

Kyowa Kirin Co., Ltd.

Appendix to the Consolidated Financial Summary (IFRS) Fiscal 2019 Interim

(January 1, 2019 - June 30, 2019)

- These materials were made as a supplement to the Kessan Tanshin (Consolidated Financial Summary, IFRS), disclosed at the Tokyo Stock Exchange on August 1, 2019 for the first six months of Fiscal 2019, from January 1, 2019 to June 30, 2019.
- 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 2019 forecasts" have not been revised from the consolidated earnings forecasts released on February 5, 2019.
- Following the conclusion of an agreement to transfer shares of Kyowa Hakko Bio Co., Ltd., the Bio-Chemicals business is categorized as a discontinued operation, effective the first quarter of Fiscal 2019 for accounting on a consolidated basis. Accordingly, FY 2018 results presented herein have been restated in order to present them similarly to the FY 2019 results.
Note that the amounts after restatement for the "FY 2018 results Jan - Sep" and "FY 2018 results Jan - Dec" have not been reviewed or audited by an audit corporation.
- Figures presented in these materials have been rounded to the nearest tenth.
- Figures inside parenthesis presented in these materials indicate negative values.

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The average exchange rates for each period were as follows:

Unit: Yen

	FY 2018 results				FY 2019 results		FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
USD	110	109	109	110	110	110	110
EUR	134	132	131	131	126	125	130
GBP	152	151	149	148	143	143	145

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I . Consolidated Financial Results

1. Trends in consolidated profit

<Accumulative>

Unit: Billions of yen

	FY 2018 results				FY 2019 results			FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec
Revenue	66.5	134.3	197.7	271.5	75.8	151.4	17.1	305.0
Cost of sales	(19.8)	(37.0)	(53.9)	(73.4)	(19.8)	(38.6)	(1.7)	(81.0)
Gross profit	46.7	97.4	143.8	198.1	56.1	112.8	15.4	224.0
<i>Gross profit to revenue ratio</i>	70.2%	72.5%	72.7%	73.0%	74.0%	74.5%	-	73.4%
Selling, general and administrative expenses	(23.5)	(48.3)	(72.3)	(102.1)	(26.7)	(55.3)	(7.0)	(117.5)
Research and development expenses	(10.2)	(21.6)	(32.3)	(45.7)	(11.9)	(24.9)	(3.3)	(52.5)
<i>R&D expenses to revenue ratio</i>	15.3%	16.1%	16.3%	16.8%	15.7%	16.4%	-	17.2%
Share of profit (loss) of investments accounted for using equity method	1.4	0.9	0.3	(0.1)	(0.2)	(0.5)	(1.4)	(1.0)
Core operating profit	14.4	28.4	39.5	50.3	17.3	32.2	3.8	53.0
<i>Core operation profit to revenue ratio</i>	21.6%	21.1%	20.0%	18.5%	22.9%	21.2%	-	17.4%
Other income	14.4	14.5	18.3	18.6	0.1	0.2	(14.4)	
Other expenses	(0.1)	(0.3)	(0.4)	(1.4)	(5.3)	(10.5)	(10.2)	
Finance income (costs)	(0.1)	(0.4)	(0.5)	(0.6)	0.1	(0.0)	0.3	
Profit before tax	28.6	42.2	56.9	66.8	12.3	21.8	(20.4)	47.0
Income tax expense	(7.7)	(10.7)	(14.1)	(17.6)	(3.0)	(3.2)	7.5	
<i>Ratio of income tax burden</i>	27.0%	25.4%	24.7%	26.3%	24.1%	14.5%	-	
Profit from continuing operations	20.9	31.5	42.8	49.2	9.3	18.7	(12.9)	37.0
<i>Profit from continuing operations to revenue ratio</i>	31.4%	23.5%	21.6%	18.1%	12.3%	12.3%	-	12.1%
Profit from discontinued operations	1.1	2.7	4.6	5.2	(1.2)	29.4	26.7	31.0
Profit	22.0	34.3	47.4	54.4	8.1	48.1	13.8	68.0
<i>Profit to revenue ratio</i>	33.1%	25.5%	24.0%	20.0%	10.7%	31.7%	-	22.3%

