

# **FY2017 2Q Consolidated Financial Overview (IFRS based)**

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# 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.



# 2Q Results Summary

## ■ Revenues: 252.8 billion yen (+5.3, +2.1% YoY)

- Domestic sales excl. Tamiflu: decrease due to impact of HIP revision (-1.2, -0.7%)
- Overseas sales: growth of Alecensa, but lower sales of Actemra mainly due to FX impact (-0.1, -0.2%)
- Royalties and other operating income: increase in milestone income (+5.6, +54.4%)

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

- Cost of sales: the ratio to sales improved due to change in product mix, etc. (-1.4% points, from 52.4% to 51.0%)
- Operating expenses: overall increase mainly due to the increase of research and development expenses and general and administration expenses, etc. (-2.8, +3.5%)

## ■ Profits

- IFRS results: operating profit 47.1 billion yen (+3.6, +8.3%)  
net income 36.5 billion yen (+4.5, +14.1%)
- Core results: operating profit 50.2 billion yen (+6.1, +13.8%)  
net income 38.8 billion yen (+6.4, +19.8%)
- Core EPS (JPY): 70.10 (+11.65, +19.9%)



# IFRS and Core Results Jan-Jun

(Billion JPY)	IFRS results	Non-core items		Core results
	2017 Jan - Jun	Intangible assets	Others	2017 Jan - Jun
<b>Revenues</b>	<b>252.8</b>			<b>252.8</b>
Sales	236.8			236.8
Royalties and other operating income	15.9			15.9
Cost of sales	-121.4	+0.6		-120.8
<b>Gross profit</b>	<b>131.3</b>	<b>+0.6</b>		<b>131.9</b>
<b>Operating expenses</b>	<b>-84.2</b>	<b>+2.5</b>		<b>-81.8</b>
Marketing and distribution	-32.2			-32.2
Research and development	-44.8	+2.5		-42.4
General and administration	-7.2			-7.2
<b>Operating profit</b>	<b>47.1</b>	<b>+3.1</b>		<b>50.2</b>
Financing costs	-0.1			-0.1
Other financial income (expense)	-0.2			-0.2
Other expense	-0.4			-0.4
<b>Profit before taxes</b>	<b>46.4</b>	<b>+3.1</b>		<b>49.5</b>
Income taxes	-9.9	-0.8		-10.7
<b>Net income</b>	<b>36.5</b>	<b>+2.3</b>		<b>38.8</b>
Chugai shareholders	36.1	+2.3		38.4
Non-controlling interests	0.4			0.4

(Billions of JPY)

## Non-Core items

- Intangible assets:
  - Amortization of intangible assets +0.6
  - Impairment +2.5
- Others
  - Environmental costs none

Core net income  
attributable to Chugai  
shareholders 38.4

(Millions of shares)

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

547

Core EPS (JPY)  
70.10

## Year on Year (Core)

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# Financial Overview Jan - Jun

(Billions of JPY)	2016		2017		Growth	
	Jan - Jun		Jan - Jun			
	vs. Revenues		vs. Revenues			
<b>Revenues</b>	<b>247.5</b>		<b>252.8</b>		<b>+5.3</b>	<b>+2.1%</b>
Sales	237.2		236.8		-0.4	-0.2%
excl. Tamiflu	230.0		228.7		-1.3	-0.6%
Domestic	184.2		183.0		-1.2	-0.7%
Export to Roche	37.4		36.9		-0.5	-1.3%
Other overseas	8.4		8.8		+0.4	+4.8%
Tamiflu	7.3		8.2		+0.9	+12.3%
Ordinary	7.3		6.3		-1.0	-13.7%
Govt. stockpiles, etc.	0.0		1.9		+1.9	-
Royalties and other operating income	10.3		15.9		+5.6	+54.4%
Cost of sales	-124.4	50.3%	-120.8	47.8%	+3.6	-2.9%
<b>Gross profit</b>	<b>123.1</b>	<b>49.7%</b>	<b>131.9</b>	<b>52.2%</b>	<b>+8.8</b>	<b>+7.1%</b>
Operating expenses	-79.0	31.9%	-81.8	32.4%	-2.8	+3.5%
<b>Operating profit</b>	<b>44.1</b>	<b>17.8%</b>	<b>50.2</b>	<b>19.9%</b>	<b>+6.1</b>	<b>+13.8%</b>
Financing costs	-0.1		-0.1		0.0	0.0%
Other financial income (expense)	0.3		-0.2		-0.5	-
Other Expenses	-		-0.4		-0.4	-
Income taxes	-12.0		-10.7		+1.3	-10.8%
<b>Net income</b>	<b>32.4</b>	<b>13.1%</b>	<b>38.8</b>	<b>15.3%</b>	<b>+6.4</b>	<b>+19.8%</b>
EPS (JPY)	58.45		70.10		+11.65	+19.9%

(Billions of JPY)

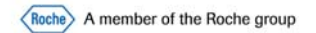
Royalties and other operating income	+5.6
Increase in milestone income	
Other financial income (expense)	-0.5
Exchange gains/losses	-2.7
Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts)	+2.2
Other Expenses	-0.4
Settlement for transfer pricing taxation	

## Cost of sales ratio vs. Sales

	2016 Jan - Jun	2017 Jan - Jun
	52.4%	51.0%

## Market average exchange rate (JPY)

	2016 Jan - Jun	2017 Jan - Jun
1 CHF	113.81	112.95
1 EUR	124.77	121.55
1 USD	111.79	112.38
1 SGD	80.96	80.01



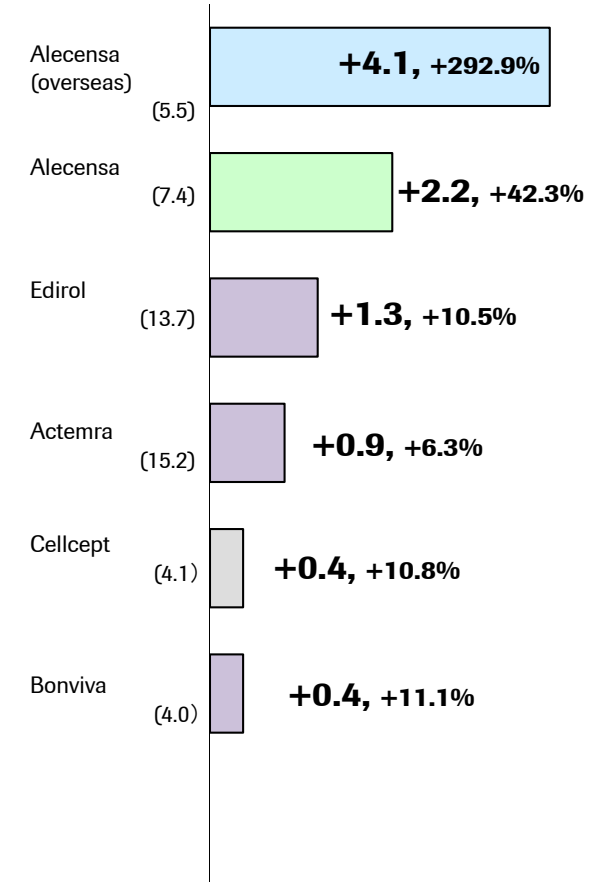
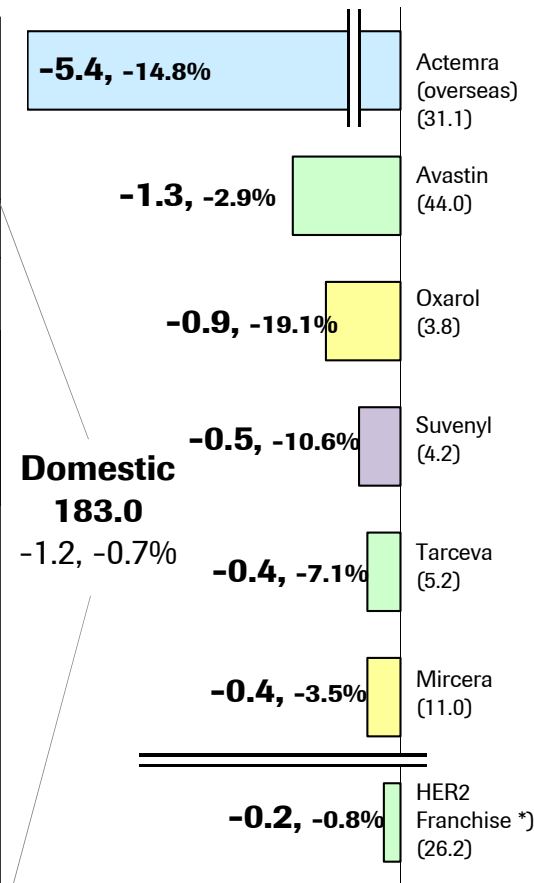
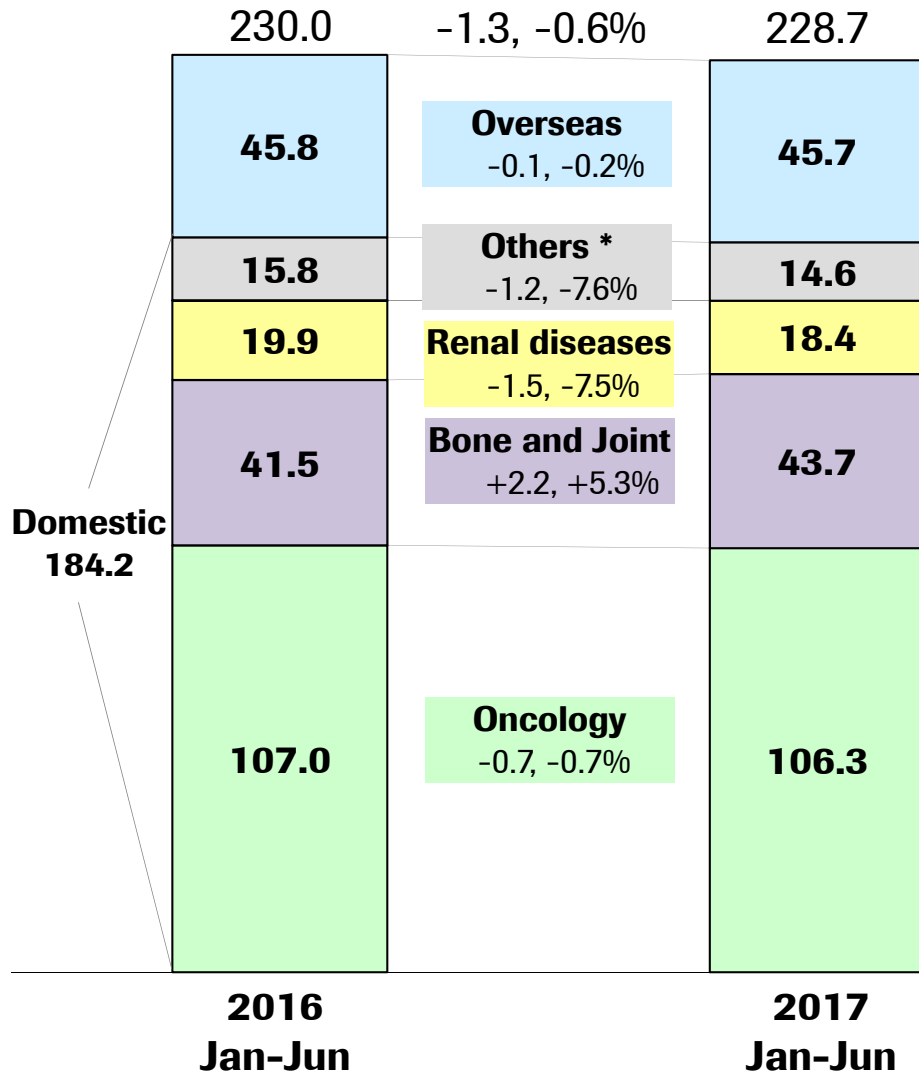
Year on Year

