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FY2018 Q1
Consolidated Financial Results
(Three Months Ended March 31, 2018)

May 11, 2018

Otsuka Holdings Co., Ltd.

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Agenda

- **Impact of IFRS 15 in FY2018**
- **Consolidated Financial Results**
- **Pharmaceutical Segment**
  - Main factors of change in sales and operating profit
  - Further Accelerate Growth of New Drugs
- **Nutraceutical* Segment**
  - Main factors of change in sales and operating profit
- **FY2018 Forecast**

*nutrition + pharmaceutical

Impact of IFRS 15 in FY2018

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Implement IFRS 15 from FY2018

(without retroactive adjustment of FY2017 results)

Changes to revenue recognition by applying IFRS 15

1. Revenue from upfront and milestone (Estimate in 2018 : Approx. +¥4.5Bil)
2. Allocation of costs related to vending machine (Estimate in 2018 : Approx. -¥6.0Bil)

FY2018 full-year forecast announced Feb 2018 implemented IFRS 15

Impact in FY2018 Q1 （Jan-Mar）				
(100 million yen)	Before	**After**	**Change**	
Net Sales	**2,934**	**2,947**	**+12**	
Upfront and milestone etc.	17	39	+23	**Before** : Revenue recognized at one time when an event occurred **After** : Revenue recognized over a period of contract
Cost related to vending machine	—	-11	-11	
COGS and SGA	**2,231**	**2,218**	**-13**	Positive and negative signs indicate impact on segment operating profit
Cost related to vending machine	11	—	-11	Positive and negative signs indicate impact on segment operating profit
Operating income	**323**	**348**	**+25**	

Consolidated Financial Results | FY2018 Q1

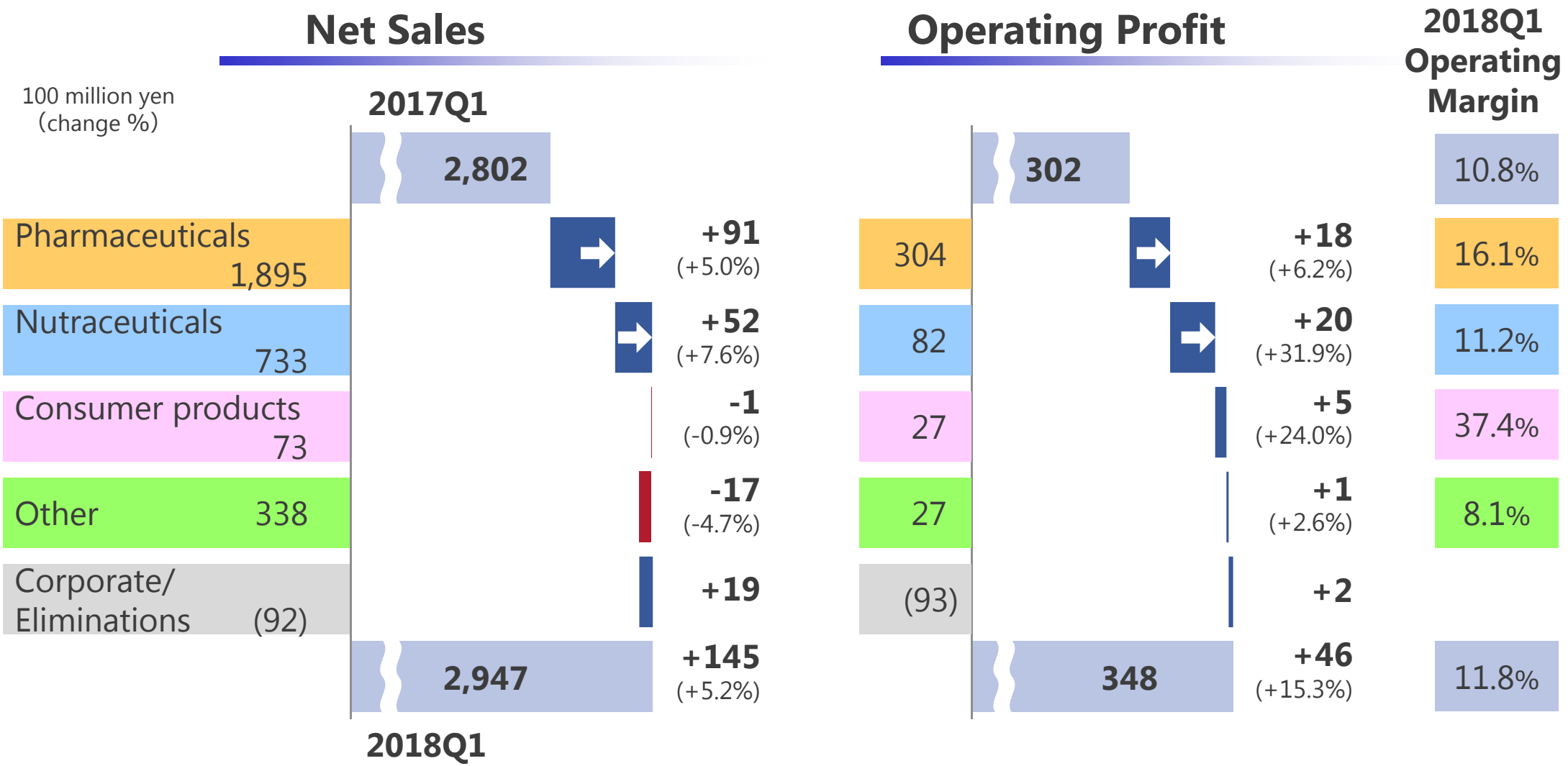
- **Good progress to FY2018H1 forecast, achieving increase in sales and profit**
- **Operating profit before R&D expenses increased by aggressive investment for sustainable growth**

