

CHUGAI PHARMACEUTICAL CO., LTD. Executive Vice President CFO Yoshio Itaya

October 23, 2012



# **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.



## Summary

#### Revenues 275.4 billion JPY (-0.2%)

- Tamiflu: approx. 30% increase, reflecting a large flu season
- Domestic sales excl. Tamiflu: +0.9% increase as approx. 7% volume growth offset the impact of NHI price revision
- Overseas sales: -8.7% decrease due to FX impact and difference in shipment timing of Actemra export
- Other operating revenues: approx. 20% decline as a YoY decrease in one-time income outweighed growth in Actemra related income
- Operating Income 48.2 billion JPY (-3.6%):
  - Decrease in gross profit associated with change in product mix and decline in other operating revenues
- Net Income 29.8 billion JPY (+10.0%)
  - Extraordinary loss of 7.4 billion JPY recorded last year due to the earthquake

EUR

113.25

101.69

FY2012 3Q Consolidated Financial Overview

4.1

2.2

7.9

0.4



## Financial Overview Jan - Sep

								(Billion Ji	- Y )
(Billi	on JPY)	2011 Jan-Sep	As % of Revenues	2012 Jan-Sep	As % of Revenues	Growth	%	Sales excl. Tamiflu Domestic	+2.1
Revenue	S	276.0		275.4		-0.6	-0.2	Overseas	-2.9
Sales		267.5		268.6		+1.1	+0.4	Sales of Tamiflu*	+1.9
excl.	Tamiflu	261.2		260.4		-0.8	-0.3	Other Operating Revenues	-1.7
Tamif	lu	6.3		8.2		+1.9	+30.2	Decline in one-time income	;
Other Ope	erating Revenues	8.5		6.8		-1.7	-20.0		
Operating	Income	50.0	18.1	48.2	17.5	-1.8	-3.6	Operating Income	-1.8
	erating Income	3.3		1.2		-2.1	-63.6	Non-operating Inc./Exp.	-1.2
Non-oper	ating Expenses	2.2		1.4		-0.8	-36.4		
Ordinary	Income	51.1	18.5	48.1	17.5	-3.0	-5.9	Extraordinary Gain/Loss	+9.1
Extraoro	linary Gain	0.0		0.0		+0.0	-	Decline in Extraordinary Lo	SS
Extraoro	linary Loss	9.1		0.0		-9.1	-100.0	Loss on disaster	-7.4
Net Incon	าย	27.1	9.8	29.8	10.8	+2.7	+10.0	Asset retirement obligations	-1.0
20	nange rate (JPY )11 Jan - Sep	) 2012 Jar			* Tamiflu	J		2011 2012	
CHF	91.62		84.43				Ja	n – Sep Jan - Sep Growth	

Ordinary

Govt. Stockpile etc.

(Billion JPY)

