

July 31, 2013

FOR IMMEDIATE RELEASE

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Notice of revisions to the figures in Results Presentation for first half of the fiscal year ending December 2013

Please note that two figures in the results presentation released on July 26, 2013 have been revised as shown below:

Revision

Page 6:

Summary of H1 consolidated results: Analysis of YonY profit changes

Before revision

Extraordinary income/losses +¥4.1 billion

Taxes -¥0.4 billion

After revision

Extraordinary income/losses +¥4.6 billion

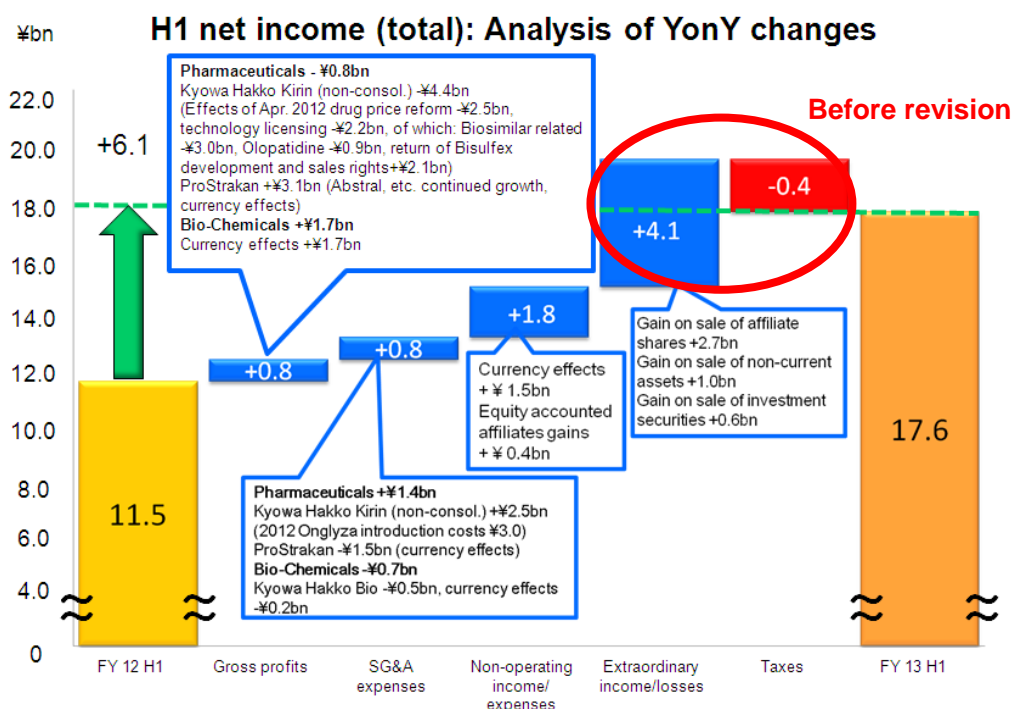
Taxes -¥1.9 billion

ENDS

For further information please access: http://www.kyowa-kirin.com/news_releases/index.html

Summary of H1 consolidated results:
Analysis of YonY profit changes

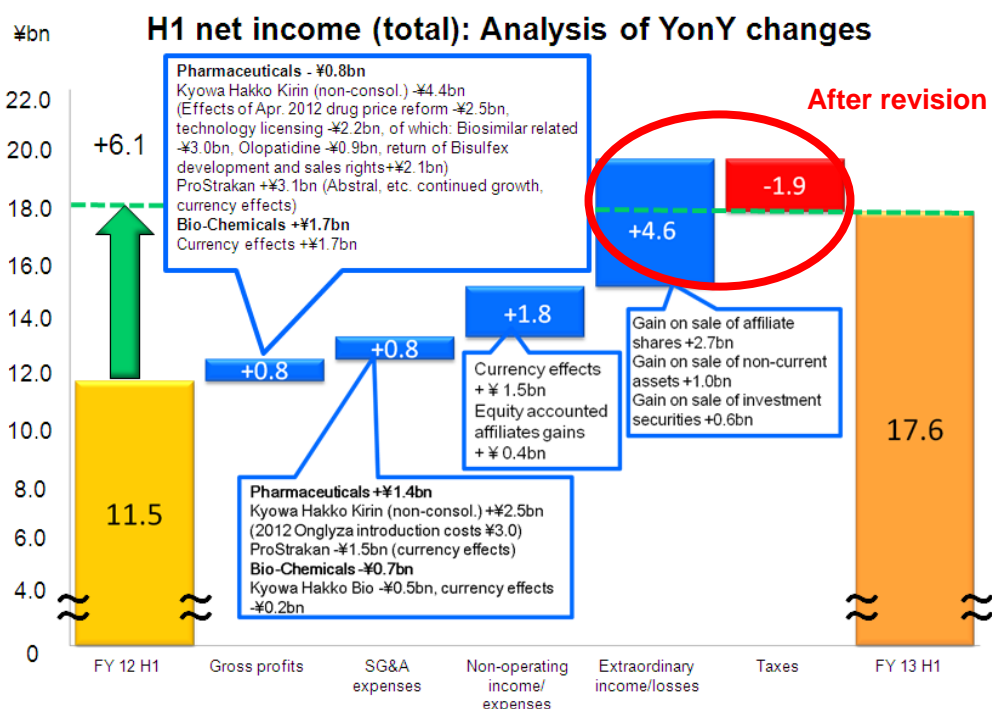
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Summary of H1 consolidated results:
Analysis of YonY profit changes

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FY ending December 2013

First half results presentation

Nobuo Hanai
President and CEO

Kyowa Hakko Kirin Co., Ltd.

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 associated with the pharmaceutical industry's domestic and international operating environment, intellectual property risks, the risk of adverse reactions to pharmaceutical products, legal risks, risks arising from product manufacturing deficiencies, risks due to fluctuations in the market prices of raw materials, fuel and products, as well as exchange rate and financial market volatility.

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

1. Summary of H1 results
2. Revision of full year forecasts
3. Topics
4. Development pipeline

Summary of H1 results



Summary of H1 results (consolidated)

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Sales and profits increased in H1 driven by a good performance by pharmaceutical products in Japan, continued strong growth at ProStrakan, and further weakening of the yen

