



Aiming to Achieve the Mid-term Business Plan “IBI 21” - FY2019 Half Year Results -

Tatsuro Kosaka
President and CEO
CHUGAI PHARMACEUTICAL CO., LTD.

July 25/26, 2019



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.

FY2019 Half Year Financial Performance



- Significant year-on-year increase in revenues and operating profit
- Progress beyond our expectation due to strong sales of new products such as Tecentriq in addition to favorable Hemlibra related revenues in Japan and overseas

billions JPY	2018 Jan - Jun actual	2019 Jan - Jun actual	Growth		2019 Jan - Dec forecast	Progress (%)
Revenues	285.1	320.3	+35.2	+12.3%	592.5	54.1%
Sales	255.6	282.4	+26.8	+10.5%	528.0	53.5%
Domestic	191.1	210.0	18.9	+9.9%	389.1	54.0%
Overseas	64.5	72.4	+7.9	+12.2%	138.9	52.1%
Royalties and other operating income (ROOI)	29.5	37.9	+8.4	+28.5%	64.5	58.8%
Core Operating Profit	71.6	103.5	+31.9	+44.6%	143.0	72.4%
Core EPS (yen)	95.27	137.11	+41.84	+43.9%	198.00	69.2%



New Mid-Term Business Plan: 5 Strategies

Accelerate corporate and social development through innovation focused on innovative products

Create global growth drivers and maximize value

1 Value Creation

Realize innovative drug discovery to cure and manage diseases

2 Value Delivery

Deliver patient-centric solutions to maximize value of growth drivers

3 Promote advances in personalized healthcare

Realize the further advancement of PHC and innovate R&D process by utilizing digital technology and data

Strengthen HR and infrastructure that support Chugai's business

4 Human capital and structural reform

Develop high-caliber HR talent that supports innovation, and drastically reform costs, systems and processes

5 Strengthen sustainable platforms

Simultaneously realize company growth and sustainable social development

Major Achievements in FY2019 Half Year (1)



1. Value Creation / 2. Value Delivery / 3. Promote Advances in PHC

Progress in development projects [Strategy 1&2]

- Hemlibra: “Hemophilia A without inhibitors” (Approval in EU)
- Rozlytrek: “*NTRK*+ solid tumors” Approval, “*ROS1*+ NSCLC” Filing
- Nemolizumab: “Atopic dermatitis” Achievement of primary end point
- Telomelysin: Exclusive licensing and capital tie-up agreements
- Others: “Actemra CRS, Adult Still’s disease” Approval for additional indications
“Alecensa ALCL” Filing for additional indication

Progress in PHC [Strategy 3]

- FMI business: “F1CDx cancer genomic profile” Launch, “Rozlytrek CDx” Approval

Digital and IT strategy reinforcement [Strategy 1-3]

- Establishment of Digital & IT Supervisory Division: Acceleration in value creation and process innovation

PHC: personalized health care
NSCLC: non-small cell lung cancer
CRS: cytokine release syndrome



ALCL: anaplastic large cell lymphoma
F1CDx: FoundationOne CDx

Steady progress in IBI 21 first year’s projects

Major Achievements in FY2019 Half Year (2)



4. Human Capital and Structural Reform / 5. Strengthen Sustainable Platforms

Human capital and structural reform [Strategy 4]

- Business transfer:
 - ✓ Long-Term Listed Products (Oxarol dermatological products, ULCERLMIN)
- Outsourcing:
 - ✓ Logistics operations (Mitsubishi Logistics Corporation)
 - ✓ Packaging operations (Under consideration of full outsourcing)
- Early retirement incentive program:
 - ✓ Providing support for employees seeking for a new life plan
 - ✓ Addressing the Company's management issues in the fast and dramatically changing business environment

Strengthen sustainable platforms [Strategy 5]

- Engagement with stakeholders:
 - ✓ Held an ESG meeting



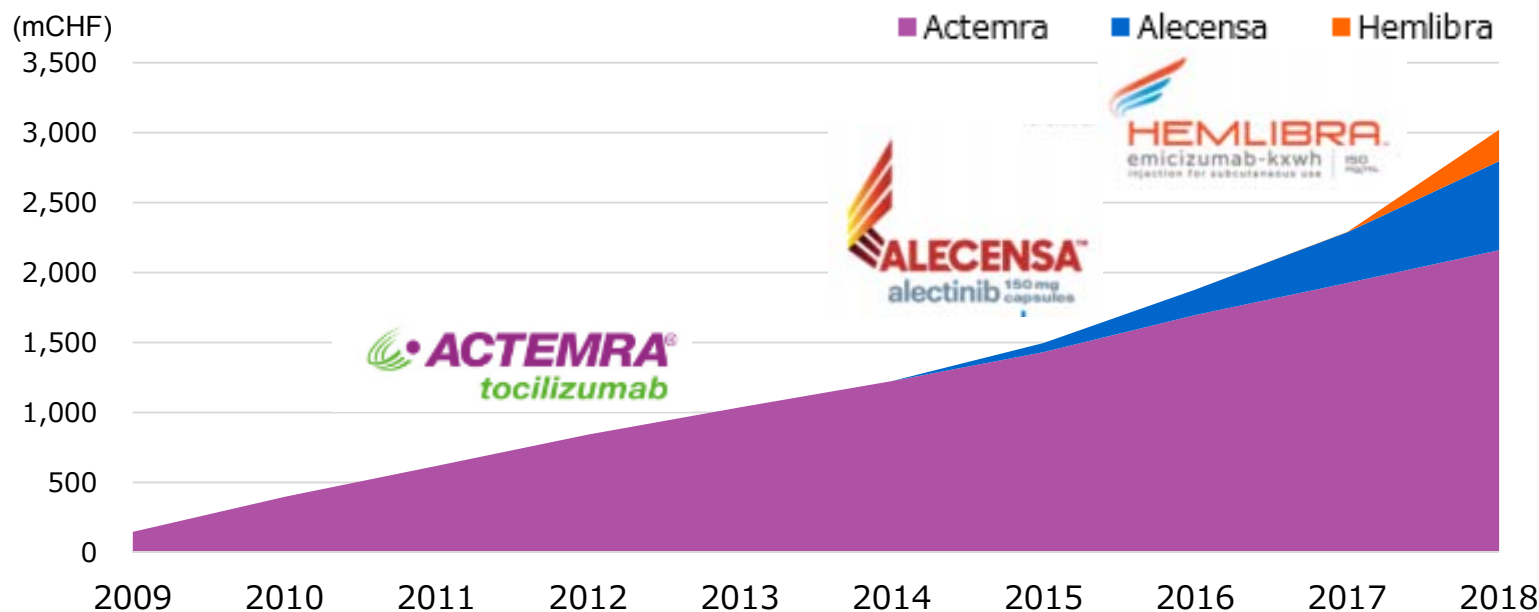
IBI 21's core issues are progressing as planned

Sales Trend of In-house Global Products



The total of Roche's global sales* for **three in-house products** reached **300 billion yen** at the end of last year.

IBI 21 outlook: While factoring in Actemra's maturation, we project dramatic growth in global sales of Alecensa and Hemlibra.



Roche's global sales / () Chugai's sales**	Actemra	Alecensa	Hemlibra
Half year 2019	1,135 (188)	421 (105)	535 (82)
Full year 2018	2,160 (354)	637 (188)	224 (26)
Full year 2017	1,926 (304)	362 (147)	3 (-)

* Roche's global sales: In addition to Roche's worldwide sales, Chugai's sales are included. **Chugai's sales: Sum of Chugai's domestic sales and overseas sales from its territory (excluding export sales)
 Graphs and tables are based on Roche's financial results in units of CHF 1 million.

Key Activities for Future Growth



Active investment in research and production functions as a foundation of growth after IBI 21

Chugai Life Science Park Yokohama <Yokohama, Kanagawa pref.>

<Purpose>

Establish a global base for creating innovative new drugs at its highest quality (Consolidation of research laboratories)

<Total Investment>

127.3 billion yen (Expected completion year: 2022)

<Environmental aspects>

Design in harmony with the local community and incorporate environmental considerations such as energy saving measures and CO₂ reduction



Manufacturing building for small and middle molecule APIs <Fujieda, Shizuoka pref.>

<Purpose>

- ✓ Newly establish the manufacturing capability of middle molecule APIs for clinical studies
- ✓ Enhance the supply capacity of small molecule APIs for clinical studies

<Total Investment>

18.2 billion yen (Expected completion year: 2022)

<Environmental aspects>

Adopt advanced containment facility for highly active compounds



APIs: Active pharmaceutical ingredients

FY2019 Half Year Results



- **Financial performance exceeded our expectation of full year forecast**
- **Development projects and structural reforms are progressing as planned**
- **Initiate key activities and upfront investments for future growth**



Great start of IBI 21 towards achieving the mid-term business plan



FY2019 2Q Consolidated Financial Overview

Toshiaki Itagaki
Executive Vice President & CFO
CHUGAI PHARMACEUTICAL CO., LTD.

