



# **FY2015 3Q 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



## 3Q Results Summary

### ■ Revenues: 367.8 billion yen (+34.4, +10.3% YoY)

- Domestic sales excl. Tamiflu: increase due to steady growth of mainstay products and new products (+21.2, +8.3%)
- Overseas sales: increase due to growth in Actemra export driven by both yen depreciation and volume expansion (+17.4, +32.4%)
- Royalties and other operating income: decrease due to milestone income in the previous year, etc. (-3.8, -20.8%)

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

- Cost of sales: the ratio to sales worsened due primarily to yen depreciation (+0.6% point, from 49.7% to 50.3%)
- Operating expenses: increase mainly in research and development expenses (+2.9, +2.5%)

### ■ Profits

- IFRS results: operating profit 67.1 billion yen (+8.0, +13.5%)  
net income 48.6 billion yen (+8.0, +19.7%)
- Core results: operating profit 70.3 billion yen (+10.2, +17.0%)  
EPS 91.01 yen (+17.16, +23.2%)



# IFRS and Core Results Jan - Sep

(Billions of JPY)	IFRS results		Non-core items		Core results	
	2015 Jan - Sep		Intangible assets and Business combinations	Other eliminated items	2015 Jan - Sep	
<b>Revenues</b>	<b>367.8</b>				<b>367.8</b>	
Sales	353.3				353.3	
Royalties and other operating income	14.5				14.5	
Cost of sales	-178.7		+1.0		-177.7	
<b>Gross profit</b>	<b>189.0</b>		<b>+1.0</b>		<b>190.1</b>	
<b>Operating expenses</b>	<b>-122.0</b>		<b>+2.0</b>	<b>+0.2</b>	<b>-119.8</b>	
Marketing and distribution	-52.1		+0.1		-52.0	
Research and development	-60.7		+1.9		-58.8	
General and administration	-9.1			+0.2	-8.9	
<b>Operating profit</b>	<b>67.1</b>		<b>+3.0</b>	<b>+0.2</b>	<b>70.3</b>	
Financing costs	-0.1				-0.1	
Other financial income (expense)	0.4				0.4	
<b>Profit before taxes</b>	<b>67.4</b>		<b>+3.0</b>	<b>+0.2</b>	<b>70.6</b>	
Income taxes	-18.8		-1.1	-0.1	-20.0	
<b>Net income</b>	<b>48.6</b>		<b>+2.0</b>	<b>+0.1</b>	<b>50.7</b>	
Chugai shareholders	47.6		+2.0	+0.1	49.8	
Non-controlling interests	0.9				0.9	

(Billions of JPY)

## Non-Core items

- Intangible/Business combinations
  - Amortization of intangible assets +1.2
  - Impairment of intangible assets +1.9
  - No business combinations
- Other eliminated items
  - Environmental costs +0.2

Core net income  
attributable to Chugai  
shareholders 49.8 <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>

(JPY)  
Core EPS 91.01 <sup>Ⓐ</sup>/<sup>Ⓑ</sup>

## Year on Year (Core)

# Financial Overview Jan – Sep

Innovation all for the patients



Roche A member of the Roche group

(Billions of JPY)	2014		2015		Growth	
	Jan - Sep		Jan - Sep			
	vs. Revenues		vs. Revenues			
<b>Revenues</b>	<b>333.4</b>		<b>367.8</b>		<b>+34.4</b>	<b>+10.3%</b>
Sales	315.1		353.3		+38.2	+12.1%
excl. Tamiflu	308.0		346.5		+38.5	+12.5%
Domestic	254.2		275.4		+21.2	+8.3%
Export to Roche	39.5		56.3		+16.8	+42.5%
Other overseas	14.3		14.7		+0.4	+2.8%
Tamiflu	7.2		6.7		-0.5	-6.9%
Ordinary	7.0		6.7		-0.3	-4.3%
Govt. stockpiles etc.	0.2		0.0		-0.2	-100.0%
Royalties and other operating income	18.3		14.5		-3.8	-20.8%
Cost of sales	-156.5	46.9%	-177.7	48.3%	-21.2	+13.5%
<b>Gross profit</b>	<b>176.9</b>	<b>53.1%</b>	<b>190.1</b>	<b>51.7%</b>	<b>+13.2</b>	<b>+7.5%</b>
Operating expenses	-116.9	35.1%	-119.8	32.6%	-2.9	+2.5%
<b>Operating profit</b>	<b>60.1</b>	<b>18.0%</b>	<b>70.3</b>	<b>19.1%</b>	<b>+10.2</b>	<b>+17.0%</b>
Financing costs	-0.0		-0.1		-0.1	-
Other financial income (expense)	0.3		0.4		+0.1	+33.3%
Income taxes	-19.2		-20.0		-0.8	+4.2%
<b>Net income</b>	<b>41.2</b>	<b>12.4%</b>	<b>50.7</b>	<b>13.8%</b>	<b>+9.5</b>	<b>+23.1%</b>
EPS (JPY)	73.85		91.01		+17.16	+23.2%