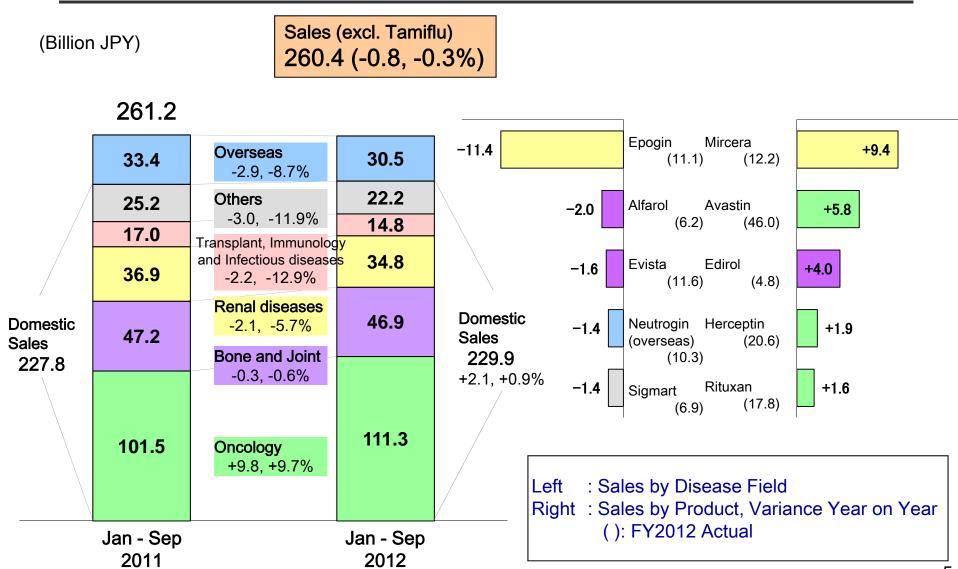
4

+3.8

-1.8



# Sales (excl. Tamiflu) Jan - Sep

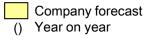




## **Tamiflu Sales Performance**

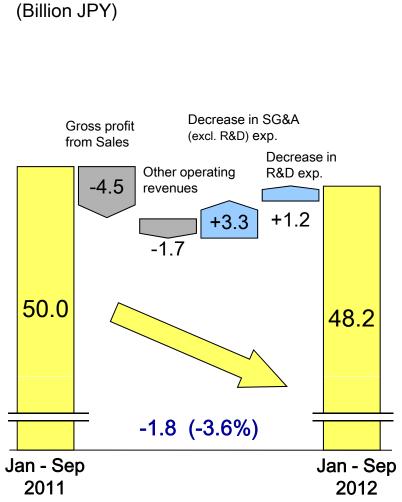
									Fiscal Term	n Sales									
(E	Billion JPY)	FY20	005.12	FY20	06.12	FY20	07.12	FY20	08.12	FY20	09.12	FY20	10.12	FY20	11.12	FY2012.12		Seasonal	Cases p sentine
	1	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Sales	(million
	2004-05	23.2																24.6	1.47
	2005-06		11.9	9.9														21.8	0.92
	2006-07				3.7	5.0												8.7	1.01
	2007-08						5.2	1.4										6.6	0.66
Ordinary	2008-09								5.7	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
	2011-12														1.3	7.8		9.1	1.63
	2012-13																1.5	-	-
	Ordinary	35.1	(+26.5)	13.6	(-21.5)	10.2	(-3.4)	7.1	(-3.1)	36.2	(+29.1)	1.6	(-34.6)	5.4	(+3.8)	9.3	(+3.9)		
	2005-06		0.2	6.5														6.7	1
	2006-07		0.2	0.0	17.9	18.9												36.8	
					17.9	18.9													
	2007-08						9.6	0.2										9.8	
Govt.	2008-09								1.1	14.4								15.5	
Stockpile etc.	2009-10										25.6	10.6						36.2	
	2010-11												5.9	0.5				6.4	
	2011-12														2.8	0.4		3.2	
	2012-13																0.0		
	Govt. Stockpile etc.	0.2	(+0.2)	24.4	(+24.2)	28.5	(+4.1)	1.3	(-27.2)	40.0	(+38.7)	16.6	(-23.4)	3.3	(-13.3)	0.4	(-2.9)		•
		23.2	12.0	16.3	21.6	23.8	14.8	1.6	6.8	25.4	50.8	12.0	6.1	4.6	4.1	8.1	1.5	1	
	Total	35.2	(+26.6)	38.0	(+2.8)	38.7	(+0.7)	8.4	I		(+67.8)	18.2		8.7	(-9.5)	9.7	L		

\*Total patient number of the controlled samples in the infectious Diseases Weekly Report, period between late October and mid-April (between early July 2009 and mid-March 2010 for 2009/2010), published by Japan's National Institute of Infectious Diseases.





# **Operating Income** Jan - Sep



(Billion JPY)	2011	2012	Growth		
(Billion JFT)	Jan-Sep	Jan-Sep	Growth	(%)	
Revenues	276.0	275.4	-0.6	-0.2	
Cost of Sales	115.4	121.0	+5.6	+4.9	
Gross Profit	160.7	154.4	-6.3	-3.9	
Sales	152.1	147.6	-4.5	-3.0	
Other Operating Revenues	8.5	6.8	-1.7	-20.0	
SG&A (excl. R&D) exp.	69.4	66.1	-3.3	-4.8	
R&D exp.	41.2	40.0	-1.2	-2.9	
Operating Income	50.0	48.2	-1.8	-3.6	

- Decrease in Gross Profit from Sales -4.5
- Decrease in Other Operating Revenues -1.7
  Decrease in one-time income
- Decrease in SG&A (excl. R&D) exp. +3.3
  Cost containment
- Decrease in R&D exp. +1.2
  Completion of late stage projects



# Financial Overview Jul - Sep

(Dillion IDV)	2011		2012		Orouth		
(Billion JPY)	Jul-Sep	As % of Revenues	Jul-Sep	As % of Revenues	Growth	%	
Revenues	94.1		90.1		-4.0	-4.3	
Sales	92.7		88.6		-4.1	-4.4	
excl. Tamiflu	91.0		88.5		-2.5	-2.7	
Tamiflu	1.7		0.1		-1.6	-94.1	
Other Operating Revenues	1.4		1.5		+0.1	+7.1	
Cost of Sales	40.8		39.3		-1.5	-3.7	
Gross Profit	53.3	56.6	50.8	56.4	-2.5	-4.7	
SG&A (excl. R&D) exp.	24.1		23.1		-1.0	-4.1	
R&D exp.	14.3		13.8		-0.5	-3.5	
Operating Income	14.8	15.7	13.9	15.4	-0.9	-6.1	
Non-operating Income	2.1		0.6		-1.5	-71.4	
Non-operating Expenses	2.0		0.8		-1.2	-60.0	
Ordinary Income	14.9	15.8	13.7	15.2	-1.2	-8.1	
Extraordinary Gain	0.0		-		+0.0	-	
Extraordinary Loss	1.5		0.0		-1.5	-100.0	
Net Income	10.0	10.6	9.0	10.0	-1.0	-10.0	

#### (Billion JPY)

Sales excl. Tamiflu	-2.5
Avastin	+2.6
Herceptin	+2.3
Edirol	+2.1
Mircera	+1.8
Actemra (overseas)	-4.9
Epogin	-2.6
Alfarol	-1.0
Sales of Tamiflu*	-1.6
Other Operating Revenu	es
	+0.1
Operating Income	-0.9

* Tamiflu	2011 Jul-Sep	2012 Jul-Sep	Growth		
Ordinary	0.0	0.1	-0.1		
Govt. Stockpile etc.	1.7	-	-1.7		



## Financial Overview Jan - Sep

						Actual	Forecast	on Feb. 1
			(Billion JPY)	2012	2012	Prog.		
					Sales excl. Tamiflu	Jan-Sep 260.4	Jan-Dec	(%) 66.1
		Actual	Forecast	on Feb. 1	Oncology	111.3	394.1 165.4	67.3
		2012	2012		Avastin	46.0	68.8	66.9
	(Billion JPY)	2012	2012	D	Herceptin	20.6	27.3	75.5
		Jan-Sep	Jan-Dec	Progress	Rituxan	17.8	25.3	70.4
		•		(%)	Xeloda	7.9	16.8	47.0
R	evenues	275.4	418.5	65.8	Tarceva	6.9	8.2	84.1
	Salas	269 6	402.7	66 5	Bone and Joint	46.9	70.3	66.7
	Sales	268.6	403.7	66.5	Actemra	12.1	18.3	66.1
	excl. Tamiflu	260.4	394.1	66.1	Evista	11.6	16.9	68.6
	<b>T</b> :0			05.4	Suvenyl	9.0	14.7	61.2
	Tamiflu	8.2	9.6	85.4	Edirol	4.8	7.8	61.5
	Other Operating Revenues	6.8	14.8	45.9	Renal	34.8	62.7	55.5
					Mircera	12.2	29.6	41.2
0	perating Income	48.2	80.0	60.3	Epogin	11.1	16.8	66.1
0	rdinary Income	48.1	80.5	59.8	Transp., Immun., Infectious	14.8	25.6	57.8
ordinary income		40.1 00.3		59.0	Pegasys	5.1	12.1	42.1
Net Income		29.8	49.0	60.8	Copegus	1.5	2.7	55.6
					Others	22.2	30.0	74.0
					Overseas	30.5	40.2	75.9
					Actemra	18.2	24.1	75.5

78.6

13.1

10.3

Neutrogin



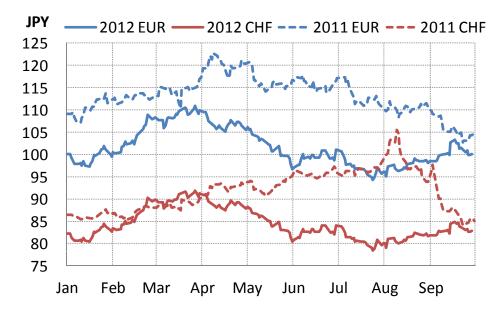
# Impact from Foreign Exchange

(Billion JPY)	FX impact Jan - Sep (vs. Forecast on Feb. 1 <b>)</b>				
	-1.1				
Revenues	Neutrogin (Overseas)	-0.7			
	Actemra (Export)	-0.1			
	Other Operating Revenues	-0.3			
Cost of sales SG&A expenses	Cost of Roche products Overseas SG&A exp., etc.	+0.1 +0.4			
Operating Income	-0.6				
Non-operating Inc./Exp.	Gain/loss on foreign exchange and exchange forward contracts -0.				
Ordinary Income	-1.4				

FX rate to the JPY	1CHF	1EUR
Assumption as of Feb 1 (Jan – Dec)	85.00	109.00
Actual Jan – Sep avg.	84.43	101.69

#### [Reference]

Historical exchange rates to the JPY (Jan - Sep)





# **Overview of Development Pipeline**

CHUGAI PHARMACEUTICAL CO., LTD. Department Manager of R&D Portfolio Management Dept.

Hisanori Takanashi

October 23, 2012



# Development Status – Oncology (1)



### RG435/Avastin:

Recurrent glioblastoma Filed in Sep 2012 Ovarian cancer Filed in Oct 2012



### RG3638/onartuzumab (MetMAb):

Non-small cell lung cancer

Decided to participate in P3 multinational study by the end of this year



### RG3502/trastuzumab emtansine (T-DM1):

Gastric cancer Started P2/3 multinational study in Sep 2012



# Development Status – Oncology (2)

In-license d

RG7204/vemurafenib: Melanoma Started P1 in Sep 2012



WT2725/WT1 peptide cancer vaccine: Advanced cancer

Started P1(overseas) in Aug 2012 Co-development with Dainippon Sumitomo Pharma



## AF802:

Decided to license out to Roche

(Expected indication: Non-small cell lung cancer)

# **Development Status**



- Bone & Joint, Autoimmune, Others



Actemra (US): Rheumatoid arthritis (Expanded indication to DMARDs-IR) Approved in Oct 2012



RG484 (Oral): Osteoporosis Started P3 in Oct 2012



ACE910/bispecific antibody: Hemophilia A Started P1 in Aug 2012



# ACE910 – Hemophilia A

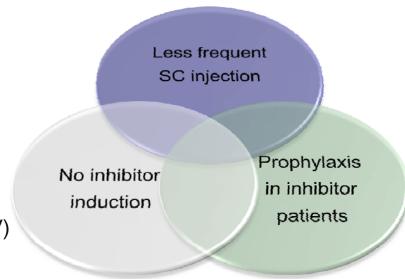
Definition: Congenital bleeding disorder caused by deficiency or dysfunction of coagulation factor VIII (FVIII)

 Patient number: 38,000 registered patients in North America/EU/Japan (World Federation of Hemophilia, Global Survey 2010)

