Conference call materials

KYOWA KIRIN

Results Presentation

Fiscal 2015 Third Quarter

(January 1, 2015 – September 30, 2015)

Kyowa Hakko Kirin Co., Ltd.

October 28, 2015

Forward-looking statements

KYOWA KIRIN

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.

Agenda

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FY 2015 Q3 Highlights

Kazuyoshi Tachibana, Managing Executive Officer

Financial review

Kazuyoshi Tachibana, Managing Executive Officer

R & D review

Yoichi Sato, Managing Executive Officer,
Vice President, Head of R&D Division

Q & A session

FY 2015 Q3 Highlights

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In FY2015 Q3, the Pharmaceuticals business and the Bio-Chemicals business both saw an increase in sales and profits resulting in increased sales and profits on a consolidated basis and steady progress in line with full-year plans

- In the Pharmaceuticals business, new products G-Lasta®, Dovobet®, Onglyza®, and NOURIAST® progressed steadily, and Japan sales increased year on year to ¥13.3 billion
- In the Pharmaceuticals business, overseas pharmaceuticals sales increased year on year to ¥11.5 billion due to growth in sales by sales subsidiaries in Europe and Asia
- In the Bio-Chemicals business, sales increased ¥4.3 billion YoY due to foreign currency effects and growth in overseas sales

Financial review

Summary of 2015 Q3 results

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Sales and profits increased on year on year on a consolidated basis due to the growth of domestic products and other factors despite increased R&D expenses in the Pharmaceuticals business

(Unit: ¥bn)	FY2014 Q3 results	FY2015 Q3 results	Change	FY2015 forecast	Rate of progress
Net sales	238.9	272.9	34.0 (+14%)	360.0	76%
Operating Income *Operating margin*	26.2 *11.0%*	40.8 *15.0%*	14.6 (+56%)	47.0	87%
Ordinary income	23.8	36.6	12.8 (+54%)	41.0	89%
Net income	12.0	26.0	14.0 (+116%)	26.0	100%

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

(Rate of progress of FY 2015 sales forecast, disclosed July 24, 2015)

- ✓Ordinary income increased due to growth in operating income and other factors and despite an increase in equity in losses of affiliates.
- ✓Net income increased due to growth in ordinary income and gain on sales of investment securities, and other factors.

Summary of FY2015 Q3 consolidated results: Analysis of YoY profit changes

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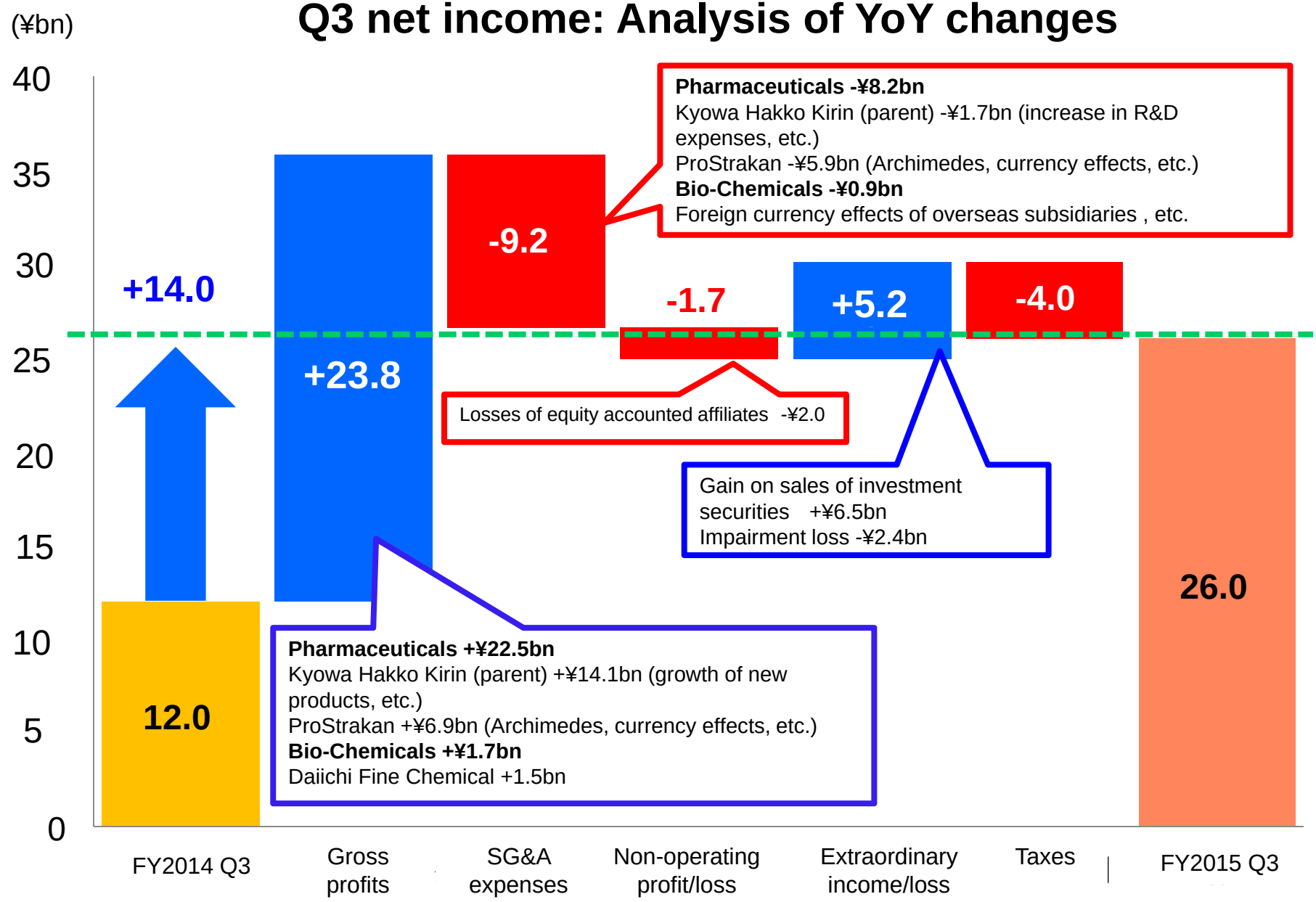
Q3 net income: Analysis of YoY changes



