

# **Aiming to Achieve Mid-term Business Plan “IBI 18” - 2017 Results and 2018 Outlook -**

CHUGAI PHARMACEUTICAL CO., LTD.  
President, COO  
Tatsuro Kosaka

February 1/2, 2018

# Forward-Looking Statements

Innovation all for the patients



Roche A member of the Roche group

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

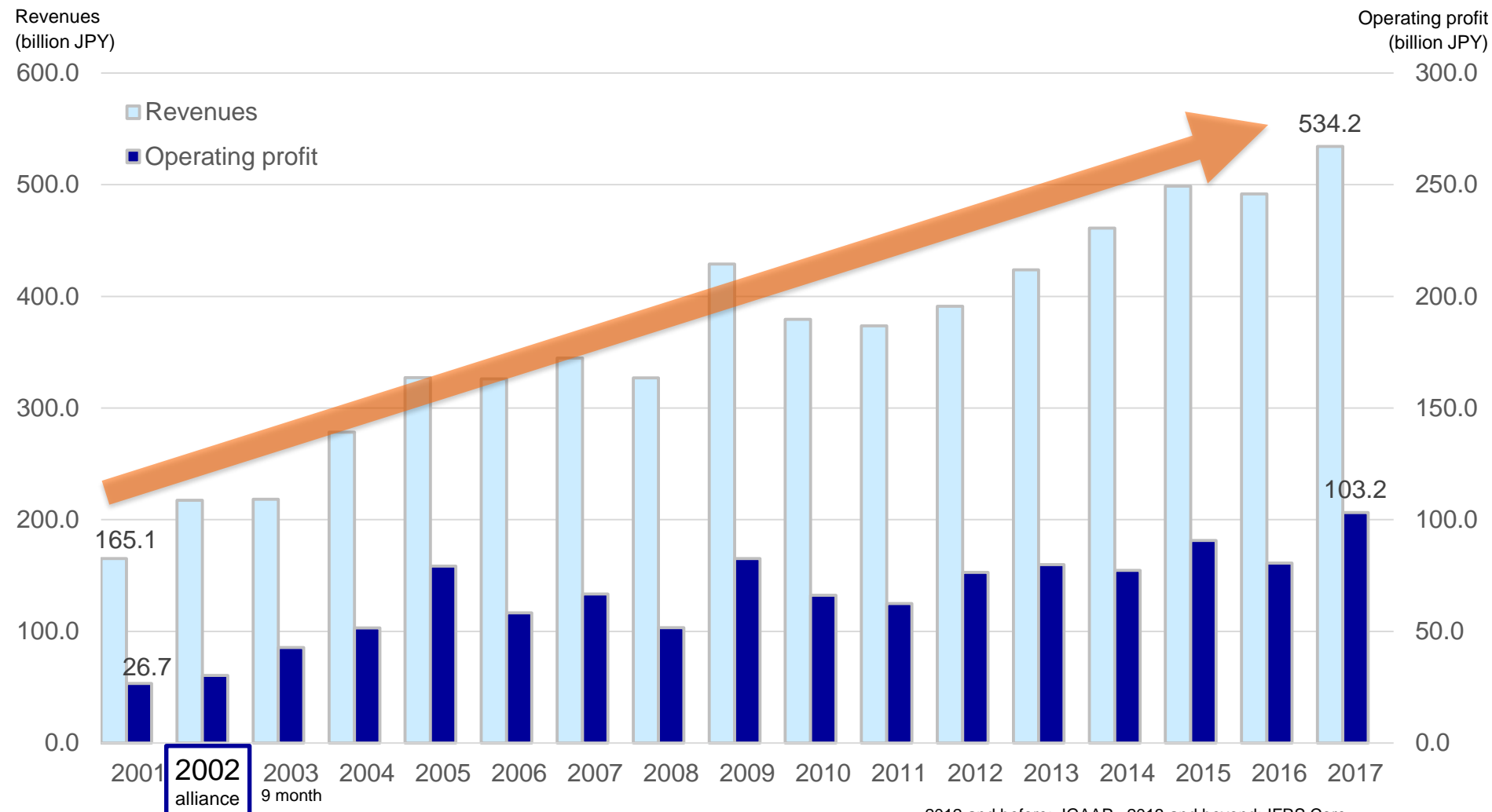
# 2017 Results

Achieved record-high revenues and operating profit  
in the 15th anniversary year of the Strategic Alliance with Roche

Innovation all for the patients



Roche A member of the Roche group



2012 and before: JGAAP, 2013 and beyond: IFRS Core  
Revenues excluding OTC and diagnostics



# 2017 Financial Performance

Strong growth in revenues and operating profit mainly due to increase in exports/ROOI driven by global expansion of Alecensa and Actemra

billions JPY	2016 Jan -Dec actual	2017 Jan - Dec actual	Growth		2017 Jan - Dec forecast	achiev. (%)
<b>Revenues</b>	<b>491.8</b>	<b>534.2</b>	<b>+42.4</b>	<b>+8.6%</b>	<b>520.5</b>	<b>102.6%</b>
Sales	472.7	499.3	+26.6	+5.6%	490.4	101.8%
excl. Tamiflu	459.2	482.4	+23.2	+5.1%	482.2	100.0%
Domestic	379.7	388.4	+8.7	+2.3%	393.9	98.6%
Overseas	79.5	94.0	+14.5	+18.2%	88.4	106.3%
Tamiflu	13.5	16.9	+3.4	+25.2%	8.2	206.1%
Royalties and other operating income (ROOI)	19.1	34.9	+15.8	+82.7%	30.0	116.3%
<b>Core Operating Profit</b>	<b>80.6</b>	<b>103.2</b>	<b>+22.6</b>	<b>+28.0%</b>	<b>92.0</b>	<b>112.2%</b>
<b>Core EPS (yen)</b>	<b>102.50</b>	<b>138.68</b>	<b>+36.18</b>	<b>+35.3%</b>	<b>124.11</b>	<b>111.7%</b>



# Achievements in 2017

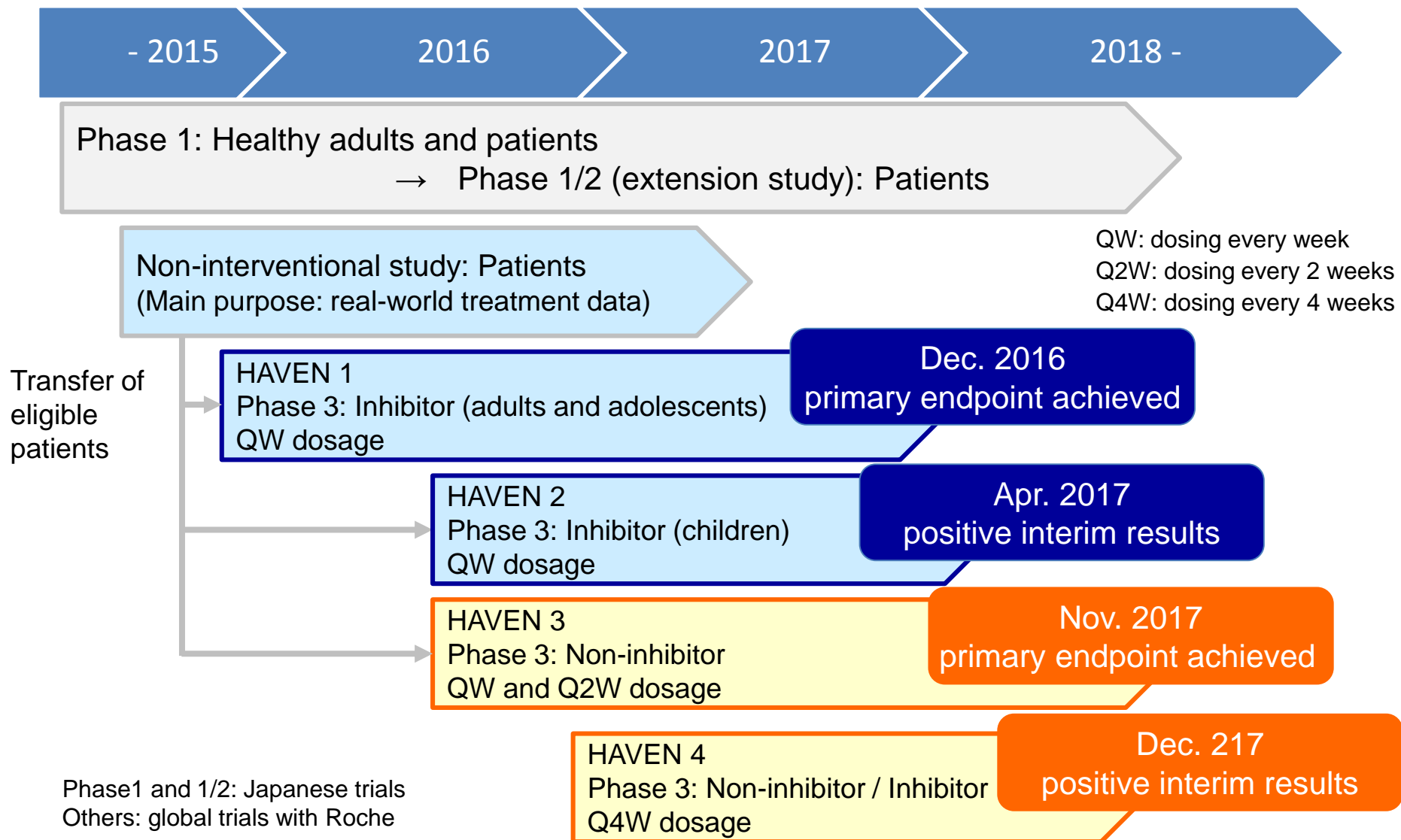
- emicizumab: US approval/launch for HA with inhibitors to FVIII
- Alecensa: EU launch, 1<sup>st</sup> line NSCLC approval in EU and US
- Regulatory filing for five projects
  - emicizumab (US/EU/Japan simultaneous filing for HA with inhibitors)
  - Alecensa (1<sup>st</sup> line NSCLC in EU/US), Tecentriq (2<sup>nd</sup> line NSCLC)
  - obinutuzumab (follicular lymphoma), Perjeta (adjuvant breast cancer)
- Established a new system to provide solutions initiated through collaboration of three divisions
- Divestment of 13 long-term listed products

HA: hemophilia A  
NSCLC: non-small cell lung cancer

**Steady progress in key subjects towards  
the final year of IBI 18**



# Emicizumab: Clinical Data to Support Global Rollout





# Priority Agenda of IBI 18

- ✓ Acquisition and implementation of competitiveness at a top global level
- ✓ Selection and Concentration strategy for acceleration of growth

## Drug Discovery

- Continuous creation of engineered antibody projects
- Establishment of drug discovery technologies for middle molecules
- Research base for oncology/immunology

## Development

- emicizumab, atezolizumab
- Realization of early PoC with TCR
- Proof process for medical/economic value

## Pharmaceutical Technology

- Enhancement of CMC development infrastructure for early PoC acquisition
- Strengthening competitive advantages from late development to initial commercial production
- QA, QC and Regulatory functions

## Sales/Medical Affaires/Safety

- Growth driver products, emicizumab, atezolizumab
- Providing advanced solutions through a cross-functional system
- Establishment of system adapted to local characteristics

## Whole Company

- Acquisition, development and assignment of global top-class talents to lead value creation activities through innovation

● Expansion of achievements through selection and concentration utilizing competitive advantage

● Strengthening competitive foundation for global top-class level



# Progress of IBI 18

- Cutting-edge immunology research in comprehensive collaboration with IFReC
- Initiated clinical trials for two in-house engineered antibody projects
- Advancement in middle-molecule drug discovery research

