

Supplementary Materials for
Consolidated Financial Results for
the 2nd Quarter of Fiscal Year 2018. 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
3. Exchange rates used for each period are as follows.

QTR

(Yen)

		Actual*				Actual*			
		FY2017				FY2018			
		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		113.21	112.69	115.33	114.41	114.33	110.77		
EUR		121.09	122.03	130.36	132.93	133.17	130.06		
USD		113.69	111.07	111.01	112.89	108.40	109.08		
SGD		80.25	79.76	81.57	83.38	82.16	81.78		

*Market average exchange rate

YTD

	Actual*	Actual*				Actual*				Assumption
	FY2016	FY2017				FY2018				FY2018
	1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
	Full-year	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year	Full-year
CHF	110.46	113.21	112.95	113.73	113.90	114.33	112.52			115.00
EUR	120.42	121.09	121.55	124.33	126.39	133.17	131.59			133.00
USD	108.83	113.69	112.38	111.92	112.17	108.40	108.74			111.00
SGD	78.82	80.25	80.01	80.52	81.22	82.16	81.97			84.00

*Market average exchange rate

Period-end

	Actual	Actual				Actual			
	FY2016	FY2017				FY2018			
	31 Dec.	31 Mar.	30 Jun.	30 Sep.	31 Dec.	31 Mar.	30 Jun.	30 Sep.	31 Dec.
CHF	113.94	111.76	117.37	115.80	115.35	111.67	110.78		
EUR	122.27	119.47	128.35	132.41	134.82	131.49	127.83		
USD	116.55	111.92	112.18	112.35	112.89	106.83	110.50		
SGD	80.47	80.04	81.33	82.73	84.39	81.43	80.79		

Financial highlights (YTD)

(Billions of yen)

	Actual	Actual				Actual							
	FY2016	FY2017				FY2018							
	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	491.8	125.5	252.8	387.6	534.2	147.4	+17.5	285.1	+12.8				
Sales	472.7	118.1	236.8	364.8	499.3	124.7	+5.6	255.6	+7.9				
excl. Tamiflu	459.2	110.8	228.7	354.8	482.4	116.3	+5.0	247.2	+8.1				
Domestic	379.7	85.1	183.0	281.0	388.4	84.5	(0.7)	182.7	(0.2)				
Sales to Roche	62.8	21.3	36.9	60.6	76.4	27.4	+28.6	55.2	+49.6				
Overseas	16.8	4.3	8.8	13.2	17.7	4.5	+4.7	9.2	+4.5				
Tamiflu sales	13.5	7.4	8.2	10.0	16.9	8.4	+13.5	8.4	+2.4				
Ordinary use	12.0	6.1	6.3	6.3	11.9	8.3	+36.1	8.3	+31.7				
Govt. stockpiles etc.	1.5	1.3	1.9	3.7	5.0	0.1	(92.3)	0.1	(94.7)				
Royalties and other operating income	19.1	7.3	15.9	22.9	34.9	22.7	+211.0	29.5	+85.5				
Cost of sales	(247.9)	(61.2)	(121.4)	(186.5)	(254.2)	(63.8)	+4.2	(129.1)	+6.3				
(% of Sales)	52.4	51.8	51.3	51.1	50.9	51.2	-	50.5	-				
Gross profit	243.8	64.3	131.3	201.1	280.0	83.6	+30.0	156.1	+18.9				
(% of Revenues)	49.6	51.2	51.9	51.9	52.4	56.7	-	54.8	-				
Operating expenses	(167.0)	(38.0)	(84.2)	(124.9)	(181.1)	(45.2)	+18.9	(89.5)	+6.3				
(% of Revenues)	34.0	30.3	33.3	32.2	33.9	30.7	-	31.4	-				
Marketing and distribution	(69.8)	(15.4)	(32.2)	(49.2)	(72.8)	(15.9)	+3.2	(33.2)	+3.1				
(% of Revenues)	14.2	12.3	12.7	12.7	13.6	10.8	-	11.6	-				
Research and development	(85.0)	(19.3)	(44.8)	(65.7)	(92.9)	(25.1)	+30.1	(48.5)	+8.3				
(% of Revenues)	17.3	15.4	17.7	17.0	17.4	17.0	-	17.0	-				
General and administration	(12.2)	(3.3)	(7.2)	(10.0)	(15.3)	(4.3)	+30.3	(7.8)	+8.3				
(% of Revenues)	2.5	2.6	2.8	2.6	2.9	2.9	-	2.7	-				
Operating profit	76.9	26.3	47.1	76.2	98.9	38.4	+46.0	66.6	+41.4				
(% of Revenues)	15.6	21.0	18.6	19.7	18.5	26.1	-	23.4	-				
Financing costs	(0.1)	(0.0)	(0.1)	(0.1)	(0.1)	(0.0)	0.0	(0.1)	0.0				
Other financial income (expense)	1.1	(0.3)	(0.2)	(0.2)	(0.1)	(0.1)	(66.7)	0.0	-				
Other expense	(3.5)	(1.1)	(0.4)	(1.1)	(1.7)	(0.6)	(45.5)	(1.5)	+275.0				
Profit before taxes	74.4	25.0	46.4	74.9	97.0	37.7	+50.8	65.0	+40.1				
(% of Revenues)	15.1	19.9	18.4	19.3	18.2	25.6	-	22.8	-				
Income taxes	(20.1)	(6.2)	(9.9)	(17.0)	(23.5)	(9.5)	+53.2	(15.9)	+60.6				
Net income	54.4	18.7	36.5	57.9	73.5	28.2	+50.8	49.0	+34.2				
(% of Revenues)	11.1	14.9	14.4	14.9	13.8	19.1	-	17.2	-				
Attributable to													
Chugai shareholders	53.6	18.5	36.1	57.2	72.7	27.9	+50.8	48.7	+34.9				
Non-controlling interests	0.8	0.2	0.4	0.7	0.8	0.3	+50.0	0.4	0.0				
Earnings per share													
Basic (yen)	98.12	33.86	66.07	104.66	133.04	51.00	+50.6	89.00	+34.7				
Diluted (yen)	97.97	33.81	65.97	104.51	132.83	50.91	+50.6	88.85	+34.7				

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

Financial highlights (QTR)

(Billions of yen)

