b/2: EV-103	Cohorts A - G and K (mUC): A-G: Combo with Pembro and other chemo K: EV mono vs. EV + Pembro Cohorts H, J and L (MIBC, Cis-ineligible, + RC): H: EV mono (neoadjuvant) J (optional): EV+Pembro (neoadjuvant) L: EV mono (perioperative)	n=457	Added Cohort L to start in 1H 2021
P2: EV-203	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n≈40	Currently under preparation (IND approved)

For other solid tumors

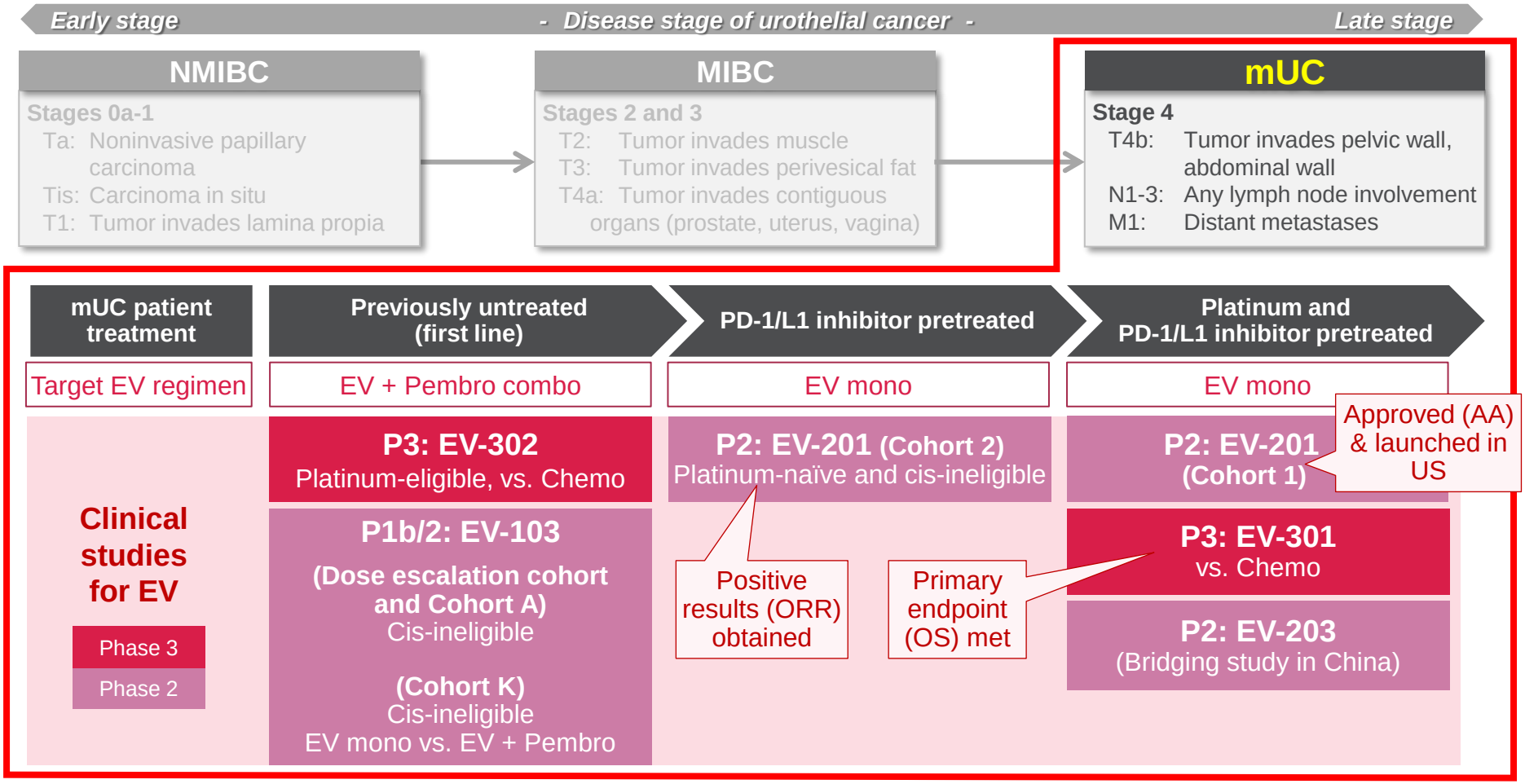
P2: EV-202	HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric, gastroesophageal junction or esophageal cancer; EV mono	n=240	FSFT: Mar 2020

