

# **FY2016 2Q Consolidated Financial Overview** (IFRS based)

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

July 21/22, 2016

## **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: 247.5 billion yen (+7.3, +3.0% YoY)
- Domestic sales excl. Tamiflu: increase due to steady growth of new products and mainstay products (+5.1, +2.8%)
- Overseas sales: decrease due to impact of supply price reduction on Actemra export, etc.
   (-1.0, -2.1%)
- Royalties and other operating income: increase due to Actemra-related revenues, etc. (+2.8, +37.3%)

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

- Cost of sales: the ratio to sales worsened due to HIP revision and impact of supply price reduction on Actemra export, etc. (+2.3% points, from 50.1% to 52.4%)
- Operating expenses: increase mainly due to increase of research and development expenses related to the progress of projects (+1.3, +1.7%)

#### ■ Profits

- IFRS results: operating profit 43.5 billion yen (+0.3, +0.7%) net income 32.0 billion yen (+1.2, +3.9%)
- Core results: operating profit 44.1 billion yen (-1.8, -3.9%) net income 32.4 billion yen (-0.1, -0.3%)
- Core EPS (JPY): 58.45 (+0.15, +0.3%)

#### Innovation all for the patients

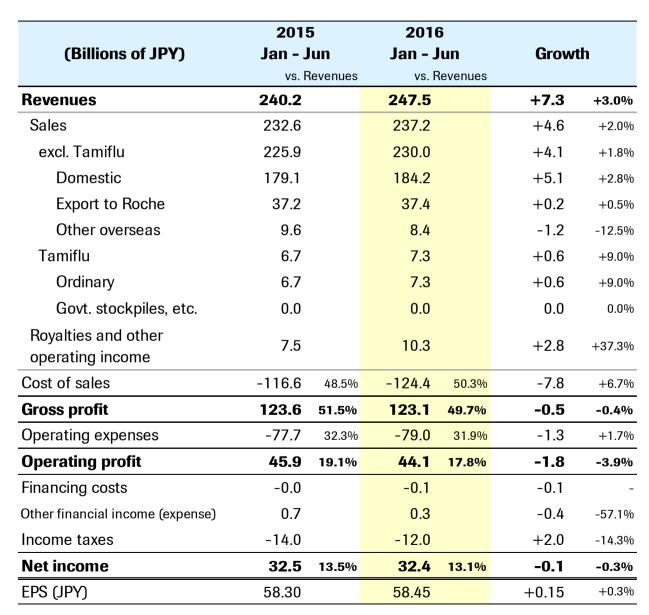


## **IFRS** and **Core Results Jan-Jun**

	IFRS results	Non-core	items	Core results			
(Billion JPY)	2016	Intangible assets	Others	2016	(Billions of JPY)		
	Jan Jun.	ilitaligible assets Oulers		Jan Jun.	(Non-Core items)		
Revenues	247.5			247.5			
Sales	237.2			237.2	<ul> <li>Intangible assets:</li> <li>Amortization of intangible assets +0.6</li> </ul>		
Royalties and other operating income	10.3			10.3	Impairment non		
Cost of sales	-125.0	+0.6		-124.4	Others     Environmental costs     non		
Gross profit	122.5	+0.6		123.1	Environmental costs non		
Operating expenses	-79.0	+0.0		-79.0			
Marketing and distribution	-33.1			-33.1	Core net income attributable to Chugai		
Research and development	-40.1	+0.0		-40.1	shareholders 32.0		
General and administration	-5.8			-5.8	-		
Operating profit	43.5	+0.6		44.1	(Millions of shares)		
Financing costs	-0.1			-0.1	Weighted average number		
Other financial income (expense)	0.3			0.3	of shares and equity securities in issue used to calculate		
Profit before taxes	43.8	+0.6		44.4	diluted earnings per share		
Income taxes	-11.8	-0.2		-12.0	547		
Net income	32.0	+0.4		32.4			
Chugai shareholders	31.5	+0.4		32.0	(JPY)		
Non-controlling interests	0.5			0.5	Core EPS 58.45		

Year on Year (Core)

### Financial Overview Jan - Jun





(Billions of JPY)

•Royalties and other operating income +2.8
Increase in Actemra-related revenue, etc.