Summary of FY2015 Q3 financial results by segment

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In the Pharmaceuticals business, sales and profits increased due to growth of domestic products, in particular new products, and other factors.
In the Bio-Chemicals business, growth in amino acids for overseas supplements and infusion-use and others resulted in increased sales and profits

(Unit：¥bn)		FY2014 3Q results	FY2015 3Q results	Change
Pharmaceuticals business	Net sales	178.6	208.7	30.0 (+17%)
	Operating income *Operating margin*	20.6 *11.5%*	34.9 *16.7%*	14.3 (+70%)
Bio-Chemicals business	Net sales	62.7	67.1	4.3 (+7%)
	Operating income *Operating margin*	5.6 *9.0%*	6.4 *9.6%*	0.7 (+14%)

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

Pharmaceuticals business: FY2015 Q3: Analysis of YoY profit changes

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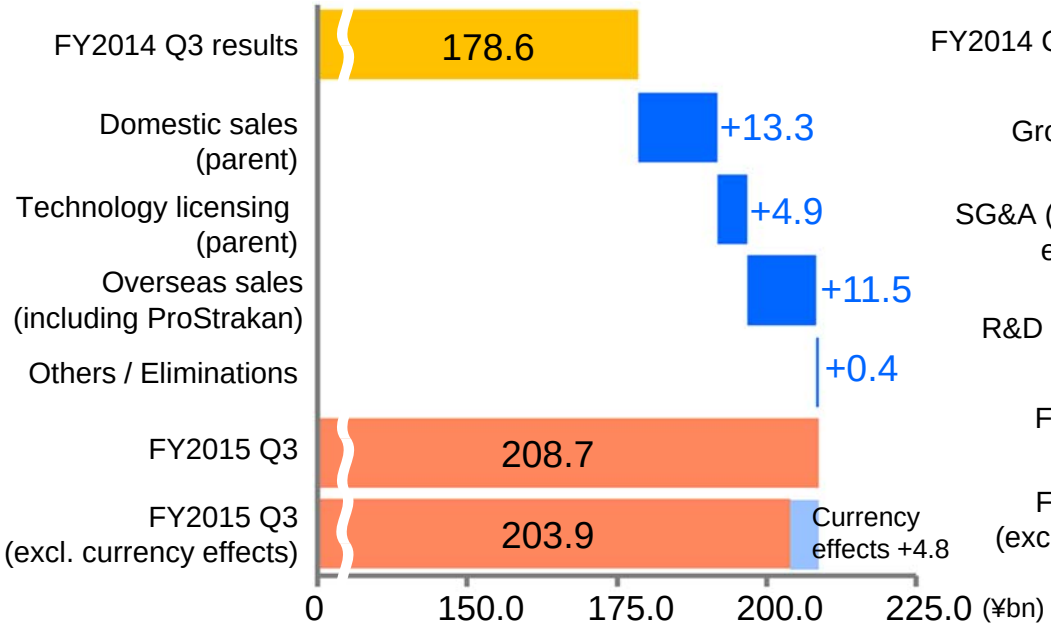
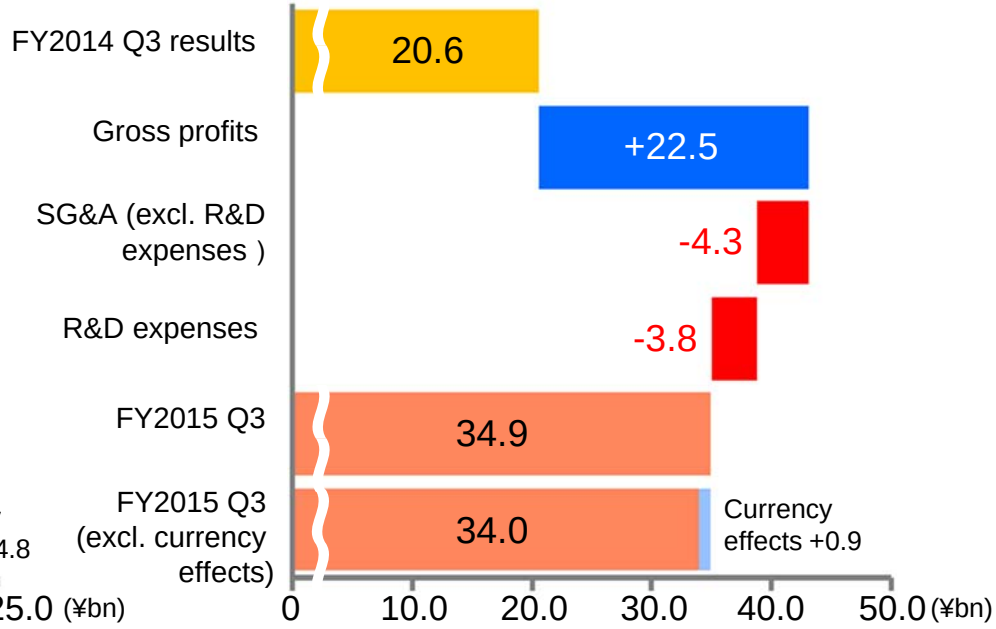
Net sales



Operating income



Net sales (+¥30bn):

- Domestic pharmaceutical products (+¥13.3bn):
  - Products (shipments): New products G-Lasta® +¥6.7bn, Dovobet® +¥3.0bn, Onglyza® +¥2.8bn, NOURIAST® +¥1.9bn, ALLELOCK® -¥1.0bn, CONIEL® -¥1.5bn, GRAN® -¥2.3bn.
  - NESP® (+¥1.9bn): Sales volume and net sales increased YoY due to additional indication for Anemia with Myelodysplastic Syndrome and other factors despite the impact of the drug price revision. Our share was maintained.
- Technology licensing, etc. (+¥4.9bn): Currency effects +¥0.7bn.
  - Upfront payment of US$45 million associated with option agreement for exclusive sales of KHK4563 in Japan.
- Overseas sales (+¥11.5bn): Currency effects +¥3.8bn.
  - ProStrakan (+¥9.0bn): Effects of consolidation of Archimedes, etc.

Operating income (+¥14.3bn)

- Gross profits (+¥22.5bn): Currency effects +¥4.2bn.
  - 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®).
  - Upfront contractual payment and ProStrakan growth contributed to further growth in profits.
- SG&A (-¥4.3bn): Currency effects -¥2.1bn.
  - Despite a reduction in SG&A at Kyowa Hakko Kirin (parent) and others, ProStrakan's costs, etc. increased.
- R&D expenses (-¥3.8bn): Currency effects -¥1.2bn.
  - Launch of clinical trials in Japan for late-stage development products.
  - Increase in overseas R&D expenses and other factors.

