

Results Presentation
Fiscal 2016 First Quarter
(January 1, 2016 – March 31, 2016)

Kyowa Hakko Kirin Co., Ltd.

**FY 2016 Q1 Highlights
Financial review**

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R & D review

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Q & A session

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities of the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, legal regulation risks, product defect risks, risks of changes to prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation.

In Q1 of FY2016, the Pharmaceuticals business saw a decline in sales and profits, and the Bio-Chemicals business saw a decline sales but an increase in profits. Despite a YoY decline in sales and profits on a consolidated basis, we are making steady progress towards H1 plans.

- In the Pharmaceuticals business, Japan sales increased ¥1.7 billion YoY due to steady sales of new products G-Lasta[®], NOURIAST[®], Dovobet[®] and Onglyza[®], and key product NESP[®].
- In the Pharmaceuticals business, overseas sales declined ¥2.0 billion YoY due to a decrease in technology out-licensing revenue, currency effects, and other factors.
- In the Pharmaceuticals business, R&D expenses increased ¥1.6 billion YoY due in part to the steady progress of late-stage development products.
- In the Bio-Chemicals business, profits increased ¥0.8 billion YoY due to steady growth in overseas sales of amino acids and Japan mail order sales and despite currency effect.

Financial review

Summary of 2016 Q1 results (consolidated)

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Despite growth in domestic pharmaceutical products, especially new products, sales and profits declined on a consolidated basis due to a decline in technology out-licensing revenue and increased R&D and other expenses.

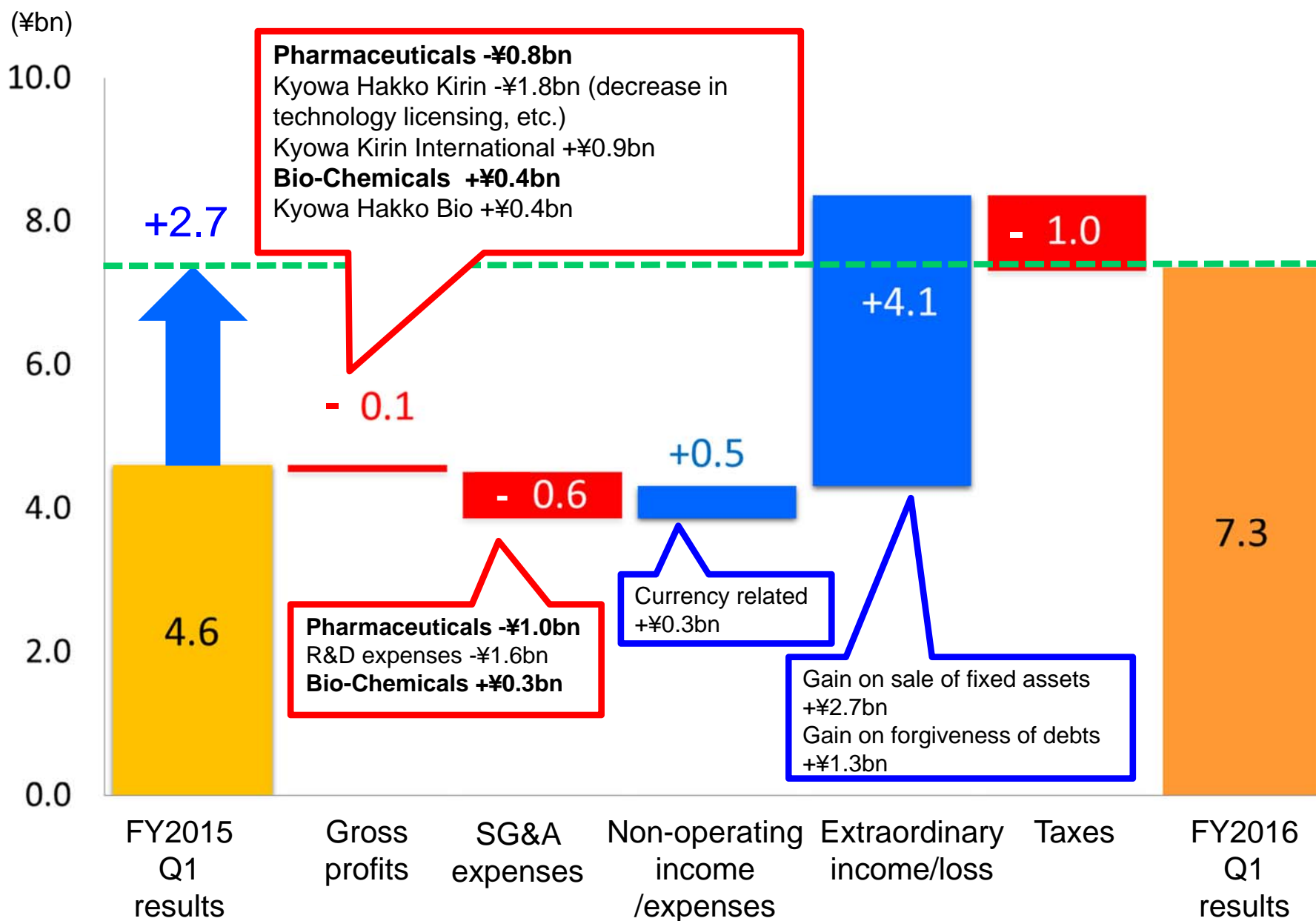
(Unit: ¥bn)	FY2015 Q1 results	FY2016 Q1 results	Change
Net sales	89.5	88.4	-1.1 (-1%)
Operating income <i>Operating margin</i>	9.3 10.4%	8.5 9.6%	-0.8 (-9%)
Ordinary income	8.0	7.8	-0.2 (-3%)
Net profit	4.6	7.3	+2.7 (+61%)

