

Supplementary Materials for
Consolidated Financial Results for
the 1st Quarter of Fiscal Year 2024. 12 (IFRS)

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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.

Weighted average rate

(Yen)

	Actual FY2023				Actual FY2024				Assumption FY2024	Assumption FY2024
	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-3	1-12
	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year	YTD	Full-year
CHF	137.05	138.30	138.62	140.31	162.70				160.57	159.00
EUR	141.96	141.96	149.03	151.38	161.10				157.00	157.00
USD	132.79	133.45	133.42	134.21	131.49				137.46	136.00
SGD	99.24	99.39	101.74	103.75	110.08				108.00	108.00

*Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

Market average rate

	Actual FY2023				Actual FY2024			
	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12
	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year
CHF	143.05	147.78	152.93	156.31	169.79			
EUR	141.99	145.68	149.52	151.91	161.11			
USD	132.35	134.79	138.03	140.49	148.35			
SGD	99.32	100.90	102.98	104.62	110.71			

Period-end rate

	Actual FY2023				Actual FY2024			
	31 Mar.	30 Jun.	30 Sep.	31 Dec.	31 Mar.	30 Jun.	30 Sep.	31 Dec.
CHF	145.27	160.96	163.06	167.49	167.93			
EUR	144.63	157.31	157.65	156.45	163.33			
USD	132.66	144.78	149.24	141.38	151.39			
SGD	99.92	106.73	109.25	107.09	112.12			

Reconciliation of IFRS results to Core results

(Billions of yen)

	FY2023				FY2024			
	1-3				1-3			
	IFRS results	Intangible assets	Others	Core results	IFRS results	Intangible assets	Others	Core results
Revenue	312.2	–	–	312.2	236.9	–	–	236.9
Sales	291.5	–	–	291.5	204.5	–	–	204.5
Other revenue	20.7	–	–	20.7	32.5	–	–	32.5
Cost of sales	(151.3)	0.3	–	(151.0)	(72.9)	0.3	–	(72.6)
Gross profit	160.9	0.3	–	161.2	164.0	0.3	–	164.3
Research and development	(42.9)	4.9	1.9	(36.1)	(41.4)	0.2	0.0	(41.2)
Selling, general and administration	(21.0)	–	0.0	(21.0)	(22.6)	–	1.4	(21.2)
Other operating income (expense)	1.3	–	0.0	1.3	(0.2)	–	0.4	0.2
Operating profit	98.3	5.2	1.9	105.4	99.9	0.5	1.8	102.1
Financing costs	(0.0)	–	–	(0.0)	0.0	–	–	0.0
Other financial income (expense)	1.4	–	–	1.4	0.0	–	–	0.0
Other expense	–	–	–	–	–	–	–	–
Profit before taxes	99.7	5.2	1.9	106.7	99.9	0.5	1.8	102.1
Income taxes	(26.2)	(1.6)	(0.6)	(28.3)	(25.5)	(0.1)	(0.5)	(26.2)
Net income	73.5	3.6	1.3	78.4	74.4	0.3	1.2	76.0
Attributable to	73.5	3.6	1.3	78.4	74.4	0.3	1.2	76.0
Chugai shareholders	73.5	3.6	1.3	78.4	74.4	0.3	1.2	76.0
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 (0.5 billion yen in 2023 and 0.4 billion yen in 2024)

Impairment (4.7 billion yen in 2023 and 0.1 billion in 2024)

Others

Business rebuilding expenses (None in 2023 and 1.4 billion yen in 2024), Restructuring expenses (1.9 billion yen in 2023 and 0.4 billion yen in 2024)

IFRS results (QTR)

(Billions of yen)

	Actual FY2023				Actual FY2024							
	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	
Revenue	312.2	267.4	257.9	273.8	236.9	(24.1)						
Sales	291.5	231.5	219.0	232.4	204.5	(29.8)						
Domestic	192.7	120.9	115.6	128.8	103.2	(46.4)						
Overseas	98.8	110.6	103.4	103.6	101.3	+2.5						
Other revenue	20.7	35.9	38.9	41.4	32.5	+57.0						
Royalty income and profit-sharing income	20.7	28.6	38.4	39.8	21.0	+1.4						
Other operating income	0.0	7.3	0.5	1.6	11.5	-						
Cost of sales	(151.3)	(91.7)	(78.3)	(92.1)	(72.9)	(51.8)						
(% of Sales)	51.9	39.6	35.8	39.6	35.6	-						
Gross profit	160.9	175.8	179.6	181.8	164.0	+1.9						
(% of Revenue)	51.5	65.7	69.6	66.4	69.2	-						
Research and development	(42.9)	(44.6)	(45.6)	(41.9)	(41.4)	(3.5)						
(% of Revenue)	13.7	16.7	17.7	15.3	17.5	-						
Selling, general and administration	(21.0)	(33.3)	(27.5)	(30.8)	(22.6)	+7.6						
(% of Revenue)	6.7	12.5	10.7	11.2	9.5	-						
Other operating income (expense)	1.3	14.7	0.2	12.4	(0.2)	-						
Operating profit	98.3	112.6	106.7	121.6	99.9	+1.6						
(% of Revenue)	31.5	42.1	41.4	44.4	42.2	-						
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	0.0	-						
Other financial income (expense)	1.4	1.4	0.8	1.1	0.0	-						
Profit before taxes	99.7	114.0	107.5	122.7	99.9	+0.2						
(% of Revenue)	31.9	42.6	41.7	44.8	42.2	-						
Income taxes	(26.2)	(30.8)	(29.9)	(31.5)	(25.5)	(2.7)						
Net income	73.5	83.2	77.6	91.2	74.4	+1.2						
(% of Revenue)	23.5	31.1	30.1	33.3	31.4	-						
Attributable to												
Chugai shareholders	73.5	83.2	77.6	91.2	74.4	+1.2						
Non-controlling interests	-	-	-	-	-	-						
Earnings per share												
Basic (yen)	44.68	50.57	47.15	55.43	45.22	+1.2						
Diluted (yen)	44.67	50.56	47.14	55.43	45.21	+1.2						

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

IFRS results (YTD)

(Billions of yen)