Pharmaceuticals business: Domestic sales of key products

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While sales were affected by the drug price revision 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 growth of key products such as NESP®

Product name, other information	FY2014 Q3 results	FY2015 Q3 results	Change	Reason for change	FY2015 forecast	Rate of progress*
NESP®	40.1	42.0	1.9 (+5%)	(+) Effect of additional indication for MDS※ (-) Drug price revisions in the previous year	56.9	74%
REGPARA®	11.7	13.2	1.4 (+13%)	(+)Steady growth in the market	17.7	74%
ALLELOCK®	17.9	16.8	-1.0 (-6%)	(+) Increase in airborne pollen count level (-) Drug price revisions in the previous year, market penetration of generics	20.5	82%
Patanol®	9.9	10.7	0.7 (+ 8%)	(+) Increase in airborne pollen level and other factors	11.9	90%
G-Lasta®	-	6.7	6.7 (N/A)	(+) Steady penetration of the market following launch end of November, 2014	8.9	75%
NOURIAST®	1.7	3.6	1.9 (+116%)	(+) Steady penetration of the market	5.5	67%
Technology out-licensing	6.4	11.3	4.9 (+7.6%)	(+) Upfront contractual payment and other factors	12.8	88%

※ Myelodysplastic Syndrome
* Rate of progress of FY2015 sales forecast, disclosed on July 31, 2015

(Unit: ¥bn, figures rounded down)

Bio-Chemicals business: FY2015 Q3: Analysis of YoY profit changes

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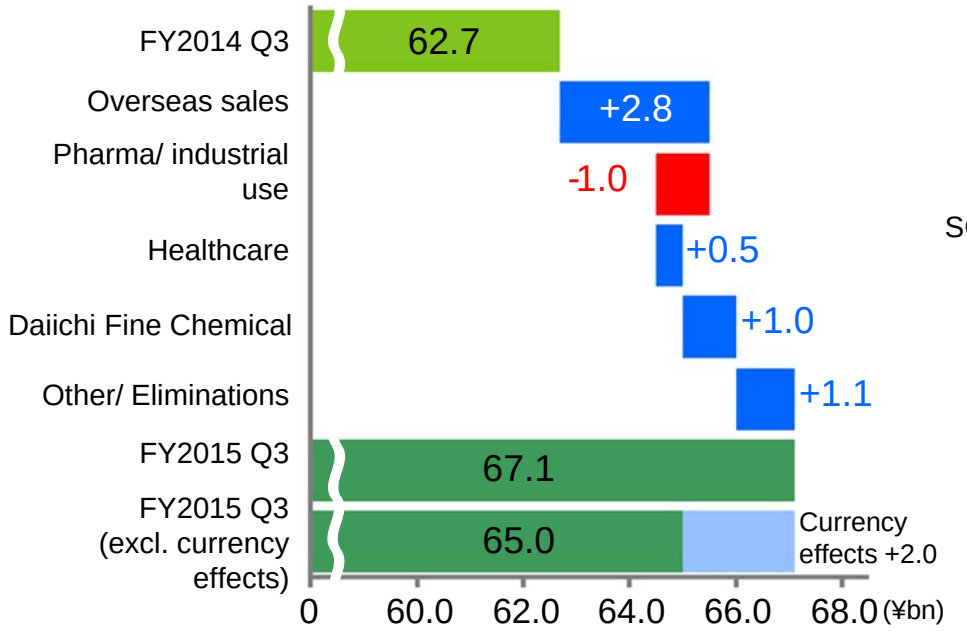
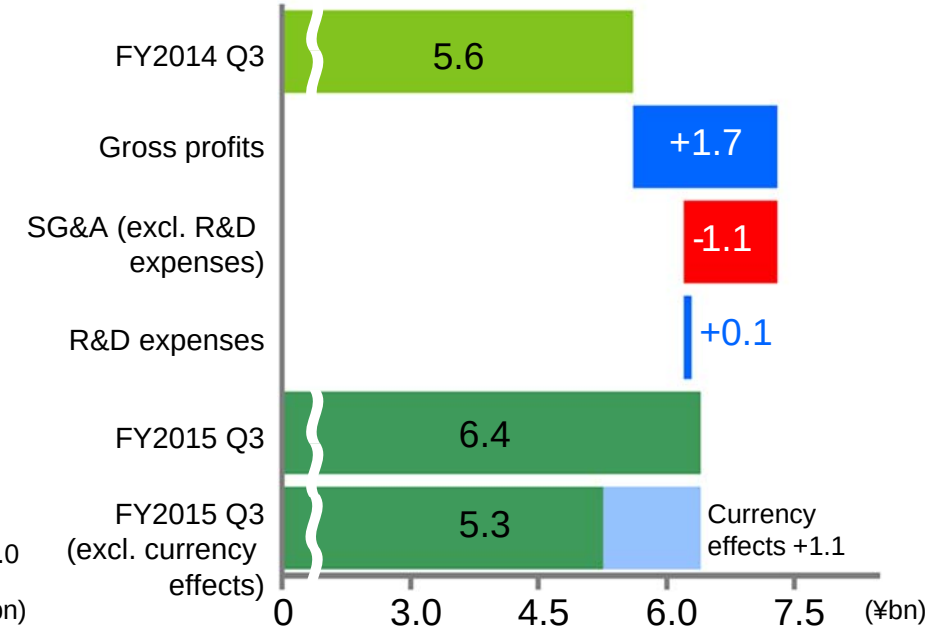
Net sales



