

Mid-term Business Plan "IBI 21" - 2019 Results and 2020 Strategic Policies -

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

January 30/31, 2020

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 nonrecurring 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.





New title: Senior Advisor, Honorary Chairman Mr. Osamu Nagayama

New title: Representative Director, Chairman and CEO Mr. Tatsuro Kosaka

New title: Representative Director, President and COO Dr. Osamu Okuda



2019 Results

2019 Financial Performance



- Significant year-on-year increase in income and profit
- Achieved record-high revenues, operating profit and net income for three consecutive years due to strong Hemlibra-related revenues in Japan and overseas, and favorable market penetration of new products such as Tecentriq

	2018		2019			2019	h.:	
billion JPY	Jan -Dec	Jan - Dec		Grov	wth	Jan - Dec	achiev. (%)	
	actual	ć	actual			revised forecast	(70)	
Revenues	579.8		686.2	+106.4	+18.4%	680.0	100.9%	
Sales	527.8		588.9	+61.1	+11.6%	586.0	100.5%	
Domestic	399.9		437.6	37.7	+9.4%	437.0	100.1%	
Overseas	127.9		151.3	+23.4	+18.3%	149.0	101.5%	
Royalties and other operating income (ROOI)	51.9		97.3	+45.4	+87.5%	94.0	103.5%	
Core Operating Profit	130.3		224.9	+94.6	+72.6%	218.0	103.2%	
Core EPS (yen)	176.42		305.80	+129.38	+73.3%	302.00	101.3%	



Progress of IBI 21 - Main Achievements in 2019 -

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

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



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

IBI 21 Main Achievements in 2019 (1)



Strategy 1:	 Hemlibra: Hemophilia A without inhibitors (Approved in EU) Rozlytrek: <i>NTRK</i> + solid tumors (Approved), <i>ROS1</i> + NSCLC (Filed) Nemolizumab: Achieved primary endpoint in domestic P3 for AD,
Value Creation	Breakthrough Therapy Designation by US FDA for PN Telomelysin: Concluded exclusive licensing and capital tie-up agreements Actemra: Approval of additional indications for CRS and Adult Still's disease Satralizumab: Filing of NMOSD in Japan, EU and US NXT007: Next-generation of Hemlibra (P1/2 started) OWL833(GLP-1 receptor agonist) : Licensed out to Eli Lilly (P1 started) Alecensa: Filing of additional indication for ALCL
Strategy 2:	 Successful launch of new products:
Value Delivery	Hemlibra (without inhibitors), Tecentriq (1L NSCLC) Hemlibra reached Blockbuster status
Strategy 3: Advances in PHC	 FoundationOne CDx Cancer Genomic Profile launched Additional approval as companion diagnostic for Rozlytrek
Strategy 1/2/3	 Establishment of Digital & IT Supervisory Division

NSCLC: non-small cell lung cancer, AD: atopic dermatitis, PN: prurigo nodularis, CRS: cytokine release syndrome, NMOSD: neuromyelitis optica spectrum disorder , ALCL: anaplastic large cell lymphoma

IBI 21 Main Achievements in 2019 (2)



Strategy 4: Human capital and structural reform	 Transfer of business: Long-term listed products (Oxarol, Ulcermin) Outsourcing: Logistics operations / Packaging operations Implementation of early retirement incentive program Completion of the design of new personnel system
Strategy 5: Strengthen sustainable platforms	 Enhancement of ESG activities: Held ESG meeting, selected for DJSI APAC Index



The progress in the first year of IBI 21 is on track to meet the target of each project and key issue



Targets and Strategic Policies for 2020

Business Policy for 2020



Concentrate on the following points to achieve the goals of IBI 21;

Focus

- Maximize value of growth drivers
- Create opportunities for future growth

Reinforce

 Establish a business platform for mid- to longterm sustainable growth

Achievement of IBI 21

Business Environment Changes and Our Opportunities & Risks





Megatrends

Opportunities / Risks

Remarkable advances in life sciences & digital technologies

Fiscal pressure due to shifting demographics

Threats to sustainability of global environment & social systems, etc.

Advances in cell/gene therapy & nucleic acid drugs, etc.

- Drug discovery in novel target / mode of action and tissue selectivity
- Effects on existing products by new therapeutic modalities

Advances in AI & other digital technologies and penetration in society

- Creation of business model and process leveraged by Al/digital technologies
- Data dominated by digital platformers entering the healthcare industry

Changes in Pharmaceutical business

- Progress in value- based pricing system
- Pricing pressure
- Rapid penetration of Biosimilars /Generics

Greater demand/expectation in society for sustainability

- Demand for proactive ESG initiatives
- Supply-chain risk by natural disasters etc.

Priority for 2020

Maximize value of growth drivers

Create nextgeneration growth opportunities

Promote digital transformation and PHC

Implement drastic structural reform and Strengthen sustainable platforms

4 Strategic Policies for 2020



1	Maximize value of growth drivers	 Hemlibra: Capture further market penetration Tecentriq: Increase market share by additional indications Satralizumab: Obtain approval and achieve rapid market penetration
2	Create next- generation growth opportunities	 Middle molecule project: Prepare for P1 Antibody project: Start P1 for Switch antibody Nemolizumab: Filing of AD in Japan, start Global P3 (PN) Crovalimab/SKY59: Start Global P3 (PNH)
3	Promote digital transformation and PHC	 Filing of FoundationOne Liquid Promote AI in drug discovery and acquire and train digital human resources Accelerate collaboration with external partners
4	Implement drastic structural reform and Strengthen sustainable platforms	Implement and manage new HR systemAchieve higher scores in ESG

Nemolizumab is under development by licensees; Atopic dermatitis (AD) by Maruho (Japan) and Prurigo nodularis (PN) by Galderma (overseas), PNH: Paroxysmal nocturnal hemoglobinuria



Outlook of Growth during IBI 21

Growth Factors Driving IBI 21



- Earning structure remains unchanged: Domestic sales as 'Source of Revenue,' and overseas expansion of in-house products as 'Source of Growth'
- Risk factors: Severe domestic environment will be covered by the global expansion of in-house products





- Continuous creation of innovative global in-house products
- Global sales expansion of in-house products
- Accelerated penetration of new products in Japanese market
- Additional indications of existing products in Japan and overseas
- Enhancement of R&D and Manufacturing facility
- Establishment of platforms to support future growth, etc.