(Billions of JPY)

Royalties and other operating income	-3.8
Decrease in milestone income, etc.	
Other financial income (expense)	+0.1
Exchange gains/losses	-0.9
Gains/Losses on derivatives	+1.1
(Gains/Losses on foreign exchange forward contracts)	

## Cost of sales ratio vs. Sales

2014 Jan - Sep	2015 Jan - Sep
49.7%	50.3%

## Average exchange rate (JPY)

	2014 Jan - Sep	2015 Jan - Sep
1CHF	114.59	126.82
1EUR	139.58	134.83
1USD	102.96	120.89
1SGD	81.87	88.69

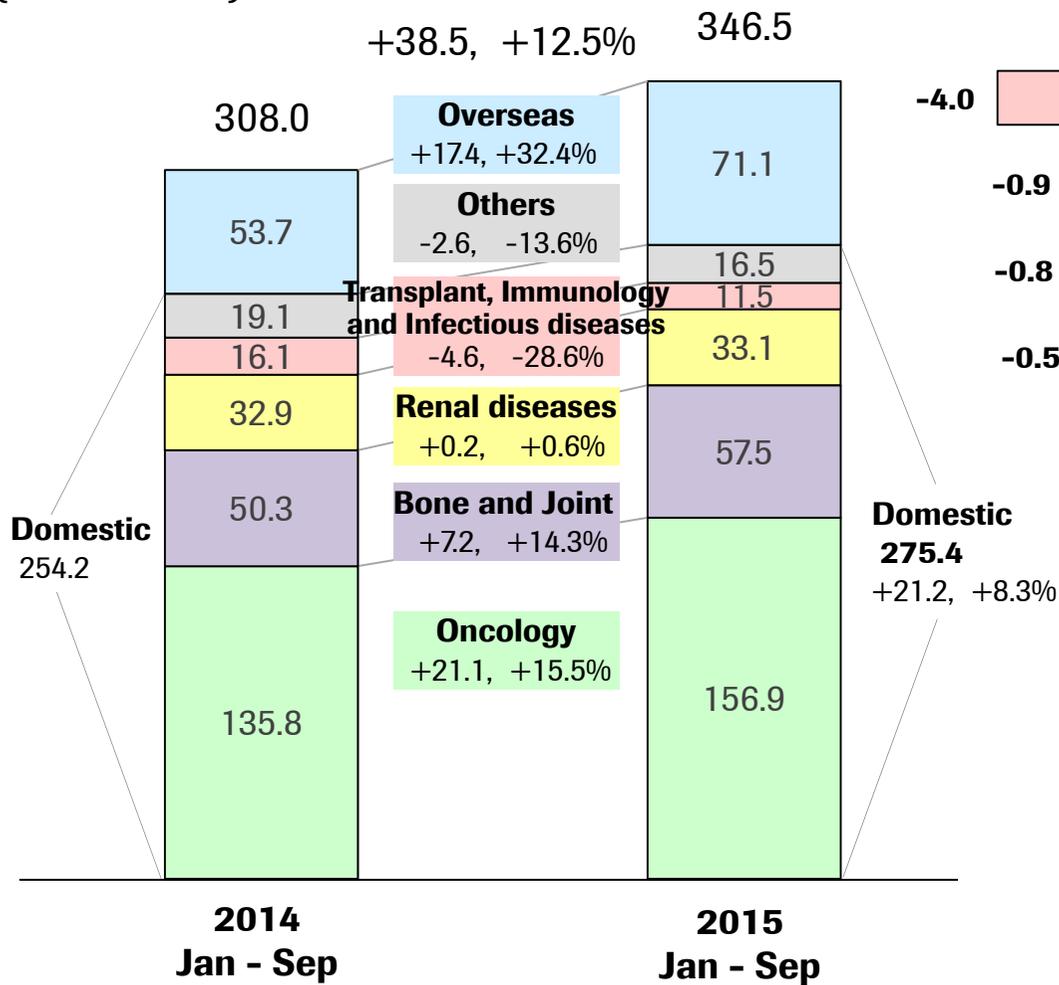


Year on Year

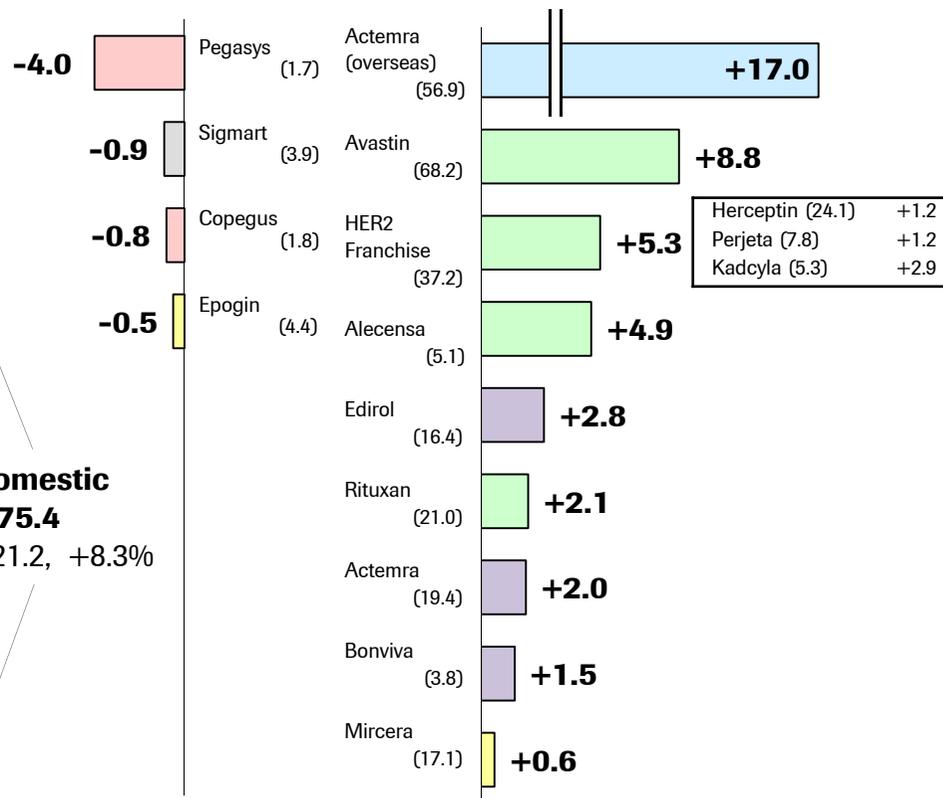
# Sales (excl. Tamiflu) Jan - Sep

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)																Forecast		Seasonal Sales	Cases per sentinel* (millions)										
		FY2009.12		FY2010.12		FY2011.12		FY2012.12		FY2013.12		FY2014.12		FY2015.12															
		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-Sep	Oct-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>															

