

August 3, 2023

Kyowa Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2023 Interim

(January 1, 2023 - June 30, 2023)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock
- This document is an English translation of the Japanese-language original.
- The statements, including earnings forecasts, contained in these materials are based on the information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons.
- Figures presented in these materials have been rounded to the nearest tenth
- Figures inside parenthesis presented in these materials indicate negative values.
- Change amount in these materials presents change amount compared to the same period of the previous fiscal year.

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The average exchange rates for each period were as follows:

Unit: Yen

	FY 2022 results				FY 2023 results		FY 2023 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
USD	114	120	126	130	132	134	130
GBP	154	158	160	161	161	164	160
EUR	129	133	135	137	141	144	135

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I . Consolidated Financial Results

1. Trends in consolidated profit

<Accumulative>

The "★" symbol indicates financial KPIs (numerical guidance) that were set as targets in the FY2021-2025 Medium Term Business Plan.

Unit: Billions of yen

	FY 2022 results				FY 2023 results				FY 2023 forecasts		FY2021-2025 Medium Term Business Plan Financial KPIs
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Rate of change	Jan - Dec	Progress	
Revenue	87.8	185.3	283.8	398.4	93.5	199.2	13.9	8%	426.0	47%	10% or higher
★ CAGR (compared to FY 2020)	-	-	-	11.9%	-	-	-	-	10.2%	-	
Cost of sales	(22.2)	(43.4)	(64.1)	(86.9)	(18.9)	(47.0)	(3.7)	8%	(100.0)	47%	Target of 18-20%
Gross profit	65.6	141.9	219.6	311.5	74.6	152.2	10.3	7%	326.0	47%	
Gross profit to revenue ratio	74.7%	76.6%	77.4%	78.2%	79.7%	76.4%	-	-	76.5%	-	
Selling, general and administrative expenses	(36.1)	(76.4)	(117.3)	(166.2)	(41.8)	(82.4)	(6.0)	8%	(162.0)	51%	Target of 18-20%
Research and development expenses	(13.6)	(27.9)	(44.1)	(62.9)	(16.6)	(33.7)	(5.7)	21%	(79.0)	43%	
★ R&D expense ratio	15.5%	15.1%	15.6%	15.8%	17.8%	16.9%	-	-	18.5%	-	
Share of profit (loss) of investments accounted for using equity method	1.4	2.4	2.6	4.3	0.8	1.4	(1.0)	(41)%	3.0	46%	25% or higher
Core operating profit	17.3	39.9	60.9	86.7	17.0	37.5	(2.4)	(6)%	88.0	43%	
★ Core operating profit ratio	19.8%	21.5%	21.4%	21.8%	18.2%	18.8%	-	-	20.7%	-	
Other income	0.4	0.6	1.0	1.7	0.2	0.5	(0.0)	(11)%			25% or higher
Other expenses	(0.2)	(1.2)	(5.1)	(23.1)	(2.6)	(14.2)	(13.0)	-			
Finance income (costs)	1.2	4.2	3.6	2.2	1.0	2.2	(2.0)	(47)%			
Profit before tax	18.7	43.5	60.4	67.6	15.6	26.0	(17.4)	(40)%	86.0	30%	
Income tax expense	(2.7)	(8.5)	(11.2)	(14.0)	(2.8)	(4.4)	4.1	(48)%	(16.0)	28%	
Ratio of income tax burden	14.3%	19.5%	18.5%	20.7%	18.1%	16.9%	-	-	18.6%	-	
Profit	16.0	35.0	49.2	53.6	12.8	21.6	(13.4)	(38)%	70.0	31%	
Profit to revenue ratio	18.3%	18.9%	17.3%	13.4%	13.6%	10.9%	-	-	16.4%	-	

EPS (¥/share)	29.85	65.16	91.57	99.68	23.74	40.27	(24.89)	-	130.23	-
Core EPS (¥/share) ¹	29.52	66.14	97.70	131.19	27.33	61.40	(4.74)	-	136.37	-
Annual dividend (¥/share)				51.00					54.00	-
★ Dividend payout ratio (%) ²				38.9					39.6	- Target of 40%
★ ROE (%)				7.1					8.9	- 10% or higher

¹ Core EPS is calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting "other income," "other expenses" and the related "income tax expense" from "profit") by the average number of shares during the period.