# Sales (excl. Tamiflu) Jan - Jun

Sales by Disease Area,  
Year on Year Comparisons

Sales by Products,  
Year on Year Changes

(Billions of JPY)



\*) Details of HER2 franchise

Herceptin (16.2)	-0.4	-2.4%
Perjeta (6.3)	+0.6	+10.5%
Kadcyla (3.7)	-0.5	-11.9%

\*Sales in transplant, immunology and infectious diseases area are included in "Others" from FY2017 forecast. It was disclosed separately until FY2016.

( ): FY2017 Actual

%: Year-on-year percentage change



# 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		
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>
		<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>6.3</b>	<b>(-1.0)</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		
	<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>1.9</b>	<b>(+1.9)</b>	
<b>Total</b>	<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>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>8.2</b>	<b>(+0.9)</b>	

\* From July 2016 to June 2017

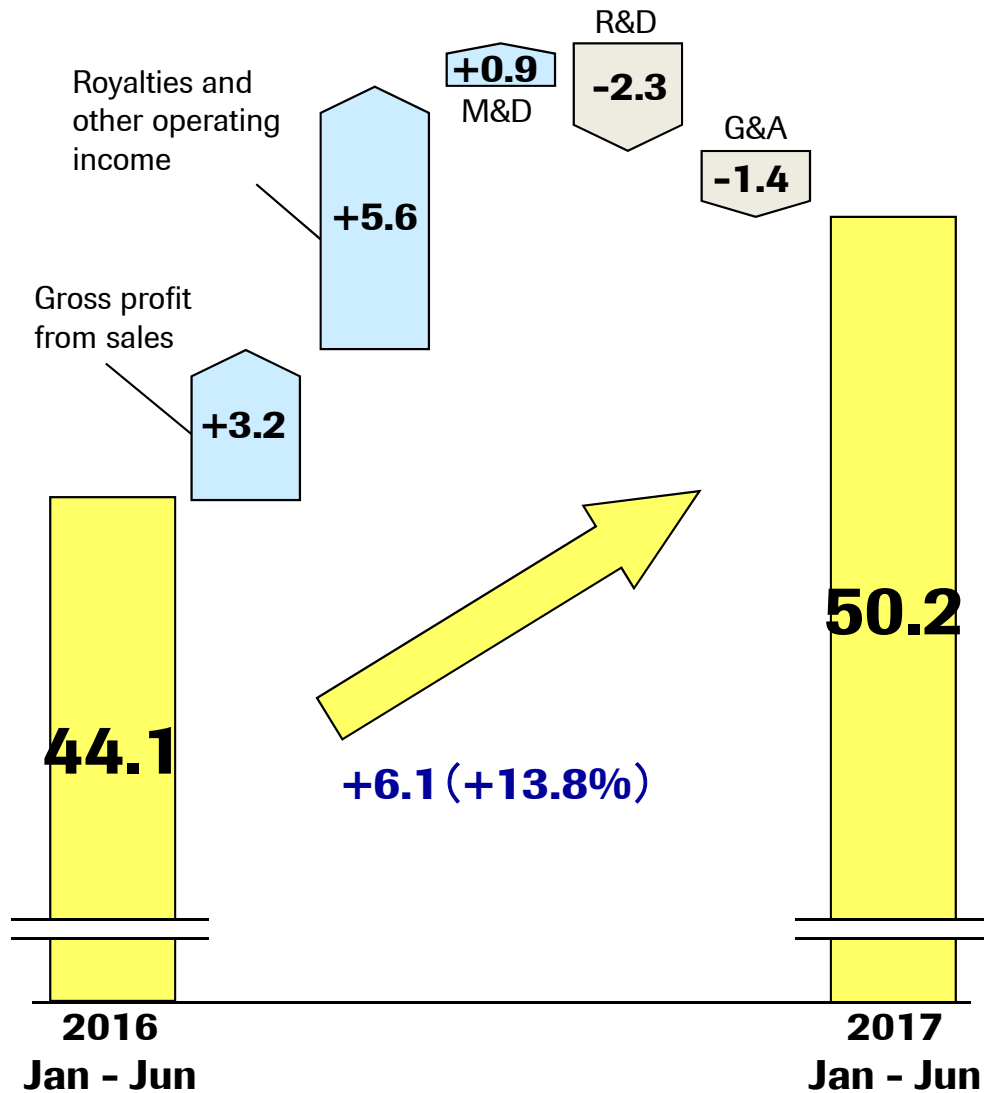
( ) Year on year



Year on Year (Core)

# Operating Profit Jan - Jun

(Billion of JPY)



(Billions of JPY)	2016 Jan - Jun	2017 Jan - Jun	Growth
<b>Revenues</b>	<b>247.5</b>	<b>252.8</b>	<b>+5.3</b>
Cost of sales	-124.4	-120.8	+3.6
<b>Gross profit</b>	<b>123.1</b>	<b>131.9</b>	<b>+8.8</b>
<i>of which</i> Sales	112.8	116.0	+3.2
Royalties, etc.	10.3	15.9	+5.6
Marketing and distribution	-33.1	-32.2	+0.9
Research and development	-40.1	-42.4	-2.3
General and administration	-5.8	-7.2	-1.4
<b>Operating profit</b>	<b>44.1</b>	<b>50.2</b>	<b>+6.1</b>

