October 30, 2025

Kyowa Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS)
Fiscal 2025 Third Quarter

(January 1, 2025 - September 30, 2025)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock Exchange on October 30, 2025 for the first nine months of Fiscal 2025, from January 1, 2025 to September 30, 2025.
- 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.

Index Page

The average exchange rates for each period were as follows:

Unit: Yen

	FY 2024 results				FY 2025 results			FY2025 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec
USD	147	151	151	151	154	150	149	145
GBP	187	191	193	193	193	193	195	190
EUR	160	163	164	164	161	162	165	160

Contact
Kyowa Kirin Co., Ltd.
Corporate Communications Department
Tel +81 3 5205 7206

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 2024 results				FY 2025 results					FY 2025 forecasts		FY2021-2025 Medium Term Business Plan Financial KPIs
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Change amount	Rate of change	Jan - Dec	Progress	
Revenue	105.6	233.0	362.8	495.6	104.7	230.7	349.5	(13.3)	(4)%	478.0	73%	
★ *CAGR (compared to FY 2020)*	-	-	-	11.7%	-	-	-	-	-	8.5%	-	10% or higher
Cost of sales	(25.6)	(59.5)	(94.0)	(132.6)	(24.6)	(61.9)	(90.1)	3.9	(4)%	(126.0)	71%	
Gross profit	80.0	173.5	268.8	362.9	80.1	168.8	259.4	(9.4)	(3)%	352.0	74%	
Gross profit to revenue ratio	75.8%	74.5%	74.1%	73.2%	76.5%	73.2%	74.2%	-	-	73.6%	-	
Selling, general and administrative expenses	(40.2)	(83.2)	(123.6)	(167.5)	(42.0)	(82.8)	(121.5)	2.1	(2)%	(166.0)	73%	
Research and development expenses	(23.3)	(49.2)	(74.3)	(103.5)	(28.6)	(52.5)	(76.8)	(2.5)	3%	(107.0)	72%	
★ *R&D expense ratio*	22.1%	21.1%	20.5%	20.9%	27.3%	22.8%	22.0%	-	-	22.4%	-	Target of 18-20%
Share of profit (loss) of investments accounted for using equity method	0.9	3.1	3.5	3.5	(0.9)	1.5	1.0	(2.5)	(72)%	1.0	99%	
Core operating profit	17.4	44.1	74.4	95.4	8.6	35.0	62.0	(12.4)	(17)%	80.0	77%	
★ *Core operating profit ratio*	16.5%	18.9%	20.5%	19.3%	8.2%	15.2%	17.7%	-	-	16.7%	-	25% or higher
Other income	2.6	4.4	13.3	13.1	0.4	0.6	0.7	(12.5)	(94)%			
Other expenses	(2.8)	(4.7)	(16.9)	(19.3)	(1.6)	(12.9)	(14.7)	2.1	(13)%			
Finance income (costs)	0.8	2.6	0.8	(5.8)	0.4	(0.7)	(0.1)	(0.8)	(110)%			
Profit before tax	18.1	46.5	71.6	83.5	7.9	22.0	47.9	(23.6)	(33)%	74.0	65%	
Income tax expense	(3.5)	(8.7)	(15.7)	(23.6)	(1.7)	(5.7)	(15.3)	0.3	(2)%	(17.0)	90%	
Ratio of income tax burden	19.2%	18.8%	21.9%	28.3%	21.5%	25.7%	32.0%	-	-	23.0%	-	
Profit	14.6	37.8	55.9	59.9	6.2	16.3	32.6	(23.3)	(42)%	57.0	57%	
Profit to revenue ratio	13.9%	16.2%	15.4%	12.1%	5.9%	7.1%	9.3%	-	-	11.9%	-	
EPS (¥/share)	27.26	70.76	105.20	113.06	11.78	31.18	62.28	(42.92)	-	108.91	-	
Core EPS (¥/share)*1	27.46	71.16	110.52	121.44	13.57	48.63	80.46	(30.06)	-	119.23	-	
Annual dividend (¥/share)				58.00						60.00	-	
★ Dividend payout ratio (%)*2				47.76						50.32	-	Target of 40%
★ ROE (%)				7.10						6.60	-	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 2024 results				FY 2025 results				
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Change amount	Rate of change
Revenue	105.6	127.4	129.8	132.8	104.7	125.9	118.8	(11.0)	(8)%
Cost of sales	(25.6)	(33.9)	(34.5)	(38.6)	(24.6)	(37.3)	(28.2)	6.3	(18)%
Gross profit	80.0	93.5	95.3	94.2	80.1	88.7	90.6	(4.7)	(5)%
Gross profit to revenue ratio	75.8%	73.4%	73.4%	70.9%	76.5%	70.4%	76.3%	-	-
Selling, general and administrative expenses	(40.2)	(43.1)	(40.4)	(43.9)	(42.0)	(40.8)	(38.7)	1.7	(4)%
Research and development expenses	(23.3)	(25.9)	(25.0)	(29.3)	(28.6)	(23.9)	(24.3)	0.7	(3)%
★ *R&D expense ratio*	22.1%	20.4%	19.3%	22.0%	27.3%	19.0%	20.5%	-	-
Share of profit (loss) of investments accounted for using equity method	0.9	2.2	0.4	0.0	(0.9)	2.5	(0.6)	(1.0)	(233)%
Core operating profit	17.4	26.7	30.3	21.0	8.6	26.4	27.0	(3.3)	(11)%
★ *Core operating profit ratio*	16.5%	21.0%	23.3%	15.8%	8.2%	21.0%	22.7%	-	-
Other income	2.6	1.8	8.9	(0.2)	0.4	0.2	0.2	(8.7)	(98)%
Other expenses	(2.8)	(1.9)	(12.2)	(2.4)	(1.6)	(11.3)	(1.9)	10.4	(85)%
Finance income (costs)	0.8	1.8	(1.9)	(6.5)	0.4	(1.2)	0.7	2.5	(135)%
Profit before tax	18.1	28.4	25.1	11.9	7.9	14.1	25.9	0.9	4%
Income tax expense	(3.5)	(5.3)	(6.9)	(7.9)	(1.7)	(4.0)	(9.7)	(2.7)	40%
Profit	14.6	23.1	18.1	4.0	6.2	10.2	16.3	(1.8)	(10)%
Profit to revenue ratio	13.9%	18.2%	14.0%	3.0%	5.9%	8.1%	13.7%	-	-

