

Kyowa Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2024 Semi Annual

(January 1, 2024 - June 30, 2024)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock Exchange on August 1, 2024 for the first six months of Fiscal 2024, from January 1, 2024 to June 30, 2024.
- 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.
- "FY 2024 forecasts" in these materials have been revised from the forecasts released on February 7, 2024
- 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 2023 results				FY 2024 results		FY 2024 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
USD	132	134	137	140	147	151	151
GBP	161	164	170	174	187	191	191
EUR	141	144	148	151	160	163	163

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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 2023 results				FY 2024 results				FY 2024 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	93.5	199.2	306.1	442.2	105.6	233.0	33.8	17%	492.0	47%	10% or higher
★ CAGR (compared to FY 2020)	-	-	-	11.6%	-	-	-	-	11.5%	-	
Cost of sales	(18.9)	(47.0)	(77.0)	(111.2)	(25.6)	(59.5)	(12.4)	26%	(128.0)	46%	
Gross profit	74.6	152.2	229.1	331.0	80.0	173.5	21.3	14%	364.0	48%	
Gross profit to revenue ratio	79.7%	76.4%	74.8%	74.9%	75.8%	74.5%	-	-	74.0%	-	
Selling, general and administrative expenses	(41.8)	(82.4)	(119.3)	(163.1)	(40.2)	(83.2)	(0.8)	1%	(168.0)	50%	
Research and development expenses	(16.6)	(33.7)	(51.2)	(72.1)	(23.3)	(49.2)	(15.6)	46%	(105.0)	47%	Target of 18-20%
★ R&D expense ratio	17.8%	16.9%	16.7%	16.3%	22.1%	21.1%	-	-	21.3%	-	
Share of profit (loss) of investments accounted for using equity method	0.8	1.4	2.3	0.9	0.9	3.1	1.7	124%	1.0	311%	
Core operating profit	17.0	37.5	60.9	96.8	17.4	44.1	6.7	18%	92.0	48%	25% or higher
★ Core operating profit ratio	18.2%	18.8%	19.9%	21.9%	16.5%	18.9%	-	-	18.7%	-	
Other income	0.2	0.5	16.6	16.8	2.6	4.4	3.9	779%			
Other expenses	(2.6)	(14.2)	(16.6)	(21.0)	(2.8)	(4.7)	9.5	(67)%			
Finance income (costs)	1.0	2.2	3.5	4.7	0.8	2.6	0.4	18%			
Profit before tax	15.6	26.0	64.3	97.2	18.1	46.5	20.5	79%	92.0	51%	
Income tax expense	(2.8)	(4.4)	(10.8)	(16.1)	(3.5)	(8.7)	(4.3)	99%	(24.0)	36%	
Ratio of income tax burden	18.1%	16.9%	16.8%	16.5%	19.2%	18.8%	-	-	26.1%	-	
Profit	12.8	21.6	53.6	81.2	14.6	37.8	16.1	75%	68.0	56%	
Profit to revenue ratio	13.6%	10.9%	17.5%	18.4%	13.9%	16.2%	-	-	13.8%	-	

EPS (¥/share)	23.74	40.27	99.62	151.03	27.26	70.76	30.49	-	128.42	-	
Core EPS (¥/share) ¹	27.33	61.40	99.69	157.58	27.46	71.16	9.76	-	131.26	-	
Annual dividend (¥/share)				56.00					58.00	-	
★ Dividend payout ratio (%) ²				35.5					44.2	-	Target of 40%
★ ROE (%)				10.2					8.1	-	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 2023 results				FY 2024 results				
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount	Rate of change	
Revenue	93.5	105.7	106.8	136.2	105.6	127.4	21.7	21%	
Cost of sales	(18.9)	(28.1)	(29.9)	(34.2)	(25.6)	(33.9)	(5.8)	21%	
Gross profit	74.6	77.6	76.9	101.9	80.0	93.5	15.9	21%	
Gross profit to revenue ratio	79.7%	73.4%	72.0%	74.9%	75.8%	73.4%	-	-	
Selling, general and administrative expenses	(41.8)	(40.6)	(36.9)	(43.8)	(40.2)	(43.1)	(2.4)	6%	
Research and development expenses	(16.6)	(17.0)	(17.5)	(20.9)	(23.3)	(25.9)	(8.9)	52%	
★ R&D expense ratio	17.8%	16.1%	16.4%	15.4%	22.1%	20.4%	-	-	
Share of profit (loss) of investments accounted for using equity method	0.8	0.6	0.9	(1.3)	0.9	2.2	1.6	275%	
Core operating profit	17.0	20.5	23.4	35.9	17.4	26.7	6.3	31%	
★ Core operating profit ratio	18.2%	19.4%	21.9%	26.4%	16.5%	21.0%	-	-	
Other income	0.2	0.3	16.1	0.2	2.6	1.8	1.5	530%	
Other expenses	(2.6)	(11.6)	(2.5)	(4.4)	(2.8)	(1.9)	9.7	(84)%	
Finance income (costs)	1.0	1.3	1.3	1.2	0.8	1.8	0.5	41%	
Profit before tax	15.6	10.5	38.3	32.9	18.1	28.4	18.0	172%	
Income tax expense	(2.8)	(1.6)	(6.4)	(5.3)	(3.5)	(5.3)	(3.7)	234%	
Profit	12.8	8.9	31.9	27.6	14.6	23.1	14.3	160%	
Profit to revenue ratio	13.6%	8.4%	29.9%	20.3%	13.9%	18.2%	-	-	