EPS (¥/share) 40.20 62.61 86.62 99.40 14.97 89.02 26.41 126.30

Annual dividend (¥/share) 35.00 40.00

Dividend payout ratio (%) 35.2 31.7

ROE (%) 8.6 10.5

* Profit from discontinued operations is presented separately from continuing operations on the condensed quarterly consolidated statement of profit or loss. Accordingly, the amounts displayed from revenue through profit from continuing operations are amounts of the continuing operations and exclude the discontinued operations.

<Quarterly>

Unit: Billions of yen

	FY 2018 results				FY 2019 results		
	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount
Revenue	66.5	67.9	63.4	73.8	75.8	75.6	7.7
Cost of sales	(19.8)	(17.2)	(17.0)	(19.4)	(19.8)	(18.9)	(1.7)
Gross profit	46.7	50.7	46.4	54.4	56.1	56.7	6.0
Selling, general and administrative expenses	(23.5)	(24.8)	(24.0)	(29.8)	(26.7)	(28.6)	(3.8)
Research and development expenses	(10.2)	(11.4)	(10.6)	(13.4)	(11.9)	(13.0)	(1.5)
Share of profit (loss) of investments accounted for using equity method	1.4	(0.5)	(0.6)	(0.4)	(0.2)	(0.3)	0.2
Core operating profit	14.4	14.0	11.2	10.8	17.3	14.8	0.9
Other income	14.4	0.1	3.7	0.3	0.1	0.1	(0.0)
Other expenses	(0.1)	(0.2)	(0.1)	(1.0)	(5.3)	(5.2)	(4.9)
Finance income (costs)	(0.1)	(0.3)	(0.1)	(0.1)	0.1	(0.2)	0.0
Profit before tax	28.6	13.6	14.6	10.0	12.3	9.6	(4.1)
Income tax expense	(7.7)	(3.0)	(3.4)	(3.5)	(3.0)	(0.2)	2.8
Profit from continuing operations	20.9	10.6	11.3	6.4	9.3	9.3	(1.3)
Profit from discontinued operations	1.1	1.6	1.9	0.6	(1.2)	30.6	29.0
Profit	22.0	12.3	13.1	7.0	8.1	39.9	27.7

<Breakdown of profit for FY 2019 Jan - Jun from discontinued operations>

Unit: Billions of yen

	FY 2018 results				FY 2019 results	
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun
Revenue	18.2	37.8	56.2	75.0	18.1	18.1
Gross profit	7.1	14.6	22.2	29.0	6.8	6.8
Core operating profit	1.9	3.8	6.4	8.4	1.3	1.3
Profit before tax	1.7	3.5	5.9	6.6	(0.6)	43.2
Profit	1.1	2.7	4.6	5.2	(1.2)	29.4

* Regarding transactions between continuing operations and discontinued operations, considering the continuity of the transactions in the future, revenue and the expenses generated from transactions between such operations have been eliminated from the results of discontinued operations.

2. Revenue by geographic region (continuing operations)

Unit: Billions of yen

	FY 2018 results					FY 2019 results			FY 2019 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	45.7	91.4	135.1	183.5	67.6%	48.8	95.5	63.1%	185.5	60.8%
International	20.8	43.0	62.7	88.0	32.4%	27.1	55.9	36.9%	119.5	39.2%
Americas	4.2	10.9	14.6	23.0	8.5%	8.9	20.4	13.5%	50.0	16.4%
Europe	11.5	21.5	31.8	42.3	15.6%	11.8	22.0	14.5%	45.0	14.8%
Asia	4.9	10.5	16.2	22.5	8.3%	6.3	13.4	8.8%	24.0	7.9%
Others	0.2	0.1	0.1	0.2	0.1%	0.0	0.1	0.0%	0.5	0.2%
Total consolidated revenue	66.5	134.3	197.7	271.5	100%	75.8	151.4	100%	305.0	100%