Seagen astellas

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020

ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, OS: Overall survival, ASCO GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, ORR: Objective response rate, IND: Investigational New Drug application, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer

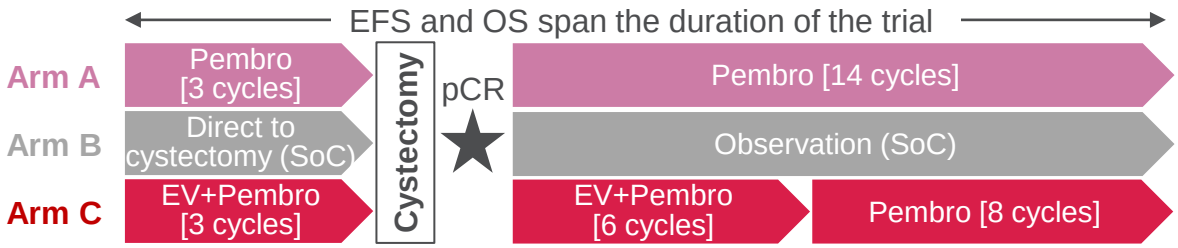
ENFORTUMAB VEDOTIN (EV) (2/5): OVERALL mUC PROGRAM



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

ENFORTUMAB VEDOTIN (EV) (3/5): CLINICAL STUDIES IN MIBC

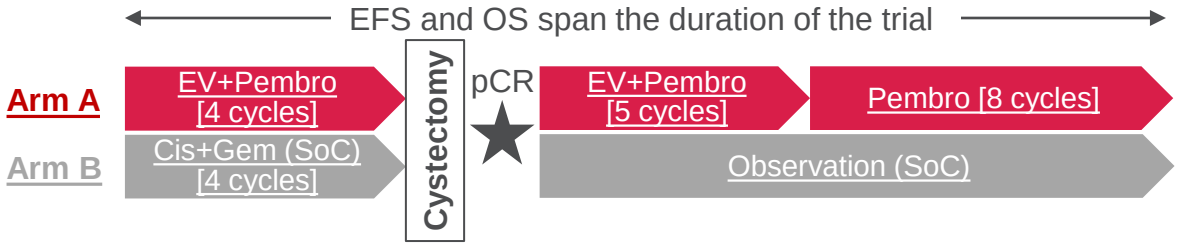
1) Phase 3 study in *cis-ineligible* MIBC (KEYNOTE-905/EV-303): Perioperative EV+Pembro vs. Cystectomy alone



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

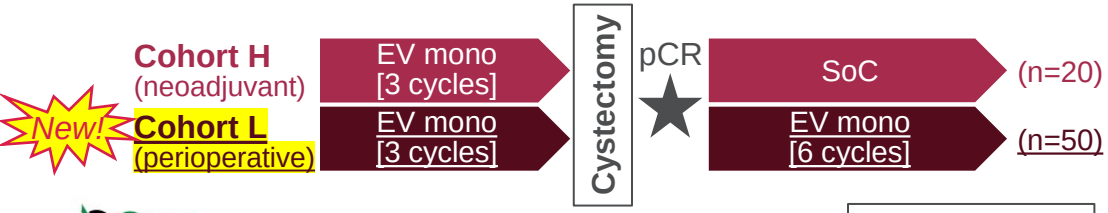
New!

2) Phase 3 study in *cis-eligible* MIBC (KEYNOTE-B15/EV-304): Perioperative EV+Pembro vs. Neoadjuvant chemo



- Endpoints:
  - ✓ Primary (dual): EFS and pCR
  - ✓ Key secondary: OS
- n=784, randomized 1:1
- Sponsored by Merck. Funded by 3 companies; Seagen, Astellas, and Merck
- Study start planned in Q4 FY2020

3) Phase 1b/2 study in *cis-ineligible* MIBC (cohorts in EV-103): Neoadjuvant/Perioperative EV mono



New!

