

Results Presentation

Fiscal 2015 First Quarter

(January 1, 2015 – March 31, 2015)

Kyowa Hakko Kirin Co., Ltd.

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.

FY2015 Q1 Highlights

**In Q1 of the final year of the medium-term business plan, sales increased and profits declined in the Pharmaceuticals business, while sales and profits declined in the Bio-Chemicals business
Made steady progress with FY2015 H1 plan on a consolidated basis**

- In the Pharmaceuticals business, despite the impact of the drug price revision in April of the previous year, new products G-Lasta[®], Dovobet[®], Onglyza[®], and NOURIAST[®] progressed steadily and sales of domestic pharmaceutical products increased by ¥1 billion year on year
- In the Pharmaceuticals business, overseas late-stage development products progressed steadily and R&D costs increased by ¥1.7 billion year on year
- In the Bio-Chemicals business sales and profits declined due to reduced shipments of some pharmaceutical products to China, reflecting concentrated shipments in the previous year, and inventory adjustments by major domestic API customers

Financial review

Summary of 2015 Q1 results YoY

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Performance was steady due to the effect of the consolidation of Archimedes, the growth of domestic and new products, and other factors. However, while sales increased, profit declined due to an increase in development costs of late-stage development products, and other factors

(Unit: ¥bn)	FY2014 Q1 results	FY2015 Q1 results	Change
Net sales	86.0	89.5	+3.5 (+4%)
Operating income <i>Operating margin</i>	12.4 14.5%	9.3 10.4%	-3.1 (-25%)
Ordinary income	12.0	8.0	-3.9 (-33%)
Net income	6.3	4.6	-1.7 (-27%)

✓ The decline in ordinary income and net income was due to lower operating income, an increase in losses of equity accounted affiliates, and other factors

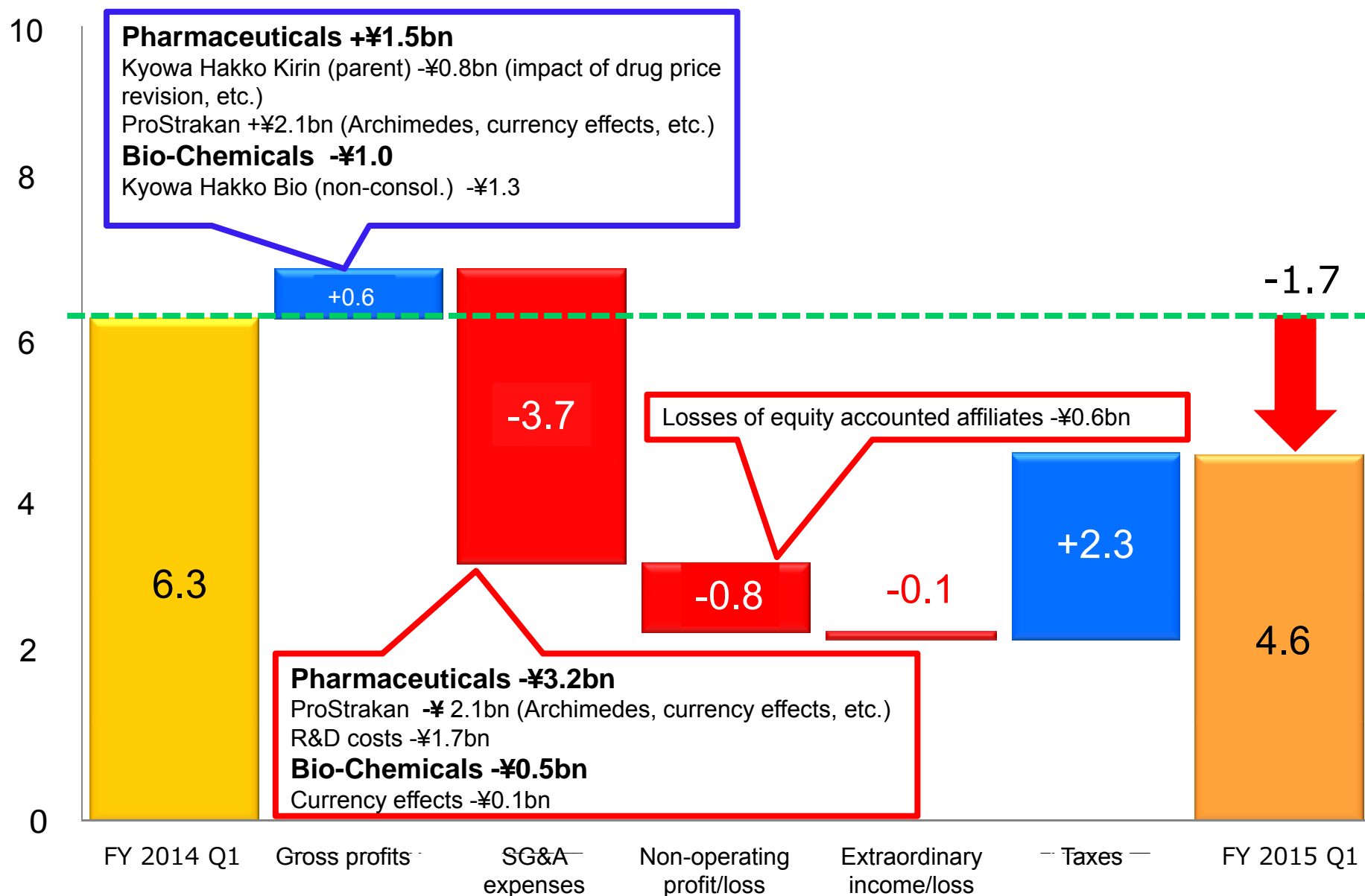
Summary of FY2015 Q1 consolidated results:

Analysis of YoY profit changes

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(¥bn)

Q1 net income: Analysis of YoY changes



Summary of FY2015 Q1 financial results by segment

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In the Pharmaceuticals business, sales increased due to growth in new products* and other factors, but profit declined due to an increase in R&D expenses
In the Bio-Chemicals business, sales and profits declined due to a decrease in shipments reflecting concentrated shipments of some overseas APIs in the previous year and inventory adjustments by major domestic API customers

(Unit: ¥bn)		FY2014 Q1 results	FY2015 Q1 results	Change
Pharmaceuticals business	Net sales	63.1	68.0	4.8 (+8%)
	Operating income Operating margin	9.4 14.9%	7.7 11.4%	-1.6 (-17%)
Bio-Chemicals business	Net sales	23.5	22.1	-1.4 (-6%)
	Operating income Operating margin	3.0 12.9%	1.4 6.6%	-1.5 (-52%)

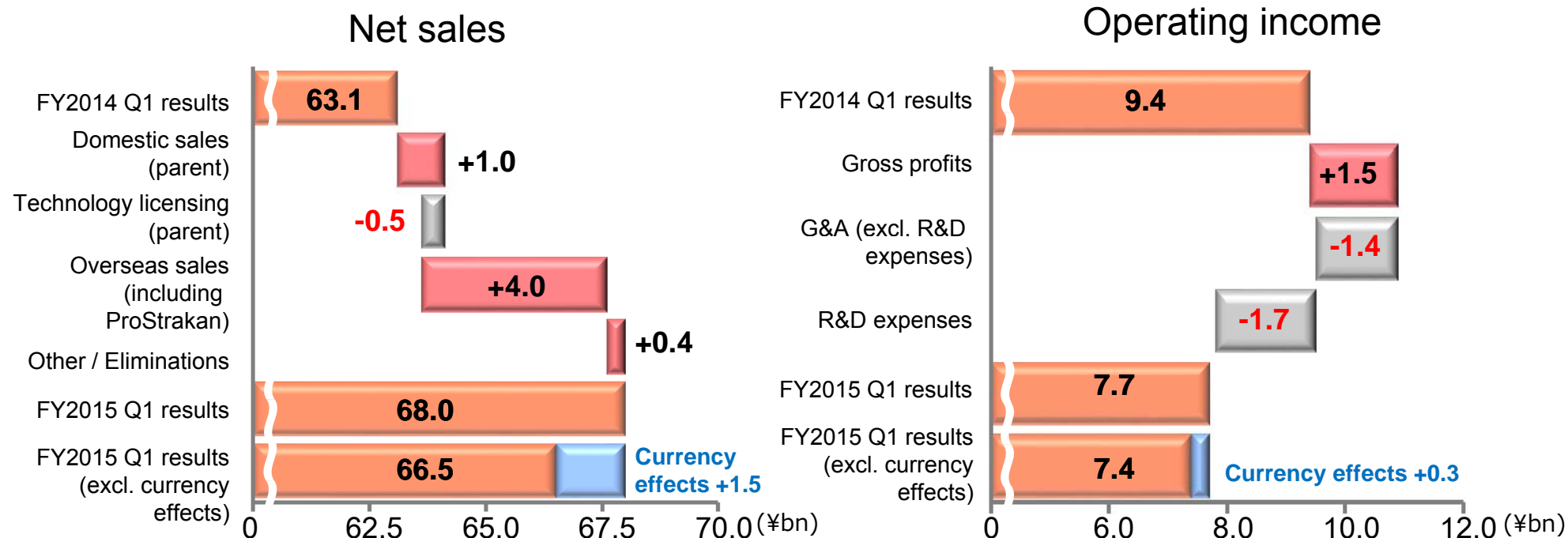
(Profits stated after amortization of goodwill. Figures rounded down)