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

3. Capital expenditures and intangible assets investment (continuing operations)

Unit: Billions of yen

	FY 2018 results				FY 2019 results		FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
Capital expenditures (property, plant and equipment)	0.8	1.8	3.3	4.5	2.6	4.5	10.6
Intangible assets investment	0.6	4.4	5.7	9.0	3.4	3.7	11.5
Total	1.4	6.2	9.0	13.5	6.0	8.2	22.1

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

4. Depreciation and amortization (continuing operations)

Unit: Billions of yen

	FY 2018 results				FY 2019 results		FY 2019 forecasts
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Jan - Dec
Depreciation (property, plant and equipment)	1.6	3.5	5.4	7.3	2.5	5.5	9.3
Amortization (intangible assets)	2.1	4.2	6.2	8.9	2.2	4.5	8.6
Total	3.8	7.7	11.7	16.2	4.7	10.0	17.9

II. Consolidated Statement of Cash Flows

Unit: Billions of yen

	FY 2018 results				FY 2019 results		
	Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount
Cash flows from operating activities	19.5	29.8	46.4	56.2	9.2	19.8	(10.0)
Of which, cash flows of discontinued operations	1.6	2.1	3.5	6.8	6.3	6.3	4.2
Cash flows from investing activities	(14.5)	(23.0)	(30.8)	(39.9)	29.3	10.6	33.6
Of which, cash flows of discontinued operations	(2.3)	(4.3)	(5.2)	(6.4)	(1.9)	103.2	107.5
Cash flows from financing activities	(8.3)	(8.4)	(16.5)	(16.5)	(34.5)	(35.2)	(26.8)
Of which, cash flows of discontinued operations	(0.3)	(0.3)	(0.2)	(0.2)	(0.0)	(0.0)	0.3
Effect of exchange rate changes on cash and cash equivalents	(0.1)	(0.6)	(0.4)	0.4	(0.4)	(0.2)	0.4
Net increase (decrease) in cash and cash equivalents	(3.5)	(2.2)	(1.3)	0.1	3.7	(4.9)	(2.8)
Transfer to assets held for sale	1.1	1.1	1.1	1.1	(3.6)	-	(1.1)
Cash and cash equivalents at beginning of period	14.7	14.7	14.7	14.7	15.9	15.9	1.2
Cash and cash equivalents at end of period*	12.3	13.6	14.5	15.9	15.9	10.9	(2.7)

* Cash reserves at end of period

Cash and cash equivalents at end of period	12.3	13.6	14.5	15.9	15.9	10.9	(2.7)
+ Loans receivable from parent in excess of three months	168.0	172.4	179.6	181.3	144.6	283.7	111.3
+ Time deposits whose maturity periods exceed three months	0.0	0.0	0.0	0.0	-	0.8	0.8
Cash reserves at end of period	180.3	186.0	194.1	197.2	160.5	295.4	109.4

