Q3/FY2018 FINANCIAL RESULTS
ENDED DECEMBER 31, 2018

Chikashi Takeda
Chief Financial Officer
Astellas Pharma Inc.
January 31, 2019

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/FY2018 Consolidated Financial Results

II Pipeline

III Initiatives for Sustainable Growth

Q3/FY2018 FINANCIAL RESULTS (CORE BASIS)

(billion yen)	Q3/FY17	Q3FY18	Change	FY18 FCST*	Progress	CER growth
Net sales	**999.4**	**1,005.0**	**+0.6%**	**1,300.0**	**77.3%**	+0.6%
Cost of sales	238.9	227.7	-4.7%			
% of sales	23.9%	22.7%				
SG&A expenses	350.0	355.8	+1.6%			
% of sales	35.0%	35.4%				
R&D expenses	161.6	150.0	-7.2%	216.0	69.4%	
% of sales	16.2%	14.9%		16.6%		
Amortisation of intangible assets	27.0	26.5	-1.9%			
Share of profits/losses of associates and JVs	- 1.4	- 1.1	-			
Core operating profit	**220.5**	**244.0**	**+10.7%**	**270.0**	**90.4%**	+7.4%
Core profit for the period	**167.9**	**217.9**	**+29.8%**	**221.0**	**98.6%**	
Core EPS (yen)	**82.22**	**112.20**	**+36.5%**	**114.11**	**98.3%**	

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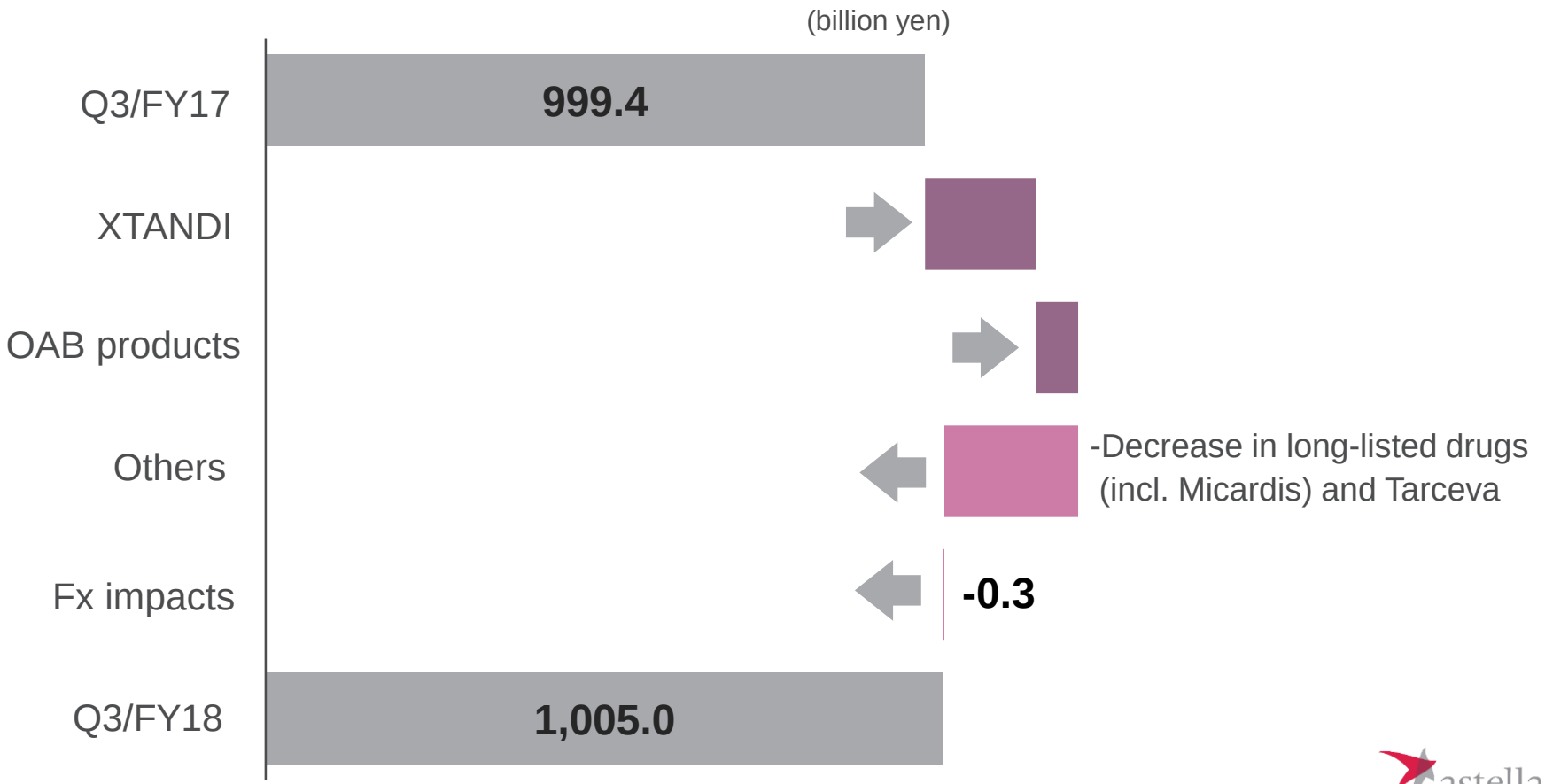
*Announced in Oct. 2018

CER : Constant Exchange Rate

SALES ANALYSIS (YEAR ON YEAR)