●Other financial income (expense) -0.4

Exchange gains/losses +3.8

Gains/Losses on derivatives -4.1
(Gains/Losses on foreign exchange forward contracts)

#### Cost of sales ratio vs. Sales

2015	2016
Jan – Jun	Jan – Jun
50.1%	52.4%

#### Average exchange rate (JPY)

	2015 Jan – Jun	2016 Jan - Jun
1 CHF	126.88	113.81
1 EUR	134.27	124.77
1 USD	120.24	111.79
1 SGD	89.10	80.96

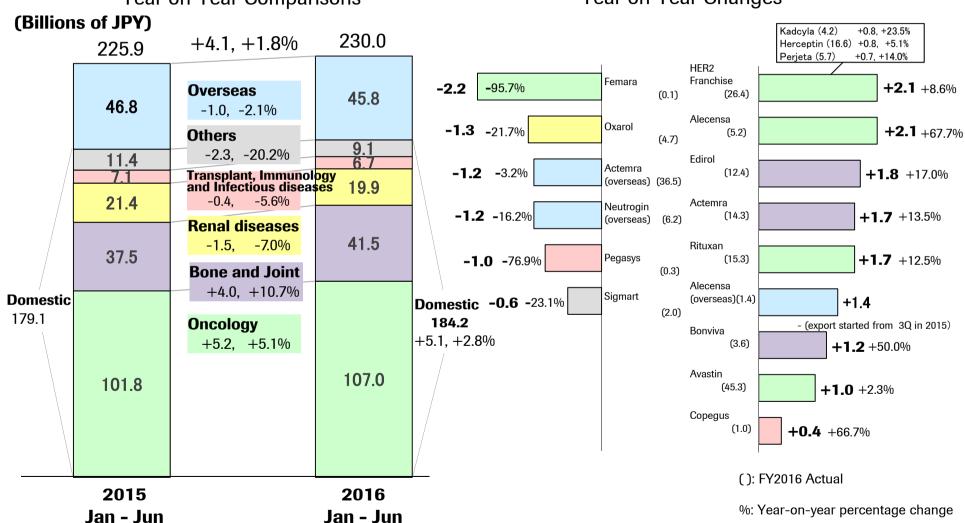
**Year on Year** 

FY2016 2Q Consolidated Financial Overview

## Sales (excl. Tamiflu) Jan - Jun



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



## **Tamiflu Sales Performance**



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							Fisc	al Term S	ales						Forecast	
(Billio	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-Jun	Jul-Dec	Sales
	2009-10	1.4														26.6
	2010-11		0.2	4.1												4.3
	2011-12				1.3	7.8										9.1
Ordinary	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	7.3		8.7
	2016-17														0.4	-
0	rdinary	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	tockpile etc.	16.6	(-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)	
		12.0	6.1	4.6	4.1	8.1	3.9	9.0	2.0	7.1	5.9	6.7	1.5	7.3	1.3	
	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 (Core)

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## **Operating Profit Jan - Jun**



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(Rillion o	T JPT)		
	Gross profit from sales +1.5  M&D  -2.8		<u> </u>
45.9	Royalties and other operating income  -1.8 (-3.9%)	44.1	
	<u></u>		
2015 Jan - Ju	n	2016 Jan - Jun	

(Billions of JPY)	2015 Jan - Jun	2016 Jan - Jun	Growth
Revenues	240.2	247.5	<b>+7.</b> 3
Cost of sales	-116.6	-124.4	-7.8
Gross profit	123.6	123.1	-0.5
of which Sales	116.1	112.8	-3.3
Royalties, etc.	7.5	10.3	+2.8
Marketing and distribution	-34.6	-33.1	+1.5
Research and development	-37.3	-40.1	-2.8
General and administration	-5.8	-5.8	0
Operating profit	45.9	44.1	-1.8

- •Decrease in gross profit from sales -3.3 Cost of sales ratio to sales worsened due to HIP revision and supply price reduction on Actemra export, etc.
- •Increase in royalties and other operating income +2.8
- Decrease in marketing and distribution +1.5

