Q1/FY2020 FINANCIAL RESULTS
ENDED JUNE 30, 2020

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Chief Strategy Officer and Chief Financial Officer
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August 4, 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 Q1/FY2020 Consolidated Financial Results and FY2020 Revised Forecasts

II Initiatives for Sustainable Growth

III Capital Allocation

Q1/FY2020 FINANCIAL RESULTS: OVERVIEW

Revenue and Core OP decreased overall
Sales of growth drivers steadily increased

- In particular, sales of XTANDI and PADCEV exceeded expectations; growth of main products offset most of the sales decreases from termination of sales and distribution in Japan and LOE

- Negative impact on financial results from the spread of COVID-19

LOE: Loss of exclusivity

Q1/FY2020 FINANCIAL RESULTS

(billion yen)	Q1/FY19	Q1/FY20	Change (amount)	Change (%)	CER growth
Revenue	**334.1**	**307.0**	**-27.2**	**-8.1%**	-6.0%
Cost of sales	70.5	59.7	-10.9	-15.4%	
% of revenue	21.1%	19.4%			
SG&A expenses	117.5	120.8	+3.3	+2.8%	
R&D expenses	53.5	57.3	+3.8	+7.1%	
Amortisation of intangible assets	7.2	5.9	-1.3	-18.4%	
Core operating profit	**84.7**	**63.4**	**-21.4**	**-25.2%**	-18.4%
<Full basis>					
Other income	4.5	2.2	-2.3	-50.4%	
Other expense	12.2	4.8	-7.4	-60.6%	
Operating profit	**77.1**	**60.8**	**-16.3**	**-21.1%**	
Profit before tax	76.5	60.2	-16.3	-21.3%	
Profit	**58.5**	**50.4**	**-8.1**	**-13.9%**	

Q1/FY2020 FINANCIAL RESULTS: REVENUE

Growth of main products offset most of the sales decreases from termination of sales and distribution in Japan and LOE

	Q1/FY19	Q1/FY20	Change
Revenue	**334.1 bil. yen**	**307.0 bil. yen**	**-27.2 bil. yen**

Sales increases in main products

XTANDI, XOSPATA, PADCEV, mirabegron, New products in Japan **+28.1 bil. yen**

Impact of the LOE/termination of sales and distribution in Japan

Vesicare EU, Tarceva, Celecox, MYCAMINE US/Funguard Symbicort, KM bio products, Micardis **-28.8 bil. yen**

Impact of COVID-19: Aprrox. **-23.0 bil. yen**

- Reversal of inventory build in Q4/FY19 (XTANDI EU, Prograf EU, etc.)
- Demand volume decrease due to reduction of in-person hospital/clinic visits (OAB products, Lexiscan, EVENITY, etc.)

New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)
OAB (overactive bladder) products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

Q1/FY2020 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

Q1/FY2020 sales

XTANDI
112.0 billion yen +16.0 (+17%)

- ✓ Record quarterly sales
- ✓ Demand grew in excess of 30% in US
- ✓ Approved additional indication in Japan in May 2020

XOSPATA
5.6 billion yen +3.2 (+128%)

- ✓ In addition to Japan and US, contribution from sales in Europe (+1.0 bil. yen)

PADCEV
3.0 billion yen +3.0

- ✓ Launched in US in Dec 2019
  Positive uptake thus far

mirabegron
40.4 billion yen +0.5 (+1%)

- ✓ Double-digit growth in US
- ✓ Global sales remain flat as demand reduced due to the impact of COVID-19

New products in Japan
18.2 billion yen +5.4 (+42%)

- ✓ Steady growth driven by EVENITY (+3.4 bil. yen) and Suglat-Family (+1.1 bil. yen)

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

Q1/FY2020 FINANCIAL RESULTS: COST ITEMS

Core basis: Year-on-Year comparison

Cost of sales % of revenue
1.7ppt decrease ↓

- ✓ Decrease mainly due to changes in product mix
  (FX impact on elimination of unrealized gain: Increase in COGs ratio (+1.1ppt))

SG&A expenses
2.8% increase ↑

- ✓ 4.8% decrease, excluding increased XTANDI co-promotion fee due to sales expansion in US
- ✓ Decrease in spending of sales promotion expenses and travel expenses due to the impact of COVID-19

R&D expenses
7.1% increase ↑

- ✓ In addition to investment increase in development costs for late-stage projects, Audentes' R&D expenses increased
- ✓ Decrease in development costs due to the impact of COVID-19

Amortisation of intangible assets
18.4% decrease ↓

- ✓ Completion of amortisation of Tarceva US intangible asset in Q1/FY19

FY2020 REVISED FORECAST

- Downward revision of initial forecasts for revenue and core OP
  - ✓ Reflect the latest business outlook:
    Upward revision of sales forecasts for main products in oncology area due to continuously robust growth trend
  - ✓ Reflect the impact of COVID-19:
    Downward revision of forecasts for revenue and costs
- Aiming for core OP margin of 20%

(billion yen)	FY20 Initial FCST	FY20 Revised FCST	Change
Revenue	**1,282.0**	**1,256.5**	**-25.5**
R&D expenses	239.0	233.5	-5.5
Core operating profit	**257.0** 20.0%	**251.0** 20.0%	**-6.0**

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FY2020 REVISED FORECAST: FACTORS OF REVISION

	Revenue	Core OP
Variance from initial forecast	-25.5 bil. yen	-6.0 bil. yen
(Breakdown)		
Latest business outlook	+13.0 bil. yen • Favorable sales of XTANDI US and PADCEV	+8.5 bil. yen • Profit increase due to upward revision of sales • Efficient management of expenses • Further promotion of global procurement efficiencies
Impact of COVID-19	-35.0 bil. yen • Reversal of inventory build ✓ XTANDI EU, Prograf EU, etc. • Sales decreases due to reduction of in-person hospital/clinic visits ✓ OAB products, Lexiscan, EVENITY, etc. • XTANDI EU: M1 CSPC approval delay	-13.0 bil. yen • Gross profit decrease: -27.0 bil. yen • Costs decrease: +14.0 bil. yen ✓ Underspending due to restrictions on activities ✓ Clinical trial delay
FX impact	-3.5 bil. yen	-1.5 bil. yen

