

Supplementary Materials for
Consolidated Financial Results for
the 1st Quarter of Fiscal Year 2022. 12 (IFRS)

Innovation all for the patients



CHUGAI PHARMACEUTICAL CO., LTD.



A member of the Roche group

- Notes: 1. Portions of this report that refer to performance forecasts or any other future events are believed to be reasonable under information available at the time of the forecasts. Actual results may materially differ from these forecasts due to potential risks and uncertainties.
2. Amounts shown in this report are rounded to the nearest 0.1 billion yen. Variance and % are calculated based on the amounts shown.
3. Exchange rates used for each period are as follows.

QTR

(Yen)

		Actual*				Actual*			
		FY2021				FY2022			
		1-3	4-6	7-9	10-12	1-3	4-6	7-9	10-12
		QTR	QTR	QTR	QTR	QTR	QTR	QTR	QTR
CHF		117.08	120.11	119.88	123.26	125.78			
EUR		127.65	131.87	129.78	130.02	130.43			
USD		105.83	109.44	110.08	113.66	116.17			
SGD		79.47	82.12	81.39	83.75	85.92			

*Market average exchange rate

YTD

		Actual*				Actual*				Assumption
		FY2021				FY2022				FY2022
		1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12
		Full-year	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year
CHF		113.72	117.08	118.60	119.03	120.10	125.78			122.00
EUR		121.69	127.65	129.76	129.77	129.83	130.43			130.00
USD		106.80	105.83	107.63	108.45	109.75	116.17			112.00
SGD		77.41	79.47	80.80	81.00	81.69	85.92			84.00

*Market average exchange rate

Period-end

		Actual				Actual			
		FY2021				FY2022			
		31 Dec.	31 Mar.	30 Jun.	30 Sep.	31 Dec.	31 Mar.	30 Jun.	30 Sep.
CHF		117.10	117.14	120.02	119.76	125.95	131.93		
EUR		126.89	129.30	131.48	129.85	130.31	135.92		
USD		103.19	110.37	110.52	111.97	115.07	121.82		
SGD		77.98	81.87	82.15	82.27	85.09	90.07		

Reconciliation of IFRS results to Core results

(Billions of yen)

	FY2021				FY2022			
	1-3				1-3			
	IFRS results	Intangible assets	Others	Core results	IFRS results	Intangible assets	Others	Core results
Revenues	168.8	–	–	168.8	360.6	–	(91.9)	268.6
Sales	130.3	–	–	130.3	242.7	–	–	242.7
Royalties and other operating income	38.6	–	–	38.6	25.9	–	–	25.9
Other revenue	–	–	–	–	91.9	–	(91.9)	–
Cost of sales	(55.3)	0.3	–	(55.0)	(114.4)	0.3	–	(114.1)
Gross profit	113.5	0.3	–	113.8	246.1	0.3	(91.9)	154.5
Operating expenses	(49.5)	0.0	1.1	(48.5)	(59.1)	0.2	3.4	(55.6)
Marketing and distribution	(15.9)	–	0.0	(15.8)	(16.8)	–	0.1	(16.7)
Research and development	(29.7)	0.0	1.0	(28.7)	(33.9)	0.2	0.8	(32.9)
General and administration	(3.9)	–	0.0	(3.9)	(8.5)	–	2.5	(6.0)
Operating profit	64.0	0.3	1.1	65.4	187.0	0.4	(88.5)	98.9
Financing costs	(0.0)	–	–	(0.0)	(0.0)	–	–	(0.0)
Other financial income (expense)	0.3	–	–	0.3	1.6	–	–	1.6
Other expense	–	–	–	–	(2.4)	–	–	(2.4)
Profit before taxes	64.2	0.3	1.1	65.6	186.2	0.4	(88.5)	98.1
Income taxes	(16.8)	(0.1)	(0.3)	(17.2)	(54.4)	(0.1)	27.0	(27.5)
Net income	47.4	0.2	0.8	48.4	131.8	0.3	(61.5)	70.6
Attributable to								
Chugai shareholders	47.4	0.2	0.8	48.4	131.8	0.3	(61.5)	70.6
Non-controlling interests	–	–	–	–	–	–	–	–

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. Chugai's recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. 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.

The table above shows the reconciliation of IFRS results into Core results. The detail is as below.

Intangible assets

Amortization (0.3 billion yen in 2021 and 0.3billion yen in 2022)

Impairment (None in 2021 and 0.2billion in 2022)

Others

Income from settlement agreement (None in 2021 and –91.9billion yen in 2022)

Restructuring expenses etc. (1.1 billion yen in 2021 and 3.4billion yen in 2022)

IFRS results (QTR)

(Billions of yen)

	Actual FY2021				Actual FY2022							
	1-3	4-6	7-9	10-12	1-3	Change	4-6	Change	7-9	Change	10-12	Change
	QTR	QTR	QTR	QTR	QTR	(%)	QTR	(%)	QTR	(%)	QTR	(%)
Revenues	168.8	221.4	287.3	322.3	360.6	+113.6						
Sales	130.3	173.9	234.5	264.1	242.7	+86.3						
Domestic	94.9	108.5	159.2	156.3	161.7	+70.4						
Overseas	35.4	65.3	75.3	107.8	81.0	+128.8						
Royalties and other operating income	38.6	47.5	52.7	58.1	25.9	(32.9)						
Royalty and profit-sharing income	36.6	46.7	52.1	51.8	25.2	(31.1)						
Other operating income	2.0	0.8	0.6	6.4	0.7	(65.0)						
Other revenue	–	–	–	–	91.9	–						
Cost of sales	(55.3)	(68.1)	(104.2)	(110.6)	(114.4)	+106.9						
(% of Sales)	42.4	39.2	44.4	41.9	47.1	–						
Gross profit	113.5	153.4	183.1	211.7	246.1	+116.8						
(% of Revenues)	67.2	69.3	63.7	65.7	68.2	–						
Operating expenses	(49.5)	(56.6)	(60.9)	(72.6)	(59.1)	+19.4						
(% of Revenues)	29.3	25.6	21.2	22.5	16.4	–						
Marketing and distribution	(15.9)	(17.9)	(18.5)	(24.3)	(16.8)	+5.7						
(% of Revenues)	9.4	8.1	6.4	7.5	4.7	–						
Research and development	(29.7)	(33.6)	(36.2)	(37.8)	(33.9)	+14.1						
(% of Revenues)	17.6	15.2	12.6	11.7	9.4	–						
General and administration	(3.9)	(5.2)	(6.3)	(10.5)	(8.5)	+117.9						
(% of Revenues)	2.3	2.3	2.2	3.3	2.4	–						
Operating profit	64.0	96.7	122.2	139.1	187.0	+192.2						
(% of Revenues)	37.9	43.7	42.5	43.2	51.9	–						
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0						
Other financial income (expense)	0.3	0.3	0.3	(0.9)	1.6	+433.3						
Other expense	–	(0.0)	(2.8)	0.3	(2.4)	–						
Profit before taxes	64.2	97.0	119.7	138.4	186.2	+190.0						
(% of Revenues)	38.0	43.8	41.7	42.9	51.6	–						
Income taxes	(16.8)	(26.3)	(33.7)	(39.6)	(54.4)	+223.8						
Net income	47.4	70.7	86.0	98.8	131.8	+178.1						
(% of Revenues)	28.1	31.9	29.9	30.7	36.6	–						
Attributable to												
Chugai shareholders	47.4	70.7	86.0	98.8	131.8	+178.1						
Non-controlling interests	–	–	–	–	–	–						
Earnings per share												
Basic (yen)	28.84	43.02	52.31	60.11	80.14	+177.9						
Diluted (yen)	28.82	42.99	52.28	60.08	80.09	+177.9						

Other financial income (expense) includes net amount of FX related gains/losses.