² Dividend payout ratio is shown based on core EPS.

<Quarterly>

Unit: Billions of yen

	FY 2022 results				FY 2023 results			
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount	Rate of change
Revenue	87.8	97.5	98.5	114.6	93.5	105.7	8.2	8%
Cost of sales	(22.2)	(21.2)	(20.8)	(22.8)	(18.9)	(28.1)	(6.9)	32%
Gross profit	65.6	76.3	77.7	91.8	74.6	77.6	1.3	2%
Gross profit to revenue ratio	74.7%	78.2%	78.9%	80.1%	79.7%	73.4%	-	-
Selling, general and administrative expenses	(36.1)	(40.4)	(40.8)	(48.9)	(41.8)	(40.6)	(0.3)	1%
Research and development expenses	(13.6)	(14.3)	(16.2)	(18.8)	(16.6)	(17.0)	(2.7)	19%
★ R&D expense ratio	15.5%	14.7%	16.5%	16.4%	17.8%	16.1%	-	-
Share of profit (loss) of investments accounted for using equity method	1.4	0.9	0.3	1.7	0.8	0.6	(0.3)	(37)%
Core operating profit	17.3	22.6	21.0	25.8	17.0	20.5	(2.1)	(9)%
★ Core operating profit ratio	19.8%	23.1%	21.3%	22.5%	18.2%	19.4%	-	-
Other income	0.4	0.2	0.5	0.7	0.2	0.3	0.1	80%
Other expenses	(0.2)	(1.0)	(3.9)	(18.0)	(2.6)	(11.6)	(10.6)	-
Finance income (costs)	1.2	3.1	(0.6)	(1.4)	1.0	1.3	(1.8)	(58)%
Profit before tax	18.7	24.8	16.9	7.2	15.6	10.5	(14.3)	(58)%
Income tax expense	(2.7)	(5.8)	(2.7)	(2.8)	(2.8)	(1.6)	4.2	(73)%
Profit	16.0	19.0	14.2	4.4	12.8	8.9	(10.1)	(53)%
Profit to revenue ratio	18.3%	19.5%	14.4%	3.8%	13.6%	8.4%	-	-

2. Revenue by regional control function

Unit: Billions of yen

	FY 2022 results				FY 2023 results			FY 2023 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Progress
Japan	35.4	72.8	109.2	148.7	34.0	70.9	(1.9)	145.6	49%
North America	20.7	47.5	75.9	112.6	25.7	60.3	12.8	132.5	46%
EMEA	14.5	30.9	48.0	66.9	15.4	30.8	(0.1)	66.1	47%
APAC	7.2	14.8	22.5	30.1	7.4	16.0	1.2	34.5	46%
Others	9.8	19.3	28.1	40.1	11.0	21.2	1.9	47.4	45%
Total consolidated revenue	87.8	185.3	283.8	398.4	93.5	199.2	13.9	426.0	47%

* Revenue by regional control function is classified based on consolidated revenue from products of regional control functions in the One Kyowa Kirin (OKK) matrix global management structure, which combines a regional organization based on four regions of Japan, North America, EMEA and APAC, a functional organization, and a product organization (product franchises).

* EMEA consists of Europe, the Middle East, Africa, etc.

* Others consists of revenue from technology out-licensing, original equipment manufacturing, etc.

3. Revenue by location of customer

Unit: Billions of yen

	FY 2022 results					FY 2023 results			FY 2023 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Percentage of consolidated revenue	Jan - Mar	Jan - Jun	Percentage of consolidated revenue	Jan - Dec	Percentage of consolidated revenue
Japan	36.9	75.8	111.3	154.6	39%	35.0	73.7	37%	153.3	36%
International	50.9	109.5	172.5	243.7	61%	58.5	125.6	63%	272.7	64%
Americas	28.2	62.2	99.8	143.9	36%	34.2	76.9	39%	169.2	40%
Of which, the U.S.	27.3	60.3	97.1	139.9	35%	32.8	74.4	37%	162.6	38%
Europe	13.5	28.8	44.9	62.3	16%	14.4	28.5	14%	61.9	15%
Asia	9.1	18.4	27.6	37.4	9%	9.7	19.8	10%	40.9	10%
Others	0.0	0.1	0.2	0.2	0%	0.2	0.4	0%	0.7	0%
Total consolidated revenue	87.8	185.3	283.8	398.4	100%	93.5	199.2	100%	426.0	100%

* Revenue by location of customer is classified by region or country based on location of customer.