	Actual FY2017				Actual FY2018							
	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	125.5	127.3	134.9	146.6	147.4	+17.5	137.7	+8.2				
Sales	118.1	118.7	127.9	134.5	124.7	+5.6	130.8	+10.2				
excl. Tamiflu	110.8	117.9	126.1	127.7	116.3	+5.0	130.8	+10.9				
Domestic	85.1	97.9	97.9	107.5	84.5	(0.7)	98.3	+0.4				
Sales to Roche	21.3	15.6	23.7	15.8	27.4	+28.6	27.8	+78.2				
Overseas	4.3	4.5	4.4	4.5	4.5	+4.7	4.7	+4.4				
Tamiflu sales	7.4	0.8	1.9	6.8	8.4	+13.5	0.0	(100.0)				
Ordinary use	6.1	0.2	0.0	5.6	8.3	+36.1	0.0	(100.0)				
Govt. stockpiles etc.	1.3	0.6	1.8	1.2	0.1	(92.3)	-	(100.0)				
Royalties and other operating income	7.3	8.6	6.9	12.0	22.7	+211.0	6.8	(20.9)				
Cost of sales	(61.2)	(60.3)	(65.1)	(67.7)	(63.8)	+4.2	(65.2)	+8.1				
(% of Sales)	51.8	50.8	50.9	50.3	51.2	-	49.8	-				
Gross profit	64.3	67.0	69.8	78.9	83.6	+30.0	72.5	+8.2				
(% of Revenues)	51.2	52.6	51.7	53.8	56.7	-	52.7	-				
Operating expenses	(38.0)	(46.3)	(40.7)	(56.2)	(45.2)	+18.9	(44.2)	(4.5)				
(% of Revenues)	30.3	36.4	30.2	38.3	30.7	-	32.1	-				
Marketing and distribution	(15.4)	(16.8)	(17.0)	(23.6)	(15.9)	+3.2	(17.3)	+3.0				
(% of Revenues)	12.3	13.2	12.6	16.1	10.8	-	12.6	-				
Research and development	(19.3)	(25.6)	(20.8)	(27.3)	(25.1)	+30.1	(23.5)	(8.2)				
(% of Revenues)	15.4	20.1	15.4	18.6	17.0	-	17.1	-				
General and administration	(3.3)	(3.9)	(2.9)	(5.3)	(4.3)	+30.3	(3.5)	(10.3)				
(% of Revenues)	2.6	3.1	2.1	3.6	2.9	-	2.5	-				
Operating profit	26.3	20.8	29.1	22.7	38.4	+46.0	28.2	+35.6				
(% of Revenues)	21.0	16.3	21.6	15.5	26.1	-	20.5	-				
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0	(0.0)	0.0				
Other financial income (expense)	(0.3)	0.1	0.0	0.1	(0.1)	(66.7)	0.1	0.0				
Other expense	(1.1)	0.7	(0.7)	(0.6)	(0.6)	(45.5)	(0.9)	-				
Profit before taxes	25.0	21.5	28.4	22.2	37.7	+50.8	27.3	+27.0				
(% of Revenues)	19.9	16.9	21.1	15.1	25.6	-	19.8	-				
Income taxes	(6.2)	(3.6)	(7.1)	(6.5)	(9.5)	+53.2	(6.4)	+77.8				
Net income	18.7	17.8	21.3	15.7	28.2	+50.8	20.9	+17.4				
(% of Revenues)	14.9	14.0	15.8	10.7	19.1	-	15.2	-				
Attributable to					-		-					
Chugai shareholders	18.5	17.6	21.1	15.5	27.9	+50.8	20.8	+18.2				
Non-controlling interests	0.2	0.2	0.2	0.2	0.3	+50.0	0.1	(50.0)				
Earnings per share												
Basic (yen)	33.86	32.20	38.59	28.38	51.00	+50.6	38.00	+18.0				
Diluted (yen)	33.81	32.15	38.53	28.33	50.91	+50.6	37.94	+18.0				

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

Financial highlights (Core results YTD)

(Billions of yen)

	Actual	Actual				Actual								Forecast (Feb 1st Announced)		
	FY2016	FY2017				FY2018								FY2018		
	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	491.8	125.5	252.8	387.6	534.2	147.4	+17.5	285.1	+12.8					541.5	+1.4	
Sales	472.7	118.1	236.8	364.8	499.3	124.7	+5.6	255.6	+7.9					498.5	(0.2)	
excl. Tamiflu	459.2	110.8	228.7	354.8	482.4	116.3	+5.0	247.2	+8.1					492.9	+2.2	
Domestic	379.7	85.1	183.0	281.0	388.4	84.5	(0.7)	182.7	(0.2)					374.8	(3.5)	
Sales to Roche	62.8	21.3	36.9	60.6	76.4	27.4	+28.6	55.2	+49.6					99.6	+30.4	
Overseas	16.8	4.3	8.8	13.2	17.7	4.5	+4.7	9.2	+4.5					18.5	+4.5	
Tamiflu sales	13.5	7.4	8.2	10.0	16.9	8.4	+13.5	8.4	+2.4					5.6	(66.9)	
Ordinary use	12.0	6.1	6.3	6.3	11.9	8.3	+36.1	8.3	+31.7					5.0	(58.0)	
Govt. stockpiles etc.	1.5	1.3	1.9	3.7	5.0	0.1	(92.3)	0.1	(94.7)					0.6	(88.0)	
Royalties and other operating income	19.1	7.3	15.9	22.9	34.9	22.7	+211.0	29.5	+85.5					43.0	+23.2	
Cost of sales	(246.7)	(60.9)	(120.8)	(185.6)	(252.9)	(63.5)	+4.3	(128.6)	+6.5					(252.0)	(0.4)	
(% of Sales)	52.2	51.6	51.0	50.9	50.7	50.9	-	50.3	-					50.6	-	
Gross profit	245.0	64.6	131.9	202.1	281.3	83.9	+29.9	156.6	+18.7					289.5	+2.9	
(% of Revenues)	49.8	51.5	52.2	52.1	52.7	56.9	-	54.9	-					53.5	-	
Operating expenses	(164.5)	(37.9)	(81.8)	(123.4)	(178.1)	(41.1)	+8.4	(84.9)	+3.8					(181.5)	+1.9	
(% of Revenues)	33.4	30.2	32.4	31.8	33.3	27.9	-	29.8	-					33.5	-	
Marketing and distribution	(69.8)	(15.4)	(32.2)	(49.2)	(72.8)	(15.9)	+3.2	(33.2)	+3.1							
(% of Revenues)	14.2	12.3	12.7	12.7	13.6	10.8	-	11.6	-							
Research and development	(82.6)	(19.2)	(42.4)	(63.2)	(88.9)	(20.9)	+8.9	(44.0)	+3.8							
(% of Revenues)	16.8	15.3	16.8	16.3	16.6	14.2	-	15.4	-							
General and administration	(12.1)	(3.3)	(7.2)	(11.0)	(16.3)	(4.3)	+30.3	(7.8)	+8.3							
(% of Revenues)	2.5	2.6	2.8	2.8	3.1	2.9	-	2.7	-							
Operating profit	80.6	26.7	50.2	78.7	103.2	42.8	+60.3	71.6	+42.6					108.0	+4.7	
(% of Revenues)	16.4	21.3	19.9	20.3	19.3	29.0	-	25.1	-					19.9	-	
Financing costs	(0.1)	(0.0)	(0.1)	(0.1)	(0.1)	(0.0)	0.0	(0.1)	0.0							
Other financial income (expense)	1.1	(0.3)	(0.2)	(0.2)	(0.1)	(0.1)	(66.7)	0.0	-							
Other expense	(3.5)	(1.1)	(0.4)	(1.1)	(1.7)	(0.6)	(45.5)	(1.5)	+275.0							
Profit before taxes	78.1	25.3	49.5	77.3	101.3	42.1	+66.4	70.1	+41.6							
(% of Revenues)	15.9	20.2	19.6	19.9	19.0	28.6	-	24.6	-							
Income taxes	(21.3)	(6.3)	(10.7)	(17.6)	(24.5)	(10.9)	+73.0	(17.5)	+63.6							
Net income	56.8	18.9	38.8	59.7	76.7	31.2	+65.1	52.6	+35.6							
(% of Revenues)	11.5	15.1	15.3	15.4	14.4	21.2	-	18.4	-							
Attributable to																
Chugai shareholders	56.1	18.7	38.4	59.0	75.9	31.0	+65.8	52.2	+35.9							
Non-controlling interests	0.8	0.2	0.4	0.7	0.8	0.3	+50.0	0.4	0.0							
Weighted average number of shares in issue used to calculate diluted earnings per share (Millions of shares)	547	547	547	547	547	548	+0.2	548	+0.2							
Core earnings per share (diluted) (yen)	102.50	34.22	70.10	107.80	138.68	56.52	+65.2	95.27	+35.9					147.00	+6.0	
Core payout ratio (%)	50.7					44.7									42.2	-
Dividend per share (Full year) (yen)	52					62									62	-
Dividend per share (Half year) (yen)	26					29					31				31	-

Please see page 5 "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.

