

# **New Mid-term Business Plan**

## **“IBI 21”**

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

January 31/ February 1, 2019

# 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.

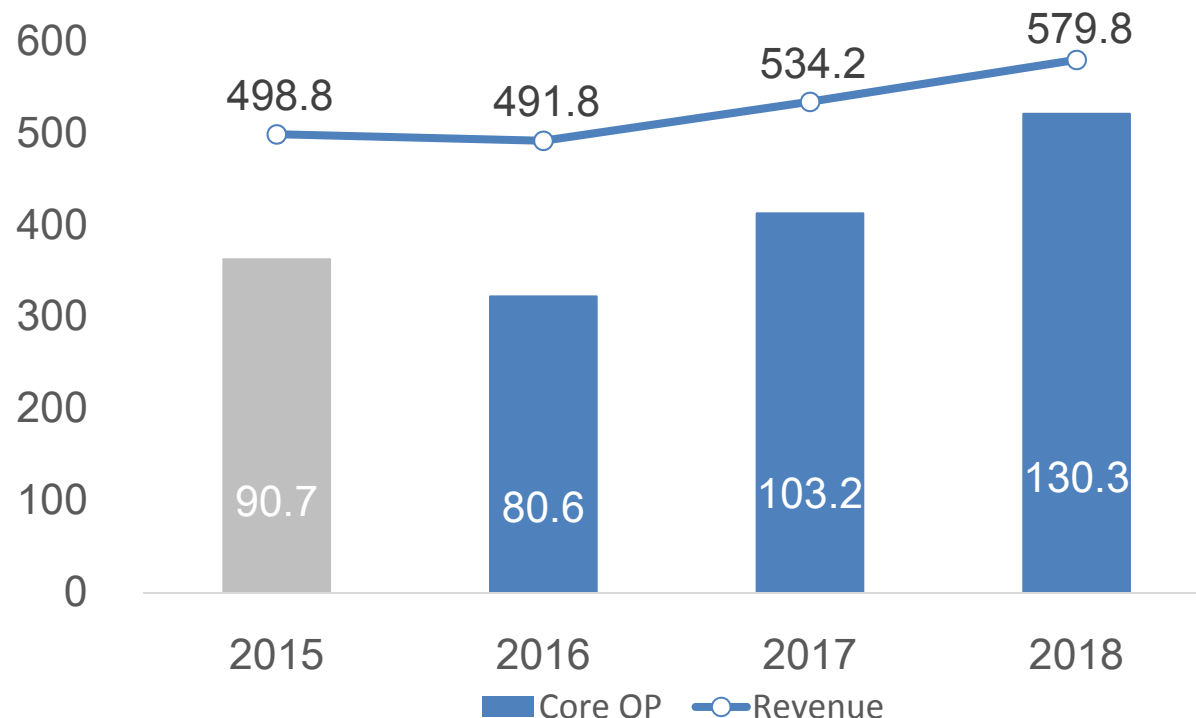


# **Review of 2016 – 2018 Mid-term Business Plan “IBI 18”**



# Business Performance during IBI 18

Revenue  
(bn JPY)



Core OP  
(bn JPY)

2015-18  
CAGR\*

Revenue  
+5.1%

Core OP  
+12.8%

Core EPS  
+14.9%

Core EPS	116.4 JPY	102.5 JPY	138.7 JPY	176.4 JPY
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**IBI 18  
Target**

Core EPS CAGR\*  
(2015-18)

Initial Target

Low single digit\*\*

Result

17.1%\*\*

Status



\*CAGR: Compound Annual Growth Rate (%) \*\* 3 years, average constant exchange rate for 2015



# Summary of IBI 18

Achieving record high profit, Chugai is enriching our platforms for further growth

Status

## Financial targets

- Posted consecutive record revenues and operating profit
- Achieved industry-leading market capitalization



## Priority agenda

Acquisition and implementation of global top-class competitiveness

Selection and concentration for accelerated growth

- Continuously generated new antibody projects and enhanced drug discovery platform for middle molecules
- Obtained early approval for Hemlibra
- Obtained Tecentriq approval and simultaneously developed drugs for 19 indications
- Established system to manage FDA GMP inspections
- Established framework to execute regional strategy through collaboration of 3 Chugai divisions (Marketing & Sales/Medical Affairs/Safety)
- Made steady inroads towards accelerated growth based on Hemlibra and Tecentriq





# **Realization of Becoming a Top Pharmaceutical Company**



# Goals of “Top Pharmaceutical Company”

## Corporate Vision

Company that focuses on first-in-class/best-in-class products and services, and continuously provides new solutions to patients and medical communities around the world  
— Innovation all for patients —

### Quantitative Targets (in late 2010s)

- ✓ Gain a position among the top 3 major Japanese pharmaceutical companies
- ✓ No. 1 presence in our strategic therapeutic areas in Japan
- ✓ Expanded presence in global market

### Qualitative Targets (in late 2010s)

- ✓ A company that satisfies all its stakeholders and receives their active support and trust
- ✓ A company that works proactively on a global level



# Top Pharma: Quantitative Targets (1)

**Goal: Rank within the top 3 major Japanese pharmaceutical companies in the following categories**

Domestic sales share		5th*
Consolidated operating profit margin	✓	2nd
Consolidated operating profit per employee	✓	2nd
Domestic sales per MR	✓	1st**

**Goal: No.1 domestic presence in strategic disease areas**

	Market share	Stakeholder satisfaction
Oncology ✓	1st*	1st***

Renal: 2nd\*/2nd\*\*\*, Bone & Joint: 2nd\*/2nd\*\*\*, RA (biologics): 2nd\*/1st\*\*\*

**Goal: No.1 presence in hospital market based on medical care networks linking healthcare providers**

	Market share	Stakeholder satisfaction
Share of hospital sales (≥100 beds) ✓	1st*	1st***

\* Copyright© 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai. (Other companies: 2017, 2018 or years ended March 31, 2018)

\*\* Calculated by Chugai, based on data from Fuji-Keizai Co., Ltd. \*\*\* Copyright© 2019 anterior. Source: Rep-i 201808. Reprinted with permission. The scope of the market is defined by Chugai.





# Top Pharma: Quantitative Targets (2)

## Goal: Expansion of global presence

Increase overseas sales ratio

2008: 10.4%  
2018: 24.2%

Possess 3 major global products

Actemra  
Alecensa  
Hemlibra

Number of global projects in late-stage development (possess  $\geq 3$  projects)

nemolizumab  
satralizumab  
SKY59 (expected)

Continuous addition of FIC/BIC in-house projects to the portfolio (average 3 projects /year)

During IBI 18  
8 projects/  
3 years



# Top Pharma: Qualitative Targets (1)

**Goal: A company that satisfies all its stakeholders and receives their active support and trust**

## 【Patients and Healthcare Professionals】

Play a part in increasing treatment satisfaction and the contribution of drugs in cancer treatments in our capacity as a leading oncology company



## 【Shareholders and Investors】

Realize growth strategies based on innovation  
(market capitalization: 31<sup>st</sup> in Japan overall, 1<sup>st</sup> in domestic pharmaceutical industry)  
※as of Dec. 28, 2018



## 【Roche】

Contribute to growth of Roche Group by out-licensing Actemra, Alecensa, and Hemlibra.  
Realize revenue and profit growth by fully leveraging our alliance with Roche.





# Top Pharma: Qualitative Targets (2)

**Goal: A company that works proactively on a global level**

**Continuous creation, development, and domestic and overseas launches of products with a competitive advantage in clinical results**

- FDA breakthrough therapy designation for 7 times in 4 products (No. 1 in domestic pharm.)
- Establish world-class manufacturing base (completion of HEM/ALC global inspections)

**Contribution to the Roche Group's results through product-appropriate fostering and sales**

- Maximize product value through simultaneous global development and filing of Roche products
- No. 1 customer satisfaction in strategic disease areas by establishing a system for providing new solutions

**Leadership in pharmaceutical industry activities**

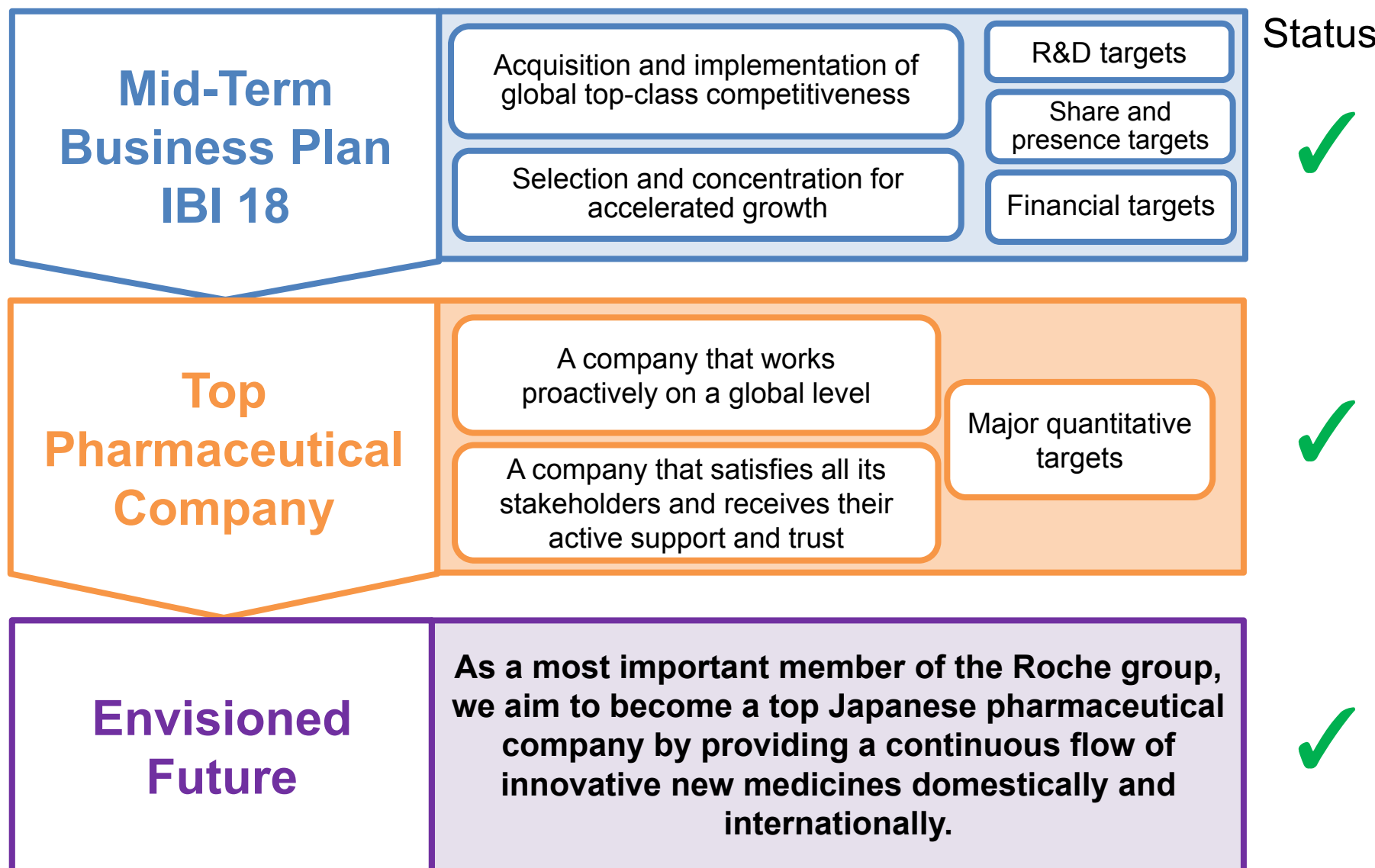
- Promote personalized healthcare in Japan
- Become an industry leader in biotechnology
- Lead the field of drug safety by establishing a system to provide value-added safety information

**Activities in which all employees have an awareness, sense of responsibility and pride as part of a top pharmaceutical company**

- Raise awareness among employees of Chugai's goal of becoming a top pharmaceutical company
- Become a world-class company in employees engagement
- Facilitate human resource development that also creates win-win relationships at the individual level through collaboration with Roche



