



CHUGAI PHARMACEUTICAL CO., LTD. President, COO Tatsuro Kosaka

January 28/29, 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



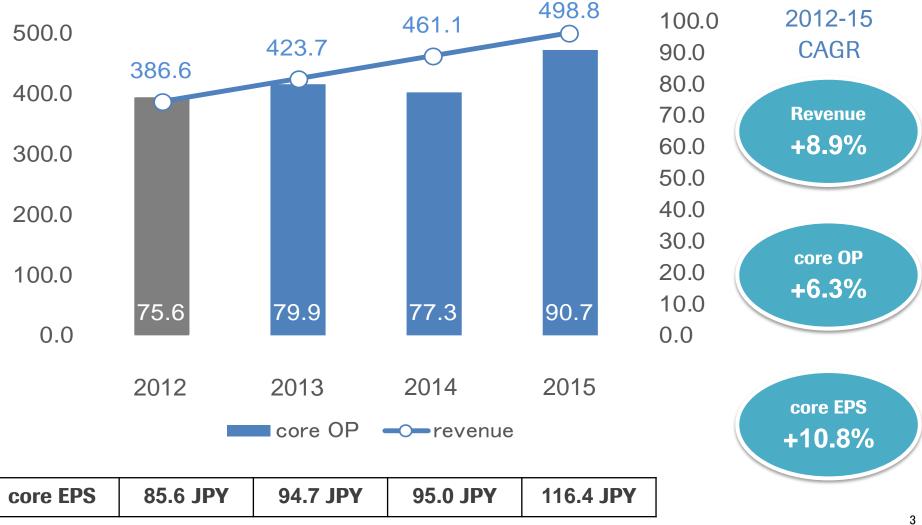
## Review of 2013 – 2015 Mid-term Business Plan "ACCEL 15"

Revenue (bn JPY)

**IBI18** Aiming to become "Top Pharmaceutical Company"

New Mid-term Business Plan "IBI 18"

### Innovation all for the patients **Business Performance during ACCEL 15** CHUGAI A member of the Roche group Core OP (bn JPY) 498.8 2012-15 100.0 CAGR 90.0 80.0 70.0 **Revenue**

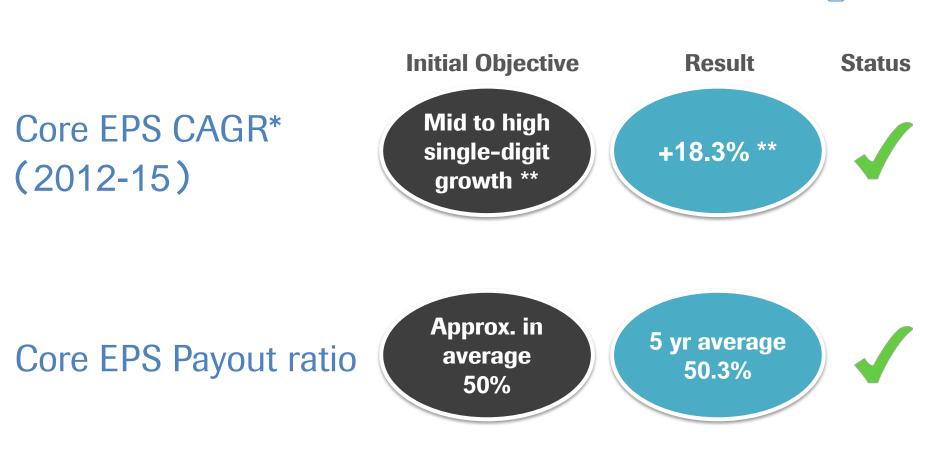


**ACCEL 15 Achievements** 

IBI18 Aiming to become "Top Pharmaceutical Company"

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI



\* CAGR: compound annual growth rate (%)

\*\* Core EPS growth rate: average constant exchange rate for 2012

IBI18 Aiming to become "Top Pharmaceutical Company"

INNOVATION BEYOND IMAGINATION

**Achievement of ACCEL 15** 

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI

Strategic Th	emes	A member of the Roche gr
Increase of marketing productivity	<ul> <li>Achieved above average market growth (Domestic, Actemra overseas)</li> <li>Domestic MR sales productivity up more than 22%, reached top-class level</li> </ul>	Status
Acceleration of global development	<ul> <li>Alecensa: out-licensed to Roche, approved in US, filed in EU</li> <li>ACE910: achieved PoC, out-licensed to Roche, P3 started</li> <li>3 breakthrough therapy designations in US</li> <li>Developing 11 original global projects</li> </ul>	
Continuous generation of innovative projects	<ul> <li>PCO371 &amp; EOS789 (P1 started), URC102 (Enter into P2)</li> <li>atezolizumab: in-licensed from Roche, P3 started</li> <li>In-licensed 15 new projects domestically and globally</li> <li>Pursuing 20 engineered antibody projects at CPR</li> </ul>	
Further strengthening of management infrastructure	<ul> <li>Established new global development scheme with Roche</li> <li>Enhancing global R&amp;D functions with expanded CPR and establishment of TCR Division, strengthening supply system for clinical trial materials</li> <li>Strengthening Medical and Drug Safety information functions</li> </ul>	

Non-Japanese staff up 49%, Women managers up 35%

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INNOVATION BEYOND IMAGINATION

New Mid-term Business Plan "IBI 18"

### **Powerful Product Portfolio and Late-stage Development Projects (as of End of 2015)**



Innovation all for the patients

	Annual sales over 20 bn JPY	New products (2013-)	PoC – to be launched (NMEs)
Oncology area	<ul> <li><u>Avastin</u> (93.8bn)</li> <li><u>Herceptin</u>* (32.7bn)</li> <li><u>Rituxan</u> (29.0bn)</li> </ul>	<ul> <li><u>Perjeta</u>*</li> <li><u>Kadcyla</u>*</li> <li>Alecensa*(Japan)</li> <li>Alecensa*(Overseas)</li> </ul>	<ul> <li><u>GA101</u></li> <li><u>atezolizumab</u></li> <li>peretinoin</li> </ul>
Non- oncology area	<ul> <li>Actemra (90.4bn)</li> <li>Mircera (23.8bn) New</li> <li>Edirol (23.1bn) New</li> </ul>	<ul> <li>Bonviva</li> <li><u>Actemra SC(Japan)</u></li> <li><u>Actemra SC(overseas)</u></li> <li>tofogliflozin (out-licensed)</li> </ul>	<ul> <li>ACE910 (emicizumab)</li> <li>SA237</li> <li>CIM331 (nemolizumab)</li> <li>gantenerumab</li> <li>lebrikizumab</li> </ul>

: increase from 2012 New : newly ranked during ACCEL 15

- Blue: Chugai originated products
- <u>underlined</u>: anti-body products
- asterisk\*: PHC products (launched)

Overview of Development Pipeline



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

2017

**Projected Submissions** (Post PoC NMEs and Products)

2018-



## **Business Environment and Vision for Growth**

## **Environment Expected Around the Pharma Industry during the Next Mid-term Plan**

[Globally]

Increasing importance of pharmaceutical drugs due to increase of global population and aging societies

**Expansion of opportunities to create innovation based on advancements in life sciences and ICT** 

Further intensified competition among various players in the speed of creating innovation

### 【Japan】



Pressure to hold down rises in drug costs due to rapid aging and financial difficulties in the social security system

Introduction of additional (huge-seller) re-pricing rule in April 2016

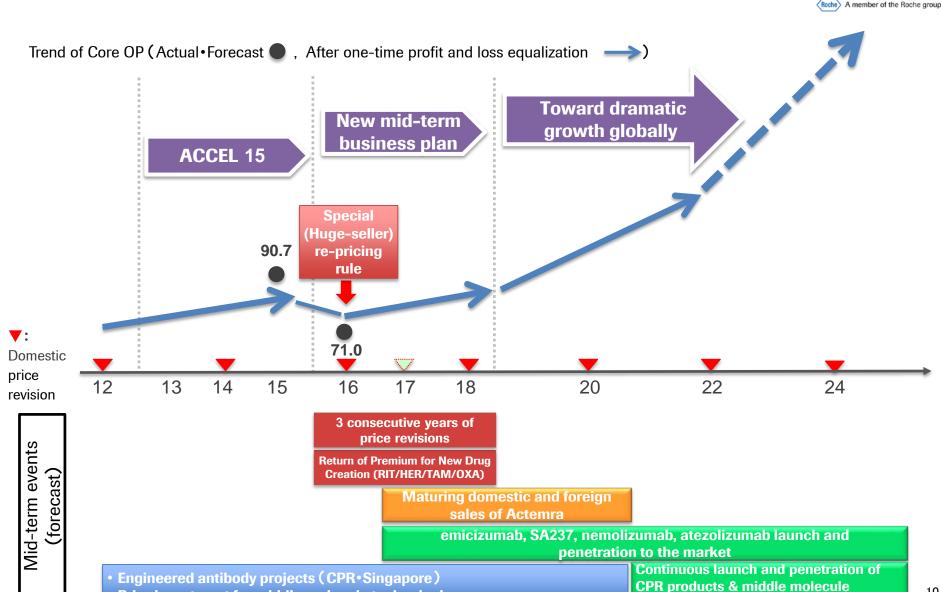


Possibility of NHI price revisions for 3 consecutive years (2016-2018) due to the hike in the consumption tax in 2017



products





Prior investment for middle molecule technologies

**Mid-term Events and Performance Trend** 

INNOVATION BEYOND IMAGINATION

#### IBI18 Aiming to become "Top Pharmaceutical Company"

New Mid-term Business Plan "IBI 18"