July 25/26, 2019

Core



Roche Roche Group

2Q Results Summary

- Significant year-on-year increase in revenues and operating profit
- Record-high Q2 revenues, operating profit and net income
- Strong progress vs. full-year forecast

(Billions of JPY)	2019 Jan – Jun	Growth (year on year)		Forecast on Jan. 31 Progress
Revenues	320.3	+35.2	+12.3%	54.1%
Cost of sales cost to sales ratio	-127.5 45.1%	+1.1 -5.2%pts	-0.9%	50.5%
Operating expenses	-89.2	-4.3	+5.1%	45.3%
Operating profit operating margin	103.5 32.3%	+31.9 +7.2%pts	+44.6%	72.4%
Net income	75.1	+22.5	+42.8%	Not disclosed
EPS (JPY)	137.11	+41.84	+43.9%	69.2%

Year on Year (Core)



Financial Overview Jan - Jun

(Billions of JPY)	2018 Jan - Jun	2019 Jan - Jun	Growth	
Revenues	285.1	320.3	+35.2	+12.3%
Sales	255.6	282.4	+26.8	+10.5%
Domestic	191.1	210.0	+18.9	+9.9%
Overseas	64.5	72.4	+7.9	+12.2%
Royalties and other operating income	29.5	37.9	+8.4	+28.5%
Royalty and profit-sharing income	10.1	30.2	+20.1	+199.0%
Other operating income	19.5	7.6	-11.9	-61.0%
Cost of sales	-128.6	-127.5	+1.1	-0.9%
(cost to sales ratio)	50.3%	45.1%	-5.2%pts	-
Gross profit	156.6	192.7	+36.1	+23.1%
Operating expenses	-84.9	-89.2	-4.3	+5.1%
Operating profit	71.6	103.5	+31.9	+44.6%
(operating margin)	25.1%	32.3%	+7.2%pts	-
Financial account balance	-1.6	-1.3	+0.3	-18.8%
Income taxes	-17.5	-27.1	-9.6	+54.9%
Net income	52.6	75.1	+22.5	+42.8%
EPS (JPY)	95.27	137.11	+41.84	+43.9%

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 to mainly increase of research and development expenses

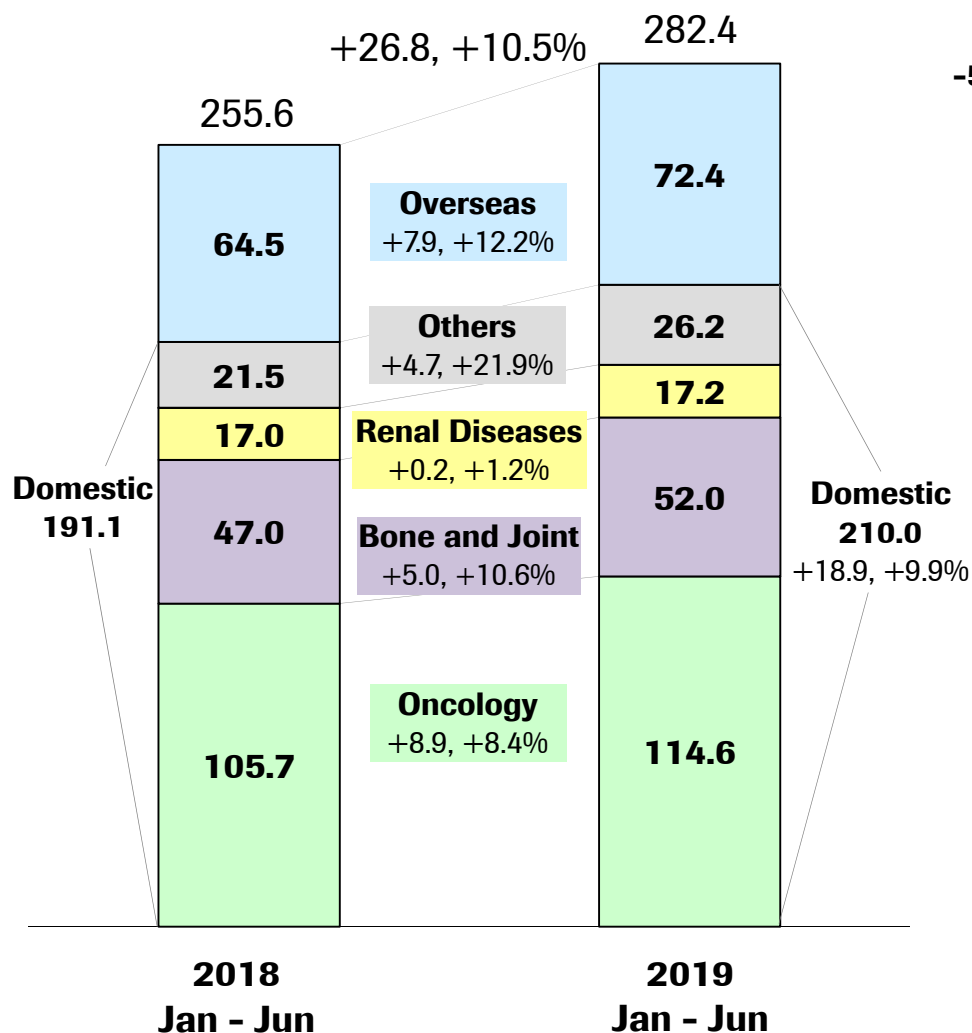


Year on Year (Core)

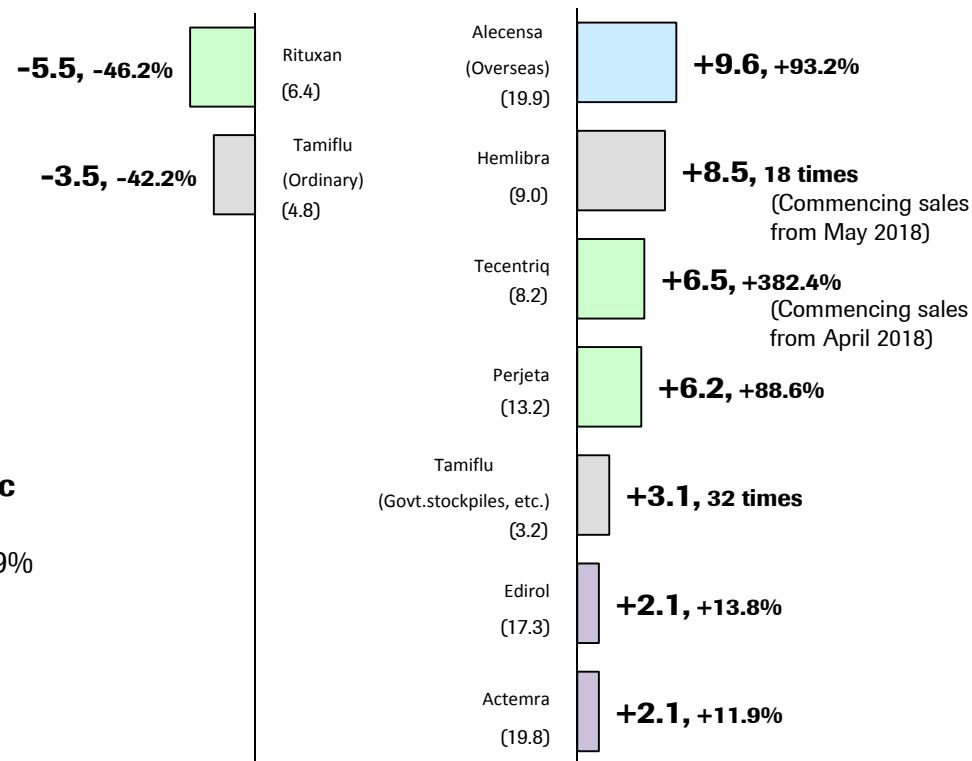
Sales Jan - Jun

Sales by Disease Area,
Year on Year Comparisons

(Billions of JPY)