III. Revenue from Main Products

<Accumulative>

Unit: Billions of yen

Indication / Product name		FY 2018 results				FY 2019 results			FY 2019 forecasts		
		Jan - Mar	Jan - Jun	Jan - Sep	Jan - Dec	Jan - Mar	Jan - Jun	Change amount	Jan - Dec	%	
Japan	Renal anemia treatment drug Nesp	12.0	25.6	39.2	53.7	11.8	25.6	0.1	48.4	90%	
	Secondary hyperparathyroidism Regpara	3.6	7.8	10.7	13.3	1.8	3.8	(4.0)	5.1	38%	
	Secondary hyperparathyroidism Orkedia	-	0.4	1.1	2.4	1.2	3.0	2.7	9.5	397%	
	Secondary hyperparathyroidism Rocaltrol	0.9	1.9	2.8	3.8	0.8	1.7	(0.1)	3.6	96%	
	Type-2 diabetes Onglyza	1.6	3.6	5.4	7.4	1.7	3.7	0.1	7.6	102%	
	Cardiovascular (Hypertension & angina pectoris) Coniel	1.2	2.5	3.6	4.8	1.0	2.0	(0.5)	3.9	81%	
	Agent for decreasing the incidence of febrile neutropenia G-Lasta	4.3	9.5	14.8	20.7	5.3	11.5	2.0	22.8	110%	
	Transdermal persistent pain Fentos	1.2	2.6	4.0	5.4	1.1	2.3	(0.3)	4.8	89%	
	Anticancer Poteligeo	0.4	0.9	1.3	1.8	0.4	1.0	0.1	1.7	96%	
	Anticancer Rituximab BS [KHK]	0.3	1.1	2.4	4.3	1.8	4.2	3.0	8.4	195%	
	Chronic idiopathic thrombocytopenic purpura Romiplate	0.7	1.5	2.4	3.2	0.8	1.6	0.1	4.4	136%	
	Antiallergenic Allelock	4.6	7.5	9.7	12.6	4.0	6.4	(1.0)	9.3	74%	
	Antiallergic eyedrops Patanol	7.7	9.7	11.5	13.4	8.5	9.9	0.2	11.3	84%	
	Ulcerative colitis Asacol	0.7	1.5	2.2	2.9	0.6	1.2	(0.3)	2.2	77%	
	Psoriasis vulgaris Dovobet	1.2	2.8	4.2	5.9	1.5	3.4	0.6	7.8	132%	
	Psoriasis Lumicef	0.4	0.9	1.4	2.0	0.5	1.2	0.3	2.7	134%	
	Parkinson's disease Nourias	1.9	4.4	6.8	9.4	2.2	4.8	0.4	10.0	107%	
	Antiepileptic Depakene	1.3	2.7	4.0	5.3	1.1	2.3	(0.4)	4.3	82%	
	Technology out-licensing		1.1	1.5	2.2	2.7	0.9	1.7	0.2	4.4	162%
	International	X-linked hypophosphatemia (XLH) Crysvita	-	0.8	3.2	7.7	5.7	13.4	12.5		
		Anticancer Poteligeo	-	-	-	2.1	2.4	5.4	5.4	10.0	478%
		Cancer pain Abstral	3.4	6.5	9.5	12.8	3.1	5.8	(0.6)	12.3	96%
		Cancer pain Pecfent	1.0	2.0	3.2	4.4	1.1	1.9	(0.1)	5.0	113%
Chemotherapy-induced nausea and vomiting drug Sancuso		0.6	1.3	2.1	3.0	0.7	1.4	0.2	2.9	99%	
Opioid-induced constipation (OIC) Moventig		0.3	0.6	1.0	1.4	0.5	1.0	0.4	2.5	174%	
Replacement therapy with testosterone for male hypogonadism Tostran/Fortesta		0.6	1.4	2.1	2.8	0.6	1.2	(0.2)	1.9	68%	
Osteoporosis drug Adcal-D3		0.9	1.8	2.7	3.5	0.8	1.6	(0.2)	3.1	90%	
Anticancer Mitomycin-C		0.6	1.3	1.7	2.3	0.6	1.0	(0.2)	2.1	88%	
Renal anemia treatment drug Nesp		1.5	3.1	4.7	6.4	1.7	3.3	0.2	5.9	93%	
Secondary hyperparathyroidism Regpara		0.7	1.5	2.3	3.2	1.1	2.4	0.9	3.7	114%	
Agent for decreasing the incidence of febrile neutropenia Neulasta/Peglasta		0.4	1.0	1.7	2.4	1.0	1.9	0.9	4.2	173%	
Neutropenia treatment drug Gran		1.4	2.7	4.2	5.4	1.5	3.1	0.4	5.6	104%	
Technology out-licensing		6.5	12.4	13.9	15.8	3.2	5.2	(7.2)	12.9	82%	
Of which, Benralizumab royalty		0.0	0.5	1.7	3.3	2.0	3.8	3.3			

* Revenue is classified as Japan or International (other than Japan) based on customer location.