# Potential of Projects after PoC (Outlook as of End of 2015)



	$\star \star \star$	$\dot{\mathbf{x}}$	$\mathbf{\mathbf{x}}$
Chugai original products	• <u>emicizumab</u> • <u>nemolizumab</u>	• Alecensa	• <u>SA237</u>
In-licensed products	<ul> <li><u>atezolizumab</u></li> <li><u>GA101</u></li> <li><u>gantenerumab</u></li> </ul>	<ul> <li><u>lebrikizumab</u></li> <li>peretinoin</li> </ul>	

• <u>Underline</u>: Antibody drug



[Peak sales scale]

Chugai ] Global (local) Over 200 billion JPY [Introduction] Domestic over 20 billion JPY

[Chugai] Global (local) Over 100 billion JPY [Introduction] Domestic over 10 billion JPY

[Chugai] Global (local) Below 100 billion JPY

**Realizing the Goal of** 

**"Top Pharmaceutical Company"** 

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI

Corporate Vision Company that focuses on first-in-class/best-in-class products and services, and continuously provides new solutions to patients and medical communities around the world. — Innovation all for patients —

### Quantitative Targets (~Late 2010s)

### Gain a position among the top 3 major Japanese pharmaceutical companies

- ✓ Domestic share
- $\checkmark\,$  Consolidated operating profit rate
- ✓ Consolidated operating profit per employee
- ✓ Domestic sales per MR

### No.1 presence in strategic disease areas

- ✓ Oncology/Renal/Bone & Joint/RA: Sales share, <u>Stakeholder satisfaction</u>
- ✓ Establishment of top brand in hospital market by supporting medical liaison networks between medical professional

### **Expansion of global presence**

- ✓ Raise overseas sales ratio
- ✓ Possession of large global projects
- ✓ Possession of global products in late-stage development
- ✓ Continuous portfolio-in of FIC and BIC in-house projects

## Positioning of New Mid-term Business Plan



 Transform Chugai into a globally successful company through our competitive advantage that leverages the Strategic Alliance with Roche and through the realization of the "Top Pharmaceutical Company" goal (late 2010's)



## FY2016-18 New Mid-term Business Plan "IBI 18"

IBI18 Aiming to become "Top Pharmaceutical Company"

New Mid-term Business Plan "IBI 18"

## FY2016-2018

## **Name of New Mid-term Business Plan**





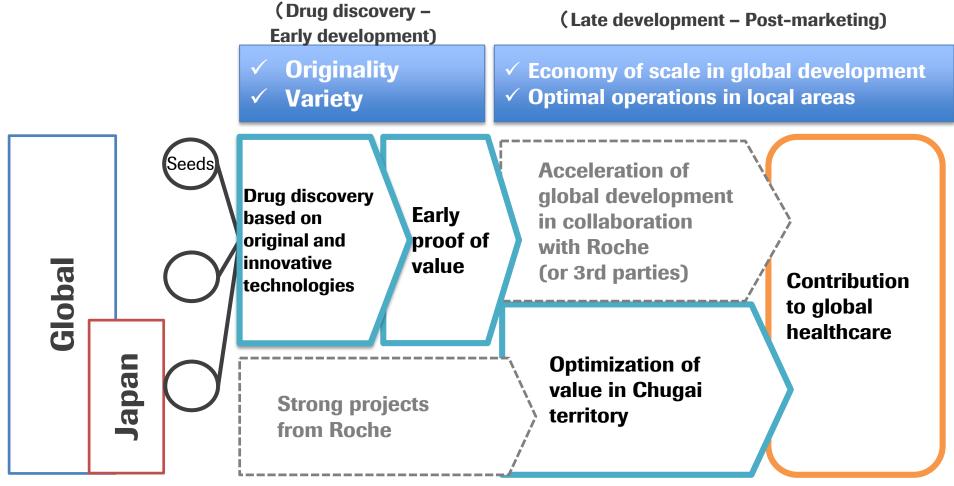
### IBI: Innovation Beyond Imagination

**Chugai Business Model** 

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI

### **KSF: From Japanese top level to global top level**



**Priority Agenda of IBI 18** 

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI

Acquisition and implementation of competitiveness at a top global level
 Selection and Concentration strategy for acceleration of growth

Drug Discovery	Development	Pharmaceutical Technology	Sales/Medical Affairs/Safety							
<ul> <li>Continuous creation of engineered antibody projects</li> <li>Establishment of drug discovery technologies for middle molecules</li> <li>Research base for oncology/immunology</li> </ul>	<ul> <li>emicizumab, atezolizumab</li> <li>Realization of early PoC with TCR</li> <li>Proof process for medical/economic value</li> </ul>	<ul> <li>Enhancement of CMC development infrastructure for early PoC acquisition</li> <li>Strengthening competitive advantages from late development to initial commercial production</li> <li>QA, QC and Regulatory functions</li> </ul>	<ul> <li>Growth driver products, emicizumab, atezolizumab</li> <li>Providing advanced solutions through a cross-functional system</li> <li>Establishment of system adapted to local characteristics</li> </ul>							
Acquisition, development and assignment of global top-class talents to lead value creation										

### Whole Company

Acquisition, development and assignment of global top-class talents to lead value creation activities through innovation

Expansion of achievements through selection and concentration utilizing competitive advantage

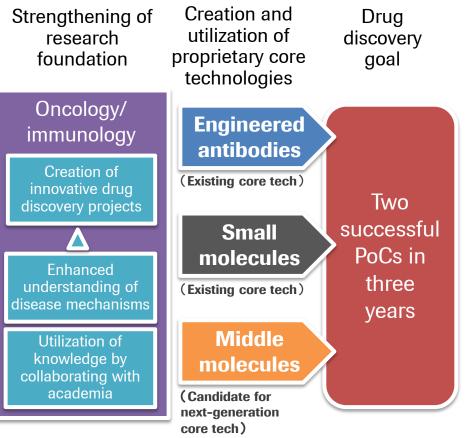


Strengthening competitive foundation for global top-class level

## **Priority Agenda** ①: **Drug Discovery**



## Continuous creation of FIC, BIC projects utilizing innovative technologies



\* FIC,BIC: First in Class, Best in Class

\*\* UMN: Unmet Medical Needs

### Continuous creation of engineered antibody

### projects

- Accelerate research projects created at CPR through prioritized investments
- Establish innovative technologies following SMART

## Establishment of drug discovery technologies for middle molecules

- Focus on cyclic peptide etc. as candidates for nextgeneration technologies
- Fulfill UMN that cannot be solved with small molecules and antibodies

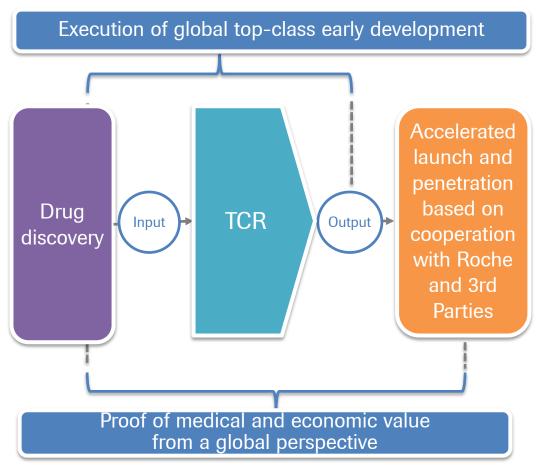
### <u>Strengthening of research foundation for</u> <u>oncology and immunology</u>

- Acquire innovative seeds by collaborating with academia
- Strengthen biomarker discovery and utilize molecular information by cooperating with Roche

## Priority Agenda 2: Development



### **Promotion of faster launch and quick market penetration based on global top-class TCR\* and development activities**



Acceleration of emicizumab and atezolizumab development as a top priority

• Prioritize resources for executing the clinical development plan and promoting the medical plan

### Realization of early PoC through TCR

- Execute with global top-class quality and speed in Japan, US, and Europe
- Focus resources on early development to acquire PoC

Strengthening process to create medical and economic value proposition

- Develop and promote IDCP\*\* which aims to maximize the product value in the market
- Accelerate late-stage development through the realization of smooth out-licensing to Roche or third parties
- Further enhance speed and efficiency in development in Japan

\*\* IDCP: Integrated Development and Commercialization Plan

<sup>\*</sup> TCR: Translational Clinical Research

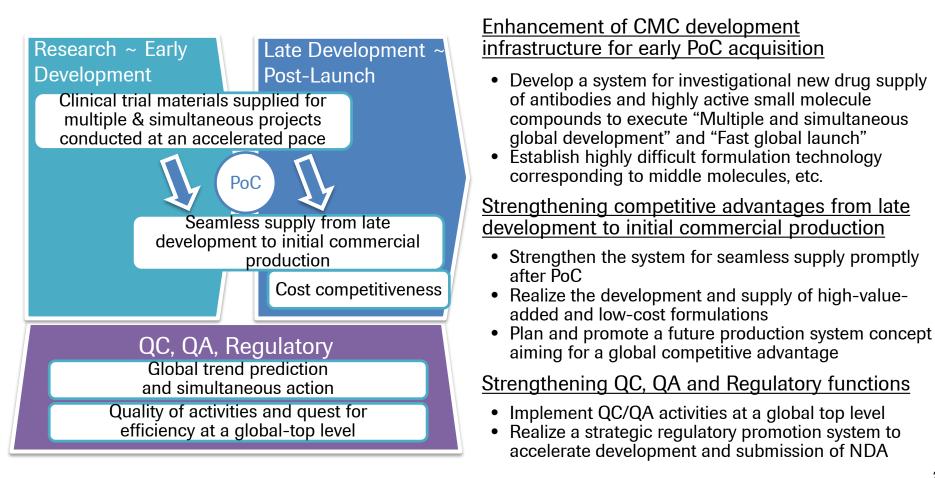
**Priority Agenda ③**:

**Pharmaceutical Technology** 

New Mid-term Business Plan "IBI 18"

## Innovation all for the patients CHUGAI

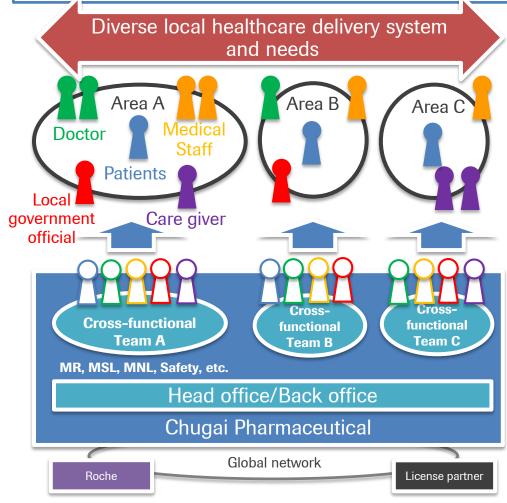
Strengthening of PT system for "Multiple and simultaneous global development," "Fast global launch," and "Cost reductions"



## Priority Agenda **4**: Sales/Medical Affairs/Safety



Provision of advanced and diverse solutions through both independent roles and cross-functional cooperation



### Realization of sales growth by concentrating on sales drivers (Avastin and Actemra etc.) & emicizumab, atelolizumab

• Focus on growth products and promising new products

### Delivery of advanced solutions through cross-functional teams

- Resolve medical issues through the cooperation of experts by breaking divisional silos
- Provide highly specialized information in specialty care and assistance for healthcare network

### Establishment of system adapted to local <u>characteristics</u>

- Organize cross-functional teams and formulate/implement strategies adapted to local characteristics and needs
- Support from head office, back office and global network

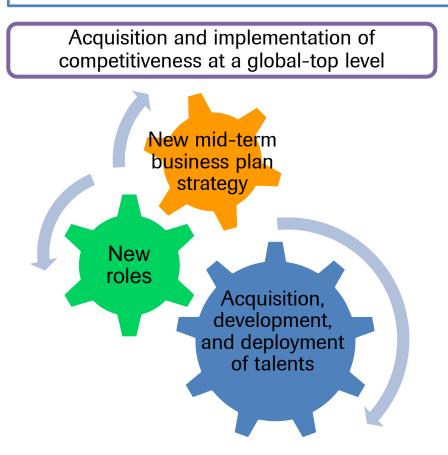
**Priority Agenda** (5):

**Global Top-level Talent** 

New Mid-term Business Plan "IBI 18"



Accelerate acquisition, development, and assignment of talents who are key for creating innovation and responding to environmental changes



Selection of critical positions to accelerate innovation

- Identify critical positions/roles in creating innovation and responding to environmental changes at a global-top level, and establish their talent profiles
- Review positions and roles in conjunction with PDCA cycle of strategy

<u>Planned and speedy acquisition, development,</u> <u>and deployment of human resources with "the</u> <u>right position filled by the right person"</u>

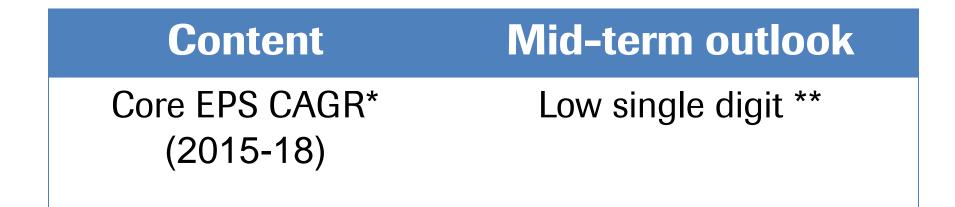
- Select candidates for important positions and early development into global top level talents through tough assignments, etc.
- Make timely appointments from both internal and external talent pools with "the right position filled by the right person"

IBI18 Aiming to become "Top Pharmaceutical Company"

New Mid-term Business Plan "IBI 18"

## **IBI 18 Quantitative Outlook**





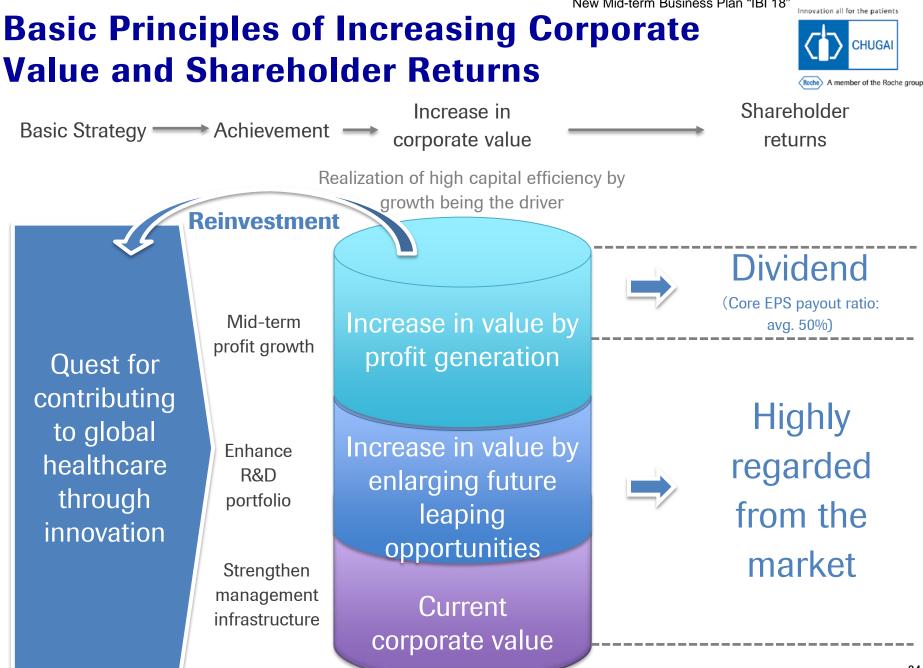
\* CAGR: compound annual growth rate (%)

\*\* Core EPS growth rate: constant average exchange rate for 2015, ~3% growth range

INNOVATION BEYOND IMAGINATION

Aiming to become "Top Pharmaceutical Company" **IBI18** 

New Mid-term Business Plan "IBI 18"







## **FY2015 Consolidated Financial Overview** (**IFRS based**)

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

January 28/29, 2016

FY2015 Consolidated Financial Overview

## **Full Year Results Summary**

INNOVATION BEYOND IMAGINATION



- Revenues: 498.8 billion yen (+37.7, +8.2% YoY)
- Domestic sales excl. Tamiflu: increase due to steady growth of new products and mainstay products (+28.5, +8.2%)
- Overseas sales: increase due to growth in Actemra export driven by both yen depreciation and volume expansion (+7.9, +10.6%)
- Royalties and other operating income: increase due to milestone income, etc. (+6.2, +25.6%)
- Cost of sales / Operating expenses (Core basis)
- Cost of sales: the ratio to sales worsened due primarily to yen depreciation (+1.3% points, from 49.7% to 51.0%)
- Operating expenses: slight increase due to yen depreciation and increased research and development activity, etc. (+2.5, +1.5%)

### Profits

 IFRS results: operating profit 86.8 billion yen (+10.9, +14.4%) net income 62.4 billion yen (+10.3, +19.8%)

 Core results: operating profit
 90.7 billion yen (+13.4, +17.3%)

 net income
 64.9 billion yen (+11.9, +22.5%)

 EPS
 116.42 yen (+21.38, +22.5%)

FY2015 Consolidated Financial Overview

#### INNOVATION BEYOND IMAGINATION

<b>IFRS</b>	and	Core	<b>Results</b>	Jan –	Dec
		0010	noodno	- an	



	IFRS results	Non-core	items	Core results					
(Billions of JPY)	2015	Intangible	Others	2015	(Billions of JPY)				
	Jan - Dec	assets		Jan - Dec	Non-Core items				
Revenues	498.8			498.8	1. Intangible assets				
Sales	468.4			468.4	Amortization +1.6 Impairment +1.9				
Royalties and other operating income	30.4			30.4	2. Others				
Cost of sales	-240.2	+1.4		-238.9	Environmental costs +0.5				
Gross profit	258.6	+1.4		260.0					
Operating expenses	-171.8	+2.1	+0.5	-169.3	Core net income				
Marketing and distribution	-74.8	+0.2		-74.7	attributable to Chugai shareholders 63.7 (A)				
Research and development	-83.8	+1.9		-81.9					
General and administration	-13.2		+0.5	-12.8	(Millions of shares)				
Operating profit	86.8	+3.5	+0.5	90.7	Weighted average number				
Financing costs	-0.1			-0.1	of shares and equity				
Other financial income (expense)	0.6			0.6	securities in issue used to calculate diluted earnings				
Profit before taxes	87.3	+3.5	+0.5	91.2	per share				
Income taxes	-24.9	-1.2	-0.2	-26.3	547 ®				
Net income	62.4	+2.2	+0.3	64.9					
Chugai shareholders	61.1	+2.2	+0.3	63.7	(JPY)				
Non-controlling interests	1.2			1.2	Core EPS 116.42				