- Increase in gross profit from sales +3.2
  - Improvement of cost of sales ratio to sales due to change in product mix, etc.
- Increase in royalties and other operating income +5.6
- Decrease in marketing and distribution expenses +0.9
  - Reclassification of some expenses due to organizational changes, etc.
- Increase in research and development expenses -2.3
  - Progress of projects and reclassification of some expenses due to organizational changes, etc.
- Increase in general and administration expenses, etc. -1.4
  - 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)	2016		2017		Growth	
	Apr - Jun		Apr - Jun			
	vs. Revenues		vs. Revenues			
<b>Revenues</b>	<b>127.6</b>		<b>127.3</b>		<b>-0.3</b>	<b>-0.2%</b>
Sales	121.6		118.7		-2.9	-2.4%
excl. Tamiflu	121.4		117.9		-3.5	-2.9%
Domestic	96.4		97.9		+1.5	+1.6%
Export to Roche	20.9		15.6		-5.3	-25.4%
Other overseas	4.1		4.5		+0.4	+9.8%
Tamiflu	0.3		0.8		+0.5	+166.7%
Ordinary	0.3		0.2		-0.1	-33.3%
Govt. stockpiles, etc.	-		0.6		+0.6	-
Royalties and other operating income	6.0		8.6		+2.6	+43.3%
Cost of sales	-63.5	49.8%	-60.0	47.1%	+3.5	-5.5%
<b>Gross profit</b>	<b>64.1</b>	<b>50.2%</b>	<b>67.3</b>	<b>52.9%</b>	<b>+3.2</b>	<b>+5.0%</b>
Operating expenses	-40.4	31.7%	-43.8	34.4%	-3.4	+8.4%
<b>Operating profit</b>	<b>23.7</b>	<b>18.6%</b>	<b>23.5</b>	<b>18.5%</b>	<b>-0.2</b>	<b>-0.8%</b>
Financing costs	-0.0		-0.0		0.0	0.0%
Other financial income (expense)	0.2		0.1		-0.1	-50.0%
Other Expenses	-		0.7		+0.7	-
Income taxes	-6.4		-4.4		+2.0	-31.3%
<b>Net income</b>	<b>17.5</b>	<b>13.7%</b>	<b>19.9</b>	<b>15.6%</b>	<b>+2.4</b>	<b>+13.7%</b>
EPS (JPY)	31.51		35.89		+4.38	+13.9%

Increase in gross profit from sales	+0.6
Improvement of cost of sales ratio to sales	
Increase in royalties and other operating income	+2.6
Increase in milestone income	
Increase in operating expenses	-3.4
Increase in marketing and distribution	-0.2
Increase in research and development Progress of projects, etc.	-2.3
Increase in general and administration Increase in various expenses	-1.0

## Cost of sales ratio vs. Sales

2016 Apr - Jun	2017 Apr - Jun
52.2%	50.5%



vs. Forecast (Core)

# Financial Progress Jan - Jun

(Billions of JPY)	Actual		Forecast on Feb. 1		2016 Progress *
	2017 Jan - Jun	2017 Jan - Dec	Progress		
<b>Revenues</b>	<b>252.8</b>	<b>520.5</b>	<b>48.6%</b>		<b>50.3%</b>
Sales	236.8	490.4	48.3%		50.2%
excl. Tamiflu	228.7	482.2	47.4%		50.1%
Domestic	183.0	393.9	46.5%		48.5%
Export to Roche	36.9	67.4	54.7%		59.6%
Other overseas	8.8	20.9	42.1%		50.0%
Tamiflu	8.2	8.2	100.0%		54.1%
Royalties and other operating income	15.9	30.0	53.0%		53.9%
Cost of sales	-120.8	-252.0	47.9%		50.4%
<b>Gross profit</b>	<b>131.9</b>	<b>268.5</b>	<b>49.1%</b>		<b>50.2%</b>
Operating expenses	-81.8	-176.5	46.3%		48.0%
<b>Operating profit</b>	<b>50.2</b>	<b>92.0</b>	<b>54.6%</b>		<b>54.7%</b>
EPS (JPY)	70.10	124.11	56.5%		57.0%

\* Jan - Jun progress versus Jan - Dec

Cost of sales ratio vs. Sales

2017 Jan - Jun Actual	2017 Jan - Dec Forecast
51.0%	51.4%

Exchange rate (JPY)

	2017 Jan - Jun Actual *	2017 Jan - Dec Assumption
1CHF	112.95	106.00
1EUR	121.55	122.00
1USD	112.38	115.00
1SGD	80.01	80.00

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

vs. Forecast (Core)

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# Sales Progress (excl. Tamiflu) Jan - Jun

(Billions of JPY)	Actual		Forecast on Feb. 1		2016 Progress *	(Billions of JPY)	Actual		Forecast on Feb. 1		2016 Progress *
	2017 Jan - Jun	2017 Jan - Dec	Progress	2017 Jan - Dec			Progress	2017 Jan - Jun	2017 Jan - Dec	Progress	
<b>Sales excl. Tamiflu</b>	<b>228.7</b>	<b>482.2</b>	<b>47.4%</b>		<b>50.1%</b>	<b>Renal</b>	<b>18.4</b>	<b>39.0</b>	<b>47.2%</b>		<b>48.4%</b>
<b>Domestic</b>	<b>183.0</b>	<b>393.9</b>	<b>46.5%</b>		<b>48.5%</b>	Mircera	11.0	25.0	44.0%		47.1%
<b>Oncology</b>	<b>106.3</b>	<b>230.0</b>	<b>46.2%</b>		<b>48.6%</b>	Oxarol	3.8	6.8	55.9%		51.6%
Avastin	44.0	92.7	47.5%		49.2%	<b>Others</b>	<b>14.6</b>	<b>30.3</b>	<b>48.2%</b>		<b>49.1%</b>
HER2 Franchise	26.2	57.5	45.6%		48.7%	CellCept	4.1	9.0	45.6%		46.8%
Herceptin	16.2	35.1	46.2%		48.7%	<b>Overseas</b>	<b>45.7</b>	<b>88.4</b>	<b>51.7%</b>		<b>57.6%</b>
Perjeta	6.3	12.9	48.8%		47.9%	Actemra	31.1	59.4	52.4%		60.5%
Kadcyla	3.7	9.4	39.4%		50.6%	Export to Roche	30.4	58.0	52.4%		60.9%
Rituxan	15.4	34.0	45.3%		47.7%	Neutrogen	5.9	11.6	50.9%		50.8%
Alecensa	7.4	15.9	46.5%		43.7%	Alecensa	5.5	9.5	57.9%		37.8%
Xeloda	5.9	13.7	43.1%		49.6%						
Tarceva	5.2	11.3	46.0%		48.7%						
Zelboraf	0.1	0.4	25.0%		75.0%						
<b>Bone and Joint</b>	<b>43.7</b>	<b>94.5</b>	<b>46.2%</b>		<b>48.2%</b>						
Actemra	15.2	32.3	47.1%		47.4%						
Edirol	13.7	29.5	46.4%		46.4%						
Bonviva	4.0	9.2	43.5%		49.3%						
Suvenyl	4.2	9.2	45.7%		50.5%						

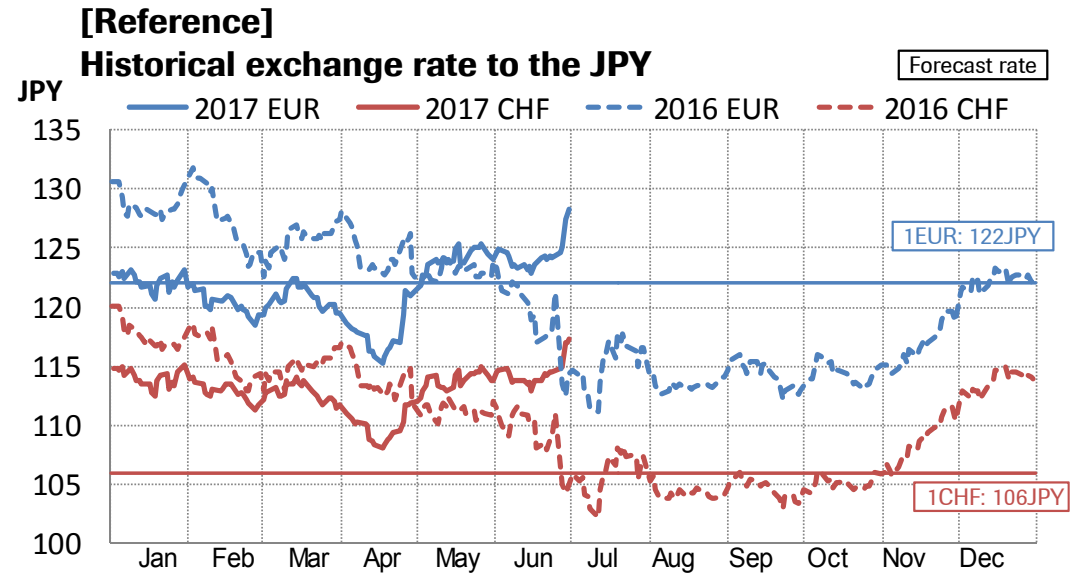
\* Jan - Jun progress versus Jan - Dec.