Financial highlights (Core results QTR)

(Billions of yen)

	Actual				Actual							
	FY2017				FY2018							
	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	125.5	127.3	134.9	146.6	147.4	+17.5	137.7	+8.2				
Sales	118.1	118.7	127.9	134.5	124.7	+5.6	130.8	+10.2				
excl. Tamiflu	110.8	117.9	126.1	127.7	116.3	+5.0	130.8	+10.9				
Domestic	85.1	97.9	97.9	107.5	84.5	(0.7)	98.3	+0.4				
Sales to Roche	21.3	15.6	23.7	15.8	27.4	+28.6	27.8	+78.2				
Overseas	4.3	4.5	4.4	4.5	4.5	+4.7	4.7	+4.4				
Tamiflu sales	7.4	0.8	1.9	6.8	8.4	+13.5	0.0	(100.0)				
Ordinary use	6.1	0.2	0.0	5.6	8.3	+36.1	0.0	(100.0)				
Govt. stockpiles etc.	1.3	0.6	1.8	1.2	0.1	(92.3)	–	(100.0)				
Royalties and other operating income	7.3	8.6	6.9	12.0	22.7	+211.0	6.8	(20.9)				
Cost of sales	(60.9)	(60.0)	(64.8)	(67.3)	(63.5)	+4.3	(65.1)	+8.5				
(% of Sales)	51.6	50.5	50.7	50.0	50.9	–	49.8	–				
Gross profit	64.6	67.3	70.1	79.2	83.9	+29.9	72.6	+7.9				
(% of Revenues)	51.5	52.9	52.0	54.0	56.9	–	52.7	–				
Operating expenses	(37.9)	(43.8)	(41.7)	(54.7)	(41.1)	+8.4	(43.8)	0.0				
(% of Revenues)	30.2	34.4	30.9	37.3	27.9	–	31.8	–				
Marketing and distribution	(15.4)	(16.8)	(17.0)	(23.6)	(15.9)	+3.2	(17.3)	+3.0				
(% of Revenues)	12.3	13.2	12.6	16.1	10.8	–	12.6	–				
Research and development	(19.2)	(23.1)	(20.8)	(25.8)	(20.9)	+8.9	(23.0)	(0.4)				
(% of Revenues)	15.3	18.1	15.4	17.6	14.2	–	16.7	–				
General and administration	(3.3)	(3.9)	(3.9)	(5.3)	(4.3)	+30.3	(3.5)	(10.3)				
(% of Revenues)	2.6	3.1	2.9	3.6	2.9	–	2.5	–				
Operating profit	26.7	23.5	28.5	24.5	42.8	+60.3	28.8	+22.6				
(% of Revenues)	21.3	18.5	21.1	16.7	29.0	–	20.9	–				
Financing costs	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0	(0.0)	0.0				
Other financial income (expense)	(0.3)	0.1	0.0	0.1	(0.1)	(66.7)	0.1	0.0				
Other expense	(1.1)	0.7	(0.7)	(0.6)	(0.6)	(45.5)	(0.9)	–				
Profit before taxes	25.3	24.2	27.8	24.0	42.1	+66.4	28.0	+15.7				
(% of Revenues)	20.2	19.0	20.6	16.4	28.6	–	20.3	–				
Income taxes	(6.3)	(4.4)	(6.9)	(6.9)	(10.9)	+73.0	(6.6)	+50.0				
Net income	18.9	19.9	20.9	17.1	31.2	+65.1	21.3	+7.0				
(% of Revenues)	15.1	15.6	15.5	11.7	21.2	–	15.5	–				
Attributable to												
Chugai shareholders	18.7	19.6	20.6	16.9	31.0	+65.8	21.2	+8.2				
Non-controlling interests	0.2	0.2	0.2	0.2	0.3	+50.0	0.1	(50.0)				
Core earnings per share (diluted) (yen)	34.22	35.89	37.70	30.88	56.52	+65.2	38.75	+8.0				

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

Reconciliation of IFRS results to Core results

(Billions of yen)

	FY2017				FY2018			
	1-6				1-6			
	IFRS results	Intangible assets	Others	Core results	IFRS results	Intangible assets	Others	Core results
Revenues	252.8	–	–	252.8	285.1	–	–	285.1
Sales	236.8	–	–	236.8	255.6	–	–	255.6
Royalties and other operating income	15.9	–	–	15.9	29.5	–	–	29.5
Cost of sales	(121.4)	0.6	–	(120.8)	(129.1)	0.5	–	(128.6)
Gross profit	131.3	0.6	–	131.9	156.1	0.5	–	156.6
Operating expenses	(84.2)	2.5	–	(81.8)	(89.5)	4.6	–	(84.9)
Marketing and distribution	(32.2)	–	–	(32.2)	(33.2)	–	–	(33.2)
Research and development	(44.8)	2.5	–	(42.4)	(48.5)	4.6	–	(44.0)
General and administration	(7.2)	–	–	(7.2)	(7.8)	–	–	(7.8)
Operating profit	47.1	3.1	–	50.2	66.6	5.1	–	71.6
Financing costs	(0.1)	–	–	(0.1)	(0.1)	–	–	(0.1)
Other financial income (expense)	(0.2)	–	–	(0.2)	0.0	–	–	0.0
Other expense	(0.4)	–	–	(0.4)	(1.5)	–	–	(1.5)
Profit before taxes	46.4	3.1	–	49.5	65.0	5.1	–	70.1
Income taxes	(9.9)	(0.8)	–	(10.7)	(15.9)	(1.6)	–	(17.5)
Net income	36.5	2.3	–	38.8	49.0	3.5	–	52.6
Attributable to								
Chugai shareholders	36.1	2.3	–	38.4	48.7	3.5	–	52.2
Non-controlling interests	0.4	–	–	0.4	0.4	–	–	0.4

Core results

Chugai discloses its results on a Core basis from 2013 in conjunction with its decision to apply IFRS. Core results are the results after adjusting non-Core items to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the underlying business performance both internally and externally, and as the basis for payment-by-results such as a return to shareholders.

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

Intangible assets

Amortization (0.6 billion yen in 2017 and 0.6 billion yen in 2018)

Impairment (2.5 billion yen in 2017 and 4.4 billion yen in 2018)

Statements of revenues (YTD)