Trends of Revenue Structure in Japan and Overseas



- Overseas revenues are increasing with the global growth of in-house products
- While Actemra enters into the maturity phase, Hemlibra, Alecensa and satralizumab are expected to drive growth in the future



Domestic revenues
Overseas revenues

Outlook for 2020



- Despite the growth of new products, domestic sales will decrease due to the impact of drug price revision and launch of generics. In contrast, overseas sales will grow due to increase in Hemlibra export to Roche
- Royalties and other operating income will increase due to Hemlibra related incomes
- Record high revenues and operating profits are expected for this year

	2019	2020		
billion JPY	Jan - Dec	Jan - Dec	Gro	wth
	actual	forecast		
Revenues	686.2	740.0	+53.8	+7.8%
Sales	588.9	580.0	-8.9	-1.5%
Domestic	437.6	411.6	-26.0	-5.9%
Overseas	151.3	168.4	+17.1	+11.3%
Royalties and other operating income (ROOI)	97.3	160.0	+62.7	+64.4%
Core Operating Profit	224.9	275.0	+50.1	+22.3%
	205.90	122.00		
Core EPS (yen)	305.80	* 366.00	+60.20	+19.7%

* Amount excludes effect of the stock split. Ordinary share will be split three-for-one, with July 1, 2020 as the effective date.

IBI 21 Quantitative Target (revised)



- Under IBI 21, we will make essential investment for future growth, while maintaining the momentum of growth realized during IBI 18, and realize sustainable profit growth and expansion of corporate value
- Reflecting the 2019 results and expected business expansion over the coming years, we upgraded the target from 'High single digit' to 'Around 30%'

Core EPS CAGR* (2018-2021)

Around 30% **

* Compound Annual Growth Rate (%)
 ** 3 years, based on constant exchange rate
 ** core EPS CAGR is calculated based on the assumption of no stock split scheduled on July 1, 2020

Revision of Dividend Policy



New policy	Aim for a consolidated dividend payout ratio of $50\% \Rightarrow 45\%$ on average in comparison with Core EPS to provide stable allocation of profit
Background behind the revision	 Chugai maintains the objective of continuing a stable allocation of profit considering the strategic funding needs and earnings prospects It is necessary to secure a financial base solid enough to support flexible and focused strategic investment to take bold challenges for innovation amid the rapid development of life science and digital technologies. Considering the investment opportunities in the future and financing plans, Chugai decided to revise its dividend policy to continue providing stable dividend payments

	FY 2018	FY 2019	FY 2020 (forecast)
Core payout ratio 5-year average	48.6%	47.4%	44.7%
Annual dividends	86 JPY	140 JPY	150 JPY



Summary

- Record-high revenues and operating profit for three consecutive years in 2019
- Each strategy under IBI 21 is making progress as planned
- Expect increase in revenue and operating profit in 2020, and will initiate key activities and upfront investment for future growth



- Great start in the first year towards achieving the goals of the mid-term business plan
- To accomplish the goals of IBI 21, 2020 will be a year to focus and reinforce a business platform with a view to sustainable growth over the mid- to long-term



FY2019 Consolidated Financial Overview

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

January 30/31, 2020

Core

Executive Summary





- Record high revenues and operating profit for the third straight year due to significant year-on-year increase in revenues; full year forecasts achieved.
- Year-on-year increases in revenues and operating profit expected to continue in 2020
- Dividends in 2019 are planned to be JPY 140 per share, an increase of JPY 54 from 2018, and dividends in 2020 are forecast to be JPY 150^{*2} per share
- ROIC increased by 31.9% in 2019

		201	9		2020			
(Billions of JPY)	Actual	Grow (vs FY 2			Forecast	Growth (vs FY 2019)		
Revenues	686.2	+106.4	+18.4%	100.9%	740.0	+53.8	+ 7.8 %	
Operating profit operating margin	224.9 32.8%	+94.6 +10.3%pts	+ 72.6 %	103.2%	275.0 37.2%	+50.1 +4.4%pts	+22.3%	
Net income	167.6	+70.3	+72.3%	Not disclosed	201.0	+33.4	+19.9%	
EPS (JPY)	305.80	+129.38	+73.3%	101.3%	122.00 *2 366.00	- +60.20	- + 19.7%	
Dividends per share (JPY)	140	+54	-	-	*3 2Q:75, 4Q:25 *2 150	- +10	-	
Dividend payout ratio	45.8%	-2.9%pts	-	-	41.0%	-4.8%pts	-	
ROIC	31.9%	+10.7%pts	-	Not disclosed	Not	disclosed		

*1 Announced on October 24, 2019

*2 Amount excludes effect of the stock split. Ordinary share will be split three-for-one, with July 1, 2020 as the effective date.

21 *³ The annual dividends per share forecast is not stated because the amounts cannot be simply combined due to the implementation of the stock split.

Year on Year (Core)

Financial Overview Jan - Dec



FY2019 Consolidated Financial Overview

(Billions of JPY)	2018	2019	Growth			
	Jan - Dec	Jan - Dec				
Revenues	579.8	686.2	+ 106.4	+ 18.4%		
Sales	527.8	588.9	+ 61.1	+ 11.6%		
Domestic	399.9	437.6	+ 37.7	+ 9.4%		
Overseas	127.9	151.3	+ 23.4	+ 18.3%		
Royalties and other operating income	51.9	97.3	+ 45.4	+ 87.5%		
Royalty and profit-sharing income	24.1	76.5	+ 52.4	+ 217.4%		
Other operating income	27.9	20.8	- 7.1	- 25.4%		
Cost of sales	-261.9	-265.1	- 3.2	+ 1.2%		
(cost to sales ratio)	49.6%	45.0%	-4.6%pts	-		
Gross profit	317.9	421.1	+ 103.2	+ 32.5%		
Operating expenses	-187.6	-196.2	- 8.6	+ 4.6%		
Research and development	-94.2	-102.1	- 7.9	+ 8.4%		
Operating profit	130.3	224.9	+ 94.6	+ 72.6%		
(operating margin)	22.5%	32.8%	+10.3%pts	-		
Financial account balance	-2.9	-2.7	+ 0.2	- 6.9%		
Income taxes	-30.2	-54.6	- 24.4	+ 80.8%		
Net income	97.3	167.6	+ 70.3	+ 72.3%		
EPS (JPY)	176.42	305.80	+129.38	+ 73.3%		