(100 million yen)	FY2017Q1 (Jan-Mar)	FY2018Q1 (Jan-Mar)	Change	FY2018H1 Forecast	% Progress
Net Sales	2,802	2,947	+5.2%	6,200	47.5%
Sales of Global Products & New Drugs in Japan*	756	914	+20.9%	1,890	48.4%
Operating Profit (Excl. Impairment Loss)	302	352	+16.3%	600	58.6%
Impairment Loss (SGA+R&D)	1	4	–	–	–
Operating Profit	302	348	+15.3%	600	57.9%
Net Profit**	210	227	+8.2%	460	49.4%
R&D Expenses***	367	426	+16.2%	900	47.3%
Operating Profit Before R&D Expenses	668	774	+15.8%	1,500	51.6%

*Global products(SAMSCA/JINARC, Rexulti, Abilify Maintena), Next-generation products (Lonsurf) and New drugs in Japan (products launched after 2009, excluding the global products) above. **Profit attributable to owners of the Company, ***Impairment loss related to R&D intangible assets included

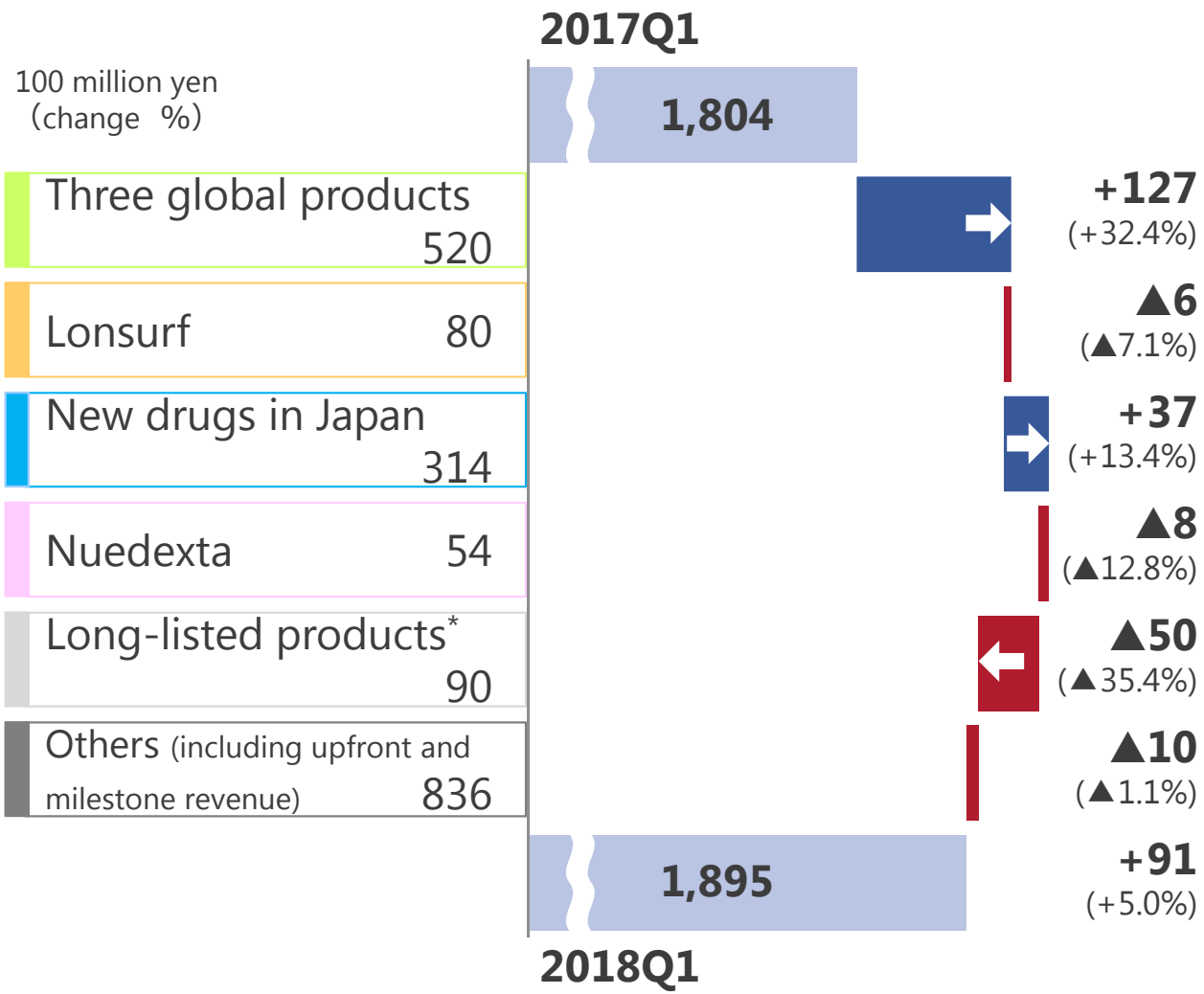
Consolidated Financial Results | by Segment

■ Pharmaceutical and Nutraceutical businesses drive company's performance



Pharmaceutical Segment | Sales

■ **Achieved sales growth lead by three global products, offsetting the sales decrease of long-listed products in Japan**



Main Factors

■ **Three Global Products**
- ✓ Abilify Maintena | Increased market share in US by expanded indication for bipolar disorder
- ✓ Rexulti | TRx driven by DTC** for major depression indication
- ✓ Samsca/JINARC | Increased awareness and growth as diuretic and ADPKD*** treatment

■ **New Drugs in Japan**
- ✓ Sales expansion of E Keppra and Takecab etc.

