

## Kyowa Hakko Kirin Co., Ltd.

# Appendix to the Fiscal 2012 Third Quarter Consolidated Financial Statements

Third quarter results for Fiscal 2012

(January 1, 2012 - September 30, 2012)

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This document is a supplement to the Kessan Tanshin (financial report) for the third quarter period of the fiscal year ending December 31, 2012 as filed with the Tokyo Stock Exchange on 26 October 2012. This document contains forecasts and forward-looking statements based on information and assumptions which management believes to be reasonable in the light of information currently available. However, actual financial results may differ materially from the forecasts presented here for a variety of reasons.

#### I. Consolidated Financial Results

1. Trends in income Millions of yen, rounded down

	F	Y2011 result	S		FY 2012	results		FY 2012 forecasts	
	January 1 to June 30	January 1 to September	January 1 to December	January 1 to June 30	January 1 to September	2011		January to	
	Julie 30	30 (A)	31	Julie 30	30 (B)	Amount (B-A)	%	December	
Net sales	186,367	262,358	343,722	166,290	244,691	(17,667)	93%	333,000	
Gross Profit	100,234	147,334	197,555	104,321	154,386	7,051	105%		
Selling, general and administrative expenses	70,297	108,830	150,940	78,736	117,043	8,212	108%		
Operating income (before amortization of									
goodwill)	34,576	45,456	55,881	30,212	44,283	(1,173)	97%	61,255	
Operating income	29,936	38,503	46,614	25,585	37,343	(1,160)	97%	52,000	
Non-operating income	1,316	1,878	2,233	1,419	1,933	55			
Non-operating expenses	1,040	1,858	2,093	3,909	6,694	4,835			
Ordinary income	30,212	38,523	46,754	23,094	32,581	(5,914)	85%	46,500	
Extraordinary income	8,421	7,444	7,332			(7,444)			
Extraordinary loss	5,363	4,580	7,903	324	1,246	(3,334)			
Net income before income taxes	33,270	41,387	46,183	22,769	31,335	(10,051)	76%	45,500	
Corporate, local and enterprise taxes	15,507	18,640	20,489	11,212	15,847	(2,793)			
Income from minority interests	44	74	86	32	47	(26)			
Net income	17,718	22,672	25,608	11,523	15,440	(7,231)	68%	23,000	
Comprehensive income	16,745	15,719	18,693	13,356	18,348	2,629	117%		
EPS before goodwill amortization (¥/share)	39.24	52.03	61.50	29.40	40.79			58.81	

#### Notes:

### 2. Trends in results by segment

(1) Results by operating segment Millions of yen, rounded down FY 2012 FY 2011 results FY 2012 results forecasts Change on January 1 January to September January 1 to January 1 to January 1 to January 1 to January to to September December 2011 June 30 June 30 September December 30 (A) Amount 30 (B) % Net sales 186,367 262,358 343,722 166,290 244,691 (17,667)93% 333,000 Pharmaceuticals 112,534 168,218 229,339 122,833 182,406 14,188 108% 248,000 **Bio-Chemicals** 40,360 58,973 77,563 (1,485)40,082 57,488 97% 79,000 33,550 33,550 (33,550)Chemicals 33,550 Other 5,306 7,856 10,659 5,173 7,703 (152)98% 10,000 Total 351,113 247,597 168,088 (21,000) 92% 191,752 268,598 337,000 (5,384) (6,239) (1,798) Eliminations (7,390)(2,906)3,333 (4,000)Operating income 29,936 38,503 46,614 25,585 37,343 (1,160)97% 52,000 \*Before goodwill amortization 34,576 45,456 55,881 30,212 44,283 (1, 173)97% 61,255 105% Pharmaceuticals 25 145 33,114 41 314 23 364 34,837 1,722 48,700 29,459 39,585 49,942 27,678 41,308 1,722 104% 57,329 Bio-Chemicals 2,519 3,018 2,896 2,040 2,213 (804)73% 3,000 2 832 3 487 3 52 1 2.353 2 683 (804) 3.626 77% Chemicals 2,135 (2,135)2,135 2,135 2,147 2,147 2,147 (2, 147)Other 255 360 259 148 155 3 102% 300 148 255 360 155 259 3 102% 300 Total 29,948 38,524 46,706 25,560 37,311 (1,213)97% 52,000 34.588 45.477 55,973 30,187 44.251 (1,225) 97% 61,255 Eliminations (12) (20) (92) 24 31 52

#### Note:

<sup>1.</sup> Before amortization of goodwill refers to profit figures prior to the amortization associated with the April 2008 reverse acquisition (share swap with Kirin Pharma.)

