Q3/FY2021 FINANCIAL RESULTS
ENDED DECEMBER 31, 2021

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February 2, 2022

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/FY2021 Consolidated Financial Results

II Initiatives for Sustainable Growth

Q3/FY2021 FINANCIAL RESULTS: OVERVIEW

Revenue increased 6% YoY and is in line with full-year forecast
Core OP increased 8% YoY and is above full-year forecast

- Sales of XTANDI and Strategic products increased more than 20% YoY, in line with ambitious full-year forecast offsetting sales decrease due to termination of sales and distribution / transfer of products
- SG&A expenses are slightly above full-year forecast
  R&D expenses are on track
- Gain on divestiture of intangible assets*: 24.1 billion yen
  Established a new account, which includes gain on sale of rights of in-market products or pipeline assets
- Core basis profit is above full-year forecast

Full basis: OP increased YoY and is above full-year forecast

- Severance expenses due to early retirement incentive program in Japan (Booked in Q3: 15.8 bil. yen)

Applicant for early retirement program: 650 employees

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Strategic products: XOSPATA, PADCEV, EVRENZO
*Breakdown of Gain on divestiture of intangible assets: Transfer of products to Cheplapharm (12.3 billion yen), Transfer of pipeline asset (9.2 billion yen), Transfer of Bendamustine (2.0 billion yen), etc.

Q3/FY2021 FINANCIAL RESULTS

(billion yen)	Q3/FY20	Q3/FY21	Change	Change (%)	FY21 FCST*	Progress	FX impact
Revenue	**940.9**	**992.3**	**+51.4**	**+5.5%**	**1,323.0**	**75.0%**	+42.8 bil. yen
Cost of sales	187.7	194.1	+6.4	+3.4%			
% of revenue	20.0%	19.6%	-0.4 ppt				
SG&A expenses	363.0	406.4	+43.4	+11.9%	541.0	75.1%	
US XTANDI co-pro fee	90.2	108.7	+18.5	+20.5%			
SG&A excl. the above	272.8	297.7	+24.9	+9.1%			
R&D expenses	168.8	177.6	+8.8	+5.2%	242.0	73.4%	
Amortisation of intangible assets	17.3	20.2	+3.0	+17.1%			
Gain on divestiture of intangible assets	-	24.1	+24.1	-			
Core operating profit	**203.7**	**220.0**	**+16.3**	**+8.0%**	**270.0**	**81.5%**	+15.4 bil. yen
<Full basis>							
Other income	7.0	4.2	-2.8	-			
Other expense	51.3	54.9	+3.6	-			
Operating profit	**159.5**	**169.4**	**+9.9**	**+6.2%**	**218.0**	**77.7%**	
Profit before tax	164.2	167.4	+3.2	+1.9%	216.0	77.5%	
Profit	**132.9**	**132.5**	**-0.4**	**-0.3%**	**174.0**	**76.1%**	

* Announced in Oct 2021

Q3/FY2021 FINANCIAL RESULTS: REVENUE

Revenue increase driven by growth of XTANDI and Strategic products, which offsets sales decrease due to termination of sales and distribution / transfer of products

	Q3/FY20	Q3/FY21	Change	Change (%)
Revenue	**940.9 bil. yen**	**992.3 bil. yen**	**+51.4 bil. yen**	**+5.5%**

Increase in XTANDI and Strategic products

XTANDI, XOSPATA, PADCEV, EVRENZO **+83.6 bil. yen**

- Returned sales of Lexiscan, negatively impacted by COVID-19 in Q1/FY20 **+12.8 bil. yen**

Termination of sales and distribution / transfer of products

Celecox, Lipitor, Eligard **-34.7 bil. yen**

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Strategic products: XOSPATA, PADCEV, EVRENZO

Q3/FY2021 FINANCIAL RESULTS: SALES OF MAIN PRODUCTS

Q3/FY2021 Act and FY2021 FCST (billion yen)

XTANDI

411.6

YoY: +68.9 (+20%)

Progress against FCST: 74%

FY2021 FCST: 554.1

- ✓ Global sales increased 20% YoY, in line with forecast
- ✓ In addition to US, sales expansion in EU following approval of M1 HSPC indication
- ✓ Strong growth continues in Japan and China

XOSPATA

25.7

YoY: +8.1 (+46%)

Progress against FCST: 73%

FY2021 FCST: 35.4

- ✓ Global sales increased, almost in line with forecast, driven by growth mainly in US and EU
- ✓ Sales contribution from China newly launched in Apr. 2021

PADCEV

14.6

YoY: +5.2 (+56%)

Progress against FCST: 70%

FY2021 FCST: 20.7

- ✓ Revenue in US grew steadily, in line with forecast
- ✓ Launched in Japan in Nov. 2021 and initial uptake has been very strong thus far

EVRENZO

2.1

YoY: +1.4 (+199%)

Progress against FCST: 29%

FY2021 FCST: 7.2

- ✓ Sales in Japan are behind full-year forecast
- ✓ Launched in Established Markets from Sep. 2021 and initial uptake has been slower than forecast

mirabegron

126.9

YoY: +4.6 (+4%)

Progress against FCST: 72%

FY2021 FCST: 176.3

- ✓ Global sales are behind full-year forecast
- ✓ In US, sales are behind forecast due to lower than expected US OAB market growth and increased pricing pressure

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M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, PADCEV (US): Co-promotion revenue from Seagen, mirabegron (Product name: Betanis/Myrbetriq/BETMIGA), OAB: Overactive bladder

Q3/FY2021 FINANCIAL RESULTS: COST ITEMS

SG&A expenses increased YoY and slightly above full-year FCST
R&D expenses increased YoY and in line with full-year FCST

Core basis: Main items for YoY and progress against FCST

Cost of sales % of revenue

YoY: -0.4ppt

- ✓ Decrease mainly due to changes in product mix
- ✓ FX impact on elimination of unrealized gain: +0.2 ppt

SG&A expenses

YoY: +11.9%
Progress against FCST: 75.1%

- ✓ SG&A excl. XTANDI US co-pro fee: +24.9 bil. yen (YoY +9.1%)
- ✓ FX impact (+16.5 bil. yen)
- ✓ Investment in Digital Transformation (Approx. +6.0 bil. yen)
- ✓ Increase in sales promotion expenses for new product launch readiness (Approx. +2.5 bil. yen)
- ✓ Global optimization of personnel aligned with transformation of product portfolio (Approx. -5.0 bil. yen)

R&D expenses

YoY: +5.2%
Progress against FCST: 73.4%

- ✓ Increase in development cost of zolbetuximab and expanded investment in iota
- ✓ Decrease in development cost of fezolinetant
- ✓ On track with full-year forecast

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COMMERCIAL ORGANIZATION REFORMS

Aiming to maximize VALUE by pursuing optimal commercial organization to achieve CSP2021 goals

Changes in the product portfolio

- **Shift to specialty products**

Changes in business environment

- **Changes in contact methods due to spread of COVID-19**
- **Expansion of virtual engagement and digital communication**

- Establish commercial organization's response to the new business environment
  - Enhance Omni-Channel activities and shift to "product dedicated model" in Japan
  - Reducing resources for mature products and focusing on Strategic products
  - Decrease of approx. 1,000 personnel (Japan, Europe, U.S., China, South Korea, etc.)
  - Annual costs reduction when completed to be approx. 18.0 billion yen
    (Cost reduction in FY2021 to be approx. 9.0 billion yen)

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Personnel: Subject to Works Council, consultative, and legal requirements