# Realization of Top Pharmaceutical Company



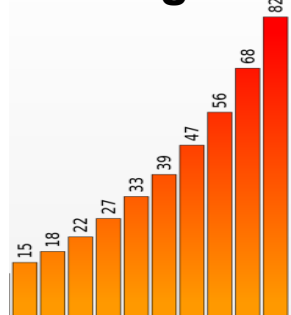


# Business Environment and Vision for Growth

# Drastic Reforms Required for Healthcare Industry while Experiencing Big Changes in the Environment

## Mega-trends

### Exponential changes



Remarkable  
advances in  
life sciences  
and digital  
technologies

Dramatic  
demographic  
shifts

Threats to  
sustainability  
of global  
environment and  
social systems

### Simultaneous global threats



## Impact on healthcare industry

Higher benchmarks  
set for innovation

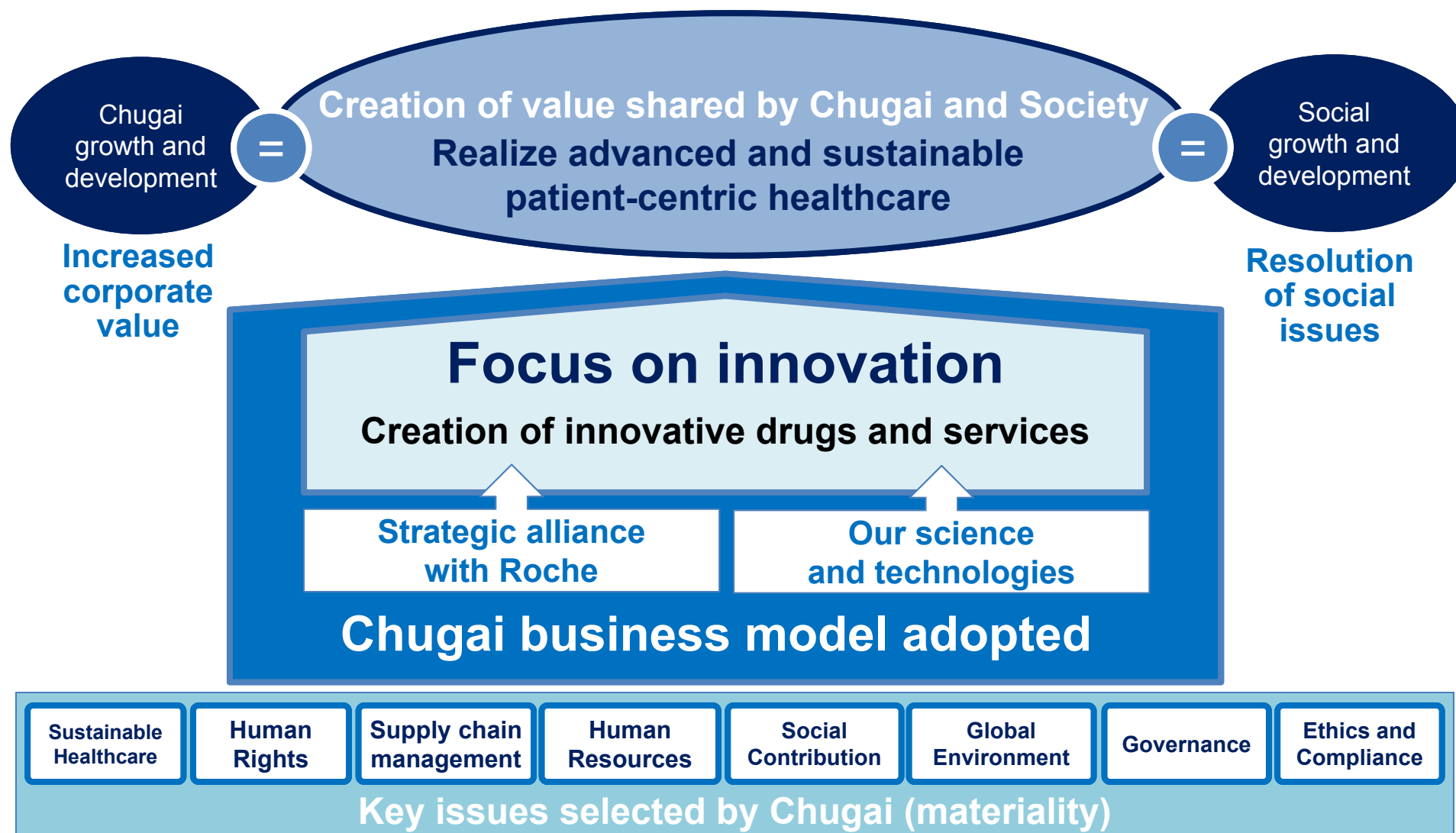
- Falling drug prices due to clampdown on healthcare costs
- Stricter evaluation of cost-effectiveness

Increased calls to participate  
in resolving social issues



# Chugai's Basic Policy

Striving for the mutual development of Chugai and Society by solving social issues through the creation of innovative drugs and services



# Renewal of Core Values & Envisioned Future

## Mission Statement ~Innovation all for the patients~

**No change:**  
Maintain as  
starting point

### Mission

Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world

**Change:**  
Succinctly  
describe the most  
important value  
assessment criteria

### Core Values

- |                             |   |
|-----------------------------|---|
| <b>1. Patient Centric</b>   | Make each patient's wellbeing our highest priority                              |
| <b>2. Pioneering Spirit</b> | Pursue innovation by improving ourselves and thinking differently               |
| <b>3. Integrity</b>         | Maintain the highest standards in all we do to create shared value with society |

**Change:**  
Redefine the aspect  
of evolving with  
society as a higher  
objective

### Envisioned Future

Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strength in science and technology and the alliance with Roche





# **FY2019-21 New Mid-term Business Plan “IBI 21”**

# Name of New Mid-Term Business Plan



 Roche Group

While maintaining the concept of “**IBI**” which express our attitude to pursue continuous innovation and creation, “**21**” expresses the new stage in which we will take on new challenges.

# IBI 21

IBI: INNOVATION BEYOND IMAGINATION



# New Mid-Term Business Plan: 5 Strategies

Accelerate corporate and social development through innovation  
focused on innovative products

## Create global growth drivers and maximize value

### 1 Value Creation

Realize innovative drug discovery  
to cure and manage diseases

### 2 Value Delivery

Deliver patient-centric solution  
to maximize value of growth drivers

### 3 Promote advances in personalized healthcare

Realize the further advancement of PHC and innovate R&D process  
by utilizing digital technology and data

## Strengthen HR and infrastructure that support Chugai's business

### 4 Human capital and structural reform

Develop high-caliber HR talent that support innovation,  
and drastically reform costs, systems and processes

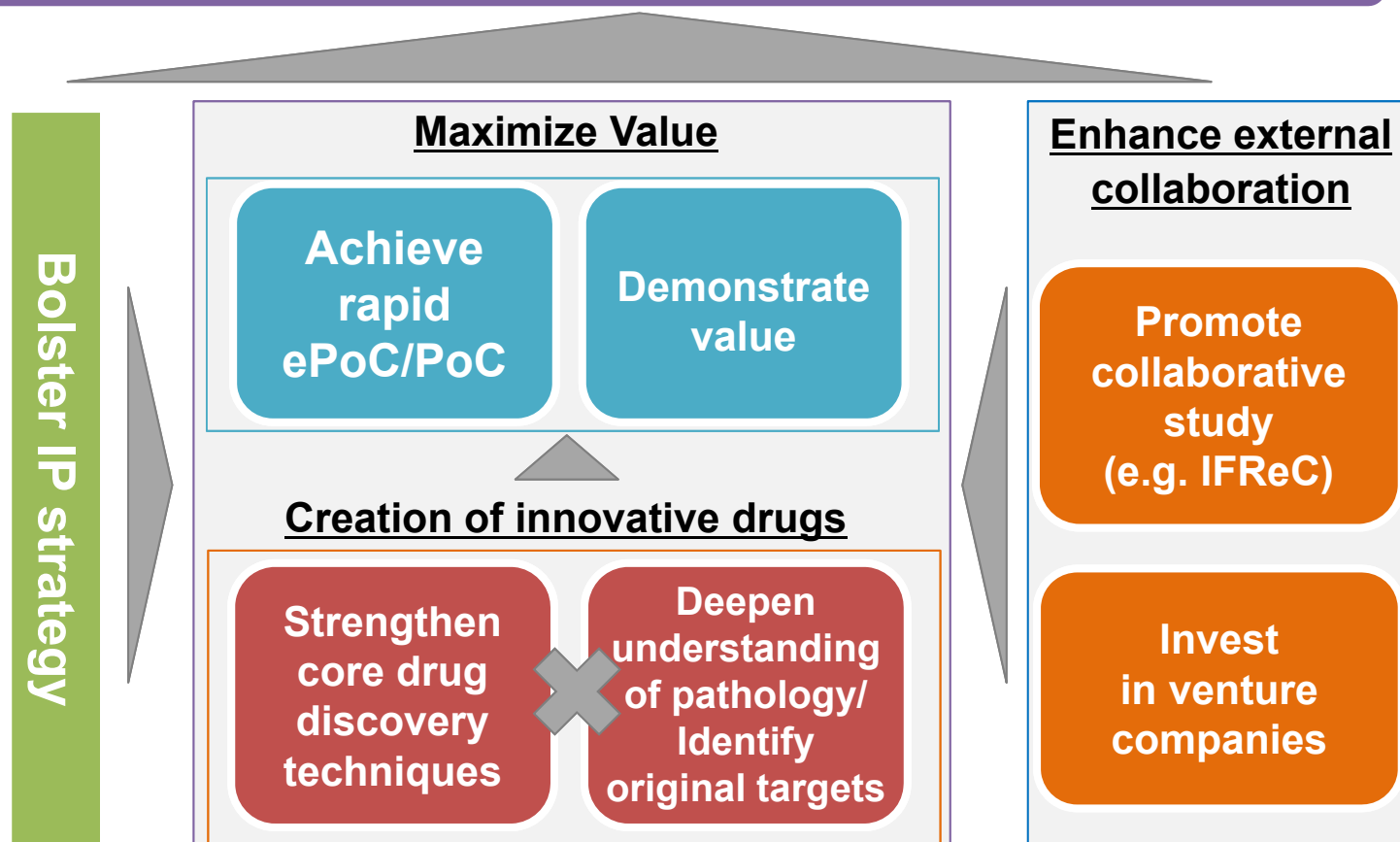
### 5 Strengthen sustainable platforms

Simultaneously realize company growth and sustainable social development

# Strategy 1: Value Creation

Realize innovative drug discovery to cure and manage diseases by integrating our core drug discovery techniques and biology, and by achieving rapid PoC

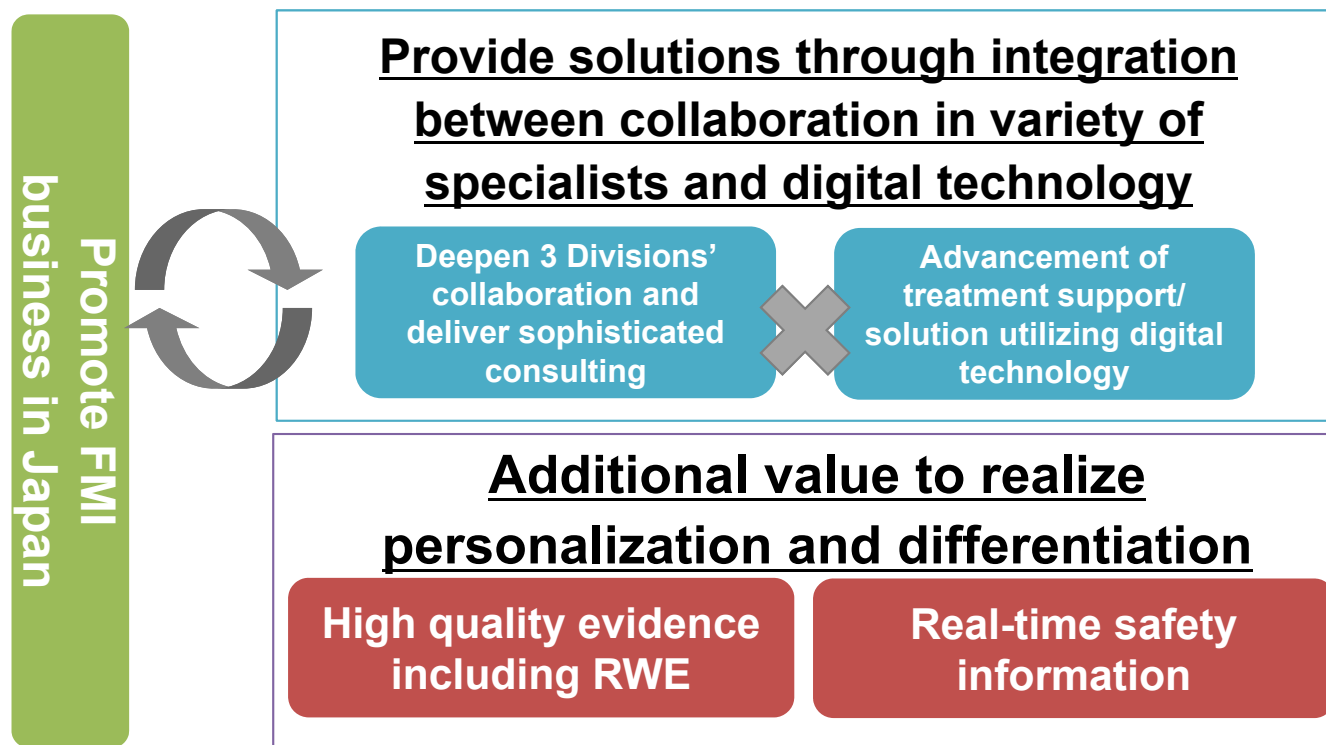
Consecutive FIC/BIC generation to realize cure



## Strategy 2: Value Delivery

Maximize growth drivers (innovative drugs and services)  
through patient centric consulting and digital solution