IFRS results (YTD)

(Billions of yen)

	Actual	Actual				Actual							
	FY2020	FY2021				FY2022							
	1-12	1-3	1-6	1-9	1-12	1-3	Change	1-6	Change	1-9	Change	1-12	Change
	YTD	YTD	YTD	YTD	YTD	YTD	(%)	YTD	(%)	YTD	(%)	YTD	(%)
Revenues	786.9	168.8	390.2	677.5	999.8	360.6	+113.6						
Sales	633.3	130.3	304.1	538.7	802.8	242.7	+86.3						
Domestic	409.1	94.9	203.4	362.6	518.9	161.7	+70.4						
Overseas	224.2	35.4	100.7	176.0	283.9	81.0	+128.8						
Royalties and other operating income	153.6	38.6	86.1	138.8	196.9	25.9	(32.9)						
Royalty and profit-sharing income	129.6	36.6	83.3	135.4	187.2	25.2	(31.1)						
Other operating income	24.1	2.0	2.8	3.4	9.8	0.7	(65.0)						
Other revenue	–	–	–	–	–	91.9	–						
Cost of sales	(273.5)	(55.3)	(123.4)	(227.6)	(338.1)	(114.4)	+106.9						
(% of Sales)	43.2	42.4	40.6	42.2	42.1	47.1	–						
Gross profit	513.5	113.5	266.8	449.9	661.6	246.1	+116.8						
(% of Revenues)	65.3	67.2	68.4	66.4	66.2	68.2	–						
Operating expenses	(212.3)	(49.5)	(106.2)	(167.1)	(239.7)	(59.1)	+19.4						
(% of Revenues)	27.0	29.3	27.2	24.7	24.0	16.4	–						
Marketing and distribution	(72.6)	(15.9)	(33.8)	(52.2)	(76.6)	(16.8)	+5.7						
(% of Revenues)	9.2	9.4	8.7	7.7	7.7	4.7	–						
Research and development	(117.9)	(29.7)	(63.3)	(99.5)	(137.3)	(33.9)	+14.1						
(% of Revenues)	15.0	17.6	16.2	14.7	13.7	9.4	–						
General and administration	(21.8)	(3.9)	(9.1)	(15.3)	(25.8)	(8.5)	+117.9						
(% of Revenues)	2.8	2.3	2.3	2.3	2.6	2.4	–						
Operating profit	301.2	64.0	160.7	282.8	421.9	187.0	+192.2						
(% of Revenues)	38.3	37.9	41.2	41.7	42.2	51.9	–						
Financing costs	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0						
Other financial income (expense)	(1.5)	0.3	0.6	0.9	0.1	1.6	+433.3						
Other expense	(1.5)	–	(0.0)	(2.8)	(2.5)	(2.4)	–						
Profit before taxes	298.2	64.2	161.3	280.9	419.4	186.2	+190.0						
(% of Revenues)	37.9	38.0	41.3	41.5	41.9	51.6	–						
Income taxes	(83.5)	(16.8)	(43.1)	(76.8)	(116.4)	(54.4)	+223.8						
Net income	214.7	47.4	118.1	204.2	303.0	131.8	+178.1						
(% of Revenues)	27.3	28.1	30.3	30.1	30.3	36.6	–						
Attributable to													
Chugai shareholders	214.7	47.4	118.1	204.2	303.0	131.8	+178.1						
Non-controlling interests	–	–	–	–	–	–	–						
Earnings per share													
Basic (yen)	130.66	28.84	71.86	124.17	184.29	80.14	+177.9						
Diluted (yen)	130.53	28.82	71.81	124.09	184.17	80.09	+177.9						

Other financial income (expense) includes net amount of FX related gains/losses.

Effective July 1, 2020, Chugai Pharmaceutical Co., Ltd. (“Chugai”) implemented a three-for-one stock split of its common stock.

“Earnings per share (Basic)” and “Earnings per share (Diluted)” presents the amount after the stock split.

Core results (QTR)

(Billions of yen)

	Actual				Actual							
	FY2021				FY2022							
	1-3	4-6	7-9	10-12	1-3	Change	4-6	Change	7-9	Change	10-12	Change
	QTR	QTR	QTR	QTR	QTR	(%)	QTR	(%)	QTR	(%)	QTR	(%)
Revenues	168.8	221.4	287.3	322.3	268.6	+59.1						
Sales	130.3	173.9	234.5	264.1	242.7	+86.3						
Domestic	94.9	108.5	159.2	156.3	161.7	+70.4						
Overseas	35.4	65.3	75.3	107.8	81.0	+128.8						
Royalties and other operating income	38.6	47.5	52.7	58.1	25.9	(32.9)						
Royalty and profit-sharing income	36.6	46.7	52.1	51.8	25.2	(31.1)						
Other operating income	2.0	0.8	0.6	6.4	0.7	(65.0)						
Cost of sales	(55.0)	(66.8)	(103.8)	(109.8)	(114.1)	+107.5						
(% of Sales)	42.2	38.4	44.3	41.6	47.0	-						
Gross profit	113.8	154.6	183.4	212.5	154.5	+35.8						
(% of Revenues)	67.4	69.8	63.8	65.9	57.5	-						
Operating expenses	(48.5)	(54.1)	(58.5)	(69.1)	(55.6)	+14.6						
(% of Revenues)	28.7	24.4	20.4	21.4	20.7	-						
Marketing and distribution	(15.8)	(18.1)	(18.2)	(23.6)	(16.7)	+5.7						
(% of Revenues)	9.4	8.2	6.3	7.3	6.2	-						
Research and development	(28.7)	(31.1)	(34.3)	(35.7)	(32.9)	+14.6						
(% of Revenues)	17.0	14.0	11.9	11.1	12.2	-						
General and administration	(3.9)	(4.9)	(6.0)	(9.9)	(6.0)	+53.8						
(% of Revenues)	2.3	2.2	2.1	3.1	2.2	-						
Operating profit	65.4	100.5	124.9	143.4	98.9	+51.2						
(% of Revenues)	38.7	45.4	43.5	44.5	36.8	-						
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0						
Other financial income (expense)	0.3	0.3	0.3	(0.9)	1.6	+433.3						
Other expense	-	(0.0)	(2.8)	0.3	(2.4)	-						
Profit before taxes	65.6	100.8	122.5	142.7	98.1	+49.5						
(% of Revenues)	38.9	45.5	42.6	44.3	36.5	-						
Income taxes	(17.2)	(27.4)	(34.5)	(40.9)	(27.5)	+59.9						
Net income	48.4	73.3	87.9	101.8	70.6	+45.9						
(% of Revenues)	28.7	33.1	30.6	31.6	26.3	-						
Attributable to												
Chugai shareholders	48.4	73.3	87.9	101.8	70.6	+45.9						
Non-controlling interests	-	-	-	-	-	-						
Core earnings per share (diluted) (yen)	29.42	44.58	53.45	61.90	42.91	+45.9						

Please see page 1 "Reconciliation of IFRS results to Core results" for the detail of the adjustments.

Core earnings per share (diluted) (yen) : Net income attributable to Chugai shareholders / Weighted average number of shares in issue used to calculate diluted earnings per share.

Other financial income (expense) includes net amount of FX related gains/losses.