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

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 Mainly increase of research and development expenses

INNOVATION BEYOND IMAGINATION

Year on Year (Core)

Sales Jan - Dec

Sales by Disease Area, Year on Year Comparisons (Billions of JPY)

+61.1, +11.6%588.9 Rituxan Hemlibra **-9.4,** -44.1% +22.2, +740.0% (25.2) (11.9)(Launched in May 2018) Alecensa 527.8 Xeloda +15.8, +53.6% **Overseas** -4.5. -36.0% (Overseas) (8.0) 151.3 (45.3) +23.4, +18.3% Perjeta Tarceva 127.9 +14.6, +90.7% -3.8, -45.8% (4.5) (30.7) Others +16.6, +44.3%54.1 Tecentrig +11.5, +126.4% 37.5 **Renal Diseases** (20.6)(Launched in April 2018) 34.6 -1.7, -4.7% 36.3 Actemra +7.7, +9.6% Domestic (Overseas) **Domestic** 108.4 (88.3) 399.9 437.6 **Bone and Joint** 100.5 Edirol +37.7, +9.4% +7.9, +7.9% +3.8, +11.6% (36.7) Actemra +3.6, +9.4% (41.8)Oncology +14.8, +6.6%240.5 225.7 Gazyva +3.0, +500.0% (3.6) (Launched in August 2018) Details of HER2 franchise (66.5) +13.7, +25.9% Herceptin (26.7)-1.4, -5.0% 2018 2019 (): Actual sales in FY2019 Perjeta (30.7) +14.6, +90.7% Jan - Dec Jan - Dec %: Year-on-year percentage change (9.0) Kadcyla +0.5, +5.9%

Sales by Products, Year on Year Changes

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Year on Year (Core)

Operating Profit Jan - Dec

FY2019 Consolidated Financial Overview

2019

2018



Growth

(Billions of JPY)

		(Billions of JPY)	Jan - Dec	Jan - Dec	Growth
		Revenues	579.8	686.2	+ 106.4
M&D R&D		Sales	527.8	588.9	+ 61.1
+0.2 <u>G&A</u>	·	Royalties and other operating income	51.9	97.3	+ 45.4
-7.9 -0.9		Cost of sales	- 261.9	- 265.1	- 3.2
5.4		(cost to sales ratio)	49.6%	45.0%	-4.6%pts
		Gross profit	317.9	421.1	+ 103.2
$\overline{\}$		of which Sales	266.0	323.8	+ 57.8
Royalties and other		Marketing and distribution	- 73.7	- 73.5	+ 0.2
operating income		Research and development	- 94.2	- 102.1	- 7.9
		General and administration	- 19.7	- 20.6	- 0.9
	224.9	Operating profit	130.3	224.9	+ 94.6
		(operating margin)	22.5%	32.8%	+10.3%pts
+94.6(+72.6%)		Increase in gross profit from s	ales		+57.8
		In addition to the increase in	sales, cost to	sales ratio imp	roved
5		due to a change in product r	nix, etc. based	on sales expar	nsion of
		in-house products.			
<u> </u>		_ ·		ncome	+45.4
			elopment exp	enses	-7.9
	2019	Progress of projects, etc.			
Ja	an - Dec	2			24
	+0.2 -7.9 -0.9 5.4 -0.9 -0.9 Royalties and other operating income -0.9 -0.9 +94.6 (+72.6%) -0.9 -0.9	G&A -7.9 -0.9 6.4 Royalties and other operating income +94.6 (+72.6%) 224.9 2019	M&D R&D G&A +0.2 -7.9 -0.9 5.4 -7.9 -0.9 Royalties and other operating income Cost of sales (cost to sales ratio) Gross profit of which Sales Marketing and distribution Research and development General and administration Operating profit (operating margin) Increase in gross profit from s In addition to the increase in due to a change in product r in-house products. Increase in royalties and other Increase in income for Hemli Increase in research and develop	M&D R&D G&A +0.2 -7.9 -0.9 6.4 -7.9 -0.9 Royalties and other operating income 51.9 Royalties and other operating income 51.9 Cost of sales -261.9 (cost to sales ratio) 49.6% Gross profit 317.9 of which Sales 266.0 Marketing and distribution -73.7 Research and development -94.2 General and administration -19.7 Operating profit 130.3 (operating margin) 22.5% Increase in gross profit from sales Increase in royalties and other operating in income for Hemilbra Increase in royalties and other operating in Increase in research and development exp Progress of projects, etc. Progress of projects, etc.	M&D R&D G&A +0.2 -7.9 G&A +0.2 -7.9 -0.9 Side 527.8 588.9 Royalties and other operating income 51.9 97.3 Cost of sales - 261.9 - 265.1 (cost to sales ratio) 49.6% 45.0% Gross profit 317.9 421.1 of which Sales 266.0 323.8 Marketing and distribution - 73.7 - 73.5 Research and development - 94.2 - 102.1 General and administration - 19.7 - 20.6 Operating profit 130.3 224.9 (operating margin) 22.5% 32.8% Increase in gross profit from sales In addition to the increase in sales, cost to sales ratio imp due to a change in product mix, etc. based on sales expansion-house products. Increase in income for Hemilibra Increase in income for Hemilibra Increase in research and development expenses Progress of projects, etc.

