

# FY2016 1Q Consolidated Financial Overview (IFRS based)

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April 22, 2016

FY2016 1Q Consolidated Financial Overview

## **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

FY2016 1Q Consolidated Financial Overview

## **1Q Results Summary**



- Revenues: 119.9 billion yen (+2.8, +2.4% YoY)
- Domestic sales excl. Tamiflu: increase due to steady growth of new products and mainstay products (+3.9, +4.6%)
- Overseas sales: decrease due to impact of supply price reduction, etc on Actemra export (-2.0, -8.8%)
- Royalties and other operating income: increase due to Actemra-related revenues, etc. (+0.6, +16.2%)
- Cost of sales / Operating expenses (Core basis)
- Cost of sales: the ratio to sales worsened due to yen depreciation and impact of supply price reduction on Actemra export (+2.1% points, from 50.6% to 52.7%)
- Operating expenses: slight increase mainly due to increase of research and development expenses with progress of projects (+0.4, +1.0%)
- Profits
- IFRS results: operating profit 20.1 billion yen (-0.6, -2.9%)

net income 14.7 billion yen (-0.1, -0.7%)

- Core results: operating profit 20.4 billion yen (-1.1, -5.1%) net income 14.9 billion yen (-0.4, -2.6%)
- Core EPS (JPY): 26.94 (-0.60, -2.2%)

FY2016 1Q Consolidated Financial Overview

## IFRS and Core Results Jan - Mar



(Billion JPY)	IFRS results 2016	Non-core	items Others	Core results 2016	(Billions of JPY)		
	Jan - Mar			Jan - Mar	Non-Core items		
Revenues	119.9			119.9	1. Intangible assets		
Sales	115.6			115.6	Amortization of intangible assets +0.4 Impairment non		
Royalties and other operating income	4.3			4.3	2. Others		
Cost of sales	-61.2	+0.3		-60.9	Environmental costs non		
Gross profit	58.7	+0.3		59.0			
Operating expenses	-38.7	+0.1		-38.6	Core net income attributable to Chugai shareholders		
Marketing and distribution	-16.6	+0.0		-16.5	14.7 (A)		
Research and development	-19.3	+0.0		-19.2			
General and administration	-2.8			-2.8	(Millions of shares)		
Operating profit	20.1	+0.4		20.4	Weighted average number of		
Financing costs	-0.0			-0.0	shares and equity securities		
Other financial income (expense)	0.1			0.1	in issue used to calculate diluted earnings per share		
Profit before taxes	20.1	+0.4		20.5			
Income taxes	-5.4	-0.1		-5.6	547 ®		
Net income	14.7	+0.2		14.9			
Chugai shareholders	14.5	+0.2		14.7	(JPY)		
Non-controlling interests	0.2			0.2	Core EPS         26.94 (A)/(B)		

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Year on Year (Core)

## Financial Overview Jan - Mar

(Billions of JPY)	201 Jan - N	<b>/</b> ar	201) Jan - N	Mar	Grow	th
Revenues	vs. F 117.1	Revenues	vs. F	Revenues	+2.8	+2.4%
Sales	113.4		115.6		+2.2	+1.9%
excl. Tamiflu	106.7		108.6		+1.9	+1.8%
Domestic	83.9		87.8		+3.9	+4.6%
Export to Roche	18.0		16.5		-1.5	-8.3%
Other overseas	4.8		4.3		-0.5	-10.4%
Tamiflu	6.7		7.0		+0.3	+4.5%
Ordinary	6.7		7.0		+0.3	+4.5%
Govt. stockpiles etc.	0.0		0.0		+0.0	0.0%
Royalties and other operating income	3.7		4.3		+0.6	+16.2%
Cost of sales	-57.4	49.0%	-60.9	50.8%	-3.5	+6.1%
Gross profit	59.7	51.0%	59.0	<b>49.2%</b>	-0.7	-1.2%
Operating expenses	-38.2	32.6%	-38.6	32.2%	-0.4	+1.0%
Operating profit	21.5	18.4%	20.4	<b>17.0%</b>	-1.1	-5.1%
Financing costs	-0.0		-0.0		0.0	0.0%
Other financial income (expense)	0.5		0.1		-0.4	-80.0%
Income taxes	-6.6		-5.6		+1.0	-15.2%
Net income	15.3	13.1%	14.9	<b>12.4%</b>	-0.4	-2.6%
EPS (JPY)	27.54		26.94		-0.60	-2.2%