## Drug Discovery

- Emicizumab trilateral regulatory filing (US, EU and Japan) and US approval
- Progress of atezolizumab development in multiple cancer types and approval in 2<sup>nd</sup> line NSCLC

## Development

## Pharmaceutical Technology

- Progress in construction of high-mix low-volume production site for antibody API
- Completion of FDA pre-license inspection for emicizumab and enhancement of QC, QA, regulatory system for global supply

## Sales/Medical Affaires/Safety

- Established a new system for providing solutions initiated through collaboration of three divisions
- Area strategy scheme to meet diverse regional medical needs

**Established foundation to acquire and implement competitiveness at a top global level**





# 2018 Outlook

Final year of "IBI 18"

Deliver expanded achievements as a culmination of three years

Core EPS CAGR\* (2015-18) forecast: **9.5%**

billion JPY	2017	2018	Growth	
	Jan - Dec actual	Jan - Dec forecast		
<b>Revenues</b>	<b>534.2</b>	<b>541.5</b>	<b>+7.3</b>	<b>+1.4%</b>
Sales	499.3	498.5	-0.8	-0.2%
excl. Tamiflu	482.4	492.9	+10.5	+2.2%
Domestic	388.4	374.8	-13.6	-3.5%
Overseas	94.0	118.1	+24.1	+25.6%
Tamiflu	16.9	5.6	-11.3	-66.9%
Royalties and other operating income (ROOI)	34.9	43.0	+8.1	+23.2%
<b>Core Operating Profit</b>	<b>103.2</b>	<b>108.0</b>	<b>+4.8</b>	<b>+4.7%</b>
<b>Core EPS (yen)</b>	<b>138.68</b>	<b>147.00</b>	<b>+8.32</b>	<b>+6.0%</b>

\* CAGR: compound annual growth rate (%). Based on an constant average exchange rate for 2015



# Priority Agenda for 2018

## Continuous creation of innovative engineered antibody projects and establishing the drug creation technology of middle molecule

- Initiated clinical trials for two antibody projects: 2018-2019
- Further progress in middle molecule drug discovery: select clinical drug candidate by the end of IBI 18

## Secure development of growth-driver projects

- Regulatory filing for seven projects
  - emicizumab: hemophilia A without inhibitor (Japan, US, EU)
  - Tecentriq: three line extensions (RCC, BC, 1<sup>st</sup> line NSCLC)
  - Actemra (systemic sclerosis), Avastin (RCC), Ediol (osteoporosis [China])

## Strengthen the system for providing solutions and secure market penetration of new products

- Fastest product value maximization of four new products (Tecentriq, Alaglio, emicizumab, obinutuzumab) and Perjeta line extension (adjuvant BC)
- Emicizumab co-promotion in Europe
- FMI collaboration: contribute to PHC with cancer genomic medicine as the No.1 company in Oncology



# Tecentriq Launch and Immuno-Oncology Projects

Immune checkpoint inhibitor

日本標準商品分類番号 874291

抗癌性腫瘍剤／抗PD-L1<sup>注1</sup>ヒト化モノクローナル抗体  
生物由来製品、創薬、処方箋医薬品<sup>注2</sup>

**テセントリク®** 点滴静注 1200mg

**TECENTRIQ®**  
atezolizumab

アテゾリズマブ（遺伝子組換え）注  
注1 PD-L1 (Programmed Death-Ligand 1)  
注2 注1は第一相試験等の臨床試験にのみ使用すること

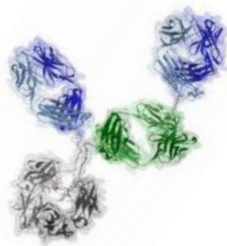
※効能・効果、用法・用量、警告・禁忌を含む使用上の注意、効能・効果に関連する使用上の注意、用法・用量に関連する使用上の注意等は製品添付文書をご参照ください。  
※F, ホフマン・ラ・ロシュ社（スイス）登録商標

- Approved for NSCLC (2nd line) in Jan. 2018
- Extension of overall survival was confirmed across patient groups regardless of PD-L1 progression in 2<sup>nd</sup> and 3<sup>rd</sup> line NSCLC (OAK study)
- Seven trials ongoing in lung cancer with different patient groups/combination therapies; eight trials ongoing in different cancer types



Anti-glypican 3 (GPC3)/  
CD3 bispecific antibody  
**ERY974**

- Created by utilizing Chugai's proprietary antibody engineering technology [TRAB]
- Designed to redirect T cells to tumor cells by bivalently binding to CD3 on T cells and GPC3 on tumor cells, and active T cells to kill tumor cells
- Overseas P1 study is being conducted by Chugai



Anti-CEA/CD3  
bispecific antibody  
(CEA-TCB)  
**RG7802**

- Bispecific antibody in 2:1 format, in-licensed from Roche
- Designed to simultaneously bind to CEA with two arms and CD3 with one arm to trigger T cell migration, activation and antitumor effect
- Chugai decided to conduct development in Japan



# Governmental Activities in Genomic Medicine and the FMI Collaboration

Government

Chugai

Genomic medicine  
promotion council

Taskforce to promote  
medical and other use of  
genomic information

2015

The 3<sup>rd</sup> Phase  
Basic Plan to Promote  
Cancer Control  
Programs

2016

2017

Stated practical use of "gene panel testing"  
for cancer

- regulatory approval and the NHI coverage by the end of 2018 (Report of Cancer Genomic Medicine Promotion Consortium Council)

2018

Establish framework for the FMI collaboration

**Preparation for  
FMI collaboration**



# Contribute to Oncology through the FMI Collaboration

Committed to advance PHC with innovative medical products and services as the No.1 company in Oncology

**Improve patient access to appropriate treatment**

Accelerate drug development based on genetic information

Ultimate consulting promotion  
Synergy with pharmaceutical business

**New "Subscription Business" to provide highly precise information service**

Companion diagnostics

Complementary diagnostics with BM through gene profiling

**Next generation sequencer detects 324 cancer related genes**

BM: biomarker

# **FY2017 Consolidated Financial Overview (IFRS based)**

CHUGAI PHARMACEUTICAL CO., LTD.  
Executive Vice President, CFO  
Yoshio Itaya

February 1/2, 2018



# Full Year Results Summary

## ■ Revenues: 534.2 billion yen (+42.4, +8.6% YoY)

- Domestic sales excl. Tamiflu: increase as growth of mainstay products exceeded impact of HIP revision (+8.7, +2.3%)
- Overseas sales: growth of Alecensa export to Roche, etc. (+14.5, +18.2%)
- Royalties and other operating income: increase in milestone income (+15.8, +82.7%)

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

- Cost of sales: the ratio to sales improved due to change in product mix, etc. (-1.5% points, from 52.2% to 50.7%)
- Operating expenses: increase in marketing and distribution expenses, research and development expenses, and general and administration expenses, etc. (-13.6, +8.3%)

## ■ Profits

- IFRS results: operating profit 98.9 billion yen (+22.0, +28.6%)  
net income 73.5 billion yen (+19.1, +35.1%)
- Core results: operating profit 103.2 billion yen (+22.6, +28.0%)  
net income 76.7 billion yen (+19.9, +35.0%)
- Core EPS (JPY): 138.68 (+36.18, +35.3%)



# IFRS and Core Results Jan - Dec

(Billions of JPY)

## Non-Core items

Intangible assets:

Amortization of intangible assets +1.3

Impairment +4.0

Others

Legal income and expenses -1.0

Core net income

attributable to Chugai  
shareholders

75.9

(Millions of shares)

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

547

(JPY)

Core EPS

138.68

(Billion JPY)	IFRS results	Non-core items		Core results
	2017 Jan. - Dec.	Intangible assets	Others	2017 Jan. - Dec.
<b>Revenues</b>	<b>534.2</b>			<b>534.2</b>
Sales	499.3			499.3
Royalties and other operating income	34.9			34.9
Cost of sales	-254.2	+1.2		-252.9
<b>Gross profit</b>	<b>280.0</b>	<b>+1.2</b>		<b>281.3</b>
<b>Operating expenses</b>	<b>-181.1</b>	<b>+4.0</b>	<b>-1.0</b>	<b>-178.1</b>
Marketing and distribution	-72.8			-72.8
Research and development	-92.9	+4.0		-88.9
General and administration	-15.3		-1.0	-16.3
<b>Operating profit</b>	<b>98.9</b>	<b>+5.3</b>	<b>-1.0</b>	<b>103.2</b>
Financing costs	-0.1			-0.1
Other financial income (expense)	-0.1			-0.1
Other expenses	-1.7			-1.7
<b>Profit before taxes</b>	<b>97.0</b>	<b>+5.3</b>	<b>-1.0</b>	<b>101.3</b>
Income taxes	-23.5	-1.4	+0.3	-24.5
<b>Net income</b>	<b>73.5</b>	<b>+3.9</b>	<b>-0.7</b>	<b>76.7</b>
Chugai shareholders	72.7	+3.9	-0.7	75.9
Non-controlling interests	0.8			0.8



## Year on Year (Core)

## FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

# Financial Overview Jan - Dec

(Billions of JPY)	2016		2017		Growth	
	Jan - Dec	vs. Revenues	Jan - Dec	vs. Revenues		
<b>Revenues</b>	<b>491.8</b>		<b>534.2</b>		<b>+42.4</b>	<b>+8.6%</b>
Sales	472.7		499.3		+26.6	+5.6%
excl. Tamiflu	459.2		482.4		+23.2	+5.1%
Domestic	379.7		388.4		+8.7	+2.3%
Export to Roche	62.8		76.4		+13.6	+21.7%
Other overseas	16.8		17.7		+0.9	+5.4%
Tamiflu	13.5		16.9		+3.4	+25.2%
Ordinary	12.0		11.9		-0.1	-0.8%
Govt. stockpiles, etc.	1.5		5.0		+3.5	+233.3%
Royalties and other operating income	19.1		34.9		+15.8	+82.7%
Cost of sales	-246.7	50.2%	-252.9	47.3%	-6.2	+2.5%
<b>Gross profit</b>	<b>245.0</b>	<b>49.8%</b>	<b>281.3</b>	<b>52.7%</b>	<b>+36.3</b>	<b>+14.8%</b>
Operating expenses	-164.5	33.4%	-178.1	33.3%	-13.6	+8.3%
<b>Operating profit</b>	<b>80.6</b>	<b>16.4%</b>	<b>103.2</b>	<b>19.3%</b>	<b>+22.6</b>	<b>+28.0%</b>
Financing costs	-0.1		-0.1		0.0	0.0%
Other financial income (expense)	1.1		-0.1		-1.2	-
Other Expenses	-3.5		-1.7		+1.8	-51.4%
Income taxes	-21.3		-24.5		-3.2	+15.0%
<b>Net income</b>	<b>56.8</b>	<b>11.5%</b>	<b>76.7</b>	<b>14.4%</b>	<b>+19.9</b>	<b>+35.0%</b>
EPS (JPY)	102.50		138.68		+36.18	+35.3%

(Billions of JPY)

Royalties and other operating income	+15.8
Increase in milestone income	
Other financial income (expense)	-1.2
Exchange gains/losses	-0.3
Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts)	+0.4
Gain on sales of securities for investment (previous year), etc.	-1.3
Other Expenses	+1.8
Settlement for transfer pricing taxation	