Core results (YTD)

(Billions of yen)

	Actual	Actual				Actual								Forecast (Feb 3th announced)	
	FY2020	FY2021				FY2022								FY2022	
	1-12	1-3	1-6	1-9	1-12	1-3	Change (%)	1-6	Change (%)	1-9	Change (%)	1-12	Change (%)	1-12	Change (%)
	YTD	YTD	YTD	YTD	YTD	YTD		YTD		YTD		YTD		YTD	
Revenues	786.9	168.8	390.2	677.5	999.8	268.6	+59.1							1,150.0	+15.0
Sales	633.3	130.3	304.1	538.7	802.8	242.7	+86.3							1,031.5	+28.5
Domestic	409.1	94.9	203.4	362.6	518.9	161.7	+70.4							646.3	+24.6
Overseas	224.2	35.4	100.7	176.0	283.9	81.0	+128.8							385.2	+35.7
Royalties and other operating income	153.6	38.6	86.1	138.8	196.9	25.9	(32.9)							118.5	(39.8)
Royalty and profit-sharing income	129.6	36.6	83.3	135.4	187.2	25.2	(31.1)							114.0	(39.1)
Other operating income	24.1	2.0	2.8	3.4	9.8	0.7	(65.0)							4.5	(54.1)
Cost of sales	(272.3)	(55.0)	(121.9)	(225.7)	(335.5)	(114.1)	+107.5							(460.0)	+37.1
(% of Sales)	43.0	42.2	40.1	41.9	41.8	47.0	–							44.6	–
Gross profit	514.7	113.8	268.4	451.8	664.3	154.5	+35.8							690.0	+3.9
(% of Revenues)	65.4	67.4	68.8	66.7	66.4	57.5	–							60.0	–
Operating expenses	(206.7)	(48.5)	(102.5)	(161.1)	(230.2)	(55.6)	+14.6							(250.0)	+8.6
(% of Revenues)	26.3	28.7	26.3	23.8	23.0	20.7	–							21.7	–
Marketing and distribution	(71.5)	(15.8)	(34.0)	(52.2)	(75.8)	(16.7)	+5.7								
(% of Revenues)	9.1	9.4	8.7	7.7	7.6	6.2	–								
Research and development	(113.5)	(28.7)	(59.9)	(94.1)	(129.8)	(32.9)	+14.6							(149.5)	+15.2
(% of Revenues)	14.4	17.0	15.4	13.9	13.0	12.2	–							13.0	–
General and administration	(21.7)	(3.9)	(8.7)	(14.7)	(24.6)	(6.0)	+53.8								
(% of Revenues)	2.8	2.3	2.2	2.2	2.5	2.2	–								
Operating profit	307.9	65.4	165.8	290.7	434.1	98.9	+51.2							440.0	+1.4
(% of Revenues)	39.1	38.7	42.5	42.9	43.4	36.8	–							38.3	–
Financing costs	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0								
Other financial income (expense)	(1.5)	0.3	0.6	0.9	0.1	1.6	+433.3								
Other expense	(1.5)	–	(0.0)	(2.8)	(2.5)	(2.4)	–								
Profit before taxes	304.9	65.6	166.4	288.9	431.6	98.1	+49.5								
(% of Revenues)	38.7	38.9	42.6	42.6	43.2	36.5	–								
Income taxes	(85.5)	(17.2)	(44.7)	(79.2)	(120.1)	(27.5)	+59.9								
Net income	219.4	48.4	121.7	209.7	311.5	70.6	+45.9							312.5	+0.3
(% of Revenues)	27.9	28.7	31.2	31.0	31.2	26.3	–							27.2	–
Attributable to															
Chugai shareholders	219.4	48.4	121.7	209.7	311.5	70.6	+45.9								
Non-controlling interests	–	–	–	–	–	–	–								
Weighted average number of shares in issue used to calculate diluted earnings per share (Millions of shares)	1,645	1,645	1,645	1,645	1,645	1,645	0.0								
Core earnings per share (diluted) (yen)	133.39	29.42	73.99	127.45	189.35	42.91	+45.9							190.00	+0.3
Core payout ratio (%)	41.2				40.1									40.0	–
Dividend per share (Full year) (yen)	–				76									76	–
Dividend per share (Year end) (yen)	30				46									38	–
Dividend per share (Half year) (yen)	75				30									38	–

Please see page 1 “Reconciliation of IFRS results to Core results” for the detail of the adjustments.

Core earnings per share (diluted) (yen) : Net income attributable to Chugai shareholders / Weighted average number of shares in issue used to calculate diluted earnings per share.

Other financial income (expense) includes net amount of FX related gains/losses.

Effective July 1, 2020, Chugai Pharmaceutical Co., Ltd. (“Chugai”) implemented a three-for-one stock split of its common stock. Core EPS presents the amount after the stock split.

Weighted average number of shares in issue used to calculate diluted earnings per share presents the amount after the stock split.

The dividend for the second quarter of the fiscal year 2020 presents the amount prior to the stock split.

The annual dividend per share for the fiscal year ended December 31, 2020 is not stated because the amounts cannot be simply combined due to the implementation of the stock split.

The annual dividend per share is ¥165 when calculated based on the assumption of no stock split, and ¥55 when calculated with the stock split taken into account.

Core statements of revenues (QTR)

	Actual				Actual							
	FY2021				FY2022							
	1-3	4-6	7-9	10-12	1-3	Change	4-6	Change	7-9	Change	10-12	Change
	QTR	QTR	QTR	QTR	QTR	(%)	QTR	(%)	QTR	(%)	QTR	(%)
Sales	130.3	173.9	234.5	264.1	242.7	+86.3						
Domestic	94.9	108.5	159.2	156.3	161.7	+70.4						
Oncology	57.9	66.2	67.0	70.4	58.4	+0.9						
Avastin	18.8	20.4	20.6	21.1	16.5	(12.2)						
Tecentriq	14.1	16.4	15.5	16.1	13.4	(5.0)						
Perjeta	7.4	8.2	8.1	8.5	7.4	0.0						
Alecensa	6.0	7.1	7.0	7.5	6.3	+5.0						
Polivy	–	0.9	2.6	3.3	2.7	–						
Kadcyla	3.2	4.0	4.1	4.4	4.1	+28.1						
Herceptin	2.6	2.6	2.3	2.3	1.8	(30.8)						
Gazyva	1.0	1.1	1.1	1.2	1.0	0.0						
Rituxan	1.2	1.2	1.2	1.5	1.0	(16.7)						
Foundation Medicine	1.0	1.2	1.3	1.6	1.6	+60.0						
Other products	2.6	3.1	3.1	2.9	2.6	0.0						
Primary	36.9	42.3	92.3	85.9	103.2	+179.7						
Ronapreve	–	–	42.8	34.6	60.8	–						
Hemlibra	8.8	9.9	10.6	12.3	10.0	+13.6						
Actemra	9.2	11.0	11.6	11.4	9.9	+7.6						
Enspryng	1.4	2.2	2.6	3.5	3.3	+135.7						
Edirol	2.9	4.7	9.9	4.9	3.3	+13.8						
Mircera	3.4	3.6	3.7	3.7	2.6	(23.5)						
Evrysdi	–	–	0.4	1.9	2.1	–						
CellCept	2.0	2.2	2.0	2.2	1.8	(10.0)						
Bonviva	2.0	2.1	2.0	2.1	1.7	(15.0)						
Oxarol	1.4	1.5	1.6	1.6	1.4	0.0						
Other products	5.8	5.1	5.0	7.6	6.3	+8.6						
Overseas	35.4	65.3	75.3	107.8	81.0	+128.8						
Hemlibra	8.5	24.7	28.5	52.5	44.7	+425.9						
To Roche	8.0	24.2	27.8	52.0	44.2	+452.5						
Actemra	17.4	20.5	25.6	39.3	25.7	+47.7						
To Roche	16.9	19.7	24.9	38.7	24.6	+45.6						
Alecensa	6.0	15.0	17.2	11.8	5.2	(13.3)						
To Roche	5.6	14.5	16.7	11.3	4.6	(17.9)						
Enspryng	–	0.9	0.3	0.3	1.2	–						
To Roche	–	0.9	0.3	0.3	1.2	–						
Neutrogen	2.2	2.5	2.1	2.3	2.4	+9.1						
Other products	1.2	1.7	1.6	1.7	1.9	+58.3						
Royalties and other operating income	38.6	47.5	52.7	58.1	25.9	(32.9)						
Royalty and profit-sharing income	36.6	46.7	52.1	51.8	25.2	(31.1)						
Other operating income	2.0	0.8	0.6	6.4	0.7	(65.0)						
Revenues	168.8	221.4	287.3	322.3	268.6	+59.1						
Domestic	95.3	109.0	159.8	158.3	162.7	+70.7						
Overseas	73.6	112.4	127.5	164.0	105.9	+43.9						