Sales by Products,
Year on Year Changes



Details of HER2 franchise (31.2) +6.4, +25.8%

Herceptin	(13.6)	-0.2	-1.4%
Perjeta	(13.2)	+6.2	+88.6%
Kadcyla	(4.4)	+0.4	+10.0%

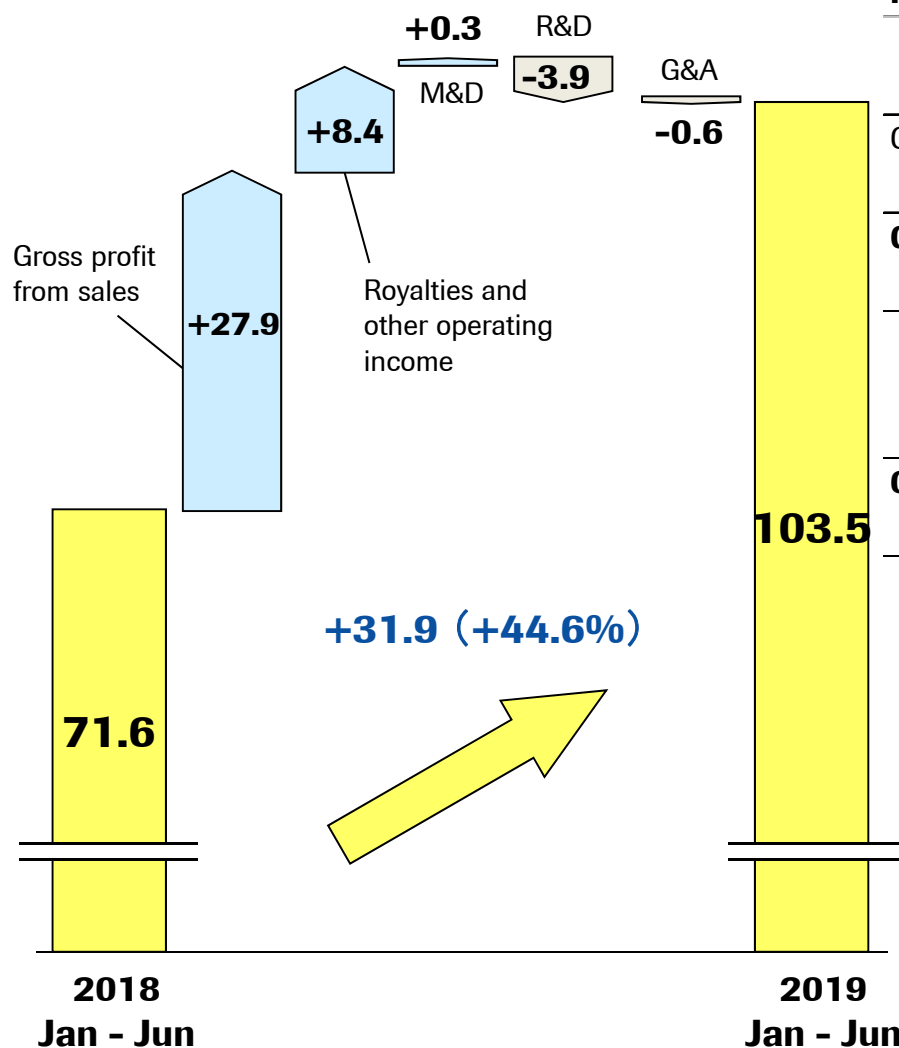
(): Actual sales in FY2019
%: Year-on-year percentage change

Year on Year (Core)



Operating Profit Jan - Jun

(Billion of JPY)



(Billions of JPY)	2018 Jan - Jun	2019 Jan - Jun	Growth
Revenues	285.1	320.3	+35.2
Sales	255.6	282.4	+26.8
Royalties and other operating income	29.5	37.9	+8.4
Cost of sales	-128.6	-127.5	+1.1
(cost to sales ratio)	50.3%	45.1%	-5.2%pts
Gross profit	156.6	192.7	+36.1
<i>of which</i> Sales	127.0	154.9	+27.9
Marketing and distribution	-33.2	-32.9	+0.3
Research and development	-44.0	-47.9	-3.9
General and administration	-7.8	-8.4	-0.6
Operating profit	71.6	103.5	+31.9
(operating margin)	25.1%	32.3%	+7.2%pts

- Increase in gross profit from sales** **+27.9**
 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** **+8.4**
 Increase in income for Hemlibra
- Increase in research and development expenses** **-3.9**
 Progress of projects, etc.

Year on Year (Core)

Financial Overview Apr - Jun



(Billions of JPY)	2018	2019	Growth	
	Apr - Jun	Apr - Jun		
Revenues	137.7	166.0	+28.3	+20.6%
Sales	130.8	144.7	+13.9	+10.6%
Domestic	98.3	110.7	+12.4	+12.6%
Overseas	32.6	34.0	+1.4	+4.3%
Royalties and other operating income	6.8	21.3	+14.5	+213.2%
Royalty and profit-sharing income	5.1	16.6	+11.5	+225.5%
Other operating income	1.8	4.7	+2.9	+161.1%
Cost of sales	-65.1	-63.9	+1.2	-1.8%
(cost to sales ratio)	49.8%	44.2%	-5.6%pts	-
Gross profit	72.6	102.1	+29.5	+40.6%
Operating expenses	-43.8	-46.5	-2.7	+6.2%
Operating profit	28.8	55.7	+26.9	+93.4%
(operating margin)	20.9%	33.6%	+12.7%pts	-
Financial account balance	-0.9	-0.6	+0.3	-33.3%
Income taxes	-6.6	-16.2	-9.6	+145.5%
Net income	21.3	38.9	+17.6	+82.6%
EPS (JPY)	38.75	70.95	+32.20	+83.1%

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

Increase in milestone income

Cost of sales

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, general and administration expenses

vs. Forecast (Core)

Financial Overview Jan - Jun



(Billions of JPY)	Actual	Forecast on Jan. 31		2018
	2019 Jan - Jun	2019 Jan - Dec	Progress	Progress *
Revenues	320.3	592.5	54.1%	49.2%
Sales	282.4	528.0	53.5%	48.4%
Domestic	210.0	389.1	54.0%	47.8%
Overseas	72.4	138.9	52.1%	50.4%
Royalties and other operating income	37.9	64.5	58.8%	56.8%
Royalty and profit-sharing income	30.2	53.5	56.4%	41.9%
Other operating income	7.6	11.0	69.1%	69.9%
Cost of sales	-127.5	-252.5	50.5%	49.1%
(cost to sales ratio)	45.1%	47.8%		
Gross profit	192.7	340.0	56.7%	49.3%
Operating expenses	-89.2	-197.0	45.3%	45.3%
Research and development	-47.9	-102.0	47.0%	46.7%
Operating profit	103.5	143.0	72.4%	55.0%
(operating margin)	32.3%	24.1%		
EPS (JPY)	137.11	198.00	69.2%	54.0%

* Jan - Jun progress versus Jan - Dec

Domestic sales

Steady progress due to sales growth of new products as well as mainstay products

Overseas sales

Progress nearly in line with forecast

Royalty and profit-sharing income

Income for Hemlibra progressed well in view of the forecast

Other operating income

Progress nearly in line with forecast

Cost of sales

 Cost to sales ratio lower than forecast
 A portion of royalties booked in the previous year and included in the current year forecast as well, was not recognized in the 1H of 2019

Operating expenses

Progress nearly in line with forecast

Billions of JPY

FX impact	
Jan - Jun 2019 FX impact vs. Assumption	
Revenue	-1.3
Sales	-0.4
Royalties and other operating income	-0.9
Cost of sales	+0.1
Expenses	+0.3
Operating profit	-1.0

vs. Forecast (Core)