#### IBI18 Aiming to become "Top Pharmaceutical Company"

FY2015 Consolidated Financial Overview

### Year on Year (Core)

## **Financial Overview** Jan – Dec



(Billions of JPY)

Innovation all for the patients

(Billions of JPY)	2014 Jan - E		201 Jan - E		Growth			
		Revenues		Revenues				
Revenues	461.1		498.8		+37.7	+8.2%		
Sales	436.9		468.4		+31.5	+7.2%		
excl. Tamiflu	423.8		460.2		+36.4	+8.6%		
Domestic	349.5		378.0		+28.5	+8.2%		
Export to Roche	55.1		63.1		+8.0	+14.5%		
Other overseas	19.3		19.1		-0.2	-1.0%		
Tamiflu	13.0		8.2		-4.8	-36.9%		
Ordinary	12.9		8.2		-4.7	-36.4%		
Govt. stockpiles etc.	0.2		0.0		-0.2	-100.0%		
Royalties and other operating income	24.2		30.4		+6.2	+25.6%		
Cost of sales	-217.0	47.1%	-238.9	<mark>47.9%</mark>	-21.9	+10.1%		
Gross profit	244.2	53.0%	260.0	<b>52.1%</b>	+15.8	+6.5%		
Operating expenses	-166.8	36.2%	-169.3	<mark>33.9%</mark>	-2.5	+1.5%		
Operating profit	77.3	16.8%	90.7	<b>18.2%</b>	+13.4	+17.3%		
Financing costs	-0.0		-0.1		-0.1	-		
Other financial income (expense)	0.3		0.6		+0.3	+100.0%		
Income taxes	-24.6		-26.3		-1.7	+6.9%		
Net income	53.0	11.5%	64.9	<b>13.0%</b>	+11.9	+22.5%		
EPS (JPY)	95.04		116.42		+21.38	+22.5%		

Royalties and other operating income Increase in milestone income, etc.	+6.2
Other financial income (expense)	+0.3
Exchange gains/losses	+0.1
Gains/Losses on derivatives	+0.4
(Gains/Losses on foreign exchange forward contracts)	

### Cost of sales ratio vs. Sales

2014	2015
Jan – Dec	Jan – Dec
49.7%	51.0%

#### Average exchange rate (JPY)

	2014 Jan – Dec	2015 Jan - Dec
1CHF	115.69	125.74
1EUR	140.49	134.36
1USD	105.84	121.03
1SGD	83.54	88.07

INNOVATION BEYOND IMAGINATION

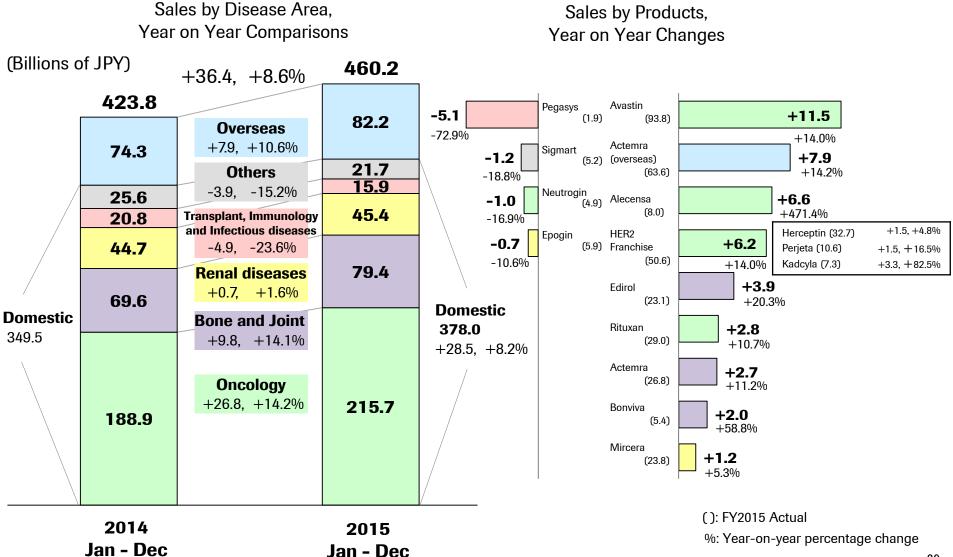
IBI18 Aiming to become "Top Pharmaceutical Company"

FY2015 Consolidated Financial Overview

**Year on Year** 

## Sales (excl. Tamiflu) Jan – Dec





**Tamiflu Sales Performance** 

FY2015 Consolidated Financial Overview

## 

Roche A member of the Roche group

		Fiscal Term Sales															
(Bill	ions of JPY)	FY20	FY2009.12 FY2010.12 FY2011.12 FY2012.12 FY2013.12 FY2014.12 FY20			)15.12	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	
	2008-09	11.0														16.7	
	2009-10		25.2	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	
	2013-14										1.9	7.0				9.0	
	2014-15												5.8	6.7		12.6	
	2015-16														1.5	-	
(	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)	8.2	(-4.7)		
	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														0.0	-	
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	1.5		
	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)	8.2	(-4.8)		

() Year on year

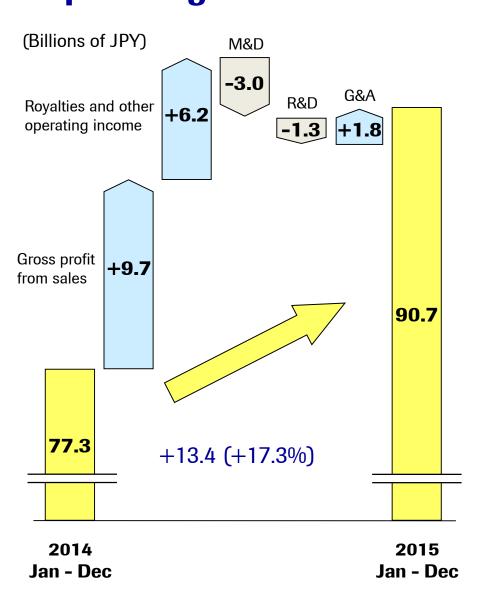
Year on Year (Core)

FY2015 Consolidated Financial Overview

Innovation all for the patients

## **Operating Profit** Jan – Dec





(Billions of JPY)		2014 Jan - Dec	2015 Jan - Dec	Growth			
Revenue	S	461.1	498.8	+37.7			
Cost of	sales	-217.0	-238.9	-21.9			
Gross pro	ofit	244.2	260.0	+15.8			
of which	Sales	219.9	229.6	+9.7			
	Royalties, etc.	24.2	30.4	+6.2			
Marketing and distribution		-71.7	-74.7	-3.0			
Research and development		-80.6	-81.9	-1.3			
General and administration		-14.6	-12.8	+1.8			
Operatin	g profit	77.3	90.7	+13.4			
Increase in	gross profit from sa	ales		+9.7			
Steady g	rowth of new produ	cts and mainst	ay products				
Increase in	Increase in royalties and other operating income +6.						
Increase in	Marketing and dist	ribution	-3.0 (-0.6)				
Increase in various expenses related to sales activity, etc.							
Increase in research and development -1.3							
Increased activity in research and development with the advance of projects, negative foreign exchange impact, etc.							
Decrease in general and administration +1.8 (+1							
One-time increase in the previous year due to cost of building demolition, etc.							

(): Changes excluding the impact of donation reclassification 31

### IBI18 Aiming to become "Top Pharmaceutical Company"

FY2015 Consolidated Financial Overview

### Year on Year (Core)

## **Financial Overview** Oct – Dec



	2014		201				
(Billions of JPY)	Oct - Dec		Oct - Dec		Growth		
	vs. Revenues		vs. Revenues				
Revenues	127.7		131.1		+3.4	+2.7%	
Sales	121.7		115.2		-6.5	-5.3%	
excl. Tamiflu	115.9		113.7		-2.2	-1.9%	
Domestic	95.3		102.6		+7.3	+7.7%	
Export to Roche	15.6		6.7		-8.9	-57.1%	
Other overseas	5.0		4.4		-0.6	-12.0%	
Tamiflu	5.8		1.5		-4.3	-74.1%	
Ordinary	5.8		1.5		-4.3	-74.1%	
Govt. stockpiles etc.	0.0		0.0		0.0	0.0%	
Royalties and other	5.9		15.9		+10.0	+169.5%	
operating income	5.9		10.9		+10.0	+109.5%	
Cost of sales	-60.5	47.4%	-61.2	46.7%	-0.7	+1.2%	
Gross profit	67.2	52.6%	69.9	53.3%	+2.7	+4.0%	
Operating expenses	-50.0	39.2%	-49.5	37.8%	+0.5	-1.0%	
Operating profit	17.2	13.5%	20.4	15.6%	+3.2	+18.6%	
Financing costs	0.0		-0.0		0.0	-	
Other financial income (expense)	0.0		0.2		+0.2	-	
Income taxes	-5.4		-6.3		-0.9	+16.7%	
Net income	11.8	9.2%	14.2	10.8%	+2.4	+20.3%	
EPS (JPY)	21.19		25.42		+4.23	+20.0%	