2. Revenue by regional control function

<Accumulative>

Unit: Billions of yen

	FY 2024 results				FY 2025 results				FY 2025 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Change amount	Jan - Dec	Progress
Japan	31.6	65.3	98.0	134.7	27.2	58.4	89.7	(8.3)	121.8	74%
North America	32.3	79.9	120.1	174.4	35.5	88.4	129.9	9.8	191.0	68%
EMEA	16.7	36.9	65.7	84.9	19.7	37.0	62.4	(3.3)	73.7	85%
Others	25.0	50.9	78.9	101.5	22.3	46.9	67.5	(11.5)	91.5	74%
Total consolidated revenue	105.6	233.0	362.8	495.6	104.7	230.7	349.5	(13.3)	478.0	73%
Japan (location of customer)	34.3	68.6	100.9	141.2	28.3	63.1	96.0	(4.9)	130.0	74%
Overseas (location of customer)	71.3	164.4	261.9	354.4	76.4	167.6	253.4	(8.5)	348.0	73%
Overseas ratio	68%	71%	72%	72%	73%	73%	73%	-	73%	-

* 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, 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, revenue from APAC, hematopoietic stem cell gene therapy (revenue from Orchard Therapeutics), original equipment manufacturing, etc.

* Revenue that was classified under "APAC" in 2024, will be included in "Others" starting from 2025 due to the business reoraganization in the APAC region.