2. Revenue by regional control function

Unit: Billions of yen

	FY 2023 results				FY 2024 results			FY 2024 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Progress
Japan	34.0	70.9	107.0	147.0	31.6	65.3	(5.7)	134.1	49%
North America	25.7	60.3	92.9	137.8	32.3	79.9	19.6	177.8	45%
EMEA	15.4	30.8	45.7	73.3	16.7	36.9	6.1	78.5	47%
APAC	7.4	16.0	26.0	35.7	9.4	19.8	3.8	40.5	49%
Others	11.0	21.2	34.5	48.4	15.6	31.1	9.9	61.1	51%
Total consolidated revenue	93.5	199.2	306.1	442.2	105.6	233.0	33.8	492.0	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, hematopoietic stem cell gene therapy (revenue from Orchard Therapeutics plc), original equipment manufacturing, etc.

3. Revenue by location of customer

Unit: Billions of yen

	FY 2023 results					FY 2024 results		FY 2024 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Percentage of consolidated revenue	Jan - Mar	Jan - Jun	Jan - Dec	Percentage of consolidated revenue
Japan	35.0	73.7	111.1	153.5	35%	34.3	68.6	142.2	29%
International	58.5	125.6	194.9	288.8	65%	71.3	164.4	349.8	71%
Americas	34.2	76.9	121.5	177.3	40%	41.9	102.3	223.4	45%
Of which, the U.S.	32.8	74.4	117.7	172.2	39%	40.7	99.6	212.9	43%
Europe	14.4	28.5	40.9	65.7	15%	16.7	35.2	77.2	16%
Asia	9.7	19.8	31.9	44.8	10%	12.3	26.3	48.0	10%
Others	0.2	0.4	0.7	1.0	0%	0.3	0.6	1.2	0%
Total consolidated revenue	93.5	199.2	306.1	442.2	100%	105.6	233.0	492.0	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 2023 results				FY 2024 results		FY 2024 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
Capital expenditures (property, plant and equipment)* ¹	3.7	7.0	10.5	16.5	4.9	12.3	27.0
Intangible assets investment	2.3	4.7	13.6	15.6	17.7	21.9	25.0
Total	6.0	11.7	24.1	32.1	22.5	34.2	52.0
Depreciation (property, plant and equipment)	3.1	6.3	9.7	13.2	<u>3.7</u> ²	7.4	15.0
Amortization (intangible assets)	1.8	3.6	5.8	7.9	2.0	4.7	9.0
Total	4.8	9.9	15.5	21.1	5.6	12.1	24.0

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

*2 The underlined portion indicates that the amount has been changed from the amount [2.6] presented in "Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2024 First Quarter."

5. Number of employees by regional control function

	FY 2023 results				FY 2024 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	4,154	4,236	4,207	4,225	4,225	4,238	2
North America	574	608	630	638	652	661	53
EMEA	743	714	587	553	543	548	(166)
APAC	571	578	568	558	566	561	(17)
Others	-	-	-	-	168	173	173
Total	6,042	6,136	5,991	5,974	6,154	6,181	45

* Others consists of number of employees of Orchard Therapeutics plc.