■ **Long-listed products**
- ✓ Decreased due to the impact of promotion of generic products in Japan

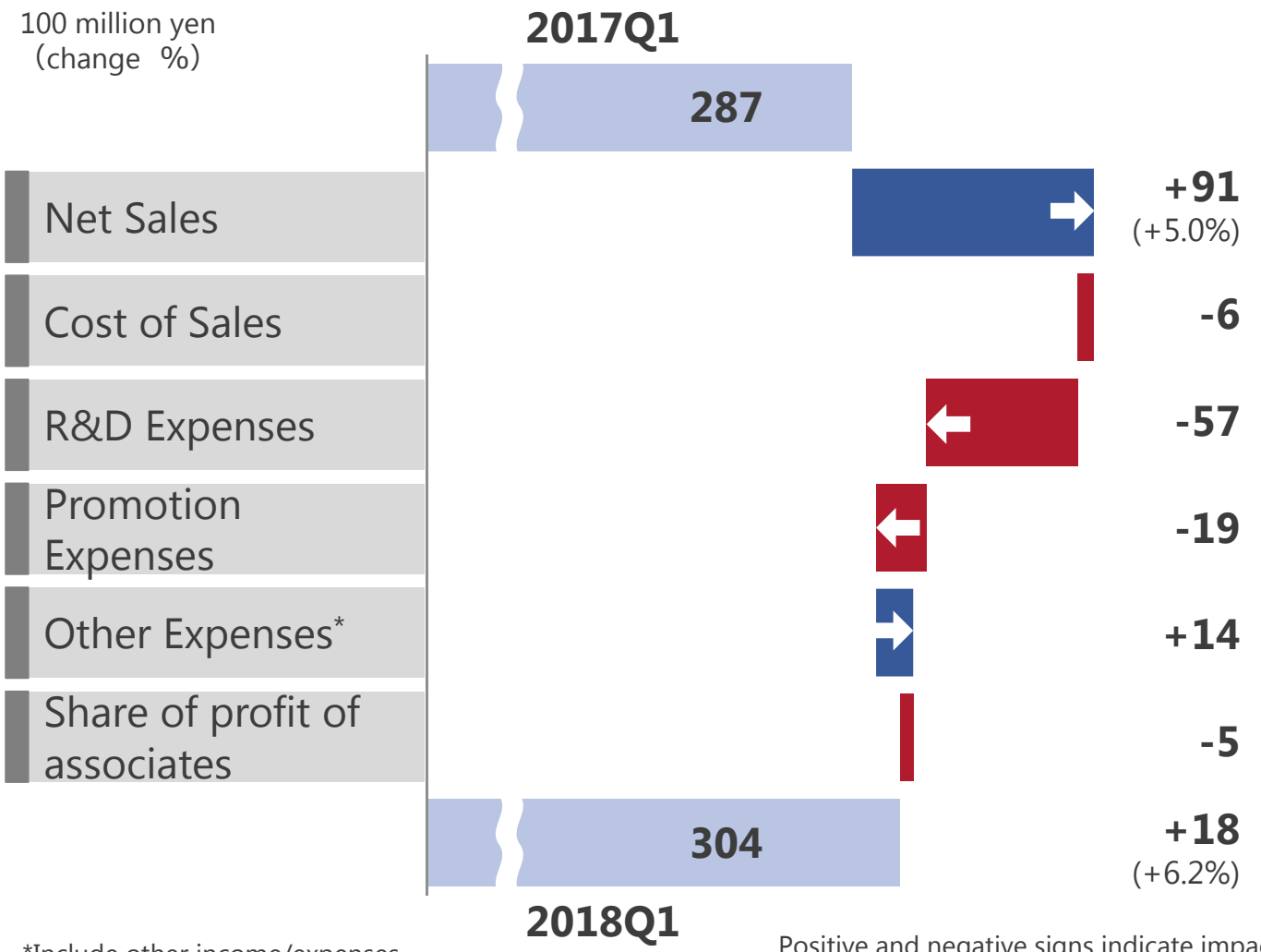
Global products: SAMSCA/JINARC, Rexulti, Abilify Maintena, New drugs in Japan: products launched after 2009, excluding the global products and next-generation products (Lonsurf) above.

*pletaal, Mucosta, TS-1
**DTC : Direct to consumer
***Autosomal dominant polycystic kidney disease

Pharmaceutical Segment | Operating profit

- **Gross profit increased driven by good growth of global products etc.**
- **Achieved increase in sales while investing R&D aggressively for sustainable growth**

100 million yen
(change %)



*Include other income/expenses

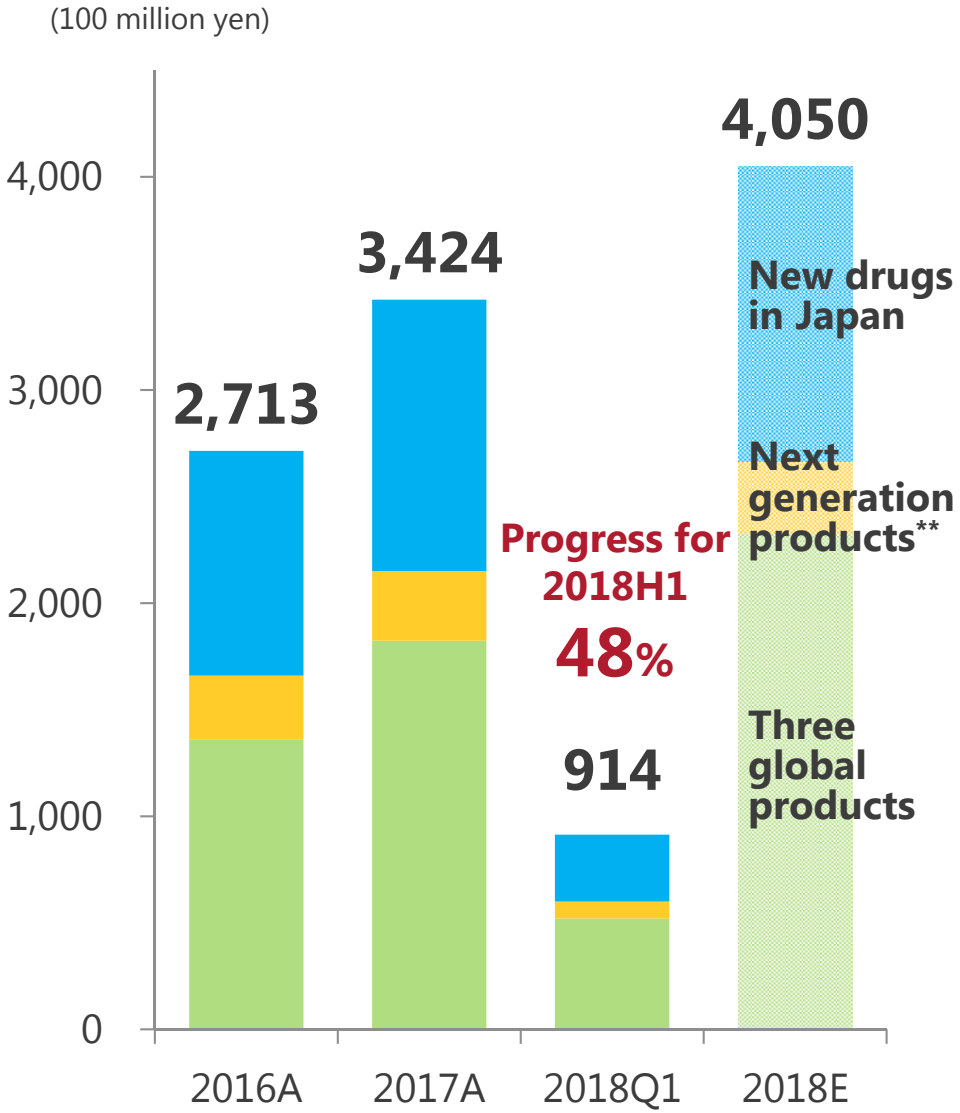
Positive and negative signs indicate impact on segment operating profit