(Billions of JPY)

Year on Year (Core)

Financial Overview Oct - Dec



FY2019 Consolidated Financial Overview

Revenues 153.3 177.3 + 24.0 + 15.7% Domestic sal Sales 139.1 148.4 + 9.3 + 6.7% Overseas sale Domestic 109.1 113.1 + 4.0 + 3.7% Royalty and profit-sharing income 14.2 28.9 + 14.7 + 103.5% Other operating income 14.2 28.9 + 14.7 + 103.5% Other operating income 0ther operating Cost of sales - 67.6 - 63.8 + 3.8 - 5.6% Cost of sales Cost of sales - 67.6 - 63.8 + 3.8 - 5.6% Operating ex (cost to sales ratio) 48.6% 43.0% -5.6%pts - Operating ex	(Billions of JPY)	2018	2019	Grow	rth	
Sales139.1148.4+ 9.3+ 6.7%Overseas sale Increase in a Increase in a Royalties and other operating income109.1113.1+ 4.0+ 3.7%Overseas sale Increase in a Royalties and other operating incomeRoyalty113.1+ 4.0+ 3.7%Royalty and p Increase in a Decrease in a Decreas				+ 24 0	+ 15 7%	Domestic sales Increase due to
Domestic109.1113.1+ 4.0+ 3.7%Overseas30.035.3+ 5.3+ 17.7%Royalties and other operating income14.228.9+ 14.7+ 103.5%Royalty and profit-sharing income8.327.7+ 19.4+ 233.7%Other operating income5.91.1- 4.8- 81.4%Cost of sales-67.6-63.8+ 3.8- 5.6%(cost to sales ratio)48.6%43.0%-5.6%pts-Operating ex						
Royalties and other operating income14.228.9+ 14.7+ 103.5%Other operating Decrease in Decrease in Decrease in 						Increase in exp
Royalties and other operating income14.228.9+ 14.7+ 103.5%Other operating Decrease in Decrease in Decrease in Decrease in Decrease in Cost of sales- 4.8- 81.4%Cost of sales Cost to saleCost of sales product mix Cost to sales ratio)- 67.6- 63.8+ 3.8- 5.6%Cost of sales product mixCost to sales ratio)48.6%43.0%-5.6%ptsOperating explanation					+ 17.7%	Royalty and prof
Royalty and profit-sharing income8.327.7+ 19.4+ 233.7%Decrease inOther operating income5.91.1- 4.8- 81.4%Cost of salesCost of sales-67.6-63.8+ 3.8- 5.6%Cost to sale product mix(cost to sales ratio)48.6%43.0%-5.6%pts-	Royalties and other operating income	14.2	28.9	+ 14.7	+ 103.5%	
Cost of sales-67.6-63.8+ 3.8- 5.6%Cost to sale product mix(cost to sales ratio)48.6%43.0%-5.6%pts-Operating ex	Royalty and profit-sharing income	8.3	27.7	+ 19.4	+ 233.7%	Decrease in mil
Cost of sales -67.6 -63.8 + 3.8 - 5.6% product mix (cost to sales ratio) 48.6% 43.0% -5.6%pts - Operating ex	Other operating income	5.9	1.1	- 4.8	- 81.4%	
(cost to sales ratio) 48.6% 43.0% -5.6%pts Operating ex	ost of sales	-67.6	-63.8	+ 3.8	- 5.6%	Cost to sales ra product mix, etc
	(cost to sales ratio)	48.6%	43.0%	-5.6%pts	-	•
	ross profit	85.8	113.5	+ 27.7	+ 32.3%	Increase of rese due to progress
Operating expenses -58.7 -59.7 - 1.0 + 1.7%	perating expenses	-58.7	-59.7	- 1.0	+ 1.7%	due to progress
Research and development -27.9 -30.0 - 2.1 + 7.5%	Research and development	-27.9	-30.0	- 2.1	+ 7.5%	
Operating profit 27.1 53.8 + 26.7 + 98.5%	perating profit	27.1	53.8	+ 26.7	+ 98.5%	
(operating margin) 17.7% 30.3% +12.6%pts -	(operating margin)	17.7%	30.3%	+12.6%pts	-	
Financial account balance -0.6 -0.4 + 0.2 - 33.3%	nancial account balance	-0.6	-0.4	+ 0.2	- 33.3%	
Income taxes -3.8 -10.3 - 6.5 + 171.1%	come taxes	-3.8	-10.3	- 6.5	+ 171.1%	
Net income 22.7 43.2 + 20.5 + 90.3%	et income	22.7	43.2	+ 20.5	+ 90.3%	
EPS (JPY) 41.28 78.75 +37.47 + 90.8%	PS (JPY)	41.28	78.75	+37.47	+ 90.8%	

oyalty and profit-sharing income
verseas sales Increase in export of Actemra to Roche
Increase due to sales growth of new products

Increase in income for Hemlibra

Other operating income Decrease in milestone income

Cost of sales

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

Operating expenses Increase of research and development expenses, due to progress of projects, etc.

INNOVATION BEYOND IMAGINATION

Year on Year (Core)

Sales Oct - Dec

Sales by Disease Area, Year on Year Comparisons (Billions of JPY)

Sales by Products, Year on Year Changes



vs. Forecast (Core)

Financial Overview Jan - Dec

	2019 Jan - Dec			
(Billions of JPY)	Forecast*	Actual	+/-	ment
Revenues	680.0	686.2	+ 6.2	100.9%
Sales	586.0	588.9	+ 2.9	100.5%
Domestic	437.0	437.6	+ 0.6	100.1%
Overseas	149.0	151.3	+ 2.3	101.5%
Royalties and other operating income	94.0	97.3	+ 3.3	103.5%
Royalty and profit-sharing income	74.0	76.5	+ 2.5	103.4%
Other operating income	20.0	20.8	+ 0.8	104.0%
Cost of sales	- 265.0	- 265.1	- 0.1	100.0%
(cost to sales ratio)	45.2%	45.0%	-0.2%pts	-
Gross profit	415.0	421.1	+ 6.1	101.5%
Operating expenses	- 197.0	- 196.2	+ 0.8	99.6%
Research and development	- 102.5	- 102.1	+ 0.4	99.6%
Operating profit	218.0	224.9	+ 6.9	103.2%
(operating margin)	32.1%	32.8%	+0.7%pts	-
EPS (JPY)	302.00	305.80	+ 3.80	101.3%

Overseas sales

Mainly an increase in export of Alecensa to Roche, due to difference in timing of export

Royalty and profit-sharing income Income for Hemlibra progressed well in view of the forecast