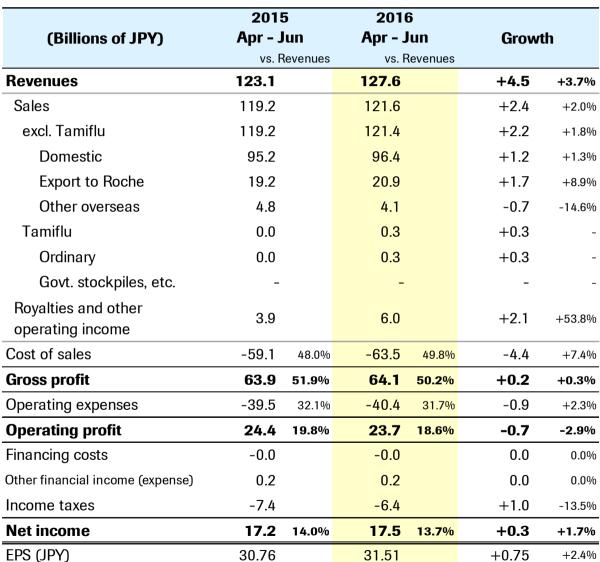
FX impact and decrease in various expenses

•Increase in research and development expenses -2.8

Progress of projects, etc.

#### Year on Year (Core)

## Financial Overview Apr – Jun





(Billions of JPY)

●Decrease in gross profit from sales	-2.0
Cost of sales ratio to sales worsened due to HIP revision and impact of supply price reduction on Actemra export, etc.	
•Increase in royalties and other operating income	+2.1
•Increase in operating expenses	-0.9
Decrease in marketing and distribution FX impact and decrease in various expenses	+1.4
Increase in research and development Progress of projects, etc.	-2.1
Increase in general and administration	-0.1

#### Cost of sales ratio vs. Sales

2015	2016
Apr – Jun	Apr – Jun
49.6%	52.2%

vs. Forecast (Core)

## Financial Progress Jan – Jun



(Billions of JPY)	Actual Forecast on Jan 28			2015
	2016 Jan - Jun	2016 Jan - Dec	Progress	Progress*
Revenues	247.5	495.0	<b>50.0</b> %	48.2%
Sales	237.2	475.4	49.9%	49.7%
excl. Tamiflu	230.0	466.8	49.3%	49.1%
Domestic	184.2	379.0	48.6%	47.4%
Export to Roche	37.4	70.5	53.0%	59.0%
Other overseas	8.4	17.3	48.6%	50.3%
Tamiflu	7.3	8.6	84.9%	81.7%
Royalties and other operating income	10.3	19.6	52.6%	24.7%
Cost of sales	-124.4	-254.0	49.0%	48.8%
Gross profit	123.1	241.0	51.1%	47.5%
Operating expenses	-79.0	-170.0	46.5%	45.9%
Operating profit	44.1	71.0	62.1%	50.6%
EPS (JPY)	58.45	92.54	63.2%	50.1%

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

vs. Forecast (Core)

## Sales Progress (excl. Tamiflu) Jan – Jun



	Actual	Forec	ast	2015
(Billions of JPY)	2016	2016	D	D*
	Jan - Jun	Jan - Dec	Progress	Progress*
Sales excl. Tamiflu	230.0	466.8	49.3%	49.1%
Domestic	184.2	379.0	48.6%	47.4%
Oncology	107.0	220.3	48.6%	47.2%
Avastin	45.3	93.4	48.5%	47.2%
HER2 Franchise	26.4	53.9	49.0%	48.0%
Herceptin	16.6	34.9	47.6%	48.3%
Perjeta	5.7	11.3	50.4%	47.2%
Kadcyla	4.2	7.6	55.3%	46.6%
Xeloda	6.1	12.6	48.4%	47.7%
Tarceva	5.6	12.5	44.8%	47.4%
Alecensa	5.2	9.6	54.2%	38.8%
Bone and Joint	41.5	85.8	48.4%	47.2%
Actemra	14.3	29.7	48.1%	47.0%
Edirol	12.4	25.6	48.4%	45.9%
Bonviva	3.6	7.7	46.8%	44.4%
Renal	19.9	40.8	48.8%	47.1%
Mircera	11.4	23.7	48.1%	46.2%
Oxarol	4.7	9.2	51.1%	46.5%
Epogin	2.5	5.3	47.2%	49.2%
Transp., Immun., Infectious	6.7	14.1	47.5%	44.7%
CellCept	3.7	8.1	45.7%	47.1%
Copegus	1.0	1.5	66.7%	20.7%
Pegasys	0.3	0.9	33.3%	68.4%
Others	9.1	18.0	50.6%	52.5%
Overseas	45.8	87.8	52.2%	56.9%
Export to Roche	37.4	70.5	53.0%	59.0%
Actemra	36.0	68.0	52.9%	59.4%
Alecensa	1.4	2.5	56.0%	-
Other overseas	8.4	17.3	48.6%	50.3%

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

vs. Forecast (Core)

## Impact from Foreign Exchange

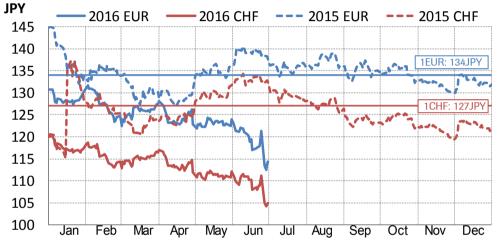


(Billions of JPY)	FX impact Jan – Jun 2016 (FX impact vs. Forecast)
	-1.3
Revenues	Sales -0.7
	Royalties and other -0.6
	operating income
Cost of sales	Cost of sales +0.8
Operating expenses	Expenses +0.9
Operating profit	+0.4

Actual / Forecast rate* (JPY)	2015 Jan - Jun Actual	2016 Jan -Dec Forecast	2016 Jan - Jun Actual
1CHF	126.88	127.00	113.81
1EUR	134.27	134.00	124.77
1USD	120.24	120.00	111.79
1SGD	89.10	87.00	80.96

## [Reference] Historical exchange rate to the JPY

Forecast rate





vs. 2015 Year End

### **Balance Sheet Items**

< Assets, Liabilities, and Net Assets >

(Billions of JPY)	2015 Dec	2016 Jun	Change
Trade accounts receivable	134.5	124.5	- 10.0
Inventories	161.1	173.5	+ 12.4
Trade accounts payable	-41.2	-37.5	+ 3.7
Other net working capital	-39.8	-16.5	+ 23.3
Net working capital	214.6	244.1	+ 29.5
Property, plant and equipment	153.5	157.6	+ 4.1
Intangible assets	13.5	16.6	+ 3.1
Other long-term assets - net	-1.3	-2.4	- 1.1
Long-term net operating assets	165.8	171.8	+ 6.0
Net operating assets	380.4	415.9	+ 35.5
Debt	-0.7	-0.7	0.0
Marketable securities	134.4	109.4	- 25.0
Cash and cash equivalents	101.7	100.1	- 1.6
Net cash	235.4	208.8	- 26.6
Other non-operating assets - net	11.5	4.7	- 6.8
Net non-operating assets	246.8	213.5	- 33.3
Total net assets	627.3	629.4	+ 2.1
Total assets	787.4	766.9	- 20.5
Total liabilities	-160.1	-137.5	+ 22.6

Other net working capital: accrued receivable, accrued payable, accrued expenses, etc
Other long-term assets - net: long term prepaid expenses, long-term provisions, etc
Other non-operating assets - net: deferred income tax assets, accrued corporate tax, etc

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+29.5

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Decrease in trade accounts receivable -10.0

Seasonal change, etc.

Increase in net working capital

Increase in inventories +12.4

Decrease in trade accounts payable +3.7

Increase in other net working capital +23.3

Decrease in accounts payable for property, plant and equipment relating to plant for bio antibody API production

●Increase in long-term net operating assets +6.0

Increase in Property, plant and equipment +4.1

Purchase of land for business in Totsuka and investment expenditure in production facilities, etc.

Decrease in net cash -26.6

●Decrease in other non-operating assets – net -6.8

● Equity ratio attributable to Chugai shareholders +2.5% pts.

2016 Jun 82.0%

2015 Dec 79.5%

FX rate to the JPY (end of period)			
	2015	2016	
	Dec	Jun	
1 CHF	121.89	104.96	
1 EUR	131.75	114.39	
1 USD	120.52	102.83	
1 SGD	85.20	76.27	

#### vs. 2015 Year End

## **Net Cash**

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	Total decrease in net	(Billions of JPY)	Operating cash flow after adjustments	+53.3
	working capital, etc.		Operating profit	+43.5
Operating	cash flow Total investment		Depreciation and amortization, etc.	+9.8
after adjus	tments		●Total increase in net working capital, etc.	-18.5
	+53.3		Decrease in trade accounts receivable	+9.7
			Increase in inventories	-13.8
	Others		Decrease in trade accounts payable	-3.5
	-11.1	Dividends <u>paid</u>	Change in other net working capital, etc.	-11.0
		Net effect of currency translation on net	●Total investment	-27.8
	-26.6	cash, etc. *1  -4.5	Investment in Property, plant and equipment	-24.2
	Operating free cash flow		Investment in plant for bio antibody APA production and purchase of land for business in Totsuka, etc.	
Net Cash	+7.0		Investment in intangible assets	-3.5
235.4		208.8	Operating free cash flow	+7.0
	1		● Others	-11.1
	Free cash flow *3 -4.2		Treasury activities (interest income/expenses, foreign exchange gains/losses, etc.)	+1.7
2015		2016	Tax paid	-12.8
2015 Dec		Jun	Free cash flow *3	-4.2

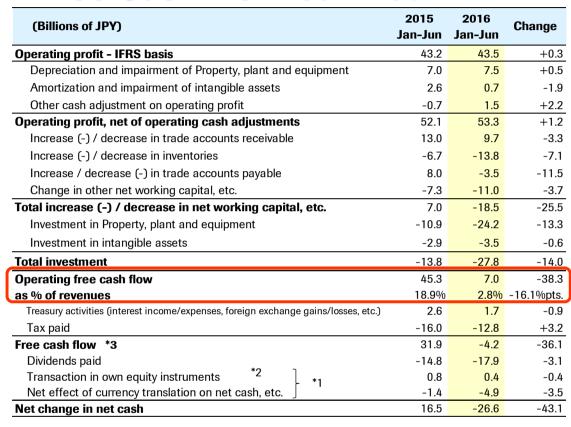
<sup>\*1</sup> Net effect of currency transactions on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash(\*2)

<sup>\*2</sup> It result from using different exchange rate types 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)

<sup>\*3</sup> Our free cash flow (FCF) was calculated by taking operating free cash flow and subtracting dividends paid out. Due to the change in the definition used by Roche, our FCF from 2Q FY2016 is the cash flow before paid dividends are subtracted from operating cash flow. This is identical with the standard definition.

#### **Year on Year**

### Free Cash Flow Jan - Jun





◆Total increase (-) / decrease in net working capital, etc.	-25.5
Increase (-) / decrease in trade accounts receivable	-3.3
Increase (-) / decrease in inventories	-7.1
Increase / decrease (-) in trade accounts payable	-11.5
Purchase timing	
Change in other net working capital, etc.	-3.7
● Total investment	-14.0
Investment in Property, plant and equipment	-13.3
Investment in plant for bio antibody production and purchase of land for business in Totsuka, etc.	
●Operating free cash flow	-38.3
● Operating free cash flow as % of revenues	-16.1% pts.
Revenues	+7.3

#### Average exchange rate (JPY)

	2015 Jan - Jun	2016 Jan - Jun
1CHF	126.88	113.81
1EUR	134.27	124.77
1USD	120.24	111.79
1SGD	89.10	80.96

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CHUGAI PHARMACEUTICAL CO., LTD.
Associate Vice President
Deputy General Manager of Research Division
Minoru Watanabe

July 21/22, 2016

## Oncology Field Projects under Development (as of 21 July, 2016)



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

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

NHL: non-Hodgkin's lymphoma HCC: hepatocellular carcinoma MPM: malignant pleural mesothelioma NSCLC: non-small cell lung cancer SCLC: small cell lung cancer MIBC: muscle invasive bladder cancer Letters in orange: in-house projects

★: Projects with advances in stages since 22 April, 2016

## Primary Field Projects under Development (as of 21 July, 2016)



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	Dhacal	Dhoon II	Dhoo III	Filed
	Phase I	Phase II	Phase III	Filed
Bone & Joint			ED-71 / Edirol (China) - osteoporosis	
Renal	EOS789 - hyperphosphatemia			
Autoimmune			MRA / Actemra - large-vessel vasculitis - giant cell arteritis (overseas) - systemic sclerosis  SA237 - neuromyelitis optica★	
CNS	RG1662 / basmisanil - improvement of intellectual ability in individuals with Down syndrome		RG1450 / gantenerumab - Alzheimer's disease	
Others	PCO371 (overseas) - 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 22 April, 2016