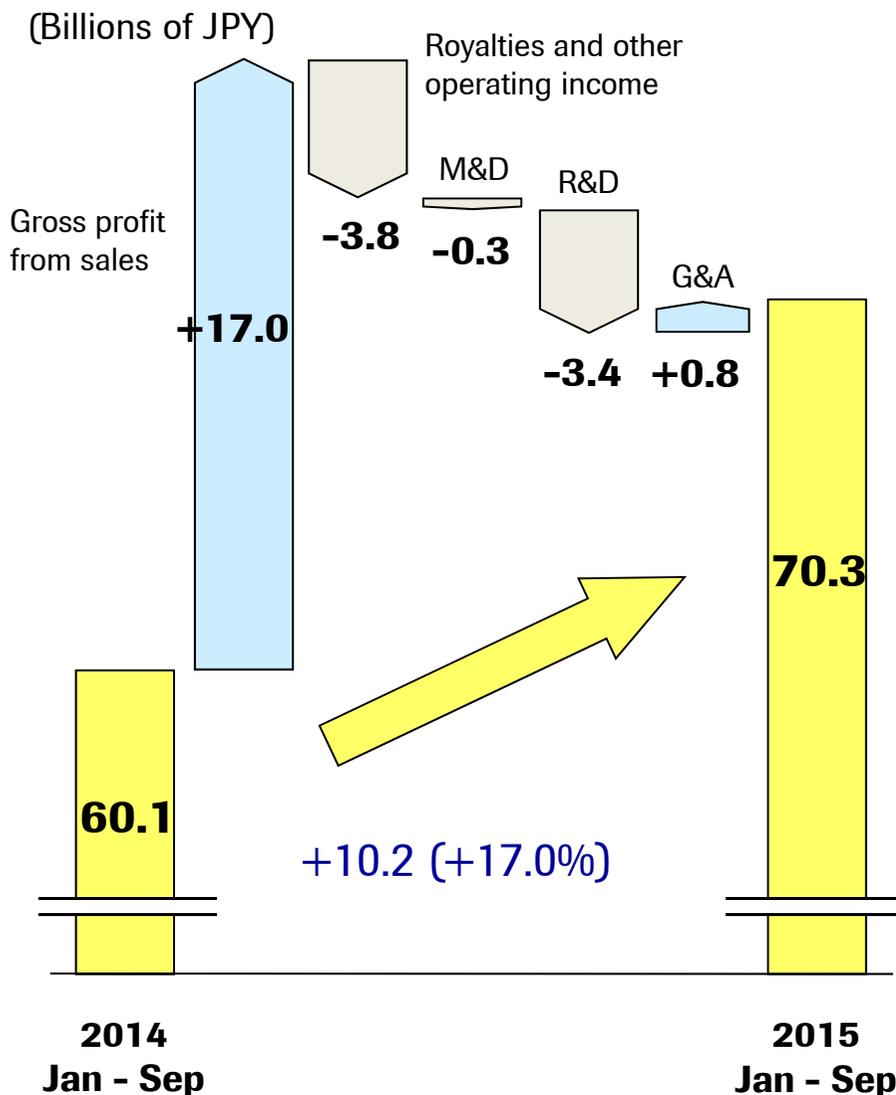
( ) Year on year

\* 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 - Sep



(Billions of JPY)	2014 Jan - Sep	2015 Jan - Sep	Growth
<b>Revenues</b>	<b>333.4</b>	<b>367.8</b>	<b>+34.4</b>
Cost of sales	-156.5	-177.7	-21.2
<b>Gross profit</b>	<b>176.9</b>	<b>190.1</b>	<b>+13.2</b>
<i>of which</i> Sales	158.6	175.6	+17.0
Royalties, etc.	18.3	14.5	-3.8
Marketing and distribution	-51.7	-52.0	-0.3
Research and development	-55.4	-58.8	-3.4
General and administration	-9.7	-8.9	+0.8
<b>Operating profit</b>	<b>60.1</b>	<b>70.3</b>	<b>+10.2</b>

- Increase in gross profit from sales +17.0  
Steady growth of mainstay products and new products
- Decrease in royalties and other operating income -3.8
- Increase in Marketing and distribution -0.3
- Increase in research and development -3.4  
Increased activity in research and development with the advance of projects, negative foreign exchange impact, etc.
- Decrease in general and administration +0.8  
One-time increase in the previous year (Buildings, etc.)

## Year on Year (Core)

# Financial Overview Jul – Sep



(Billions of JPY)	2014		2015		Growth	
	Jul - Sep vs. Revenues		Jul - Sep vs. Revenues			
<b>Revenues</b>	<b>111.4</b>		<b>127.6</b>		<b>+16.2</b>	<b>+14.5%</b>
Sales	107.0		120.6		+13.6	+12.7%
excl. Tamiflu	106.9		120.6		+13.7	+12.8%
Domestic	88.9		96.3		+7.4	+8.3%
Export to Roche	13.2		19.1		+5.9	+44.7%
Other overseas	4.8		5.2		+0.4	+8.3%
Tamiflu	0.1		0.0		-0.1	-100.0%
Ordinary	0.0		0.0		0.0	0.0%
Govt. stockpiles etc.	0.1		-		-0.1	-100.0%
Royalties and other operating income	4.4		7.0		+2.6	+59.1%
Cost of sales	-54.4	48.8%	-61.1	47.9%	-6.7	+12.3%
<b>Gross profit</b>	<b>57.0</b>	<b>51.2%</b>	<b>66.5</b>	<b>52.1%</b>	<b>+9.5</b>	<b>+16.7%</b>
Operating expenses	-40.7	36.5%	-42.0	32.9%	-1.3	+3.2%
<b>Operating profit</b>	<b>16.3</b>	<b>14.6%</b>	<b>24.4</b>	<b>19.1%</b>	<b>+8.1</b>	<b>+49.7%</b>
Financing costs	0.0		-0.0		0.0	-
Other financial income (expense)	-0.0		-0.3		-0.3	-
Income taxes	-5.0		-6.0		-1.0	+20.0%
<b>Net income</b>	<b>11.3</b>	<b>10.1%</b>	<b>18.2</b>	<b>14.3%</b>	<b>+6.9</b>	<b>61.1%</b>
EPS (JPY)	20.19		32.71		+12.52	+62.0%

	(Billions of JPY)
Increase in gross profit from sales	+6.9
Increase in sales	
Increase in royalties and other operating income	+2.6
Increase in milestone income, etc.	
Increase in operating expenses	-1.3
Change in marketing and distribution	0.0
Increase in research and development	-2.7
Increased activity in research and development with the advance of projects, negative foreign exchange impact, etc.	
Decrease in general and administration	+1.4
One-time increase in the previous year (Buildings, etc.)	
Cost of sales ratio vs. Sales	

2014 Jul - Sep	2015 Jul - Sep
50.8%	50.7%

vs. Forecast (Core)