### Maximize value of growth drivers

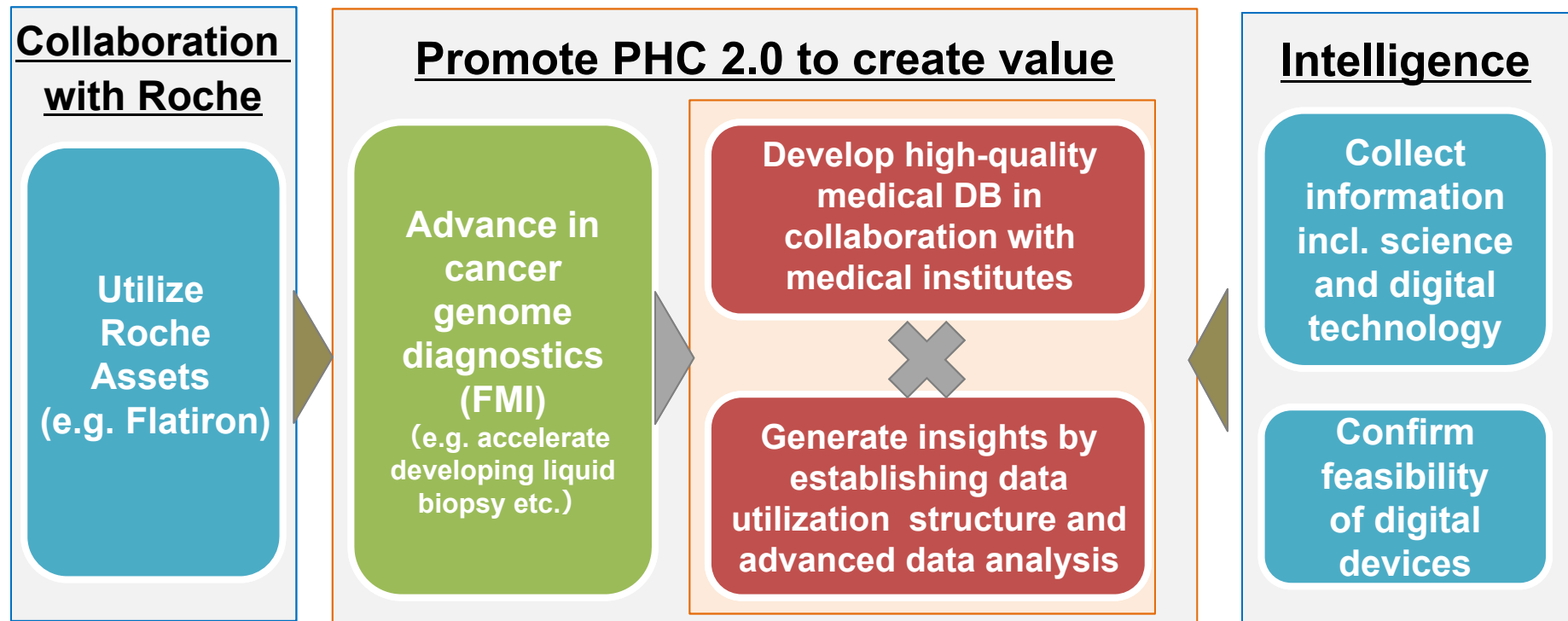


Innovative drugs/services such as Hemlibra/Tecentriq

## Strategy 3: Promote Advances in PHC

Realize further advancements in PHC and innovate R&D process through 'PHC2.0' by utilizing digital technology and data

Further advance PHC and innovate R&D process



# Strategy 4: Strengthen Human Capital and Conduct Drastic Structural Reform

Recruit and develop diverse and high-caliber HR talent that support innovation, and conduct drastic structural reforms

Accelerate innovation  
by implementing strategies ①—③

## Strengthen business platforms

### Recruit and develop HR talent



### Drastic structural reform

Structural reform by reviewing costs, systems and processes



Shift resources to facilitate innovation

## Strategy 5: Strengthen Sustainable Platforms



Roche Roche Group

With the aim of improving corporate value continuously, specify 6 priority agendas that support our challenge toward innovation, based on expectation/request from the society, economic/environmental/social effects by Chugai, and interest of stakeholders.

**Corporate  
value****=****Economic value****+****Social value**



# IBI 21 Quantitative Outlook



Under the new mid-term business plan, we will make essential investment for future growth, while maintaining the momentum of growth achieved during IBI 18, and realize sustainable profit growth and expansion of corporate value.

**Core EPS CAGR\*  
(2018 – 2021)**

\* Compound Annual Growth Rate (%)

**High single digit\*\***

\*\* 3 years, based on constant exchange rate



# Basic Policy of Shareholder Returns

## Profit

To be distributed considering the balance between internal reserves necessary for increasing corporate value, and profit distribution with shareholders

## Dividend Policy

Aim for a dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable dividend to shareholders

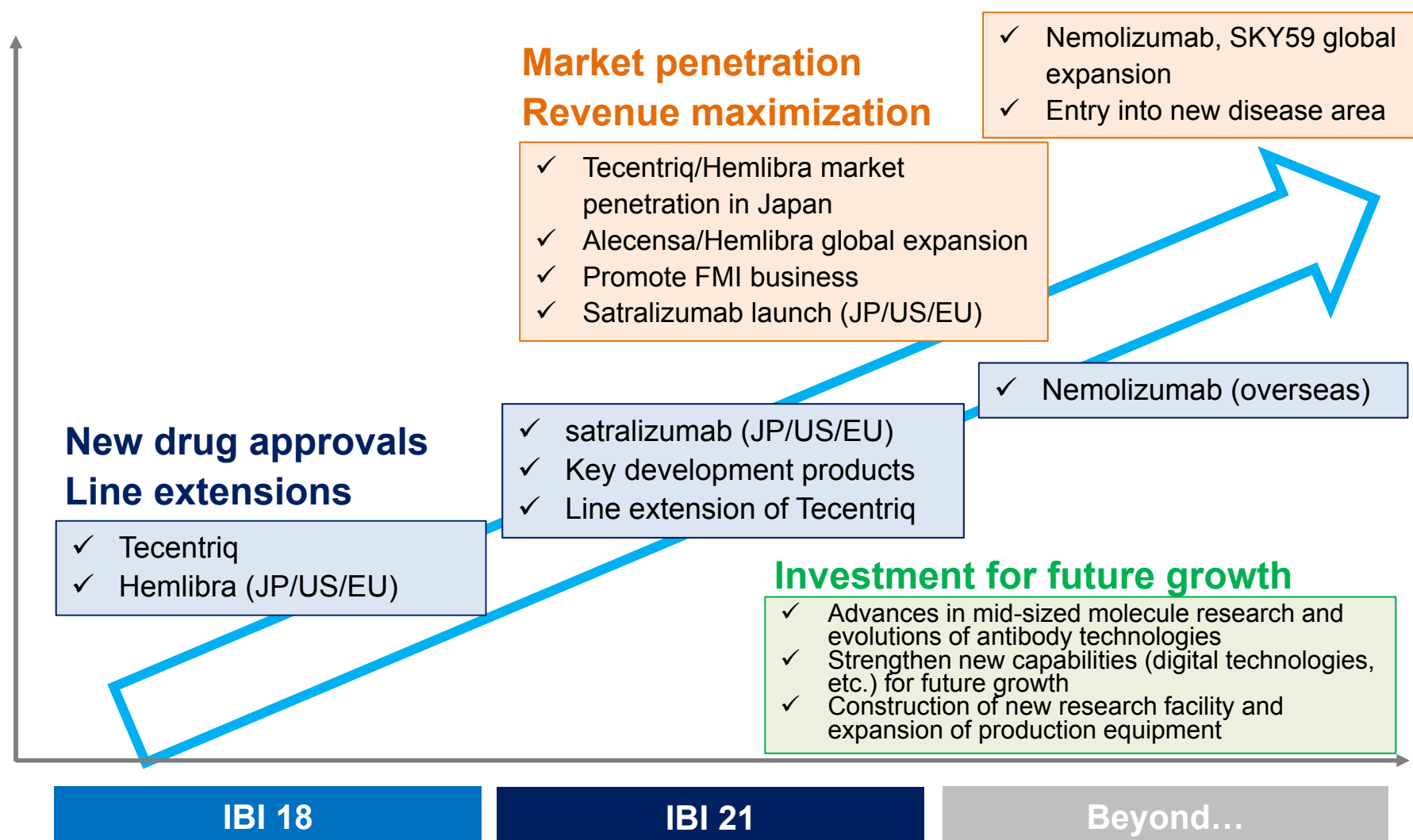
## FY2019 Dividend

96 JPY (forecast)



# IBI 21 Growth Outlook

In addition to market penetration of growth drivers in Japan and overseas, the approval and launch of satralizumab will support further growth



# **FY2018 Consolidated Financial Overview (IFRS based)**

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

January 31/ February 1, 2019



# Full Year Results Summary

## ■ Revenues: 579.8 billion yen (+45.6, +8.5% YoY)

- Domestic sales excl. Tamiflu: despite impact from HIP revision, slight increase due to steady sales growth of mainstay products (+0.8, +0.2%)
- Overseas sales: increase in exports of Actemra and Alecensa to Roche (+33.9, +36.1%)
- Royalties and other operating income: one-time income from transfer of long-term listed products, and from out-licensing of developed products, etc. (+17.0, +48.7%)

## ■ Cost of sales / Operating expenses (Core basis)

- Cost of sales: the ratio to sales improved due to a change in product mix, etc. (-1.1% points, from 50.7% to 49.6%)
- Operating expenses: overall increase mainly due to increase of research and development expenses and general administration expenses, etc. (-9.5, +5.3%)

## ■ Profits

- IFRS results: operating profit 124.3 billion yen (+25.4, +25.7%)  
net income 93.1 billion yen (+19.6, +26.7%)
- Core results: operating profit 130.3 billion yen (+27.1, +26.3%)  
net income 97.3 billion yen (+20.6, +26.9%)
- Core EPS (JPY): 176.42 (+37.74, +27.2%)

# IFRS and Core Results Jan-Dec



(Billion JPY)	IFRS results	Non-core items		Core results
	2018 Jan. - Dec.	Intangible assets	Others	2018 Jan. - Dec.
<b>Revenues</b>	<b>579.8</b>			<b>579.8</b>
Sales	527.8			527.8
Royalties and other operating income	51.9			51.9
Cost of sales	-262.8	+1.0		-261.9
<b>Gross profit</b>	<b>316.9</b>	<b>+1.0</b>		<b>317.9</b>
<b>Operating expenses</b>	<b>-192.6</b>	<b>+5.0</b>		<b>-187.6</b>
Marketing and distribution	-73.7			-73.7
Research and development	-99.2	+5.0		-94.2
General and administration	-19.7			-19.7
<b>Operating profit</b>	<b>124.3</b>	<b>+6.0</b>		<b>130.3</b>
Financing costs	-0.1			-0.1
Other financial income (expense)	0.4			0.4
Other expense	-3.2			-3.2
<b>Profit before taxes</b>	<b>121.4</b>	<b>+6.0</b>		<b>127.5</b>
Income taxes	-28.4	-1.8		-30.2
<b>Net income</b>	<b>93.1</b>	<b>+4.2</b>		<b>97.3</b>
Chugai shareholders	92.5	+4.2		96.7
Non-controlling interests	0.6			0.6

(Billions of JPY)

**Non-Core items**

Intangible assets:

Amortization of intangible assets +1.2

Impairment +4.8

Others

none

Core net income

attributable to Chugai  
shareholders

96.7

(Millions of shares)

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

548

(JPY)

Core EPS

176.42



# Financial Overview Jan-Dec

(Billions of JPY)	2017		2018		Growth	
	Jan - Dec		Jan - Dec			
	vs. Revenues		vs. Revenues			
Revenues	534.2		579.8		+45.6	+8.5%
Sales	499.3		527.8		+28.5	+5.7%
excl. Tamiflu	482.4		517.2		+34.8	+7.2%
Domestic	388.4		389.2		+0.8	+0.2%
Export to Roche	76.4		109.9		+33.5	+43.8%
Other overseas	17.7		18.0		+0.3	+1.7%
Tamiflu	16.9		10.7		-6.2	-36.7%
Ordinary	11.9		10.1		-1.8	-15.1%
Govt. stockpiles, etc.	5.0		0.5		-4.5	-90.0%
Royalties and other operating income	34.9		51.9		+17.0	+48.7%
Cost of sales	-252.9	47.3%	-261.9	45.2%	-9.0	+3.6%
Gross profit	281.3	52.7%	317.9	54.8%	+36.6	+13.0%
Operating expenses	-178.1	33.3%	-187.6	32.4%	-9.5	+5.3%
Operating profit	103.2	19.3%	130.3	22.5%	+27.1	+26.3%
Financing costs	-0.1		-0.1		0.0	0.0%
Other financial income (expense)	-0.1		0.4		+0.5	-
Other Expenses	-1.7		-3.2		-1.5	+88.2%
Income taxes	-24.5		-30.2		-5.7	+23.3%
Net income	76.7	14.4%	97.3	16.8%	+20.6	+26.9%
EPS (JPY)	138.68		176.42		+37.74	+27.2%

Royalties and other operating income +17.0

One-time income from transfer of long-term listed products, and from out-licensing developed products, etc.