Core statements of revenues (YTD)

(Billions of yen)

		Actual	Actual				Actual								Forecast (Feb 3th announced)		
		FY2020	FY2021				FY2022								FY2022		
		1-12	1-3	1-6	1-9	1-12	1-3	Change (%)	1-6	Change (%)	1-9	Change (%)	1-12	Change (%)	1-12	Change (%)	
		YTD	YTD	YTD	YTD	YTD	YTD		YTD		YTD		YTD		YTD		
Sales		633.3	130.3	304.1	538.7	802.8	242.7	+86.3								1,031.5	+28.5
Domestic		409.1	94.9	203.4	362.6	518.9	161.7	+70.4								646.3	+24.6
Oncology		232.3	57.9	124.1	191.1	261.5	58.4	+0.9								260.5	(0.4)
Avastin		81.5	18.8	39.2	59.8	80.9	16.5	(12.2)								69.4	(14.2)
Tecentriq		37.5	14.1	30.5	46.1	62.2	13.4	(5.0)								62.0	(0.3)
Perjeta		33.5	7.4	15.7	23.8	32.2	7.4	0.0								33.7	+4.7
Alecensa		26.0	6.0	13.1	20.1	27.7	6.3	+5.0								28.7	+3.6
Polivy		-	-	0.9	3.5	6.8	2.7	-								16.2	+138.2
Kadcyla		10.2	3.2	7.2	11.2	15.7	4.1	+28.1								16.0	+1.9
Herceptin		15.9	2.6	5.2	7.5	9.8	1.8	(30.8)								8.3	(15.3)
Gazyva		4.6	1.0	2.1	3.2	4.5	1.0	0.0								5.4	+20.0
Rituxan		7.2	1.2	2.4	3.6	5.1	1.0	(16.7)								4.1	(19.6)
Foundation Medicine		2.8	1.0	2.2	3.5	5.1	1.6	+60.0								9.1	+78.4
Other products		13.0	2.6	5.7	8.8	11.6	2.6	0.0								7.5	(35.3)
Primary		176.8	36.9	79.3	171.6	257.4	103.2	+179.7								385.8	+49.9
Ronapreve		-	-	-	42.8	77.4	60.8	-								199.0	+157.1
Hemlibra		34.1	8.8	18.7	29.3	41.6	10.0	+13.6								51.8	+24.5
Actemra		39.3	9.2	20.3	31.9	43.2	9.9	+7.6								41.9	(3.0)
Enspryng		1.3	1.4	3.5	6.2	9.7	3.3	+135.7								16.7	+72.2
Edirol		27.8	2.9	7.6	17.5	22.3	3.3	+13.8								10.8	(51.6)
Mircera		17.5	3.4	7.1	10.7	14.4	2.6	(23.5)								10.2	(29.2)
Evrysdi		-	-	-	0.4	2.3	2.1	-								8.8	+282.6
CellCept		9.1	2.0	4.1	6.2	8.4	1.8	(10.0)								7.4	(11.9)
Bonviva		8.9	2.0	4.1	6.1	8.2	1.7	(15.0)								7.0	(14.6)
Oxarol		6.4	1.4	3.0	4.6	6.2	1.4	0.0								5.1	(17.7)
Other products		32.4	5.8	11.0	16.0	23.6	6.3	+8.6								27.1	+14.8
Overseas		224.2	35.4	100.7	176.0	283.9	81.0	+128.8								385.2	+35.7
Hemlibra		26.1	8.5	33.2	61.7	114.2	44.7	+425.9								186.0	+62.9
To Roche		24.6	8.0	32.2	60.0	112.0	44.2	+452.5								182.7	+63.1
Actemra		134.4	17.4	37.9	63.5	102.8	25.7	+47.7								144.4	+40.5
To Roche		132.0	16.9	36.5	61.5	100.1	24.6	+45.6								141.5	+41.4
Alecensa		44.3	6.0	21.1	38.3	50.1	5.2	(13.3)								34.1	(31.9)
To Roche		43.0	5.6	20.1	36.9	48.2	4.6	(17.9)								32.0	(33.6)
Enspryng		5.6	-	0.9	1.2	1.5	1.2	-								4.6	+206.7
To Roche		5.6	-	0.9	1.2	1.5	1.2	-								4.5	+200.0
Neutrogin		9.0	2.2	4.8	6.8	9.1	2.4	+9.1								8.8	(3.3)
Other products		4.8	1.2	3.0	4.6	6.2	1.9	+58.3								7.4	+19.4
Royalties and other operating income		153.6	38.6	86.1	138.8	196.9	25.9	(32.9)								118.5	(39.8)
Royalty and profit-sharing income		129.6	36.6	83.3	135.4	187.2	25.2	(31.1)								114.0	(39.1)
Other operating income		24.1	2.0	2.8	3.4	9.8	0.7	(65.0)								4.5	(54.1)
Revenues		786.9	168.8	390.2	677.5	999.8	268.6	+59.1								1,150.0	+15.0
Domestic		419.0	95.3	204.3	364.1	522.3	162.7	+70.7								649.0	+24.3
Overseas		368.0	73.6	185.9	313.4	477.4	105.9	+43.9								501.0	+4.9

Financial position

(Billions of yen)