II. Consolidated Statement of Cash Flows

Unit: Billions of yen

	FY 2023 results				FY 2024 results		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount
Cash flows from operating activities	29.4	60.3	84.3	115.6	19.2	46.9	(13.5)
Cash flows from investing activities	(9.1)	(14.0)	(12.5)	(20.4)	(50.3)	(80.5)	(66.5)
Cash flows from financing activities	(15.2)	(16.1)	(31.4)	(32.5)	(41.3)	(63.2)	(47.2)
Effect of exchange rate changes on cash and cash equivalents	0.5	2.6	2.7	1.3	2.5	4.9	2.3
Net increase (decrease) in cash and cash equivalents	5.7	32.9	43.1	63.9	(70.0)	(91.9)	(124.9)
Cash and cash equivalents at beginning of period	339.2	339.2	339.2	339.2	403.1	403.1	63.9
Cash and cash equivalents at end of period	344.8	372.1	382.3	403.1	333.1	311.1	(61.0)

III. Revenue from Main Products

<Accumulative>

Unit: Billions of yen

Product name		FY 2023 results				FY 2024 results			FY 2024 forecasts	
		Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Progress
Japan	Crysvita	2.3	4.8	7.4	10.5	2.5	5.4	0.5	12.9	42%
	Poteligeo	0.4	0.9	1.4	1.9	0.4	1.0	0.0	1.9	50%
	Nesp	0.8	1.5	2.3	3.2	0.7	1.4	(0.2)	2.8	49%
	Darbepoetin Alfa Injection Syringe [KKF]	3.5	6.9	10.3	14.0	2.8	5.6	(1.3)	11.7	48%
	Duvroq	1.8	4.2	6.9	9.9	2.5	5.7	1.4	12.2	46%
	PHOZEVEL	-	-	-	-	0.6	1.7	1.7	3.3	51%
	Regpara	0.4	0.8	1.2	1.7	0.3	0.5	(0.4)	0.9	54%
	Orkedia	2.2	5.0	7.6	10.6	2.2	4.9	(0.1)	11.7	42%
	Rocaltrol	0.7	1.4	2.1	2.9	0.6	1.2	(0.2)	2.8	44%
	Onglyza	1.1	2.2	3.2	4.3	0.8	1.7	(0.4)	3.0	58%
	Coniel	0.4	0.7	1.1	1.5	0.3	0.6	(0.1)	1.2	52%
	G-Lasta	7.0	15.0	23.2	31.9	5.8	10.5	(4.5)	20.5	51%
	Fentos	0.7	1.6	2.5	3.5	0.7	1.5	(0.1)	3.0	51%
	Rituximab BS [KHK]	2.2	4.4	6.7	9.0	1.9	3.8	(0.6)	7.9	48%
	Romiplate	2.7	5.7	8.7	12.0	3.0	6.5	0.7	13.2	49%
	Allelock	1.9	3.1	4.1	5.5	1.7	2.7	(0.4)	3.6	75%
	Patanol	1.4	1.5	1.7	2.0	0.8	1.0	(0.5)	1.3	76%
	Dovobet	1.8	3.9	5.7	7.9	1.8	3.9	0.0	7.1	55%
	Lumicef	0.6	1.3	2.1	2.8	0.6	1.3	(0.1)	2.6	50%
	Nourias	1.7	3.7	5.5	7.6	1.5	3.4	(0.3)	7.1	47%
HARUROPI	0.9	2.1	3.2	4.5	1.0	2.2	0.1	5.2	42%	
Depakene	0.6	1.4	2.1	2.8	0.6	1.3	(0.1)	2.4	54%	
International	Crysvita	27.1	61.9	95.7	142.0	35.4	85.5	23.6	187.8	46%
	Poteligeo	5.8	12.5	19.9	28.4	8.2	18.1	5.7	34.8	52%
	Libmeldy/Lenmeldy	-	-	-	-	1.1	1.4	1.4	4.9	29%
	Nourianz	1.7	3.5	5.5	8.2	1.6	3.5	0.0	9.1	39%
	Nesp	2.2	4.4	7.0	9.1	2.9	5.7	1.2	10.7	53%
	Regpara	0.9	1.9	3.1	4.0	1.2	2.4	0.5	3.9	61%
	Neulasta/Peglasta	1.3	2.8	4.5	5.7	1.1	2.4	(0.4)	4.8	51%
	Gran	1.4	3.2	5.2	6.9	1.8	3.7	0.5	7.2	51%
Technology out-licensing		9.2	18.4	30.1	41.9	12.1	24.3	5.9	49.0	50%
Of which, Benralizumab royalty		5.7	11.6	19.1	27.4	6.4	14.4	2.8		