CHUGAI



INNOVATION BEYOND IMAGINATION

vs. Forecast (Core)

Sales Jan - Dec

Sales by Disease Area, Actual vs Forecast Comparisons (Billions of JPY) Sales by Products, Actual vs Forecast* Comparisons





vs. 2018 Year End

Overview of Financial Position

(Billions of JPY)	2018 Dec	2019 Dec	Change
Trade accounts receivable	150.8	139.6	- 11.2
Inventories	159.4	168.1	+ 8.7
Trade accounts payable	-35.9	-47.7	- 11.8
Other net working capital ^{*1}	-39.1	-22.9	+ 16.2
Net working capital	235.1	237.2	+ 2.1
Property, plant and equipment	222.4	255.6	+ 33.2
Right-of-use assets	-	9.7	+ 9.7
Intangible assets	22.7	23.5	+ 0.8
Other long-term assets - net ^{*2}	25.1	21.0	- 4.1
Long-term net operating assets	270.1	309.8	+ 39.7
Net operating assets	505.3	547.0	+ 41.7
Debt	-0.2	-	+ 0.2
Marketable securities	102.5	129.1	+ 26.6
Cash and cash equivalents	146.9	203.9	+ 57.0
Net cash	249.2	333.1	+ 83.9
Other non-operating assets - net^{*3}	2.1	-26.1	- 28.2
Net non-operating assets	251.3	307.0	+ 55.7
Total net assets	756.5	854.0	+ 97.5
Total net assets Total assets	756.5 919.5	854.0 1,058.9	+ 97.5 + 139.4

FY2019 Consolidated Financial Overview



Increase in net working capital

Increase in other net working capital grew 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 Chugai Life Science Park Yokohama.

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

Decrease in other non-operating assets - net

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

Equity ratio attributable to Chugai shareholders

End of December 2019	80.6%
End of December 2018	82.2%

FX rate to the JPY (end of period)		2018 Dec	2019 Dec
	1CHF	112.03	112.31
	1EUR	126.13	121.93
	1USD	110.28	108.88
	1SGD	80.70	80.72

*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.

vs. 2018 Year End



Roche Roche Group **Operating profit after adjustment** +245.2Operating profit +210.6Decrease in net working capital, etc. +6.2**Total investment** -70.0 Property, plant and equipment -53.0 Payment for lease liabilities -8.9 Intangible assets -8.2 **Operating free cash flow** +181.4Income tax payable, etc. -38.8 Income tax payable -34.8 Contribution for defined-benefit pension plan -11.5 Sales of investment securities +6.7Free cash flow +142.6**Dividends paid** -56.4 Net effect of currency translation on net cash, etc. -2.4 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) 30



Core

ROIC

FY2019 Consolidated Financial Overview



Net operating assets (NOA) increased significantly, especially Long-term net operating assets, due to aggressive capital investment such as Chugai Life Science Park Yokohama. Meanwhile, Core ROIC increased year-on-year due to growth of Core operating profit (after taxes).

(Billions of JPY)		2016 Dec	2017 Dec	2018 Dec	2019 Dec
Core operating profit		80.6	103.2	130.3	224.9
Income taxes		-21.3	-24.5	-30.2	-54.6
Core operating profit (after taxes)	(1)	59.3	78.6	100.1	170.3
Net working capital		258.5	250.7	235.1	237.2
Long-term net operating assets		172.7	189.5	270.1	309.8
Net operating assets	(2)	431.1	440.2	505.3	547.0
Core ROIC	(=(1)/(2)*)	14.6%	18.1%	21.2%	31.9%

*Balance of NOA is the average of opening and ending balances. Opening balance as of FY2019 was adjusted by the adoption of IFRS16 Leases.

2020 Forecast (Core)

Forecast 2020 Jan - Dec



FY2019 Consolidated Financial Overview

(Billions of JPY)	Actual 2019 Jan - Dec	Forecast 2020 Jan - Dec	Grow	wth	
Revenues	686.2	740.0	+ 53.8	+ 7.8%	Domestic sales
Sales	588.9	580.0	- 8.9	- 1.5%	Despite increase due to sales growth of new products, decrease due to impact from NHI
Domestic	437.6	411.6	- 26.0	- 5.9%	drug price revision and launching of generic drugs, etc.
Overseas	151.3	168.4	+ 17.1	+ 11.3%	Overseas sales
Royalties and other operating income	97.3	160.0	+ 62.7	+ 64.4%	Increase in export of Hemlibra to Roche
Royalty and profit-sharing income	76.5	141.0	+ 64.5	+ 84.3%	Royalty and profit-sharing income Increase in income for Hemlibra
Other operating income	20.8	19.0	- 1.8	- 8.7%	Cost of sales
Cost of sales	- 265.1	- 252.0	+ 13.1	- 4.9%	Cost to sales ratio improved due to a chang product mix, etc.
(cost to sales ratio)	45.0%	<mark>43.4%</mark>	-1.6%pts	-	Operating expenses
Gross profit	421.1	488.0	+ 66.9	+ 15.9%	Mainly increase of research and development
Operating expenses	- 196.2	- 213.0	- 16.8	+ 8.6%	Схреносо
Research and development	- 102.1	- 115.0	- 12.9	+ 12.6%	Average exchange rate
Operating profit	224.9	275.0	+ 50.1	+ 22.3%	2019 2020 Jan – Dec Jan – Dec
				Τ ΖΖ.3%	Actual *2 Forecast
(operating margin)	32.8%	37.2%	+4.4%pts	-	1CHF 109.72 110.00
Net income	167.6	201.0	+ 33.4	+ 19.9%	1EUR 122.08 121.00
		122.00	_	_	1USD 109.05 107.00
EPS (JPY)	305.80	^{*1} 366.00	+ 60.2	+ 19.7%	1SGD 79.94 80.00
wa					*2 Actual: market average exchange rate

^{*1} Amount excludes effect of the stock split. Ordinary share will be split three-for-one, with July 1, 2020 as the effective date.

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	2019	2020
	Jan – Dec	Jan – Dec
	Actual *2	Forecast
1CHF	109.72	110.00
1EUR	122.08	121.00
1USD	109.05	107.00
1SGD	79.94	80.00

*² Actual: market average exchange rate for the period of Jan – Dec.

