



ACCEL 15 Aiming to become "Top Pharmaceutical Company"

# **FY2015 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: 240.2 billion yen (+18.2, +8.2% YoY)

- Domestic sales excl. Tamiflu: increase due to steady growth of mainstay products and new products (+13.8, +8.3%)
- Overseas sales: increase due to growth in Actemra export driven by both yen depreciation and volume expansion (+11.1, +31.1%)
- Royalties and other operating income: decrease due to milestone income in the previous year, etc. (-6.4, -46.0%)

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

- Cost of sales: the ratio to sales worsened due primarily to yen depreciation (+1.0% point, from 49.1% to 50.1%)
- Operating expenses: increase mainly in research and development expenses and general and administration expenses (+1.5, +2.0%)

### ■ Profits

- IFRS results: operating profit 43.2 billion yen (+0.1, +0.2%)  
net income 30.8 billion yen (+1.4, +4.8%)
- Core results: operating profit 45.9 billion yen (+2.2, +5.0%)  
EPS 58.30 yen (+4.64, +8.6%)



# IFRS and Core Results Jan – Jun

(Billions of JPY)

(Billions of JPY)	IFRS results		Non-core items		Core results	
	2015 Jan - Jun		Intangible assets and Business combinations	Other eliminated items	2015 Jan - Jun	
<b>Revenues</b>	<b>240.2</b>				<b>240.2</b>	
Sales	232.6				232.6	
Royalties and other operating income	7.5				7.5	
Cost of sales	-117.2		+0.7		-116.6	
<b>Gross profit</b>	<b>122.9</b>		<b>+0.7</b>		<b>123.6</b>	
<b>Operating expenses</b>	<b>-79.7</b>		<b>+1.9</b>	<b>+0.1</b>	<b>-77.7</b>	
Marketing and distribution	-34.7		+0.1		-34.6	
Research and development	-39.2		+1.8	+0.0	-37.3	
General and administration	-5.9			+0.1	-5.8	
<b>Operating profit</b>	<b>43.2</b>		<b>+2.6</b>	<b>+0.1</b>	<b>45.9</b>	
Financing costs	-0.0				-0.0	
Other financial income (expense)	0.7				0.7	
<b>Profit before taxes</b>	<b>43.9</b>		<b>+2.6</b>	<b>+0.1</b>	<b>46.5</b>	
Income taxes	-13.1		-0.9	-0.0	-14.0	
<b>Net income</b>	<b>30.8</b>		<b>+1.7</b>	<b>+0.1</b>	<b>32.5</b>	
Chugai shareholders	30.1		+1.7	+0.1	31.9	
Non-controlling interests	0.7				0.7	

## Non-Core items

- Intangible/Business combinations
  - Amortization of intangible assets +0.8
  - Impairment of intangible assets +1.8
  - No business combinations

- Other eliminated items
  - Environmental costs +0.1

Core net income  
attributable to Chugai  
shareholders 31.9 <sup>Ⓐ</sup>

(Millions of shares)

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

 547 <sup>Ⓑ</sup>

Core EPS 58.30 <sup>Ⓐ/Ⓑ</sup> (JPY)

## Year on Year (Core)

# Financial Overview Jan – Jun

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(Billions of JPY)	2014		2015		Growth	
	Jan - Jun		Jan - Jun			
	vs. Revenues		vs. Revenues			
<b>Revenues</b>	<b>222.0</b>		<b>240.2</b>		<b>+18.2</b>	<b>+8.2%</b>
Sales	208.1		232.6		+24.5	+11.8%
excl. Tamiflu	201.0		225.9		+24.9	+12.4%
Domestic	165.3		179.1		+13.8	+8.3%
Export to Roche	26.3		37.2		+10.9	+41.4%
Other overseas	9.5		9.6		+0.1	+1.1%
Tamiflu	7.1		6.7		-0.4	-5.6%
Ordinary	7.0		6.7		-0.3	-4.3%
Govt. stockpiles etc.	0.1		0.0		-0.1	-100.0%
Royalties and other operating income	13.9		7.5		-6.4	-46.0%
Cost of sales	-102.1	46.0%	-116.6	48.5%	-14.5	+14.2%
<b>Gross profit</b>	<b>119.9</b>	<b>54.0%</b>	<b>123.6</b>	<b>51.5%</b>	<b>+3.7</b>	<b>+3.1%</b>
Operating expenses	-76.2	34.3%	-77.7	32.3%	-1.5	+2.0%
<b>Operating profit</b>	<b>43.7</b>	<b>19.7%</b>	<b>45.9</b>	<b>19.1%</b>	<b>+2.2</b>	<b>+5.0%</b>
Financing costs	-0.0		-0.0		0.0	0.0%
Other financial income (expense)	0.3		0.7		+0.4	+133.3%
Income taxes	-14.2		-14.0		+0.2	-1.4%
<b>Net income</b>	<b>29.8</b>	<b>13.4%</b>	<b>32.5</b>	<b>13.5%</b>	<b>+2.7</b>	<b>+9.1%</b>
EPS (JPY)	53.66		58.30		+4.64	+8.6%

(Billions of JPY)

Royalties and other operating income	-6.4
decrease in milestone income, etc.	
Other financial income (expense)	+0.4
Exchange gains/losses	-2.0
Gains/Losses on derivatives	+2.4
(Gains/Losses on foreign exchange forward contracts)	

