Q2/FY2018 FINANCIAL RESULTS
ENDED SEPTEMBER 30, 2018



Kenji Yasukawa, Ph.D
President and CEO
Astellas Pharma Inc.
October 31, 2018

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

AGENDA

I Q2/FY2018 Consolidated Financial Results and FY2018 Revised Forecasts

II Pipeline

III Initiatives for Sustainable Growth

Q2/FY2018 FINANCIAL RESULTS (CORE BASIS)

(billion yen)	Q2/FY17	Q2/FY18	Change	FY18 FCST*	Progress	CER growth
Net sales	**639.8**	**647.1**	**+1.1%**	**1,278.0**	**50.6%**	+0.6%
Cost of sales	148.8	143.5	-3.5%			
% of sales	23.3%	22.2%				
SG&A expenses	228.3	231.5	+1.4%			
% of sales	35.7%	35.8%				
R&D expenses	107.5	99.6	-7.4%	214.0	46.5%	
% of sales	16.8%	15.4%		16.7%		
Amortisation of intangible assets	17.9	17.7	-1.5%			
Share of profits/losses of associates and JVs	- 0.9	- 0.6	-			
Core operating profit	**136.4**	**154.2**	**+13.1%**	**262.0**	**58.9%**	+10.0%
Core profit for the period	**106.6**	**124.8**	**+17.0%**	**210.0**	**59.4%**	
Core EPS (yen)	**51.90**	**63.92**	**+23.2%**	**106.98**	**59.7%**	

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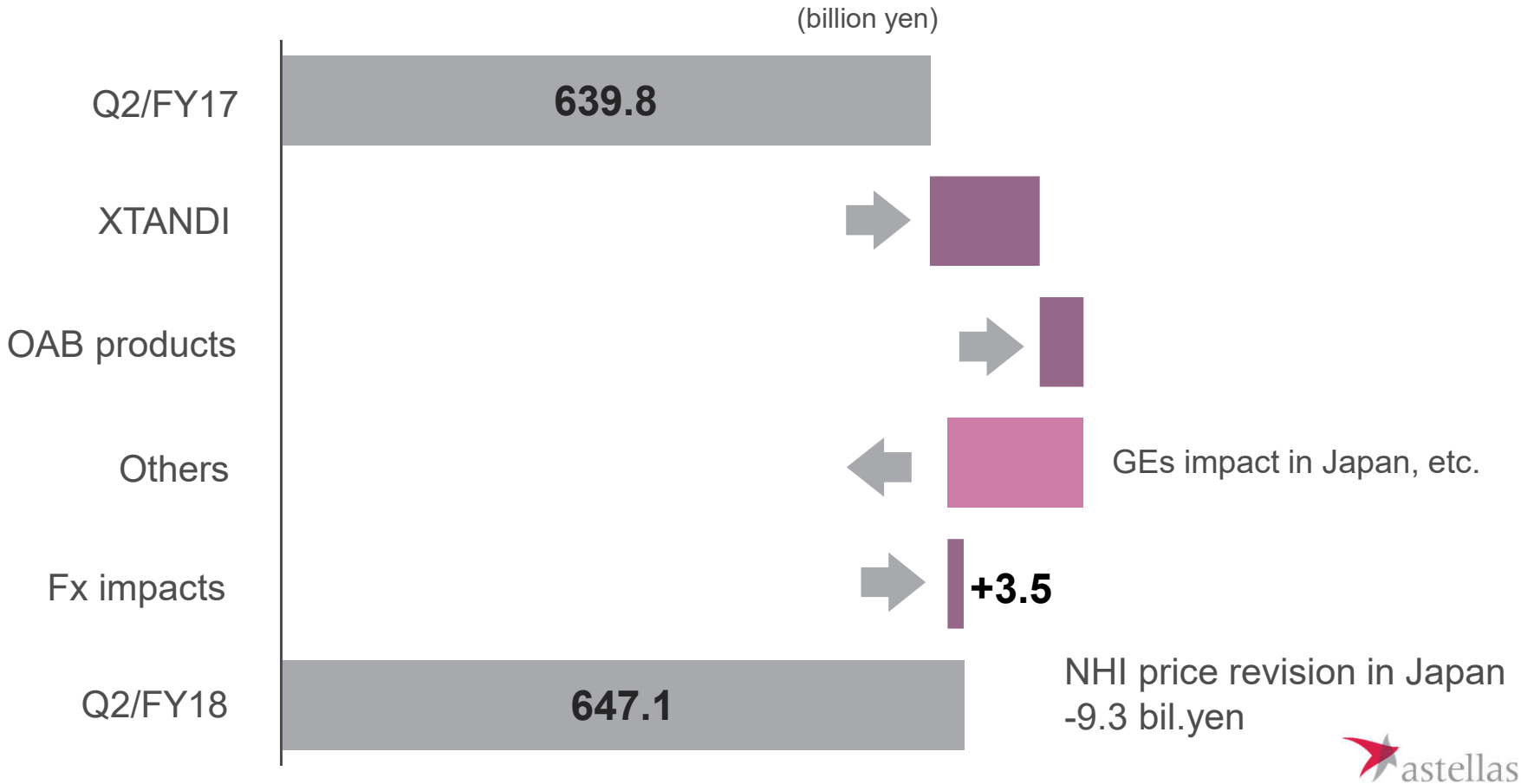
*Announced in April 2018

CER : Constant Exchange Rate

SALES ANALYSIS (YEAR ON YEAR)