Other financial income (expense) +0.5

Exchange gains/losses +0.5

Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts) +0.0

Other Expenses -1.5

Settlement for transfer pricing taxation

Cost of sales ratio vs. Sales

2017 Jan - Dec	2018 Jan - Dec
50.7%	49.6%

Market average exchange rate (JPY)

	2017 Jan - Dec	2018 Jan - Dec
1 CHF	113.90	112.92
1 EUR	126.39	130.36
1 USD	112.17	110.45
1 SGD	81.22	81.87

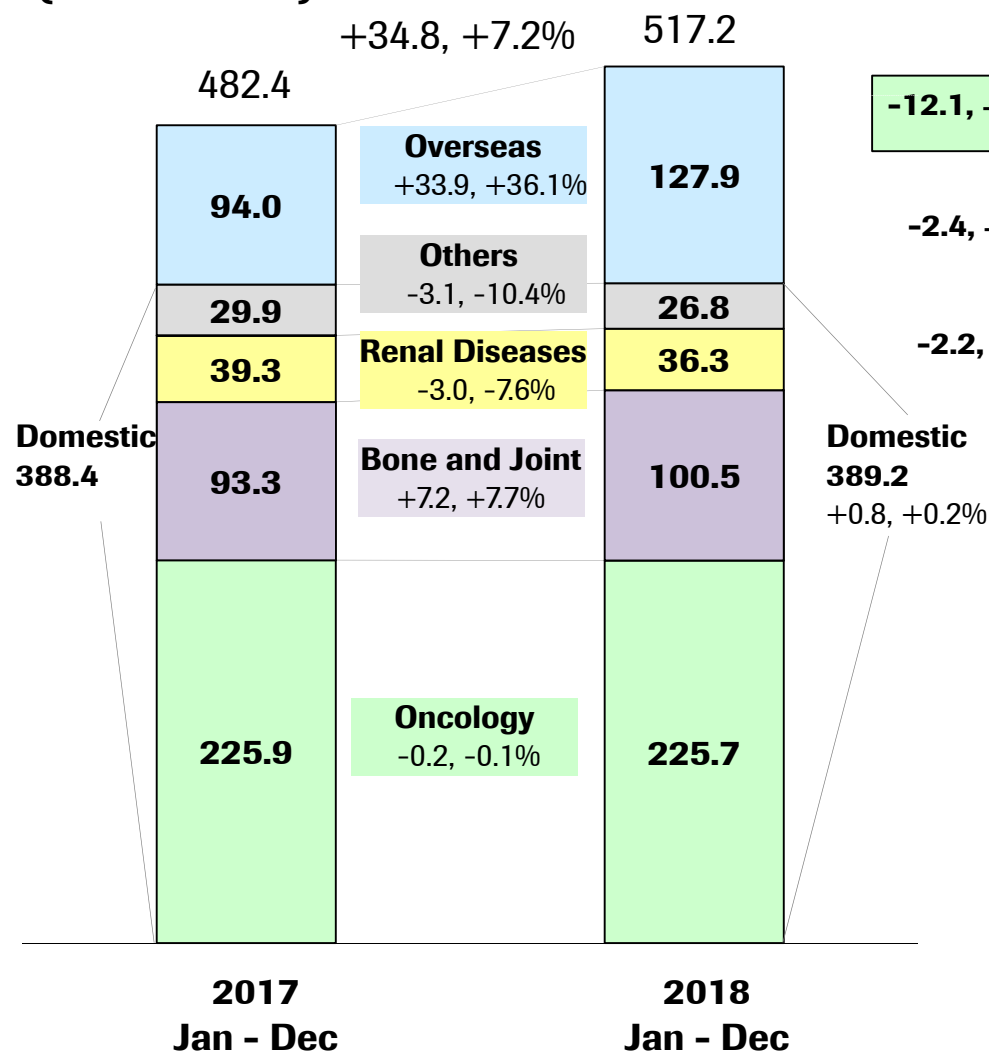
Year on Year



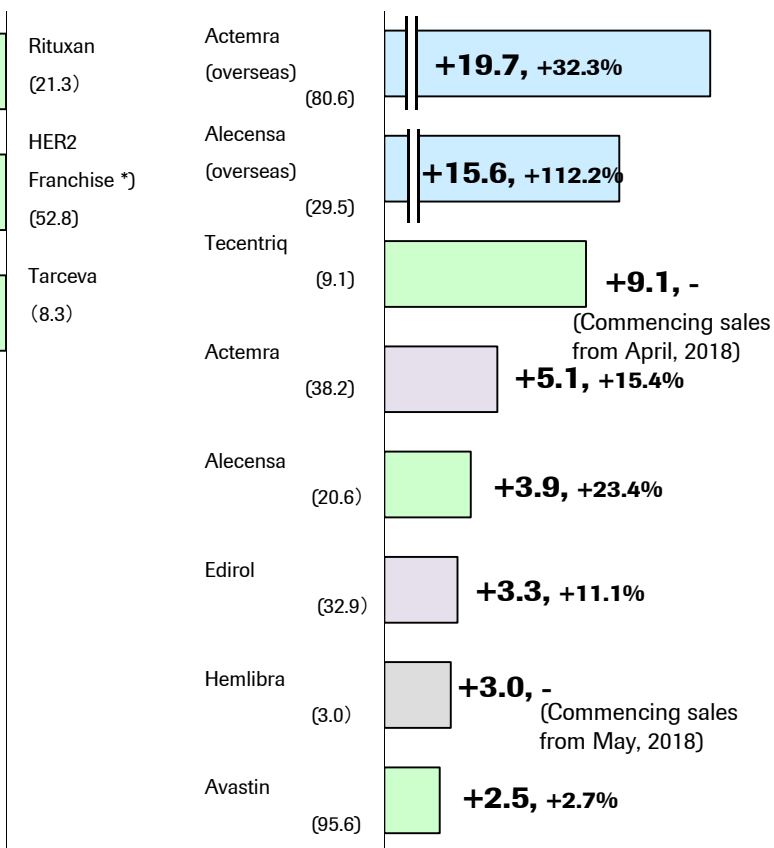
# Sales (excl. Tamiflu) Jan-Dec

Sales by Disease Area,  
Year on Year Comparisons

(Billions of JPY)



Sales by Products,  
Year on Year Changes



\*) Details of HER2 franchise

Herceptin (28.1)	-5.5	-16.4%
Perjeta (16.1)	+2.5	+18.4%
Kadcyla (8.5)	+0.5	+6.3%

( ): 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	Jul-Dec		
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
												1.8		
	10.1	(-0.1)	12.9	(+2.8)	8.2	(-4.7)	12.0	(+3.8)	11.9	(-0.1)	10.1	(-1.8)		
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	0.4		
	0.9	(-1.0)	0.2	(-0.7)	0.0	(-0.2)	1.5	(+1.5)	5.0	(+3.5)	0.5	(-4.5)		
Total	9.0	2.0	7.1	5.9	6.7	1.5	7.3	6.2	8.2	8.7	8.4	2.2		
	11.0	(-1.0)	13.0	(+2.0)	8.2	(-4.8)	13.5	(+5.3)	16.9	(+3.4)	10.7	(-6.2)		

( ) Year on year

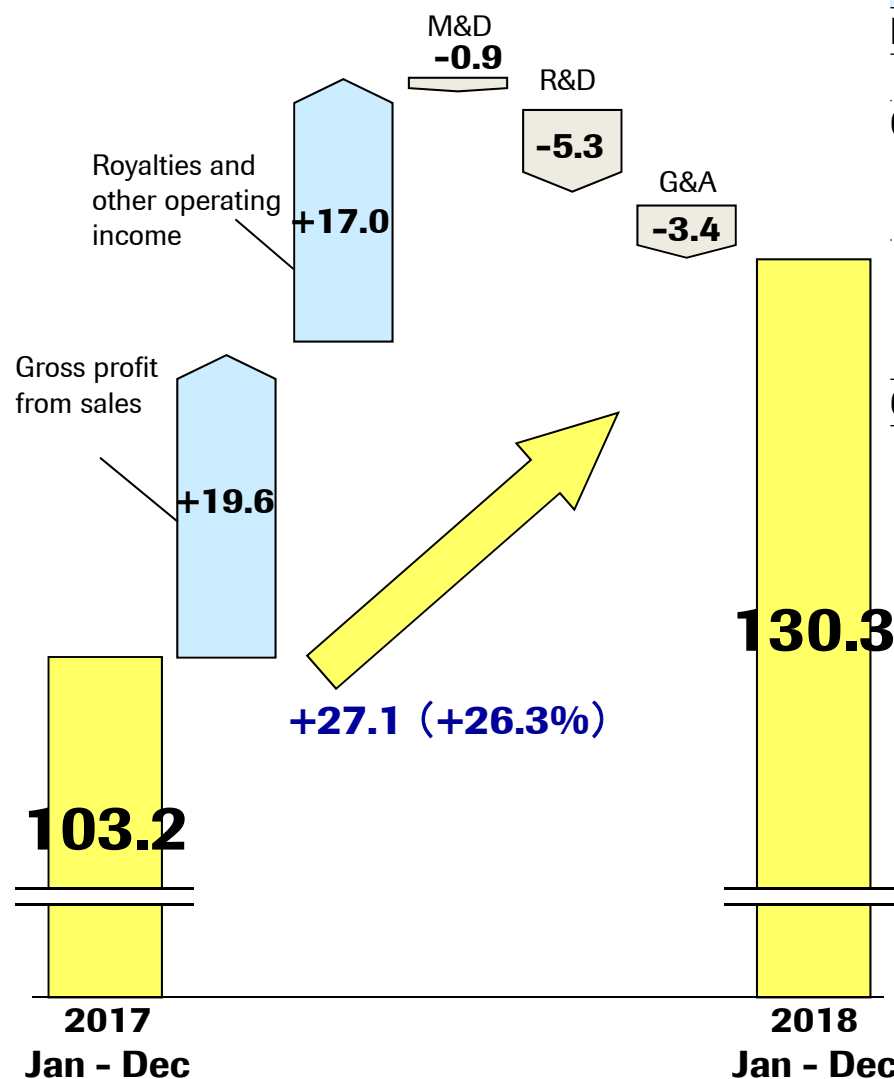
Year on Year (Core)



Roche Roche Group

# Operating Profit Jan - Dec

(Billion of JPY)



(Billions of JPY)	2017 Jan - Dec	2018 Jan - Dec	Growth
<b>Revenues</b>	<b>534.2</b>	<b>579.8</b>	<b>+45.6</b>
Cost of sales	-252.9	-261.9	-9.0
<b>Gross profit</b>	<b>281.3</b>	<b>317.9</b>	<b>+36.6</b>
Sales	246.4	266.0	+19.6
Royalties, etc.	34.9	51.9	+17.0
Marketing and distribution	-72.8	-73.7	-0.9
Research and development	-88.9	-94.2	-5.3
General and administration	-16.3	-19.7	-3.4
<b>Operating profit</b>	<b>103.2</b>	<b>130.3</b>	<b>+27.1</b>

Increase in gross profit from sales	+19.6
Increase in export to Roche and improvement of cost of sales ratio to sales due to change in product mix, etc.	
Increase in royalties and other operating income	+17.0
Increase in marketing and distribution expenses	-0.9
Increase in research and development expenses	-5.3
Progress of projects, etc.	
Increase in general and administration expenses, etc.	-3.4
Increase in various expenses, including legal expenses and the enterprise tax, etc.	



# Financial Overview Oct - Dec

(Billions of JPY)	2017 Oct - Dec vs. Revenues	2018 Oct - Dec vs. Revenues	Growth	
<b>Revenues</b>	<b>146.6</b>	<b>153.3</b>	<b>+6.7</b>	<b>+4.6%</b>
Sales	134.5	139.1	+4.6	+3.4%
excl. Tamiflu	127.7	137.3	+9.6	+7.5%
Domestic	107.5	107.3	-0.2	-0.2%
Export to Roche	15.8	25.8	+10.0	+63.3%
Other overseas	4.5	4.3	-0.2	-4.4%
Tamiflu	6.8	1.8	-5.0	-73.5%
Ordinary	5.6	1.8	-3.8	-67.9%
Govt. stockpiles, etc.	1.2	-	-1.2	Δ100.0%
Royalties and other operating income	12.0	14.2	+2.2	+18.3%
Cost of sales	-67.3 45.9%	-67.6 44.1%	-0.3	+0.4%
<b>Gross profit</b>	<b>79.2 54.0%</b>	<b>85.8 56.0%</b>	<b>+6.6</b>	<b>+8.3%</b>
Operating expenses	-54.7 37.3%	-58.7 38.3%	-4.0	+7.3%
<b>Operating profit</b>	<b>24.5 16.7%</b>	<b>27.1 17.7%</b>	<b>+2.6</b>	<b>+10.6%</b>
Financing costs	-0.0	-0.0	0.0	0.0%
Other financial income (expense)	0.1	0.5	+0.4	+400.0%
Other Expenses	-0.6	-1.1	-0.5	+83.3%
Income taxes	-6.9	-3.8	+3.1	-44.9%
<b>Net income</b>	<b>17.1 11.7%</b>	<b>22.7 14.8%</b>	<b>+5.6</b>	<b>+32.7%</b>
EPS (JPY)	30.88	41.28	+10.40	+33.7%

Increase in gross profit from sales +4.4

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

Increase in royalties and other operating income +2.2

Increase in milestone income

Increase in operating expenses -4.0

Decrease in marketing and distribution +0.3

Increase in research and development Progress of projects, etc. -2.1

Increase in general and administration, etc. Increase in legal expenses, etc. -2.2

Cost of sales ratio vs. Sales

2017 Oct - Dec	2018 Oct - Dec
50.0%	48.6%

Market average exchange rate (JPY)

	2017 Oct - Dec	2018 Oct - Dec
1 CHF	114.41	113.33
1 EUR	132.93	128.72
1 USD	112.89	112.84
1 SGD	83.38	82.04

vs. Forecast (Core)

# Financial Overview Jan - Dec

FY2018 Consolidated Financial Overview



(Billions of JPY)	2018 Jan - Dec			
	Forecast	Actual	+/-	Achievement
<b>Revenues</b>	<b>541.5</b>	<b>579.8</b>	<b>+38.3</b>	<b>107.1%</b>
Sales	498.5	527.8	+29.3	105.9%
excl. Tamiflu	492.9	517.2	+24.3	104.9%
Domestic	374.8	389.2	+14.4	103.8%
Export to Roche	99.6	109.9	+10.3	110.3%
Other overseas	18.5	18.0	-0.5	97.3%
Tamiflu	5.6	10.7	+5.1	191.1%
Royalties and other operating income	43.0	51.9	+8.9	120.7%
Cost of sales	-252.0	-261.9	-9.9	103.9%
<b>Gross profit</b>	<b>289.5</b>	<b>317.9</b>	<b>+28.4</b>	<b>109.8%</b>
Operating expenses	-181.5	-187.6	-6.1	103.4%
<b>Operating profit</b>	<b>108.0</b>	<b>130.3</b>	<b>+22.3</b>	<b>120.6%</b>
EPS (JPY)	147.00	176.42	+29.42	120.0%

Increase in gross profit from sales +19.4

Increase in domestic sales and export to Roche, and improvement of cost of sales ratio to sales due to a change in product mix, etc.

Increase in royalties and other operating income +8.9

Increase in one-time income from out-licensing developed products, etc.