Main Factors

- **Cost of Sales Ratio**
  - ✓ Improved by increasing sales of products developed in-house, upfront and milestone etc.
- **R&D Expenses**
  - ✓ Increased by accelerated investment to vadadustat etc.
- **Promotion Expenses**
  - ✓ Co-promotion fee increased associated with sales growth
- **Other Expenses**
  - ✓ Decreased by indirect cost optimization

Further Acceleration of New Drugs

■ Maximize value of new drugs by market expansion and LCM* strategies



Growth strategies

Lonsurf

P3 Gastric cancer | positive results

✓ Prepare for early filing

Abilify Maintena

Newly approved for bipolar

✓ Expand of bipolar LAI market

REXULTI brexpiprazole tablets

Launched in Japan from 4/2018

✓ New treatment choice for schizophrenia

JYNARQUE™

Newly approved for ADPKD*

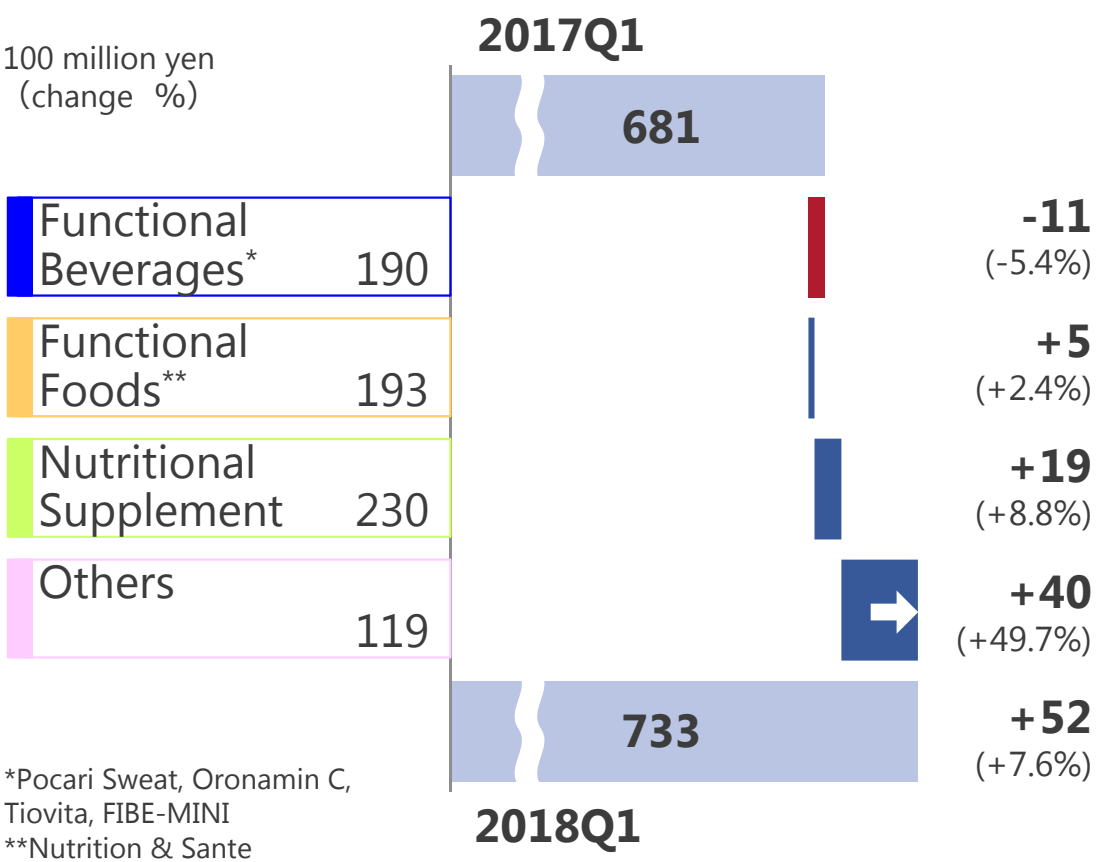
✓ Prepare for early launch

*Life cycle management, , **Lonsurf, *** ADPKD：Autosomal dominant polycystic kidney disease

NC

Nutraceutical Segment | Sales

- **Nutritional Supplement：Steady growth exceeding US market growth rate**
- **Others：New consolidation of Daiya Foods**



*Pocari Sweat, Oronamin C, Tiovita, FIBE-MINI
**Nutrition & Sante products, Calorie Mate, SOYJOY

Main Factors

Functional beverages

- ✓ Pocari Sweat : Sales decreased due to IFRS 15 although sales volume increased
- ✓ Oronamin C : Sales decreased due to overseas sales decline and IFRS 15

Functional Foods

- ✓ Calorie Mate：Earned good reputation as a balanced food
- ✓ N&S：Showed good growth of sugar free products in EU