	Actual	Actual					Actual									
	FY2020	FY2021					FY2022									
	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31	Mar. 31	vs. Mar. 31, 2021	vs. Dec. 31, 2021	Jun. 30	vs. Jun. 30, 2021	vs. Dec. 31, 2021	Sep. 30	vs. Sep. 30, 2021	vs. Dec. 31, 2021	Dec. 31	vs. Dec. 31, 2021
Trade accounts receivable	195.6	138.4	180.5	223.2	281.3	256.9	118.5	(24.4)								
Inventories	183.9	184.7	199.2	201.4	208.8	225.5	40.8	16.7								
Trade accounts payable	(58.3)	(42.1)	(68.7)	(100.7)	(97.2)	(111.2)	(69.1)	(14.0)								
Other net working capital	(21.2)	0.3	4.0	0.6	(22.9)	52.9	52.6	75.8								
Net working capital	300.0	281.3	315.0	324.5	370.1	424.1	142.8	54.0								
Property, plant and equipment	289.2	291.4	310.6	327.6	338.8	348.4	57.0	9.6								
Right-of-use assets	8.3	7.4	6.3	5.6	13.3	12.8	5.4	(0.5)								
Intangible assets	23.9	26.0	25.3	24.8	22.0	24.9	(1.1)	2.9								
Other long-term assets – net	24.6	25.5	24.7	25.7	28.4	24.8	(0.7)	(3.6)								
Long-term net operating assets	346.0	350.3	366.8	383.7	402.4	410.9	60.6	8.5								
Net operating assets	646.0	631.6	681.8	708.2	772.6	834.9	203.3	62.3								
Debt	–	–	–	–	–	–	–	–								
Marketable securities	166.3	181.3	204.1	204.1	204.2	201.3	20.0	(2.9)								
Cash and cash equivalents	212.3	162.0	187.1	192.5	267.8	230.5	68.5	(37.3)								
Net cash	378.6	343.4	391.2	396.6	472.0	431.8	88.4	(40.2)								
Other non-operating assets – net	(44.6)	7.7	(21.0)	(14.2)	(56.5)	(26.2)	(33.9)	30.3								
Net non-operating assets	334.0	351.0	370.2	382.5	415.5	405.6	54.6	(9.9)								
Total net assets	980.0	982.6	1,052.1	1,090.6	1,188.0	1,240.5	257.9	52.5								
Total net assets																
Total assets	1,235.5	1,144.6	1,275.8	1,353.4	1,538.7	1,584.9	440.3	46.2								
Total liabilities	(255.5)	(162.0)	(223.7)	(262.7)	(350.7)	(344.4)	(182.4)	6.3								
Attributable to																
Chugai shareholders	980.0	982.6	1,052.1	1,090.6	1,188.0	1,240.5	257.9	52.5								
Non-controlling interests	–	–	–	–	–	–	–	–								

Trade accounts receivable: trade receivable and notes receivable

Trade accounts payable: trade payable and notes payable

Other net working capital: accrued receivable (other receivable), accrued payable (other payable), accrued expenses (other current liabilities) etc.

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

Other non-operating assets-net: deferred income tax assets, current income tax liabilities etc.

Net operating assets (NOA) and Net assets:

The consolidated balance sheet has been prepared in accordance with International Accounting Standards (IAS) No. 1, “Presentation of Financial Statements.” On the other hand, Net operating assets (NOA) and Net assets are a reconfiguration of the consolidated balance sheet as internal indicators and are identical to the indicators disclosed by Roche. Furthermore, no items from Net operating assets (NOA) and Net assets of IFRS have been excluded, as the Core results concept only applies to the income statement.

Net operating assets (NOA):

Net operating assets allow for an assessment of the Group’s operating performance of the business independently from financing and tax activities. Net operating assets are calculated as net working capital, long-term net operating assets that includes property, plant and equipment, right-of-use assets, intangible assets etc. minus provisions.

Cash flows

(Billions of yen)

	Actual	Actual					Actual			
	FY2020	FY2021					FY2022			
	1-12	1-3	1-6	1-9	1-12		1-3	1-6	1-9	1-12
	YTD	YTD	YTD	YTD	YTD		YTD	YTD	YTD	YTD
Operating profit – IFRS basis	301.2	64.0	160.7	282.8	421.9		187.0			
Depreciation and impairment of property, plant and equipment	22.3	5.3	10.5	15.7	21.0		5.5			
Depreciation and impairment of right-of-use assets	5.5	1.3	2.8	4.3	5.9		1.2			
Amortization and impairment of intangible assets	3.6	0.7	4.0	6.0	10.3		0.8			
Other cash adjustment on operating profit	2.9	0.9	2.7	3.8	7.3		3.4			
Operating profit, net of operating cash adjustments	335.5	72.2	180.7	312.6	466.4		197.9			
(Increase) decrease in trade accounts receivable	(55.9)	57.4	15.4	(27.2)	(85.2)		24.6			
(Increase) decrease in inventories	3.3	(1.0)	(15.6)	(18.1)	(25.5)		(16.1)			
Increase (decrease) in trade accounts payable	10.5	(16.5)	10.0	41.9	38.1		13.8			
Change in other net working capital etc.	(22.3)	0.3	(22.7)	(18.1)	(10.5)		(55.5)			
Total (increase) decrease in net working capital etc.	(64.4)	40.2	(12.9)	(21.5)	(83.1)		(33.2)			
Investment in property, plant and equipment	(57.0)	(28.9)	(35.4)	(58.1)	(66.0)		(34.1)			
Lease liabilities paid	(8.4)	(2.2)	(4.3)	(6.3)	(9.0)		(1.8)			
Investment in intangible assets	(4.3)	(2.9)	(4.4)	(6.9)	(6.9)		(2.6)			
Operating free cash flows	201.2	78.3	123.7	219.8	301.4		126.2			
as % of revenues	25.6%	46.4%	31.7%	32.4%	30.1%		35.0%			
Treasury activities (interest income/expenses, foreign exchange gains/losses etc.)	2.5	(2.5)	0.5	0.9	(5.4)		(4.3)			
Settlement for transfer pricing taxation	(1.5)	–	(0.0)	(2.8)	(2.5)		(2.4)			
Tax paid	(66.8)	(63.3)	(64.3)	(103.6)	(104.1)		(85.5)			
Free cash flows	135.4	12.4	59.9	114.3	189.4		33.9			
Dividends paid	(91.4)	(49.0)	(49.3)	(98.3)	(98.6)		(75.2)			
Transaction in own equity instruments	0.4	0.2	0.2	0.3	0.3		0.1			
Purchase of non-controlling interests	–	–	–	–	–		–			
Net effect of currency translation on net cash	1.2	1.2	1.8	1.8	2.3		0.9			
Net change in net cash	45.5	(35.2)	12.6	18.0	93.4		(40.2)			

Other cash adjustment on operating profit: adjustments for all non-cash income and expense items other than amortization expenses and impairment included in operating profit (such as loss on inventory differences, reserve for doubtful accounts, stock option expenses, loss on asset retirement, and increase/decrease in reserves) as well as all non-operating income and expense cash flows relating to net operating assets (NOA) including proceeds from the sales of assets and reserve payments.

Operating free cash flow (Operating FCF): pretax cash flow after adjusting changes in working capital and operating investments in assets (tangible and intangible) to “operating profit, net of operating cash adjustments,” which shows the company’s cash generation ability from operating activities.

Free cash flow (FCF): the ability to generate net cash from a management perspective after deducting tax, dividends, and other payments from operating FCF.

Net change in net cash: dividends paid, increases and decreases in marketable securities and interest-bearing debt, changes in equity are included.

The concepts of operating profit, operating FCF and Net operating assets (NOA) presented in the previous page are mutually consistent.

Free cash flow (FCF):

The consolidated statement of cash flows has been prepared in accordance with International Accounting Standard (IAS) No. 7, “Statement of Cash Flows.” FCF is a reconfiguration of the consolidated statement of cash flows as internal indicators and is identical to the indicators disclosed by Roche. Furthermore, no items from FCF have been excluded, as the Core results concept only applies to the income statement.