## Cost of sales ratio vs. Sales

2014 Jan - Jun	2015 Jan - Jun
49.1%	50.1%

## Average exchange rate (JPY)

	2014 Jan - Jun	2015 Jan - Jun
1CHF	115.04	126.88
1EUR	140.51	134.27
1USD	102.49	120.24
1SGD	81.29	89.10

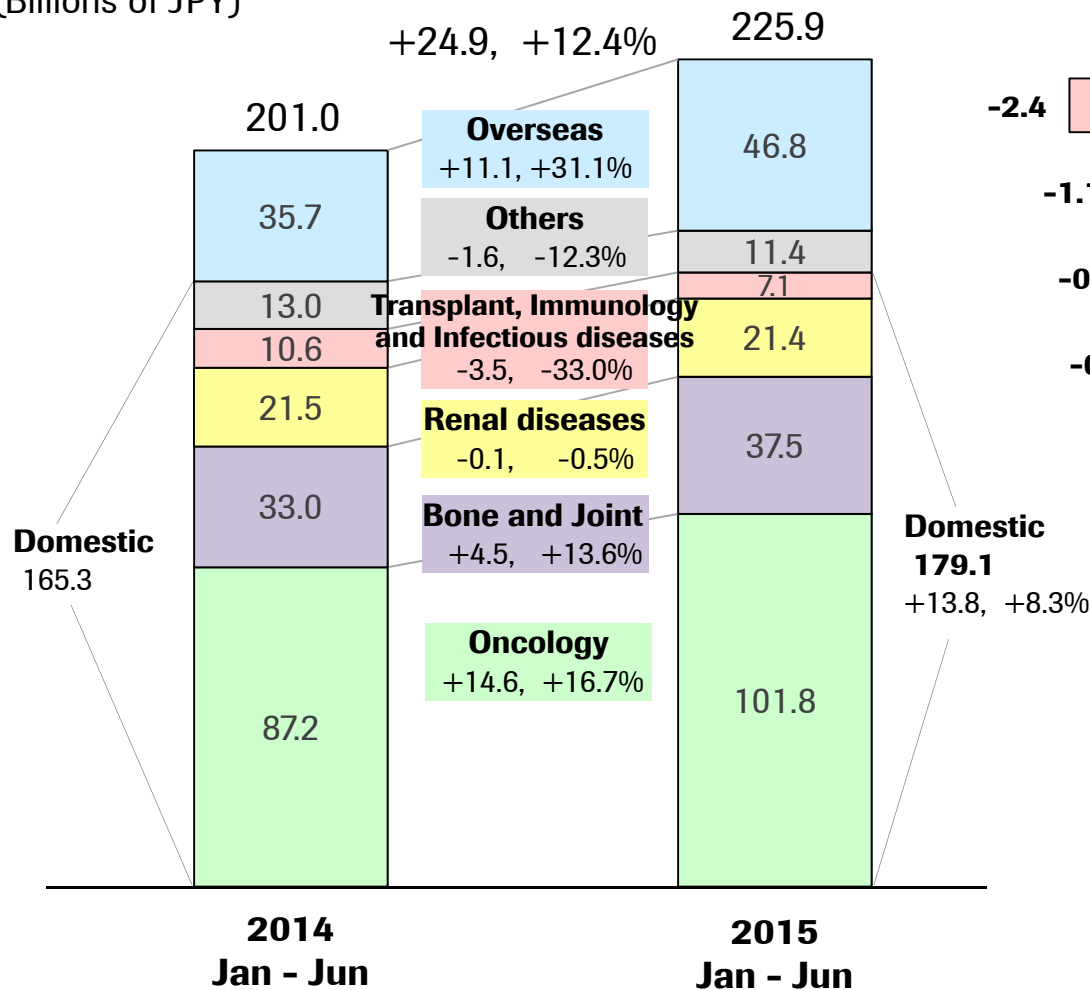


Year on Year

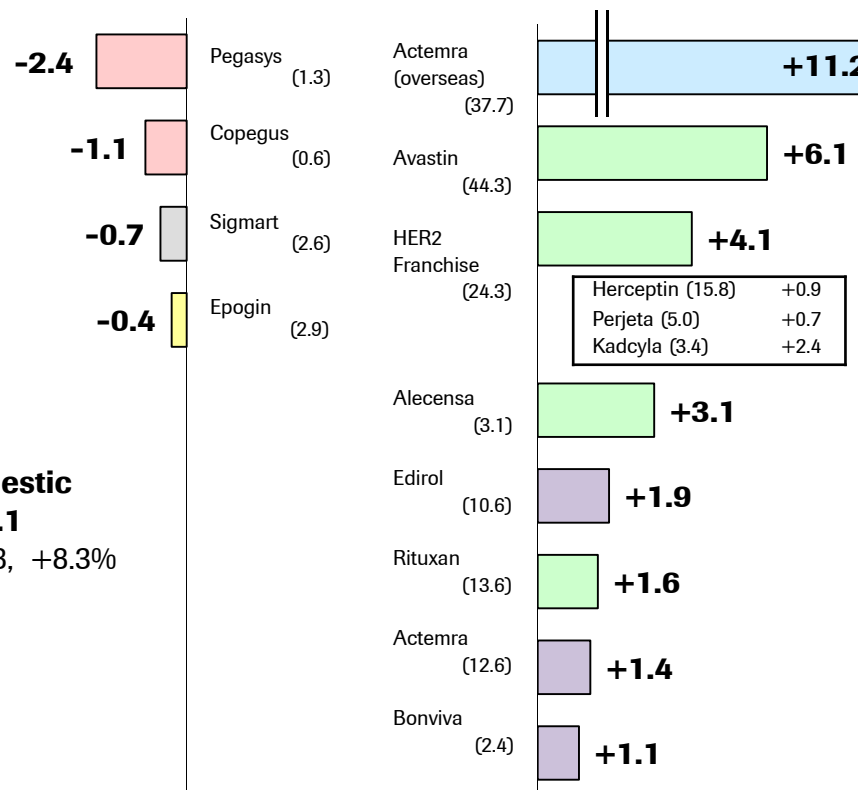
# Sales (excl. Tamiflu) Jan - Jun

Sales by Disease Area, Year on Year Comparisons

(Billions of JPY)



Sales by Products, Year on Year Changes



( ): FY2015 Actual



# Tamiflu Sales Performance

(Billions of JPY)		Fiscal Term Sales														Forecast		
		FY2009.12		FY2010.12		FY2011.12		FY2012.12		FY2013.12		FY2014.12		FY2015.12		Seasonal Sales	Cases per sentinel* (millions)	
		Jan-Jun	Jul-Dec	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	2008-09	11.0															<b>16.7</b>	<b>1.27</b>
	2009-10		25.2	1.4													<b>26.6</b>	<b>2.02</b>
	2010-11				0.2	4.1											<b>4.3</b>	<b>1.26</b>
	2011-12						1.3	7.8									<b>9.1</b>	<b>1.63</b>
	2012-13								2.4	8.2							<b>10.6</b>	<b>1.11</b>
	2013-14										1.9	7.0					<b>9.0</b>	<b>1.44</b>
	2014-15												5.8	6.7			<b>12.6</b>	<b>1.39</b>
	2015-16														0.7		-	-
<b>Ordinary</b>		<b>36.2 (+29.1)</b>	<b>1.6 (-34.6)</b>	<b>5.4 (+3.8)</b>	<b>10.2 (+4.8)</b>	<b>10.1 (-0.1)</b>	<b>12.9 (+2.8)</b>	<b>7.4 (-5.5)</b>										
Govt. Stockpiles etc.	2008-09	14.4															<b>15.5</b>	
	2009-10		25.6	10.6													<b>36.2</b>	
	2010-11				5.9	0.5											<b>6.4</b>	
	2011-12						2.8	0.4									<b>3.2</b>	
	2012-13								1.5	0.8							<b>2.3</b>	
	2013-14										0.1	0.1					<b>0.2</b>	
	2014-15												0.1	0.0			<b>0.1</b>	
	2015-16																-	-
<b>Govt. Stockpile etc.</b>		<b>40.0 (+38.7)</b>	<b>16.6 (-23.4)</b>	<b>3.3 (-13.3)</b>	<b>1.9 (-1.4)</b>	<b>0.9 (-1.0)</b>	<b>0.2 (-0.7)</b>	<b>0.0 (-0.2)</b>										
<b>Total</b>		<b>25.4</b>	<b>50.8</b>	<b>12.0</b>	<b>6.1</b>	<b>4.6</b>	<b>4.1</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>0.7</b>			
		<b>76.2 (+67.8)</b>	<b>18.2 (-58.0)</b>	<b>8.7 (-9.5)</b>	<b>12.0 (+3.3)</b>	<b>11.0 (-1.0)</b>	<b>13.0 (+2.0)</b>	<b>7.4 (-5.6)</b>										

( ) Year on year

\* Total number of patients of the controlled samples in the "Infectious Diseases Weekly Report" (IDWR) for the period from late October to mid-April (from the 44th week of every year to the 16th week of the next year; from early July 2009 and mid-March 2010 for 2009/2010). IDWR is published by Japan's National Institute of Infectious Diseases.