OAB (overactive bladder) products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
M1 CSPC: Metastatic castration-sensitive prostate cancer

FY2020 REVISED FORECAST: OUTLOOK FROM Q2/FY2020 ONWARDS

- Smaller downward revision of revenue
  In addition to steady growth of main products in oncology area, the impact of COVID-19, which was significant in Q1, to be moderate
- Upward revision of Core OP
  More than offsetting revenue decrease by pursuing further cost efficiency in addition to decrease in spending due to the impact of COVID-19

(billion yen)	Q1 Variance between initial FCST and actual	Q2 - Q4 Variance between initial FCST and revised FCST	FY2020 Variance between initial FCST and revised FCST
Revenue	-19.5	**-6.0**	-25.5
Core OP	-8.5	**+2.5**	-6.0

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KEY POST-POC PROJECTS: STATUS UPDATE

(Underlined: Updates since FY2019 financial results announcement in May 2020)

enzalutamide

M0 CRPC

- Phase 3 study OS data published in NEJM presented at ASCO 2020
- Filed in US in May 2020 and EU in Jun 2020 for label update to include the OS data

M1 CSPC

- Approved in JP in May 2020 for prostate cancer with distant metastasis
- 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

zolbetuximab

Gastric and gastroesophageal junction adenocarcinoma

- Phase 3 studies ongoing

Pancreatic adenocarcinoma

- Phase 2 study ongoing

gilteritinib

Relapsed or refractory acute myeloid leukemia

- **China:** Filed in Mar 2020

Earlier-stage acute myeloid leukemia

- Phase 3 studies 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

enfortumab vedotin

Metastatic urothelial cancer

- **Previously untreated (first line; combo with pembrolizumab):** Phase 3 study ongoing
- **Second or later lines:** Phase 2 and Phase 3 studies ongoing

Other solid tumors

- Phase 2 study ongoing

fezolinetant

Menopause-related vasomotor symptoms

- **US & EU:** Phase 3 studies ongoing
- **JP:** Independent development plan under preparation
- **Asia:** Asian Phase 3 study ongoing

AT132 (resamirigene bilparvovec) XLMTM

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

Genetic Regulation

PoC: Proof of concept, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, OS: Overall survival, NEJM: New England Journal of Medicine, ASCO: American Society of Clinical Oncology, CKD: Chronic kidney disease, XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration

ENZALUTAMIDE: 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 0.19 ✔ 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)	(Median not reached)	✔ 29.5 months	✔ 33.9 months	✔ 17.5 months	✔ 8.3 months

✔: Data obtained, *: Prespecified interim analysis, Yellow-highlighted: Updated at Q1/FY2020 earnings

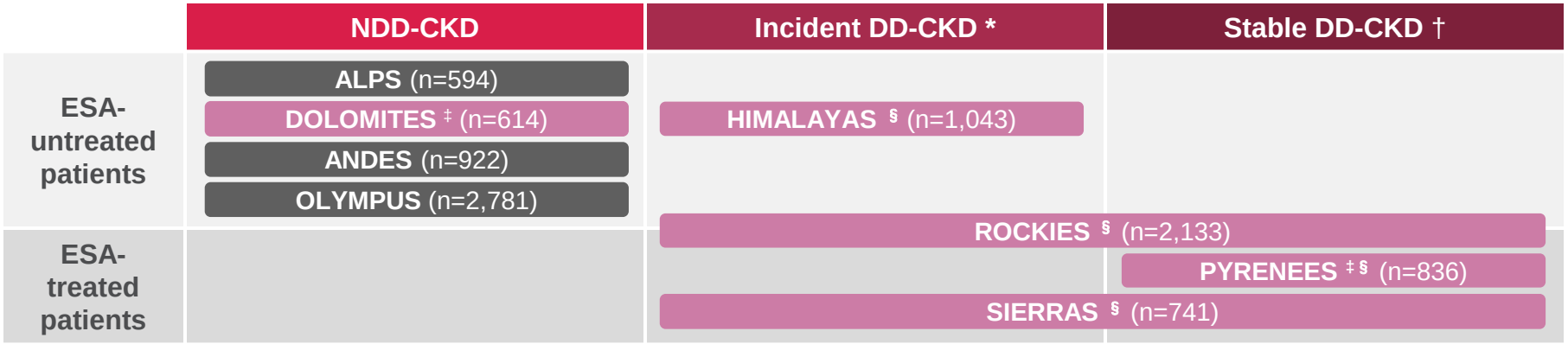
M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment

ROXADUSTAT: MAA SUBMISSION

Filed in EU for the treatment of anemia in adult patients with chronic kidney disease (CKD) both dialysis dependent (DD) and non-dialysis dependent (NDD), based on the data of 8 Phase 3 studies involving more than 9,000 patients

- ✓ *Proved to be efficacious in increasing and maintaining target hemoglobin levels with reduced use of intravenous iron*
- ✓ *The cardiovascular and general safety profile is reflective of the underlying conditions in the CKD population*
  - *Pooled safety analysis showed non-inferiority of roxadustat in both MACE and MACE+ to ESA in DD-CKD and to placebo in NDD-CKD*

Global Phase 3 program for roxadustat



* Subset of patients with ≥ 2 weeks and ≤ 4 months of dialysis at the time of randomization
† Subset of patients with > 4 months of dialysis at the time of randomization
‡ Darbepoetin-alfa as an active comparator, § Epoetin-alfa as an active comparator

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MAA: Marketing Authorization Application, ESA: Erythropoiesis-stimulating agent,
MACE: Major adverse cardiovascular events (composite endpoint of all-cause mortality, stroke and myocardial infarction),
MACE+: MACE plus congestive heart failure requiring hospitalization and unstable angina requiring hospitalization