*New products: G-Lasta®, Dovobet®, NOURIAST®, Onglyza®
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Pharmaceuticals business:

FY2015 Q1: Analysis of YoY profit changes

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Net sales (+¥4.8bn):

- Domestic pharmaceutical products (+¥1.0bn):
 - Products (shipments): G-Lasta® +¥1.4bn, Dovobet® +¥0.9bn, Onglyza® +¥0.8bn, NOURIAST® +¥0.6bn, ALLELOCK® -¥0.6bn, GRAN® -¥0.7bn, CONIEL® -¥0.8bn
 - NESP®: Despite the impact of drug price revision, sales volume increased and net sales were mostly unchanged due to additional indication for Anemia with Myelodysplastic. Our share was maintained.
- Technology licensing, etc. (-¥0.5bn): Currency effects +¥0.2bn
 - Accumulation of minor factors
- Overseas sales (+¥4.0bn): Currency effects +¥1.0bn
 - Effects of ProStrakan's consolidation of Archimedes, etc. +¥3.2bn

Operating income (-¥1.6bn)

- Gross profits (+¥1.5bn): Currency effects +¥1.3bn
 - The decline in profits due to drug price revision in the previous year was offset by growth in domestic products (in particular new products such as G-Lasta®) and the effect of ProStrakan's consolidation of Archimedes.
- SG&A (-¥1.4bn): Currency effects -¥0.5bn
 - Despite a reduction in SG&A at Kyowa Hakko Kirin (parent) and others, ProStrakan's consolidation of Archimedes led to an increase in costs.
- R&D expenses (-¥1.7bn): Currency effects -¥0.4bn
 - Increase in costs of overseas late-stage development products and other factors.

Pharmaceuticals business:

Domestic sales of key products

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While sales were affected by drug price revisions in the previous year and the market penetration of generics, sales increased year on year as a result of the market penetration of new products and other factors

Product name, other information	FY2014 Q1 results	FY2015 Q1 results	Change	Reason for change	FY2015 forecast	Rate of achievement ¹
NESP [®]	12.1	12.3	+0.1 (+1%)	Effect of additional indication for MDS ² (+) Drug price revisions in the previous year (-)	26.2	47%
REGPARA [®]	4.5	3.9	-0.6 (-15%)	Impacted by lower shipments following bulk buying in previous year ahead of drug price revision.	8.6	45%
ALLELOCK [®]	8.4	7.8	-0.6 (-8%)	Increase in airborne pollen count (+) Drug price revisions in the previous year, market penetration of generics (-)	11.1	70%
Patanol [®]	7.1	7.4	+0.3 (+5%)	Increase in airborne pollen count	8.5	88%
G-Lasta [®]	-	1.4	+1.4 (-)	Steady penetration of G-CSF drug market following launch on November 27, 2014	2.5	55%
NOURIAST [®]	0.2	0.9	+0.6 (+250%)	Steady penetration of antiparkinsonian drug market	2.4	40%
Technology out- licensing	2.0	1.7	-0.3 (-18%)		4.6	36%