	Actual FY2023				Actual FY2024							
	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	
Revenue	312.2	579.7	837.6	1,111.4	236.9	(24.1)						
Sales	291.5	523.0	742.1	974.5	204.5	(29.8)						
Domestic	192.7	313.6	429.2	558.0	103.2	(46.4)						
Overseas	98.8	209.4	312.9	416.5	101.3	+2.5						
Other revenue	20.7	56.6	95.5	136.9	32.5	+57.0						
Royalty income and profit-sharing income	20.7	49.3	87.7	127.5	21.0	+1.4						
Other operating income	0.0	7.3	7.7	9.4	11.5	-						
Cost of sales	(151.3)	(243.0)	(321.2)	(413.3)	(72.9)	(51.8)						
(% of Sales)	51.9	46.5	43.3	42.4	35.6	-						
Gross profit	160.9	336.7	516.3	698.1	164.0	+1.9						
(% of Revenue)	51.5	58.1	61.6	62.8	69.2	-						
Research and development	(42.9)	(87.4)	(133.0)	(174.9)	(41.4)	(3.5)						
(% of Revenue)	13.7	15.1	15.9	15.7	17.5	-						
Selling, general and administration	(21.0)	(54.3)	(81.8)	(112.6)	(22.6)	+7.6						
(% of Revenue)	6.7	9.4	9.8	10.1	9.5	-						
Other operating income (expense)	1.3	16.0	16.1	28.6	(0.2)	-						
Operating profit	98.3	210.9	317.6	439.2	99.9	+1.6						
(% of Revenue)	31.5	36.4	37.9	39.5	42.2	-						
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	0.0	-						
Other financial income (expense)	1.4	2.8	3.6	4.7	0.0	-						
Profit before taxes	99.7	213.7	321.1	443.8	99.9	+0.2						
(% of Revenue)	31.9	36.9	38.3	39.9	42.2	-						
Income taxes	(26.2)	(57.0)	(86.9)	(118.3)	(25.5)	(2.7)						
Net income	73.5	156.7	234.3	325.5	74.4	+1.2						
(% of Revenue)	23.5	27.0	28.0	29.3	31.4	-						
Attributable to												
Chugai shareholders	73.5	156.7	234.3	325.5	74.4	+1.2						
Non-controlling interests	-	-	-	-	-	-						
Earnings per share												
Basic (yen)	44.68	95.25	142.40	197.83	45.22	+1.2						
Diluted (yen)	44.67	95.23	142.37	197.80	45.21	+1.2						

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

Core results (QTR)

(Billions of yen)

	Actual				Actual							
	FY2023				FY2024							
	1-3 QTR	4-6 QTR	7-9 QTR	10-12 QTR	1-3 QTR	Change (%)	4-6 QTR	Change (%)	7-9 QTR	Change (%)	10-12 QTR	Change (%)
Revenue	312.2	267.4	257.9	273.8	236.9	(24.1)						
Sales	291.5	231.5	219.0	232.4	204.5	(29.8)						
Domestic	192.7	120.9	115.6	128.8	103.2	(46.4)						
Overseas	98.8	110.6	103.4	103.6	101.3	+2.5						
Other revenue	20.7	35.9	38.9	41.4	32.5	+57.0						
Royalty income and profit-sharing income	20.7	28.6	38.4	39.8	21.0	+1.4						
Other operating income	0.0	7.3	0.5	1.6	11.5	-						
Cost of sales	(151.0)	(91.3)	(78.0)	(91.7)	(72.6)	(51.9)						
(% of Sales)	51.8	39.4	35.6	39.5	35.5	-						
Gross profit	161.2	176.2	179.9	182.1	164.3	+1.9						
(% of Revenue)	51.6	65.9	69.8	66.5	69.4	-						
Research and development	(36.1)	(40.4)	(45.1)	(41.1)	(41.2)	+14.1						
(% of Revenue)	11.6	15.1	17.5	15.0	17.4	-						
Selling, general and administration	(21.0)	(24.0)	(26.4)	(30.5)	(21.2)	+1.0						
(% of Revenue)	6.7	9.0	10.2	11.1	8.9	-						
Other operating income (expense)	1.3	14.9	0.2	(0.3)	0.2	(84.6)						
Operating profit	105.4	126.6	108.6	110.1	102.1	(3.1)						
(% of Revenue)	33.8	47.3	42.1	40.2	43.1	-						
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	0.0	-						
Other financial income (expense)	1.4	1.4	0.8	1.1	0.0	-						
Profit before taxes	106.7	128.0	109.3	111.3	102.1	(4.3)						
(% of Revenue)	34.2	47.9	42.4	40.7	43.1	-						
Income taxes	(28.3)	(35.0)	(30.5)	(28.0)	(26.2)	(7.4)						
Net income	78.4	93.0	78.9	83.3	76.0	(3.1)						
(% of Revenue)	25.1	34.8	30.6	30.4	32.1	-						
Attributable to												
Chugai shareholders	78.4	93.0	78.9	83.3	76.0	(3.1)						
Non-controlling interests	-	-	-	-	-	-						
Core earnings per share (diluted) (yen)	47.66	56.53	47.92	50.59	46.16	(3.1)						

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								Forecast (Feb 1st announced)	
	FY2023				FY2024								FY2024	
	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	
Revenue	312.2	579.7	837.6	1,111.4	236.9	(24.1)							1,070.0	(3.7)
Sales	291.5	523.0	742.1	974.5	204.5	(29.8)							922.0	(5.4)
Domestic	192.7	313.6	429.2	558.0	103.2	(46.4)							454.9	(18.5)
Overseas	98.8	209.4	312.9	416.5	101.3	+2.5							467.1	+12.1
Other revenue	20.7	56.6	95.5	136.9	32.5	+57.0							148.0	+8.1
Royalty income and profit-sharing income	20.7	49.3	87.7	127.5	21.0	+1.4							134.4	+5.4
Other operating income	0.0	7.3	7.7	9.4	11.5	-							13.6	+44.7
Cost of sales	(151.0)	(242.3)	(320.2)	(412.0)	(72.6)	(51.9)							(337.5)	(18.1)
(% of Sales)	51.8	46.3	43.1	42.3	35.5	-							36.6	-
Gross profit	161.2	337.4	517.3	699.4	164.3	+1.9							732.5	+4.7
(% of Revenue)	51.6	58.2	61.8	62.9	69.4	-							68.5	-
Research and development	(36.1)	(76.5)	(121.7)	(162.8)	(41.2)	+14.1							(171.0)	+5.0
(% of Revenue)	11.6	13.2	14.5	14.6	17.4	-							16.0	-
Selling, general and administration	(21.0)	(45.0)	(71.4)	(102.0)	(21.2)	+1.0							(102.0)	0.0
(% of Revenue)	6.7	7.8	8.5	9.2	8.9	-							9.5	-
Other operating income (expense)	1.3	16.2	16.3	16.1	0.2	(84.6)							0.5	(96.9)
Operating profit	105.4	232.0	340.5	450.7	102.1	(3.1)							460.0	+2.1
(% of Revenue)	33.8	40.0	40.7	40.6	43.1	-							43.0	-
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	0.0	-								
Other financial income (expense)	1.4	2.8	3.6	4.7	0.0	-								
Profit before taxes	106.7	234.7	344.1	455.3	102.1	(4.3)								
(% of Revenue)	34.2	40.5	41.1	41.0	43.1	-								
Income taxes	(28.3)	(63.3)	(93.8)	(121.8)	(26.2)	(7.4)								
Net income	78.4	171.4	250.3	333.6	76.0	(3.1)							335.5	+0.6
(% of Revenue)	25.1	29.6	29.9	30.0	32.1	-							31.4	-
Attributable to														
Chugai shareholders	78.4	171.4	250.3	333.6	76.0	(3.1)								
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	1,646	0.1								
Core earnings per share (diluted) (yen)	47.66	104.19	152.11	202.71	46.16	(3.1)							204.00	+0.6
Core payout ratio (%)													40.2	-
Dividend per share (Full year) (yen)				80									82	-
Dividend per share (Year end) (yen)				40									41	-
Dividend per share (Half year) (yen)				40									41	-

