

FY2020 Q3 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

Financial Overview



- Significant year-on-year increase in revenues and operating profit
- Record-high Q3 revenues, operating profit and net income
- Progress steady in revenues, strong in operating profit and net income

(Billions of JPY)	2020 Jan – Sep	Growth (year on year)		Forecast on Jan. 30 Progress
Revenues	576.5	+67.6	+13.3%	77.9%
Cost of sales cost to sales ratio	-200.3 43.1%	+1.0 -2.6%pts	-0.5%	79.5%
Operating expenses Research and development	-144.3 -82.2	-7.8 -10.2	+5.7% +14.2%	67.7% 71.5%
Operating profit operating margin	231.9 40.2%	+60.8 +6.6%pts	+35.5%	84.3%
Net income	165.6	+41.1	+33.0%	82.4%
EPS (JPY) *	100.68	+24.99	+33.0%	82.5%

* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

Business Update



In blue : actions related to development pipeline

Jul

- Nemolizumab: Domestic P3 study conducted by Maruho published in NEJM
- Partnering with Biofourmis to develop a digital solution platform for pain management in patients with endometriosis
- Actemra: Roche announced the results of COVACTA study

Aug

- Continues to be listed for all ESG indices selected by GPIF
- Enspryng: Approved in USA
- Kadcyla: Obtained additional indication for adjuvant therapy of HER2-positive early breast cancer
- Selected as Digital Transformation Stock (DX Stock) 2020
- Switch Antibody STA551: Non-clinical research results published in Cancer Discovery
- Enspryng: Launched in Japan

Sep

- Introduction of LINE WORKS by WORKS MOBILE Japan for medical representatives
- Completed demonstration of AI-based clinical trial efficiency solution with NTT DATA
- Joint clinical collaboration with Takeda for global P3 studies for combo therapy with Tecentriq and Cabometyx in Japan
- Actemra: Roche announced the results of EMPACTA study
- Tecentriq: Obtained additional indication for hepatocellular carcinoma in combo with Avastin
- Organized the 2nd ESG meeting



Impact on Value Chain due to Spread of COVID-19

- Although there were no major negative impacts on revenues and profits to date, there was a partial impact on the progress of each business activity

Revenues	Regulatory Affairs/R&D	Manufacturing	Capital Investment etc.
<p>[Domestic] Delay in market penetration of TEC and HEM due to restraint in sales activities, reduction in the number of hospitalizations and outpatients, etc. [Overseas] Exports were favorable since the delay in switching to HEM was temporary. ACT exports including those for clinical trials increased significantly</p>	<p>[Regulatory Affairs] No significant impact on application/approval timing so far [Development] Some delays in the start and progress of clinical trials but are expected to be resolved in the future [Drug discovery] No delays in high-priority projects</p>	<ul style="list-style-type: none"> - Maintain a stable product supply system while maximizing the safety of employees/stakeholders - No impact on product supply both domestically and internationally so far - Continue to maintain a stable product supply system 	<p>[Capital Investment] Resumed all construction works for CLSPY with limited impact on overall construction period. [Expenses] Some expenses were curbed due to the cancellation of overseas travel and refraining from domestic sales activities.</p>

TEC: Tecentriq; HEM: Hemlibra; ACT: Actemra

CLSPY: Chugai Life Science Park Yokoyama



By taking advantage of changes in the business environment, improve efficiency and speed of R&D and information provision activities through the promotion and acceleration of digitalization, as well as business process and work style reforms

Year on Year (Core)

Financial Overview Jan - Sep



(Billions of JPY)	2019 Jan - Sep	2020 Jan - Sep	Growth	
Revenues	508.9	576.5	+ 67.6	+ 13.3%
Sales	440.5	464.8	+ 24.3	+ 5.5%
Domestic	324.4	303.2	- 21.2	- 6.5%
Overseas	116.0	161.6	+ 45.6	+ 39.3%
Royalties and other operating income	68.4	111.7	+ 43.3	+ 63.3%
Royalty and profit-sharing income	48.8	89.1	+ 40.3	+ 82.6%
Other operating income	19.6	22.6	+ 3.0	+ 15.3%
Cost of sales	-201.3	-200.3	+ 1.0	- 0.5%
(cost to sales ratio)	45.7%	43.1%	-2.6%pts	-
Gross profit	307.5	376.2	+ 68.7	+ 22.3%
Operating expenses	-136.5	-144.3	- 7.8	+ 5.7%
Marketing and distribution	-51.0	-49.0	+ 2.0	- 3.9%
Research and development	-72.0	-82.2	- 10.2	+ 14.2%
General and administration	-13.5	-13.1	+ 0.4	- 3.0%
Operating profit	171.1	231.9	+ 60.8	+ 35.5%
(operating margin)	33.6%	40.2%	+6.6%pts	-
Financial account balance	-2.3	-2.2	+ 0.1	- 4.3%
Income taxes	-44.3	-64.1	- 19.8	+ 44.7%
Net income	124.5	165.6	+ 41.1	+ 33.0%
EPS (JPY) *	75.69	100.68	+24.99	+ 33.0%

Domestic sales

Decrease due to NHI drug price revision and launch of generic drugs

Overseas sales

Increase in export of Actemra and Hemlibra to Roche

Royalty and profit-sharing income

Increase in income for Hemlibra

Other operating income

Increase in one-time income

Cost of sales

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

Operating expenses

Decrease of marketing and distribution expenses due to restraint in sales activities
Increase of research and development expenses due to progress of projects, etc.

Operating profit

Significant year-on-year increase

* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

Year on Year (Core)

Sales Jan - Sep

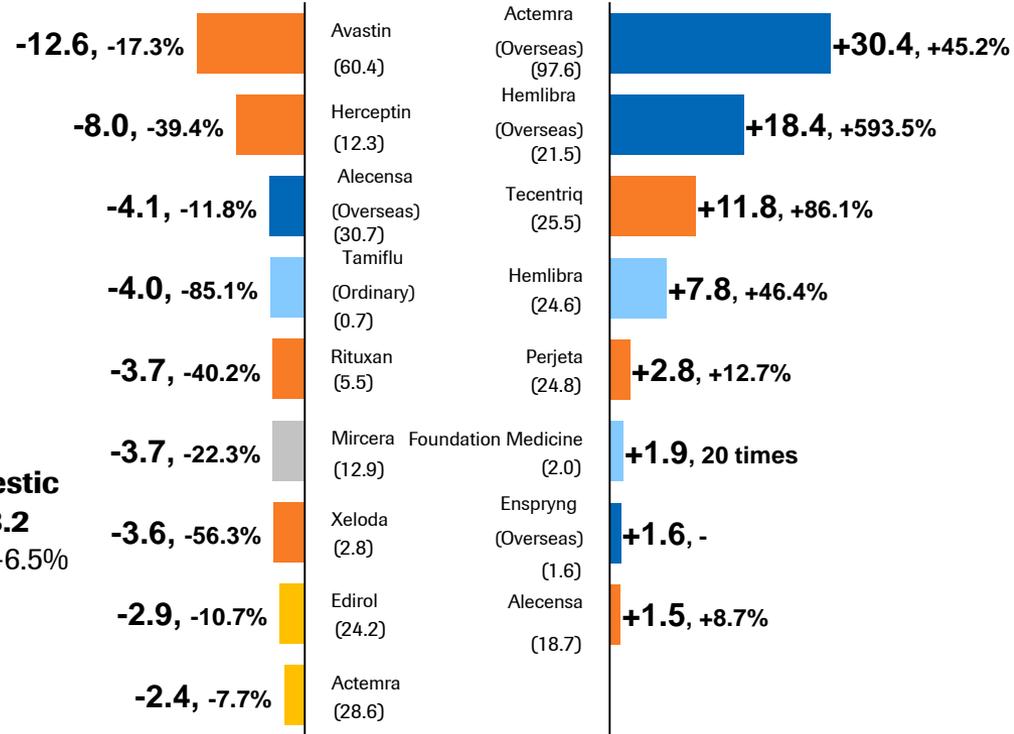
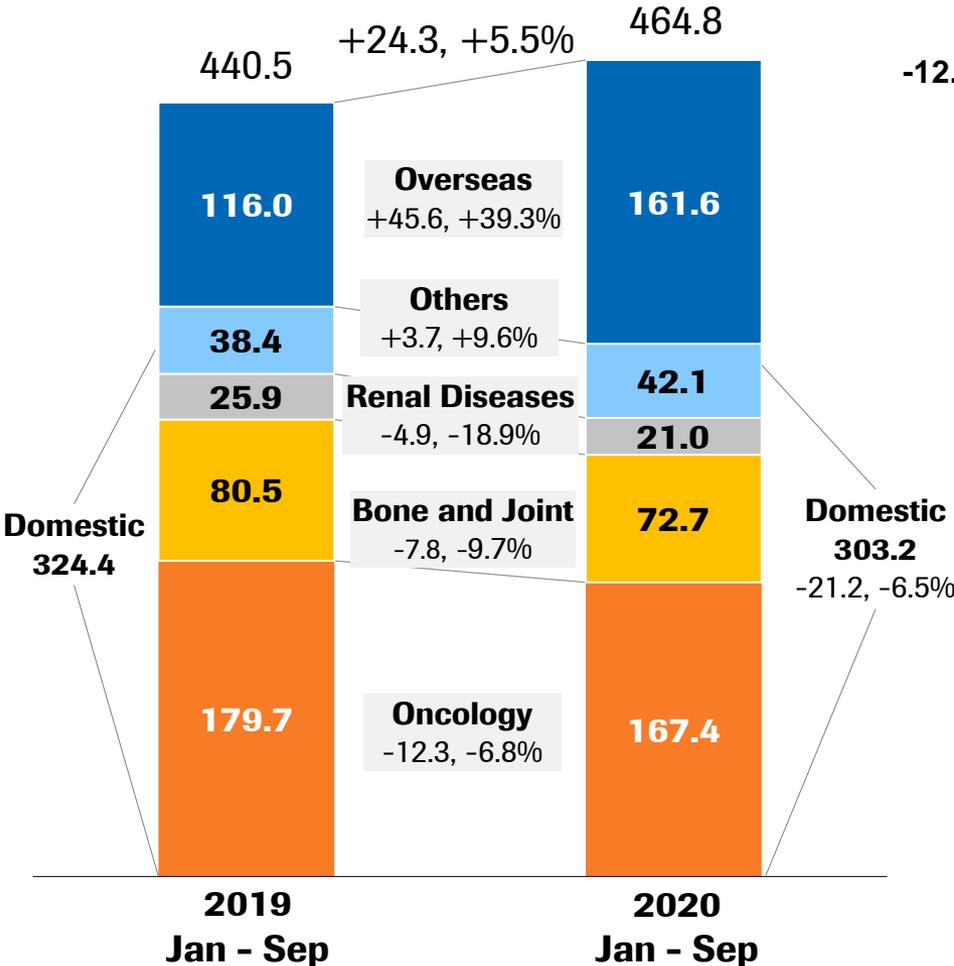