2020 Forecast (Core)

FY2019 Consolidated Financial Overview



Movement of Operating Profit 2018 - 2020

(Billions of JPY)



INNOVATION BEYOND IMAGINATION

2020 Forecast (Core)

Sales Forecast vs. 2019 Actual



FY2019 Consolidated Financial Overview



34

Core



FY2019 Consolidated Financial Overview

Roche Roche Group

Cost to sales ratio and operating expenses ratio are decreasing; in contrast,

research and development expenses are rising steadily.

With the increase of ROOI, operating margin exceeded cost ratio in 2019. This trend is expected to be more pronounced in 2020.



* Cost to sales ratio is the ratio of product sales to total sales, and operating expenses ratio and operating profit ratio are the ratio of net sales to total revenues. 35
Outline of Hemlibra Sales to Roche



	2017	2018	2019	2020	2021 ~
	Export at i	nitial supply price			
Export sales	3.1 billion yen (actual)	2.3 billion yen (actual)	3.3 billion yen (actual) 3.3 billion yen (forecast*)	Export at ordinary supply pri	ice
				23.0 billion yen (forecast)	
		R	loyalty income for ini	tial shipment	
Royalty and profit-		2.0 billion yen (actual)	41.7 billion yen (actual) 40.0 billion yen (forecast*)	85.7 billion yen (forecast)	
sharing income	Roya	Ity income for intelled	tual properties		
		Profit-sharing in	come for co-promot	ion activities in UK, Germa	any, France, etc.
Expenses		Expenses for co-pron	notion activities in U	K, Germany, France, etc. s	hared by Chugai
				* Announced	on October 24, 2019 36



Basic profit distribution principles

Striving to provide a stable allocation of profit to all shareholders, taking into account \checkmark the strategic funding needs and earnings prospects

Basic profit distribution principles and dividends

for the fiscal year and the following fiscal year

Aiming for a consolidated dividend payout ratio of **50%** (**45% from next fiscal year**) \checkmark on average in comparison with Core EPS





FY2019 Consolidated Financial Overview



Stock Split

Purpose

Reduce the investment unit price for the Company's stock, increase the liquidity of the stocks, and to further expand the investor base

Outline

	Total number of shares issued	Before stock split	559,685,889	
Will be split		After stock split	1,679,057,667	
three-for-one	Announcement of record date	Monday, June 15, 2020		
	Record date	Tuesday, June 30, 2020		
	Effective date	Wednesday, July 1, 2020		

■ Core EPS and dividends per share forecast for 2020

(JPY)

	Core EPS	Dividends per share			
	COLE EPS	Interim	End of FY	Total	
After stock split*	122.00	75	25	-	
Effect of stock split excluded	366.00	75	75	150	

*Total dividends are not disclosed as simple totals for the Interim dividend (before stock split) and End of FY dividend (after stock split) are not possible.



Appendix

IFRS and Core Results Jan-Dec



	IFRS results	Non-core	e items	Core results	
(Billion JPY)	2019	Intangible	Others	2019	
	Jan - Dec	assets	others	Jan - Dec	
Revenues	686.2			686.2	
Sales	588.9			588.9	Non-Core
Royalties and other operating income	97.3			97.3	NOII-COIE
Cost of sales	-266.1	+1.0		-265.1	Intangible
Gross profit	420.1	+1.0		421.1	Amortiza Impairm
Operating expenses	-209.5	+2.8	+10.5	-196.2	mpann
Marketing and distribution	-77.2		+3.7	-73.5	Others
Research and development	-107.9	+2.8	+3.0	-102.1	Early ret Restruct
General and administration	-24.4		+3.8	-20.6	Legal inc
Operating profit	210.6	+3.8	+10.5	224.9	
Financing costs	-0.1			-0.1	
Other financial income (expense)	0.5			0.5	
Other expense	-3.1			-3.1	
Profit before taxes	207.9	+3.8	+10.5	222.2	
Income taxes	-50.3	-1.1	-3.1	-54.6	
Net income	157.6	+2.6	+7.4	167.6	
EPS(JPY)	287.43			305.80	

(Billions of JPY)

<u>items</u>

itangible assets	
Amortization	+1.2
Impairment	+2.6

Early retirement incentive program	+5.1
Restructuring expenses	+2.8
Legal income and expenses	+2.6

vs. Forecast (Core)

FY2019 Consolidated Financial Overview



Impact from Foreign Exchange



^{*1} Announced on October 24, 2019 ^{*2} Actual: market average exchange rate for the period Jan - Dec



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

January 30/31, 2020

Projects under Development (1)



As of January 30, 2020

	Phase I	Phase II	PNa	ase III	Filed
Oncology	GC33 / codrituzumab - HCC ERY974 - solid tumors RG7421 / cobimetinib - solid tumors RG7802 / cibisatamab - solid tumors RG7828 / mosunetuzumab - hematologic tumors RG7461 (FAP-IL2v) - solid tumors ★ RG6058 / tiragolumab - solid tumors ★		RG435 / Avastin (Tecentriq combo) - SCLC ★ - RCC - HCC - HCC (adjuvant) ★ RG7440 / ipatasertib - prostate cancer - breast cancer RG7596 / polatuzumab vedotin - DLBCL RG6264 (Herceptin+Perjeta) - breast cancer (Fixed-dose combination, subcutaneous injection)	AF802 (RG7853) / Alecensa - NSCLC (adjuvant) RG7446 / Tecentriq - NSCLC (adjuvant) - NSCLC (neoadjuvant) - NSCLC (neoadjuvant) - urothelial carcinoma - MIUC (adjuvant) - RCC - RCC (adjuvant) - early breast cancer - ovarian cancer - HCC - HCC (adjuvant) ★ - HNC (adjuvant)	RG6268 / Rozlytrek - NSCLC RG3502 / Kadcyla - breast cancer (adjuvant)
Bone & Joint			NRD101 / Suvenyl (Chi - knee osteoarthritis/sho		ED-71 / Edirol (China) - osteoporosis
Renal	EOS789 - Hyperphosphatemia				