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 statements of revenue (QTR)

(Billions of yen)

	Actual				Actual							
	FY2023				FY2024							
	1-3 QTR	4-6 QTR	7-9 QTR	10-12 QTR	1-3 QTR	Change (%)	4-6 QTR	Change (%)	7-9 QTR	Change (%)	10-12 QTR	Change (%)
Sales	291.5	231.5	219.0	232.4	204.5	(29.8)						
Domestic	192.7	120.9	115.6	128.8	103.2	(46.4)						
Oncology	60.0	66.6	64.8	68.8	56.1	(6.5)						
Tecentriq	15.1	16.6	16.3	17.6	14.5	(4.0)						
Polivy	7.2	8.7	9.6	10.0	7.4	+2.8						
Avastin	13.0	13.2	12.1	11.5	8.7	(33.1)						
Alecensa	6.6	8.0	7.5	8.2	6.6	0.0						
Perjeta	7.5	8.6	8.5	9.0	6.1	(18.7)						
Kadcyla	3.8	3.9	4.0	4.3	3.6	(5.3)						
Phesgo	-	-	-	0.7	3.2	-						
Herceptin	1.3	1.2	1.1	1.1	0.7	(46.2)						
Foundation Medicine	1.9	1.8	1.9	1.8	1.8	(5.3)						
Other products	3.6	4.6	3.9	4.6	3.4	(5.6)						
Specialty	132.7	54.4	50.8	60.0	47.0	(64.6)						
Hemlibra	12.4	14.4	13.8	14.3	12.5	+0.8						
Actemra	9.9	11.2	11.1	12.0	10.2	+3.0						
Vabysmo	3.0	3.8	4.0	4.6	4.0	+33.3						
Enspryng	4.7	6.2	6.0	7.1	5.8	+23.4						
Evryydi	3.0	3.5	3.7	4.2	3.4	+13.3						
Mircera	2.0	2.1	2.1	2.2	1.5	(25.0)						
CellCept	1.6	1.8	1.7	1.9	1.5	(6.3)						
Edirol	1.8	2.0	1.8	1.9	1.4	(22.2)						
Ronapreve	81.2	-	-	-	-	-						
Other products	13.1	9.4	6.6	11.9	6.7	(48.9)						
Tamiful	5.3	0.1	0.7	3.7	1.3	(75.5)						
Overseas	98.8	110.6	103.4	103.6	101.3	+2.5						
Hemlibra	46.0	58.0	67.9	40.5	57.8	+25.7						
To Roche	45.2	57.1	67.1	39.4	56.9	+25.9						
Actemra	31.8	33.3	21.5	41.0	23.4	(26.4)						
To Roche	30.7	32.3	20.3	40.0	22.1	(28.0)						
Alecensa	16.7	14.7	6.5	17.8	14.0	(16.2)						
To Roche	16.0	14.1	5.8	16.9	13.2	(17.5)						
Enspryng	0.7	0.4	3.2	(0.1)	2.1	+200.0						
To Roche	0.7	0.4	3.2	(0.1)	2.1	+200.0						
Neutrogin	1.9	2.0	2.1	2.1	2.1	+10.5						
Edirol	0.0	0.0	0.0	0.0	0.1	-						
Other products	1.8	2.2	2.2	2.3	1.8	0.0						
Other revenue	20.7	35.9	38.9	41.4	32.5	+57.0						
Revenue	312.2	267.4	257.9	273.8	236.9	(24.1)						
Domestic	193.1	121.1	115.9	129.2	103.5	(46.4)						
Overseas	119.1	146.3	141.9	144.6	133.5	+12.1						

Core statements of revenue (YTD)

(Billions of yen)