<sup>2.</sup> On April 21, 2011, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan Group plc and as a result ProStrakan Group and its subsidiaries were newly included in the scope of consolidation. However, June 30, 2011 is deemed to be the date the acquisition was completed for accounting purposes and therefore the results of ProStrakan and its subsidiaries were included in the consolidated financial results only for the July-December period of fiscal 2011.

3. The FY2012 forecasts are the revised forecasts as announced July 19, 2012.

<sup>1.</sup> All shares of Kyowa Hakko Chemical were divested on March 31, 2011. Consequently, the results of the Chemicals segment in fiscal 2011 are consolidated on the Statements of Income only for the period January-March 2011.

(2) Regional sales Millions of yen, rounded down

			FY2011	results		FY 2012 results				
	January 1 to June 30	Percentage of consolidated sales	January 1 to September 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 September 30	Percentage of consolidated sales
Japan sales	148,987	79.9%	208,194	79.4%	272,568	79.3%	128,898	77.5%	189,990	77.6%
Overseas sales	37,379	20.1%	54,163	20.6%	71,154	20.7%	37,391	22.5%	54,700	22.4%
America	10,456	5.6%	16,083	6.1%	20,071	5.8%	10,097	6.1%	15,080	6.2%
Europe	10,919	5.9%	18,449	7.0%	25,169	7.3%	16,927	10.2%	24,001	9.8%
Asia	15,772	8.5%	19,256	7.3%	25,426	7.4%	10,088	6.1%	15,206	6.2%
Other regions	231	0.1%	374	0.1%	486	0.1%	278	0.2%	412	0.2%
Total consolidated net sales	186,367	100.0%	262,358	100.0%	343,722	100.0%	166,290	100.0%	244,691	100.0%

Note:
Sales are based on the geographic location of the customer and allocated to the appropriate country or region.

### 3. Trends in non-operating income/expenses

Millions of yen, rounded down

		FY2011 results	FY 2012	FY 2012 results		
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	
Non-operating income	1,316	1,878	2,233	1,419	1,933	
Interest income	193	343	497	285	436	
Dividend income	303	334	536	442	477	
Foreign exchange gains	112				106	
Gain on revaluation of derivatives		296		16		
Equity in earnings of affiliates	141	189	199			
Other	565	713	1,000	675	913	
Non-operating expenses	1,040	1,858	2,093	3,909	6,694	
Interest expenses	77	110	135	81	150	
Foreign exchange loss		570	154	45		
Loss on revaluation of derivatives	32		142		134	
Equity in losses of affiliates				2,549	4,643	
Loss on disposal of non-current assets	313	453	670	414	631	
Other	617	724	990	818	1,135	

# 4. Trends in extraordinary income / loss

Millions of yen, rounded down

	F	FY 2011 results		FY 2012	2 results
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30
Extraordinary income	8,421	7,444	7,332		
Gain on sales of subsidiaries and affiliates' stocks	8,320	7,339	7,217		
Reversal of allowance for doubtful accounts	100	104	115		
Extraordinary loss	5,363	4,580	7,903	324	1,246
Loss on valuation of investment securities	3,043	2,011	2,374		905
Loss on sale of investment securities			692	324	340
Advisory expenses	1,030	1,062	1,098		
Asset impairment loss	200	273	769		
Loss from natural disaster	302	447	650		
Loss from sale of fixed assets			635		
Extraordinary depreciation of fixed asset			477		
Loss on adjustment for changes of accounting standard for asset retirement	447	447	447		
Loss on business liquidation			419		
Loss on liquidation of affiliates	209	209	209		
Provision for point card certificates for prior periods	128	128	128		

5. Trends in R&D expenses

Billions of yen, rounded down

		FY 2011 results		FY 2012	FY 2012 forecasts	
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January 1 to December 31
R&D expenses (Consolidated)	22.2	34.0	47.9	22.1	33.6	44.3
R&D to net sales ratio (%)	11.9%	13.0%	14.0%	13.3%	13.8%	13.3%
Pharmaceuticals	20.4	31.5	44.5	20.5	31.3	41.0
(R&D to net sales ratio) (%)	18.2%	18.8%	19.4%	16.8%	17.2%	16.5%
Bio-Chemicals	1.5	2.2	3.2	1.5	2.3	3.3
Chemicals	0.2	0.2	0.2			
Other						