Year on Year (Core)

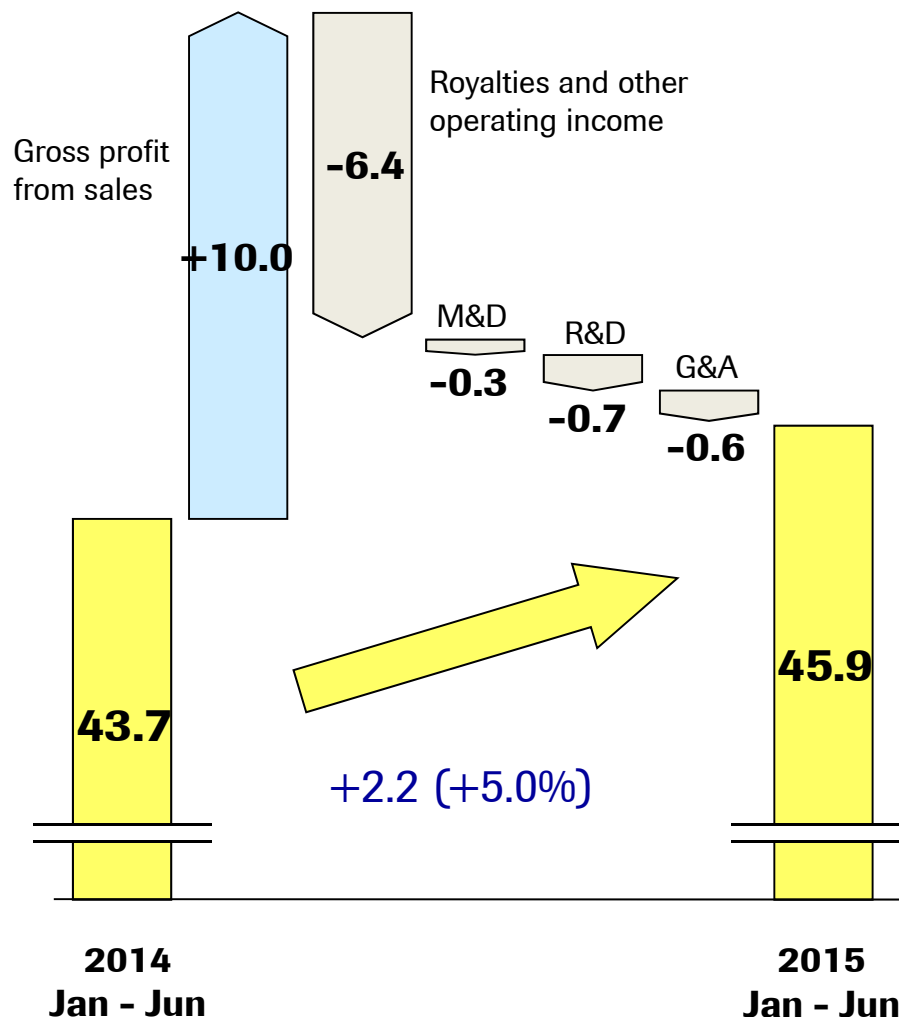
# Operating Profit Jan - Jun

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(Billions of JPY)



(Billions of JPY)	2014 Jan - Jun	2015 Jan - Jun	Growth
<b>Revenues</b>	<b>222.0</b>	<b>240.2</b>	<b>+18.2</b>
Cost of sales	-102.1	-116.6	-14.5
<b>Gross profit</b>	<b>119.9</b>	<b>123.6</b>	<b>+3.7</b>
<i>of which</i> Sales	106.1	116.1	+10.0
Royalties, etc.	13.9	7.5	-6.4
Marketing and distribution	-34.3	-34.6	-0.3
Research and development	-36.6	-37.3	-0.7
General and administration	-5.2	-5.8	-0.6
<b>Operating profit</b>	<b>43.7</b>	<b>45.9</b>	<b>+2.2</b>

Increase in gross profit from sales	+10.0
Steady growth of mainstay products and new products	
Decrease in royalties and other operating income	-6.4
Increase in Marketing and distribution	-0.3
Increase in research and development	-0.7
Negative foreign exchange impact, etc.	
Increase in general and administration	-0.6
Increase in miscellaneous expenses due primarily to communication activities to raise corporate brand awareness	



Year on Year (Core)

# Financial Overview Apr – Jun



(Billions of JPY)	2014		2015		Growth	
	Apr - Jun vs. Revenues		Apr - Jun vs. Revenues			
<b>Revenues</b>	<b>98.0</b>		<b>123.1</b>		<b>+25.1</b>	<b>+25.6%</b>
Sales	93.9		119.2		+25.3	+26.9%
excl. Tamiflu	93.7		119.2		+25.5	+27.2%
Domestic	80.1		95.2		+15.1	+18.9%
Export to Roche	9.3		19.2		+9.9	+106.5%
Other overseas	4.3		4.8		+0.5	+11.6%
Tamiflu	0.2		0.0		-0.2	-100.0%
Ordinary	0.2		0.0		-0.2	-100.0%
Govt. stockpiles etc.	-		-		-	-
Royalties and other operating income	4.1		3.9		-0.2	-4.9%
Cost of sales	-46.8	47.8%	-59.1	48.0%	-12.3	+26.3%
<b>Gross profit</b>	<b>51.1</b>	<b>52.1%</b>	<b>63.9</b>	<b>51.9%</b>	<b>+12.8</b>	<b>+25.0%</b>
Operating expenses	-38.9	39.7%	-39.5	32.1%	-0.6	+1.5%
<b>Operating profit</b>	<b>12.3</b>	<b>12.6%</b>	<b>24.4</b>	<b>19.8%</b>	<b>+12.1</b>	<b>+98.4%</b>
Financing costs	0.0		-0.0		0.0	-
Other financial income (expense)	0.1		0.2		+0.1	+100.0%
Income taxes	-1.9		-7.4		-5.5	+289.5%
<b>Net income</b>	<b>10.5</b>	<b>10.7%</b>	<b>17.2</b>	<b>14.0%</b>	<b>+6.7</b>	<b>63.8%</b>
EPS (JPY)	18.85		30.76		+11.91	+63.2%

(Billions of JPY)