Key Performance indicators

		Actual	Actual				Actual				Forecast (Feb 3th announced)
		2020	2021				2022				2022
		1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
	Units	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Dec. 31
Total indicator											
Core return on invested capital (Core ROIC)	%	37.3	7.5	18.2	31.2	44.3	8.9				
Return on invested capital (ROIC)	%	36.5	7.4	17.7	30.4	43.1	16.5				
Ratio of profit to total assets (ROA)	%	18.7	4.0	9.4	15.8	21.8	8.4				
Ratio of equity attributable to Chugai shareholders	%	79.3	85.8	82.5	80.6	77.2	78.3				
Ratio of equity attributable to Chugai shareholders (stock price base)	%	732.2	644.8	567.3	498.5	399.1	425.1				
Price book value ratio (PBR)	times	9.2	7.5	6.9	6.2	5.2	5.4				
Ratio of net income to equity attributable to Chugai shareholders (ROE)	%	23.4	4.8	11.6	19.7	28.0	10.9				
Margin indicator (Core)											
ROS	%	39.1	38.7	42.5	42.9	43.4	36.8				38.3
COS ratio (vs. Prod. sales)	%	43.0	42.2	40.1	41.9	41.8	47.0				44.6
M&D cost ratio	%	9.1	9.4	8.7	7.7	7.6	6.2				
R&D cost ratio	%	14.4	17.0	15.4	13.9	13.0	12.2				13.0
G&A cost ratio	%	2.8	2.3	2.2	2.2	2.5	2.2				
Turn over indicator											
Total asset turnover	%	68.6	14.2	31.1	52.3	72.1	23.1				
Working capital turnover	%	131.9	26.4	58.8	100.1	141.0	44.9				
Inventory turnover	Months	8.1	10.0	9.7	8.0	7.4	5.9				
Receivables turnover	Months	3.7	3.2	3.6	3.7	4.2	3.2				
Payables turnover	Months	2.6	2.3	3.3	4.0	3.4	2.9				
Fixed asset turnover	%	257.9	52.2	117.6	199.5	287.5	94.9				
PP&E turnover	%	288.9	58.2	130.1	219.7	318.4	104.9				
Intangible assets turnover	%	3,319.0	676.6	1,587.9	2,783.9	4,360.5	1,538.5				
Dividend / per stock indicator											
Dividends per share (Half year)	Yen	75				30					38
Dividends per share (Year end)	Yen	30				46					38
Dividends per share (Full year)	Yen	-				76					76
Core earnings per share (diluted)	Yen	133.39	29.42	73.99	127.45	189.35	42.91				190.00
Core payout ratio (%)	%	41.2				40.1					40.0
Equity per share attributable to Chugai shareholders (BPS)	Yen	596.16	597.67	639.86	663.31	722.50	754.35				
Ratio of dividends to equity attributable to Chugai shareholders (DOE)	%	9.9				11.5					
Cashflow indicator											
Cash conversion cycle (CCC)	Months	9.2	10.9	9.9	7.7	8.2	6.2				
Net cash turnover period	Months	5.8	6.1	6.0	5.3	5.7	3.6				
Number of employees											
Investment on property, plant and equipment	Billions of yen	75.2	7.4	32.8	55.0	72.0	15.9				70.0
Depreciation	Billions of yen	22.0	5.3	10.5	15.7	21.0	5.5				23.0
Investment on intangible assets	Billions of yen	3.9	2.9	5.4	6.9	8.4	3.7				
Amortization	Billions of yen	2.9	0.7	2.4	3.3	4.0	0.6				

Core ROIC: Core net operating profit after taxes / Net operating assets (Core ROIC is calculated by using Core Income taxes)

ROIC: Net operating profit after taxes / Net operating assets (Net operating profit after taxes = Operating profit - income taxes)

ROA: Net income / total assets, ROE: Net income attributable for Chugai shareholders / Equity attributable to Chugai shareholders

Total asset turnover: Revenues / Total asset, CCC: [Trade accounts receivable/Sales + (Inventories - Trade accounts payable)/Cost of sales]* passed months

Net cash turnover period: Net cash/Revenue* passed months

Core ROIC, ROIC, ROA, ROE, total asset turnover, working capital turnover, fixed asset turnover, PP&E turnover, and intangible assets turnover are not annualized

The Adjusted figures are used for calculating average NOA for Core ROIC and ROIC

Effective July 1, 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai") implemented a three-for-one stock split of its common stock.

The dividend for the second quarter of the fiscal year 2020 presents the amount prior to the stock split.

The annual dividend per share for the fiscal year ended December 31, 2020 is not stated because the amounts cannot be simply combined due to the implementation of the stock split.

The annual dividend per share is ¥165 when calculated based on the assumption of no stock split, and ¥55 when calculated with the stock split taken into account.

Core EPS and BPS presents the amount after the stock split.

■ Oncology
 ■ Immunology
 ■ Neuroscience
 ■ Hematology
 ■ Ophthalmology
 ■ Other Diseases

Development Pipeline [Main table] (as of April 25, 2022)

Development code Origin		Generic name Product name	Indication # Additional indication (Combination drug)	Country/ region	Projected submission	Mode of Action Modality (Dosage form)	Partner
Filed							
	RG7446 Roche	atezolizumab Tecentriq	Non-small cell lung cancer (NSCLC) (adjuvant) #	Japan	July 2021	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
	RG7596 Seagen	polatuzumab vedotin Polivy	Diffuse large B-cell lymphoma (DLBCL) (1 st Line) # (Rituxan+Chemo)	Japan	December 2021	Anti-CD79b antibody-drug conjugate Antibody (IV)	Roche
	RG7159 GlycArt Biotechnology	obinutuzumab Gazyva	Chronic lymphocytic leukemia* # (acalabrutinib)	Japan	March 2022	Glycoengineered type II anti-CD20 monoclonal antibody Antibody (IV)	Nippon shinyaku
	MRA/RG1569 in-house	tocilizumab Actemra	COVID-19 pneumonia* #	US	April 2022	Humanized anti-human IL-6 receptor monoclonal antibody Antibody (IV)	Roche
	ACE910 /RG6013	emicizumab Hemlibra	Acquired hemophilia A #	Japan	November 2021	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody Antibody (SC)	Roche
	in-house		Hemophilia A (mild-moderate)* #	EU	Q2 2021		Roche
Phase III							
	AF802/RG7853 in-house	alectinib Alecensa	NSCLC (adjuvant) #	Global	2023	ALK inhibitor Small molecule (oral)	Roche
	RG7446 Roche	atezolizumab Tecentriq	NSCLC (neoadjuvant) #	Japan	2023	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
			NSCLC (2 nd Line)* (cabozantinib)	Japan	2023		Takeda
			Urothelial carcinoma (1 st Line) #	Japan	2023		Roche
			Muscle-invasive bladder cancer (adjuvant) #	Japan	2024		Roche
			Renal cell carcinoma (adjuvant) #	Japan	2022		Roche
			Renal cell carcinoma (2 nd Line) # (cabozantinib)	Japan	2023		Takeda
			Early breast cancer (adjuvant) #	Japan	2025 and beyond		Roche
			Early breast cancer (neoadjuvant) #	Japan	2025 and beyond		Roche
			Ovarian cancer (1 st Line) # (Avastin) #	Japan	2022		Roche