(Billio	ns of JPY)
Decrease in gross profit from sales	-7.3
Decrease in export to Roche and Tamiflu sa	ales
Increase in royalties and other operating income	+10.0
Increase in milestone income, etc.	
Decrease in operating expenses	+0.5
Increase in marketing and distribution	-2.6 (-0.5)
Decrease in research and development	+2.0 (+0.4)
Increase in compensation received under co-development agreements, etc.	r
Decrease in general and administration	+1.1(+0.6)
Decrease in various expenses such as pur relations, etc.	ıblic
(): Changes excluding the impact of donation r	eclassification

Cost of sales	ratio vs.	Sales
---------------	-----------	-------

2014	2015
Oct - Dec	Oct – Dec
49.7%	53.1%

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FY2015 Consolidated Financial Overview

vs. Forecast (Core)

### **Financial Overview** Jan – Dec



2015 Jan - Dec						
(Billions of JPY)	Forecast	Actual	+/-	Achievement		
Revenues	486.5	498.8	+12.3	102.5%		
Sales	460.8	468.4	+7.6	101.6%	-	
excl. Tamiflu	453.4	460.2	+6.8	101.5%		
Domestic	360.9	378.0	+17.1	104.7%		
Export to Roche	74.9	63.1	-11.8	84.2%	(	
Other overseas *	17.6	19.1	+1.5	108.5%		
Tamiflu	7.4	8.2	+0.8	110.8%		
Royalties and other operating income	25.6	30.4	+4.8	118.8%		
Cost of sales	-230.2	-238.9	-8.7	103.8%	•	
Gross profit	256.3	260.0	+3.7	101.4%	-	
Operating expenses	-171.3	-169.3	+2.0	98.8%	-	
Operating profit	85.0	90.7	+5.7	106.7%	•	
EPS (JPY)	104.42	116.42	+12.0	111.5%	:	

Cost of sales ratio vs. Sales

2015	2015		
Jan – Dec	Jan – Dec		
Forecast	Actual		
50.0%	51.0%		

#### Exchange rate (JPY)

	2015	2015
	Jan – Dec	Jan – Dec
	Forecast	Actual *
1CHF	116.00	125.74
1EUR	142.00	134.36
1USD	119.00	121.03
1SGD	91.00	88.07

\* Including Alecensa (Forecast 2015 Jan - Dec: 0.2 billion yen, Actual 2015 Jan - Dec: 0.5 billion yen)

\* Average exchange rate for the period of Jan – Dec.

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FY2015 Consolidated Financial Overview

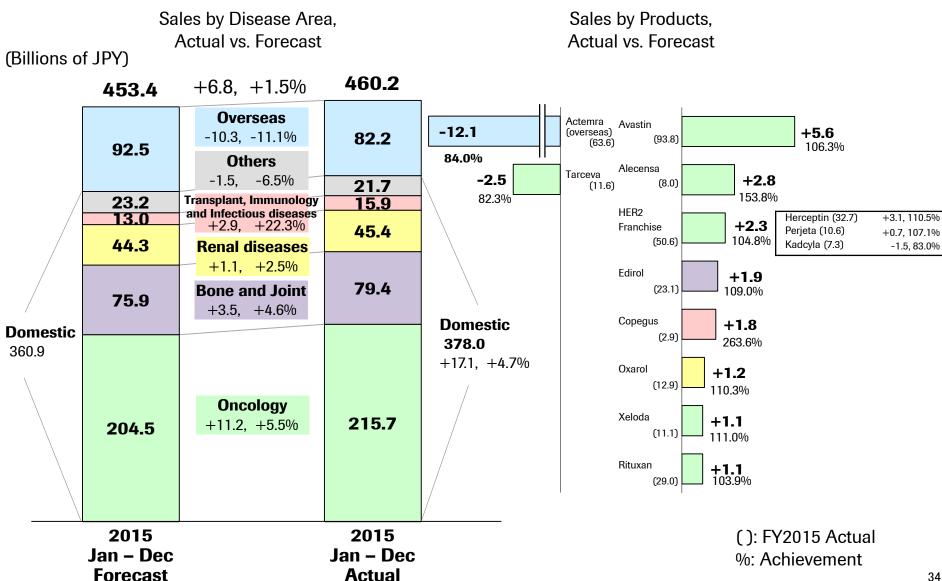
vs. Forecast (Core)

INNOVATION BEYOND IMAGINATION

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



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vs. Forecast (Core)

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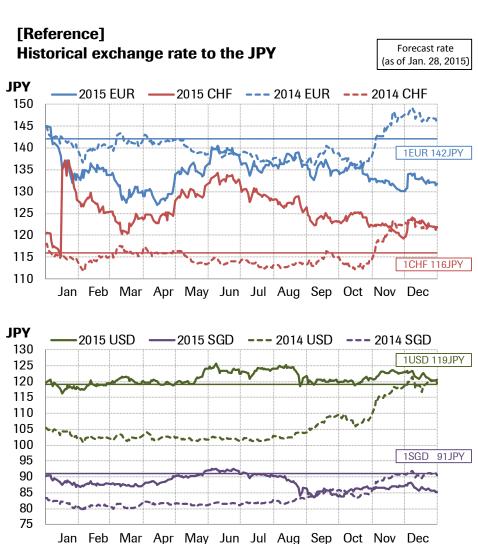
Innovation all for the patients
CHUGAI

(Billions of JI	PY)	2015 Jan - Dec (FX impact vs. forecast rate)			
Revenues		+4.0			
		Sales		+3.6	
		Royaltie income	erating +0.3		
Cost of sales Operating expenses		Cost of sales -5.4 Operating Expenses -0.0			
Operating profit					
		-1.5			
Actual / Forecast rate * (JPY)	Jai	2014 n - Dec Actual	2015 Jan -Dec Forecast	2015 Jan - Dec Actual	
1CHF	1	15 69	116.00	125 74	

**Impact from Foreign Exchange** 

Actual / Forecast rate * (JPY)	Jan - Dec Actual	Jan -Dec Forecast	Jan - Dec Actual
1CHF	115.69	116.00	125.74
1EUR	140.49	142.00	134.36
1USD	105.84	119.00	121.03
1SGD	83.54	91.00	88.07

\* Actual: average exchange rate for the period of Jan – Dec.



#### Worviow

**Balance Sheet Items** 

< Assets, Liabilities, and Net Assets >

vs. 2014 Year End

IBI18 Aiming to become "Top Pharmaceutical Company"

FY2015 Consolidated Financial Overview



(Billions of JPY)

(Billions of JPY)	2014	2015	Change	In E
	Dec	Dec	Ũ	
Trade accounts receivable	141.3	134.5	- 6.8	I
Inventories	139.6	161.1	+ 21.5	
Trade accounts payable	-35.4	-41.2	- 5.8	h
Other net working capital *1	-36.2	-39.8	- 3.6	
Net working capital	209.4	<mark>214.6</mark>	+ 5.2	C
Property, plant and equipment	140.2	153.5	+ 13.3	L
Intangible assets	11.3	13.5	+ 2.2	
Other long-term assets - net *2	-3.2	-1.3	+ 1.9	Ind
Long-term net operating assets	148.4	165.8	+ 17.4	
Net operating assets	357.7	<u>380.4</u>	+ 22.7	
				Inc
Debt	-0.2	-0.7	- 0.5	Ind
Marketable securities	116.0	134.4	+ 18.4	Eq
Cash and cash equivalents	114.0	101.7	- 12.3	
Net cash	229.9	235.4	+ 5.5	
Other non-operating assets - net $*_3$	10.2	11.5	+ 1.3	
Net non-operating assets	240.0	246.8	+ 6.8	
Total net assets	597.8	627.3	+ 29.5	

\*1 Accrued receivable, accrued payable, accrued expenses, etc.

\*2 Long-term prepaid expenses, long-term provisions, etc.

\*3 Deferred income tax assets, accrued corporate tax, etc.