AT132 (RESAMIRIGENE BILPARVOVEC): CURRENT STATUS



Clinical study for registration of AT132 in XLMTM patients put on clinical hold by FDA, due to recently observed serious adverse events

Study cohort	AT132 dose	No. of subjects enrolled (n=26 in total)	
		Treated	Untreated
Dose escalation	1 x 10^{14} vg/kg	6	-
	3 x 10^{14} vg/kg	10	-
Pivotal expansion	3 x 10^{14} vg/kg	7	3

- 3 of 17 patients who received AT132 at the 3 x 10^{14} vg/kg dose have developed progressive liver dysfunction. 2 of these 3 patients have died, and preliminary findings indicate that the immediate cause of death was sepsis. Notable features among these 3 patients include:
  - ✓ older age
  - ✓ heavier weight
  - ✓ evidence of pre-existing hepatobiliary disease
- Among the 6 patients who received AT132 at 1 x 10^{14} vg/kg, including 4 with previous history of hepatobiliary disease, none have developed serious adverse events, despite being years out from treatment
- Next steps:
  - ✓ Robust investigation and communications with the regulatory authorities ongoing
  - ✓ Plan to update filing timelines once path forward is determined
  - ✓ Remain committed to AT132 and the XLMTM patient community

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XLMTM: X-linked myotubular myopathy, FDA: Food and Drug Administration, vg/kg: Vector genomes per kilogram

COVID-19 IMPACT ON CLINICAL DEVELOPMENT (1/2)

- We have started to reactivate clinical studies in the countries such as US, EU, and Japan, where the activities were suspended due to COVID-19 pandemic, following the benefit-risk assessment of each study, while delay in the timeline might be caused in some of the studies

- We continue taking mitigation measures to maintain enrolled patients, while ensuring patient safety and reducing the burden to healthcare systems, e.g. telemedicine visits, home health care visits for blood draws and other assessments, use of local laboratories and delivery of investigational product directly to patient homes

- We are building flexibility into the protocols to respond to changes related to the ongoing pandemic

COVID-19 IMPACT ON CLINICAL DEVELOPMENT (2/2)

Major project-specific impact

Project	Study / Milestone	COVID-19 impact
enzalutamide	Regulatory decision in EU for M1 CSPC	• Delayed, because the EMA's GCP inspection was postponed due to COVID-19; regulatory decision originally expected in early FY2020, but currently in late FY2020 at the earliest
gilteritinib	Phase 3 studies	• Enrollment has been impacted especially in Phase 3 LACEWING study (newly diagnosed, intensive chemo ineligible) and Asian Phase 3 study (R/R) • Partners' studies such as Phase 3 PASHA study (newly diagnosed, intensive chemo eligible) had no pause but experienced some slowdown
enfortumab vedotin	Phase 3 and Phase 2 studies	• For Phase 3 EV-301 study (mUC, platinum and PD-1/L1 inhibitor pretreated), which was fully enrolled, innovative strategies have been implemented to continue to ensure the safety of patients, continued supply of therapy and quality of the data to support global submissions • Enrollment has been impacted in Phase 2 EV-202 study (other solid tumors), but with no significant delay expected
zolbetuximab	Phase 3 studies	• Enrollment has been impacted in Phase 3 SPOTLIGHT and GLOW studies, with the general consensus amongst investigators that a 3-6 month recovery period would be needed for screening and enrollment activities to return back to pre-COVID-19 levels
roxadustat	Regulatory review	• No impact
fezolinetant	Phase 3 studies	• Enrollment was paused in Phase 3 SKYLIGHT 1 (pivotal) and SKYLIGHT 4 (long-term) studies, but has been strong after reopening. Most sites experienced limited disruption • SKYLIGHT 4 sample size increase addresses the FDA feedback on the primary endpoint and also takes into consideration potential COVID-19 impact on end-of-study biopsy completion rates

Continue reassessing all the clinical study timelines, depending the fluid COVID-19 situation, and timely updating them on ClinicalTrials.gov and/or at the future earnings as needed

M1 CSPC: Metastatic castration-sensitive prostate cancer, EMA: European Medicines Agency, GCP: Good Clinical Practice, R/R: Relapsed or refractory, mUC: Metastatic urothelial cancer, FDA: Food and Drug Administration

KEY EVENTS EXPECTED IN FY2020

Regulatory decision	enzalutamide	M1 CSPC (EU) M0 CRPC (China) M0 CRPC, label update to include the OS data (US, EU)
	roxadustat	Anemia associated with chronic kidney disease, non-dialysis (JP)
Data readout	enfortumab vedotin	Phase 2 EV-201 study cohort 2 in metastatic urothelial cancer, PD-1/L1 inhibitor pretreated, platinum naïve and cisplatin ineligible

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

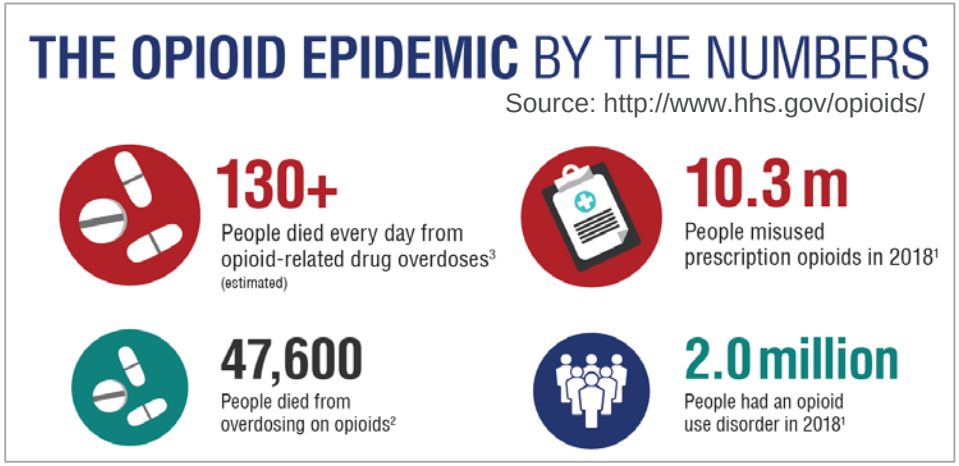
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, OS: Overall survival