## Cost of sales ratio vs. Sales

2016 Jan - Dec	2017 Jan - Dec
52.2%	50.7%

## Market average exchange rate (JPY)

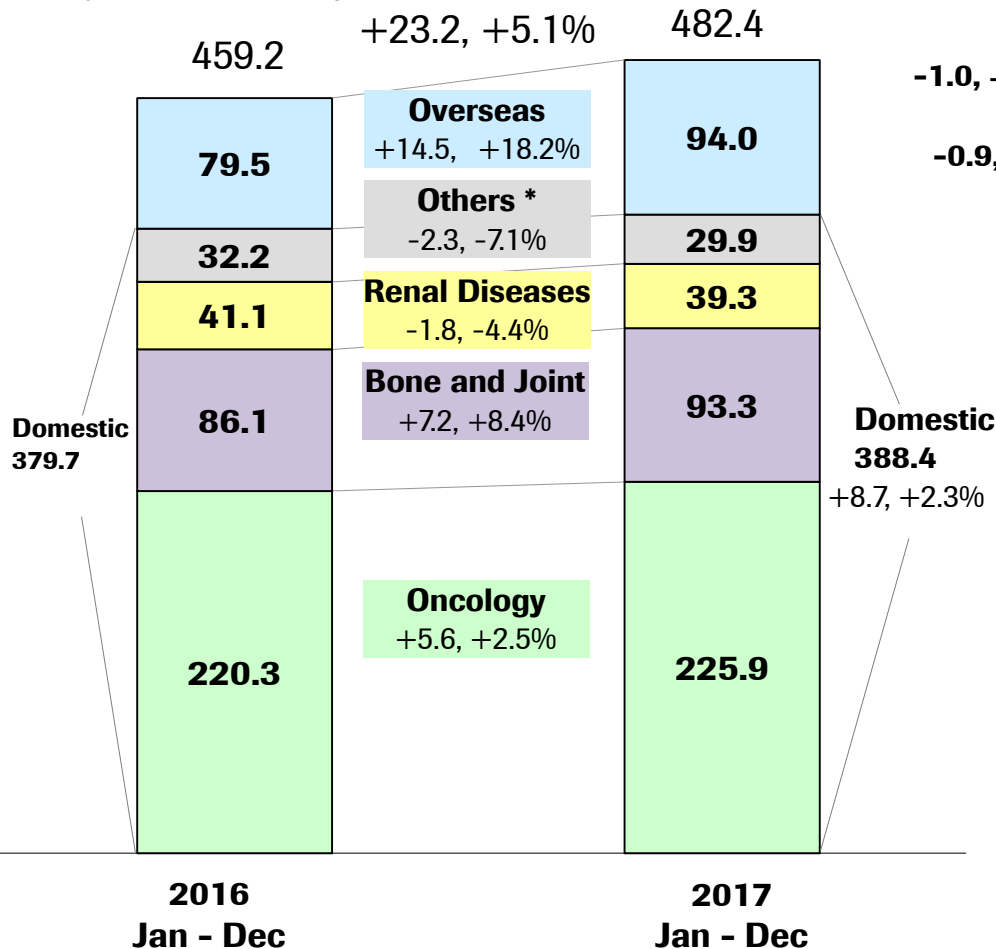
	2016 Jan - Dec	2017 Jan - Dec
1 CHF	110.46	113.90
1 EUR	120.42	126.39
1 USD	108.83	112.17
1 SGD	78.82	81.22

## Year on Year

## Sales (excl. Tamiflu) Jan - Dec

Sales by Disease Area,  
Year on Year Comparisons

(Billions of JPY)

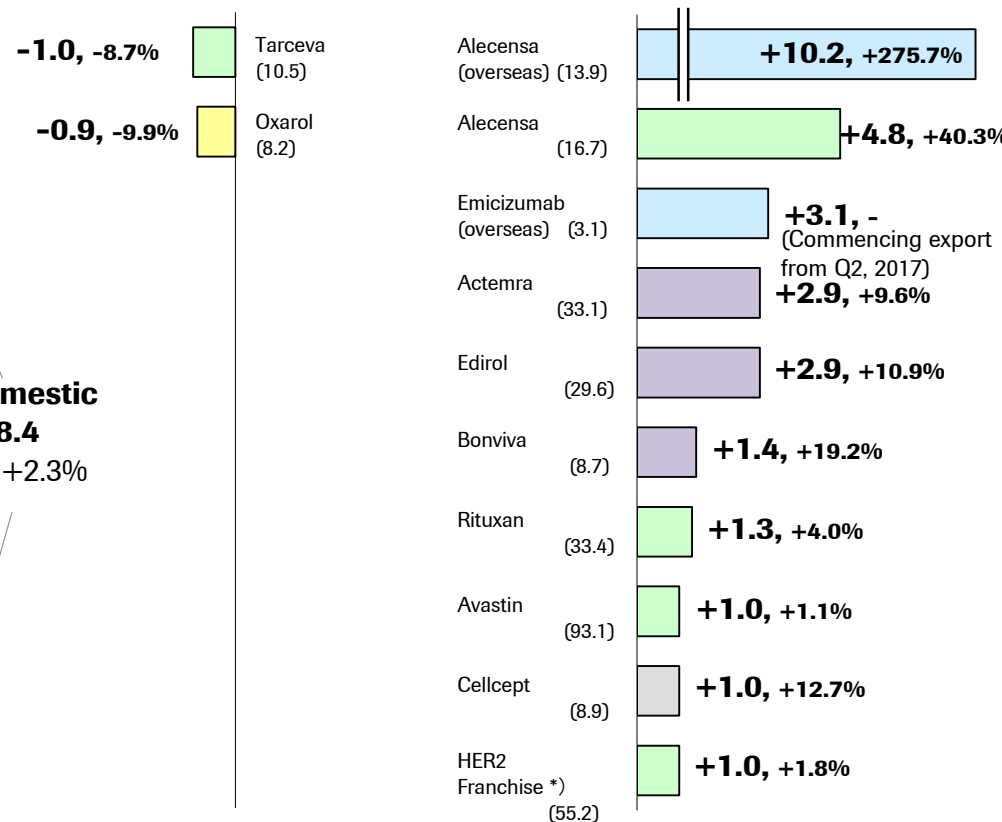
Sales by Products,  
Year on Year Changes

FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group



\*) Details of HER2 franchise

Herceptin (33.6)	-0.5, -1.5%
Perjeta (13.6)	+1.7, +14.3%
Kadcyla (8.0)	-0.3, -3.6%

(): Actual sales in FY2017

%: Year-on-year percentage change

\*Sales in transplant, immunology and infectious diseases area, which was disclosed separately until the end of FY2016, has been included in "Others" from FY2017 1Q results.



# Tamiflu Sales Trends

(Billions of JPY)	Fiscal Term Sales												Season	
	FY2012		FY2013		FY2014		FY2015		FY2016		FY2017		(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	7.8												2011	<b>9.1</b>
		2.4	8.2										2012	<b>10.6</b>
				1.9	7.0								2013	<b>9.0</b>
						5.8	6.7						2014	<b>12.6</b>
								1.5	7.3				2015	<b>8.7</b>
										4.7	6.3		2016	<b>11.0</b>
												5.6	2017	<b>-</b>
	<b>10.2</b>	<b>(+4.8)</b>	<b>10.1</b>	<b>(-0.1)</b>	<b>12.9</b>	<b>(+2.8)</b>	<b>8.2</b>	<b>(-4.7)</b>	<b>12.0</b>	<b>(+3.8)</b>	<b>11.9</b>	<b>(-0.1)</b>		
Govt. Stockpiles etc.	0.4	1.5	0.8	0.1	0.1	0.1	0.0	0.0	0.0	1.5	1.9	3.1		
	<b>1.9</b>	<b>(-1.4)</b>	<b>0.9</b>	<b>(-1.0)</b>	<b>0.2</b>	<b>(-0.7)</b>	<b>0.0</b>	<b>(-0.2)</b>	<b>1.5</b>	<b>(+1.5)</b>	<b>5.0</b>	<b>(+3.5)</b>		
Total	<b>8.1</b>	<b>3.9</b>	<b>9.0</b>	<b>2.0</b>	<b>7.1</b>	<b>5.9</b>	<b>6.7</b>	<b>1.5</b>	<b>7.3</b>	<b>6.2</b>	<b>8.2</b>	<b>8.7</b>		
	<b>12.0</b>	<b>(+3.3)</b>	<b>11.0</b>	<b>(-1.0)</b>	<b>13.0</b>	<b>(+2.0)</b>	<b>8.2</b>	<b>(-4.8)</b>	<b>13.5</b>	<b>(+5.3)</b>	<b>16.9</b>	<b>(+3.4)</b>		

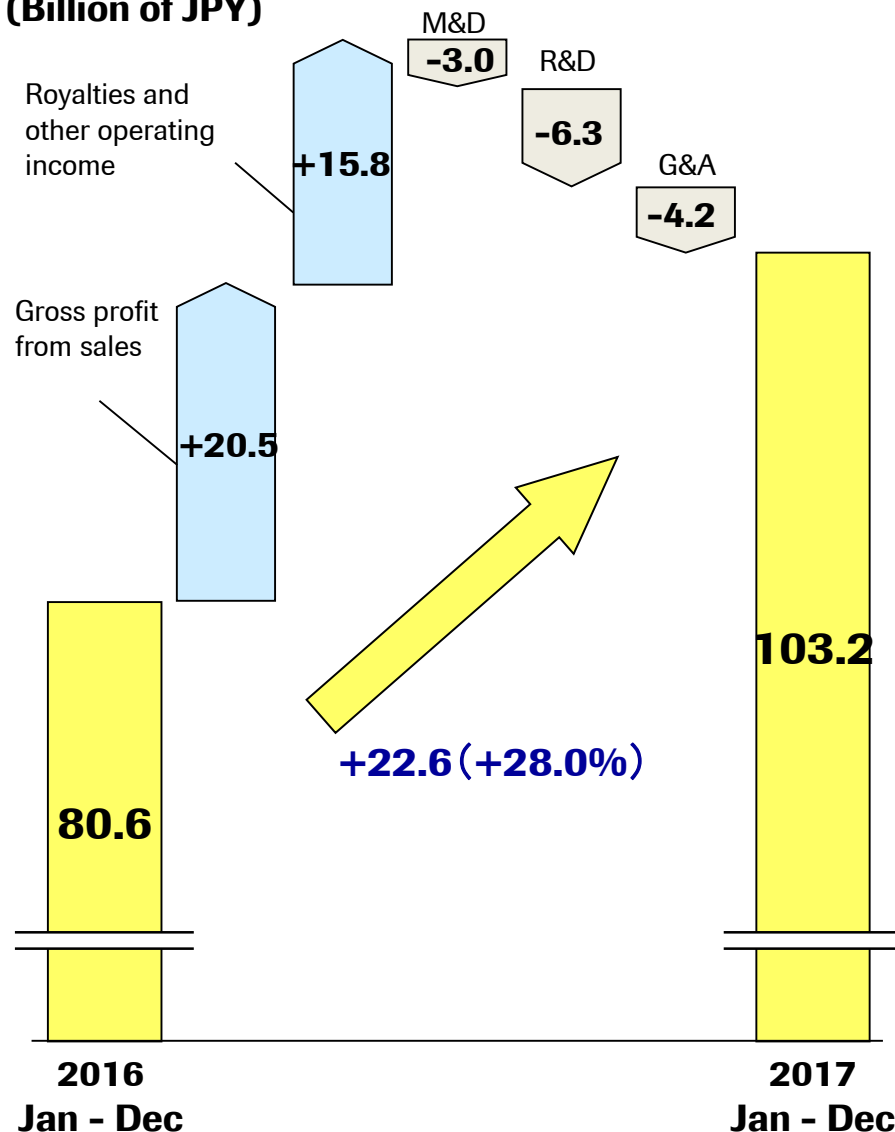
( ) Year on year



## Year on Year (Core)

# Operating Profit Jan - Dec

(Billion of JPY)