<Quarterly>

Unit: Billions of yen

	FY 2024 results				FY 2025 results			
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr- Jun	Jul- Sep	Change amount
Japan	31.6	33.7	32.8	36.6	27.2	31.2	31.3	(1.4)
North America	32.3	47.6	40.2	54.3	35.5	52.8	41.5	1.3
EMEA	16.7	20.1	28.8	19.2	19.7	17.3	25.3	(3.5)
Others	25.0	26.0	28.0	22.6	22.3	24.5	20.6	(7.4)
Total consolidated revenue	105.6	127.4	129.8	132.8	104.7	125.9	118.8	(11.0)

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

Unit: Billions of yen

	FY 2024 results				FY 2025 results			FY 2025 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec
Capital expenditures (property, plant and equipment)*	4.9	12.3	19.0	29.5	8.2	14.9	22.9	34.5
Intangible assets investment	17.7	21.9	25.5	79.3	1.3	9.9	21.3	48.5
Total	22.5	34.2	44.6	108.7	9.4	24.9	44.2	83.0
Depreciation (property, plant and equipment)	3.7	7.4	11.0	14.8	3.8	7.6	11.7	16.5
Amortization (intangible assets)	2.0	4.7	7.8	10.0	2.3	4.7	7.1	9.0
Total	5.6	12.1	18.8	24.8	6.1	12.3	18.8	25.5

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

4. Number of employees by regional control function

	FY 2024 results				FY 2025 results			
	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	Change amount
Japan	4,090	4,103	4,093	4,020	3,898	3,890	3,882	(211)
North America	648	664	664	668	709	678	699	35
EMEA	543	548	553	547	538	540	544	(9)
Others	873	866	877	434	375	381	387	(490)
Total	6,154	6,181	6,186	5,669	5,520	5,489	5,512	(674)

* Others consists of number of employees of APAC subsidiaries, Orchard Therapeutics, etc.

* Number of employees that were classified under "APAC" in 2024, will be included in "Others" starting from 2025 due to the business reoraganization in the APAC region.

II. Consolidated Statement of Cash Flows

Unit: Billions of yen

	FY 2024 results				FY 2025 results			
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Change amount
Cash flows from operating activities	19.2	46.9	69.6	67.9	7.4	39.8	69.6	0.0
Cash flows from investing activities	(50.3)	(80.5)	(95.8)	(142.4)	(21.5)	(34.7)	(41.6)	54.2
Cash flows from financing activities	(41.3)	(63.2)	(83.7)	(84.7)	(16.5)	(17.2)	(33.6)	50.1
Effect of exchange rate changes on cash and cash equivalents	2.5	4.9	3.1	0.8	0.3	2.0	1.2	(2.0)
Net increase (decrease) in cash and cash equivalents	(70.0)	(91.9)	(106.8)	(158.4)	(30.3)	(10.1)	(4.5)	102.3
Cash and cash equivalents at beginning of period	403.1	403.1	403.1	403.1	244.7	244.7	244.7	(158.4)
Cash and cash equivalents at end of period	333.1	311.1	296.3	244.7	214.4	234.6	240.2	(56.1)