6. Trends in Capital Expenditure (Tangible fixed assets)

Billions of yen, rounded down

	t C illians of yen, rounded a							
		FY 2011 results		FY 2012	FY 2012 forecasts			
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January 1 to December 31		
Capital expenditure (Consolidated)	5.9	10.4	14.3	7.9	14.7	21.4		
Pharmaceuticals	2.8	5.1	6.5	4.0	7.3	10.9		
Bio-Chemicals	2.7	4.9	7.4	3.9	7.4	10.4		
Chemicals	0.3	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

7. 11011G5	in Depreciation i	-xpciioco		Billions of yen, rounded down			
			FY 2011 results		FY 2012	FY 2012 forecasts	
		January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January 1 to December 31
Depreciation (Consolidate	•	10.4	16.2	22.8	9.6	14.5	21.3
Pharmace	euticals	6.8	11.0	15.3	6.6	10.1	14.5
Bio-Chem	icals	2.6	4.2	6.4	2.9	4.4	6.7
Chemicals	3	0.9	0.9	0.9			
Other		0.0	0.0	0.0	0.0	0.0	0.0

8. Exchange rates

o. Exchange rates										
		FY 2011 results		FY 2012	FY 2012 forecasts					
	January 1 to June 30	January 1 to September 30	January 1 to December 31	January 1 to June 30	January 1 to September 30	January 1 to December 31				
US Dollar (¥/US\$)	82	81	80	80	79	81				
Euro (¥/Euro)	115	113	111	103	102	102				
GBP (¥/GBP)	132	130	128	126	125	124				

#### II. Consolidated Subsidiaries and Affiliates

(As of September 30, 2012)

					(As of September 30, 2012)																																
Segment	Туре	Region	Company name	Percentage owned (direct and indirect)	Principal business																																
		Japan	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 subsidiaries (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)																																
			Hematech-GAC Venture, LLC	51.0%	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 subsidiary		ProStrakan Limited	100.0%	Sales of pharmaceuticals (UK)																																
Pharmaceuticals	aceuticals		ProStrakan Pharma S.A.S	100.0%	Sales of pharmaceuticals (France)																																
		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)																																
I			ProStrakan Pharma B.V.	100.0%	Sales of pharmaceuticals (Netherlands)																																
I			ProStrakan S.r.l.	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)																																
											71010	ASIA .	ASIA "	Asia	nəld	, wid	710.0	Asia	Asia	Asia	, void					71014	Asia	, tota "	-  -					Asia	Asia "	Kyowa Hakko Kirin (Hong Kong) Co., Ltd.	100.0%
			Kyowa Hakko Kirin (Singapore) Pte. Ltd.	100.0%	Sales of pharmaceuticals (Singapore)																																
	Affiliate accounted by the equity method	Japan	FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	Development, manufacture and sale of biosimilar products																																
			Kyowa Hakko Bio Co., Ltd.	100.0%	Manufacture and sale of pharmaceutical and industrial raw materials, 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)																																
	Consolidated	The Americas	Kyowa Hakko U.S.A., Inc.	100.0%	Sale and import/export of fine chemicals including amino acids (US)																																
Bio-Chemicals	subsidiary		Kyowa Hakko Bio U.S. Holdings, Inc.	100.0%	Holding company for administration and management of US special companies (US)																																
		Furana	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)																																
		Asia	Kyowa Hakko (H.K.) Co., Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids (Hong Kong)																																
			Kyowa Hakko Bio Singapore Pte. Ltd.	100.0%	Sale and import/export of fine chemicals including amino acids (Singapore)																																
	Consolidated subsidiary		Chiyoda Kaihatsu Co., Ltd.	100.0%	Transportation, insurance, wholesale sales of food, etc.																																
Other	Affiliate accounted by the equity method	Japan	Japan Synthetic Alcohol Co., Ltd.	33.3%	Manufacture and sale of industrial use alcohol																																
		l .	to September 30, 2012)		l .																																