(Billions of JPY)	2016 Jan - Dec	2017 Jan - Dec	Growth
<b>Revenues</b>	<b>491.8</b>	<b>534.2</b>	<b>+42.4</b>
Cost of sales	-246.7	-252.9	-6.2
<b>Gross profit</b>	<b>245.0</b>	<b>281.3</b>	<b>+36.3</b>
of which Sales	225.9	246.4	+20.5
Royalties, etc.	19.1	34.9	+15.8
Marketing and distribution	-69.8	-72.8	-3.0
Research and development	-82.6	-88.9	-6.3
General and administration	-12.1	-16.3	-4.2
<b>Operating profit</b>	<b>80.6</b>	<b>103.2</b>	<b>+22.6</b>

Increase in gross profit from sales	+20.5
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	+15.8
Increase in marketing and distribution expenses	-3.0
Increase in sales promotion activities, etc.	
Increase in research and development expenses	-6.3
Progress of projects and reclassification of some expenses due to organizational changes, etc.	
Increase in general and administration expenses, etc.	-4.2
Increase in various expenses, including corporate enterprise tax (pro forma standard taxation)	

## Year on Year (Core)

## FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

# Financial Overview Oct - Dec

(Billions of JPY)	2016		2017		Growth	
	Oct - Dec		Oct - Dec			
	vs. Revenues		vs. Revenues			
Revenues	130.3		146.6		+16.3	+12.5%
Sales	125.2		134.5		+9.3	+7.4%
excl. Tamiflu	120.2		127.7		+7.5	+6.2%
Domestic	102.4		107.5		+5.1	+5.0%
Export to Roche	13.6		15.8		+2.2	+16.2%
Other overseas	4.1		4.5		+0.4	+9.8%
Tamiflu	5.0		6.8		+1.8	+36.0%
Ordinary	4.7		5.6		+0.9	+19.1%
Govt. stockpiles, etc.	0.3		1.2		+0.9	+300.0%
Royalties and other operating income	5.1		12.0		+6.9	+135.3%
Cost of sales	-63.8	49.0%	-67.3	45.9%	-3.5	+5.5%
Gross profit	66.5	51.0%	79.2	54.0%	+12.7	+19.1%
Operating expenses	-45.5	34.9%	-54.7	37.3%	-9.2	+20.2%
Operating profit	21.0	16.1%	24.5	16.7%	+3.5	+16.7%
Financing costs	-0.0		-0.0		0.0	0.0%
Other financial income (expense)	0.6		0.1		-0.5	-83.3%
Other Expenses	-3.5		-0.6		+2.9	-82.9%
Income taxes	-5.6		-6.9		-1.3	+23.2%
Net income	12.5	9.6%	17.1	11.7%	+4.6	+36.8%
EPS (JPY)	22.57		30.88		+8.31	+36.8%

Increase in gross profit from sales +5.8

Increase in sales due to growth of  
mainstay products etc. and improvement  
of cost of sales ratio to salesIncrease in royalties and other operating  
income +6.9

Increase in milestone income

Increase in operating expenses -9.2

Increase in marketing and distribution  
Increase in sales promotion activities,  
etc. -3.7Increase in research and development  
Progress of projects, etc. -3.4Increase in general and administration  
Increase in various expenses -2.0

Cost of sales ratio vs. Sales

2016 Oct - Dec	2017 Oct - Dec
51.0%	50.0%

Market average exchange rate for the period  
of Oct - Dec

	2016 Oct - Dec	2017 Oct - Dec
1CHF	109.22	114.41
1EUR	117.91	132.93
1USD	109.30	112.89
1SGD	77.55	83.38

vs. Forecast (Core)

FY2017 Consolidated Financial Overview

Innovation all for the patients



A member of the Roche group

# Financial Overview Jan - Dec

(Billions of JPY)	2017 Jan - Dec		+/-	Achievement
	Forecast	Actual		
<b>Revenues</b>	<b>520.5</b>	<b>534.2</b>	<b>+13.7</b>	<b>102.6%</b>
Sales	490.4	499.3	+8.9	101.8%
excl. Tamiflu	482.2	482.4	+0.2	100.0%
Domestic	393.9	388.4	-5.5	98.6%
Export to Roche *	70.5	76.4	+5.9	108.4%
Other overseas	17.8	17.7	-0.1	99.4%
Tamiflu	8.2	16.9	+8.7	206.1%
Royalties and other operating income	30.0	34.9	+4.9	116.3%
Cost of sales	-252.0	-252.9	-0.9	100.4%
<b>Gross profit</b>	<b>268.5</b>	<b>281.3</b>	<b>+12.8</b>	<b>104.8%</b>
Operating expenses	-176.5	-178.1	-1.6	100.9%
<b>Operating profit</b>	<b>92.0</b>	<b>103.2</b>	<b>+11.2</b>	<b>112.2%</b>
EPS (JPY)	124.11	138.68	+14.57	111.7%

Cost of sales ratio vs. Sales

2017 Jan - Dec Forecast	2017 Jan - Dec Actual
51.4%	50.7%

Exchange rate (JPY)

	2017 Jan - Dec Assumption	2017 Jan - Dec Actual *
1CHF	106.00	113.90
1EUR	122.00	126.39
1USD	115.00	112.17
1SGD	80.00	81.22

\* Including Efficizumab (2017 Jan - Dec Forecast: 3.1, 2017 Jan - Dec Actual: 3.1)

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

## vs. Forecast (Core)

FY2017 Consolidated Financial Overview

Innovation all for the patients

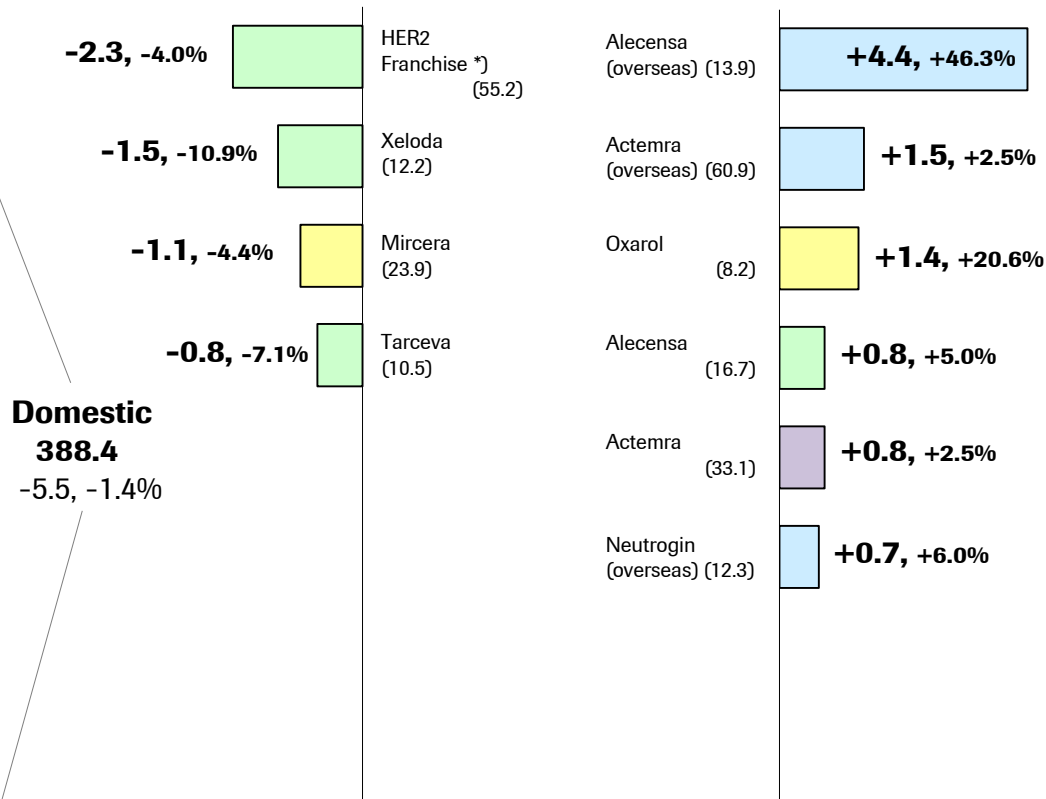
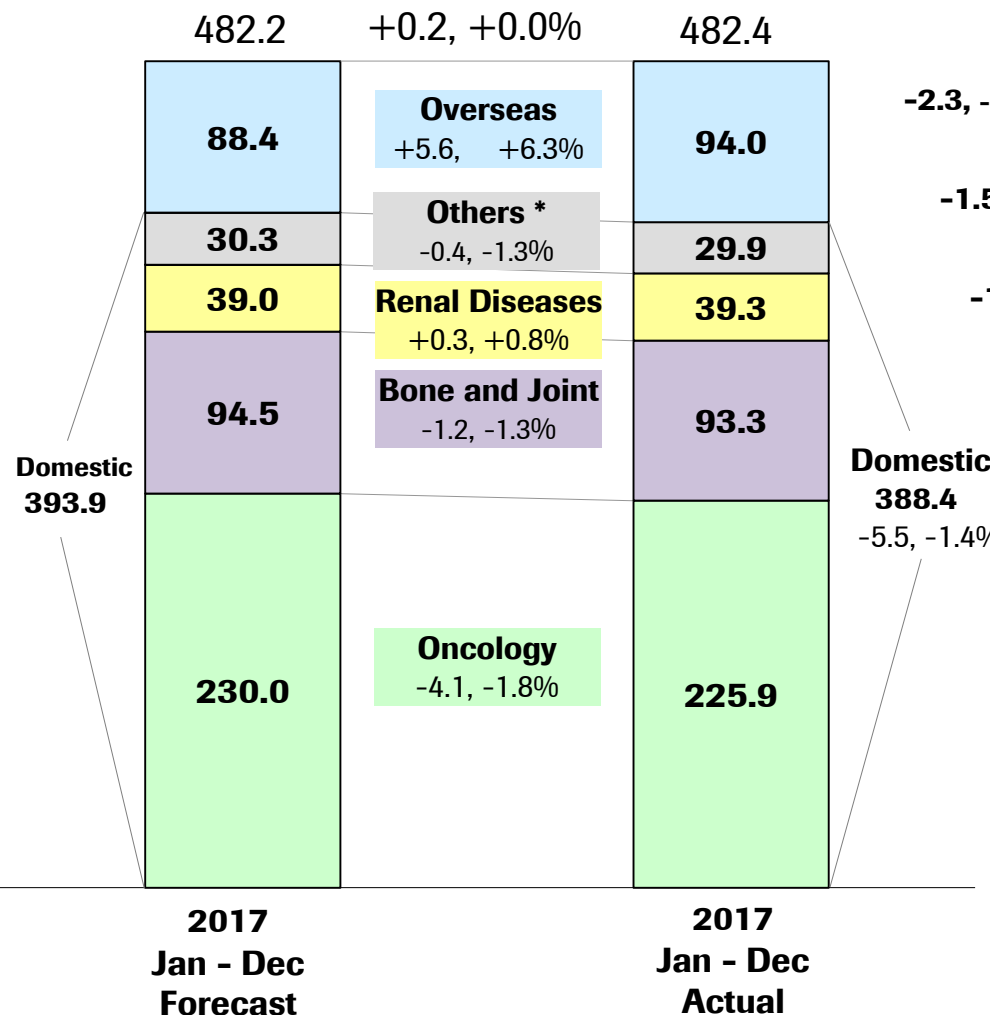


A member of the Roche group

# 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 (33.6)	-1.5, -4.3%
Perjeta (13.6)	+0.7, +5.4%
Kadcyla (8.0)	-1.4, -14.9%

( ): FY2017 Actual  
%: Achievement

\*Sales in transplant, immunology and infectious diseases area, which was disclosed separately until the end of FY2016, has been included in "Others" from FY2017 1Q results.



vs. Forecast (Core)

