

# **FY2019 1Q Consolidated Financial Overview**

CHUGAI PHARMACEUTICAL CO., LTD.  
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# Important Reminder



## 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.

## Core Results

Chugai discloses its results on a Core basis from 2013 in conjunction with its transition to IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results, including return to shareholders.

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

- Increased revenues and operating profit
- Record-high Q1 revenues, operating profit and net income
- Strong progress vs. full-year forecast

(Billions of JPY)	2019 Jan - Mar	Growth (year on year)		Forecast on Jan. 31 Progress
<b>Revenues</b>	<b>154.3</b>	<b>+6.9</b>	<b>+4.7%</b>	<b>26.0%</b>
<b>Cost of sales</b> cost to sales ratio	<b>-63.7</b> 46.3%	<b>-0.2</b> -4.6%pts	<b>+0.3%</b>	<b>25.2%</b>
<b>Operating expenses</b>	<b>-42.7</b>	<b>-1.6</b>	<b>+3.9%</b>	<b>21.7%</b>
<b>Operating profit</b> operating margin	<b>47.9</b> 31.0%	<b>+5.1</b> +2.0%pts	<b>+11.9%</b>	<b>33.5%</b>
<b>Net income</b>	<b>36.3</b>	<b>+5.1</b>	<b>+16.3%</b>	<b>Not disclosed</b>
<b>EPS (JPY)</b>	<b>66.15</b>	<b>+9.63</b>	<b>+17.0%</b>	<b>33.4%</b>

## Year on Year (Core)



# Financial Overview Jan - Mar

(Billions of JPY)	2018 Jan - Mar	2019 Jan - Mar	Growth	
<b>Revenues</b>	<b>147.4</b>	<b>154.3</b>	<b>+6.9</b>	<b>+4.7%</b>
Sales	124.7	137.7	+13.0	+10.4%
Domestic	92.9	99.3	+6.4	+6.9%
Overseas	31.9	38.4	+6.5	+20.4%
Royalties and other operating income	22.7	16.6	-6.1	-26.9%
Royalty and profit-sharing income	5.0	13.7	+8.7	+174.0%
Other operating income	17.7	2.9	-14.8	-83.6%
Cost of sales	-63.5	-63.7	-0.2	+0.3%
( cost to sales ratio)	59.0%	46.3%	-4.6%pts	-
<b>Gross profit</b>	<b>83.9</b>	<b>90.6</b>	<b>+6.7</b>	<b>+8.0%</b>
Operating expenses	-41.1	-42.7	-1.6	+3.9%
<b>Operating profit</b>	<b>42.8</b>	<b>47.9</b>	<b>+5.1</b>	<b>+11.9%</b>
(operating margin)	29.0%	31.0%	+2.0%pts	-
Financial account balance	-0.7	-0.7	0.0	0.0%
Income taxes	-10.9	-10.9	0.0	0.0%
<b>Net income</b>	<b>31.2</b>	<b>36.3</b>	<b>+5.1</b>	<b>+16.3%</b>
<b>EPS (JPY)</b>	<b>56.52</b>	<b>66.15</b>	<b>+9.63</b>	<b>+17.0%</b>

**Domestic sales**

Despite impact from HIP revision, increase due to sales growth of new products as well as mainstay products

**Overseas sales**

Increase in exports of Alecensa and Actemra to Roche

**Royalty and profit-sharing income**

Increase in income for Hemlibra

**Other operating income**

Decrease due to one-time income in the previous year from the transfer of long-term listed products, etc.

**Cost of sales**

Cost to sales ratio improved due to a change in product mix

**Operating expenses**

Overall increase due to increase of research and development expenses

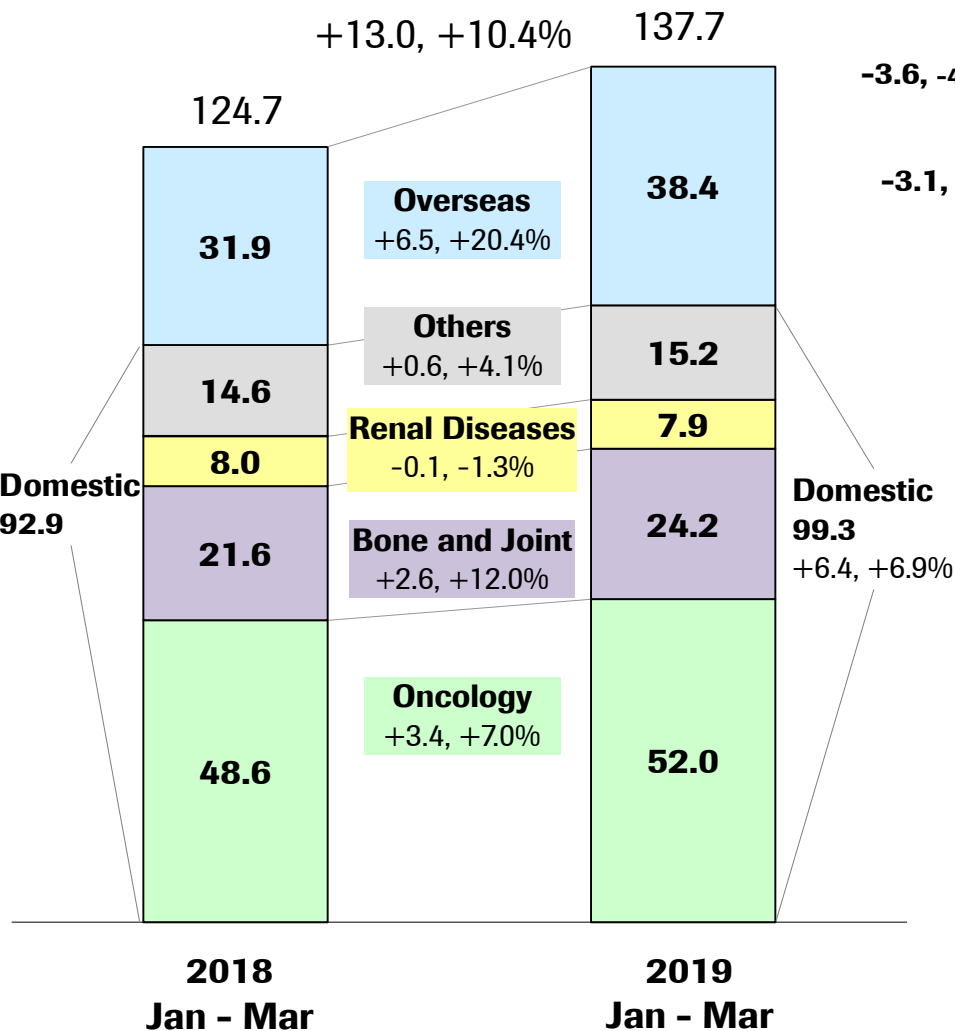
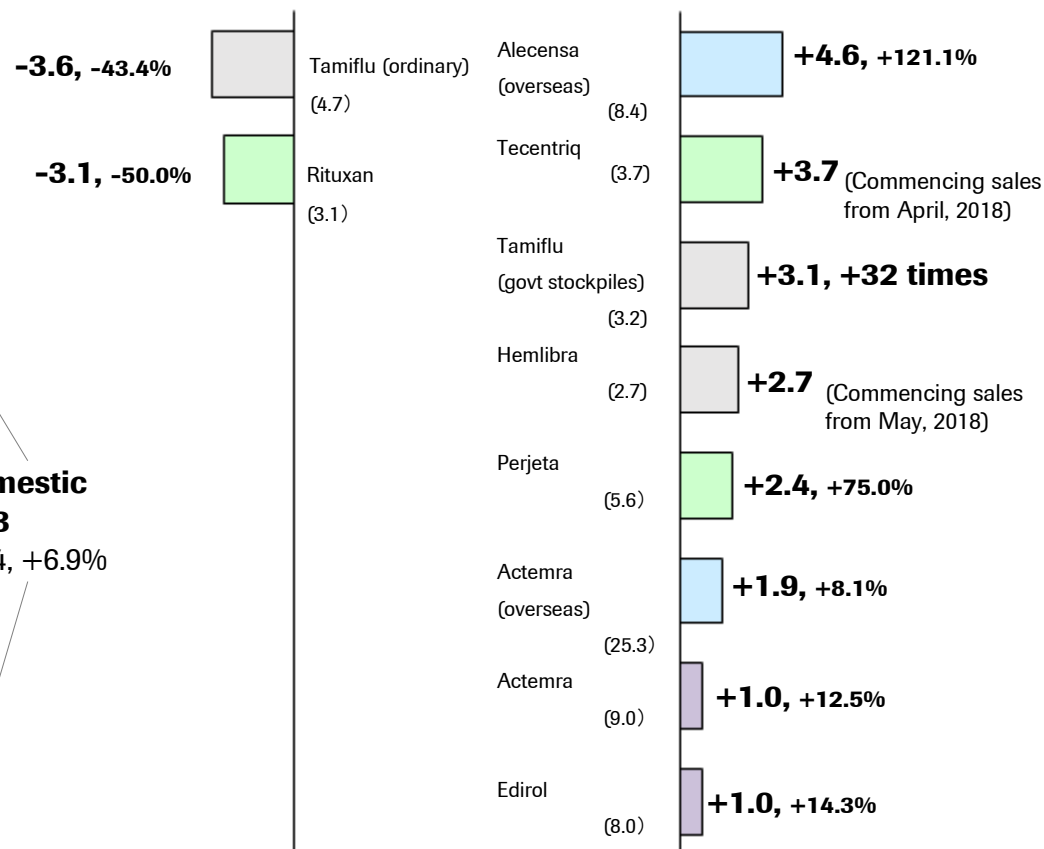
Year on Year (Core)

