

# FY2019 3Q Consolidated Financial Overview

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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.

Core



# 3Q Results Summary

- Significant year-on-year increase in revenues and operating profit
- Record high Q3 revenues, operating profit and net income
- Full-Year Forecast revised upward

(Billions of JPY)	2019 Jan – Sep	Growth (year on year)		Original Forecast <sup>*1</sup>		Revised Forecast <sup>*2</sup>	
				2019 Jan – Dec	Progress	2019 Jan – Dec	Progress
<b>Revenues</b>	<b>508.9</b>	<b>+82.5</b>	<b>+19.3%</b>	<b>592.5</b>	<b>85.9%</b>	<b>680.0</b>	<b>74.8%</b>
<b>Cost of sales</b> cost to sales ratio	<b>-201.3</b> 45.7%	<b>-7.0</b> -4.3%pts	<b>+3.6%</b>	<b>-252.5</b> 47.8%	<b>79.7%</b>	<b>-265.0</b> 45.2%	<b>76.0%</b>
<b>Operating expenses</b>	<b>-136.5</b>	<b>-7.6</b>	<b>+5.9%</b>	<b>-197.0</b>	<b>69.3%</b>	<b>-197.0</b>	<b>69.3%</b>
<b>Operating profit</b> operating margin	<b>171.1</b> 33.6%	<b>+67.8</b> +9.4%pts	<b>+65.6%</b>	<b>143.0</b> 24.1%	<b>119.7%</b>	<b>218.0</b> 32.1%	<b>78.5%</b>
<b>Net income</b>	<b>124.5</b>	<b>+49.9</b>	<b>+66.9%</b>	<b>Not disclosed</b>		<b>Not disclosed</b>	
<b>EPS (JPY)</b>	<b>227.06</b>	<b>+91.92</b>	<b>+68.0%</b>	<b>198.00</b>	<b>114.7%</b>	<b>302.00</b>	<b>75.2%</b>

<sup>\*1</sup>Announced on January 31, 2019 <sup>\*2</sup>Announced on October 24, 2019 To be the same afterwards.

## Year on Year (Core)

## Financial Overview Jan - Sep



(Billions of JPY)	2018 Jan - Sep	2019 Jan - Sep	Growth	
<b>Revenues</b>	<b>426.4</b>	<b>508.9</b>	<b>+ 82.5</b>	<b>+ 19.3%</b>
Sales	388.7	440.5	+ 51.8	+ 13.3%
Domestic	290.8	324.4	+ 33.6	+ 11.6%
Overseas	97.9	116.0	+ 18.1	+ 18.5%
Royalties and other operating income	37.7	68.4	+ 30.7	+ 81.4%
Royalty and profit-sharing income	15.8	48.8	+ 33.0	+ 208.9%
Other operating income	21.9	19.6	- 2.3	- 10.5%
Cost of sales	-194.3	-201.3	- 7.0	+ 3.6%
(cost to sales ratio)	50.0%	45.7%	-4.3%pts	-
<b>Gross profit</b>	<b>232.1</b>	<b>307.5</b>	<b>+ 75.4</b>	<b>+ 32.5%</b>
Operating expenses	-128.9	-136.5	- 7.6	+ 5.9%
<b>Operating profit</b>	<b>103.3</b>	<b>171.1</b>	<b>+ 67.8</b>	<b>+ 65.6%</b>
(operating margin)	24.2%	33.6%	+9.4%pts	-
Financial account balance	-2.3	-2.3	0.0	0.0%
Income taxes	-26.4	-44.3	- 17.9	+ 67.8%
<b>Net income</b>	<b>74.6</b>	<b>124.5</b>	<b>+ 49.9</b>	<b>+ 66.9%</b>
EPS (JPY)	135.14	227.06	+91.92	+ 68.0%

**Domestic sales**

Increase due to sales growth of new products as well as mainstay products

**Overseas sales**

Increase in export of Alecensa 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, etc.

**Operating expenses**

Overall increase due mainly to increase of research and development expenses

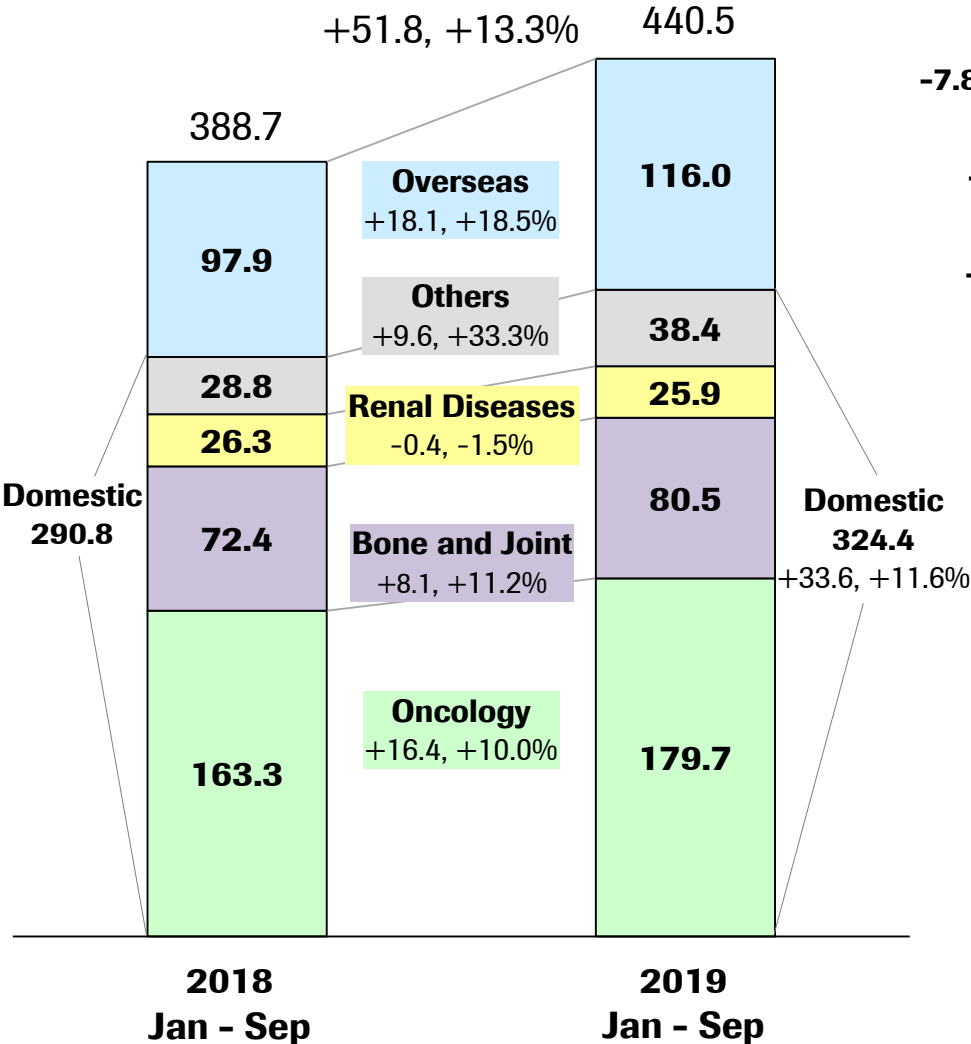
Year on Year (Core)