(Profits stated after amortization of goodwill. Figures rounded down)

- ✓ Ordinary income declined due to a decrease in operating income
- ✓ While ordinary income declined, net profit increased due to an increase in extraordinary income from gains on sale of fixed assets

Summary of FY2016 Q1 consolidated results: Analysis of YoY profit changes

2016 Q1 net profit: Analysis of YoY changes



Summary of FY2016 Q1 financial results by segment

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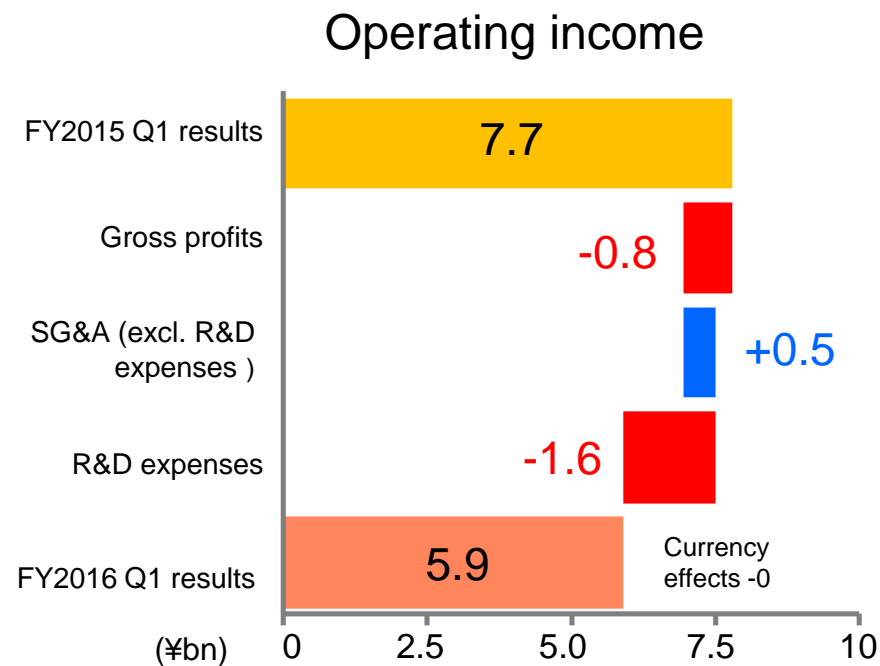
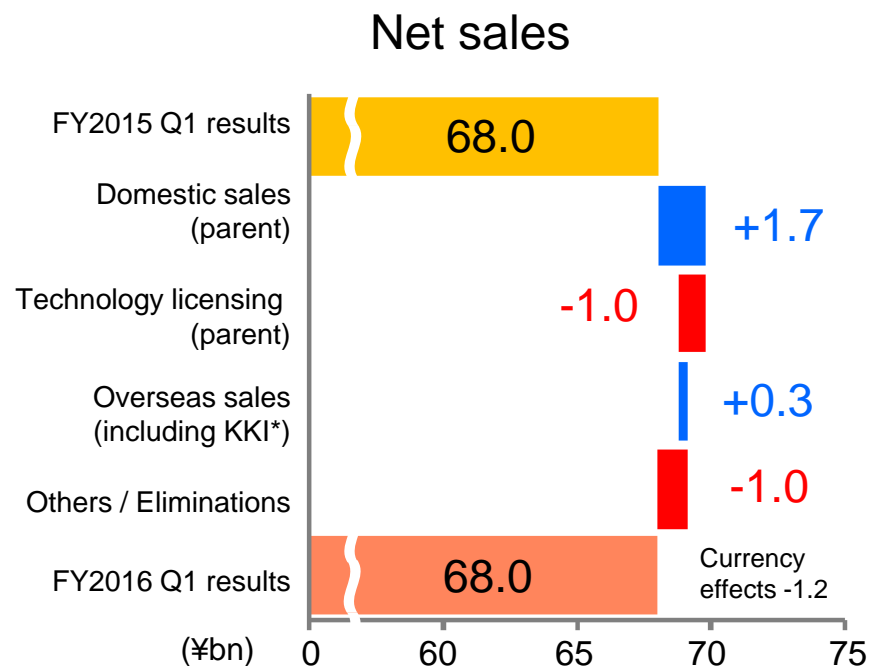
In the Pharmaceuticals business, despite growth in domestic products, especially new products, sales and profits declined due to a fall in technology out-licensing revenue.

In the Bio-Chemicals business, despite ongoing yen weakness, sales declined but profits increased due to growth in amino acids overseas.

(Unit : bn)		FY2015 Q1 results	FY2016 Q1 results	Change
Pharmaceuticals business	Net sales	68.0	68.0	-0.0 (-0%)
	Operating income <i>Operating margin</i>	7.7 11.4%	5.9 8.7%	-1.8 (-24%)
Bio-Chemicals business	Net sales	22.1	21.2	-0.9 (-4%)