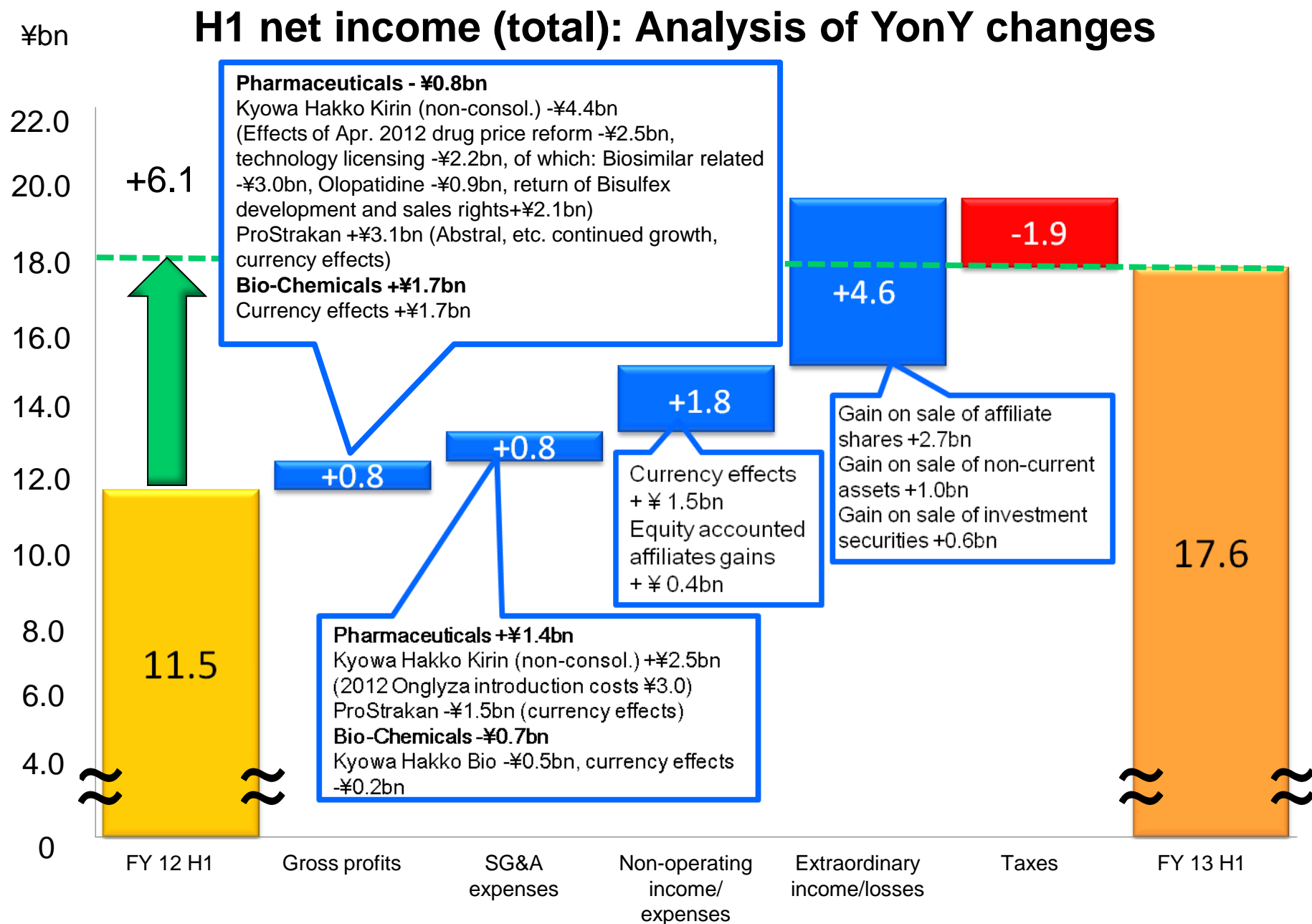
(Unit: ¥bn)	FY 2012 H1	FY 2013 H1	Change
Net sales	166.2	169.7	+3.4
Operating income (Operating margin)	25.5 (15.4%)	27.1 (16.0%)	+1.5
Ordinary income	23.0	26.5	+3.4
Net income	11.5	17.6	+6.1

- ✓ Growth in ordinary income was boosted by forex gains and lower losses from equity-accounted affiliates, as well as higher operating income
- ✓ The increase in net income was helped by extraordinary income including gains on sale of related companies' shares

Summary of H1 consolidated results:

Analysis of YonY profit changes

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**Sales and profits increased YoY in both
Pharmaceuticals business and Bio-Chemicals business**

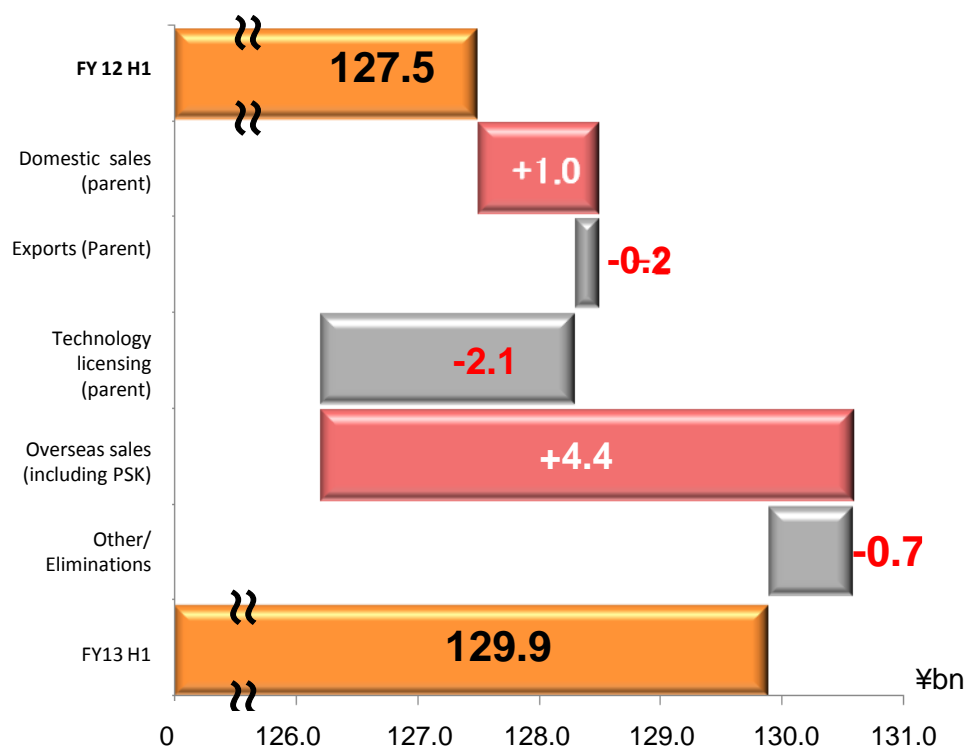
(Unit: ¥bn)		FY 2012 H1	FY 2013 H1	Change
Pharmaceuticals	Net sales	127.5	129.9	+2.3
	Operating income (Operating margin)	23.5 (18.4%)	24.1 (18.6%)	+0.5
Bio-Chemicals	Net sales	40.0	41.2	+1.1
	Operating income (Operating margin)	2.0 (5.1%)	3.1 (7.5%)	+1.0

Pharmaceuticals Business: H1 results: Analysis of YonY profit changes

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(Consolidated)