4. Capital expenditures and intangible assets investment, depreciation and amortization

Unit: Billions of yen

	FY 2022 results				FY 2023 results			FY 2023 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec	
Capital expenditures (property, plant and equipment)	1.8	5.0	10.3	17.7	3.7	7.0	24.0	
Intangible assets investment	1.0	3.1	4.9	13.3	2.3	4.7	15.0	
Total	2.8	8.2	15.2	31.0	6.0	11.7	39.0	
Depreciation (property, plant and equipment)	2.9	6.0	9.0	11.4	3.1	6.3	13.0	
Amortization (intangible assets)	1.7	3.5	5.3	7.0	1.8	3.6	7.0	
Total	4.6	9.5	14.3	18.5	4.8	9.9	20.0	

* Acquisitions of right-of-use assets are not included.

5. Number of employees by regional control function

	FY 2022 results				FY 2023 results		
	As of March 31	As of June 30	As of September 30	As of December 31	As of March 31	As of June 30	Change amount
Japan	4,035	4,114	4,146	4,135	4,154	4,236	142
North America	446	490	532	560	574	608	118
EMEA	781	768	747	729	743	714	(54)
APAC	536	540	555	558	571	578	38
Total	5,798	5,912	5,980	5,982	6,042	6,136	244

II. Consolidated Statement of Cash Flows

Unit: Billions of yen

	FY 2022 results				FY 2023 results		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount
Cash flows from operating activities	8.8	22.5	35.5	48.7	29.4	60.3	37.9
Cash flows from investing activities	(4.6)	(6.8)	(13.4)	(17.2)	(9.1)	(14.0)	(7.1)
Cash flows from financing activities	(13.2)	(14.1)	(27.9)	(29.0)	(15.2)	(16.1)	(2.0)
Effect of exchange rate changes on cash and cash equivalents	0.4	3.3	3.5	1.7	0.5	2.6	(0.6)
Net increase (decrease) in cash and cash equivalents	(8.6)	4.8	(2.3)	4.1	5.7	32.9	28.1
Cash and cash equivalents at beginning of period	335.1	335.1	335.1	335.1	339.2	339.2	4.1
Cash and cash equivalents at end of period	326.5	339.9	332.8	339.2	344.8	372.1	32.2