FY2021 FULL-YEAR OUTLOOK

- YoY Revenue increase is on track driven by XTANDI and Strategic products
- SG&A expenses are slightly above full-year FCST but aiming to control for the full year
  - Thorough budget control on a quarter basis
  - Starting to realize impact of global personnel optimization aligned with transformation of product portfolio
- R&D expenses are on track
- Booked “Gain on divestiture of intangible assets” in Q3/FY2021, not included into full-year forecast
  - Transfer of pipeline asset (9.2 billion yen)
  - Transfer of Bendamustine (2.0 billion yen)

  *Already included transfer of products to Cheplapharm into full-year forecast
- As a result, Core OP to exceed full-year forecast
- Full basis profit to slightly exceed full-year forecast, as with Core basis
- No changes have been made to FY2021 forecast for Revenue and OP

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Strategic products: XOSPATA, PADCEV, EVRENZO

AGENDA

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XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (1/2)

(Red: Updates since the last financial results announcement)

Key Events Expected in FY2021

Milestone	Project / Product	Indication / Clinical study	Achieved
Regulatory decision	enzalutamide / XTANDI	M1 hormone-sensitive prostate cancer (EU)	Apr 2021
	enfortumab vedotin / PADCEV	mUC, platinum and PD-1/L1 inhibitor pretreated (US [a,b])	Jul 2021
		mUC, cis-ineligible and who have previously received one or more therapy (US [a])	Jul 2021
		mUC, platinum and PD-1/L1 inhibitor pretreated (EU)	CHMP positive opinion received in Dec 2021 *The EC decision-making process has been paused for additional CHMP questions related to severe skin reactions in a French compassionate access program
		Radically unresectable UC that has progressed after anti-cancer chemotherapy (JP [c])	Sep 2021
	roxadustat / EVRENZO	Symptomatic anemia associated with CKD (EU)	Aug 2021
Regulatory submission	gilteritinib / XOSPATA	R/R AML (China [d])	
Data readout	fezolinetant	52-week safety results from Phase 3 SKYLIGHT 1, 2 & 4 studies	Jul 2021 (SKYLIGHT 2) Oct 2021 (SKYLIGHT 1)

a: Priority Review granted, Real-Time Oncology Review pilot program and Project Orbis applied
b: sBLA to convert Accelerated Approval to regular approval
c: Priority Review granted
d: sNDA to convert conditional approval to full approval

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Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
M1: Metastatic, (m)UC: (metastatic) Urothelial cancer, CHMP: Committee for Medicinal Products for Human Use, EC: European Commission, CKD: Chronic kidney disease, R/R: Relapsed or refractory, AML: Acute myeloid leukemia, sBLA: Supplemental Biologics License Application, sNDA: Supplemental New Drug Application

XTANDI & STRATEGIC PRODUCTS: HIGHLIGHT (2/2)

Other Updates since the last financial results announcement

Project / Product	Indication	Updated status
enzalutamide / XTANDI	M1 CSPC	Filed label update to include the OS data in US and EU in Dec 2021
gilteritinib / XOSPATA	AML, post-HSCT maintenance	Filing timeline shifted to FY2023 due to slower-than-expected RFS events in Phase 3 MORPHO study
	AML, newly diagnosed and HIC-ineligible	Phase 1 study in combo with venetoclax and azacitidine under preparation to start in Q1 FY2022
enfortumab vedotin / PADCEV	Muscle-invasive bladder cancer	Cohort H data in EV-103 study to be presented at ASCO GU in Feb 2022
	Non-muscle-invasive bladder cancer	FSFT in Phase 1 study in Jan 2022
fezolinetant	VMS associated with menopause	LSLV in Phase 3 SKYLIGHT 4 study in Jan 2022 FSFT in Phase 3b DAYLIGHT study in Nov 2021 FSFT in Japan Phase 2b STARLIGHT study in Nov 2021 Completed 12-week treatment [a] in Asia Phase 3 MOONLIGHT 1 study in Jan 2022

a: Double-blind, placebo-controlled period followed by 12-week active treatment extension period:

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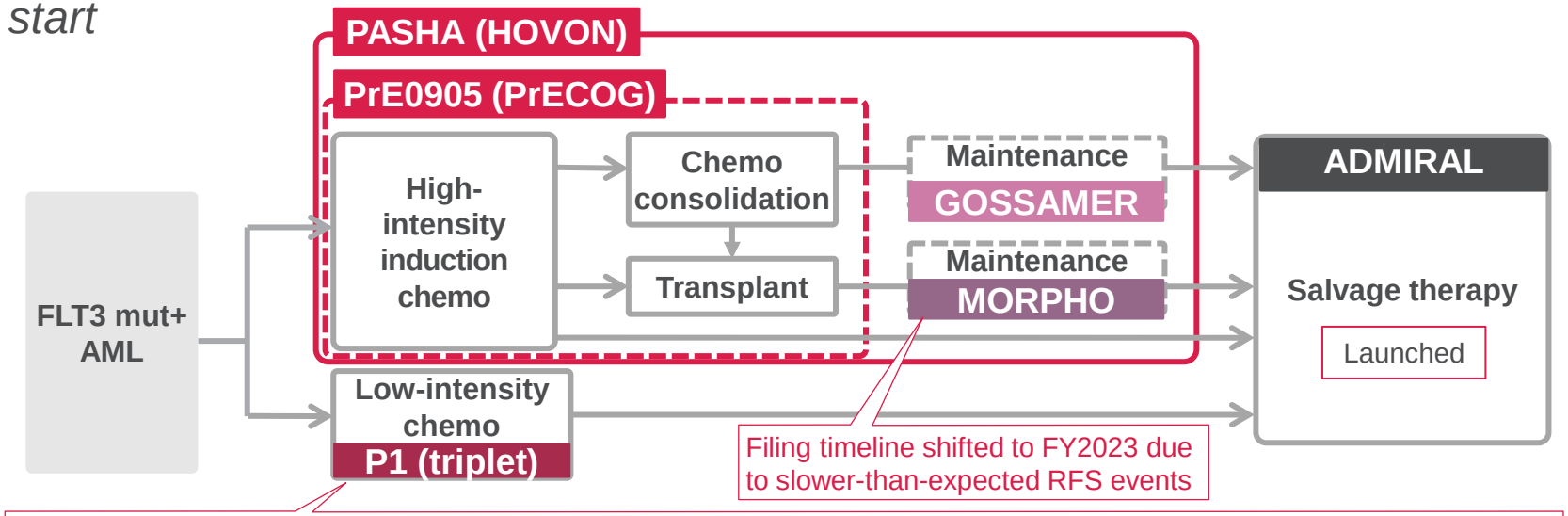
Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
M1 CSPC: Metastatic castration-sensitive prostate cancer, OS: Overall survival, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, RFS: Relapse-free survival, HIC: High-intensity chemotherapy, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, FSFT: First subject first treatment, VMS: Vasomotor symptoms, LSLV: Last subject last visit

GILTERITINIB: DEVELOPMENT STATUS

New study in newly diagnosed and high intensity chemotherapy-ineligible AML to start



Phase 1 study in newly diagnosed and HIC-ineligible AML under preparation to start in Q1 FY2022

Treatment	Triplet combination of gilteritinib/venetoclax/azacitidine
Patient segment	Newly diagnosed and HIC-ineligible FLT3 mutated AML (same as that in LACEWING study)
Mechanistic rationale	Expected to lead to more efficient and complete eradication of both FLT3 and non-FLT3 mutated AML clones
Relevant clinical data	High morphologic and molecular responses and survival outcomes treated with triplet combo therapy of FLT3 inhibitor, venetoclax and HMA observed in 3 independent studies* *CR >70% in all studies; 16.2% in LACEWING study (gilteritinib + azacitidine group)