Notes: Changes to the scope of consolidation (January 1, 2012 to September 30, 2012)

Newly consolidated: 1 company: ProStrakan AB (\*1)

Removed: 1 company: Kyowa Hakko Kirin Italia S.r.l. (\*2)

<sup>\*1</sup> 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. As of June 1, 2012, Kyowa Hakko Kirin Italia Sr.I. was merged with ProStrakan Sr.I. and eliminated.

\*3. As of April 23, 2012, Kirin Kunpeng (China) Bio- Pharmaceutical Co., Ltd.changed its corporate name to Kyowa Hakko Kirin China Pharmaceutical Co., Ltd.

\*4. As of June 1, 2012, Jeil-Kirin Pharm. Inc. changed its corporate name to Kyowa Hakko Kirin Korea Co., Ltd.

# III. Net sales by division (Items and main products)

# 1. Kyowa Hakko Kirin

Billions of yen, rounded down

·	Billions of yen, rou								
	Fisc	cal 2011 results			Fiscal 2012 results		FY 2012 forecasts		
Pharmaceuticals division (non-consolidated)	January 1 to June 30 results	January 1 to September 30 results (A)	January 1 to December 31 results	January 1 to June 30 results	January 1 to September 30 results (B)	Change on January 1 to September 30, 2011 (B/A)	January 1 to December 31		
Pharmaceuticals division total	104.6	152.3	206.0	107.8	159.4	5%	213.9		
Indication / Product									
ESA formulation									
Nesp	25.4	40.4	56.4	26.8	41.0	2%	53.7		
ESA formulation									
Espo	2.7	4.0	5.3	1.9	2.9	-28%	4.0		
Nesp and Espo Total	(28.2)	(44.4)	(61.8)	(28.8)	(43.9)	(-1%)	(57.7		
Secondary hyperparathyroidism									
Regpara	5.3	8.2	11.5	6.2	9.5	16%	13.0		
Antiallergenic									
Allelock	18.1	22.2	29.1	16.1	21.8	-2%	29.1		
Antiallergenic									
Celtect	1.3	1.9	2.5	1.0	1.4	-26%	1.8		
Antiallergic eyedrops									
Patanol	8.6	9.8	11.4	6.9	8.5	-13%	10.1		
G-CSF									
Gran	6.7	10.5	14.8	6.4	9.8	-7%	13.4		
Cancer pain									
Fentos	1.2	2.0	3.1	2.0	3.2	57%	4.5		
Anticancer <b>5-FU</b>	1.5	2.3	3.1	1.4	2.1	-10%	2.7		
Anticancer	1.5	2.3	3.1	1.4	2.1	-10%	2.1		
Navelbine	0.8	1.3	1.7	0.6	0.9	-25%	1.2		
Cardiovascular	0.0	1.0		0.0	0.0	2070			
Coniel	9.6	14.3	19.7	8.5	12.5	-12%	17.2		
Cardiovascular (Hypertension)									
Coversyl	1.9	2.8	3.9	1.7	2.5	-10%	3.4		
Cardiovascular									
Inovan / Pre Dopa	1.3	2.0	2.8	1.1	1.7	-17%	2.4		
Antiepileptic	5.0	0.4	44.0	5.0	7.0	407	40.0		
Depakene Parkinson's disease	5.3	8.1	11.2	5.2	7.8	-4%	10.8		
Permax	1.1	1.6	2.1	0.8	1.2	-22%	1.7		
Gastrointestinal	1.1	1.0	۷.۱	0.6	1.2	-2270	1.7		
Nauzelin	2.3	3.3	4.8	2.2	3.2	-3%	4.7		
Inflammatory bowel disease					- :				
Asacol	1.1	1.9	2.8	1.8	2.8	45%	3.8		
Exports and Technology									
Licensing Revenue	11.4	17.7	22.3	17.9	26.7	51%	34.7		