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

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

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

INNOVATION	BEYOND	IMAGINATION

Projects under Development (2)





As of January 30, 2020

Roche Roche Group

	Phase I	Phase II	Phase III	Filed
Autoimmune	RG7845 / fenebrutinib - rheumatoid arthritis RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
	RG7935 / prasinezumab - Parkinson's disease		RG1450 / gantenerumab - Alzheimer's disease	SA237 (RG6168) / satralizumab (JP★/US/EU)
	GYM329 (RG6237) - neuromuscular disease		RG6042 (HTT ASO) - Huntington's disease	- NMOSD
Nerverler	RG7906 - psychiatric disorders		RG7916 / risdiplam - spinal muscular atrophy (PII/III)	
Neurology	RG6100 / semorinemab - Alzheimer's disease			
	RG7314 / balovaptan - autism spectrum disorder			
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis	SKY59 (RG6107) / crovalimab - PNH (PI/II)	RG7716 / faricimab - DME - nAMD	
	NXT007 - hemophilia A (PI/II)		Lotters in orange: in house proje	

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

Letters in orange: in-house projects

PNH: paroxysmal nocturnal hemoglobinuria DME: diabetic macular edema nAMD: neovascular age-related macular degeneration

HTT ASO: Antisense oligonucleotide targeting *HTT* mRNA NMOSD: neuromyelitis optica spectrum disorder *: Projects with advances in stages since October 24, 2019

Key News Flows in Q4 or later (1)



Launched	Hemlibra	Hemophilia A with inhibitors (Taiwan)	November, 2019
	Tecentriq	Optimal formulation for TNBC (iv 840 mg)	November, 2019
Approved	Hemlibra	Hemophilia A without inhibitors (Taiwan)	October, 2019
	Tecentriq	NSCLC 1 st line (with other antitumor agents)	November, 2019
	F1 CDx	CDx for Rozlytrek (<i>ROS1</i> + NSCLC)	December, 2019
Filed	satralizumab	NMOSD (JP)	November, 2019
New to Pipeline	Tecentriq + Avastin	Hepatocellular carcinoma (adjuvant)	P3 study
	Tecentriq + Avastin	Small cell lung cancer	P3 study
	tiragolumab	Solid tumors	P1 study
	FAP-IL2v	Solid tumors	P1 study
Removed from Pipeline	CKI27 anti-myostatin adnectin nemolizumab	Verastem Oncology Duchenne muscular dystrophy Pruritus in dialysis patients	Out-licensed (January, 2020) Development discontinued Temporary suspension of development
Designation	<mark>nemolizumab</mark>	Pruritus associated with prurigo nodularis	BTD
	polatuzumab vedotin	Diffuse large B-cell lymphoma	ODD

TNBC: triple negative breast cancer iv: intravenous infusion NSCLC: non-small cell lung cancer F1 CDx: FoundationOne CDx Cancer Genomic Profile CDx: companion diagnostics NMOSD: neuromyelitis optica spectrum disorder BTD: breakthrough therapy designation ODD: orphan drug designation

Letters in orange: in-house projects

Key News Flows in Q4 or later (2)



Late-stage Readouts	risdiplam risdiplam Tecentriq	Type 2 or 3 spinal muscular atrophy Type 1 spinal muscular atrophy Muscle invasive urothelial carcinoma (adjuvant)	P2/3 study (SUNFISH) P2/3 study (FIREFISH) P3 study (IMvigor010)
Medical Conference	Tecentriq + Avastin Perjeta / Herceptin <mark>crovalimab</mark> Perjeta	Hepatocellular carcinoma / IMbrave150 study Fixed-dose combination, sc / FeDeriCa study PNH / P1/P2 COMPOSER study HER2+ eBC (adjuvant) / APHINITY study	ESMO ASIA2019 SABCS2019 ASH2019 SABCS2019
Others	satralizumab	NMOSD / SAkuraSky study (Add-on)	Published in NEJM

sc: subcutaneous injection PNH: paroxysmal nocturnal hemoglobinuria eBC: early breast cancer NMOSD: neuromyelitis optica spectrum disorder ESMO: European Society for Medical Oncology SABCS: San Antonio Breast Cancer Symposium ASH: American Society of Hematology Letters in orange: in-house projects

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

[2nd wave] Tecentriq + Avastin in HCC Medically Meaningful Improvement





Source: Roche JPMorgan Healthcare Conference, San Francisco 2020 (partially modified)

[3rd wave] RG6058(tiragolumab) Anti-TIGIT human monoclonal antibody



Mode of Action

- TIGIT is an immune checkpoint receptor, expressed on NK cells and T cells
- CD226 expressed on immunes cells binds to PVR on tumor cells and activates immune system. However, TIGIT is believed to inactivate immune cells through binding with PVR with high affinity
- Tiragolumab is expected to enhance tumor immune response by blocking the interaction of TIGIT and PVR

Tiragolumab restores and maintains an immune response in a different pathway from Tecentriq, and a combination of both is expected to provide further therapeutic effects.

TIGIT: T-cell immunoreceptor with Ig and ITIM domains PVR: poliovirus receptor



Breast Cancer Portfolio of Roche Group Expanding beyond HER2+ Disease



	mAb	Small Molecule	ADC	CPI	Bispecific
HER2+ BC 20%*	HERCEPTIN PERJETA		KADCYLA	TECENTRIQ	RG6194 (HER2 × CD3)
HR+/HER2- BC 65%*		ipatasertib (AKTi) GDC-0077 (PI3Ki) GDC-9545 (SERD)			
TNBC 15%*		ipatasertib (AKTi)		TECENTRIQ	

* Estimated by Roche

mAB: monoclonal antibody, ADC: antibody drug conjugate, CPI: checkpoint inhibitor, TNBC: triple negative breast cancer

Roche has Established the Standard of Care across HER2+ Breast Cancer

Roche Roche Group

Early Breast Cancer		Metastatic Breast Cancer		
Neoadjuvant	Adjuvant	1L mBC	2L mBC	
HERCEPTIN + PERJETA	HERCEPTIN + PERJETA	HERCEPTIN + PERJETA	KADCYLA	
NeoSphere ✓ 2013	APHINITY 🗸 2017	CLEOPATRA 🗸 2012	EMILIA ✓ 2013	
	KADCYLA		 Primary endpoint met 	
	KATHERINE ✓ 2019		Source: Roche Analyst Event at 2019 SABCS (partially modified)	