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AML: Acute myeloid leukemia, FLT3 mut+: FLT3 mutation positive, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, RFS: Relapse-free survival, HIC: High-intensity chemotherapy, HMA: Hypomethylating agent, CR: Complete remission
*63rd ASH Annual Meeting & Exposition Abstract 696 (2021), Blood Cancer J 11:25 (2021), Blood Cancer J. 11:104 (2021)

PROGRESS IN FOCUS AREA APPROACH (1/3): CLINICAL PROOF AND EXPANSION OF KEY PLATFORMS

Primary Focuses have robust pipeline to newly build Post-PoC portfolio by end FY2025

Primary Focus	Biology/Modality/Technology [1]	FY21	FY22-23	FY24-25	No. of projects aiming PoC by end FY25	
					CSP [2]	Status
Genetic regulation	Gene replacement (AAV)				7	Delay: 1
	Gene regulation (AAV)		a			
Immuno-Oncology	Checkpoint		b		15	Judge: 1 (PoC not achieved: 1)
	Artificial adjuvant vector cell (aAVC)		c			
	Oncolytic virus (intratumoral)					
	Oncolytic virus (systemic)					
	Bispecific immune cell engager		d			
	Cancer cell therapy (UDC) [3]					
Blindness & Regeneration	Cell replacement				3	
	Cell replacement (UDC)					
	Gene regulation (AAV)					
Mitochondria Biology	Gene regulation & mitochondrial biogenesis				5	
	Mitochondrial stress					
	Mitochondrial transfer					
Primary Focus Candidates	Immune modulating/regulatory cells				1	
	Tissue-specific immune regulation					
	Protein degrader					
				Total	31	

Modality
- Small molecule
- Antibody
- Gene
- Cell
- Other

Stage of the most advanced project in the category
- Discovery/ Preclinical
- Pre-PoC
- Post-PoC

Updates from Q2
a. PoC timing shifted to beyond FY25 in a research project
b. PoC not achieved for ASP1948
c. PoC timing shifted due to delay in enrollment in clinical study for ASP7517
d. ASP2138 entered clinical phase; PoC timing shifted based on the latest development plan

1. Not exhaustively listed. 2. Estimated based on standard development timelines, assuming 100% probability of success (at CSP2021 announcement).
3. The first convertibleCAR program (with autologous cells) IND is planned for late FY2021.
PoC: Proof of concept (key clinical data supporting a decision to initiate late-stage development), AAV: Adeno-associated virus, UDC: Universal donor cell

PROGRESS IN FOCUS AREA APPROACH (2/3): CURRENT STATUS IN PRIMARY FOCUS

(Red: Updates since the last financial results announcement)

Primary Focus	Biology/Modality/Technology [1]	Project	Current status
Genetic Regulation	Gene replacement (AAV)	AT132	ASPIRO study put on clinical hold by FDA in Sep 2021
		AT845	Completed dosing in the second dose cohort in Phase 1 study Interim data in Phase 1 study to be presented at WORLDSymposium in Feb 2022
	Gene regulation (AAV)		
Immuno-Oncology	Checkpoint	ASP1948	Terminated
		ASP1951	Phase 1 study ongoing
	Artificial adjuvant vector cell (aAVC)	ASP7517	Phase 2 study in R/R AML and MDS ongoing FSFT in Phase 1 study in advanced solid tumors in Dec 2021
		ASP0739	FSFT in Phase 1 study in Jan 2022
	Oncolytic virus (intratumoral)	ASP9801	Phase 1 study ongoing
	Oncolytic virus (systemic)		
	Bispecific immune cell engager	ASP2138	Phase 1 study to start in Q1 FY2022
	Cancer cell therapy (UDC)		
	(other)	ASP1570	FSFT in Phase 1 study in Nov 2021
Blindness & Regeneration	Cell replacement	ASP7317	Screening and enrollment in Phase 1b study put on hold, due to a manufacturing delay
	Cell replacement (UDC)		
	Gene regulation (AAV)		
Mitochondria Biology	Gene regulation & mitochondrial biogenesis	ASP1128	Enrollment discontinued in Phase 2a study, based on the interim analysis for futility
		ASP0367	Phase 2/3 study in PMM ongoing Phase 1b study in DMD ongoing
	Mitochondrial stress		
	Mitochondrial transfer		
Primary Focus Candidates	Immune modulating/regulatory cells		
	Tissue-specific immune regulation		
	Protein degrader		

Modality
- Small molecule
- Antibody
- Gene
- Cell
- Other

1. Not exhaustively listed.

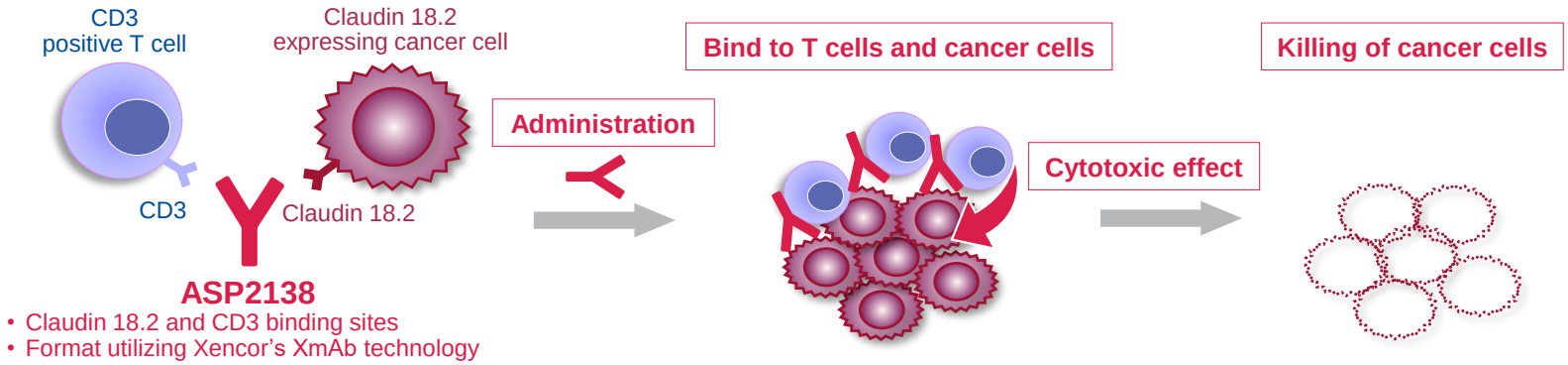
AAV: Adeno-associated virus, UDC: Universal donor cell, FDA: Food and Drug Administration, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, MDS: Myelodysplastic syndrome, FSFT: First subject first treatment, PMM: Primary mitochondrial myopathies, DMD: Duchenne muscular dystrophy

PROGRESS IN FOCUS AREA APPROACH (3/3): ASP2138

The lead program of bispecific immune cell engager to enter clinical phase

Characteristics of ASP2138

- Bispecific antibody targeting Claudin 18.2 and CD3
  - ✓ Forms a synapse between Claudin 18.2 expressing cancer cells and CD3 positive T cells and kills cancer cells by cytotoxic effect
  - ✓ Created through research collaboration with Xencor
  - ✓ Positioned as a successor of zolbetuximab with expected higher efficacy
- Under preparation to initiate Phase 1 study in Q1 FY2022
  - ✓ Target disease: gastric and GEJ adenocarcinoma, pancreatic adenocarcinoma