* Revenue from main products does not include revenue from the Early Access Program (EAP).

* FY 2019 forecasts for Nesp include revenue of authorized generics ("Darbepoetin Alfa Injection Syringe [KKF]") planned to start sales on August 5, 2019.

* Revenue listed as "Technology out-licensing" specifies revenue from the upfront payment, milestone revenue, and running royalties revenue 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 Fasena by AstraZeneca (including the Company's own estimates).

III. Revenue from Main Products

<Quarterly>

Unit: Billions of yen

Indication / Product name		FY 2018 results				FY 2019 results			
		Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Change amount	
Japan	Renal anemia treatment drug Nesp	12.0	13.6	13.6	14.5	11.8	13.8	0.3	
	Secondary hyperparathyroidism Regpara	3.6	4.2	2.9	2.6	1.8	1.9	(2.3)	
	Secondary hyperparathyroidism Orkedia	-	0.4	0.8	1.3	1.2	1.8	1.5	
	Secondary hyperparathyroidism Rocaltrol	0.9	1.0	0.9	1.0	0.8	0.9	(0.0)	
	Type-2 diabetes Onglyza	1.6	1.9	1.8	2.1	1.7	2.0	0.0	
	Cardiovascular (Hypertension & angina pectoris) Coniel	1.2	1.3	1.1	1.2	1.0	1.1	(0.2)	
	Agent for decreasing the incidence of febrile neutropenia G-Lasta	4.3	5.1	5.3	5.9	5.3	6.2	1.1	
	Transdermal persistent pain Fentos	1.2	1.4	1.4	1.4	1.1	1.2	(0.2)	
	Anticancer Poteligeo	0.4	0.5	0.4	0.5	0.4	0.5	0.0	
	Anticancer Rituximab BS [KHK]	0.3	0.8	1.3	1.8	1.8	2.3	1.5	
	Chronic idiopathic thrombocytopenic purpura Romiplate	0.7	0.8	0.8	0.9	0.8	0.9	0.1	
	Antiallergenic Allelock	4.6	2.9	2.3	2.8	4.0	2.4	(0.4)	
	Antiallergic eyedrops Patanol	7.7	2.0	1.7	1.9	8.5	1.4	(0.6)	
	Ulcerative colitis Asacol	0.7	0.8	0.7	0.7	0.6	0.6	(0.1)	
	Psoriasis vulgaris Dovobet	1.2	1.6	1.4	1.7	1.5	1.9	0.3	
	Psoriasis Lumicef	0.4	0.5	0.5	0.6	0.5	0.7	0.2	
	Parkinson's disease Nourias	1.9	2.5	2.4	2.6	2.2	2.6	0.1	
	Antiepileptic Depakene	1.3	1.4	1.3	1.3	1.1	1.2	(0.2)	
	Technology out-licensing		1.1	0.4	0.8	0.5	0.9	0.7	0.3
	International	X-linked hypophosphatemia (XLH) Crysvita	-	0.8	2.4	4.5	5.7	7.7	6.8
		Anticancer Poteligeo	-	-	-	2.1	2.4	3.0	3.0
		Cancer pain Abstral	3.4	3.1	3.1	3.2	3.1	2.7	(0.3)
		Cancer pain Pecfent	1.0	1.0	1.2	1.2	1.1	0.9	(0.1)
		Chemotherapy-induced nausea and vomiting drug Sancuso	0.6	0.7	0.8	0.9	0.7	0.7	0.0
		Opioid-induced constipation (OIC) Moventig	0.3	0.3	0.4	0.4	0.5	0.5	0.2
		Replacement therapy with testosterone for male hypogonadism Tostran/Fortesta	0.6	0.8	0.7	0.7	0.6	0.6	(0.2)
Osteoporosis drug Adcal-D3		0.9	0.9	0.9	0.8	0.8	0.8	(0.1)	
Anticancer Mitomycin-C		0.6	0.6	0.5	0.6	0.6	0.4	(0.2)	
Renal anemia treatment drug Nesp		1.5	1.6	1.6	1.7	1.7	1.6	0.0	
Secondary hyperparathyroidism Regpara		0.7	0.8	0.9	0.9	1.1	1.3	0.4	
Agent for decreasing the incidence of febrile neutropenia Neulasta/Peglasta		0.4	0.6	0.7	0.7	1.0	1.0	0.4	
Neutropenia treatment drug Gran		1.4	1.3	1.5	1.2	1.5	1.7	0.4	
Technology out-licensing		6.5	5.9	1.5	1.9	3.2	2.0	(3.9)	
Of which, Benralizumab royalty		0.0	0.5	1.2	1.6	2.0	1.8	1.3	