Operating income



Net sales (+¥4.3bn)

- Overseas sales (+¥2.8bn): Currency effects +¥1.9bn
  - U.S. (+¥1.6bn): Currency effects (+¥1.0bn), sales increased due to growth in health-food-use amino acids, etc.
  - Europe (-¥0.0bn): Currency effects (-¥0.4bn), no change from previous year due to recovery in demand of infusion-use amino acids from some customers and despite impact of transfer of cosmetics ingredients business.
  - Asia and others (+¥1.2bn): Currency effects (+¥1.3bn), sales increased YoY due to ongoing yen weakness and despite concentrated shipments of some APIs in the previous year driven by a renewal of import licenses and other factors.
- Pharma/industrial use (-¥1.0bn): concentrated shipments of some generic drug APIs in the previous year and other factors.
- Healthcare (+¥0.5bn):
  - Mail order sales were strong and increased from the previous year.
  - Raw materials/OEM sales unchanged from previous year.
- Daiichi Fine Chemical (+¥1.0bn): due to difference in accounting period in which sales of pharmaceutical intermediates were recorded, etc.

Operating income (+¥0.7bn)

- Gross profit (+¥1.7bn): Currency effects (+¥1.4bn)
  - Positive factors were currency effects and cost improvements in some of Daiichi Fine Chemical's products, etc.
  - Negative factors were an increase in costs related to planned reorganization of production facilities at Yamaguchi Production Center, etc.
- SG&A (-¥1.1bn): Currency effects (-¥0.3bn)
  - Increase in sales promotion costs for mail order sales, etc.

*On October 1, 2015 the company name (trade name) of Daiichi Fine Chemical Co., Ltd. was changed to Kyowa Pharma Chemical Co., Ltd.

R & D review

Key development events timeline

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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/Bristol-Myers Squibb) in combination with KW-0761 (brand name in Japan: POTELIGEO®) targeting solid tumors (July)
- ☑ Application for marketing authorization of fully human anti-IL-17 receptor antibody KHK4827(July)
- ☑ Approval for marketing authorization of recombinant human antithrombin drug KW-3357 (brand name in Japan: ACOALAN®) (July) and sale (September)
- ☑ Initiation of Phase 3 trials of KHK4563 targeting COPD (July)
- ☐ Initiation of Phase 3 trials of KHK7580 targeting secondary hyperparathyroidism

Note: Events with a ticked checkbox were completed between Jan. 1, 2015-Oct. 21, 2015.

Key development events timeline

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Overseas:

- ☑ Application for marketing authorization of KRN321 (brand name in Japan: NESP®) (February, China)
- ☑ Initiation of Phase 1 trials of PF-05082566 (Pfizer) in combination with KW-0761 targeting solid tumors (June, U.S.)
- ☑ Agreement to collaborate on development of Phase 1/2 trials of Nivolumab (Bristol-Myers Squibb) in combination with KW-0761 targeting solid tumors (July, U.S.)
- ☑ Initiation of Phase 3 trials of AMG531 (brand name in Japan: Romiplate®) targeting ITP (September, China)
- ☐ Initiation of Phase 3 trials of KRN23 targeting adult XLH (North America, Europe, Asia)

Note: Events with a ticked checkbox were completed between Jan. 1, 2015-Oct. 21, 2015.