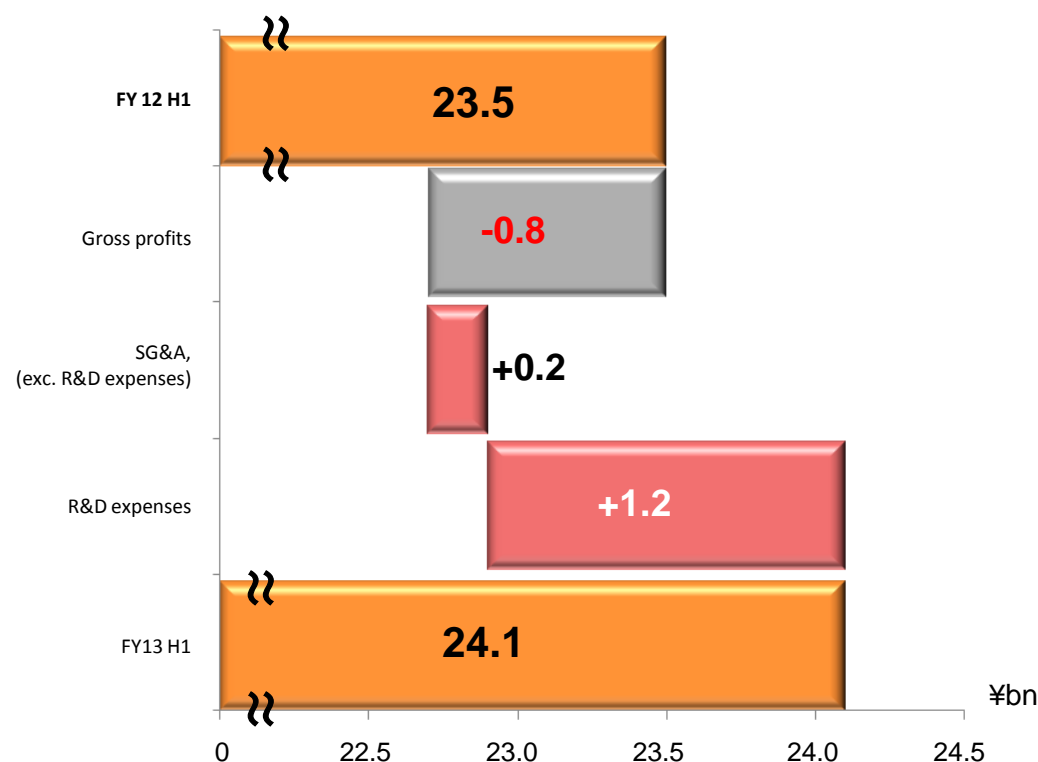
Net sales



Net sales

- Domestic pharmaceutical products (+¥1.0bn):
 - Products (shipments): PTN+3.1, REG +0.6, ASA +0.6, NSP-1.8, CONL-0.9, GRN-0.5
 - NESP (NSP): Sales declined due to lower shipments following launch of unified dosage product last year, reductions in NHI drug prices. Our share was maintained.
- Exports (-¥0.2bn): Similar to last year
- Technology licensing (-¥2.1bn): Currency effects approx. +¥0.6bn
 - Biosimilar related (- ¥3.0bn), etc.
- Overseas sales (+¥4.4bn): Currency effects approx. +¥2.4bn
 - ProStrakan +¥3.0bn (forex +¥1.4bn), remainder Asia sales.

Operating income



Operating income

- Gross profits (-¥0.8bn):
 - Effects of NHI drug price cuts offset by ProStrakan's growth and other factors but the large effect of the fall in licensing income from biosimilars led to lower profits
- SG&A (+¥0.2bn): Similar to last year
- R&D expenses (+¥1.2bn):
 - Decrease in depreciation, and amortization expenses, and other factors

Sales up year on year despite April 2012 reductions in NHI drug prices

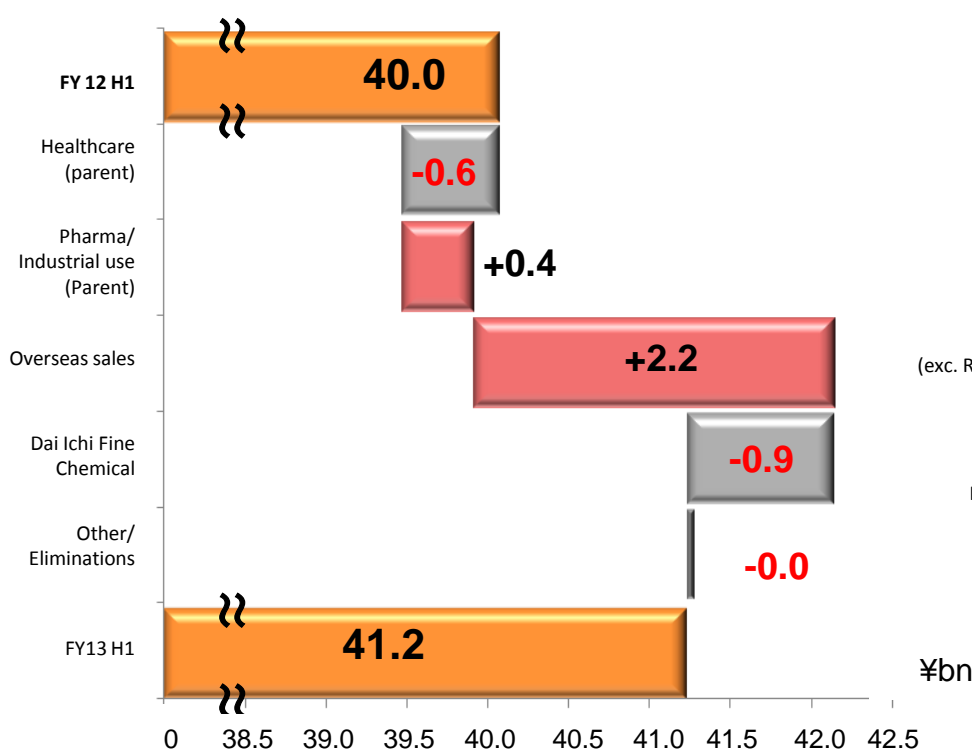
(Unit: ¥bn)	2012 H1 results	2013 H1 results	Change	Reasons for changes
Nesp	26.8	25.0	-1.8	Sales declined due to lower shipments following launch of unified dosage product at end of 2012 Leading share in ESA market unchanged
Regpara	6.2	6.9	+0.6	Growing market penetration
Allelock	16.1	15.9	-0.1	Despite increase in pollen count in line with previous year due to impact of generics
Patanol	6.9	10.1	+3.1	Increase in pollen count Top share in anti-allergy eye drops
Gran	6.4	5.8	-0.5	Maintained high share but sales down due to G-CSF market shrinkage
Exports	5.7	5.4	-0.2	
Licensing income	12.0	9.7	-2.2	Decline in biosimilars licensing income

Bio-Chemicals Business: H1 results: Analysis of YonY profit changes

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(Consolidated)