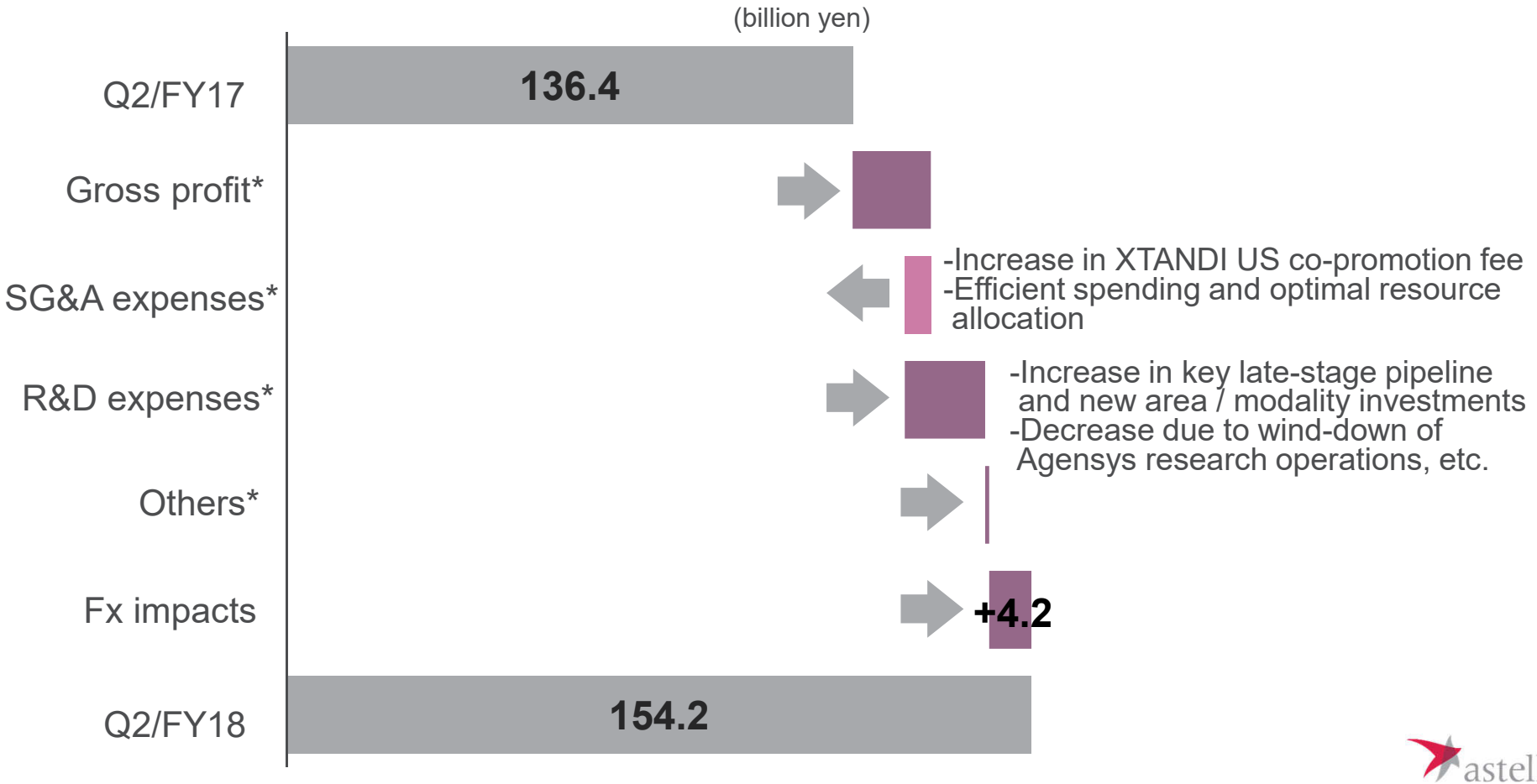
Growth of XTANDI and mirabegron contributed to increase in net sales despite sales decrease in Japan due to NHI price revision and GEs impact



OAB：Overactive bladder
OAB products：Vesicare＋mirabegron (Betanis/Myrbetriq/BETMIGA)

CORE OP ANALYSIS (YEAR ON YEAR)

Increased core OP by 13% with combination of increased sales of main products and optimal resource allocation



*Excluding Fx impacts

Q2/FY2018 FINANCIAL RESULTS (FULL BASIS)

(billion yen)	Q2/FY17	Q2/FY18	Change	FY18FCST*	Progress
Core operating profit	**136.4**	**154.2**	**+13.1%**	**262.0**	**58.9%**
Other income	10.0	4.7	-53.1%		
Other expense	50.3	32.0	-36.3%		
Operating profit	**96.1**	**126.8**	**+32.0%**	**265.0**	**47.9%**
Profit before tax	101.2	128.3	+26.7%	266.0	48.2%
Profit for the period	**82.1**	**103.9**	**+26.5%**	**213.0**	**48.8%**
EPS (yen)	**39.97**	**53.20**	**+33.1%**	**108.51**	**49.0%**

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*Announced in April 2018

SALES OF MAIN PRODUCTS

Main growth products contributing to increased net sales

(billion yen)	Q2/FY17	Q2/FY18	Change	CER growth	FY18 FCST*	Progress
XTANDI	**140.3**	**164.0**	**+16.9%**	**+16.3%**	**310.3**	**52.8%**
OAB products in Urology	**107.3**	**116.7**	**+8.8%**	**+8.5%**	**243.1**	**48.0%**
Vesicare	49.7	48.1	-3.2%	-3.8%	96.9	49.6%
Mirabegron	57.6	68.6	+19.1%	+19.0%	146.2	46.9%
Prograf	**99.3**	**100.4**	**+1.1%**	**-0.2%**	**190.7**	**52.7%**

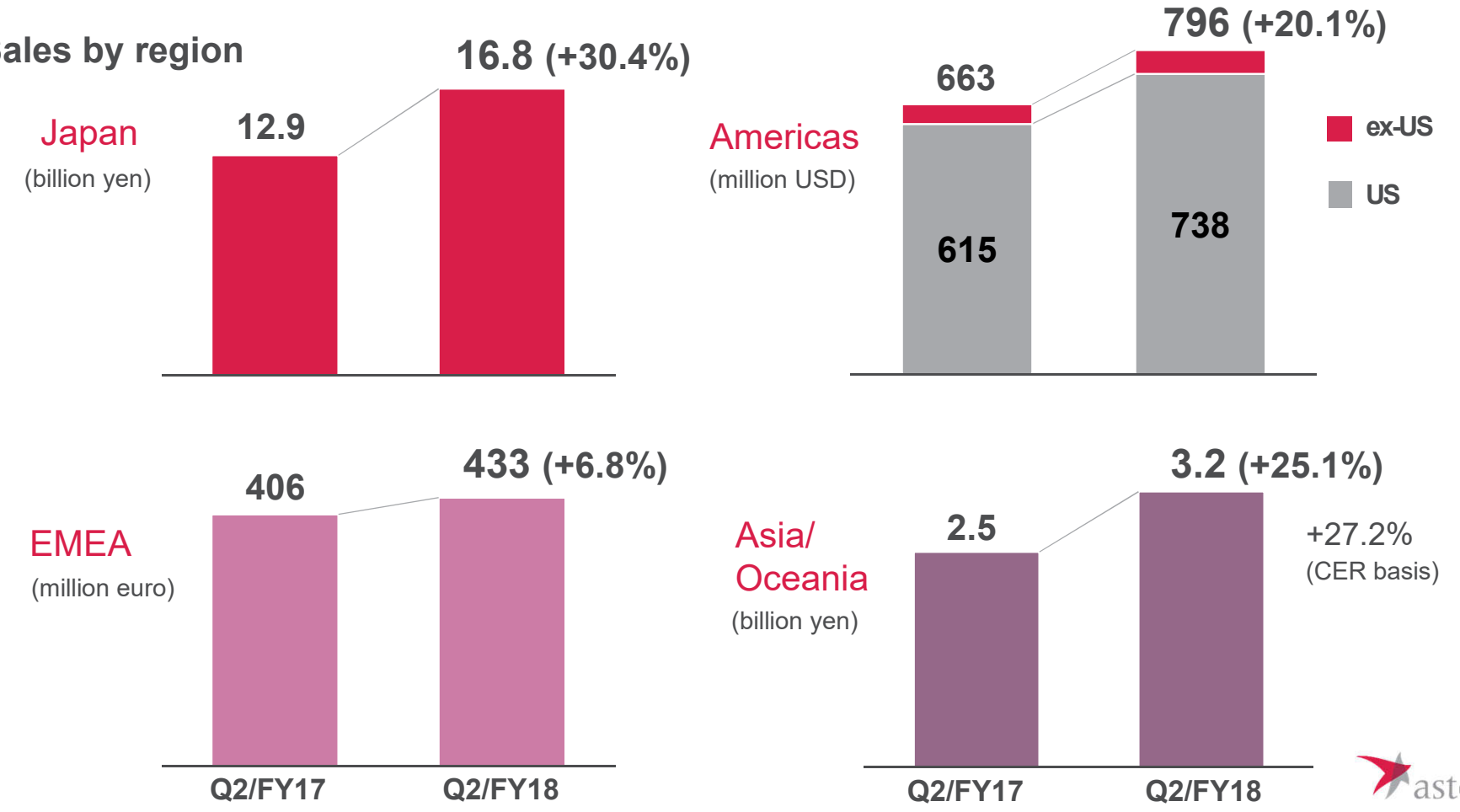
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
OAB products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