Key domestic development updates

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KHK7580: A next generation calcimimetic drug (phase 3 in preparation)

Indication	Country/ region	Development stage (Scheduled trial completion date)			Estimated enrollment	
		Phase 2	Phase 3	Application		
Secondary hyperparathyroidism	Japan	2015/2	In preparation		600	2)
			In preparation		120	3)
			In preparation		30	4)

Estimated number of patients Japan: approx. 47,000[1]

1) Number of patients with intact PTH of over 240pg/ml stated in: *Current state of chronic dialysis treatment in Japan*, Statistical Survey Committee of the Japanese Society for Dialysis Therapy, Dec. 31, 2012.

ClinicalTrials.gov identifier:
2) NCT02549391; 3) NCT02549404; 4) NCT02549417

KHK7580:
A next generation calcimimetic drug

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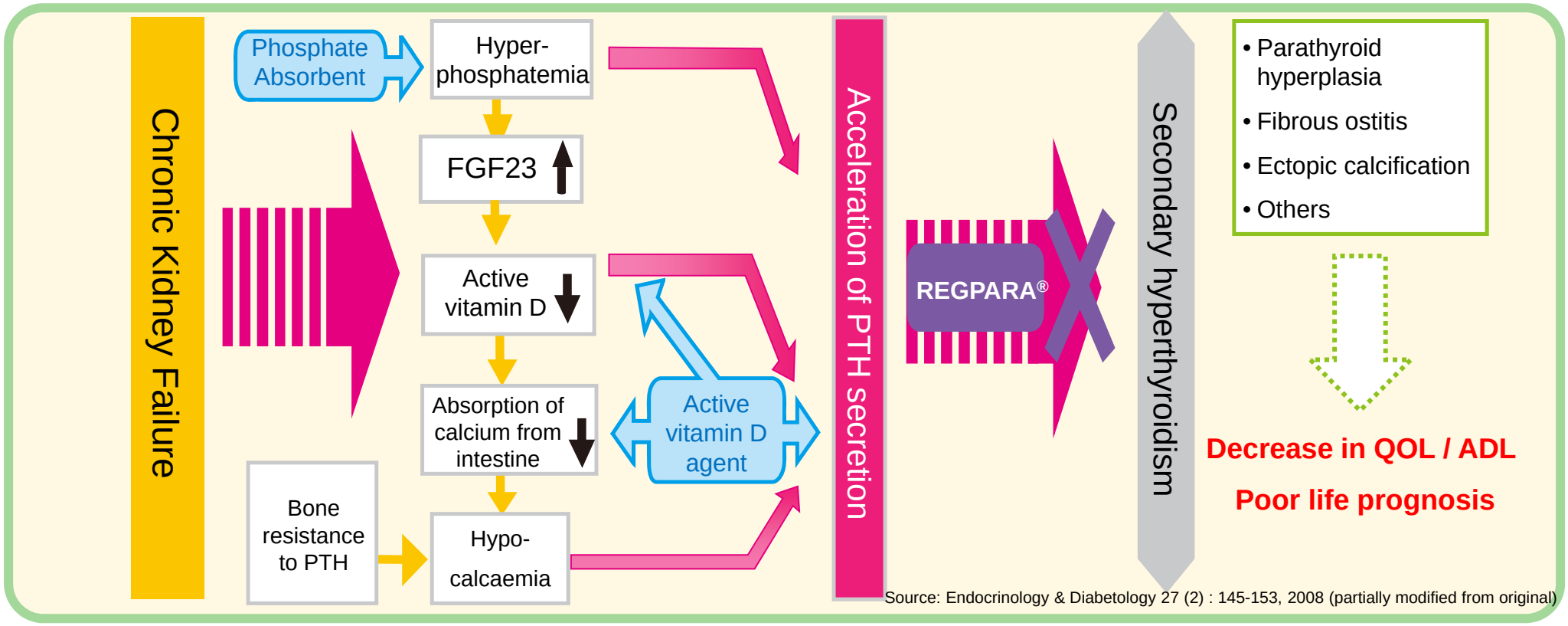
[Secondary hyperthyroidism]

The parathyroid glands secrete PTH to correct hyperphosphatemia and hypocalcaemia associated with chronic kidney disease. Continued secretion results in parathyroid hyperplasia, and the pathological condition of excessive secretion of PTH is called secondary hyperthyroidism. REGPARA®, a calcimimetic drug, has been sold since 2008.