Growth of XTANDI and mirabegron contributed to increase in net sales

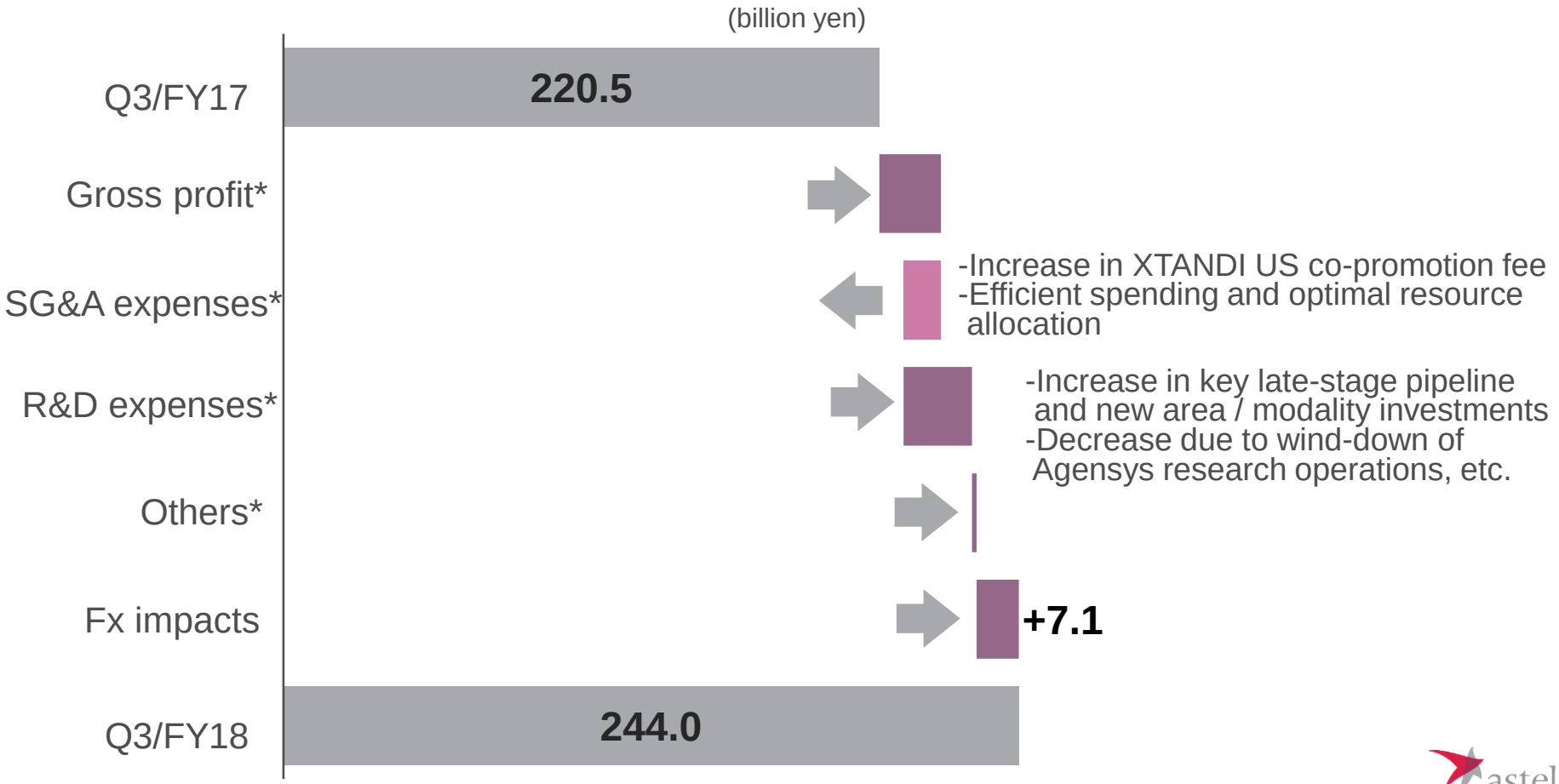


OAB：Overactive bladder
OAB products：Vesicare＋mirabegron (Betanis/Myrbetriq/BETMIGA)

Impact of NHI price revision in Japan :-13.9 bil.yen

CORE OP ANALYSIS (YEAR ON YEAR)

Increased core OP by 11% through combination of increased sales of main products and optimal resource allocation



*Excluding Fx impacts

Q3/FY2018 FINANCIAL RESULTS (FULL BASIS)

(billion yen)	Q3/FY17	Q3/FY18	Change	FY18 FCST*	Progress
Core operating profit	**220.5**	**244.0**	**+10.7%**	**270.0**	**90.4%**
Other income	10.4	13.1	+25.8%		
Other expense	51.2	47.8	-6.6%		
Operating profit	**179.8**	**209.4**	**+16.5%**	**234.0**	**89.5%**
Profit before tax	184.6	212.8	+15.3%	236.0	90.2%
Profit for the period	**142.6**	**191.5**	**+34.3%**	**195.0**	**98.2%**
EPS (yen)	**69.84**	**98.63**	**+41.2%**	**100.69**	**98.0%**

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*Announced in Oct. 2018

SALES OF MAIN PRODUCTS

Main growth products contributing to increased net sales

(billion yen)	Q3/FY17	Q3/FY18	Change	CER growth	FY18 FCST*	Progress
XTANDI	**219.9**	**253.4**	**+15.2%**	**+15.3%**	**325.9**	**77.7%**
OAB products in Urology	**171.6**	**184.3**	**+7.4%**	**+7.5%**	**245.7**	**75.0%**
Vesicare	78.5	74.4	-5.2%	-5.2%	96.1	77.4%
Mirabegron	93.1	109.9	+18.0%	+18.3%	149.6	73.5%
Prograf	**150.2**	**150.0**	**-0.1%**	**-0.2%**	**196.0**	**76.5%**

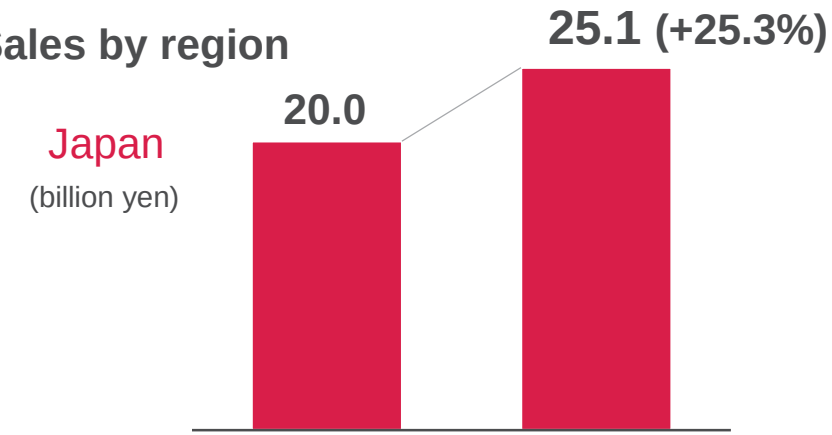
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL
OAB products: Vesicare＋mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
OAB：Overactive bladder

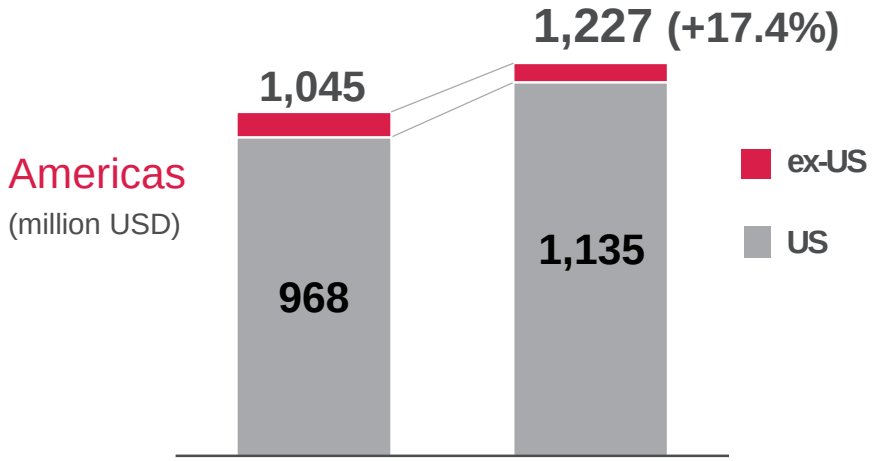
*Announced in Oct. 2018
CER：Constant Exchange Rate

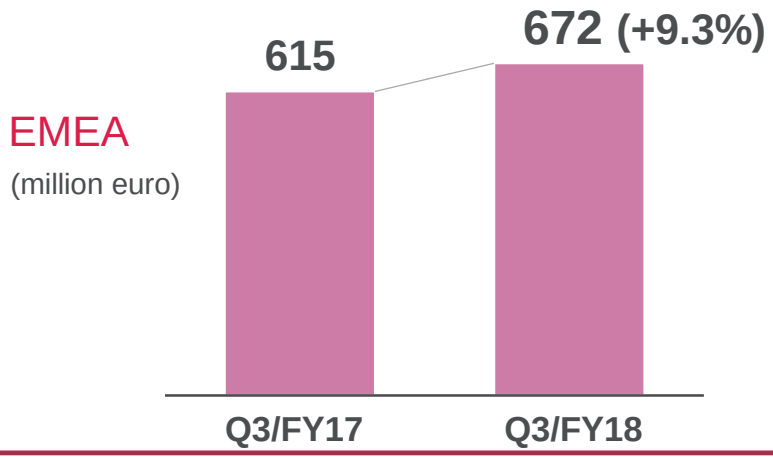
XTANDI

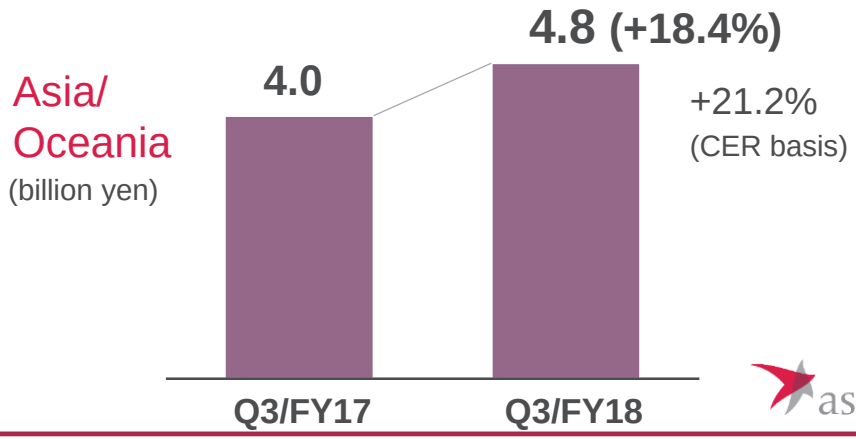
XTANDI sales increased in all regions due to penetration in earlier stage of prostate cancer