*Announced in April 2018
CER：Constant Exchange Rate

XTANDI

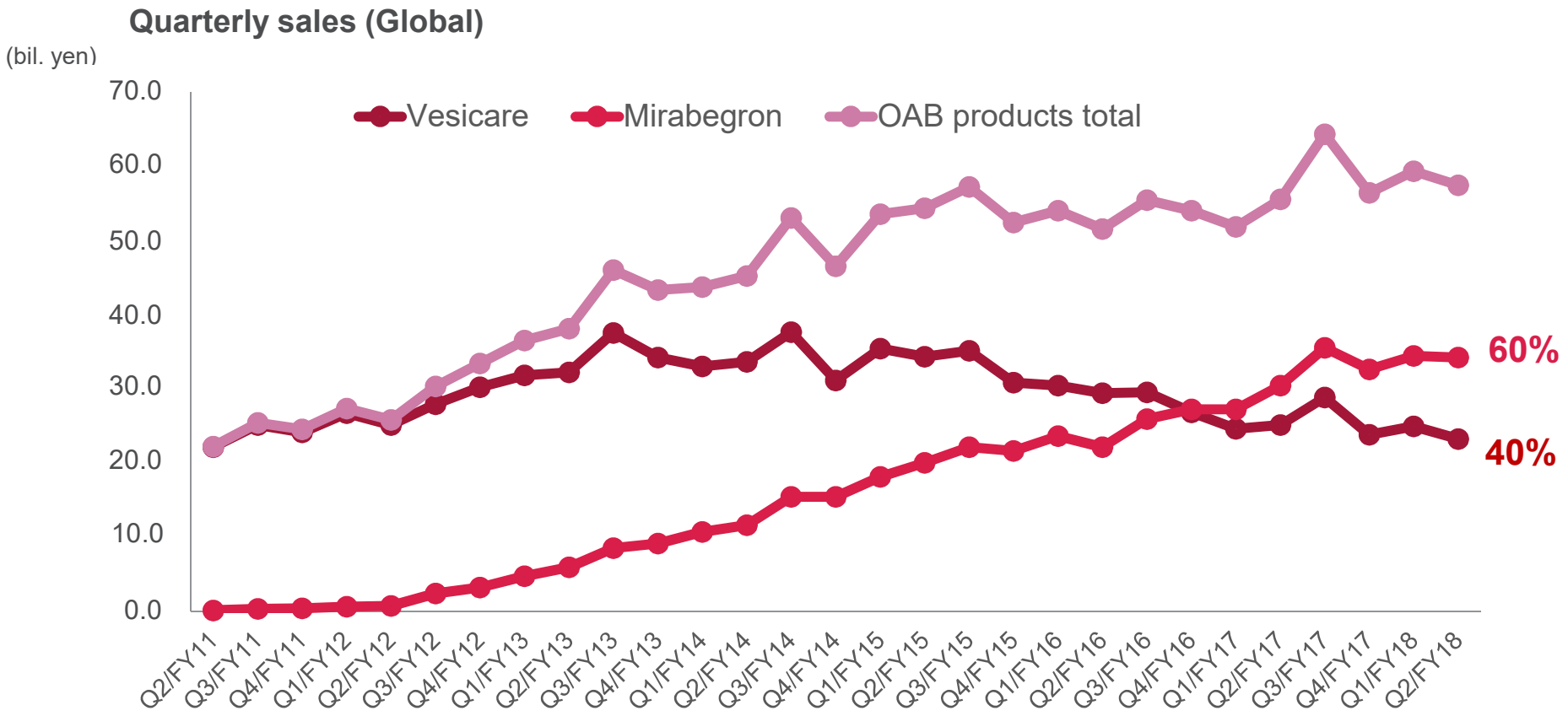
Steadily increasing XTANDI sales in all regions.
Record quarterly sales in Americas

Sales by region



OAB FRANCHISE IN UROLOGY

Mirabegron growth from novel mechanism of action and product features driving OAB franchise sales



Mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

REVISED FORECASTS FOR FY2018 (CORE BASIS)

Upward revision of initial forecasts for net sales and profit based on Q2/FY2018 results and Fx trend

(billion yen)	FY18 Initial Forecasts	FY18 Revised Forecasts	Change
Net sales	**1,278.0**	**1,300.0**	**+22.0**
R&D expenses as % of sales	214.0 16.7%	216.0 16.6%	+2.0
Core operating profit	**262.0**	**270.0**	**+8.0**
Core profit for the year	**210.0**	**221.0**	**+11.0**
Core EPS (yen)	**106.98**	**114.12**	**+7.14**

Exchange rate (yen) Average for the period	Initial Forecasts	Revised Forecasts
USD	105	110
EUR	130	130

Fx impacts
(billion yen)

- Net sales : +16.7
- Core operating profit: -0.8

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REVISED FORECASTS FOR FY2018 (FULL BASIS)

Downward revision of initial OP forecasts based on other income/expenses booked in Q2/FY2018 and estimated ones to be booked by the end of FY2018

(billion yen)	FY18 Initial Forecasts	FY18 Revised Forecasts	Change
Net sales	1,278.0	1,300.0	+22.0
Operating profit	265.0	234.0	-31.0
Profit before tax	266.0	236.0	-30.0
Profit for the year	213.0	195.0	-18.0
EPS (yen)	108.51	100.69	-7.82

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SUMMARY OF PROGRAM PROGRESS
SINCE Q1/FY2018 FINANCIAL RESULTS ANNOUNCEMENT IN JULY

Steady progression of pipeline

P1 Entry	P2 Entry	P3 Entry	Filing	Approval*
ASP1951/ PTZ-522 Cancer	**ASP1650** Testicular cancer		**evolocumab** **Aug 2018 (JP)** Statin intolerant hypercholesterolemia	**linaclotide** **Aug 2018 (JP)** Chronic constipation	**blinatumomab** **Sep 2018 (JP)** Relapsed or refractory B-cell ALL
	isavuconazole Invasive aspergillosis and mucormycosis in pediatric patients		**roxadustat** **Sep 2018 (JP)** Anemia associated with CKD in dialysis	**gilteritinib** **Sep 2018 (JP)** Relapsed or refractory AML	**enzalutamide** **Oct 2018 (EU)** High-risk M0 CRPC

*Please refer the label/package insert for detailed indication.