Increase in gross profit from sales	+13.0
Increase in sales	
Decrease in royalties and other operating income	-0.2
Increase in operating expenses	-0.6
Increase in marketing and distribution	-0.3
Increase in research and development	-0.3
Increase in general and administration	-0.1

Cost of sales ratio vs. Sales

2014 Apr - Jun	2015 Apr - Jun
49.8%	49.6%

vs. Forecast (Core)

# Financial Progress Jan – Jun

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(Billions of JPY)	Actual	Forecast on Jan 28		2014
	2015 Jan - Jun	2015 Jan - Dec	Progress	Progress*
<b>Revenues</b>	<b>240.2</b>	<b>486.5</b>	<b>49.4%</b>	<b>48.1%</b>
Sales	232.6	460.8	50.5%	47.6%
excl. Tamiflu	225.9	453.4	49.8%	47.4%
Domestic	179.1	360.9	49.6%	47.3%
Export to Roche	37.2	74.7	49.8%	47.7%
Other overseas	9.6	17.8	53.9%	49.2%
Tamiflu	6.7	7.4	90.5%	54.6%
Royalties and other operating income	7.5	25.6	29.3%	57.4%
Cost of sales	-116.6	-230.2	50.7%	47.1%
<b>Gross profit</b>	<b>123.6</b>	<b>256.3</b>	<b>48.2%</b>	<b>49.1%</b>
Operating expenses	-77.7	-171.3	45.4%	45.7%
<b>Operating profit</b>	<b>45.9</b>	<b>85.0</b>	<b>54.0%</b>	<b>56.5%</b>
EPS (JPY)	58.30	104.42	55.8%	56.5%

\* Jan - Jun progress versus Jan - Dec.

vs. Forecast (Core)

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# Sales Progress (excl. Tamiflu) Jan – Jun

(Billions of JPY)	Actual	Full-year forecast		2014
	2015 Jan - Jun	2015 Jan - Dec	Progress	Progress*1
<b>Sales excl. Tamiflu</b>	<b>225.9</b>	<b>453.4</b>	<b>49.8%</b>	<b>47.4%</b>
<b>Domestic</b>	<b>179.1</b>	<b>360.9</b>	<b>49.6%</b>	<b>47.3%</b>
<b>Oncology</b>	<b>101.8</b>	<b>204.5</b>	<b>49.8%</b>	<b>46.2%</b>
Avastin	44.3	88.2	50.2%	46.4%
HER2 Franchise	24.3	48.3	50.3%	45.5%
Herceptin	15.8	29.6	53.4%	47.8%
Perjeta	5.0	9.9	50.5%	47.3%
Kadcyla	3.4	8.8	38.6%	25.0%
Tarceva	5.5	14.1	39.0%	48.7%
Xeloda	5.3	10.0	53.0%	48.1%
Alecensa	3.1	5.2	59.6%	-
Zelboraf *2	0.2	0.2	100.0%	-
<b>Bone and Joint</b>	<b>37.5</b>	<b>75.9</b>	<b>49.4%</b>	<b>47.4%</b>
Actemra	12.6	26.3	47.9%	46.5%
Edirol	10.6	21.2	50.0%	45.3%
Bonviva	2.4	4.9	49.0%	38.2%
<b>Renal</b>	<b>21.4</b>	<b>44.3</b>	<b>48.3%</b>	<b>48.1%</b>
Mircera	11.0	24.5	44.9%	47.8%
Epogin	2.9	5.2	55.8%	50.0%
<b>Transp., Immun., Infectious</b>	<b>7.1</b>	<b>13.0</b>	<b>54.6%</b>	<b>51.0%</b>
Pegasys	1.3	2.1	61.9%	52.9%
Copegus	0.6	1.1	54.5%	54.8%
<b>Others</b>	<b>11.4</b>	<b>23.2</b>	<b>49.1%</b>	<b>50.8%</b>
<b>Overseas</b>	<b>46.8</b>	<b>92.5</b>	<b>50.6%</b>	<b>48.0%</b>
Export to Roche	37.2	74.7	49.8%	47.7%
Other overseas	9.6	17.8	53.9%	49.2%

\*1 Jan - Jun progress versus Jan - Dec.

\*2 Forecast for Zelboraf was disclosed on Apr. 22. The figure of 100% for progress versus Jan - Dec was calculated based on an amount rounded to the nearest 0.1 billion yen. The progress ratio is substantial at slightly more than 60%.



vs. Forecast (Core)

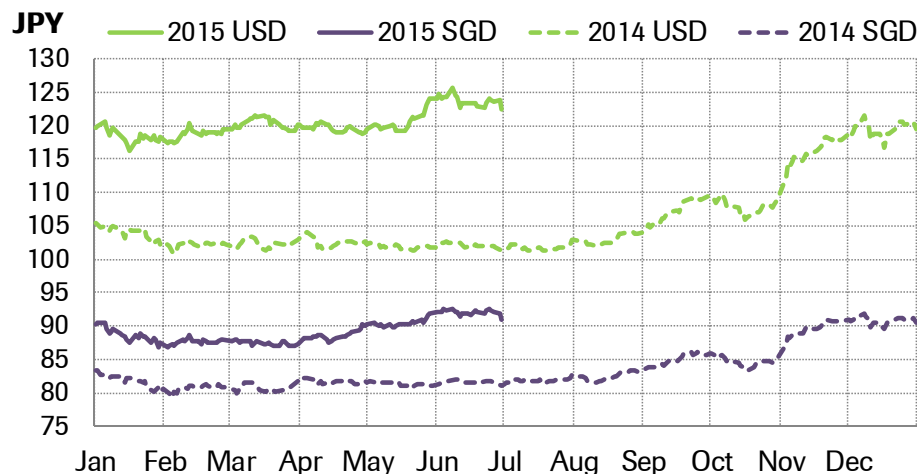
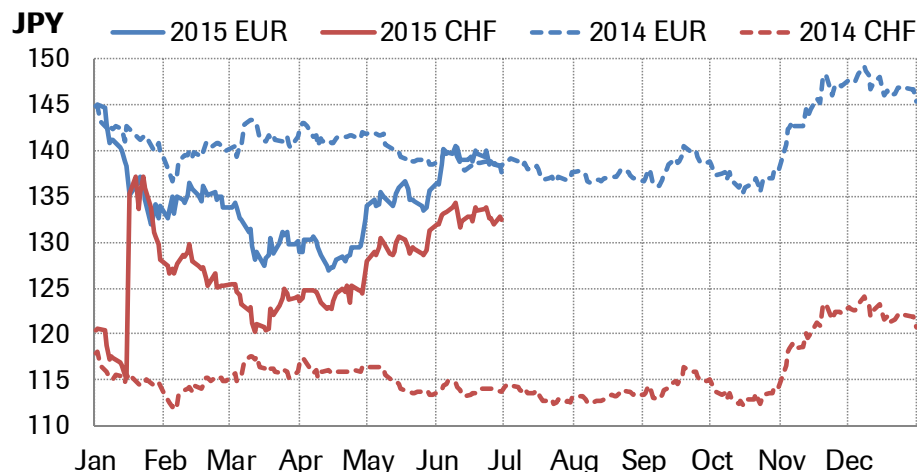
# Impact from Foreign Exchange