### (Billions of JPY)

Royalties and other operating income	+0.6
Actemra-related revenues increased, etc.	
Other financial income (expense)	-0.4
Exchange gains/losses	+1.8
Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts)	-2.1

### Cost of sales ratio vs. Sales

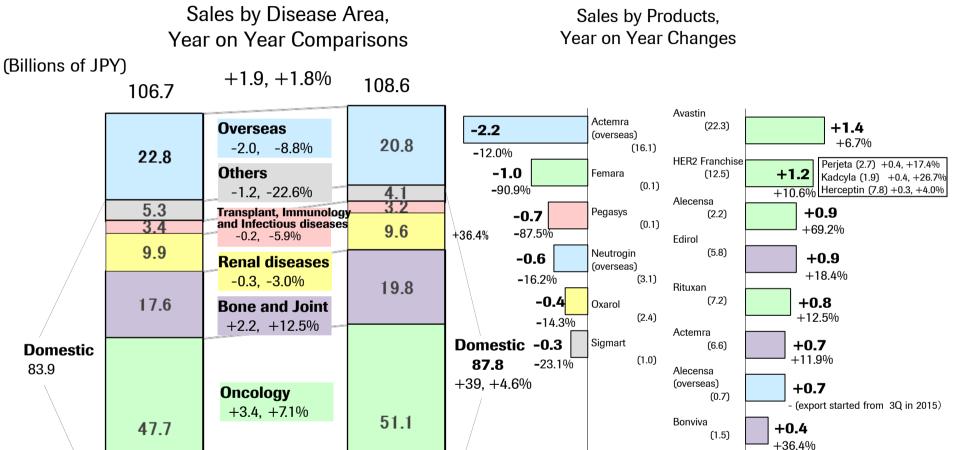
2015 Jan – Mar	2016 Jan – Mar
50.6%	52.7%

#### Average exchange rate (JPY)

	2015 Jan – Mar	2016 Jan - Mar
CHF	124.98	116.14
EUR	134.38	127.29
USD	119.15	115.43
SGD	87.88	82.22

%: Year-on-year percentage change

5



2016

Jan - Mar

# Sales (excl. Tamiflu) Jan - Mar

INNOVATION BEYOND IMAGINATION

2015

Jan - Mar

Year on Year

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Copegus

(0.5)

(): FY2016 Actual

**+0.3** +150.0%

**IBI 18** 

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## **Tamiflu Sales Performance**



Roche A member of the Roche group

							Fisc	al Term S	Sales						Forecast	
(Billi	ons of JPY)	FY20	10.12	FY20	11.12	FY20	12.12	FY20	13.12	FY20	14.12	FY20	15.12	FY20	16.12	Seasonal
		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-Mar	Apr-Dec	Sales
	2009-10	1.4														26.6
	2010-11		0.2	4.1												4.3
	2011-12				1.3	7.8										9.1
Ondinana	2012-13						2.4	8.2								10.6
Ordinary	2013-14								1.9	7.0						9.0
	2014-15										5.8	6.7				12.6
	2015-16												1.5	7.0		8.5
	2016-17														0.6	-
0	Irdinary	1.6	(-34.6)	5.4	(+3.8)	10.2	(+4.8)	10.1	(-0.1)	12.9	(+2.8)	8.2	(-4.7)	7.6	(-0.6)	
	2009-10	10.6														36.2
	2010-11		5.9	0.5												6.4
	2011-12				2.8	0.4										3.2
Govt.	2012-13						1.5	0.8								2.3
Stockpiles etc.	2013-14								0.1	0.1						0.2
	2014-15										0.1	0.0				0.1
	2015-16												0.0	0.0		0.0
	2016-17														1.0	-
Govt. S	Govt. Stockpile etc.		(-23.4)	3.3	(-13.3)	1.9	(-1.4)	0.9	(-1.0)	0.2	(-0.7)	0.0	(-0.2)	1.0	(+1.0)	
	Tatal	12.0	6.1	4.6	4.1	8.1	3.9	9.0	2.0	7.1	5.9	6.7	1.5	7.0	1.6	
	Total	18.2	(-58.0)	8.7	(-9.5)	12.0	(+3.3)	11.0	(-1.0)	13.0	(+2.0)	8.2	(-4.8)	8.6	(+0.4)	