	Operating income <i>Operating margin</i>	1.4 6.6%	2.3 10.9%	0.8 (+59%)

(Profits stated after amortization of goodwill. Figures rounded down)

Pharmaceuticals business: FY2016 Q1 Analysis of YoY changes



Net sales (-¥0.0bn)

- Domestic pharmaceutical products (+¥1.7bn):
 - Key product NESP[®] had strong sales, and new products G-Lasta[®] and NOURIAST[®] grew steadily.
 - Sales of long-term prescription products such as ALLELOCK[®] decreased due to penetration of generics.
- Technology licensing, etc. (-¥1.0bn): Currency effects -¥0.0bn
 - Decrease in royalties, etc.
- Overseas sales (+¥0.3bn): Currency effects -¥1.1bn
 - KKI* (+¥0.4bn): growth of Abstral and PecFent, etc.

Operating income (-¥1.8bn)

- Gross profits (-¥0.8bn): Currency effects -¥0.8bn
 - Decrease in royalties, etc.
- SG&A (+¥0.5bn): Currency effects +¥0.6bn
 - Yen strengthening, etc.
- R&D expenses (-¥1.6bn): Currency effects +¥0.1bn
 - Increase in expenses for late-stage development products in Japan.
 - Increase in overseas R&D expenses, etc.

* On February 22, 2016, ProStrakan Group plc's company name was changed to Kyowa Kirin International plc (KKI).