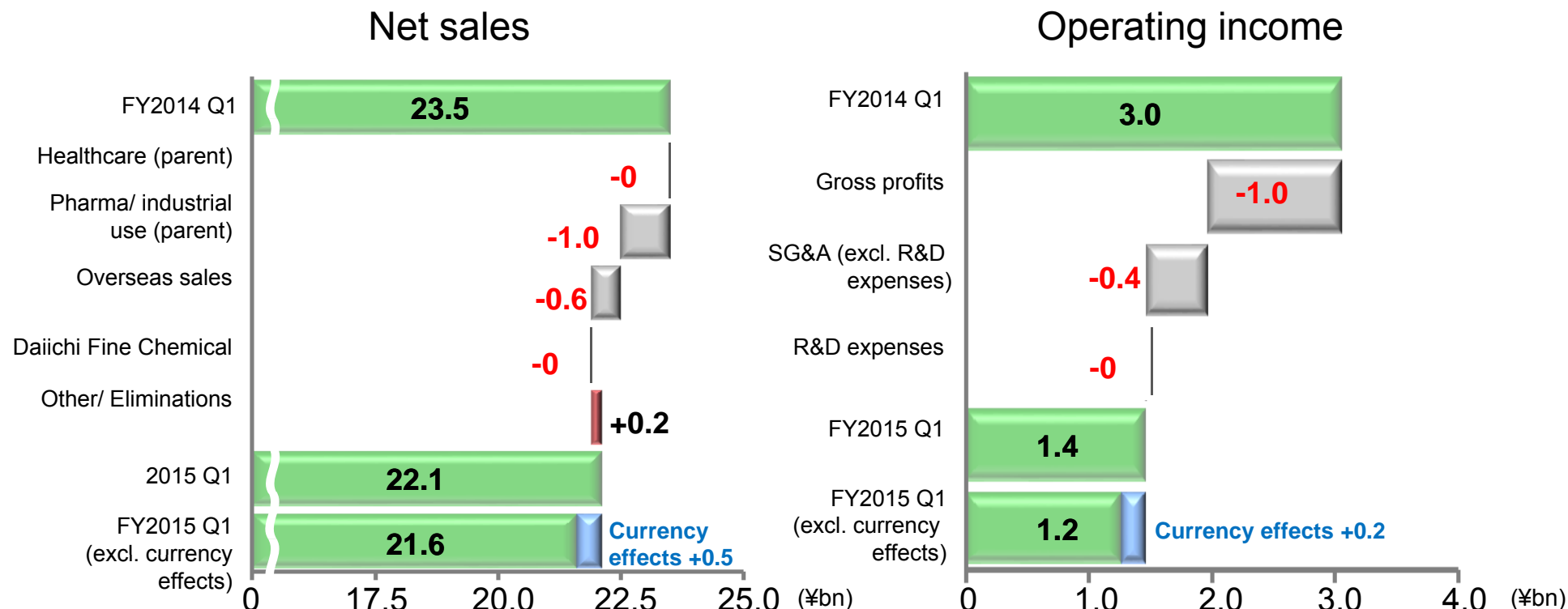
¹Rate of progress compared to 2015 H1 sales forecasts (as of January 30, 2015)

²Myelodysplastic Syndrome

Bio-Chemicals business:

FY2015 Q1: Analysis of YoY profit changes

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Net sales (-¥1.4bn)