III. Revenue from Main Products

<Accumulative>

Unit: Billions of yen

	FY 2024 results				FY 2025 results				FY 2025 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Change amount	Jan - Dec	Progress
Products[*1]	93.4	208.7	327.9	446.8	91.8	205.2	310.1	(17.8)	425.7	73%
Crysvita	37.8	90.9	134.9	196.6	42.4	99.8	146.7	11.9	210.2	70%
Poteligeo	8.6	19.1	29.1	39.9	9.8	21.6	33.7	4.6	45.4	74%
Libmeldy/Lenmeldy	1.1	1.4	2.2	3.3	2.1	4.4	4.4	2.2	6.9	64%
Nourianz	1.6	3.5	6.2	8.8	2.0	4.6	6.9	0.7	8.2	84%
PHOZEVEL	0.6	1.7	2.9	4.7	1.5	3.7	5.9	3.0	8.9	66%
Duvroq	2.5	5.7	8.9	12.7	3.0	6.9	10.9	2.0	15.5	70%
Nesp	0.7	1.4	2.0	2.6	0.5	0.9	1.1	(0.9)	2.0	57%
Darbepoetin Alfa Injection Syringe [KKF]	2.8	5.6	8.5	11.6	2.3	4.9	7.6	(0.8)	9.6	79%
G-Lasta	5.8	10.5	15.3	20.5	4.3	9.1	13.7	(1.6)	17.0	80%
Romiplate	3.0	6.5	9.9	13.9	3.4	7.3	11.5	1.6	14.6	79%
Orkedia	2.2	4.9	7.5	10.4	2.4	5.4	8.2	0.8	10.7	77%
Rituximab BS [KHK]	1.9	3.8	5.7	7.8	1.5	3.2	5.0	(0.6)	6.0	84%
Nouriast	1.5	3.4	5.1	6.9	1.4	3.1	4.6	(0.4)	6.5	71%
HARUROPI	1.0	2.2	3.3	4.6	1.0	2.1	3.3	0.0	4.8	68%
Dovobet[*2]	1.8	3.9	5.8	7.9	-	-	-	(5.8)	-	-
Technology out-licensing[*3]	12.1	24.3	34.9	48.8	13.0	25.5	39.4	4.4	52.3	75%
Benralizumab royalty[*4]	6.4	14.4	21.6	31.4	7.4	15.7	25.4	3.8		
Total	105.6	233.0	362.8	495.6	104.7	230.7	349.5	13.3	478.0	75%

*1 For revenue for Japan, the figures shown are those before the deduction of discounts and other items, and for revenue for overseas, the figures shown are those after the deduction of discounts and other items and include the impact of exchange rates.

*2 Due to the termination of the distribution and co-promotion agreement with LEO Pharma K.K. for Dovobet, sales by the Company ended on December 31, 2024.

*3 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.

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

III. Revenue from Main Products

<Quarterly>

Unit: Billions of yen

	FY 2024 results				FY 2025 results			
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Change amount
Products[*1]	93.4	115.3	119.2	118.9	91.8	113.4	104.9	(14.2)
Crysvita	37.8	53.0	44.0	61.7	42.4	57.3	46.9	2.9
Poteligeo	8.6	10.4	10.0	10.8	9.8	11.8	12.1	2.0
Libmeldy/Lenmeldy	1.1	0.3	0.7	1.1	2.1	2.3	(0.0)	(0.7)
Nourianz	1.6	2.0	2.6	2.6	2.0	2.6	2.3	(0.3)
PHOZEVEL	0.6	1.1	1.2	1.8	1.5	2.1	2.2	1.0
Duvroq	2.5	3.2	3.3	3.8	3.0	3.8	4.1	0.8
Nesp	0.7	0.7	0.6	0.7	0.5	0.4	0.3	(0.4)
Darbepoetin Alfa Injection Syringe [KKF]	2.8	2.8	2.9	3.1	2.3	2.6	2.7	(0.1)
G-Lasta	5.8	4.7	4.8	5.2	4.3	4.8	4.6	(0.2)
Romiplate	3.0	3.4	3.5	4.0	3.4	3.9	4.2	0.8
Orkedia	2.2	2.7	2.5	3.0	2.4	2.9	2.9	0.3
Rituximab BS [KHK]	1.9	1.9	1.9	2.1	1.5	1.7	1.8	(0.1)
Nouriast	1.5	1.9	1.7	1.9	1.4	1.7	1.6	(0.1)
HARUROPI	1.0	1.2	1.1	1.3	1.0	1.2	1.1	0.0
Dovobet[*2]	1.8	2.1	1.8	2.1	-	-	-	(1.8)
Technology out-licensing[*3]	12.1	12.2	10.7	13.8	13.0	12.5	13.9	3.2
Benralizumab royalty[*4]	6.4	8.0	7.1	9.9	7.4	8.3	9.7	2.5
Total	105.6	127.4	129.8	132.8	104.7	125.9	118.8	(11.0)

*1 For revenue for Japan, the figures shown are those before the deduction of discounts and other items, and for revenue for overseas, the figures shown are those after the deduction of discounts and other items and include the impact of exchange rates.

*2 Due to the termination of the distribution and co-promotion agreement with LEO Pharma K.K. for Dovobet, sales by the Company ended on December 31, 2024.