APHINITY study (Interim analysis at 6 years) Adjuvant therapy for HER2+ early breast cancer

	IDFS Hazard Rat	io		6-yr IDFS ra	te
Population	Primary analysis	Updated analysis	Perjeta +Herceptin	Herceptin	Absolute benefit
ITT	0.81 (0.66-1.00)	0.76 (0.64-0.91)	90.6%	87.8%	+2.8% points
LN+	0.77 (0.62-0.96)	0.72 (0.59-0.87)	87.9%	83.4%	+4.5% points
LN-	1.13 (0.68-1.86)	1.02 (0.69-1.53)	95.0%	94.9%	+0.1% points
HR+	0.86 (0.66-1.13)	0.73 (0.59-0.92)	91.2%	88.2%	+3.0% points
HR-	0.76 (0.56-1.04)	0.83 (0.63-1.10)	89.5%	87.0%	+2.5% points

• The node + cohort continues to derive clear benefit from the addition of Perjeta

Treatment benefit of Perjeta is now seen in both HR+ and HR- cohorts

TNBC Treatment Landscape

Overview of Development Pipeline

Roche Group

TNBC is not one disease, but a constellation of diseases



Tecentriq is the first new agent approved in TNBC in ~15 years

TNBC: triple negative breast cancer, mBC: metastatic breast cancer, PHC: personalized healthcare, NME: new moleculear entity PI3K/AKT/PTENm includes any of the three mutations

* Estimated by Roche



Licensable Antibody Engineering Technologies



SMART-Ig®

Creates the Recycling Antibody®, which is designed to achieve a longer duration of action than conventional antibodies by binding to an antigen multiple times.

SMART-Fc[®]

Creates the Sweeping Antibody®, which eliminates soluble antigens from plasma.

ACT-Ig[®]

Reduces clearance from plasma.

ART-Fc[®]

Expected to enhance the antibody-dependent cellular cytotoxicity (ADCC) activity and/or antibody-dependent cellular phagocytosis (ADCP) activity by improving the binding activity of the antibody to specific type of FcvRs. Potential applications in the oncology field.

∆GK™

Makes manufacturing process less complex. Removes heavy chain C-terminal amino acids (glycine and lysine). This technology reduces the heterogeneity of IgG antibody and can be widely applicable to IgG antibodies.

ART-Ig[®]/FAST-Ig[™]

Enable large-scale production of bispecific lgG antibodies which bind to two different antigens. Eliminates complex downstream process and enables highly efficient manufacturing process.

TRAB[®]

Activates T cells in an antigen-dependent manner to specifically kill cancer cells without non-specific FcyR dependent T cell activation.

TwoB-lg®

Increases binding selectivity of the Fc region to inhibitory Fcγ receptor IIb. Potential applications in autoimmune diseases and other areas.

pl-Fc™

Improves agonistic activity or efficiency of soluble antigen elimination from plasma through the facilitation of Fc-FcγR interaction. Enhances the potency when used in combination of SMART-Fc[®]/TwoB-Ig[®]

as of January 30, 2020

Projected Submissions (Post PoC NMEs and Products)

CHUGAI

Filed		NME li	ne extension			
AVASTIN (RG435)	ROZLYTREK (RG6268) NSCLC (<i>ROS1</i> +)	satralizumab (SA237/RG6168) NMOSD (US)	in-house in-licensed NSCLC: non-small cell lung cancer RCC: renal cell carcinoma	NMOSD: neuromyelitis optica spectrum disorder nAMD: neovascular age-related macular degeneration		
HCC TECENTRIQ (RG7446)	KADCYLA (RG3502) Breast Cancer (adjuvant)	satralizumab (SA237/RG6168) NMOSD (EU)	MIUC: muscle invasive urothelial carcinoma HCC: hepatocellular carcinoma HNC: hepatocellular carcinoma Sc: subcutaneous injection HTT ASO: Antisense oligonucleotide targeting H SCLC: small cell lung cancer		combination s injection ense oligonucleotide targeting <i>HTT</i> mRNA	
HCC TECENTRIQ (RG7446) Ovarian Cancer	EDIROL (ED-71) Osteoporosis (China)	satralizumab (SA237/RG6168) NMOSD (JP)		TECENTRIQ (RG7446) RCC (adjuvant)	faricimab (RG7716) nAMD	
AVASTIN (RG435) RCC	risdiplam (RG7916) Spinal Muscular Atrophy			AVASTIN (RG435) HCC (adjuvant)	HTT ASO (RG6042) Huntington's Disease	
TECENTRIQ (RG7446) RCC	SUVENYL (NRD101) Knee Osteoarthritis /Shoulder Periarthritis (China)	ipatasertib (RG7440) Prostate Cancer		TECENTRIQ (RG7446) HCC (adjuvant)	gantenerumab (RG1450) Alzheimer's Disease	
TECENTRIQ (RG7446) MIUC (adjuvant)	polatuzumab vedotin (RG7596) DLBCL	TECENTRIQ (RG7446) Early Breast Cancer	faricimab (RG7716) Diabetic Macular Edema	AVASTIN (RG435) SCLC	ALECENSA (AF802/RG7853) NSCLC (adjuvant)	
TECENTRIQ (RG7446) Urothelial Carcinoma	ipatasertib (RG7440) Breast Cancer	TECENTRIQ (RG7446) NSCLC (neoadjuvant)	RG6264 (FDC, sc) Breast Cancer	TECENTRIQ (RG7446) NSCLC (adjuvant)	TECENTRIQ (RG7446) HNC (adjuvant)	

2020

2021

2022 and beyond

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 five indications of five products, and one of

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
CellCept®	Inhibition of graft versus host disease (GVHD) in patients received allogeneic hematopoietic stem cell transplantation	Submitted company opinion and waiting for evaluation by the committee

Letters in orange: projects with advances in status since July 25, 2019 57

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