Nutritional Supplement

- ✓ Nature Made：Showed steady growth exceeding to US market growth rate

Others

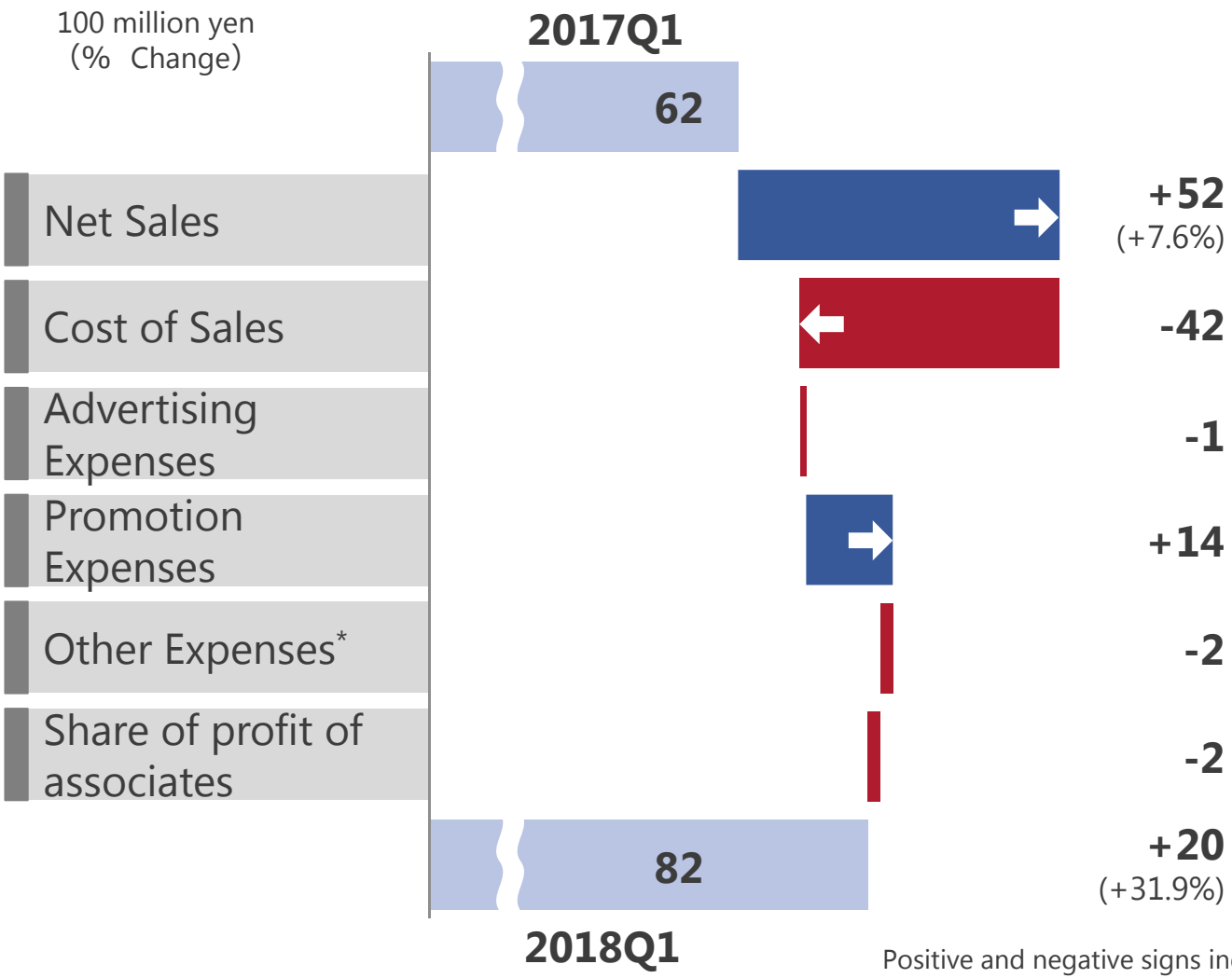
- ✓ Daiya Foods：Newly consolidated in Sep 2017

NC

Nutraceutical Segment | Operating Profit

■ **Improving profitability due to reviewing business assets that support value chain**

100 million yen
(% Change)



Main Factors

■ **Cost of Sales**

- ✓ Increased associated with sales growth
- ✓ Cost of sales ratio increased by applying IFRS 15 and product mix

■ **Promotion Expenses**

- ✓ Decreased by applying IFRS 15

*Include other income/expenses and R&D expenses

Positive and negative signs indicate impact on segment operating profit

FY2018 Forecast

■ **No changes from previous announcement on Feb. 2018**

(100 million yen)	FY2018 Q1	FY2018H1 Forecast	FY2018 Forecast	% Progress
Net Sales	2,947	6,200	13,000	22.7%
Operating Profit	348	600	1,400	24.8%
Net Profit*	227	460	1,050	21.6%
R&D Expenses**	426	900	1,900	22.4%
Operating Profit Before R&D Expenses	774	1,500	3,300	23.4%

*Profit attributable to owners of the Company, **Impairment loss related to R&D intangible assets included

Appendix (1)

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【Exchange rate】

Currency	Exchange rate (average rate)			FY2018 Estimate
	2017Q1	2018Q1	Change	
1USD	¥113.60	¥108.22	-¥5.38	¥110
1EUR	¥121.05	¥133.14	+¥12.09	¥130

【Foreign exchange impact : 2018Q1】

Sales	Operating profit
Approx. -2.0billion yen	—

【Estimated foreign exchange fluctuation in FY2018 by 1 yen depreciation】

Currency	Sales	Operating profit
1USD	Approx. +3.5 billion yen	—
1EUR	Approx. +0.9 billion yen	—

Appendix (2)

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【Sales of Products】

Unit : 100 million yen

Products	2017Q1	2018Q1	Change	Change (%)	2018H1 Forecast	2018 Forecast
Abilify Maintena	156	197	+41	+26.5%	410	870
Samsca/JINARC/JYNARQUE	136	177	+42	+30.8%	370	810
Rexulti	101	146	+44	+43.5%	285	645
Three Global Products Total	**393**	**520**	**+127**	**+32.4%**	**1,065**	**2,325**
Lonsurf	86	80	-6	-7.1%	175	340
New Drugs in Japan	277	314	+37	+13.4%	650	1,385
Total	**756**	**914**	**+158**	**+20.9%**	**1,890**	**4,050**