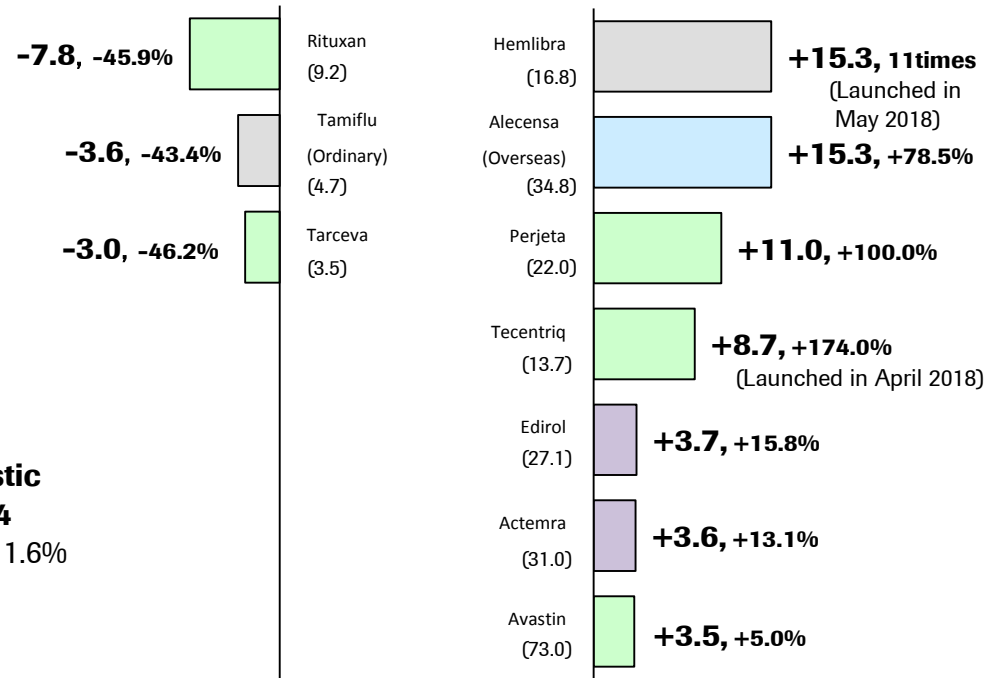
# Sales Jan - Sep

Sales by Disease Area,  
Year on Year Comparisons

(Billions of JPY)



## Sales by Products, Year on Year Changes



Details of HER2 franchise (49.2) +11.4, +30.2%

Herceptin	(20.3)	-0.3	-1.5%
Perjeta	(22.0)	+11.0	+100.0%
Kadcyla	(6.8)	+0.6	+9.7%

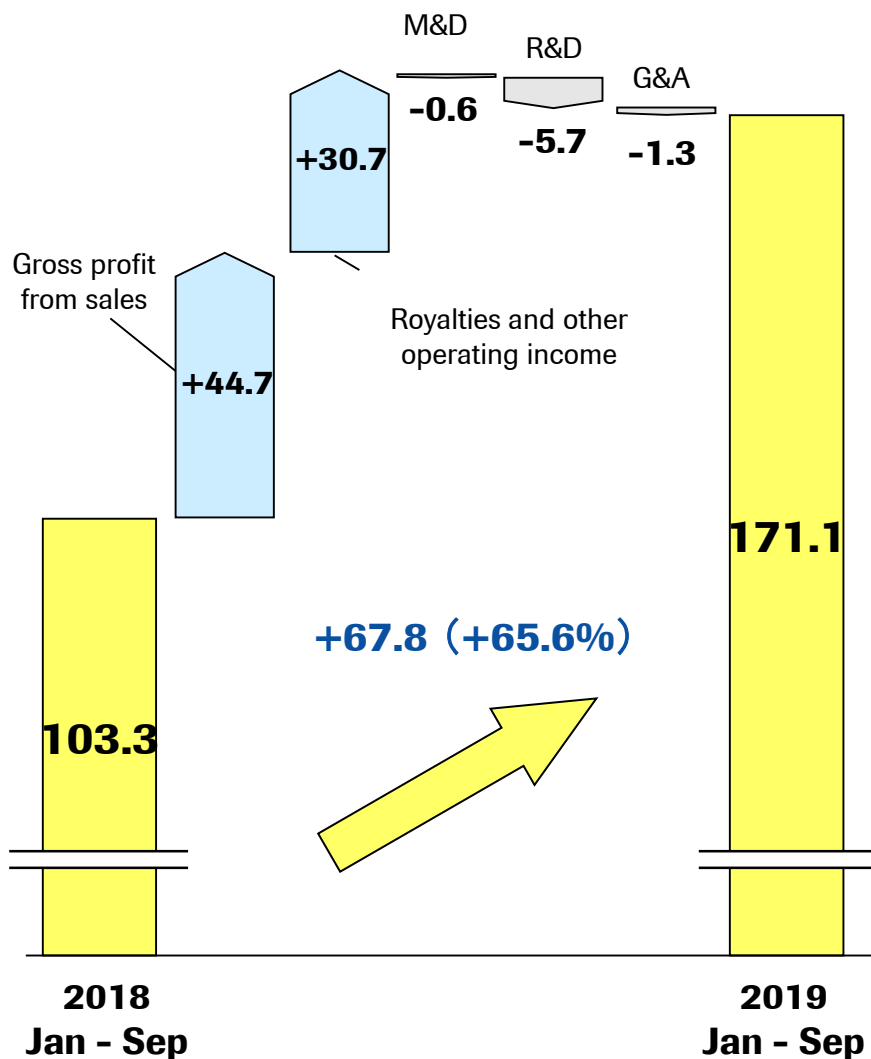
( ): Actual sales in FY2019  
%: Year-on-year percentage change

Year on Year (Core)



# Operating Profit Jan - Sep

(Billion of JPY)



(Billions of JPY)	2018 Jan - Sep	2019 Jan - Sep	Growth
<b>Revenues</b>	<b>426.4</b>	<b>508.9</b>	<b>+82.5</b>
Sales	388.7	440.5	+51.8
Royalties and other operating income	37.7	68.4	+30.7
<b>Cost of sales</b>	<b>-194.3</b>	<b>-201.3</b>	<b>-7.0</b>
(cost to sales ratio)	50.0%	45.7%	-4.3%pts
<b>Gross profit</b>	<b>232.1</b>	<b>307.5</b>	<b>+75.4</b>
of which Sales	194.4	239.1	+44.7
Marketing and distribution	-50.4	-51.0	-0.6
Research and development	-66.3	-72.0	-5.7
General and administration	-12.2	-13.5	-1.3
<b>Operating profit</b>	<b>103.3</b>	<b>171.1</b>	<b>+67.8</b>
(operating margin)	24.2%	33.6%	+9.4%pts

**Increase in gross profit from sales**
**+44.7**

In addition to the increase in sales, cost to sales ratio improved due to a change in product mix, etc. based on sales expansion of in-house products.

**Increase in royalties and other operating income**
**+30.7**

Increase in income for Hemlibra

**Increase in research and development expenses**
**-5.7**

Progress of projects, etc.