GEJ: Gastroesophageal junction

PROGRESS IN Rx+ PROGRAM

Key events expected in FY2021 (announced in Apr 2021)

Sphere *	Program	Event	Achieved
Chronic disease progression prevention	Fit-eNce	Initiation of pilot marketing for at-home service (Fit-eNce Home)	Sep 2021
	Game application for exercise support	Initiation of pilot marketing	
	BlueStar	Initiation of clinical study (Japan)	
	My Holter II	Commercialization of service	Jul 2021
Patient outcome maximization	ASP5354 (pudexacianinium chloride)	Topline results for Phase 2 study	Nov 2021

Topline results for Phase 2 study of ASP5354

- Safety and efficacy support proceeding to Phase 3 study
- Study results will be announced at SAGES in March 2022

* Business areas to focus on for realization of Rx+ Story
SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

PROGRESS TOWARD ACHIEVING CSP2021

Revenue, Pipeline Value

1 XTANDI and Strategic products:
≥ ¥1.2T in FY2025

- ✓ Sales growth in line with ambitious forecast
- ✓ XTANDI: Filing label update to include OS data in US & EU
- ✓ XOSPATA: Initiating Phase 1 study of triplet combo therapy for newly diagnosed and HIC-ineligible AML
- ✓ PADCEV: CHMP positive opinion, presentation of MIBC data, FSFT in Phase 1 study for NMIBC
- ✓ fezolinetant: LSLV in SKYLIGHT 4 study, progress of clinical studies as planned
- ✓ Lexiscan (US): Settled patent infringement litigation against some defendants. Litigation ongoing against other defendants. Currently predict generic entry of Lexiscan within CSP2021 period

2 Post-PoC projects
from Primary Focuses

3 Multiple technology platforms

4 Focus Area projects:
≥ ¥0.5T in FY2030

- ✓ AT845: Dosing completion in Cohort 2 in Phase 2 study
- ✓ ASP7517 (solid tumors), ASP0739, ASP1570: FSFT in Phase 1 study
- ✓ ASP2138: Entry into clinical phase

Core OP

5 Flat SG&A in absolute terms

6 Sufficient R&D investments
Core OP margin of ≥ 30% in FY2025

7 Steady increase in dividends

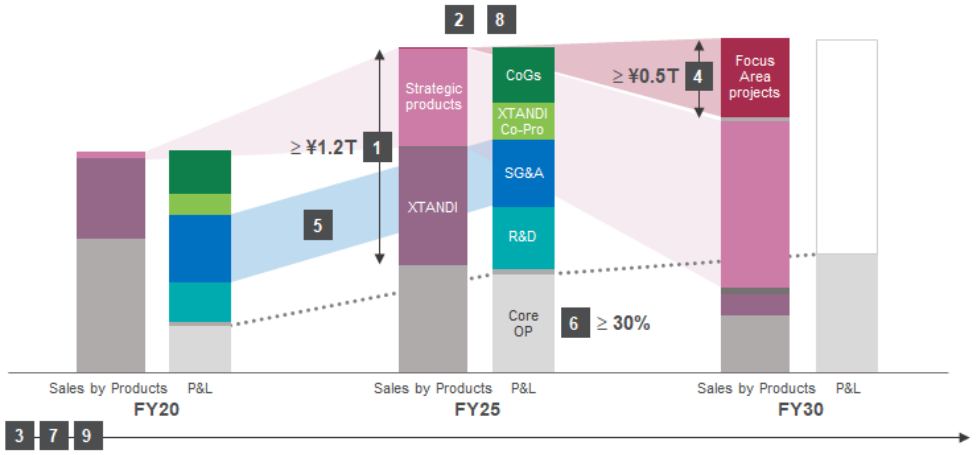
- ✓ Investment for new product launch
- ✓ Thorough budget control on a quarter basis
- ✓ Starting to realize impact of global personnel optimization aligned with transformation of product portfolio

Future Growth

8 Rx+:
Breakeven by FY2025

9 Sustainability

- ✓ ASP5354: Topline results obtained



Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
CSP: Corporate Strategic Plan, OS: Overall survival, HIC: High-intensity chemotherapy, AML: Acute myeloid leukemia, CHMP: Committee for Medicinal Products for Human Use, MIBC: Muscle-invasive bladder cancer, NMIBC: Non-muscle-invasive bladder cancer, FSFT: First subject first treatment, LSLV: Last subject last visit

SCHEDULE

Sustainability Meeting

- Feb 28th 2022, 15:00-16:30 (JST)

R&D Meeting

- Mar 9th 2022, 9:30-11:00 (JST)

  - Initiatives for gene therapy -

APPENDIX

GAIN ON DIVESTITURE OF INTANGIBLE ASSETS

- P/L has a new account from Q3/FY2021: Gain on divestiture of intangible assets
  - This account includes gain on sale of rights of in-market products or pipeline assets from Q3 onward
  - Included this account as a core basis performance
  - Upfront payment and royalty income from license agreements to be booked as Revenue

<Type of transaction and Accounting>

P/L item	Revenue	Gain on divestiture of intangible assets
Form of transaction	✓ License-out of rights of in-market products or pipeline assets (The rights are owned by Astellas)	✓ Transfer of rights of in-market products or pipeline assets
Accounting	✓ Upfront payment, milestone and royalty income booked as Revenue	Followings booked as Gain on divestiture of intangible assets ✓ Difference between upfront payment and book value of intangible assets ✓ Milestone and royalty income

Reference information: Gain on transfer of products to Cheplapharm (¥12.3 billion), gain on transfer of pipeline asset (¥9.2 billion), and gain on transfer of Bendamustine (¥2.0 billion), etc. were booked as Gain on divestiture of intangible assets in Q3/FY2021.

Q3/FY2021: REVENUE BY REGION

(billion yen)	Q3/FY20	Q3/FY21	Change (%)
Japan	221.8	203.2	-8.4%
United States	355.8	407.9	+14.7%
Established Markets	218.0	239.2	+9.8%
Greater China	43.8	50.3	+14.8%
International Markets	87.6	83.0	-5.3%

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

Q3/FY2021: SALES OF MAIN PRODUCTS

(billion yen)	Q3/FY20	Q3/FY21	Change	CER growth	FY21 FCST*
XTANDI	342.7	411.6	+20.1%	+14.4%	554.1
XOSPATA	17.6	25.7	+45.8%	+39.0%	35.4
PADCEV	9.4	14.6	+55.7%	+49.0%	20.7
EVRENZO	0.7	2.1	+198.6%	+197.5%	7.2
mirabegron	122.3	126.9	+3.8%	-0.3%	176.3
Prograf	138.3	141.1	+2.0%	-3.5%	185.7

PADCEV (US): Co-promotion revenue from Seagen
mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

*Announced revised forecast in Oct 2021

Q3/FY2021 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

XTANDI	Global sales increased steadily as expected given the ongoing focus on recent M1 HSPC launches and continuous strong growth is expected. In the US, demand grew +15% YoY. In Europe, reimbursement for M1 HSPC continues to expand to most major markets (Germany, UK, Spain, France, Netherlands, Switzerland, etc.) supporting growth YoY. Strong growth continues in Japan and China
XOSPATA	Sales across regions steadily expanded and global sales are in line with forecast. Initial sales trend is positive thus far in China - launched in Apr 2021 (Q3/FY21 sales: 1.3 billion yen). Recent approvals in International Markets (Russia, Saudi Arabia, Turkey) will contribute to the future growth of XOSPATA
PADCEV	Revenue in the US grew steadily as expected following approval of additional indication in Jul 2021. Further global launches occurred in Q3/FY21: Japan (Nov 2021), Switzerland (Dec 2021) Initial PADCEV uptake has been very strong thus far in Japan (Q3/FY21 sales: 0.5 billion yen)
EVRENZO	Overall sales performance is below expectations. Sales in Japan increased aligned with the expansion of the HIF-PHI class. However, sales have increased slower than expected due to increased competitive pressure. Following the EU approval and launches in Germany, UK, Netherlands, Austria, Nordics, etc. sales have begun to increase, though slower than anticipated given COVID-19 impact on launch execution
mirabegron	Global sales increased, driven by growth mainly in Japan and Established Markets, but behind full-year forecast. In the US, Myrbetriq sales against forecast are behind due to lower than expected US OAB market growth and increased pricing pressure