Sales by Disease Area, Year on Year Comparisons

Sales by Products, Year on Year Changes

(Billions of JPY)

(): Actual sales in FY2020
%: Year-on-year percentage change



Details of HER2 franchise (44.2) -5.0, -10.2%

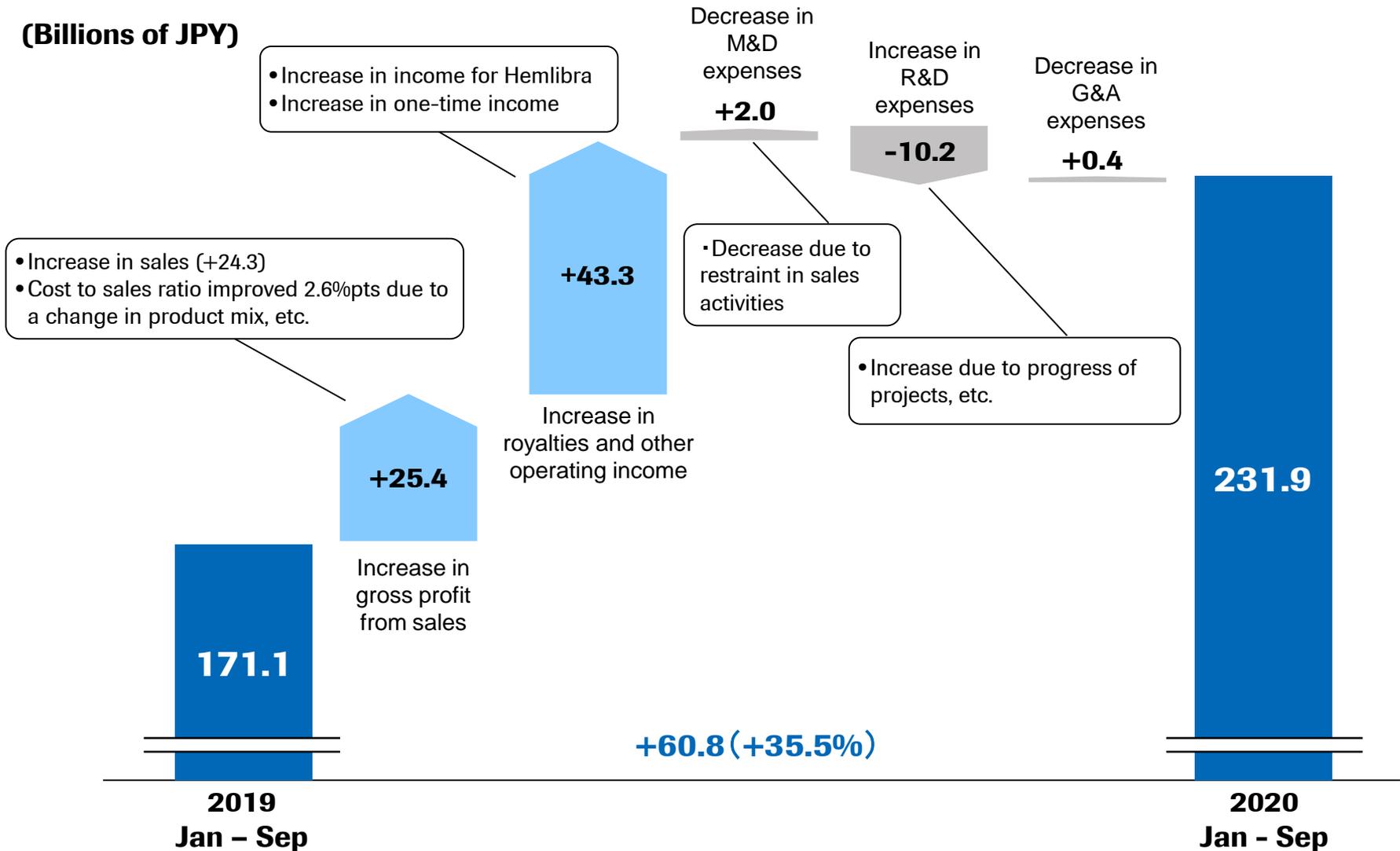
Perjeta	(24.8)	+2.8	+12.7%
Herceptin	(12.3)	-8.0	-39.4%
Kadcyla	(7.1)	+0.3	+4.4%



Year on Year (Core)

Operating Profit Jan - Sep

(Billions of JPY)

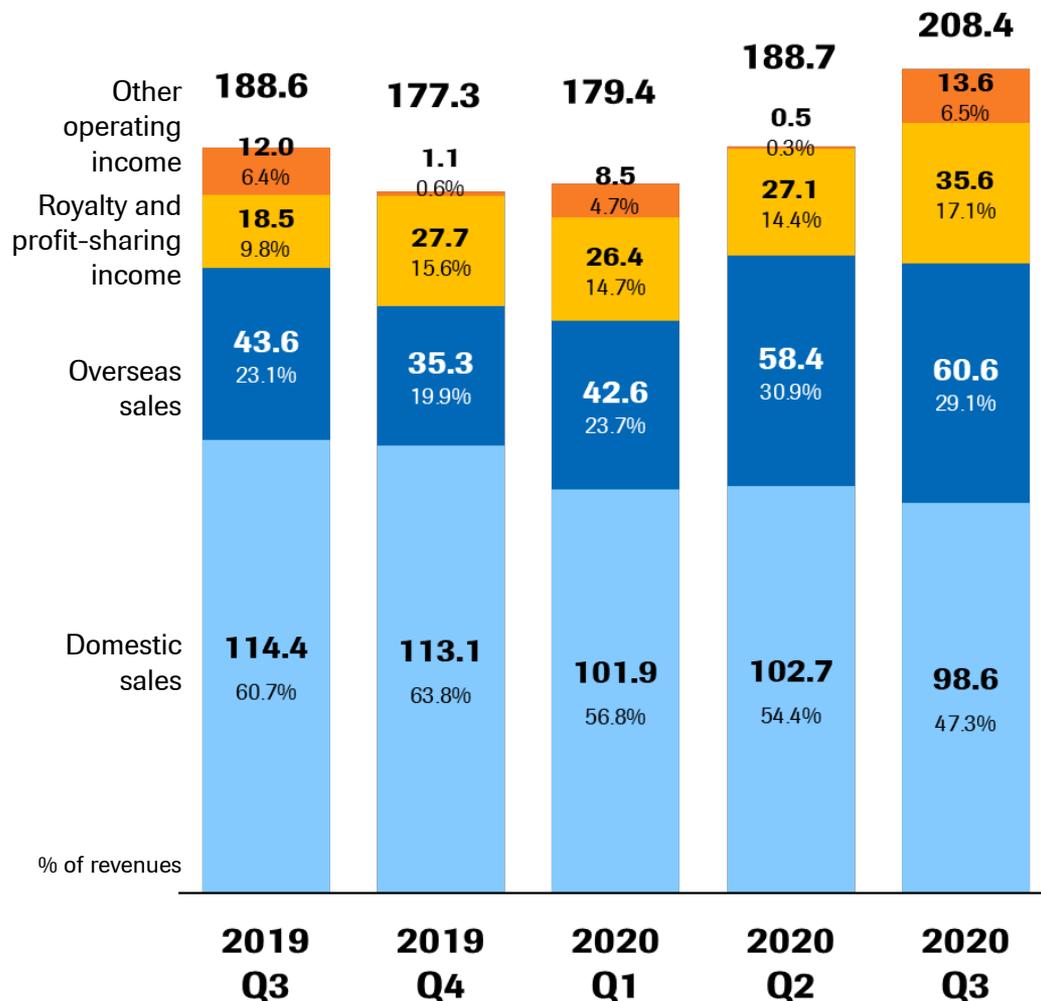


Quarterly (Core)



Structure of Revenues by Quarter

(Billions of JPY)



vs. Year on Year (2019 Q3)

Domestic sales: decrease due to NHI drug price revision and launch of generic drugs, etc.