【Share of Profit of Associates/Impairment Loss by segment】

Unit : 100 million yen

Segment	Share of profit of associates		Impairment loss（R&D）		Impairment loss（SGA）	
	2017Q1	2018Q1	2017Q1	2018Q1	2017Q1	2018Q1
Pharmaceuticals	8	4	1	4	0	0
Nutraceuticals	0	-2	-	-	-	0
Consumer Products	25	31	-	-	-	-
Other	10	7	-	-	0	-
Total	**44**	**40**	**1**	**4**	**0**	**0**

Pharmaceutical Development Update

May 11, 2018

Otsuka Holdings Co., Ltd.

Agenda

- **Key development progress in Q1/2018**
  - Approval
  - Phase transition
- **Topics in Q1/2018**
  - Psychiatry & Neurology (REXULTI® tablets)
  - Oncology (ASTX727)
  - Cardiovascular & Renal system (JYNARQUE™)
- **Key projects scheduled for P-3 & NDA submission**
  - Progress on FY2018 initial plan
  - Estimated study completion date of major P-3 trials

Key development progress in Q1/2018

(as of Mar. 31, 2018)

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■ REXULTI® tablets for schizophrenia: Approved and launched in Japan JYNARQUE™ for ADPKD: Approved in the U.S.

Status	Generic name/ Development code (Brand name)	Country/ Region	Indication and features
Approval	**brexpiprazole (REXULTI® tablets)**	**Japan**	➢ Indication: Schizophrenia ➢ Launched on April 18 ➢ Serotonin Dopamine Activity Modulator (SDAM) ✓ Dopamine D_2 receptor partial agonist ✓ Serotonin 5-HT_{1A} receptor partial agonist ✓ Serotonin 5-HT_{2A} receptor antagonist
	tolvaptan (JINARC®)	**Taiwan**	➢ Indication: ADPKD ➢ Vasopressin V_2-receptor antagonist
	delamanid (DELTYBA® Tablets 50 mg)	**China**	➢ Indication: MDR-TB ➢ It inhibits production of mycolic acids which compose the cell wall of tuberculosis bacillus.
	guselkumab (TREMFYA®)	**Japan**	➢ Indication: PsV, PsA, GPP and EP ➢ A human anti-interleukin (IL)-23 p19 monoclonal antibody ➢ Obtained distribution rights under the terms of a co-promotion agreement with Janssen Pharmaceutical K.K.

<Event after Mar. 31, 2018>

JYNARQUE™ for ADPKD: Approved in the U.S. (April, 2018)

ADPKD: Autosomal dominant polycystic kidney disease MDR-TB: Multidrug-resistant tuberculosis
PsV: Psoriasis vulgaris PsA: Psoriatic arthritis GPP: Generalized pustular psoriasis EP: Erythrodermic psoriasis

Key development progress in Q1/2018

(as of Mar. 31, 2018)

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■ ASTX727 for MDS advanced to P-3 as scheduled

Status	Generic name/ Development code (Brand name)	Country /Region	Condition and features
⇒P-3	ASTX727	US	➢ Condition: Treatment naive high-risk myelodysplastic syndromes ➢ Oral delivery of combination, DNA methylation inhibitor (i.e., decitabine) and its metabolic enzyme inhibitor
⇒P-2	AVP-786	US	➢ Condition: Intermittent explosive disorder (IED) ➢ Combination of deuterated dextromethorphan and low-dose quinidine
⇒P-1	TAS0313	Japan	➢ Condition: Solid tumor ➢ Novel cancer peptide vaccine ➢ TAS0313 is incorporated into dendritic cell and activates CTL by presenting epitope peptide.

<Event after Mar. 31, 2018>

TBI-1301 for synovial sarcoma and TBI-1501 for acute lymphoblastic leukemia :
P1/2 in Japan (added due to an agreement with Takara Bio for co-development & exclusive sales rights in April, 2018)

<Discontinued project in this period>

AVP-786 for disinhibition syndrome in neurodegenerative disorders: Strategic reason

MDS: Myelodysplastic syndromes

Topics: Psychiatry & Neurology

REXULTI® tablets

Overview

Generic name	brexpiprazole
Launch date (JP)	April 18, 2018
Indication	Schizophrenia
Dosing info	The recommended starting dosage for adults is 1 mg/day, taken orally. After a minimum of 4 days, the dose is increased to 2 mg/day.
Dosage form	Tablets: 1 mg and 2 mg

【Reference】 Schizophrenia

- Schizophrenia is a mental disorder characterized by continuous disorganized thinking. Symptoms include hallucinations, delusion, thought disorder, flat affect and avolition, etc.
- Number of diagnosed lifetime prevalent cases of schizophrenia* in Japan is 804,000. (2016)

*Notes: Numbers reflect rounding. Estimates include males and females aged 15 or older.
Last update date: March 2016
Source: Decision Resources Group,
Laursen T, 2014; Nielsen R, 2013; Sutterland A, 2013; Vanasse A, 2012

Features

- **Mechanism of action classified as SDAM***
  - ✓ Partial agonist activity at dopamine D_2 and serotonin 5-HT_{1A} receptors
  - ✓ Antagonist activity at serotonin 5-HT_{2A} receptors

*SDAM: Serotonin-Dopamine Activity Modulator

- **Binding affinity for receptor (in vitro)**

Inhibitory constant (Ki)=nM

Receptor	brexpiprazole	aripiprazole
D_2	0.30	0.34
D_3	1.1	0.8
5-HT_{1A}	0.12	1.7
5-HT_{2A}	0.47	3.4
5-HT_{2C}	34	15
5-HT_7	3.7	39
α_1	3.8	57
H_1	19	61
M_1	>1000	6800