* Revenue is classified as Japan or International (other than Japan) based on customer location.

* Revenue from main products does not include revenue from the Early Access Program (EAP).

* Revenue listed as "Technology out-licensing" specifies revenue from the upfront payment, milestone revenue, and running royalties revenue 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).

V. R&D Pipeline

 Filed • Approved antibody protein small molecule As of Jun. 30, 2019

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Filed in CN	Kirin-Amgen	
				Renal Anemia	Filed in ID		
		KHK7580 Evocalcet Oral	Calcium Receptor Agonist	Hypercalcemia In Patients With Parathyroid Carcinoma or Primary Hyperparathyroidism	Filed in JP	Licensed from Mitsubishi Tanabe Pharma	
Immunology/Allergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	Filed in KR	Kirin-Amgen	
					Filed in SG		
					Filed in MY		
					Filed in CN		
Central Nervous System		KW-6002 Istradefylline Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Filed in US	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	Filed in TW	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
					Filed in CH		
					Filed in KW		
					Filed in SA		
					Filed in CN		
					Filed in HK		
	Filed in JP						
		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Who Have Had an Inadequate Response to Conventional Therapy	Approved in JP	Kirin-Amgen	

Phase II, Phase III

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		©RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	Diabetic Kidney Disease	Phase III in JP	Licensed from Reata	
		KHK7580 Evocalcet Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase III in CN, KR, TW and HK	Licensed from Mitsubishi Tanabe Pharma	
		©KHK7791 Tenapanor Oral	NHE3 inhibitor	Hyperphosphatemia Under Maintenance Dialysis	Phase II in JP	Licensed from Ardelyx	
Oncology		©KHK2375 Entinostat Oral	HDAC Inhibitor	Breast Cancer	Phase II in JP	Licensed from Syndax	
		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Adult T-cell Leukemia/Lymphoma	Phase II in US, EU and others	In-House	POTELLIGENT®
		KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony Stimulating Factor	Mobilization of Hematopoietic stem cell into Peripheral blood	Phase II in JP	Kirin-Amgen	
Immunology/Allergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Ulcerative Colitis	Phase II in US, EU and others	In-House	POTELLIGENT® Human Antibody-Producing Technology
				Atopic Dermatitis	Phase II in JP, US, CA and EU		
		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Axial Spondyloarthritis (axSpA)	Phase III in JP, KR and TW	Kirin-Amgen	
				Systemic Sclerosis	Phase III in JP		
		©ASKP1240 Bleselumab Injection	Anti-CD40 Fully Human Antibody	Recurrence of Focal Segmental Glomerulosclerosis (FSGS) in <i>de</i> <i>novo</i> kidney transplant recipients	Phase II in US	In-House	Human Antibody-Producing Technology Jointly Developed with Astellas
Central Nervous System		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	HTLV-1 associated myelopathy (HAM)	Phase III in JP	In-House	POTELLIGENT®
		©KW-6356 Oral	Adenosine A _{2A} Receptor Antagonist	Parkinson's Disease	Phase II in JP	In-House	
Other		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH) in adult patients	Phase III in US, CA, EU, JP and KR	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
				X-linked Hypophosphatemia (XLH) in pediatric patients	Phase III in US, CA, EU, AU, JP and KR		
				Tumor Induced Osteomalacia(TIO)/Epidermal Nevus Syndrome (ENS)	Phase II in US Phase II in JP and KR		
		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Who Have Had an Inadequate Response to Conventional Therapy	Phase II / III in KR	Kirin-Amgen	
				Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	Phase II / III in JP, KR and TW		
			Idiopathic (Immune) Thrombocytopenic Purpura	Phase III in CN			