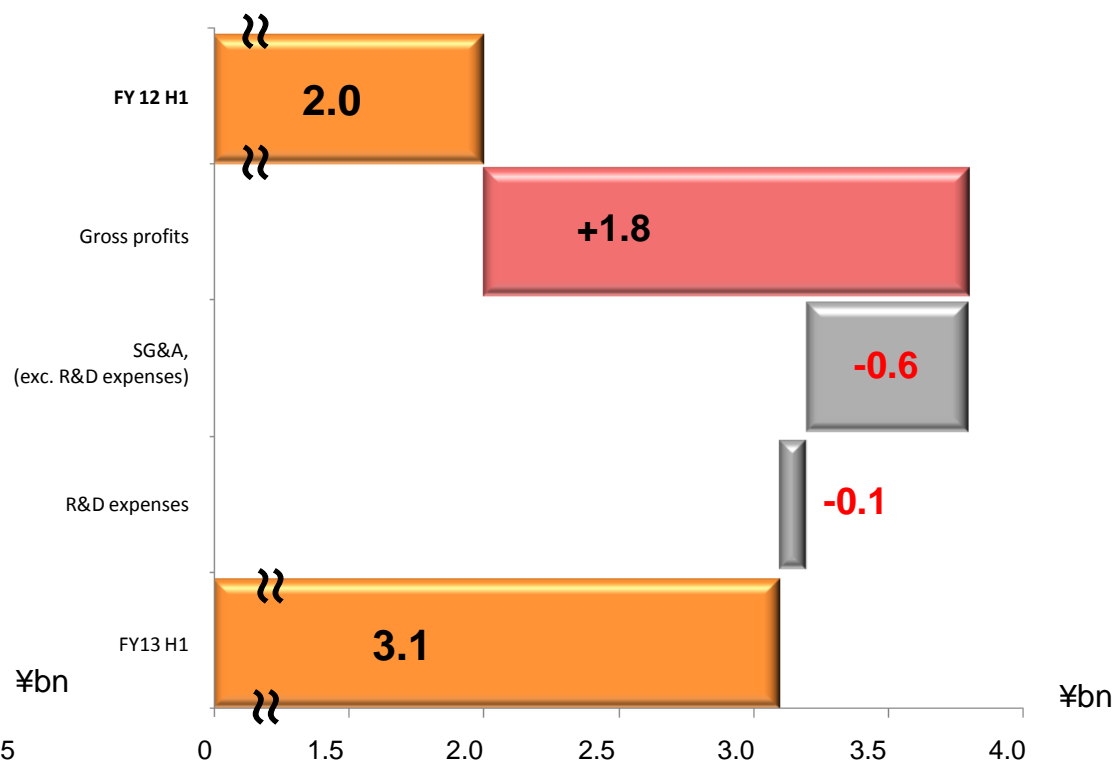
Net sales



Net sales

- Healthcare (-¥0.6bn): Mail order sales in line with 2012 H2, raw materials/OEM sales of amino acids for beverages sluggish, etc.
- Pharma/ Industrial use (+¥0.4bn): Raw materials for generic pharmaceuticals strong, etc.
- Overseas sales (+¥2.2bn): currency effects approx. +¥2.7bn
 - U.S.: Currency effects (+0.6), impact of intensifying competition in sales of some raw materials for supplements (-0.1)
 - Europe: Currency effects (+1.1), Other, decline in demand accompanying customer production timing in industrial-use products (-0.2)
 - Asia and others: Currency effects (+0.8), Other, some pharmaceutical raw materials were sluggish (-0.1)
- Daiichi Fine Chemical (-¥0.9): Delay of shipments of Transexamic acid planned for H1 this year (-0.7), Other, affected by business reorganization and exit from unprofitable products, etc. (-0.3)

Operating income



Operating income

- Gross profits (+¥1.8bn): Currency effects approx. +¥1.7bn
- SG&A(-¥0.6bn): Impact of exchange rates on overseas distributors

Revision of full year forecasts



Revision of full year forecasts

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(Unit: ¥bn)	FY 2012 results	FY2013 initial forecasts (a)	FY 2013 revised forecasts (b)	Difference (b)-(a)
Net sales	333.1	338.0	339.0	+1.0
Operating income	52.9	55.0	51.0	-4.0
Ordinary income	49.0	49.0	48.0	-1.0
Net income	24.1	30.0	28.0	-2.0

Assumptions: Average fore x rates for the period

¥/USD	80	85	95	¥10 decline
¥/EUR	103	115	124	¥9 decline
¥/GBP	127	140	145	¥5 decline

(Profits are stated after amortization of goodwill)

Revision of full year forecasts: Sales

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(Unit: ¥bn)		FY2012 results	FY2013 initial forecasts (a)	FY 2013 revised forecasts (b)	Difference (b)-(a)
Net sales	Consolidated	333.1	338.0	339.0	+1.0
	Pharmaceuticals	259.3	260.0	258.0	-2.0
	Bio-Chemicals	76.9	81.0	84.0	+3.0
	Eliminations	-3.1	-3.0	-3.0	---

As a result of the discontinuation of the 'Other' segment from 2013 , FY2012 results and FY2013 initial forecasts have been reclassified

Reasons for revision

Main +ve factors: Strong performance by pharmaceutical-use amino and nucleic acid related materials (Bio-Chemicals)

Main -ve factors: Nesp: Downward revision in sales forecast due to lower shipments following the launch of unified dosage product at end of last year (Pharmaceuticals)
Some licensing income included in initial forecasts will be booked in FY2014 (Pharmaceuticals)
Review of plans for beverage/food-use raw materials in healthcare business (Bio-Chemicals)

Forex effects: +¥4.4bn (Pharmaceuticals +¥1.5bn; Bio-Chemicals +¥2.9bn)

Revision of full year forecasts: Operating income

KYOWA KIRIN

(Unit: ¥bn)		FY2012 results	FY2013 initial forecasts (a)	FY 2013 revised forecasts (b)	Difference (b)-(a)
Operating income	Consolidated	52.9	55.0	51.0	-4.0
	Pharmaceuticals	50.7	49.2	45.0	-4.2
	Bio-Chemicals	2.1	5.8	6.0	+0.2
	Eliminations	0.0	---	---	---

As a result of the discontinuation of the 'Other' segment from 2013 , FY2012 results and FY2013 initial forecasts have been reclassified