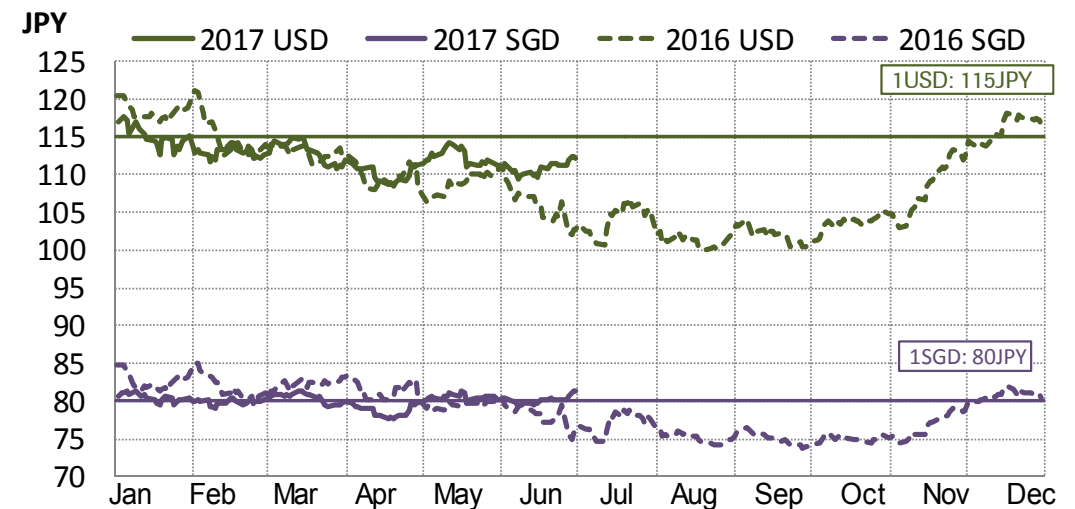
vs. Forecast (Core)

# Impact from Foreign Exchange

(Billions of JPY)	FX impact Jan – Jun 2017 (FX impact vs. Assumption)	
<b>Revenues</b>	<b>+0.0</b>	
	Sales	-0.1
	Royalties and other operating income	+0.2
Cost of sales	Cost of sales	-0.4
Operating expenses	Expenses	-0.3
<b>Operating profit</b>	<b>-0.7</b>	



Actual / Forecast rate* (JPY)	2016 Jan - Jun Actual	2017 Jan - Dec Assumption	2017 Jan - Jun Actual
1CHF	113.81	106.00	112.95
1EUR	124.77	122.00	121.55
1USD	111.79	115.00	112.38
1SGD	80.96	80.00	80.01



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

vs. 2016 Year End

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# Balance Sheet Items

< Assets, Liabilities, and Net Assets >

(Billions of JPY)	2016 Dec	2017 Jun	Change
Trade accounts receivable	140.7	128.9	- 11.8
Inventories	185.4	188.3	+ 2.9
Trade accounts payable	-42.5	-50.6	- 8.1
Other net working capital *1	-25.2	-19.6	+ 5.6
<b>Net working capital</b>	<b>258.5</b>	<b>247.0</b>	<b>- 11.5</b>
Property, plant and equipment	157.1	171.3	+ 14.2
Intangible assets	19.3	19.6	+ 0.3
Other long-term assets - net *2	-3.7	-2.9	+ 0.8
<b>Long-term net operating assets</b>	<b>172.7</b>	<b>188.1</b>	<b>+ 15.4</b>
<b>Net operating assets</b>	<b>431.1</b>	<b>435.0</b>	<b>+ 3.9</b>
Debt	-0.6	-0.4	+ 0.2
Marketable securities	110.2	110.2	0.0
Cash and cash equivalents	95.4	110.7	+ 15.3
<b>Net cash</b>	<b>204.9</b>	<b>220.5</b>	<b>+ 15.6</b>
Other non-operating assets - net *3	10.5	12.6	+ 2.1
<b>Net non-operating assets</b>	<b>215.4</b>	<b>233.1</b>	<b>+ 17.7</b>
<b>Total net assets</b>	<b>646.5</b>	<b>668.2</b>	<b>+ 21.7</b>
Total assets	806.3	821.7	+ 15.4
Total liabilities	-159.8	-153.5	+ 6.3

\*1 Other net working capital: accrued receivable, accrued payable, accrued expenses, etc.

\*2 Other long-term assets - net: long term prepaid expenses, long-term provisions, etc.

\*3 Other non-operating assets - net: deferred income tax assets, accrued corporate tax, etc.

● Decrease in net working capital	-11.5
Decrease in trade accounts receivable	-11.8
Mainly due to seasonal reasons	
Increase in inventories	+2.9
Increase in trade accounts payable	-8.1
Increase in other net working capital	+5.6
● Increase in long-term net operating assets	+15.4
Increase in Property, plant and equipment	+14.2
Investment expenditure in production facilities, such as plant for bio antibody API for initial commercial products (UK3), etc.	
● Increase in net cash	+15.6
● Increase in other non-operating assets	+2.1
● Equity ratio attributable to Chugai shareholders	+1.2% pts.
2017 Jun	81.3%
2016 Dec	80.1%

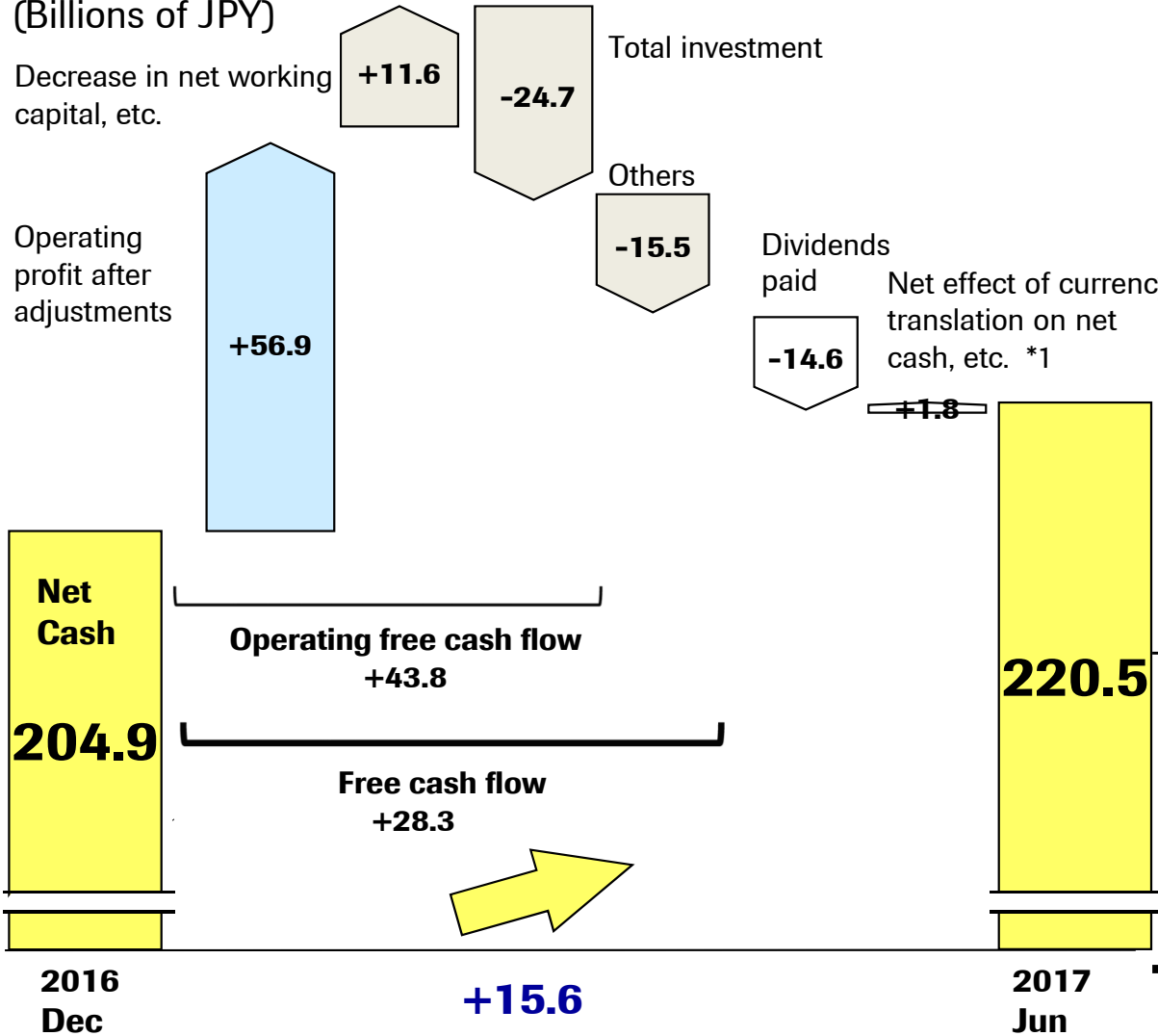
FX rate to the JPY (end of period)