Citrome, LK. et al.: Expert Rev. Neurother.,15（10）,1219-1229, 2015
Tetsuro Kikuchi et al. : Japanese journal of clinical psychiatry, 34（4）,461-468, 2005
Application documents for REXULTI® approval

Topics: Oncology

ASTX727

Features

- Combination of DNA methylation inhibitor (i.e., decitabine) and cytidine deaminase inhibitor (E7727)
- Available for oral administration by inhibiting decitabine degradation

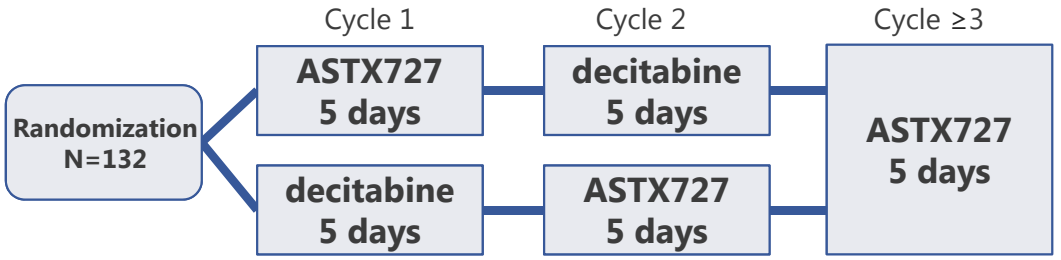
【Reference】 Myelodysplastic syndromes (MDS)

- MDS are a group of disorders causing abnormal hematopoietic cells which produce erythrocytes, platelets and leucocytes.
- Number of diagnosed incident cases of MDS* in the U.S. is 19,275.(2017)

*Notes: Numbers reflect rounding. Estimates include males and females of all ages.
Last update date: February 2017
Source: Decision Resources Group,
NCI, 2017 (SEER 2004-2013)

P-3 trial (US)

- **Condition**: Treatment naive high-risk myelodysplastic syndromes
- **Study design**



(28 days per cycle)

・2 treatment cycles, crossover assignment
ASTX727: 1 tablet daily×5
decitabine: 20 mg/m^2 one-hour IV infusion dailyx5

・Primary endpoint: Total 5-day Area Under the Curve (AUC) exposures of decitabine

・Secondary endpoint: Safety
Pharmacokinetics parameter, etc.

Topics: Cardiovascular & Renal system

JYNARQUE™ (U.S. brand name)

Overview

Generic name	tolvaptan
Approval date (US)	April, 2018
Indication	To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

【Reference】 ADPKD

- ADPKD is a genetic disorder in which fluid-filled cysts develop and enlarge in both kidneys, eventually leading to kidney failure. While the disease is asymptomatic in the early phase, more than 50 percent of patients with ADPKD will develop end-stage kidney disease by age 60.
- Diagnosed in approximately 140 thousand people* in the U.S.

*Epidemiology: Internal estimates based on external market research

Features

➢ Mechanism of action

✓ Vasopressin V_2-receptor antagonist

➢ For risk of serious liver problems

✓ JYNARQUE is only available through a restricted distribution program called the JYNARQUE REMS* Program.

✓ Safety information will be provided. Liver functions will be monitored in all patients.

*REMS: Risk evaluation and mitigation strategy

➢ Slow kidney function decline

✓ REPRISE study

eGFR: estimated glomerular filtration rate

Primary endpoint	tolvaptan	placebo	Results
Change of eGFR over a 1-year period	-2.34 (ml/min/1.73m^2)	-3.61	Decreased by 35% ($p<0.0001$)

✓ TEMPO 3:4 study

TKV: Total Kidney Volume

Primary endpoint	tolvaptan	placebo	Results
Percentage change per year in TKV from baseline to month 36	2.80%	5.51%	Suppress an increase by 49% ($p<0.0001$)

Project progress in FY2018

Projects planned for NDA submission

NDA filing & Advanced to P-3 as scheduled

	Therapy area	Generic name/ Development code	Country/Region	Indication
1	Oncology	SGI-110	US	Treatment naive acute myelogenous leukemia (AML)
2	Others	delamanid	US	MDR-TB

Projects scheduled to advance to P-3

	Therapy area	Generic name/ Development code	Country/Region	Condition
1	Psychiatry & Neurology	brexpiprazole	Japan	Adjunctive treatment for major depressive disorder (MDD)
2			Japan	Agitation associated with dementia of the Alzheimer's type
3		centanafadine	US	Attention deficit hyperactivity disorder (ADHD)
4	Oncology	ASTX727	US	Treatment naive high-risk myelodysplastic syndromes (MDS)