Reasons for revision

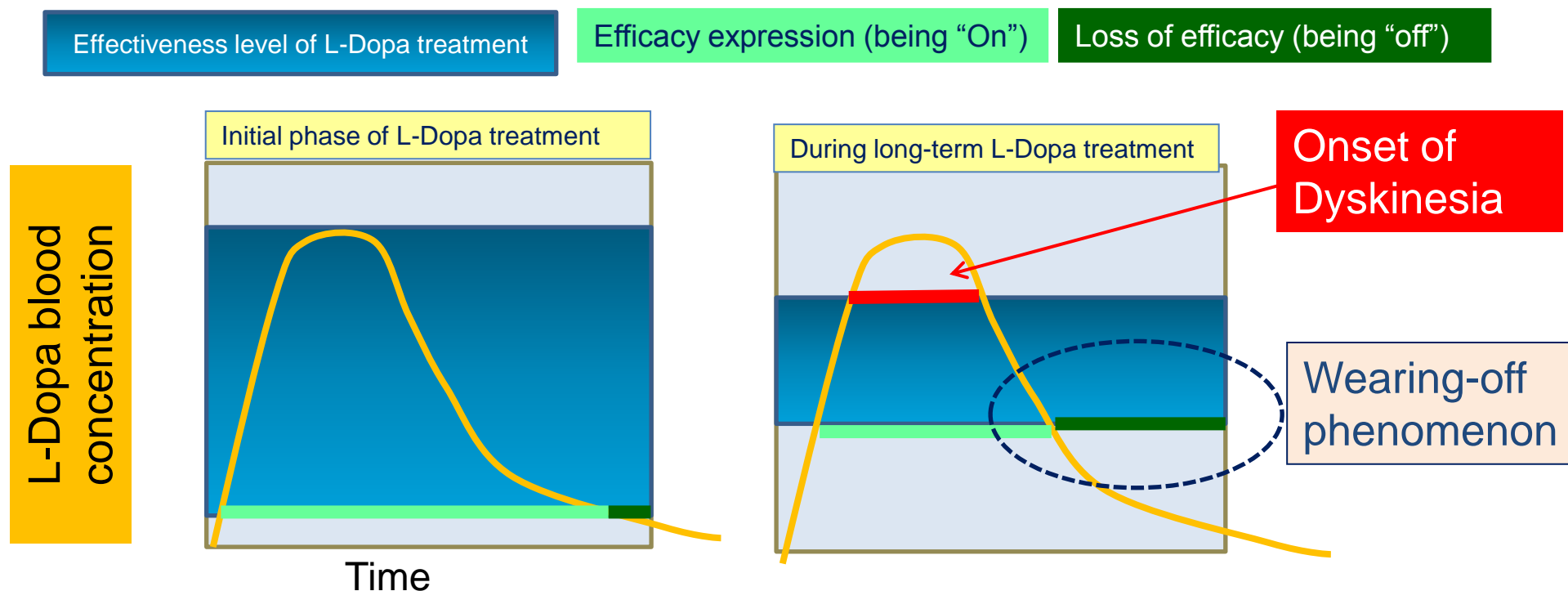
Main –ve factors: Some licensing income included in initial forecasts will be booked in FY2014 (Pharmaceuticals)
 Nesp: Downward revision in sales forecast due to lower shipments following the launch of unified dosage product at end of last year (Pharmaceuticals)
 Review of plans for beverage/food-use raw materials in healthcare business (Bio-Chemicals)

Forex effects: +¥2.9bn (Pharmaceuticals +¥1.0bn; Bio-Chemicals +¥1.9bn)

Topics: Pharmaceuticals Business

Motor complications associated with L-DOPA treatment: Complications brought about by the long-term continuation of L-DOPA treatment (dopamine replacement therapy) that significantly impair patient QOL

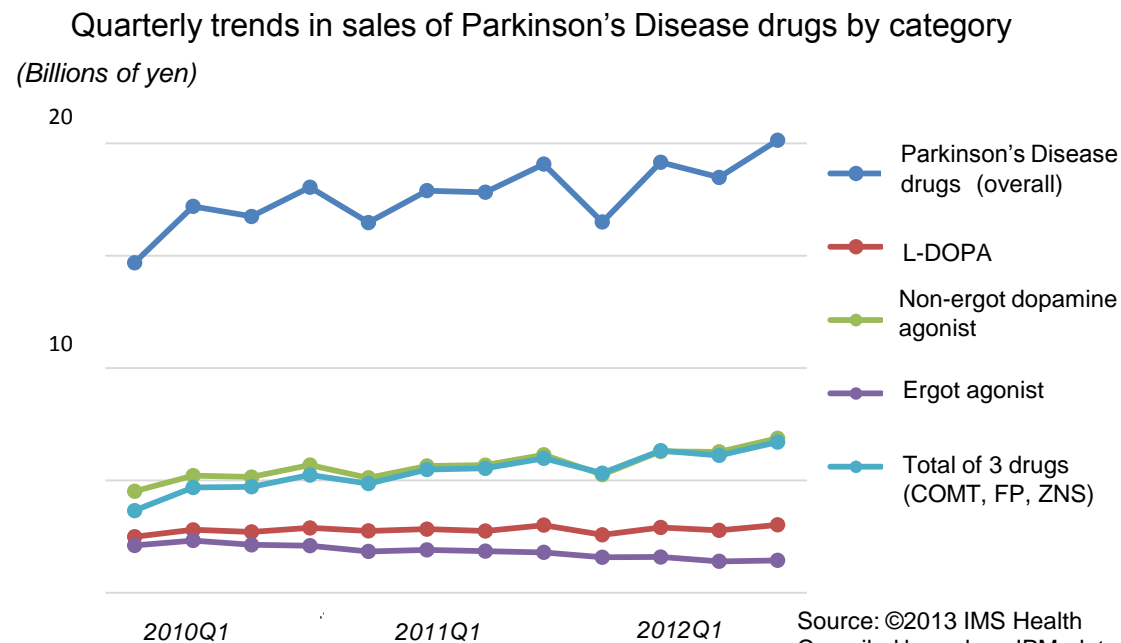
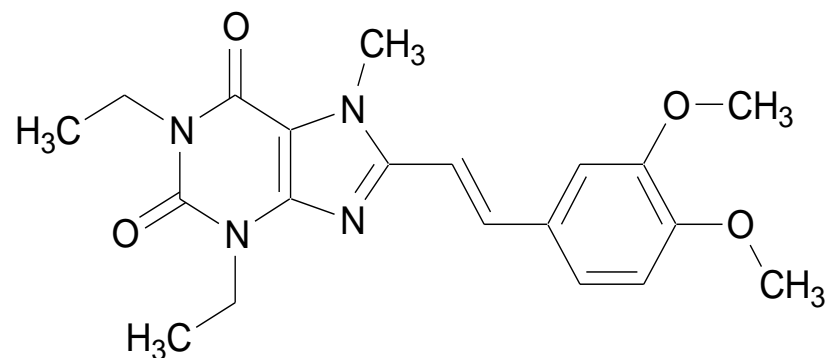
- Wearing-off phenomenon: Reduction in the time taken for the benefit of one dose of medication to fade
- Dyskinesia: Involuntary movements
- On-off phenomenon: Fluctuating benefits of medication



World's first adenosine A_{2A} receptor antagonist (non-dopaminergic antiparkinsonian agent)

- Reduces average “off” time in Parkinson's patients receiving treatment with L-DOPA who are experiencing wearing off phenomenon
- 40mg dose improves motor capacity* during “on” time
- One dose daily