★: Multinational study managed by Chugai

## **Development Status**





#### RG435 / Avastin®

Cervical cancer (additional indication)
Approved in May 2016
Malignant pleural mesothelioma
Started P2 in July 2016



#### RG7446 / atezolizumab

Small cell lung cancer
Started global P3 in June 2016
Breast cancer (triple negative)
Started global P3 in May 2016

## Other Progress (1/2)





#### Marduox® Ointment

Psoriasis vulgaris (combination topical ointment)
Launched in June 2016



#### CellCept<sup>®</sup>

Lupus Nephritis (additional indication)

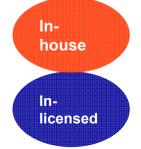
Approved in May 2016 (public knowledge-based application)



#### **ERY974**

Solid tumor

Decided to start development



### GC33 / codrituzumab RG7446 / atezolizumab

Hepatocellular carcinoma

Decided to start development in combination

## Other Progress (2/2)





#### CIM331 / nemolizumab

- Entered license agreement with Galderma S.A. in July 2016



#### **SA237 / RG6168**

- Entered license agreement with Roche in June 2016
- Designated as an orphan drug for the expected indication of neuromyelitis optica in June 2016 (EU)



Concluded a comprehensive collaboration agreement for advanced research in immunology with Osaka University Immunology Frontier Research Center (IFReC) in May 2016

## Oncology Field Data Presentation / Results of Clinical Trials





#### AF802 / Alecensa®

Detailed data of J-ALEX study (P3 in Japan) was presented at the American Society of Clinical Oncology in June 2016



#### GA101 / obinutuzumab

- Showed prolonged progression-free survival compared to Rituxan® in global P3 (GALLIUM study) for previously untreated follicular lymphoma in May 2016
- Global P3 (GOYA study) for previously untreated diffuse large B-cell lymphoma did not meet its primary endpoint in July 2016

## Primary Field Data Presentation / Results of Clinical Trials





#### MRA / Actemra®

- Efficacy of subcutaneous injection confirmed in Dose Interval Reduction study for rheumatoid arthritis patients who inadequately respond to bi-weekly dose in May 2016
- Overseas P3 study for Giant Cell Arteritis (GiACTA study) achieved primary and secondary endpoint in June 2016



#### ACE910 / emicizumab

- Phase I data in patients with hemophilia A published in The New England Journal of Medicine in May 2016
- Updated long-term P1/2 study results to be presented at the World Federation of Hemophilia in July 2016

## **ERY974 (TRAB): Mode of Action**



#### What is T-cell redirecting antibody (TRAB)?

- TRAB is a bispecific antibody intended to create a short bridge between CD3 on T cells and tumor antigen on tumor cells
- TRAB activates T cells in a tumor antigen-dependent manner and demonstrates strong cytotoxicity against tumor cells

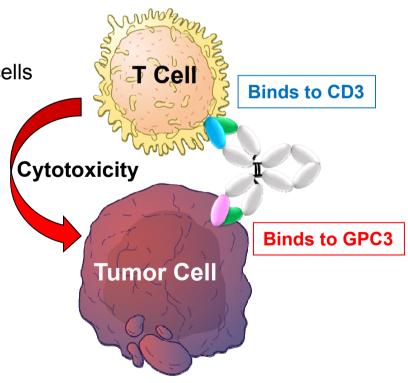
#### What is ERY974?

- Chugai's first TRAB
- Targeting glypican-3 (GPC3) expressed in tumor cells
- Expected to induce strong antitumor effects on various GPC3 positive tumors

#### What is GPC3?

 GPC3 is a heparan sulfate proteoglycan expressed in multiple types of tumor cells, such as hepatocellular carcinoma<sup>1,2)</sup>, gastric cancer, esophageal cancer<sup>3,4)</sup> and so on.

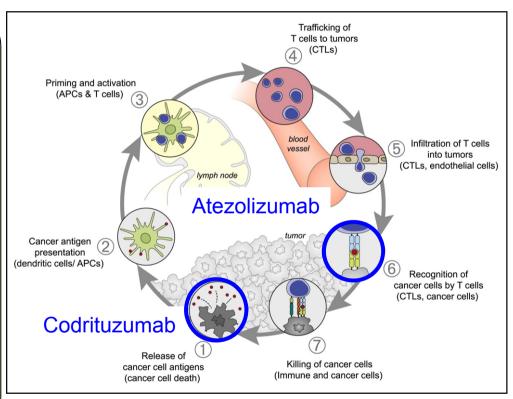
- 1) Filmus. Glycobiology. 2001;11:19R-23R5.
- 2) Yorita et al., Liver Int. 2011:31;120-131.
- 3) Ushiku et al., Cancer Sci. 2009;100:626-636.
- 4) Mounajjed et al., Human Pathology. 2013;44:542-550.