Overseas sales: significant increase in export of Actemra to Roche

Royalty and profit-sharing income: increase in income for Hemlibra

vs. Previous Quarter (2020 Q2)

Domestic sales: decrease due to the launch of generic drugs, etc.

Overseas sales: increase in export of Alecensa to Roche

Royalty and profit-sharing income: increase in income for Hemlibra

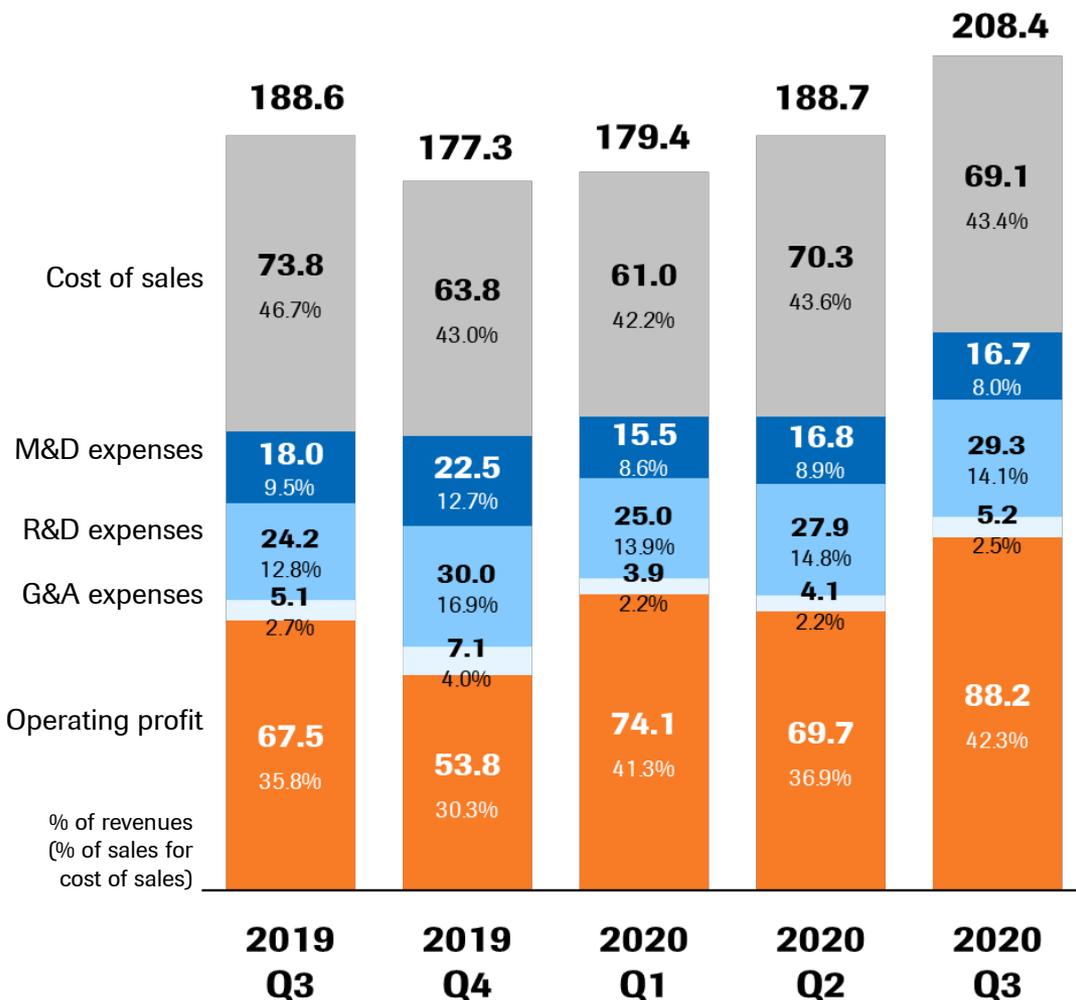
Other operating income: increase in onetime income

Quarterly (Core)



Structure of Costs and Profit by Quarter

(Billions of JPY)



vs. Year on Year (2019 Q3)

Cost of sales ratio: despite NHI drug price revisions, improved due to a change in product mix, etc.

M&D expenses: decrease due to restraint in sales activities

R&D expenses: increase based on progress of projects, etc.

Operating profit: increase of +20.7 (+30.7%)

vs. Previous Quarter (2020 Q2)

R&D expenses: increase due to progress of projects, etc.

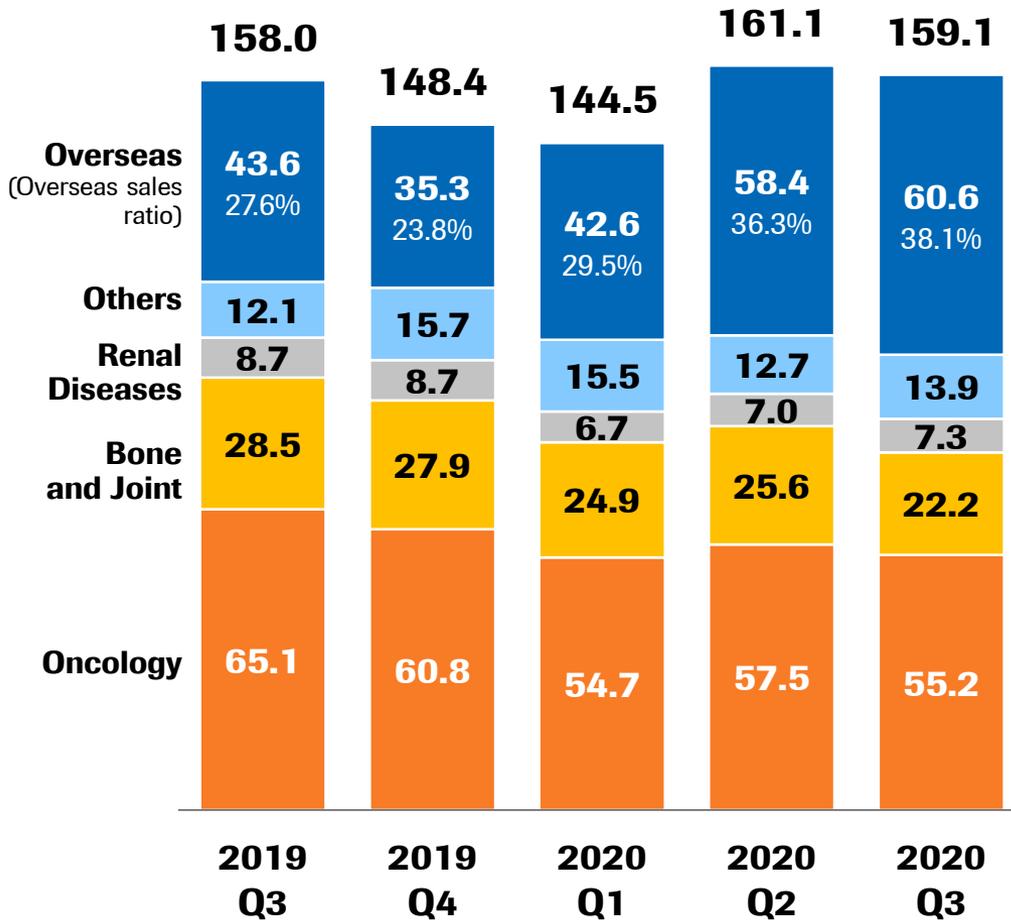
Operating profit: increase of +18.5 (+26.5%)

Quarterly (Core)



Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2019 Q3)

Overseas

Actemra (+13.3), Hemlibra (+3.6)

Domestic

Increase: oncology Tecentriq (+3.4)
 Decrease: oncology Avastin (-6.6)
 Herceptin (-3.1)
 bone and joint Ediroi (-3.9)

vs. Previous Quarter (2020 Q2)

Overseas

Alecensa (+3.2)

Domestic

Decrease: bone and joint Ediroi (-3.6)



vs. Forecast (Core)

Financial Overview Jan - Sep

(Billions of JPY)	Actual	Forecast	2019	
	2020 Jan - Sep	2020 Jan - Dec	Progress	Progress *1
Revenues	576.5	740.0	77.9%	74.2%
Sales	464.8	580.0	80.1%	74.8%
Domestic	303.2	411.6	73.7%	74.1%
Overseas	161.6	168.4	96.0%	76.7%
Royalties and other operating income	111.7	160.0	69.8%	70.3%
Royalty and profit-sharing income	89.1	141.0	63.2%	63.8%
Other operating income	22.6	19.0	118.9%	94.2%
Cost of sales	- 200.3	- 252.0	79.5%	75.9%
(cost to sales ratio)	43.1%	43.4%	-	-
Gross profit	376.2	488.0	77.1%	73.0%
Operating expenses	- 144.3	- 213.0	67.7%	69.6%
Research and development	- 82.2	- 115.0	71.5%	70.5%
Operating profit	231.9	275.0	84.3%	76.1%
(operating margin)	40.2%	37.2%	-	-
Net income	165.6	201.0	82.4%	74.3%
EPS (JPY) *2	100.68	122.00	82.5%	74.3%