Discontinuation

YM311/FG-2216: Renal anemia (P2)
ASP6981: Cognitive impairment associated with schizophrenia (P1)
AGS67E: Lymphoid malignancies (P1)

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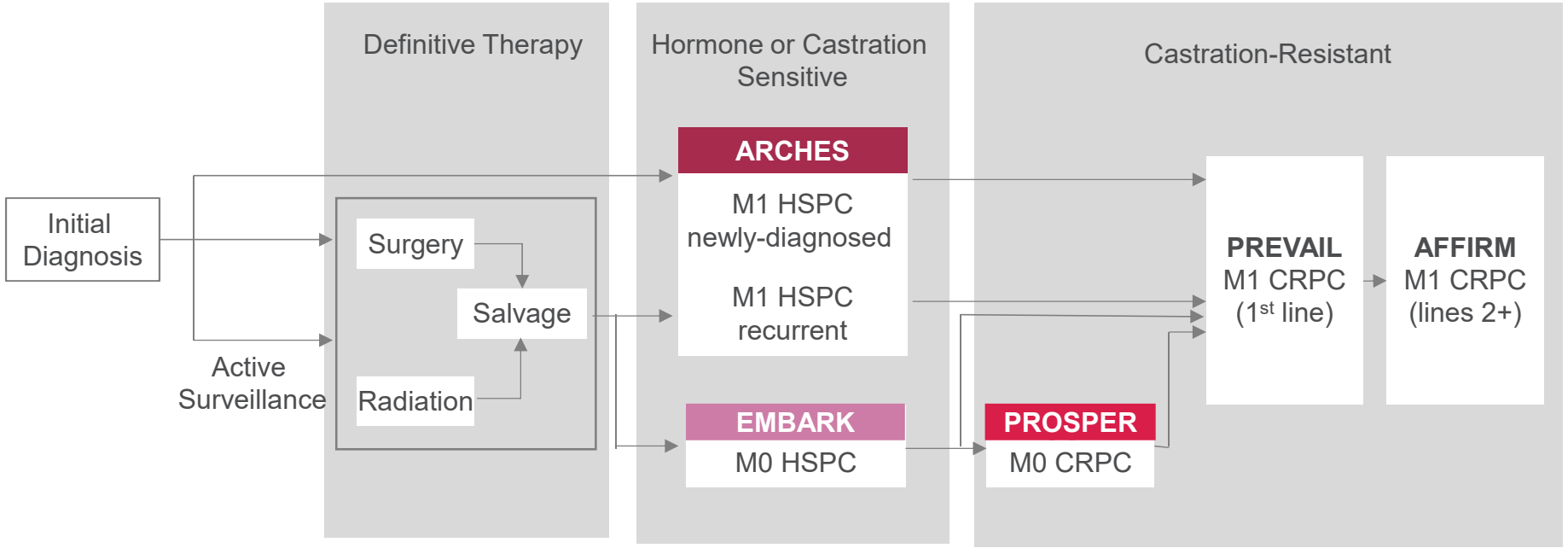
Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase.
Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body.
CKD: Chronic kidney disease, AML: Acute myeloid leukemia, ALL: Acute lymphoblastic leukemia, M0 CRPC: Non-metastatic castration-resistant prostate cancer

ENZALUTAMIDE

Approved in Europe for high-risk M0 CRPC in Oct. 2018
Amended protocols for ARCHES and EMBARK, accelerating study timeline



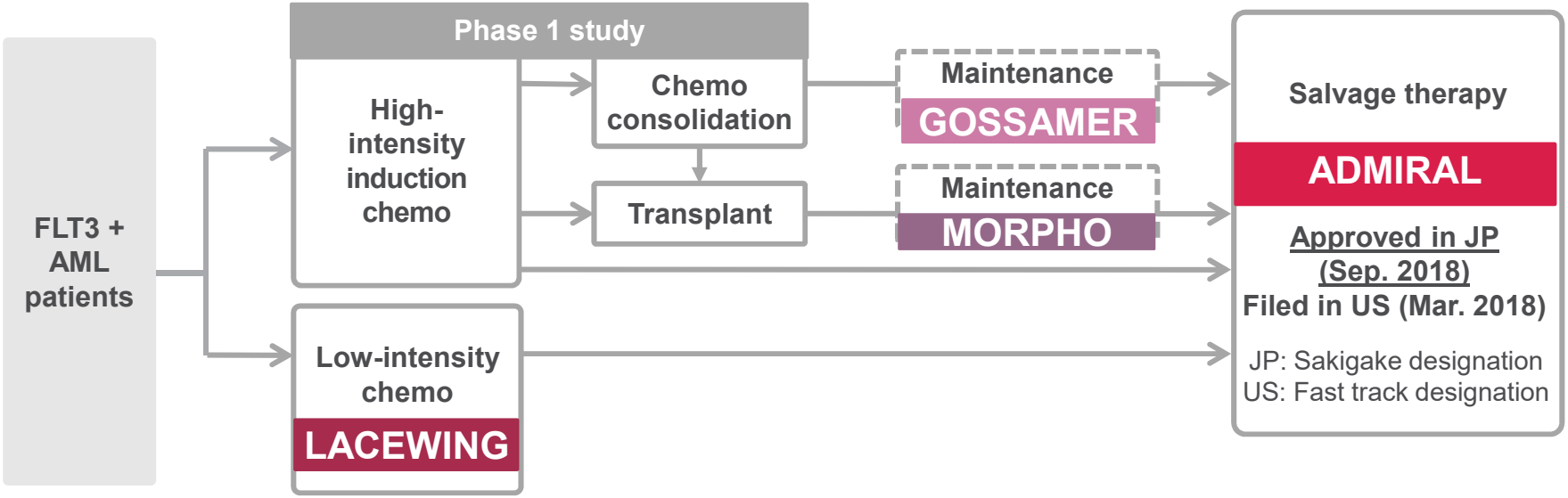
P3: PROSPER	**M0 CRPC**	vs. placebo, combination with ADT, n=1,401	Approved in US, Approved in Europe
P3: ARCHES	**M1 HSPC**	vs. placebo, combination with ADT, n=1,068	Enrollment completed, TLR expected in 1Q/2019
P3: EMBARK	**M0 HSPC**	vs. placebo, combination with ADT, n=1,150	Enrollment completed

Underline indicates the changes from the previous announcement on July 27, 2018.