(Billions of JPY)	FX impact Jan - Jun (vs. Forecast on Jan. 28)	
<b>Revenues</b>	<b>+1.6</b>	
	Sales	+1.9
	Royalties and other operating income	-0.3
Cost of sales	Cost of sales	-0.9
Operating expenses	Expenses	+0.1
<b>Operating profit</b>	<b>+0.8</b>	

Actual/Assumption rate* (JPY)	Actual Jan - Jun avg. (2014)	Assumption Jan - Dec (as of Jan. 28)	Actual Jan - Jun avg. (2015)
1CHF	115.04	116.00	126.88
1EUR	140.51	142.00	134.27
1USD	102.49	119.00	120.24
1SGD	81.29	91.00	89.10

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

**[Reference]**  
Historical exchange rate to the JPY



vs. 2014 Year End

# Balance Sheet Items

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

(Billions of JPY)	2014 Dec	2015 Jun	Change
Trade accounts receivable	141.3	128.3	- 13.0
Inventories	139.6	145.9	+ 6.3
Trade accounts payable	-35.4	-43.4	- 8.0
Other net working capital *1	-36.2	-26.2	+ 10.0
<b>Net working capital</b>	209.4	204.6	- 4.8
Property, plant and equipment	140.2	141.9	+ 1.7
Intangible assets	11.3	10.9	- 0.4
Other long-term assets - net *2	-3.2	-2.1	+ 1.1
<b>Long-term net operating assets</b>	148.4	150.7	+ 2.3
<b>Net operating assets</b>	357.7	355.3	- 2.4
Debt	-0.2	-0.2	0.0
Marketable securities	116.0	120.0	+ 4.0
Cash and cash equivalents	114.0	126.6	+ 12.6
<b>Net cash</b>	229.9	246.4	+ 16.5
Other non-operating assets - net *3	10.2	11.7	+ 1.5
<b>Net non-operating assets</b>	240.0	258.2	+ 18.2
<b>Total net assets</b>	597.8	613.4	+ 15.6
<b>Total net assets</b>	597.8	613.4	+ 15.6
Total assets	739.5	744.3	+ 4.8
Total liabilities	-141.8	-130.9	+ 10.9

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

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

\*3 Deferred income tax assets, accrued corporate tax, etc.

FY2015 2Q Consolidated Financial Overview

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(Billions of JPY)

Decrease in net working capital	-4.8
Decrease in trade accounts receivable	-13.0
Seasonal change, etc.	
Increase in inventories	+6.3
Increase in trade accounts payable	-8.0
Negative foreign exchange impact and timing of purchase, etc.	
Increase in other net working capital	+10.0
Decrease in accrued expenses, etc.	
Increase in long-term net operating assets	+2.3
Increase in net cash	+16.5
Increase in other non-operating assets - net	+1.5
Equity ratio attributable to Chugai shareholders	+1.7% pts.
2015 Jun	82.3%
2014 Dec	80.6%

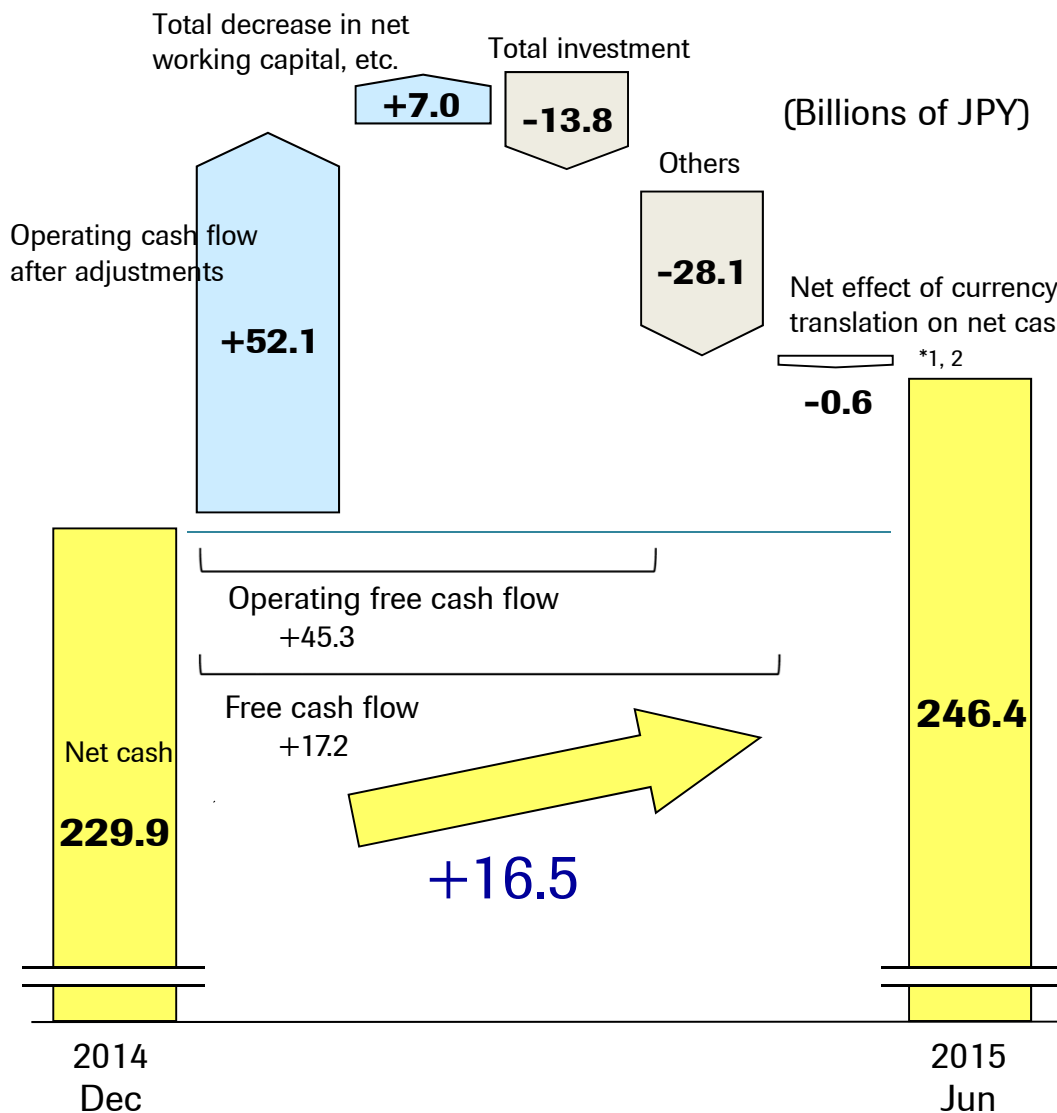
FX rate to the JPY (end of period)