# Financial Progress Jan – Sep

Innovation all for the patients



Roche A member of the Roche group

(Billions of JPY)	Actual	Full-year forecast		2014
	2015 Jan - Sep	2015 Jan - Dec	Progress	Progress*1
<b>Revenues</b>	<b>367.8</b>	<b>486.5</b>	<b>75.6%</b>	<b>72.3%</b>
Sales	353.3	460.8	76.7%	72.1%
excl. Tamiflu	346.5	453.4	76.4%	72.7%
Domestic	275.4	360.9	76.3%	72.7%
Export to Roche *2	56.3	74.9	75.2%	71.7%
Other overseas	14.7	17.6	83.5%	74.1%
Tamiflu	6.7	7.4	90.5%	55.4%
Royalties and other operating income	14.5	25.6	56.6%	75.6%
Cost of sales	-177.7	-230.2	77.2%	72.1%
<b>Gross profit</b>	<b>190.1</b>	<b>256.3</b>	<b>74.2%</b>	<b>72.4%</b>
Operating expenses	-119.8	-171.3	69.9%	70.1%
<b>Operating profit</b>	<b>70.3</b>	<b>85.0</b>	<b>82.7%</b>	<b>77.7%</b>
EPS (JPY)	91.01	104.42	87.2%	77.7%

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

\*2 Including Alecensa (Actual 2015 Jan - Sep: 0.2 billion yen, Full-year forecast 2015 Jan - Dec: 0.2 billion yen)

vs. Forecast (Core)

# Sales Progress (excl. Tamiflu) Jan – Sep

Innovation all for the patients



Roche A member of the Roche group

(Billions of JPY)	Actual	Full-year forecast		2014
	2015 Jan - Sep	2015 Jan - Dec	Progress	Progress*1
<b>Sales excl. Tamiflu</b>	<b>346.5</b>	<b>453.4</b>	<b>76.4%</b>	<b>72.7%</b>
<b>Domestic</b>	<b>275.4</b>	<b>360.9</b>	<b>76.3%</b>	<b>72.7%</b>
<b>Oncology</b>	<b>156.9</b>	<b>204.5</b>	<b>76.7%</b>	<b>71.9%</b>
Avastin	68.2	88.2	77.3%	72.2%
HER2 Franchise	37.2	48.3	77.0%	71.8%
Herceptin	24.1	29.6	81.4%	73.4%
Perjeta	7.8	9.9	78.8%	72.5%
Kadcyla	5.3	8.8	60.2%	60.0%
Tarceva	8.6	14.1	61.0%	73.0%
Xeloda	8.1	10.0	81.0%	73.1%
Alecensa	5.1	5.2	98.1%	14.3%
Zelboraf *2	0.3	0.2	150.0%	-
<b>Bone and Joint</b>	<b>57.5</b>	<b>75.9</b>	<b>75.8%</b>	<b>72.3%</b>
Actemra	19.4	26.3	73.8%	72.2%
Edirol	16.4	21.2	77.4%	70.8%
Bonviva	3.8	4.9	77.6%	67.6%
<b>Renal</b>	<b>33.1</b>	<b>44.3</b>	<b>74.7%</b>	<b>73.6%</b>
Mircera	17.1	24.5	69.8%	73.0%
Epogin	4.4	5.2	84.6%	74.2%
<b>Transp., Immun., Infectious</b>	<b>11.5</b>	<b>13.0</b>	<b>88.5%</b>	<b>77.4%</b>
Pegasys	1.7	2.1	81.0%	81.4%
Copegus	1.8	1.1	163.6%	83.9%
<b>Others</b>	<b>16.5</b>	<b>23.2</b>	<b>71.1%</b>	<b>74.6%</b>
<b>Overseas</b>	<b>71.1</b>	<b>92.5</b>	<b>76.9%</b>	<b>72.3%</b>
Export to Roche	<b>56.3</b>	<b>74.9</b>	<b>75.2%</b>	<b>71.7%</b>
Actemra	<b>56.1</b>	<b>74.7</b>	<b>75.1%</b>	<b>71.7%</b>
Alecensa *3	<b>0.2</b>	<b>0.2</b>	<b>100.0%</b>	-
Other overseas	<b>14.7</b>	<b>17.6</b>	<b>83.5%</b>	<b>74.1%</b>

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

\*2 Forecast for Zelboraf was disclosed on Apr. 22.

\*3 Forecast for Alecensa (overseas) was disclosed on Oct. 22.



vs. Forecast (Core)