* Revenue from products is classified into Japan or international (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 2023 results				FY 2024 results		
		Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount
Japan	Crysvita	2.3	2.5	2.6	3.1	2.5	2.9	0.4
	Poteligeo	0.4	0.5	0.5	0.5	0.4	0.5	0.0
	Nesp	0.8	0.8	0.8	0.8	0.7	0.7	(0.1)
	Darbepoetin Alfa Injection Syringe [KKF]	3.5	3.4	3.5	3.7	2.8	2.8	(0.6)
	Duvroq	1.8	2.4	2.6	3.1	2.5	3.2	0.8
	PHOZEVEL	-	-	-	-	0.6	1.1	1.1
	Regpara	0.4	0.5	0.4	0.4	0.3	0.2	(0.3)
	Orkedia	2.2	2.7	2.6	3.0	2.2	2.7	(0.0)
	Rocaltrol	0.7	0.7	0.7	0.8	0.6	0.6	(0.1)
	Onglyza	1.1	1.1	1.0	1.1	0.8	0.9	(0.2)
	Coniel	0.4	0.4	0.4	0.4	0.3	0.3	(0.1)
	G-Lasta	7.0	7.9	8.2	8.7	5.8	4.7	(3.2)
	Fentos	0.7	0.9	0.9	1.0	0.7	0.8	(0.1)
	Rituximab BS [KHK]	2.2	2.3	2.2	2.4	1.9	1.9	(0.4)
	Romiplate	2.7	3.0	3.0	3.3	3.0	3.4	0.4
	Allelock	1.9	1.2	1.0	1.3	1.7	1.0	(0.2)
	Patanol	1.4	0.2	0.2	0.3	0.8	0.2	0.0
	Dovobet	1.8	2.1	1.8	2.2	1.8	2.1	0.0
	Lumicef	0.6	0.7	0.7	0.7	0.6	0.7	(0.0)
	Nourias	1.7	2.0	1.9	2.0	1.5	1.9	(0.2)
HARUROPI	0.9	1.1	1.1	1.3	1.0	1.2	0.1	
Depakene	0.6	0.7	0.7	0.7	0.6	0.7	(0.0)	
International	Crysvita	27.1	34.8	33.8	46.2	35.4	50.1	15.3
	Poteligeo	5.8	6.6	7.5	8.5	8.2	9.9	3.3
	Libmeldy/Lenmeldy	-	-	-	-	1.1	0.3	0.3
	Nourianz	1.7	1.9	2.0	2.7	1.6	2.0	0.1
	Nesp	2.2	2.2	2.6	2.1	2.9	2.8	0.5
	Regpara	0.9	1.0	1.2	1.0	1.2	1.2	0.2
	Neulasta/Peglata	1.3	1.5	1.7	1.2	1.1	1.3	(0.2)
	Gran	1.4	1.8	2.0	1.8	1.8	1.9	0.1
Technology out-licensing		9.2	9.2	11.8	11.7	12.1	12.2	3.0
Of which, Benralizumab royalty		5.7	5.9	7.5	8.3	6.4	8.0	2.1

* Revenue from products is classified into Japan or international (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 Fasenra by AstraZeneca (including the Company's own estimates).

III. Revenue from Main Products

Revenue of global strategic products

<Accumulative>

Unit: Billions of yen

Product name	FY 2023 results				FY 2024 results			FY 2024 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	Progress
Crysvita	29.4	66.7	103.1	152.4	37.8	90.9	24.1	200.7	45%
Japan	2.3	4.8	7.4	10.5	2.5	5.4	0.5	12.9	42%
North America	18.8	46.0	70.2	105.2	22.8	58.7	12.7	187.8	46%
[Millions of USD]	143	344	512	747	155	388	44		
EMEA	8.0	15.3	24.5	35.1	11.9	25.4	10.1	187.8	46%
[Millions of GBP]	50	93	144	202	64	133	40		
APAC	0.3	0.6	1.1	1.6	0.6	1.3	0.8		
Poteligeo	6.3	13.4	21.3	30.3	8.6	19.0	5.6	36.8	52%
Japan	0.4	0.9	1.4	1.9	0.4	1.0	0.0	1.9	50%
North America	4.3	9.4	15.1	21.5	6.3	14.1	4.7	25.1	56%
[Millions of USD]	33	70	110	153	43	93	23	166	
EMEA	1.5	3.1	4.8	6.9	1.9	3.9	0.9	9.3	42%
[Millions of GBP]	9	19	28	40	10	21	2	49	
APAC	-	-	0.0	0.0	0.0	0.1	0.1	0.5	18%
Total of global strategic products	35.7	80.1	124.5	182.7	46.4	109.9	29.7	237.5	46%