	Actual				Actual								Forecast (Feb 1st announced)	
	FY2023				FY2024								FY2024	
	1-3 YTD	1-6 YTD	1-9 YTD	1-12 YTD	1-3 YTD	Change (%)	1-6 YTD	Change (%)	1-9 YTD	Change (%)	1-12 YTD	Change (%)	1-12 YTD	Change (%)
Sales	291.5	523.0	742.1	974.5	204.5	(29.8)							922.0	(5.4)
Domestic	192.7	313.6	429.2	558.0	103.2	(46.4)							454.9	(18.5)
Oncology	60.0	126.5	191.4	260.2	56.1	(6.5)							246.5	(5.3)
Tecentriq	15.1	31.6	47.9	65.5	14.5	(4.0)							66.2	+1.1
Polivy	7.2	15.9	25.5	35.5	7.4	+2.8							37.3	+5.1
Avastin	13.0	26.2	38.2	49.8	8.7	(33.1)							33.9	(31.9)
Alecensa	6.6	14.5	22.0	30.3	6.6	0.0							31.3	+3.3
Perjeta	7.5	16.1	24.6	33.6	6.1	(18.7)							22.0	(34.5)
Kadcyla	3.8	7.7	11.7	16.0	3.6	(5.3)							16.2	+1.3
Phesgo	-	-	-	0.7	3.2	-							15.5	22times
Herceptin	1.3	2.5	3.6	4.8	0.7	(46.2)							2.2	(54.2)
Foundation Medicine	1.9	3.7	5.6	7.4	1.8	(5.3)							7.1	(4.1)
Other products	3.6	8.2	12.1	16.6	3.4	(5.6)							14.8	(10.8)
Specialty	132.7	187.1	237.9	297.8	47.0	(64.6)							208.4	(30.0)
Hemlibra	12.4	26.7	40.5	54.8	12.5	+0.8							56.5	+3.1
Actemra	9.9	21.1	32.2	44.3	10.2	+3.0							45.9	+3.6
Vabysmo	3.0	6.7	10.8	15.3	4.0	+33.3							22.8	+49.0
Enspryng	4.7	10.9	16.9	23.9	5.8	+23.4							22.4	(6.3)
Evrysdi	3.0	6.6	10.3	14.5	3.4	+13.3							16.5	+13.8
Mircera	2.0	4.2	6.3	8.4	1.5	(25.0)							6.8	(19.0)
CellCept	1.6	3.5	5.2	7.0	1.5	(6.3)							6.3	(10.0)
Edirol	1.8	3.8	5.6	7.5	1.4	(22.2)							5.6	(25.3)
Ronapreve	81.2	81.2	81.2	81.2	-	-							-	-
Other products	13.1	22.4	29.0	40.9	6.7	(48.9)							25.7	(37.2)
Tamiflu	5.3	5.4	6.1	9.9	1.3	(75.5)							3.7	(62.6)
Overseas	98.8	209.4	312.9	416.5	101.3	+2.5							467.1	+12.1
Hemlibra	46.0	103.9	171.8	212.3	57.8	+25.7							267.3	+25.9
To Roche	45.2	102.3	169.4	208.8	56.9	+25.9							262.5	+25.7
Actemra	31.8	65.1	86.5	127.5	23.4	(26.4)							109.8	(13.9)
To Roche	30.7	63.0	83.2	123.3	22.1	(28.0)							105.4	(14.5)
Alecensa	16.7	31.4	37.9	55.7	14.0	(16.2)							58.9	+5.7
To Roche	16.0	30.1	35.9	52.9	13.2	(17.5)							56.2	+6.2
Enspryng	0.7	1.1	4.3	4.2	2.1	+200.0							6.4	+52.4
To Roche	0.7	1.1	4.3	4.2	2.1	+200.0							6.2	+47.6
Neutrogin	1.9	3.9	6.0	8.1	2.1	+10.5							6.8	(16.0)
Edirol	0.0	0.0	0.1	0.1	0.1	-							1.8	18times
Other products	1.8	3.9	6.2	8.5	1.8	0.0							16.1	+89.4
Other revenue	20.7	56.6	95.5	136.9	32.5	+57.0							148.0	+8.1
Revenue	312.2	579.7	837.6	1,111.4	236.9	(24.1)							1,070.0	(3.7)
Domestic	193.1	314.2	430.1	559.3	103.5	(46.4)							456.5	(18.4)
Overseas	119.1	265.4	407.5	552.1	133.5	+12.1							613.5	+11.1

Financial position

(Billions of yen)

	Actual				Actual											
	FY2023				FY2024											
	Mar. 31	Jun. 30	Sep. 30	Dec. 31	Mar. 31	vs. Mar. 31, 2022	vs. Dec. 31, 2022	Jun. 30	vs. Jun. 30, 2022	vs. Dec. 31, 2022	Sep. 30	vs. Sep. 30, 2022	vs. Dec. 31, 2022	Dec. 31	vs. Dec. 31, 2022	
Trade accounts receivable	304.5	246.0	260.0	252.5	209.4	(95.1)	(43.1)									
Inventories	278.9	266.4	277.5	273.5	276.7	(2.2)	3.2									
Trade accounts payable	(112.5)	(42.9)	(53.9)	(54.2)	(40.4)	72.1	13.8									
Other net working capital	(56.6)	(45.6)	(51.5)	(49.2)	(69.5)	(12.9)	(20.3)									
Net working capital	414.2	423.9	432.1	422.6	376.1	(38.1)	(46.5)									
Property, plant and equipment	389.1	395.6	406.0	409.9	416.3	27.2	6.4									
Right-of-use assets	10.7	10.2	11.8	10.8	10.1	(0.6)	(0.7)									
Intangible assets	19.7	20.7	20.0	19.9	19.6	(0.1)	(0.3)									
Other long-term assets – net	42.1	42.5	37.0	37.8	40.6	(1.5)	2.8									
Long-term net operating assets	461.5	468.9	474.8	478.3	486.6	25.1	8.3									
Net operating assets	875.8	892.8	907.0	900.9	862.7	(13.1)	(38.2)									
Debt	–	–	–	–	–	–	–									
Marketable securities	306.9	300.0	287.4	280.3	301.7	(5.2)	21.4									
Cash and cash equivalents	247.7	365.0	331.3	458.7	462.9	215.2	4.2									
Net cash	554.6	665.0	618.8	739.0	764.6	210.0	25.6									
Other non-operating assets – net	6.5	(44.5)	9.3	(14.3)	14.8	8.3	29.1									
Net non-operating assets	561.2	620.5	628.0	724.7	779.4	218.2	54.7									
Total net assets	1,436.9	1,513.3	1,535.0	1,625.6	1,642.0	205.1	16.4									
Total net assets																
Total assets	1,772.0	1,831.6	1,817.6	1,932.5	1,897.8	125.8	(34.7)									
Total liabilities	(335.1)	(318.3)	(282.7)	(307.0)	(255.7)	79.4	51.3									
Attributable to																
Chugai shareholders	1,436.9	1,513.3	1,535.0	1,625.6	1,642.0	205.1	16.4									
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 FY2023				Actual FY2024			
	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12
	YTD	YTD	YTD	YTD	YTD	YTD	YTD	YTD
Operating profit – IFRS basis	98.3	210.9	317.6	439.2	99.9			
Depreciation and impairment of property, plant and equipment	6.8	13.7	19.6	25.0	6.1			
Depreciation and impairment of right-of-use assets	1.2	2.4	3.6	4.8	1.3			
Amortization and impairment of intangible assets	5.4	6.3	7.1	7.6	0.6			
Other cash adjustment on operating profit	15.2	6.0	9.9	14.9	0.3			
Operating profit, net of operating cash adjustments	126.8	239.3	357.7	491.5	108.2			
(Increase) decrease in trade accounts receivable	132.0	190.7	176.8	184.3	43.6			
(Increase) decrease in inventories	13.1	26.8	13.3	16.7	(0.0)			
Increase (decrease) in trade accounts payable	(31.6)	(101.6)	(90.8)	(90.3)	(14.2)			
Change in other net working capital etc.	10.7	13.6	18.6	20.0	14.7			
Total (increase) decrease in net working capital etc.	124.2	129.6	117.9	130.6	44.1			
Investment in property, plant and equipment	(27.2)	(45.2)	(54.1)	(71.9)	(12.4)			
Lease liabilities paid	(2.0)	(3.9)	(5.9)	(7.9)	(2.0)			
Investment in intangible assets	–	(1.4)	(1.9)	(2.3)	(0.1)			
Operating free cash flows	221.8	318.3	413.6	540.1	137.9			
as % of Revenue	71.0%	54.9%	49.4%	48.6%	58.2%			
Treasury activities (interest income/expenses, foreign exchange gains/losses etc.)	(11.0)	(0.7)	4.1	(0.2)	(9.7)			
Tax paid	(95.6)	(96.0)	(175.8)	(176.1)	(41.0)			
Free cash flows	115.2	221.6	242.0	363.8	87.2			
Dividends paid	(65.4)	(65.8)	(131.2)	(131.6)	(65.0)			
Transaction in own equity instruments	0.1	0.2	0.2	0.2	0.1			
Net effect of currency translation on net cash	1.5	6.0	4.7	3.5	3.3			
Net change in net cash	51.5	161.9	115.7	235.9	25.6			