# Impact from Foreign Exchange

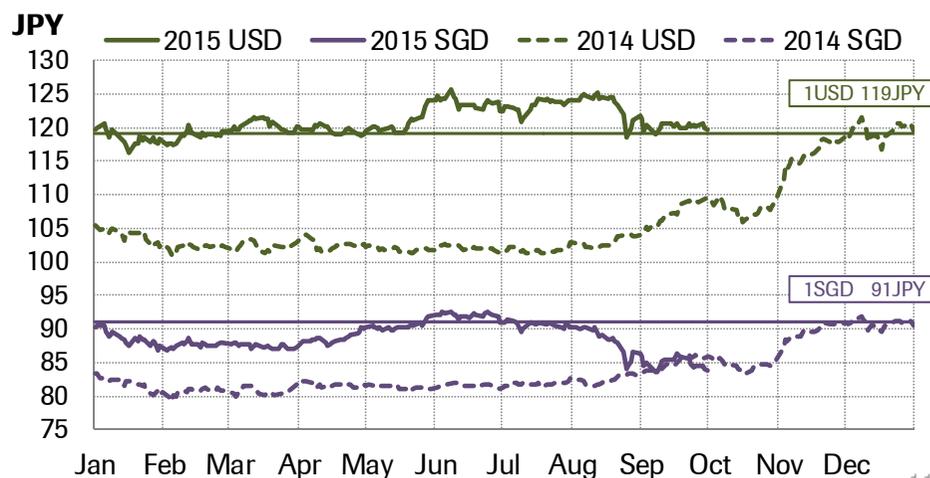
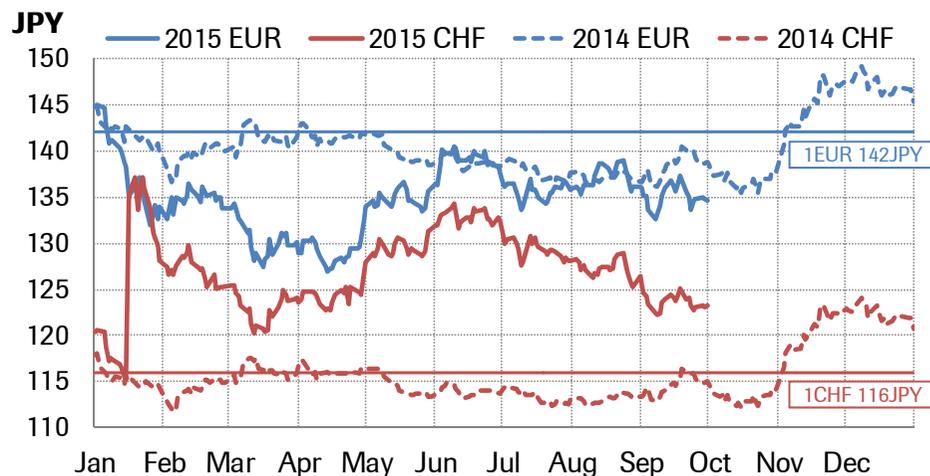
(Billions of JPY)	FX impact Jan - Sep (vs. Forecast on Jan. 28)	
<b>Revenues</b>	<b>+3.4</b>	
	Sales	+3.4
	Royalties and other operating income	+0.0
Cost of sales	Cost of sales	-2.8
Operating expenses	Expenses	-0.0
<b>Operating profit</b>	<b>+0.5</b>	

Actual/Assumption rate* (JPY)	Actual Jan - Sep avg. (2014)	Assumption Jan - Dec (as of Jan. 28)	Actual Jan - Sep avg. (2015)
1CHF	114.59	116.00	126.82
1EUR	139.58	142.00	134.83
1USD	102.96	119.00	120.89
1SGD	81.87	91.00	88.69

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

## [Reference] Historical exchange rate to the JPY

Assumption rate  
(as of Jan. 28)





## Overview of Development Pipeline

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Associate Vice President  
Deputy Head of Project & Lifecycle Management Unit  
Department Manager of R&D Portfolio Management Dept.  
Minoru Watanabe

2015.10.22

# Oncology Field Projects under Development (as of 22 October, 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 / taselesib</b> - solid tumors</p> <p><b>RG7440 / ipatasertib</b> - solid tumors</p>	<p><b>GC33 / RG7686</b> - hepatocellular carcinoma</p>	<p><b>AF802 (RG7853) / Alecensa (overseas)</b> - NSCLC [1L]</p> <p><b>RG1273 / Perjeta</b> - breast cancer (adjuvant) - gastric cancer</p> <p><b>RG3502 / Kadcyra</b> - breast cancer (adjuvant) - gastric cancer (PII/III)</p> <p><b>GA101 (RG7159) / 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> <p><b>AF802 (RG7853) / Alecensa (overseas)</b> - NSCLC [2L] ★</p> <p><b>RG435 / Avastin</b> - cervical cancer★</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 23 July, 2015**

# Primary Field Projects under Development (as of 22 October, 2015)



	Phase I	Phase II	Phase III	Filed
Bone & Joint			<b>ED-71 / Ediol (China)</b> - osteoporosis★	<b>RG484 / Bonviva (oral)</b> - osteoporosis
Renal	<b>EOS789</b> - hyperphosphatemia★			
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>RG1662 / basmisanil</b> - improvement of intellectual ability in individuals with Down syndrome		<b>RG1450 / gantenerumab</b> - Alzheimer's disease	
Others	<b>PCO371 (overseas)</b> - hypoparathyroidism	<b>RG3637 / lebrikizumab</b> - IPF <b>CIM331 / nemolizumab</b> - atopic dermatitis★ - pruritus in dialysis patients★ <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 23 July, 2015**