ASP8062 FOR OPIOID USE DISORDER (OUD)

NIH awards grant to fund early clinical studies of ASP8062, $GABA_B$ PAM, to investigate potential novel therapeutic approach to address the opioid crisis

Opioid crisis in US

- The White House declared the opioid crisis a national Public Health Emergency under federal law in Oct 2017[4], with the loss of many American lives due to overdose of an opioid
- The NIH Helping to End Addiction Long-Term (HEAL) Initiative strategy aims to accelerate scientific solutions to stem the national opioid public health crisis



$GABA_B$ PAM

- "Ten most wanted" pharmacological mechanisms by NIDA[2] include $GABA_B$ PAM, based on the existing data showing $GABA_B$ receptors involvement with reducing self-administration and drug-seeking behavior across several substances of abuse
- This NIH grant application was based on the supportive preclinical data utilizing ASP8062 in various models of substance of abuse

ASP8062 clinical studies for OUD under the NIH grant

- Two Phase 1 drug-drug interaction/safety studies, with morphine and with Suboxone (buprenorphine/naloxone) [ongoing]
- A Phase 2 PoC study in OUD patients [planned; following the Phase 1 studies]

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1: 2019 National Survey on Drug Use and Health. Mortality in the United States, 2018. 2: NCHS Data Brief No. 329, Nov 2018. 3: NCHS, National Vital Statistics System. Estimates for 2018 and 2019 are based on provisional data. 4: The White House. The Opioid Crisis. 2017. 5: Rasmussen K, *et al.*, 2019.
NIH: National Institute of Health, PAM: Positive allosteric modulator, NIDA: National Institute on Drug Abuse (the NIH's division), PoC: Proof of concept

PROGRESS IN Rx+ PROGRAM: Fit-eNce - NEW STYLE FITNESS SERVICE

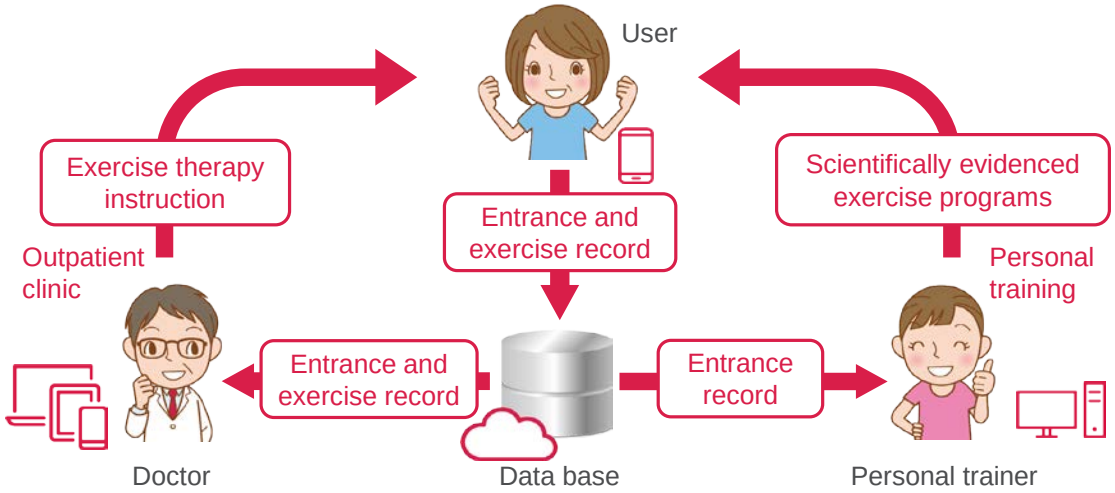
Chronic disease progression prevention

As the first program of Rx+ business,
pilot marketing of a scientifically evidenced exercise support service scheduled to start

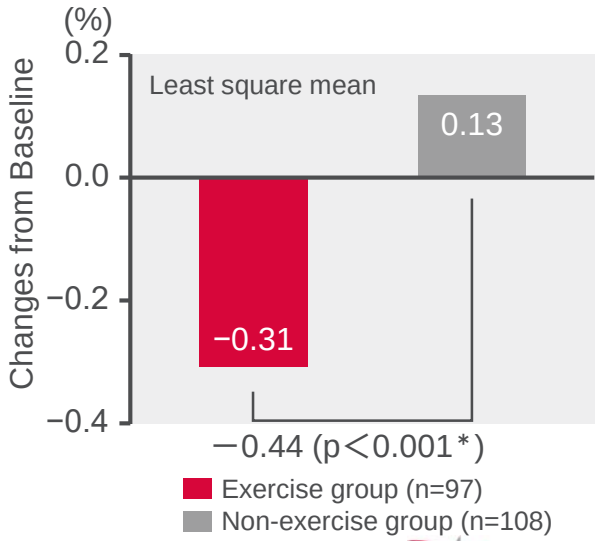
- ✓ Developed scientifically based exercise programs through industry-government-academia collaboration with Yokohama City and Yokohama City University
- ✓ Planning to begin sales of this fitness service in limited regions in 2020, utilizing scientifically based exercise programs through fitness clubs

その運動には、科学がある、根拠がある。
フィットネス × サイエンス
Fit-eNce™

Scientifically evidenced exercise programs and service which support regular exercise provided by Astellas



Change in HbA1c at Week 13
(Results of medical and health research)



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* Analysis set: Full analysis set
Mixed model for repeated measures with treatment group and visit as factors, with baseline value as a covariate as well as an interaction of treatment by visit and an interaction of baseline value by visit