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

	Units	Actual				Actual				Forecast (Feb 1st announced)
		2023				2024				2024
		1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
		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)	%	8.2	17.8	25.9	34.6	8.6				
Return on invested capital (ROIC)	%	7.7	16.3	24.2	33.8	8.4				
Ratio of profit to total assets (ROA)	%	4.0	8.5	12.7	17.1	3.9				
Ratio of equity attributable to Chugai shareholders	%	81.1	82.6	84.4	84.1	86.5				
Ratio of equity attributable to Chugai shareholders (stock price base)	%	303.6	367.0	418.5	454.8	500.6				
Price book value ratio (PBR)	times	3.7	4.4	5.0	5.4	5.8				
Ratio of net income to equity attributable to Chugai shareholders (ROE)	%	5.1	10.7	15.8	21.3	4.6				
Margin indicator (Core)										
ROS	%	33.8	40.0	40.7	40.6	43.1				43.0
COS ratio(vs. Prod. sales)	%	51.8	46.3	43.2	42.3	35.5				36.6
R&D cost ratio	%	11.6	13.2	14.5	14.6	17.4				16.0
Selling, general and administration cost ratio	%	6.7	7.8	8.5	9.2	9.0				9.5
Turn over indicator										
Total asset turnover	%	17.1	31.3	45.4	58.5	12.4				
Working capital turnover	%	33.3	61.3	87.9	117.0	26.9				
Inventory turnover	Months	5.4	6.6	7.8	7.9	11.4				
Receivables turnover	Months	3.1	2.8	3.2	3.1	3.1				
Payables turnover	Months	2.2	1.1	1.5	1.6	1.7				
Fixed asset turnover	%	75.1	138.3	197.2	260.8	53.5				
PP&E turnover	%	81.7	150.4	214.4	283.1	57.4				
intangible assets turnover	%	1,392.9	2,529.6	3,712.4	4,939.3	1,202.2				
Dividend / per stock indicator										
Dividends per share (Half year)	Yen				40					41
Dividends per share (Year end)	Yen				40					41
Dividends per share (Full year)	Yen				80					82
Core earnings per share (diluted)	Yen	47.66	104.19	152.11	202.71	46.16				204.00
Core payout ratio (%)	%				39.5					40.2
Equity per share attributable to Chugai shareholders (BPS)	Yen	873.44	919.80	932.97	988.01	997.97				
Ratio of dividends to equity attributable to Chugai shareholders (DOE)	%				8.6					
Cashflow indicator										
Cash conversion cycle (CCC)	Months	6.4	8.3	9.4	9.5	12.8				
Net cash turnover period	Months	5.3	6.9	6.6	8.0	9.7				
Number of employees										
Investment on property, plant and equipment	Billions of yen	21.1	37.5	53.8	68.3	15.5				65.0
Depreciation	Billions of yen	6.8	12.5	18.3	24.3	6.1				23.5
Investment on intangible assets	Billions of yen	-	1.8	1.9	2.4	0.3				
Amortization	Billions of yen	0.8	1.4	2.0	2.6	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

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Development Pipeline [Main table] (as of April 24, 2024)

Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
Filed						
AF802/RG7853 in-house	alectinib Alecensa	Non-small cell lung cancer (NSCLC) (adjuvant) #	EU	November 2023	ALK inhibitor Small molecule (oral)	Roche
			China	November 2023		
			Japan	December 2023		
RG7446 Roche	atezolizumab Tecentriq	Alveolar soft part of sarcoma #	Japan	March 2024	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	–
RG7828 Roche	mosunetuzumab -	Follicular lymphoma (3rd Line)	Japan	March 2024	Anti-CD20/CD3 bispecific antibody Antibody (IV)	–
RG7916 PTC Therapeutics	risdiplam Evrysdi	Pre-symptomatic spinal muscular atrophy #	Japan	February 2024	SMN2 splicing modifier Small molecule (oral)	Roche
SKY59/RG6107 in-house	crovalimab -	Paroxysmal nocturnal hemoglobinuria (PNH)	EU	June 2023	Anti-C5 recycling antibody Antibody (SC)	Roche
			US	June 2023		
– Roche	mycophenolate mofetil CellCept	Systemic sclerosis with interstitial lung disease (SSc- ILD) #	Japan	February 2024	Immunosuppressant Small molecule (oral)	–
Phase III						
AF802/RG7853 in-house	alectinib Alecensa	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy #	Global	-	ALK inhibitor Small molecule (oral)	Roche
RG7446 Roche	atezolizumab Tecentriq	NSCLC (periadjuvant) #	Japan	2026	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
		Muscle-invasive bladder cancer (adjuvant) #	Japan	2025		Roche
		Early breast cancer (periadjuvant) #	Japan	2026		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	2024		Roche
		HCC (intermediate stage) # (Avastin) #	Japan	2025		Roche
		HCC (2nd Line) # (lenvatinib or sorafenib)	Japan	-		Roche
		Prostate cancer (2nd Line) # (cabozantinib)	Japan	-		Takeda
RG435 Roche	bevacizumab Avastin	Small cell lung cancer (SCLC) (1st Line) # (Tecentriq)	Japan/ China	2024	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody Antibody (IV)	Roche (China)
RG6058 Roche	tiragolumab -	NSCLC (1st Line) (Tecentriq)	Japan	2025	Anti-TIGIT human monoclonal antibody Antibody (IV)	Roche
		NSCLC (stage III) (Tecentriq) #	Japan	2025		Roche
		Non-squamous NSCLC (1st Line) (Tecentriq)	Japan	2026		Roche
		Esophageal cancer (Tecentriq) #	Japan	2025		Roche
		HCC (1st line) (Tecentriq/Avastin)	Japan	2027 and beyond		Roche
RG6171 Roche	giredestrant -	Breast cancer (adjuvant)	Japan	2027 and beyond	SERD (Selective Estrogen Receptor Degradery) Small molecule (Oral)	Roche
		Breast cancer (1st Line) (palbociclib + letrozole)	Japan	2026		Roche
		Breast cancer (1st Line-3rd Line) (everolimus)	Japan	2025		Roche
RG7828 Roche	mosunetuzumab -	Follicular lymphoma (2nd Line) (lenalidomide)	Japan	2026	Anti-CD20/CD3 bispecific antibody Antibody (IV)	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
		Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma (Polivy) #	Japan	2025	Anti-CD20/CD3 bispecific antibody Antibody (SC)	Roche
RO6026 Roche	glofitamab	Previously untreated large B-cell lymphoma (Polivy)	Japan	2027 and beyond	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
RG6396 Blueprint Medicines	pralsetinib -	NSCLC (1st Line) (pembrolizumab)	Japan	-	RET inhibitor Small molecule (Oral)	Roche
RG7159 GlycArt Biotechnology	obinutuzumab Gazyva	Lupus nephritis #	Japan	2026	Glycoengineered type II anti-CD20 monoclonal Antibody Antibody (IV)	Nippon shinyaku
		Pediatric nephrotic syndrome #	Japan	2026		Nippon shinyaku
		Extra renal lupus #	Japan	2027 and beyond		Nippon shinyaku
SA237/RG6168 in-house	satralizumab Enspryng	Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) #	Global	2027 and beyond	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
		Autoimmune encephalitis (AIE) #	Global	2025		Roche
RG6356/ SRP-9001 Sarepta	delandistrogene moxeparvovec -	Duchenne muscular dystrophy (DMD)	Japan	2024	Microdystrophin gene therapy Gene therapy (IV)	Sarepta*
SKY59/RG6107 in-house	crovalimab -	Atypical hemolytic uremic syndrome (aHUS) #	Global	2026	Anti-C5 recycling antibody Antibody (SC)	Roche
RG7716 Roche	faricimab Vabysmo	Angioid streaks #	Japan	2025	Anti-VEGF/Anti-Ang-2 bispecific antibody Antibody (vitreous injection)	-
RG6179 Roche	vamikibart -	Noninfectious uveitic macular edema	Japan	2026	Anti-IL-6 monoclonal antibody Antibody (vitreous injection)	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	Thyroid eye disease (TED) #	Global	2025	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
Phase II/III						
GYM329/ RG6237 in-house	- -	Spinal muscular atrophy (Evrysdi)	Global	2027 and beyond	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
Phase II						
RG6396 Blueprint Medicines	pralsetinib -	NSCLC (2 nd Line)	Japan	-	RET inhibitor Small molecule (Oral)	Roche
		Solid tumors	Japan	-		Roche
GYM329/ RG6237 in-house	- -	Facioscapulohumeral muscular dystrophy (FSHD)	Global	2027 and beyond	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
RG6042 Ionis Pharmaceuticals	tominersen -	Huntington's disease	Japan	-	Antisense oligonucleotide targeting <i>HTT</i> mRNA Nucleic acid (IV)	Roche
SKY59/RG6107 in-house	crovalimab -	Sickle cell disease (SCD)	US · EU	2027 and beyond	Anti-C5 recycling antibody Antibody (SC)	Roche
AMY109 in-house	- -	Endometriosis	Global	-	Anti-IL-8 recycling antibody Antibody (SC)	-
Phase I/II						
RG6102 MorphoSys	trontinemab —	Alzheimer's disease	Japan	-	Anti-amyloid beta/TFR1 fusion protein Antibody (IV)	Roche
NXT007/ RG6512 in-house	- -	Hemophilia A	Global	-	Anti-coagulation factor Ixa/X bispecific antibody Antibody (SC)	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
RG6321 Roche	ranibizumab (Port delivery system) -	Neovascular age-related macular degeneration	Japan	2026	Humanized anti-VEGF monoclonal antibody	-
		Diabetic macular edema	Japan	2026	Fragment Fab Antibody (injection via implant)	-
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)	-
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
ALPS12/RG6524 in-house	- -	Solid tumors	Global	-	Anti-DLL3/CD3/CD137 trispecific antibody Antibody (IV)	Roche
SAIL66 in-house	- -	CLDN6 positive solid tumors	Global	-	Anti- CLDN6/CD3/CD137 trispecific antibody Antibody (IV)	-
ROSE12 in-house	- -	Solid tumors	Global	-	- Antibody (IV)	-
SPYK04 in-house	- -	Solid tumors	Global	-	- Small molecule (Oral)	-
RG7421 Exelixis	cobimetinib -	Solid tumors	Japan	-	MEK inhibitor Small molecule (Oral)	-