Domestic sales

Delay in market penetration of new products and products obtaining additional indication

Overseas sales

Sales of Actemra progressed well in view of the forecast

Royalty and profit-sharing income

Income for Hemlibra progressed slightly lower than forecast

Other operating income

One-time income occurred earlier than forecast

Cost of Sales

Cost to sales ratio nearly in line with forecast

Operating expenses

Progress lower than forecast due to voluntary restraint of some activities

Operating profit

Progress steadily in view of the forecast

*1 Jan - Sep progress versus Jan - Dec

*2 Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented.

vs. Forecast (Core)



Sales Jan - Sep

(Billions of JPY)	Actual		Forecast		2019 Progress *1	(Billions of JPY)	Actual		Forecast		2019 Progress *1		
	2020		2020				Progress	2020		2020		Progress	
	Jan - Sep	Jan - Sep	Jan - Dec	Jan - Dec				Jan - Sep	Jan - Sep	Jan - Dec			Jan - Dec
Sales	464.8	580.0	80.1%		74.8%	Renal	21.0	24.7	85.0%		74.9%		
Domestic	303.2	411.6	73.7%		74.1%	Mircera	12.9	15.4	83.8%		74.8%		
Oncology	167.4	228.8	73.2%		74.7%	Oxarol	4.7	5.2	90.4%		75.4%		
Avastin	60.4	73.3	82.4%		76.4%	Other	3.5	4.1	85.4%		75.9%		
Tecentriq	25.5	44.6	57.2%		66.5%	Others	42.1	68.0	61.9%		71.0%		
Perjeta	24.8	28.8	86.1%		71.7%	Hemlibra	24.6	42.1	58.4%		66.7%		
Alecensa	18.7	24.8	75.4%		74.8%	CellCept	6.7	8.4	79.8%		74.2%		
Herceptin	12.3	19.2	64.1%		76.0%	Tamiflu(Ordinary use)	0.7	3.4	20.6%		63.5%		
Kadcyla	7.1	11.7	60.7%		75.6%	Tamiflu(Govt. stockpiles, etc.)	3.0	3.2	93.8%		100.0%		
Rituxan	5.5	6.3	87.3%		77.3%	Foundation Medicine	2.0	4.5	44.4%		25.0%		
Gazyva	3.2	5.4	59.3%		69.4%	Enspryng *2	0.3	0.9	33.3%		-		
Xeloda	2.8	3.1	90.3%		80.0%	Other	5.0	5.6	89.3%		77.9%		
Rozlytrek	0.2	1.0	20.0%		-	Overseas	161.6	168.4	96.0%		76.7%		
Other	6.9	10.5	65.7%		74.3%	Actemra	97.6	90.8	107.5%		76.1%		
Bone and Joint	72.7	90.1	80.7%		74.3%	Alecensa	30.7	39.0	78.7%		76.8%		
Actemra	28.6	38.2	74.9%		74.2%	Hemlibra	21.5	23.9	90.0%		86.1%		
Edirol	24.2	26.1	92.7%		73.8%	Neutrogen	6.8	9.1	74.7%		76.8%		
Bonviva	6.5	9.7	67.0%		74.2%	Enspryng *3	1.6	1.6	100.0%		-		
Other	13.5	16.0	84.4%		75.2%	Other	3.4	4.0	85.0%		81.0%		

*1 Jan - Sep progress versus Jan - Dec

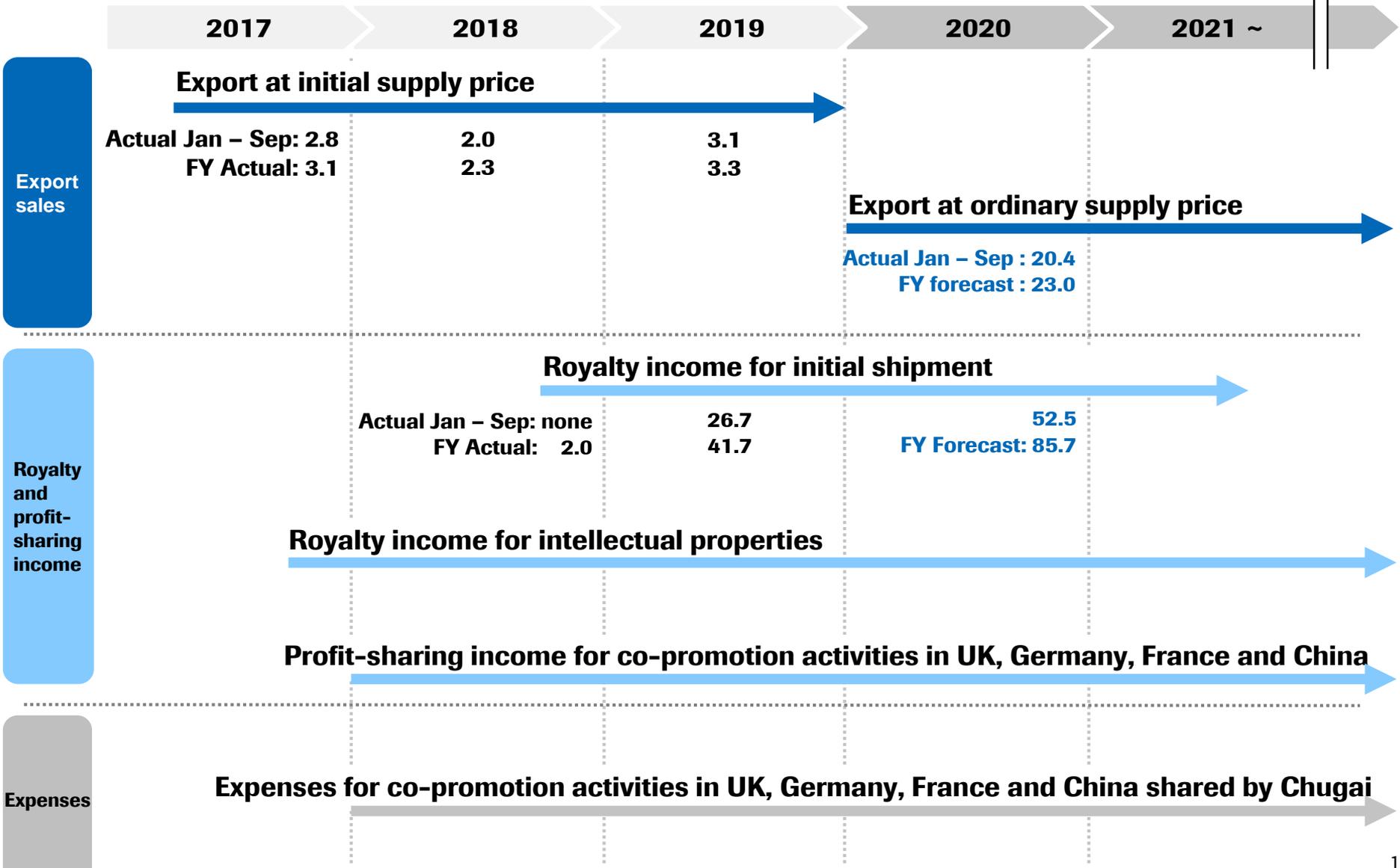
*2 Enspryng (Domestic): Forecast announced on Oct 22

*3 Enspryng (Overseas): Forecast announced on Jul 27

Outline of Hemlibra Sales to Roche



(Billions of JPY)

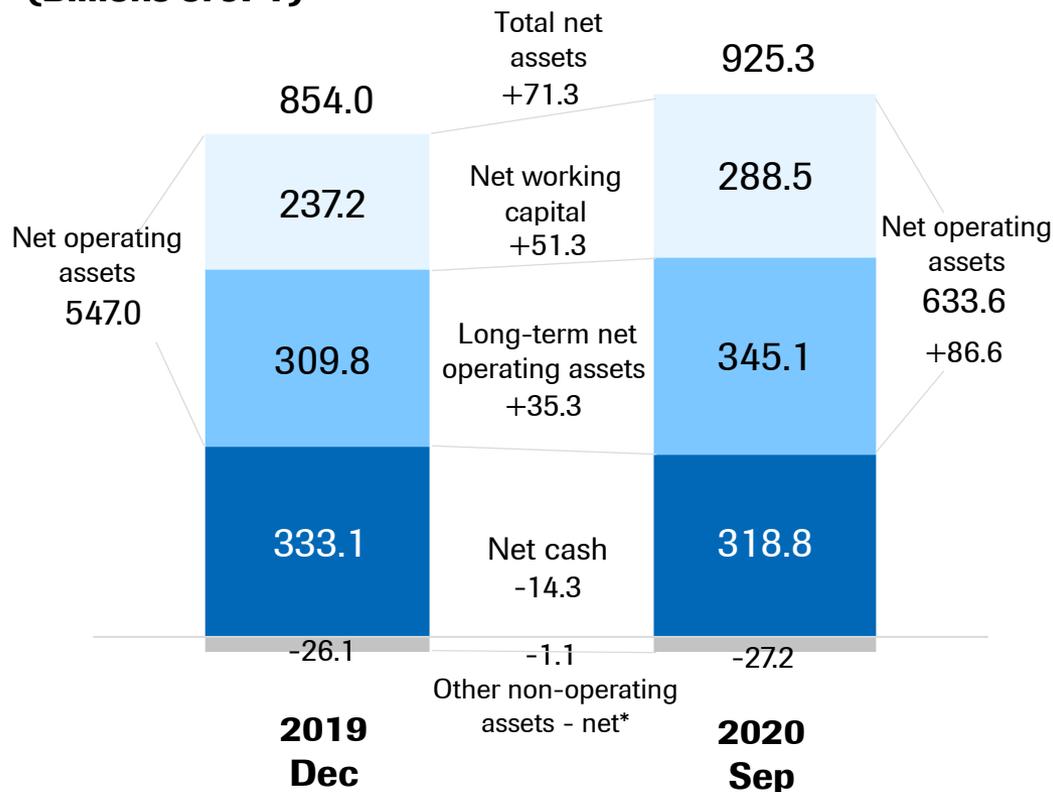


vs. 2019 Year End

Overview of Financial Position



(Billions of JPY)



Increase in net working capital

Increase in trade accounts receivable due to increase of export to Roche

Increase in long-term net operating assets

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

Decrease in net cash

Please refer to the next slide

Increase in other non-operating assets – net

Mainly increase in derivative financial liabilities

* e.g. deferred income tax assets, accrued corporate tax, etc.

Total assets	1,058.9	+77.2	1,136.1
Total liabilities	-204.9	-5.9	-210.8
Total net assets	854.0	+71.3	925.3
Ratio of equity attributable to Chugai shareholders	80.6%	+0.8%pts	81.4%

FX rate to the JPY
(end of period)

	2019 Dec	2020 Sep
1CHF	112.31	114.92
1EUR	121.93	124.08
1USD	108.88	105.66
1SGD	80.72	77.19

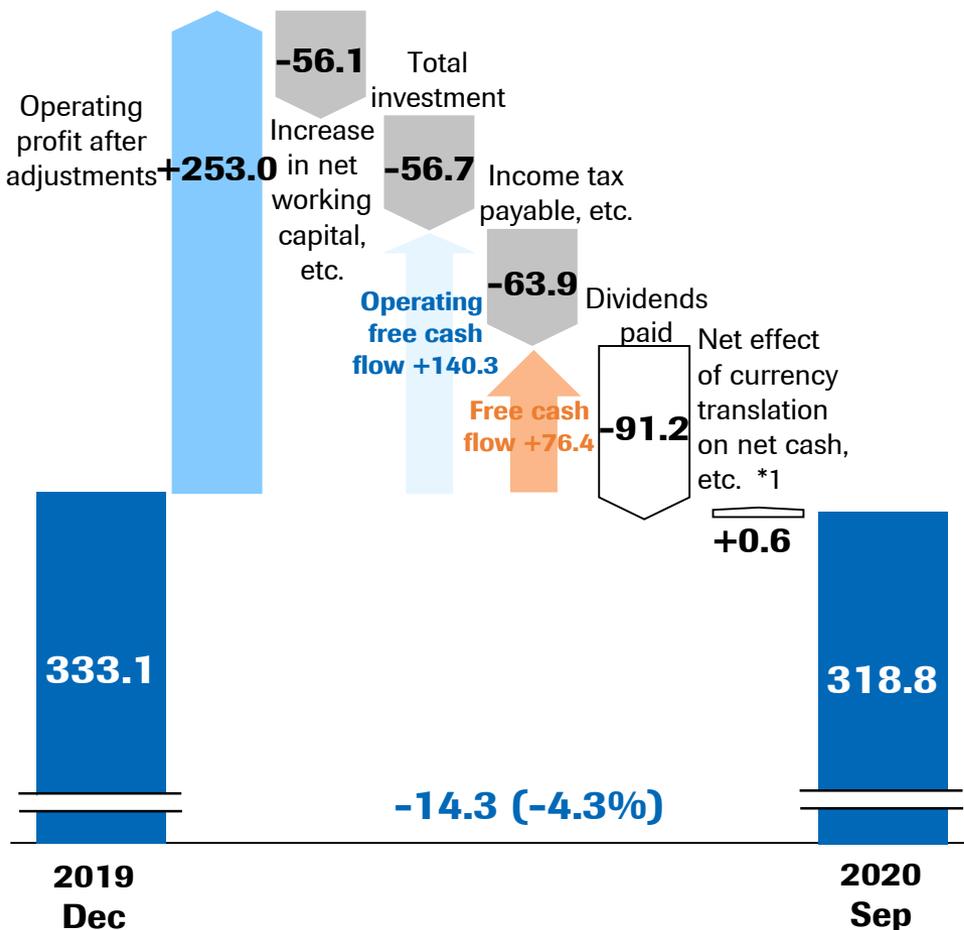
vs. 2019 Year End

Net Cash

(Billions of JPY)



Roche Roche Group



Operating profit after adjustment	+253.0
Operating profit	+227.3
Depreciation, amortization and impairment	+22.6
Increase in net working capital, etc.	-56.1
Total investment	-56.7
Property, plant and equipment	-47.3
Payment for lease liabilities	-6.3
Intangible assets	-3.1
Operating free cash flow	+140.3
Income tax payable, etc.	-63.9
Income tax payable	-66.4
Free cash flow	+76.4
Dividends paid	-91.2
End of FY 2019 (92 JPY per share)	-50.3
Interim 2020 (75 JPY per share)	-40.9
Net effect of currency translation on net cash, etc.	+0.6

*1 Net effect of currency translation 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



Rate of NHI Drug Price Revisions

(%)	2018 Apr	2019 Oct*	2020 Apr	Notes
Domestic Sales	- 6.7	- 0.2	- 9.2	
Oncology				
Avastin	-	+1.9	- 15.7	Apr 2016: -10.9, Special re-pricing for market expansion Apr 2012: -8.8, Re-pricing for market expansion
Tecentriq	-	+1.9	-	
Perjeta	-	+1.9	- 15.0	
Alecensa	-	+1.9	-	
Herceptin	- 20.4	- 2.8	- 3.8	Apr 2010: -18.0, Re-pricing for market expansion
Kadcyla	- 1.5	+1.9	-	
Rituxan	- 26.2	- 3.5	- 2.2	Apr 2006: -13.1, Re-pricing for market expansion
Gazyva	-	+1.9	-	
Xeloda	- 0.6	- 3.2	- 27.4	
Rozlytrek	-	+1.9	-	
Bone and Joint				
Actemra	-	+1.9	- 18.5	Apr 2012: -25.0, Re-pricing for market expansion
Edirol	- 1.3	+0.7	- 0.4	
Bonviva	- 4.7	- 2.4	- 0.9	
Renal				
Mircera	- 8.6	- 4.7	- 1.9	Apr 2016: -19.7, Including return of price maintenance premium
Oxarol	- 8.9	- 6.5	- 1.2	
Others				
Hemlibra	-	+1.9	- 15.0	Apr 2018: Including return of price maintenance premium (dry syrup)
CellCept	- 9.3	- 7.2	- 4.0	Apr 2016: -11.0, Including return of price maintenance premium (capsule)
Tamiflu(Ordinary use)	- 10.6	- 1.9	- 0.4	Apr 2006: -13.0, Re-pricing for market expansion

Legend:

Minus sign indicates price reduction, plus sign indicates price increase

Includes reduction due to return of price maintenance premium

Re-pricing for market expansion

* Includes impact of consumption tax increase



IFRS and Core Results Jan - Sep

(Billions of JPY)	IFRS results		Non-core items		Core results
	2020 Jan - Sep		Intangible assets	Others	2020 Jan - Sep
Revenues	576.5				576.5
Sales	464.8				464.8
Royalties and other operating income	111.7				111.7
Cost of sales	-201.2		+0.9		-200.3
Gross profit	375.3		+0.9		376.2
Operating expenses	-148.0		+0.2	+3.5	-144.3
Marketing and distribution	-49.8			+0.8	-49.0
Research and development	-85.0		+0.2	+2.6	-82.2
General and administration	-13.2			+0.1	-13.1
Operating profit	227.3		+1.1	+3.5	231.9
Financing costs	-0.0				-0.0
Other financial income (expense)	-1.0				-1.0
Other expense	-1.1				-1.1
Profit before taxes	225.1		+1.1	+3.5	229.7
Income taxes	-62.7		-0.3	-1.0	-64.1
Net income	162.4		+0.8	+2.4	165.6
EPS(JPY) *	98.74				100.68

(Billions of JPY)

Non-Core items

Intangible assets	
Amortization	+1.0
Impairment	+0.1
Others	
Restructuring expenses	+3.4
Expenses for environmental measures	+0.1

* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented.