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M1 HSPC: Metastatic Hormone-sensitive prostate cancer, HIF-PHI: Hypoxia-inducible factor prolyl hydroxylase inhibitor, OAB: Overactive bladder

Q3/FY2021 ACTUAL: FX RATE

Average rate for the period

Currency	Q3/FY20	Q3/FY21	Change
USD	106 yen	111 yen	+5 yen
EUR	122 yen	131yen	+8 yen

Change in closing rate from previous fiscal year end

Currency	Q3/FY20	Q3/FY21
USD	-5 yen	+4 yen
EUR	+7 yen	+1 yen

<Impact of exchange rate on financial results>

- 42.8 billion yen increase in revenue, 15.4 billion yen increase in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.2 ppt

FY2021 FCST: FX RATE & FX SENSITIVITY

Exchange rate Average for the period	FY21 Forecast
USD	110 yen
EUR	130 yen

Forecast rates from Q3/FY2021 onward: 110 USD/yen, 130 EUR/yen

Estimated FX sensitivity (Q3 onward) of FY2021 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. -6.4 bil. yen	Approx. -0.8 bil. yen	Approx. +0.6 bil. yen
EUR	Approx. -2.8 bil. yen	Approx. -1.0 bil. yen	Approx. +0.3 bil. yen

* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q3/FY2021 onward

BALANCE SHEET & CASH FLOW HIGHLIGHTS

(billion yen)	FY20 end	Dec. 31, 2021
Total assets	2,273.6	2,356.2
Cash and cash equivalents	326.1	350.2
Total equity attributable to owners of the parent	1,386.1	1,466.3
Equity ratio (%)	61.0%	62.2%

(billion yen)	Q3/FY20	Q3/FY21	FY20
Cash flows from operating activities	225.1	208.9	306.8
Cash flows from investing activities	-67.7	-47.6	-81.9
Free cash flows	157.4	161.3	224.9
Cash flows from financing activities	-171.3	-141.3	-229.5
Bonds and short-term borrowings	-161.0	-40.0	-206.0
Proceeds from long-term borrowings	80.0	-	80.0
Dividends paid	-76.2	-85.2	-76.2

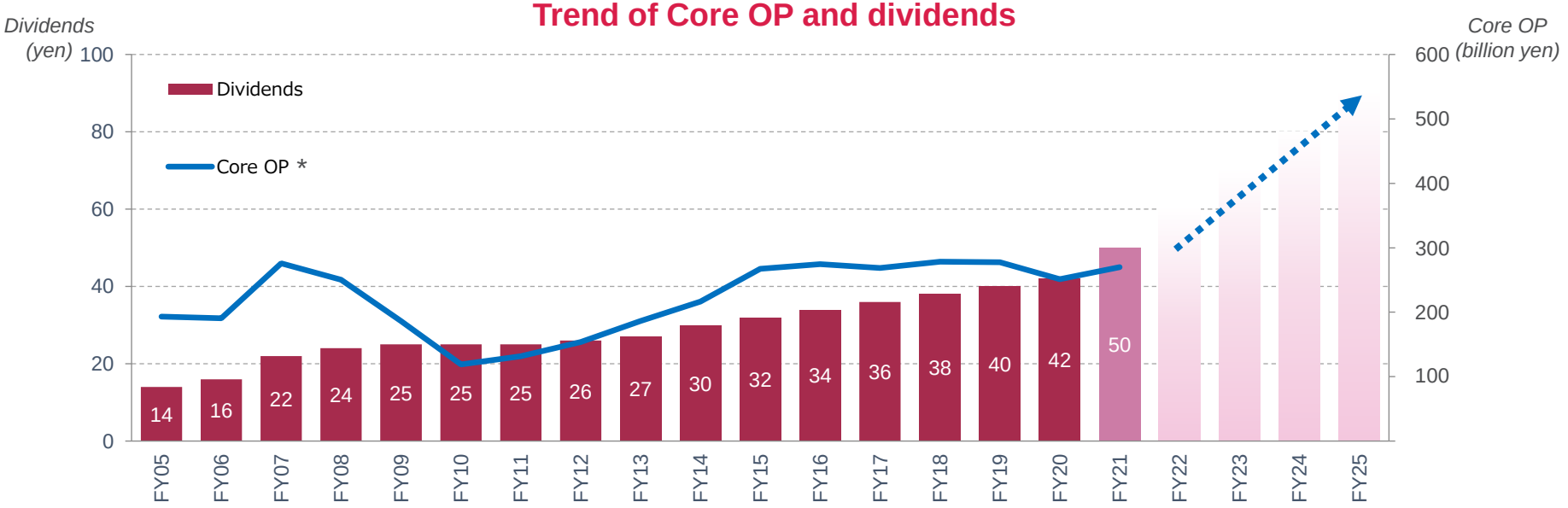
Balance of bonds and borrowings：160.0 billion yen
(Decreased by 40.0 billion yen from FY2020 end)

CAPITAL ALLOCATION

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

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

Trend of Core OP and dividends



For illustrative purposes only

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* Prior to FY2012, operating profit is in accordance with J-GAAP
CSP: Corporate Strategic Plan

ROBUST PIPELINE OF ASTELLAS

Phase 1

- enfortumab vedotin (NMIBC)
- gilteritinib (Newly diagnosed AML, HIC-ineligible)
- ASP1951
- ASP9801
- ASP7517 (Solid tumors)
- ASP0739
- ASP7317
- bocidelpar/ASP0367 (Duchenne muscular dystrophy)
- AT845
- ASP0598
- ASP2390
- ASP1570
- ASP2138
- ASP8062 (Alcohol use disorder)

Phase 2

- enfortumab vedotin (Other solid tumors)
- zolbetuximab (Pancreatic adenocarcinoma)
- roxadustat (Chemotherapy-induced anemia)
- resamirigene bilparvovec /AT132 (XLMTM)
- ASP7517 (AML and MDS)
- ASP1128 (Acute kidney injury)
- bocidelpar/ASP0367 (Primary mitochondrial myopathies)
- ASP3772 (Pneumococcal disease)
- FX-322 (Sensorineural hearing loss)
- isavuconazole (Pediatric use: US)
- ASP8062 (Opioid use disorder)

Phase 3

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

Filed

- enfortumab vedotin (mUC, pretreated: EU)

XTANDI and Strategic products (XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132)

Projects with Focus Area approach

Others

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

The listed compounds are investigational agents the safety and efficacy of which has not yet been established.
There is no guarantee that the agents will receive regulatory approval or become commercially available for uses being investigated

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NMIBC: Non-muscle-invasive bladder cancer, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, XLMTM: X-linked myotubular myopathy, MDS: Myelodysplastic syndrome, M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, mUC: Metastatic urothelial cancer, MIBC: Muscle-invasive bladder cancer, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms

PROGRESS IN OVERALL PIPELINE

Phase 1 Entry to Approval since the Last Financial Results Announcement

Phase 1 Entry	Phase 2 Entry	Phase 3 Entry	Filing	Approval
gilteritinib Newly diagnosed AML, high-intensity chemotherapy-ineligible				
ASP2138 gastric and GEJ adenocarcinoma, pancreatic adenocarcinoma				

Discontinuation

ASP1948: 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, AML: Acute myeloid leukemia, GEJ: Gastroesophageal junction

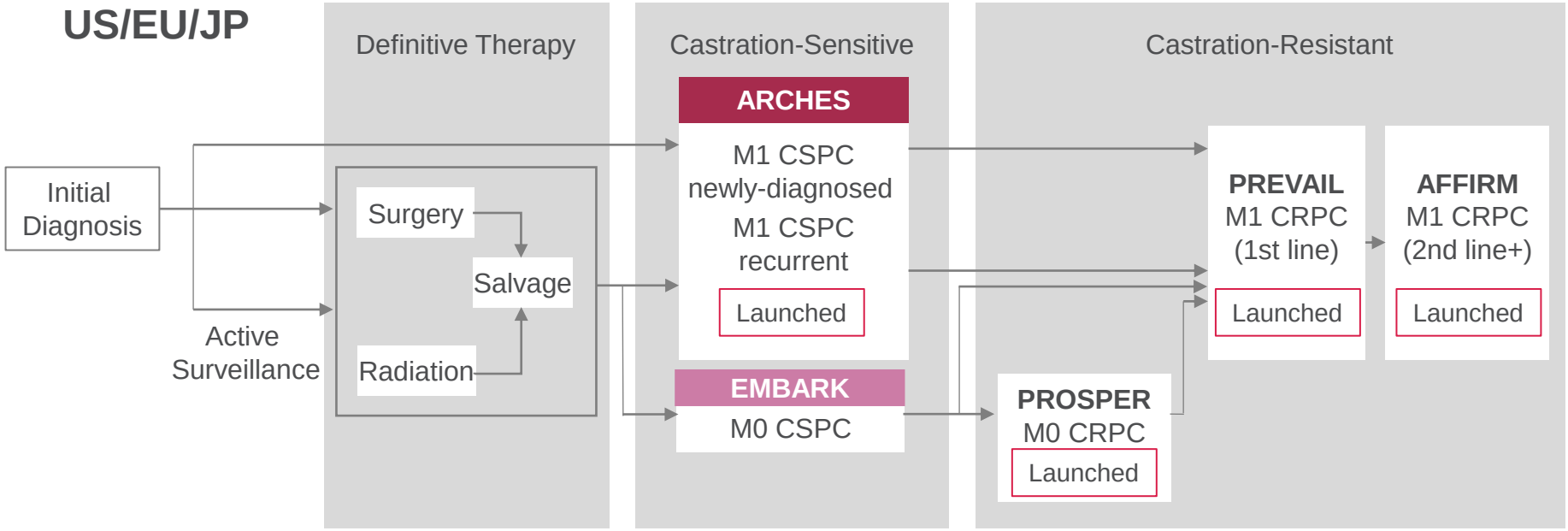
XTANDI & STRATEGIC PRODUCTS: STATUS UPDATE

(Red: Updates since the last financial results announcement)

	Indication	Current status
enzalutamide / XTANDI	M1 CSPC	• **US & EU:** Filed label update to include the OS data in Dec 2021 • **China:** Phase 3 study ongoing (enrollment completed)
	M0 CSPC	• Phase 3 study ongoing (enrollment completed)
gilteritinib / XOSPATA	Relapsed and refractory AML	• **China:** Phase 3 study stopped due to efficacy
	AML, post-HSCT maintenance	• Phase 3 study ongoing (enrollment completed); Filing timeline shifted to FY2023
	AML, newly diagnosed (HIC-eligible)	• Phase 3 study ongoing
	AML, newly diagnosed (HIC-ineligible)	• Phase 1 study in combo with venetoclax and azacitidine under preparation to start in Q1 FY2022
	AML, post-chemotherapy	• Obtained topline results of Phase 2 GOSSAMER study
enfortumab vedotin / PADCEV	Metastatic urothelial cancer	• **Pretreated:** CHMP positive opinion received in Dec 2021 • **Previously untreated (first line):** Phase 3 study ongoing • **China:** Phase 2 bridging study ongoing
	Muscle-invasive bladder cancer	• Phase 3 studies ongoing • Cohort H data in EV-103 study to be presented at ASCO GU in Feb 2022
	Non-muscle-invasive bladder cancer	• Phase 1 study ongoing (FSFT in Jan 2022)
	Other solid tumors	• Phase 2 study ongoing
zolbetuximab	Gastric & GEJ adenocarcinoma	• Phase 3 studies ongoing
	Pancreatic adenocarcinoma	• Phase 2 study ongoing
roxadustat / EVRENZO	Chemotherapy-induced anemia	• Obtained topline results of Phase 2 study
fezolinetant	VMS associated with menopause	• **US & EU:** Obtained 52w data of Phase 3 pivotal studies, SKYLIGHT 1 and SKYLIGHT 2. Phase 3 long-term study (SKYLIGHT 4) ongoing (LSLV in Jan 2022). Phase 3b DAYLIGHT study ongoing (FSFT in Nov 2021) • **Asia:** Phase 3 pivotal study (MOONLIGHT 1) ongoing (completed 12w DB treatment in Jan 2022). Phase 3 long-term study (MOONLIGHT 3) ongoing (enrollment completed) • **Japan:** Phase 2b STARLIGHT study ongoing (FSFT in Nov 2021)
AT132 (resamirigene bilparvovec)	X-linked myotubular myopathy	• ASPIRO study put on clinical hold by FDA due to a serious adverse event

Strategic products: XOSPATA, PADCEV, zolbetuximab, EVRENZO, fezolinetant, AT132
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, OS: Overall survival, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, HIC: High-intensity chemotherapy, CHMP: Committee for Medicinal Products for Human Use, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, FSFT: First subject first treatment, GEJ: Gastroesophageal junction, VMS: Vasomotor symptoms, LSLV: Last subject last visit, DB: Double-blind, FDA: Food and Drug Administration

ENZALUTAMIDE (1/2): ANDROGEN RECEPTOR INHIBITOR



	P3: ARCHES	**M1 CSPC**	Combo with ADT, vs. placebo	n=1,150	Approved in US in Dec 2019, in JP in May 2020, and in EU in Apr 2021 Filed label update to include the OS data in US and EU in Dec 2021
	P3: EMBARK	**M0 CSPC**	Combo with ADT, vs. placebo	n=1,068	Enrollment completed

China • **M1 CSPC:** Enrollment completed in Phase 3 China-ARCHES study

Red: Updates since the last financial results announcement
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy, OS: Overall survival