2. ProStrakan Millions of GBP, rounded down

riostiakaii						Millions of GBP,	rounded down
		FY 2011 result	s		FY 2012 results		FY 2012 forecasts
Pharmaceuticals division	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30, 2012 (B)	Change on January to September 2011 (B/A)	January 1 to December 31
Net sales	48	78	105	61	92	18%	139
Chemotherapy-induced nausea and vomiting drug							
Sancuso	4	6	9	5	9	46%	16
Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain.  Abstral	12	20	27	16	24	21%	36
Replacement therapy with testosterone for male hypogonadism				-	24		
Tostran	2	4	5	2	4	8%	4
Prevention and treatment of post-operative nausea and vomiting (PONV).					_		_
Xomolix	4	6	8	4	6	-7%	9
Relief of pain associated with chronic anal fissures							
Rectogesic	4	6	9	4	7	4%	9
Osteoporosis drug							
Adcal-D3	11	17	24	12	19	6%	25
Others	8	16	20	14	21	34%	37
Gross profit	29	50	65	40	64	29%	101
Selling, general and administrative expenses	40	58	75	39	58	-1%	84
Operating income	(4.4)	(0)	(0)	4			47
(prior to consolidated adjustment)  Consolidated adjustment	(11)	(8)	(9)	(18)	(27)		17 (34
Operating income				(10)	(21)		(34
(after consolidated adjustment)  Notes:				(16)	(20)		(17

Sales ratio by region (January 1 to September 30, 2012)		Europe (excluding UK)	USA	Other	Total
	33.9%	42.6%	21.6%	1.9%	100.0%

3. Kyowa Hakko Bio Billions of yen, rounded down

S. Nyowa Harro Bio								
Bio-Chemicals division	FY 2011 results				FY 2012 forecasts			
(non-consolidated)	January 1 to June 30	January 1 to September 30 (A)	January 1 to December 31	January 1 to June 30	January 1 to September 30 (B)	Change on January to September 2011 (R/A)	January 1 to December 31	
Bio-Chemical division total	25.9	38.0	49.6	25.9	38.0	0%	52.1	
Pharmaceuticals / Industrial raw materials								
Amino acids	10.1	14.9	19.1	10.2	15.1	1%	20.6	
Nucleic acids and vitamins	2.7	4.0	5.2	2.5	3.8	-4%	5.2	
Other	3.8	5.4	7.2	3.7	5.4	-1%	6.6	
Healthcare products	4.7	7.0	9.3	4.7	7.1	1%	10.1	

Notes:

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

2. 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.

3. The sales ratio by region is as shown below.

## R&D Pipeline







# **KYOWA KIRIN**

			protein 41° sm Approved			A:	s of Oct 18th 2012		
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks		
Oncology	*	Granisetron Patch	5HT3 Serotonin Recpter Antagonist	Chemotheraphy induced Nausea and Vomiting	Approved in Taiwan Oct/2012 Filed in Asia	Solasia Pharma (ProStrakan)	Asia: Singapore, Malaysia and Hong Kong		
Nephrology	水	Cinacalcet Hydrochloride Oral	Calcium Receptor Agonist	Secondary Hyperparathyroidism	Filed in Asia	Licensed from NPS	Asia: Philippine, Malaysia, Thailand and China		
Nepi II Ology	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Pediatric Renal Anemia	Filed in Japan	Kirin- Amgen			
Central Nervous System	×	@KW-6002 lstradefylline Oral	Adenosine A <sub>2A</sub> Receptor Antagonist	Parkinson's Disease	Filed in USA	In-House			
Other	8	AMG531 Romiplostim	Thrombopoietin Receptor Agonist	Idiopathic (Immune) Thrombocytopenic	Filed in Japan  Approved in Taiwan Oct/2012	Kirin- Amgen			
	<b>**</b>	Injection Phase 1	I, Phase II	Purpura	330 23 12	, anger			
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks		
	xķ-	KW-2246 Fentanyl Citrate Sublingual Tablet	μ-Opioid Receptor Agonist	Cancer Pain	Phase III in Japan	Licensed from Orexo			
	8	KRN125 Pegfilgrastim Injection	Long-Acting Granulocyte Colony Stimulating Factor	Chemotherapy induced Febrile Neutropenia	Phase III in Japan	Kirin- Amgen			
	v.	©ARQ 197 Tivantinib	c-Met Inhibitor	Lung Cancer	Phase III in Japan, Korea and Taiwan	Licensed from			
	Oral					Gastric Cancer	Phase II in Japan and Korea	ArQule	
					Adult T-cell Leukemia/Lymphoma, Add-on Therapy (for Untreated Patients)	Phase II in Japan			
Oncology			mulizumab   Anti-CCD4	Peripheral T/NK-cell Lymphoma	Phase II in Japan	In-House			
	<b>Y</b>	KW-0761 Mogamulizumab Injection		Peripheral T-cell Lymphoma and Cutaneous T-cell Lymphoma	Phase I/II in USA		POTELLIGENT≎		
				Peripheral T-cell Lymphoma	Phase II in EU				
				Adult T-cell Leukemia/Lymphoma	Phase II in US and EU				
	χř	KRN1 493 Cinacalcet Hydrochloride Oral	Calcium Receptor Agonist	☆Hypercalcemia with Parathyroid Carcinoma or Intractable Primary Hyperparathyroidism	Phase II in Japan	Licensed from NPS			
	×ķ.	©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			
	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Phase II in China	Kirin- Amgen			
Vephrology	*	©RTA 402 Bardoxolone Methyl Oral	Antioxidant Inflammation Modulator	CKD in Patients with Type 2 Diabetes	Phase II in Japan	Licensed from Reata			
	Y	©KHK4563 Benralizumab Injection	Anti-IL-5 Receptor Humanized Antibody	Asthma	Phase II in Japan and Korea	In-House	Being Developed by Medlmmune as MEDI-563 Worldwide except in Japan and other Asian Countries POTELLIGENT*		
mmunology /Allergy	Y	@ASKP1240 Injection	Anti-CD40 Fully Human Antibody	Organ Transplant Rejection	Phase I in Japan Phase II in USA	- In-House	Jointly Developed with Astellas KM mouse		
	*	Z-206 Mesalazine Oral	pH Dependent Controlled Release Tablet	Crohn's Disease	Phase II in Japan	Licensed from Zeria Pharma.	Jointly Developed with Zeria Pharm		
Central Nervous System	*	KW-6485 Topiramate Oral	Antiepileptic Drug	Pediatric Epilepsy	Phase <b>Ⅲ</b> in Japan	Licensed from Janssen Pharmaceu tical K.K.			
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			