	Increase in net working capital	+5.2
ge	Decrease in trade accounts receivable	-6.8
- 6.8	Increase in inventories	+21.5
· 21.5	Negative foreign exchange impact and timing of p	urchase, etc.
- 5.8	Increase in trade accounts payable	-5.8
- 3.6	Timing of purchase, etc.	
+ 5.2	Decrease in other net working capital	-3.6
13.3	Increase in accrued payable for property, plant and	d equipment, etc.
+ 2.2	Increase in long-term net operating assets	+17.4
+ 1.9	Increase in property, plant and equipment	+13.3
- 17.4		
- 22.7	Investment related to antibody API manufacturi	ng plant
	Increase in net cash	+5.5
- 0.5	Increase in other non-operating assets - net	+1.3
18.4	Equity ratio attributable to Chugai shareholders	-1.1% pts.
- 12.3	2015 Dec	79.5%
+ 5.5	2014 Dec	80.6%
		00.070

#### FX rate to the JPY (end of period)

	2014 Dec	2015 Dec
1CHF	120.81	121.89
1EUR	145.26	131.75
1USD	119.48	120.52
1SGD	90.41	85.20

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vs. 2014 Year End

#### IBI18 Aiming to become "Top Pharmaceutical Company"

FY2015 Consolidated Financial Overview



Net Cash	Total increase in net working capital, etc.		Roche P	CHUGAI
Operating cash flow after adjustments	-15.9 Total investment -24.8 Others	(Billions of JPY)	<ul> <li>Operating cash flow after adjustments</li> <li>Operating profit</li> <li>Depreciation and amortization, etc.</li> <li>Total increase in net working capital, etc.</li> </ul>	
+105.4	-57.0	Net effect of currency translation on net cash, etc *1, 2 -2.1	Decrease in trade accounts receivable	-15.9 +6.7 -23.3 +5.9 -5.2
Operatin +64. Free cash +7.6	h flow	<b>235.4</b>	Total investment Expenses for the acquisition of property, plant and equipment Payments for investment in production facilities, etc. Expenses for the acquisition of intangible assets	-24.8 -18.4 -6.5
229.9	+5.5		Operating free cash flow Others Tax paid	+64.6 -57.0 -29.1
2014 Dec	rrency translation on net cash. etc.: Transaction	2015 Dec	Dividends paid Free cash flow	-29.4 +7.6

\*1 Net effect of currency translation on net cash, etc.: Transaction in own equity instruments + Net effect of currency translation on net cash

\*2 Net effect on currency translation is a result of using different types of exchange rates 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). Year on Year

FY2015 Consolidated Financial Overview

Innovation all for the patients CHUGAI

(Billions of JPY)

(Billions of JPY)	2014 Jan-Dec	2015 Jan-Dec	Change	
Operating profit - IFRS basis	75.9	86.8	+10.9	0
Depreciation and impairment of Property, plant and equipment	15.5	14.2	-1.3	Т
Amortization and impairment of intangible assets	1.4	3.5	+2.1	
Other cash adjustment on operating profit	3.7	1.0	-2.7	
Operating profit, net of operating cash adjustments	96.4	105.4	+9.0	
Increase (-) / decrease in trade accounts receivable	-30.2	6.7	+36.9	
Increase (-) / decrease in inventories	-12.2	-23.3	-11.1	
Increase / decrease (-) in trade accounts payable	-0.6	5.9	+6.5	
Change in other net working capital, etc.	9.7	-5.2	-14.9	
Total increase (-) / decrease in net working capital, etc.	-33.3	-15.9	+17.4	
Investment in Property, plant and equipment	-16.2	-18.4	-2.2	Т
Investment in intangible assets	-2.9	-6.5	-3.6	_
Total investment	-19.2	-24.8	-5.6	0
Operating free cash flow	43.9	64.6	+20.7	
as % of revenues	9.5%	13.0%	+3.5%pts.	J
Treasury activities (interest income/expenses, foreign exchange gains/losses, etc.)	0.3	1.6	+1.3	
Tax paid	-25.2	-29.1	-3.9	
Dividends paid	-25.5	-29.4	-3.9	С
Free cash flow	-6.5	7.6	+14.1	
Transaction in own equity instruments	1.2	1.4	+0.2	
Net effect of currency translation on net cash, etc.*2 *1	0.7	-3.5	-4.2	
Net change in net cash	-4.5	5.5	+10.0	

**Free Cash Flow Jan - Dec** 

Operating profit, net of operating cash adjustmen	ts +9.0
Total increase (-) / decrease in net working capit	tal, etc. +17.4
Increase (-) / decrease in trade accounts receive	able +36.9
Impact of advance payments received at the end fiscal year, etc.	nd of previous
Increase (-) / decrease in inventories	-11.1
Increase / decrease (-) in trade accounts payab	le +6.5
Change in other net working capital, etc.	-14.9
Total investment	-5.6
Operating free cash flow	+20.7
Special factors in 2014 fiscal year, such as pay accounts receivable partly made in advance in impact on changes in operating free cash flow compared to the previous year	2013 Dec., had an
Operating free cash flow as % of revenues	+3.5% pts.
Revenues	+20.7

#### Average exchange rate (JPY)

	2014 Jan – Dec	2015 Jan - Dec
1CHF	115.69	125.74
1EUR	140.49	134.36
1USD	105.84	121.03
1SGD	83.54	88.07

\*1 Net effect of currency translation on net cash, etc.: Transaction in own equity instruments + Net effect of currency translation on net cash

\*2 Net effect on currency translation is a result of using different types of exchange rates 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).

FY2015 Consolidated Financial Overview

2016 Forecast (Core)

### Forecast 2016 Jan – Dec



	Actua	al	Foreca	ist	0	41.
(Billions of JPY)	2015 Jan	- Dec	2016 Jan	- Dec	Grow	'n
	VS	. Revenues	VS	. Revenues		
Revenues	498.8		495.0		-3.8	-0.8%
Sales	468.4		475.4		+7.0	+1.5%
excl. Tamiflu	460.2		466.8		+6.6	+1.4%
Domestic	378.0		379.0		+1.0	+0.3%
Export to Roche	63.1		70.5		+7.4	+11.7%
Other overseas	19.1		17.3		-1.8	-9.4%
Tamiflu	8.2		8.6		+0.4	+4.9%
Ordinary	8.2		7.6		-0.6	-7.3%
Govt. stockpiles etc.	0.0		1.0		+1.0	-
Royalties and other operating income	30.4		19.6		-10.8	-35.5%
Cost of Sales	-238.9		-254.0		-15.1	+6.3%
Gross Profit	260.0	52.1%	241.0	<b>48.7</b> %	-19.0	-7.3%
Operating Expenses	-169.3	33.9%	-170.0	34.3%	-0.7	+0.4%
<b>Operating Profit</b>	90.7	18.2%	71.0	<mark>14.3%</mark>	-19.7	-21.7%
EPS (JPY)	116.42		92.54		-23.88	-20.5%

Cost of sales ratio vs. Sales

2015	2016
Jan – Dec	Jan – Dec
51.0%	53.4%

Exchange rate (JPY)			
	2015	2016	
	Jan – Dec	Jan – Dec	
	Actual *	Forecast	
1CHF	125.74	127.00	
1EUR	134.36	134.00	
1USD	121.03	120.00	
1SGD	88.07	87.00	

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

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FY2015 Consolidated Financial Overview

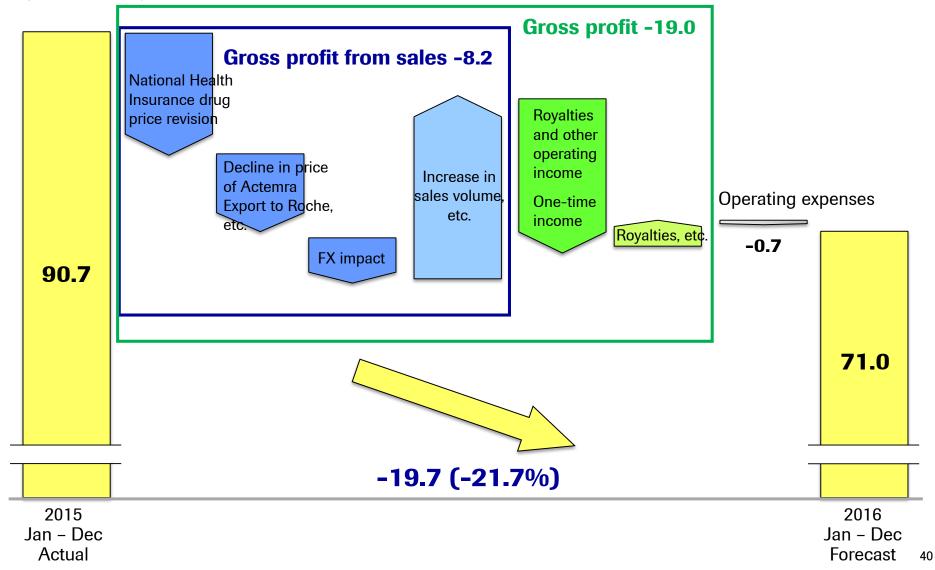
2016 Forecast (Core)

### **Operating Profit 2016 Jan – Dec**

Innovation all for the patients



(Billions of JPY)



INNOVATION BEYOND IMAGINATION

FY2015 Consolidated Financial Overview

## **Foreign Exchange Impact on Cost of Sales**

Note: Figure and numbers below are for illustrative purposes



Innovation all for the patients

Cost of sales depends on FX Cost of sales will be fixed Cost of sales for the year rate at the time of purchase even if FX rate change is enclosed by red without hedging exchange risks when hedging exchange risks frames below Inventory Inventory Inventory carried purchased in purchased in 2015 FX rate over from current year current year previous vear **127 JPY/CHF PPV** \* Increase due to Increase due to FX **PPV** impact of change rate differences 11 **JPY 11 JPY** in **FX rate** during between previous the **current** year and current year Inventory carried over from 2014 FX rate previous year **116 JPY/CHF** Standard Cost 127 **PY PPV** Increase due to FX rate differences **10 JPY** Standard between previous Standard and current year Cost Cost 2013 FX rate 116 JPY 116 **JPY 106 JPY/CHF** Standard Cost 106 JPY