	2016 Dec	2017 Jun
CHF	113.94	117.37
EUR	122.27	128.35
USD	116.55	112.18
SGD	80.47	81.33

vs. 2016 Year End

# Net Cash

(Billions of JPY)



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● Operating profit after adjustments	+56.9
Operating profit	+47.1
Depreciation and amortization, etc.	+9.8
● Decrease in net working capital, etc.	+11.6
Decrease in trade accounts receivable	+11.9
Increase in inventories	-0.4
Increase in trade accounts payable	+8.1
Change in other net working capital, etc.	-7.9
● Total investment	-24.7
Investment in Property, plant and equipment	-17.3
Investment in intangible assets	-7.4
Operating free cash flow	+43.8
● Others	-15.5
Treasury activities (interest income/expenses, foreign exchange gains/losses, etc.)	-0.6
Settlement for transfer pricing taxation	-3.9
Tax paid	-11.0
<b>Free cash flow</b>	<b>+28.3</b>

\*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)



## Year on Year

# Free Cash Flow Jan - Jun

FY2017 2Q Consolidated Financial Overview

Innovation all for the patients



Roche A member of the Roche group

(Billions of JPY)	2016 Jan-Jun	2017 Jan-Jun	Change
<b>Operating profit - IFRS basis</b>	43.5	47.1	+3.6
Depreciation and impairment of Property, plant and equipment	7.5	7.2	-0.3
Amortization and impairment of intangible assets	0.7	3.3	+2.6
Other cash adjustment on operating profit	1.5	-0.7	-2.2
<b>Operating profit, net of operating cash adjustments</b>	53.3	56.9	+3.6
Increase (-) / decrease in trade accounts receivable	9.7	11.9	+2.2
Increase (-) / decrease in inventories	-13.8	-0.4	+13.4
Increase / decrease (-) in trade accounts payable	-3.5	8.1	+11.6
Change in other net working capital, etc.	-11.0	-7.9	+3.1
<b>Total increase (-) / decrease in net working capital, etc.</b>	-18.5	11.6	+30.1
Investment in Property, plant and equipment	-24.2	-17.3	+6.9
Investment in intangible assets	-3.5	-7.4	-3.9
<b>Total investment</b>	-27.8	-24.7	+3.1
<b>Operating free cash flow</b>	7.0	43.8	+36.8
<b>as % of revenues</b>	2.8%	17.3%	+14.5%pts
Treasury activities (interest income/expenses, foreign exchange gains/losses, etc.)	1.7	-0.6	-2.3
Settlement for transfer pricing taxation	-	-3.9	-3.9
Tax paid	-12.8	-11.0	+1.8
<b>Free cash flow</b>	-4.2	28.3	+32.5
Dividends paid	-17.9	-14.6	+3.3
Transaction in own equity instruments	0.4	0.5	+0.1
Net effect of currency translation on net cash, etc. <sup>*2</sup> } <sup>*1</sup>	-4.9	1.4	+6.3
<b>Net change in net cash</b>	-26.6	15.6	+42.2

● Operating profit after adjustment	+3.6
● Total increase (-) / decrease in net working capital, etc.	+30.1
Increase (-) / decrease in trade accounts receivable	+2.2
Increase (-) / decrease in inventories	+13.4
Increase / decrease (-) in trade accounts payable	+11.6
Change in other net working capital, etc.	+3.1
● Total investment	+3.1
Investment in Property, plant and equipment	+6.9
Investment in plant for bio antibody API production (UK3) and purchase of land for business, etc. in the previous year	
Investment in intangible assets	-3.9
● Operating free cash flow	+36.8
● Operating free cash flow as % of revenues	+14.5% pts.
Revenues	+5.3

Market average exchange rate (JPY)

	2016 Jan - Jun	2017 Jan - Jun
CHF	113.81	112.95
EUR	124.77	121.55
USD	111.79	112.38
SGD	80.96	80.01

\*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.  
Senior Vice President  
Head of Project & Lifecycle Management Unit  
Yasushi Ito

July 27/28, 2017





# Projects under Development (1) (as of Jul. 27, 2017)

	Phase I	Phase II	Phase III	Filed
Oncology	<p><b>CKI27</b> (Japan / overseas) - solid tumors</p> <p><b>RG7596 / polatuzumab vedotin</b> - NHL</p> <p><b>RG7604 / taselisib</b> - solid tumors</p> <p><b>GC33 (RG7686) / codrituzumab</b> - HCC★</p> <p><b>ERY974 (overseas)</b> - solid tumors</p> <p><b>RG7421 / cobimetinib</b> - solid tumors★</p>	<p><b>RG1273 / Perjeta</b> - breast cancer (adjuvant) - gastric cancer</p> <p><b>RG3502 / Kadcyla</b> - breast cancer (adjuvant)</p> <p><b>GA101 (RG7159) / obinutuzumab</b> - indolent NHL</p> <p><b>RG435 / Avastin</b> - RCC</p> <p><b>RG7440 / ipatasertib</b> - prostate cancer★</p>	<p><b>RG7446 / atezolizumab</b> - NSCLC (adjuvant) - SCLC - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - breast cancer - ovarian cancer - prostate cancer</p>	<p><b>RG7446 / atezolizumab</b> - NSCLC</p> <p><b>AF802 (RG7853) / Alecensa (overseas)</b> - NSCLC [1L]</p>
Bone & Joint			<p><b>ED-71 / Ediolol (China)</b> - Osteoporosis</p> <p><b>NRD101 / Suvenyl (China)</b> Knee osteoarthritis /Shoulder peri-arthritis★</p>	

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

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

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

★: Multinational study managed by Chugai

NHL: non-Hodgkin's lymphoma

HCC: hepatocellular carcinoma

NSCLC: non-small cell lung cancer

SCLC: small cell lung cancer

MIUC: muscle invasive urothelial carcinoma

RCC: renal cell carcinoma



# Projects under Development (2) (as of Jul. 27, 2017)

	Phase I	Phase II	Phase III	Filed
Renal	<b>EOS789</b> (Japan / overseas) - Hyperphosphatemia			
Autoimmune	<b>RG7845</b> - rheumatoid arthritis★		<b>MRA / Actemra</b> - systemic sclerosis <b>SA237 / RG6168</b> - neuromyelitis optica★	<b>MRA / Actemra</b> - large-vessel vasculitis - giant cell arteritis
CNS	<b>RG7916</b> - spinal muscular atrophy		<b>RG1450 / gantenerumab</b> - Alzheimer's disease <b>RG7412 / crenezumab</b> - Alzheimer's disease	
Others	<b>PCO371 (overseas)</b> - hypoparathyroidism	<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)</b> / emicizumab - hemophilia A (non-inhibitor)	<b>ACE910 (RG6013)</b> / emicizumab (Japan / overseas) - hemophilia A (inhibitor) ★

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

IPF: idiopathic pulmonary fibrosis

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

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

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

★: Multinational study managed by Chugai



# Development Status (1)

In-  
house

## **Actemra®**

Giant-cell arteritis

Approved in May 2017 (US)

Recommendation for approval granted in July 2017 (EU)

In-  
house

## **ACE910 / emicizumab**

Hemophilia A (inhibitor)

Filed for marketing approval in June (US/EU),  
July (Japan) 2017

In-  
licensed

## **RG7446 / atezolizumab**

Triple-negative breast cancer (neoadjuvant)

Started global Phase 3 study in July 2017

In-  
licensed

## **RG7440 / ipatasertib**

Prostate cancer (castration-resistant)

Started global Phase 3 study in June 2017



# Development Status (2)

In-house

## Suvenyl®

Knee osteoarthritis / Shoulder periarthritits

Started Phase 3 study in July 2017 (China)

In-licensed

## RG7845 (BTK inhibitor)

Rheumatoid arthritis

Started Phase 1 study in June 2017

In-licensed

## RG7421 / cobimetinib (MEK inhibitor)

Solid tumors

Started Phase 1 study in July 2017

In-licensed

## RG6078 (IDO inhibitor)

Solid tumors

Development suspended



# Other Progress

In-  
house

## **Actemra®**

Rheumatoid arthritis, weekly dosing  
Approved in June 2017

In-  
house

## **ACE910 / emicizumab**

License agreement with JW Pharmaceutical to grant  
exclusive marketing right in South Korea in May 2017