Sales Progress Jan - Jun



(Billions of JPY)	Actual		Forecast	2018 Progress *1
	2019 Jan - Jun	2019 Jan - Dec	Progress	
Sales	282.4	528.0	53.5%	48.4%
Domestic	210.0	389.1	54.0%	47.8%
Oncology	114.6	215.9	53.1%	46.8%
Avastin	46.7	89.4	52.2%	47.5%
Alecensa	11.1	25.1	44.2%	45.6%
Herceptin	13.6	24.0	56.7%	49.1%
Perjeta	13.2	21.2	62.3%	43.5%
Rituxan	6.4	13.5	47.4%	55.9%
Tecentriq	8.2	13.1	62.6%	18.7%
Xeloda	4.7	9.4	50.0%	48.8%
Kadcyla	4.4	9.1	48.4%	47.1%
Tarceva	2.5	5.6	44.6%	53.0%
Gazyva	1.5	1.8	83.3%	-
Alaglio	0.1	0.4	25.0%	33.3%
Bone and Joint	52.0	103.1	50.4%	46.8%
Actemra	19.8	38.2	51.8%	46.3%
Edirol	17.3	35.3	49.0%	46.2%
Bonviva	4.8	10.9	44.0%	46.8%
Suvenyl	3.6	6.1	59.0%	47.4%

(Billions of JPY)	Actual		Forecast	2018 Progress *1
	2019 Jan - Jun	2019 Jan - Dec	Progress	
Renal	17.2	31.8	54.1%	46.8%
Mircera	11.0	20.5	53.7%	45.9%
Oxarol	3.4	5.9	57.6%	47.9%
Others	26.2	38.3	68.4%	57.3%
Hemlibra	9.0	12.9	69.8%	16.7%
CellCept	4.6	9.0	51.1%	47.8%
Tamiflu(Ordinary use)	4.8	3.4	141.2%	82.2%
Tamiflu(Govt. stockpiles, etc.)	3.2	3.2	100.0%	20.0%
Foundation Medicine ^{*2}	0.0	0.2	0.0%	-
Overseas	72.4	138.9	52.1%	50.4%
Actemra	43.5	84.6	51.4%	55.7%
Export to Roche	42.6	82.7	51.5%	56.0%
Alecensa	19.9	36.6	54.4%	34.9%
Export to Roche	19.4	36.0	53.9%	34.6%
Neutrogen	5.0	9.5	52.6%	51.4%
Hemlibra	1.6	2.4	66.7%	52.2%
Export to Roche	1.6	2.4	66.7%	52.2%

*1 Jan - Jun progress versus Jan - Dec

*2 Foundation Medicine : Forecast announced on Jul 25

vs. 2018 Year End



Overview of Financial Position

(Billions of JPY)	2018 Dec	2019 Jun	Change
Trade accounts receivable	150.8	154.9	+ 4.1
Inventories	159.4	167.7	+ 8.3
Trade accounts payable	-35.9	-44.8	- 8.9
Other net working capital *1	-39.1	-33.1	+ 6.0
Net working capital	235.1	244.6	+ 9.5
Property, plant and equipment	222.4	243.8	+ 21.4
Right-of-use assets	-	11.5	+ 11.5
Intangible assets	22.7	22.4	- 0.3
Other long-term assets - net *2	25.1	27.7	+ 2.6
Long-term net operating assets	270.1	305.5	+ 35.4
Net operating assets	505.3	550.1	+ 44.8
Debt	-0.2	-	+ 0.2
Marketable securities	102.5	111.9	+ 9.4
Cash and cash equivalents	146.9	149.2	+ 2.3
Net cash	249.2	261.0	+ 11.8
Other non-operating assets - net *3	2.1	-18.9	- 21.0
Net non-operating assets	251.3	242.1	- 9.2
Total net assets	756.5	792.2	+ 35.7
Total assets	919.5	986.6	+ 67.1
Total liabilities	-163.0	-194.5	- 31.5

*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 inventories due to demand increase of new products almost offset by increase in trade accounts payable

Despite increase in accrued payable for establishment of Chugai Life Science Park Yokohama, etc., 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 to the investment in the Chugai Life Science Park Yokohama, etc.

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

Decrease in other non-operating assets - net

Increase in lease liabilities by adoption of IFRS16, etc.

Equity ratio attributable to Chugai shareholders

End of June 2019 80.3%

End of December 2018 82.2%

FX rate to the JPY
(end of period)

	2018 Dec	2019 Jun
1CHF	112.03	110.39
1EUR	126.13	122.56
1USD	110.28	107.80
1SGD	80.70	79.64

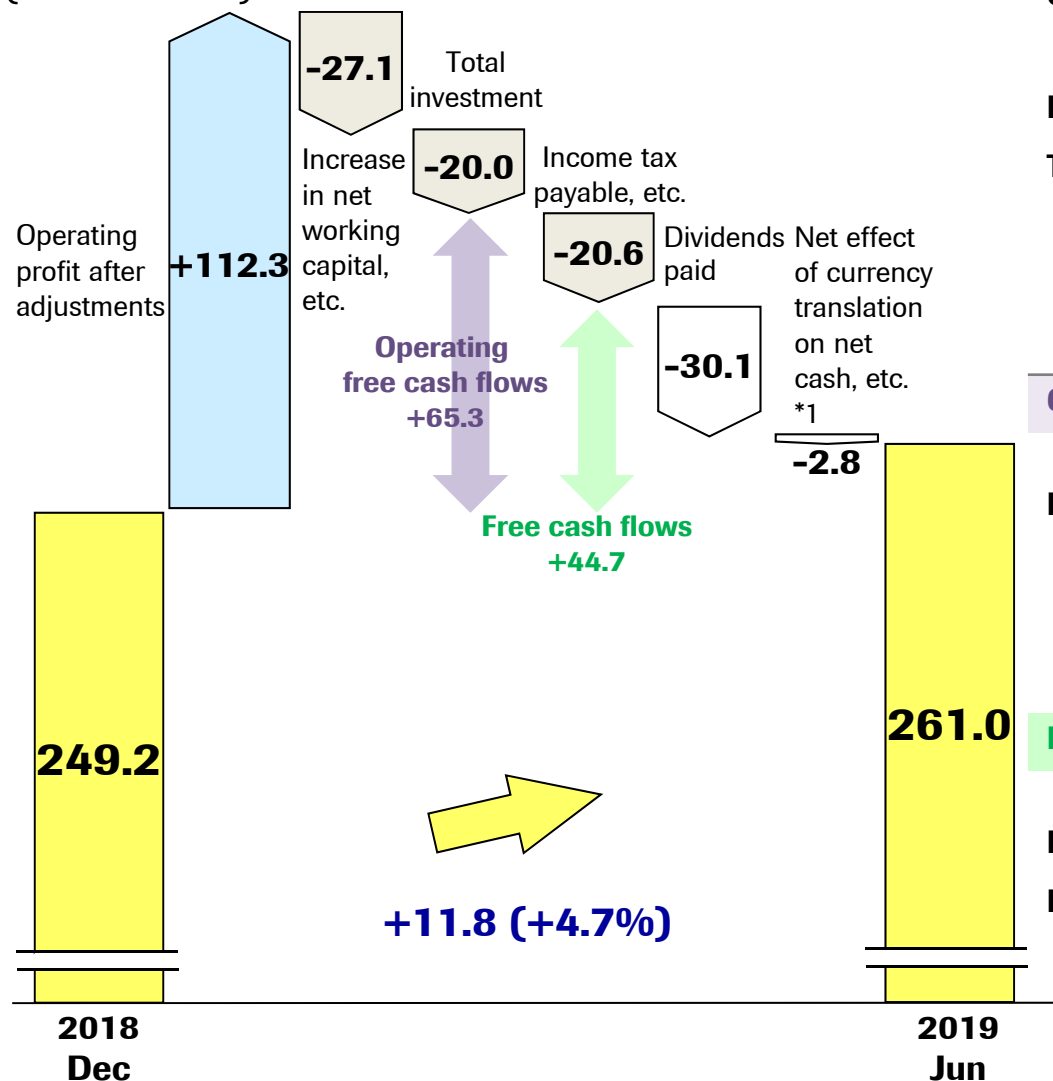
vs. 2018 Year End



Roche Roche Group

Net Cash

(Billions of JPY)



Operating profit after adjustment	+112.3
Operating profit	+95.1
Increase in net working capital, etc.	-27.1
Total investment	-20.0
Property, plant and equipment	-10.1
Payment for lease liabilities	-4.5
Intangible assets	-5.4
Operating free cash flows	+65.3
Income tax payable, etc.	-20.6
Income tax payable	-18.2
Transfer pricing taxation	-1.5
Purchases of investment securities	-0.9
Free cash flows	+44.7
Dividends paid	-30.1
Net effect of currency translation on net cash, etc.	-2.8
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)