# Impact from Foreign Exchange

FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

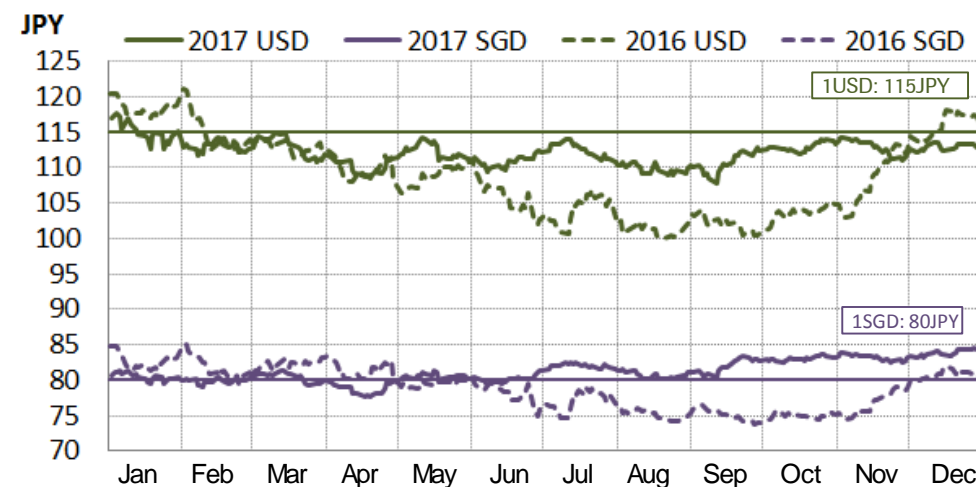
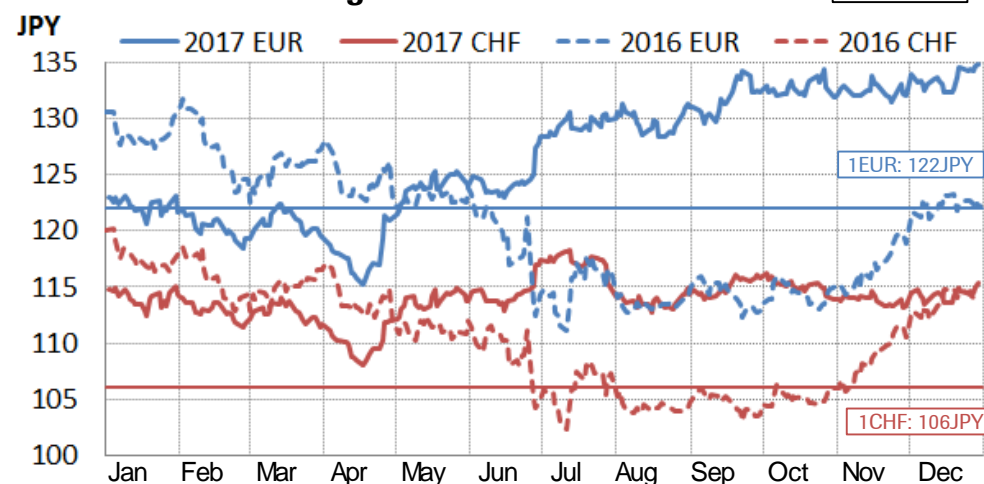
(Billions of JPY)	FX impact Jan – Dec 2017 (FX impact vs. Assumption)	
Revenues	<b>+3.2</b>	
	Sales	+1.7
	Royalties and other operating income	+1.5
Cost of sales	Cost of sales	-1.4
Operating expenses	Expenses	-1.1
<b>Operating profit</b>	<b>+0.7</b>	

Actual / Forecast rate* (JPY)	2016 Jan - Dec Actual	2017 Jan - Dec Assumption	2017 Jan - Dec Actual
1CHF	110.46	106.00	113.90
1EUR	120.42	122.00	126.39
1USD	108.83	115.00	112.17
1SGD	78.82	80.00	81.22

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

[Reference]

Historical exchange rate to the JPY





vs. 2016 Year End

FY2017 Consolidated Financial Overview

Innovation all for the patients



A member of the Roche group

# Balance Sheet Items

&lt; Assets, Liabilities, and Net Assets &gt;

(Billions of JPY)	2016 Dec	2017 Dec	Change
Trade accounts receivable	140.7	148.5	+ 7.8
Inventories	185.4	169.1	- 16.3
Trade accounts payable	-42.5	-38.4	+ 4.1
Other net working capital *1	-25.2	-28.4	- 3.2
<b>Net working capital</b>	<b>258.5</b>	<b>250.7</b>	<b>- 7.8</b>
Property, plant and equipment	157.1	171.6	+ 14.5
Intangible assets	19.3	21.1	+ 1.8
Other long-term assets - net *2	-3.7	-3.1	+ 0.6
<b>Long-term net operating assets</b>	<b>172.7</b>	<b>189.5</b>	<b>+ 16.8</b>
<b>Net operating assets</b>	<b>431.1</b>	<b>440.2</b>	<b>+ 9.1</b>
Debt	-0.6	-0.3	+ 0.3
Marketable securities	110.2	104.0	- 6.2
Cash and cash equivalents	95.4	139.1	+ 43.7
<b>Net cash</b>	<b>204.9</b>	<b>242.8</b>	<b>+ 37.9</b>
Other non-operating assets - net *3	10.5	9.9	- 0.6
<b>Net non-operating assets</b>	<b>215.4</b>	<b>252.7</b>	<b>+ 37.3</b>
<b>Total net assets</b>	<b>646.5</b>	<b>692.9</b>	<b>+ 46.4</b>
Total assets	806.3	852.5	+ 46.2
Total liabilities	-159.8	-159.6	+ 0.2

\*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	-7.8
Increase in trade accounts receivable	+7.8
Increase in sales	
Decrease in inventories	-16.3
Impact from front-loaded purchases in the previous year, etc.	
Decrease in trade accounts payable	+4.1
Decrease in other net working capital	-3.2
Increase in long-term net operating assets	+16.8
Increase in Property, plant and equipment	+14.5
Investment expenditure in production facilities, etc.	
Increase in net cash	+37.9
Decrease in other non-operating assets	-0.6
Equity ratio attributable to Chugai shareholders	+1.1% pts.
2017 Dec	81.2%
2016 Dec	80.1%

FX rate to the JPY (end of period)

	2016 Dec	2017 Dec
1CHF	113.94	115.35
1EUR	122.27	134.82
1USD	116.55	112.89
1SGD	80.47	84.39

vs. 2016 Year End

FY2017 Consolidated Financial Overview

Innovation all for the patients

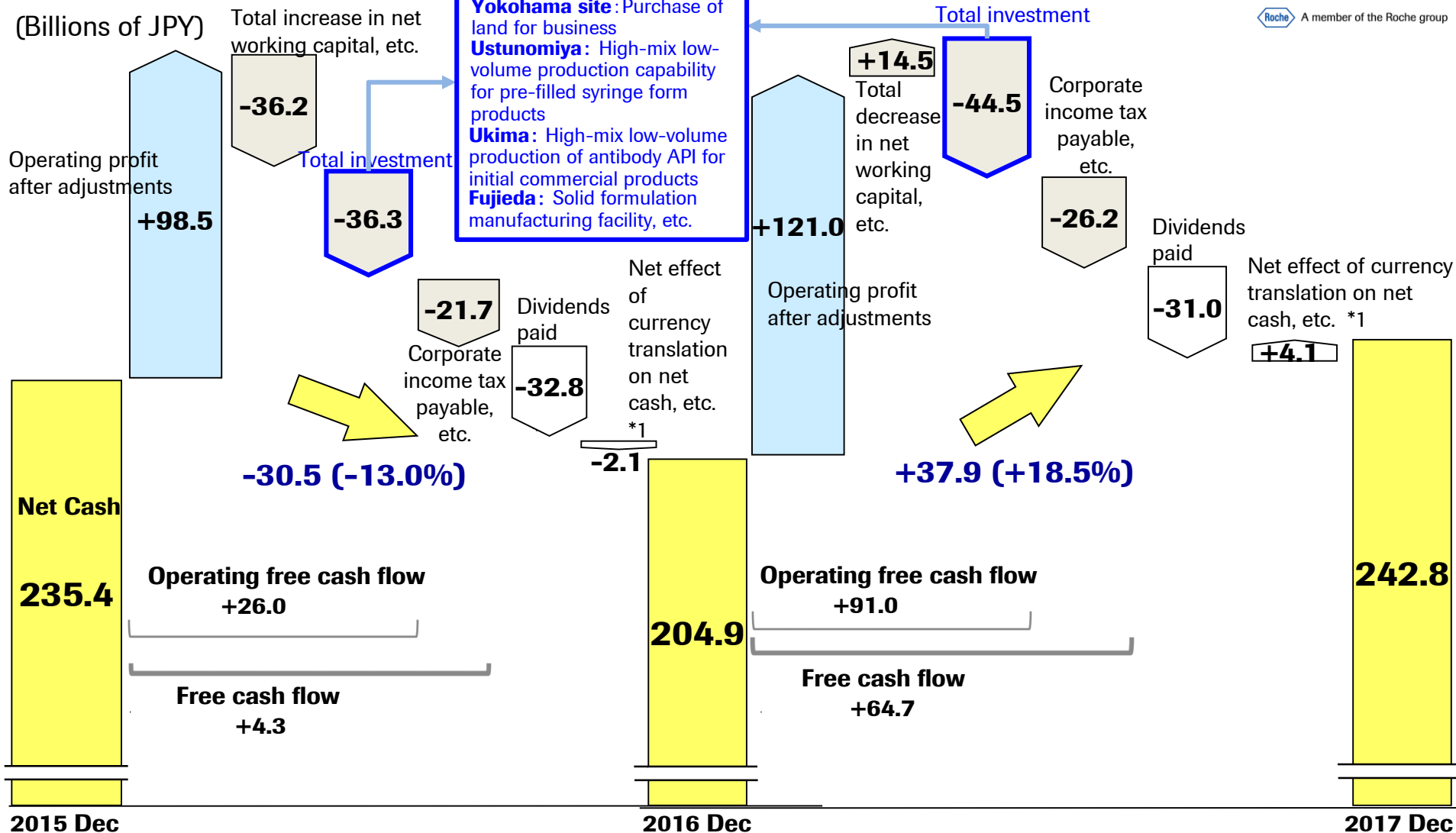


Roche A member of the Roche group

# Net Cash

## Main investment for P.P.E

**Yokohama site**: Purchase of land for business  
**Utsunomiya**: 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.



\*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)



# Summary of Earnings Prospects for 2018

## ■ Revenues:

- Domestic sales excl. Tamiflu: despite continuous growth on a quantity basis, decrease due to impact of HIP revision
- Overseas sales: overall growth mainly due to Actemra and Alecensa export to Roche
- Royalties and other operating income: overall increase from the previous year due to ordinary income from Actemra, etc. and one-time income from transfer of long-listed products on HIP list

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

- Cost of sales: the ratio to sales will remain nearly the same as in the previous year
- Operating expenses: overall increase mainly due to the increase of research and development expenses from progress of projects, etc.