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

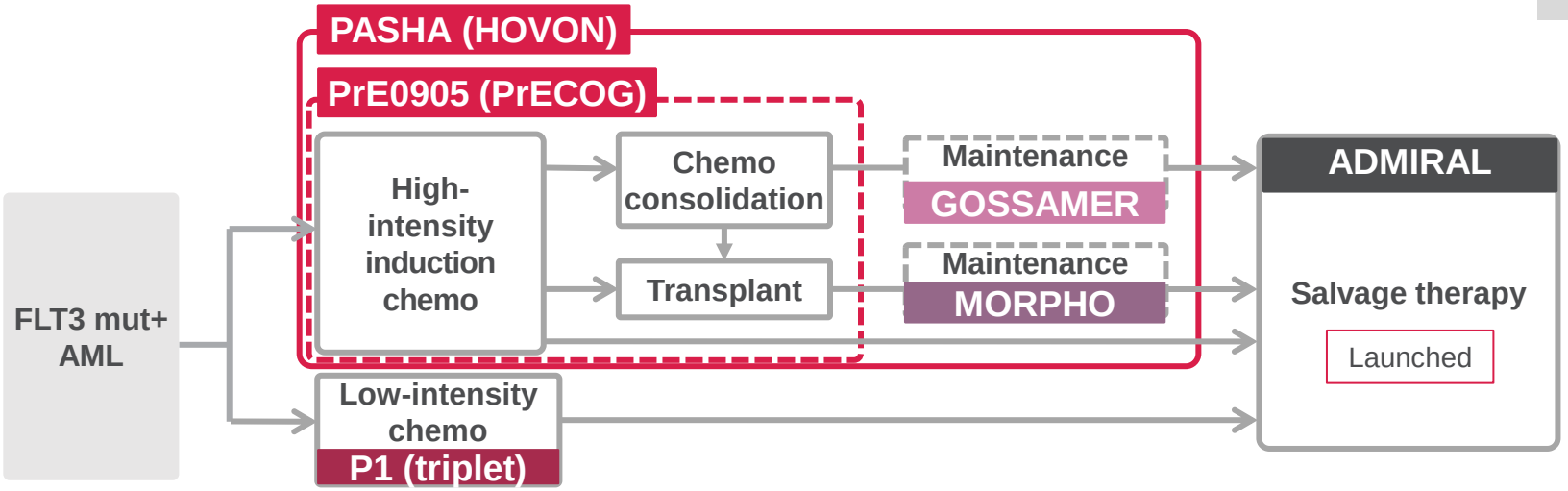
Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

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)	✔ HR 0.66	✔ HR 0.67	✔ HR 0.73	✔ HR 0.77	✔ HR 0.63
DoT	(Ongoing)	✔ 40.2 months	✔ 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
	Newly diagnosed (HIC-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 (HIC-ineligible)	**P1**	Combo with venetoclax and azacitidine	TBD	To start in Q1 FY2022
	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	Obtained topline results in Aug 2021

China

- **R/R AML:** Conditional approval obtained in Jan 2021, based on ADMIRAL study data (full approval contingent on COMMODORE study data) and launched in Apr 2021. Phase 3 COMMODORE study (including China and other countries) stopped due to efficacy based on the planned interim analysis

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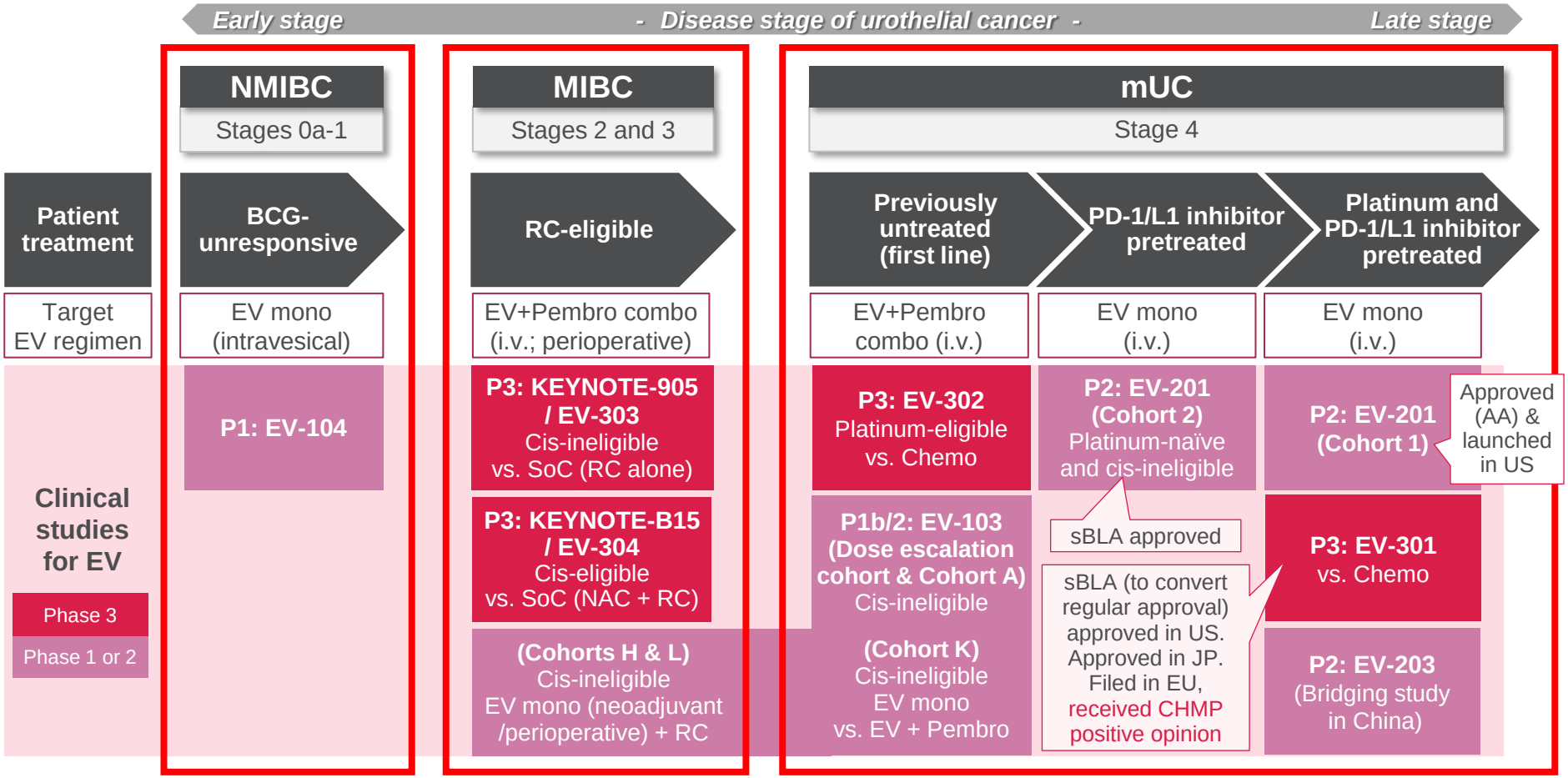
Red: Updates since the last financial results announcement

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, HIC: High-intensity chemotherapy, 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, R/R: Relapsed or refractory

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



Red: Updates since the last financial results announcement

ADC: Antibody-drug conjugate, mUC: Metastatic urothelial cancer, NMIBC: Non-muscle-invasive bladder cancer, MIBC: Muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, RC: Radical cystectomy, mono: Monotherapy, Pembro: Pembrolizumab, i.v.: Intravenous, Cis: Cisplatin, SoC; Standard of care, NAC: Neoadjuvant chemotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, AA: Accelerated Approval, CHMP: Committee for Medicinal Products for Human Use

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

For urothelial cancer

P3: EV-301	mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo	n=608	sBLA (to convert regular approval) approved in US in Jul 2021. Approved in JP in Sep 2021. CHMP positive opinion received in Dec 2021
P3: EV-302	mUC, Previously untreated, Platinum-eligible; EV + Pembro vs. Chemo	n=860	FSFT: Apr 2020
P3: EV-303 /KEYNOTE-905	MIBC, Cis-ineligible; Pembro +/- EV (perioperative) + RC vs. RC alone	n=836	FSFT in Pembro + EV arm: Dec 2020
P3: EV-304 /KEYNOTE-B15	MIBC, Cis-eligible; EV+Pembro (perioperative) + RC vs. Chemo (neoadjuvant) + RC	n=784	FSFT: May 2021
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: sBLA approved in US in Jul 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	Cohort K: Enrollment completed in Oct 2021 Cohort L: Enrollment ongoing Note) Data from Cohort K along with other cohorts evaluating EV + Pembro as first-line therapy for cis-ineligible patients could potentially support registration for Accelerated Approval in US
P2: EV-203	<Bridging study in China> mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono	n=40	FSFT: Aug 2021
P1: EV-104	NMIBC, High-risk BCG-unresponsive; Intravesical EV mono	n=58	FSFT: Jan 2022