Appendix



IFRS and Core Results Jan-Jun

(Billion JPY)	IFRS results	Non-core items		Core results
	2019 Jan-Jun	Intangible assets	Others	2019 Jan-Jun
Revenues	320.3			320.3
Sales	282.4			282.4
Royalties and other operating income	37.9			37.9
Cost of sales	-128.0	+0.4		-127.5
Gross profit	192.3	+0.4		192.7
Operating expenses	-97.3	+2.6	+5.4	-89.2
Marketing and distribution	-35.8		+2.9	-32.9
Research and development	-51.8	+2.6	+1.3	-47.9
General and administration	-9.6		+1.2	-8.4
Operating profit	95.1	+3.1	+5.4	103.5
Financing costs	-0.1			-0.1
Other financial income (expense)	0.3			0.3
Other expense	-1.5			-1.5
Profit before taxes	93.8	+3.1	+5.4	102.3
Income taxes	-24.5	-0.9	-1.6	-27.1
Net income	69.3	+2.1	+3.8	75.1
Chugai shareholders	69.3	+2.1	+3.8	75.1

(Billions of JPY)

Non-Core items

Intangible assets	
Amortization	+0.6
Impairment	+2.5
Others	
Early retirement incentive program	+5.1
Restructuring	+0.3
Core net income attributable to Chugai shareholders	75.1

(Millions of shares)

Weighted average number of shares in issue used to calculate diluted earnings per share	548
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(JPY)

Core EPS	137.11
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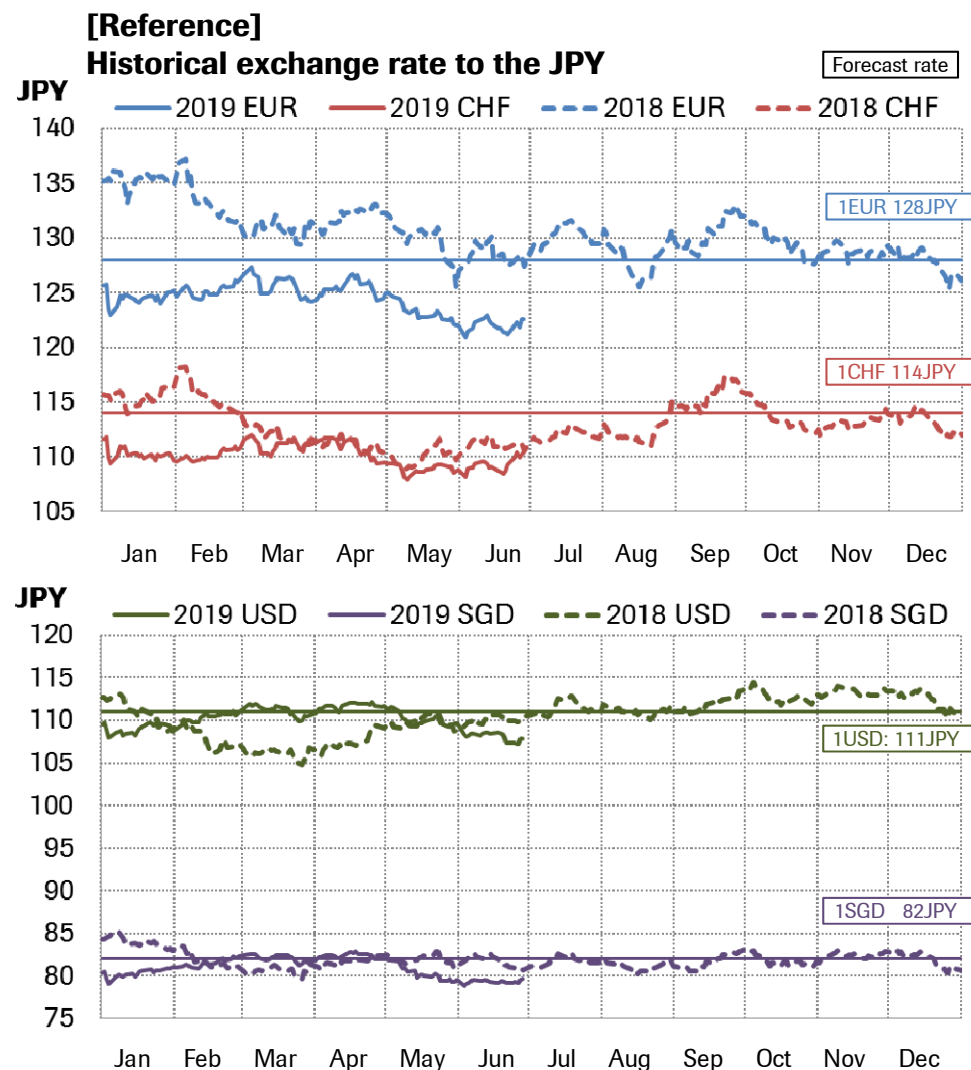


vs. Forecast (Core)

Impact from Foreign Exchange

(Billions of JPY)	FX impact Jan – Jun 2019 (FX impact vs. Assumption)	
Revenues	-1.3	
	Sales	-0.4
	Royalties and other operating income	-0.9
Cost of sales	Cost of sales	+0.1
Operating expenses	Expenses	+0.3
Operating profit	-1.0	

Actual / Forecast rate* (JPY)	2018 Jan - Jun Actual	2019 Jan -Dec Assumption	2019 Jan - Jun Actual
1CHF	112.52	114.00	110.09
1EUR	131.59	128.00	124.34
1USD	108.74	111.00	110.07
1SGD	81.97	82.00	80.99



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



Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.
Executive Vice President
Co-Head of Project & Lifecycle Management Unit
Dr. Yasushi Ito

July 25/26, 2019



Projects under Development (1)

As of July 25, 2019

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

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 April 24, 2019

★: Multinational study managed by Chugai

Projects under Development (2)



As of July 25, 2019

	Phase I	Phase II	Phase III	Filed
Autoimmune	RG7845 / fenebrutinib - rheumatoid arthritis			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG7906 - psychiatric disorders RG6100 (anti-tau MAb) - Alzheimer's disease RG7314 / balovaptan - Autism Spectrum Disorder ★		RG1450 / gantenerumab - Alzheimer's disease SA237 (RG6168) / satralizumab - NMOSD ★ RG6042 (HTT ASO) - Huntington's disease RG6206 (anti-myostatin adnectin) - DMD (PII/III) RG7916 / risdiplam - spinal muscular atrophy(PII/III)	
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis	CIM331 / nemolizumab* - pruritus in dialysis patients SKY59 (RG6107) / crovalimab - PNH (PI/II)	RG7716 / faricimab - 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 PNH: paroxysmal nocturnal hemoglobinuria

Letters in orange: in-house projects

★: Projects with advances in stages since April 24, 2019

★: Multinational study managed by Chugai

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

Key News Flows in Q2



Approved	Actemra (Japan)	Adult Still's Disease	May, 2019
	Rozlytrek	<i>NTRK+</i> solid tumor	June, 2019
	F1 CDx	CDx for Rozlytrek (<i>NTRK+</i> solid tumor)	June, 2019
Service Initiated	F1 CDx	Cancer genome profiling Assessing anticancer drug indications	June, 2019
Filed	Alecensa (Japan)	Recurrent or Refractory <i>ALK+</i> ALCL	June, 2019
New to Pipeline	Tecentriq balovaptan	NSCLC (neoadjuvant) Autism Spectrum Disorder	Global Phase 3 study Phase 1 study
Development Discontinued	Actemra (Japan)	Systemic Sclerosis	-
Medical Conference	Rozlytrek	<i>NTRK+</i> solid tumor, <i>ROS1+</i> NSCLC	ASCO
	HER2 franchise	Breast cancer	ASCO, etc.
	Hemlibra	Hemophilia A	ISTH
Others	Alecensa (Japan)	Recurrent or Refractory <i>ALK+</i> ALCL	Orphan Drug Designation

F1 CDx: FoundationOne CDx Cancer Genomic Profile

ALCL: Anaplastic large cell lymphoma

NSCLC: Non-small cell lung cancer

HER2 franchise: Herceptin/Perjeta/Kadcyla

ASCO: American Society of Clinical Oncology

ISTH: International Society on Thrombosis and Haemostasis

Letters in orange: in-house projects



RG7314 / balovaptan (1) Vasopressin 1a Receptor Antagonist

Autism Spectrum Disorder (ASD)