*UPDRS part III



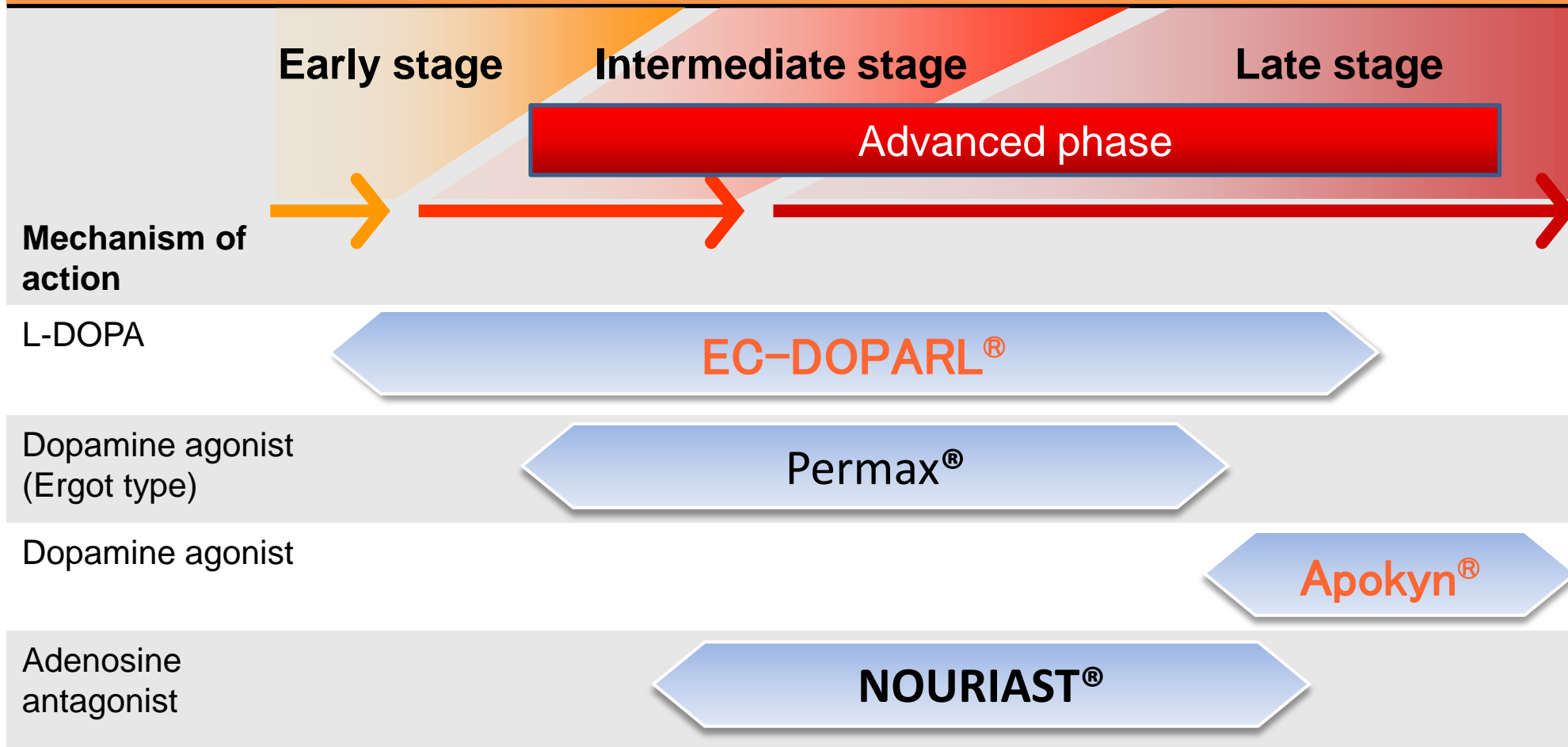
Source: ©2013 IMS Health
Compiled based on JPM data from January 2010 to June 2013
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NOURIAST®



Aim to be a leading company in the field of Parkinson's disease treatment, leveraging our strong position of having four drugs on the market

Pathogenesis of Parkinson's Disease



1. Increase in type 2 diabetes patients

	Patients with severe diabetes
1997	6.9 million people
2002	7.4 million people
2007	8.9 million people

2007 National Health and Nutrition Survey

2. Increase in ratio of patients who continue treatment

	Ratio continuing treatment
Current (2010)	63.7%
Target (2022)	75%

Materials related to implementation of Health Japan 21 (phase 2)

3. Increase in patients prescribed DPP-4 inhibitors

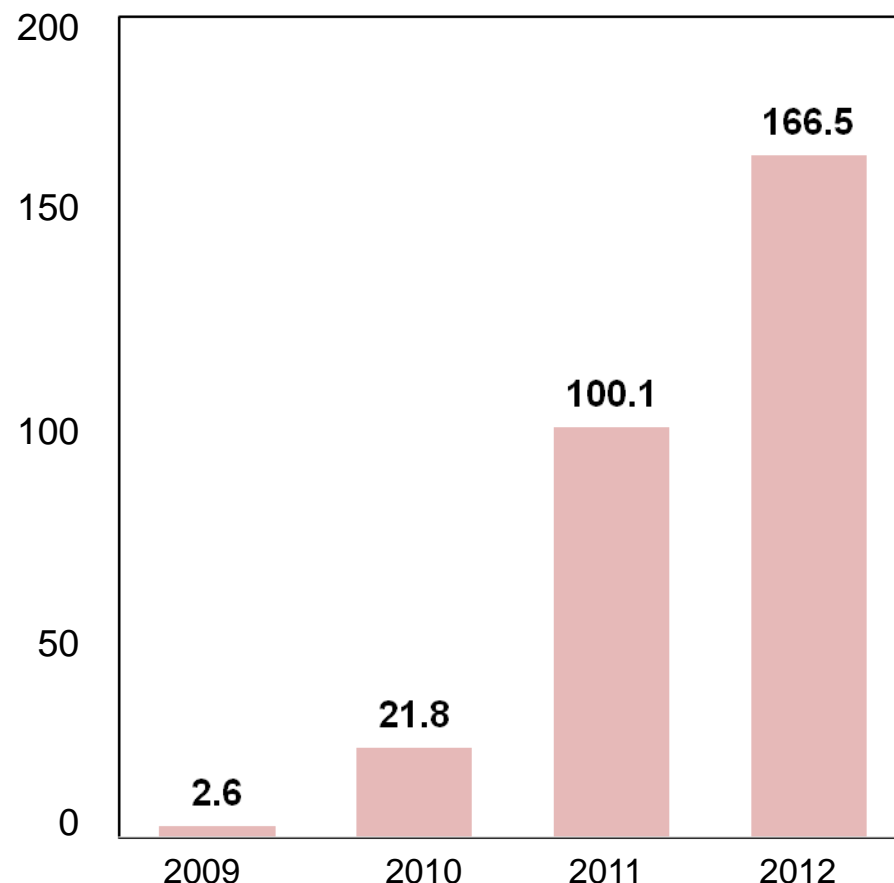
Correction of postprandial hyperglycemia

Lower incidence of hypoglycemia

Lower incidence of weight gain

(¥ bn)

DPP-4 inhibitor market



(c)2013IMSHealth
Calculated based on MIDAS 2009-2012
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Aiming for ¥21.6bn in domestic Onglyza sales at peak

DPP-4 inhibitor sales No. 2 globally

Cardio vascular evidence
(Meta-analysis of U.S. clinical trials
SAVOR-TIMI53)