## Combination of GC33/codrituzumab (Anti-GPC3 Mab) and Atezolizumab (Anti-PDL1 MAb)



- Codrituzumab is an IgG1 type humanized monoclonal antibody against GPC3
- In the global single agent P2 study for advanced HCC conducted with Roche, codrituzumab was well tolerated but did not show clinical benefit
- As the results of retrospective analysis, high GPC3 expression in tumors or enough immune status was associated with prolonged overall survival<sup>1)</sup>
- In combination with atezolizumab, induction of acquired immunity in addition to innate immunity contribution would augment antitumor activity
  - 1) Abou-Alfa G et al., J Hepatol. 2016, in press.



(Chen DS and Mellman I, Immunity, 2013; 39: 1-10)

## Framework of IFReC-Chugai **Comprehensive Collaboration**



Comprehensive

Collaboration

**Agreement** 

~ New academia-industry alliance collaborating from the stage of autonomous basic research at IFReC ~

**IFReC** Autonomous Research

Contribution for Research fund 1 bn. yen/yr. x 10 years

- Uncontrolled Cutting-edge Immunology Research by IFReC Researchers
- Periodical Disclosure of Autonomous Research Results\* to Chugai

Disclosure of **Research Results** 

1st refusal right for Joint research

\*: Excluding ongoing collaboration projects with 3rd Parties

Joint Research

· Collaboration Lab: Interaction of Researchers, Conducting Joint Research **Specific Joint** Research Agreement

Chugai **Project** 

 Goal: A number of Creative Innovative **Projects** 

**Innovative New Drugs** 

# Projected Submissions (Post PoC NMEs and Products)



#### **Filed**

ALECENSA (AF802/RG7853) NSCLC [post-crizotinib] (EU)

obinutuzumab (GA101/RG7159) Indolent NHL emicizumab (ACE910/RG6013) Hemophilia A

SA237 Neuromyelitis Optica ACTEMRA (MRA) Systemic Sclerosis

obinutuzumab (GA101/RG7159) Aggressive NHL lebrikizumab (RG3637) Asthma PERJETA (RG1273) Gastric Cancer atezolizumab (RG7446) MIBC (adjuvant) nemolizumab (CIM331) Pruritus in Dialysis Patients

PERJETA (RG1273) Breast Cancer (adjuvant) Edirol (ED-71) Osteoporosis (China) atezolizumab (RG7446) Breast Cancer atezolizumab nemolizumab (CIM331) SCLC Atopic Dermatitis

ACTEMRA (MRA) Giant Cell Arteritis (overseas)

ALECENSA (AF802/RG7853) NSCLC[1L] (overseas) atezolizumab (RG7446) Bladder Cancer atezolizumab (RG7446) Renal Cell Carcinoma atezolizumab lebriki (RG7446) (RG36 NSCLC (adjuvant) IPF

lebrikizumab (RG3637) IPF

ACTEMRA (MRA) Large-vessel Vasculitis AVASTIN (RG435) MPM

atezolizumab (RG7446) NSCLC

AVASTIN (RG435) Renal Cell Carcinoma KADCYLA (RG3502) Breast Cancer (adjuvant)

gantenerumab (RG1450) Alzheimer's Disease

2016 2017 2018 2019-

# **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 1<sup>st</sup> round requests have been approved
- Three indications of three products from the 2<sup>nd</sup> round requests have been approved

	Product	Indication	Current Situation
2nd round requests	CellCept <sup>®</sup>	Lupus nephritis	Approved (May 13, 2016)

• Among candidates at the 3<sup>rd</sup> round, two indications of two products were requested for development

	Product	Indication	Current Situation
3rd round	Tamiful <sup>®</sup>	Addition of dosage and administration for newborn and infant	Submitted company opinion and waiting for evaluation by the committee
requests	Xeloda <sup>®</sup>	Adjuvant chemotherapy for rectal cancer	Filed (Public Knowledge–based application on March 2, 2016)

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