## ■ Profits (Core basis)

- Despite decrease from impact of HIP revision or decrease in one-time income in the previous year, increase due to growth of mainstay products on a quantity basis and income from transfer of long-listed products on HIP list

## 2018 Forecast (Core)

FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

# Forecast 2018 Jan - Dec

(Billions of JPY)	Actual		Forecast		Growth	
	2017 Jan - Dec		2018 Jan - Dec			
		vs. Revenues		vs. Revenues		
Revenues	534.2		541.5		+7.3	+1.4%
Sales	499.3		498.5		-0.8	-0.2%
excl. Tamiflu	482.4		492.9		+10.5	+2.2%
Domestic	388.4		374.8		-13.6	-3.5%
Export to Roche	76.4		99.6		+23.2	+30.4%
Other overseas	17.7		18.5		+0.8	+4.5%
Tamiflu	16.9		5.6		-11.3	-66.9%
Ordinary	11.9		5.0		-6.9	-58.0%
Govt. stockpiles etc.	5.0		0.6		-4.4	-88.0%
Royalties and other operating income	34.9		43.0		+8.1	+23.2%
Cost of Sales	-252.9		-252.0		+0.9	-0.4%
Gross Profit	281.3	52.7%	289.5	53.5%	+8.2	+2.9%
Operating Expenses	-178.1	33.3%	-181.5	33.5%	-3.4	+1.9%
Operating Profit	103.2	19.3%	108.0	19.9%	+4.8	+4.7%
EPS (JPY)	138.68		147.00		+8.32	+6.0%

## Cost of sales ratio vs. Sales

2017 Jan - Dec	2018 Jan - Dec
50.7%	50.6%

## Exchange rate (JPY)

	2017 Jan - Dec Actual *	2018 Jan - Dec Assumption
1CHF	113.90	115.00
1EUR	126.39	133.00
1USD	112.17	111.00
1SGD	81.22	84.00

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

## 2018 Forecast (Core)

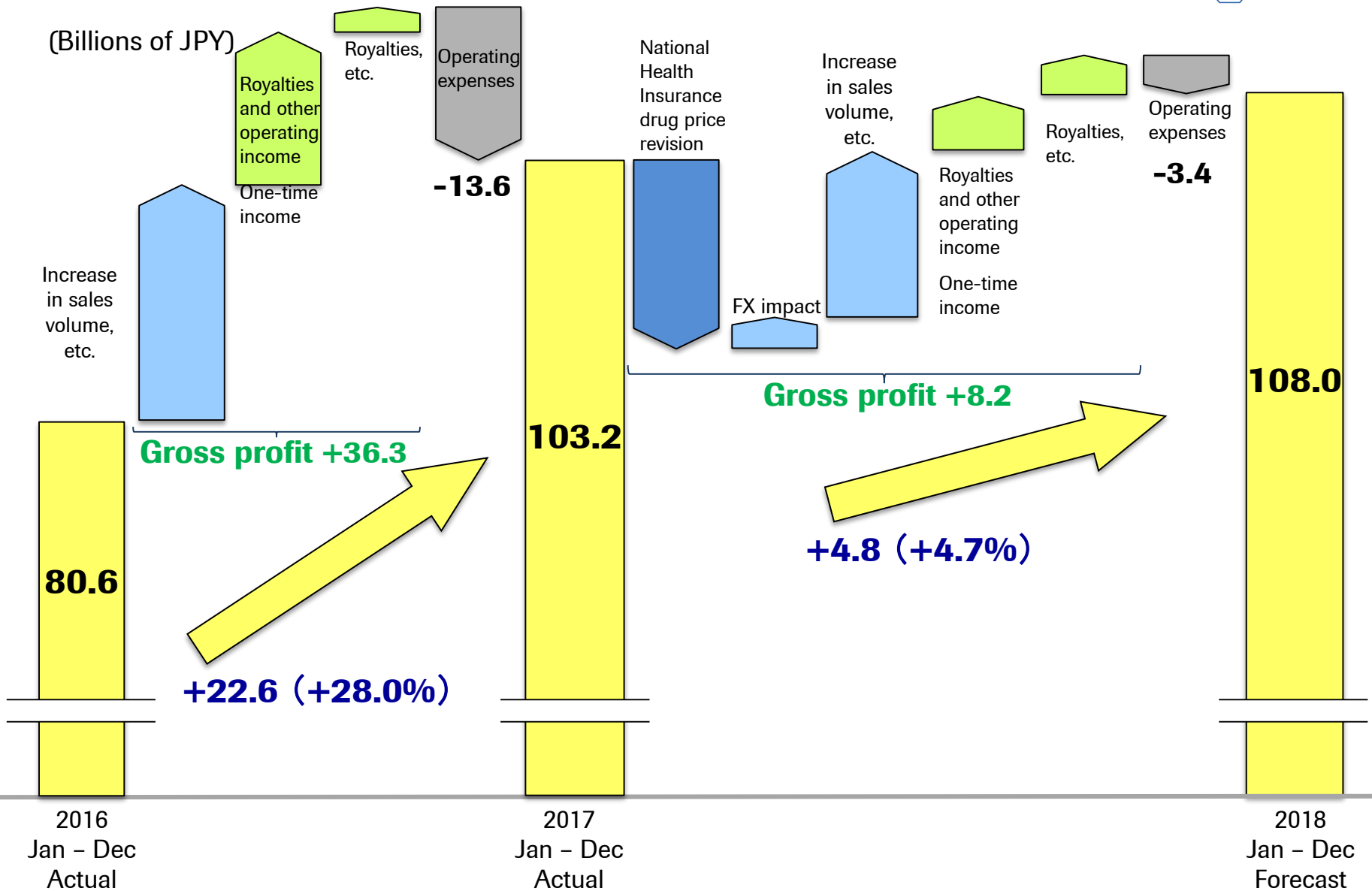
FY2017 Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

# Movement of Operating Profit 2016 - 2018



## 2018 Forecast (Core)

FY2017 Consolidated Financial Overview

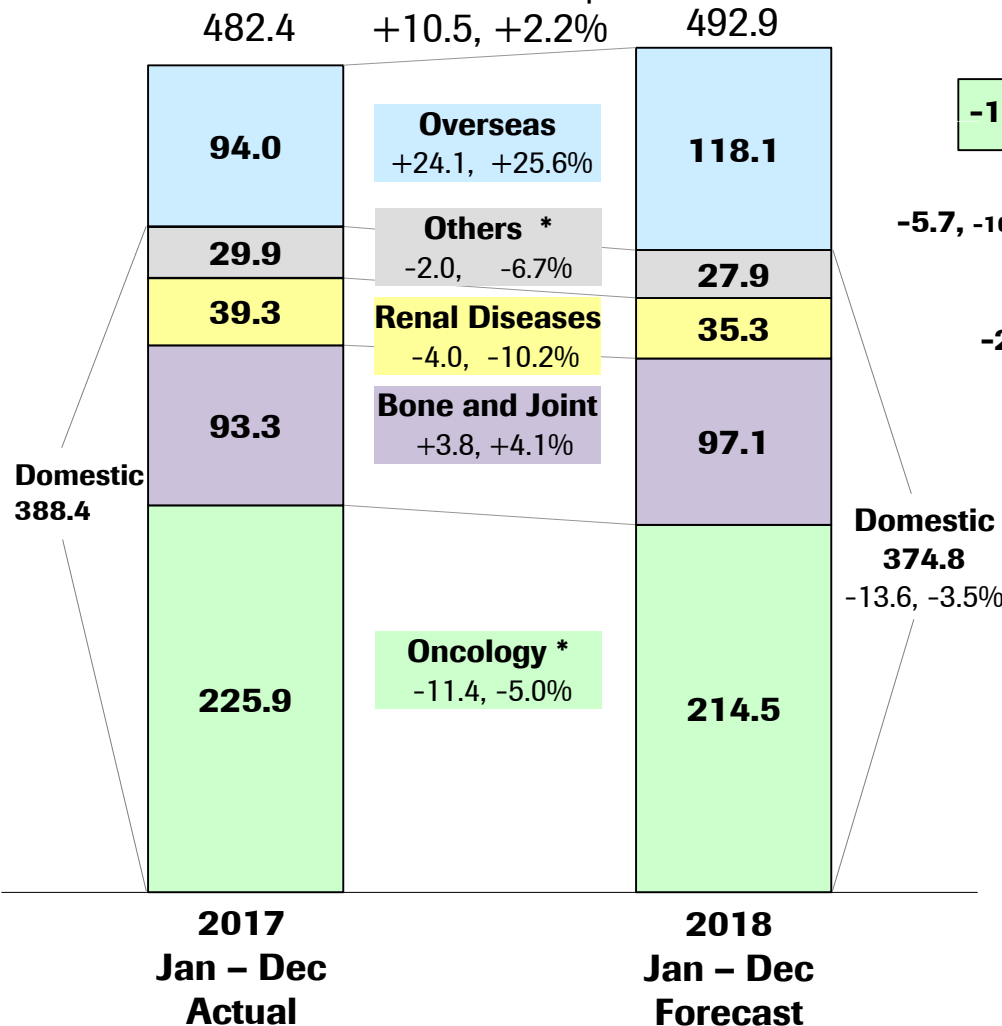
Innovation all for the patients



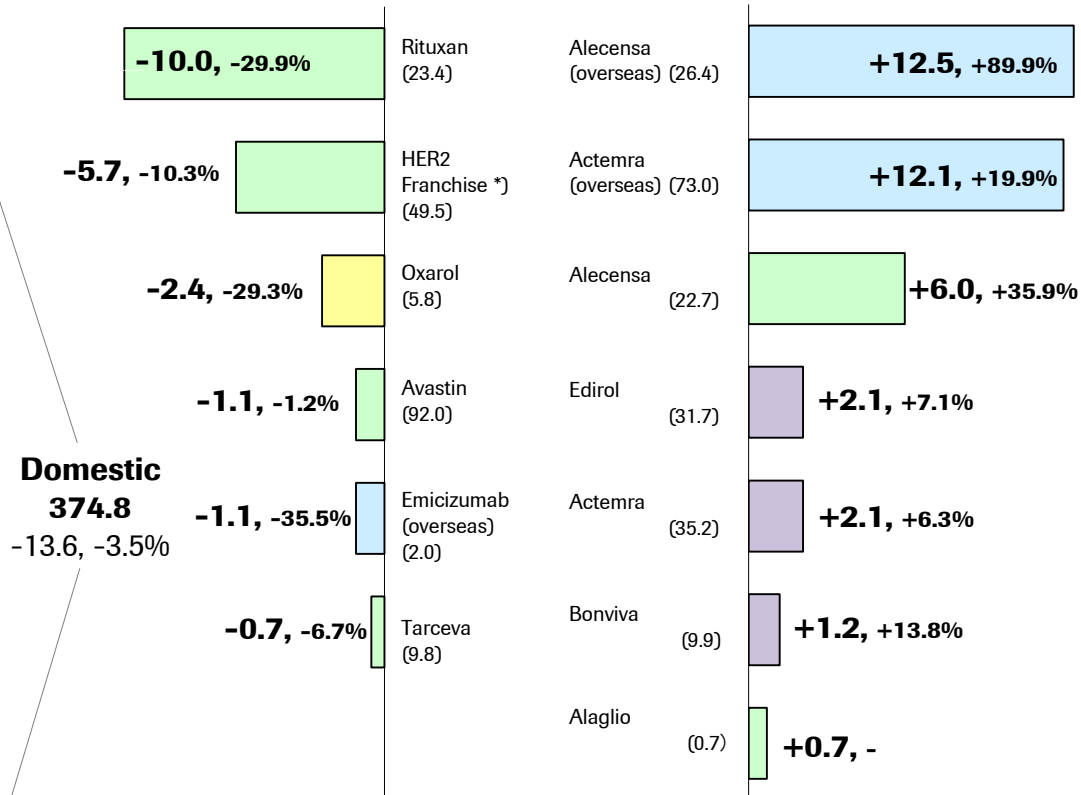
Roche A member of the Roche group

## Sales (excl. Tamiflu) Forecast vs. 2017 Actual

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



Sales by Products,  
Year on Year Changes



(): FY2018 forecast

\*) Details of HER2 franchise %: Year-on-year percentage change

Herceptin (26.6)	-7.0, -20.8%
Perjeta (14.6)	+1.0, +7.4%
Kadcyla (8.3)	+0.3, +3.8%

\*Part of sales decrease from transfer of long-term listed products are included in the sales of disease areas of "Others" and "Oncology".