Increase in operating expenses -6.1  
Increase in legal expenses and expenses for further market penetration of new products and mainstay products

Cost of sales ratio vs. Sales

2018 Jan - Dec Forecast	2018 Jan - Dec Actual
50.6%	49.6%

Exchange rate (JPY)

	2018 Jan - Dec Assumption	2018 Jan - Dec Actual *
1 CHF	115.00	112.92
1 EUR	133.00	130.36
1 USD	111.00	110.45
1 SGD	84.00	81.87

\* Market average exchange rate for the period Jan - Dec.

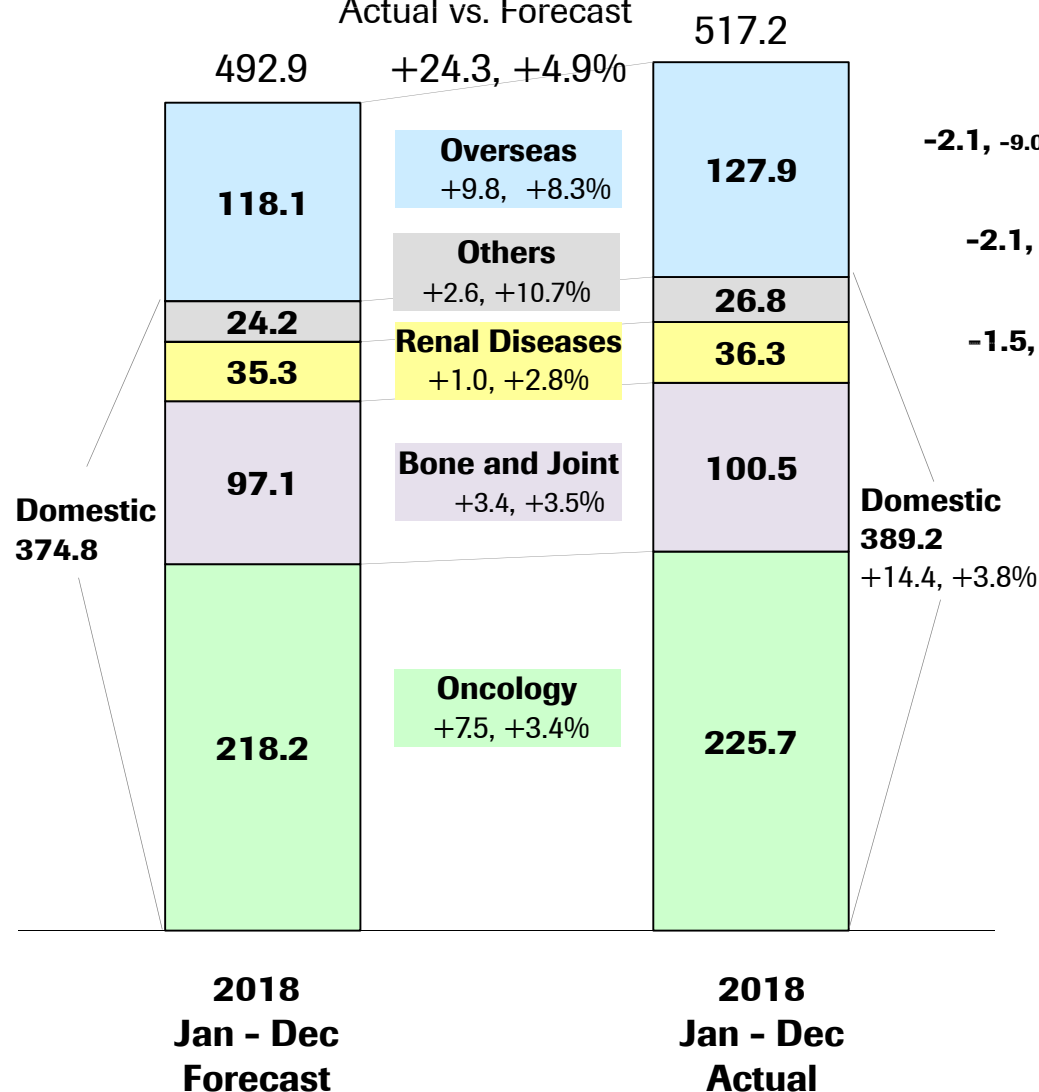
vs. Forecast (Core)

FY2018 Consolidated Financial Overview

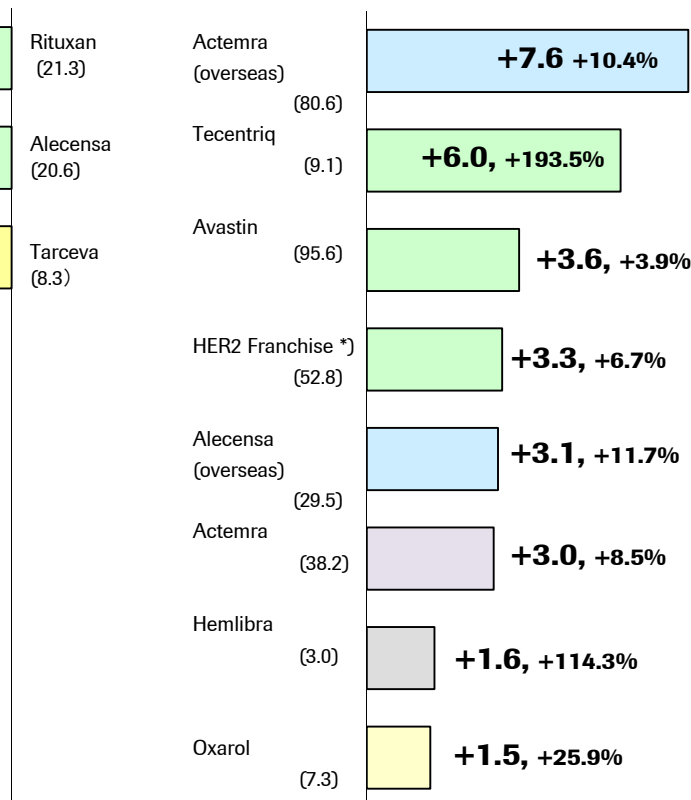


# Sales Progress (excl. Tamiflu) Jan - Dec

(Billions of JPY) Sales by Disease Area,  
Actual vs. Forecast



Sales by Products,  
Actual vs. Forecast



\*) Details of HER2 franchise

Herceptin (28.1)	+1.5,	+5.6%
Perjeta (16.1)	+1.5,	+10.3%
Kadcyla (8.5)	+0.2,	+2.4%

( ): FY2018 Actual  
%: Achievement

vs. Forecast (Core)



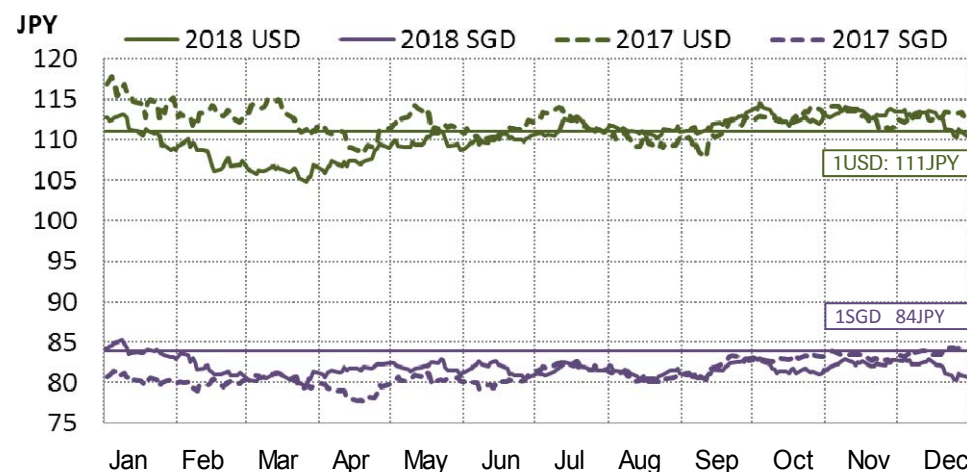
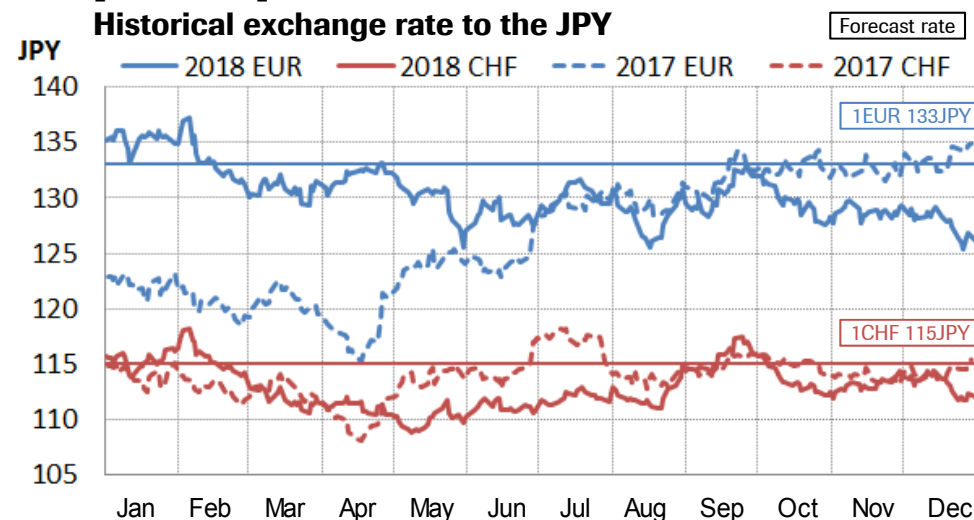
# Impact from Foreign Exchange

(Billions of JPY)	FX impact Jan – Dec 2018 (FX impact vs. Assumption)	
Revenues	<b>-1.2</b>	
	Sales	-0.7
	Royalties and other operating income	-0.5
Cost of sales	Cost of sales	+0.3
Operating expenses	Expenses	+0.6
<b>Operating profit</b>	<b>-0.3</b>	

Actual / Forecast rate* (JPY)	2017 Jan - Dec Actual	2018 Jan - Dec Assumption	2018 Jan - Dec Actual
1CHF	113.90	115.00	112.92
1EUR	126.39	133.00	130.36
1USD	112.17	111.00	110.45
1SGD	81.22	84.00	81.87

\* Actual: market average exchange rate for the period Jan - Dec

[Reference]  
Historical exchange rate to the JPY



vs. 2017 Year End

FY2018 Consolidated Financial Overview



# Overview of Financial Position

(Billions of JPY)	2017 Dec	2018 Dec	Change
Trade accounts receivable	148.5	150.8	+ 2.3
Inventories	169.1	159.4	- 9.7
Trade accounts payable	-38.4	-35.9	+ 2.5
Other net working capital	-28.4	-39.1	- 10.7
<b>Net working capital</b> *1	<b>250.7</b>	<b>235.1</b>	<b>- 15.6</b>
Property, plant and equipment	171.6	222.4	+ 50.8
Intangible assets	21.1	22.7	+ 1.6
Other long-term assets - net	-3.1	25.1	+ 28.2
<b>Long-term net operating assets</b> *2	<b>189.5</b>	<b>270.1</b>	<b>+ 80.6</b>
<b>Net operating assets</b>	<b>440.2</b>	<b>505.3</b>	<b>+ 65.1</b>
Debt	-0.3	-0.2	+ 0.1
Marketable securities	104.0	102.5	- 1.5
Cash and cash equivalents	139.1	146.9	+ 7.8
<b>Net cash</b>	<b>242.8</b>	<b>249.2</b>	<b>+ 6.4</b>
Other non-operating assets - net	9.9	2.1	- 7.8
<b>Net non-operating assets</b> *3	<b>252.7</b>	<b>251.3</b>	<b>- 1.4</b>
<b>Total net assets</b>	<b>692.9</b>	<b>756.5</b>	<b>+ 63.6</b>
Total assets	852.5	919.5	+ 67.0
Total liabilities	-159.6	-163.0	- 3.4

\*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	-15.6
Decrease in inventories	-9.7
Impact from front-loaded purchases in the previous year and transfer of long-term listed products, etc.	
Decrease in other net working capital	-10.7
Increase in long-term net operating assets	+80.6
Increase in Property, plant and equipment	+50.8
Purchase of a business site in Yokohama for a new laboratory	
Increase in Other long-term assets	+28.2
Mainly decrease of the deferred income on applying IFRS15 and increase in long-term prepaid expenses for outsourcing of Manufacturing	
Increase in net cash	+6.4
Decrease in other non-operating assets - net	-7.8
Equity ratio attributable to Chugai shareholders	+1.0% pts.
2018 Dec	82.2%
2017 Dec	81.2%

FX rate to the JPY  
(end of period)