III. Revenue from Main Products

<Accumulative>

Unit: Billions of yen

Product name		FY 2022 results				FY 2023 results			FY 2023 forecasts	
		Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Progress
Japan	Nesp	0.8	1.6	2.5	3.4	0.8	1.5	(0.1)	2.8	54%
	Darbepoetin Alfa Injection Syringe [KKF]	4.4	8.8	13.2	17.6	3.5	6.9	(2.0)	13.8	50%
	Duvroq	1.1	2.7	4.4	6.6	1.8	4.2	1.5	7.8	54%
	Regpara	0.5	1.1	1.7	2.2	0.4	0.8	(0.3)	2.1	40%
	Orkedia	2.2	4.9	7.5	10.3	2.2	5.0	0.1	11.2	44%
	Rocaltrol	0.7	1.5	2.3	3.1	0.7	1.4	(0.1)	2.4	58%
	Onglyza	1.2	2.6	3.8	5.2	1.1	2.2	(0.4)	4.3	50%
	Coniel	0.6	1.1	1.6	2.0	0.4	0.7	(0.4)	1.4	51%
	G-Lasta	7.1	14.8	22.7	31.1	7.0	15.0	0.2	33.5	45%
	Fentos	0.8	1.8	2.7	3.7	0.7	1.6	(0.2)	3.3	50%
	Poteligeo	0.5	1.0	1.5	2.0	0.4	0.9	(0.0)	2.0	47%
	Rituximab BS [KHK]	2.5	5.0	7.6	10.3	2.2	4.4	(0.6)	8.7	51%
	Romiplate	2.2	4.8	7.5	10.4	2.7	5.7	1.0	11.2	51%
	Allelock	2.4	3.8	4.8	6.0	1.9	3.1	(0.7)	4.7	66%
	Patanol	1.8	2.2	2.4	2.8	1.4	1.5	(0.6)	1.9	80%
	Dovobet	1.7	3.8	5.6	7.8	1.8	3.9	0.1	7.6	51%
	Lumicef	0.7	1.5	2.2	3.0	0.6	1.3	(0.1)	3.5	38%
	Nourias	1.8	3.9	5.9	8.0	1.7	3.7	(0.2)	7.5	49%
	HARUROPI	0.8	1.8	2.8	4.0	0.9	2.1	0.3	4.7	44%
	Depakene	0.8	1.7	2.5	3.3	0.6	1.4	(0.3)	3.0	46%
Crysvita	2.0	4.1	6.4	8.9	2.3	4.8	0.7	11.1	44%	
International	Crysvita	22.2	49.4	78.7	118.2	27.1	61.9	12.5	138.0	45%
	Poteligeo	4.2	10.3	16.1	22.3	5.8	12.5	2.2	27.5	45%
	Nourianz	1.1	2.6	4.5	6.5	1.7	3.5	0.9	7.5	47%
	Abstral	1.4	3.6	5.4	6.9	1.1	2.6	(1.0)	2.0	129%
	Pecfent	1.0	1.7	3.0	3.7	0.9	1.7	0.1	1.2	140%
	Moventig	0.7	1.5	2.2	3.1	0.8	1.6	0.1	1.2	132%
	Adcal-D3	0.7	1.5	2.2	3.0	0.7	1.5	(0.0)	1.2	119%
	Nesp	1.9	3.9	5.9	7.6	2.2	4.4	0.5	8.0	56%
	Regpara	1.0	2.0	2.9	3.9	0.9	1.9	(0.1)	3.9	49%
	Neulasta/Peglata	1.7	3.0	4.4	5.6	1.3	2.8	(0.2)	5.7	49%
Gran	2.1	3.8	6.4	8.2	1.4	3.2	(0.6)	8.2	39%	
Technology out-licensing		7.8	15.7	23.8	33.8	9.2	18.4	2.7	40.2	46%
Of which, Benralizumab royalty		4.7	9.3	15.4	21.6	5.7	11.6	2.3		

* Revenue from products is classified into Japan or overseas (other than Japan) based on consolidated revenue of regional control functions.

* Revenue listed as "Technology out-licensing" represents the upfront income, milestone revenue and running royalty income that are obtained based on licensing agreements recognizing the granting to third parties the rights for development, manufacturing and sales of the Group's pipeline compounds or the use of technology, etc.

* Benralizumab royalty only refers to the royalty on sales of Fasenna by AstraZeneca (including the Company's own estimates).

III. Revenue from Main Products

<Quarterly>

Unit: Billions of yen

Product name		FY 2022 results				FY 2023 results		
		Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount
Japan	Nesp	0.8	0.8	0.9	0.9	0.8	0.8	(0.1)
	Darbepoetin Alfa Injection Syringe [KKF]	4.4	4.4	4.4	4.4	3.5	3.4	(1.0)
	Duvroq	1.1	1.6	1.8	2.1	1.8	2.4	0.8
	Regpara	0.5	0.6	0.5	0.5	0.4	0.5	(0.2)
	Orkedia	2.2	2.7	2.6	2.8	2.2	2.7	0.0
	Rocaltrol	0.7	0.8	0.8	0.8	0.7	0.7	(0.0)
	Onglyza	1.2	1.3	1.3	1.3	1.1	1.1	(0.2)
	Coniel	0.6	0.5	0.4	0.4	0.4	0.4	(0.2)
	G-Lasta	7.1	7.7	7.9	8.4	7.0	7.9	0.2
	Fentos	0.8	1.0	0.9	1.0	0.7	0.9	(0.1)
	Poteligeo	0.5	0.5	0.5	0.5	0.4	0.5	(0.0)
	Rituximab BS [KHK]	2.5	2.5	2.5	2.7	2.2	2.3	(0.3)
	Romiplate	2.2	2.6	2.7	2.9	2.7	3.0	0.4
	Allelock	2.4	1.4	0.9	1.2	1.9	1.2	(0.3)
	Patanol	1.8	0.3	0.3	0.4	1.4	0.2	(0.2)
	Dovobet	1.7	2.1	1.8	2.1	1.8	2.1	0.0
	Lumicef	0.7	0.8	0.7	0.8	0.6	0.7	(0.0)
	Nourias	1.8	2.1	2.0	2.1	1.7	2.0	(0.1)
	HARUROPI	0.8	1.0	1.0	1.2	0.9	1.1	0.1
	Depakene	0.8	0.8	0.8	0.8	0.6	0.7	(0.1)
Crysvita	2.0	2.2	2.3	2.5	2.3	2.5	0.4	
International	Crysvita	22.2	27.2	29.3	39.5	27.1	34.8	7.6
	Poteligeo	4.2	6.1	5.8	6.2	5.8	6.6	0.6
	Nouriaz	1.1	1.4	1.9	2.0	1.7	1.9	0.4
	Abstral	1.4	2.2	1.8	1.5	1.1	1.4	(0.8)
	Pecfent	1.0	0.7	1.3	0.7	0.9	0.9	0.2
	Moventig	0.7	0.8	0.8	0.8	0.8	0.8	0.1
	Adcal-D3	0.7	0.8	0.7	0.8	0.7	0.8	(0.1)
	Nesp	1.9	2.0	2.0	1.7	2.2	2.2	0.2
	Regpara	1.0	1.0	0.9	1.0	0.9	1.0	(0.0)
	Neulasta/Peglata	1.7	1.3	1.4	1.3	1.3	1.5	0.2
	Gran	2.1	1.8	2.5	1.8	1.4	1.8	0.0
	Technology out-licensing	7.8	7.9	8.1	10.0	9.2	9.2	1.3
Of which, Benralizumab royalty	4.7	4.6	6.1	6.2	5.7	5.9	1.3	