	2014 Dec	2015 Jun
1CHF	120.81	132.49
1EUR	145.26	137.69
1USD	119.48	122.54
1SGD	90.41	91.03



vs. 2014 Year End

# Net Cash



Operating cash flow after adjustments	+52.1
Operating profit	+43.2
Depreciation and amortization, etc.	+8.9
Total decrease in net working capital, etc.	+7.0
Decrease in trade accounts receivable	+13.0
Increase in inventories	-6.7
Increase in trade accounts payable	+8.0
Change in other net working capital, etc.	-7.3
Total investment	-13.8
Investment in property, plant and equipment	-10.9
Payments for investment in production facilities, etc.	-2.9
Investment in intangible assets	-2.9
Operating free cash flow	+45.3
Others	-28.1
Tax paid	-16.0
Dividends paid	-14.8
Free cash flow	+17.2

\*1 Net effect of currency translation on net cash, etc.: Transaction in own equity instruments + Net effect of currency translation on net cash

\*2 Net effect on currency translation is a result of using different types of exchange rates 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 - June

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(Billions of JPY)	2014 Jan-Jun	2015 Jan-Jun	Change
<b>Operating profit - IFRS basis</b>	43.1	43.2	+0.1
Depreciation and impairment of Property, plant and equipment	6.8	7.0	+0.2
Amortization and impairment of intangible assets	0.6	2.6	+2.0
Other cash adjustment on operating profit	1.4	-0.7	-2.1
<b>Operating profit, net of operating cash adjustments</b>	51.9	52.1	+0.2
Increase (-) / decrease in trade accounts receivable	4.5	13.0	+8.5
Increase (-) / decrease in inventories	-14.3	-6.7	+7.6
Increase / decrease (-) in trade accounts payable	7.0	8.0	+1.0
Change in other net working capital, etc.	-2.8	-7.3	-4.5
<b>Total increase (-) / decrease in net working capital, etc.</b>	-5.6	7.0	+12.6
Investment in Property, plant and equipment	-9.2	-10.9	-1.7
Investment in intangible assets	-1.3	-2.9	-1.6
<b>Total investment</b>	-10.5	-13.8	-3.3
<b>Operating free cash flow</b>	35.8	45.3	+9.5
<b>as % of revenues</b>	16.1%	18.9%	+2.8%pts
Treasury activities (interest income/expenses, foreign exchange gains/losses, etc.)	0.4	2.6	+2.2
Tax paid	-13.3	-16.0	-2.7
Dividends paid	-12.9	-14.8	-1.9
<b>Free cash flow</b>	10.0	17.2	+7.2
Transaction in own equity instruments	0.5	0.8	+0.3
Net effect of currency translation on net cash, etc.*2	-1.3	-1.4	-0.1
<b>Net change in net cash</b>	9.2	16.5	+7.3

(Billions of JPY)

Operating profit, net of operating cash adjustments	+0.2
Total increase (-) / decrease in net working capital, etc.	+12.6
Increase (-) / decrease in trade accounts receivable	+8.5
Impact of advance payments received at the end of previous fiscal year, etc.	
Increase (-) / decrease in inventories	+7.6
Increase / decrease (-) in trade accounts payable	+1.0
Change in other net working capital, etc.	-4.5
Total investment	-3.3
Operating free cash flow	+9.5
Increase due to special factors such as payment for trade accounts receivable partly made in advance in the same period of the previous year, etc.	
Operating free cash flow as % of revenues	+2.8% pts.
Revenues	+18.2

Average exchange rate (JPY)

	2014 Jan - Jun	2015 Jan - Jun
1CHF	115.04	126.88
1EUR	140.51	134.27
1USD	102.49	120.24
1SGD	81.29	89.10

\*1 Net effect of currency translation on net cash, etc.: Transaction in own equity instruments + Net effect of currency translation on net cash

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



# Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.  
Executive Vice President  
Yutaka Tanaka

2015.7.23



# Oncology Field Projects under Development (as of 23 July, 2015)



	Phase I	Phase II	Phase III	Filed
Oncology	<p><b>CKI27 / RG7304</b> (Japan / overseas) - solid tumors</p> <p><b>RG7596 / polatuzumab vedotin</b> - NHL</p> <p><b>RG7604 / taselisib</b> - solid tumors</p> <p><b>RG7440 / ipatasertib</b> - solid tumors ★</p>	<p><b>AF802 (RG7853)</b> / <b>Alecensa (overseas)</b> - NSCLC [2L] ★</p> <p><b>RG435 / Avastin</b> - cervical cancer</p> <p><b>GC33 / RG7686</b> - hepatocellular carcinoma</p>	<p><b>AF802 (RG7853)</b> / <b>Alecensa (overseas)</b> - NSCLC [1L] ★</p> <p><b>RG1273 / Perjeta</b> - breast cancer (adjuvant) - gastric cancer</p> <p><b>RG3502 / Kadcyca</b> - breast cancer (adjuvant) - gastric cancer (PII/III)</p> <p><b>GA101 (RG7159)</b> / <b>obinutuzumab</b> - aggressive NHL - indolent NHL</p> <p><b>RG7446 / atezolizumab</b> - NSCLC - bladder cancer - renal cell carcinoma ★</p> <p><b>RG435 / Avastin</b> - renal cell carcinoma ★</p>	<p><b>RG340 / Xeloda</b> - gastric cancer (adjuvant)</p>

In principle, completion of first dose is regarded as the start of clinical studies in each phase.  
 NHL: non-Hodgkin's lymphoma  
 NSCLC: non-small cell lung cancer

**Letters in orange: in-house projects**  
**★: Projects with advances in stages since 22 April, 2015**

# Primary Field Projects under Development (as of 23 July, 2015)



	Phase I	Phase II	Phase III	Filed
Bone & Joint				<b>RG484 / Bonviva (oral)</b> - osteoporosis
Autoimmune		<b>MRA / Actemra (overseas)</b> - systemic sclerosis	<b>MRA / Actemra</b> - large-vessel vasculitis - giant cell arteritis (overseas) <b>SA237</b> - neuromyelitis optica★	
CNS	<b>RG1577 / sembragiline</b> - Alzheimer's disease <b>RG1662</b> - improvement of intellectual ability in individuals with Down syndrome	<b>RG7090 / basimglurant</b> - major depressive disorder	<b>RG1450 / gantenerumab</b> - Alzheimer's disease	
Others	<b>PC0371 (overseas)</b> - hypoparathyroidism ★	<b>RG3637 / lebrikizumab</b> - IPF <b>CIM331</b> - atopic dermatitis★ <b>URC102 (South Korea)</b> - gout <b>ACE910 / RG6013</b> - hemophilia A (PI/II)	<b>RG3637 / lebrikizumab</b> - asthma	

In principle, completion of first dose is regarded as the start of clinical studies in each phase.  
IPF: idiopathic pulmonary fibrosis

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

★: **Projects with advances in stages since 22 April, 2015**

★: **Multinational study managed by Chugai**

# Development Status

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## **RG7446 / atezolizumab (Engineered anti-PDL1 antibody)** **RG435 / Avastin®**