Pharmaceuticals business:

Domestic sales of key products

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Sales of domestic pharmaceutical products increased YoY due to market penetration of new products and growth of key products such as NESP®

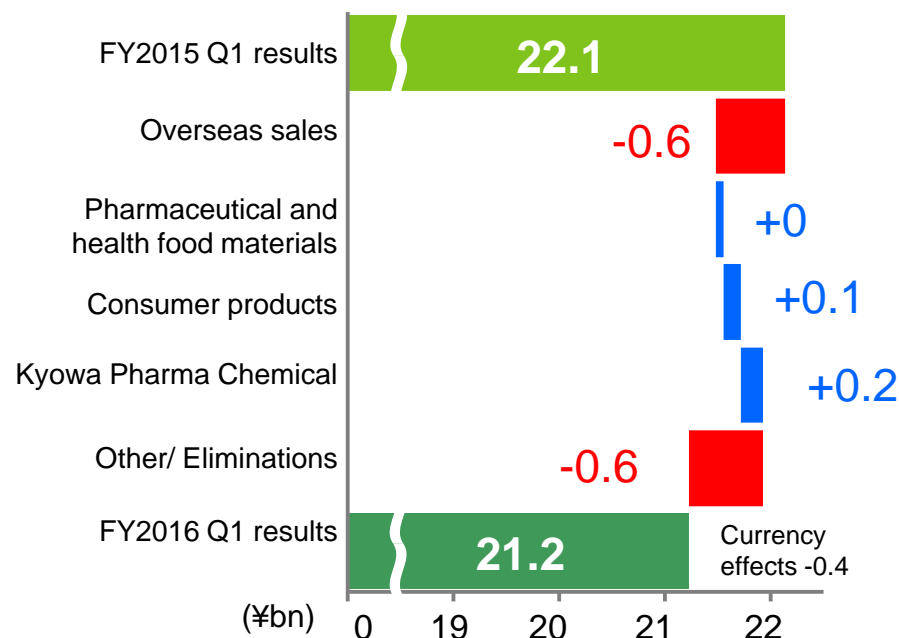
Product name, other information	FY2015 Q1 results	FY2016 Q1 results	Change	Reason for change	FY2016 1H forecast	Rate of achievement ¹
NESP®	12.3	13.3	1.0 (+9%)	(+) Steady growth of the market	26.8	50%
REGPARA®	3.9	4.3	0.4 (+10%)	(+) Steady penetration of the market	9.1	47%
ALLELOCK®	7.8	6.8	-0.9 (-12%)	(-) Market penetration of generics	11.0	62%
Patanol®	7.4	7.3	-0.1 (-2%)	(-) Market penetration of competitors	9.2	79%
G-Lasta®	1.4	3.6	2.2 (+159%)	(+) Steady penetration of the market	6.9	53%
NOURIAST®	0.9	1.4	0.4 (+51%)	(+) Steady penetration of the market	3.2	46%
Technology out-licensing	1.7	0.5	-1.1 (-70%)	(-) Decrease in royalties	2.0	25%

¹Rate of progress compared to 2016 H1 sales forecasts (as of January 29, 2016)

(Unit: ¥bn, figures rounded down)