- ASD is a lifelong neurodevelopmental disorder presenting impairments of social interaction and communication, repetitive behaviors (restricted interests) and associated symptoms
- Overall prevalence rate is estimated to be approximately 1%
- Multiple therapeutic agents exist for associated symptoms; however, none address the core symptoms of ASD

Core symptoms¹⁻³

Deficits in social communication and social interaction



Restricted, repetitive patterns of behavior, interests, or activities



Associated symptoms¹⁻³

Epilepsy

Anxiety

Cognitive impairment

Sleep disorders

Attention deficit hyperactivity disorder

Self-injurious behavior

Obsessive compulsive behavior

Depression

1. Farmer C, et al. *Drugs*. 2013;73:303–314; 2. Lord C, Jones RM, *J Child Psychol Psychiatry*. 2012;53:490–509; 3. Mazzone et al. *J Clin Med*. 2018;7:102.²⁶

RG7314 / balovaptan (2) Vasopressin 1a Receptor Antagonist



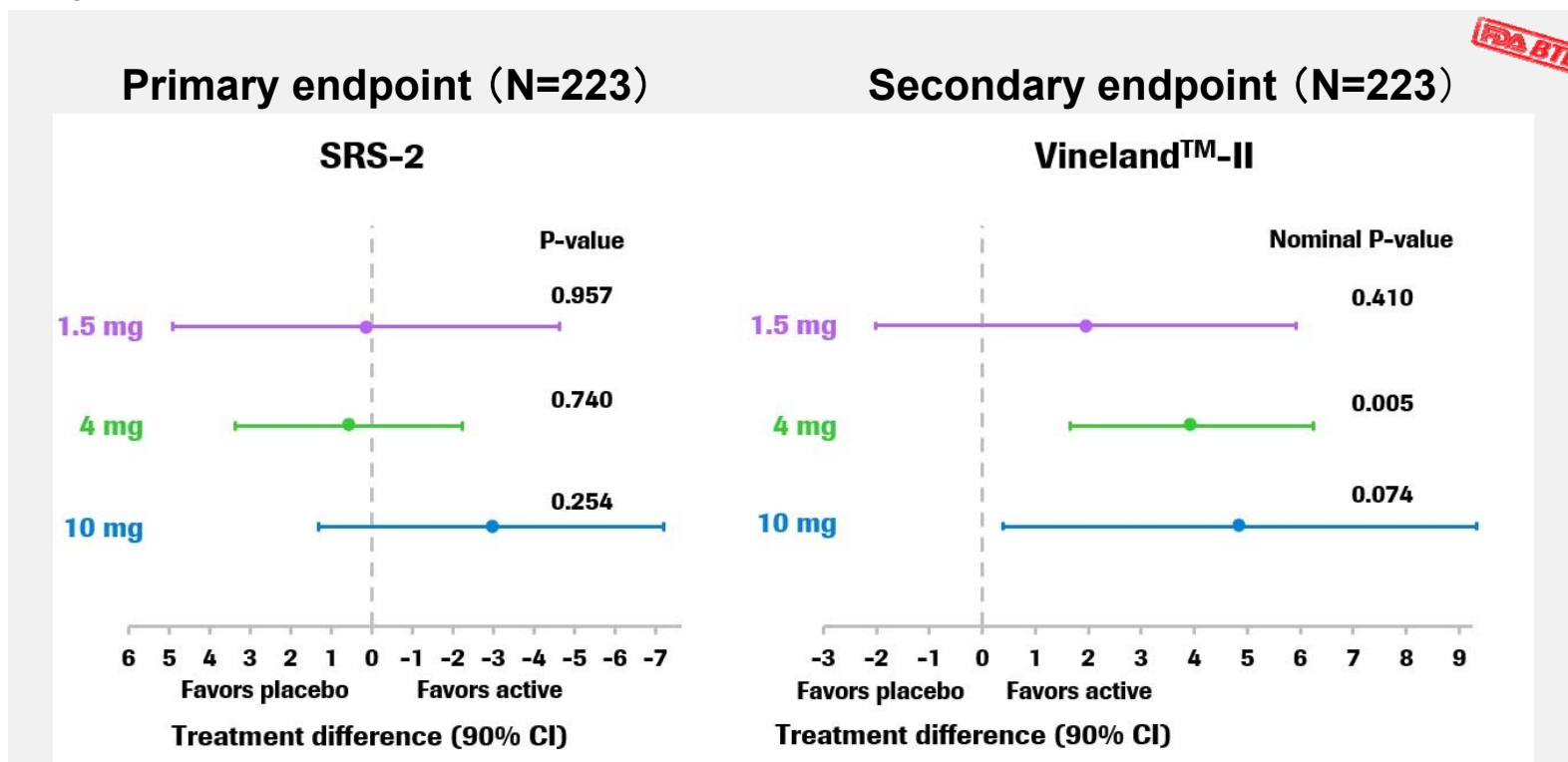
Mode of Action

- Vasopressin plays an important role in social behaviors and stress control via V1a receptors in the brain
- V1a antagonism has effects in the brain that may result in pro-social behaviors and has the potential to help with social and communication challenges of people with ASD



VANILLA Study (P2) : Efficacy of balovaptan in Adult ASD

- Primary endpoint (SRS-2) not met; however main secondary endpoint (Vineland™-II) met
- Vineland™-II selected and agreed upon with health authorities as primary endpoint in future studies
- Major adverse events: headache (placebo: 21.3%, treatment: 1.5mg 12.5%, 4mg 13.0%, 10mg 12.8%)



Bolognani F. et al., IMFAR 2017; SRS-2=social responsiveness scale-2; Vineland™-II=Vineland Adaptive Behavior Scale 2nd Edition

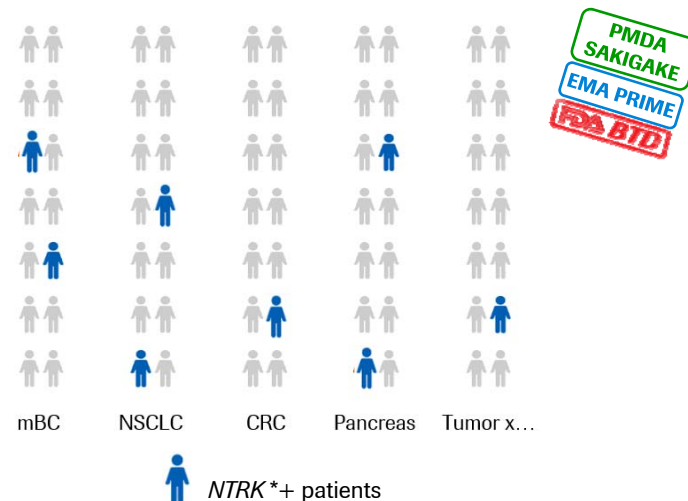
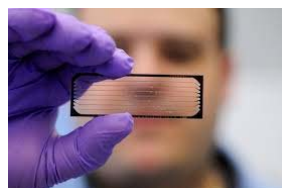
Note: No participation from Japanese facilities in this study

“FoundationOne CDx × Rozlytrek” Approved - To the Era of Advanced Personalized Healthcare Realization -