*3 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.

*4 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 by location

<Accumulative>

Unit: Billions of yen

Product name	FY 2024 results				FY 2025 results				FY 2025 forecasts	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Sep	Change amount	Jan - Dec	Progress
Crysvita	37.8	90.9	134.9	196.6	42.4	99.8	146.7	11.9	210.2	70%
Japan	2.5	5.4	8.2	11.7	2.8	6.1	9.7	1.5	13.1	74%
North America	22.8	58.7	87.2	130.0	24.1	64.0	92.0	4.8		
[Millions of USD]	155	388	575	860	157	430	620	45		
EMEA	11.9	25.4	37.1	51.5	14.8	28.0	42.4	5.3	197.1	70%
[Millions of GBP]	64	133	193	267	77	145	219	26		
Others	0.6	1.3	2.3	3.3	0.8	1.7	2.6	0.3		
Poteligeo	8.6	* 19.1	* 29.1	39.9	9.8	21.6	33.7	4.6	45.4	74%
Japan	0.4	1.0	1.4	1.8	0.3	0.7	1.2	(0.2)	1.9	61%
North America	6.3	14.1	21.6	29.7	6.9	16.0	25.1	3.5	34.1	74%
[Millions of USD]	43	93	143	197	45	107	169	26	235	72%
EMEA	1.9	3.9	6.0	8.2	2.6	4.9	7.3	1.4	9.2	80%
[Millions of GBP]	10	21	31	43	13	25	38	7	48	78%
Others	0.0	0.1	0.1	0.1	0.0	0.1	0.1	(0.0)	0.3	32%
Libmeldy/Lenmeldy	1.1	1.4	2.2	3.3	2.1	4.4	4.4	2.2	6.9	64%
US	-	-	-	-	1.1	1.6	1.6	1.6		
EMEA	1.1	1.4	2.2	3.3	1.0	2.8	2.8	0.7		

* The underlined portion indicates that the amount has been changed from the amount [19.0] and [29.0] presented in"Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2025 Second Quarter".

<Quarterly>

Unit: Billions of yen

Product name	FY 2024 results				FY 2025 results			
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Change amount
Crysvita	37.8	53.0	44.0	61.7	42.4	57.3	46.9	2.9
Japan	2.5	2.9	2.8	3.6	2.8	3.3	3.6	0.8
North America	22.8	35.9	28.6	42.8	24.1	39.9	28.0	(0.5)
[Millions of USD]	155	233	187	285	157	273	191	4
EMEA	11.9	13.5	11.7	14.4	14.8	13.2	14.4	2.7
[Millions of GBP]	64	70	59	74	77	68	74	14
Others	0.6	0.7	0.9	1.0	0.8	1.0	0.9	(0.1)
Poteligeo	8.6	10.4	10.0	*1 10.9	9.8	11.8	12.0	2.0
Japan	0.4	0.5	0.4	0.5	0.3	0.4	0.5	0.0
North America	6.3	7.8	7.5	8.1	6.9	9.1	9.1	1.6
[Millions of USD]	43	51	49	54	45	62	62	13
EMEA	1.9	2.0	2.0	2.3	2.6	2.3	2.5	0.4
[Millions of GBP]	10	10	10	12	13	12	13	2
Others	0.0	0.1	0.0	0.0	0.0	0.0	0.0	(0.0)
Libmeldy/Lenmeldy	1.1	0.3	0.7	1.1	2.1	2.3	(0.0)	(0.8)
US	-	-	-	-	1.1	0.5	(0.0)	(0.0)
EMEA	1.1	0.3	0.7	1.1	1.0	1.8	0.0	(0.7)

*1 The underlined portion indicates that the amount has been changed from the amount [10.8] presented in"Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2025 First Quarter".

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

* Revenue that was classified under "APAC" in 2024, will be included in "Others" starting from 2025 due to the business reoraganization in the APAC region.