M0: Non-metastatic, CRPC: Castration resistant prostate cancer, ADT: Androgen deprivation therapy, M1: Metastatic, HSPC: Hormone-sensitive prostate cancer, TLR: Top line results

GILTERITINIB

Approved in Japan for FLT3mut+ relapsed or refractory AML in Sep. 2018
Obtained full OS data of ADMIRAL study, to be presented at a future medical conference



	P3: ADMIRAL	Relapsed or refractory	Monotherapy vs salvage chemo (2:1), n=371	TLR obtained
	P2/3: LACEWING	1st line intensive chemo ineligible	Combo with azacitidine vs azacitidine alone (2:1), n=323	First Patient in: Nov 2016
	P3: GOSSAMER	Post-chemo maintenance	Monotherapy vs placebo (2:1), n=354	First Patient In: Apr 2017
	P3: MORPHO	Post-HSCT maintenance	Monotherapy vs placebo (1:1), n=346	First Patient In: Jul 2017 Collaborating with BMT-CTN

Underline: indicates the changes from the previous announcement on Jul 27, 2018.
FLT3: Fms-like tyrosine kinase 3, AML: Acute myeloid leukemia, OS: Overall survival, HSCT: Hematopioetic Stem Cell Transplant, TLR: Top line results,
BMT-CTN: Blood and Marrow Transplant – Clinical Trial Network

ROXADUSTAT

Filed in Japan for anemia associated with CKD (dialysis) in Sep. 2018
Data readout of all 6 global Phase 3 studies expected by the end of 2018

	Dialysis	Non-dialysis
Global	**HIMALAYAS:** Incident dialysis, vs epoetin alfa Data readout planned in 4Q/2018 FibroGen	**DOLOMITES:** vs darbepoetin alfa Data readout planned in 4Q/2018*1 astellas
	SIERRAS: Stable dialysis, vs epoetin alfa Data readout planned in 4Q/2018 FibroGen	**ALPS:** vs placebo TLR obtained astellas
	PYRENEES: Stable dialysis, vs epoetin alfa or darbepoetin alfa TLR obtained astellas	**ANDES:** vs placebo Data readout planned in 4Q/2018 FibroGen
Japan astellas	**1517-CL-0307:** HD, ESA-switch, vs darbepoetin alfa TLR obtained, Data presented at ASN2018	**1517-CL-0310:** ESA-switch, vs darbepoetin alfa Recruiting
	1517-CL-0312: HD, ESA-switch, long-term TLR obtained	
	1517-CL-0308: HD, ESA-naïve TLR obtained	**1517-CL-0314:** ESA-untreated TLR obtained
	1517-CL-0302: PD, ESA-untreated/ESA-switch TLR obtained, Data presented at ASN2018	

Note: Company logo in the table shows the sponsor of studies.

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Underline indicates the changes from the previous announcement on July 27, 2018. *1: Data readout of interim analysis.
CKD: Chronic kidney disease, TLR: Top line results, HD: Hemodialysis, ESA: Erythropoietin stimulation agents, ASN: American Society of Nephrology, PD: Peritoneal dialysis

FEZOLINETANT

TLR obtained from Phase 2b study in MR-VMS, the analysis is ongoing
Proceed to Phase 3 study preparation

Design

Target patient

- Post menopausal woman suffering from at least 50 moderate to severe vasomotors symptoms per week (n=352)

Study design:

- Double-blind, randomized, vs placebo
- Cohorts:
  Placebo (n=44)
  fezolinetant QD (3 dose, n=44/cohort)
  fezolinetant BID (4 dose, n=44/cohort)

Co-primary endpoints:

- Mean change from baseline in the number of hot flashes (moderate and severe)*
- Mean change from baseline in the severity of hot flashes (moderate and severe)*

*: At Week 4 and Week 12

TLR obtained

- TLR obtained in Oct. 2018
- The detailed analyses including PK/PD analyses are ongoing
- Proceed to Phase 3 study preparation
- Regulatory meetings are planned to consult for Phase 3 program based on Phase 2b study data including dose-selection

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TLR: Top line results, MR-VMS: Menopause related vasomotor symptoms, QD: once daily, BID: twice daily, PK: Pharmacokinetics, PD: Pharmacodynamics

PROGRAM UPDATES

Oncology

enfortumab vedotin

- Data readout of Cohort 1 (CPI-pretreated/ platinum-pretreated) in Phase 2 study planned in 1Q/2019

SeattleGenetics

zolbetuximab

- FPI achieved for Phase 3 SPOTLIGHT study (combination with mFOLFOX6) and Phase 2 ILUSTRO study (monotherapy, combination with mFOLFOX6)

ASP1650 (formerly known as IMAB027)

- POC study in incurable platinum refractory testicular cancer to start in 1H/2019
- Target: Claudin-6 (CLDN6)
  CLDN6 expression, of any level of intensity, in testicular tumors is approximately 93%.

reldesemtiv

Next steps currently under discussion

COPD

- Phase 2 study: TLR obtained.
- The study did not meet the primary endpoint and secondary endpoints.
- Adverse events were similar between the cohorts.

Physical frailty (elderly with limited mobility)

- A futility analysis of Phase 1b study was conducted. The independent DMC determined that the pre-defined criteria for lack of efficacy had been met. The study was halted for further enrollment.
- Phase 1b study will proceed to the planned analysis per protocol.

ALS

- Phase 2 study: Recruiting patients
- TLR planned in 1H/2019

Cytokinetics

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CPI: Checkpoint inhibitor, POC: Proof of concept, COPD: Chronic obstructive pulmonary disease, TLR: Top line results, ALS: Amyotrophic lateral sclerosis, DMC: Data monitoring committee

EXPECTED KEY EVENTS IN NEXT 12 MONTHS

Important milestones from POC through registration

Data Readouts

Phase 2 (POC) study

reldesemtiv (CK-2127107)
ALS

ASP5094
Rheumatoid arthritis

Phase 2 study

enfortumab vedotin
mUC,
Cohort 1 (CPI-pretreated/ platinum-pretreated)

Phase 3 study

roxadustat

EU: Non-dialysis pts
DOLOMITES study
ANDES study

EU: Dialysis patients
HIMALAYAS study
SIERRAS study

JP: Non-dialysis patients
1517-CL-0310 study

enzalutamide
M1 HSPC (ARCHES study)**

Filing*

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

gilteritinib
R/R AML (EU)

enzalutamide
M1 HSPC

Regulatory Decisions

gilteritinib
R/R AML (US)

peficitinib
Rheumatoid arthritis (Japan)

roxadustat
Anemia associated with CKD, Dialysis (Japan)

romosozumab
Osteoporosis (Japan)

evolocumab
Statin intolerant hypercholesterolemia (Japan)

ipragliflozin
Type 1 diabetes (Japan)

*Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate, **: event-driven study

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Please refer to pipeline list for details including target disease.
POC: Proof of concept, ALS: Amyotrophic lateral sclerosis, mUC: Metastatic urothelial cancer, CPI: Check point inhibitor, R/R: Relapsed and refractory, M1 HSPC: Metastatic hormone-sensitive prostate cancer, CKD: Chronic kidney disease, AML: Acute myeloid leukemia

POTENTIAL GROWTH DRIVERS IN OUR PIPELINE

Future growth driven by compounds that already have achieved POC

Filed/Expected filing

FY2018	FY2019-FY2020	FY2021 -
gilteritinib (Relapsed or Refractory AML)	**enzalutamide** (M1 HSPC)	**enzalutamide** (M0 HSPC)
roxadustat (Anemia associated with CKD Dialysis: JP)	**enfortumab vedotin** (Metastatic urothelial cancer)	**gilteritinib** (Other segment of AML)
peficitinib (Rheumatoid arthritis)	**roxadustat** (Anemia associated with CKD Non-dialysis: JP Dialysis/Non-dialysis: EU)	**zolbetuximab** (Gastric and gastroesophageal junction adenocarcinoma)
romosozumab (Osteoporosis)		**fezolinetant** (MR-VMS)

Subject to study outcome, internal assessment, decision and regulatory consultation, as appropriate.