() Year on year

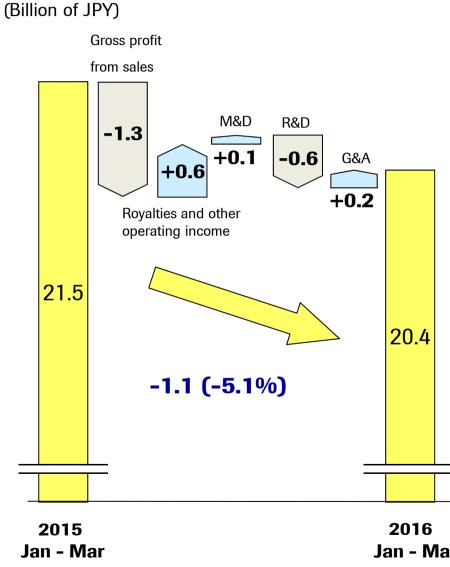
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Year on Year (Core)

## **Operating Profit Jan - Mar**

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(Bill	ions of JPY)	2015 Jan - Mar	2016 Jan - Mar	Growth
Revenue	es	117.1	119.9	+2.8
Cost o	f sales	-57.4	-60.9	-3.5
Gross pr	rofit	59.7	59.0	-0.7
of which	Sales	56.0	54.7	-1.3
	Royalties, etc.	3.7	4.3	+0.6
Marketi	ng and distribution	-16.6	-16.5	+0.1
Researc	h and development	-18.6	-19.2	-0.6
General	and administration	-3.0	-2.8	+0.2
Operatii	ng profit	21.5	20.4	-1.1

	Decrease in gross profit from sales	-1.3
	The ratio to sales worsened due to yen depreciation and	
	supply price reduction for Actemra export	
	Increase in royalties and other operating income	+0.6
	Decrease in marketing and distribution	+0.1
_	Increase in research and development expenses	-0.6
_	Progress in in-house projects, etc.	
	Decrease in general and administration	+0.2
r		

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vs. Forecast (Core)

## Financial Progress Jan - Mar



(Billions of JPY)	Actual	Forec on Ja		2015
	2016 Jan - Mar	2016 Jan - Dec	Progress	Progress*
Revenues	119.9	495.0	24.2%	23.5%
Sales	115.6	475.4	24.3%	24.2%
excl. Tamiflu	108.6	466.8	23.3%	23.2%
Domestic	87.8	379.0	23.2%	22.2%
Export to Roche	16.5	70.5	23.4%	28.5%
Other overseas	4.3	17.3	24.9%	25.1%
Tamiflu	7.0	8.6	81.4%	81.7%
Royalties and other operating income	4.3	19.6	21.9%	12.2%
Cost of sales	-60.9	-254.0	24.0%	24.0%
Gross profit	59.0	241.0	24.5%	23.0%
Operating expenses	-38.6	-170.0	22.7%	22.6%
Operating profit	20.4	71.0	28.7%	23.7%
EPS (JPY)	26.94	92.54	29.1%	23.7%

\* Jan - Mar progress versus Jan - Dec.

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### vs. Forecast (Core)

## Sales Progress (excl. Tamiflu) Jan - Mar



	Actual	Fore		
(Billions of JPY)		on Ja	n 28	2015
	2016	2016	Progress	Progress*
Sales excl. Tamiflu	Jan - Mar <b>108.6</b>	Jan - Dec <b>466.8</b>	23.3%	23.2%
Domestic	87.8	379.0	23.2%	22.2%
Oncology	51.1	220.3	23.2%	22.1%
Avastin	22.3	93.4	23.9%	22.3%
HER2 Franchise	12.5	53.9	23.2%	22.3%
Herceptin	7.8	34.9	22.3%	22.9%
Perjeta	2.7	11.3	23.9%	21.7%
Kadcyla	1.9	7.6	25.0%	20.5%
Xeloda	2.9	12.6	23.0%	23.4%
Tarceva	2.5	12.5	20.0%	21.6%
Alecensa	2.2	9.6	22.9%	16.3%
Bone and Joint	19.8	85.8	23.1%	22.2%
Actemra	6.6	29.7	22.2%	22.0%
Edirol	5.8	25.6	22.7%	21.2%
Bonviva	1.5	7.7	19.5%	20.4%
Renal	9.6	40.8	23.5%	21.8%
Mircera	5.3	23.7	22.4%	21.0%
Oxarol	2.4	9.2	26.1%	21.7%
Epogin	1.2	5.3	22.6%	23.7%
Transp., Immun., Infectious	3.2	14.1	22.7%	21.4%
CellCept	1.7	8.1	21.0%	22.9%
Copegus	0.5	1.5	33.3%	6.9%
Pegasys	0.1	0.9	11.1%	42.1%
Others	4.1	18.0	22.8%	24.4%
Overseas	20.8	87.8	23.7%	27.7%
Export to Roche	16.5	70.5	23.4%	28.5%
Actemra	15.8	68.0	23.2%	28.8%
Alecensa	0.7	2.5	28.0%	-
Other overseas	4.3	17.3	<b>24.9</b> %	25.1%

vs. Forecast (Core)

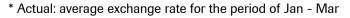
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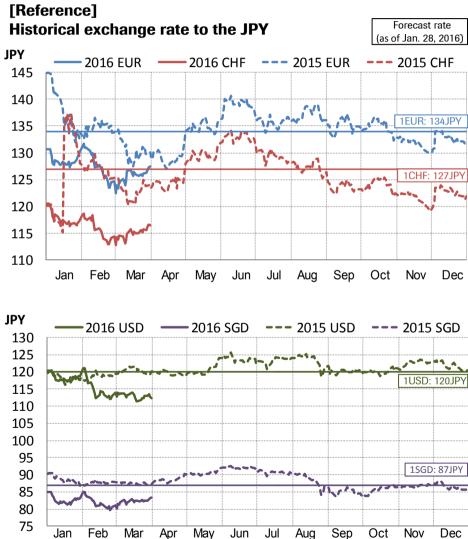


Impact from	Foreign	Exchange
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(Billions of JPY)	2016 Jan - Mar (FX impact vs. Forecast rate)				
	-0.4				
Revenues	Sales -0 Royalties and other -0 operating income				
Cost of sales Operating expenses	Cost of sales+0Expenses+0	-			
Operating profit	+0.2				

Actual / Forecast rate* (JPY)	2015 Jan - Mar Actual	2016 Jan -Dec Forecast	2016 Jan - Mar Actual
1CHF	124.98	127.00	116.14
1EUR	134.38	134.00	127.29
1USD	119.15	120.00	115.43
1SGD	87.88	87.00	82.22





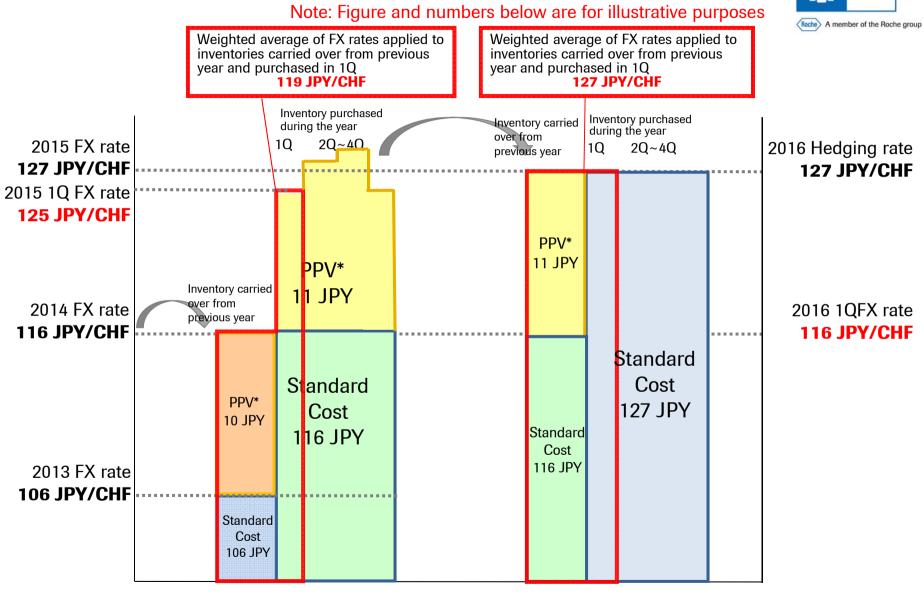


### Foreign Exchange Impact on Cost of Sales

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## **Overview of Development Pipeline**

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April 22, 2016

**Overview of Development Pipeline** 

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# CHUGAI

Oncology Field Projects under Development (as of 22 April, 2016)

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

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 MIBC: muscle invasive bladder cancer Letters in orange: in-house projects

★: Projects with advances in stages since 28 January, 2016

**Overview of Development Pipeline** 

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# CHUGAI

Primary Field Projects under Development (as of 22 April, 2016)

	Phase I	Phase II	Phase III	Filed
Bone & Joint			<b>ED-71 / Edirol (China)</b> - osteoporosis	
Renal	<b>EOS789</b> - hyperphosphatemia			
Autoimmune			<ul> <li>MRA / Actemra</li> <li>large-vessel vasculitis</li> <li>giant cell arteritis (overseas)</li> <li>systemic sclerosis</li> <li>SA237</li> <li>neuromyelitis optica★</li> </ul>	
CNS	RG1662 / basmisanil - improvement of intellectual ability in individuals with Down syndrome		<b>RG1450 / gantenerumab</b> - Alzheimer's disease	
Others	<b>PCO371 (overseas)</b> - hypoparathyroidism	RG3637 / lebrikizumab - IPF CIM331 / nemolizumab - atopic dermatitis★ - pruritus in dialysis patients URC102 (South Korea) - gout	RG3637 / lebrikizumab - asthma ACE910 (RG6013) /emicizumab - hemophilia A	

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 28 January, 2016
- ★: Multinational study managed by Chugai

**Overview of Development Pipeline** 

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## **Development Status**



## RG484 / Bonviva® Tablet Osteoporosis

Launched in April 2016

**Other Progress** 

**Overview of Development Pipeline** 





## RG340 / Xeloda $^{\mathbb{R}}$

Rectal cancer (adjuvant) [public knowledge-based application] Filed in March 2016



### MRA / Actemra®

Systemic sclerosis Designated as Orphan Drug in March 2016



### **Marduox<sup>®</sup> Ointment**

Psoriasis vulgaris (combination topical ointment) Approved in March 2016

**Overview of Development Pipeline** 

## Data Presentation / Results of Clinical Trials



Inhouse

### AF802 / Alecensa®

J-ALEX study (PIII in Japan) stopped early for benefit in February 2016

- Primary endpoint (progression-free survival) was achieved with a statistically significant improvement compared to crizotinib
- Detailed data to be presented at the American Society of Clinical Oncology in June 2016



### RG3637 / lebrikizumab

Top-line results of PIII global studies in patients with severe asthma were released in February 2016

• Within the two identical PIII studies, one study met its primary endpoint while the other study did not



### CIM331 / nemolizumab

Results of PII global study in patients with atopic dermatitis were presented at the American Academy of Dermatology in March 2016

• Efficacy and tolerability for 12 weeks treatment were observed



### Aplidin<sup>®</sup> (PharmaMar)

Top-line results of PIII global study in patients with multiple myeloma were released in April 2016

• Study met its primary endpoint

**Overview of Development Pipeline** 

Innovation all for the patients



## Projected Submissions (Post PoC NMEs and Products)

Filed AVASTIN (RG435) Cervical Cancer ALECENSA (AF802/RG7853) NSCLC [post-crizotinib] (EU)	atezolizumab (RG7446) NSCLC			NME in-house = in-licensed =	line extension
	obinutuzumab (GA101/RG7159) Indolent NHL	emicizumab (ACE910/RG6013) Hemophilia A	SA237 Neuromyelitis Optica	ACTEMRA (MRA) Systemic Sclerosis	nemolizumab (CIM331) Pruritus in Dialysis Patients
	obinutuzumab (GA101/RG7159) Aggressive NHL	lebrikizumab (RG3637) Asthma	PERJETA (RG1273) Gastric Cancer	atezolizumab (RG7446) MIBC (adjuvant)	nemolizumab (CIM331) Atopic Dermatitis
ACTEMRA (MRA) Giant Cell Arteritis (overseas)	PERJETA (RG1273) Breast Cancer (adjuvant)	Edirol (ED-71) Osteoporosis (China)	atezolizumab (RG7446) Renal Cell Carcinoma	atezolizumab (RG7446) NSCLC (adjuvant)	lebrikizumab (RG3637) IPF
ACTEMRA (MRA) Large-vessel Vasculitis	ALECENSA (AF802/RG7853) NSCLC[1L] (overseas)	atezolizumab (RG7446) Bladder Cancer	AVASTIN (RG435) Renal Cell Carcinoma	KADCYLA (RG3502) Breast Cancer (adjuvant)	gantenerumab (RG1450) Alzheimer's Disease
2016	20	17	2018	20	19-

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