#### New Molecular Entity

Phase I

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Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
	水	@KW-2450 Oral	IGF-1 Receptor Signal Inhibitor	Cancer	Phase I/II in USA	In-House	
	Y	©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	水	©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
	水	©ARQ 197 Tivantinib Oral	c-Met Inhibitor	Hepatocellular Cancer	Phase I in Japan	Licensed from ArQule	
Immunology	Y	KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Asthma	Phase I in Japan	In-House	POTELLIGENT®
/Allergy	Y	©KHK4827 Injection	Anti-IL-17 Receptor Fully Human Antibody	Psoriasis	Phase I in Japan	Kirin- Amgen	
Other	Y	@KRN23 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemic Rickets/Osteomalacia (XLH)	Phase I/II in USA and Canada	In-House	KM mouse

Updated since Jul 17th, 2012 (Area, Stage, Filed, Approved, Launched etc.)

O New Molecular Entity

### Updated since Jul 17th, 2012 (Area, Stage, Filed, Approved, Launched etc.)

		Filed •	Approved	As of Oct 18th 2012			
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology	水	Granisetron Patch	5HT3 Serotonin Recpter Antagonist	Chemotheraphy induced Nausea and Vomiting	Approved in Taiwan Oct/2012	Solasia Pharma (ProStrakan)	Asia: Singapore, Malaysia and Hong Kong
Nephrology	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Pediatric Renal Anemia	Filed in Japan	Kirin- Amgen	
Other	8	AMG531 Romiplostim	Thrombopoietin Receptor Agonist	Idiopathic (Immune) Thrombocytopenic	Approved in Taiwan Oct/2012	Kirin- Amgen	

		Phase 1	I, Phase II				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology	Y	KW-0761 Mogamulizumab Injection	Anti-CCR4 Humanized Antibody	Adult T-cell Leukemia/Lymphoma	Phase II in US and EU	In-House	POTELLIGENT≎

		Ph	ase I				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Remarks
Oncology	ķ	©ARQ 197 Tivantinib Oral	c-Met Inhibitor	Hepatocellular Cancer	<u>Phase I</u> in Japan	Licensed from ArQule	

		Disco	ontinued				
Area		Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	In-House or Licensed	Reason
Nephrology	8	KRN321 Darbepoetin Alfa Injection	Long-Acting Erythropoiesis Stimulating Agent	Renal Anemia (on Dialysis)	Phase III in India	Kirin- Amgen	Reconsidered the product development portfolio based on change in business environment
Oncology	Y	KRN330 Injection	Anti-A33 Fully Human Antibody	Cancer	Phase I/Ia in USA	In-House	Revision for priority of product development portfolio in oncology area