Renal cell carcinoma

Started global P3 in June 2015

In-  
licensed

## **RG7440 / ipatasertib**

Solid tumors

Started P1 in June 2015

In-  
house

## **PC0371**

Hypoparathyroidism

Started P1 in June 2015 (US)

In-  
licensed

## **RG7321 / pictilisib**

Solid tumors

Development discontinued

## Other Progress



In-house

### **MRA / Actemra®**

Systemic sclerosis

US FDA granted Breakthrough Therapy designation in June 2015 (Roche)

Decided to participate in global P3 (Chugai)

In-house

### **ACE910**

Hemophilia A

Planned to start global P3 for "inhibitor" patients in 2015

Planned to start global P3 for "non-inhibitor" patients in 2016

In-licensed

### **Netupitant-Palonosetron Fixed-Dose Combination (NEPA) / Akynzeo®**

Prevention of Chemotherapy-Induced Nausea and Vomiting

EMA approved in June 2015 (Helsinn)

In-licensed

### **Peretinoin**

Prevention of Recurrence of Hepatocellular Carcinoma

Obtained exclusive marketing rights in Japan from Kowa Co., Ltd. in July 2015

# Data Presentation at Scientific Meetings: AF802 / Alecensa®



Presented P1/2 study data for *ALK* positive NSCLC at American Society of Clinical Oncology (ASCO) in June 2015

	Overseas P1/2 * (Global)	Overseas P1/2 * (North America)	Japanese P1/2
ORR	50%	47.8%	93.5%
CNS ORR	57.1%	68.8%	-
Median PFS	8.9 months	6.3 months	≥29 months
Safety profile	Consistent with that observed in previous studies		

\* Patients with disease progression on or after crizotinib

# Data Presentation at Scientific Meetings: ACE910

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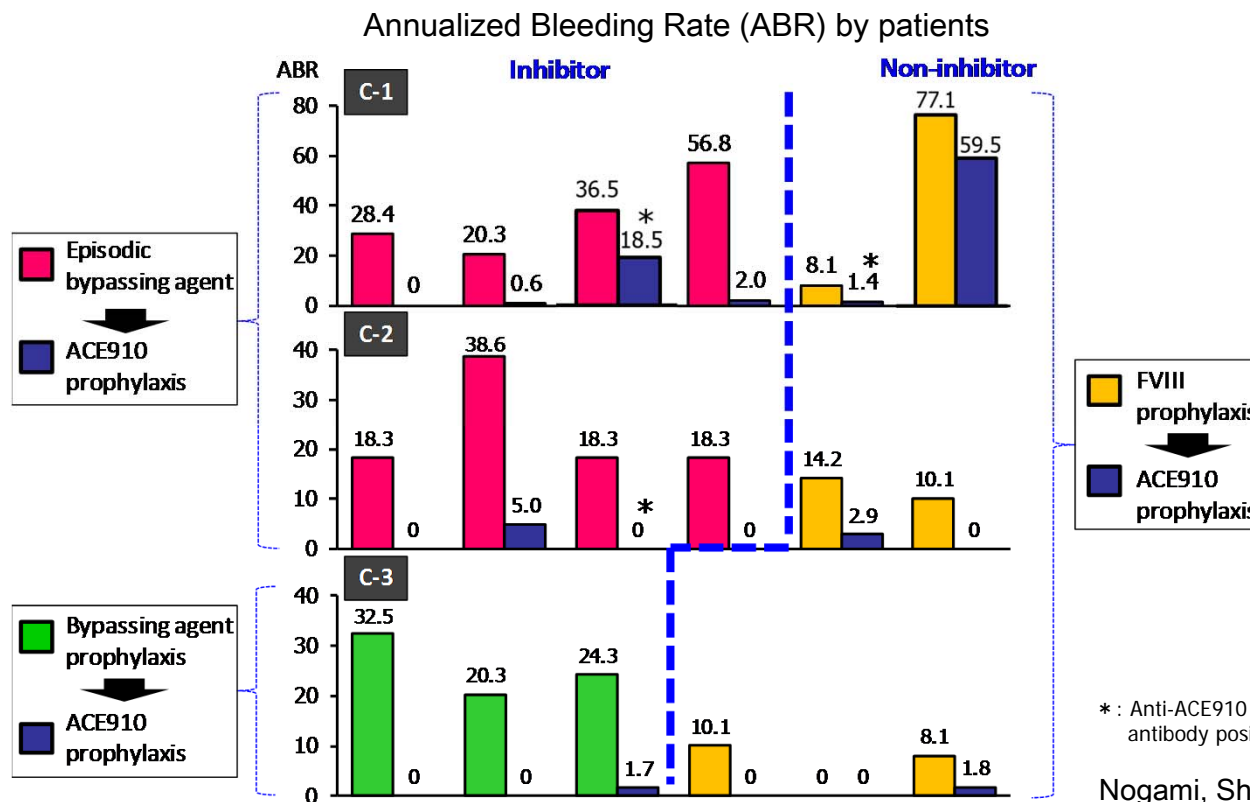


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**In-house**

Presented long-term treatment data in the Japanese P1/2 study for Hemophilia A at The International Society on Thrombosis and Haemostasis in June 2015

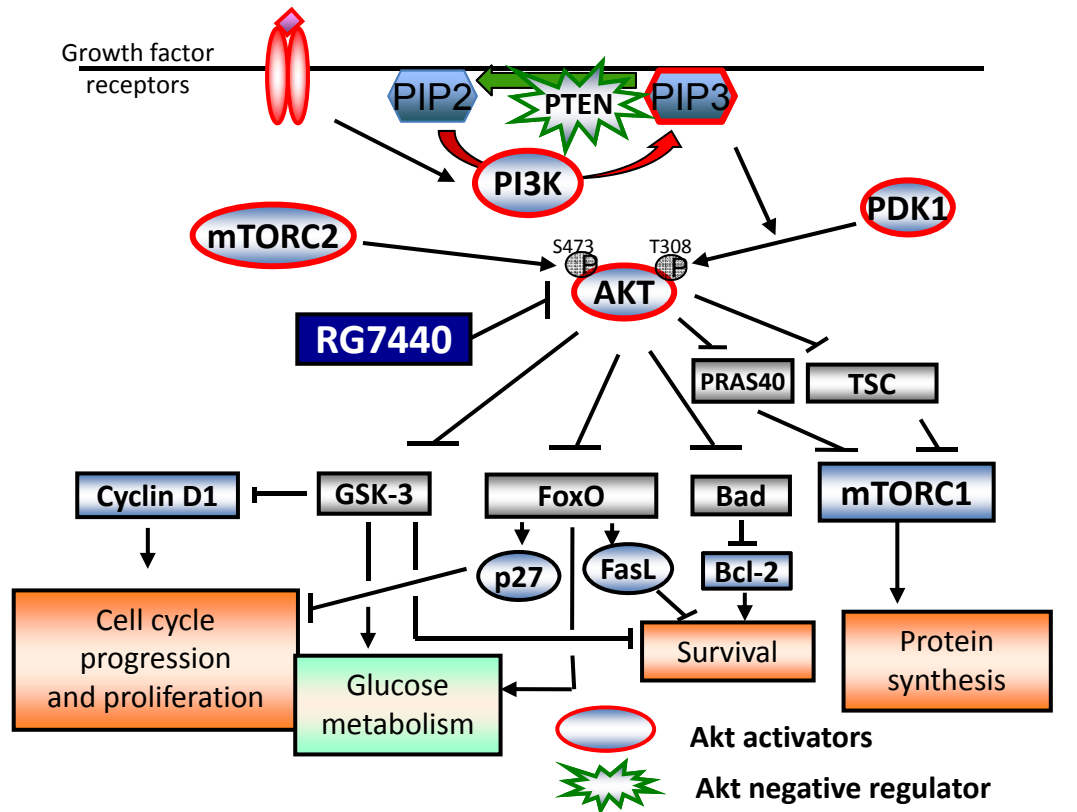
- Once weekly SC administration of ACE910 was well tolerated in patients treated 5.6-18.5 months
- ACE910 markedly reduced ABR irrespective of the presence of FVIII inhibitors
- Three patients developed anti-ACE910 antibodies, none of which affected the PK or PD of ACE910
- Dose dependent reduction in ABR was observed in patients with dose escalation