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Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/ region	Projected submission	Mode of Action Modality (Dosage form)	Partner
		Hepatocellular carcinoma (HCC) (adjuvant) # (Avastin) #	Japan	2023		Roche
		HCC (intermediate stage) # (Avastin) #	Japan	2025 and beyond		Roche
		HCC (2 nd Line)* (lenvatinib or sorafenib)	Japan	2025 and beyond		Roche
		Head and neck carcinoma (adjuvant) #	Japan	2022		Roche
		Prostate cancer (2 nd Line)* # (cabozantinib)	Japan	-		Takeda
RG435 Roche	bevacizumab Avastin	Small cell lung cancer (SCLC) (1 st Line) # (Tecentriq)	Japan/ China	2023	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody Antibody (IV)	Roche (China)
RG7440 Array BioPharma	ipatasertib	Prostate cancer (1 st Line) (abiraterone)	Japan	2023	AKT inhibitor Small molecule (Oral)	Roche
RG6264 Roche	trastuzumab /pertuzumab	Breast cancer	Japan	2022	Anti-HER2 humanized monoclonal antibody/ HER2 dimerization inhibitory humanized monoclonal antibody Antibody (Fixed-dose combination, SC)	Roche
RG6058 Roche	tiragolumab	SCLC (1 st Line) (Tecentriq)	Japan	—	Anti-TIGIT human monoclonal antibody Antibody (IV)	Roche
		NSCLC (1st Line) (Tecentriq)	Japan	2023		Roche
		NSCLC (stage III) (Tecentriq) #	Japan	2024		Roche
		Esophageal cancer (Tecentriq) #	Japan	2024		Roche
RG6171 Roche	giredestrant	Breast cancer (adjuvant)	Japan	2025 and beyond	SERD (Selective Estrogen Receptor Degradar) Small molecule (Oral)	Roche
		Breast cancer (1 st Line) (palbociclib + letrozole)	Japan	2025 and beyond		Roche
RG7828 Roche	mosunetuzumab	Follicular lymphoma (2 nd Line) (lenalidomide)	Japan	2025 and beyond	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
RG6396 Blueprint Medicines	pralsetinib	NSCLC (1st Line) (pembrolizumab)	Japan	2024	RET inhibitor Small molecule (Oral)	Roche

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Development code Origin		Generic name Product name	Indication # Additional indication (Combination drug)	Country/ region	Projected submission	Mode of Action Modality (Dosage form)	Partner
	SA237/RG6168 in-house	satralizumab Enspryng	Generalized myasthenia gravis (gMG) #	Global	2024	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
	RG1450 MorphoSys	gantenerumab	Alzheimer’s disease	Japan	2023	Anti-amyloid-beta human monoclonal antibody Antibody (SC)	Roche
	RG6042 Ionis Pharmaceuticals	tominersen	Huntington’s disease	Japan	—	Antisense oligonucleotide targeting HTT mRNA Nucleic acid (IV)	Roche
	RG6356/ SRP-9001 Sarepta	delandistrogene moxeparvovec	Duchenne muscular dystrophy (DMD)*	Japan	2024	Microdystrophin gene therapy Gene therapy (Intramuscular injection)	Sarepta**
	SKY59/RG6107 in-house	crovalimab	Paroxysmal nocturnal hemoglobinuria (PNH)	Global	2023 (China: 2022)	Anti-C5 recycling antibody Antibody (SC)	Roche
			Atypical hemolytic uremic syndrome (aHUS)	Global	2024		Roche
	RG7716 Roche	faricimab Vabysmo	Retinal vein occlusion #	Japan	2023	Anti-VEGF/Anti-Ang-2 bispecific antibody Antibody (vitreous injection)	Roche
Phase II							
	RG7906 Roche	ralmitaront	Schizophrenia	Japan	—	Partial TAAR1 agonist Small molecule (Oral)	Roche
	SKY59/RG6107 in-house	crovalimab	Sickle cell disease (SCD)*	US · EU	2025 and beyond	Anti-C5 recycling antibody Antibody (SC)	Roche
Phase I/II							
	NXT007 in-house	—	Hemophilia A	Global	—	Anti-coagulation factor IXa/X bispecific antibody Antibody (SC)	—
	RG6321 Roche	ranibizumab (Port delivery system)	Neovascular age-related macular degeneration	Japan	2024	Humanized anti-VEGF monoclonal antibody Fragment Fab Antibody (injection via implant)	Roche
			Diabetic macular edema	Japan	2024		Roche
Phase I							
	LUNA18 in-house	—	Solid tumors	Global	—	RAS inhibitor Mid-size molecule (Oral)	—
	GC33 in-house	codrituzumab	HCC	Global	—	Anti-Glypican-3 humanized monoclonal antibody Antibody (IV)	—
	ERY974 in-house	—	Solid tumors	Global	—	Anti-Glypican-3/CD3 bispecific antibody Antibody (IV)	—

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Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/ region	Projected submission	Mode of Action Modality (Dosage form)	Partner
■ STA551 in-house	—	Solid tumors	Global	—	Anti-CD137 agonistic Switch antibody Antibody (IV)	—
■ SOF10/RG6440 in-house	—	Solid tumors	Global	—	Anti-latent TGF-β1 monoclonal antibody Antibody (IV)	Roche
■ SPYK04 in-house	—	Solid tumors	Global	—	— Small molecule (Oral)	—
■ RG7828 Roche	mosunetuzumab	Follicular lymphoma (3 rd Line)	Japan	2024	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
■ RG7421 Exelixis	cobimetinib	Solid tumors	Japan	—	MEK inhibitor Small molecule (Oral)	Roche
■ RG7802 Roche	cibisatamab	Solid tumors	Japan	—	Anti-CEA/CD3 bispecific antibody Antibody (IV)	Roche
■ RG6026 Roche	glofitamab	Hematologic tumors	Japan	—	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
■ RG6194 Roche	—	Solid tumors	Japan	—	Anti-HER2/CD3 bispecific antibody Antibody (IV)	Roche
■ RG7880 Roche	efmarodocokin alfa	Inflammatory bowel disease	Japan	—	Human IL-22 fusion protein Non-antibody protein (IV)	Roche
■ GYM329/ RG6237 in-house	—	Neuromuscular disease	Global	—	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
■ RG7935 Prothena	prasinezumab	Parkinson's disease	Japan	—	Anti-α-synuclein monoclonal antibody Antibody (IV)	Roche
■ RG6100 AC Immune	semorinemab	Alzheimer's disease	Japan	—	Anti-tau humanized monoclonal antibody Antibody (IV)	Roche
■ RG6102 MorphoSys	—	Alzheimer's disease	Japan	—	Anti-amyloid beta/TfR1 fusion protein Antibody (IV)	Roche
■ AMY109 in-house	—	Endometriosis	Global	—	— Antibody (SC)	—
Development discontinued						
■ RG7992 Roche		Non-alcoholic steatohepatitis	Japan	—	Anti-FGFR1/KLB bispecific antibody Antibody (SC)	Roche

In principle, completion of first dose is regarded as the start of clinical studies in each phase. * Added due to changes in development pipeline disclosure standards

** Sarepta manages the global study including Japan

Changes from the last announcement on February 3, 2022

Oncology

- RG7828 Phase I (Follicular lymphoma [3rd Line]: development started)

Hematology

- SKY59/RG6107 Phase II (Sickle cell disease: development started in the United States and Europe)

Ophthalmology

- RG7716 Filed → Approved (age-related macular degeneration associated with subfoveal choroidal neovascularization)
- RG7716 Filed → Approved (diabetic macular edema (DME))
- RG6321 (Port delivery system)
Phase I / II (nAMD: development started)
- RG6321 (Port delivery system)
Phase I/II (DME: development started)

Other diseases

- RG7992 Phase I (Non-alcoholic steatohepatitis: development discontinued)

R&D Activities

For the changes during the FY2022 (January 1 – March 31), please refer to page 4 of “CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the first quarter of the fiscal year 2022).”