## Sales Jan - Mar

Sales by Disease Area,  
Year on Year Comparisons

Roche Roche Group

(Billions of JPY)

Sales by Products,  
Year on Year Changes

Details of HER2 franchise (13.8) +2.0, +16.9%

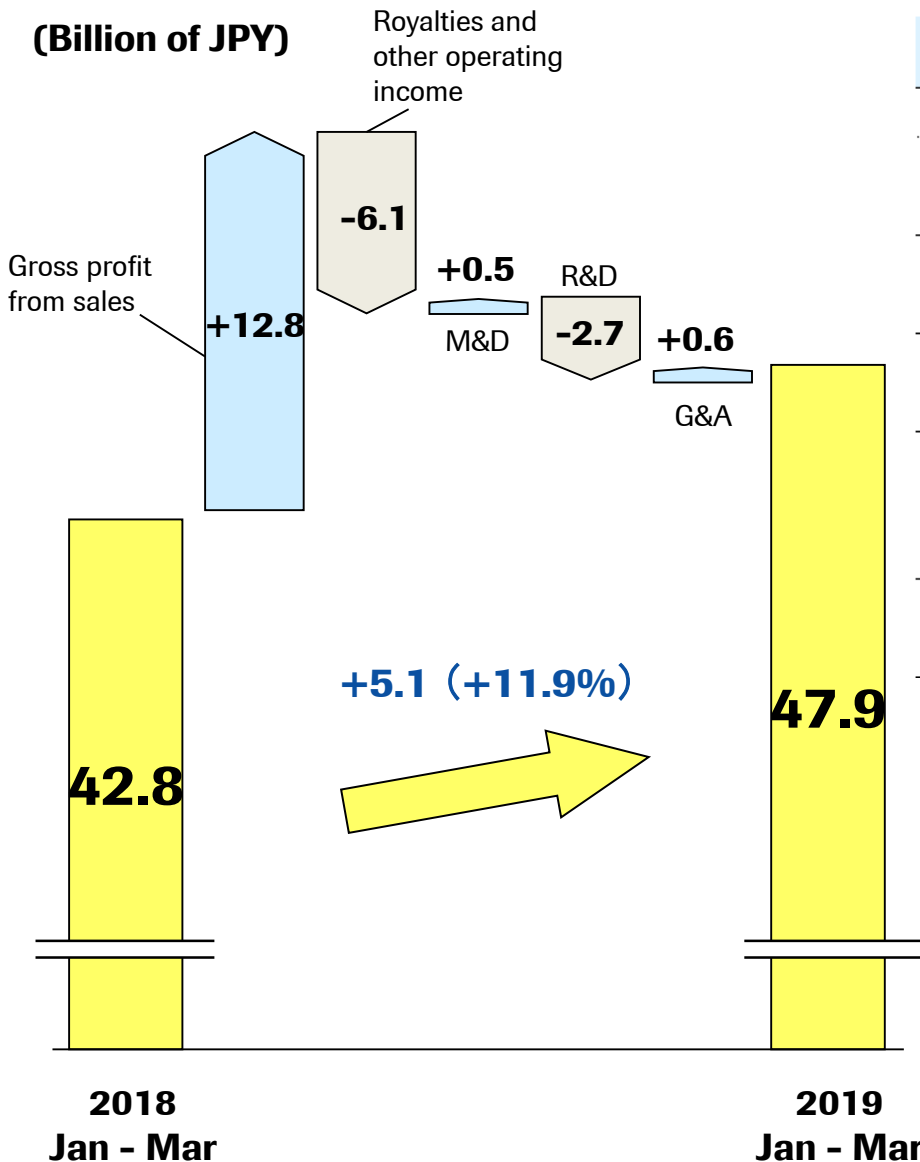
Herceptin (6.2)	-0.6	-8.8%
Perjeta (5.6)	+2.4	+75.0%
Kadcyla (2.0)	+0.2	+11.1%

( ): Actual sales in FY2019  
%: Year-on-year percentage change

## Year on Year (Core)



# Operating Profit Jan - Mar



(Billions of JPY)	2018 Jan - Mar	2019 Jan - Mar	Growth
<b>Revenues</b>	<b>147.4</b>	<b>154.3</b>	<b>+6.9</b>
Sales	124.7	137.7	+13.0
Royalties and other operating income	22.7	16.6	-6.1
<b>Cost of sales</b>	<b>-63.5</b>	<b>-63.7</b>	<b>-0.2</b>
(cost to sales ratio)	50.9%	46.3%	-4.6%pts
<b>Gross profit</b>	<b>83.9</b>	<b>90.6</b>	<b>+6.7</b>
of which Sales	61.2	74.0	+12.8
Marketing and distribution	-15.9	-15.4	+0.5
Research and development	-20.9	-23.6	-2.7
General and administration	-4.3	-3.7	+0.6
<b>Operating profit</b>	<b>42.8</b>	<b>47.9</b>	<b>+5.1</b>
(operating margin)	29.0%	31.0%	+2.0%pts

**Increase in gross profit from sales** **+12.8**

Increase in export to Roche and improvement of cost to sales ratio due to change in product mix

**Decrease in royalties and other operating income** **-6.1**

Despite increase in income for Hemlibra, decrease due to one-time income in the previous year from the transfer of long-term listed products