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 adenocarcinoma or esophageal carcinoma or GEJ adenocarcinoma, Esophageal squamous cell carcinoma; EV mono	n=280	FSFT: Mar 2020

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Red: Updates since the last financial results announcement

mUC: Metastatic urothelial cancer, mono: Monotherapy, Chemo: Chemotherapy, sBLA: Supplemental Biologics License Application, CHMP: Committee for Medicinal Products for Human Use, Pembro: Pembrolizumab, FSFT: First subject first treatment, Cis: Cisplatin, MIBC: Muscle-invasive bladder cancer, RC: Radical cystectomy, NMIBC: Non-muscle-invasive bladder cancer, BCG: Bacillus Calmette-Guerin, HR+: Hormone receptor positive, HER2-: HER2 negative, NSCLC: Non-small cell lung cancer, GEJ: Gastroesophageal junction

ENFORTUMAB VEDOTIN (EV) (3/3): STUDY DATA BY DISEASE STAGE OF UC

Disease stage	Early stage → Late stage							
	MIBC		mUC					
	Surgery eligible		Previously untreated (first line)			PD-1/L1 inhibitor pretreated		
	Cis-eligible	Cis-ineligible	Platinum eligible	Cis-ineligible		Platinum naïve and cis-ineligible	Platinum pretreated	
Study phase	Phase 3	Phase 3	Phase 3	Phase 1b/2	Phase 1b/2	Phase 2	Phase 2	Phase 3
Study No.	**KN-B15 / EV-304**	**KN-905 / EV-303**	**EV-302**	**EV-103 Cohort K**	**EV-103 Cohort A & Others**	**EV-201 Cohort 2**	**EV-201 Cohort 1**	**EV-301**
No. of subjects	784 (2 arms)	836 (3 arms)	860 (2 arms)	150 (2 arms)	45	89	125	608 (2 arms)
EV regimen	Combo w/ Pembro (perioperative)	Combo w/ Pembro (perioperative)	Combo w/ Pembro	Mono vs. Combo w/ Pembro	Combo w/ Pembro	Mono	Mono	Mono
Control	Chemo (neoadjuvant)	SoC	Chemo	n/a	n/a	n/a	n/a	Chemo
Primary endpoint	pCR & EFS	pCR & EFS	PFS & OS	ORR	✔ ORR 73% ** (CR 16% **)	✔ ORR 51% ** (CR 22% **)	✔ ORR 44% (CR 12%)	✔ OS HR 0.70 *
OS	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ (26.1 mos **)	✔ (14.7 mos)	✔ (12.4 mos **)	✔ HR 0.70 * (12.9 mos vs.9 mos)
PFS	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ (12.3 mos **)	✔ (5.8 mos)	✔ (5.8 mos)	✔ HR 0.62 * (5.6 mos vs.3.7 mos)
ORR	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ 73% ** (CR 16% **)	✔ 52% (CR 20%)	✔ 44% (CR 12%)	✔41% vs.18% * (CR 4.9% vs.2.7%)
DoR	(Ongoing)	(Ongoing)	(Ongoing)	(Ongoing)	✔ 25.6 mos **	✔ 13.8 mos **	✔ 7.6 mos	✔ 7.39 mos vs. 8.11 mos *

Seagen

✔: Data obtained, *: Prespecified interim analysis, **: Updated data

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(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer, Pembro: Pembrolizumab, mono: Monotherapy, Chemo: Chemotherapy, pCR: Pathologic complete response, EFS: Event-free survival, ORR: Objective response rate, CR: Complete response, OS: Overall survival, HR: Hazard ratio, PFS: Progression-free survival, DoR: Duration of response

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
  - ✓ Prevalence of patients with high expression of Claudin 18.2 is substantial: 33% - 37%
  - ✓ ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

Gastric and (GEJ) adenocarcinoma

- Target patient population:
  HER2-, Claudin 18.2+ locally advanced and metastatic gastric and GEJ adenocarcinoma
- Metastatic gastric cancer is an area of significant unmet need, especially in advanced stages with ~4% five-year survival rate at Stage IV and limited treatment options have been limited

	Gastric and GEJ adenocarcinoma	**P3: SPOTLIGHT**	First line, Combo with mFOLFOX6, DB, vs. placebo	n=550	FSFT: Oct 2018
		P3: GLOW	First line, Combo with CAPOX, DB, 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 Cohort 4: First line, Combo with mFOLFOX6 and nivolumab	n=116	FSFT: Sep 2018
	Pancreatic adenocarcinoma	**P2**	First line, Combo with nab-paclitaxel and gemcitabine, open	n=369	FSFT: May 2019

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GEJ: Gastroesophageal junction, HER2-: HER2 negative, Claudin 18.2+: Claudin 18.2 positive, mFOLFOX6: 5-FU, leucovorin and oxaliplatin, DB: Double-blind, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment

FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

VMS has a significant negative impact on QoL

- Physical symptoms include hot flashes and night sweats, which can impact sleep.
- Physical symptoms may 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 breast cancer
- Since WHI's findings, use of HRT has dropped
- Although subsequent analysis of the WHI data have demonstrated that HRT is safe and effective when initiated in the appropriate patient in the appropriate manner (i.e. right time, formulation, dose and duration), prescriptions have not rebounded, leaving some women with minimal options to satisfactorily manage their VMS

US and EU

	P3: SKYLIGHT 1	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1) The last 40 weeks: Active extension treatment period, 30 mg or 45 mg	n=527	Primary endpoints met (12w DB period topline results). Obtained 52w data
	P3: SKYLIGHT 2		n=501	Primary endpoints met (12w DB period topline results). Obtained 52w data
	P3: SKYLIGHT 4	VMS associated with menopause; 52 weeks: DB, 30 mg and 45 mg vs. placebo (1:1:1)	n=1,831	LSLV: Jan 2022
	P3b: DAYLIGHT	Moderate to severe VMS associated with menopause, unsuitable for HRT; 24 weeks, DB, 45 mg vs. placebo (1:1)	n=440	FSFT: Nov 2021

Asia (except for Japan)

	P3: MOONLIGHT 1	Moderate to severe VMS associated with menopause; The first 12 weeks: DB, 30 mg vs. placebo (1:1) The last 12 weeks: Active extension treatment period, 30 mg	n=302	Completed 12w DB treatment in Jan 2022
	P3: MOONLIGHT 3	VMS associated with menopause; open label, 30 mg for 52 weeks	n=150	Enrollment completed

Japan

	P2b: STARLIGHT	Peri- and post-menopausal patients with mild to severe VMS; 12 weeks: DB, 2 doses vs. placebo (1:1:1)	n=135	FSFT: Nov 2021

Red Updates since the last financial results announcement

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.
VMS: Vasomotor symptoms, QoL: Quality of life, HRT: Hormone replacement therapy, DB: Double-blind, LSLV: Last subject last visit, FSFT: First subject first treatment

ON THE FOREFRONT OF HEALTHCARE CHANGE