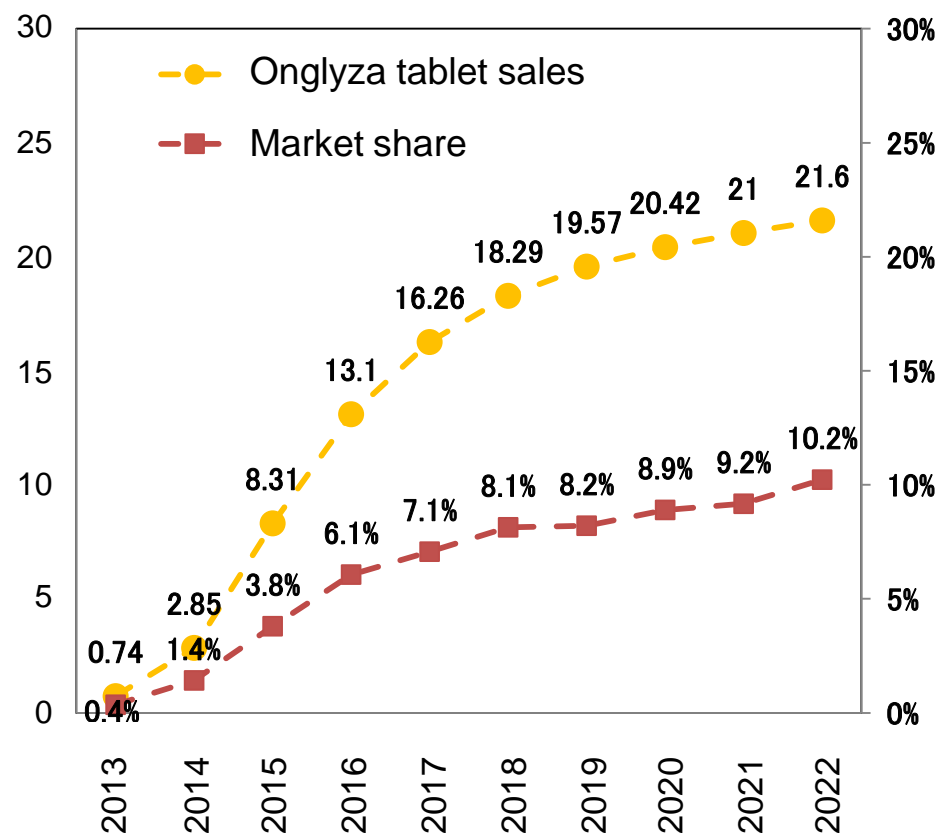
Joint treatment with all oral hypoglycemic
agents possible from launch

Multidisciplinary treatment possible for
managing blood sugar, blood pressure and
anemia in type 2 diabetes patients

Drug price comparatively cheap

Onglyza
Sales (¥ bn)

Onglyza
Market share



We will launch Onglyza on the type 2 diabetes treatment market as a DPP-4 inhibitor backed by highly reliable evidence, and rapidly disseminate data on its effectiveness and safety

Increase in KW-0761 indications accelerating value maximization

Indications		Country/ region	Development stage	Annual incidence per disease, other
ATL	Relapsed/ refractory	Japan*	On sale (May 2012)	ATL: 1,100 ¹⁾
ATL	Untreated	Japan*	On file (Jul 2013)	ATL: 1,100 ¹⁾
ATL	Relapsed/ refractory	US Europe	Phase 2	Europe: investigating
PTCL	Relapsed/ refractory	Japan*	On file (Jul 2013)	PTCL/CTCL together: 2,000 ²⁾
PTCL	Relapsed/ refractory	Europe	Phase 2	US: approx. 3,600 ³⁾
CTCL	Relapsed/ refractory	Japan*	On file (Jul 2013)	PTCL/CTCL together: 2,000 ²⁾
CTCL	Relapsed/ refractory	US	Phase 3	US: approx. 1,500 ³⁾

***Expansion of indications in Japan leading to increased use of POTELIGIO® TEST**

Sources

- 1) Survey of and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report by Kazunari Yamaguchi (March 2010)
- 2) Ministry of Health, Labor and Welfare: Number of patients on October 2011 clinical trial inspection chart 97, divided by basic illness
- 3) SEER Data (2001-2007)

Topics: Bio-Chemicals Business

Investment in production facilities

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◆ Facility enhancement associated with Yamaguchi Production Center consolidation at Hofu

Sequential consolidation of functions through phased investment

After completion of new refining facility in March, break ground for new manufacturing facility in November (completion in February 2015)

◆ Overseas facility enhancement associated with expansion of the amino acid market

Investment in increased production in existing plants to contribute from next fiscal year. New fermentation plant in Thailand also performing well

◆ Daiichi Fine Chemicals facility enhancement in line with basic production strategy

After plant 21 last year, plant 22 was completed in July for manufacture of Kyowa Kirin's bulk pharmaceuticals

Yamaguchi Production Center Hofu
New refining facility
Completed in March



Yamaguchi Production Center Hofu
New manufacturing facility
(Groundbreaking in November)



BIOKYOWA
New manufacturing facility
(Completed in March)



Daiichi Fine Chemicals
Plant 22
(Completed in July)



Development pipeline

Approval for two new drugs in Japan, including first in class Began clinical trials for Adalimumab biosimilar FKB327

Japan:

- ✓ Sale of NOURIAST[®], a novel anti-Parkinson's agent (May 2013)
- ✓ Inherited approval from Otsuka for manufacturing and marketing of Onglyza[®], to treat type 2 diabetes (May 2013)
- ✓ Application filed for sustained duration G-CSF product KRN125 (Jun 2013)
- ✓ Began Phase 3 study of KHK4827 for psoriasis (Mar 2013)

Late-stage development pipeline is progressing steadily
KW-2246 (on file), KW-3357 (Phase3), KHK4563 (Phase2)

Overseas:

- ✓ Began Phase 1 study of FKB327 on healthy subjects in Europe

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**If you have any inquiries regarding this presentation please call:
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Tel: +81-3-3282-0009**

Appendix

Forex rates	2013	H1 2013	2012	H1 2012
¥/USD	¥95	¥ 94	¥80	¥ 80
¥/EUR	¥124	¥123	¥103	¥103
¥/GBP	¥145	¥145	¥127	¥126

Foreign exchange effects 1H 2013 (Year on year) (unit: Y million)

Segment	Conversion currency	Net sales	Operating income
Pharmaceuticals	USD	+900	+500
	EUR	+100	+100
	GBP	+1,400	-0
Bio-Chemicals	USD	+1,300	+700
	EUR	+1,200	+600
	GBP	—	—

Development progress with outlicensed compounds

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Name	Partner	Phase			Remarks
		I	II	III	
Tivozanib	AVEO				Cancer (VEGF receptor inhibitor) (KRN951)
MEDI-563	MedImmune				Asthma (Anti-IL-5R antibody) (KHK4563) POTELLIGENT®
KRN5500	DARA				Peripheral neuropathy
RGI2001	REGiMMUNE	Phase1/2			Immunosuppressive
SAR252067	Sanofi				Ulcerative colitis and Crohn's disease (anti-LIGHT antibody)

(as of July 19, 2013)

Participants:

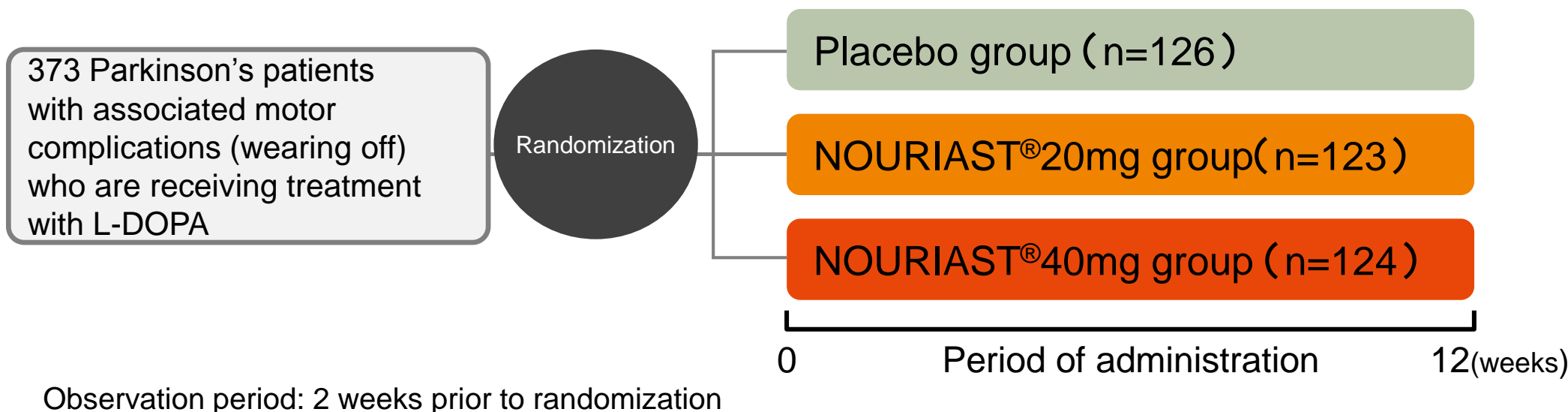
373 Parkinson's patients with associated motor complications (wearing off) who are receiving treatment with levodopa

Method:

Multicenter, placebo-controlled, randomized, double-blind, parallel-group trial
Randomly assigned study patients received placebo, NOURIAST® 20mg, or NOURIAST® 40mg orally once daily over 12 weeks

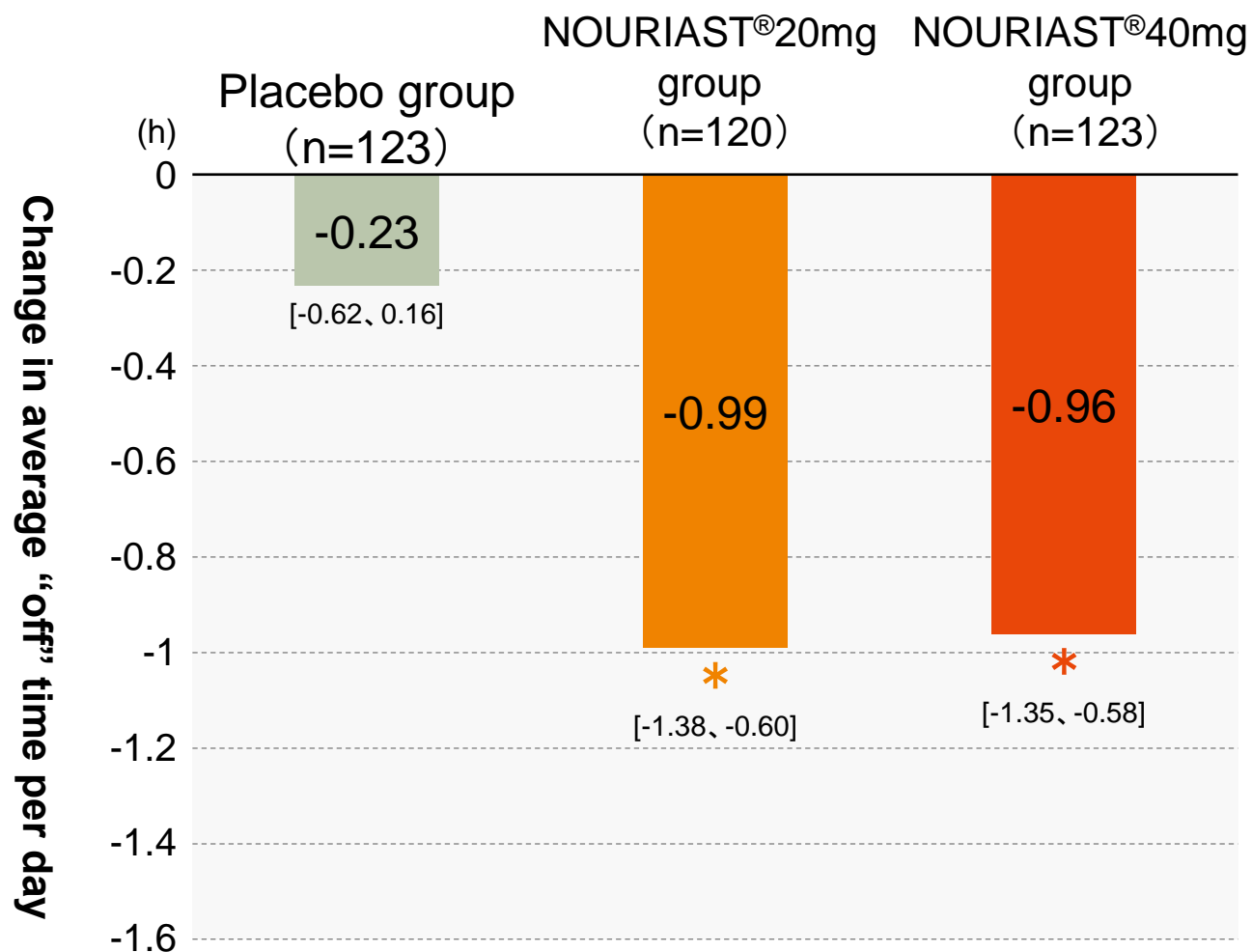
Primary endpoint:

Change in average "off" time in one waking day



NOURIAST: Change in average “off” time per day

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Least mean square value (95%C.I.)

*: p<0.025(vs Placebo)

Williams’ test (one-tailed significance level of 2.5%)

“Off” time in observation period (h): Placebo group 6.05 NOURIAST®20mg group 5.29, NOURIAST®40mg group 5.31

Target	New onset untreated ATL (CCR4-positive)
Dosage schedule	<ul style="list-style-type: none"> ◇mLSG15+KW-0761 group mLSG15 treatment + 1.0mg/kg dosage intravenously eight times at two-week intervals ◇mLSG15 group mLSG15 treatment
Efficacy	<p>Complete response rate</p> <ul style="list-style-type: none"> ◇mLSG15+KW-0761 group: 52% (95%CI; 33-71%) ◇mLSG15 group: 33% (95%CI: 16-55%) <p>Objective response rate</p> <ul style="list-style-type: none"> ◇mLSG15+KW-0761 group: 86% (95%CI; 68-96%) Effective in 25 of 29 patients (Complete response in 15, partial response in 10) ◇mLSG15 group: 75% (95%CI: 53-90%) Effective in 18 of 24 patients (Complete response in 8, partial response in 10)
Safety	Based on this trial's dosage schedule concluded that mLSG15 treatment with KW-0761 was tolerable