Source: Endocrinology & Diabetology 27 (2) : 145-153, 2008 (partially modified from original)

REGPARA® : medical needs for further improvement

- ✓ Frequency of nausea, vomiting: dose reduction, cessation
- ✓ Comparatively strong CYP2D6 inhibition: concerns over drug interactions

Start of R&D for agonist for next generation calcium receptor

KHK7580: Phase 3 Study design

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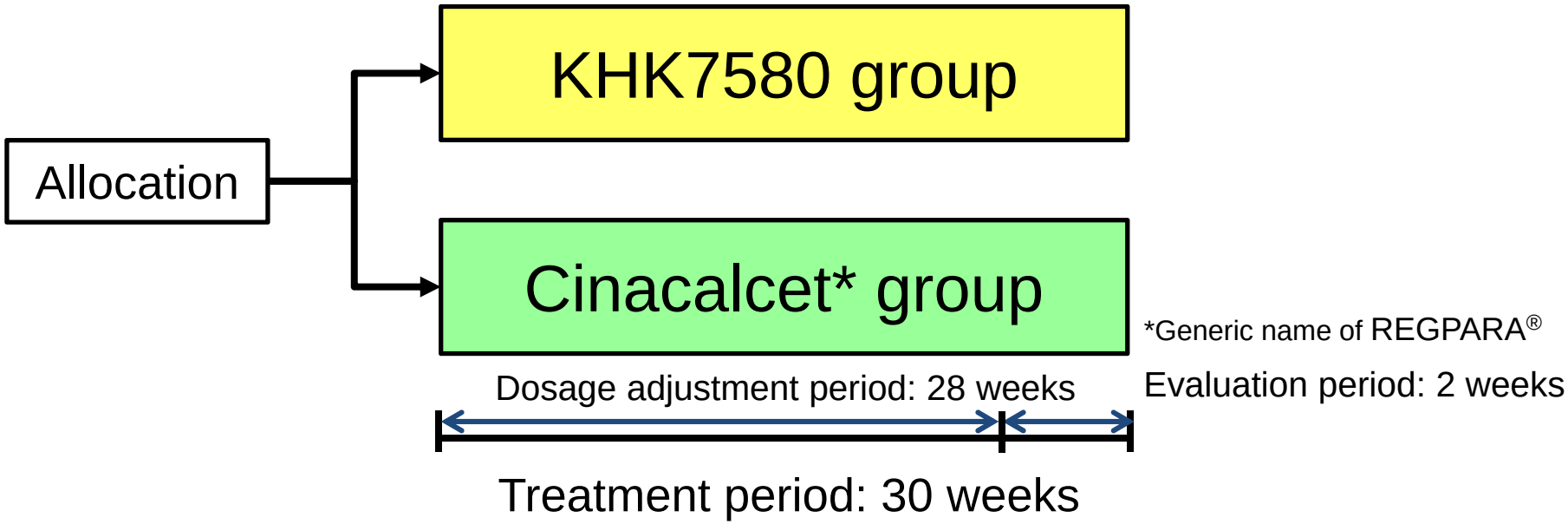
KHK7580 Phase 3 clinical study:
Randomized, double-blind, intra-subject dose-adjustment, parallel-group study evaluating KHK7580 and cinacalcet hydrochloride for secondary hyperparathyroidism patients receiving hemodialysis.



Primary endpoint: Number and ratio of subjects with average intact PTH level over 60pg/ml and less than 240pg/ml during the evaluation period

Target number of patients: 600

ClinicalTrials.gov identifier: NCT02549391

Key global development updates (1)

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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]	(2015/12)				70[6]
PTCL	Relapsed/ refractory	Japan				2014/3[2]	
		Europe	2015/5				38[7]
CTCL	Relapsed/ refractory	Japan				2014/3[2]	
		U.S., Europe, Japan, others[1]		(2017/2)			317[8]

Annual incidence per disease Japan ATL: approx. 1,100[3] patients; PTCL/CTCL: approx. 2,000[4] patients;
U.S. PTCL: approx. 3,600[5] patients; CTCL: approx. 1,500[5] patients

[1]CCR4 not included in selection criteria
[2]Launched in Japan (brand name POTELIGEO®)
[3]Survey of and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report by Kazunari Yamaguchi (March 2010)
[4]Ministry of Health, Labour and Welfare: Patient survey in October 2011 (chart 97), by basic illness
[5]SEER Data (2001-2007)
ClinialTrials.gov identifier:
[6]NCT01626664; [7]NCT01611142; [8]NCT01728805