\* Purchase Price Variance

INNOVATION BEYOND IMAGINATION

**IBI18** Aiming to become "Top Pharmaceutical Company"

Innovation all for the patients

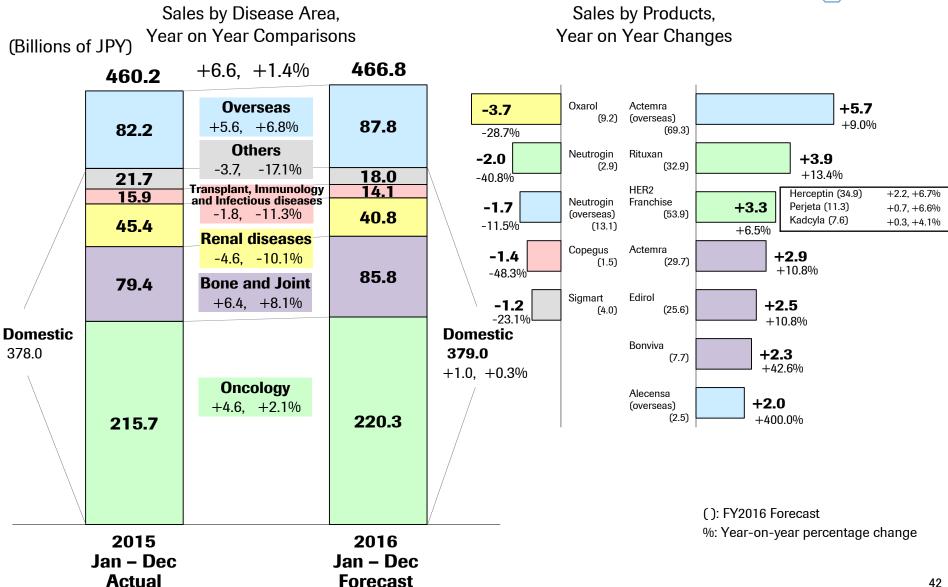
**CHUGAI** 

A member of the Roche group

FY2015 Consolidated Financial Overview

2016 Forecast (Core)

### Sales (excl. Tamiflu) Forecast vs. 2015 Actual



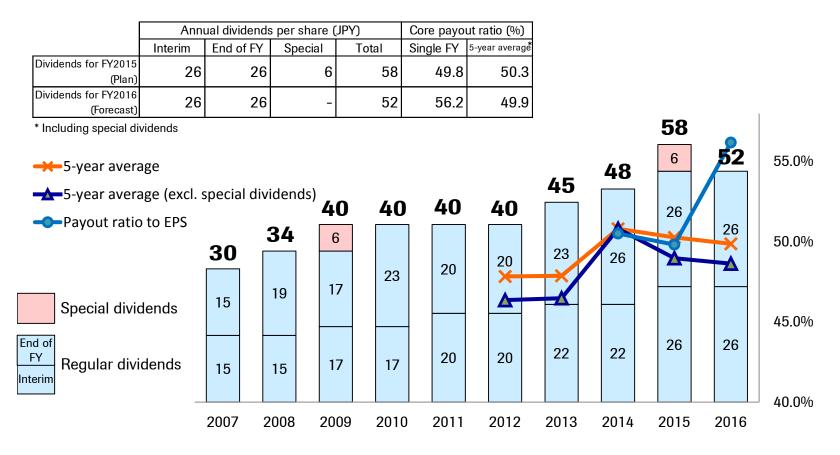
**Dividend Policy** 

FY2015 Consolidated Financial Overview

## Innovation all for the patients CHUGAI

### ➢Policy

Aiming to ensure stable profit for all shareholders and a consolidated dividend payout ratio of 50% on average to Core EPS, taking account of strategic funding needs and earnings prospects.



**Objective** 

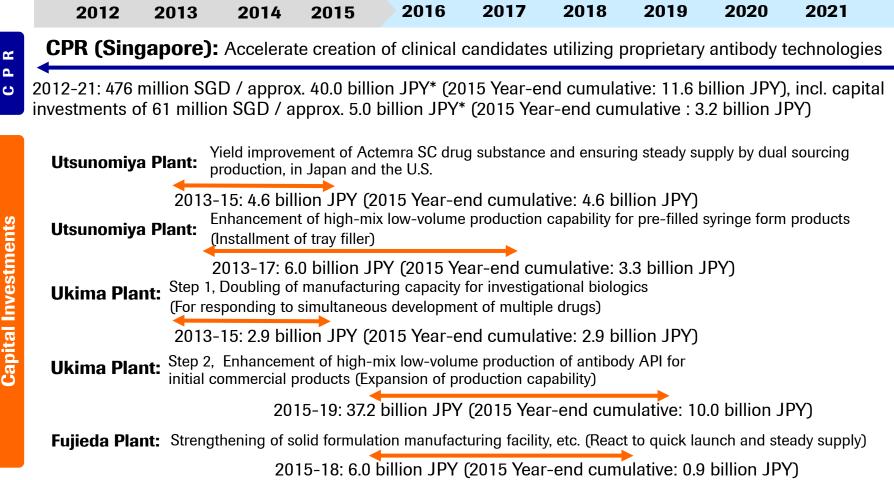
FY2015 Consolidated Financial Overview Innovation all for the patients

### **Current Status / Plan for Major Capital Investments**





- Simultaneous development and quick launch of therapeutic antibodies, etc.
- Reduction of manufacturing costs for in-house products



Research

\* Actual rate for 2012 - 14, converted at 90.0 JPY/SGD from 2015 onward





## **Overview of Development Pipeline**

CHUGAI PHARMACEUTICAL CO., LTD. Executive Vice President Yutaka Tanaka

January 28/29, 2016

Overview of Development Pipeline

## Innovation all for the patients CHUGAI

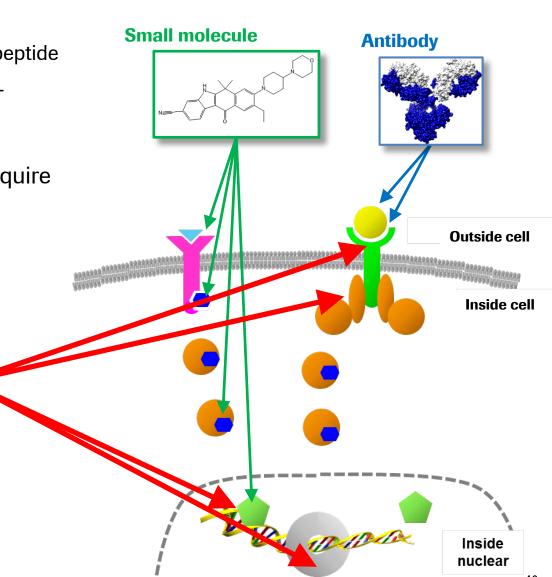
### **Next-Generation Core Technologies**



ex) cyclic peptide

- Encompassing advantages of smallmolecule and antibody drugs
- Target
  - intercellular molecules which require high specificity
  - protein-protein interaction
  - protein-nucleic acid interaction

Middle molecule



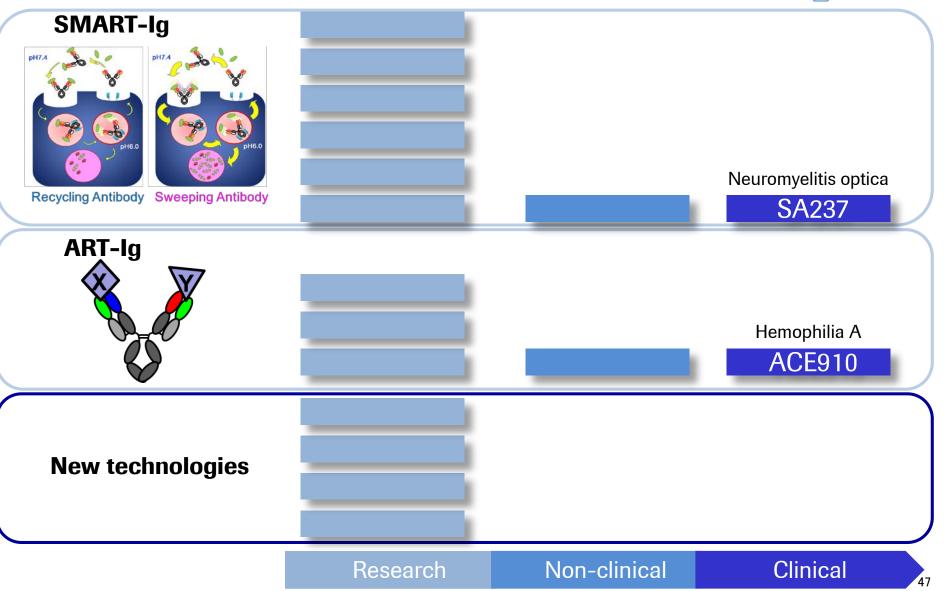
**Acceleration in Antibody Discovery** 

#### IBI18 Aiming to become "Top Pharmaceutical Company"

Overview of Development Pipeline

# СНИДАІ

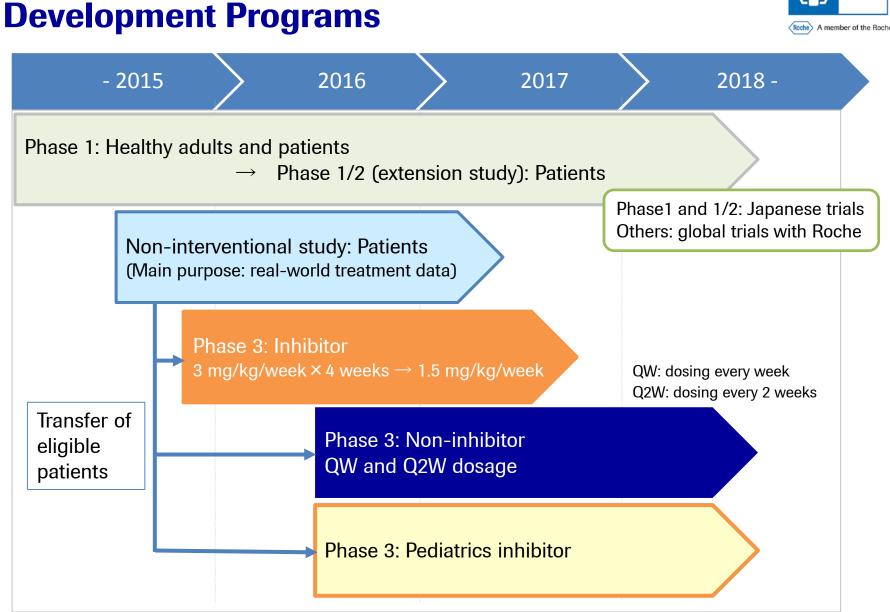
che A member of the Roche group



ACE910 (emicizumab)