In-  
house

## **CIM331 / nemolizumab**

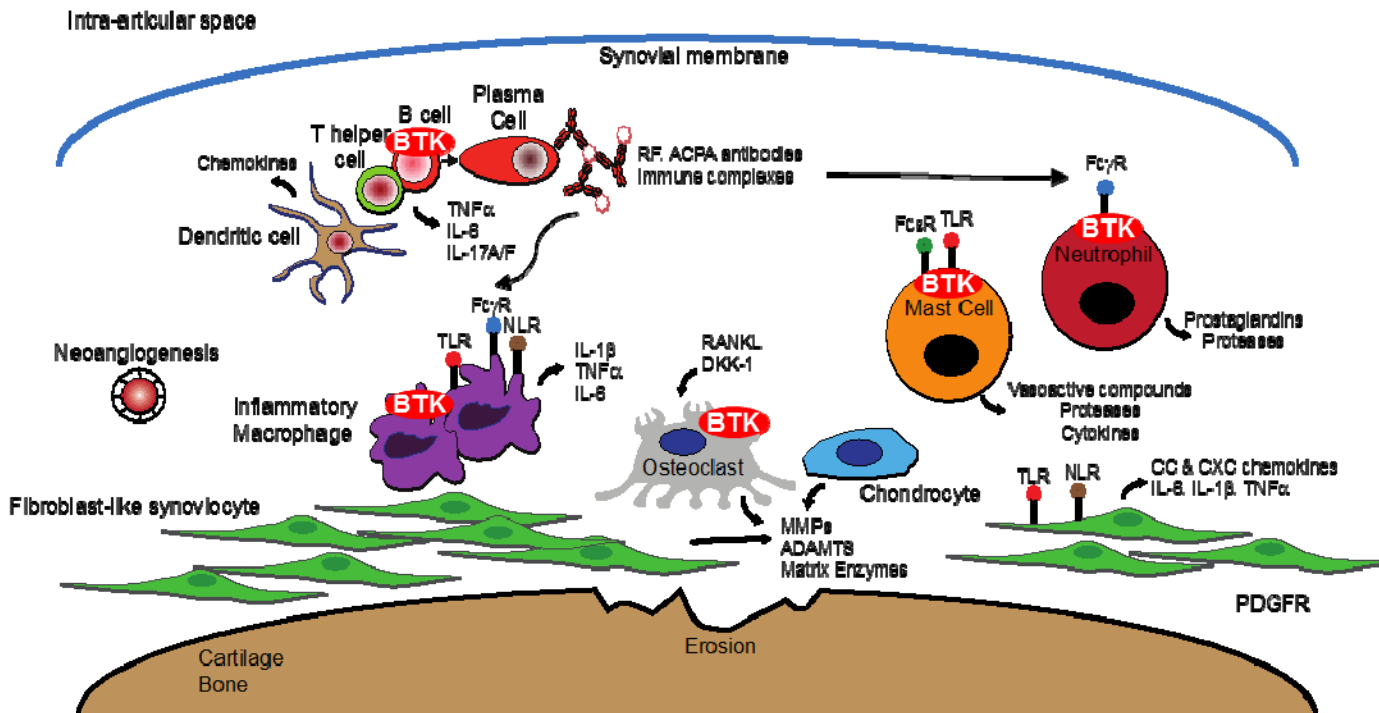
Atopic dermatitis  
Phase 2b study started by Galderma in July 2017



# MoA of RG7845 (BTK inhibitor)

- BTK is a non-receptor tyrosine kinase which plays an important role in the pathogenesis of autoimmune diseases: proliferation of B cells and differentiation into antibody-producing cells, cytokine production of myeloid cells etc.
- BTK is involved in arteritis and joint destruction associated with rheumatoid arthritis (RA)
- RG7845 is a small molecule, highly selective BTK inhibitor which can reversibly bind to the target molecule. With its BTK inhibition mechanism, the compound is expected to improve RA symptoms.

BTK: Bruton's tyrosine kinase



## <Pathological role of BTK in RA >

- ✓ **B cell:** proliferation, differentiation, autoantibody & cytokine production, and T cell activation by co-stimulatory molecule
- ✓ **Plasma cells:** autoantibody production
- ✓ **Macrophage / Mast cell / Neutrophil:** production and secretion of cytokine & inflammatory mediator
- ✓ **Osteoclast:** differentiation & regulation



# Results of Clinical Trials (1)

In-  
licensed

## **RG7446 / atezolizumab**

### **Locally advanced or metastatic urothelial carcinoma**

Primary endpoint not achieved in global Phase 3 study (IMvigor211)

- Statistically significant improvement in overall survival compared to chemotherapy was not demonstrated

In-  
licensed

## **Perjeta<sup>®</sup>**

### **HER2+ Breast cancer (adjuvant)**

Global Phase 3 study (APHINITY)

- June 2017: efficacy and safety data presented at the 2017 annual meeting of The American Society of Clinical Oncology
- June 2017: efficacy and safety data published in The New England Journal of Medicine Online





# Results of Clinical Trials (2)

In-  
house

## Alecensa® ALK+ NSCLC

Japanese Phase 3 study (J-ALEX)

- May 2017: efficacy and safety data published in The Lancet Online

Global Phase 3 study (ALEX)

- June 2017: efficacy and safety data presented at the 2017 annual meeting of The American Society of Clinical Oncology
- June 2017: efficacy and safety data published in The New England Journal of Medicine Online

In-  
house

## ACE910 / emicizumab Hemophilia A (inhibitor)

Global Phase 3 study in adults and adolescents (HAVEN 1)\*<sup>1</sup>

- June 2017: efficacy and safety data presented at the 2017 meeting of The International Society on Thrombosis and Haemostasis
- June 2017: efficacy and safety data published in The New England Journal of Medicine Online

Interim analysis of global Phase 3 study in children (HAVEN 2)\*<sup>2</sup>

- June 2017: efficacy and safety data presented at the 2017 meeting of The International Society on Thrombosis and Haemostasis

\*1 patients 12 years of age and older

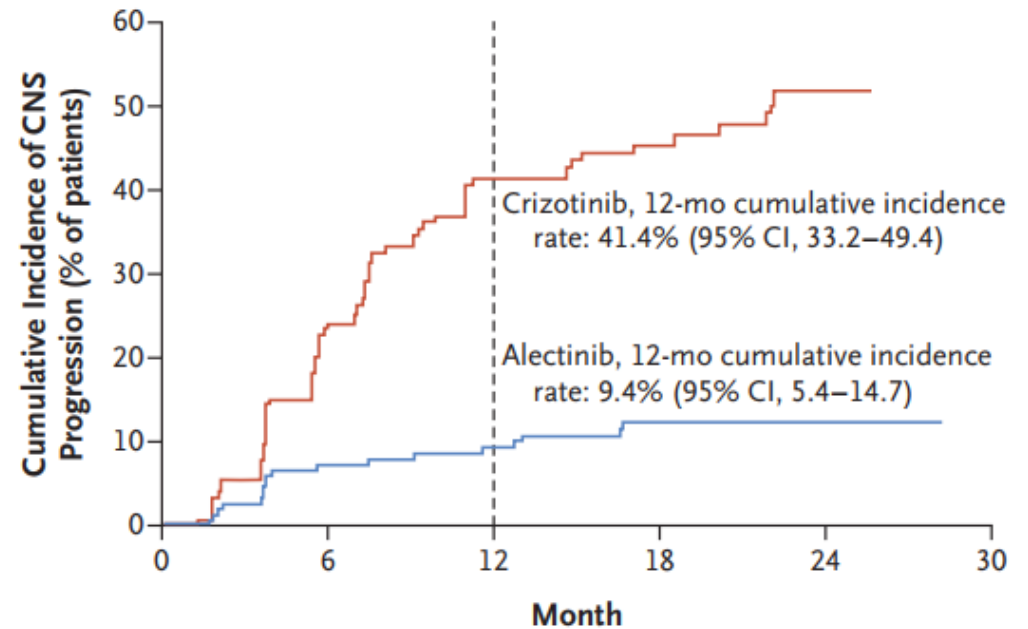
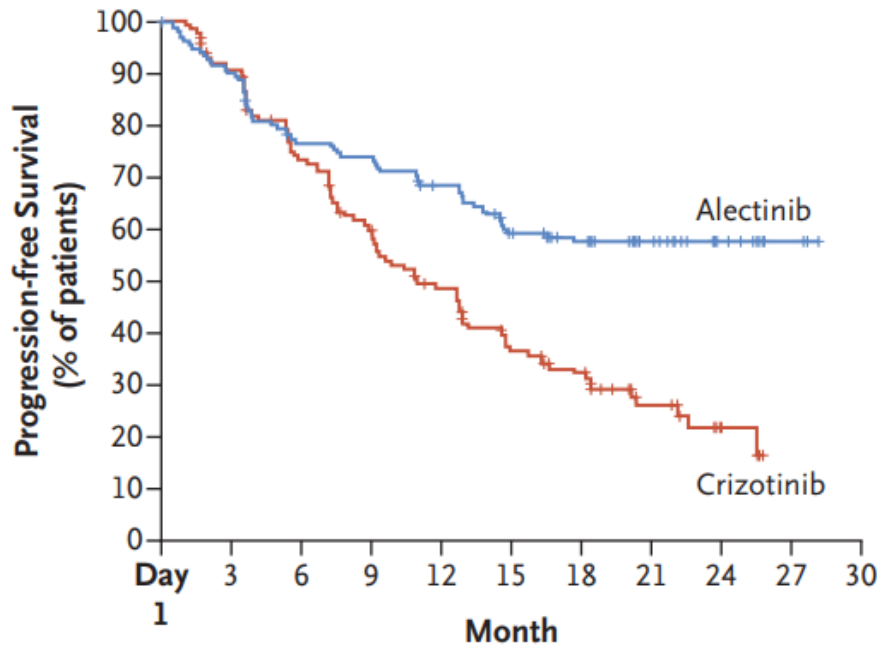
\*2 patients less than 12 years of age, with allowance for patients 12 to 17 years of age, who weigh less than 40kg.