**Increase in research and development expenses** **-2.7**

Progress of projects, etc.

vs. Forecast (Core)



# Financial Overview Jan - Mar

(Billions of JPY)	Actual	Forecast on Jan. 31	
	2019 Jan - Mar	2019 Jan - Dec	Progress
<b>Revenues</b>	<b>154.3</b>	<b>592.5</b>	<b>26.0%</b>
Sales	137.7	528.0	26.1%
Domestic	99.3	389.1	25.5%
Overseas	38.4	138.9	27.6%
Royalties and other operating income	16.6	64.5	25.7%
Royalty and profit-sharing income	13.7	53.5	25.6%
Other operating income	2.9	11.0	26.4%
Cost of sales	-63.7	-252.5	25.2%
( cost to sales ratio)	46.3%	47.8%	
<b>Gross profit</b>	<b>90.6</b>	<b>340.0</b>	<b>26.6%</b>
Operating expenses	-42.7	-197.0	21.7%
Research and development	-23.6	-102.0	23.1%
<b>Operating profit</b>	<b>47.9</b>	<b>143.0</b>	<b>33.5%</b>
(operating margin)	31.0%	24.1%	
EPS (JPY)	66.15	198.00	33.4%

<b>2018</b>	<b>Domestic sales</b>
Progress *	1Q results slightly above forecast
<b>25.4%</b>	<b>Overseas sales</b>
23.6%	Progress nearly in line with forecast
<b>23.2%</b>	<b>Royalty and profit-sharing income</b>
<b>24.9%</b>	Income for Hemlibra progressed well in view of the forecast
<b>43.7%</b>	<b>Other operating income</b>
<b>20.7%</b>	Progress nearly in line with forecast
<b>63.4%</b>	<b>Cost of sales</b>
<b>24.2%</b>	Cost to sales ratio slightly better than forecast
	<b>Operating expenses</b>
	Progress nearly in line with forecast

Billions of JPY

FX impact	
Jan - Mar 2019 FX impact vs. Assumption	
<b>Revenue</b>	<b>-0.6</b>
Sales	-0.2
Royalties and other operating income	-0.4
Cost of sales	+0.0
Expenses	+0.1
<b>Operating profit</b>	<b>-0.4</b>

\* Jan - Mar progress versus Jan - Dec

vs. Forecast (Core)



# Sales Progress Jan - Mar

(Billions of JPY)	Actual	Forecast		2018 Progress *1		(Billions of JPY)	Actual	Forecast		2018 Progress *1
	2019 Jan - Mar	2019 Jan - Dec	Progress				2019 Jan - Mar	2019 Jan - Dec	Progress	
<b>Sales</b>	<b>137.7</b>	<b>528.0</b>	<b>26.1%</b>	<b>23.6%</b>		<b>Renal</b>	<b>7.9</b>	<b>31.8</b>	<b>24.8%</b>	<b>22.0%</b>
<b>Domestic</b>	<b>99.3</b>	<b>389.1</b>	<b>25.5%</b>	<b>23.2%</b>		Mircera	5.0	20.5	24.4%	21.2%
<b>Oncology</b>	<b>52.0</b>	<b>215.9</b>	<b>24.1%</b>	<b>21.5%</b>		Oxarol	1.6	5.9	27.1%	23.3%
Avastin	21.4	89.4	23.9%	22.0%		<b>Others</b>	<b>15.2</b>	<b>38.3</b>	<b>39.7%</b>	<b>38.9%</b>
Alecensa	4.9	25.1	19.5%	19.4%		Hemlibra	2.7	12.9	20.9%	-
Herceptin	6.2	24.0	25.8%	24.2%		CellCept	2.2	9.0	24.4%	22.2%
Perjeta	5.6	21.2	26.4%	19.9%		Tamiflu(Ordinary use)	4.7	3.4	138.2%	82.2%
Rituxan	3.1	13.5	23.0%	29.1%		Tamiflu(Govt. stockpiles etc.)	3.2	3.2	100.0%	20.0%
Tecentriq	3.7	13.1	28.2%	-		<b>Overseas</b>	<b>38.4</b>	<b>138.9</b>	<b>27.6%</b>	<b>24.9%</b>
Xeloda	2.4	9.4	25.5%	22.4%		Actemra	25.3	84.6	29.9%	29.0%
Kadcyla	2.0	9.1	22.0%	21.2%		Export to Roche	24.9	82.7	30.1%	29.2%
Tarceva	1.2	5.6	21.4%	22.9%		Alecensa	8.4	36.6	23.0%	12.9%
Gazyva	0.6	1.8	33.3%	-		Export to Roche	8.2	36.0	22.8%	12.8%
Alaglio	0.1	0.4	25.0%	33.3%		Neutrogen	2.5	9.5	26.3%	27.0%
<b>Bone and Joint</b>	<b>24.2</b>	<b>103.1</b>	<b>23.5%</b>	<b>21.5%</b>		Hemlibra	0.7	2.4	29.2%	30.4%
Actemra	9.0	38.2	23.6%	20.9%						
Edirol	8.0	35.3	22.7%	21.3%						
Bonviva	2.3	10.9	21.1%	22.3%						
Suvenyl	1.7	6.1	27.9%	21.8%						

\*1 Jan - Mar progress versus Jan - Dec





# Appendix



# IFRS and Core Results Jan - Mar

(Billions of JPY)	IFRS results	Non-core items		Core results	
	2019 Jan - Mar	Intangible assets	Others	2019 Jan - Mar	
<b>Revenues</b>	<b>154.3</b>			<b>154.3</b>	(Billions of JPY)
Sales	137.7			137.7	<b>Non-Core items</b>
Royalties and other operating income	16.6			16.6	Intangible assets:
Cost of sales	-63.9	+0.2		-63.7	Amortization +0.3
<b>Gross profit</b>	<b>90.4</b>	<b>+0.2</b>		<b>90.6</b>	Impairment +1.5
<b>Operating expenses</b>	<b>-44.3</b>	<b>+1.6</b>		<b>-42.7</b>	Others none
Marketing and distribution	-15.4			-15.4	
Research and development	-25.1	+1.6		-23.6	Core net income attributable to Chugai shareholders 36.3
General and administration	-3.7			-3.7	
<b>Operating profit</b>	<b>46.1</b>	<b>+1.8</b>		<b>47.9</b>	
Financing costs	-0.0			-0.0	(Millions of shares)
Other financial income (expense)	0.2			0.2	Weighted average number of shares in issue used to calculate diluted earnings per share
Other expense	-0.8			-0.8	548
<b>Profit before taxes</b>	<b>45.4</b>	<b>+1.8</b>		<b>47.2</b>	
Income taxes	-10.4	-0.5		-10.9	
<b>Net income</b>	<b>35.0</b>	<b>+1.2</b>		<b>36.3</b>	(JPY)
Chugai shareholders	35.0	+1.2		36.3	Core EPS 66.15



# Early Retirement Incentive Program

## Background

- Advent of a severe market environment, e.g. growing difficulty of new drug development and the fundamental reform of the drug pricing system in Japan, etc.
- Reform of business activities associated with advances in technology including digitalization, etc.