Key global development updates (2)

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KW-0761 (solid tumor)

Indication	Country/ region	Concomitant Drug	Development stage (Scheduled trial completion date) Phase 1	Partner	Estimated enrollment
Solid tumor	U.S.	MEDI4736 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	In preparation	Bristol-Myers Squibb	-
	U.S.	Docetaxel	(2016/2)	-	27[4]

ClinicalTrials.gov identifier:
[1] NCT02301130; [2] NCT02444793; [3] NCT02476123; [4] NCT02358473

Key global development updates (3)

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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]	
	North America, Europe, Others		(2016/2)			609[4]

Patient numbers Japan: approx. 140,000[2]
U.S.: approx. 570,000[3]

[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

Key global development updates (4)

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KRN23

Indication		Country/ region	Development stage (Scheduled trial completion date)			Partner	Estimated enrollment
			Phase 1	Phase 2	Phase 3		
XLH	Pediatric	U.S., Europe		(2017/3)	In preparation	Ultragenyx Pharmaceutical (U.S., Europe)	50[4]
	Adult	U.S.		(2016/9)			25[5]
		NA., Europe Japan, Korea					120[6]
		U.S.			In preparation		15[7]
		Japan, Korea	(2015/12)				15[8]
TIO/ENS		U.S.		(2016/9)			6[9]

Estimated no. of patients

XLH
Japan: approx. 5,000[1] adult patients
approx. 1,000[1] pediatric patients
U.S.: approx.12,000[1] adult patients
approx. 3,000[1] pediatric cases

TIO / ENS
Japan: approx. 30[2] patients
U.S.: approx.500 – 1,000[3] patients

[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

ClinialTrials.gov identifier:
[4]NCT02163577; [5]NCT02312687; [6]NCT02526160; [7]NCT02537431 [8]NCT02181764; [9]NCT02304367

List of acronyms

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ATL	Adult T-cell Leukemia/Lymphoma
CCR4	Chemokine (C-C motif) Receptor 4
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
DIC	Disseminated Intravascular Coagulation
ENS	Epidermal Nevus Syndrome
ITP	Idiopathic Thrombocytopenic Purpura
PTCL	Peripheral T-Cell Lymphoma
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

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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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APPENDIX

Appendix: 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			2
Not disclosed	Not disclosed	Not disclosed	Not disclosed	Determined target product		

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

ClinialTrials.gov identifier: [1]NCT02260791

2) Development scheduled to be conducted by joint venture between AstraZeneca and FKB

Appendix:
Name change - Kyowa Pharma Chemical Co., Ltd.

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To clarify the responsibilities of a member of the Kyowa Hakko Kirin Group, Daiichi Fine Chemical Co., Ltd. has changed its name to Kyowa Pharma Chemical Co., Ltd. (Effective Oct. 1, 2015)

History

1946: Company founded
2001: Name changed to Daiichi Fine Chemical Co., Ltd.
2007: Became wholly owned subsidiary of Kyowa Hakko Bio Co., Ltd.
2012: API manufacturing facility (21st facility) constructed
2013: API manufacturing facility (22nd facility) constructed
2015: Name changed to Kyowa Pharma Chemical Co., Ltd.

Key products manufactured

Tranexamic acid
Olopatadine hydrochloride
Benidipine hydrochloride
Sodium valproate

Appendix: FOREX related

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Period average rate

Average exchange rate	2014 Q3 Results	2015 Q3 Results	Change	*2015 full-year Forecast*
¥/$	**¥103**	**¥120**	**+¥17**	***¥120***
¥/€	**¥140**	**¥135**	**-¥5**	***¥133***
¥/£	**¥171**	**¥186**	**+¥15**	***¥181***

FY2015 Q3 currency effects (YoY)

Segment	Currency	Net sales	Operating income
Pharmaceuticals business	$	**+¥1.1bn**	**-¥0.2bn**
	€	**-¥0bn**	**+¥0bn**
	£	**+¥2.4bn**	**+¥0.1bn**
Bio-Chemicals business	$	**+¥2.3bn**	**+¥1.4bn**
	€	**-¥0.4bn**	**-¥0.2bn**
	£	**-**	**-**

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	

(as of October 21st, 2015)