Please refer to pipeline list for details including target disease.
POC: Proof of Concept, AML: Acute myeloid leukemia, CKD: Chronic kidney disease, M1: Metastatic, HSPC: Hormone-sensitive castration resistant prostate cancer, M0: Non-metastatic, MR-VMS: Menopause-related vasomotor symptoms

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FOCUS AREA APPROACH

Adding novel gene therapy programs through acquisition and alliance

■ ***Acquisition of Quethera***

Novel gene therapy program for glaucoma at high risk of blindness*

Strengths of Quethera's gene therapy program

- Demonstrated significantly improved survival of retinal ganglion cells in pre-clinical models
- Unique mechanism of action through an independent of intraocular pressure

*Gene therapy program utilizing a recombinant adeno-associated viral vector system to introduce therapeutic genes into target retinal cells

Quethera

■ ***Option agreement with Gene Therapy Research Institution***

GT0001X* for the treatment of sporadic ALS

- Gene therapy program with new mechanism focusing on decreased activity of ADAR2 which has been reported to be a possible cause of sporadic ALS
- Aim is to prevent the motor neuron death (degeneration and deficit) and stop the progress of the symptom.

*GT0001X is a modified adeno-associated virus vector expressing human ADAR2.

Gene Therapy Research Institution

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ALS: Amyotrophic lateral sclerosis,
ADAR2: Adenosine deaminase acting on RNA2

CAPITAL EXPENDITURES FOR R&D

Facilities for the research, development and manufacture of new products with innovative modalities/technologies

- **Center for Active Ingredient for Biopharmaceuticals (provisional name) in Toyama**
  - Manufacture of antibodies for use in both CTM and commercial products
  - Total cost: Approx. 10.0 billion yen
  - Scheduled for completion in Sep. 2019

- **Center for Multimodality Clinical Trial Materials (provisional name) in Tsukuba**
  - Manufacture of CTM for use in early-stage clinical trials designed for cell therapy and gene therapy development
  - Total cost: Approx. 5.0 billion yen
  - Scheduled for completion in Mar. 2019

- **Relocation and renovation of the AIRM* in the US**
  - Accelerates research and development in the field of regenerative medicine and cell therapy, and enhances production facility capability
  - Total cost: Approx. 14.0 billion yen
  - Scheduled for completion in Jan. 2020

*AIRM: Astellas Institute for Regenerative Medicine

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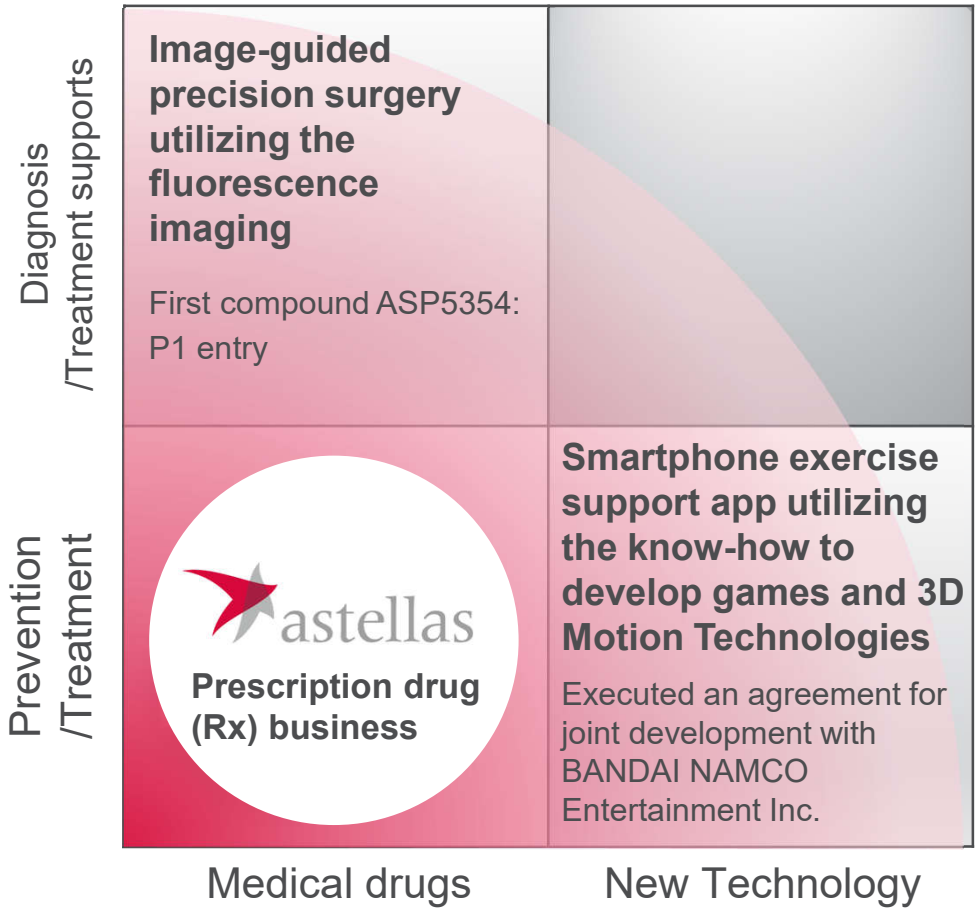
DEVELOPING Rx+™ PROGRAMS

Steady progress on each program and continuing to capture new business opportunities



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

- **Rx+™ Business:** Established US basis

  Astellas Rx+ Business Accelerator, LLC.

- **Venture Capital (VC) collaborations**
  - Digital Health field: Established focused Rx+™ venture fund with Astellas as a single Limited Partner — digiTx PARTNERS
  - Medical Device field: Initiated collaboration with a new VC with presence in Silicon Valley and Ireland — strategic healthcare investment partners

- **Organize and/or support matchmaking events with academic institutions and startups**

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SCHEDULE

R&D meeting
-Approaches to cell therapy-

Date: December 13, 2018
Time: 14:00-15:30

APPENDIX

Q2/FY2018: SALES BY REGION

(billion yen)	Q2/FY17	Q2/FY18	Change
Japan	**213.0**	**195.3**	-8.3%
Americas	**208.4**	**227.9**	+9.4%
EMEA	**169.1**	**172.3**	+1.9%
Asia/Oceania	**49.4**	**51.6**	+4.6%

FX RATE (ACTUAL)

Average rate for the period

Currency	Q2/FY17	Q2/FY18	Change
USD	111	110	-1
EUR	126	130	+4

Change in closing rate from PY end

Currency	Q2/FY17	Q2/FY18
USD	+1	+7
EUR	+13	+2

Fx impact on elimination of unrealized gain: COGs ratio -0.1 ppt

FY2018 REVISED FCST：FX RATE & FX SENSITIVITY

Forecast rates from Q3/FY2018 onwards: 110 USD/yen, 130 EUR/yen

Estimated Fx sensitivity (Q3 and onward) of FY2018 revised forecasts by 1 yen appreciation*