Sales by region







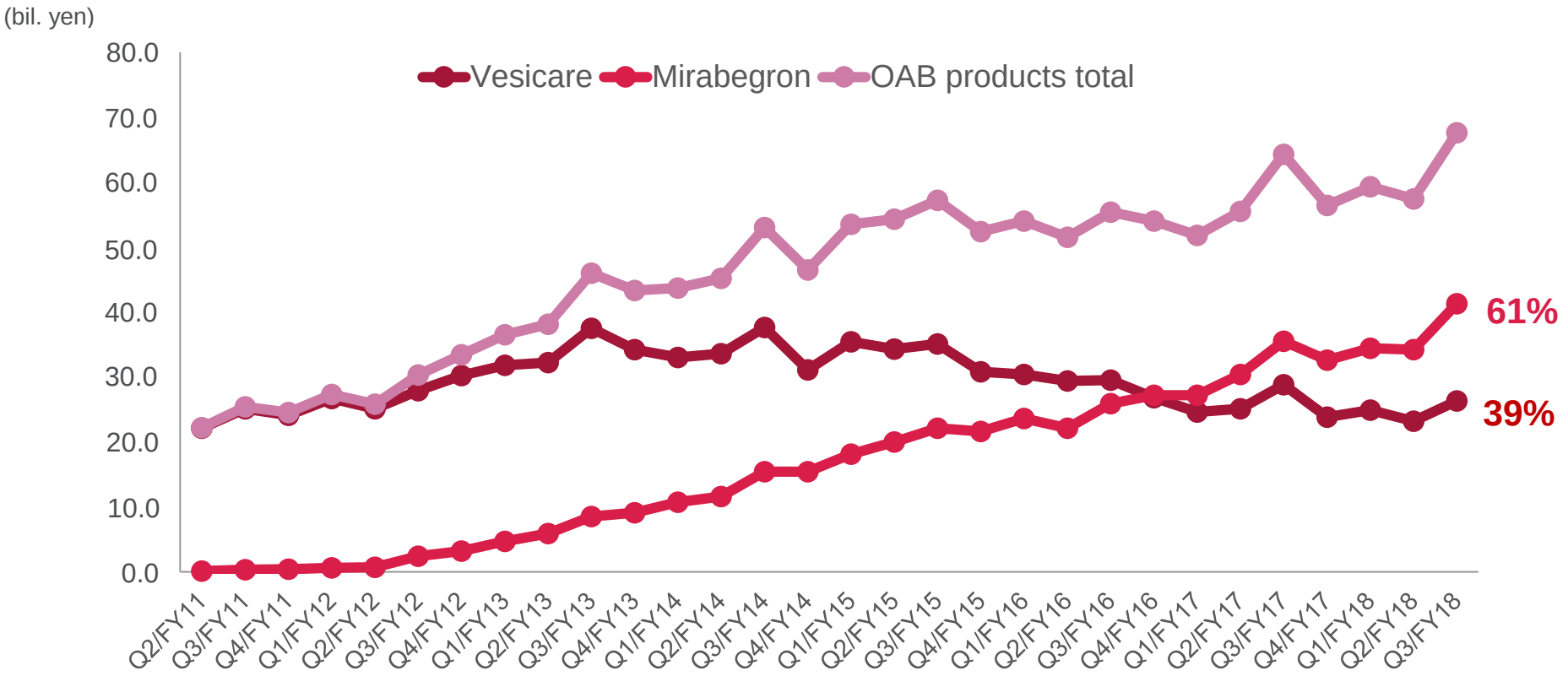


CER : Constant Exchange Rate

OAB FRANCHISE IN UROLOGY

Mirabegron growth driving OAB franchise sales.
Educating on novel mechanism of action with balance of efficacy and safety

Quarterly sales (Global)



Mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)

OAB：Overactive bladder

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FOUR APPROVALS OBTAINED SINCE LAST EARNINGS

Continue to deliver VALUE for patients

New molecular entity

gilteritinib

Nov 2018 (US)

Relapsed or refractory (R/R) FLT3 mut+ AML

First FLT3 inhibitor for R/R AML

ipragliflozin

Dec 2018 (JP)

Type I diabetes

First SGLT2 inhibitor for type 1 diabetes, which has limited treatment options (insulin and α-GI)

New molecular entity

romosozumab

Jan 2019 (JP)

Osteoporosis in patients at high risk of fracture

First approval of romosozumab in the world, with a new mechanism of action

degarelix

Jan 2019 (JP)

Prostate cancer (12-week formulation)

Reduce the treatment burden for prostate cancer patients

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*Please refer the label/package insert for detailed indication.
FLT3 mut+: FMS-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, α-GI: α-glucosidase inhibitor, SGLT-2: Sodium-glucose co-transporter 2

GILTERITINIB: APPROVED AS FIRST FLT3 INHIBITOR FOR R/R AML

Achieved important milestone in accordance with Strategic Plan 2018

- Approved in US in Nov 2018, launched in Japan and US in Dec 2018, for FLT3 mut+ R/R AML
- First FLT3 inhibitor for this patient segment
- Utilized regulatory expedited pathways including Sakigake designation in Japan and Priority Review and Fast track in US.
- Patients with AML with activating FLT3 mutations have short survival and high relapse rates and are less likely to respond to chemotherapy. No standard of care established for R/R AML with FLT3 mutation.
- Gilteritinib inhibits both FLT3-ITD and FLT3-TKD, two well characterized mutations in AML, which are associated with poor prognosis[1]
- Phase 3 ADMIRAL study met OS endpoint and full data to be presented at a future scientific meeting
- Deliver value for patients through highly specialized hematologists/oncologists

XOSPATA gilteritinib 40mg tablets

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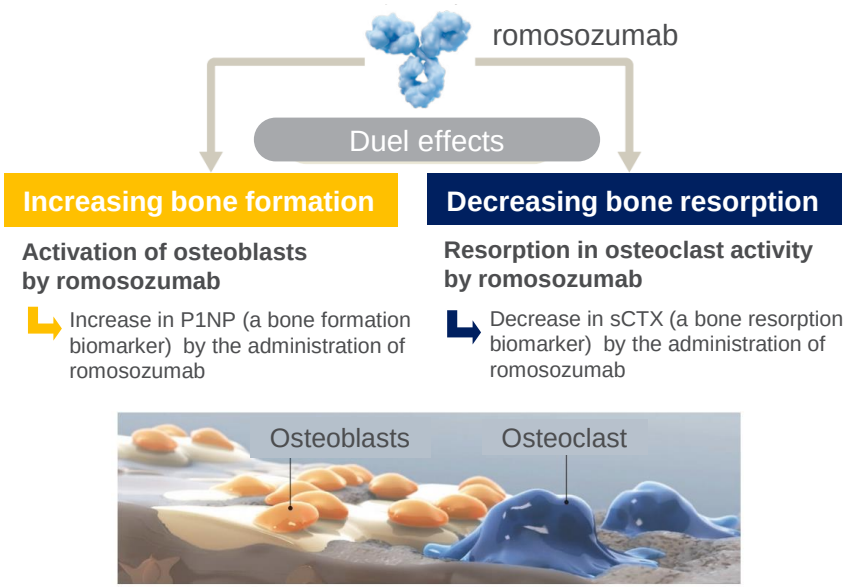
1: Yanada M et al., Leukemia. 2005;19:1345-9