<Quarterly>

Unit: Billions of yen

Product name	FY 2023 results				FY 2024 results		
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount
Crysvita	29.4	37.3	36.4	49.3	37.8	53.0	15.7
Japan	2.3	2.5	2.6	3.1	2.5	2.9	0.4
North America	18.8	27.2	24.1	35.0	22.8	35.9	8.7
[Millions of USD]	143	202	168	235	155	233	32
EMEA	8.0	7.3	9.2	10.7	11.9	13.5	6.2
[Millions of GBP]	50	43	50	58	64	70	26
APAC	0.3	0.3	0.5	0.5	0.6	0.7	0.4
Poteligeo	6.3	7.1	8.0	9.0	8.6	10.4	3.3
Japan	0.4	0.5	0.5	0.5	0.4	0.5	0.0
North America	4.3	5.1	5.7	6.4	6.3	7.8	2.8
[Millions of USD]	33	37	39	43	43	51	13
EMEA	1.5	1.6	1.8	2.1	1.9	2.0	0.5
[Millions of GBP]	9	9	10	11	10	10	1
APAC	-	-	0.0	0.0	0.0	0.1	0.1
Total of global strategic products	35.7	44.4	44.3	58.3	46.4	63.4	19.0

* 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.

R&D pipeline

small molecule
 large molecule
 antibody
 HSC-GT
 Updated since Dec. 31, 2023
 Updated since Mar. 31, 2024

As of Jun. 30, 2024

Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage			[In-House or Licensed] Remarks
			PhI	PhII	PhIII	
KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia				[In-House] Preparation underway for PhI as a global product
KK2845	Anti-TIM-3 ADC	Acute Myelogenous Leukemia				[In-House] Antibody-Drug Conjugate Preparation underway for PhI in Japan as a global product
OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)				[In-House] Rare Pediatric Disease (RPD) and Fast Track designations (FDA) Priority Medicines (PRIME) designation (EMA) Area of clinical study: NA and EU
OTL-201	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IIIA (Sanfilippo Syndrome type A)				[In-House] Rare Pediatric Disease (RPD) designation (FDA) Preparation underway for registrational study (equivalent to Ph III study)
KHK4083/AMG 451 rocatinimab Injection	Anti-OX40 Antibody	Moderate to Severe Atopic Dermatitis				[In-House] POTELLIGENT Human monoclonal antibody production technology Collaboration agreement with Amgen for the development of rocatinimab in all the countries except for Japan. Clinical study is being conducted in JP, NA, EU, UK, Middle East, Asia, Oceania, and other regions as a global product
		Moderate to Severe Asthma				Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
		Prurigo Nodularis				Preparation underway for Ph III as a global product
KHK4951 tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Diabetic Macular Edema				[In-House] Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
		Neovascular Age-Related Macular Degeneration				Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
KK2260 Injection	EGFR-TfR1 Bispecific Antibody	Solid Tumor				[In-House] REGULGENT Fully human antibody production technology A clinical study is being conducted in JP, and a clinical study is prepared under way for PH I in NA as a global product.
KK2269 Injection	EpCAM-CD40 Bispecific Antibody	Solid Tumor				[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP and NA as a global product
AMG531 romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Previously Untreated with Immunosuppressive Therapy				[Amgen K-A] product name in Japan: Romiplate Area of clinical study: Asia
KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus				[SBI Biotech] POTELLIGENT Clinical study is being conducted in JP and Asia

Major Applications and Approvals

Code Name, Generic Name, Product Name	Indication	Application/Under Review	Countries/Regions Received Approval in 2024
KRN125(pegfilgrastim, Product name in Japan:G-LASTA)	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	—	JP
OTL-200(atidarsagene autotemcel, Product name in Europe/US : Libmeldy/Lenmeldy)	Metachromatic Leukodystrophy	—	US
KHK4827(brodalumab, Product name in Japan and Asia: Lumicef)	Systemic Sclerosis	JP	—
	Palmoplantar Pustulosis	TW	—
KHK7580(evocalcet, Product name in Japan: Orkedia)	Secondary Hyperparathyroidism	—	CN, TW
AMG531(romiplostim, Product name in Japan: Romiplate)	Aplastic Anemia	TW	—
	Severe Aplastic Anemia	KR	—