Major P-3 trials: Estimated study completion date

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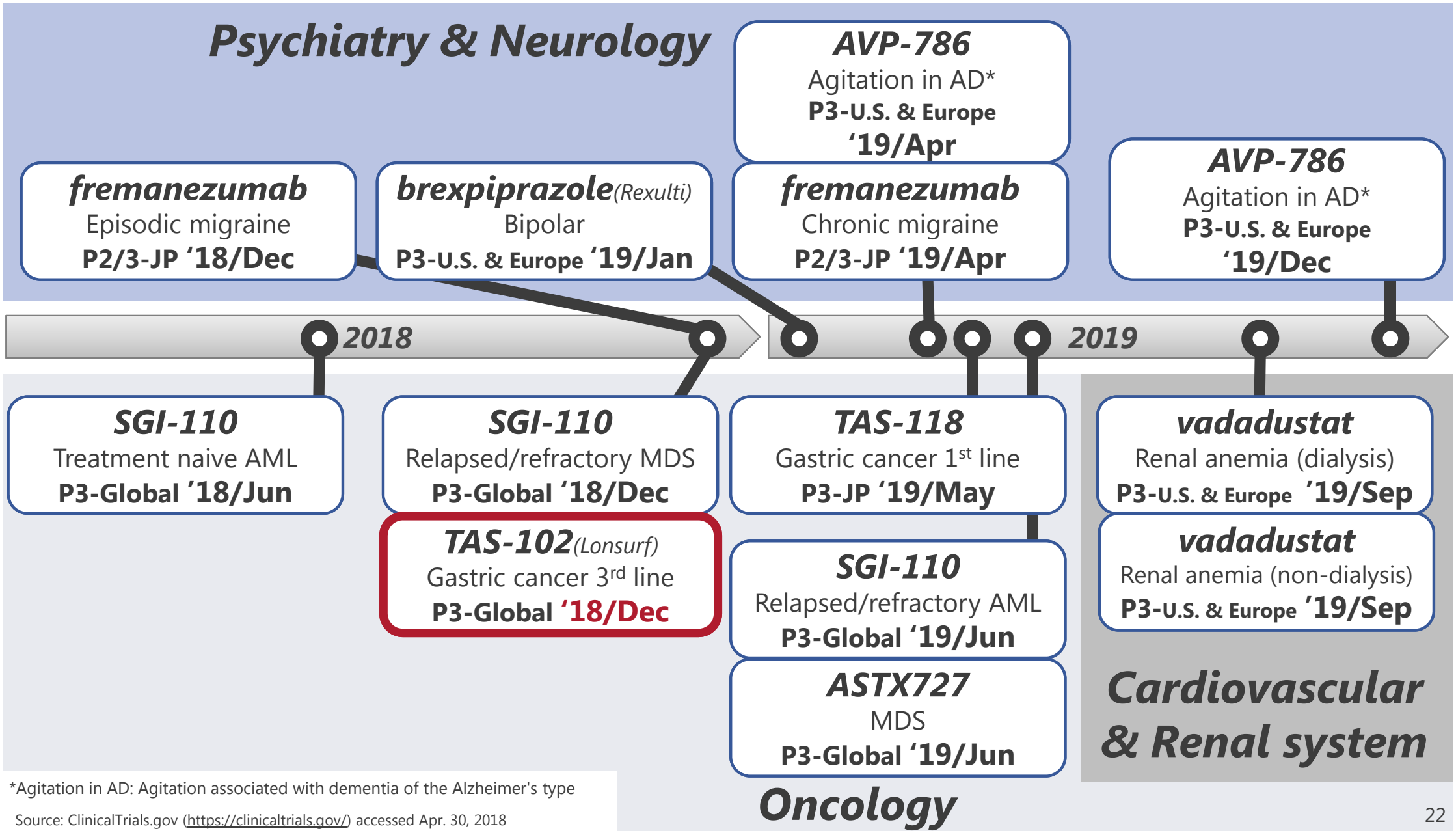
■ Announced topline results of LONSURF® on May 9, 2018



*Agitation in AD: Agitation associated with dementia of the Alzheimer's type

Source: ClinicalTrials.gov (https://clinicaltrials.gov/) accessed Apr. 30, 2018

Appendix

Major projects: Psychiatry& Neurology (as of Mar. 31, 2018)

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		P-1	P-2	P-3	NDA
Psychiatry	SZ	brexpiprazole long acting injection US	AVP-786 US		brexpiprazole Europe
	MDD			brexpiprazole Europe	
				ASC-01 Asia	ASC-01 JP
	Others		brexpiprazole PTSD US Europe	brexpiprazole Bipolar I disorder US Europe	nalmefene Alcoholism JP
			centanafadine ADHD US		
			OPC-64005 ADHD US		
Neurology	AD	AF20513 Europe		brexpiprazole Agitation US Europe	
				AVP-786 Agitation US Europe	
	Others		AVP-923 PD US	fremanezumab Migraine P2/3 JP	
			AVP-786 TBI US		
			AVP-786 IED US		Global PROJ
			TAS-205 DMD JP		

Changes from the last update

PTSD: Post traumatic stress disorder PD: Parkinson's disease TBI: Traumatic brain injury DMD: Duchenne muscular dystrophy

Major projects: Oncology (as of Mar. 31, 2018)

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	P-1	P-2	P-3	NDA
Solid tumor	TAS-116 (US, Europe) TAS-117 (JP) TAS-119 (US, Europe) TAS-120 (JP,US, Europe) TAS-121 (JP) TAS0313 (JP) TAS3681 (US, Europe) TAS4464 (JP,US, Europe) ET-743 (JP) OCV-C02 (JP) HF10 (JP)	SGI-110 Ovarian cancer (US, Europe) TAS-114 NSCLC (JP, US, Europe) TAS-115 Prostate cancer (JP) TAS-116 GIST (JP) ASTX660 Solid tumor (US) HF10 MM (JP)	TAS-102 Gastric cancer (JP,US, Europe) TAS-118 Gastric cancer (JP, Asia)	TAS-102 Colorectal cancer (Asia)
Blood cancer	OPB-111077 (US, Asia)	ASTX660 Lymphoma (US) OCV-501 AML (JP, Asia)	SGI-110 AML (JP,US, Europe, Asia) SGI-110 MDS (JP,US, Europe, Asia) ASTX727 MDS (US)	Global PROJ
Supportive care		Pro-NETU Antiemetics (JP)		

Changes from the last update

NSCLC: Non-small cell lung cancer GIST: Gastrointestinal stromal tumor MM: Malignant melanoma

Major projects: Others (as of Mar. 31, 2018)

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	P-1	P-2	P-3	NDA
Cardiovascular & Renal system		OPC-61815 Cardiac edema JP	tolvaptan SIADH JP vadadustat Renal anemia US Europe	tolvaptan Hepatic edema Asia tolvaptan ADPKD US
Others		delamanid Pediatric MDR-TB Europe OPS-2071 Infectious disease JP Asia OPA-15406 Atopic dermatitis JP TAS-303 Stress incontinence JP TAC-302 Detrusor underactivity associated with OAB JP	delamanid MDR-TB US rebamipide ophthalmic suspension MD Dry eye JP OPF-105 PPN infusion JP	
Diagnostics		C13-CAC Diagnostic kit for gastric acid-related disease JP		ODK-1403 Diagnostic kit for Graves' disease JP

Global PROJ

OAB: Overactive bladder SIADH: Syndrome of inappropriate antidiuretic hormone PPN: Peripheral parenteral nutrition