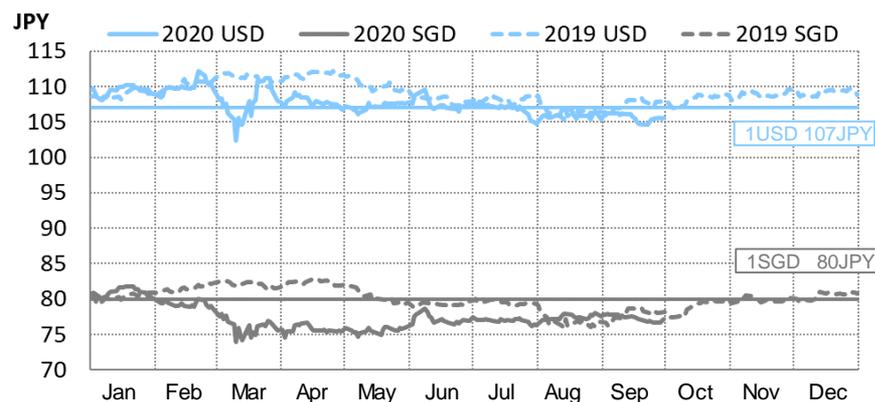
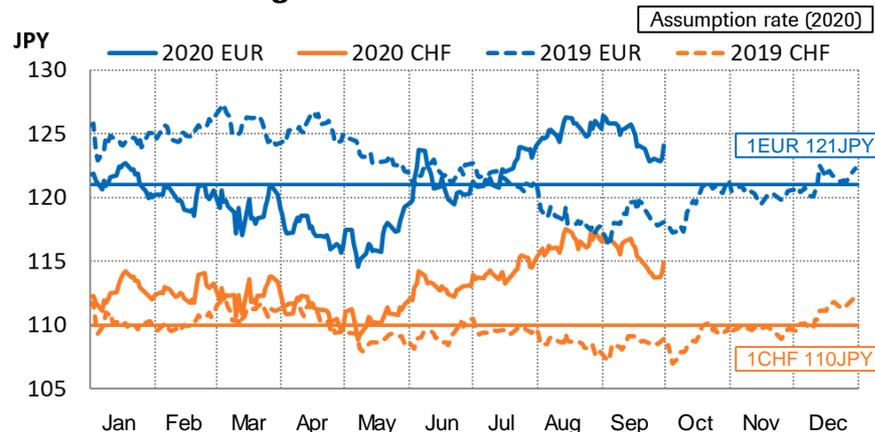
vs. Forecast (Core)



Impact from Foreign Exchange

(Billions of JPY)	FX impact Jan – Sep 2020 (FX impact vs. Assumption)	
Revenues	+1.2	
	Sales	+0.4
	Royalties and other operating income	+0.8
Cost of sales	Cost of sales	-0.1
Operating expenses	Expenses	-0.0
Operating profit	+1.1	

Historical exchange rate to the JPY



Actual / Assumption rate * (JPY)	2019 Jan - Sep Actual	2020 Jan -Dec Assumption	2020 Jan - Sep
1CHF	109.69	110.00	113.14
1EUR	122.66	121.00	120.80
1USD	109.15	107.00	107.57
1SGD	80.00	80.00	77.36

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

Business Update



In blue : actions related to development pipeline

Jan

- Global licensing agreement with Verastem Oncology for RAF/MEK inhibitor CKI27
- Resolution of three-for-one stock split effective July 1, 2020
- Announcement of change in management system effective March 30, 2020

Feb

- Additional indications filed for Tecentriq and Avastin for the treatment of unresectable hepatocellular carcinoma
- Changes to marketing arrangements for SGLT2 inhibitor tofogliflozin hydrate
- Rituxan obtained additional indication of acquired thrombotic thrombocytopenic purpura
- Rozlytrek obtained additional indication of *ROS1* fusion-positive non-small cell lung cancer
- Alecensa obtained additional indication of recurrent or refractory *ALK* fusion gene-positive anaplastic large-cell lymphoma
- Workshop on multidisciplinary team care held in Cambodia

Mar

- Application filed for approval of FoundationOne Liquid CDx
- As a general rule, employees started telecommuting as a countermeasure against COVID-19
- Resolution of year-end dividends of ¥92 per share (including special dividends of ¥44)
- Announcement of CHUGAI DIGITAL VISION 2030

Business Update



In blue : actions related to development pipeline

Apr

- Implemented a new personnel system
- Enspyrng: Global P3 study (monotherapy) published in Lancet Neurology

May

- Actemra: Started domestic P3 for severe COVID-19 pneumonia
- Started joint research with A★STAR on antibody drug for COVID-19
- Non-exclusive license agreement with Eli Lilly for the usage of antibody engineering technologies to develop drugs for COVID-19
- Actemra: Roche started global P3 study (REMDACTA study) for severe COVID-19 pneumonia in combo with remdesvir
- FoundationOne CDx: Approved as a companion diagnostic MET inhibitor – capmatinib
- License agreement with FRONTEO for AI-based drug discovery support system

Jun

- Enspyrng: Approved in Japan
- Polatuzumab Vedotin: Filed for relapsed or refractory diffuse large B-cell lymphoma in Japan



Outline of Arrangements for Sales, Royalties, and Expenses of Four Products to Roche

P/L account of Chugai	Details of transactions	Actemra	Alecensa	Hemlibra	Enspryng
Sales (Export to Roche)	Export to Roche at the agreed supply price	✓	✓	✓	✓
Royalty and profit-sharing income	Royalty income *1	✓	✓	✓	✓
	Profit Sharing income in co-promotion country*2	✓		✓	
M&D expenses	Cost sharing in co-promotion countries *2	✓		✓	
	Receive promotion service fee from Roche (reimbursement of expenses) *3		✓		

*1 For Hemlibra, there are two kinds of royalty income, for intellectual properties and initial shipment

*2 Main co-promotion countries are as follows:

- UK, Germany, France (for Actemra)
- UK, Germany, France, China (for Hemlibra)

*3 Chugai provides promotion service in UK, Germany, France

Overview of Development Pipeline

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

October 22, 2020



Projects under Development (1)

As of October 22, 2020

	Phase I	Phase II	Phase III		Filed
Oncology	<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>RG7461 (FAP-IL2v) - solid tumors</p> <p>AMY109 - solid tumors</p> <p>STA551 - solid tumors</p> <p>SPYK04 - solid tumors ★</p> <p>RG6026 / glofitamab - hematologic tumors</p>	<p>OBP-301 - esophageal cancer</p>	<p>RG435 / Avastin (Tecentriq combo) - SCLC - HCC (adjuvant)</p> <p>RG7440 / ipatasertib - prostate cancer - breast cancer</p> <p>RG6264 (Herceptin+Perjeta) - breast cancer (Fixed-dose combination, subcutaneous injection)</p> <p>RG6058 / tiragolumab (Tecentriq combo) - SCLC - NSCLC - NSCLC(stage III) ★ - esophageal cancer★</p> <p>RG6171 - breast cancer★</p>	<p>AF802 (RG7853) / Alecensa - NSCLC (adjuvant)</p> <p>RG7446 / Tecentriq - NSCLC (adjuvant) - NSCLC (neoadjuvant) - NSCLC(stage III)★ - urothelial carcinoma - RCC (adjuvant) - RCC★ - early breast cancer - ovarian cancer - HCC (adjuvant) - HNC (adjuvant) - esophageal cancer★</p> <p>RG7596 / polatuzumab vedotin - DLBCL</p>	<p>RG7596 / polatuzumab vedotin - r/r DLBCL</p>
Bone & Joint			<p>NRD101 / Suvenyl (China) - knee osteoarthritis / shoulder periarthritis</p>		<p>ED-71 / Ediolol (China) - osteoporosis</p>

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

★: Projects with advances in stages since July 27, 2020

Letters in orange: in-house projects*

*Includes projects that Chugai owns / retains domestic and overseas development rights

HCC: hepatocellular carcinoma

SCLC: small cell lung cancer

RCC: renal cell carcinoma

DLBCL: diffuse large B-cell lymphoma

r/r: relapsed / refractory

NSCLC: non-small cell lung cancer

HNC: head and neck carcinoma

Projects under Development (2)



As of October 22, 2020

	Phase I	Phase II	Phase III	Filed
Renal	EOS789 - Hyperphosphatemia			
Autoimmune	RG7845 / fenebrutinib - rheumatoid arthritis RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG6100 / semorinemab - Alzheimer's disease	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease	SA237 (RG6168) / Enspryng (EU) - NMO RG7916 / risdiplam - spinal muscular atrophy★
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II)		RG7716 / faricimab - DME - nAMD MRA (RG1569) / Actemra (JPN) - COVID-19 pneumonia ACE910 (RG6013) / Hemlibra - Acquired hemophilia A SKY59 (RG6107) / crovalimab - PNH★	

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

PNH: paroxysmal nocturnal hemoglobinuria

NMO: neuromyelitis optica spectrum disorder

DME: diabetic macular edema

nAMD: neovascular age-related macular degeneration

Letters in orange: in-house projects*

★: Projects with advances in stages since July 27, 2020

*Includes projects that Chugai owns / retains domestic and overseas development rights

Key News Flows in Q3



Approved	Enspryng Kadcyla Tecentriq Avastin	Neuromyelitis optica spectrum disorder (NMOSD) HER2+ Breast Cancer (adjuvant) Hepatocellular carcinoma (HCC) Hepatocellular carcinoma (HCC)	August, 2020*1 August, 2020 September, 2020 September, 2020
Filed	F1CDx F1CDx Risdiplam	CDx for larotrectinib (<i>NTRK1/2/3</i> fusion gene) CDx for pemigatinib (<i>FGFR2</i> fusion genes) Spinal muscular atrophy (SMA)	July, 2020 September, 2020 October, 2020
Phase Progress	crovalimab RG6171 (SERD)	Paroxysmal nocturnal hemoglobinuria (PNH) Breast cancer	P3 study P3 study
New to Pipeline	SPYK04 Tecentriq TIR / Tecentriq TIR / Tecentriq	Solid tumors Renal cell carcinoma (combination with cabozantinib) Stage III NSCLC Esophageal cancer	P1 study P3 study (CONTACT-03) P3 study (SKYSCRAPER-03) P3 study (SKYSCRAPER-07)
Late-stage Readouts	Actemra Actemra Tecentriq	COVID-19 pneumonia COVID-19 pneumonia Triple negative breast cancer (TNBC)	P3 study (COVACTA) P3 study (EMPACTA) P3 (IMpassion131)
Medical Conference	Enspryng Tecentriq risdiplam	SAkuraStar / SAkuraSky studies (data from open-label extension period) IMpassion031, IMpassion130, IMpassion131 studies FIREFISH study part 1 (after two-year treatment)	ACTRIMS-ECTRIMS ESMO World Muscle Society
Others	nemolizumab STA551 Joint development Technology transfer	Atopic dermatitis (Japan) filed*2 Solid tumors / non-clinical research combination therapy of Tecentriq and cabozantinib (domestic) Antibody engineering technologies	Q3, 2020 Published in Cancer Discovery Takeda argenx / Novo Nordisk