FLT3: FML-like tyrosine kinase 3, R/R AML: Relapsed or refractory acute myeloid leukemia, ITD: Internal tandem duplication, TKD: Tyrosine kinase domain, OS: Overall survival

ROMOSOZUMAB: JAPAN APPROVAL FIRST IN THE WORLD

Aiming at paradigm shift in osteoporosis treatment

- Approved in Japan in Jan. 2019 for osteoporosis in patients at high risk of fracture
- Prior fracture is one of the major risk factors for further fractures in osteoporosis patients. Especially the risk of secondary fracture is high within a year after fracture,[1] requiring early treatment effect.
- Romosozumab has duel effects of increasing bone formation and decreasing bone resorption. It reduces the risk of fracture by increasing bone density rapidly and maintaining and improving the micro structure of bone and strengthening it.
- Reduces the risk of fracture by administration of 12 months
- Administered once a month for 12 months, expected to improve adherence to treatment



Effects of osteoporosis treatments*[2]

	romosozumab	Bisphosphonates, Anti-RANKL antibodies	PTH
Bone formation	↑	→	↑
Bone resorption	↓	↓	↑

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1: van Geek TA et al. Ann Rheum Dis. 2009, 68:99, 2: Gennari L et al. Expert Opin Pharmacother. 2016;17:1141-52,
P1NP：N-terminal propeptide of type I procollagen, sCTX：serum C-telopeptide cross-link of type 1 collagen, RANKL: Receptor activator of NF-κB ligand, PTH: Parathyroid hormone

UPDATES IN 6 POST-POC PROJECTS

Since Q2/FY2018 financial results announcement in Oct 2018

Steady progress and successful achievements of late-stage projects

enzalutamide

M1 HSPC

- **ARCHES study:** Met primary endpoint (rPFS)
- Filing planned by mid-2019 in US/EU/Japan

gilteritinib

FLT3 mut+ R/R AML

- **ADMIRAL study:** Met primary endpoint (OS) for final analysis
- **US:** Approved in Nov. 2018
- **EU:** MAA planned in 1Q/2019
- Plan to include OS data in label (US sNDA in 1Q/2019, JP in 3Q/2019)

enfortumab vedotin

mUC with prior CPI treatment

- TLR of Phase 2 study Cohort 1 (platinum-pretreated) planned in 1Q/2019
- If TLR is positive, BLA submission planned in US in 2019

zolbetuximab

Gastric and GEJ adenocarcinoma

- GLOW study (combination with CAPOX): FPI achieved

roxadustat

Anemia associated with CKD

- **EU:** TLRs obtained from 6 P3 studies required for MAA and reimbursement. MAA planned in mid-2019
- **JP:** Filed for patients on dialysis in Sep. 2018. For non-dialysis, TLR of remaining study expected in 2019

fezolinetant

MR-VMS

- Phase 2b study met all four co-primary endpoints in most cohorts.
- Phase 2b study results to be presented at ENDO2019

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M1 HSPC: Metastatic hormone-sensitive prostate cancer, rPFS: Radiographic progression free survival, OS: Overall survival, MAA: Marketing authorization application, sNDA: Supplemental new drug application, mUC: metastatic urothelial cancer, CPI: Check point inhibitor, TLR: Tope line result, BLA: Biologics License Application, GEJ: Gastroefophafeal junction, FPI: First patient in, CKD: Chronic kidney disease, MR-VMS: Menopause-related vasomotor symptom, ENDO: Endocrine Society

ENZALUTAMIDE

ARCHES study in M1 HSPC met its primary endpoint.
Filing for M1 HSPC in US/EU/Japan planned by mid-2019

M1 HSPC

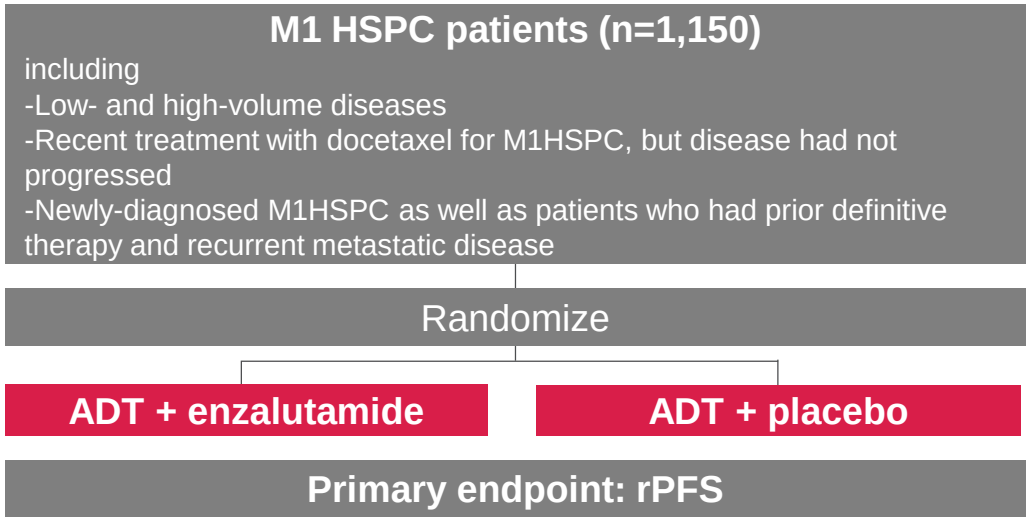
Disease background

- Approximately 38,000 men in the US develop M1 HSPC every year.[1,2]
- Currently, androgen deprivation therapy is commonly used as first line treatment.

Unmet medical needs

- Men with prostate cancer who have developed distant metastases have a worse prognosis, requiring improved treatment.
- M1 HSPC is a heterogeneous disease; limited data on how to treat M1 HSPC patients with low-volume or recurrent disease.