# RG7440(AKT inhibitor): Mode of Action



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<Conceptual Illustration>  
Created by Genentech (modified)

PI3K: Phosphoinositide 3-kinase  
 AKT (PKB): Protein kinase B  
 mTOR: mammalian target of rapamycin

- AKT transmits intracellular signaling from the receptor through PI3K-AKT-mTOR pathway
- AKT is one of the most frequently activated protein kinases in human malignancies, and it plays a critical role in tumor growth and resistance to therapy<sup>1)</sup>
- RG7440 is a new, potent, highly selective small-molecule inhibitor of AKT
- Wide therapeutic window is expected based on selective activated AKT inhibition by competition with ATP

1) Bellacosa et al. 2005; Manning and Cantley 2007; Jiang and Liu 2008; Tokunaga et al. 2008; Robey and Hay 2009

# Updates on the Development Requests for Unapproved Drugs/Indications



- Review Committee of Development Requests for Unapproved Drugs/Indication
  - Ten indications (including additional dosages and administrations) of eight products from the first round requests have been approved
  - Two indications of two products among three indications of three products from the second round requests have been approved

	Product	Indication	Current Situation
2nd round requests	CellCept	Lupus nephritis	Public Knowledge-based application (Kouchi submission) was judged to be proper

- Among the third round development demands, 1 product has been requested for development.

	Product	Indication	Current Situation
3rd round requests	Tamiful	Addition of Dosage and administration for newborn and infant	Submitted company opinion and waiting for evaluation by the committee

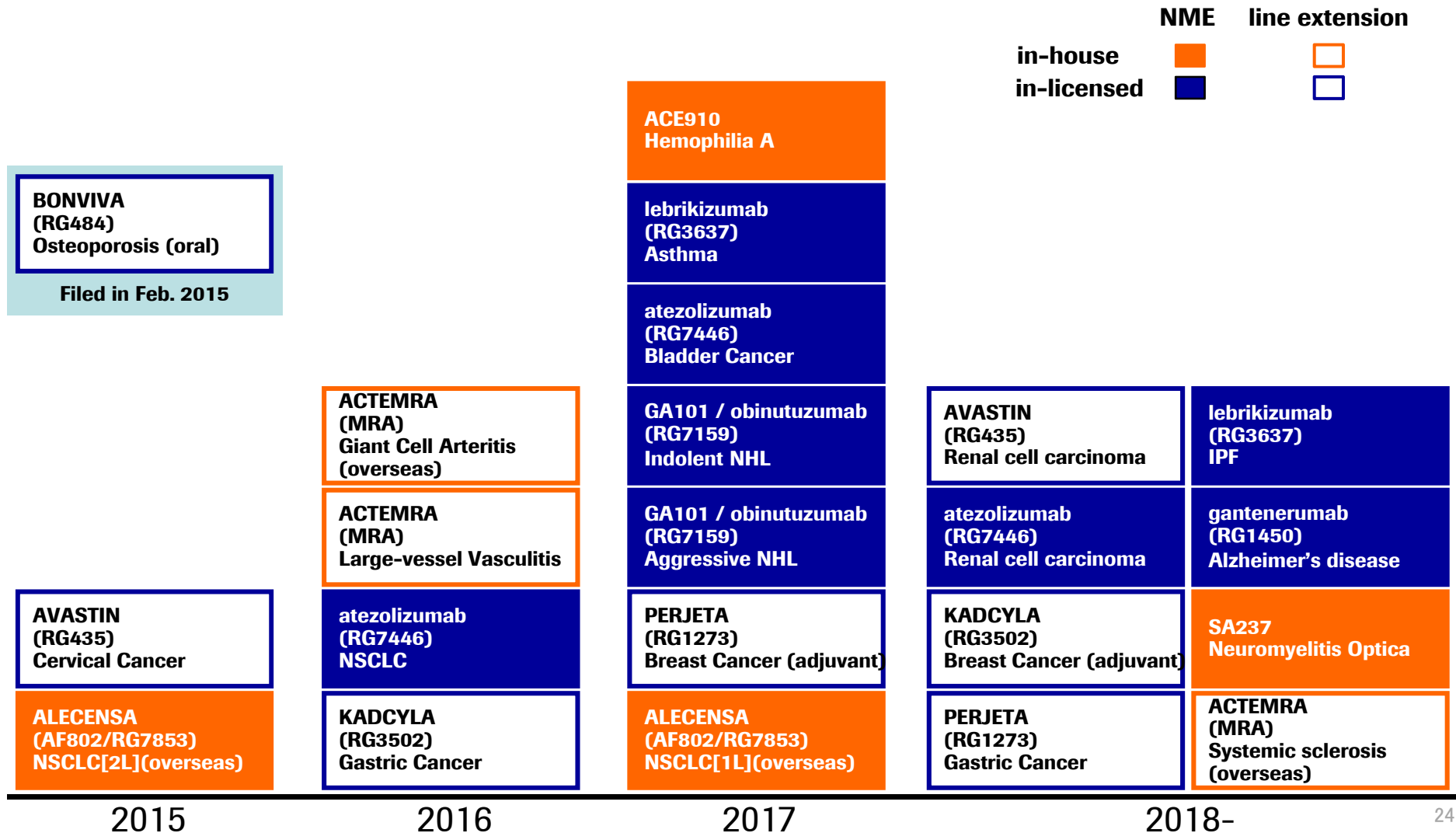
Letters in red: Projects with change in status since January 28, 2015



# Projected Submissions (Post PoC NMEs and Products)



- Seamless filings every year



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