# Alecensa<sup>®</sup> / alectinib ALEX Study

- Results from alectinib arm compared with crizotinib arm demonstrated:
  - a 53% reduction in the risk of disease progression or death (primary endpoint)
  - a 12-month cumulative incidence rate of CNS progression of 9.4% vs. 41.4% in crizotinib arm
- The safety profile of Alecensa was consistent with that observed previously



**No. at Risk**

Alectinib	152	135	113	109	97	81	67	35	15	3
Crizotinib	151	132	104	84	65	46	35	16	5	

Solange Peters et al. *NEJM* 2017,  
<http://www.nejm.org/doi/pdf/10.1056/NEJMoa1704795>

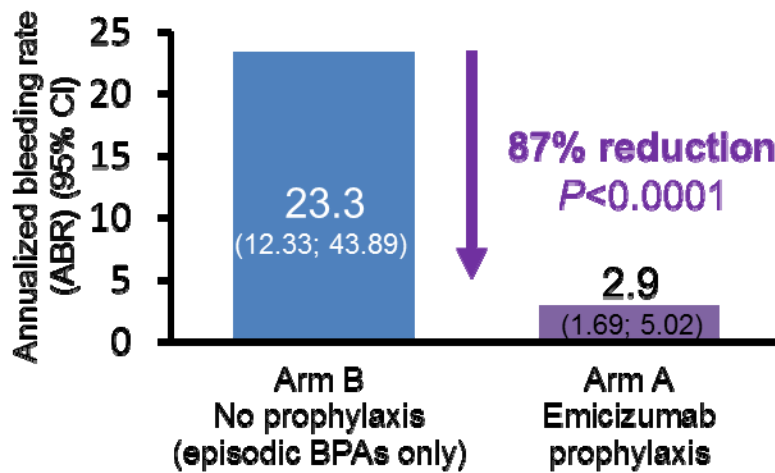
Dosage of Alecensa in ALEX study is 600mg BID  
 Approved dosage of Alecensa in Japan is 300mg BID

# ACE910 / Emicizumab HAVEN 1 Study

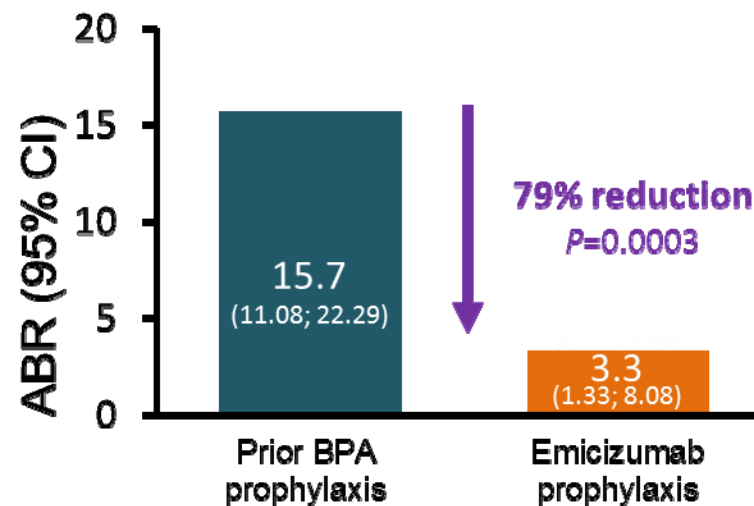


Roche A member of the Roche group

- Study was conducted in adult or adolescent (>12 years of age) hemophilia A patients with inhibitors
- A 87% reduction in treated bleeds was observed compared with No prophylaxis group (primary endpoint)
- A 79% reduction in treated bleeds after treatment with emicizumab was observed in an intra-patient analysis which was conducted in the group of patients who had previously received prophylactic use of BPA and then received emicizumab
- Adverse events (AEs) occurring in 5% or more of patients treated with emicizumab were injection site reactions, headache, fatigue, upper respiratory tract infection and arthralgia.



Median ABR (IQR)	<b>18.8</b> (12.97; 35.08)	<b>0.0</b> (0.00; 3.73)
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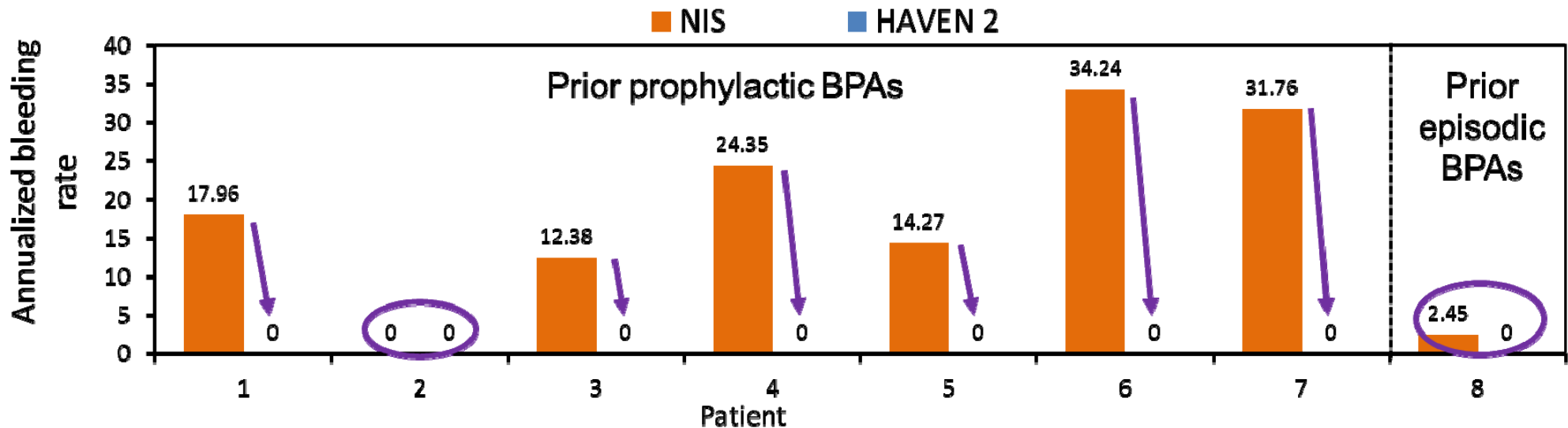
Median ABR (IQR)	<b>12.0</b> (5.73; 24.22)	<b>0.0</b> (0.00; 2.23)
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# ACE910 / Emicizumab HAVEN 2 Study



Roche A member of the Roche group

- Interim analysis was conducted in 19 children (<12 years of age) with hemophilia A with inhibitors (median observation period: 12 weeks)
- Only one of 19 children receiving emicizumab reported a treated bleed
- An intra-patient comparison (n=8) in patients who were previously enrolled in the NIS showed that all patients experienced zero treated bleeds
- The most common AEs with emicizumab in the HAVEN 2 study were mild injection site reactions and common cold symptoms (nasopharyngitis).