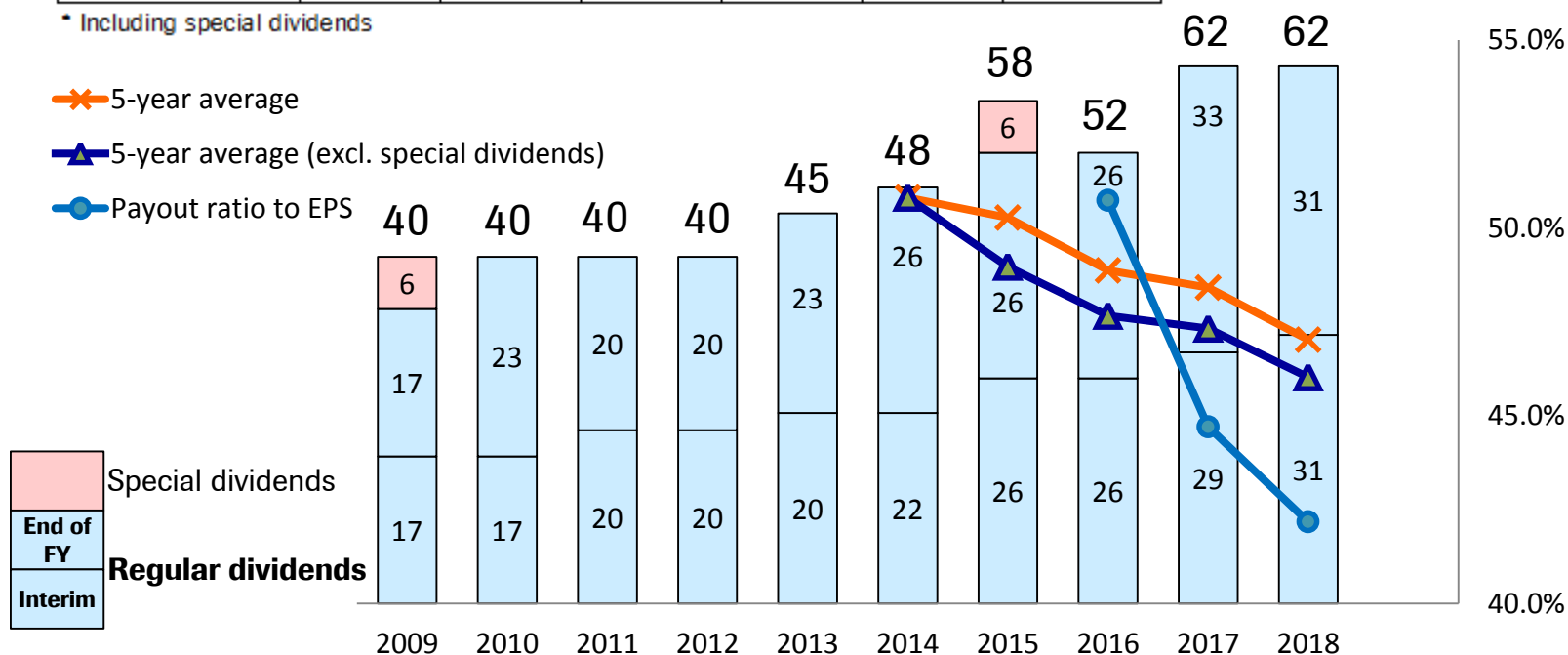
# Dividend Policy

## Policy

Aiming to ensure stable profit for all shareholders and a consolidated dividend payout ratio of 50% on average to Core EPS, taking account of 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 (Plan)	29	33	-	62	44.7%	48.4%
Dividends for FY2018 (Forecast)	31	31	-	62	42.2%	47.0%

\* Including special dividends





# 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

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021

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

2012-21: 476 million SGD / (225 million SGD), incl. capital investments of 61 million SGD / (49 million SGD)

**Yokohama site:** Purchase of land for business

2016-18: 43.4 billion JPY (4.8 billion JPY)

**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 (5.3 billion JPY)

**Ukima Plant:** Step 2, 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 (24.3 billion JPY)

**Fujieda Plant:** Strengthening of solid formulation manufacturing facility, etc. (React to quick launch and steady supply)

2015-17: 6.0 billion JPY (5.7 billion JPY)

( ): Cumulative amount at the end of Dec., 2017





# Outline of Arrangements for Sales, Royalties, and Expenses of Three Products to Roche

	Actemra	Alecensa	Emicizumab
Export	S: Export to Roche at the agreed supply price	S: Export to Roche at the agreed supply price	S: Export to Roche at the agreed supply price
Co-Promotion, etc. (UK, Germany, France)	R : Profit Sharing	R : Royalty income	R : Profit Sharing
	E : Cost sharing in agreed proportions	E : Receive promotion service fee from Roche (reimbursement of expenses)	E : Cost sharing in agreed proportions
Other Region	R : Royalty income	R : Royalty income	R : Royalty income

S : Sales

R : Royalties and other operating income

E : Expenses

# Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.  
Senior Vice President  
Head of Project & Lifecycle Management Unit  
Yasushi Ito

February 1/2, 2018



# Projects under Development (1)

## (as of Feb. 1, 2018)

	Phase I	Phase II	Phase III		Filed
Oncology	<b>CKI27</b> (Japan / overseas) - solid tumors  <b>RG7604 / taselisib</b> - solid tumors  <b>GC33 (RG7686)</b> <b>/ codrituzumab</b> - HCC★  <b>ERY974 (overseas)</b> - solid tumors  <b>RG7421 / cobimetinib</b> - solid tumors		<b>RG3502 / Kadcyla</b> - breast cancer (adjuvant)  <b>RG435 / Avastin</b> - RCC  <b>RG7440 / ipatasertib</b> - prostate cancer - breast cancer★  <b>RG7596 /</b> <b>polatuzumab vedotin</b> - DLBCL★	<b>RG7446 /</b> <b>atezolizumab</b> - NSCLC (adjuvant) - SCLC - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - breast cancer - ovarian cancer - prostate cancer	<b>GA101 (RG7159)</b> <b>/ obinutuzumab</b> - follicular lymphoma  <b>RG1273 / Perjeta</b> - breast cancer (adjuvant)
Bone & Joint			<b>ED-71 / Ediolol (China)</b> - osteoporosis  <b>NRD101 / Suvenyl (China)</b> - knee osteoarthritis /shoulder periartthritis		
Renal	<b>EOS789</b> <b>(Japan / overseas)</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

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

★: Projects with advances in stages since Oct. 25, 2017

★: Multinational study managed by Chugai



# Projects under Development (2) (as of Feb. 1, 2018)

	Phase I	Phase II	Phase III	Filed
Autoimmune	<b>RG7845</b> - rheumatoid arthritis		<b>MRA / Actemra</b> - systemic sclerosis  <b>SA237(RG6168) / satralizumab</b> - neuromyelitis optica★	
Neurology		<b>RG7916</b> - spinal muscular atrophy★	<b>RG1450 / gantenerumab</b> - Alzheimer's disease  <b>RG7412 / crenezumab</b> - Alzheimer's disease  <b>RG6206</b> - DMD(PII/III) ★	
Others	<b>PCO371 (overseas)</b> - hypoparathyroidism  <b>RG7716</b> - wAMD / DME	<b>RG3637 / lebrikizumab</b> - IPF  <b>CIM331 / nemolizumab*</b> - pruritus in dialysis patients  <b>URC102 (South Korea)</b> - gout  <b>SKY59 (RG6107)</b> - paroxysmal nocturnal hemoglobinuria (PI/II)	<b>ACE910 (RG6013) / emicizumab</b> - hemophilia A (non-inhibitor)	<b>ACE910 (RG6013) / emicizumab (Japan / EU)</b> - hemophilia A (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

IPF: idiopathic pulmonary fibrosis

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 Oct. 25, 2017

★: Multinational study managed by Chugai



# Development Status (1)

In-house

## **AF802 / Alecensa®**

Advanced ALK-positive NSCLC [1st line]

Approved in November 2017 (US)

Approved in December 2017 (EU)

In-licensed

## **RG7446 / atezolizumab**

Unresectable advanced or recurrent NSCLC

Approved in January 2018

NSCLC [1st line] (B-FAST)

Started global Phase 2/3 study in November 2017

In-house

## **ACE910 / emicizumab**

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

Approved in November 2017 (US)

Recommendation for approval granted in January 2018 (EU)



# Development Status (2)

In-  
licensed

## **RG7440 / ipatasertib**

Triple negative breast cancer

Started global Phase 3 study in January 2018

In-  
licensed

## **RG7596 / polatuzumab vedotin**

Diffuse large B-cell lymphoma

Started global Phase 3 study in November 2017

In-  
licensed

## **RG7916 (SMN2 splicing modifier)**

Spinal muscular atrophy

Started global Phase 2 study in November 2017



# Development Status (3)

In-  
licensed

## **RG6206 (Anti-myostatin adnectin)**

Duchenne muscular dystrophy

Started global Phase 2/3 study in November 2017

In-  
licensed

## **RG7802 (Anti-CEA/CD3 bispecific antibody(CEA-TCB))**

Solid tumors

Decided to start development

In-  
licensed

## **RG1273 / Perjeta®**

Gastric cancer

Development discontinued



# Other Progress

In-  
licensed

## **Alaglio® divided granules 1.5g (photodynamic diagnostic agent)**

Diagnostic agent to visualize non-muscle invasive bladder cancer at the operation of its transurethral resection

Launched in December 2017

In-  
house

## **CIM331 / nemolizumab**

Atopic dermatitis

Phase 3 study started by Maruho in November 2017 (Japan)



# Results of Clinical Trials / Conference (1)



Roche A member of the Roche group

In-  
licensed

## **RG7446 / atezolizumab**

### **NSCLC 1<sup>st</sup> line:** global Phase 3 study (IMpower150)

- One of the primary endpoints, progression-free survival (PFS) was achieved in November 2017
  - Statistically significant improvement in PFS with the addition of atezolizumab versus Avastin® + chemotherapy was demonstrated
- Detailed data of IMpower150 was presented at the European Society of Medical Oncology Immuno Oncology Congress in December 2017

### **RCC 1<sup>st</sup> line:** global Phase 3 study (IMmotion151)

- One of the primary endpoints, PFS was achieved in December 2017
  - atezolizumab + Avastin® showed statistically significant improvement in PFS versus sunitinib (PD-L1 expression  $\geq 1\%$ , Investigator's assessment)

# Results of Clinical Trials / Conference (2)



Roche A member of the Roche group

In-house

## **ACE910 / emicizumab hemophilia A**

**Non-inhibitor:** global Phase 3 study (HAVEN 3)

- Primary endpoint was achieved in November 2017
  - A statistically significant reduction in the number of bleeds was confirmed in patients treated with emicizumab prophylaxis (weekly/biweekly dosing) compared to those receiving no prophylactic treatment

**Every four weeks dosing:** global Phase 3 study (HAVEN 4)

- Interim results were announced in December 2017
  - Clinically meaningful reduction in the number of bleeds after a median of 17 weeks of treatment

**Data presentation at American Society of Hematology meeting**

- Inhibitor: Long-term expansion data from global Phase 3 study (HAVEN 1)
- Pediatrics inhibitor: Long-term expansion data from global Phase 3 study (HAVEN 2)
- Every four weeks dosing: Pharmacokinetic data assessing the cohort from global Phase 3 study (HAVEN 4)