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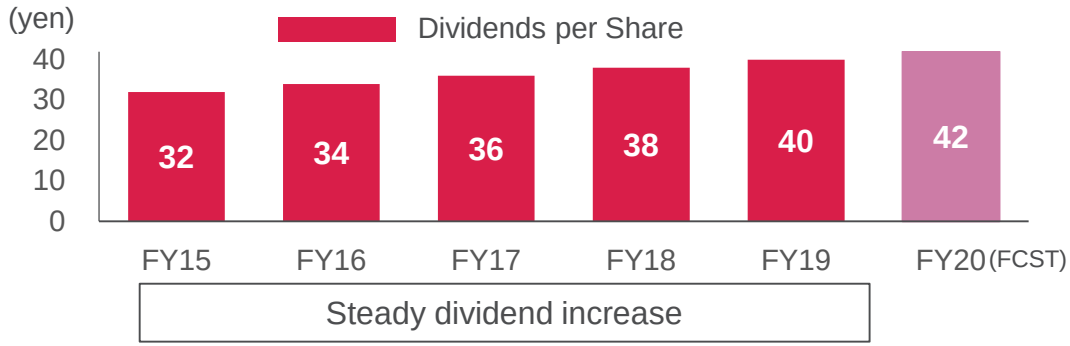
CAPITAL ALLOCATION

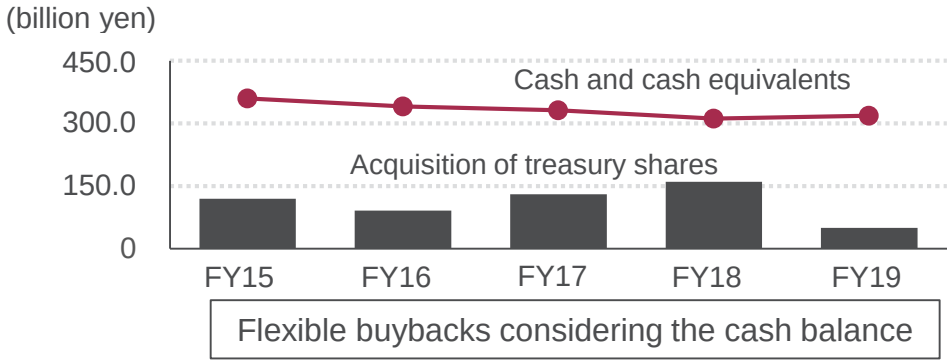
- *Top priority is investment for strategic business growth*



- *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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APPENDIX

ACCOUNTING TREATMENT OF BUSINESS COMBINATION WITH AUDENTES

Revised fair value measurement of Audentes balance sheet at acquisition date (as of Jan 15, 2020)
FY19 end consolidated balance sheet retrospectively revised

<As of Mar 31, 2020>

($ million)

Other assets 389	Other liabilities 116
Intangible assets 2,620	Deferred tax liabilities 382
Goodwill 391	Acquisition cost 2,902

<As of Jun 30, 2020 *>

($ million)

Other assets 389	Other liabilities 116
Intangible assets 2,494 (-126)	Deferred tax liabilities 354 (-27)
Goodwill 490 (+99)	Acquisition cost 2,902

Breakdown of intangible assets $2,494M
- In-Process R&D: $1,839M
- Patent and technology: $656M

Amortisation of intangible assets for patent and technology:
FY20 FCST (12 months) $42M

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* Subject to change due to the provisional accounting treatment at this moment

Q1/FY2020: REVENUE BY REGION

(billion yen)	Q1/FY19	Q1/FY20	Change (%)
Japan	98.5	77.8	-21.0%
United States	105.3	117.2	+11.3%
Established Markets	75.8	64.0	-15.5%
Greater China	14.7	14.2	-3.4%
International	34.2	30.2	-11.8%

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.

Q1/FY2020: SALES OF MAIN PRODUCTS

(billion yen)	Q1/FY19	Q1/FY20	Change	CER growth	FY20 Initial FCST *	FY20 Revised FCST **
XTANDI	**96.0**	**112.0**	**+16.6%**	**+19.7%**	**459.3**	**464.6**
XOSPATA	**2.5**	**5.6**	**+128.3%**	**+133.1%**	**23.2**	**23.1**
PADCEV	**-**	**3.0**	**-**	**-**		**13.0**
OAB products	**53.5**	**48.1**	**-10.0%**	**-8.2%**	**204.9**	**197.9**
mirabegron	39.9	40.4	+1.2%	+3.3%	172.5	167.9
Vesicare	13.6	7.7	-43.0%	-42.1%	32.4	30.0
Prograf	**50.4**	**45.3**	**-10.2%**	**-7.4%**	**186.3**	**182.0**

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

* Announced in May 2020
** Announced in Aug 2020

FY2020 REVISED FORECAST

(billion yen)	FY20 Initial FCST	FY20 Revised FCST	Change
Revenue	**1,282.0**	**1,256.5**	**-25.5**
R&D expenses	239.0	233.5	-5.5
Core operating profit	**257.0**	**251.0**	**-6.0**
Core profit	**206.0**	**200.5**	**-5.5**
<Full basis>			
Operating profit	**252.0**	**246.5**	**-5.5**
Profit	**202.0**	**197.5**	**-4.5**

Q1/FY2020 ACTUAL: FX RATE

Average rate for the period

Currency	Q1/FY19	Q1/FY20	Change
USD	110 yen	108 yen	-2 yen
EUR	123 yen	118 yen	-5 yen

Change in closing rate from previous fiscal year end

Currency	Q1/FY19	Q1/FY20
USD	-3 yen	-1 yen
EUR	-2 yen	+2 yen

<Impact of exchange rate on financial results>

- 7.1 billion yen decrease in revenue, 5.8 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +1.1ppt

FY2020 REVISED FCST: FX RATE & FX SENSITIVITY

Exchange rate (yen) Average for the period	FY20 Initial FCST	FY20 Revised FCST
USD	110 yen	109 yen
EUR	120 yen	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