Changes from April 1 to April 25, 2022 are as follows:

Immunology

- The U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) and has granted Priority Review for the humanized anti-human IL-6 receptor monoclonal antibody MRA/RG1569 (Product name: Actemra) for the treatment of COVID-19 in

hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), in April 2022.

Development pipeline [Attached table] (Major Chugai originated developments licensed out to 3rd party excluding Roche)

Development code In-house/licensee	Generic name Product name	Indication # Additional Indication (combination)	Stage Country/region	Mode of Action Modality (Dosage form)	Licensee (Granted rights)
CKI27/VS-6766	—	Ovarian cancer (defactinib)	Phase II Global	RAF/MEK inhibitor Small molecule (Oral)	Verastem (exclusive global license for the manufacturing, development and marketing)
		NSCLC (defactinib)	Phase II Global		
CIM331	nemolizumab Mitchga	Itching associated with atopic dermatitis (only when existing treatment is insufficiently effective)	Approved (March 2022) Japan	Anti-IL-31 receptor A humanized monoclonal antibody Antibody (SC)	Maruho (rights for development and marketing in the skin disease area for the Japanese market)
		Prurigo nodularis	Phase II/III Japan		
		Atopic dermatitis	Phase III Global		Galderma (exclusive global license for the development and marketing excluding Japan and Taiwan)
		CKD associated pruritus	Phase II/III Global		
OWL833/ LY3502970	—	Type 2 diabetes	Phase II Global	Oral non-peptidic GLP-1 receptor agonist Small molecule (Oral)	Eli Lilly and Company (worldwide development and commercialization rights)
		Obesity	Phase II Global		

Progress made in R&D activities of major Chugai originated developments licensed out to 3rd party excluding Roche during the period from January 1, 2022 to April 25, 2022 was as follows.

- In Japan, Maruho obtained approval for the anti-IL-31 receptor A humanized monoclonal antibody CIM331 (Product name: Mitchga) for the treatment of itching associated with atopic dermatitis (only when existing treatment is insufficiently effective) in March 2022.

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of April 25, 2022)

Development Request	Product	Indication	Development Status
Third development request	Avastin	Additional Q2W dosage and administration for ovarian cancer	Evaluated by the Review Committee in December 2021 as eligible for public knowledge-based application; application approved February 4, 2022, by the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council
Fourth development request	Xeloda	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by committee
	Avastin	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by committee
	Neutrogin	Combination therapy with chemotherapy including fludarabine for relapsed/refractory acute myeloid leukemia	Evaluated by the Review Committee in December 2021 as eligible for public knowledge-based application; application approved February 4, 2022, by the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council

Major clinical trials in oncology field

Treatment	Expected Indication	Study design	Study name	Stage	Planned filing year
RG7446 (Tecentriq)	NSCLC [1 st line]	PD-L1 positive: Tecentriq ± RG6058	SKYSCRAPER-01	Phase III	2023
	NSCLC [stage III]	Tecentriq + RG6058 vs. durvalumab	SKYSCRAPER-03	Phase III	2024
	NSCLC [2 nd line]	Tecentriq + cabozantinib vs. docetaxel	CONTACT-01	Phase III	2023
	NSCLC (neoadjuvant)	Chemo ± Tecentriq	IMpower030	Phase III	2023
	NSCLC (adjuvant)	Tecentriq vs. best supportive care	IMpower010	Phase III	Filed
	SCLC	Tecentriq + chemo ± Avastin	BEAT-SC	Phase III	2023
		Tecentriq + chemo ± RG6058	SKYSCRAPER-02	Phase III	-
	Urothelial carcinoma (UC)	Tecentriq ± chemo vs. chemo	IMvigor130	Phase III	2023
	Muscle-invasive bladder cancer (adjuvant)	Tecentriq	IMvigor011	Phase III	2024
	Prostate cancer [2 nd line]	Tecentriq + cabozantinib vs. novel hormonal therapy	CONTACT-02	Phase III	-
	Renal cell carcinoma (adjuvant)	Tecentriq	IMmotion010	Phase III	2022
	Renal cell carcinoma [2 nd line]	cabozantinib ± Tecentriq	CONTACT-03	Phase III	2023
	Early breast cancer	TNBC (adjuvant): paclitaxel ± Tecentriq	IMpassion030	Phase III	2025 and beyond
		TNBC (neoadjuvant): nab-paclitaxel ± Tecentriq	IMpassion031	Phase III	
	Ovarian cancer	carboplatin + paclitaxel + Avastin ± Tecentriq	IMagyn050	Phase III	2022
	HCC (adjuvant)	Tecentriq + Avastin vs. active surveillance	IMbrave050	Phase III	2023
	HCC (intermediate stage)	Tecentriq + Avastin + TACE vs. TACE	TALENTACE	Phase III	2025 and beyond
	HCC [2 nd line]	Tecentriq + lenvatinib or sorafenib vs. lenvatinib or sorafenib	IMbrave251	Phase III	2025 and beyond

Treatment	Expected Indication	Study design	Study name	Stage	Planned filing year
	Head and neck carcinoma (adjuvant)	Tecentriq	IMvoke010	Phase III	2022
	Esophageal cancer	Tecentriq + RG6058 vs. Tecentriq vs. placebo	SKYSCRAPER-07	Phase III	2024
RG7440 (ipatasertib)	Prostate cancer [1 st line]	castration-resistant: abiraterone ± RG7440	IPATential150	Phase III	2023
RG7596 (polatuzumab vedotin)	DLBCL	Rituxan + Chemo ± RG7596	POLARIX	Phase III	Filed
RG6264	Breast cancer	RG6264 (SC) + chemo vs. Herceptin (IV) + Perjeta (IV) + chemo	FeDeriCa	Phase III	2022
AF802 (Alecensa)	NSCLC (adjuvant)	ALK fusion-positive: Alecensa vs. chemo	ALINA	Phase III	2023
RG6171 / SERD	Breast cancer	HR positive: RG6171 + palbociclib ± Letrozole	persevERA	Phase III	2025 and beyond
	Breast cancer (adjuvant)	HR positive: RG6171 vs. endocrine therapy	lidERA	Phase III	2025 and beyond
RG7828	Follicular lymphoma [2 nd line]	RG7828 + lenalidomide vs Rituxan + lenalidomide	CELESTIMO	Phase III	2025 and beyond
	Follicular lymphoma [3 rd line]	RG7828	Mosun	Phase I (domestic)	2024
RG6396	NSCLC	RG6396 vs. platinum-based chemotherapy ± pembrolizumab	AcceleRET-Lung	Phase III	2024

FoundationOne CDx Cancer Genomic Profile: companion diagnostic indications (as of April 25, 2022)

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, <u>dacomitinib hydrate</u>
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib, <u>brigatinib</u>
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<u><i>BRAF</i> V600E alterations</u>		<u>dabrafenib mesilate, trametinib dimethyl sulfoxide</u>
<i>BRAF</i> V600E and V600K alterations	Malignant melanoma	dabrafenib mesilate, trametinib dimethyl sulfoxide, vemurafenib, <u>encorafenib, binimetinib</u>
<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)
Microsatellite instability-high		nivolumab (genetical recombination)
Microsatellite instability-high	Solid tumors	pembrolizumab (genetical recombination)
Tumor mutational burden-high		pembrolizumab (genetical recombination)

<i>NTRK1/2/3</i> fusion gene		entrectinib, larotrectinib sulfate
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib
<i>FGFR2</i> fusion genes	Biliary Tract Cancer	pemigatinib

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

FoundationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of April 25, 2022)

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>NTRK1/2/3</i> fusion gene	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib