KYOWA KIRIN

Kyowa Hakko Kirin Co., Ltd.

Appendix to the Fiscal 2012 Consolidated Financial Statements

(January 1, 2012 - December 31, 2012)

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This document was made as a supplement to the Kessan Tanshin (financial report) for the fiscal year ending December 31, 2012. This document contains forward-looking statements based on a number of assumptions and beliefs made by management in light of information currently available. For a variety of reasons, actual financial results may differ materially from the forecasts presented here.

I. Consolidated Financial Results

1. Trends in income

	FY 2011	l results		FY 2012 results					FY 2013 forecasts		
	January 1 to June 30	January 1 to December	January 1 to June 30	January 1 to December 31 (forecast	January 1 to December	Cha	nge	January 1 to June 30	January 1 to December 31		
	Sune So	31 (A)		as at 7/19)	31 (B)	Amount (B-A)	%		51		
Net sales	186,367	343,722	166,290	333,000	333,158	(10,564)	97%	169,000	338,000		
Gross Profit	100,234	197,555	104,321	-	210,690	13,135	107%	-	-		
Selling, general and administrative expenses	70,297	150,940	78,736	-	157,785	6,845	105%	-	_		
Operating income (prior to amortization of goodwill)	34,576	55,881	30,212	61,255	62,159	6,278	111%	33,627	64,254		
Operating income	29,936	46,614	25,585	52,000	52,905	6,290	113%	29,000	55,000		
Other income	1,316	2,233	1,419	-	4,167	1,933		-	-		
Other expenses	1,040	2,093	3,909	-	8,070	5,977		-	-		
Ordinary income	30,212	46,754	23,094	46,500	49,001	2,246	105%	-	49,000		
Extraordinary income	8,421	7,332	-	-	-	(7,332)		-	-		
Extraordinary expenses	5,363	7,903	324	-	3,976	(3,927)		-	-		
Net income before income taxes	33,270	46,183	22,769	45,500	45,025	(1,158)	97%	-	52,000		
Corporate, local and enterprise taxes	15,507	20,489	11,212	-	20,609	120		-	-		
Income from minority interests	44	86	32	-	215	129		-	-		
Net income	17,718	25,608	11,523	23,000	24,199	(1,408)	94%	-	30,000		
Comprehensive income	16,745	18,693	13,356	-	34,709	16,016	186%	-	-		
EPS before goodwill amortization (¥/share)	39.24	61.50	29.40	58.81	61.00	(0.51)	99%	-	71.71		

Millions of yen, rounded down

Millions of yen, rounded down

Notes : 1. Figures before goodwill amortization represent amounts prior to subtraction of the goodwill amortization* which occurred as a result of the reverse acquisition (exchange of Kirin Pharma Co. stock) implemented in April 2008.

2. On April 21, 2011, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan Group plc and as a result ProStrakan Group, and its ten subsidiaries were newly included in the scope of consolidation. In terms of accounting treatment, June 30, 2011 will be considered as the date that the acquisition was completed and therefore results from ProStrakan have not been included in the consolidated financial results for the first half of the current fiscal year. Financial results from ProStrakan and its 10 subsidiary companies as of July have been included in the January to December financial results for 2011.

2. Trends in results by segment

(1) Results by operating segment

FY 2011 results FY 2012 results FY 2013 forecasts January 1 January 1 to Change January 1 to January 1 to January 1 January 1 January 1 to to December December to June 30 December to June 30 June 30 December 31 (forecast 31 31 (B) Amount 31 (A) as at 7/19) % (B-A) Net sales 166,290 (10,564) 186,367 343,722 333,000 333,158 97% 169,000 338,000 112,534 229,339 122,833 249,891 126,000 251,000 Pharmaceuticals 248,000 20,551 109% Bio-Chemicals 40,360 77,563 40,082 79,000 76,966 (597) 99% 40,000 81,000 Chemicals 33,550 33,550 (33,550) (230) Other 5,306 10,659 5,173 10,000 10,429 98% 5,000 10,000 Total 191,752 351,113 168,088 337,000 337,286 (13,826) 96% 171,000 342,000 (1,798) (4,000) Eliminations (5,384) (40,000) (4,127) (2,000) (7, 390)3,262 56% **Operating income** 29.936 46,614 25,585 52,000 52,905 6,290 113% 29.000 55,000 *Before goodwill amortization 34,576 55,881 30,212 61,255 6,278 33,627 64,254 62,159 111% Pharmaceuticals 25,145 41,314 23,364 48,700 50,392 9,077 122% 25,500 49,000 29.459 49.942 27.678 57.329 59.020 9.077 29.814 57.628 118% Bio-Chemicals 2,519 2,896 2,040 3,000 2,127 (768) 73% 3,400 5,800 2.353 3,713 2.832 3.521 3,626 2,753 (768) 78% 6,426 Chemicals 2,135 2,135 (2, 135)2,147 2,147 (2,147) Other 148 360 155 300 338 (21) 94% 100 200 148 360 155 300 338 94% 100 200 (21) Total 29,948 46,706 25,560 52,000 52,859 6,152 113% 29,000 55,000 34 588 55 973 30.187 61.255 62.113 6 139 33.627 64.254 111% Eliminations (12) (92) 24 46 138 Notes: 1. Figures representing amounts before goodwill amortization have been italicized. 2. The Chemicals Business was discontinued at the end of the first quarter following the transfer of all shares of Kyowa Hakko Chemical on March 31, 2011.

As a result, income from Chemicals was consolidated on the Statements of Income only until March 31, 2011.

			FY 2011	results		FY 2012 results			
		January 1 to June 30	Percentage of consolidated sales	January 1 to December 31	Percentage of consolidated sales	January 1 to June 30	Percentage of consolidated sales	January 1 to December 31	Percentage of consolidated sales
Já	apan sales	148,987	79.9%	272,568	79.3%	128,898	77.5%	260,524	78.2%
0	verseas sales	37,379	20.1%	71,154	20.7%	37,391	22.5%	72,633	21.8%
	America	10,456	5.6%	20,071	5.8%	10,097	6.1%	21,207	6.4%
	Europe	10,919	5.9%	25,169	7.3%	16,927	10.2%	30,997	9.3%
	Asia	15,772	8.5%	25,426	7.4%	10,088	6.1%	19,880	6.0%
	Other regions 231 0.1% 48		486	0.1%	278	0.2%	548	0.2%	
Тс	otal consolidated net sales							333,158	100.0%

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

3. Trends in non-operating income/expenses

Millions of yen, rounded down

	FY 2011	results	FY 2012 results		
	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	
Non-operating income	1,316	2,233	1,419	4,167	
Interest income	193	497	285	604	
Dividends income	303	536	442	993	
Foreign exchange gains	112	-	-	1,224	
Gain on revaluation of derivatives	-	-	16	-	
Income from investment in equity method	141	199	-	-	
Other	565	1,000	675	1,343	
Non-operating expenses	1,040	2,093	3,909	8,070	
Interest expenses	77	135	81	205	
Foreign exchange loss	-	154	45	-	
Loss on revaluation of derivatives	32	142	-	784	
Loss from investment in equity method	-	-	2,549	4,861	
Loss on disposal of non-current assets	313	670	414	874	
Other	617	990	818	1,344	

4. Trends in extraordinary income / loss Millions of yen, rounded down

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	FY 2011	results	FY 201	2 results	
	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	
Extraordinary income	8,421	7,332	-	-	
Gain on sales of affiliates' stocks	8,320	7,217	-	-	
Reversal of allowance for doubtful accounts	100	115	-	-	
Extraordinary loss	5,363	7,903	324	3,976	
Impairment loss	200	769	-	1,341	
Loss on liquidation of affiliates	209	209	-	1,035	
Loss on valuation of investment securities	3,043	2,374	-	1,007	
Loss on sale of investment securities	-	692	324	344	
Loss from business restructuring	-	-	-	247	
Advisory fee	1,030	1,098	-	-	
Loss on disaster	302	650	-	-	
Loss from sale of fixed assets	-	635	-	-	
Non-recurring depreciation on non-current assets	-	477	-	-	
Loss on adjustment for changes of accounting standard for asset retirement	447	447	-	-	
Loss on business liquidation	-	419	-	-	
Provision for point card certificates for prior periods	128	128	-	-	

5. Trends in R&D Expenses

Billions of yen, rounded down

	FY 201	1 results	FY 201	12 results	FY 2013 forecasts		
	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	
R&D expenses (Consolidated)	22.2	47.9	22.1	44.8	22.2	44.0	
R&D to net sales ratio	11.9%	14.0%	13.3%	13.4%	13.2%	13.0%	
Pharmaceuticals	20.4	44.5	20.5	41.3	20.5	40.7	
(R&D to net sales ratio)	18.2%	19.4%	16.8%	16.6%	16.3%	16.2%	
Bio-Chemicals	1.5	3.2	1.5	3.4	1.7	3.3	
Chemicals	0.2	0.2	-	-	-	-	
Other	-	-	-	-	-	-	

6. Trends in Capital Expenditure (Tangible fixed assets)

Billions of yen, rounded down

	FY 201	11 results	FY 20	12 results	FY 2013 forecasts		
	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	
Capital expenditure (Consolidated)	5.9	14.3	7.9	19.7	7.4	19.2	
Pharmaceuticals	2.8	6.5	4.0	10.3	3.7	9.5	
Bio-Chemicals	2.7	7.4	3.9	9.4	3.7	9.7	
Chemicals	0.3	0.3	-	-	-	-	
Other	0.0	0.0	0.0	0.0	0.0	0.0	

7. Trends in Depreciation Expenses

Billions of yen, rounded down FY 2012 results FY 2013 forecasts FY 2011 results January 1 to June 30 January 1 to December 31 January 1 to June 30 January 1 to December 31 January 1 to June 30 January 1 to December 31 Depreciation expenses 10.4 22.8 9.6 20.9 9.9 21.2 (Consolidated) Pharmaceuticals 6.8 15.3 6.6 14.5 6.7 14.6 **Bio-Chemicals** 2.6 6.4 2.9 6.2 3.1 6.6 Chemicals 0.9 0.9 Other 0.0 0.0 0.0 0.0 0.0 0.0

8. Trends in Employee Numbers

	FY 2011	FY 2012
	December 31	December 31
 umber of staff at end of term consolidated)	7,229	7,243
Pharmaceuticals	5,390	5,374
Bio-Chemicals	1,632	1,668
Other	207	201

9. Exchange rates

	FY 201	11 results	FY 20	12 results	FY 2013 forecasts		
	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31	
US Dollar (¥/US\$)	82	80	80	80	85	85	
Euro (¥/Euro)	115	111	103	103	115	115	
Pound (¥/Pound)	133	128	126	127	140	140	

II. Consolidated Subsidiaries and Affiliates

Segment	Туре	Region	Company name	Percentage owned (direct and indirect)	Principal business
		les es	Kyowa Medex Co., Ltd.	100.0%	Manufacture and sale of diagnostic reagents
		Japan	Kyowa Medical Promotion Co., Ltd.	100.0%	Promotion and sales of pharmaceuticals
			Kyowa Hakko Kirin America, Inc.	100.0%	Holding company for administration and management of subsidiarie (US)
			BioWa, Inc.	100.0%	Out-licensing of anti-body technology (US)
			Kyowa Hakko Kirin Pharma, Inc.	100.0%	Development of outsourced pharmaceutical products (US)
		The Americas	Kyowa Hakko Kirin California, Inc.	100.0%	Generate new candidate substances and develop pharmaceuticals (US)
			Hematech, Inc.	100.0%	Technology research for manufacture of therapeutic antibody (US)
			ProStrakan Inc.	100.0%	Sales of pharmaceuticals (US)
			ProStrakan Group plc	100.0%	Supervision and management of special companies (UK)
			Strakan Inernational S.a r.l.	100.0%	Sales, licensing-in and licensing-out of pharmaceuticals (UK)
			Strakan Pharmaceuticals Limited	100.0%	Development of pharmaceuticals (UK)
	Consolidated		ProStrakan Limited	100.0%	Sales of pharmaceuticals (UK)
Dhaannaantiaala	subsidiary		ProStrakan Pharma S.A.S	100.0%	Sales of pharmaceuticals (France)
Pharmaceuticals		Europe	ProStrakan Farmaceutica SLU	100.0%	Sales of pharmaceuticals (Spain)
			ProStrakan Pharma GmbH	100.0%	Sales of pharmaceuticals (Germany)
			ProStrakan Holdings B.V.	100.0%	Holding company for special companies (Netherlands)
			ProStrakan Pharma B.V.	100.0%	Sales of pharmaceuticals (Netherlands)
			ProStrakan S.r.I.	100.0%	Sales of pharmaceuticals (Italy)
			ProStrakan AB	100.0%	Sales of pharmaceuticals (Sweden)
			Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.	100.0%	Manufacture and sale of pharmaceuticals (China)
			Kyowa Hakko Kirin Korea Co., Ltd.	100.0%	Sales of pharmaceuticals (Korea)
		Asia	Kyowa Hakko Kirin (Taiwan) Co., Ltd.	100.0%	Sales of pharmaceuticals (Taiwan)
			Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%	Sales of pharmaceuticals (Hong Kong)
			Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	Sales of pharmaceuticals (Singapore)
	Affiliate accounted for by the equity method	Japan	FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	Development, manufacture and sale of biosimilar pharmaceuticals
			Kyowa Hakko Bio Co., Ltd.	100.0%	Manufacture and sale of pharmaceutical and industrial raw material and health care products
		Japan	Daiichi Fine Chemical Co., Ltd.	100.0%	Manufacture and sale of active pharmaceutical ingredients and pharmaceutical intermediates
			Kyowa Wellness Co., Ltd.	100.0%	Sale of healthcare products
			Kyowa Engineering Co., Ltd.	100.0%	Design and installation of plant facilities and equipment
			BioKyowa Inc.	100.0%	Manufacture and sale of amino acids (US)
		The Americas	Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US)
Bio-Chemicals	Consolidated subsidiary		Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	Holding company for administration and management of US special companies (US)
		_	Kyowa Hakko Europe GmbH	100.0%	Sale and import/export of fine chemicals including amino acids (Germany)
		Europe	Kyowa Hakko Bio Italia S.r.l.	100.0%	Sale and import/export of fine chemicals including amino acids (Italy
			Shanghai Kyowa Amino Acid Co., Ltd.	70.0%	Manufacture and sale of amino acids (China)
			Thai Kyowa Biotechnologies Co., Ltd.	100.0%	Manufacture and sale of amino acids (Thailand)
		Asia	Kyowa Hakko (H.K.) Co., Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids
			Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%	(Hong Kong) Sale and import/export of fine chemicals including amino acids
	Consolidated		Chiyoda Kaihatsu Co., Ltd.	100.0%	(Singapore) Distribution, insurance, wholesale and retail
Other	Subsidiary Affiliate accounted for by the equity method	Japan	Japan Synthetic Alcohol Co., Ltd.	33.3%	Manufacture and sale of industrial use alcohol

 method

 Notes:
 Changes to the scope of consolidation (January 1, 2012 to December 31, 2012)

 Newly consolidated:
 2 companies:

 ProStrakan AB (*1)
 Thai Kyowa Biotechnologies (*2)

Removed: 2 companies: Kyowa Hakko Kirin Italia S.r.l. (*3) Hematech-GAC Venture, LLC (*4)

*1 On June 1, 2012, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan AB which was newly included as a subsidiary in the scope of consolidation.

*2 Thai Kyowa Biotechnologies Co., Ltd. was established on November 12, 2012 and made into a consolided subsidiary.

*3. On June 1, 2012, Kyowa Hakko Kirin Italia S.r.l. merged with ProStraken S.r.l. and was eliminated.

*4 Hematech-GAC Venture, LLC was excluded from the scope of consolidation following the transfer of all outstanding shares on December 31, 2012

*5. As of April 23, 2012, Kirin Kunpeng (China) Bio- Pharmaceutical Co., Ltd.changed its corporate name to Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.

*6. As of June 1, 2012, Jeil-Kirin Pharm. Inc. changed its corporate name to Kyowa Hakko Kirin Korea Co., Ltd.

III. Non-Consoliadted Net Sales by Division (Items and main products)

1. Kyowa Hakko Kirin

I. Kyowa Hakko Kirin							Billions of yen, rounded down		
	FY 201	1 results		FY2012	FY 2013 forecasts				
Pharmaceuticals division (non-consolidated)	January 1 to June 30	January 1 to December 31 (A)	January 1 to June 30	January 1 to December 31 (forecast as at 7/19)	January 1 to December 31 (B)	Change (B/A)	January 1 to June 30	January 1 t December 3	
Pharmaceuticals division total	104.6	206.0	107.8	213.9	218.1	106%	108.7	212.3	
Indication / Product name									
ESA formulation									
Nesp	25.4	56.4	26.8	53.7	58.1	103%	27.7	57.8	
ESA formulation	-								
Espo	2.7	5.3	1.9	4.0	3.9	73%	1.7	3.	
Nesp/Espo	28.2	61.8	28.8	57.7	62.0	100%	29.5	61.3	
Secondary hyperparathyroidism									
Regpara	5.3	11.5	6.2	13.0	13.4	116%	6.7	14.	
Secondary hyperparathyroidism	4 -		10			44004	10		
Rocatrol*1	1.5	3.2	1.6	-	3.6	113%	1.8	3.	
Antiallergenic									
Allelock	18.1	29.1	16.1	29.1	29.9	103%	16.2	27.	
Antiallergenic									
Celtect	1.3	2.5	1.0	1.8	1.9	75%	1.0	1.	
Antiallergic eyedrops									
Patanol	8.6	11.4	6.9	10.1	10.2	90%	8.1	11.	
G-CSF Gran	6.7	14.8	6.4	13.4	13.5	92%	6.0	12.	
Cancer pain	0.7	14.0	0.4	10.4	10.0	0270	0.0	12.	
Fentos	1.2	3.1	2.0	4.5	4.6	148%	2.4	5.	
Anticancer									
5-FU	1.5	3.1	1.4	2.7	2.8	90%	1.4	2.	
Anticancer									
Navelbine	0.8	1.7	0.6	1.2	1.3	76%	0.6	1.	
Chronic idiopathic thrombocytopenic purpura	0.1	0.7	0.7		4 7	0400/	0.0	4	
Romiplate *2 Cardiovascular	0.1	0.7	0.7	-	1.7	243%	0.8	1.	
Cardiovascular Coniel	9.6	19.7	8.5	17.2	17.1	87%	7.6	15.	
Cardiovascular (Hypertension)	5.0	10.7	0.0	17.2	17.1	0170	7.0	10.	
Coversyl	1.9	3.9	1.7	3.4	3.5	90%	1.5	3.	
Cardiovascular									
Inovan / Pre Dopa	1.3	2.8	1.1	2.4	2.4	85%	0.9	1.	
Antiepileptic									
Depakene	5.3	11.2	5.2	10.8	10.7	95%	5.1	10.	
Parkinson's disease				. –					
Permax	1.1	2.1	0.8	1.7	1.7	78%	0.8	1.	
Gastrointestinal Nauzelin	2.3	4.8	2.2	4.7	4.9	102%	2.4	4.	
Inflammatory bowel disease	2.3	4.0	2.2	4./	4.9	10270	2.4	4.	
Asacol	1.1	2.8	1.8	3.8	4.1	142%	2.3	4.	
Exports and Technology									
Out-Licensing	11.4	22.3	17.9	34.7	34.2	154%	16.0	28.	

*1 On April 1, 2012, manufacturing and sales rights, etc., for Rocatrol were received from Chugai Pharmaceutical *2 Sales of Romiplate began April 13, 2011

2. ProStrakan

Millions of GBP. rounded down

L. FIUSIIAKAII						IV.	IIIIIONS OF GBP, I	ounded down
	FY 2011	1 results		FY 201		FY 2013 forecasts		
Pharmaceuticals division	January 1 to June 30	January 1 to December 31	January 1 to June 30	January 1 to December 31 (Forecast as at 7/19)	January 1 to December 31	Change (B/A)	January 1 to June 30	January 1 to December 31
Net sales	48	105	61	139	129	123%	74	154
Chemotherapy-induced nausea and vomiting drug								
Sancuso	4	9	5	16	12	131%	9	19
Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. Abstral	12	27	16	36	33	124%	20	42
Replacement therapy with testosterone for male hypogonadism Tostran	2	5	2	4	7	145%		11
Prevention and treatment of post-operative nausea and vomiting (PONV). Xomolix	4	8	4	9	8	94%	3	7
Relief of pain associated with chronic anal fissures								
Rectogesic	4	9	4	9	10	109%	6	12
Osteoporosis drug								
Adcal-D3	11	24	12	25	26	106%	12	26
Others	8	20	14	37	30	151%	17	33
Gross profit	29	65	40	101	91	140%	56	118
Selling, general and								
administrative expenses	40	75	39	84	76	102%	47	90
Operating income								
(prior to consolidated adjustment)	(11)	(9)	1	17	15		9	28
Consolidated adjustment			(18)	(34)	(35)		(16)	(32)
Operating income (after consolidated adjustment)			(16)	(17)	(19)		(6)	(4)

Notes: 1. The results of ProStrakan were consolidated from July 2011.

The results of Prostrakan are shown on a local basis (IFRS standards) for fiscal 2011 and on the Kyowa Hakko Kirin standards for fiscal 2012. The consolidated adjustment amounts are mainly the goodwill and amortization of product sales rights associated with the Prostrakan acquistion.
 The sales ratio by region is as shown below.

*Sales ratio by region	UK	Europe (excluding UK)	USA	Other
(January 1 to December 31, 2012)	33.4%	41.8%	22.9%	1.9%

3. Kyowa Hakko Bio

3. Kyowa Hakko Bio	Kyowa Hakko Bio Billions of yen, rounded down									
Bio-Chemicals division	FY 2011	l results		FY 201	FY 2013 forecasts					
(non-consolidated)	January 1 to June 30	January 1 to December 31 (A)	January 1 to June 30	January 1 to December 31 (forecast as at 7/19)	January 1 to December 31 (B)	Change (B/A)	January 1 to June 30	January 1 to December 31		
Bio-Chemical division total	25.9	49.6	25.9	52.1	51.2	103%	28.7	57.2		
Pharmaceuticals / Industrial raw materials										
Amino acids	10.1	19.1	10.2	20.6	20.2	106%	11.5	22.6		
Nucleic acids and vitamins	2.7	5.2	2.5	5.2	5.2	100%	2.7	5.4		
Other	3.8	7.2	3.7	6.6	7.2	99%	3.2	6.5		
Health care products	4.7	9.3	4.7	10.1	9.3	100%	6.4	13.1		

R&D Pipeline 😵 protein 🌱 antibody small molecule Filed · Approved As of Jan 24th 2013 Code Name Generic Name Formulation In-House Area Mechanism of Action Indication Stage or Remarks KW-2246 Fentanyl citrate Sublingual Tablet X μ-Opioid Receptor Agonist Licensed from Orexo Cancer Pain Filed in Japan Oncology Solasia Pharma (ProStrakan) X Granisetron Patch 5HT3 Serotonin Recpter Antagonist Chemotheraphy induced Nausea and Vomiting Asia: Singapore, Malaysia and Hong Kong Filed in Asia Cinacalcet Hydrochloride Oral Asia: Philippine, Malaysia, Thailand and China X Calcium Receptor Agonist Secondary Hyperparathyroidism Licensed from NPS Filed in Asia Nephrology Ş KRN321 Darbepoetin Alfa Injection Long-Acting Erythropoiesis Stimulating Agent Kirin-Amgen Pediatric Renal Anemia Filed in Japan ©KW-6002 Istradefyiline Oral Filed in USA X Adenosine A_{2A} Receptor Antagonist Parkinson's Disease In-House Central Nervous System Filed in Japan KW-6485 Topiramate Oral Licensed from Janssen Pharmaceutic al K.K. X Antiepileptic Drug Filed in Japan Pediatric Epilepsy

Phase II, Phase II									
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks		
	S	KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony Stimulating Factor	Chemotherapy induced Febrile Neutropenia	Phase II in Japan	Kirin- Amgen			
		©ARQ 197 Tivantinib	c-Met Inhibitor	Lung Cancer (EGF-receptor mutated)	Phase II in Japan	Licensed from			
	X1-	Oral	C-Wet Inhibitor	Gastric Cancer	Phase I in Japan and Korea	ArQule			
				Peripheral T/NK-cell Lymphoma	Phase II in Japan				
		KW-0761		Adult T-cell Leukemia/Lymphoma, Add-on Therapy (for Untreated Patients)	Phase II in Japan				
Oncology	Y	Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Peripheral T-cell Lymphoma	Phase I in EU	In-House	POTELLIGENT*		
				Adult T-cell Leukemia/Lymphoma	Phase II in US and EU				
				Cutaneous T-cell Lymphoma	Phase II in US				
	XF	KRN1493 Cinacalcet Hydrochloride Oral	Calcium Receptor Agonist	Hypercalcemia with Parathyroid Carcinoma or Intractable Primary Hyperparathyroidism	Phase III in Japan	Licensed from NPS			
	*	©KW-2478 Injection	HSP90 inhibitor	Multiple Myeloma	Phase I / II in UK/US/PH	In-House			
	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Myelodysplastic Syndrome related Anemia	Phase II in Japan and Korea	Kirin- Amgen			
Nephrology	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Phase II in China	Kirin- Amgen			
1 (0) 1 0 00 0	*	©RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	CKD in patients with type 2 diabetes	Phase II in Japan	Licensed from Reata			
	Y	©KHK4563 Benraìizumab Injection	Anti-IL-5 Receptor Humanized Antibody	Asthma	Phase II in Japan and Korea	In-House	Being Developed by MedImmune as MEDI-563 Worldwide except in Japan and other Asian Countries POTELLIGENT®		
Immunology /Allergy	Y	©ASKP1240 Injection	Anti-CD40 Fully Human Antibody	Organ Transplant Rejection	Phase I in Japan Phase I in USA	In-House	Jointly Developed with Astellas KM mouse		
, 1015)	*	Z-206 Mesalazine Oral	pH Dependent Controlled Release Tablet	Crohn's Disease	Phase II in Japan	Licensed from Zeria Pharma.	Jointly Developed with Zeria Pharma		
	Y	©KHK4827 Injection	Anti-IL-17 Receptor Fully Human Antibody	Psoriasis	Phase II in Japan	Kirin- Amgen			
Central Nervous System	*	©KHK6188 Oral	Cannabinoid CB2 Receptor Agonist	Neuropathic Pain	Phase II in Japan	In-House			
Other	8	©KW-3357 Antithrombin Injection	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Phase II in Japan Phase I in Europe	In-House			
L	_			Deficiency	I HASE THE LUI UPP	1			

Updated since Oct 18th, 2012 (Area, Stage, Filed, Approved, Launched etc.)

New Molecular Entity

As of Jan 24th 2013

Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
	¥	©KW-2450 Oral	IGF-1 Receptor Signal Inhibitor	Cancer	Phase I / II in USA	In-House	
		©BIW-8962 Injection	Anti-GM2 Humanized Antibody	Cancer	Phase I/Ia in USA	In-House	POTELLIGENT®
	*	©KRN951 Tivozanib Oral	VEGF Receptor Inhibitor	Cancer	Phase I in Japan	In-House	Filled in US by AVEO as AV-951
	Y	©KHK2866 Injection	Anti-HB-EGF Humanized Antibody	Cancer	Phase I in USA	In-House	POTELLIGENT®
Oncology	*	©LY2523355 Litronesib Injection	M phase Kinesin Eg5 Inhibitor	Cancer	Phase I in Japan	In-House	Being Developed by Eli Lilly as LY2523355 Worldwide except in Japan
	Y	©CEP-37250/K HK2804 Injection	Anti-Tumor Specific Glycoprotein Humanized Antibody	Cancer	Phase I in USA	Cephalon	Jointly Developed with Cephalon POTELLIGENT®
	Y	©KHK2898 Injection	Anti-CD98 Fully Human Antibody	Cancer	Phase I in Singapore	In-House	POTELLIGENT® KM mouse
	X	©ARQ 197 Tivantinib Oral	c-Met Inhibitor	Hepatocellular Cancer	Phase I in Japan	Licensed from ArQule	
Nephrology	×r-	©KHK7580 Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase I in Japan	Mitsubishi Tanabe	
	Y	KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Asthma	Phase I in Japan	In-House	POTELLIGENT®
Immunology /Allergy	1	©KHK4083 Injection	Immunomodulator	Autoimmune diseases	Phase I in Canada	In-House	POTELLIGENT© KM mouse
	*	©KHK4577 Oral	Anti-inflammatory Agent	Inflammatory disease	Phase I in Japan	In-House	
Other	Y	©KRN23 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemic Rickets/Osteomalacia (XLH)	Phase I/I in USA and Canada	In-House	KM mouse

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New Molecular Entity

Phase I

Updated since Oct 18th, 2012 (Area, Stage, Filed, Approved, Launched etc.)

	Filed · Approved					As	s of Jan 24th 2013
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology	*	KW-2246 Fentanyl citrate Sublingual Tablet	µ-Opioid Receptor Agonist	Cancer Pain	Filed in Japan	Licensed from Orexo	
Central Nervous System	*	KW-6485 Topiramate Oral	Antiepileptic Drug	Pediatric Epilepsy	<u>Filed in Japan</u>	Licensed from Janssen Pharmaceutic al K.K.	

		Phase 1	I, Phase II				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology	≺	KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Cutaneous T-cell Lymphoma	<u>Phase</u> Ⅲ in US	In-House	POTELLIGENT®
Immunology /Allergy	*	©KHK4827 Injection	Anti-IL-17 Receptor Fully Human Antibody	Psoriasis	<u>Phase II</u> in Japan	Kirin- Amgen	

		Ph	ase I				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Nephrology	¥	©KHK7580 Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Phase I in Japan	Mitsubishi Tanabe	
Immunology /Allergy		©KHK4083 Injection	Immunomodulator	Autoimmune diseases	<u>Phase I</u> in Canada	In-House	POTELLIGENT® KM mouse
Immunology /Allergy	¥	©KHK4577 Oral	Anti-inflammatory Agent	Inflammatory disease	<u>Phase I</u> in Japan	In-House	

		Study Dis	continuation				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Reason
Oncology	×	©ARQ 197 Tivantinib Oral	c-Met Inhibitor	Lung Cancer (EGF-receptor wild type)	Phase II in Japan, Korea and Taiwan	Licensed from ArQule	Following the safety review committee recommendation by higher frequency of interstitial lung disease cases in the study as one of drug related adverse reactions.