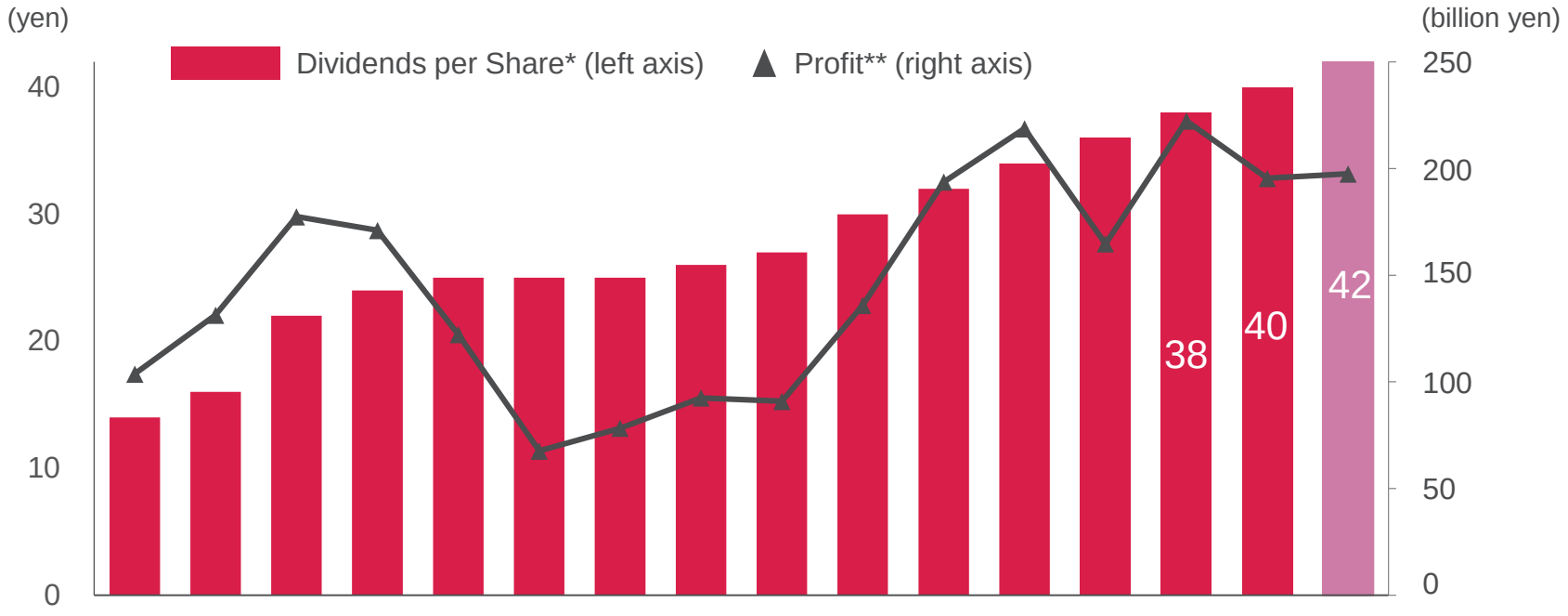
* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q2/FY2020 and onwards

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY19 end	Jun 30, 2020
Total assets	2,315.2	2,256.0
Cash and cash equivalents	318.4	239.9
Total equity attributable to owners of the parent	1,289.2	1,306.7
Equity ratio (%)	55.7%	57.9%

(billion yen)	Q1/FY19	Q1/FY20	FY19
Cash flows from operating activities	7.4	21.6	222.0
Cash flows from investing activities	-14.0	-28.3	-389.8
Free cash flows	-6.6	-6.7	-167.8
Cash flows from financing activities	-40.4	-73.0	181.1
Bonds and short-term borrowings	-	-110.0	326.0
Proceeds from long-term borrowings	-	80.0	-
Acquisition of treasury shares	-0.0	-0.9	-52.9
Dividends paid	-35.8	-37.2	-73.5

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 Aug 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

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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

- ASP1235/AGS62P1
- ASP8374/PTZ-201
- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP9801
- ASP7517
- ASP0892
- ASP0367/MA-0211
- ASP2390
- ASP0598
- AT845
- ASP8062
- ASP1617

Phase 2

- zolbetuximab (Pancreatic adenocarcinoma)
- ASP1650 (Testicular cancer)
- 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)
- bleselumab (rFSGS)
- ASP8302 (Underactive bladder)
- roxadustat (CIA)
- isavuconazole (Pediatric use: US)

Phase 3

- enzalutamide (M0 CSPC, M1 CSPC: China)
- gilteritinib (Earlier-stage AML, Pediatric use)
- enfortumab vedotin (Metastatic urothelial cancer)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use)
- 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)

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

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

AMD: Age-related macular degeneration, AKI: Acute kidney injury, XLMTM: X-linked myotubular myopathy, 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, GEJ: Gastroesophageal junction, MR-VMS: Menopause-related vasomotor symptoms, CKD: Chronic kidney disease