* Revenue from products is classified into Japan or overseas (other than Japan) based on consolidated revenue of regional control functions.

* Revenue listed as "Technology out-licensing" represents the upfront income, milestone revenue and running royalty income that are obtained based on licensing agreements recognizing the granting to third parties the rights for development, manufacturing and sales of the Group's pipeline compounds or the use of technology, etc.

* Benralizumab royalty only refers to the royalty on sales of Fasentra by AstraZeneca (including the Company's own estimates).

III. Revenue from Main Products

Revenue of three global strategic products

<Accumulative>

Unit: Billions of yen

Product name	FY 2022 results				FY 2023 results			FY 2023 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Rate of change
Crysvita	24.2	53.5	85.1	127.1	29.4	66.7	13.2	149.1	45%
Japan	2.0	4.1	6.4	8.9	2.3	4.8	0.7	11.1	44%
North America	15.8	35.9	57.4	87.0	18.8	46.0	10.2	138.0	45%
[Millions of USD]	139	298	456	662	143	344	46		
EMEA	6.3	13.5	21.2	31.0	8.0	15.3	1.8	138.0	45%
[Millions of GBP]	41	85	133	192	50	93	8		
APAC	0.0	0.1	0.1	0.3	0.3	0.6	0.5		
Poteligeo	4.7	11.3	17.5	24.2	6.3	13.4	2.1	29.5	45%
Japan	0.5	1.0	1.5	2.0	0.4	0.9	(0.0)	2.0	47%
North America	3.3	8.1	12.6	17.2	4.3	9.4	1.3	19.4	49%
[Millions of USD]	29	67	100	132	33	70	3	149	
EMEA	0.9	2.1	3.5	5.1	1.5	3.1	0.9	8.0	38%
[Millions of GBP]	6	14	22	32	9	19	5	50	
Nourias/Nourianz	2.9	6.5	10.3	14.5	3.3	7.2	0.7	15.1	48%
Japan	1.8	3.9	5.9	8.0	1.7	3.7	(0.2)	7.5	49%
North America	1.1	2.6	4.5	6.5	1.7	3.5	0.9	7.5	47%
Total of three global strategic products	31.8	71.3	113.0	165.8	39.0	87.3	16.1	193.6	45%