Updated since Mar. 31, 2019 (Area, Stage, Filed, Approved, etc.)
 New Molecular Entity

V. R&D Pipeline

antibody
 protein
 small molecule

As of Jun. 30, 2019

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		©KHK2455 Oral	IDO1 Inhibitor	Solid Tumor	Phase I in US	In-House	Combination with KW-0761
		KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Solid Tumor	Phase I / II in US	In-House	POTELLIGENT® Combination with Nivolumab (Jointly Developed with Bristol-Myers Squibb)
		©ME-401 Oral	PI3Kδ inhibitor	B-cell malignancies	Phase I in JP	Licensed from MEI Pharma	
Immunology/ Allergy		©KHK4083 Injection	Anti-OX40 Fully Human Antibody	Ulcerative Colitis	Phase I in JP	In-House	POTELLIGENT® Human Antibody-Producing Technology
		KHK4323 Injection		Atopic Dermatitis	Phase I in JP	In-House	
Central Nervous System		©KHK6640 Injection	Anti-Amyloid Beta Peptide Antibody	Alzheimer's Disease	Phase I in EU Phase I in JP	Licensed from Immunas Pharma	
	Others		KW-3357 Antithrombin Gamma Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Phase I in EU	In-House

Updated since Mar. 31, 2019 (Area, Stage, Filed, Approved, etc.)
 © New Molecular Entity

Updated since Mar. 31, 2019 (Area, Stage, Filed, Approved, etc.)

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Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		KHK7580 Evocalcet Oral	Calcium Receptor Agonist	Hypercalcemia In Patients With Parathyroid Carcinoma or Primary Hyperparathyroidism	Filed in JP	Licensed from Mitsubishi Tanabe Pharma	
Immunology/ Allergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Psoriasis	Filed in CN	Kirin-Amgen	
Others		©KRN23 Burosumab Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia (XLH)	Filed in SA Filed in CN Filed in HK	In-House	Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU
			AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Who Have Had an Inadequate Response to Conventional Therapy	Approved in JP	Kirin-Amgen

Phase II, Phase III

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology		KHK7580 Evocalcet Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase III in CN, KR, TW and HK	Licensed from Mitsubishi Tanabe Pharma	
Oncology		KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony Stimulating Factor	Mobilization of Hematopoietic stem cell into Peripheral blood	Phase II in JP	Kirin-Amgen	
Immunology /Allergy		KHK4827 Brodalumab Injection	Anti-IL-17 Receptor A Fully Human Antibody	Systemic Sclerosis	Phase III in JP	Kirin-Amgen	
Others		AMG531 Romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy	Phase II/III in JP, KR and TW	Kirin-Amgen	

Phase I

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		©ME-401 Oral	PI3Kδ inhibitor	B-cell malignancies	Phase I in JP	Licensed from MEI Pharma	

Terminated

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology		©KHK2823 Injection	Anti-CD123 Fully Human Antibody	Cancer	Phase I in UK	In-House	POTELLIGENT® Human Antibody-Producing Technology