PROGRESS IN OVERALL PIPELINE

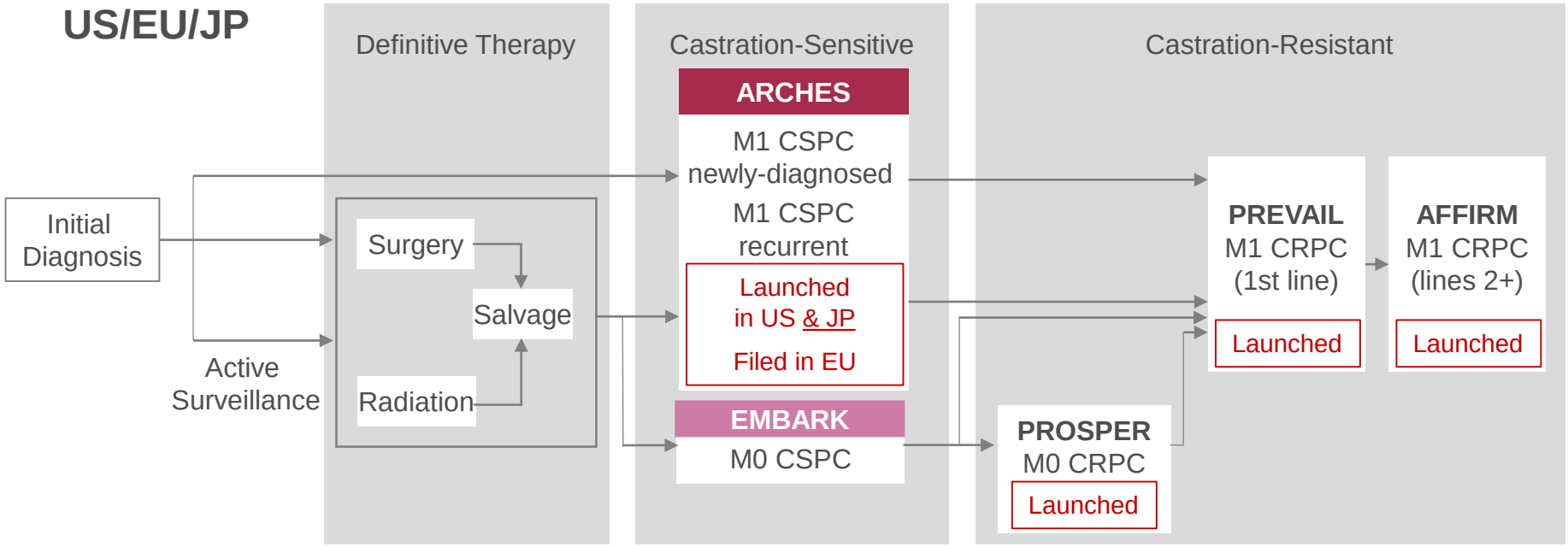
Phase 1 entry to approval since FY2019 financial results announcement in May 2020

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
			roxadustat Anemia in adult patients with chronic kidney disease: EU	**solifenacin** Neurogenic detrusor overactivity in pediatric patients aged 2 years and older: US **enzalutamide** Prostate cancer with distant metastasis: 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



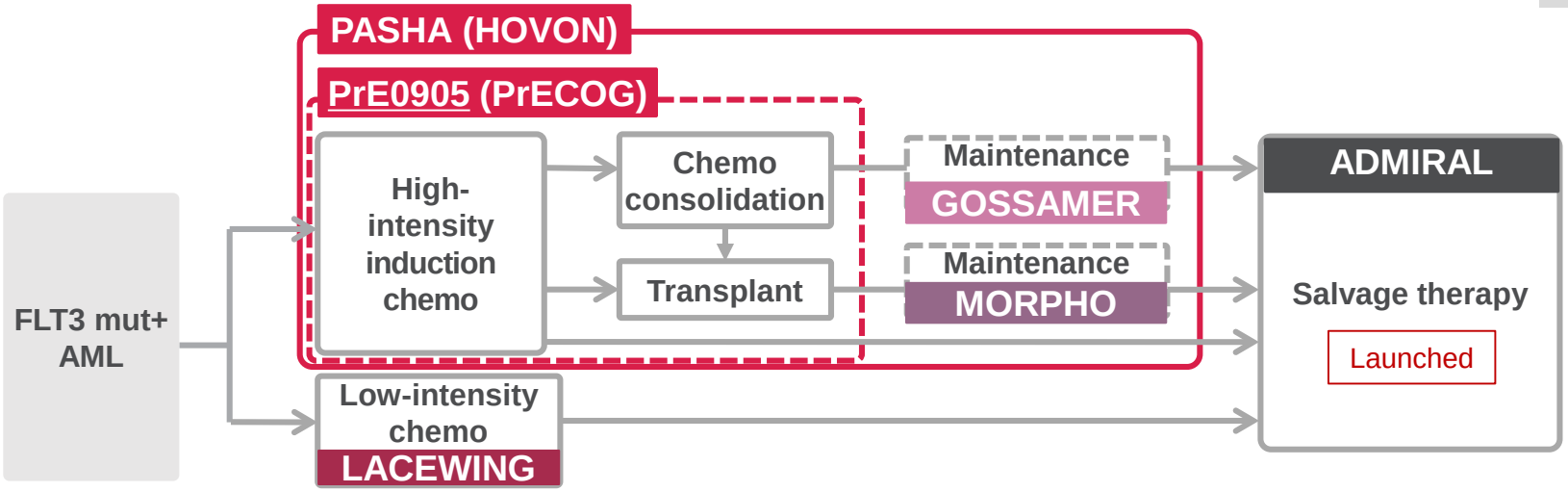
	P3: ARCHES	**M1 CSPC**	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019 and in JP in May 2020 Filed in EU in Jul 2019
	P3: EMBARK	**M0 CSPC**	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

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

Underlined: Updates since FY2019 financial results announcement in May 2020
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer,
ADT: Androgen deprivation therapy, FSFT: First subject first 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
	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 FY2019 financial results announcement in May 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)

Treatment landscape for metastatic urothelial cancer and clinical studies for EV

mUC patient treatment	Previously untreated (first line)	Platinum or PD-1/L1 inhibitor pretreated	Platinum and PD-1/L1 inhibitor pretreated
Standard of care*	**Cis-eligible:** • **Gem-Cis** **Cis-ineligible:** • **Gem-Carbo** • **PD-1/L1 inhibitor** (for patients with high PD-L1 expression)	**Platinum pretreated:** • **PD-1/L1 inhibitor** **PD-1/L1-inhibitor pretreated:** • **Gem-Carbo**	• **Single agent chemo** • **Clinical trial** • **Palliative care** • **EV monotherapy** (US only)
Clinical studies for EV Phase 3 Phase 2	**P3: EV-302** Platinum eligible, EV + Pembro +/- Platinum (Carbo/Cis)	**P2: EV-201 (Cohort 2)** PD-1/L1 inhibitor pretreated, Platinum naïve and cis-ineligible	**P2: EV-201 (Cohort 1)** Platinum and PD-1/L1 inhibitor pretreated Launched in US
	P1b/2: EV-103 Combo w/ Pembro and other chemotherapy		**P3: EV-301** Platinum and PD-1/L1 inhibitor pretreated, vs. chemotherapy