(Billions of yen)															
		Actual	Actual					Actual							
		FY2016	FY2017					FY2018							
		1-12	1-3	1-6	1-9	1-12	1-3	Change (%)	1-6	Change (%)	1-9	Change (%)	1-12	Change (%)	Forecast (Feb 1st announced)
		YTD	YTD	YTD	YTD	YTD	YTD		YTD		YTD		YTD		YTD
Sales		472.7	118.1	236.8	364.8	499.3	124.7	+5.6	255.6	+7.9					498.5 (0.2)
	Excl. Tamiflu	459.2	110.8	228.7	354.8	482.4	116.3	+5.0	247.2	+8.1					492.9 +2.2
	Domestic	379.7	85.1	183.0	281.0	388.4	84.5	(0.7)	182.7	(0.2)					374.8 (3.5)
	Oncology	220.3	49.3	106.3	163.5	225.9	48.6	(1.4)	105.7	(0.6)					217.6 (3.7)
	Avastin	92.1	20.5	44.0	67.6	93.1	21.0	+2.4	45.4	+3.2					92.0 (1.2)
	Herceptin	34.1	7.5	16.2	24.6	33.6	6.8	(9.3)	13.8	(14.8)					26.6 (20.8)
	Rituxan	32.1	7.0	15.4	24.1	33.4	6.2	(11.4)	11.9	(22.7)					23.4 (29.9)
	Alecensa	11.9	3.3	7.4	11.7	16.7	4.0	+21.2	9.4	+27.0					22.7 +35.9
	Perjeta	11.9	2.9	6.3	9.8	13.6	3.2	+10.3	7.0	+11.1					14.6 +7.4
	Xeloda	12.3	2.8	5.9	8.9	12.2	2.8	0.0	6.1	+3.4					12.6 +3.3
	Tarceva	11.5	2.4	5.2	7.7	10.5	1.9	(20.8)	4.4	(15.4)					9.8 (6.7)
	Kadcyla	8.3	1.8	3.7	5.8	8.0	1.8	0.0	4.0	+8.1					8.3 +3.8
	Tecentriq	-	-	-	-	-	-	-	1.7	-					3.1 -
	Alaglo	-	-	-	-	0.0	0.1	-	0.1	-					0.7 -
	Zelboraf	0.4	0.0	0.1	0.1	0.1	0.0	0.0	0.0	(100.0)					0.1 0.0
	Other products	5.8	1.0	2.2	3.3	4.6	0.8	(20.0)	1.8	(18.2)					3.7 (19.6)
	Bone and joint diseases	86.1	20.4	43.7	67.1	93.3	21.6	+5.9	47.0	+7.6					97.1 +4.1
	Actemra	30.2	7.0	15.2	23.6	33.1	8.0	+14.3	17.7	+16.4					35.2 +6.3
	Ediol	26.7	6.3	13.7	21.1	29.6	7.0	+11.1	15.2	+10.9					31.7 +7.1
	Bonviva	7.3	1.8	4.0	6.2	8.7	2.1	+16.7	4.4	+10.0					9.9 +13.8
	Suvenyl	9.3	1.9	4.2	6.4	8.8	1.7	(10.5)	3.7	(11.9)					8.3 (5.7)
	Other products	12.6	3.4	6.6	9.8	13.1	2.9	(14.7)	6.0	(9.1)					11.9 (9.2)
	Renal diseases	41.1	8.3	18.4	28.3	39.3	8.0	(3.6)	17.0	(7.6)					35.3 (10.2)
	Mircera	24.2	4.9	11.0	17.2	23.9	4.9	0.0	10.6	(3.6)					23.5 (1.7)
	Oxarol	9.1	1.7	3.8	5.9	8.2	1.7	0.0	3.5	(7.9)					5.8 (29.3)
	Other products	7.8	1.7	3.5	5.3	7.2	1.4	(17.6)	2.8	(20.0)					6.0 (16.7)
	Others	32.2	7.1	14.6	22.0	29.9	6.2	(12.7)	13.0	(11.0)					24.8 (17.1)
	CellCept	7.9	1.9	4.1	6.4	8.9	2.0	+5.3	4.3	+4.9					8.5 (4.5)
	Hemlibra	-	-	-	-	-	-	-	0.5	-					1.4 -
	Other products	24.3	5.2	10.5	15.7	21.0	4.2	(19.2)	8.3	(21.0)					14.9 (29.0)
	Overseas	79.5	25.6	45.7	73.8	94.0	31.9	+24.6	64.5	+41.1					118.1 +25.6
	Actemra	60.3	18.0	31.1	48.7	60.9	23.4	+30.0	44.9	+44.4					73.0 +19.9
	To Roche	59.1	17.7	30.4	47.6	59.4	23.0	+29.9	44.1	+45.1					71.4 +20.2
	Alecensa	3.7	3.6	5.5	10.2	13.9	3.8	+5.6	10.3	+87.3					26.4 +89.9
	To Roche	3.7	3.6	5.5	10.2	13.9	3.7	+2.8	10.0	+81.8					26.3 +89.2
	Neutrogen	12.2	2.9	5.9	9.2	12.3	3.0	+3.4	5.7	(3.4)					12.0 (2.4)
	Hemlibra	-	-	1.0	2.8	3.1	0.7	-	1.2	+20.0					2.0 (35.5)
	Akynzeo	0.1	0.1	0.1	0.2	0.3	0.1	0.0	0.1	0.0					0.4 +33.3
	Aloxi	0.2	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0					0.1 0.0
	Other products	3.0	1.1	2.0	2.6	3.5	1.0	(9.1)	2.3	+15.0					4.2 +20.0
	Tamiflu	13.5	7.4	8.2	10.0	16.9	8.4	+13.5	8.4	+2.4					5.6 (66.9)
	Ordinary use	12.0	6.1	6.3	6.3	11.9	8.3	+36.1	8.3	+31.7					5.0 (58.0)
	Govt. stockpiles etc.	1.5	1.3	1.9	3.7	5.0	0.1	(92.3)	0.1	(94.7)					0.6 (88.0)
Royalties and other operating income		19.1	7.3	15.9	22.9	34.9	22.7	+211.0	29.5	+85.5					43.0 +23.2
Revenues		491.8	125.5	252.8	387.6	534.2	147.4	+17.5	285.1	+12.8					541.5 +1.4
	Domestic	395.1	95.7	196.2	296.5	410.9	110.6	+15.6	210.3	+7.2					400.1 (2.6)
	Overseas	96.6	29.7	56.6	91.1	123.3	36.9	+24.2	74.8	+32.2					141.4 +14.7

Tecentriq sales forecast has been individually disclosed from consolidated financial results announcement for the 1st quarter on April 24th 2018.

Hemlibra domestic sales forecast has been individually disclosed from consolidated financial results announcement for the 2nd quarter on July 26th 2018.

The total sales forecast for this fiscal year is unchanged from the announcement of February 1st 2018.

Statements of revenues (QTR)

(Billions of yen)