- Symptoms: Bleeding into articuli, muscles, subcutaneous tissues, GI, skull, etc.
  - Hemophilic arthropathy caused by repeated intra-articular bleeding is the most serious complication, which affects patients' QOL
- Standard therapy: FVIII replacement therapy
  - On-demand treatment
  - □ Prophylaxis (3 times/week, IV)

Induction of FVIII inhibitor (20-30%)

- Current therapy for inhibitor patients
  - On-demand treatment by bypassing agents (IV)
  - Immune tolerance induction



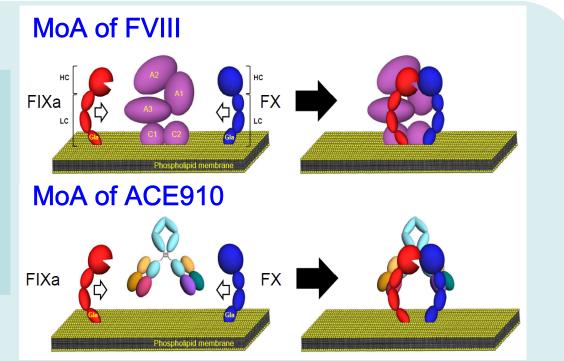
#### Unmet needs in hemophilia A



# ACE910 – Mode of action

ACE910: Humanized anti-factor IXa x anti-factor X bispecific antibody

ACE910 supports the interaction between FIXa and FX, thereby promotes FX activation and accelerates coagulation.



Nature Medicine, Published online 30 September 2012

#### Expected features

- □ Longer half-life, subcutaneously available
- Effective in the presence of FVIII inhibitor
- □ No potentials to induce FVIII inhibitor

Prophylaxis by weekly SC injections both in inhibitor patients and non-inhibitor patients



# **About Melanoma**

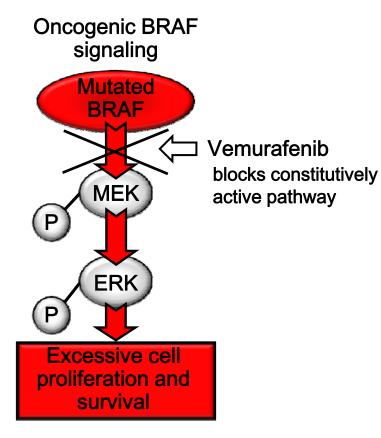
- 1,300-1,400 patients are diagnosed each year in Japan
- Global incidence is on the rise at 3-5% per year
- Poor prognosis in metastatic cases
  - □ Rapid disease progression (median PFS ~2 months)
  - □ Fewer than 10% survive >5 years
  - Amongst most common fatal cancers in young adults
  - Primary risk factor UV/sun
  - Until recently, limited treatment options (chemotherapy, radiotherapy, immunotherapy) with minimal efficacy and high toxicity





# Vemurafenib is a Selective Inhibitor of the Oncogenic BRAF Kinase

- Binds to and selectively inhibits oncogenic BRAF<sup>V600</sup>
- Companion diagnostic: cobas® 4800 BRAF V600 Mutation Test



- Mutated BRAF leads to constitutive activation and dysregulation of the RAS-RAF signaling cascade
- Mutated BRAF is identified in various cancer
  - ~50% melanoma
  - ~30-70% thyroid cancer
  - ~10% colorectal cancer
  - ~8% of all solid tumors

### Contacts: Corporate Communications Dept.

**Corporate Communications Group** 

Tel: +81 (0)3-3273-0881 Fax: +81 (0)3-3281-6607 e-mail: pr@chugai-pharm.co.jp Hitoshi Aikawa, Koichi Kawahara, Kae Miyata, Hiroshi Araki

**Investor Relations Group** 

Tel: +81 (0)3-3273-0554 Fax: +81 (0)3-3281-6607 e-mail: ir@chugai-pharm.co.jp

Mac Uchida, Yusuke Tokita, Chisato Kitamura, Yuka Minoshima