R&D pipeline

small molecule　antibody　HSC-GT　Updated since Dec. 31, 2024　✓ Updated since Jun. 30, 2025

As of Sep 30, 2025

Code Name / Generic Name / Formulation	Mechanism of Action	Indication	Stage	[In-House or Licensed] Remarks
KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia	PhI	[In-House] Clinical study is being conducted in NA and EU as a global product
KK8398 infigratinib Oral	FGFR3 Inhibitor	Achondroplasia		[QED Therapeutics] Preparation underway for Ph Ⅲ in JP
ziftomenib ※ Oral	Menin Inhibitor	Acute Myeloid Leukemia (AML) (Monotherapy)	PhI–PhII	[Kura Oncology] The detailed results presented at ASCO in June 2025 and published on JCO in September 2025 Adult Relapsed or Refractory AML with a NPM1 Mutation KOMET-001
		Acute Lymphoblastic Leukemia (ALL) (Monotherapy)	PhI	Clinical study is being conducted in NA and EU as a global product KMT2A-rearranged ALL KOMET-001
		Acute Myeloid Leukemia (AML) (Monotherapy)	PhI	Clinical study is being conducted in NA and EU as a global product Non-NPM1-mutant AML/Non-KMT2A-rearranged AML KOMET-001
		Acute Myeloid Leukemia (AML) (Combination)	PhI	Clinical study is being conducted in NA as a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with venetoclax + azacitidine, and cytarabine + daunorubicin KOMET-007
			PhI	Clinical study is being conducted in NA and EU as a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with gilteritinib, FLAG-IDA, LDAC KOMET-008
			PhI–PhII–PhIII ✓	Clinical study is being conducted as a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with venetoclax + azacitidine, and cytarabine + daunorubicin KOMET-017
KK2845	Anti-TIM-3 ADC	Acute Myeloid Leukemia (AML)	PhI	[In-House] Antibody-Drug Conjugate Clinical study is being conducted in JP as a global product
OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)	PhI–PhII–PhIII	[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)	PhI–PhII Ph Ⅰ/Ⅱ	[In-House] Rare Pediatric Disease (RPD) designation (FDA) Preparation underway for registrational study (equivalent to PhⅢ study)
KHK4083/AMG 451 rocatinlimab Injection	Anti-OX40 Antibody	Moderate to Severe Atopic Dermatitis	PhI–PhII–PhIII	[In-House] POTELLIGENT Human monoclonal antibody production technology Collaboration agreement with Amgen for the development of rocatinlimab 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
		Prurigo Nodularis	PhI–PhII–PhIII	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
		Moderate to Severe Asthma	PhI–PhII	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
KHK4951 tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Diabetic Macular Edema	PhI–PhII	[In-House] Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
		Neovascular Age-Related Macular Degeneration	PhI–PhII	Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
KK2260 Injection	EGFR-TfR1Bispecific Antibody	Advanced or Metastatic Solid Tumors	PhI	[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP, and a clinical study is prepared under way for PhI in NA as a global product

IV. R&D pipeline

Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage			[In-House or Licensed] Remarks
			PhI	PhII	PhIII	
KK2269 Injection	EpCAM-CD40Bispecific Antibody	Advanced or Metastatic Solid Tumors				[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP and NA as a global product
KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus				[SBI Biotech] POTELLIGENT Clinical study is being conducted in JP and Asia
KK3910 Injection		Essential Hypertension				[In-House] Clinical study is being conducted in JP as a global product

※ For detailed information on ziftomenib's development status, please refer to Kura Oncology's website. https://kuraoncology.com/

Note:Our main progress from September 30, 2025 is as follows.

・Launch of clinical trial of ziftomenib evaluating dual inhibition of NPM1 and FLT3 mutations in patients with newly diagnosed AML (KOMET-007) was announced on October 2, 2025.

・OTL-200 was granted orphan regenerative medicine product designation for early-onset MLD in Japan in October 2025.

Major Applications and Approvals

Code Name, Generic Name, Product Name	Indication	Application/Under Review	Countries/Regions Received Approval in 2025
ziftomenib	Adult Relapsed or Refractory (R/R) Acute Myeloid Leukemia (AML) with a Nucelophosmin1 (NPM1) Mutation	US	–