## Purpose

- Support for employees who, due to the diversification of views on employment and lifestyles, are considering early retirement to make a new life plan
- Address the Company's management issues in the fast and dramatically changing business environment

## Outline

Eligible employees	Employees aged 45 or over (Detailed criteria are specified separately)
Application period	From April 1, 2019 to April 19, 2019
Retirement Date	June 30, 2019
Number of applicants	172 employees
Incentives	(i) Special additional allowance on top of regular retirement allowance and (ii) reemployment support services
Impact on financial performance	Special additional allowance and other expenses related to this program of approximately JPY 5.1 billion as Non-Core *Slight impact on the forecast for FY2019 consolidated core results

vs. Forecast (Core)



# Impact from Foreign Exchange

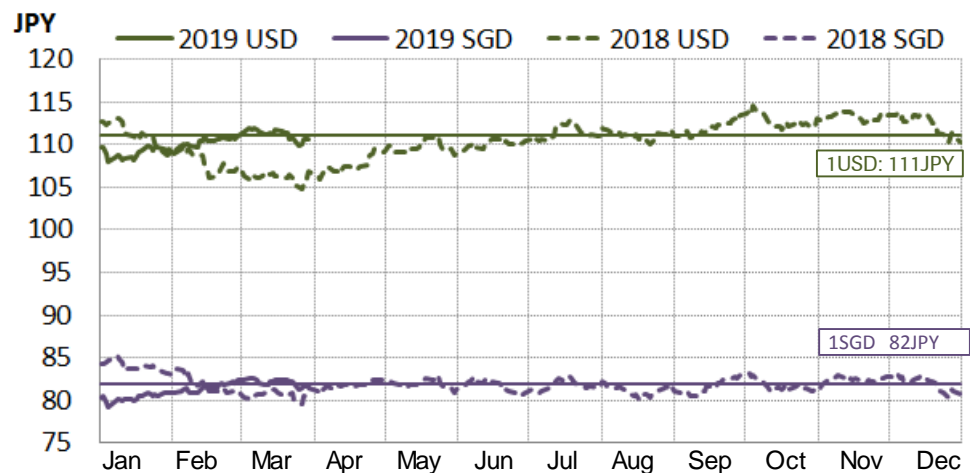
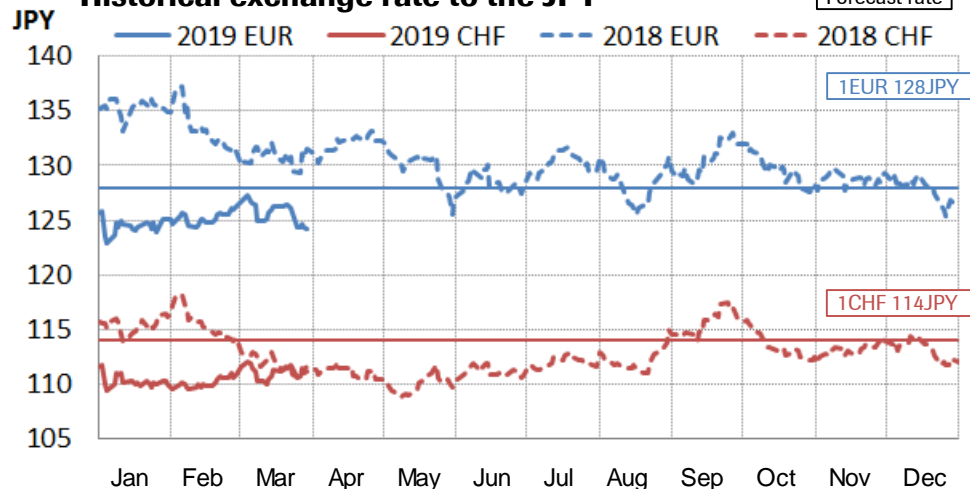
(Billions of JPY)	FX impact Jan – Mar 2019 (FX impact vs. Assumption)	
Revenues	<b>-0.6</b>	
	Sales	-0.2
	Royalties and other operating income	-0.4
Cost of sales	Cost of sales	+0.0
Operating expenses	Expenses	+0.1
<b>Operating profit</b>	<b>-0.4</b>	

Actual / Forecast rate* (JPY)	2018 Jan - Mar Actual	2019 Jan - Dec Assumption	2019 Jan - Mar Actual
1CHF	114.33	114.00	110.52
1EUR	133.17	128.00	125.17
1USD	108.40	111.00	110.18
1SGD	82.16	82.00	81.32

\* Actual: market average exchange rate for the period Jan - Mar

[Reference]

Historical exchange rate to the JPY



vs. 2018 Year End



# Overview of Financial Position

(Billions of JPY)	2018 Dec	2019 Mar	Change
Trade accounts receivable	150.8	149.6	- 1.2
Inventories	159.4	168.7	+ 9.3
Trade accounts payable	-35.9	-54.9	- 19.0
Other net working capital *1	-39.1	-19.1	+ 20.0
<b>Net working capital</b>	<b>235.1</b>	<b>244.3</b>	<b>+ 9.2</b>
Property, plant and equipment	222.4	222.1	- 0.3
Right-of-use assets	-	12.5	+ 12.5
Intangible assets	22.7	21.9	- 0.8
Other long-term assets - net *2	25.1	27.9	+ 2.8
<b>Long-term net operating assets</b>	<b>270.1</b>	<b>284.3</b>	<b>+ 14.2</b>
<b>Net operating assets</b>	<b>505.3</b>	<b>528.6</b>	<b>+ 23.3</b>
Debt	-0.2	-	+ 0.2
Marketable securities	102.5	111.5	+ 9.0
Cash and cash equivalents	146.9	125.8	- 21.1
<b>Net cash</b>	<b>249.2</b>	<b>237.4</b>	<b>- 11.8</b>
Other non-operating assets - net *3	2.1	-5.5	- 7.6
<b>Net non-operating assets</b>	<b>251.3</b>	<b>231.8</b>	<b>- 19.5</b>
<b>Total net assets</b>	<b>756.5</b>	<b>760.5</b>	<b>+ 4.0</b>
Total assets	919.5	932.2	+ 12.7
Total liabilities	-163.0	-171.8	- 8.8

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

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

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

## Increase in net working capital **+9.2**

Increase in inventories	+9.3
Increase in trade accounts payable	-19.0
Increase in other net working capital	+20.0
Royalties for Hemlibra and settlement of long-term prepaid expenses for outsourcing manufacturing, etc.	

## Increase in long-term net operating assets **+14.2**

Increase in right-of-use assets	+12.5
Adoption of IFRS16	
Increase in Other long-term assets	+2.8

## Decrease in net cash **-11.8**

## Decrease in other non-operating assets - net **-7.6**

Increase in lease liabilities by adoption of IFRS16, etc.

## Equity ratio attributable to Chugai shareholders **-0.6% pts.**

End of March 2019 81.6%

End of December 2018 82.2%

FX rate to the JPY  
(end of period)