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Net sales	Core OP	Core OP
USD	Approx. -2.6 bil yen	Approx. -0.6 bil yen	Approx. +0.6 bil yen
EUR	Approx. -1.3 bil yen	Approx. -0.6 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/FY2018 and onwards

BALANCE SHEET/CASH FLOW HIGHLIGHTS

(billion yen)	FY17 end	Sep. 2018
Total assets	1,858.2	1,886.9
Cash and cash equivalents	331.7	306.9
Total net assets	1,268.3	1,282.7
Equity ratio (%)	68.3%	68.0%

(billion yen)	Q2/FY17	Q2/FY18	FY17
Cash flows from operating activities	115.3	112.1	312.6
Cash flows from investing activities	(72.7)	(7.8)	(121.8)
Free cash flows	42.6	104.3	190.8
Cash flows from financing activities	(85.9)	(136.5)	(203.4)
Acquisition of treasury shares	(50.2)	(100.4)	(130.7)
Dividends paid	(35.1)	(35.6)	(71.6)

DETAILS OF SHAREHOLDER RETURNS



(billion yen)	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18 (Forecast)
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	73.0
Acquisition of own share	46.2	219.9	81.8	123.4	27.0	-	-	49.4	30.0	58.2	119.3	91.4	129.9	100.0
Total return ratio(%)	82	200	77	106	70	85	74	118	100	92	97	74	123	

*The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 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 fiscal year 2005.

**From fiscal year 2013, figures are in accordance with International Financial Reporting Standards (IFRS).

ROBUST PIPELINE OF ASTELLAS

Phase 1

- ASP1235/AGS62P1
- ASP8374/PTZ-201
- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP0892
- MA-0211
- ASP7713
- MA-0217
- ASP1807/CC8464
- MucoRice-CTB

Phase 2

- AGS-16C3F (Renal cell carcinoma)
- ASP1650 (Testicular cancer)
- bleselumab (ASKP1240) (rFSGS)
- ASP4070/JRC2-LAMP-vax (Pollinosis caused by Japanese red cedar: JP)
- ASP5094 (Rheumatoid arthritis)
- reldesemtiv(CK-2127107) (SMA, COPD, ALS)
- ASP7317 (Dry AMD etc.)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- fezolinetant (ESN364) (MR-VMS)
- ASP0819 (Fibromyalgia)
- ASP4345 (CIAS)
- isavuconazole (Pediatric: US)

Phase 3

- enzalutamide (M0 HSPC:US/EU/Asia, M1 HSPC:US/EU/JP/Asia,)
- gilteritinib (ASP2215) (R/R AML: EU/Asia, Other AML: US/EU/JP/Asia)
- enfortumab vedotin (ASG-22ME) (Urothelial cancer: US/EU/JP/Asia)
- zolbetuximab (IMAB362) (Gastric and gastroesophageal junction adenocarcinoma: US/EU/JP/Asia)
- mirabegron (YM178) (Pediatric NDO: EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU:Non-dialysis/dialysis, JP: non-dialysis)
- fidaxomicin (Pediatric: EU)

Filed

- gilteritinib (ASP2215) (R/R AML: US)
- degarelix (ASP3550) (3-month: JP)
- peficitinib (ASP015K) (Rheumatoid arthritis: JP)
- solifenacin* (YM905) (Pediatric NDO: US)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD in dialysis: JP)
- romosozumab (AMG 785) (Osteoporosis: JP)
- evolocumab (AMG 145) (Statin intolerant hypercholesterolemia: JP)
- ipragliflozin (ASP1941) (Type 1 diabetes: JP)

*: Received Complete Response Letter from FDA in Aug 2017.

Oncology | Immunology, Muscle disease, Ophthalmology | Urology, Nephrology | Others

Outline of the projects are shown. Please refer to pipeline list for details including target disease.

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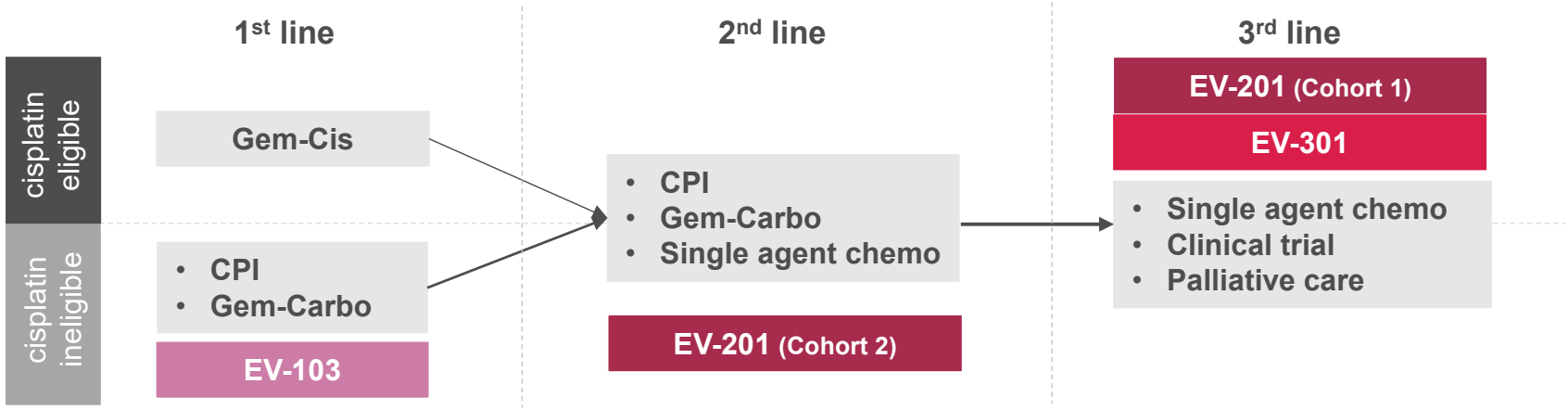
rFSGS: Recurrence of focal segmental glomerulosclerosis, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, BPS/IC: Bladder pain syndrome/Interstitial cystitis, MR-VMS: Menopause-related vasomotor symptoms, CIAS: Cognitive impairment associated with schizophrenia, M0 HSPC: Non-metastatic hormone sensitive prostate cancer, M1 HSPC: Metastatic hormone sensitive prostate cancer, R/R: Relapsed and refractory, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, FDA: Food and Drug Administration

ENFORTUMAB VEDOTIN

Data readout of Cohort 1 (platinum-pretreated) in Phase 2 study planned in 1Q/2019

	P3: EV-301	Pts with prior CPI treatment (platinum-pretreated)	n=550	First Patient In: Jul 2018
	P2: EV-201	Pts with prior CPI treatment Cohort 1: Platinum-pretreated Cohort 2: Platinum naïve/cisplatin ineligible	n=200	First Patient In: Oct 2017 Cohort 1: Enrollment completed Cohort 2: Recruiting
	P1b: EV-103	Combination with CPI	n=85	First Patient In: Nov 2017
	P1: EV-101	Part A: mUC pts Part B: mUC pts with renal insufficiency metastatic NSCLC, metastatic ovarian cancer Part C: mUC pts with prior CPI treatment	n= 215	First Patient In: Jun 2014