Bio-Chemicals business: FY2016 Q1: Analysis of YoY profit

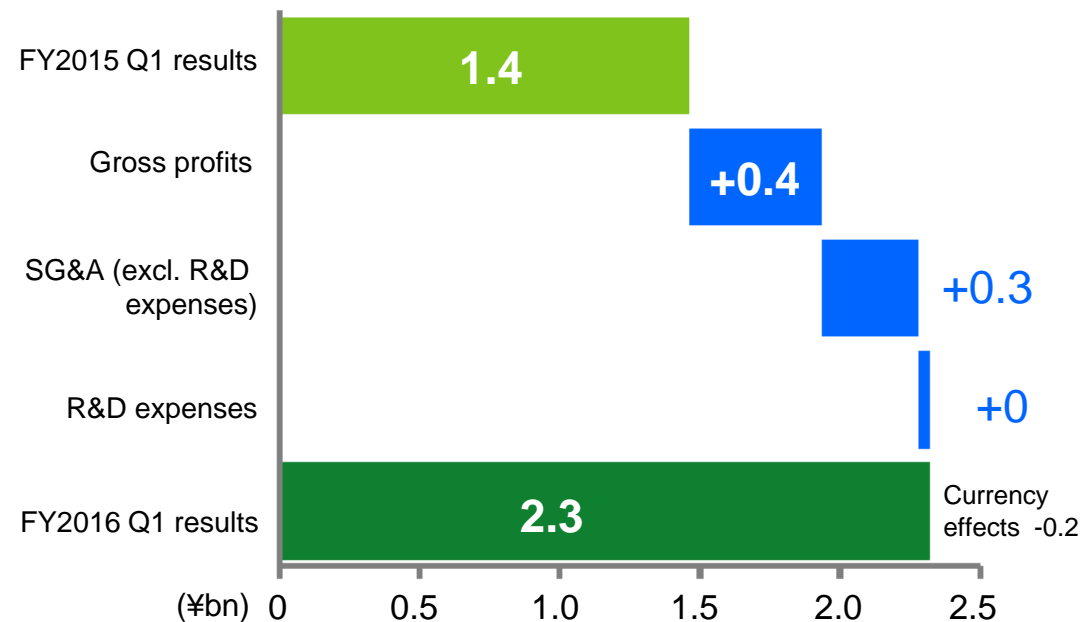
Net sales



Net sales (-¥0.9bn)

- Overseas sales (-¥0.6bn): Currency effects -¥0.4bn
 - U.S. (+¥0.3bn): Currency effects (-¥0.0bn), growth in health-food-use amino acids, infusion-use amino acids, etc.
 - Europe (-¥0.8bn): Currency effects (-¥0.2bn), effects from the May 2015 transfer of cosmetics raw materials business.
 - Asia and others (-¥0.1bn): Currency effects (-¥0.0bn), effects from customer production adjustments in industrial-use amino acids, etc.
- Pharma / health-food use (+¥0bn):
- Mail order sales, etc. (+¥0.1bn): Mail order sales were strong.
- Kyowa Pharma Chemical (+¥0.2bn): Growth in active pharmaceutical ingredients (APIs), etc.

Operating income



Operating income (-¥0.8bn)

- Gross profit (+¥0.4bn): Currency effects -¥0.2bn
 - Positive factors were particularly strong performance in U.S., growth of mail order sales, temporary improvements in manufacturing costs due to high operation rate of some products, etc.
 - Negative factors were currency effects of the strong yen.
- SG&A (+¥0.3bn): Currency effects +¥0.0bn
 - Decrease in sales promotion costs for mail order sales. (sales promotion costs increased temporarily in 2015 Q1)

R&D review

Overseas:

- **Initiation of Phase 1/2 trials of Nivolumab (Bristol-Myers Squibb) in combination with KW-0761 targeting solid tumors (February, U.S.)**

Note: Listed events were completed between Jan. 23, 2016 and Apr. 20, 2016.

KW-0761 (hematological cancer)¹

Indication		Country/region	Development stage (Scheduled trial completion date)			Estimated enrollment
			Phase 2	Phase 3	Application	
ATL	Relapsed/refractory	U.S., Europe, others ²	(2016/11)			70 ⁴
CTCL	Relapsed/refractory	U.S., Europe, Japan, others ²		(2017/2)		317 ⁵

Annual incidence per disease: U.S. CTCL: approx. 1,500³ patients

¹ Launched in Japan (brand name POTELIGEO®)

² CCR4 not included in selection criteria

³ SEER Data (2001-2007)

ClinialTrials.gov identifier:

⁴ NCT01626664; ⁵ NCT01728805

KW-0761 (solid tumor)

Indication	Country/ region	Concomitant Drug	Development stage (Scheduled trial completion date)	Partner	Estimated enrollment
			Phase 1		
Solid tumor	U.S.	Durvalumab or Tremelimumab	(2016/6)	AstraZeneca	108 ¹
	U.S.	PF-05082566	(2018/3)	Pfizer	70 ²
	Japan	Nivolumab	(2017/10)	ONO PHARMACEUTICAL Bristol-Myers Squibb	108 ³
	U.S.	Nivolumab	(2017/8)	Bristol-Myers Squibb	187 ⁴
	U.S.	Docetaxel	(2016/2)	-	27 ⁵