NIS: non-interventional study

Guy Young et al. ISTH 2017

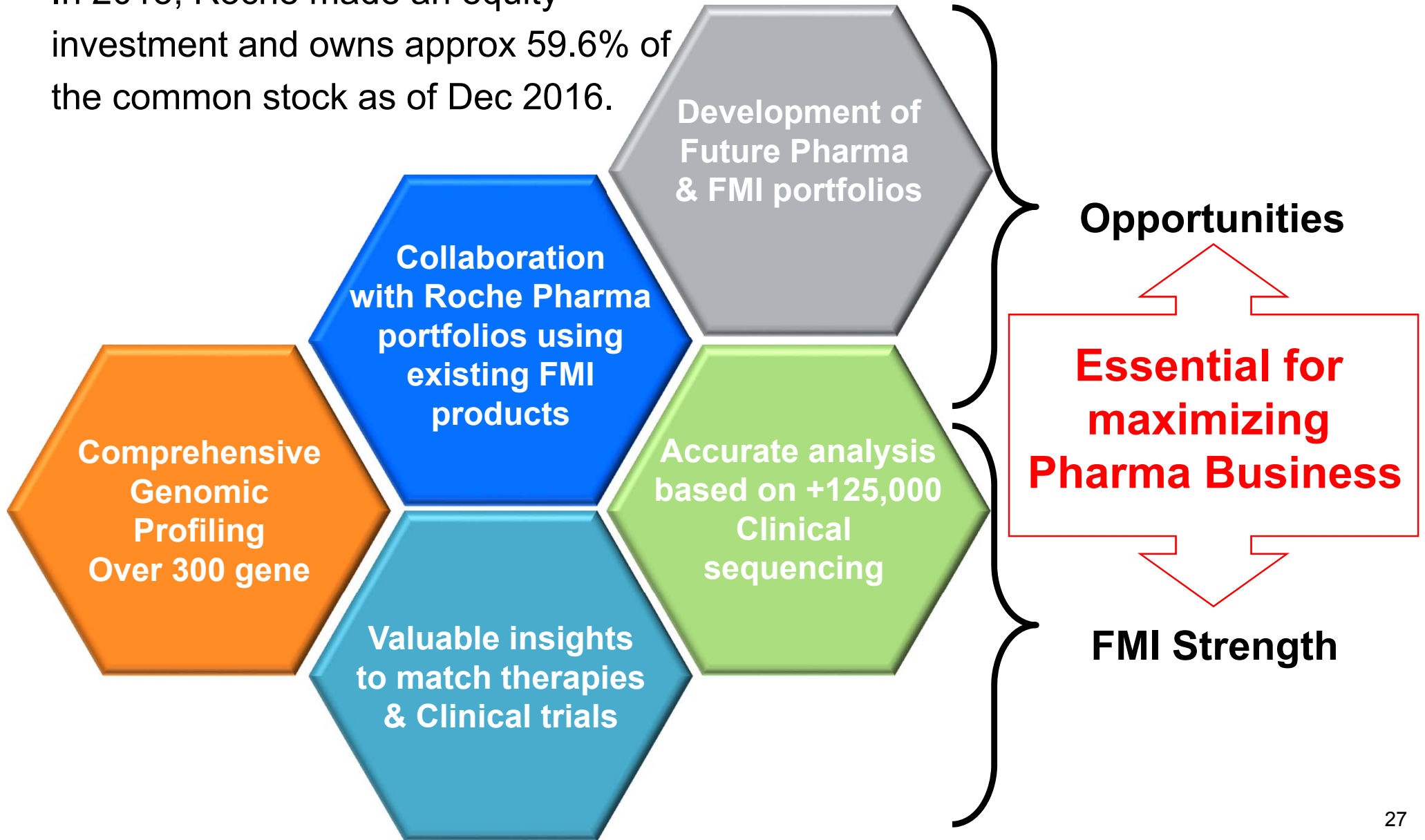
# Foundation Medicine, Inc., FMI

Innovation all for the patients



Roche A member of the Roche group

- Founded 2010 in Cambridge, MA, USA.
- In 2015, Roche made an equity investment and owns approx 59.6% of the common stock as of Dec 2016.

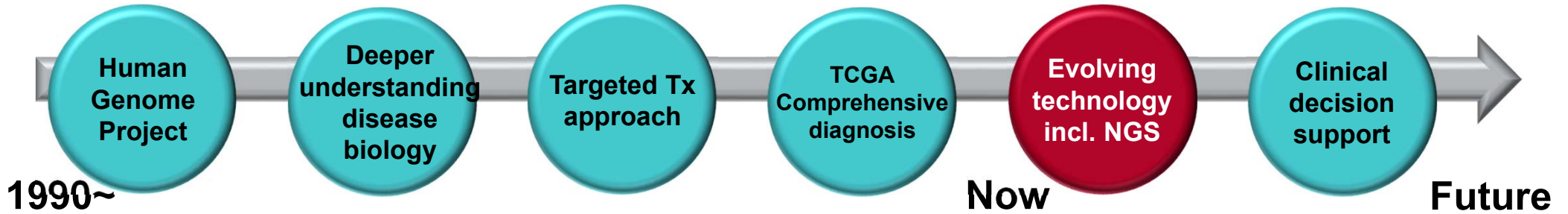


# Chugai's Contribution to PHC

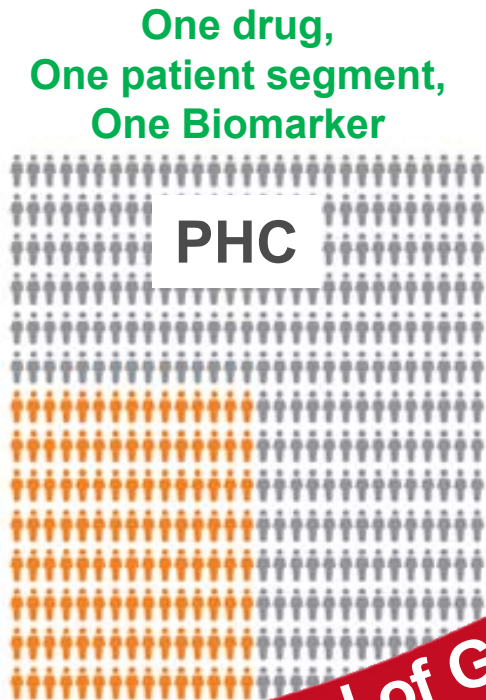
Innovation all for the patients



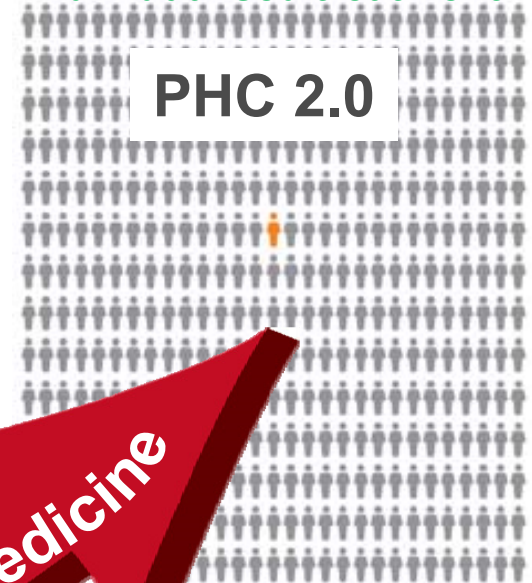
Roche A member of the Roche group



**CGP precisely connects optimal therapies to prolong survival for cancer patients**



Single patient,  
comprehensive profile,  
individualised treatment



PHC: Personalised Health Care  
Tx: Treatment  
TCGA: The cancer Genome Atlas  
NGS: Next Generation Sequence





# Projected Submissions (Post PoC NMEs and Products)

**Filed**

atezolizumab (RG7446) NSCLC	ACTEMRA (MRA) Giant Cell Arteritis (EU)
ALECENSA (AF802/RG7853) NSCLC[1L] (overseas)	ACTEMRA (MRA) Large-Vessel Vasculitis
	emicizumab (ACE910/RG6013) Hemophilia A (inhibitor) (Japan, overseas)

**NME**      **line extension**

**in-house**      ■     

**in-licensed**      ■     

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

atezolizumab (RG7446) Prostate Cancer	nemolizumab* (CIM331) Pruritus in Dialysis Patients
atezolizumab (RG7446) Ovarian Cancer	lebrikizumab (RG3637) IPF
atezolizumab (RG7446) RCC (adjuvant)	crenezumab (RG7412) Alzheimer's Disease
atezolizumab (RG7446) MIUC (adjuvant)	gantenerumab (RG1450) Alzheimer's Disease
atezolizumab (RG7446) NSCLC (adjuvant)	SUVENYL (NRD101) Knee Osteoarthritis /Shoulder Periarthritis
KADCYLA (RG3502) Breast Cancer (adjuvant)	Ipatasertib (RG7440) Prostate Cancer

	atezolizumab (RG7446) Breast Cancer	emicizumab (ACE910/RG6013) Hemophilia A (non-inhibitor)	
atezolizumab (RG7446) Urothelial Carcinoma	atezolizumab (RG7446) RCC	SA237 / RG6168 Neuromyelitis Optica	
obinutuzumab (GA101/RG7159) Indolent NHL	PERJETA (RG1273) Gastric Cancer	ACTEMRA (MRA) Systemic Sclerosis	
PERJETA (RG1273) Breast Cancer (adjuvant)	AVASTIN (RG435) RCC	Ediolol (ED-71) Osteoporosis (China)	atezolizumab (RG7446) SCLC

2017

2018

2019

2020 and beyond



# 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
Tamiflu®	Additional dosage and administration for newborn and infant	Approved [March 24, 2017]
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
Copegus®	Improvement of viraemia associated with genotype 3 chronic hepatitis C or compensated cirrhosis related to genotype 3 hepatitis C when administered in combination with sofosbuvir	Approved [March 24, 2017]
Xeloda®	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by the committee

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