- Healthcare (-¥0.0bn):
 - Mail order sales were strong and increased from the previous year
 - Raw materials/OEM: Sales declined due to a decrease in shipments following concentrated shipments the previous year due to a confluence of new product launches by key customers
- Pharma/industrial use (-¥1.0bn):
 - Inventory adjustments by major API customers, etc.
- Overseas sales (-¥0.6bn): Currency effects (+¥0.5bn)
 - U.S. (+¥0.4bn): Currency effects (+¥0.3bn), Sales increased as inventory adjustments by some infusion-use amino acid customers due to falling sales were offset by growth in health-food-use amino acids
 - Europe (+¥0.1): Currency effects (-¥0.0bn), Influence of correction in demand for amino acids for infusion-use by some customers, etc.
 - Asia and others (-¥1.2): Currency effects (-¥0.3bn), Sales declined due to a decrease in shipments reflecting concentrated shipments by some APIs to China in the previous year driven by a renewal of import licenses, and other factors

Operating income (-¥1.5bn)

- Gross profits (-¥1.0bn): Currency effects (+¥0.3bn)
 - Sales declined due to a decrease in shipments reflecting concentrated shipments of some APIs to China in the previous year
 - Sales declined due to inventory adjustments by major domestic API customers
- SG&A (-¥0.4bn): Currency effects (-¥0.1bn)
 - Investment in systems for mail order.

R & D review

Domestic:

- ☒ Initiation of Phase 2 trials of RTA 402 targeting chronic kidney disease with type-2 diabetes (March)
- ☐ Initiation of Phase 1 trials of Nivolumab (ONO PHARMACEUTICAL CO., LTD/Bristol-Myers Squibb) in combination with KW-0761 (brand name in Japan: POTELIGEO®) targeting solid tumors
- ☐ Application seeking approval for marketing authorization of fully human anti-IL-17 receptor antibody KHK4827
- ☐ Approval for marketing authorization of recombinant human antithrombin drug KW-3357 (application filed July 2014)

Overseas:

- ☐ Initiation of Phase 1 trials of PF-05082566 (Pfizer) in combination with KW-0761 (brand name in Japan: POTELIGEO®) targeting solid tumors

KW-0761 (hematological cancer)

Indication		Country/ region	Development stage (Scheduled trial completion date)				Estimated enrollment
			Phase 2	Phase 3	Application	Approval	
ATL	Untreated	Japan				2014/12 ²	
	Relapsed/ refractory	Japan				2012/3 ²	
		U.S., Europe, others ¹	(2015/8)				70 ⁶
PTCL	Relapsed/ refractory	Japan				2014/3 ²	
		Europe	(2014/10)				35 ⁷
CTCL	Relapsed/ refractory	Japan				2014/3 ²	
		U.S., Europe, Japan, others ¹		(2016/3)			317 ⁸

Annual incidence per disease Japan ATL: approx. 1,100³ patients; PTCL/CTCL: approx. 2,000⁴ patients
U.S. PTCL: approx. 3,600⁵ patients; CTCL: approx. 1,500⁵ patients

¹CCR4 not included in selection criteria

²Launched in Japan (brand name POTELIGEO®)

³Survey of, and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report by Kazunari Yamaguchi (March 2010)

⁴Ministry of Health, Labour and Welfare: Patient survey in October 2011 (chart 97), by basic illness

⁵SEER Data (2001-2007)

ClinicalTrials.gov identifier:

⁶NCT01626664; ⁷NCT01611142; ⁸NCT01728805

KW-0761 (solid tumor)

Indication	Country/ region	Combination Drug	Development stage (Scheduled trial completion date)	Partner	Estimated enrollment
			Phase 1		
Solid tumor	U.S.	MEDI4736 or Tremelimumab	(2016/6)	AstraZeneca	108 ¹
	To be determined	PF-05082566	To be determined	Pfizer	—
	To be determined	Nivolumab	To be determined	ONO PHARMACEUTICAL CO., LTD. Bristol-Meyers Squibb	—
	U.S.	Docetaxel	(2016/2)	—	27 ²

ClinicalTrials.gov identifier:

¹NCT02301130; ²NCT02358473

KW-6002

Indication	Country/ region	Development stage (Scheduled trial completion date)				Estimated enrollment
		Phase 2	Phase 3	Application	Approval	
Parkinson's disease	Japan				2013/3 ¹	609 ⁴
	North America, Europe, others		(2016/2)			