ClinicalTrials.gov identifier:

¹ NCT02301130; ² NCT02444793; ³ NCT02476123; ⁴ NCT02705105; ⁵ NCT02358473

KW-6002¹

Indication	Country/region	Development stage (Scheduled trial completion date)		Estimated enrollment
		Phase 3	Application	
Parkinson's disease	North America Europe, Others	(2016/4)		609 ⁴

Patient numbers: Japan: approx. 140,000², U.S.: approx. 570,000³

¹ Launched in Japan (brand name: NOURIAST®)

² Ministry of Health, Labour and Welfare: 2011 Patient survey (illness classification)

³ Study by Decision Resources

ClinialTrials.gov identifier:

⁴ NCT01968031

KRN23

Indication	Country/region	Development stage (Scheduled trial completion date)		Partner	Estimated enrollment
		Phase 2	Phase 3		
XLH	Pediatric	U.S., Europe	(2017/3)	Ultragenyx Pharmaceutical (U.S., Europe)	50 ⁴
	Adult	U.S.	(2016/9)		25 ⁵
		NA., Europe Japan, Korea	(2017/3)		120 ⁶
		NA., Europe Japan, Korea	(2017/1)		10 ⁷
TIO/ENS	U.S.	(2016/9)	6 ⁸		

Estimated no. of patients: XLH Japan: approx. 5,000¹ (adult), approx. 1,000¹ (pediatric)
 U.S.: approx. 12,000¹ (adult), approx. 3,000¹ (pediatric)
 TIO/ENS Japan: approx. 30² patients, U.S. approx. 500 – 1,000³

¹ Estimate based on reported prevalence of 1 in 20,000 people

² 2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms

³ Survey by Ultragenyx Pharmaceutical

ClinicalTrials.gov identifier:

⁴ NCT02163577; ⁵ NCT02312687;

⁶ NCT02526160; ⁷ NCT02537431;

⁸ NCT02304367

ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
CTCL	Cutaneous T-Cell Lymphoma
ENS	Epidermal Nevus Syndrome
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

Appendix

Development code	Reference bio medical product		Country/region	Development stage		
	Generic name	Brand name		Phase 1	Phase 2	Phase 3
FKB327	Adalimumab	HUMIRA	U.S., others			1
FKB238	Bevacizumab	Avastin	United Kingdom	2		
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product		

Biosimilar pharmaceutical products are developed by *FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.*

ClinialTrials.gov identifier: ¹ NCT02260791

² Development is currently conducted by Centus Biotherapeutics Limited.

Development progress with outlicensed compounds

Name	Partner	Phase			Filing	Remarks
		I	II	III		
Tivozanib	AVEO				EU Russia	Advanced Renal Cell Cancer (VEGF receptor inhibitor) (KRN951)
Benralizumab (MEDI-563)	AstraZeneca /MedImmune					Asthma (Anti-IL-5R antibody) (KHK4563)
						COPD POTELLIGEN T [®]
KRN5500	Midatech Pharma US					Peripheral neuropathy
RGI-2001	REGiMMUNE	Phase 1/2				Immunosuppressive

(as of April 20, 2016)

Period average rate

Average exchange rate	2015 Q1 Results	2016 Q1 Results	Change	FY2016 H1 Forecast
¥/\$	¥119	¥117	-¥2	¥119
¥/€	¥138	¥128	-¥10	¥137
¥/£	¥183	¥169	-¥14	¥187

FY2016 Q1 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	-¥0.0bn	+¥0.0bn
	€	-¥0.0bn	+¥0.0bn
	£	-¥0.8bn	-¥0.0bn
Bio-Chemicals business	\$	-¥0.0bn	-¥0.0bn
	€	-¥0.2bn	-¥0.1bn
	£	-	-

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The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

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