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

Development code Origin	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RG6026 Roche	glofitamab -	Hematologic tumors	Japan	-	Anti-CD20/CD3 bispecific antibody Antibody (IV)	-
RG6194 Roche	runimotamab -	Solid tumors	Japan	-	Anti-HER2/CD3 bispecific antibody Antibody (IV)	Roche
RG6160 Roche	cevostamab -	Relapsed or refractory multiple myeloma	Japan	-	Anti-FcRH5/CD3 bispecific antibody Antibody (IV)	-
RG6330 Roche	divarasib -	Solid tumors	Japan	-	KRAS G12C inhibitor Small molecule (Oral)	-
RG6433 Relay Therapeutics	migoprotafib -	Solid tumors	Japan	-	SHP2 inhibitor Small molecule (Oral)	-
RG6139 Roche	tobemstomig —	Solid tumors	Japan	—	Anti-PD-1/LAG-3 bispecific antibody Antibody (IV)	-
SKY59/RG6107 in-house	crovalimab -	Lupus nephritis	Global	-	Anti-C5 recycling antibody Antibody (SC)	Roche
DONQ52 in-house	- -	Celiac disease	Global	-	Anti-HLA-DQ2.5/gluten peptides multispecific antibody Antibody (SC)	-
RAY121 in-house	- -	Autoimmune disease	Global	-	- Antibody (-)	-
RG6299 Ionis Pharmaceuticals	— —	IgA nephropathy	Japan	—	antisense oligonucleotide targeting <i>complement factor B</i> mRNA Nucleic acid (IV)	-
RG7935 Prothena	prasinezumab -	Parkinson's disease	Japan	-	Anti- α -synuclein monoclonal antibody Antibody (IV)	-
REVN24 in-house	-	Acute diseases	Global	-	- Small molecule (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
Development discontinued						
SA237/RG6168 in-house	satralizumab Enspryng	Generalized myasthenia gravis (gMG) #	Global	-	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies.

* Sarepta manages the global study including Japan

Changes from the last announcement on February 1, 2024

Oncology

- AF802/RG7853 Filed (Non-small cell lung cancer (adjuvant)) (US) → Approved
- RG7446 Filed (Alveolar soft part of sarcoma)
- RG7828 Phase I (Follicular lymphoma (3rd Line)) → Filed
- RG6026 Phase III (Previously untreated large B-cell lymphoma: development started)

Immunology

- SKY59/RG6107 Filed (Paroxysmal nocturnal hemoglobinuria) (China) → Approved
- SKY59/RG6107 Filed (Paroxysmal nocturnal hemoglobinuria) (Japan) → Approved
- CellCept Filed (Systemic sclerosis with interstitial lung disease)
- RG6299 Phase I (IgA nephropathy: development started)

Neuroscience

- RG7916 Filed (Pre-symptomatic spinal muscular atrophy)
- RG6356/SRP-9001 Phase III (Duchenne muscular dystrophy (Non-ambulatory): development started)
- SA237/RG6168 Phase III (Generalized myasthenia gravis: development discontinued)

Ophthalmology

- RG7716 Filed (Retinal vein occlusion) → Approved

R&D Activities

For the changes during the FY2024 (January 1 – March 31), please refer to page 4 of “CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the first quarter of the fiscal year 2024).”

Changes from April 1, 2024 to April 24, 2024 are as follows:

Oncology

- We obtained approval for ALK inhibitor AF802/RG7853 (Product name: Alecensa) for an additional indication of the adjuvant treatment for early stage non-small cell lung cancer in April 2024.
- We started global phase III study SKYGLO for Anti-CD20/CD3 bispecific antibody RG6026 for the treatment of previously untreated large B-cell lymphoma in April 2024.

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

Development code licensee/In-house	Generic name Product name	Indication # Additional Indication (combination)	Stage Country/region	Mode of Action Modality (Dosage form)	Licensee (Granted rights)
VS-6766/CKI27	avutometinib —	Recurrent LGSOC (defactinib)	Phase III Global	RAF/MEK inhibitor Small molecule (Oral)	Verastem Oncology (exclusive global license for the manufacturing, development and marketing)
		NSCLC (defactinib)	Phase I/II Global, US		
		mPDAC* (defactinib)	Phase I/II US		
-/CIM331	nemolizumab	Atopic dermatitis	Filed US/EU	Anti-IL-31 receptor A humanized monoclonal antibody Antibody (SC)	Galderma (exclusive global license for the development and marketing excluding Japan and Taiwan)
		Prurigo nodularis	Filed US/EU		
		Chronic kidney disease associated pruritus	Phase II/III Global		
LY3502970/OWL833	orforglipron —	Type 2 diabetes	Phase III Global	Oral non-peptidic GLP-1 receptor agonist Small molecule (Oral)	Eli Lilly and Company (worldwide development and commercialization rights)
		Obesity	Phase III Global		
AP306/EOS789*	—	Hyperphosphatemia	Phase II China	Oral inhibitor of phosphate transporters Small molecule (Oral)	Alebund (exclusive global license for the manufacturing, development and marketing)

*Newly added according to the progress of the project

Progress made in R&D activities of major Chugai originated developments licensed out to 3rd party excluding Roche during the period from January 1, 2024 to April 24, 2024 was as follows.

- In Japan, Maruho obtained regulatory approval for the anti-IL-31 receptor A humanized monoclonal antibody nemolizumab (Product name in Japan: Mitchga) for the treatment for the following diseases in patients only when existing treatment is insufficiently effective: pruritus associated with atopic dermatitis (children aged ≥ 6 and < 13 years), prurigo nodularis (adults and children aged ≥ 13 years) in March 2024. The applications for approval of nemolizumab for the treatment of prurigo nodularis and atopic dermatitis were accepted in the US and Europe in February 2024.

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of April 24, 2024)

Development Request	Product	Indication	Development Status
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
	CellCept	Systemic sclerosis with interstitial lung disease (SSc-ILD)	Submitted public knowledge-based sNDA filing
	CellCept	Remission maintenance therapy following rituximab therapy for refractory nephrotic syndrome (frequently relapsing or steroid-dependent nephrotic syndrome)	Submitted company opinion and waiting for evaluation by committee

*Transferred the marketing authorization holder to CHEPLAPHARM K.K. as of February 1, 2024

