

# **FY2015 1Q 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

## 1Q Results Summary



#### **■ Revenues: 117.1 billion yen (-6.9, -5.6% YoY)**

- Domestic sales excl. Tamiflu: steady increase if the impact of last year's temporary demand prior to the consumption tax increase is excluded (-1.3, -1.5%)
- Overseas sales: increase due to yen depreciation and growth in Actemra export (+0.7, +3.2%)
- Royalties and other operating income: decrease due to milestone income in the previous year, etc. (-6.1, -62.2%)

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

- Cost of sales: the ratio to sales worsened due primarily to yen depreciation (+2.2% points, from 48.4% to 50.6%)
- Operating expenses: increase mainly in research and development expenses and general and administration expenses (+0.9, +2.4%)

#### Profits

IFRS results: operating profit 20.7 billion yen (-10.4, -33.4%)

net income 14.8 billion yen (-4.3, -22.5%)

Core results: operating profit 21.5 billion yen (-9.9, -31.5%)

EPS (JPY) 27.54 (-7.28, -20.9%)



# IFRS and Core Results Jan - Mar

	IFRS results	Non-core	e items	Core results	(Billions of JPY)
(Billions of JPY)	2015	Intangible assets	Other	2015	Non-Core items
	Jan - Mar	and Business combinations	eliminated items	Jan - Mar	1. Intangible/Business combinations
Revenues	117.1			117.1	Amortization of intangible assets +0.4 Impairment of intangible assets +0.3
Sales	113.4			113.4	No business combinations
Royalties and other operating income	3.7			3.7	2. Other eliminated items  Environmental costs +0.1
Cost of sales	-57.7	+0.3		-57.4	Environmental costs
Gross profit	59.3	+0.3		59.7	
Operating expenses	-38.6	+0.4	+0.1	-38.2	Core net income
Marketing and distribution	-16.6	+0.0		-16.6	attributable to Chugai shareholders 15.1 (A)
Research and development	-19.0	+0.3		-18.6	
General and administration	-3.0		+0.1	-3.0	(Millions of shares)
Operating profit	20.7	+0.7	+0.1	21.5	Weighted average number
Financing costs	-0.0			-0.0	of shares and equity
Other financial income (expense)	0.5			0.5	securities in issue used to calculate diluted earnings
Profit before taxes	21.2	+0.7	+0.1	21.9	per share
Income taxes	-6.4	-0.2	-0.0	-6.6	547 ®
Net income	14.8	+0.4	+0.0	15.3	CIPLO
Chugai shareholders	14.6	+0.4	+0.0	15.1	(JPY)
Non-controlling interests	0.2			0.2	Core EPS 27.54 (A)/(B)

#### Year on Year (Core)

### Financial Overview Jan - Mar



(Billions of JPY)	2014 Jan - N	/lar	201: Jan - N	⁄lar	Growth		
D		Revenues		Revenues			
Revenues	124.0		117.1		-6.9	-5.6%	
Sales	114.2		113.4		-0.8	-0.7%	
excl. Tamiflu	107.3		106.7		-0.6	-0.6%	
Domestic	85.2		83.9		-1.3	-1.5%	
Export to Roche	16.9		18.0		+1.1	+6.5%	
Other overseas	5.2		4.8		-0.4	-7.7%	
Tamiflu	6.9		6.7		-0.2	-2.9%	
Ordinary	6.8		6.7		-0.1	-1.5%	
Govt. stockpiles etc.	0.1		0.0		-0.1	-100.0%	
Royalties and other operating income	9.8		3.7		-6.1	-62.2%	
Cost of sales	-55.3	44.6%	-57.4	49.0%	-2.1	+3.8%	
Gross profit	68.8	55.5%	59.7	51.0%	-9.1	-13.2%	
Operating expenses	-37.3	30.1%	-38.2	32.6%	-0.9	+2.4%	
Operating profit	31.4	25.3%	21.5	18.4%	-9.9	-31.5%	
Financing costs	-0.0		-0.0		0.0	0.0%	
Other financial income (expense)	0.2		0.5		+0.3	+150.0%	
Income taxes	-12.3		-6.6		+5.7	-46.3%	
Net income	19.3	15.6%	15.3	13.1%	-4.0	-20.7%	
EPS (JPY)	34.82		27.54		-7.28	-20.9%	

#### (Billions of JPY)

Royalties and other operating income
milestone income decreased, etc.

Other financial income (expense) +0.3
Exchange gains/losses -1.0
Gains/Losses on derivatives +1.4
(Gains/Losses on foreign exchange forward contracts)

#### Cost of sales ratio vs. Sales

2014	2015
Jan – Mar	Jan – Mar
48.4%	50.6%

#### Average exchange rate (JPY)

	2014 Jan – Mar	2015 Jan - Mar
CHF	115.17	124.98
EUR	140.90	134.38
USD	102.81	119.15
SGD	81.03	87.88

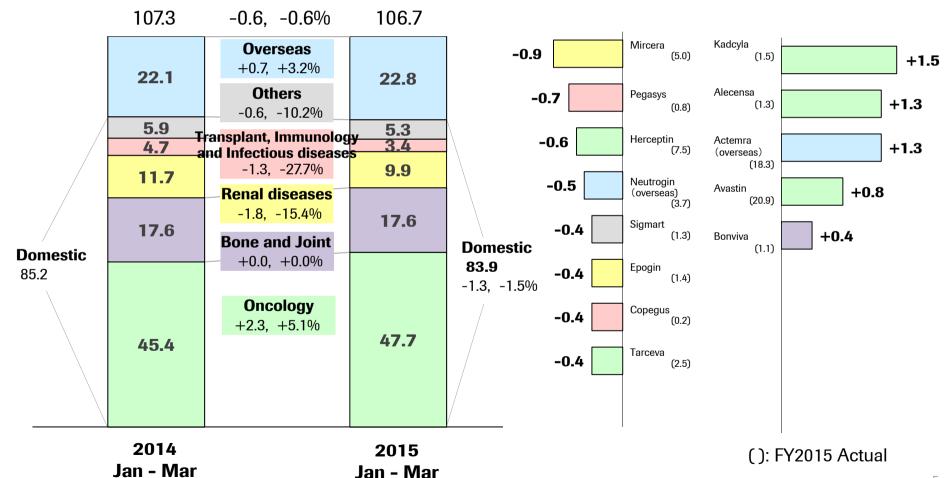
**Year on Year** 

# Sales (excl. Tamiflu) Jan - Mar



Sales by Disease Area, Year on Year Comparisons Sales by Products, Year on Year Changes

(Billions of JPY)



#### Innovation all for the patients



### **Tamiflu Sales Performance**

		Fiscal Term Sales					Forecast	]									
(Bill	ions of JPY)	FY20	09.12	FY20	10.12	FY20	11.12	FY20	12.12	FY20	13.12	FY20	14.12	FY20	15.12	Seasonal	Cases per sentinel*
	·	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	(millions)
	2008-09	11.0														16.7	1.27
	2009-10		25.2	1.4												26.6	2.02
	2010-11				0.2	4.1										4.3	1.26
Ordinary	2011-12						1.3	7.8								9.1	1.63
Oldinary	2012-13								2.4	8.2						10.6	1.11
	2013-14										1.9	7.0				9.0	1.44
	2014-15												5.8	6.7		12.6	1.37
	2015-16														0.7	-	-
(	Ordinary	36.2	(+29.1)	1.6	(-34.6)	5.4	(+3.8)	10.2	(+4.8)	10.1	(-0.1)	12.9	(+2.8)	7.4	(-5.5)		
	2008-09	14.4														15.5	
	2009-10		25.6	10.6												36.2	
	2010-11				5.9	0.5										6.4	
Govt.	2011-12						2.8	0.4								3.2	
Stockpiles etc.	2012-13								1.5	0.8						2.3	
	2013-14										0.1	0.1				0.2	
	2014-15												0.1	0.0		0.1	
	2015-16														-	-	
Govt.	Stockpile etc.	40.0	(+38.7)	16.6	(-23.4)	3.3	(-13.3)	1.9	(-1.4)	0.9	(-1.0)	0.2	(-0.7)	0.0	(-0.2)		
		25.4	50.8	12.0	6.1	4.6	4.1	8.1	3.9	9.0	2.0	7.1	5.9	6.7	0.7		
	Total	76.2	(+67.8)	18.2	(-58.0)	8.7	(-9.5)	12.0	(+3.3)	11.0	(-1.0)	13.0	(+2.0)	7.4	(-5.6)	() Ye	ar on year

<sup>\*</sup> 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. 2014/2015 consist of the period from late October (the 44th week) to early April (the 14th week).

Year on Year (Core)

# **Operating Profit Jan – Mar**



(Billions of J	IPY)	
	Gross profit from sales	
31.4	-3.0 Royalties and other operating income  -6.1  R&D  G&A  -0.4  -0.4	21.5
	-9.9 (-31.5%) =	
2014 Jan - Ma	ar	2015 Jan - Mar

(Billions of JPY)	2014 Jan - Mar	2015 Jan - Mar	Growth			
Revenues	124.0	117.1	-6.9			
Cost of sales	-55.3	-57.4	-2.1			
Gross profit	68.8	59.7	-9.1			
of which Sales	59.0	56.0	-3.0			
Royalties, etc.	9.8	3.7	-6.1			
Marketing and distribution	-16.6	-16.6	0.0			
Research and development	-18.2	-18.6	-0.4			
General and administration	-2.6	-3.0	-0.4			
Operating profit	31.4	21.5	-9.9			
Decrease in gross profit from			-3.0			
Cost of sales ratio to sales						
Decrease in royalties and oth	. •	come	-6.1			
Change in Marketing and dis			0.0 -0.4			
Increase in research and development						
Negative foreign exchange impact, etc.						
Increase in general and administration -0.4						
Increase in miscellaneous expenses due primarily to communication activities to raise corporate brand awareness						

vs. Forecast (Core)

# Financial Progress Jan – Mar



	Actual	Forecast o	n Jan 28	2014
(Billions of JPY)	2015 Jan - Mar	2015 Jan - Dec	Progress	Progress*
Revenues	117.1	486.5	24.1%	26.9%
Sales	113.4	460.8	24.6%	26.1%
excl. Tamiflu	106.7	453.4	23.5%	25.3%
Domestic	83.9	360.9	23.2%	24.4%
Export to Roche	18.0	74.7	24.1%	30.7%
Other overseas	4.8	17.8	27.0%	26.9%
Tamiflu	6.7	7.4	90.5%	53.1%
Royalties and other operating income	3.7	25.6	14.5%	40.5%
Cost of sales	-57.4	-230.2	24.9%	25.5%
Gross profit	59.7	256.3	23.3%	28.2%
Operating expenses	-38.2	-171.3	22.3%	22.4%
Operating profit	21.5	85.0	25.3%	40.6%
EPS (JPY)	27.54	104.42	26.4%	36.6%

<sup>\*</sup> Jan - Mar progress versus Jan - Dec.

vs. Forecast (Core)

# Sales Progress (excl. Tamiflu) Jan - Mar



	Actual	Full-year	forecast	2014
(Billions of JPY)	2015	2015	Progress	Progress*
	Jan - Mar	Jan - Dec	Piogless	Piogress*
Sales excl. Tamiflu	106.7	453.4	23.5%	25.3%
Domestic	83.9	360.9	23.2%	24.4%
Oncology	47.7	204.5	23.3%	24.0%
Avastin	20.9	88.2	23.7%	24.4%
Herceptin	7.5	29.6	25.3%	26.0%
Tarceva	2.5	14.1	17.7%	25.2%
Xeloda	2.6	10.0	26.0%	26.9%
Perjeta	2.3	9.9	23.2%	22.0%
Kadcyla	1.5	8.8	17.0%	-
Alecensa	1.3	5.2	25.0%	-
Zelboraf **	0.1	0.2	50.0%	-
Bone and Joint	17.6	75.9	23.2%	25.3%
Actemra	5.9	26.3	22.4%	24.5%
Edirol	4.9	21.2	23.1%	26.0%
Bonviva	1.1	4.9	22.4%	20.6%
Renal	9.9	44.3	22.3%	26.2%
Mircera	5.0	24.5	20.4%	26.1%
Epogin	1.4	5.2	26.9%	27.3%
Transp., Immun., Infectious	3.4	13.0	26.2%	22.6%
Pegasys	0.8	2.1	38.1%	21.4%
Copegus	0.2	1.1	18.2%	19.4%
Others	5.3	23.2	22.8%	23.0%
Overseas	22.8	92.5	24.6%	29.7%
Export to Roche	18.0	74.7	24.1%	30.7%
Other overseas	4.8	17.8	<b>27.0</b> %	26.9%

<sup>\*</sup> Jan - Mar progress versus Jan - Dec. \*\* Forecast for Zelboraf was disclosed on Apr. 22.

vs. Forecast (Core)

# Impact from Foreign Exchange

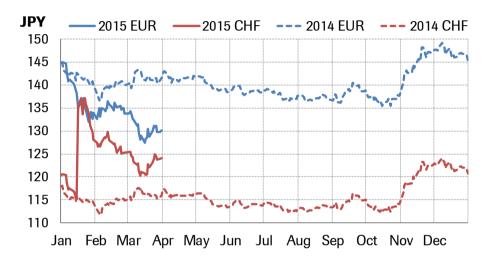


(Billions of JPY)	FX impact Jan - Mar (vs. Forecast on Jan. 28)				
	+0.6				
Revenues	Sales	+0.7			
	Royalties and other operating income	-0.1			
Cost of sales	Cost of sales	-0.2			
Operating expenses	Expenses	+0.1			
Operating profit	+0.5				

FX rate to the JPY *	Actual Jan - Mar avg. (2014)	Assumption Jan - Dec (as of Jan. 28)	Actual Jan - Mar avg. (2015)
1CHF	115.17	116.00	124.98
1EUR	140.90	142.00	134.38
1USD	102.81	119.00	119.15
1SGD	81.03	91.00	87.88