Year on Year (Core)



# Financial Overview Jul - Sep

(Billions of JPY)	2018 Jul - Sep	2019 Jul - Sep	Growth	
<b>Revenues</b>	<b>141.3</b>	<b>188.6</b>	<b>+ 47.3</b>	<b>+ 33.5%</b>
Sales	133.1	158.0	+ 24.9	+ 18.7%
Domestic	99.6	114.4	+ 14.8	+ 14.9%
Overseas	33.5	43.6	+ 10.1	+ 30.1%
Royalties and other operating income	8.2	30.5	+ 22.3	+ 272.0%
Royalty and profit-sharing income	5.7	18.5	+ 12.8	+ 224.6%
Other operating income	2.5	12.0	+ 9.5	+ 380.0%
Cost of sales	-65.7	-73.8	-8.1	+ 12.3%
(cost to sales ratio)	49.4%	46.7%	-2.7%pts	-
<b>Gross profit</b>	<b>75.6</b>	<b>114.8</b>	<b>+ 39.2</b>	<b>+ 51.9%</b>
Operating expenses	-44.0	-47.3	-3.3	+ 7.5%
<b>Operating profit</b>	<b>31.6</b>	<b>67.5</b>	<b>+ 35.9</b>	<b>+ 113.6%</b>
(operating margin)	22.4%	35.8%	+13.4%pts	-
Financial account balance	-0.7	-1.0	-0.3	+ 42.9%
Income taxes	-8.9	-17.2	-8.3	+ 93.3%
<b>Net income</b>	<b>22.0</b>	<b>49.3</b>	<b>+ 27.3</b>	<b>+ 124.1%</b>
EPS (JPY)	39.87	89.95	+50.08	+ 125.6%

**Domestic sales**

Increase due to sales growth of new products as well as mainstay products

**Overseas sales**

Increase in export of Alecensa and Actemra to Roche

**Royalty and profit-sharing income**

Increase in income for Hemlibra

**Other operating income**

Increase in milestone income

**Cost of sales**

Royalties booked in the previous year, but not recognized in the 1H of 2019 were booked in the 3Q of 2019. Meanwhile, cost to sales ratio improved due to a change in product mix, etc.

**Operating expenses**

Overall increase due to increase of research and development expenses, marketing and distribution expenses, general and administration expenses

## Revision of Forecast (Core)



# Financial Overview Jan - Dec

(Billions of JPY)	Original Forecast 2019 Jan - Dec	Revised Forecast 2019 Jan - Dec	Revision	
<b>Revenues</b>	<b>592.5</b>	<b>680.0</b>	<b>+ 87.5</b>	<b>+ 14.8%</b>
Sales	528.0	586.0	+ 58.0	+ 11.0%
Domestic	389.1	437.0	+ 47.9	+ 12.3%
Overseas	138.9	149.0	+ 10.1	+ 7.3%
Royalties and other operating income	64.5	94.0	+ 29.5	+ 45.7%
Royalty and profit-sharing income	53.5	74.0	+ 20.5	+ 38.3%
Other operating income	11.0	20.0	+ 9.0	+ 81.8%
Cost of sales	-252.5	-265.0	- 12.5	+ 5.0%
(cost to sales ratio)	47.8%	45.2%	-2.6%pts	-
<b>Gross profit</b>	<b>340.0</b>	<b>415.0</b>	<b>+ 75.0</b>	<b>+ 22.1%</b>
Operating expenses	-197.0	-197.0	0.0	0.0%
Research and development	-102.0	-102.5	- 0.5	+ 0.5%
<b>Operating profit</b>	<b>143.0</b>	<b>218.0</b>	<b>+ 75.0</b>	<b>+ 52.4%</b>
(operating margin)	24.1%	32.1%	+8.0%pts	-
EPS (JPY)	198.00	302.00	+ 104.00	+ 52.5%

**Main reasons for revision:****Domestic sales**

Increase due to sales growth of new products as well as mainstay products

**Overseas sales**

Exports to Roche will exceed the original forecast

**Royalty and profit-sharing income**

Income for Hemlibra significantly exceeded the original forecast

**Other operating income**

One-time income not included in the original forecast

**Cost of sales**

Cost to sales ratio improved due to a change in product mix, etc.

Foreign exchange rate assumption (JPY)	2019 Original Forecast	2019 Revised Forecast
1CHF	114.00	112.00
1EUR	128.00	122.00
1USD	111.00	108.00
1SGD	82.00	79.00



## Revision of Forecast (Core)

# Sales Jan – Dec



(Billions of JPY)	Original Forecast	Revised Forecast	Revision	
	2019	2019		
	Jan - Dec	Jan - Dec		
<b>Sales</b>	<b>528.0</b>	<b>586.0</b>	<b>+ 58.0</b>	<b>+ 11.0%</b>
<b>Domestic</b>	<b>389.1</b>	<b>437.0</b>	<b>+ 47.9</b>	<b>+ 12.3%</b>
<b>Oncology</b>	<b>215.9</b>	<b>240.6</b>	<b>+ 24.7</b>	<b>+ 11.4%</b>
Avastin	89.4	95.6	+ 6.2	+ 6.9%
Perjeta	21.2	29.9	+ 8.7	+ 41.0%
Tecentriq	13.1	20.8	+ 7.7	+ 58.8%
<b>Bone and Joint</b>	<b>103.1</b>	<b>109.4</b>	<b>+ 6.3</b>	<b>+ 6.1%</b>
Actemra	38.2	42.6	+ 4.4	+ 11.5%
<b>Renal</b>	<b>31.8</b>	<b>34.1</b>	<b>+ 2.3</b>	<b>+ 7.2%</b>
<b>Others</b>	<b>38.3</b>	<b>52.9</b>	<b>+ 14.6</b>	<b>+ 38.1%</b>
Hemlibra	12.9	25.1	+ 12.2	+ 94.6%
<b>Overseas</b>	<b>138.9</b>	<b>149.0</b>	<b>+ 10.1</b>	<b>+ 7.3%</b>
Actemra	84.6	89.2	+ 4.6	+ 5.4%
Export to Roche	82.7	87.3	+ 4.6	+ 5.6%
Alecensa	36.6	42.0	+ 5.4	+ 14.8%
Export to Roche	36.0	41.3	+ 5.3	+ 14.7%

**Main reasons for the revision :**
**Avastin**

Jan – Sep results exceeded original forecast on a volume basis  
Updated original assumptions for Biosimilar Pharmaceutical

**Perjeta**

Prescriptions for preoperative and postoperative adjuvant therapy for HER2-positive breast cancer exceeded original forecast

**Tecentriq**

Prescription exceeded original forecast results, mainly for non-small cell lung cancer

**Actemra (Domestic)**

Progress well in view of the original forecast on a volume basis  
Revised original assumption regarding the NHI drug price revisions

**Hemlibra (Domestic)**

Prescription switching to Hemlibra in hemophilia A with and without inhibitors exceeded original forecast

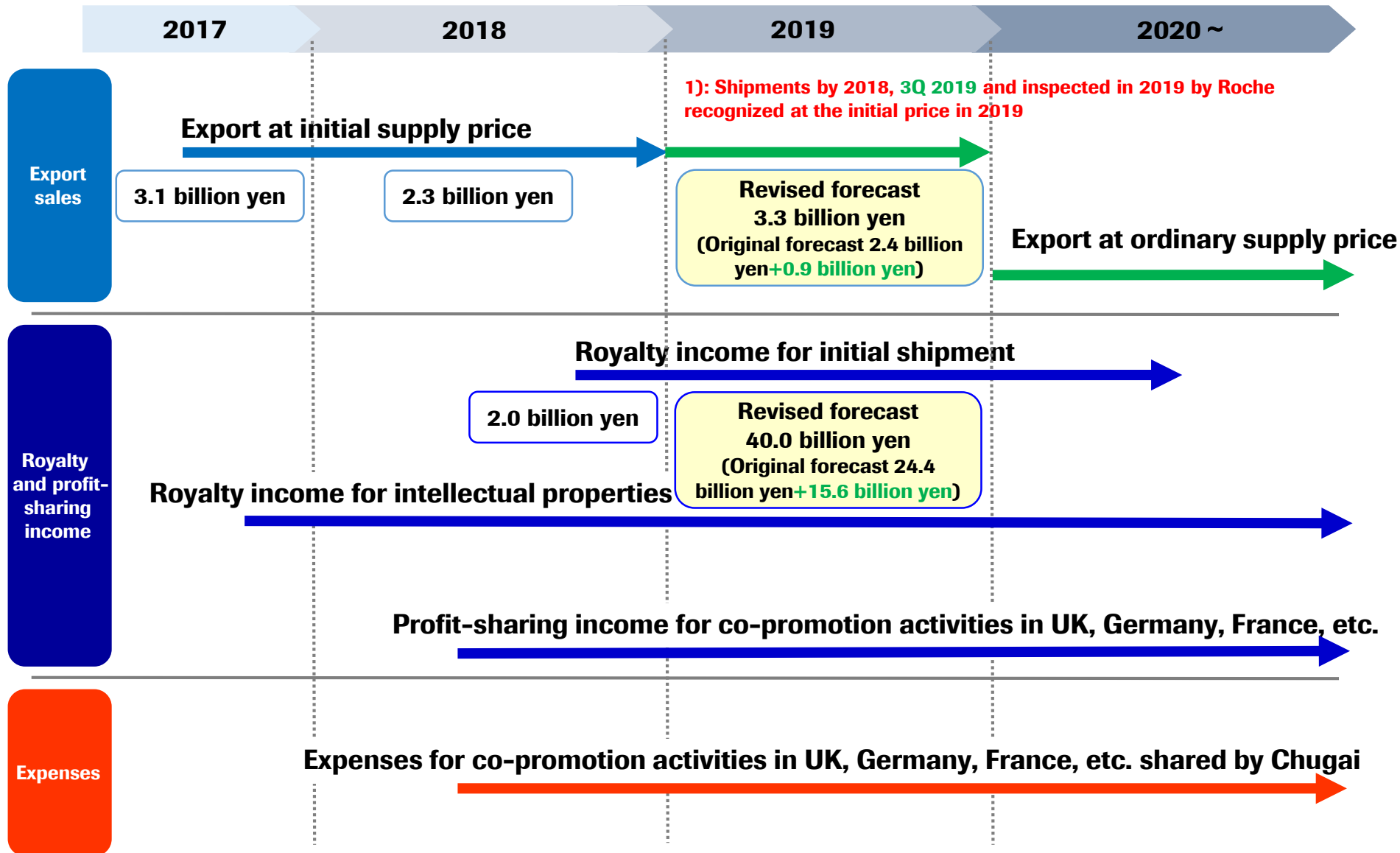
**Actemra (Overseas) and Alecensa (Overseas)**

Exports to Roche are expected to exceed original forecast on a volume basis

Revision of Forecast (Core)



# Outline of Hemlibra Sales to Roche



## Revision of Forecast



# Revised Forecast other than Earnings Forecast

## ✓ Key Performance indicators

(Billions of JPY)	Original Forecast	Revised Forecast	Revision	Reason for the revision
Investment on property, plant and equipment	56.0	49.5	- 6.5	Change in payment timing for Chugai Life Science Park Yokohama
Depreciation	15.0	17.5	+2.5	Restructuring for closing of Fuji Gotemba and Kamakura research laboratories; Closing of Chugai Distribution Co., Ltd.

## ✓ Year-End Dividend

	Original Forecast	Revised Forecast	Revision	Reason for the revision
Year-End Dividend	48.00JPY	Undecided	Undecided	<p>Reflecting the significant changes in the profit structures, year-end dividend will be decided after the fiscal year end based on basic profit distribution principles*.</p> <p>*Taking into account the strategic funding needs and earning prospects, the Company aims for a consolidated dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable allocation of profit to all shareholders.</p>

vs. Forecast (Core)



# Financial Overview Jan - Sep

(Billions of JPY)	Actual	Original Forecast	Revised Forecast		2018	
	2019 Jan - Sep	2019 Jan - Dec	Progress	2019 Jan - Dec	Progress *	
<b>Revenues</b>	<b>508.9</b>	<b>592.5</b>	<b>85.9%</b>	<b>680.0</b>	<b>74.8%</b>	<b>73.5%</b>
Sales	440.5	528.0	83.4%	586.0	75.2%	73.6%
Domestic	324.4	389.1	83.4%	437.0	74.2%	72.7%
Overseas	116.0	138.9	83.5%	149.0	77.9%	76.5%
Royalties and other operating income	68.4	64.5	106.0%	94.0	72.8%	72.6%
Royalty and profit-sharing income	48.8	53.5	91.2%	74.0	65.9%	65.6%
Other operating income	19.6	11.0	178.2%	20.0	98.0%	78.5%
Cost of sales	- 201.3	- 252.5	79.7%	- 265.0	76.0%	74.2%
(cost to sales ratio)	45.7%	47.8%	-	45.2%	-	-
<b>Gross profit</b>	<b>307.5</b>	<b>340.0</b>	<b>90.4%</b>	<b>415.0</b>	<b>74.1%</b>	<b>73.0%</b>
Operating expenses	- 136.5	- 197.0	69.3%	- 197.0	69.3%	68.7%
Research and development	- 72.0	- 102.0	70.6%	- 102.5	70.2%	70.4%
<b>Operating profit</b>	<b>171.1</b>	<b>143.0</b>	<b>119.7%</b>	<b>218.0</b>	<b>78.5%</b>	<b>79.3%</b>
(operating margin)	33.6%	24.1%	-	32.1%	-	-
EPS (JPY)	227.06	198.00	114.7%	302.00	75.2%	76.6%

\* Jan - Sep progress versus Jan - Dec

vs. Forecast (Core)



# Sales Progress Jan - Sep

(Billions of JPY)	Actual	Original Forecast	Revised Forecast		2018	
	2019	2019	2019		Progress *	
	Jan - Sep	Jan - Dec	Progress	Jan - Dec		
<b>Sales</b>	<b>440.5</b>	<b>528.0</b>	<b>83.4%</b>	<b>586.0</b>	<b>75.2%</b>	<b>73.6%</b>
<b>Domestic</b>	<b>324.4</b>	<b>389.1</b>	<b>83.4%</b>	<b>437.0</b>	<b>74.2%</b>	<b>72.7%</b>
<b>Oncology</b>	<b>179.7</b>	<b>215.9</b>	<b>83.2%</b>	<b>240.6</b>	<b>74.7%</b>	<b>72.4%</b>
Avastin	73.0	89.4	81.7%	95.6	76.4%	72.7%
Perjeta	22.0	21.2	103.8%	29.9	73.6%	68.3%
Tecentriq	13.7	13.1	104.6%	20.8	65.9%	54.9%
<b>Bone and Joint</b>	<b>80.5</b>	<b>103.1</b>	<b>78.1%</b>	<b>109.4</b>	<b>73.6%</b>	<b>72.0%</b>
Actemra	31.0	38.2	81.2%	42.6	72.8%	71.7%
<b>Renal</b>	<b>25.9</b>	<b>31.8</b>	<b>81.4%</b>	<b>34.1</b>	<b>76.0%</b>	<b>72.5%</b>
<b>Others</b>	<b>38.4</b>	<b>38.3</b>	<b>100.3%</b>	<b>52.9</b>	<b>72.6%</b>	<b>76.8%</b>
Hemlibra	16.8	12.9	130.2%	25.1	66.9%	50.0%
<b>Overseas</b>	<b>116.0</b>	<b>138.9</b>	<b>83.5%</b>	<b>149.0</b>	<b>77.9%</b>	<b>76.5%</b>
Actemra	67.2	84.6	79.4%	89.2	75.3%	79.9%
Export to Roche	65.8	82.7	79.6%	87.3	75.4%	80.2%
Alecensa	34.8	36.6	95.1%	42.0	82.9%	66.1%
Export to Roche	34.1	36.0	94.7%	41.3	82.6%	66.1%

\* Jan - Sep progress versus Jan - Dec



# Appendix



# IFRS and Core Results Jan-Sep

(Billions of JPY)	IFRS results	Non-core items		Core results
	2019 Jan - Sep	Intangible assets	Others	2019 Jan - Sep
<b>Revenues</b>	<b>508.9</b>			<b>508.9</b>
Sales	440.5			440.5
Royalties and other operating income	68.4			68.4
Cost of sales	-202.0	+0.7		-201.3
<b>Gross profit</b>	<b>306.9</b>	<b>+0.7</b>		<b>307.5</b>
<b>Operating expenses</b>	<b>-146.0</b>	<b>+2.7</b>	<b>+6.8</b>	<b>-136.5</b>
Marketing and distribution	-54.4		+3.4	-51.0
Research and development	-76.9	+2.7	+2.2	-72.0
General and administration	-14.7		+1.2	-13.5
<b>Operating profit</b>	<b>160.9</b>	<b>+3.4</b>	<b>+6.8</b>	<b>171.1</b>
Financing costs	-0.1			-0.1
Other financial income (expense)	0.0			0.0
Other expense	-2.2			-2.2
<b>Profit before taxes</b>	<b>158.6</b>	<b>+3.4</b>	<b>+6.8</b>	<b>168.8</b>
Income taxes	-41.2	-1.0	-2.1	-44.3
<b>Net income</b>	<b>117.4</b>	<b>+2.4</b>	<b>+4.7</b>	<b>124.5</b>
EPS (JPY)	214.17			227.06

(Billions of JPY)

## Non-Core items

Intangible assets	
Amortization	+0.9
Impairment	+2.5
Others	
Early retirement incentive program	+5.1
Restructuring	+1.7

vs. 2018 Year End



# Overview of Financial Position

(Billions of JPY)	2018 Dec	2019 Sep	Change
Trade accounts receivable	150.8	161.3	+ 10.5
Inventories	159.4	169.0	+ 9.6
Trade accounts payable	-35.9	-55.0	- 19.1
Other net working capital <sup>*1</sup>	-39.1	-35.8	+ 3.3
<b>Net working capital</b>	<b>235.1</b>	<b>239.4</b>	<b>+ 4.3</b>
Property, plant and equipment	222.4	247.9	+ 25.5
Right-of-use assets	-	10.4	+ 10.4
Intangible assets	22.7	22.4	- 0.3
Other long-term assets - net <sup>*2</sup>	25.1	28.0	+ 2.9
<b>Long-term net operating assets</b>	<b>270.1</b>	<b>308.7</b>	<b>+ 38.6</b>
<b>Net operating assets</b>	<b>505.3</b>	<b>548.2</b>	<b>+ 42.9</b>
Debt	-0.2	-	+ 0.2
Marketable securities	102.5	109.1	+ 6.6
Cash and cash equivalents	146.9	177.0	+ 30.1
<b>Net cash</b>	<b>249.2</b>	<b>286.2</b>	<b>+ 37.0</b>
<b>Other non-operating assets - net<sup>*3</sup></b>	<b>2.1</b>	<b>-21.2</b>	<b>- 23.3</b>
<b>Net non-operating assets</b>	<b>251.3</b>	<b>265.0</b>	<b>+ 13.7</b>
<b>Total net assets</b>	<b>756.5</b>	<b>813.1</b>	<b>+ 56.6</b>
Total assets	919.5	1,025.3	+ 105.8
Total liabilities	-163.0	-212.2	- 49.2

\*1 Other net working capital: accrued receivable, accrued payable, accrued expenses, etc.

\*2 Other long-term assets - net: long term prepaid expenses, long-term provisions, etc.

\*3 Other non-operating assets - net: deferred income tax assets, accrued corporate tax, etc.

## Increase in net working capital

Increase in trade accounts receivable and inventories due to increased sales of new products and mainstay products almost offset by increase in trade accounts payable

Despite increase in accrued payable for establishment of Chugai Life Science Park Yokohama, other net working capital increased due to increase of accrued receivable of royalties for Hemlibra, etc.

## Increase in long-term net operating assets

Increase in property, plant and equipment due mainly to the investment in the Chugai Life Science Park Yokohama.

Increase in right-of-use assets by adoption of IFRS16

## Decrease in other non-operating assets - net

Increase in lease liabilities and accrued corporate tax, etc. by adoption of IFRS16

## Equity ratio attributable to Chugai shareholders

End of September 2019 79.3%

End of December 2018 82.2%

FX rate to the JPY  
(end of period)

	2018 Dec	2019 Sep
1CHF	112.03	108.93
1EUR	126.13	118.07
1USD	110.28	107.94
1SGD	80.70	78.12



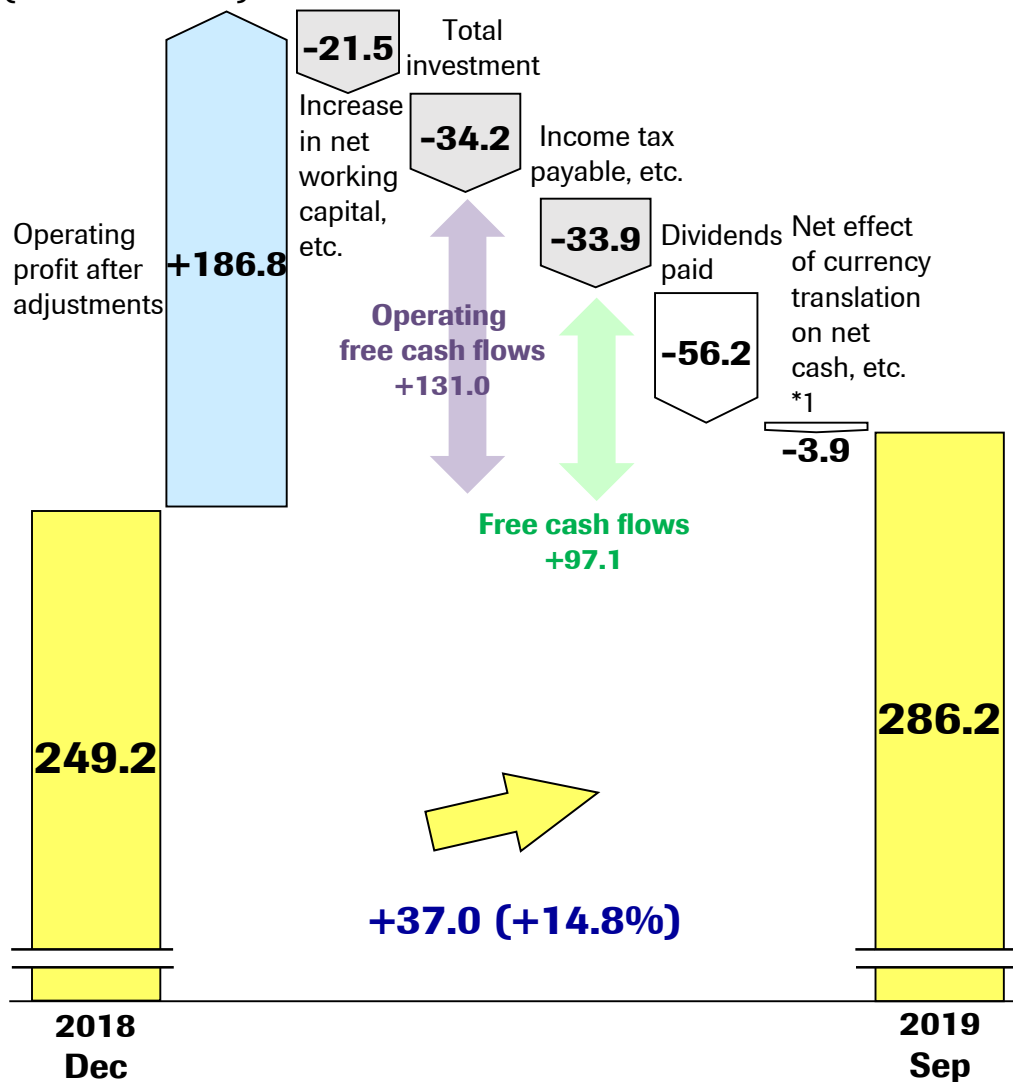
vs. 2018 Year End



Roche Roche Group

# Net Cash

(Billions of JPY)



<b>Operating profit after adjustment</b>	<b>+186.8</b>
Operating profit	+160.9
<b>Increase in net working capital, etc.</b>	<b>-21.5</b>
<b>Total investment</b>	<b>-34.2</b>
Property, plant and equipment	-21.1
Payment for lease liabilities	-6.6
Intangible assets	-6.5
<b>Operating free cash flows</b>	<b>+131.0</b>
<b>Income tax payable, etc.</b>	<b>-33.9</b>
Income tax payable	-34.5
Transfer pricing taxation	-2.2
Purchases of investment securities	-1.0
Sales of investment securities	+4.1
<b>Free cash flows</b>	<b>+97.1</b>
<b>Dividends paid</b>	<b>-56.2</b>
<b>Net effect of currency translation on net cash, etc.</b>	<b>-3.9</b>
Purchase of non-controlling interests	-2.3

\*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 flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

# Overview of Development Pipeline

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

October 24, 2019



# Projects under Development (1)

As of October 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>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) - NSCLC (neoadjuvant) - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - early breast cancer - ovarian cancer - HCC - HNC (adjuvant)	<b>RG6268 / Rozlytrek</b> - NSCLC  <b>RG3502 / Kadcylla</b> - breast cancer (adjuvant) ★
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

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 July 25, 2019**

# Projects under Development (2)



As of October 24, 2019



	Phase I	Phase II	Phase III	Filed
Autoimmune	<b>RG7845 / fenebrutinib</b> - rheumatoid arthritis  <b>RG7880 (IL-22 fusion protein)</b> - inflammatory bowel disease★			
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>RG7314 / balovaptan</b> - autism spectrum disorder		<b>RG1450 / gantenerumab</b> - Alzheimer's disease  <b>SA237 (RG6168) / satralizumab (JP)</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)	<b>SA237 (RG6168) / satralizumab (US/EU)</b> - NMOSD★
Others	<b>PCO371</b> - hypoparathyroidism  <b>AMY109</b> - endometriosis  <b>NXT007</b> - hemophilia A★	<b>CIM331 / nemolizumab*</b> - pruritus in dialysis patients  <b>SKY59 (RG6107) / crovalimab</b> - PNH (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.

DME: diabetic macular edema  
 wAMD: wet age-related macular degeneration  
 DMD: Duchenne muscular dystrophy

NMOSD: neuromyelitis optica spectrum disorder  
 HTT ASO: Antisense oligonucleotide targeting *HTT* mRNA  
 PNH: paroxysmal nocturnal hemoglobinuria

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

**★: Projects with advances in stages since July 25, 2019**

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

# Key News Flows in Q3



Launched	<b>Rozlytrek</b>	<i>NTRK+</i> solid tumor	September, 2019
Approved	<b>Tecentriq</b>	ES SCLC PD-L1+ TNBC	August, 2019 September, 2019
	<b>F1 CDx</b>	CDx for Lynparza	September, 2019
Filed	<b>satralizumab</b>	NMOSD (US/EU)	August, 2019 (EU)
	<b>Kadcyla</b>	HER2+ early breast cancer (adjuvant)	August, 2019
	<b>F1 CDx</b>	CDx for Rozlytrek ( <i>ROS1+</i> NSCLC)	September, 2019
New to Pipeline	<b>NXT007</b>	Hemophilia A	P1 study
	<b>RG7880</b>	Inflammatory bowel disease	P1 study
Development Discontinued	<b>Tecentriq</b>	Castration resistant prostate cancer	-
Late-stage Readouts	<b>Tecentriq</b>	Urothelial carcinoma* Advanced NSCLC (NSQ/SQ) Unresectable HCC	P3 study (IMvigor130)** P3 study (IMpower110)** P3 study (IMbrave150)
	<b>Perjeta/Herceptin</b>	FDC (sc)	P3 study (FeDeriCa)
Medical Conference	<b>satralizumab</b> <b>Alecensa</b> <b>nemolizumab</b>	NMOSD/SAkuraStar ALEX (update), B-FAST Prurigo nodularis/P2 study	ECTRIMS2019 ESMO2019 EADV2019
Others	<b>satralizumab</b> <b>nemolizumab</b> <b>OWL833</b>	NMO/NMOSD(JP) Atopic dermatitis (overseas) Type 2 diabetes	Orphan Drug Designation P3 initiated (Galderma) P1 initiated (Eli Lilly)

ES SCLC: extensive-stage small cell lung cancer  
 TNBC: triple negative breast cancer  
 F1 CDx: FoundationOne CDx Cancer Genomic Profile  
 CDx: companion diagnostics  
 NSCLC: non-small cell lung cancer  
 NSQ/SQ: non-squamous/squamous  
 NMO: neuromyelitis optica  
 NMOSD: neuromyelitis optica spectrum disorder

HCC: hepatocellular carcinoma  
 FDC: fixed-dose combination  
 sc: subcutaneous injection  
 ECTRIMS: European Committee for Treatment and Research in Multiple Sclerosis  
 ESMO: European Society for Medical Oncology  
 EADV: European Academy of Dermatology and Venereology

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

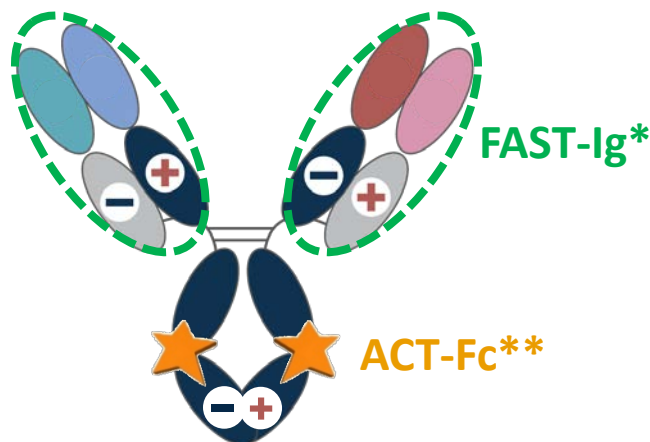
\* previously untreated locally advanced or metastatic  
 \*\* Data presented at ESMO2019

# NXT007

## A Bispecific Antibody to Coagulation Factors IXa and X

### Mode of action (MoA)

NXT007 supports the interaction between activated factor IX (FIXa) and factor X (FX), thereby promoting FIXa-catalyzed activation of FX, and accelerating coagulation (same MoA as Hemlibra)



Source: Partially revised from PEGS Boston, 2014

### Major antibody engineering technology applied to NXT007

- **FAST-Ig**  
A technology that enables improvement of large-scale production of bispecific antibody by controlling electrostatic interactions between heavy and light chains
- **ACT-Fc**  
A technology expected to improve antibody pharmacokinetics

\* Four-chain Assembly by electrostatic Steering Technology – Immunoglobulin

\*\* Antibody Clearance controlling Technology – Fc region

### Target Profile

- Achieve normal level of hemostatic ability
- Improved convenience in administration

# RG7880 human IL-22 fusion protein (1/2)

## Inflammatory bowel Disease (IBD)

- Diseases of chronic or remitting/relapsing intestinal inflammation
- Mucosal healing, the current therapeutic goal for IBD, is not achieved with existing treatment in patients who have clinical remission

### Ulcerative colitis



Erosion and/or ulcers primarily occur in the large intestine

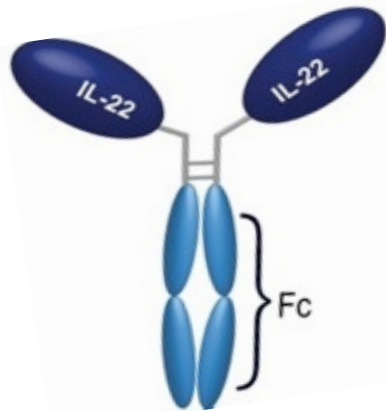
### Crohn's Disease



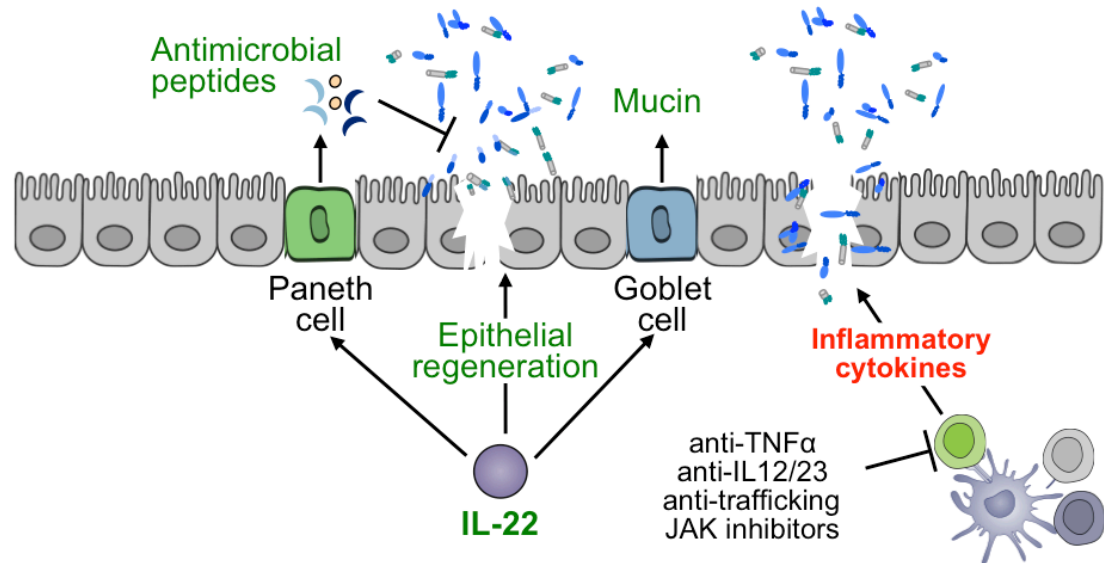
Inflammation and/or ulcer occur in the gastrointestinal tract, mainly in the small and large intestine

# RG7880 human IL-22 fusion protein (2/2)

## RG7880



RG7880 is a fusion protein of human IL-22 linked to IgG4 Fc part



Source: Genentech Inc.

## Mode of Action

RG7880 promotes regenerative and protective function of IL-22 in epithelial tissue and has the potential to treat IBD

### <Role of IL-22>

- Increase epithelial cell proliferation to repair intestinal tissue
- Stimulate mucus production to strengthen the intestinal barrier
- Modulate the intestinal microflora through the production of antibacterial peptides



# Satralizumab as add-on therapy in NMOSD

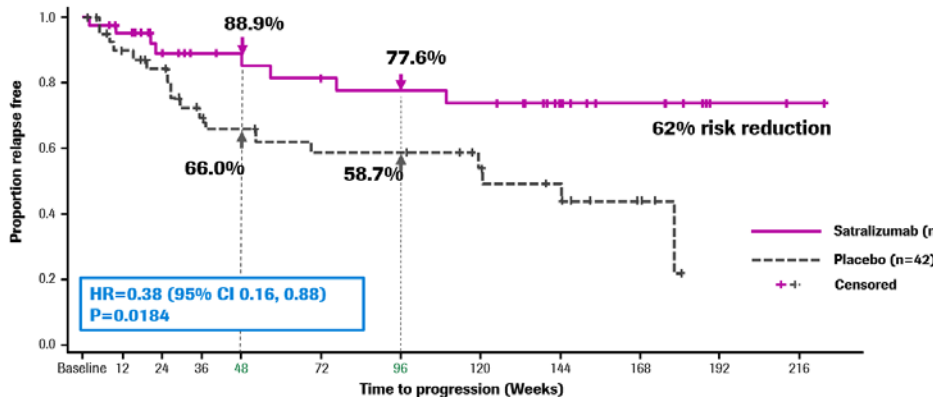


79% relapse risk reduction in AQP4+ patients

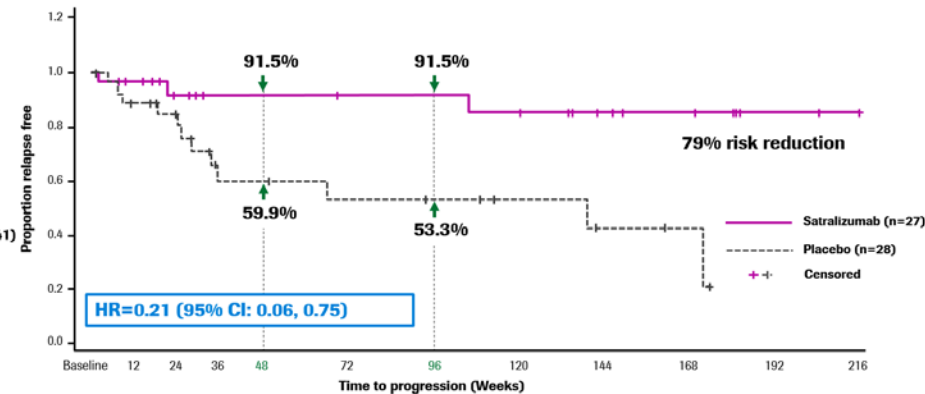
## Ph III results add-on therapy (SAkuraSky):



Risk of protocol-defined relapse (ITT population)



Risk of protocol-defined relapse (AQP4+ patients)



- Add-on therapy to baseline immunosuppressant therapy reduced risk of relapse in the ITT population by 62%, in the AQP4+ patients by 79% with 91.5% of AQP4+ patients being relapse free at 48 and 96 weeks
- Efficacy was generally consistent across pre-specified subgroups

Yamamura et al. ECTRIMS 2018; Analysis based on ITT population; p-value based on log-rank test stratified by geographic region and baseline relapse rate. Protocol-defined relapse as adjudicated by the independent clinical endpoint committee. EDSS/FSS was assessed within 7 days of relapse reporting. CI=confidence interval; EDSS=Expanded Disability Status Scale; FSS=functional system scores; ITT=intent to treat

# Satralizumab as monotherapy in NMOSD

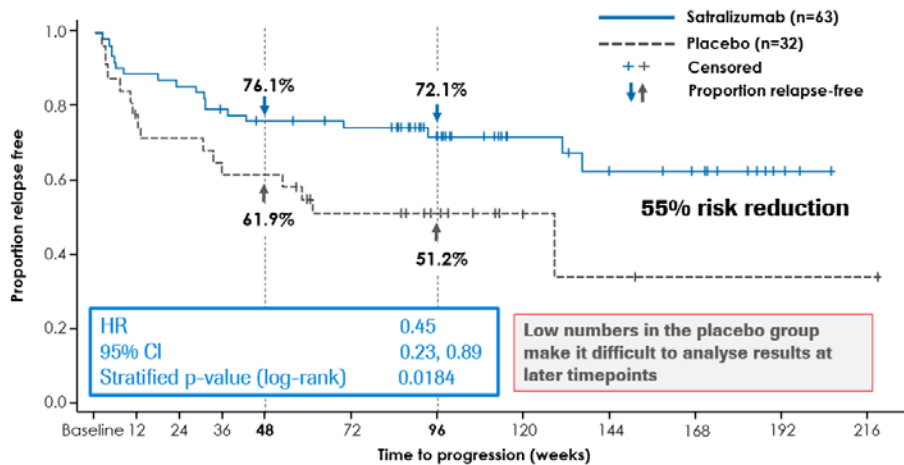


74% relapse risk reduction in AQP4+ patients

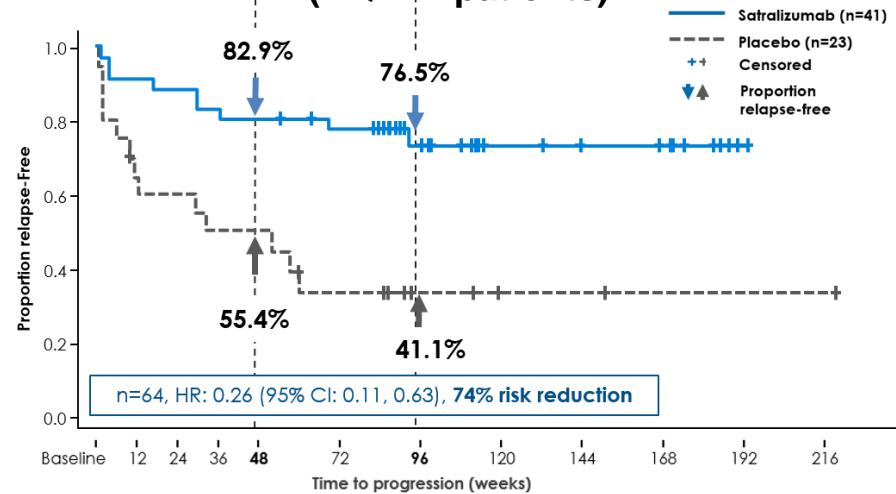


## Ph III results monotherapy (SAkuraStar):

**Risk of protocol-defined relapse (ITT population)**



**Risk of protocol-defined relapse (AQP4+ patients)**



- Relapse risk was reduced by 55% in the ITT population with 76% and 72% of patients being relapse-free at week 48 and 96, respectively
- Relapse risk was reduced by 74% in AQP4+ patients (not affected by prior therapy or most recent attack type) with 83% and 77% being relapse-free at week 48 and 96, respectively

Bennett J.L. et al., ECTRIMS 2019; Analysis based on ITT population; p-value (based on log-rank test) and hazard ratio (using Cox proportional-hazards model) stratified by prior therapy for prevention of NMOSD attack (B-cell-depleting or immunosuppressants/other) and by most recent attack in the year prior to screening (first attack vs relapse); CI=confidence interval; HR=hazard ratio; ITT=intention to treat

# Projected Submissions (Post PoC NMEs and Products)

as of October 24, 2019



Filed

<b>ROZLYTREK</b> (RG6268) NSCLC (ROS1+)	<b>satralizumab</b> (SA237/RG6168) NMOSD (US)
<b>KADCYLA</b> (RG3502) Breast Cancer (adjuvant)	<b>satralizumab</b> (SA237/RG6168) NMOSD (EU)
<b>EDIROL</b> (ED-71) Osteoporosis (China)	

**NME**      **line extension**

**in-house**      ■     

**in-licensed**      ■     

NSCLC: non-small cell lung cancer  
 RCC: renal cell carcinoma  
 MIUC: muscle invasive urothelial carcinoma  
 HCC: hepatocellular carcinoma  
 HNC: head and neck carcinoma  
 DLBCL: diffuse large B-cell lymphoma

NMOSD: neuromyelitis optica spectrum disorder  
 wAMD: wet age-related macular degeneration  
 FDC: fixed-dose combination  
 sc: subcutaneous injection  
 HTT ASO: Antisense oligonucleotide targeting *HTT* mRNA

	<b>TECENTRIQ</b> (RG7446) Ovarian Cancer	<b>risdiplam</b> (RG7916) Spinal Muscular Atrophy			<b>gantenerumab</b> (RG1450) Alzheimer's Disease	
	<b>AVASTIN</b> (RG435) RCC	<b>RG6206</b> Duchenne Muscular Dystrophy			<b>ALECENSA</b> (AF802/RG7853) NSCLC (adjuvant)	<b>nemolizumab*</b> (CIM331) Pruritus in Dialysis Patients
	<b>TECENTRIQ</b> (RG7446) RCC	<b>ipatasertib</b> (RG7440) Breast Cancer	<b>ipatasertib</b> (RG7440) Prostate Cancer		<b>TECENTRIQ</b> (RG7446) HNC (adjuvant)	<b>faricimab</b> (RG7716) wAMD
<b>satralizumab</b> (SA237/RG6168) NMOSD (JP)	<b>TECENTRIQ</b> (RG7446) MIUC (adjuvant)	<b>AVASTIN</b> (RG435) HCC	<b>TECENTRIQ</b> (RG7446) Early Breast Cancer	<b>RG6264</b> (FDC, sc) Breast cancer	<b>TECENTRIQ</b> (RG7446) RCC (adjuvant)	<b>faricimab</b> (RG7716) Diabetic Macular Edema
<b>SUVENYL</b> (NRD101) Knee Osteoarthritis /Shoulder Periarthritis (China)	<b>TECENTRIQ</b> (RG7446) Urothelial Carcinoma	<b>TECENTRIQ</b> (RG7446) HCC	<b>TECENTRIQ</b> (RG7446) NSCLC (neoadjuvant)	<b>polatuzumab vedotin</b> (RG7596) DLBCL	<b>TECENTRIQ</b> (RG7446) NSCLC (adjuvant)	<b>HTT ASO</b> (RG6042) Huntington's Disease

2019

2020

2021

2022 and beyond

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

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