	Actual				Actual							
	FY2017				FY2018							
	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	118.1	118.7	127.9	134.5	124.7	+5.6	130.8	+10.2				
Excl.Tamiflu	110.8	117.9	126.1	127.7	116.3	+5.0	130.8	+10.9				
Domestic	85.1	97.9	97.9	107.5	84.5	(0.7)	98.3	+0.4				
Oncology	49.3	57.1	57.2	62.3	48.6	(1.4)	57.0	(0.2)				
Avastin	20.5	23.5	23.5	25.6	21.0	+2.4	24.4	+3.8				
Herceptin	7.5	8.6	8.4	9.0	6.8	(9.3)	7.0	(18.6)				
Rituxan	7.0	8.5	8.7	9.3	6.2	(11.4)	5.7	(32.9)				
Alecensa	3.3	4.1	4.4	5.0	4.0	+21.2	5.4	+31.7				
Perjeta	2.9	3.4	3.5	3.8	3.2	+10.3	3.8	+11.8				
Xeloda	2.8	3.1	3.0	3.3	2.8	0.0	3.3	+6.5				
Tarceva	2.4	2.7	2.6	2.8	1.9	(20.8)	2.5	(7.4)				
Kadcyla	1.8	2.0	2.0	2.2	1.8	0.0	2.2	+10.0				
Tecentriq	-	-	-	-	-	-	1.7	-				
Alaglo	-	-	-	0.0	0.1	-	0.1	-				
Zelboraf	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0				
Other products	1.0	1.2	1.2	1.3	0.8	(20.0)	1.0	(16.7)				
Bone and joint diseases	20.4	23.2	23.4	26.3	21.6	+5.9	25.4	+9.5				
Actemra	7.0	8.2	8.4	9.5	8.0	+14.3	9.6	+17.1				
Edirol	6.3	7.4	7.4	8.5	7.0	+11.1	8.2	+10.8				
Bonviva	1.8	2.2	2.2	2.5	2.1	+16.7	2.4	+9.1				
Suvenyl	1.9	2.3	2.2	2.4	1.7	(10.5)	2.0	(13.0)				
Other products	3.4	3.2	3.2	3.3	2.9	(14.7)	3.1	(3.1)				
Renal diseases	8.3	10.1	10.0	11.0	8.0	(3.6)	9.0	(10.9)				
Mircera	4.9	6.1	6.2	6.8	4.9	0.0	5.8	(4.9)				
Oxarol	1.7	2.1	2.1	2.2	1.7	0.0	1.8	(14.3)				
Other products	1.7	1.9	1.7	1.9	1.4	(17.6)	1.4	(26.3)				
Others	7.1	7.5	7.4	7.9	6.2	(12.7)	6.8	(9.3)				
CellCept	1.9	2.2	2.2	2.5	2.0	+5.3	2.3	+4.5				
Hemlibra	-	-	-	-	-	-	0.5	-				
Other products	5.2	5.3	5.2	5.4	4.2	(19.2)	4.0	(24.5)				
Overseas	25.6	20.0	28.1	20.2	31.9	+24.6	32.6	+63.0				
Actemra	18.0	13.1	17.6	12.2	23.4	+30.0	21.5	+64.1				
To Roche	17.7	12.7	17.2	11.8	23.0	+29.9	21.0	+65.4				
Alecensa	3.6	1.8	4.8	3.7	3.8	+5.6	6.5	+261.1				
To Roche	3.6	1.8	4.8	3.7	3.7	+2.8	6.3	+250.0				
Neutrogin	2.9	3.1	3.2	3.1	3.0	+3.4	2.7	(12.9)				
Hemlibra	-	1.0	1.8	0.3	0.7	-	0.5	(50.0)				
Akynzeo	0.1	0.1	0.1	0.1	0.1	0.0	0.1	0.0				
Aloxi	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0				
Other products	1.1	0.9	0.6	0.8	1.0	(9.1)	1.3	+44.4				
Tamiflu	7.4	0.8	1.9	6.8	8.4	+13.5	0.0	(100.0)				
Ordinary use	6.1	0.2	0.0	5.6	8.3	+36.1	0.0	(100.0)				
Govt. stockpiles etc.	1.3	0.6	1.8	1.2	0.1	(92.3)	-	(100.0)				
Royalties and other operating income	7.3	8.6	6.9	12.0	22.7	+211.0	6.8	(20.9)				
Revenues	125.5	127.3	134.9	146.6	147.4	+17.5	137.7	+8.2				
Domestic	95.7	100.5	100.3	114.4	110.6	+15.6	99.7	(0.8)				
Overseas	29.7	26.8	34.5	32.2	36.9	+24.2	37.9	+41.4				

Movements of assets and liabilities (Assets, Liabilities, and Net Assets)

(Billions of yen)

	Actual	Actual					Actual										
	FY2016	FY2017					FY2018										
	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31	Mar. 31	vs. Mar. 31, 2017	vs. Dec. 31, 2017	Jun. 30	vs. Jun. 30, 2017	vs. Dec. 31, 2017	Sep. 30	vs. Sep. 30, 2017	vs. Dec. 31, 2017	Dec. 31	vs. Dec. 31, 2017	
Trade accounts receivable	140.7	125.2	128.9	146.2	148.5	137.1	11.9	(11.4)	140.6	11.7	(7.9)						
Inventories	185.4	189.5	188.3	177.7	169.1	168.1	(21.4)	(1.0)	170.0	(18.3)	0.9						
Trade accounts payable	(42.5)	(45.0)	(50.6)	(38.1)	(38.4)	(48.7)	(3.7)	(10.3)	(46.2)	4.4	(7.8)						
Other net working capital	(25.2)	(26.3)	(19.6)	(22.1)	(28.4)	(24.7)	1.6	3.7	(18.2)	1.4	10.2						
Net working capital	258.5	243.3	247.0	263.7	250.7	231.8	(11.5)	(18.9)	246.3	(0.7)	(4.4)						
Property, plant and equipment	157.1	163.3	171.3	170.5	171.6	174.6	11.3	3.0	179.2	7.9	7.6						
Intangible assets	19.3	20.3	19.6	21.2	21.1	17.9	(2.4)	(3.2)	18.1	(1.5)	(3.0)						
Other long-term assets – net	(3.7)	(3.1)	(2.9)	(3.2)	(3.1)	13.2	16.3	16.3	12.4	15.3	15.5						
Long-term net operating assets	172.7	180.5	188.1	188.4	189.5	205.7	25.2	16.2	209.6	21.5	20.1						
Net operating assets	431.1	423.7	435.0	452.2	440.2	437.5	13.8	(2.7)	455.9	20.9	15.7						
Debt	(0.6)	(0.6)	(0.4)	(0.4)	(0.3)	(0.3)	0.3	0.0	(0.3)	0.1	0.0						
Marketable securities	110.2	108.4	110.2	110.9	104.0	113.8	5.4	9.8	119.9	9.7	15.9						
Cash and cash equivalents	95.4	103.7	110.7	97.6	139.1	152.8	49.1	13.7	154.6	43.9	15.5						
Net cash	204.9	211.4	220.5	208.1	242.8	266.3	54.9	23.5	274.2	53.7	31.4						
Other non-operating assets – net	10.5	12.6	12.6	14.3	9.9	7.6	(5.0)	(2.3)	1.5	(11.1)	(8.4)						
Net non-operating assets	215.4	224.1	233.1	222.4	252.7	273.9	49.8	21.2	275.7	42.6	23.0						
Total net assets	646.5	647.8	668.2	674.6	692.9	711.3	63.5	18.4	731.7	63.5	38.8						
Total net assets																	
Total assets	806.3	798.2	821.7	817.9	852.5	852.9	54.7	0.4	873.3	51.6	20.8						
Total liabilities	(159.8)	(150.4)	(153.5)	(143.4)	(159.6)	(141.5)	8.9	18.1	(141.7)	11.8	17.9						
Attributable to																	
Chugai shareholders	645.5	647.0	667.6	673.8	691.9	710.1	63.1	18.2	731.2	63.6	39.3						
Non-controlling interests	1.0	0.8	0.5	0.8	1.0	1.2	0.4	0.2	0.5	0.0	(0.5)						

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.

Movements of assets and liabilities:

The consolidated balance sheet has been prepared in accordance with International Accounting Standards (IAS) No. 1, "Presentation of Financial Statements." On the other hand, "Movements of assets and liabilities" including net operating assets (NOA) are a reconfiguration of the consolidated balance sheet as internal indicators and are identical to the indicators disclosed by Roche. Furthermore, no items from the assets and liabilities 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, intangible assets etc. minus provisions.

IFRS 15 'Revenues from Contracts with Customers'

With the application of IFRS 15 'Revenue from Contracts with Customers,' deferred income of ¥10.6 billion after tax effect, which was included in net working capital and long-term net operating assets at the beginning of the year, has been presented as retained earnings.