	2018 Dec	2019 Mar
1CHF	112.03	111.11
1EUR	126.13	124.15
1USD	110.28	110.64
1SGD	80.70	81.56

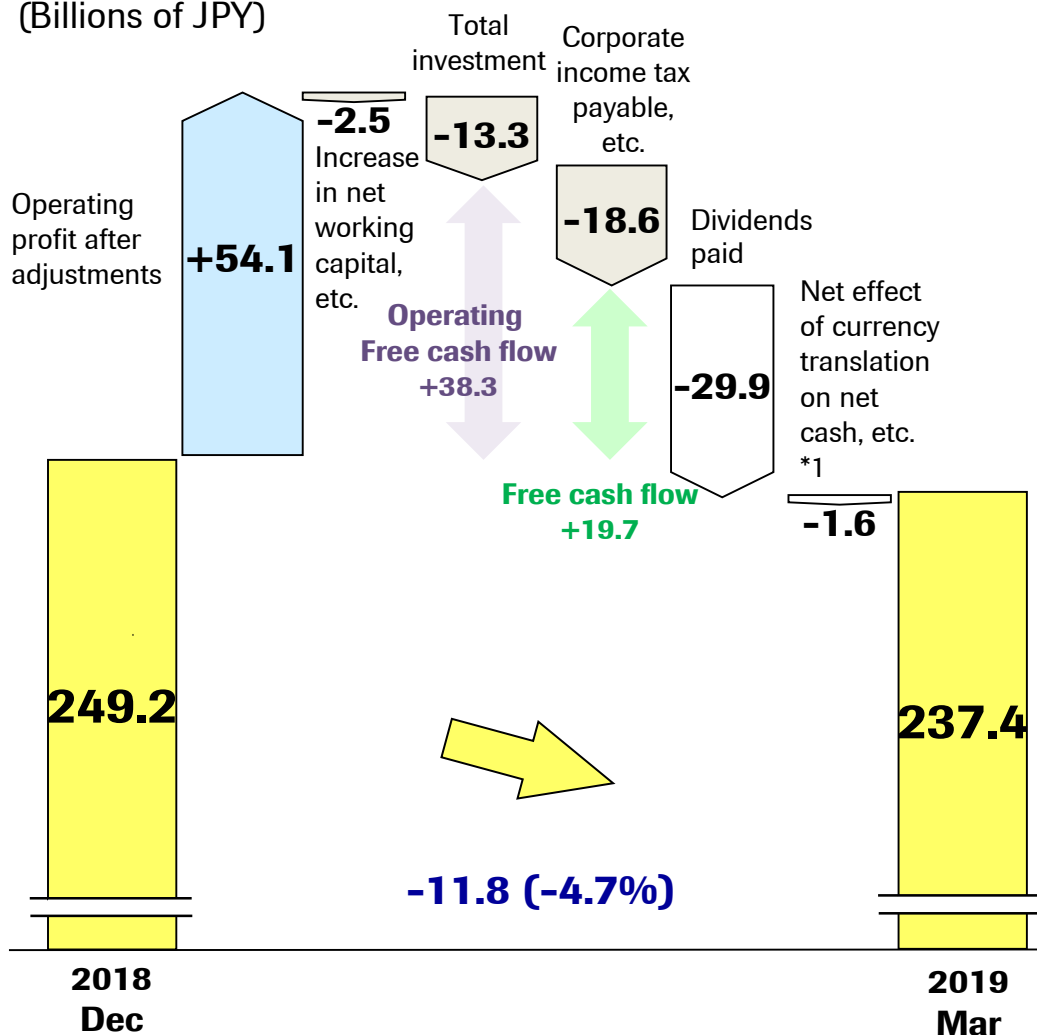
vs. 2018 Year End



Roche Roche Group

# Net Cash

(Billions of JPY)



## Operating profit after adjustment

**+54.1**

Operating profit	+46.1
Depreciation and impairment for property, plant and equipment	+3.7
Depreciation and impairment for right-of-use assets	+1.5
Amortization and impairment for intangible assets	+2.1
Other adjustments for operating profit	+0.8

## Increase in net working capital, etc.

**-2.5**

## Total investment

**-13.3**

Property, plant and equipment	-7.4
Payment for lease liabilities	-2.2
Intangible assets	-3.8

## Operating free cash flow

**+38.3**

## Corporate income tax payable, etc.

**-18.6**

## Free cash flow

**+19.7**

Dividends paid	-29.9
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Net effect of currency translation on net cash, etc.	-1.6
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\*1 Net effect of currency transactions on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(\*2)

\*2 Results from 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)

# Emphasis on Core ROIC as a Long-term Indicator for Investment Efficiency

From 2019, Core ROIC is emphasized as the management indicator (internal KPI) to realize sustained growth in profits and improved corporate value while actively making investments for future growth.

**Sustained growth in profits / Improvement of corporate value**

2008	2013	2016	2019	2022
Sunrise 2012	ACCEL 15	IBI 18	IBI 21	Beyond...

Short-term Objectives	<div> <div>JGAAP</div> <div>IFRS</div> </div>									
	[Billions of JPY]									
	2011	2012	2013	2014	2015	2016	2017	2018	2019	
	Actual	Actual	Actual	Actual	Actual	Actual	Actual	Actual	Forecast	
Revenue	372.1	386.6	423.7	461.1	498.8	491.8	534.2	579.8	592.5	
Core OP	65.8	75.6	79.9	77.3	90.7	80.6	103.2	130.3	143.0	
Core EPS(JPY)	83.27	85.64	94.69	95.04	116.42	102.50	138.68	176.42	198.00	

Medium-term Objectives	Sunrise 2012 results Revenue: 391.2 billion yen Operating profit: 76.4 billion yen Operating margin: 19.5%	ACCEL 15 results Core EPS CAGR* (2012-2015) 18.3%**	IBI 18 results Core EPS CAGR* (2015-2018) 17.1%**	IBI 21forecast Core EPS CAGR* (2018-2021) High single digit**
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**Long-term Objectives**

**Core ROIC**  
(actual results to be disclosed)



# Objectives and Purposes for Implementation of Core ROIC

- **Improvement of corporate value**
  - Improvement of ROIC brings additional economic value, and eventually improves corporate value.
- **Effectiveness as management indicator for efficiency of invested capital during investment phase**
  - Maintains a certain level of efficiency during the concentrated investment phase, and over the mid- to long-term clarifies the improvement targeted through the investment effect
- **Potential for implementation as KPI at the department level**
  - Each department can set and control its KPI indicator and its target by implementing the ROIC tree.

## ROIC and Economic Value Added

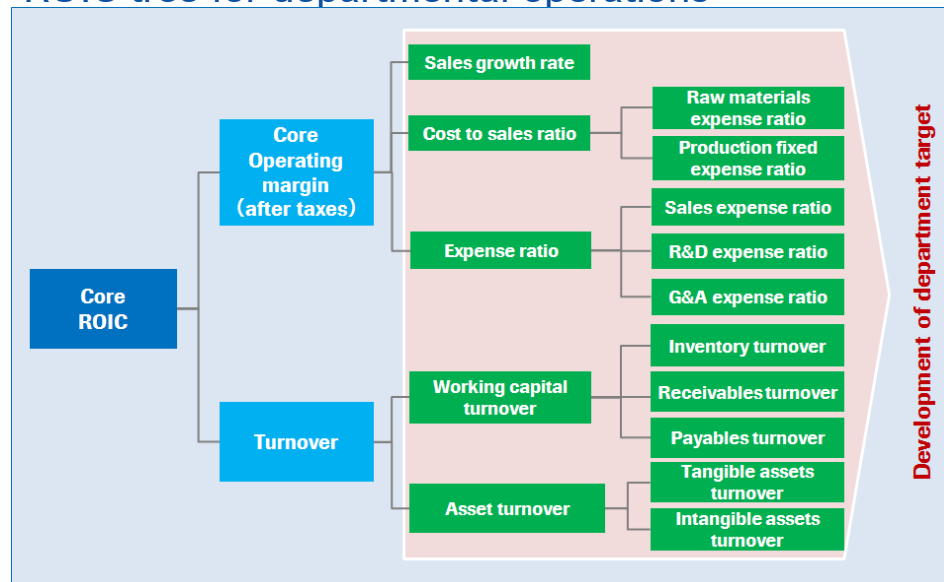
$$\text{Economic Value Added} \uparrow = \text{IC} \times (\text{ROIC} \uparrow - \text{WACC})$$

IC: Invested Capital    ROIC: Return on Invested Capital (= R/IC)  
R: Return

## Investments for future growth

- ✓ **Progress in discovery of middle molecule drugs and evolution of antibody engineering technologies**
- ✓ **Enhancement of new capabilities (e.g. digital technology) for growth**
- ✓ **Construction of a new laboratory and enlargement of production facilities**

## ROIC tree for departmental operations





# Definition and actual results of Core ROIC



- Profit: **Core operating profit (after taxes)**
- Investment capital: **NOA (Net Operating Assets)**

Adoption of asset side to raise consciousness in departments about the efficient control of investment capital

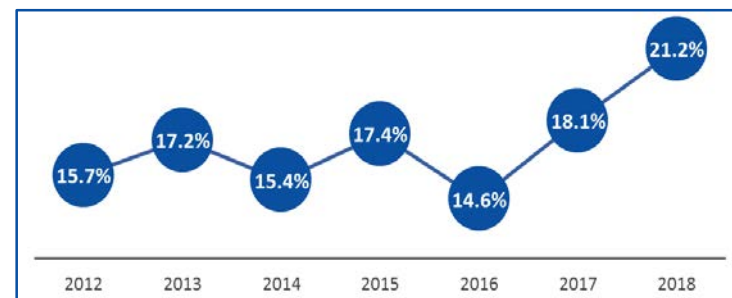
<b>【Billions of JPY】</b>	<b>2012 Dec</b>	<b>2013 Dec</b>	<b>2014 Dec</b>	<b>2015 Dec</b>	<b>2016 Dec</b>	<b>2017 Dec</b>	<b>2018 Dec</b>
<b>Core operating profit (after taxes)</b>	<b>49.4</b>	<b>54.4</b>	<b>52.7</b>	<b>64.4</b>	<b>59.3</b>	<b>78.6</b>	<b>100.1</b>
<b>Net operating assets</b>	<b>307.9</b>	<b>325.2</b>	<b>357.7</b>	<b>380.4</b>	<b>431.1</b>	<b>440.2</b>	<b>505.3</b>
<b>Non-operating assets_net</b>	<b>221.3</b>	<b>248.0</b>	<b>240.0</b>	<b>246.8</b>	<b>215.4</b>	<b>252.7</b>	<b>251.3</b>
<b>Net cash</b>	<b>211.7</b>	<b>234.4</b>	<b>229.9</b>	<b>235.4</b>	<b>204.9</b>	<b>242.8</b>	<b>249.2</b>
<b>Other non-operating assets-net</b>	<b>9.6</b>	<b>13.6</b>	<b>10.2</b>	<b>11.5</b>	<b>10.5</b>	<b>9.9</b>	<b>2.1</b>
<b>Total net assets</b>	<b>529.2</b>	<b>573.2</b>	<b>597.8</b>	<b>627.3</b>	<b>646.5</b>	<b>692.9</b>	<b>756.5</b>

## 【Core ROIC Formula / Actual results】

**Core operating profit  
(after taxes)**

**(opening NOA + ending NOA) ÷ 2**

\*Balance of NOA is the average of opening and ending balances.



# Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.  
Department Manager of R&D Portfolio  
Management Dept., Project & Lifecycle  
Management Unit  
Dr. Minoru Hirose

April 24, 2019

# Projects under Development (1)

As of April 24, 2019

	Phase I	Phase II	Phase III		Filed
Oncology	<b>CKI27</b> - solid tumors  <b>GC33 / codrituzumab</b> - HCC★  <b>ERY974</b> - solid tumors  <b>RG7421 / cobimetinib</b> - solid tumors  <b>RG7802 / cibisatamab</b> - solid tumors  <b>RG7828 / mosunetuzumab</b> - hematologic tumors		<b>RG3502 / Kadcyla</b> - breast cancer (adjuvant)  <b>RG435 / Avastin</b> - RCC - HCC  <b>RG7440 / ipatasertib</b> - prostate cancer - breast cancer  <b>RG7596 / polatuzumab vedotin</b> - DLBCL  <b>RG6264 (Herceptin+Perjeta)</b> - breast cancer (Fixed-dose combination, subcutaneous injection)	<b>AF802 (RG7853) / Alecensa</b> - NSCLC (adjuvant)  <b>RG7446 / Tecentriq</b> - NSCLC (adjuvant) - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - early breast cancer - ovarian cancer - prostate cancer - HCC - HNC (adjuvant)	<b>RG7446 / Tecentriq</b> - breast cancer - SCLC  <b>RG6268 / entrectinib</b> - solid tumors - NSCLC ★
Bone & Joint			<b>NRD101 / Suvenyl (China)</b> - knee osteoarthritis/shoulder periarthritis		<b>ED-71 / Ediolol (China)</b> - osteoporosis
Renal	<b>EOS789</b> - Hyperphosphatemia				

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

HCC: hepatocellular carcinoma  
 NSCLC: non-small cell lung cancer  
 SCLC: small cell lung cancer  
 MIUC: muscle invasive urothelial carcinoma

RCC: renal cell carcinoma  
 DLBCL: diffuse large B-cell lymphoma  
 HNC: head and neck carcinoma

**Letters in orange: in-house projects**

★: Projects with advances in stages since January 31, 2019

★: Multinational study managed by Chugai

# Projects under Development (2)



Roche Group

As of April 24, 2019

	Phase I	Phase II	Phase III	Filed
Autoimmune	<b>RG7845 / fenebrutinib</b> - rheumatoid arthritis		<b>MRA (RG1569) / Actemra</b> - systemic sclerosis	
Neurology	<b>RG7935 / prasinezumab</b> - Parkinson's disease <b>GYM329 (RG6237)</b> - neuromuscular disease <b>RG7906</b> - psychiatric disorders <b>RG6100 (anti-tau MAb)</b> - Alzheimer's disease ★		<b>RG1450 / gantenerumab</b> - Alzheimer's disease <b>SA237 (RG6168) / satralizumab</b> - NMOSD ★ <b>RG6042 (HTT ASO)</b> - Huntington's disease ★ <b>RG6206 (anti-myostatin adnectin)</b> - DMD (PII/III) <b>RG7916 / risdiplam</b> - spinal muscular atrophy(PII/III)	
Others	<b>PCO371</b> - hypoparathyroidism <b>AMY109</b> - endometriosis	<b>CIM331 / nemolizumab*</b> - pruritus in dialysis patients <b>SKY59 (RG6107) / crovalimab</b> - paroxysmal nocturnal hemoglobinuria (PI/II)	<b>RG7716 / faricimab</b> - DME - wAMD ★	

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

wAMD: wet age-related macular degeneration    NMOSD: neuromyelitis optica spectrum disorder  
DME: diabetic macular edema    HTT ASO: Antisense oligonucleotide targeting *HTT* mRNA  
DMD: Duchenne muscular dystrophy

**Letters in orange: in-house projects**

**★: Projects with advances in stages since January 31, 2019**

**★: Multinational study managed by Chugai**

\* Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

# Key News Flows in Q1

Approved	<b>Hemlibra</b> (Europe)	Hemophilia A (non-inhibitor)	March, 2019
	<b>Actemra</b> (Japan)	Cytokine Release Syndrome	March, 2019
	<b>Rituxan</b>	CD20+ CLL	March, 2019
Filed	<b>entrectinib</b>	ROS 1+ NSCLC	March, 2019
	<b>F1 CDx</b>	CDx for entrectinib	January, 2019
	<b>F1 CDx</b>	CDx for Lynparza	March, 2019
Phase Transitions	<b>faricimab</b>	Wet age-related macular degeneration	Global Phase 3 study
New to Pipeline	<b>HTT ASO</b>	Huntington's disease	Global Phase 3 study
	<b>anti-tau MAb</b>	Alzheimer's disease	Phase 1 study
Development Discontinued	<b>crenezumab</b>	Alzheimer's disease	-
Late-stage Readouts	<b>Suvenyl</b> (China)	Knee osteoarthritis /Shoulder periartthritis	Phase 3 study
	<b>nemolizumab*</b> (Japan)	Atopic dermatitis	Phase 3 study
Medical Conference	<b>nemolizumab*</b> (overseas)	Atopic dermatitis (Phase 2b)	American Academy of Dermatology
Others	<b>risdiplam</b>	Spinal muscular atrophy	Orphan Drug Designation

CLL: Chronic Lymphocytic Leukemia / NSCLC: Non-small cell lung cancer

F1 CDx: FoundationOne CDx Cancer Genomic Profile

HTT ASO: Antisense oligonucleotide targeting *HTT* mRNA

\* Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

**Letters in orange: in-house projects**



# RG6042 (HTT ASO) (1)

## Antisense oligonucleotide targeting *HTT* mRNA

### Huntington's Disease

- Cause: Autosomal dominant genetic disease due to mutation in Huntingtin (HTT) gene
- Symptoms: Involuntary movements (mainly jerky movements), psychiatric symptoms and dementia
- Age of onset: 40s\*
- Disease duration: 10-20 years
- Treatment: No definitive treatment, symptomatic treatment is common
- Causes of death: Poor nutrition, infection, asphyxia and injury, etc.
- Number of patients in Japan (number of people who received certificates issued for specific disease treatment as of 2014): 933

Source: Huntington's disease (Designated incurable disease 8), Japan Intractable Diseases Information Center WEB site

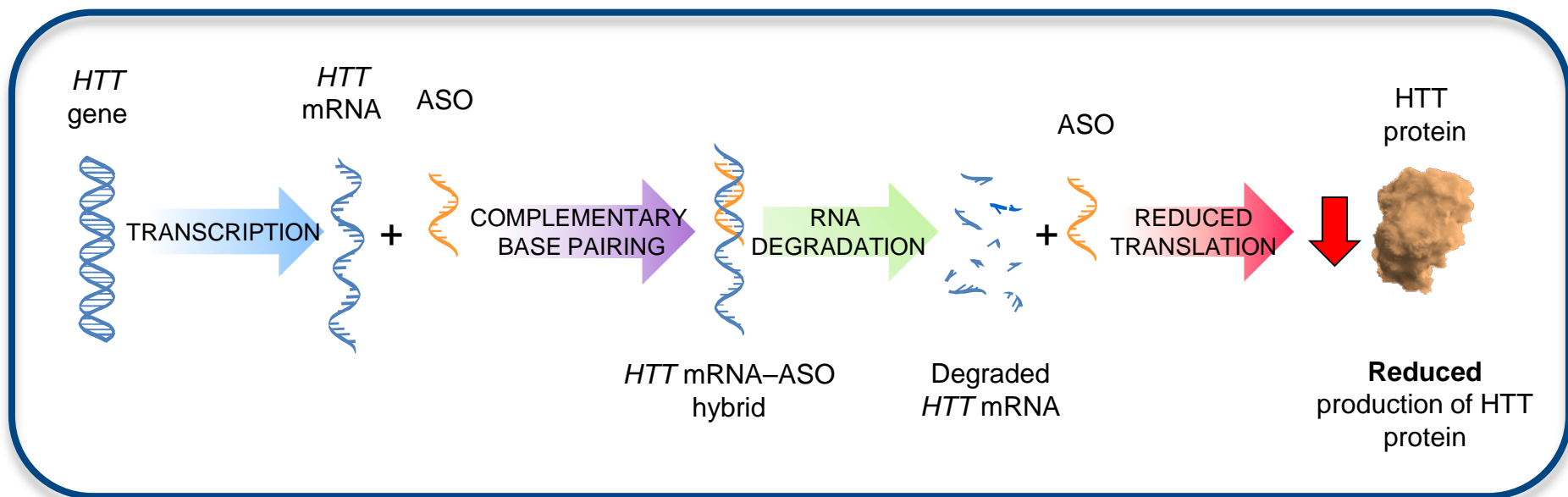
\* Nat. Rev. Neurol. 10, 204–216 (2014)

# RG6042 (HTT ASO) (2)

## Antisense oligonucleotide targeting *HTT* mRNA

### Mode of Action

- HTT ASO, antisense oligonucleotide (ASO), is complementary to *HTT* mRNA and reduces HTT protein based on degradation of the mRNA by RNase H.
- HTT ASO is expected to slow/stop clinical progression of Huntington's Disease.



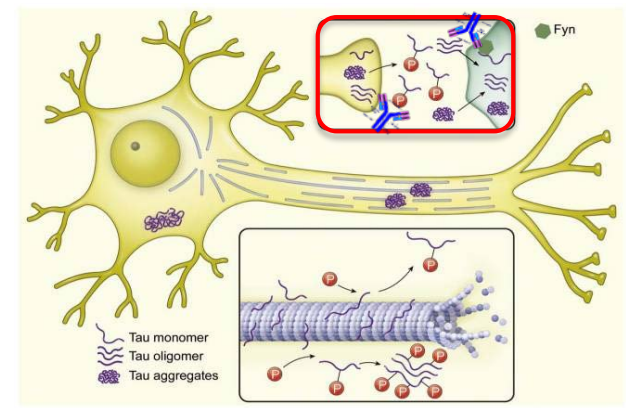
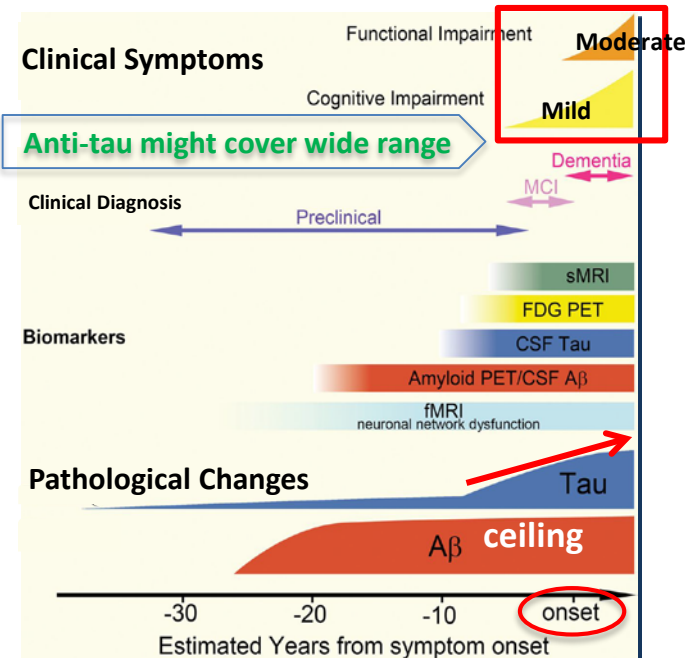
# RG6100 (Anti-Tau IgG4 Monoclonal Antibody)

## Scientific Background

- Under normal physiological conditions, tau protein stabilizes microtubules, promotes microtubule assembly, and contributes to neuronal integrity.
- Tau pathology, characterized by aggregated tau protein, is a pathological hallmark of AD and other tau-related neurodegenerative diseases.
- Pathological tau appears to propagate from cell to cell, in a prion-like manner, via the extracellular space.
- Tau pathology spreads with a characteristic spatiotemporal pattern of propagation throughout the brain, coinciding with clinical burden and disease progression in AD.

## Mode of Action

- RG6100 demonstrated binding to multiple isoforms of the tau protein.
- RG6100 is designed to bind tau in the extracellular space of the brain, and intercept the cell-to-cell propagation of pathological tau.





# OBP-301 / Telomelysin

## Oncolytic Viral Immunotherapy created by Oncolys BioPharma

### Mode of Action

- OBP-301 is a genetically modified type 5 adenovirus which can specifically replicate in and destroy cancer cells.
- OBP-301 may induce strong anti-tumor activity after causing oncolysis by specific replication in cancer cells with high telomerase activity.
- OBP-301 has extremely low replication ability in normal cells.

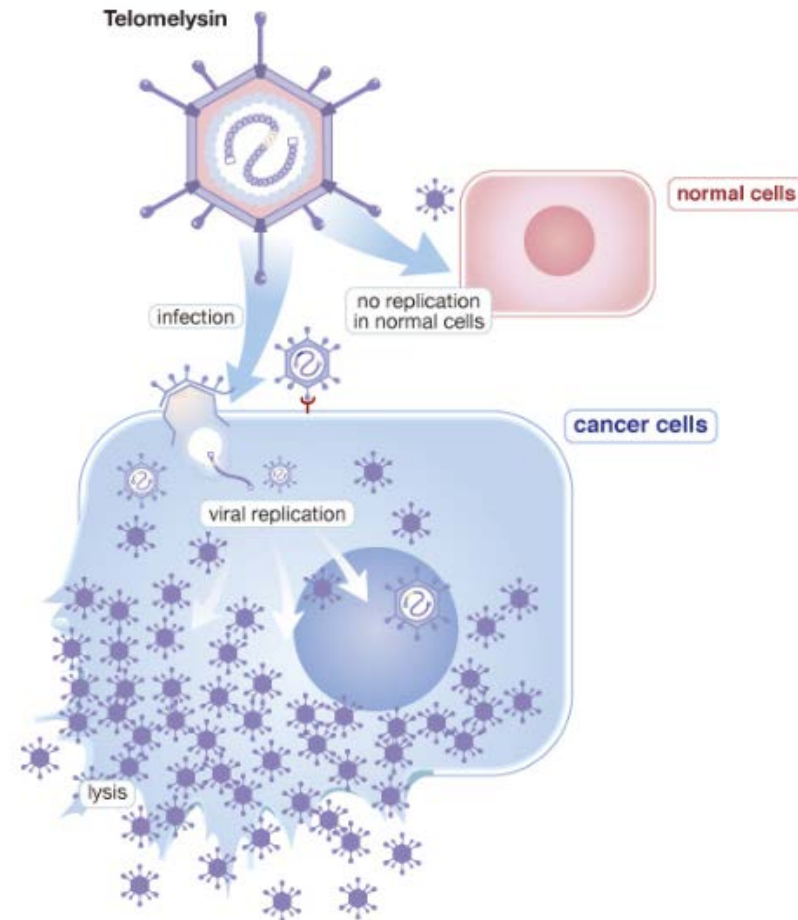
### Major Developments in Progress

#### 【Japan】

- Esophageal cancer (combo with radiotherapy): Phase I
- *SAKIGAKE* designation: April 2019

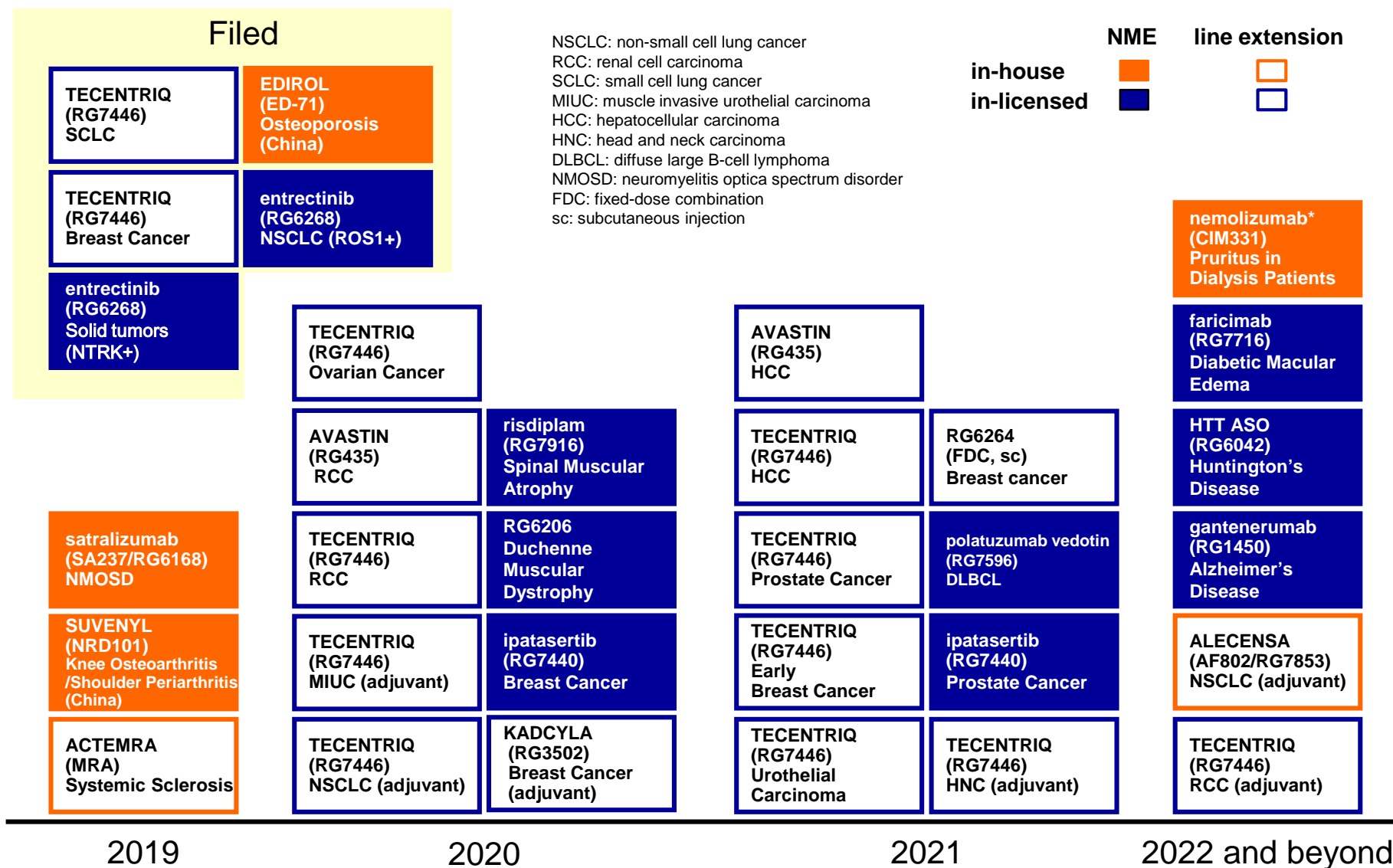
#### 【Overseas】

- Melanoma (monotherapy): Phase II (US)
- Hepatocellular carcinoma (monotherapy): Phase I/II (South Korea, Taiwan)



# Projected Submissions (Post PoC NMEs and Products)

as of April 24, 2019



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