

Aiming to Achieve the Mid-term Business Plan “IBI 18” - FY2018 Half Year Results -

CHUGAI PHARMACEUTICAL CO., LTD.
President and CEO
Tatsuro Kosaka

July 26/27, 2018



Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the “Company”). These statements reflect the Company’s current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company’s businesses.

Note: Amounts shown in this report are rounded to the nearest 0.1 billion yen
Variance and % are calculated based on the amounts shown

FY2018 Half Year Financial Performance



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Strong growth in revenues and operating profit mainly due to increases in exports/ROOI driven by global expansion of Actemra and Alecensa, and one time income from transfer of long-term listed products

billions JPY	2017 Jan - Jun actual	2018 Jan - Jun actual	Growth		2018 Jan - Dec forecast	Progress (%)
Revenues	252.8	285.1	+32.3	+12.8%	541.5	52.7%
Sales	236.8	255.6	+18.8	+7.9%	498.5	51.3%
excl. Tamiflu	228.7	247.2	+18.5	+8.1%	492.9	50.2%
Domestic	183.0	182.7	△ 0.3	△0.2%	374.8	48.7%
Overseas	45.7	64.5	+18.8	+41.1%	118.1	54.6%
Tamiflu	8.2	8.4	+0.2	+2.4%	5.6	150.0%
Royalties and other operating income (ROOI)	15.9	29.5	+13.6	+85.5%	43.0	68.6%
Core Operating Profit	50.2	71.6	+21.4	+42.6%	108.0	66.3%
Core EPS (yen)	70.10	95.27	+25.17	+35.9%	147.00	64.8%

Major Achievements in FY2018 Half Year



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- Hemlibra
 - <HA with inhibitors> Approval (EU Feb, JP Mar) / Launch (JP May)
 - <HA without inhibitors> Simultaneous Filing (JP/US/EU Apr), US BTB (Apr)
US priority review (Jun)
 - <Q4W administration> Simultaneous Filing (JP/US/EU Apr)
- Tecentriq
 - <NSCLC 2L> Approval (Jan) / Launch (Apr)
 - <NSCLC 1L> Filing (Mar)
- Gazyva
 - <Follicular lymphoma> Approval (Jul)
- Foundation Medicine Incorporated (FMI)
 - <Activities for commercialization in JP>
FoundationOne CDx™ Filing (Mar), PMDA Expedited Review (May)

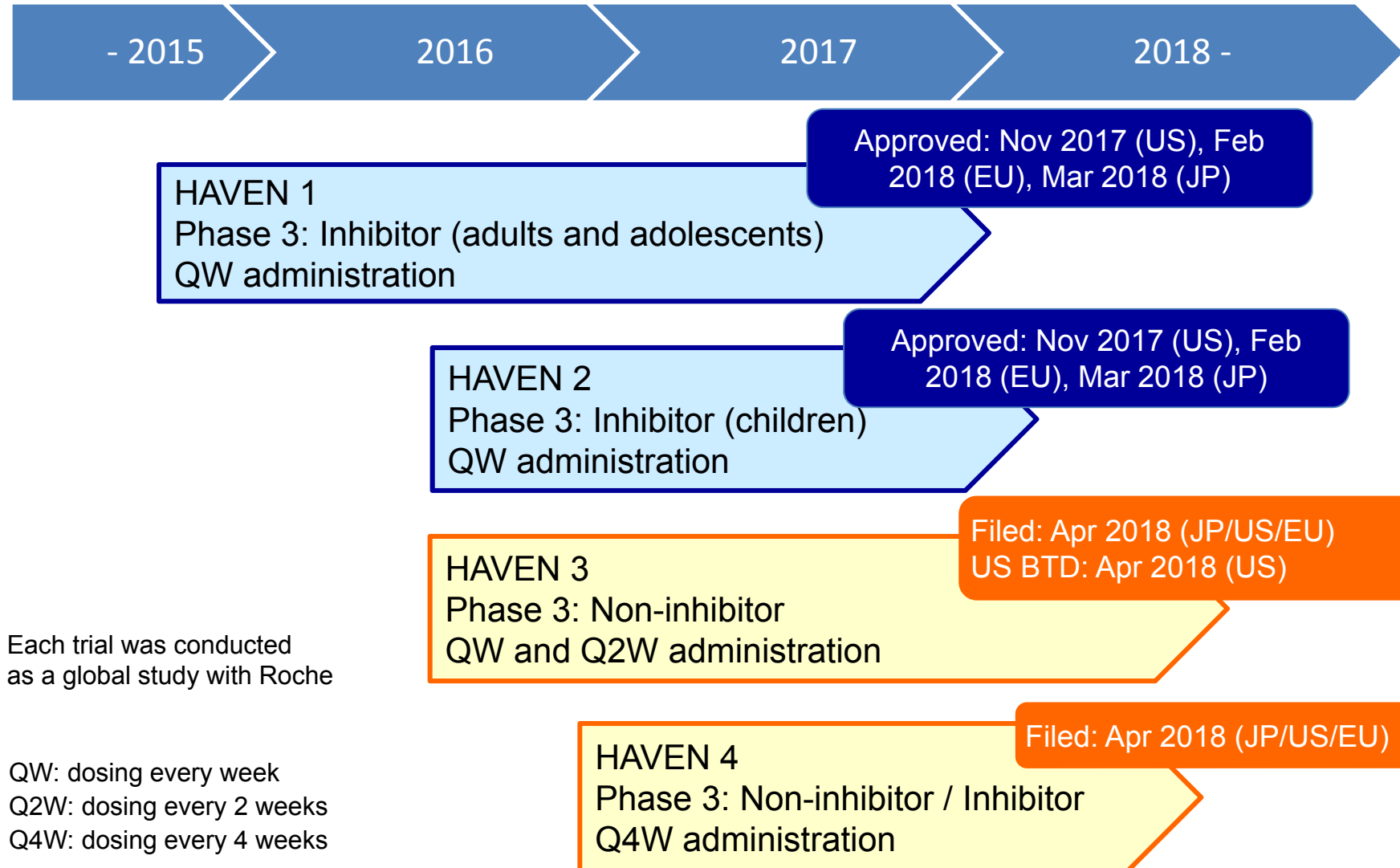
HA: hemophilia A
Q4W: dosing every 4 weeks
BTB: breakthrough therapy designation

NSCLC: non-small cell lung cancer
PMDA: Pharmaceuticals and Medical Devices Agency

Steady progress in key subjects to achieve IBI 18



Hemlibra: Steady Progress Resulted in Global Simultaneous Filing and Approval





Tecentriq: Steady Progress of Initial Development Plans During FY2018 Half Year

Achieved launch in Japan for NSCLC 2L, and steadily carried out multiple developments to obtain the additional indication during 2018 half year

Study	Cancer Type	Indication	Treatment Line	Results	Filing year
OAK	Lung	NSCLC	2L+	✓ OS	2018 (launch)
IMpower150		Non-squamous NSCLC	1L	✓ PFS, OS	2018
IMpower131		Squamous NSCLC	1L	✓ PFS	
IMpower132		Non-squamous NSCLC	1L	✓ PFS	
IMpower133		SCLC	1L	✓ PFS, OS	2019
IMmotion151	Kidney	RCC	1L	✓ PFS	2018
IMpassion130	Breast	Triple negative Breast cancer	1L	✓ PFS	2018



Key Activities for Further Growth

<Strengthening current core business>

- Extension of CPR investment (Additional 5 years from 2022)
 - Accelerate the development of clinical candidates by applying next-generation antibody technologies
- Construction of a new synthetic research building at Ukima laboratories
 - Accelerate process development of small and middle molecule APIs
- In-licensed ROS1 / TRK inhibitor "entrectinib"
 - Enhancement of the oncology product portfolio

API: active pharmaceutical ingredient
CPR: Chugai Pharmabody Research Pte. Ltd.

<Creating future business value>

- Consolidate Foundation Medicine's business basis
 - Establishment of Foundation Medicine Unit to consolidate its business basis
- Partnering with Preferred Networks
 - Accelerate innovation by utilizing artificial intelligence (AI)



Extension of CPR Investment

【Accomplishments】

- Contributed to create multiple development candidate antibodies such as SKY59, ERY974, and maximized the value of proprietary antibody technologies since its establishment in 2012

【Extended opportunities by antibodies】

- Discovery of new targets through the progress of understanding human pathology
- The breadth of target molecules has expanded, and new technologies for tough targets are required

【Purpose for extension】

- Creation of development candidates applying next-generation antibody technologies
- Development of innovative technologies that are key for future competitive advantage

Accelerate Innovation by Utilizing Artificial Intelligence (AI)



Preferred Networks, Inc.

- Establishment: March 2014
- Main Office: Tokyo, USA (California)
- Business: Research, development and sales of computer software, hardware, and network focusing on IoT
- Business domain: Transportation system, manufacturing industry, health care

<Chugai's strengths>

- Possession of unique data
- Capability for setting business challenges
- Knowledge and experience in healthcare

<PFN's strengths>

- Deep learning framework
- Development know-how / Distributed processing technology
- Data science capability

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Challenges that cannot be solved
by existing technology

Deep learning / Data analysis

New insights / Value discovery

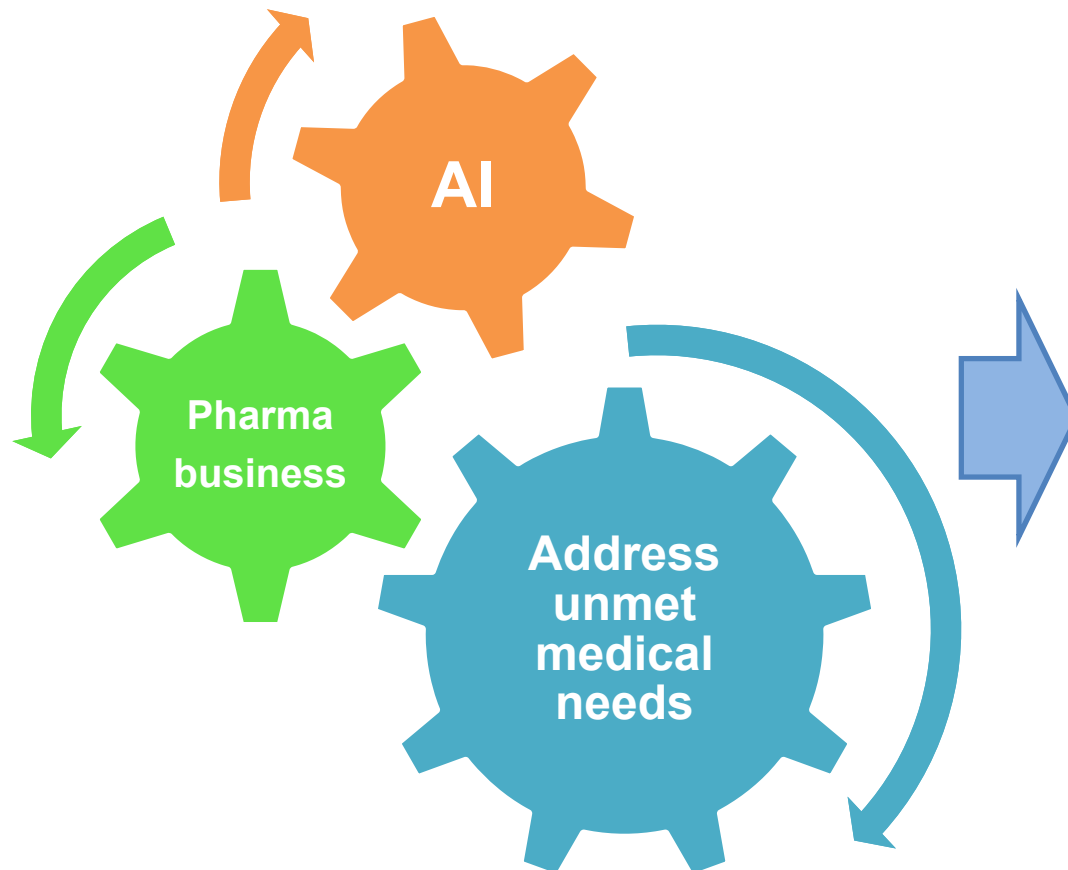


Continuous creation of innovative drugs and services,
improvement of productivity



Expected Outcomes by Partnership

- Continuous creation and delivery of innovative drugs
- Maximize value in the pharmaceutical value chain, and drastically improve productivity



Project candidates

<Insight search>

- Creation of new value from non-clinical & clinical data etc.

<Dramatic efficiency improvement>

- Drug discovery research
- Biomarker discovery
- Clinical development
- Manufacturing, etc.



FY2018 Half Year Results

- **Steady financial performance against full year plan**
- **Development projects progressing as planned**
- **Initiate key activities for further growth / upfront investment**



**Steady progress of IBI 18 towards
the next mid-term business plan**

FY2018 2Q Consolidated Financial Overview (IFRS based)

CHUGAI PHARMACEUTICAL CO., LTD.
Executive Vice President and CFO
Toshiaki Itagaki

July 26/27, 2018



2Q Results Summary

■ Revenues: 285.1 billion yen (+32.3, +12.8% YoY)

- Domestic sales excl. Tamiflu: slight decrease due to impact from HIP revision, although sales of mainstay products continued to grow (-0.3, -0.2%)
- Overseas sales: growth of Actemra export to Roche, etc. (+18.8, +41.1%)
- Royalties and other operating income: one-time income from transfer of long-listed products on HIP list, etc. (+13.6, +85.5%)

■ Cost of sales / Operating expenses (Core basis)

- Cost of sales: the ratio to sales improved due to a change in product sales mix, etc. (-0.7% points, from 51.0% to 50.3%)
- Operating expenses: overall increase mainly due to the increase of research and development expenses (-3.1, +3.8%)

■ Profits

- IFRS results: operating profit 66.6 billion yen (+19.5, +41.4%)
net income 49.0 billion yen (+12.5, +34.2%)
- Core results: operating profit 71.6 billion yen (+21.4, +42.6%)
net income 52.6 billion yen (+13.8, +35.6%)
- Core EPS (JPY): 95.27 (+25.17, +35.9%)



IFRS and Core Results Jan-Jun

(Billion JPY)	IFRS results	Non-core items		Core results
	2018 Jan. - Jun.	Intangible assets	Others	2018 Jan. - Jun.
Revenues	285.1			285.1
Sales	255.6			255.6
Royalties and other operating income	29.5			29.5
Cost of sales	-129.1	+0.5		-128.6
Gross profit	156.1	+0.5		156.6
Operating expenses	-89.5	+4.6		-84.9
Marketing and distribution	-33.2			-33.2
Research and development	-48.5	+4.6		-44.0
General and administration	-7.8			-7.8
Operating profit	66.6	+5.1		71.6
Financing costs	-0.1			-0.1
Other financial income (expense)	0.0			0.0
Other expense	-1.5			-1.5
Profit before taxes	65.0	+5.1		70.1
Income taxes	-15.9	-1.6		-17.5
Net income	49.0	+3.5		52.6
Chugai shareholders	48.7	+3.5		52.2
Non-controlling interests	0.4			0.4

(Billions of JPY)

Non-Core items

Intangible assets:

Amortization of intangible assets +0.6

Impairment +4.4

Others:

none

Core net income
attributable to Chugai
shareholders

52.2

(Millions of shares)

Weighted average number
of shares and equity securities
in issue used to calculate
diluted earnings per share

548

(JPY)

Core EPS

95.27

Year on Year (Core)

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Financial Overview Jan - Jun

(Billions of JPY)	2017 Jan - Jun vs. Revenues		2018 Jan - Jun vs. Revenues		Growth	
Revenues	252.8		285.1		+32.3	+12.8%
Sales	236.8		255.6		+18.8	+7.9%
excl. Tamiflu	228.7		247.2		+18.5	+8.1%
Domestic	183.0		182.7		-0.3	-0.2%
Export to Roche	36.9		55.2		+18.3	+49.6%
Other overseas	8.8		9.2		+0.4	+4.5%
Tamiflu	8.2		8.4		+0.2	+2.4%
Ordinary	6.3		8.3		+2.0	+31.7%
Govt. stockpiles, etc.	1.9		0.1		-1.8	-94.7%
Royalties and other operating income	15.9		29.5		+13.6	+85.5%
Cost of sales	-120.8	47.8%	-128.6	45.1%	-7.8	+6.5%
Gross profit	131.9	52.2%	156.6	54.9%	+24.7	+18.7%
Operating expenses	-81.8	32.4%	-84.9	29.8%	-3.1	+3.8%
Operating profit	50.2	19.9%	71.6	25.1%	+21.4	+42.6%
Financing costs	-0.1		-0.1		0.0	0.0%
Other financial income (expense)	-0.2		0.0		+0.2	-
Other Expenses	-0.4		-1.5		-1.1	+275.0%
Income taxes	-10.7		-17.5		-6.8	+63.6%
Net income	38.8	15.3%	52.6	18.4%	+13.8	+35.6%
EPS (JPY)	70.10		95.27		+25.17	+35.9%

(Billions of JPY)

Royalties and other operating income	+13.6
one-time income from transfer of long-listed products on HIP list, etc.	
Other financial income (expense)	+0.2
Exchange gains/losses	+1.0
Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts)	-0.8
Other Expenses	-1.1
Settlement for transfer pricing taxation	

Cost of sales ratio vs. Sales

2017 Jan - Jun	2018 Jan - Jun
51.0%	50.3%

Market average exchange rate (JPY)

	2017 Jan - Jun	2018 Jan - Jun
1 CHF	112.95	112.52
1 EUR	121.55	131.59
1 USD	112.38	108.74
1 SGD	80.01	81.97

Year on Year

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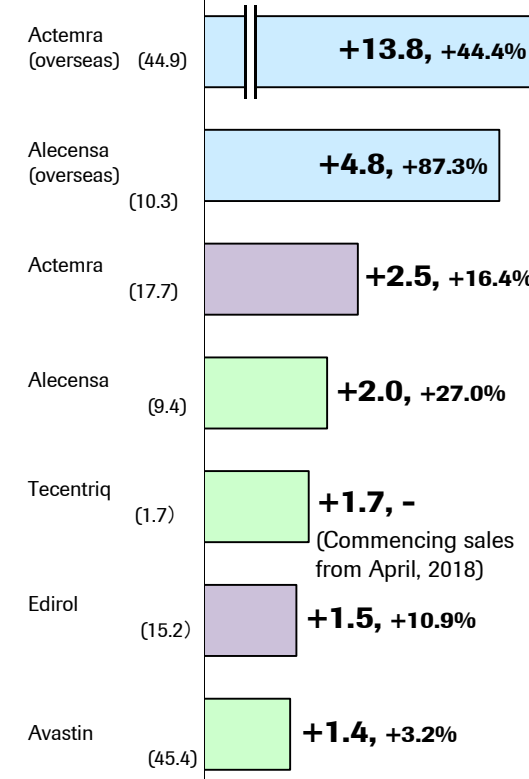
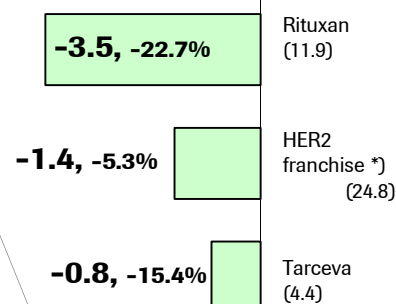
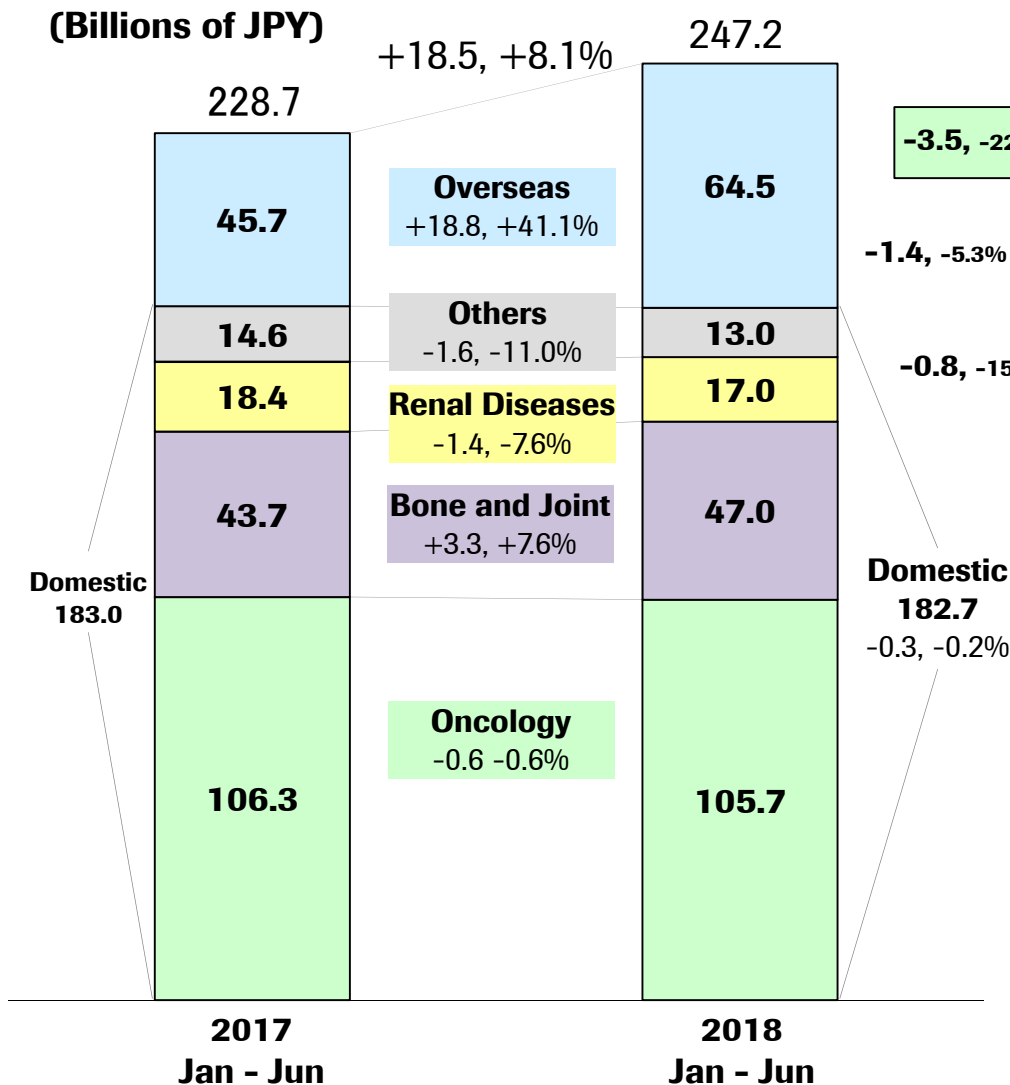


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Sales (excl. Tamiflu) Jan - Jun

Sales by Disease Area,
Year on Year Comparisons

Sales by Products,
Year on Year Changes



*) Details of HER2 franchise

Herceptin	(13.8)	-2.4	-14.8%
Perjeta	(7.0)	+0.7	+11.1%
Kadcyla	(4.0)	+0.3	+8.1%

(): Actual sales in FY2018

%: Year-on-year percentage change



Tamiflu Sales Trends

(Billions of JPY)	Fiscal Term Sales											Season	
	FY2013		FY2014		FY2015		FY2016		FY2017		FY2018	(from the second half of FY to the first half of the next FY)	
	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun		
Ordinary	8.2											2012	10.6
		1.9	7.0									2013	9.0
				5.8	6.7							2014	12.6
						1.5	7.3					2015	8.7
								4.7	6.3			2016	11.0
										5.6	8.3	2017 *	14.0
	10.1	(-0.1)	12.9	(+2.8)	8.2	(-4.7)	12.0	(+3.8)	11.9	(-0.1)	8.3	(+2.0)	
Govt. Stockpiles etc.	0.8	0.1	0.1	0.1	0.0	0.0	0.0	1.5	1.9	3.1	0.1		
	0.9	(-1.0)	0.2	(-0.7)	0.0	(-0.2)	1.5	(+1.5)	5.0	(+3.5)	0.1	(-1.8)	
Total	9.0	2.0	7.1	5.9	6.7	1.5	7.3	6.2	8.2	8.7	8.4		
	11.0	(-1.0)	13.0	(+2.0)	8.2	(-4.8)	13.5	(+5.3)	16.9	(+3.4)	8.4	(+0.2)	

* from Jul. 2017 to Jun. 2018

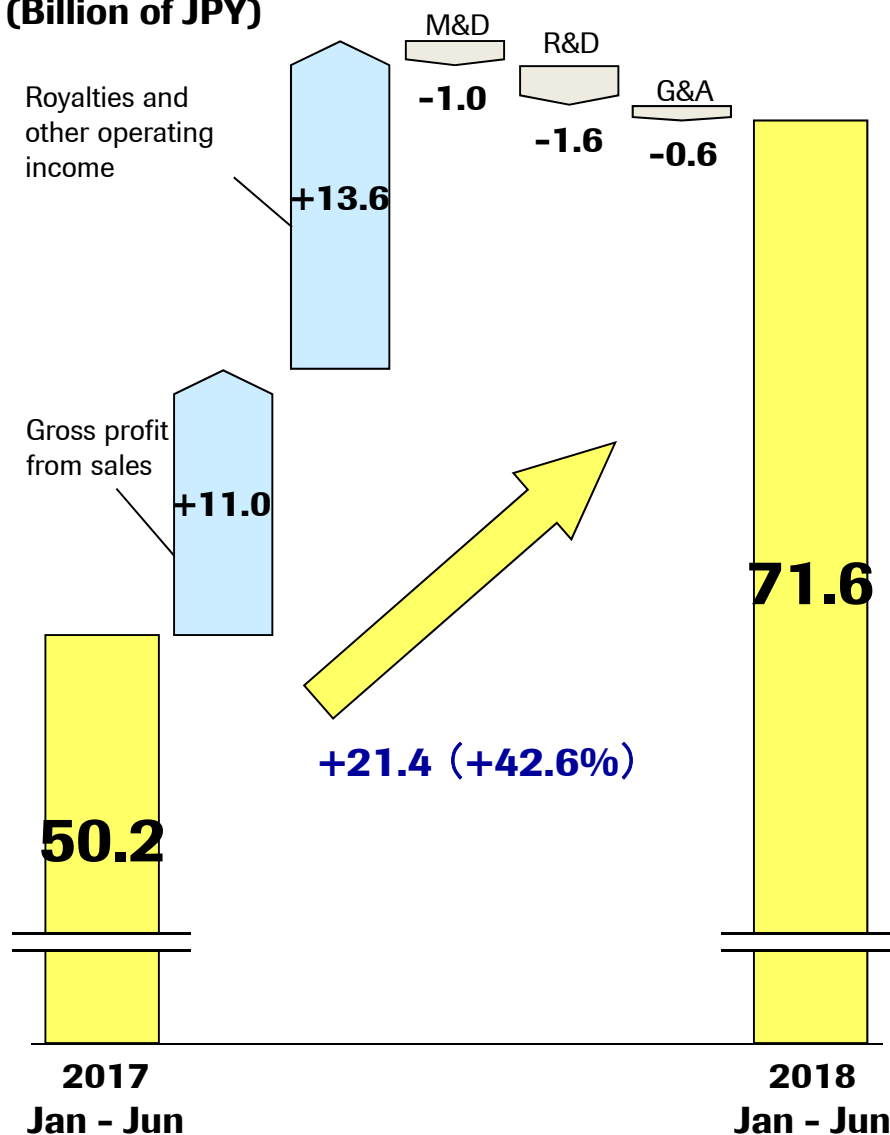
() Year on year



Year on Year (Core)

Operating Profit Jan - Jun

(Billion of JPY)



(Billions of JPY)	2017 Jan - Jun	2018 Jan - Jun	Growth
Revenues	252.8	285.1	+32.3
Cost of sales	-120.8	-128.6	-7.8
Gross profit	131.9	156.6	+24.7
of which Sales	116.0	127.0	+11.0
Royalties, etc.	15.9	29.5	+13.6
Marketing and distribution	-32.2	-33.2	-1.0
Research and development	-42.4	-44.0	-1.6
General and administration	-7.2	-7.8	-0.6
Operating profit	50.2	71.6	+21.4

Increase in gross profit from sales	+11.0
Increase in export to Roche and improvement of cost of sales ratio to sales due to change in product sales mix, etc.	
Increase in royalties and other operating income	+13.6
Increase in marketing and distribution expenses	-1.0
Increase in sales and marketing activities mainly for new products, and FX impact, etc.	
Increase in research and development expenses	-1.6
Progress of projects, etc.	
Increase in general and administration expenses, etc.	-0.6
Increase in various expenses, including corporate enterprise tax (pro forma standard taxation)	

Year on Year (Core)

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Financial Overview Apr - Jun

(Billions of JPY)	2017 Apr - Jun vs. Revenues		2018 Apr - Jun vs. Revenues		Growth	
Revenues	127.3		137.7		+10.4	+8.2%
Sales	118.7		130.8		+12.1	+10.2%
excl. Tamiflu	117.9		130.8		+12.9	+10.9%
Domestic	97.9		98.3		+0.4	+0.4%
Export to Roche	15.6		27.8		+12.2	+78.2%
Other overseas	4.5		4.7		+0.2	+4.4%
Tamiflu	0.8		0.0		-0.8	-100.0%
Ordinary	0.2		0.0		-0.2	-100.0%
Govt. stockpiles, etc.	0.6		-		-0.6	-100.0%
Royalties and other operating income	8.6		6.8		-1.8	-20.9%
Cost of sales	-60.0	47.1%	-65.1	47.3%	-5.1	+8.5%
Gross profit	67.3	52.9%	72.6	52.7%	+5.3	+7.9%
Operating expenses	-43.8	34.4%	-43.8	31.8%	0.0	0.0%
Operating profit	23.5	18.5%	28.8	20.9%	+5.3	+22.6%
Financing costs	-0.0		-0.0		0.0	0.0%
Other financial income (expense)	0.1		0.1		0.0	0.0%
Other Expenses	0.7		-0.9		-1.6	-
Income taxes	-4.4		-6.6		-2.2	+50.0%
Net income	19.9	15.6%	21.3	15.5%	+1.4	+7.0%
EPS (JPY)	35.89		38.75		+2.86	+8.0%

Increase in gross profit from sales +7.1

Increase in export to Roche and improvement of cost of sales ratio to sales

Decrease in royalties and other operating income -1.8

Decrease in milestone income

Increase/decrease in operating expenses 0.0

Increase in marketing and distribution -0.5

Decrease in research and development +0.1

Decrease in general and administration +0.4

Cost of sales ratio vs. Sales

2017 Apr - Jun	2018 Apr - Jun
50.5%	49.8%

Market average exchange rate (JPY)

	2017 Apr - Jun	2018 Apr - Jun
1 CHF	112.69	110.77
1 EUR	122.03	130.06
1 USD	111.07	109.08
1 SGD	79.76	81.78

vs. Forecast (Core)

FY2018 2Q Consolidated Financial Overview

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Financial Progress Jan - Jun

(Billions of JPY)	Actual	Forecast on Feb. 1		2017 Progress *
	2018 Jan - Jun	2018 Jan - Dec	Progress	
Revenues	285.1	541.5	52.7%	47.3%
Sales	255.6	498.5	51.3%	47.4%
excl. Tamiflu	247.2	492.9	50.2%	47.4%
Domestic	182.7	374.8	48.7%	47.1%
Export to Roche	55.2	99.6	55.4%	48.3%
Other overseas	9.2	18.5	49.7%	49.7%
Tamiflu	8.4	5.6	150.0%	48.5%
Royalties and other operating income	29.5	43.0	68.6%	45.6%
Cost of sales	-128.6	-252.0	51.0%	47.8%
Gross profit	156.6	289.5	54.1%	46.9%
Operating expenses	-84.9	-181.5	46.8%	45.9%
Operating profit	71.6	108.0	66.3%	48.6%
EPS (JPY)	95.27	147.00	64.8%	50.5%

Cost of sales ratio vs. Sales

2018 Jan - Jun Actual	2018 Jan - Dec Forecast
50.3%	50.6%

Exchange rate (JPY)

	2018 Jan - Jun Actual*	2018 Jan - Dec Assumption
1CHF	112.52	115.00
1EUR	131.59	133.00
1USD	108.74	111.00
1SGD	81.97	84.00

* Jan - Jun progress versus Jan - Dec

* Market average exchange rate for the period of Jan - Jun.

vs. Forecast (Core)

FY2018 2Q Consolidated Financial Overview

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Sales Progress (excl. Tamiflu) Jan – Jun

(Billions of JPY)	Actual		Forecast Progress	2017 Progress *1		(Billions of JPY)	Actual		Forecast Progress	2017 Progress *1
	2018 Jan - Jun	2018 Jan - Dec					2018 Jan - Jun	2018 Jan - Dec		
Sales excl. Tamiflu	247.2	492.9	50.2%	47.4%		Renal	17.0	35.3	48.2%	46.8%
Domestic	182.7	374.8	48.7%	47.1%		Mircera	10.6	23.5	45.1%	46.0%
Oncology	105.7	217.6	48.6%	47.1%		Oxarol	3.5	5.8	60.3%	46.3%
Avastin	45.4	92.0	49.3%	47.3%		Others	13.0	24.8	52.4%	48.8%
HER2 Franchise	24.8	49.5	50.1%	47.5%		CellCept	4.3	8.5	50.6%	46.1%
Herceptin	13.8	26.6	51.9%	48.2%		Hemlibra *3	0.5	1.4	35.7%	-
Perjeta	7.0	14.6	47.9%	46.3%		Overseas	64.5	118.1	54.6%	48.6%
Kadcyla	4.0	8.3	48.2%	46.3%		Actemra	44.9	73.0	61.5%	51.1%
Rituxan	11.9	23.4	50.9%	46.1%		Export to Roche	44.1	71.4	61.8%	51.2%
Alecensa	9.4	22.7	41.4%	44.3%		Alecensa	10.3	26.4	39.0%	39.6%
Xeloda	6.1	12.6	48.4%	48.4%		Export to Roche	10.0	26.3	38.0%	39.6%
Tarceva	4.4	9.8	44.9%	49.5%		Neutrogen	5.7	12.0	47.5%	48.0%
Tecentriq *2	1.7	3.1	54.8%	-		Hemlibra	1.2	2.0	60.0%	32.3%
Alaglio	0.1	0.7	14.3%	-						
Zelboraf	0.0	0.1	0.0%	100.0%						
Bone and Joint	47.0	97.1	48.4%	46.8%						
Actemra	17.7	35.2	50.3%	45.9%						
Edirol	15.2	31.7	47.9%	46.3%						
Bonviva	4.4	9.9	44.4%	46.0%						
Suvenyl	3.7	8.3	44.6%	47.7%						

*1 Jan - Jun progress versus Jan - Dec.

*2 Forecast for Tecentriq was officially announced on April 24, 2018.

*3 Forecast for Hemlibra (domestic sales) was officially announced on July 26, 2018

vs. Forecast (Core)

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Impact from Foreign Exchange

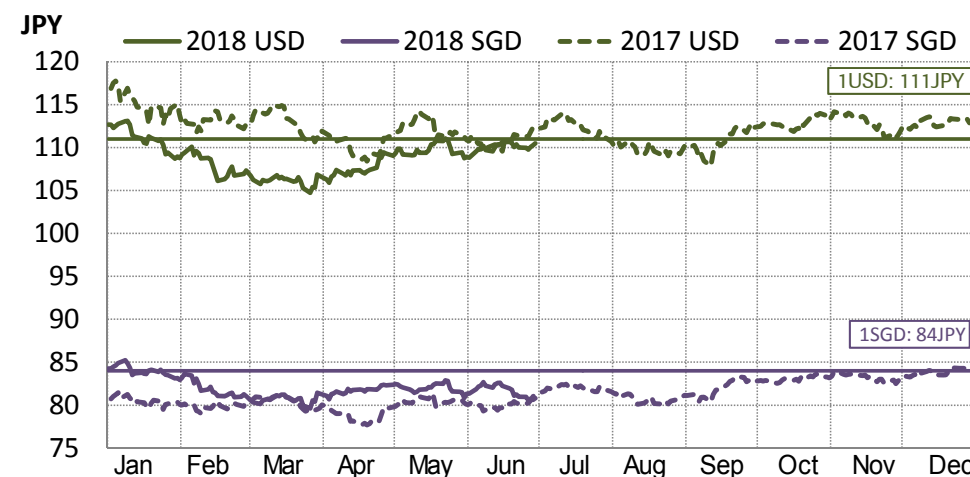
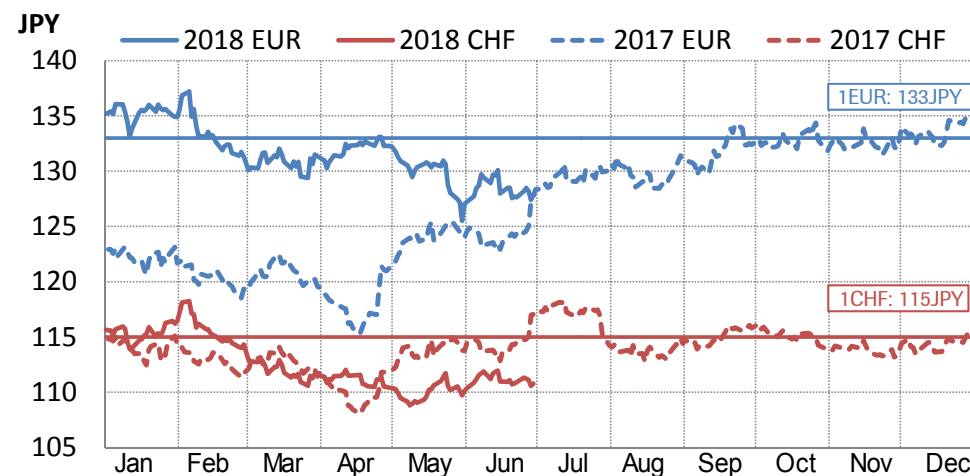
(Billions of JPY)	FX impact Jan – Jun 2018 (FX impact vs. Assumption)	
Revenues	-0.3	
	Sales	-0.3
	Royalties and other operating income	+0.0
Cost of sales	Cost of sales	+0.2
Operating expenses	Expenses	+0.2
Operating profit	+0.1	

Actual / Forecast rate* (JPY)	2017 Jan - Jun Actual	2018 Jan - Dec Assumption	2018 Jan - Jun Actual
1CHF	112.95	115.00	112.52
1EUR	121.55	133.00	131.59
1USD	112.38	111.00	108.74
1SGD	80.01	84.00	81.97

* Actual: market average exchange rate for the period of Jan - Jun

[Reference]
Historical exchange rate to the JPY

Forecast rate



vs. 2017 Year End

FY2018 2Q Consolidated Financial Overview

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Balance Sheet Items

< Assets, Liabilities, and Net Assets >

(Billions of JPY)	2017 Dec	2018 Jun	Change
Trade accounts receivable	148.5	140.6	- 7.9
Inventories	169.1	170.0	+ 0.9
Trade accounts payable	-38.4	-46.2	- 7.8
Other net working capital *1	-28.4	-18.2	+ 10.2
Net working capital	250.7	246.3	- 4.4
Property, plant and equipment	171.6	179.2	+ 7.6
Intangible assets	21.1	18.1	- 3.0
Other long-term assets - net *2	-3.1	12.4	+ 15.5
Long-term net operating assets	189.5	209.6	+ 20.1
Net operating assets	440.2	455.9	+ 15.7
Debt	-0.3	-0.3	0.0
Marketable securities	104.0	119.9	+ 15.9
Cash and cash equivalents	139.1	154.6	+ 15.5
Net cash	242.8	274.2	+ 31.4
Other non-operating assets - net *3	9.9	1.5	- 8.4
Net non-operating assets	252.7	275.7	+ 23.0
Total net assets	692.9	731.7	+ 38.8
Total assets	852.5	873.3	+ 20.8
Total liabilities	-159.6	-141.7	+ 17.9

*1 Accrued receivable, accrued payable, accrued expenses, etc.

*2 Long-term prepaid expenses, long-term provisions, etc.

*3 Deferred tax assets, corporate income tax payable, etc.

Decrease in net working capital	-4.4
Decrease in trade accounts receivable	-7.9
Increase in trade accounts payable	-7.8
Increase in other net working capital	+10.2
Increase in long-term net operating assets	+20.1
Increase in Property, plant and equipment	+7.6
Decrease in Intangible assets	-3.0
Increase in Other long-term assets	+15.5
Mainly adjustment of the opening balance of accumulated income for deferred income on applying IFRS15	
Increase in net cash	+31.4
Decrease in other non-operating assets	-8.4
Equity ratio attributable to Chugai shareholders	+2.5% pts.
2018 Jun	83.7%
2017 Dec	81.2%

FX rate to the JPY (end of period)

	2017 Dec	2018 Jun
1CHF	115.35	110.78
1EUR	134.82	127.83
1USD	112.89	110.50
1SGD	84.39	80.79

vs. 2017 Year End

FY2018 2Q Consolidated Financial Overview

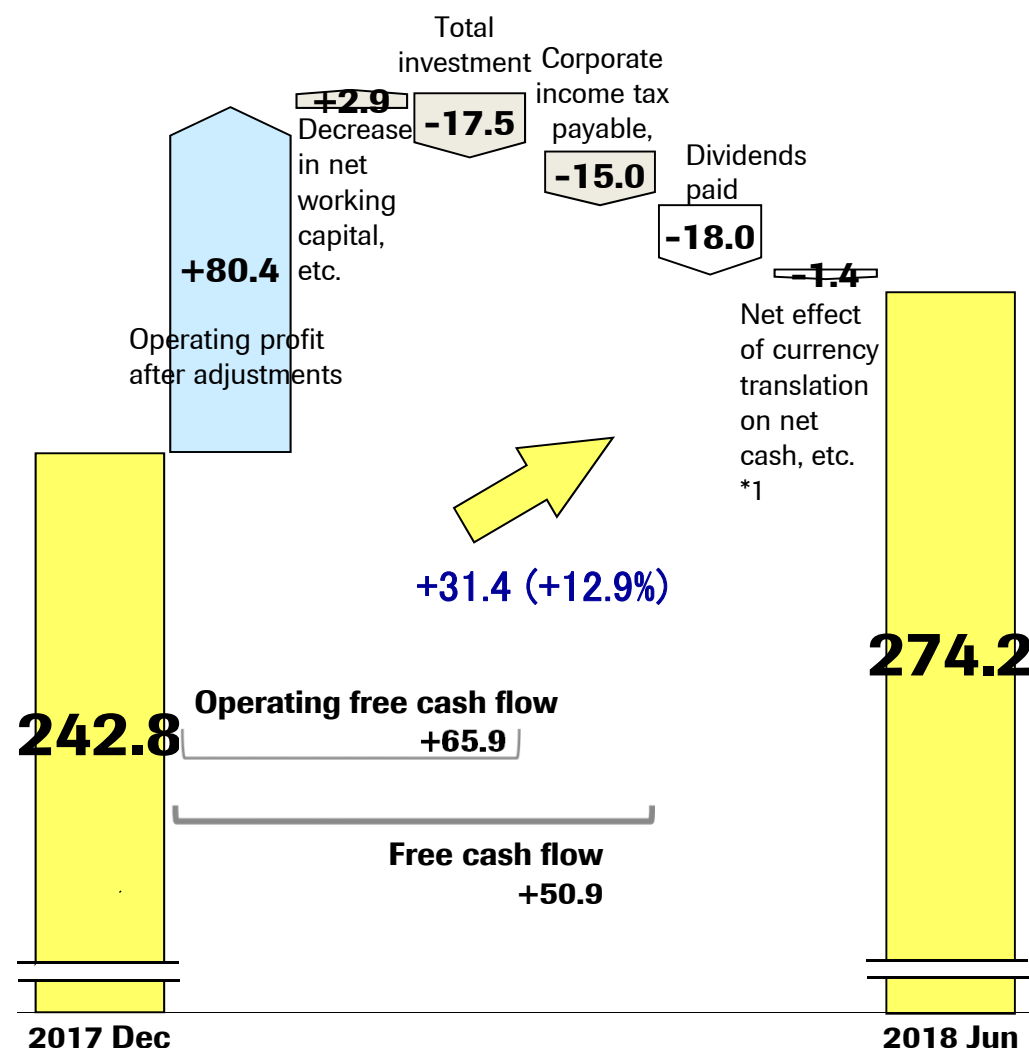
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Net Cash

(Billions of JPY)



Operating profit after adjustment	+80.4
Operating profit	+66.6
Depreciation and impairment for property, plant and equipment	+7.4
Amortization and impairment for intangible assets	+5.5
Other adjustments for operating profit	+1.0
Decrease in net working capital, etc.	+2.9
Total investment	-17.5
Property, plant and equipment	-15.1
Intangible assets	-2.4
Operating free cash flow	+65.9
Corporate income tax payable, etc.	-15.0
Free cash flow	+50.9
Dividends paid	-18.0
Net effect of currency translation on net cash, etc.	-1.4

*1 Net effect of currency transactions on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash(*2)

*2 It result from using different exchange rate types when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flow using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.
Executive Vice President
Co-Head of Project & Lifecycle Management Unit
Dr. Yasushi Ito

July 26/27, 2018



Projects under Development (1) (as of July 26, 2018)

	Phase I	Phase II	Phase III		Filed
Oncology	CKI27 (Japan / overseas) - solid tumors	RG6268 / entrectinib - NSCLC ★ - solid tumors ★	RG3502 / Kadcyla - breast cancer (adjuvant)	RG7446 / Tecentriq - NSCLC (adjuvant) - SCLC - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - breast cancer - ovarian cancer - prostate cancer - HCC - HNC★(adjuvant)	RG1273 / Perjeta - breast cancer (adjuvant) RG7446 / Tecentriq - NSCLC (1L)
	GC33 (RG7686) / codrituzumab - HCC★		RG435 / Avastin - RCC - HCC★		
	ERY974 (overseas) - solid tumors		RG7440 / ipatasertib - prostate cancer - breast cancer		
	RG7421 / cobimetinib - solid tumors		RG7596 / polatuzumab vedotin - DLBCL		
	RG7802 - solid tumors		RG6264 - breast cancer★ (Fixed-dose combination, subcutaneous injection)		
	RG7828 - hematologic tumors				
Bone & Joint			NRD101 / Suvenyl (China) - knee osteoarthritis /shoulder periarthritis		ED-71 / Ediolol (China) - osteoporosis
Renal	EOS789 (Japan / overseas) - hyperphosphatemia				

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

HCC: hepatocellular carcinoma
NSCLC: non-small cell lung cancer
SCLC: small cell lung cancer
MIUC: muscle invasive urothelial carcinoma

RCC: renal cell carcinoma
DLBCL: diffuse large B-cell lymphoma
HNC: head and neck carcinoma

Letters in orange: in-house projects

★: Projects with advances in stages since April 24, 2018

★: Multinational study managed by Chugai

Projects under Development (2) (as of July 26, 2018)

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	Phase I	Phase II	Phase III	Filed
Autoimmune	RG7845 / fenebrutinib - rheumatoid arthritis		MRA (RG1569) / Actemra - systemic sclerosis SA237 (RG6168) / satralizumab - neuromyelitis optica★	
Neurology	RG7935 / prasinezumab - Parkinson's disease	RG7916 / risdiplam - spinal muscular atrophy	RG1450 / gantenerumab - Alzheimer's disease RG7412 / crenezumab - Alzheimer's disease RG6206 - DMD (PII/III)	
Others	PCO371 (overseas) - hypoparathyroidism RG7716 - wAMD / DME AMY109 - endometriosis	CIM331 / nemolizumab* - pruritus in dialysis patients SKY59 (RG6107) - paroxysmal nocturnal hemoglobinuria (PI/II)		ACE910 (RG6013) / Hemlibra (JP/US/EU) - hemophilia A (non-inhibitor) ★

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

wAMD: wet age-related macular degeneration

DME: diabetic macular edema

DMD: Duchenne muscular dystrophy

* Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

Letters in orange: in-house projects

★: Projects with advances in stages since April 24, 2018

★: Multinational study managed by Chugai



Development Status (1)

In-
house

ACE910 / Hemlibra®

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A with factor VIII inhibitors

Launched in May 2018 (JP)

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A without factor VIII inhibitors, and addition of Q4W administration

Filed in April 2018 (JP/US/EU)

Priority review granted by US FDA in June 2018

(Expected to make a decision on approval by 4 October 2018)



Development Status (2)

In-
licensed

RG7159 / Gazyva®

CD20-positive follicular lymphoma

Approved in July 2018

In-
licensed

RG7446 / Tecentriq®

Head and neck carcinoma (adjuvant)

Started global Phase 3 study in June 2018

In-
licensed

RG6268 / entrectinib

ROS1 fusion gene positive NSCLC

NTRK fusion gene positive solid tumors

In-licensed exclusive rights for development and marketing in Japan in July 2018



Development Status (3)

In-
licensed

RG6264 / Herceptin® and Perjeta®

HER2 positive breast cancer

(Fixed-dose combination, subcutaneous injection)

Started global Phase 3 study in July 2018

In-
licensed

RG7604 / taselelisib

Solid tumors

Development discontinued

In-
house

URC102 (URAT1 inhibitor)

Gout

Development discontinued



Other Progress (1)

In-house

AF802 / Alecensa®

ALK positive advanced NSCLC (1L)

Approved in May 2018 (Taiwan)

In-house

MRA / Actemra®

Cytokine release syndrome induced by treatment with
CAR-T cell therapy

Filed in May 2018 (JP)

Recommendation for approval granted in June 2018 (EU)

Adult onset Still's disease

Filed in May 2018 (JP)



Other Progress (2)

In-
licensed

RG1450 / gantenerumab

Early Alzheimer's disease

Started global Phase 3 study (GRADUATE1) in June 2018

FMI
business

Activities towards commercialization of Foundation Medicine's products in Japan

FoundationOne CDx™

PMDA granted Expedited Review in May 2018

Results of Clinical Trials / Conference (1)



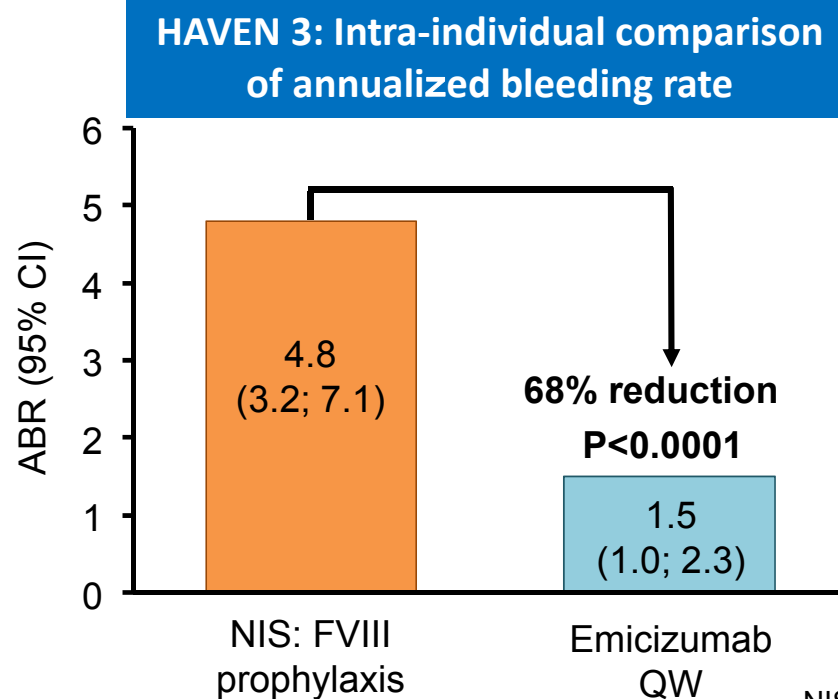
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In-house

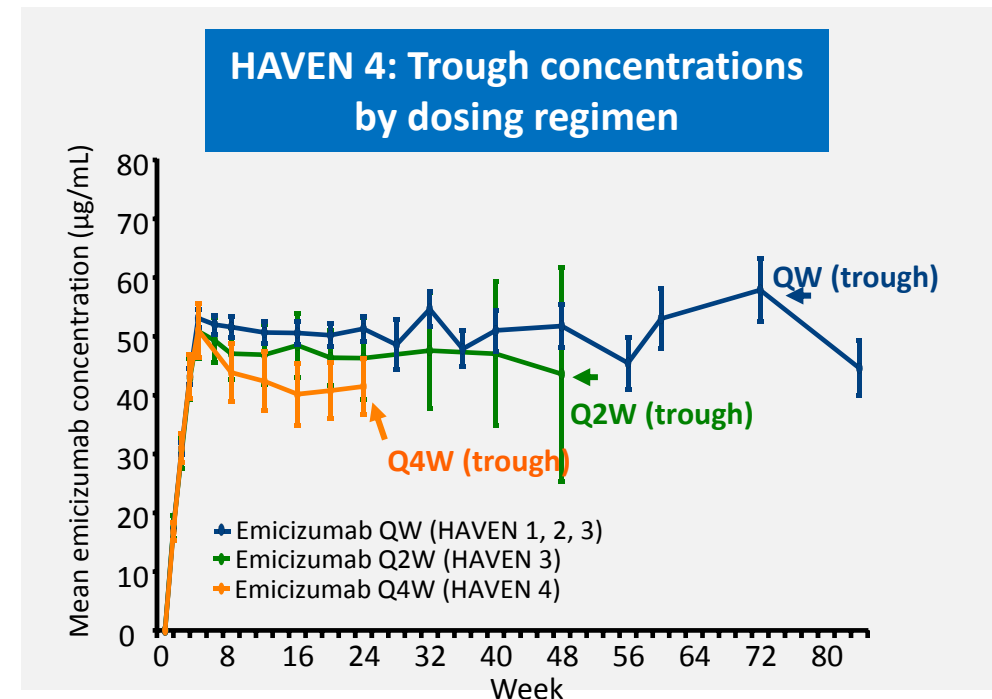
ACE910 / Hemlibra® Hemophilia A

Data from two global Phase III studies presented at WFH 2018 World Congress

- HAVEN 3: without factor VIII inhibitors
- HAVEN 4: Q4W administration (with/without factor VIII inhibitors)



NIS: non-interventional study



Source: WFH2018 presentation materials

Results of Clinical Trials / Conference (2)



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In-
licensed

RG7446 / Tecentriq®

Metastatic triple negative breast cancer (1L)

- Global Phase 3 study, IMpower130 met one of the co-primary endpoints (PFS) in July 2018
 - Statistically significant improvement in PFS with the addition of Tecentriq® versus nab-paclitaxel was demonstrated

In-
house

AF802 / Alecensa®

ALK positive advanced NSCLC (1L)

- Updates* from ALEX study was presented at ASCO2018 Annual Meeting
 - Investigator-assessed median PFS (ITT population)
 - alectinib: 34.8 months (95% CI: 17.7- not reached)
 - crizotinib: 10.9 months (95% CI: 9.1-12.9)
 - stratified HR: 0.43 (95% CI: 0.32-0.58)

* Data cut off on Dec. 1, 2017

Chugai's Portfolio in Lung Cancer

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	NSCLC (NSq)				NSCLC (Sq)	SCLC
	ALK+	EGFR+	ROS+	NTRK+	Non-Driver	
					PD-L1 positive	PD-L1 negative
Neo-/Adj	✓				IMpower010 (adj) Tecentriq IMpower030 (neoadj) Tecentriq + platinum-based chemo	
1L	Alecensa ✓	Tarceva / Avastin ✓	entrectinib	entrectinib	IMpower110 Tecentriq IMpower150 ✓ Tecentriq + Avastin + CP IMpower130 ✓ Tecentriq + CnP IMpower132 ✓ Tecentriq + pemetrexed Avastin ✓	IMpower131 ✓ Tecentriq + CnP IMpower110 Tecentriq IMpower133 ✓ Tecentriq + carboplatin + etoposide
2L	IMpower150 ✓ Tecentriq + Avastin + CP				OAK, POPLAR, BIRCH ✓ Tecentriq Tarceva ✓	

Positive Data: ✓

CP = carboplatin + paclitaxel; CnP = carboplatin + nab-paclitaxel

Conceptual illustration: Modified from
Roche Analyst Event slides at ASCO 2018

RG6268 (entrectinib) and its Mode of Action

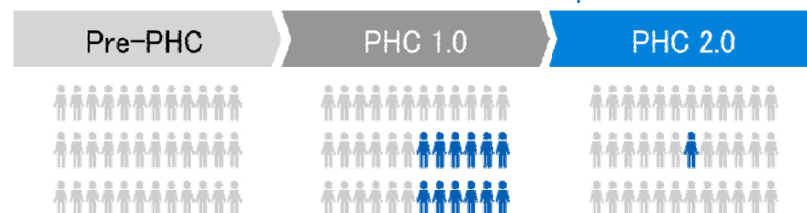
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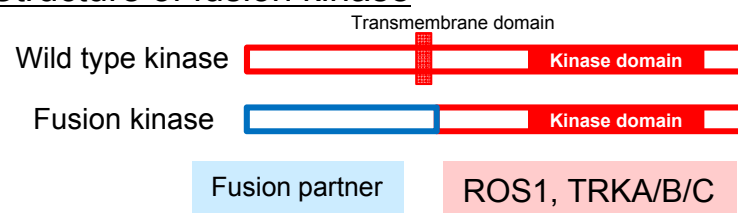
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PHC 2.0 strategy

The right drug for the
right patient by
comprehensive NGS

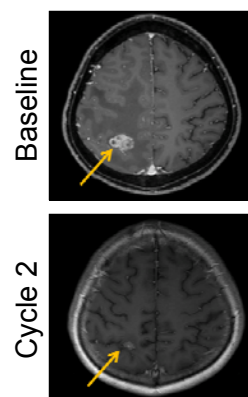


Structure of fusion kinase



Effect against brain metastasis in ROS1 fusion positive NSCLC patients

Intracranial Response (IC)	Measurable Lesions (N=6)
CNS Responders	5/6
IC-ORR (95% CI)	83.3% (35.9, 99.6)



WCLC 2017 (data cut off 13 September 2017)

Entrectinib

Entrectinib is under development that represents the PHC 2.0 strategy promoted by the Roche group. Entrectinib is an orally bioavailable CNS-active tyrosine kinase inhibitor that potently and selectively inhibits the ROS1 and TRK family. Entrectinib has been granted BTB in US, PRIME Designation in EU and also received the Sakigake Designation in Japan for the treatment of *NTRK* fusion positive solid tumors.

ROS1 fusion gene (NSCLC)

The *ROS1* fusion gene is an abnormal gene that can be formed by fusing to other genes as a result of chromosomal translocation. The *ROS1* fusion gene is found in about one to two percent in NSCLC.

NTRK fusion gene (Pan tumor)

The *NTRK* fusion gene is an abnormal gene that can be formed as a result of chromosomal translocation of the *NTRK* genes (*NTRK1*, *NTRK2* and *NTRK3* encode TRKA, TRKB and TRKC protein, respectively). The prevalence of *NTRK* fusion is rare in various solid tumors, including NSCLC, CRC, breast cancer, MASC, thyroid cancer, sarcoma, etc.

PHC: Personalized Health Care, ROS1: c-ros gene 1, NTRK: Neurotrophic Tropomyosin Receptor Kinase, BTB: Breakthrough Therapy Designation, PRIME: PRiorityMedicines, NGS: Next Generation Sequencing, CNS: Central Nervous System, CRC: Colorectal Cancer, MASC: Mammary Analogue Secretory Carcinoma

Personalized Health Care in Cancer Immunotherapy

~Moving from All Comer Trials to Disease-specific Diagnostics Subsets~

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PD-L1 expression (IHC)

- Measure PD-L1 expression in cancer tissues and intracellular domains by IHC tests
- Diagnostics used to support decision-making when administering anti-PD-1/PD-L1 antibodies

T_{eff} gene Signature (RT-PCR)

- Measured by quantifying the mRNA of 3 types of genes (PD-L1, CXCL9, IFN γ) in tumor tissues
- Most cases overlap with PD-L1 positive cases measured by the IHC method¹

tTMB (NGS)

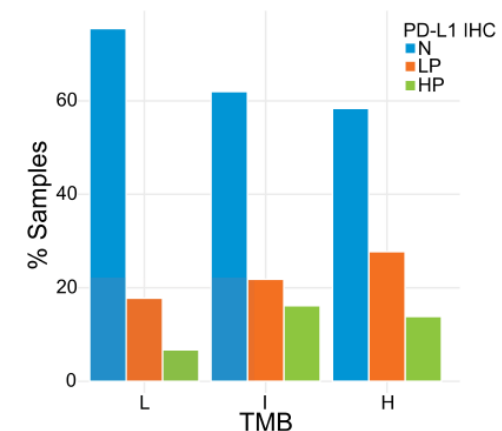
- Represents the amount of tumor gene mutation and expected as an indicator of efficacy for cancer immunotherapy^{2,3}
- tTMB positive population is not equivalent to that of PD-L1 (IHC)^{1,4}, weak correlation was observed (figure below)⁵

bTMB (NGS)

- Measure TMB as a non-invasive blood-based biomarker
- Evaluating the effectiveness in NSCLC (1L) (P2: B-F1RST, P3: B-FAST)

IHC = immunohistochemistry; RT-PCR = Real time PCR; tTMB = tissue-based tumor mutational burden; bTMB = blood-based tumor mutational burden; NGS = next generation sequencing

References: ¹ Kowanetz M, et al. WCLC, 2017; ² Rizvi NA, et al. Science. 2015;348(6230): 124-128.; ³ Patel PS and Kurzrock R. Mol Cancer Ther. 2015;14(4): 847-856.; ⁴ Topalian SL, et al. Nat Rev Cancer. 2016; ⁵ Ross JS, et al. ESMO 2017

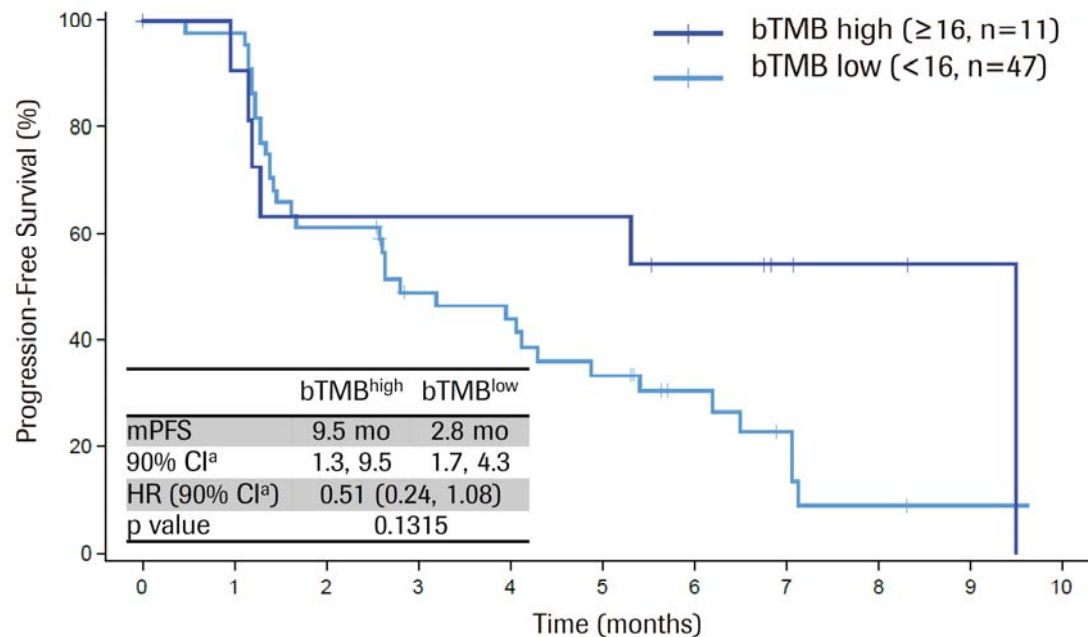


PD-L1 IHC: N=none, LP=low positive, HP=high positive
TMB: L=low, I=intermediate, H=high

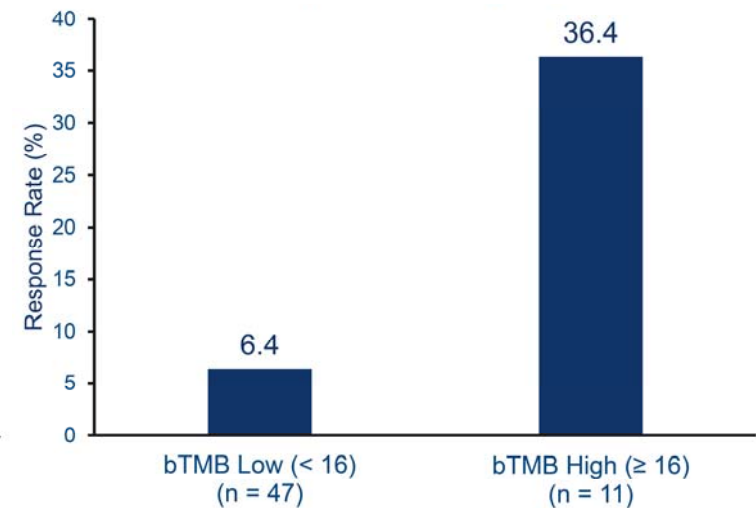


B-F1RST : Expectation for Blood-based Biomarker, bTMB on NSCLC (1L)

Atezolizumab PFS by bTMB subgroups



ORR^b by bTMB subgroups



Velcheti V, et al. ASCO 2018
Data cutoff: December 7, 2017

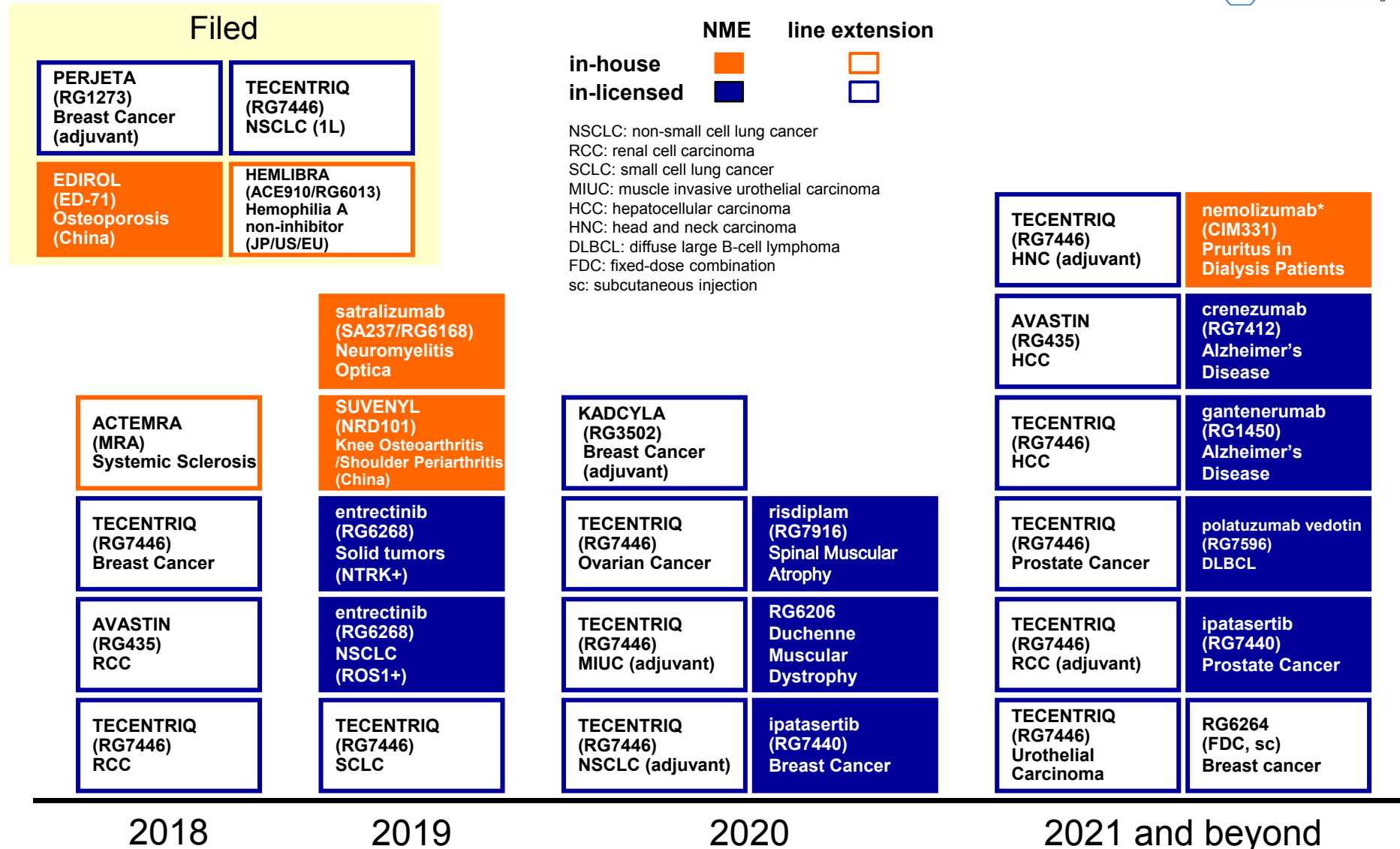
Interim analysis results: bTMB enriches for PFS benefit of atezolizumab in 1L NSCLC

^aPer protocol, efficacy differences between bTMB high vs low subgroups are tested at a significance level of 0.1, and 90% CIs are provided.;

^bUnconfirmed ORR (2 patients had only 1 scan prior to clinical cut-off).; bTMB=blood-based TMB; ORR=objective response rate



Projected Submissions (Post PoC NMEs and Products)



*Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

Updates on the Development Requests for Unapproved Drugs/Indications



Review Committee of Development Requests for Unapproved Drugs/Indication

- 1st round requests: all approved (ten indications, including additional dosages and administrations of eight products)
- 2nd round requests: all approved (three indications of three products)
- 3rd round requests: requests were made for three indications of three products, including additional dosages and administrations, and two of them were approved

Product	Indication	Current Status
Avastin®	Additional dosage and administration for ovarian cancer	Submitted company opinion and waiting for evaluation by the committee

- 4th round requests: requests were made for **three** indications of **three** products and one of them was approved

Product	Indication	Current Status
Xeloda®	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by the committee
Avastin®	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by the committee

Letters in orange: projects with advances in status since February 1, 2018



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