Movements of free cash flows

(Billions of yen)

	Actual	Actual					Actual			
	FY2016	FY2017					FY2018			
	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	76.9	26.3	47.1	76.2	98.9		38.4	66.6		
Depreciation and impairment of property, plant and equipment	14.8	3.6	7.2	10.8	14.6		3.7	7.4		
Amortization and impairment of intangible assets	4.0	0.4	3.3	3.8	5.8		4.6	5.5		
Other cash adjustment on operating profit	2.8	0.4	(0.7)	(0.4)	1.7		0.4	1.0		
Operating profit, net of operating cash adjustments	98.5	30.8	56.9	90.5	121.0		47.1	80.4		
(Increase) decrease in trade accounts receivable	(6.4)	15.5	11.9	(5.4)	(7.6)		11.4	7.8		
(Increase) decrease in inventories	(26.3)	(4.3)	(0.4)	11.8	21.1		0.5	(1.9)		
Increase (decrease) in trade accounts payable	1.5	2.5	8.1	(4.5)	(4.2)		10.3	7.8		
Change in other net working capital etc.	(5.0)	(1.6)	(7.9)	2.5	5.2		(1.7)	(10.8)		
Total (increase) decrease in net working capital etc.	(36.2)	12.2	11.6	4.4	14.5		20.5	2.9		
Investment in property, plant and equipment	(30.1)	(5.3)	(17.3)	(29.8)	(32.9)		(9.9)	(15.1)		
Investment in intangible assets	(6.2)	(4.0)	(7.4)	(8.9)	(11.6)		(1.4)	(2.4)		
Operating free cash flow	26.0	33.6	43.8	56.2	91.0		56.3	65.9		
as % of revenues	5.3%	26.8%	17.3%	14.5%	17.0%		38.2%	23.1%		
Treasury activities (interest income/expenses, foreign exchange gains/losses etc.)	3.7	(1.3)	(0.6)	1.3	1.6		3.4	3.7		
Settlement for transfer pricing taxation	–	–	(3.9)	(4.6)	(5.2)		(0.6)	(1.5)		
Tax paid	(25.3)	(10.9)	(11.0)	(21.9)	(22.7)		(16.8)	(17.1)		
Free cash flow	4.3	21.4	28.3	31.1	64.7		42.3	50.9		
Dividends paid	(32.8)	(14.4)	(14.6)	(30.9)	(31.0)		(17.9)	(18.0)		
Transaction in own equity instruments	0.5	0.3	0.5	0.6	0.9		0.2	0.5		
Net effect of currency translation on net cash	(2.6)	(0.7)	1.4	2.5	3.2		(1.0)	(2.0)		
Net change in net cash	(30.5)	6.5	15.6	3.2	37.9		23.5	31.4		

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: increases and decreases in marketable securities and interest-bearing debt are included.

The concepts of operating profit, operating FCF and movements of assets and liabilities including NOA presented in the previous page are mutually consistent.

Movements of free cash flows:

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.

Performance indicators

	Units	Actual	Actual					Actual				Forecast (Feb 1st announced)
		FY2016	FY2017					FY2018				FY2018
		1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12	1-12
		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	As of Dec. 31
Ratio of net income to equity attributable to Chugai shareholders (ROE)	%	8.4	2.9	5.5	8.7	10.9	4.0	6.8				
Ratio of profit before taxes to total assets (ROA)	%	9.3	3.1	5.7	9.2	11.7	4.4	7.5				
Ratio of equity attributable to Chugai shareholders	%	80.1	81.1	81.3	82.4	81.2	83.3	83.7				
Equity per share attributable to Chugai shareholders (BPS)	Yen	1,181.67	1,184.11	1,221.41	1,232.55	1,265.46	1,298.53	1,336.49				
Ratio of dividends to equity attributable to Chugai shareholders (DOE)	%	4.5	5.1									
Core return on net operating assets (Core RONO)	%	13.2	4.5	8.9	13.2	17.4	7.1	11.5				
Cash conversion cycle (CCC)	Months	10.5	10.3	10.1	10.3	9.7	8.9	9.1				
Net cash turnover period	Months	5.0	5.1	5.2	4.8	5.5	5.4	5.8				
Number of employees		7,245	7,224	7,384	7,375	7,372	7,331	7,490				
Investment on property, plant and equipment	Billions of yen	19.4	10.0	22.9	27.4	34.3	7.0	14.5				79.0
Depreciation	Billions of yen	14.8	3.6	7.2	10.8	14.5	3.7	7.4				14.5
Investment on intangible assets	Billions of yen	9.9				8.0						
Amortization	Billions of yen	1.6				1.8						

Core RONO: Core operating profit / Net operating assets

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

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

Ratio of net income to equity attributable to Chugai shareholders (ROE), Ratio of profit before taxes to total assets (ROA), and Core return on net operating assets (Core RONO) are not annualized.

Major capital investments plan

(The Company)

(Billions of yen)

Facilities (Location)	Description	Planned investment		Fund raising method	Start of construction	Slated completion date
		Total amount	Investment to-date			
—	Purchase of land for business in Totsuka-ku, Yokohama	43.4	4.8	Self-financing	March 2016	December 2018
Ukima research laboratories (Kita-district, Tokyo)	Construction of a new synthetic research building for strengthening the process development for small and middle molecule active pharmaceutical ingredients	4.5	1.3	Self-financing	May 2018	January 2020

(Domestic subsidiary : Chugai Pharma Manufacturing Co., Ltd.)

(Billions of yen)

Facilities (Location)	Description	Planned investment		Fund raising method	Start of construction	Slated completion date
		Total amount	Investment to-date			
Utsunomiya plant (Utsunomiya-city, Tochigi)	Enhancement of high-mix low-volume production capability for pre-filled syringe form products (Installment of tray filler)	6.0	5.9	Self-financing	September 2013	October 2018
Ukima plant (Kita-district, Tokyo)	Enhancement of high-mix low-volume production of antibody API for initial commercial products (Expansion of production capability by construction of UK3)	37.2	30.3	Self-financing	November 2015	December 2018

Plan concerning enhancement of high-mix low-volume production capability for pre-filled syringe form products (Installment of tray filler) has been entirely transferred to Chugai Pharma Manufacturing Co., Ltd. in 2015

Development pipeline (as of July 26, 2018)

Development code (Compound number)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
<u>Oncology</u>					
RG7446 (MPDL3280A)	Non-small cell lung cancer (NSCLC) [2nd line]	Launched (18/04)	atezolizumab Tecentriq Injection	Roche Tecentriq	Engineered anti-PDL1 monoclonal antibody
	NSCLC [1st line] #	Filed (18/03)			
	NSCLC (adjuvant) #	Phase III Multinational study			
	Small cell lung cancer #	Phase III Multinational study			
	Urothelial carcinoma #	Phase III Multinational study			
	Muscle invasive urothelial carcinoma (adjuvant) #	Phase III Multinational study			
	Renal cell carcinoma #	Phase III Multinational study			
	Renal cell carcinoma (adjuvant) #	Phase III Multinational study			
	Breast cancer #	Phase III Multinational study			
	Ovarian cancer #	Phase III Multinational study			
	Prostate cancer #	Phase III Multinational study			
	Hepatocellular carcinoma #	Phase III Multinational study			
	Head and neck carcinoma (adjuvant) #	Phase III Multinational study			
GA101 / RG7159 (RO5072759)	Follicular lymphoma	Approved (18/07)	obinutuzumab Gazyva Injection	Roche Gazyva/Gazyvaro (EU) (Nippon Shinyaku)	Glycoengineered type II anti-CD20 monoclonal antibody
RG1273 (RO4368451)	Breast cancer (adjuvant) #	Filed (17/10)	pertuzumab Perjeta Injection	Roche Perjeta	HER2 dimerization inhibitory humanized monoclonal antibody

Development code (Compound number)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
RG435 (RO4876646)	Renal cell carcinoma #	Phase III Multinational study	bevacizumab Avastin Injection	Roche Avastin	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody
	Hepatocellular carcinoma #	Phase III Multinational study			
RG3502 (RO5304020)	Breast cancer (adjuvant) #	Phase III Multinational study	trastuzumab emtansine Kadcyla Injection	Roche Kadcyla	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate
RG7440 (GDC-0068)	Prostate cancer	Phase III Multinational study	ipatasertib Oral	Roche/Array BioPharma	AKT inhibitor
	Breast cancer	Phase III Multinational study			
RG7596 (RO5541077)	Diffuse large B-cell lymphoma (DLBCL)	Phase III Multinational study	polatuzumab vedotin Injection	Roche	Anti-CD79b antibody-drug conjugate
RG6264 (RO7198574)	Breast cancer (Fixed-dose combination, subcutaneous injection)	Phase III Multinational study	trastuzumab/pertuzumab Herceptin/ Perjeta Injection	Roche Herceptin/Perjeta	Anti-HER2 humanized monoclonal antibody/ HER2 dimerization inhibitory humanized monoclonal antibody
RG6268 (RXDX-101)	NSCLC	Phase III Multinational study	entrectinib Oral	Roche/ Nerviano Medical Sciences	ROS1/TRK inhibitor
	Solid tumors				
GC33 / RG7686 (GC33/RO5137382)	Hepatocellular carcinoma	Phase I Multinational study*	codrituzumab Injection	In-house (Roche)	Anti-Glypican-3 humanized monoclonal antibody
CKI27 (CKI27)	Solid tumors	Phase I	Oral	In-house	Raf and MEK dual inhibitor
		Phase I Overseas			
ERY974 (ERY974)	Solid tumors	Phase I Overseas	Injection	In-house	Anti-Glypican-3/CD3 bispecific antibody
RG7421 (GDC-0973)	Solid tumors	Phase I	cobimetinib Oral	Roche/Exelixis Cotellic	MEK inhibitor
RG7802 (RO6958688)	Solid tumors	Phase I	Injection	Roche	Anti-CEA/CD3 bispecific antibody

Development code (Compound number)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
RG7828 (RO7030816)	Hematologic tumors	Phase I	Injection	Roche	Anti-CD20/CD3 bispecific antibody
RG7604 (GDC-0032)	Solid tumors	Development discontinued	taselisib Oral	Roche	PI3K inhibitor
Bone and Joint Diseases					
ED-71 (ED-71)	Osteoporosis	Filed (18/02) China	eldecalcitol Edirol Oral	In-house	Activated vitamin D ₃ agent
NRD101 (NRD101)	Knee osteoarthritis /Shoulder periarthritis	Phase III China	purified sodium hyaluronate Suvenyl Injection	In-house	Sodium hyaluronate
Renal Diseases					
EOS789 (EOS789)	Hyperphosphatemia	Phase I	Oral	In-house	–
		Phase I Overseas			
Autoimmune Diseases					
MRA / RG1569 (RO4877533)	Systemic sclerosis #	Phase III Multinational study	tocilizumab Actemra Injection	In-house Actemra/RoActemra (EU) (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
SA237 / RG6168 (SA237)	Neuromyelitis optica (NMO)	Phase III Multinational study*	satralizumab Injection	In-house (Roche)	Anti-IL-6 receptor recycling antibody
RG7845 (GDC-0853)	Rheumatoid arthritis	Phase I	fenebrutinib Oral	Roche	BTK inhibitor
Neurology					
RG1450 (RO4909832)	Alzheimer's disease	Phase III Multinational study	gantenerumab Injection	Roche/MorphoSys	Anti-amyloid-beta human monoclonal antibody
RG7412 (RO5490245)	Alzheimer's disease	Phase III Multinational study	crenezumab Injection	Roche/AC Immune	Anti-amyloid-beta humanized monoclonal antibody

Development code (Compound number)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
RG6206 (BMS-986089)	Duchenne muscular dystrophy (DMD)	Phase II/III Multinational study	Injection	Roche/Bristol-Myers Squibb	Anti-myostatin adnectin
RG7916 (RO7034067)	Spinal muscular atrophy (SMA)	Phase II Multinational study	risdiplam Oral	Roche/PTC Therapeutics	SMN2 splicing modifier
RG7935 (RO7046015)	Parkinson's disease	Phase I	prasinezumab Injection	Roche/Prothena	Anti- α -synuclein monoclonal antibody
Others					
ACE910 / RG6013 (RO5534262)	Hemophilia A (Inhibitor)	Launched (18/05) Japan	emicizumab Hemlibra Injection	In-house Hemlibra (Roche)	Anti-FIXa/FX bispecific antibody
		Approved (18/02) Europe			
	Hemophilia A (Non-inhibitor)	Filed (18/04) Japan			
		Filed (18/04) US/Europe			
CIM331** (CIM331)	Pruritus in dialysis patients	Phase II	nemolizumab Injection	In-house	Anti-IL-31 receptor A humanized monoclonal antibody
SKY59 / RG6107 (RO7112689)	Paroxysmal nocturnal hemoglobinuria (PNH)	Phase I/II Multinational study	Injection	In-house (Roche)	Anti-C5 recycling antibody
PCO371 (PCO371)	Hypoparathyroidism	Phase I Overseas	Oral	In-house	PTH1 receptor agonist
RG7716 (RO6867461)	Wet age-related macular degeneration / Diabetic macular edema	Phase I	Injection	Roche	Anti-VEFG/Ang2 bispecific antibody

Development code (Compound number)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
AMY109	Endometriosis	Phase I	Injection	In-house	—
URC102 (URC102)	Gout	Development discontinued	Oral	In-house/JW Pharmaceutical (JW Pharmaceutical)	URAT1 inhibitor

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

* Multinational studies managed by Chugai

** Development for atopic dermatitis: Out-licensed to Galderma (Overseas) and Maruho (Japan)

Changes from the last announcement on April 24, 2018Oncology

- RG7159 Filed → Approved (Follicular lymphoma)
- RG7446 Phase III multinational study (Head and neck carcinoma (adjuvant): development started)
- RG435 Phase III multinational study (Hepatocellular carcinoma: development started)
- RG6264 Phase III multinational study (Breast cancer: development started)
- RG6268 Phase II multinational study (NSCLC: development started)
Phase II multinational study (Solid tumors: development started)
- RG7604 Phase I → Development discontinued (Solid tumors)

Others

- ACE910/RG6013 Approved → Launched (Hemophilia A (inhibitor)) [Japan]
Phase III multinational study → Filed (Hemophilia A (Non-inhibitor)) [Japan]
→ Filed (Hemophilia A (Non-inhibitor)) [US/Europe]
- URC102 Phase II study (Overseas) → Development discontinued (Gout)

R&D Activities (Jan. 1, 2018- Jul. 26, 2018)