<sup>\*</sup> Actual: average exchange rate for the period of Jan - Mar

# [Reference] Historical exchange rate to the JPY







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2015.4.22

# **Oncology Field** Projects under Development (as of 22 April, 2015)



	Phase I	Phase II	Phase III	Filed
Oncology	CKI27 / RG7304 (Japan / overseas) - solid tumors  RG7321 / pictilisib - solid tumors  RG7596 / polatuzumab vedotin - NHL  RG7604 / taselisib - solid tumors	RG435 / Avastin - cervical cancer GC33 / RG7686 - hepatocellular carcinoma	AF802 (RG7853) / Alecensa (overseas) - NSCLC  RG1273 / Perjeta - breast cancer (adjuvant) - gastric cancer  RG3502 / Kadcyla - breast cancer (adjuvant) - gastric cancer (PII/III)  GA101 (RG7159) / obinutuzumab - aggressive NHL - indolent NHL  RG7446 / MPDL3280A - NSCLC - bladder cancer	RG340 / Xeloda - gastric cancer (adjuvant)

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 28 January, 2015

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



	Phase I	Phase II	Phase III	Filed
Bone & Joint				RG484 / Bonviva (oral) - osteoporosis★
Autoimmune		MRA / Actemra (overseas) - systemic sclerosis	MRA / Actemra - large-vessel vasculitis MRA / Actemra (overseas) - giant cell arteritis SA237 - neuromyelitis optica★	
CNS	RG1577 - Alzheimer's disease RG1662 - improvement of intellectual ability in individuals with Down syndrome	RG7090 / basimglurant - major depressive disorder	RG1450 / gantenerumab - Alzheimer's disease	
Others		RG3637 / lebrikizumab - IPF CIM331 - atopic dermatitis★ URC102 (South Korea) - gout ACE910 / RG6013 - hemophilia A (PI/II)	RG3637 / lebrikizumab - 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 28 January, 2015

★: Multinational study managed by Chugai

# **Development Status**





#### RG7204 / Zelboraf®

Unresectable melanoma with BRAF mutation Launched in February 2015



### RG484 / Bonviva® (oral)

Osteoporosis
Filed in February 2015



#### MRA / Actemra®

Subcutaneous injection formulation for rheumatoid arthritis Approved in Taiwan in April 2015



### **Copegus**®

Improvement of viraemia associated with Serogroup 2 chronic hepatitis C or compensated cirrhosis related to hepatitis C, when administered in combination with sofosbuvir Approved in March 2015 [additional indication]

# Other Progress





### RG7446 / MPDL3280A (Engineered anti-PDL1 antibody)

Non-small cell lung cancer (1st line)

Decided to participate in 3 multinational studies

February 2015
U.S. FDA grants Breakthrough Therapy Designation in non-small cell lung cancer (Roche)



#### RG435 / Avastin®

Primary endpoint achieved in P3 study (MERiDiAN Study) for HER2- metastatic breast cancer (Roche)

# **Upcoming Events (Planned)**



Inlicensed

#### RG484 / Bonviva® (oral): March 2015

Results of Japanese P3 study for osteoporosis presented at the World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases

- Primary endpoint achieved by demonstrating a non-inferiority to ibandronate injection
- RG484 was well tolerated with no new safety signals



#### MultiStem® (Cell therapy): April 2015

Results of overseas P2 study for ischemic stroke presented at The European Stroke Organisation Conference



### **Alecensa®:** May 2015

Updates of overseas P1/2 studies and a Japanese P1/2 study for non-small cell lung cancer will be presented at ASCO 2015



### ACE910 (anti-FIXa/FX bispecific antibody): June 2015

Efficacy and safety data from patients treated long-term in the Japanese P1/2 study for Hemophilia A to be presented at The International Society on Thrombosis and Haemostasis

# Projected Submissions (Post PoC NMEs and Products)



Seamless filings every year

NME line extension

in-house in-licensed

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BONVIVA (RG484) Osteoporosis (oral)

Filed in Feb. 2015

AVASTIN (RG435) Cervical Cancer

ALECENSA (AF802/RG7853) NSCLC (overseas) ACTEMRA (MRA) Giant Cell Arteritis (overseas)

ACTEMRA (MRA) Large-vessel Vasculitis

MPDL3280A (RG7446) NSCLC

KADCYLA (RG3502) Gastric Cancer lebrikizumab (RG3637) Asthma

MPDL3280A (RG7446) Bladder Cancer

GA101 / obinutuzumab (RG7159) Indolent NHL

GA101 / obinutuzumab (RG7159) Aggressive NHL

PERJETA (RG1273) Breast Cancer (adjuvant) ACE910 Hemophilia A

lebrikizumab (RG3637) IPF

gantenerumab (RG1450) Alzheimer's disease

SA237 Neuromyelitis Optica

ACTEMRA (MRA) Systemic sclerosis (overseas)

KADCYLA (RG3502) Breast Cancer (adjuvant)

PERJETA (RG1273) Gastric Cancer

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