**★: Multinational study managed by Chugai**

# Development Status



In-house

## **AF802 (RG7853) / Alecensa<sup>®</sup>**

Non-small cell lung cancer (crizotinib failure)

Submission for approval in July (US), September (EU) 2015

In-licensed

## **RG435 / Avastin<sup>®</sup>**

Cervical cancer

Submission for approval in September 2015

In-house

## **ED-71 / Ediol<sup>®</sup>**

Osteoporosis

Started P3 in August 2015 (China)

In-house

## **EOS789**

Hyperphosphatemia

Started P1 in September 2015

# Development Status



In-house

## **CIM331 / nemolizumab**

Pruritus in dialysis patients  
Started P2 in August 2015

In-licensed

## **RG7090 / basimglurant**

Major depressive disorder  
Development discontinued

In-licensed

## **RG1577 / sembragiline**

Alzheimer's disease  
Development discontinued

## Other Progress



In-  
licensed

### **RG3502 / Kadcyła®**

Breast cancer (1<sup>st</sup> line)

No-go decision based on global P3 (MARIANNE study)

Gastric cancer

Global P2/3 (GATSBY study) did not meet primary endpoint

In-  
licensed

### **RG1450 / gantenerumab**

Alzheimer's disease

Ongoing global P3 (Marguerite RoAD study) converted into open label to explore higher doses

In-  
house

### **CIM331 / nemolizumab**

Atopic dermatitis

Ongoing multinational P2 met primary endpoint

(statistically significant improvement in pruritus compared to placebo at week 12)

## Other Progress



In-  
house

### **ACE910 (RG6013)**

Hemophilia A

Breakthrough therapy Designation granted by US FDA in  
September 2015

In-  
licensed

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

Prevention of chemotherapy-induced nausea and vomiting  
Launched in September 2015 (UK)

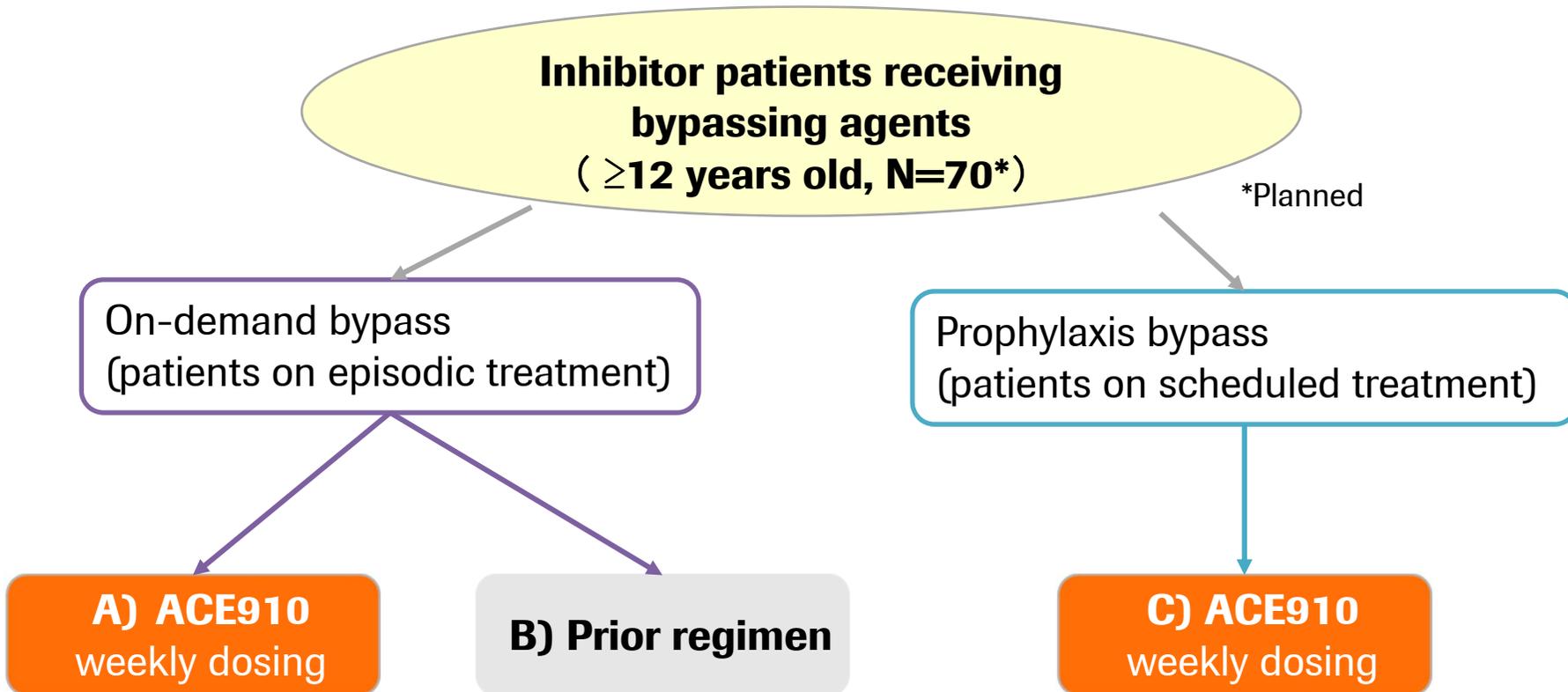
In-  
licensed

### **MultiStem® (Cell therapy)**

Ischemic stroke

Terminated license agreement with Athersys

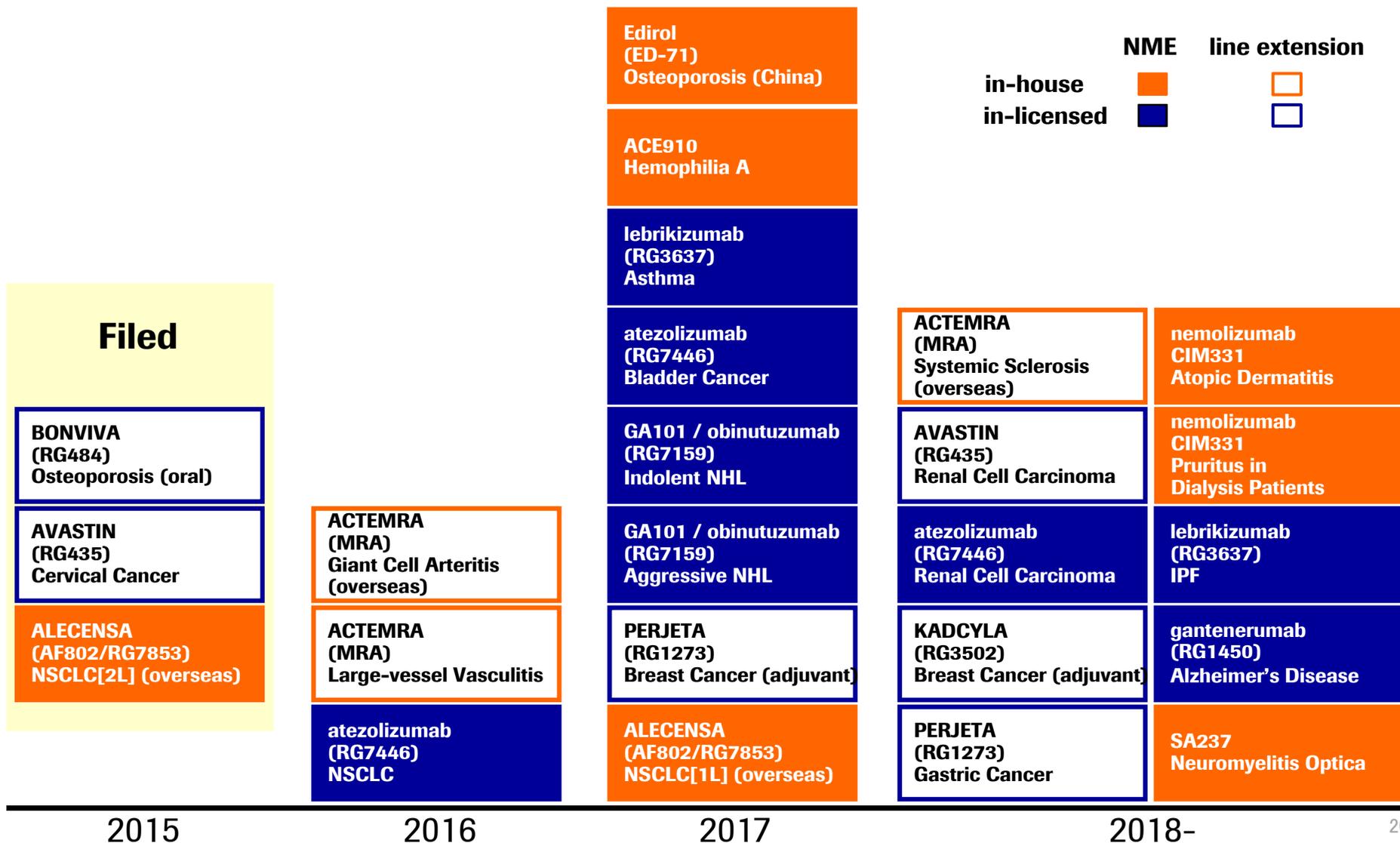
# ACE910: Phase 3 in Inhibitor Patients



**Evaluation period:** 24 weeks

**Primary endpoint:** The efficacy of prophylactic ACE910 compared with no prophylaxis in hemophilia A patients with inhibitors on the basis of number of bleeds over time

# Projected Submissions (Post PoC NMEs and Products)



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