ARCHES study



- The study met its primary endpoint, significantly improving rPFS.
- The preliminary safety analysis appears consistent with the safety profile of XTANDI in previous clinical trials in CRPC.
- Data to be presented at ASCO-GU

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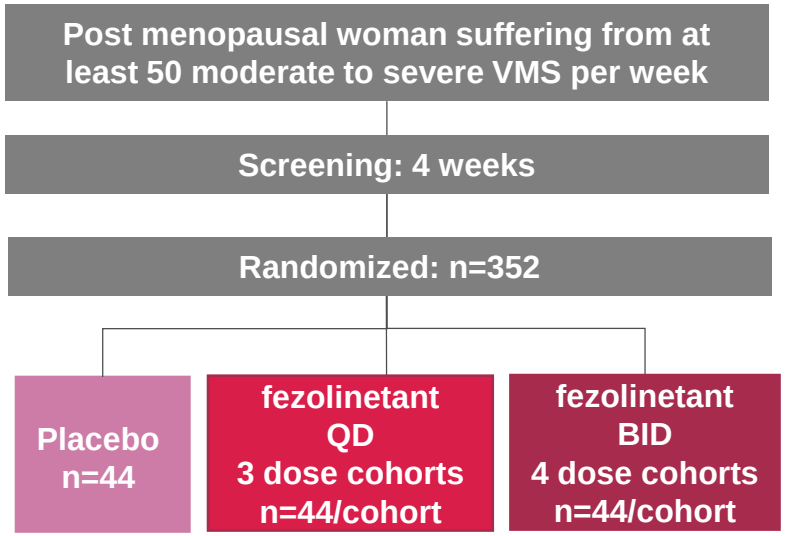
1: Scher HI et al. PLoS One. 2015; 10: e0139440, 2: Siegel RL et al. CA Cancer J Clin. 2018;68:7–30
M1 HSPC: Metastatic hormone-sensitive prostate cancer, rPFS: Radiographic progression-free survival, CRPC: Castration-resistant prostate cancer
ASCO-GU: American Society of Clinical Oncology, Genitourinary Cancers Symposium

FEZOLINETANT

Phase 2b study met all four co-primary endpoints in most cohorts.
Full results to be presented at ENDO2019 in March 2019

Study Design



Treatment duration: 12 weeks

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

Top Line Results

Efficacy

- All four co-primary endpoints demonstrated statistically significant improvement in most cohorts.
- Efficacy in hot flash frequency and severity and treatment effect size of BID and QD were similar.

Safety

- No death or treatment-related SAEs were reported.
- Overall TEAE rates were similar across cohorts and mostly mild or moderate.
- Asymptomatic liver enzyme elevations were observed in a small number of patients in the higher dosing cohorts.

Next step:

Preparing regulatory consultation for Phase 3 program including dose selection

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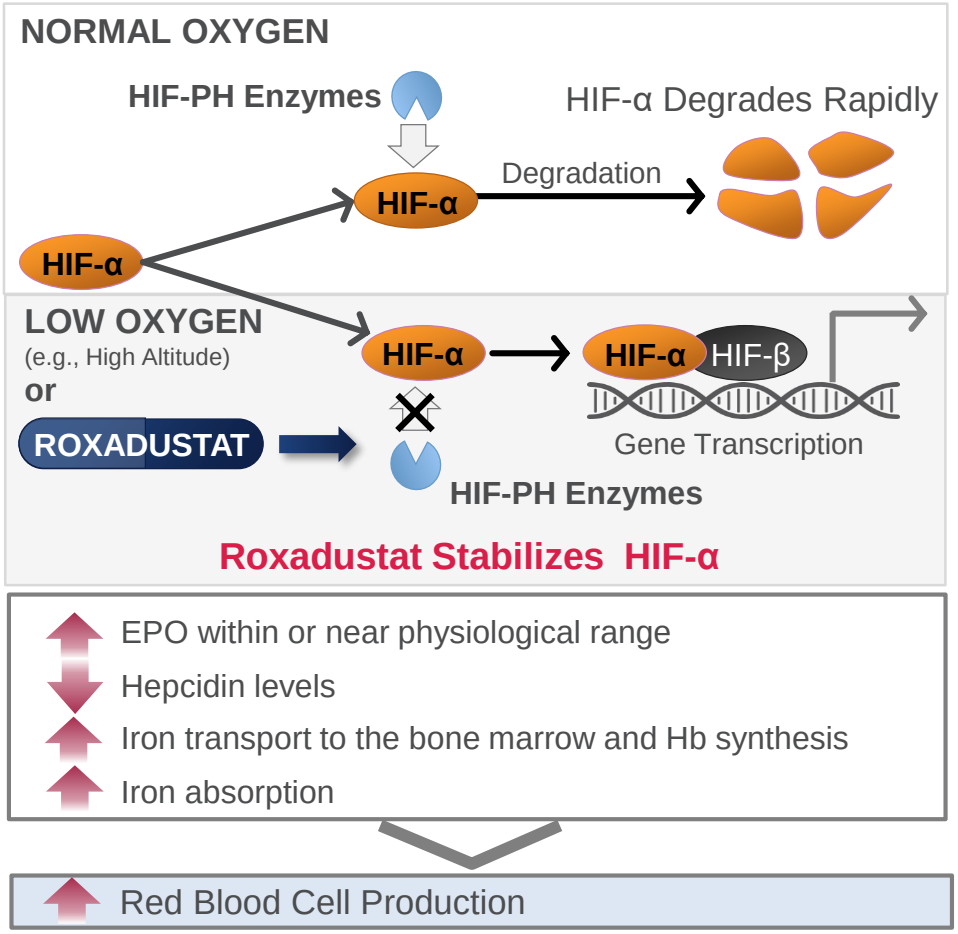
VMS: Vasomotor symptoms, QD: once daily, BID: twice daily, PoC: Proof of concept, SAE: Serious adverse event, TEAE: Treatment emergent adverse event, ENDO: Endocrine Society

ROXADUSTAT

Potential first-in-class oral treatment for anemia associated with CKD



Target profile

- Novel mechanism of action
- Potential new treatment option that is orally administered
- Potential new treatment option that may reduce the treatment burden for patients
- Comparable efficacy to the current treatment (i.e. ESAs)
- Minimize the use of IV iron
- Erythropoietin levels within or near the physiological range, potentially avoiding the concerns from the existing therapy
- Efficacy in the patients who cannot be well controlled with the current treatment (i.e. patients with inflammation)

FibroGen

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CKD: Chronic kidney disease, HIF: Hypoxia-inducible factor, PH: Prolyl hydroxylase, Hb: Hemoglobin, EPO: erythropoietin, ESAs: Erythropoiesis-stimulating agents, IV: intravenous

ROXADUSTAT

TLRs of all 6 Phase 3 studies supporting EU filing were obtained. MAA submission in EU planned in mid-2019

Phase 3 program supporting EU filing and reimbursement

Dialysis	
HIMALAYAS Incident dialysis, vs epoetin alfa, n=1,043	FibroGen
SIERRAS Stable dialysis, vs epoetin alfa, n=741	FibroGen
PYRENEES Stable dialysis, vs epoetin alfa or darbepoetin alfa, n=836	astellas
Non-dialysis	
DOLOMITES*: vs darbepoetin alfa, n=616	astellas
ALPS: vs placebo, n=594	astellas
ANDES: vs placebo, n=922	FibroGen

*Interim analysis

TLRs of all 6 Phase 3 studies obtained

- All studies met their primary endpoints.
- Roxadustat was well tolerated. Preliminary safety analysis showed that the overall safety profile is consistent with the previous clinical studies.

Pooled safety analysis:
Planned in 1H/2019

MAA submission planned in mid-2019

FibroGen astellas

TLR: Top line results, MAA: Marketing authorization application

MAXIMIZE VALUE OF KEY LATE STAGE PROJECTS

Initiated development of additional indication for zolbetuximab to expand the value for patients

Target disease: pancreatic adenocarcinoma

- Pancreatic cancer is the 7th most common cause of cancer death globally.[1]
- The 5-year survival rate remains as low as 8% in US and 4% worldwide.[1]
- 50% to 70% of pancreatic cancer patients show significant expression of CLDN18.2.[2,3,4]

Phase 2a study

- Patient segment: metastatic pancreatic adenocarcinoma with CLDN18.2 positive
- Combination with Nab-Paclitaxel and Gemcitabine as first line treatment
- Study initiation planned in 2Q/2019

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1: Ilic M and Ilic I. World J Gastroenterol, 2016; *22*: 9694-705, 2: Lee JH et al. Oncology Rep. 2011;25:971-8,
3: Sanada et al. Clin Cancer Res. 008;14:7624-34, 4: Karanjawala ZE et al, Am J Surg Pathol. 2008;32:188-96

PROGRESS IN OVERALL PIPELINE

P1 entry to filing, since Q2/FY2018 financial results announcement in Oct 2018

Steady progression of pipeline

P1 Entry | **P2 Entry** | **P3 Entry** | **Filing**

ASP3772

Prevention of pneumococcal disease

zolbetuximab

Pancreatic adenocarcinoma

ASP1128/MA-0217

Acute kidney injury

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

Discontinuation of a part of indication etc.

reldesemtiv: Chronic obstructive pulmonary disease (P2)
ASP4070/JRC2-LAMP-vax: Pollinosis caused by Japanese red cedar (P2)
ASP7713: Underactive bladder (P1)
ASP1807/CC8464: Neuropathic pain (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.