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



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Underline indicates the changes from the previous announcement on July 27, 2018, EV: enfortumab vedotin, Pts: Patients, CPI: Checkpoint inhibitor, mUC: metastatic urothelial cancer, NSCLC: Non-small cell lung carcinoma, Gem-Cis: gemcitabine and cisplatin, Gem-Carbo: gemcitabine and carboplatin

ZOLBETUXIMAB

FPI achieved for Phase 3 SPOTLIGHT study (combination with mFOLFOX6) and Phase 2 ILUSTRO study (monotherapy, combination with mFOLFOX6)

Gastric and gastroesophageal junction (GEJ) adenocarcinoma

	P3: SPOTLIGHT	Combination with mFOLFOX6	vs. placebo, n=550	First Patient In: Oct 2018
	P3: GLOW	Combination with CAPOX	vs. placebo, n=500	Study start: Sep 2018
	P2: ILUSTRO	Monotherapy, Combination with mFOLFOX6	n= 102	First Patient In: Sep 2018

Target: Claudin 18.2 (CLDN18.2)

- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ~70-90% biliary duct, pancreatic, gastric and mucinous ovarian cancer[1]
  - ~ 10% ovarian cancer and NSCLC[1]

GEJ adenocarcinoma

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin18.2 expression
- Fourth leading cause of cancer death worldwide.
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20%[2, 3]
- Median OS for Stage IV gastric cancer is 10-15 months[4, 5]

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Underline indicates the changes from the previous announcement on Jul 27, 2018.

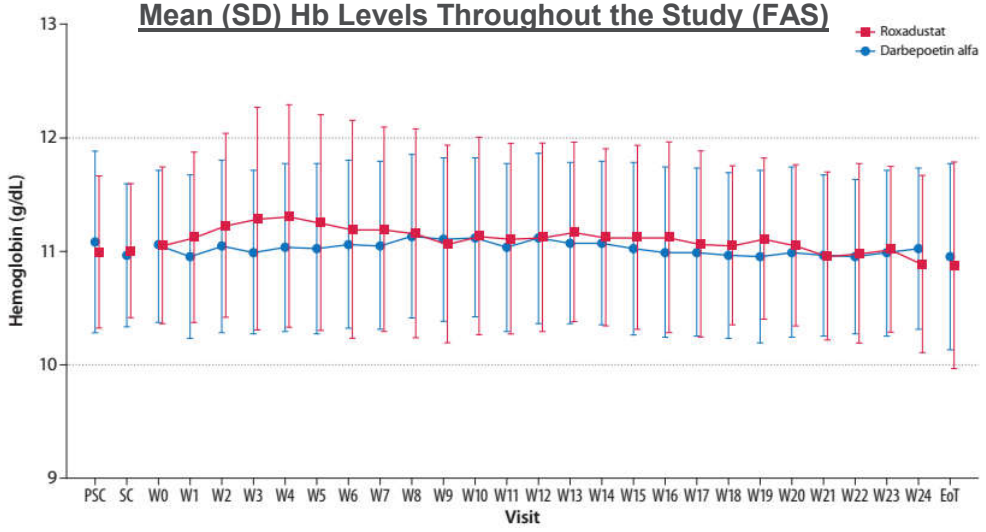
1: Al-Batran et al., ASCO2016, 2: Pennathur et al., 2013, 3: Sahin et al., 2008, 4: 2017 RDPAC survey, 5: Iizumi, S, et al., 2018

ASN Kidney Week 2018: JP Phase 3 study (hemodialysis, ESA-conversion)

Efficacy

- **Change of average Hb levels (g/dL) from baseline to Weeks 18-24 (ΔHb_{18-24})**
  - In the PPS, the mean (SE) of the average Hb levels of Weeks 18-24 in the roxadustat group was 10.99 (0.06) g/dL; the 95% CI (10.88, 11.10) was within the reference range 10.0–12.0 g/dL, confirming the efficacy of roxadustat.
  - In the PPS, the difference in LS means (SE) of the ΔHb_{18-24} between roxadustat and darbepoetin alfa (DA) was –0.02 (0.08) g/dL (95% CI: –0.18, 0.15, confirming non-inferiority of roxadustat to DA.
- **Maintenance rate of target Hb level**
  - In the FAS, the maintenance rate of target Hb levels (10.0–12.0 g/dL) during Weeks 18–24 was 79.3% (95% CI: 72.0, 85.5) and 83.4% (95% CI: 76.5, 89.0) in the roxadustat and DA groups, respectively.
  - Among patients with at least one Hb value during Weeks 18–24, the maintenance rate was 95.2% (95%CI: 89.8, 98.2) and 91.3% (95% CI: 85.3, 95.4) in the roxadustat and DA groups, respectively.

Mean (SD) Hb Levels Throughout the Study (FAS)



ASN: The American Society of Nephrology, ESA: erythropoietin stimulation agents, PPS: per protocol set, Hb: hemoglobin, SE: standard error, CI: confidence interval, LS: least square, FAS: full analysis set, SD: standard deviation, PSC: prescreening, SC: screening, EoT: end of treatment

ASN Kidney Week 2018: JP Phase 3 study (hemodialysis, ESA-conversion)

Safety

- Roxadustat was well tolerated with a safety profile similar to that of DA and consistent with previous reports.
- The proportion of patients who reported TEAEs were similar in the roxadustat and DA groups
  - Of note, 71.3% of patients in the DA group were treated with DA for ≥8 weeks before the study which may have introduced selection bias favoring patients who tolerated DA
- The incidences of serious TEAEs considered by the investigator to be drug related were similar in the roxadustat group and the DA group.
- Common (incidence ≥5%) TEAEs included nasopharyngitis, shunt stenosis, diarrhea, contusion, and vomiting.
- TEAEs classified as cardiac disorders by MedDRA system organ class occurred in 14 patients (roxadustat, n=6; DA, n=8)

Treatment-Emergent Adverse Events Occurring in ≥5% Patients in the Roxadustat or DA Group (SAF)

MedDRA Version 19.0 System Organ Class Preferred Term, n (%)	Roxadustat (n=150)	DA (n=152)
Gastrointestinal	42 (28.0)	28 (18.4)
Diarrhea	11 (7.3)	12 (7.9)
Vomiting	10 (6.7)	3 (2.0)
Infections/infestations	67 (44.7)	58 (38.2)
Nasopharyngitis	52 (34.7)	40 (26.3)
Injury, poisoning and procedural complications	41 (27.3)	45 (29.6)
Shunt stenosis	11 (7.3)	13 (8.6)
Contusion	10 (6.7)	10 (6.6)

DA: darbepoetin alfa, TEAEs: treatment-emergent adverse events, SAF: safety analysis set

ON THE FOREFRONT OF HEALTHCARE CHANGE