1 cycle = 21 days

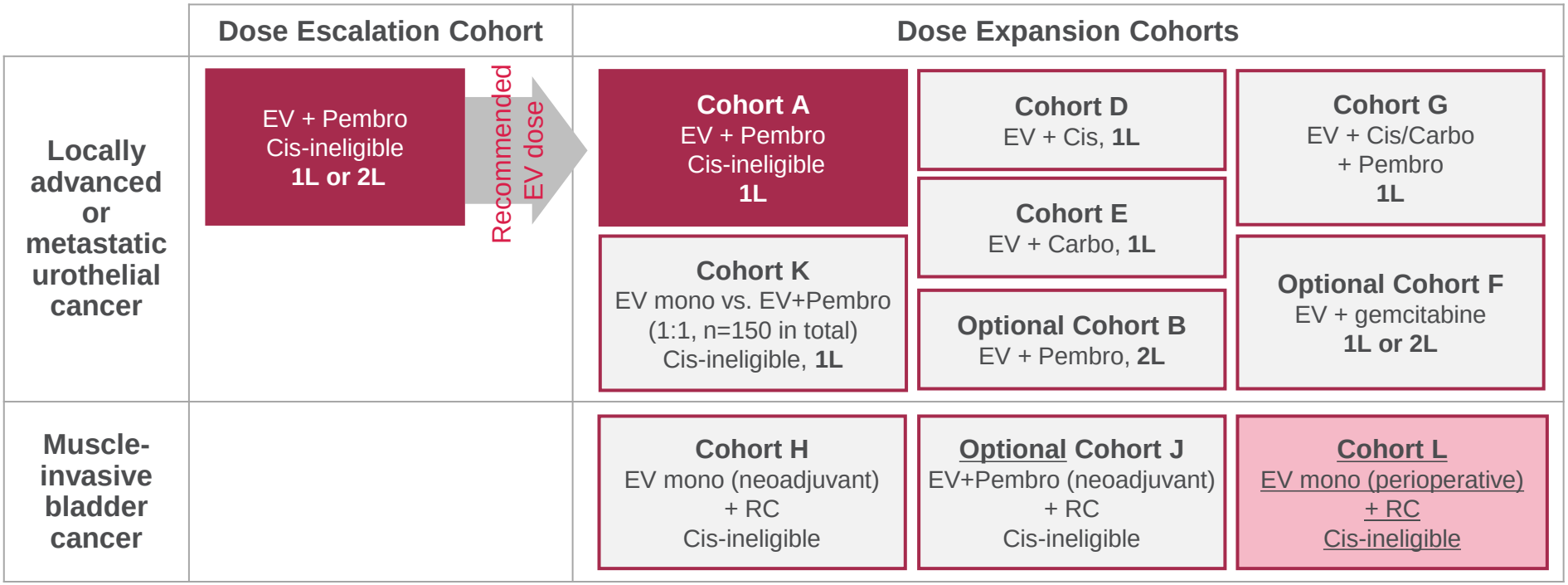
- To assess EV monotherapy in MIBC to support the EV+Pembro combo treatment outcome
- Primary endpoint: pCR
- Cohort L newly added to the ongoing Seagen-sponsored EV-103 study to start in 1H 2021

Seagen

astellas

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
MIBC: Muscle-invasive bladder cancer, Cis: Cisplatin, Pembro: Pembrolizumab, SoC: Standard of care, EFS: Event-free survival, pCR: Pathologic complete response, OS: Overall survival, chemo: Chemotherapy, Gem: Gemcitabine, mono: Monotherapy

ENFORTUMAB VEDOTIN (EV) (4/5): PHASE 1b/2 EV-103 STUDY DESIGN



Results from cis-ineligible and 1L in these cohorts presented at ESMO 2019 and ASCO GU 2020

Cohort newly added

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

Seagen

(EV-103 study is sponsored by Seagen) astellas

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
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 (5/5): 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
(m)UC: (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

astellas

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: DB, 30 mg vs. 45 mg vs. placebo (1:1:1) The last 40 weeks: non-controlled, 30 mg or 45 mg	n=527	LSLV for 12w DB period achieved
	P3: SKYLIGHT 2		n=501	12w DB period topline results obtained
	P3: SKYLIGHT 4	MR-VMS; 52 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)	n=1,833	Enrollment completed

Asia (except for Japan)

	P3: MOONLIGHT 1	Moderate to severe MR-VMS; The first 12 weeks: DB, 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 Q2/FY2020 financial results announcement in Oct 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: Double-blind, 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)	n=26	Clinical hold lifted by FDA in Dec 2020. Clinical trial re-start activities underway Discussions planned on the path forward toward global registration filings

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
(r)AAV: (recombinant) Adeno-associated virus, Des: Desmin promoter, hMTM1: Human myotubularin gene,
RMAT: Regenerative Medicine Advanced Therapy, PRIME: PRIority Medicines, FDA: Food and Drug Administration

ON THE FOREFRONT OF HEALTHCARE CHANGE