* Approved drugs and standard of care varies by region

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ADC: Antibody-drug conjugate, Gem: Gemcitabine, Cis: Cisplatin, Carbo: Carboplatin, Pembro: Pembrolizumab

ENFORTUMAB VEDOTIN (EV) (2/3): CLINICAL STUDIES

For urothelial cancer

	P3: EV-301	mUC, Platinum and PD-1/L1 inhibitor pretreated; vs. chemotherapy	n=608	Enrollment completed
	P3: EV-302	Locally advanced or mUC, Previously untreated, Platinum-eligible; EV + Pembro +/- Platinum (Carbo/Cis)	n=1,095	FSFT: Apr 2020
	P2: EV-201	mUC, PD-1/L1 inhibitor pretreated Cohort 1: Platinum pretreated Cohort 2: Platinum naïve and cisplatin ineligible	n=219	Cohort 1: Approved (under the Accelerated Approval program) and launched in US in Dec 2019 Cohort 2: Enrollment completed
	P1b/2: EV-103	Cohorts A - G and K (Locally advanced or mUC): A-G: Combo with Pembro and other chemotherapy K: EV monotherapy vs. EV + Pembro Cohorts H & J (Muscle invasive UC, Cisplatin-ineligible): H: EV monotherapy, J: EV + Pembro	n=407	FSFT: Nov 2017 Breakthrough Therapy Designation granted by FDA for EV + Pembro combo in the first line for patients with mUC not eligible for cisplatin, based on the initial results from EV-103
	P1: EV-101	Part A: mUC Part B: mUC with renal insufficiency, Metastatic NSCLC, Metastatic ovarian cancer Part C: mUC (PD-1/L1 inhibitor pretreated)	n=213	Enrollment completed

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

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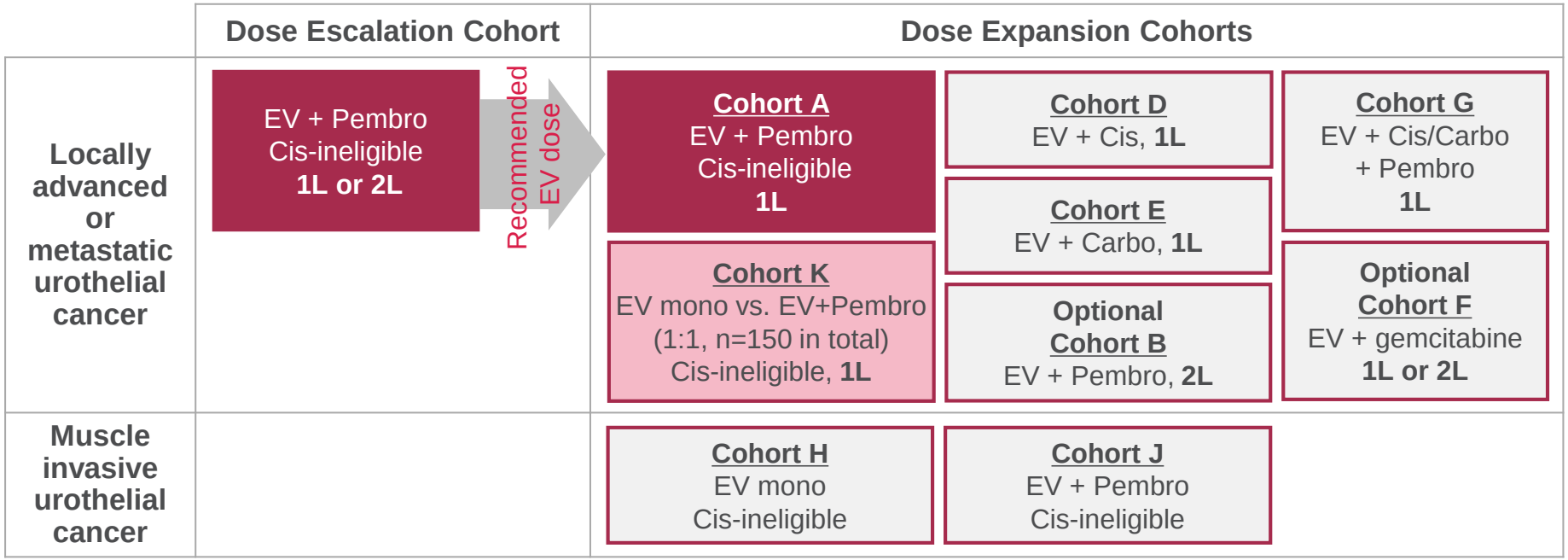
(m)UC: (metastatic) Urothelial cancer, Pembro: Pembrolizumab, Cis: Cisplatin, Carbo: Carboplatin, FSFT: First subject first treatment, FDA: Food and Drug Administration, NSCLC: Non-small cell lung cancer, HR+: Hormone receptor positive, HER2-: HER2 negative

ENFORTUMAB VEDOTIN (EV) (3/3): 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

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

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	Enrollment completed
	P3: SKYLIGHT 4	MR-VMS; 52 weeks: DBT, 30 mg vs. 45 mg vs. placebo (1:1:1)	n=1,740	FSFT: Aug 2019

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	Recruiting

Underlined: Updates since FY2019 financial results announcement in May 2020

1: DelveInsight, Epidemiology Forecast, June 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, DBT: Double-blind trial, 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 recent findings of new serious adverse events

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Underlined: Updates since FY2019 financial results announcement in May 2020
(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