Identify patients with targeted mutations

Rozlytrek: Treat selected patients across different tumors



FoundationOne CDx supports identification of rare tumor mutations

* NTRK = Neurotropic Tropomyosin Receptor Kinase

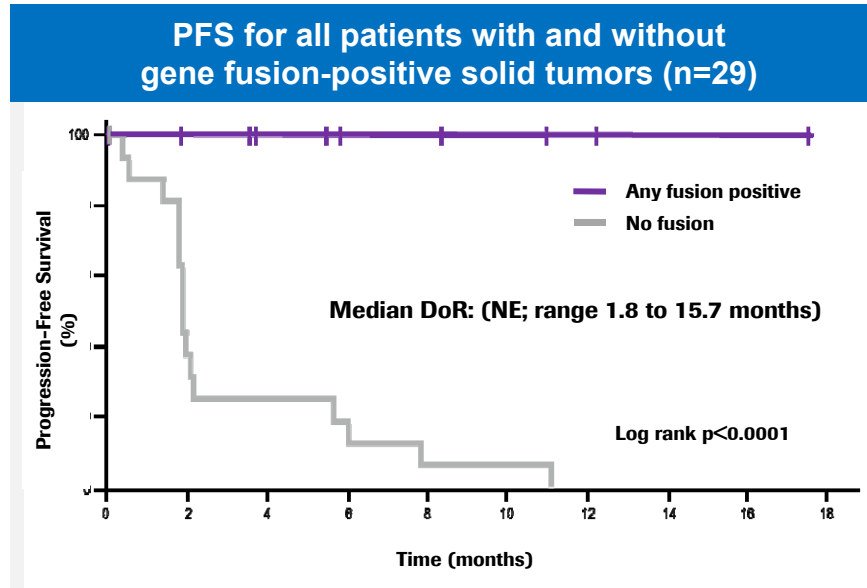
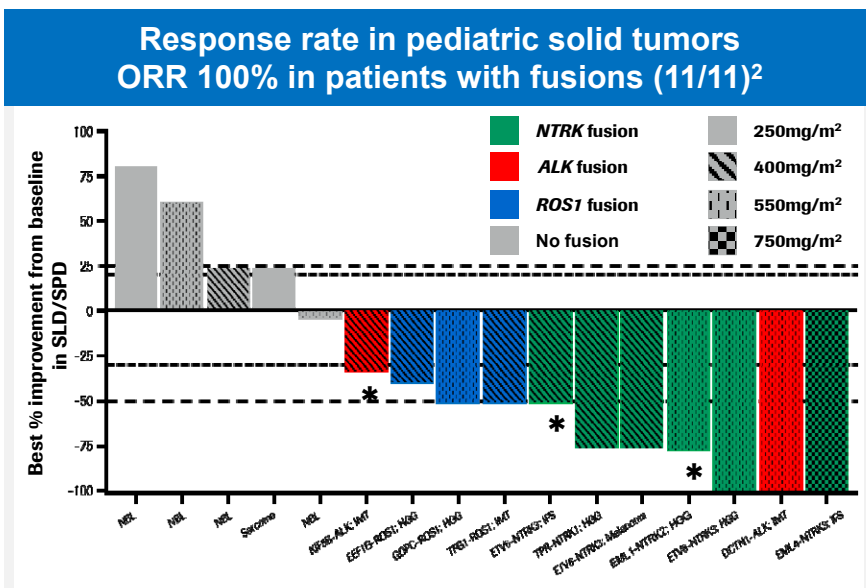
Note: Approved indication for Rozlytrek in Japan is treatment of *NTRK* fusion gene positive advanced and recurrent solid tumors



STARTRK-NG Study (P1/P1b) : Efficacy of Rozlytrek in Children and Adolescents in *NTRK*, *ROS1* or *ALK* Fusion Gene Positive Solid Tumors

- All patients with *NTRK*, *ROS1* or *ALK* fusions showed durable responses without relapse (ORR 100%)
- 5 patients with primary high-grade CNS tumors were included, and 2 patients¹ showed complete responses
- Major adverse events: elevated creatinine (41%), weight gain (28%), dysgeusia (21%), ataxia/falling (<10%)

¹ complete responses in high-grade glioma, sarcoma



Data cut-off October 31, 2018; ² Investigator assessed: includes only patients with measurable disease at baseline and tumor assessment; *unconfirmed response at time of data cut-off; Median duration of therapy was 85 days (6–592 days) for all patients; 56 days (6–338 days) for non-responders; and 281 days (56–592 days) for responders

CNS, central nervous system; SLD, sum of the longest diameters; SPD, sum of the products of diameters; NE, not estimable; ORR, overall response rate; PFS, progression-free survival

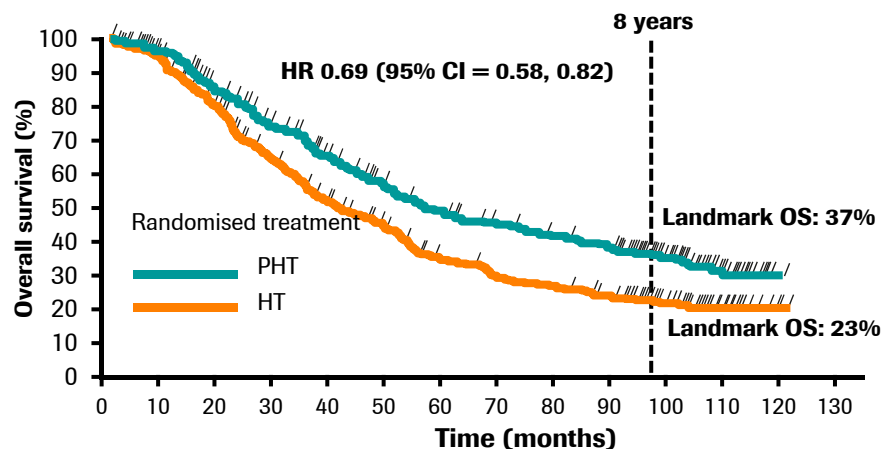
Note: No participation from Japanese facilities in this study

Accumulated Efficacy Data in HER2 Franchise



■ Efficacy data in HER2+ early/advanced breast cancer was presented

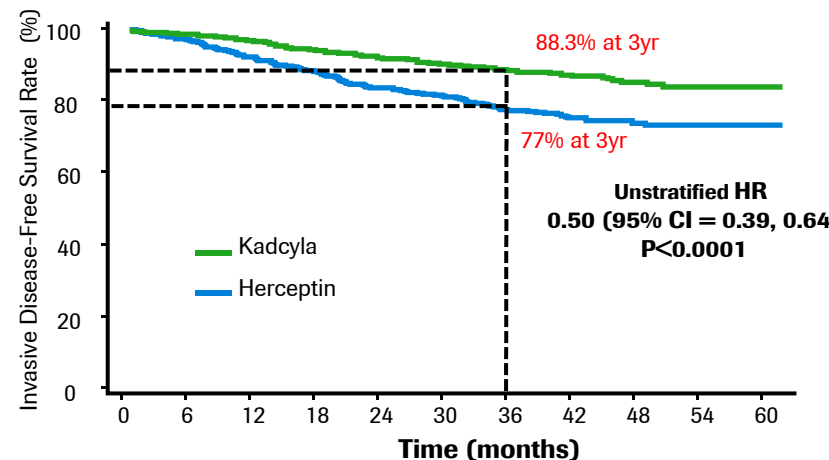
CLEOPATRA Study
1L HER2+ advanced breast cancer
(1998-2019)



* OS: Kaplan–Meier method
HR, 95% CI: stratified Cox proportional hazards model
CI, confidence interval; H, Herceptin; HR, hazard ratio;
P, PERJETA; T, docetaxel

KATHERINE Study
Adjuvant HER2+ breast cancer without pCR¹
(2013-2018)

¹ Pathological complete response after neoadjuvant therapy



* IDFS: Kaplan–Meier method
HR, 95% CI: stratified Cox proportional hazards model