Estimated no. of patients Japan: approx. 140,000²
U.S.: approx. 570,000³

¹Launched in Japan (brand name: NOURIAST®)

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

³Study by Decision Resources

ClinialTrials.gov identifier:

⁴NCT01968031

KRN23

Indication	Country/ region	Development stage (Scheduled completion date of trial)		Partner	Estimated enrollment
		Phase 1	Phase 2		
XLH	Pediatric	U.S., Europe		Ultragenyx Pharmaceutical (U.S., Europe)	30 ³
	Adult	U.S.			25 ⁴
		Japan, Korea	(not disclosed)		15 ⁵

Estimated no. of patients

Japan: approx. 5,000¹ adult patients
approx. 1,000¹ pediatric patients

U.S.: approx. 12,000¹ adult patients
approx. 3,000¹ pediatric patients

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

²2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
ClinicalTrials.gov identifier:

³NCT02163577; ⁴NCT02312687;

⁵NCT02181764

Biosimilar pharmaceutical products development update

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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			
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product		

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

ClinialTrials.gov identifier: ¹NCT02260791

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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.

If you have any inquiries regarding this presentation please call:
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APIs	Active Pharmaceutical Ingredients
ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
CTCL	Cutaneous T-Cell Lymphoma
CTLA-4	Cytotoxic T-Lymphocyte-Associated protein 4
G-CSF	Granulocyte - Colony Stimulating Factor
MDS	Myelodysplastic Syndrome
MHC	Major Histocompatibility Complex
PD-1	Programmed Death -1
PD-L1	Programmed Death - Ligand 1
TCR	T cell receptor
T reg	Regulatory T cell
PTCL	Peripheral T-Cell Lymphoma
XLH	X-linked Hypophosphatemic Rickets

APPENDIX

Period average rate

Average exchange rate	FY2014 Q1 Results	2015 Q1 Results	Change	<i>FY2015 Forecast</i>
¥/\$	¥103	¥119	+¥16	¥109
¥/€	¥141	¥138	-¥3	¥139
¥/£	¥171	¥183	+¥12	¥178

FY2015 Q1 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	\$	+¥0.4bn	+¥0.0bn
	€	-¥0.0bn	-¥0.0bn
	£	+¥0.6bn	+¥0.0bn
Bio-Chemicals business	\$	+¥0.6bn	+¥0.3bn
	€	-¥0.0bn	-¥0.0bn
	£	-	-