Oncology

- We obtained approval for the indication of unresectable advanced or recurrent non-small cell lung cancer (NSCLC), for the engineered anti-PDL1 monoclonal antibody RG7446 in January, 2018 and launched in April. We filed an application for the expected indication of NSCLC (1st line) in March, 2018. We started Phase III multinational study for the expected indications of hepatocellular carcinoma in April, 2018 and head and neck carcinoma (adjuvant) in June, 2018.
- We obtained approval for the indication of CD20-positive follicular lymphoma for glycoengineered type II anti-CD20 monoclonal antibody in July 2018.
- We started Phase III multinational study for the AKT inhibitor RG7440 for the expected indication of breast cancer in January, 2018.
- We started Phase III multinational study for the anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody (product name: Avastin) for the expected indication of hepatocellular carcinoma in April, 2018.
- We started Phase III multinational study for RG6264, fixed-dose combination of anti-HER2 humanized monoclonal antibody and HER2 dimerization inhibitory humanized monoclonal antibody (subcutaneous injection) for the expected indication of breast cancer in July, 2018.
- We in-licensed ROS1/TRK inhibitor RG6268, and started domestic development for the expected indications of NSCLC and solid tumors.
- We started Phase I study for the anti-CEA/CD3 bispecific antibody RG7802 for the expected indication of solid tumors in January, 2018.
- We started Phase I study for the anti-CD20/CD3 bispecific antibody RG7828 for the expected indication of hematologic tumors in March, 2018.
- We decided to discontinue the development of PI3K inhibitor RG7604 for solid tumors, considering the results of global studies conducted by Roche, an originator of the drug.

Bone and Joint Diseases

- We filed an application for activated vitamin D₃ agent ED-71 for the expected indication of osteoporosis in China in February, 2018.

Neurology

- We started Phase I study for the anti- α -synuclein monoclonal antibody for the expected indication of Parkinson's disease in February, 2018.

Others

- We obtained approval for once-weekly subcutaneous injection of ACE910/RG6013 for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors in Europe and Japan in February and March, 2018, respectively. Then we launched the drug in Japan in May, 2018. In addition, we filed applications for prophylactic treatment for people with hemophilia A without inhibitors to factor VIII in Japan, US and Europe in April, 2018.
- We started Phase I study for AMY109 for the expected indication of endometriosis in February, 2018.
- We decided to discontinue the development of the anti-IL-13 humanized monoclonal antibody RG3637 for Idiopathic pulmonary fibrosis considering the results of Phase II multinational study (RIFF study).
- We decided to discontinue the development of URAT1 inhibitor URC102 for gout, due to consideration of priorities in our R&D portfolio.

Major clinical trials in oncology field

Treatment	Expected Indication	Study design	Study name	Stage	Planned filing year
RG1273 Perjeta	Breast cancer (adjuvant)	Herceptin + chemotherapy (chemo) ± Perjeta	APHINITY	Phase III	Filed
RG3502 Kadcyla	Breast cancer (adjuvant)	Kadcyla + Perjeta vs. Herceptin + Perjeta + chemo	KAITLIN	Phase III	2020
RG7446 (Tecentriq)	Non-small cell lung cancer (NSCLC) [1st line]	PD-L1 positive: Tecentriq vs. chemo	IMpower110	Phase III	Filed
		TMB* positive: Tecentriq vs. chemo	B-FAST	Phase II/III	
		Non-squamous: Tecentriq + chemo ± Avastin vs. Chemo + Avastin	IMpower150	Phase III	
		Non-Squamous: Chemo ± Tecentriq	IMpower132	Phase III	
		Squamous: Chemo ± Tecentriq	IMpower131	Phase III	
	NSCLC (adjuvant)	Tecentriq vs. best supportive care	IMpower010	Phase III	2020
	Small cell lung cancer	carboplatin + etoposide ± Tecentriq	IMpower133	Phase III	2019
	Urothelial carcinoma (UC)	Tecentriq ± chemo vs. chemo	IMvigor130	Phase III	2021 and beyond
	Muscle invasive UC (adjuvant)	Tecentriq vs. observation	IMvigor010	Phase III	2020
	Renal cell carcinoma	Tecentriq + Avastin vs. sunitinib	IMmotion151	Phase III	2018
	Renal cell carcinoma (adjuvant)	Tecentriq	IMmotion010	Phase III	2021 and beyond
	Breast cancer	Triple negative breast cancer: nab-paclitaxel ± Tecentriq	IMpassion130	Phase III	2018
		Triple negative breast cancer: paclitaxel ± Tecentriq	IMpassion131	Phase III	
	Ovarian cancer	carboplatin + paclitaxel + Avastin ± Tecentriq	IMaGYN050	Phase III	2020
	Prostate cancer	Castration-resistant prostate cancer: enzalutamide ± Tecentriq	IMbassador250	Phase III	2021 and beyond
	Hepatocellular carcinoma	Tecentriq + Avastin vs. sorafenib	IMbrave150	Phase III	2021 and beyond
	Head and neck carcinoma (adjuvant)	Tecentriq	IMvoke010	Phase III	2021 and beyond
RG7440 (ipatasertib)	Prostate cancer	abiraterone ± RG7440	IPATential150	Phase III	2021 and beyond
	Breast cancer	Triple negative breast cancer: paclitaxel ± RG7440 HR+ breast cancer: paclitaxel ± RG7440	IPATunity130	Phase III	2020
RG7596 (polatuzumab vedotin)	DLBCL	Chemo ± RG7596	POLARIX	Phase III	2021 and beyond
RG6264**	Breast cancer	RG6264 (SC) + chemo vs. Herceptin (IV) + Perjeta (IV) + chemo	FeDeriCa	Phase III	2021 and beyond
RG6268 (entrectinib)	NSCLC	ROS1 fusion-positive NSCLC : RG6268	STARTRK2	Phase II	2019
	Solid tumors	NTRK fusion-positive solid tumors : RG6268			2019

* TMB: tumor mutational burden

** Fixed-dose combination, subcutaneous injection

Clinical trials for cancer immunotherapy

Cancer type	Target	Treatment	Study name	Stage
Non-small cell lung cancer	PD-L1 positive, 1st line	Tecentriq	IMpower110	Phase III
	TMB positive, 1st line	Tecentriq	B-FAST	Phase II/III
	Non-Squamous, 1st line	Tecentriq + chemotherapy (chemo) + Avastin	IMpower150	Phase III
	Non-Squamous, 1st line	Tecentriq + chemo	IMpower132	Phase III
	Squamous, 1st line	Tecentriq + chemo	IMpower131	Phase III
	Adjuvant	Tecentriq	IMpower010	Phase III
Small cell lung cancer	1st line	Tecentriq + chemo	IMpower133	Phase III
Urothelial carcinoma	1st line	Tecentriq ± chemo	IMvigor130	Phase III
	Muscle invasive carcinoma, adjuvant	Tecentriq	IMvigor010	Phase III
Renal cell carcinoma	1st line	Tecentriq + Avastin	IMmotion151	Phase III
	Adjuvant	Tecentriq	IMmotion010	Phase III
Breast cancer	Triple negative, 1st line	Tecentriq + chemo	IMpassion130	Phase III
			IMpassion131	Phase III
Ovarian cancer	1st line	Tecentriq + chemo + Avastin	IMaGYN050	Phase III
Prostate cancer	Castration-resistant, 2nd line	Tecentriq + chemo	IMbassador250	Phase III
Head and neck carcinoma	Adjuvant	Tecentriq	IMvoke010	Phase III
Hepatocellular carcinoma	—	Tecentriq + Avastin	IMbrave150	Phase III
	Glypican-3 positive	GC33 (codrituzumab) + Tecentriq	—	Phase I
Solid tumors	Glypican-3 positive	ERY974	—	Phase I
	—	RG7421 (cobimetinib) + Tecentriq	—	Phase I
	CEA positive	RG7802	—	Phase I
Hematologic tumors	CD20 positive	RG7828	—	Phase I