Note: No participation from Japanese facilities in the KATHERINE study

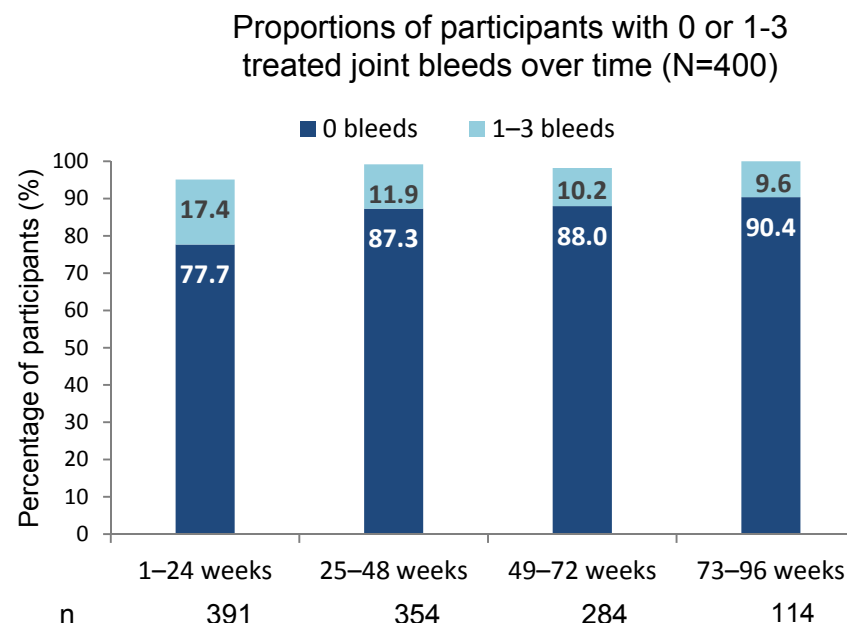
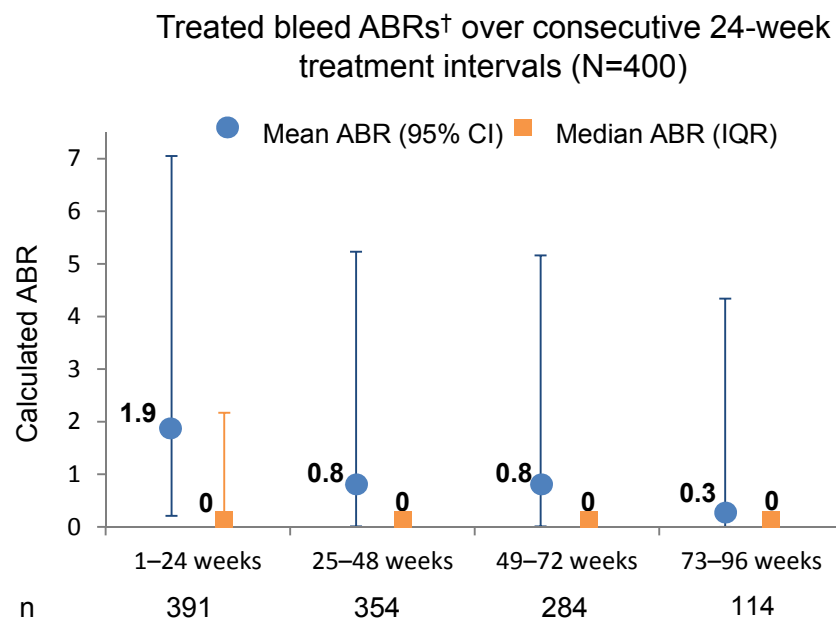
HER2 franchise: Herceptin/Perjeta/Kadcylla
OS: overall survival
IDFS: Invasive Disease Free Survival Rate

Long-term Follow-up Data of HAVEN 1-4 Studies

Hemlibra prophylaxis maintained low treated bleed rates for long-term



- Model-based ABR* for treated bleeds was 1.5 (95% CI, 1.20-1.84) over the median 83-week duration of exposure
- Over 87% of participants had no treated joint bleeds** from week 25
- Major adverse events: Injection site reactions (26.8%)



* Calculated using negative binomial regression; † Based on calculated ABRs
 ABR, annualised bleed rate; CI, confidence interval
 ** Either spontaneous or due to injury/trauma



Projected Submissions (Post PoC NMEs and Products)

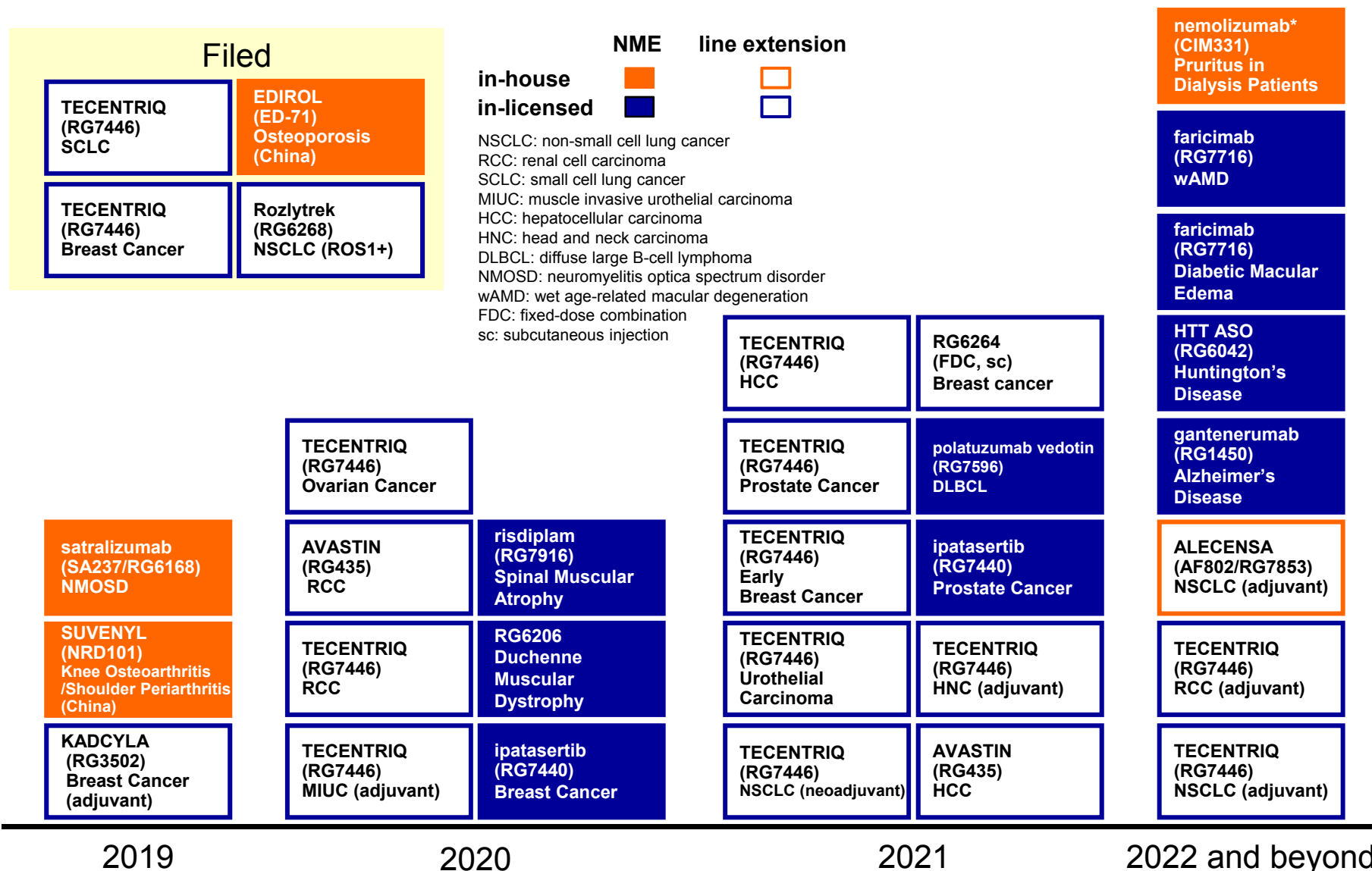
as of July 25, 2019

Filed	
TECENTRIQ (RG7446) SCLC	EDIROL (ED-71) Osteoporosis (China)
TECENTRIQ (RG7446) Breast Cancer	Rozlytrek (RG6268) NSCLC (ROS1+)

NME ■ **line extension**

in-house ■ **in-licensed**

NSCLC: non-small cell lung cancer
 RCC: renal cell carcinoma
 SCLC: small cell lung cancer
 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



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



Updates on the Development Requests for Unapproved Drugs/Indications

Review Committee of Development Requests for Unapproved Drugs/Indication

- 1st round requests: all approved (ten indications, including additional dosages and administrations of eight products)
- 2nd round requests: all approved (three indications of three products)
- 3rd round requests: requests were made for three indications of three products, including additional dosages and administrations, and two of them were approved

Product	Indication	Current Status
Avastin®	Additional dosage and administration for ovarian cancer	Submitted company opinion and waiting for evaluation by the committee

- 4th round requests: requests were made for four indications of four products, and one of them was approved

Product	Indication	Current Status
Xeloda®	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by the committee
Avastin®	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by the committee
Neutrogin®	Combination treatment with chemotherapy including fludarabine for relapsed/refractory AML	Submitted company opinion and waiting for evaluation by the committee

Contacts: Corporate Communications Dept.

Media Relations Group

Tel: +81 (0)3-3273-0881 Fax: +81 (0)3-3281-6607

e-mail: pr@chugai-pharm.co.jp

Tomoko Shimizu, Hiroshi Araki, Chisato Miyoshi, Yayoi Yamada,
Shumpei Yokoyama

Investor Relations Group

Tel: +81 (0)3-3273-0554 Fax: +81 (0)3-3281-6607

e-mail: ir@chugai-pharm.co.jp

Toshiya Sasai, Takayuki Sakurai, Tomoyuki Shimamura,
Sachiyo Yoshimura