EXPECTED KEY EVENTS WITHIN A YEAR

Important milestones from POC study through registration

Data readouts	Phase 2 (POC) study reldesemtiv (CK-2127107)	 ALS
	Phase 2 study enfortumab vedotin	 mUC, Cohort 1 (CPI-pretreated/platinum-pretreated)
Filings*	roxadustat	Anemia associated with CKD, dialysis/non-dialysis (EU)
	gilteritinib	R/R FLT3 mut+ AML (EU)
	enfortumab vedoin	mUC, CPI-pretreated/platinum-pretreated
	enzalutamide	M1 HSPC
Regulatory decisions	peficitinib	Rheumatoid arthritis (Japan)
	roxadustat	Anemia associated with CKD, dialysis (Japan)
	evolocumab	Statin-intolerant hypercholesterolemia (Japan)
Presentations at scientific meetings	enzalutamide	ASCO-GU (ARCHES)
	gilteritinib	Upcoming meeting (ADMIRAL OS)
	enfortumab vedotin	ASCO-GU (P1)
	fezolinetant	ENDO 2019 (P2b)

Please refer to pipeline list for details including target disease.

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

POC: Proof of concept, ALS: Amyotrophic lateral sclerosis, mUC: Metastatic urothelial cancer, CPI: Check point inhibitor, CKD: Chronic kidney disease, R/R: Relapsed and refractory, FLT3 mut+: FMS-like tyrosine kinase 3 mutation positive, AML: Acute myeloid leukemia, M1 HSPC: Metastatic hormone-sensitive prostate cancer, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium, ENDO: Endocrine Society

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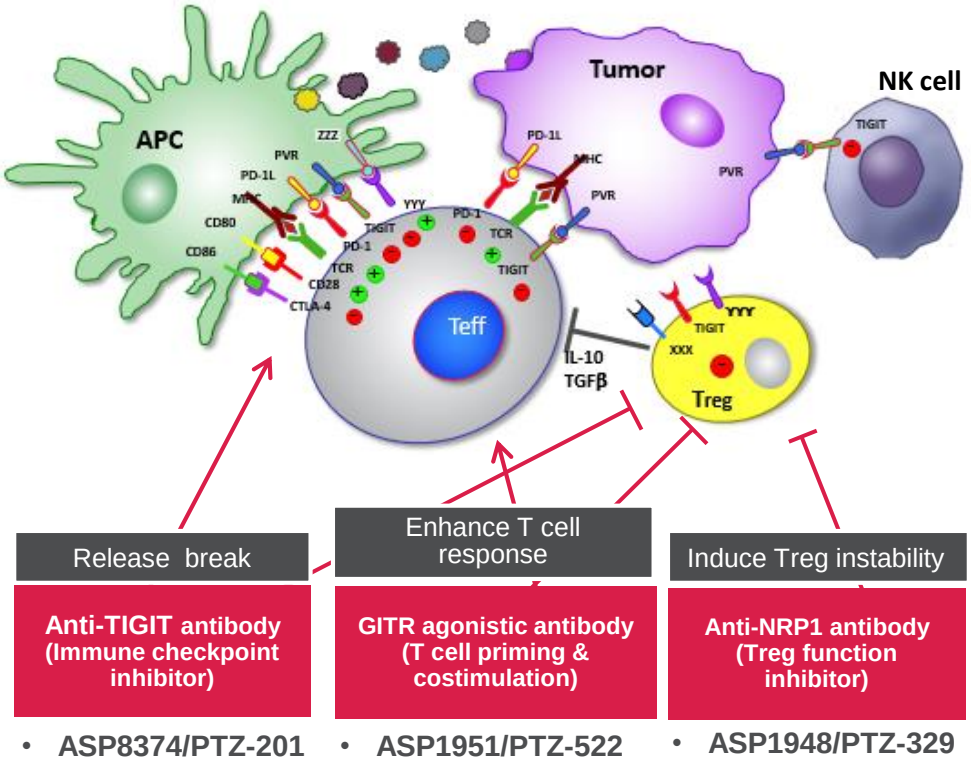
FOCUS AREA APPROACH: ACQUISITION OF POTENZA

Expand our oncology portfolio

Strategy

- Introduced novel immuno-oncology programs in clinical stage
  - ➢ 3 programs entered into Phase1
  - ➢ Targeting patient population who are non-responsive to existing immuno-oncology therapies
  - ➢ Provides platform for immuno-oncology combinations with existing pipeline products

Mechanism of Immunomodulation



POTENZA therapeutics

PURSUING OPERATIONAL EXCELLENCE

Management priorities for resource allocation in FY2018

IN

- Capex in new modality / technology
  - -New centers in Japan (Toyama and Tsukuba)
  - -Enhancement of AIRM production facility in US
- Focus Area investments

  Gene therapy:
  - -Acquisition of Quethera
  - -Alliance with Gene Therapy Research Institution
  - -Alliance with Juventas

  Novel immuno-oncology therapy:
  - -Acquisition of Potenza

OUT

- Review of organization / structure
  - -Optimization of organization / structure in EMEA
  - -Restructuring of operations in Japan
- Review of production structure
  - -Succeeding pharmaceutical manufacturing business of Nishine Plant

Underline indicates the initiatives during Q3/FY2018

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

Business investment

Acquisition

Quethera

POTENZA therapeutics

Alliance

Gene Therapy Research Institution

Juventas THERAPEUTICS

Shareholder return

Aiming for steady dividend increase during FY2018-FY2020

Flexible share buybacks

Dividends in FY2018 (Forecast):
38 yen (2 yen increase)

Acquisition of own shares (Actual) in FY2018:
100 billion yen (55 million shares)

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APPENDIX

Q3/FY2018: SALES BY REGION

(billion yen)	Q3/FY17	Q3/FY18	Change
Japan	**337.3**	**312.7**	-7.3%
Americas	**326.8**	**352.0**	+7.7%
EMEA	**260.0**	**261.8**	+0.7%
Asia/Oceania	**75.3**	**78.5**	+4.3%

FX RATE (ACTUAL)

Average rate for the period

Currency	Q3/FY17	Q3/FY18	Change
USD	112 yen	111 yen	-1 yen
EUR	129 yen	129 yen	+1 yen

Change in closing rate from PY end

Currency	Q3/FY17	Q3/FY18
USD	+1 yen	+5 yen
EUR	+15 yen	-4 yen

Fx impact on elimination of unrealized gain: COGs ratio -0.6 ppt

FY2018 FCST：FX RATE & FX SENSITIVITY

Forecast rates from October 2018 onwards: 110 USD/yen, 130 EUR/yen

Estimated Fx sensitivity (October 2018 and onward) of FY2018 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