# Results of Clinical Trials / Conference (3)

Innovation all for the patients



Roche A member of the Roche group

In-  
house

## ED-71 / Ediol®

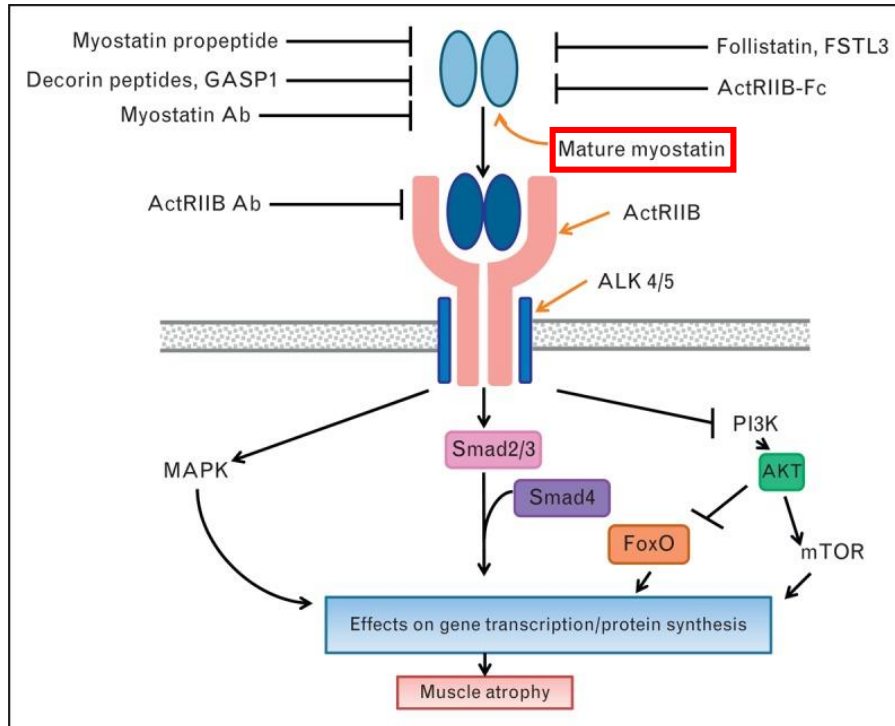
### Osteoporosis: global Phase 3 study (China)

- Primary endpoint was achieved in November 2017
  - Significantly increased the bone mineral density of osteoporosis patients compared with alfacalcidol

# RG6206 (Anti-Myostatin Adnectin) and its MoA



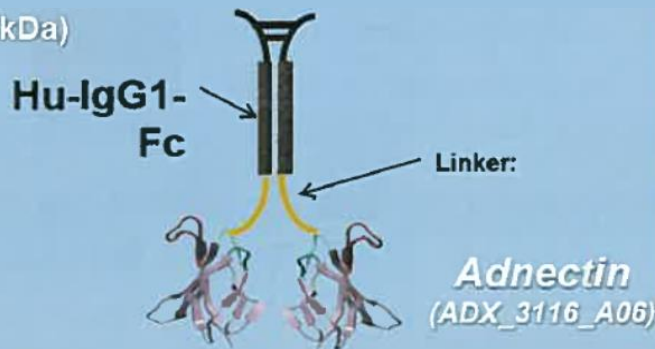
Roche A member of the Roche group



Curr Opin Support Palliat Care. 2013 Nov; 7(4): 352–360.

## RG6206

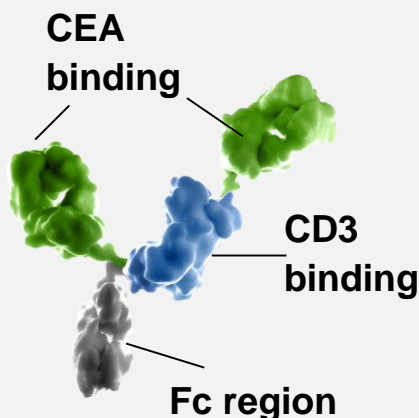
(MW: 75.5kDa)



- Duchenne Muscular Dystrophy (DMD) is a hereditary disorder with progressive muscle weakness and its major pathology is simultaneous degeneration, necrosis, regeneration of skeletal muscle cells due to the mutation of dystrophin gene.
- Myostatin is a negative regulator of skeletal muscle mass and a member of TGF- $\beta$  superfamily.
- RG6206 is a recombinant protein with two anti-myostatin adnectin molecules binding to human IgG1 Fc fragment.
- RG6206 weekly SC injection is hoped to show its therapeutic effect for DMD by increasing muscle mass associated with reduction of active free serum myostatin.



# RG7802 (CEA-TCB) and its MoA



## CEA-TCB and Target

CEA-TCB is a novel T cell bispecific (TCB) antibody being investigated for the treatment of carcinoembryonic antigen (CEA)-expressing solid tumours. CEA-TCB has the potential to work in a broad range of solid tumours as CEA is overexpressed in a variety of cancers, including colorectal cancer (CRC)<sup>1</sup>.

## Structure and MoA

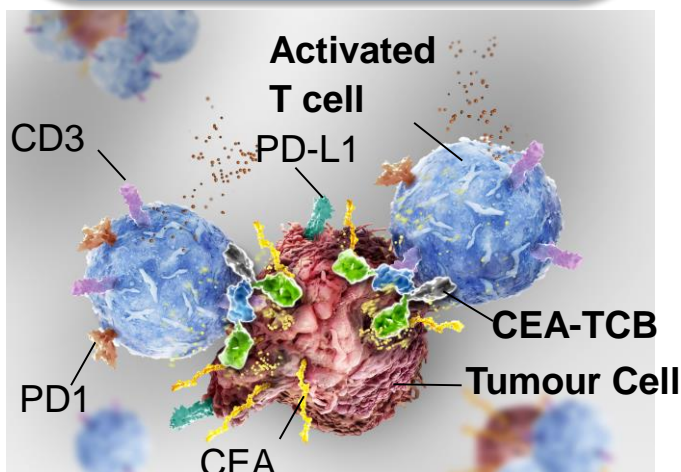
CEA-TCB uses a novel 2-to-1 molecular design. It is engineered to bind simultaneously with one arm to CD3 on T-cells and with two arms to CEA on tumour cells, bringing T-cells into close proximity to the cancer cells. This leads to T-cell activation and subsequent tumour cell killing<sup>1</sup>.

## Unmet Need

CEA-TCB-mediated T cell recruitment (and/or intra-tumour T cell expansion) may convert non-inflamed tumours into highly-inflamed tumours<sup>1</sup>, which may yield efficacy in tumour types not responsive to current cancer immunotherapies.

## Rationale for Combination

Preclinical data indicate that CEA-TCB treatment leads to up-regulation of PD-L1 on tumour cells<sup>2</sup>, providing rationale to explore efficacy of CEA-TCB in combination with aPDL1 therapy.



Source: Roche document

## References:

1. Bacac M, Fauti T, Sam J et al. Clin Cancer Res. 2016.
2. Bacac M, et al. AACR 2016 [abstract 1494]



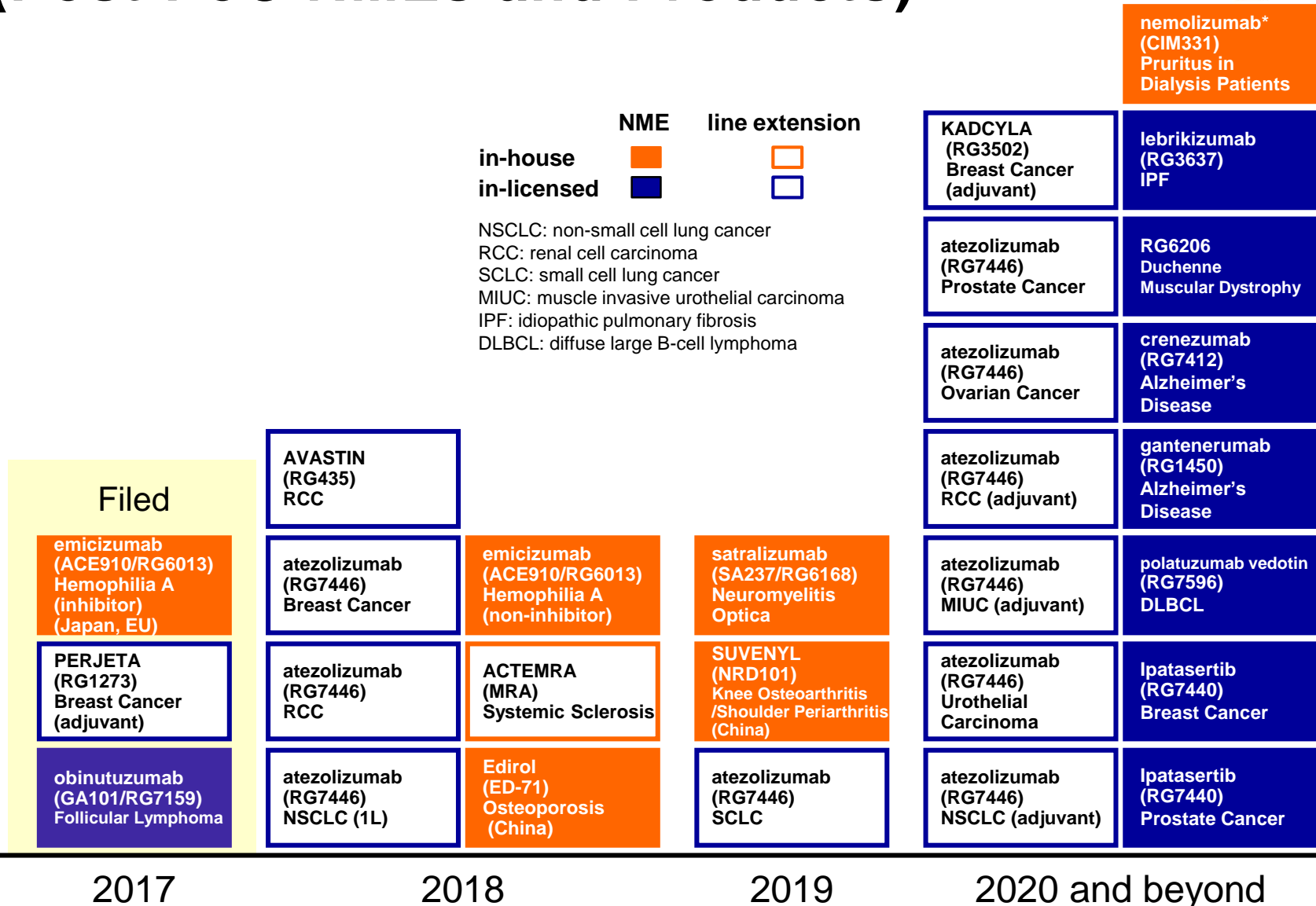
# Projected Submissions (Post PoC NMEs and Products)

**NME** **line extension**

**in-house** ■ □

**in-licensed** ■ □

NSCLC: non-small cell lung cancer  
 RCC: renal cell carcinoma  
 SCLC: small cell lung cancer  
 MIUC: muscle invasive urothelial carcinoma  
 IPF: idiopathic pulmonary fibrosis  
 DLBCL: diffuse large B-cell lymphoma



\*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 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 two indications of two products and one of them was approved

Product	Indication	Current Status
Xeloda®	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by the committee

# Contacts: Corporate Communications Dept.

## Media Relations Group

Tel: +81 (0)3-3273-0881 Fax: +81 (0)3-3281-6607

e-mail: [pr@chugai-pharm.co.jp](mailto:pr@chugai-pharm.co.jp)

Koki Harada, Hiroshi Araki, Sachiyo Yoshimura, Chisato Miyoshi,  
Yayoi Yamada

## Investor Relations Group

Tel: +81 (0)3-3273-0554 Fax: +81 (0)3-3281-6607

e-mail: [ir@chugai-pharm.co.jp](mailto:ir@chugai-pharm.co.jp)

Toshiya Sasai, Takayuki Sakurai, Tomoko Shimizu,  
Tomoyuki Shimamura