Development progress with outlicensed compounds

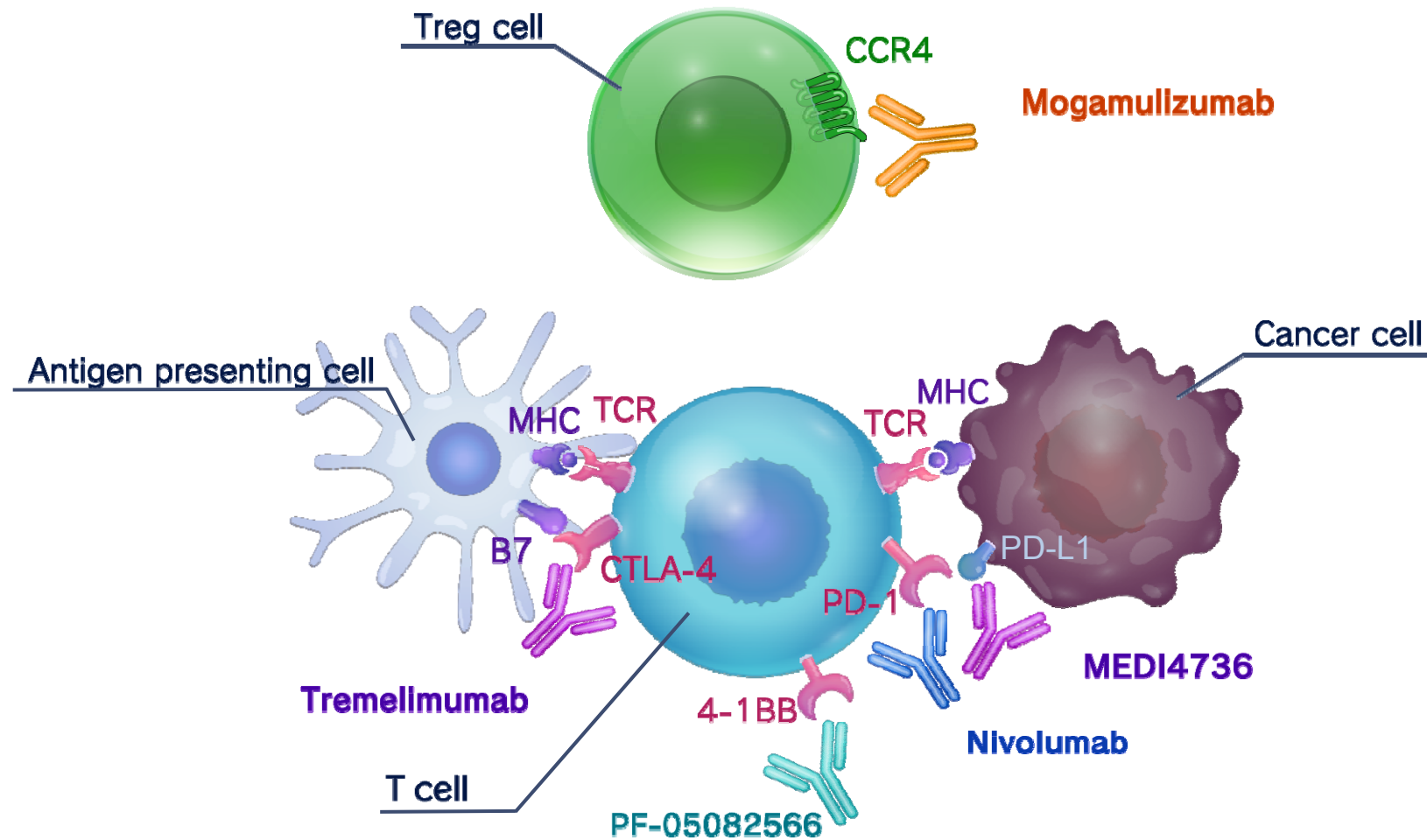
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Name	Partner	Phase			Remarks
		I	II	III	
Tivozanib	AVEO				Cancer (VEGF receptor inhibitor) (KRN951)
Benralizumab (MEDI-563)	AstraZeneca /MedImmune				Asthma (Anti-IL-5R antibody) (KHK4563) POTELLIGENT®
					COPD
KRN5500	DARA				Peripheral neuropathy
RGI-2001	REGiMMUNE	Phase1/2			Immunosuppressive
SAR252067	Sanofi				Ulcerative colitis and Crohn's disease (anti-LIGHT antibody)

(as of April 21st, 2015)

Appendix : Key antibody targets in cancer immunotherapy

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Topic: Completion of Kyowa Hakko Bio plant in Thailand

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High-value-added amino acids market: pharmaceuticals, medical and healthcare

- ✓ High global growth expected to continue, primarily overseas
- ✓ Rapid market expansion in near future associated with, in particular, population increase in Asia, economic growth, and greater health consciousness

Seize business opportunities created by market growth, strengthen production capacity and increase production bases to reduce risk of currency exchange fluctuations

Thai subsidiary completed high-value-added amino acid production plant

★ Overview of amino acids production plant ★

- Rayong province, Thailand
- Use: Manufacture of amino acids for infusion, medical food, and healthcare use
- Annual production capacity: 2200T
- Start of commercial production: Oct. 2015
- Total investment: Approx. ¥10.6bn (includes construction, land, and opening expenses)



◆ Overview of new company ◆

- THAI KYOWA BIOTECHNOLOGIES CO., LTD.
- 100% subsidiary of Kyowa Hakko Bio

Installation of latest production facility close to the market in an area rich in resources

Manufacture of high-quality amino acids through sophisticated technology and quality control

High-quality, consistent and stable supply helps to increase our customers' satisfaction and improve the lives of people using our products

Q & A session