<Quarterly>

Unit: Billions of yen

Product name	FY 2022 results				FY 2023 results		
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount
Crysvita	24.2	29.4	31.6	42.0	29.4	37.3	8.0
Japan	2.0	2.2	2.3	2.5	2.3	2.5	0.4
North America	15.8	20.0	21.5	29.6	18.8	27.2	7.2
[Millions of USD]	139	159	158	206	143	202	43
EMEA	6.3	7.1	7.8	9.7	8.0	7.3	0.1
[Millions of GBP]	41	44	47	59	50	43	(1)
APAC	0.0	0.0	0.1	0.2	0.3	0.3	0.3
Poteligeo	4.7	6.6	6.3	6.7	6.3	7.1	0.5
Japan	0.5	0.5	0.5	0.5	0.4	0.5	(0.0)
North America	3.3	4.8	4.4	4.6	4.3	5.1	0.2
[Millions of USD]	29	38	33	32	33	37	(1)
EMEA	0.9	1.2	1.4	1.6	1.5	1.6	0.4
[Millions of GBP]	6	8	8	10	9	9	2
Nourias/Nourianz	2.9	3.6	3.9	4.1	3.3	3.9	0.3
Japan	1.8	2.1	2.0	2.1	1.7	2.0	(0.1)
North America	1.1	1.4	1.9	2.0	1.7	1.9	0.4
Total of three global strategic products	31.8	39.5	41.7	52.8	39.0	48.3	8.8

* Revenue is classified based on consolidated revenue from regional control functions.

* The revenue, generated in various currencies inside each corporate region, is converted and aggregated in USD for North America and in GBP for EMEA.

IV. R&D Pipeline



antibody



protein



small molecule

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Updated since Dec. 31, 2022



Updated since Mar. 31, 2023

Nephrology

As of June 30, 2023

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
KHK7580 Evocalcet Oral	Calcimimetic	Secondary Hyperparathyroidism	CN KR TW						[Mitsubishi Tanabe Pharma] product name in Japan: Orkedia
KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Preeclampsia	JP						[In-House] product name in Japan: Acoalan
KHK7791 Tenapanor Hydrochloride Oral	NHE3 Inhibitor	Hyperphosphatemia in Patients on Dialysis	JP						[Ardelyx]
KRN1493 Cinacalcet Hydrochloride Oral	Calcimimetic	Primary Hyperparathyroidism	HK						[NPS Pharmaceuticals Inc.] product name in Japan: Regpara

Since the development of RTA 402 for Alport Syndrome, Diabetic Kidney Disease, and Autosomal Dominant Polycystic Kidney Disease was discontinued in Japan, the relevant information was deleted from this table.

Oncology

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	IL						[In-House] POTELLIGENT product name in Japan, US and Europe: Poteligeo
			ME						
			RS KW						
KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony- Stimulating Factor	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	JP						[Amgen K-A] product name in Japan: G-Lasta

Since the development of ME-401 for Indolent B-cell Non-Hodgkin's Lymphoma was discontinued in Japan, the relevant information was deleted from this table.

IV. R&D Pipeline



antibody



protein



small molecule

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Updated since Dec. 31, 2022



Updated since Mar. 31, 2023

Immunology/Allergy

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Ankylosing Spondylitis	TH	→					[Amgen K-A] product name in Japan and Asia: Lumicef
		Non-radiographic Axial Spondyloarthritis	TH	→					
		Systemic Sclerosis	JP	→					
		Palmoplantar Pustulosis	JP	→					
©KHK4083/AMG 451 Rocatinlimab Injection	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	JP NA Europe Asia Oceania others	→					[In-House] POTELLIGENT Fully human antibody production technology Collaboration agreement with Amgen for the development of KHK4083/AMG 451 in all the countries except for Japan.
©KK4277 Injection		Autoimmune Disease	JP	→					[SBI Biotech]

Other

Code Name Generic Name Formulation	Mechanism of Action	Indication	Area	Stage					[In-House or Licensed] Remarks
				Ph I	Ph II	Ph III	Filed	Approved	
KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	Tumor Induced Osteomalacia (TIO)	OM QA UAE	→					[In-House] Fully human antibody production technology Jointly Developed with Ultragenyx in US and Europe product name in Japan, US and Europe: Crysvita
			KW BH	→					
		ME RS	→						
		MO RS ME	→						
AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Previously Untreated with Immunosuppressive Therapy	JP	→					[Amgen K-A] product name in Japan: Romiplate
			Asia	→ Ph II / Ph III					
KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Europe	→					[In-House] product name in Japan: Acoalan
KHK4951 Tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Neovascular (wet) Age-Related Macular Degeneration	JP	→					[In-House]

Note: Our main progress from June 30, 2023 is as follow.

In July 2023, we applied for partial change of approved indication of KRN125 (generic name: Pegfilgrastim) in the oncology field for the mobilization of hematopoietic stem cells into peripheral blood for autologous blood stem cell transplantation in Japan.