	2017 Dec	2018 Dec
1CHF	115.35	112.03
1EUR	134.82	126.13
1USD	112.89	110.28
1SGD	84.39	80.07

vs. 2017 Year End

# Net Cash



## Main investment for P.P.E

**Ustunomiya**: High-mix low-volume production capability for pre-filled syringe form products

**Ukima**: High-mix low-volume production of antibody API for initial commercial products

**Fujieda**: Solid formulation manufacturing facility, etc.

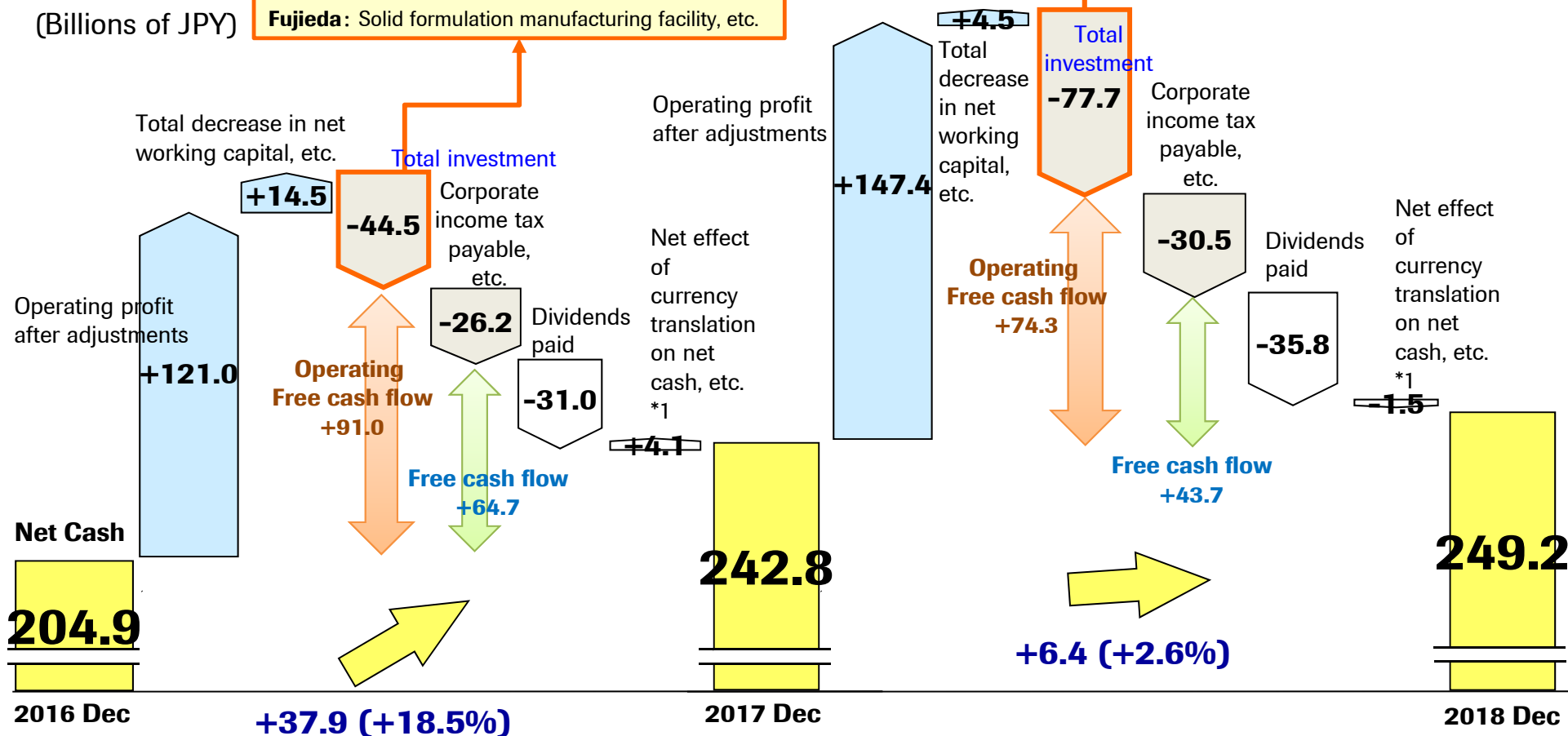
## Main investment for P.P.E

**Yokohama site**: Purchase of business site

**Ustunomiya**: High-mix low-volume production capability for pre-filled syringe form products

**Ukima Plant**: High-mix low-volume production of antibody API for initial commercial products

**Ukima Research Laboratories**: Enhancement of the process development function of small- and middle-molecule active pharmaceutical ingredients



\*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 A result of 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)





# Summary of Earnings Prospects for 2019

## ■ Revenues: 592.5 billion yen (+12.7 +2.2% YoY)

- Domestic sales <sup>1)</sup>: decrease due to competition with generic drugs and impact of HIP revision (-10.8, -2.7%)
- Overseas sales: increase mainly due to Alecensa and Actemra export to Roche (+11.0, +8.6%)
- Royalty and profit-sharing income. <sup>2)</sup>: increase in royalties from Roche for Hemlibra (+29.4, +122.0%)
- Other operating income <sup>2)</sup>: decrease in one-time income from transfer of long-term listed products in the previous year, etc. (-16.9, -60.6%)

## ■ Cost of sales / Operating expenses (Core basis)

- Cost of sales: the ratio to sales will improve due to change in product mix, etc. (-1.8% points, from 49.6% to 47.8%)
- Operating expenses: overall increase mainly due to the increase of research and development expenses from progress of projects, etc. (-9.4, +5.0%)

## ■ Profits (Core basis)

Operating profit	143.0 billion yen (+12.7, +9.7%)
EPS (JPY):	198.00 (+21.58, +12.2%)

1) Domestic sales include Tamiflu sales from FY2019.

2) Details of Royalty and profit-sharing income and Other operating income are shown separately from FY2019.



# Forecast 2019 Jan - Dec

(Billions of JPY)	Actual 2018 Jan - Dec vs. Revenues		Forecast 2019 Jan - Dec vs. Revenues		Growth	
<b>Revenues</b>	<b>579.8</b>		<b>592.5</b>		<b>+12.7</b>	<b>+2.2%</b>
Sales	527.8		528.0		+0.2	+0.0%
Domestic	399.9		389.1		-10.8	-2.7%
Overseas	127.9		138.9		+11.0	+8.6%
Royalties and other operating income	51.9		64.5		+12.6	+24.3%
Royalty and profit-sharing income	24.1		53.5		+29.4	+122.0%
Other operating income	27.9		11.0		-16.9	-60.6%
Cost of Sales	-261.9		-252.5		+9.4	-3.6%
<b>Gross Profit</b>	<b>317.9</b>	<b>54.8%</b>	<b>340.0</b>	<b>57.4%</b>	<b>+22.1</b>	<b>+7.0%</b>
Operating Expenses	-187.6	32.4%	-197.0	33.2%	-9.4	+5.0%
Research and development expenses	-94.2		-102.0		-7.8	+8.3%
<b>Operating Profit</b>	<b>130.3</b>	<b>22.5%</b>	<b>143.0</b>	<b>24.1%</b>	<b>+12.7</b>	<b>+9.7%</b>
EPS (JPY)	176.42		198.00		+21.58	+12.2%

Increase in gross profit from sales +9.5

Despite decrease in domestic sales,  
increase in export to Roche

Increase in royalties and other operating income +12.6

Increase in royalties from Hemlibra, etc.

Increase in operating expenses -9.4

Increase in research and development -7.8

Progress of projects, etc.  
Increase in research and development activities

Cost of sales ratio vs. Sales

2018 Jan - Dec	2019 Jan - Dec
49.6%	47.8%

Exchange rate (JPY)

	2018 Jan - Dec Actual *	2019 Jan - Dec Assumption
1CHF	112.92	114.00
1EUR	130.36	128.00
1USD	110.45	111.00
1SGD	81.87	82.00

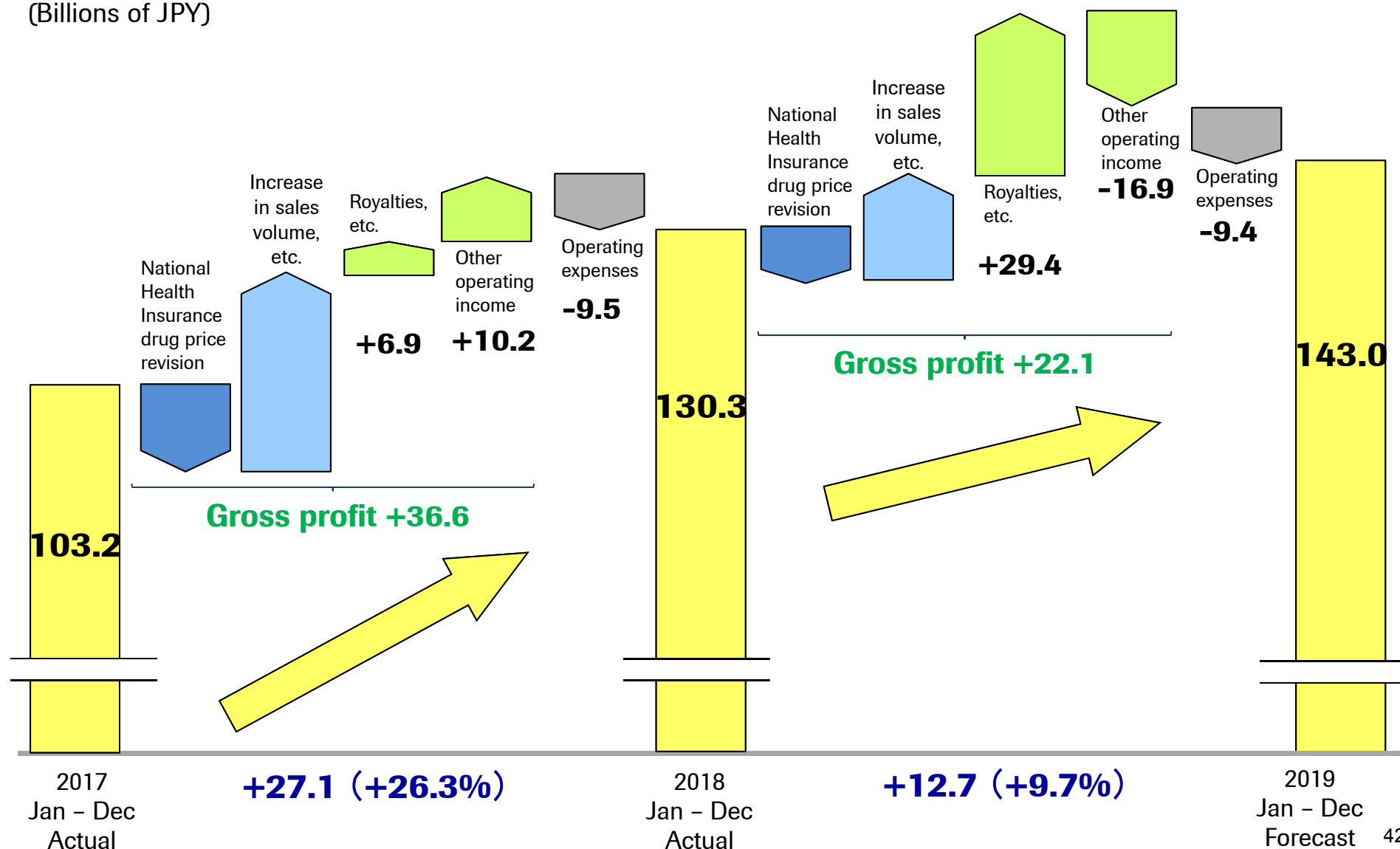
\*Actual: market average exchange rate  
for the period of Jan - Dec.

2019 Forecast (Core)



# Movement of Operating Profit 2017 - 2019

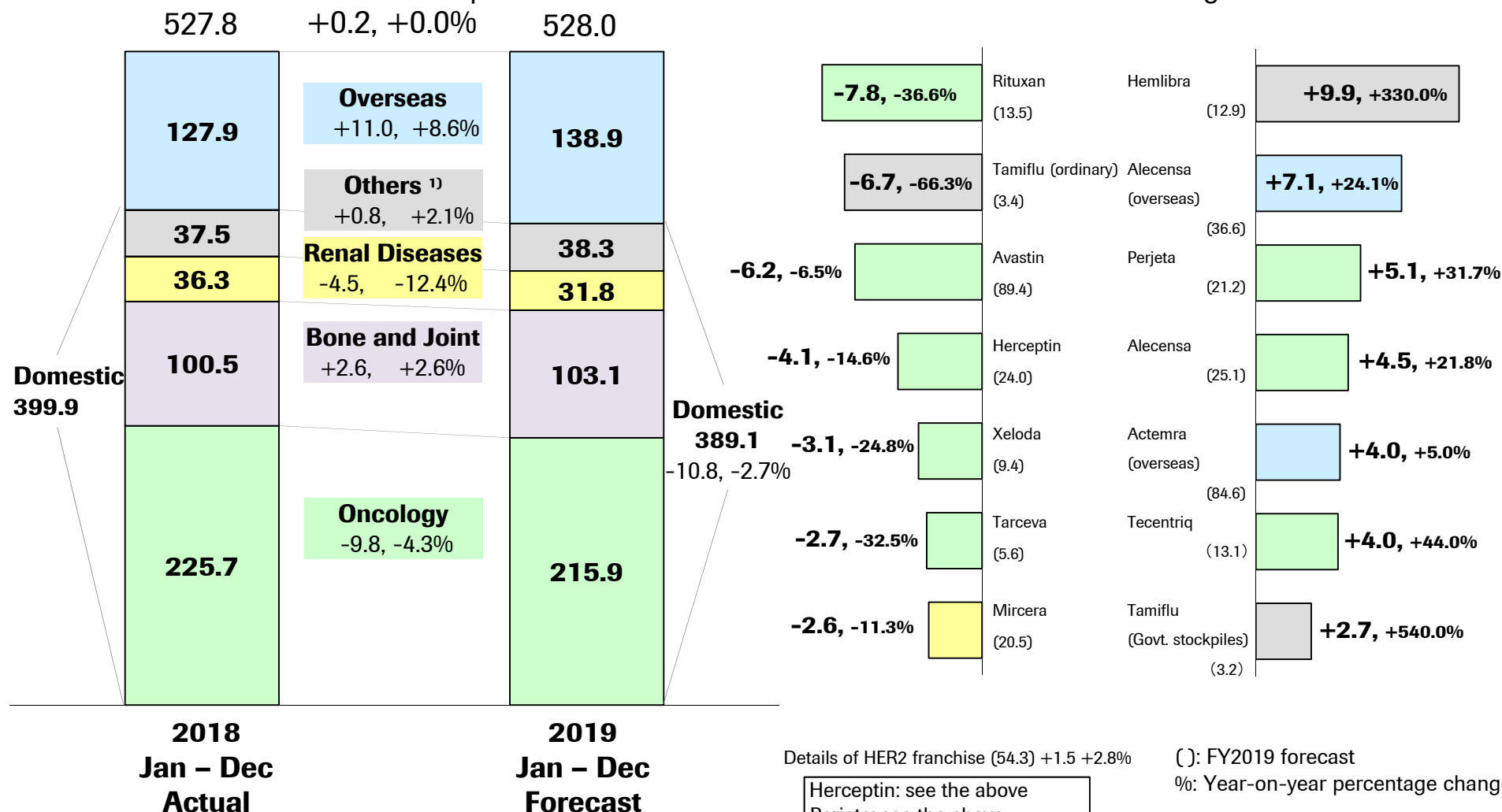
(Billions of JPY)



# Sales Forecast vs. 2018 Actual

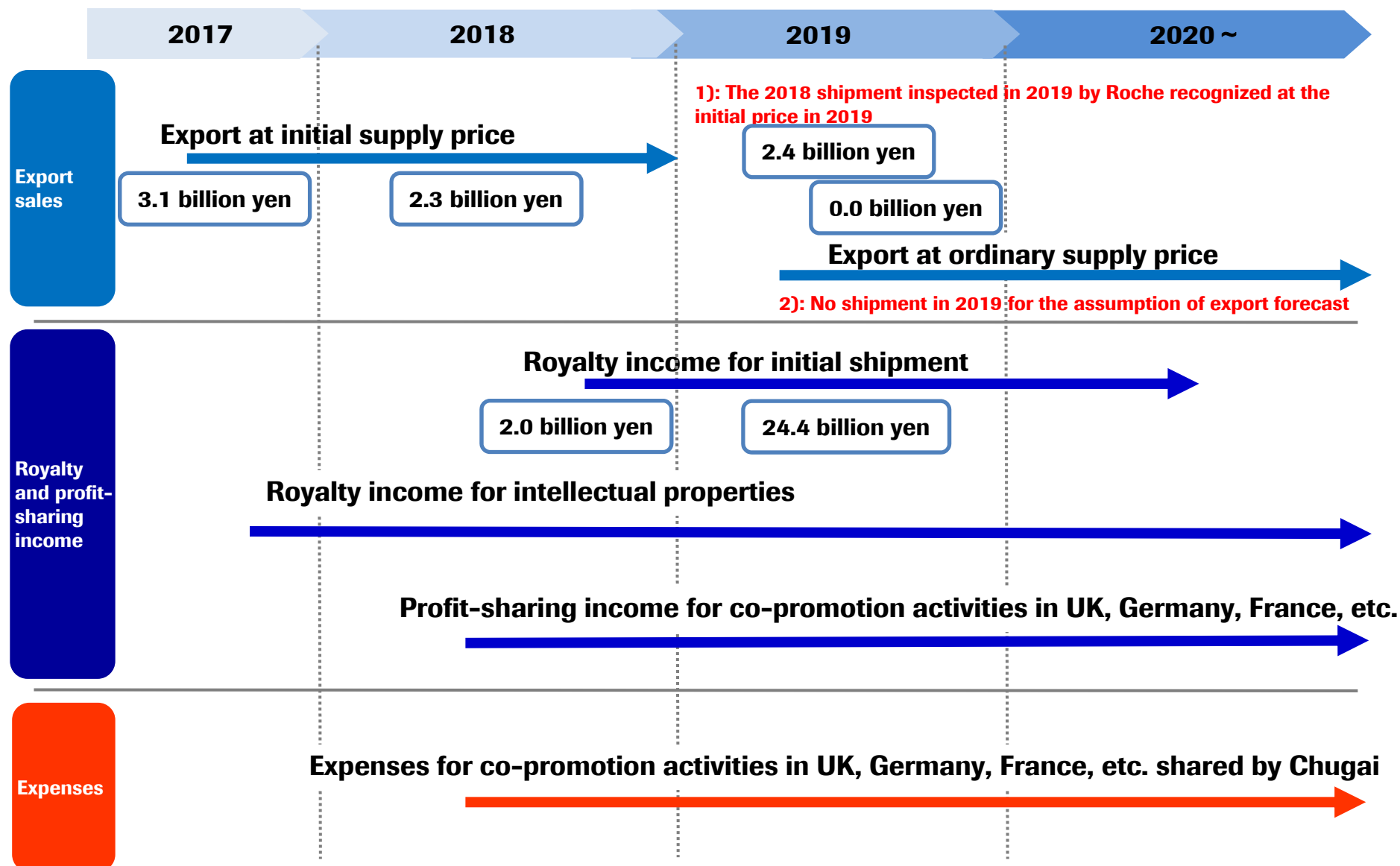
(Billions of JPY) Sales by Disease Area,  
Year on Year Comparisons

Sales by Products,  
Year on Year Changes



1) Tamiflu is included in "Others" from FY2019.

# Outline of Hemlibra Sales to Roche



# Current Status / Plan for Major Capital Investments



## Main Objective

- Building of state-of-the-art R&D site to create innovative new drug candidates
- Simultaneous development and quick launch of therapeutic antibodies, etc.
- Reduction of manufacturing costs for in-house products
- Enhancement of the process development function of small- and middle- molecule active pharmaceutical ingredients

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2026

C P R

**CPR (Singapore):** Accelerate creation of clinical candidates utilizing proprietary antibody technologies

2012-21: 476 million SGD (276 million SGD), incl. capital investments of 61 million SGD (59 million SGD)

2022-26: 282 million SGD, incl. capital investments of 21 million SGD

**Yokohama site:** Purchase of business site

2016-18: 43.4 billion JPY (43.0 billion JPY)

Construction of laboratory

(Details to be officially announced upon final decision)

**Utsunomiya Plant:** Enhancement of high-mix low-volume production capability for pre-filled syringe form products (Installment of tray filler)

2013-18: 6.0 billion JPY (6.0 billion JPY)

**Ukima Plant:** Enhancement of high-mix low-volume production of antibody API for initial commercial products (Expansion of production capability by construction of UK3)

2015-18: 37.2 billion JPY (36.7 billion JPY)

**Ukima Research Laboratories:** Construction of a new synthetic research building for strengthening the process development function of small- and middle-molecule active pharmaceutical ingredients

2018-20: 4.5 billion JPY (1.3 billion JPY)

Domestic

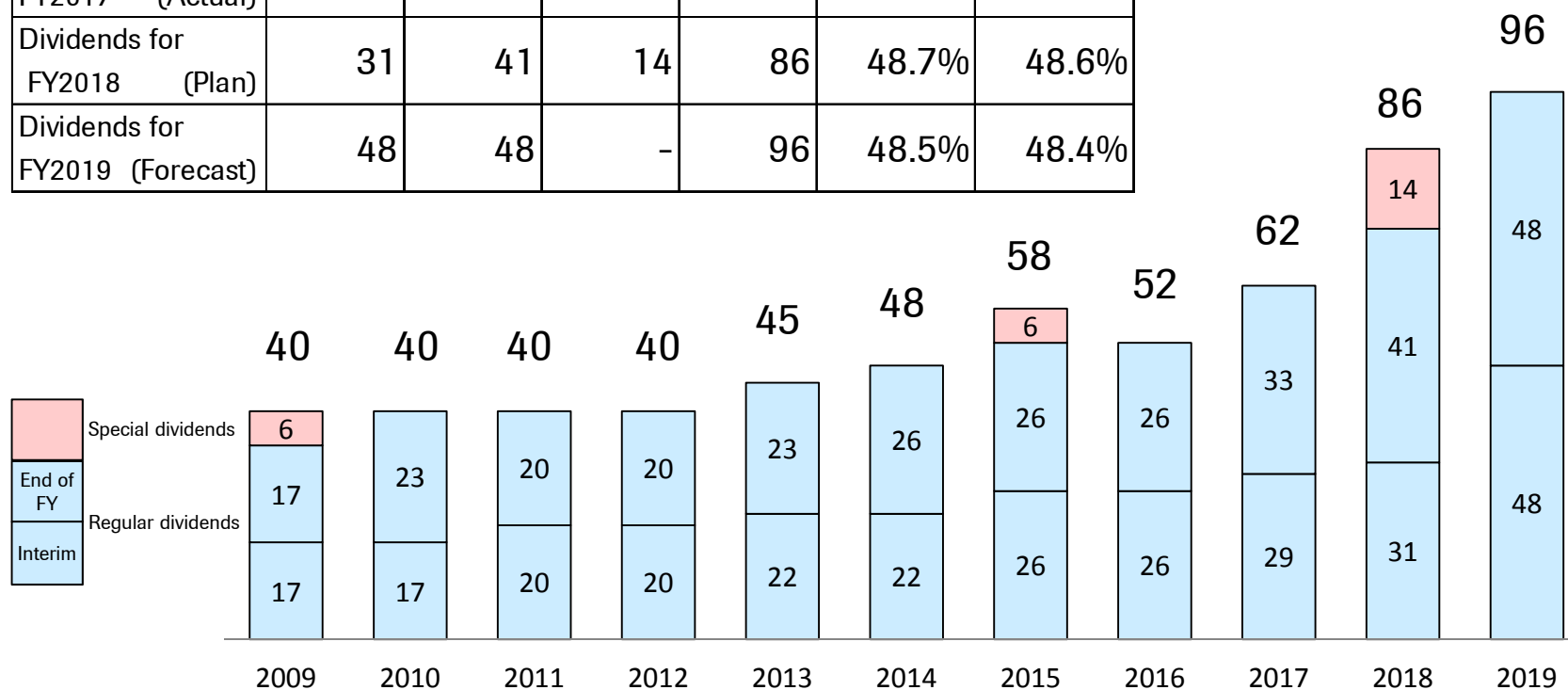


# Dividend Policy

## Policy

Aiming for a consolidated dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable allocation of profit to all shareholders, taking into account the strategic funding needs and earnings prospects.

	Annual dividends per share (JPY)				Core payout ratio	
	Interim	End of FY	Special	Total	Single FY	5-year average
Dividends for FY2017 (Actual)	29	33	-	62	44.7%	48.4%
Dividends for FY2018 (Plan)	31	41	14	86	48.7%	48.6%
Dividends for FY2019 (Forecast)	48	48	-	96	48.5%	48.4%



# Overview of Development Pipeline

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

January 31/ February 1, 2019





# New Mid-Term Business Plan: 5 Strategies

Accelerate corporate and social development through innovation focused on innovative products

## Create global growth drivers and maximize value

### 1 Value Creation

Realize innovative drug discovery to cure and manage diseases

### 2 Value Delivery

Deliver patient-centric solution to maximize value of growth drivers

### 3 Promote advances in personalized healthcare

Realize the further advancement of PHC and innovate R&D process by utilizing digital technology and data

## Strengthen HR and infrastructure that support Chugai's business

### 4 Human capital and structural reform

Develop high-caliber HR talent that support innovation, and drastically reform costs, systems and processes

### 5 Strengthen sustainable platforms

Simultaneously realize company growth and sustainable social development



# Target during IBI 21

## Create global growth drivers and maximize Value

**No. of late stage  
development  
pipeline\***

**28**  
(including additional indication)


\*Projects under development / launched products which already demonstrated PoC

**Aiming to bring middle molecule projects into the clinical phase, and continuously develop innovative novel antibody engineering technologies**

# Value brought to Roche/Chugai by PHC 2.0




**Smarter more  
efficient R&D**




0101  
1000  
0101  
1101  
1011

**Deep Scientific  
Insight**



**Better, earlier Go  
/ No go decision**




**Faster won by  
efficient trials**



**Improve  
access & PHC**



**Better patient Tx  
matching**



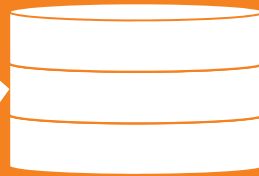
**Enhanced physician  
Tx decision**



**RWD to improve  
access based on  
Value**

**Clinical Data**

**Genome information**



**Clinical genome  
information DB which  
satisfy the requirements  
of regulatory filing**

# Design of FoundationOne CDx Report



**FOUNDATIONONE CDx™**

PATIENT: Jane Sample

TUMOR TYPE: Lung adenocarcinoma

TRF#: TRFXXXXXX

**PATIENT**  
DISEASE: Lung adenocarcinoma  
NAME: Not Given  
DATE OF BIRTH: Not Given  
SEX: Female  
MEDICAL RECORD #: Not Given

**PHYSICIAN**  
ORDERING PHYSICIAN: Not Given  
MEDICAL FACILITY: Not Given  
ADDITIONAL RECIPIENT: Not Given  
MEDICAL FACILITY ID: Not Given  
PATHOLOGIST: Not Given

**SPECIMEN**  
SPECIMEN SITE: Not Given  
SPECIMEN ID: Not Given  
SPECIMEN TYPE: Not Given  
DATE OF COLLECTION: Not Given  
SPECIMEN RECEIVED: Not Given

**CDx Associated Findings**

GENOMIC FINDINGS DETECTED	FDA-APPROVED THERAPEUTIC OPTIONS
EGFR L858R	Gilotrif® (Afatinib) Iressa® (Gefitinib) Tarceva® (Erlotinib)

**OTHER ALTERATIONS & BIOMARKERS IDENTIFIED**  
Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See professional services section for additional information.

Microsatellite Status: MS-Stable<sup>§</sup>  
Tumor Mutation Burden: 11 Muts/Mb<sup>§</sup>  
CDKN2A/B loss<sup>§</sup>  
EGFR amplification<sup>§</sup>

PTCH1 T416S  
RBM10 Q494\*  
TP53 R267P

§ Refer to appendix for limitation statements related to detection of any copy number alterations, gene rearrangements, MSI or TMB result in this section.  
Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

**BIOMARKER FINDINGS**

Tumor Mutation Burden - TMB-Intermediate (11 Muts/Mb)

9 Trials: see p.14

Microsatellite status = MS-Stable

**GENOMIC FINDINGS**

EGFR - amplification, L858R

4 Trials: see p.15

PTCH1 - T416S

**THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)**

Atezolizumab
Nivolumab
Pembrolizumab

**THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)**

Avelumab
Durvalumab

No therapies or clinical trials, see Biomarker Findings section.

**THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)**

Afatinib
Erlotinib
Gefitinib
Osimertinib
none

**THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)**

Cetuximab
Lapatinib
Panitumumab
Sonidegib

Background information of Patient, Physician etc.

Summary of detected mutations

- Approval status of corresponding targeted therapies
- Ongoing clinical trials of detected mutations

Summary of references on detected mutations and candidates of therapy



# Projects under Development (1) (as of January 31, 2019)

	Phase I	Phase II	Phase III		Filed
Oncology	<b>CKI27</b> - solid tumors	<b>RG6268 / entrectinib</b> - NSCLC	<b>RG3502 / Kadcyla</b> - breast cancer (adjuvant)	<b>AF802 (RG7853) / Alecensa</b> - NSCLC (adjuvant)	<b>RG7446 / Tecentriq</b> - breast cancer ★ - SCLC ★
	<b>GC33 (RG7686) / codrituzumab</b> - HCC★		<b>RG435 / Avastin</b> - RCC - HCC	<b>RG7446 / Tecentriq</b> - NSCLC (adjuvant) - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - early breast cancer - ovarian cancer - prostate cancer - HCC - HNC (adjuvant)	<b>RG6268 / entrectinib</b> - solid tumors ★
	<b>ERY974</b> - solid tumors		<b>RG7440 / ipatasertib</b> - prostate cancer - breast cancer		
	<b>RG7421 / cobimetinib</b> - solid tumors		<b>RG7596 / polatuzumab vedotin</b> - DLBCL		
	<b>RG7802 / cibisatamab</b> - solid tumors		<b>RG6264</b> - breast cancer (Fixed-dose combination, subcutaneous injection)		
	<b>RG7828 / mosunetuzumab</b> - hematologic tumors				
Bone & Joint			<b>NRD101 / Suvenyl (China)</b> - knee osteoarthritis /shoulder periarthritis		<b>ED-71 / Edirol (China)</b> - osteoporosis
Renal	<b>EOS789</b> - 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 October 24, 2018

★: Multinational study managed by Chugai



## Projects under Development (2) (as of January 31, 2019)

	Phase I	Phase II	Phase III	Filed
Autoimmune	<b>RG7845 / fenebrutinib</b> - rheumatoid arthritis		<b>MRA (RG1569) / Actemra</b> - systemic sclerosis	
Neurology	<b>RG7935 / prasinezumab</b> - Parkinson's disease <b>GYM329 (RG6237)</b> - neuromuscular disease <b>RG7906</b> - psychiatric disorders★	<b>RG7916 / risdiplam</b> - spinal muscular atrophy	<b>RG1450 / gantenerumab</b> - Alzheimer's disease <b>RG7412 / crenezumab</b> - Alzheimer's disease <b>SA237 (RG6168) / satralizumab</b> - NMOSD ★ <b>RG6206</b> - DMD (PII/III)	
Others	<b>PCO371</b> - hypoparathyroidism <b>RG7716 / faricimab</b> - wAMD <b>AMY109</b> - endometriosis	<b>CIM331 / nemolizumab*</b> - pruritus in dialysis patients <b>SKY59 (RG6107)</b> - paroxysmal nocturnal hemoglobinuria (PI/II)	<b>RG7716 / faricimab</b> - DME	<b>ACE910 (RG6013) / Hemlibra (EU)</b> - 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

NMOSD: neuromyelitis optica spectrum disorder

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

**Letters in orange:** in-house projects

★: Projects with advances in stages since October 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 adults and children with hemophilia A without factor VIII inhibitors, administered once weekly, every two weeks, or every four weeks. \*

Approved in December 2018 (Japan)

Filed in January 2019 (Taiwan)

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A with factor VIII inhibitors, administered once weekly.

Approved in December 2018 (Taiwan)

\* Additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with factor VIII inhibitors are also included.



# Development Status (2)

In-  
licensed

## **RG7446 / Tecentriq®**

- Previously untreated unresectable advanced or recurrent non-squamous NSCLC (combination with Avastin and chemotherapy)
  - Approved in December 2018
- SCLC (1L)
  - Filed and designated as an Orphan drug in December 2018
- Triple negative breast cancer (1L)
  - Filed in December 2018
- HER2 positive early breast cancer (neoadjuvant)  
(combination with Herceptin and Perjeta)
  - Started global Phase 3 study (IMpassion050) in January 2019

In-  
licensed

## **RG6268 / entrectiniab**

*NTRK* fusion positive solid tumors

Filed and designated as an Orphan drug in December 2018

In-  
licensed

## **RG7906**

Psychiatric disorders

Started Phase 1 study in January 2019





# Other Progress

FMI  
business

## FoundationOne<sup>®</sup> CDx / Cancer Genomic profile

- Gene mutation analysis program for solid tumors  
(for use in cancer genome profiling)  
Somatic gene mutation analysis program (for use in assessing anticancer drug indications)
  - Approved in December 2018
- Expanded use as companion diagnostic for entrectinib
  - Filed in January 2019

In-  
house

## SA237 / satralizumab NMO / NMOSD

Breakthrough Therapy Designation by the U.S. FDA in  
December 2018

# Results of Clinical Trials / Conference (1)

In-house

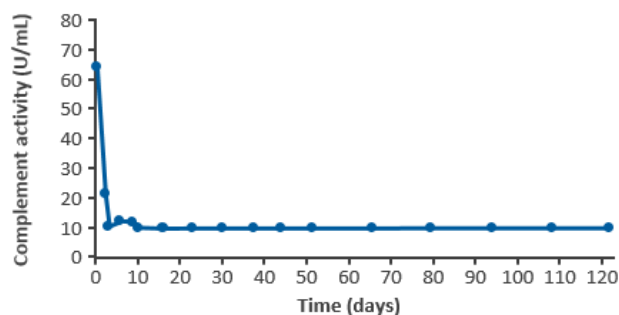
## SKY59 (RG6107)

### Paroxysmal Nocturnal Hemoglobinuria (PNH)

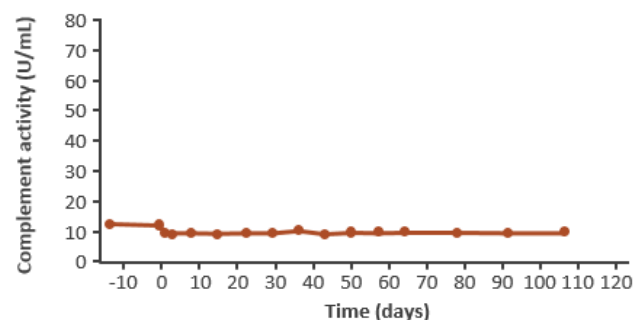
Interim analysis data of Phase 1/2 study in patient subjects presented at the American Society of Hematology (ASH) in December 2018

- Complete complement inhibition was achieved for all PNH patients treated with SKY59 and good control of intravascular hemolysis was shown
- SKY59 was well tolerated and no severe adverse events were observed

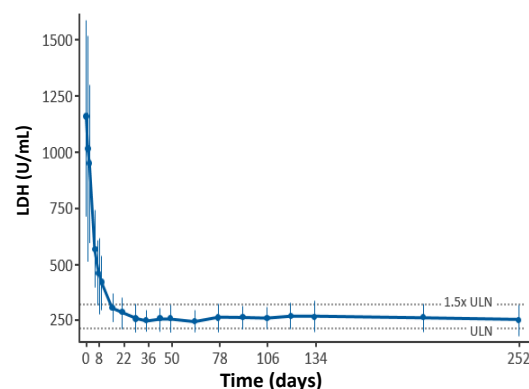
Mean Terminal Complement Activity (LIA assay)



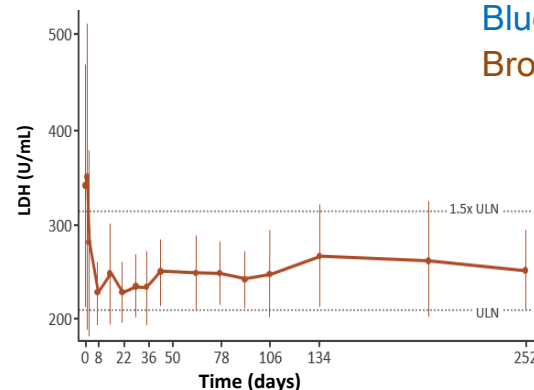
Mean Terminal Complement Activity (LIA assay)



Mean LDH Levels



Mean LDH Levels



Blue : Treatment naïve PNH patients  
Brown : ECU pre-treated PNH patients switched to SKY59

LIA : Liposome Immuno Assay  
LDH: lactate dehydrogenase  
ECU: Eculizumab

# Results of Clinical Trials / Conference (2)



In-house

## **SA237 / satralizumab** NMOSD

Primary end point was met in SAKuraStar study (Phase 3) in December 2018

- Satralizumab routine administration statistically reduced the risk of relapse as primary endpoint compared to placebo

In-house

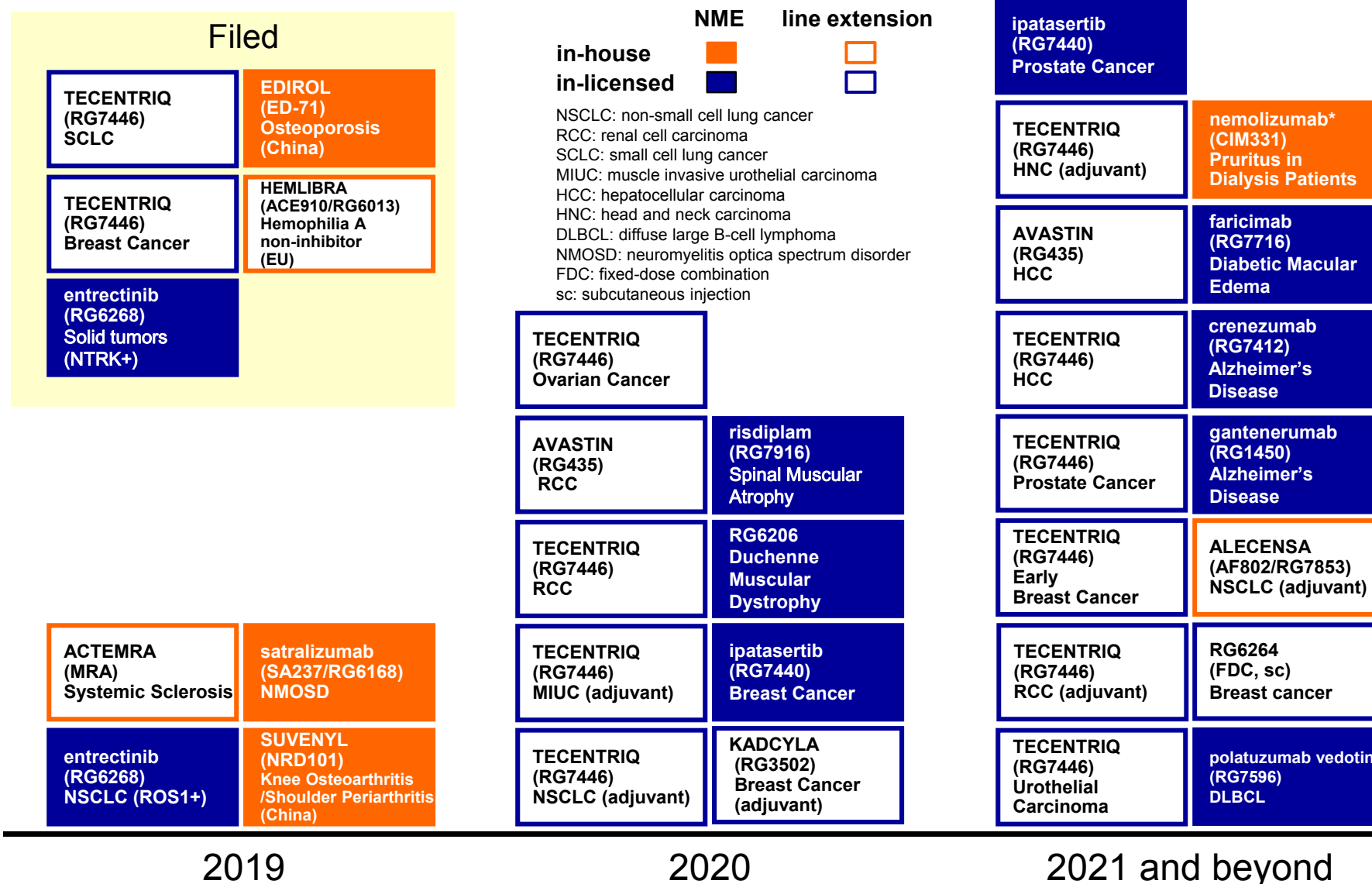
## **CIM331 / nemolizumab** Atopic dermatitis

Primary end point was met in Phase 2b study conducted by Galderma in October 2018

- Nemolizumab improved Eczema Area and Severity Index (EASI) scores from baseline compared to placebo



# Projected Submissions (Post PoC NMEs and Products) as of January 31, 2019



\*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

- 1<sup>st</sup> round requests: all approved (ten indications, including additional dosages and administrations of eight products)
- 2<sup>nd</sup> round requests: all approved (three indications of three products)
- 3<sup>rd</sup> 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

- 4<sup>th</sup> round requests: requests were made for **four** indications of **four** 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
<b>Neutrogin®</b>	<b>Combination treatment with chemotherapy including fludarabine for relapsed/refractory AML</b>	<b>Submitted company opinion and waiting for evaluation by the committee</b>

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