*1 Approved in U.S. and launched in Japan

F1CDx: FoundationOne CDx; NTRK: neurotrophic tyrosine receptor kinase; FGFR: fibroblast growth factor receptor; NSCLC: non-small cell lung cancer; TIR: tiragolumab

Letters in orange: in-house projects*3

*2 conducted by Maruho, licensee in Japan

*3 Includes projects that Chugai owns / retains domestic and overseas development rights



Response to COVID-19

1. **Clinical trial:** evaluate the efficacy and safety of Actemra against COVID-19 pneumonia

Study	Sponsor / Region	Population	Dosing regimen	Estimated filing
J-COVACTA (Phase 3)	Chugai / Japan	Hospitalized severe patients >10	Single 8mg/kg IV dose; up to one additional dose may be given	2021
COVACTA (Phase 3)	Roche / Global	Hospitalized severe patients 450	Same as above	-
EMPACTA (Phase 3)	Roche / Global	Hospitalized patients 379	Same as above	2020 (Roche)
REMDACTA (Phase 3)	Roche* / Global * collaboration with Gilead Sciences, Inc.	Hospitalized severe patients 500	Same as above** ** combination with remdesivir	2021 (Roche)

2. **Joint research:** develop antibody drug against COVID-19

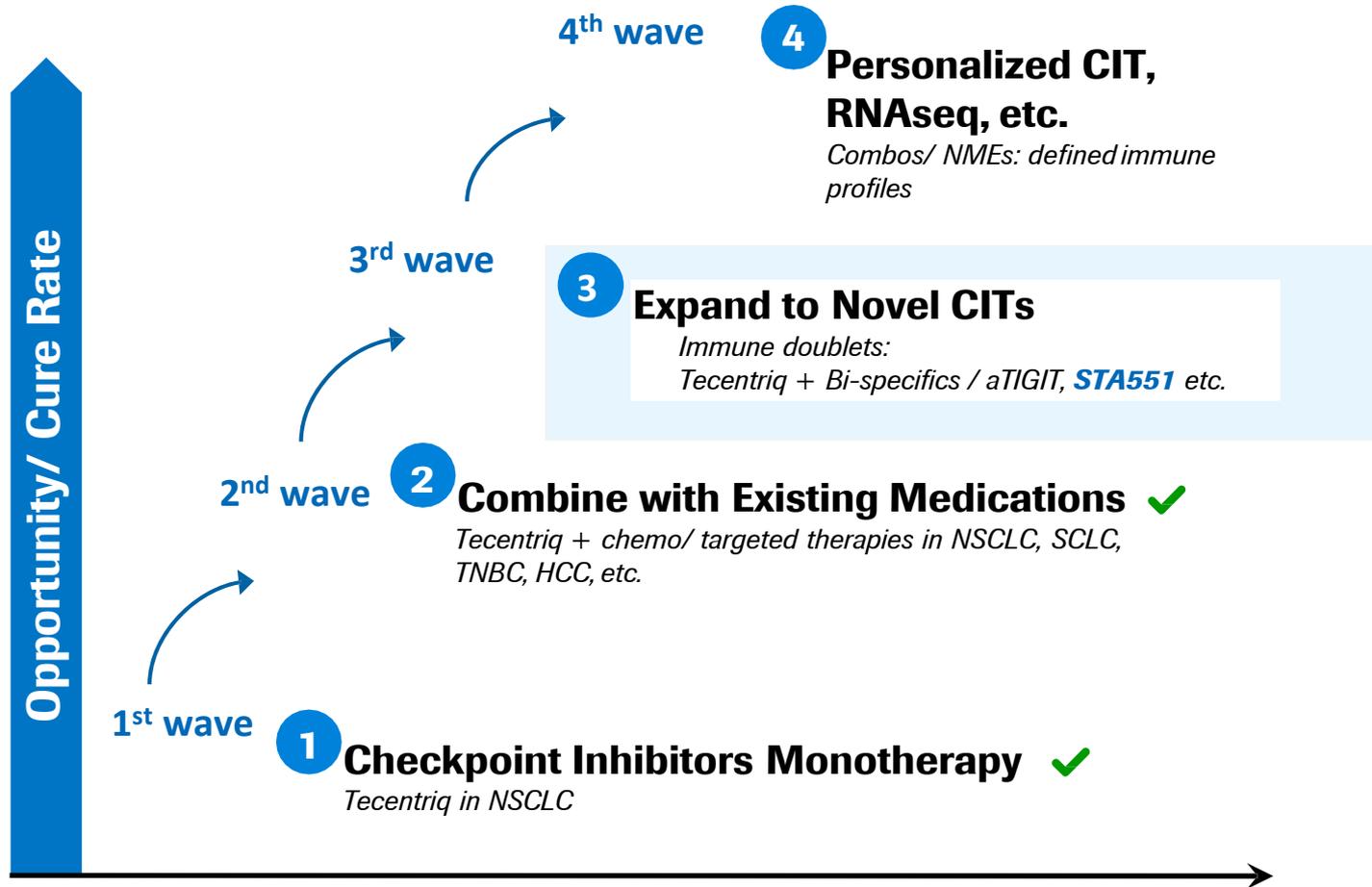
- CPR and A*STAR aim to create an antibody drug candidate with Chugai's proprietary antibody engineering technologies

3. **Technology transfer:** Chugai's antibody engineering technologies

- Elli Lilly and Company was granted rights to use Chugai's antibody engineering technologies for their research activities to develop COVID-19 treatments and the rights for the development and marketing of therapeutic antibodies applying the technologies.



Establishing Tecentriq as Standard of Care in Major Tumor Types



NSCLC: non-small cell lung cancer
 SCLC: small cell lung cancer

TNBC: triple-negative breast cancer
 HCC: hepatocellular carcinoma

STA551 (Anti-CD137 Agonist Switch Antibody)

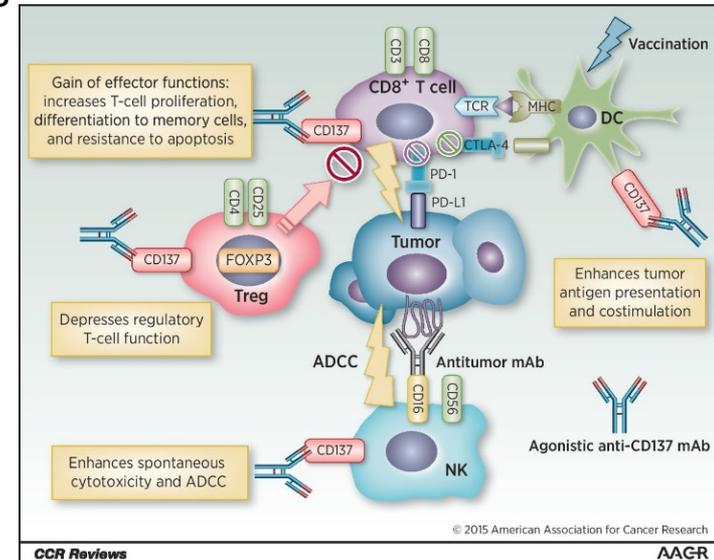
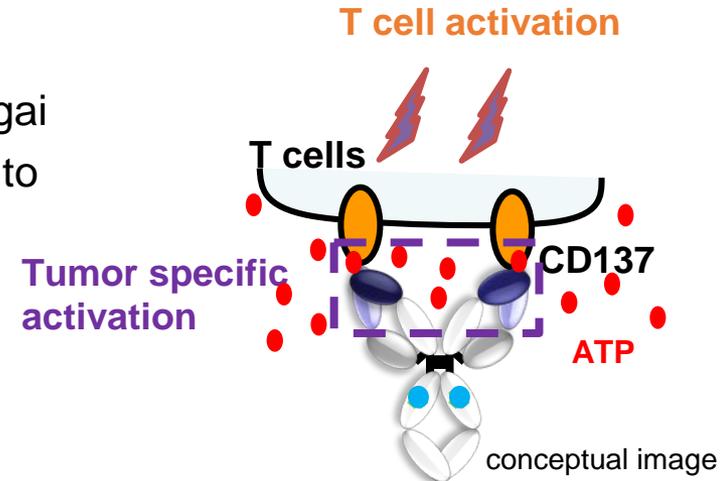


【STA551】

- Utilized Switch Antibody™ technology developed by Chugai
- In the presence of ATP (switch molecule), STA551 binds to CD137 and activates T cells, but not in the absence of ATP.