**Overview of Development Pipeline** 

## Innovation all for the patients CHUGAI



Adjuvant\*

(2017)

Adjuvant

(2018 and beyond)

Advanced/metastatic

Cancer

Bladder

Lung

**RG7446 (atezolizumab)** 

**Treatment** line

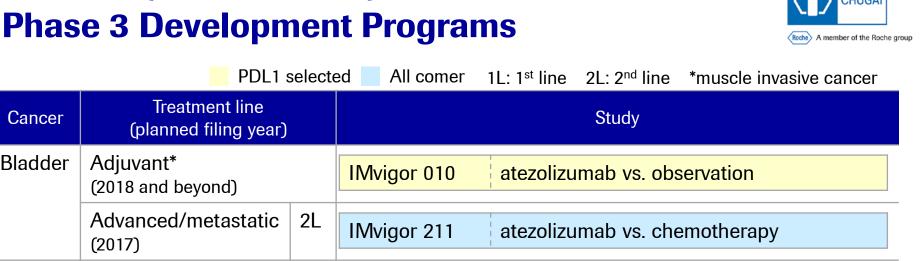
(planned filing year)

PDL1 selected

2L

**Overview of Development Pipeline** 

## Innovation all for the patients CHUGAI



IMpower 010	atezolizumab vs. supportive care
	alezonzuman vs. supportive care
 •	

9	(2018 and beyond)		INIPOWER UTU	atezolizumad vs. supportive care
	Advanced/metastatic (2017)	1L 2L	IMpower 131	Squamous atezolizumab ± chemotherapy
			IMpower 150	Non-squamous atezolizumab + chem ± Avastin vs. chem + Avastin
			IMpower 110	Non-squamous atezolizumab vs. chemotherapy
			ОАК	atezolizumab vs. chemotherapy
RCC	Advanced/metastatic (2018 and beyond)	1L	IMmotion 151	atezolizumab + Avastin vs. sunitinib

#### IBI18 Aiming to become "Top Pharmaceutical Company"

Overview of Development Pipeline

## Oncology Field Projects under Development (as of 28 January, 2016)



	Phase I	Phase II	Phase III	Filed
Oncology	CKI27 (RG7304) (Japan / overseas) - solid tumors	<b>GC33 (RG7686)</b> / codrituzumab - hepatocellular carcinoma	AF802 (RG7853) / Alecensa (overseas) - NSCLC [1L]	RG435 / Avastin - cervical cancer AF802 (RG7853) / Alecensa (overseas) - NSCLC [post-crizotinib] ★
	<b>RG7596 / polatuzumab vedotin</b> - NHL		<b>RG1273 / Perjeta</b> - breast cancer (adjuvant) - gastric cancer	
	RG7604 / taselisib - solid tumors		<b>RG3502 / Kadcyla</b> - breast cancer (adjuvant)	
	<b>RG7440 / ipatasertib</b> - solid tumors		<b>GA101 (RG7159)</b> / obinutuzumab - aggressive NHL - indolent NHL	
			RG7446 / atezolizumab - NSCLC - NSCLC (adjuvant) ★ - bladder cancer - MIBC (adjuvant) ★ - renal cell carcinoma	
			<b>RG435 / Avastin</b> - 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 NSCLC: non-small cell lung cancer MIBC: muscle invasive bladder cancer Letters in orange: in-house projects ★: Projects with advances in stages since 22 October, 2015

Overview of Development Pipeline

## Primary Field Projects under Development (as of 28 January, 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

 $\star$ : Projects with advances in stages since 22 October, 2015

★: Multinational study managed by Chugai

**Development Status** 

Overview of Development Pipeline

## Innovation all for the patients CHUGAI



### RG340 / Xeloda®

Gastric cancer (adjuvant indication added) Approved in November 2015



### AF802 / Alecensa®

ALK positive, metastatic NSCLC who have progressed on or those intolerant to crizotinib Approved in December 2015 (US)

Inlicensed

### RG7446 / atezolizumab

MIBC (adjuvant)

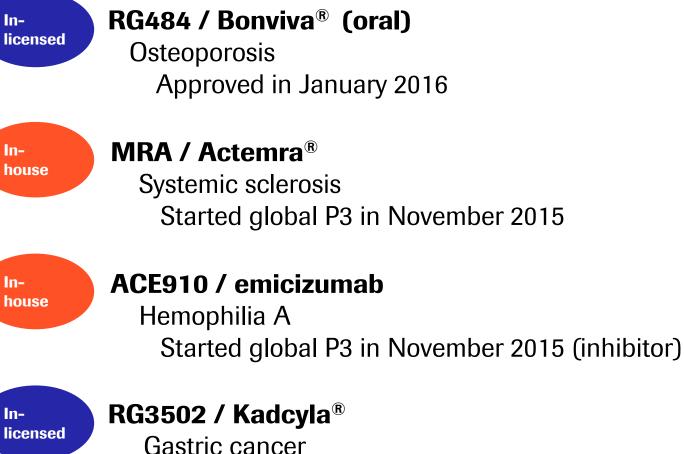
Participated in global P3 in November 2015 NSCLC (adjuvant)

Participated in global P3 in December 2015

**Development Status** 

Overview of Development Pipeline

### Innovation all for the patients CHUGAI



Development discontinued

Overview of Development Pipeline



## **Other Progress**



### AF802 / Alecensa®

150mg capsule (new dosage form) Launched in December 2015



### CSG452 / DEBERZA<sub>®</sub>

Type 2 diabetes Licensed rights for development and marketing in the US and EU to Kowa Company in November 2015

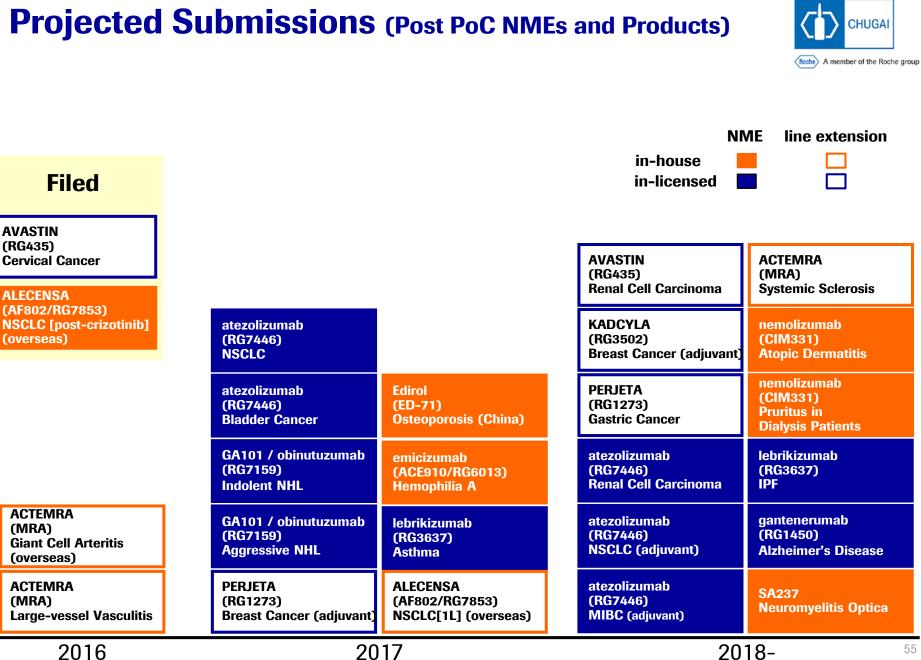


### RG3502 / lebrikizumab

Asthma

Participated in the global P3 ACOUSTICS Study for adolescent patients in December 2015

**Overview of Development Pipeline** Innovation all for the patients



**AVASTIN** (RG435)

**ALECENSA** 

(overseas)

ACTEMRA

(overseas)

**ACTEMRA** 

(MRA)

(MRA)

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## 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 first round requests have been approved
- Two indications of two products among three indications of three products from the second round requests have been approved

	Product	Indication	Current Situation
2nd round requests	CellCept	Lupus nephritis	Filed (Public Knowledge–based application (Kouchi submission) on August 24, 2015)

• Among candidates at the third round, two products were requested for development.

	Product	Indication	Current Situation
3rd round requests	Tamiflu	Addition of dosage and administration for newborn and infant	Submitted company opinion and waiting for evaluation by the committee
	Xeloda	Adjuvant chemotherapy for rectal cancer	Submitted company opinion and waiting for evaluation by the committee

Letters in red: projects with change in status since July 23, 2015

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Media Relations Group

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