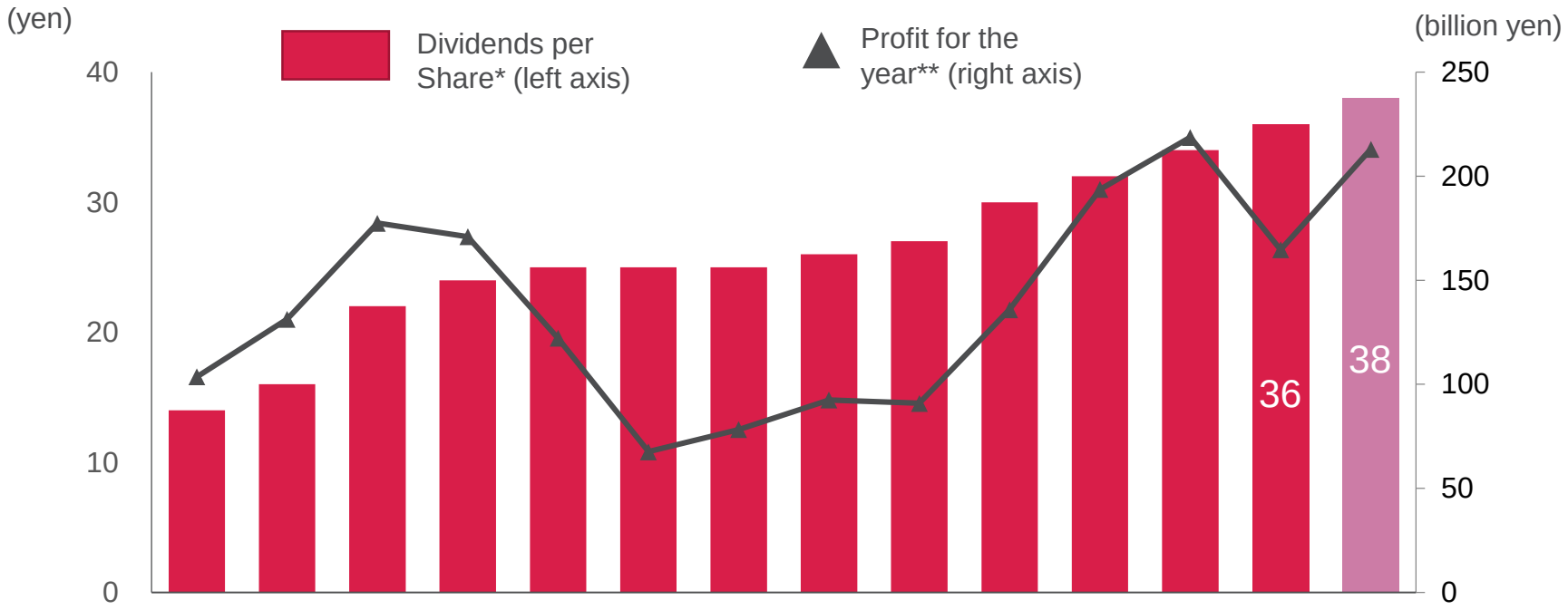
*Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates' results compared to forecasted rates from October 2018 and onwards

BALANCE SHEET/CASH FLOW HIGHLIGHTS

(billion yen)	FY17 end	Dec. 2018
Total assets	1,858.2	1,928.3
Cash and cash equivalents	331.7	331.3
Total net assets	1,268.3	1,292.2
Equity ratio (%)	68.3%	67.0%

(billion yen)	Q3/FY17	Q3/FY18	FY17
Cash flows from operating activities	215.3	203.7	312.6
Cash flows from investing activities	(93.8)	(28.5)	(121.8)
Free cash flows	121.5	175.2	190.8
Cash flows from financing activities	(143.1)	(173.3)	(203.4)
Acquisition of treasury shares	(70.7)	(100.4)	(130.7)
Dividends paid	(71.6)	(72.1)	(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
- ASP0367/MA-0211
- MucoRice-CTB
- ASP3772

Phase 2

- zolbetuximab (IMAB362) (Pancreatic adenocarcinoma)
- AGS-16C3F (Renal cell carcinoma)
- ASP1650 (Testicular cancer)
- bleselumab (ASKP1240) (rFSGS)
- ASP5094 (Rheumatoid arthritis)
- reldesemtiv (CK-2127107) (SMA, ALS)
- ASP7317 (Dry AMD etc.)
- ASP6294 (BPS/IC)
- ASP8302 (Underactive bladder)
- ASP1128/MA-0217 (AKI)
- 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 (Gastric and gastroesophageal junction adenocarcinoma, US/EU/JP/Asia)
- mirabegron (Pediatric NDO, EU)
- roxadustat (ASP1517/FG-4592) (Anemia associated with CKD, EU:Non-dialysis/dialysis, JP: non-dialysis)
- fidaxomicin (Pediatric, EU)

Filed

- peficitinib (ASP015K) (Rheumatoid arthritis, JP)
- solifenacin* (Pediatric NDO, US)
- roxadustat (Anemia associated with CKD in dialysis, JP)
- evolocumab (Statin intolerant hypercholesterolemia, 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.

astellas

rFSGS: Recurrence of focal segmental glomerulosclerosis, SMA: Spinal muscular atrophy, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, BPS/IC: Bladder pain syndrome/Interstitial cystitis, AKI: Acute kidney injury, 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 or refractory, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease

FILING TIMELINE FOR 6 KEY POST-POC PROJECTS

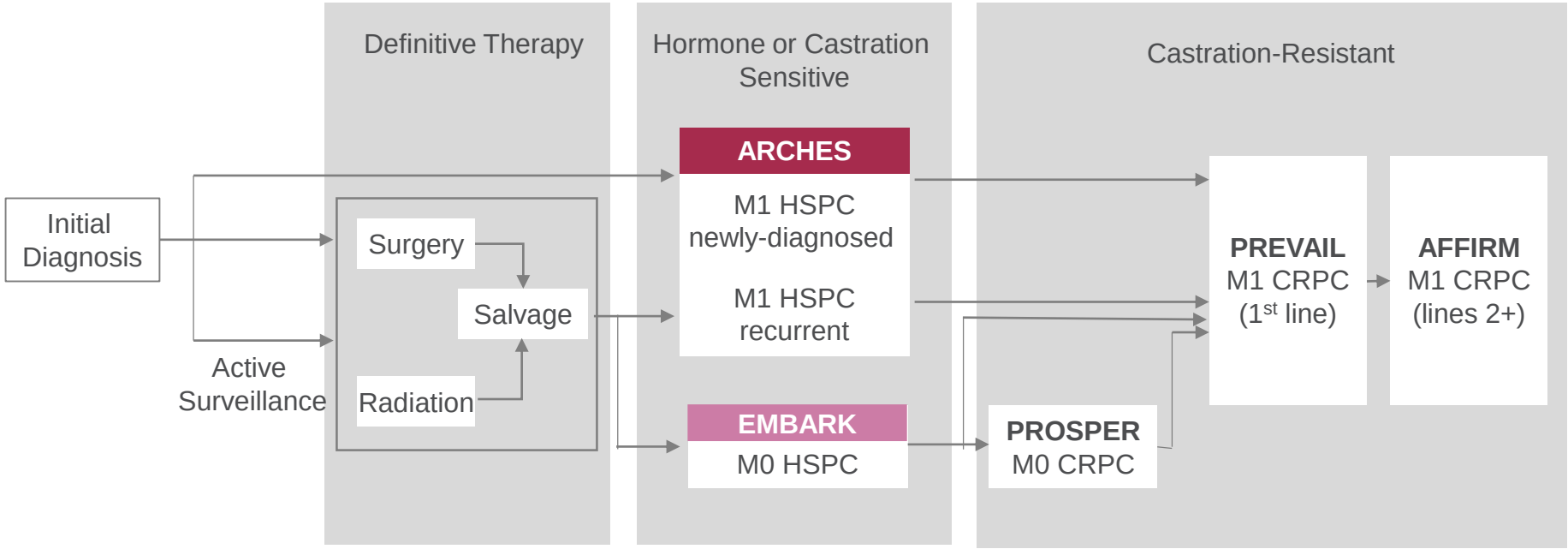
Filed/Expected filing

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

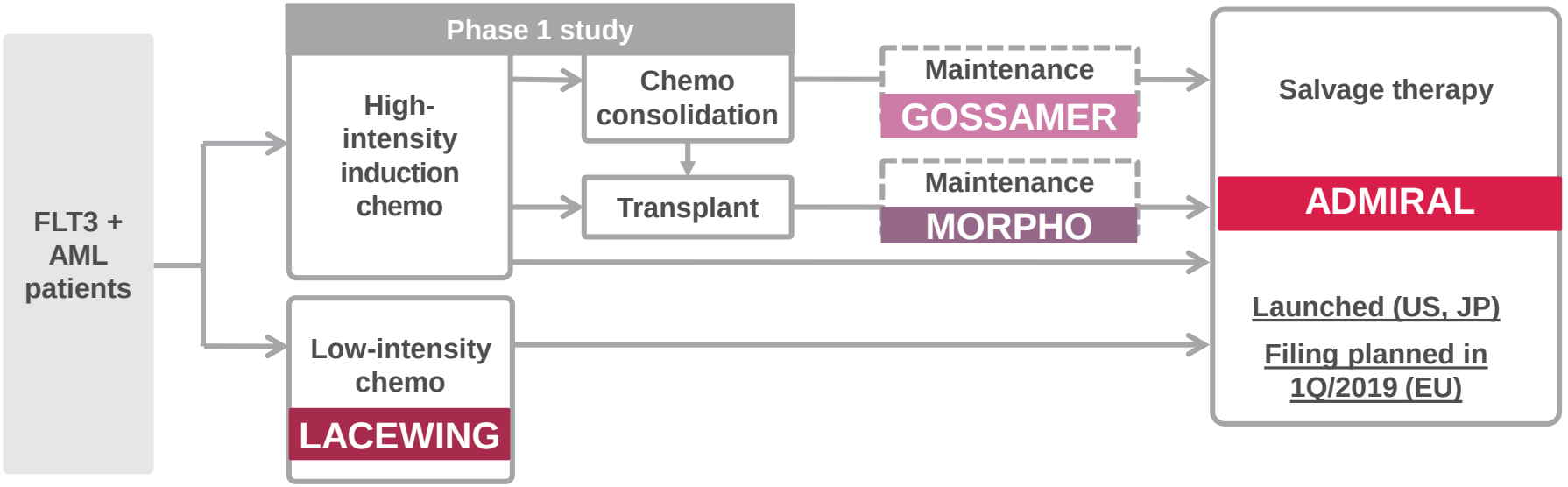
ENZALUTAMIDE



P3: ARCHES	**M1 HSPC**	vs. placebo, combination with ADT, n=1,150	TLR obtained in Dec/2018 Data to be presented at ASCO-GU Filing planned in US/EU/Japan by mid-2019
P3: EMBARK	**M0 HSPC**	vs. placebo, combination with ADT, n=1,068	Enrollment completed

Underline indicates the changes from the previous announcement on Oct 31, 2018.
M0: Non-metastatic, CRPC: Castration resistant prostate cancer, ADT: Androgen deprivation therapy, M1: Metastatic,
HSPC: Hormone-sensitive prostate cancer, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

GILTERITINIB

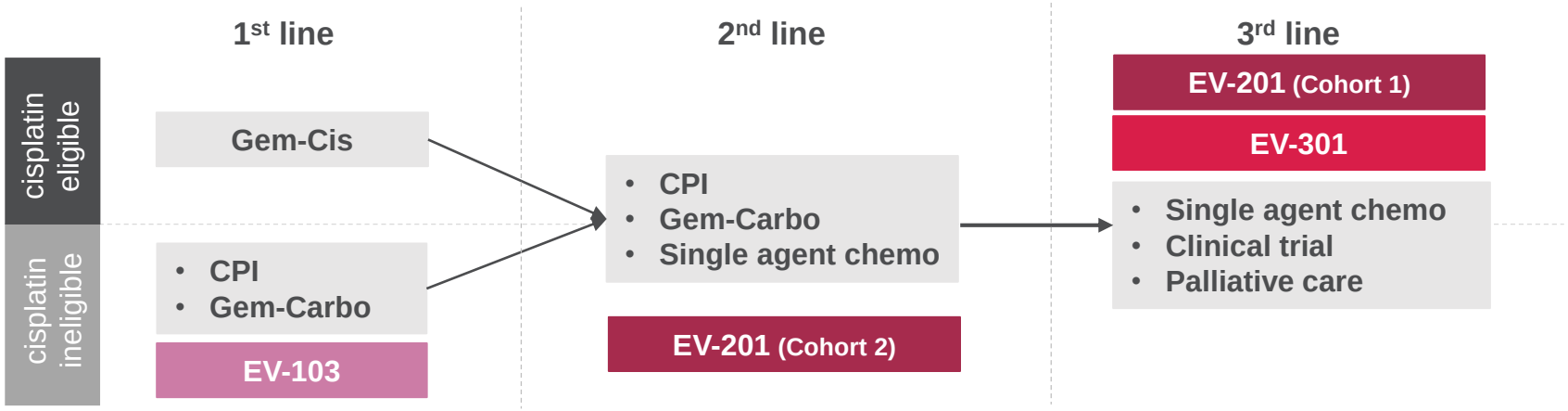


P3: ADMIRAL	Relapsed or refractory	Monotherapy vs salvage chemo (2:1), n=371	Full OS data obtained Label update to include OS data US: sNDA planned in 1Q/2019 JP: Planned in 3Q/2019
P3: LACEWING	1st line intensive chemo ineligible	Combo with azacitidine vs azacitidine alone (2:1), n=323	First Patient 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 Oct 31, 2018.
FLT3: Fms-like tyrosine kinase 3, AML: Acute myeloid leukemia, OS: Overall survival, sNDA: Supplemental new drug application, HSCT: Hematopioetic stem cell transplant, BMT-CTN: Blood and Marrow Transplant – Clinical Trial Network

ENFORTUMAB VEDOTIN

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



	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: TLR expected in 1Q/2019 Cohort 2: Recruiting
	P1b: EV-103	Combination with CPI	n=159	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 Matured data to be presented at ASCO-GU

SeattleGenetics astellas

Underline indicates the changes from the previous announcement on Oct 31, 2018, Pts: Patients, CPI: Checkpoint inhibitor, TLR: Top line results, mUC: metastatic urothelial cancer, NSCLC: Non-small cell lung carcinoma, Gem-Cis: gemcitabine and cisplatin, Gem-Carbo: gemcitabine and carboplatin, ASCO-GU: American Society of Clinical Oncology-Genitourinary Cancers Symposium

ZOLBETUXIMAB

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
  - ~70-90% biliary duct, pancreatic, gastric and mucinous ovarian cancer[1]
  - ~ 10% ovarian cancer and NSCLC[1]

Gastric and gastroesophageal junction (GEJ) adenocarcinoma

- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 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]

	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	First Patient In: Jan 2018
		P2: ILUSTRO	Monotherapy, Combination with mFOLFOX6	n= 102	First Patient In: Sep 2018
	Pancreatic adenocarcinoma	**P2**	Combination with nab-paclitaxel and gemcitabine	n=141	Study initiation planned in 2Q/2019

Underline indicates the changes from the previous announcement on Oct. 31, 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

NSCLC: Non-small cell lung cancer

ON THE FOREFRONT OF HEALTHCARE CHANGE