【CD137 (4-1BB)】

- CD137 is a co-stimulatory molecule on CD4/8 T cells, Tregs, NK cells & DCs
- On T cells, CD137 is induced by TCR signaling and leads to T cell activation
 - ✓ T cell proliferation, cytokine production, maturation, prolonged survival
- Wide variety of potential combinations
 - ✓ Immune checkpoint inhibitors, TRAB, ADCC Abs
- For conventional anti-CD137 Abs, severe toxicity (hepatotoxicity, etc.) is the main issue
- Tumor selective CD137 agonist signal induction is essential to overcome the limitation of conventional anti-CD137 antibodies

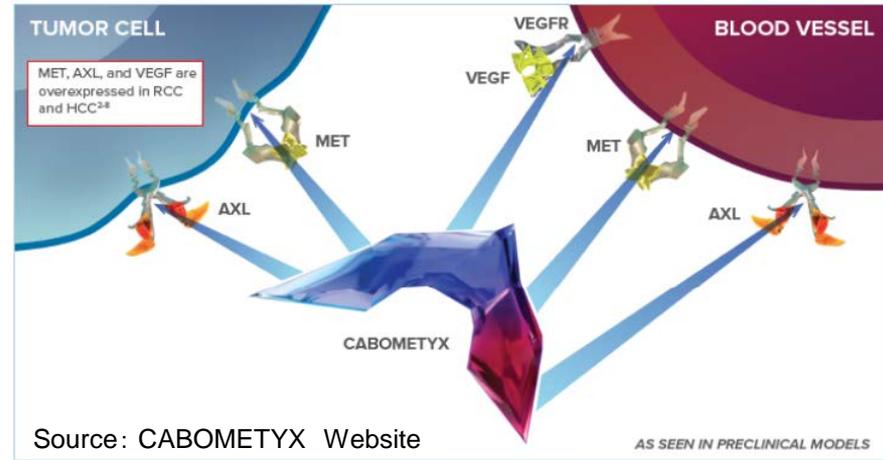


Domestic Joint Development for Combination Therapy of Tecentriq and cabozantinib (1/2)

- Collaboration with Takeda, join global phase III studies to evaluate the combination therapy with multiple tumor types in Japan -

About cabozantinib

The low-molecular compound that inhibit Vascular Endothelial Growth Factor Receptor-2 (VEGFR2), hepatocyte growth factor receptor (MET), and kinase including AXL.



Expected immunological benefits for combination therapy of Tecentriq and cabozantinib

- Inhibition of Treg and myeloid-derived suppressor cells (MDSC) through inhibition of the VEGF signaling pathway
- Increase in tumor infiltrating T cell through inhibition of TAM family (AXL etc.) and change from M2 macrophage (immunosuppression) to M1 macrophage (induction of inflammation and immune response).
- Suppression of PD-L1 overexpression induced by MET through inhibition of MET
- Increase sensitivity against attack from T cells by promoting the expression of MHC class I, FAS, etc.



Domestic Joint Development for Combination Therapy of Tecentriq and cabozantinib (2/2)

- Collaboration with Takeda, join global phase III studies to evaluate the combination therapy with multiple tumor types in Japan -

- Three studies to be conducted in domestic development

Study	Expected indication	Study Design
CONTACT-01	NSCLC (2 nd line)	Tecentriq + cabozantinib vs. docetaxel
CONTACT-02	Prostate cancer*	Tecentriq + cabozantinib vs. novel hormonal therapy
CONTACT-03	Renal cell carcinoma (2 nd line)	Tecentriq + cabozantinib vs. cabozantinib

*Domestic development for prostate cancer is led by Takeda.

NSCLC: non-small cell lung cancer



crovalimab: P3 COMMODORE 1 & 2 Studies PNH

- Initiate two P3 studies based on the results of COMPOSER study (P1/2) -

- Initiate two global P3 studies in adults and adolescents (12 years of age or older) with paroxysmal nocturnal hemoglobinuria (PNH)

Study	COMMODORE 1	COMMODORE 2
Enrolled Patient (target number)	PNH Patients currently treated with complement inhibitors (n=250)	PNH Patients not previously treated with complement inhibitors (n=200)
Study design	crovalimab vs. eculizumab	crovalimab vs. eculizumab
Primary endpoint	Mean Percentage Change in Lactate Dehydrogenase (LDH) levels from baseline to Week 25	Percentage of participants who achieve transfusion avoidance and hemolysis control from baseline to Week 25

■ Features of crovalimab

- Applied Chugai’s proprietary recycling antibody technology and is expected to extend the blood elimination half-life
- Prevent hemolysis by inhibiting complement C5 and blocking its cleavage
- Allow patients to treat at home by self-injection through subcutaneous administration every four weeks*

* Initial administration is given by intravenous loading dose, followed by subcutaneous doses in both COMMODORE 1&2 studies



risdiplam: P3 FIREFISH Study part 1 SMA

- 2-year data for risdiplam in infants with Type 1 spinal muscular atrophy (SMA) presented at WMS2020 -

Achieved continuous improvement in infant motor function for the first and second years

Study Overview

An open-label, two-part single-arm clinical trial in infants aged 17 months with Type 1 SMA

Part 1: Optimal-dose finding (n=21)

Part 2: Assessment of the efficacy and safety profile in the dose determined in Part 1 (n=41)

Part 1 Efficacy analysis (at month 24)

- 88% were alive and required no permanent ventilation
- 59% were able to sit without support for at least 5 seconds^{*1}
- 65% had maintained upright head control, and 29% could turn themselves over^{*2}
- 30% were able to stand with support^{*2}

Features of risdiplam

- Designed to durably increase SMN protein levels both throughout the central nervous system and in peripheral tissues of the body
- Suitable for home care due to an orally administered liquid (syrup)

*1: assessed by the Gross Motor Scale of the BSID-III (Bayley Scales of Infant and Toddler Development – Third Edition)

*2: assessed by the HINE-2 (Hammersmith Infant Neurological Examination Module 2)



as of October 22, 2020

Projected Submissions (Post PoC NMEs and Products)

Filed

risdiplam (RG7916) Spinal Muscular Atrophy	polatuzumab vedotin (RG7596) r/r DLBCL
EDIROL (ED-71) Osteoporosis (China)	ENSPRYNG (SA237/RG6168) NMOSD (EU)

in-house*
in-licensed (Roche)



r/r: relapsed or recurrent
DLBCL: diffuse large B-cell lymphoma
NMOSD: neuromyelitis optica spectrum disorder
FDC: fixed-dose combination
nAMD: neovascular age-related macular degeneration
HCC: hepatocellular carcinoma
RCC: renal cell carcinoma
NSCLC: non-small cell lung cancer
PNH: paroxysmal nocturnal hemoglobinuria
SCLC: small cell lung cancer
HNC: head and neck carcinoma

*Includes projects that Chugai owns / retains domestic and overseas development rights
★ Newly added projects to be filed

				crovalimab (SKY59/RG6107) PNH ★	tominersen (RG6042) Huntington's Disease	gantenerumab (RG1450) Alzheimer's Disease
SUVENYL (NRD101) Knee Osteoarthritis /Shoulder Periarthritis (China)	RG6264 (FDC, sc) Breast Cancer		AVASTIN (RG435) HCC (adjuvant)	HEMLIBRA (ACE910/RG6013) Acquired hemophilia A	SERD (RG6171) Breast Cancer★	TECENTRIQ (RG7446) Esophageal Cancer ★
ipatasertib (RG7440) Breast Cancer	polatuzumab vedotin (RG7596) 1L DLBCL	ACTEMRA (MRA/RG1569) COVID-19 pneumonia	TECENTRIQ (RG7446) HCC (adjuvant)	OBP-301 (Telomelysin) Esophageal Cancer	ALECENSA (AF802/RG7853) NSCLC (adjuvant)	tiragolumab (RG6058) Esophageal Cancer ★
TECENTRIQ (RG7446) Ovarian Cancer	ipatasertib (RG7440) Prostate Cancer	faricimab (RG7716) nAMD	TECENTRIQ (RG7446) RCC (adjuvant)	tiragolumab (RG6058) SCLC	TECENTRIQ (RG7446) 2L RCC★	TECENTRIQ (RG7446) NSCLC (Stage III)★
TECENTRIQ (RG7446) Urothelial Carcinoma	TECENTRIQ (RG7446) Early Breast Cancer	faricimab (RG7716) Diabetic Macular Edema	TECENTRIQ (RG7446) NSCLC (adjuvant)	TECENTRIQ (RG7446) HNC (adjuvant)	AVASTIN (RG435) SCLC	tiragolumab (RG6058) NSCLC (Stage III)★
					TECENTRIQ (RG7446) NSCLC (neoadjuvant)	tiragolumab (RG6058) NSCLC

2020

2021

2022

2023 and beyond



FoudationOne CDx Cancer Genomic Profile: companion diagnostic indications

As of October 22, 2020

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	Afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<i>BRAF</i> V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
<i>ERBB2</i> copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
<i>KRAS/NRAS</i> wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
<u><i>NTRK1/2/3</i> fusion gene</u>	Solid tumors	entrectinib, <u>larotrectinib</u>
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<u>HRR-related gene alterations</u>	Prostate cancer	<u>olaparib</u>
<u><i>FGFR2</i> fusion genes</u>	Cholangiocarcinoma	<u>pemigatinib</u>

* Underlined are the companion diagnostic features and relevant drugs currently filed for regulatory approval

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