Major Clinical Trials

Project	Expected Indication	Study design	Study name	Stage	CT information
Oncology					
RG7446 (Tecentriq)	NSCLC (periadjuvant)	Chemo ± Tecentriq	IMpower030	Phase III	NCT03456063
	SCLC [1st line]	Tecentriq + chemo ± Avastin	BEAT-SC	Phase III	JapicCTI-195034 (Japanese only)
	Muscle-invasive bladder cancer (adjuvant)	Tecentriq vs. placebo	IMvigor011	Phase III	NCT04660344
	Prostate cancer [2nd line]	Tecentriq + cabozantinib vs. novel hormonal therapy	CONTACT-02	Phase III	NCT04446117
	Early breast cancer (periadjuvant)	TNBC: nab-paclitaxel ± Tecentriq	IMpassion031	Phase III	NCT03197935
	HCC (adjuvant)	Tecentriq + Avastin vs. active surveillance	IMbrave050	Phase III	NCT04102098
	HCC (intermediate stage)	Tecentriq + Avastin + TACE vs. TACE	TALENTACE	Phase III	NCT04803994
	HCC [2nd line]	Tecentriq + lenvatinib or sorafenib vs. lenvatinib or sorafenib	IMbrave251	Phase III	NCT04770896
RG6058 (tiragolumab)	NSCLC [1st line]	PD-L1 positive: Tecentriq ± RG6058	SKYSCRAPER-01	Phase III	NCT04294810
	NSCLC [stage III]	Tecentriq + RG6058 vs. durvalumab	SKYSCRAPER-03	Phase III	NCT04513925
	Non-squamous NSCLC [1st line]	Tecentriq + RG6058 + Pemetrexed + Carboplatin/Cisplatin vs. Pembrolizumab + Pemetrexed + Carboplatin/Cisplatin	SKYSCRAPER-06	Phase III	NCT04619797
	Esophageal cancer	Tecentriq + RG6058 vs. Tecentriq vs. placebo	SKYSCRAPER-07	Phase III	NCT04543617

Project	Expected Indication	Study design	Study name	Stage	CT information
	HCC (1st line)	Tecentriq + Avastin ± RG6058	IMbrave152/SKYSC RAPER-14	Phase III	NCT05904886
AF802 (Alecensa)	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy	ALK fusion-positive: Alecensa vs. durvalumab	HORIZON01	Phase III	NCT05170204
RG6171/SERD (giredestrant)	Breast cancer (adjuvant)	HR positive: RG6171 vs. endocrine therapy	lidERA	Phase III	NCT04961996
	Breast cancer [1st line]	HR positive: RG6171 + palbociclib ± Letrozole	persevERA	Phase III	NCT04546009
	Breast cancer [1st line-3rd line]	HR positive: RG6171 + everolimus vs. endocrine therapy+ everolimus	evERA	Phase III	NCT05306340
RG7828 (mosunetuzumab)	Follicular lymphoma [2nd line]	RG7828 + lenalidomide vs Rituxan + lenalidomide	CELESTIMO	Phase III	NCT04712097
	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma	RG7828 + Polivy vs Rituxan + chemotherapy	SUNMO	Phase III	NCT05171647
RG6026 (glofitamab)	Previously untreated large B-cell lymphoma	RG6026 + Polivy + Rituxan + chemotherapy vs Polivy + Rituxan + chemotherapy	SKYGLO	Phase III	NCT06047080
RG6396 (pralsetinib)	NSCLC [1st line]	RG6396 vs. platinum-based chemotherapy ± pembrolizumab	AcceleRET-Lung	Phase III	NCT04222972
	Solid tumors	RG6396 (single arm)	TAPISTRY	Phase II	NCT04589845
	NSCLC [2nd line]	RG6396 (single arm)	-	Phase II (domestic)	JRCT2021210074 (Japanese only)
Immunology					
RG7159 (Gazyva)	Lupus nephritis	standard treatment ± Gazyva	-	Phase III (domestic)	JRCT2011210059 (Japanese only)
	Pediatric nephrotic syndrome	Gazyva vs. MMF	INShore	Phase III	NCT05627557
	Extra renal lupus	Gazyva vs. Placebo	-	Phase III (domestic)	JRCT2071230031
Neuroscience					
SA237 (Enspryng)	Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)	Enspryng vs. Placebo	METEOROID	Phase III	NCT05271409
	Autoimmune encephalitis (AIE)	Enspryng vs. Placebo	CIELO	Phase III	NCT05503264
RG6356/SRP-9001 (delandistrogene moxeparvovec)	Duchenne muscular dystrophy (DMD) (ambulatory)	RG6356 vs. Placebo	EMBARK	Phase III	NCT05096221
	Duchenne muscular dystrophy (DMD) (non-ambulatory)	RG6356 vs. Placebo	ENVISION	Phase III	NCT05881408
GYM329/RG6237	Spinal muscular atrophy (SMA)	GYM329 ± Evrysdi	MANATEE	Phase II/III	NCT05115110

Project	Expected Indication	Study design	Study name	Stage	CT information
	Facioscapulohumeral muscular dystrophy (FHD)	GYM329 ± Placebo	MANOEUVRE	Phase II	NCT05548556
Hematology					
SKY59/RG6107 (crovalimab)	Atypical hemolytic uremic syndrome (aHUS)	crovalimab (single arm)	COMMUTE-a	Phase III	NCT04861259
	Sickle cell disease (SCD)	crovalimab vs. Placebo	COMMUTE-p	Phase III	NCT04958265
			CROSSWALK-c	Phase IIa	NCT05075824
Ophthalmology					
RG7716 (Vabysmo)	Angioid streaks	Vabysmo (single arm)	NIHONBASHI	Phase III (domestic)	JRCT2071220090 (Japanese only)
RG6179	Noninfectious uveitic macular edema	RG6179 (single arm)	Sandcat	Phase III	NCT05642325
SA237 (Enspryng)	Thyroid eye disease (TED)	Enspryng vs. Placebo	SatraGo 1/ Satra Go 2	Phase III	NCT05987423
RG6321 (ranibizumab (Port delivery system))	Neovascular age-related macular degeneration / Diabetic macular edema	RG6321 (single arm)	-	Phase I/II (domestic)	JRCT2071210073 (Japanese only)

FoundationOne CDx Cancer Genomic Profile: companion diagnostic indications (as of April 24, 2024)

Alterations	Cancer type	Relevant drugs
Activating <i>EGFR</i> alterations	NSCLC	afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, dacomitinib hydrate
<i>EGFR</i> exon 20 T790M alteration		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<i>BRAF</i> V600E and V600K alterations	Malignant melanoma	dabrafenib mesilate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib
<i>ERBB2</i> copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
<i>AKT1</i> alterations		capivasertib
<i>PIK3CA</i> alterations		
<i>PTEN</i> alterations		

<i>KRAS/NRAS</i> wildtype	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 genes		entrectinib, larotrectinib sulfate
<i>RET</i> fusion genes		selpercatinib
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib, talazoparib tosilate
<i>FGFR2</i> fusion genes	Biliary tract cancer	pemigatinib

FoundationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of April 24, 2024)

Alterations	Cancer type	Relevant drugs
Activating <i>EGFR</i> alterations	NSCLC	afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
<i>EGFR</i> exon 20 T790M alteration		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<i>NTRK1/2/3</i> fusion genes	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib