KYOWA KIRIN

Results Presentation
Fiscal 2018 Third Quarter

Kyowa Hakko Kirin Co., Ltd.

Agenda

KYOWA KIRIN

Results Summary & Financial Review

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R&D Review

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Business Topics

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Q&A

Forward-looking statements

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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 the 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 in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the 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 is used only for the purpose of providing the information to investors. Though it may contain the information concerning pharmaceutical products (including products under development), it is not for the purpose of promotion, advertising, or medical advice.

Results Summary & Financial Review

Summary of the Consolidated Results

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	2017Q3 Results	2018Q3 Results	Changes	2018Q4 Plan (30-Oct-2018)	Progression Rate
Revenue	261.3	253.9	-7.3 (-3%)	335.0→ 335.0	76%
Core OP *[Margin]* OP: Operating Profit	44.7 *[17.1%]*	45.9 *[18.1%]*	+1.3 (+3%)	51.0→ 54.0 *[16.1%]*	85%
Profit	29.5	47.4	+18.0 (+61%)	44.0→ 52.0	91%

(Billion Yen / Rounded)

Revision to Full-Year Forecast

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	2018Q4 Original Plan (8-Feb-2018)	2018Q4 Revised Plan (30-Oct-2018)	Changes
Revenue	335.0	335.0	—
Core OP	51.0	54.0	+3.0
Profit Before Tax	61.0	71.0	+10.0
Profit	44.0	52.0	+8.0

(Billion Yen / Rounded)

Gain/loss on the equity method +3.0

Gain on reversal of impairment losses +3.4

Gain on sales of fixed assets +3.7

Consolidated: YoY Analysis -Profit-

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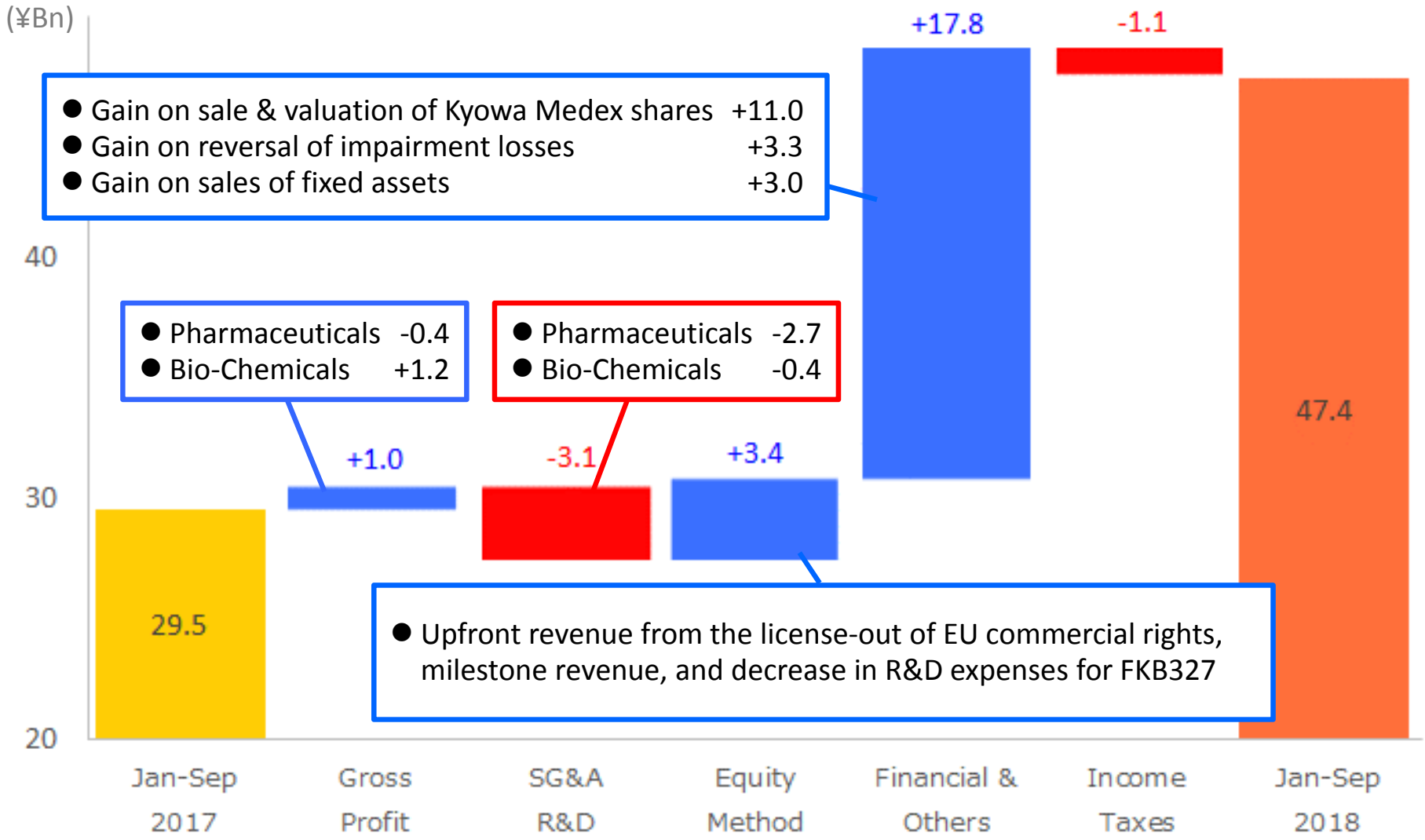
Profit (Jan-Sep) +18.0 billion yen



Summary of the Results by Segment

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- **Pharmaceuticals' Core OP slightly increased due to an improvement in the gain/loss on the equity method despite the lower revenue & higher expenses.**
- **Bio-Chemicals' Core OP increased due to improved profitability despite the lower revenue.**

		2017Q3 Results	2018Q3 Results	Changes	2018Q4 Plan* (30-Oct-2018)	Progression Rate
Pharma-ceuticals	Revenue	203.0	197.7	-5.3 (-3%)	262.0	75%
	Core OP *[Margin]*	39.2 *[19.3%]*	39.5 *[20.0%]*	+0.3 (+1%)	43.0→ 46.0 *[17.6%]*	86%
Bio-Chemicals	Revenue	60.7	58.4	-2.3 (-4%)	76.0	77%
	Core OP *[Margin]*	5.2 *[8.5%]*	6.0 *[10.3%]*	+0.8 (+16%)	8.0 *[10.5%]*	75%

(Billion Yen / Rounded)

*No revisions have been made except Pharmaceuticals' core OP plan.

Pharmaceuticals: YoY Analysis -Revenue-

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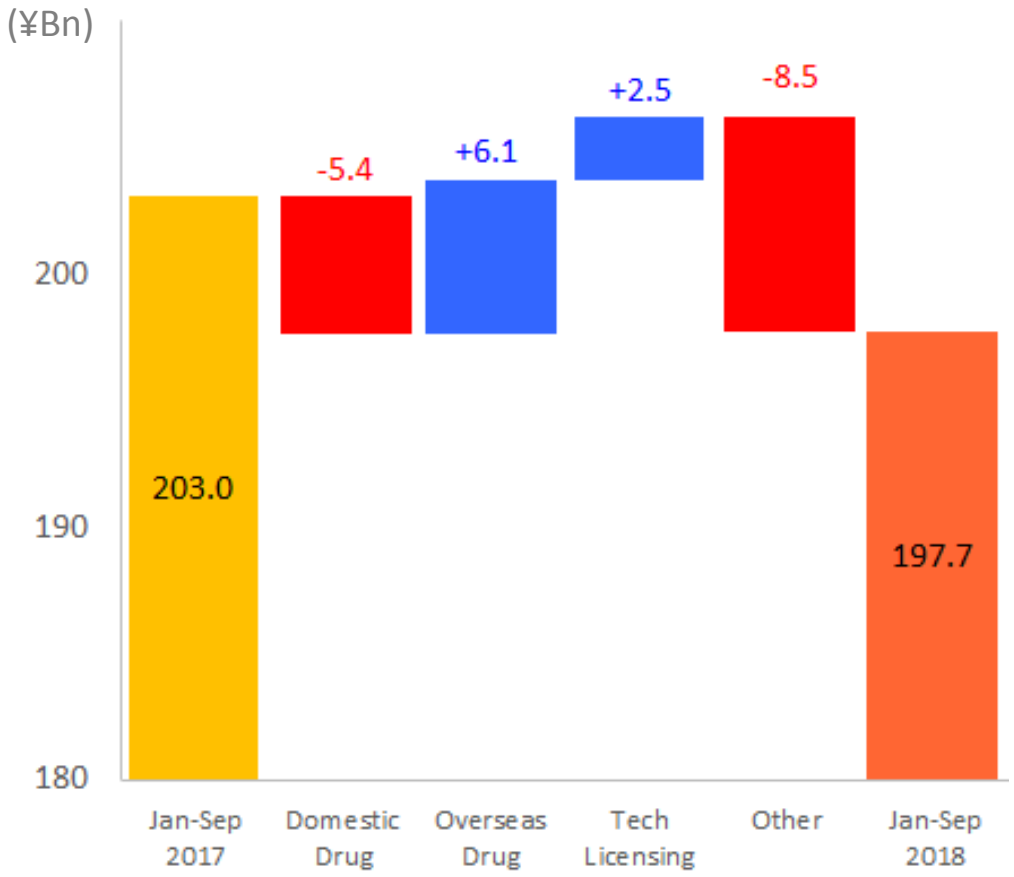
-5.3 billion yen
(incl. forex effect +1.3)



● Domestic Drug -5.4

- **Positive:** Rituximab-BS which was launched in Jan (+2.4), Orkedia which was released in May (+1.1), and the other new products such as G-Lasta (+2.0), Lumicef (+0.9), Nouriast (+0.7) maintained strong growth. Patanol rose due to the higher amount of pollen in the air (+0.7).
- **Negative:** Regpara dropped due to the presence of a competing product (-3.2). Nesp declined due to the drug price cut (-1.8). Long-listed products including Allelock (-2.4), Coniel (-1.1), Asacol (-1.0), Depakene (-0.9) fell mainly due to the penetration of generic drugs.

● Overseas Drug +6.1 (incl. forex effect +1.5)

- **EU/US:** Crysvita which was launched in the U.S. and Germany in April was strong (+3.6). Abstral maintained steady growth (+0.7).
- **Asia:** Regpara (+0.7) & Gran (+0.3) achieved favorable sales especially in China.

● Tech Licensing +2.5 (incl. forex effect -0.2)

- Increased due to net proceeds from the Priority Review Voucher (US$80.6M×50%), despite the lower Benralizumab-related revenue.

● Others -8.5 (incl. forex effect)

- Mainly due to the deconsolidation of Kyowa Medex.

Pharmaceuticals: YoY Analysis -Core OP-

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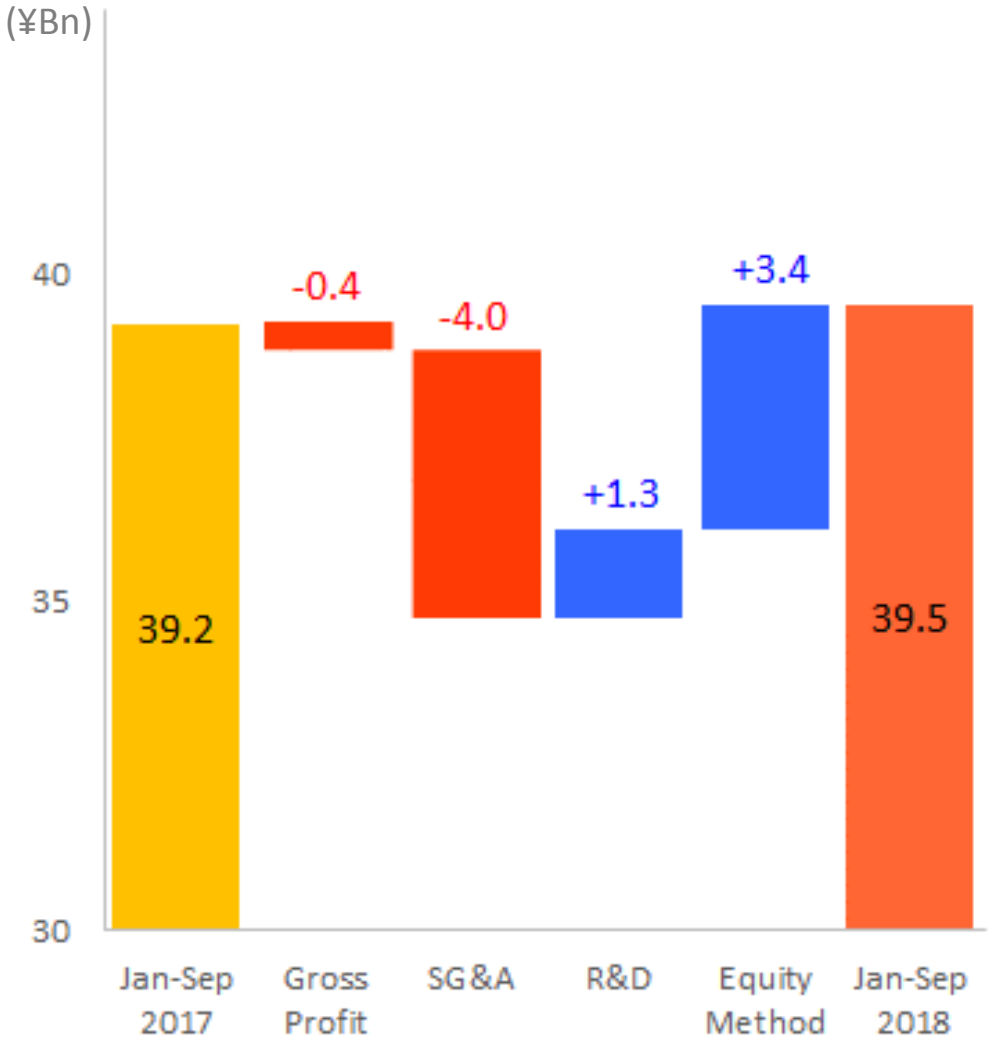
+0.3 billion yen
(incl. forex effect -0.1)



- **Gross Profit -0.4 (incl. forex effect +1.1)**
  - Remained at the same level as the last year as the increased overseas drug segment covered the lower domestic drug segment and the impact of the deconsolidation of Kyowa Medex.

- **SG&A -4.0 (incl. forex effect -1.1)**
  - Increased selling and launch readiness expenses for Crysvita & Poteligeo in the EU/US.
    *Including profit sharing expenses in North America.

- **R&D +1.3 (incl. forex effect -0.1)**
  - Decreased mainly due to the decline in late-stage developments including KW-0761 (Poteligeo).

- **Gain/Loss on Equity Method +3.4**
  - Upfront revenue from the license-out of EU commercial rights, milestone revenue, and decrease in R&D expenses for FKB327.

Pharmaceuticals: Revenue of Major Items

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Item		2017Q3 Results	2018Q3 Results	Changes	Reason	2018Q4 Plan*	Progression Rate
Nesp	JP	41.0	39.2	-1.8 (-4%)	Drug price cut	52.4	75%
Regpara	JP	13.9	10.7	-3.2 (-23%)	Market penetration of a competitor & shift to Orkedia	13.2	81%
Allelock	JP	12.2	9.7	-2.4 (-20%)	Market penetration of generic drugs & higher amount of pollen in the air	11.7	83%
Patanol	JP	10.8	11.5	+0.7 (+6%)	Higher amount of pollen in the air	12.1	95%
G-Lasta	JP	12.8	14.8	+2.0 (+16%)	Steady market penetration	20.1	74%
Nouriast	JP	6.1	6.8	+0.7 (+12%)	Steady market penetration	9.4	72%
Technology licensing	JP	2.8	2.2	-0.6 (-22%)		4.6	49%
Crysvita	ex-JP	—	3.6	+3.6	Newly launched	Undisclosed	—
Abstral	ex-JP	8.8	9.5	+0.7 (+8%)	Steady market penetration	13.2	72%
Technology licensing	ex-JP	10.8	13.9	+3.1 (+28%)	Sale of priority review voucher	17.3	80%

(Billion yen / Rounded)

*No revisions have been made to the revenue plans.

Bio-Chemicals: YoY Analysis -Revenue-

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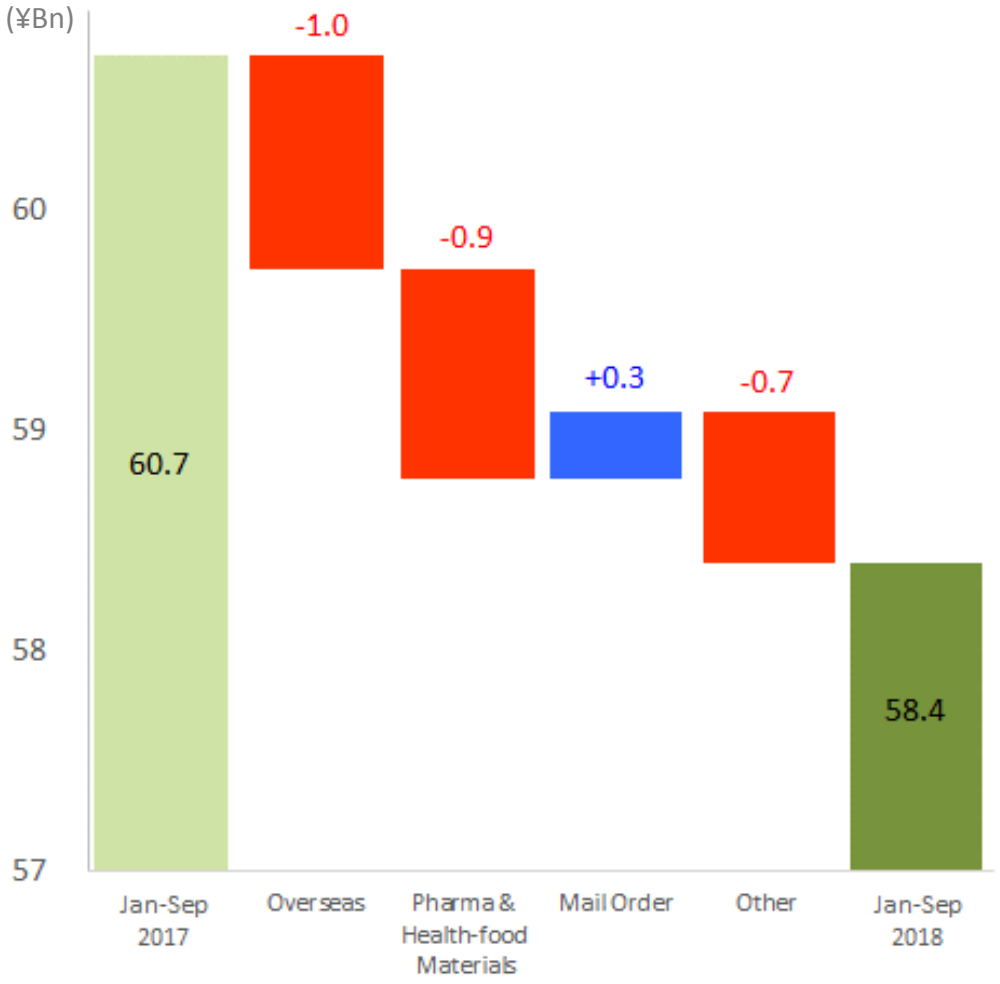
-2.3 billion yen
(incl. forex effect +0.4)



- **Overseas -1.0 (incl. forex effect +0.4)**
  - **Americas -0.3 (incl. forex effect -0.2)**
  - **Europe -0.1 (incl. forex effect +0.6):** Due to fiercer competition in certain products.
  - **Asia & others -0.6 (incl. forex effect -0.0):** Due to fiercer competition in certain products.

- **Pharma & Health-food Materials -0.9**
  - Declined due to the revamping of certain product lineups.

- **Mail Order +0.3**
  - "Arginine EX" continued to grow.

- **Other -0.7**
  - Decreased mainly due to the transfer of the Plant Growth Regulator Business.

Bio-Chemicals: YoY Analysis -Core OP-

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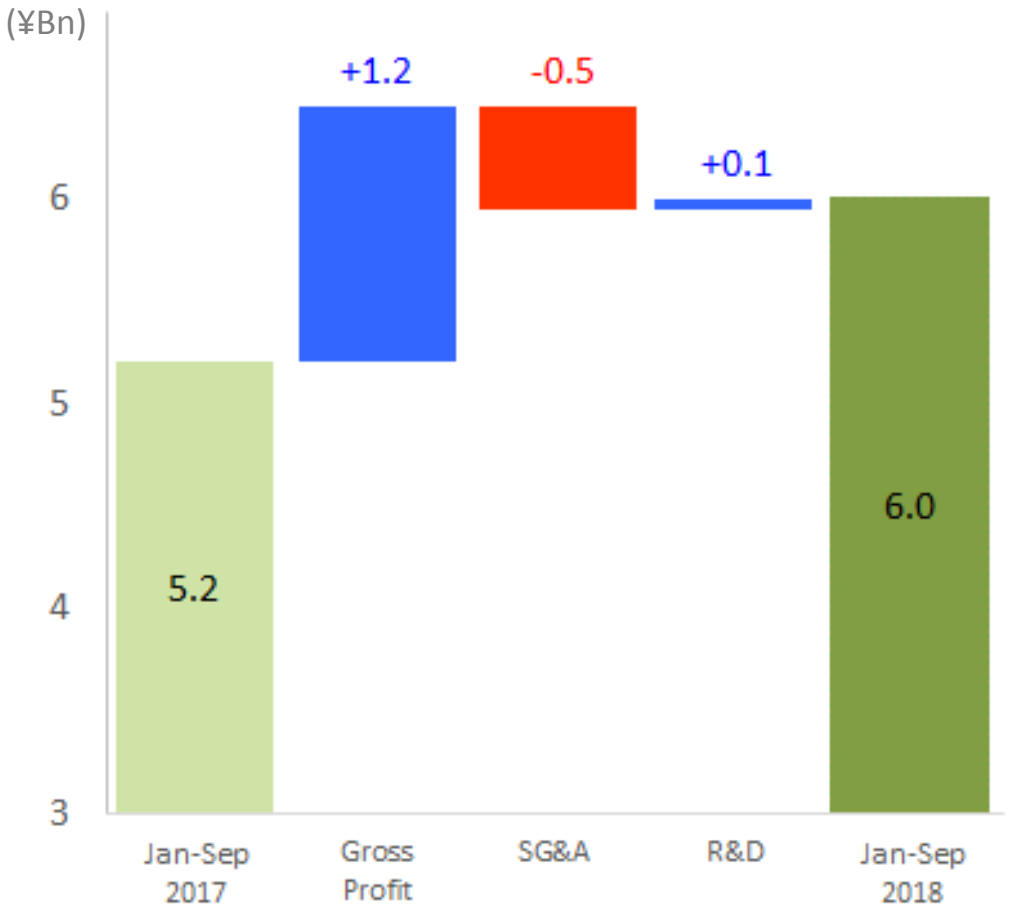
+0.8 billion yen
(incl. forex effect +0.1)



- **Gross Profit +1.2 (incl. forex effect +0.1)**
  - Manufacturing costs decreased by an increase in the overseas production.

- **SG&A -0.5 (incl. forex effect -0.0)**
  - Increased advertisements aimed at expanding the mail order business.

R&D Review

Key development events in 2018 (1)

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Generic name Code	Indication	Country/ region	Month	Event
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Mar.	Designated under the SAKIGAKE system[1]
			May	Initiated phase 3 study
Benralizumab[2] KHK4563	Asthma	Europe	Jan.	Approved (BN: Fasenra)
		Japan	Jan.	Approved (BN: Fasenra subcutaneous infusion)
Brodalumab KHK4827	Psoriasis	Asia	Apr.	Approved in Taiwan, Filed in Hong Kong
			Jul.	Filed in Korea
			Aug.	Approved in Thailand
Burosumab KRN23	XLH (pediatric)	Europe	Feb.	Conditionally approved (BN: Crysvita)
		multiple[3]	May	Met primary endpoint in phase 3 study
	XLH (pediatric, adult)	U.S.	Apr.	Approved (BN: Crysvita)
		Canada	May	Filed

[1]The priority review and designation system by Ministry of Health, Labor and Welfare in Japan
[2]NDA holder is AstraZeneca
[3]North America, Europe, Japan, Korea, and Australia
BN: brand name
Note: Listed events were completed between January 1, 2018 and September 30, 2018.

Key development events in 2018 (2)

KYOWA KIRIN

Generic name Code	Indication	Country/ region	Month	Event
Evocalcet KHK7580	Secondary hyperparathyroidism	Japan	Mar.	Approved (BN: Orkedia tablets)
Granisetron -	Chemotherapy induced nausea and vomiting	Malaysia	Jan.	Approved (BN: Sancuso)
Mogamulizumab KW-0761	CTCL	U.S.	May	Extended PDUFA goal date by FDA
			Aug.	Approved[1] (BN: Poteligeo)
		Europe	Sep.	Received positive CHMP opinion

[1]Approved indications are MF and SS

BN: brand name

Note: Listed events were completed between January 1, 2018 and September 30, 2018.

Key development updates in 18Q3 (1)

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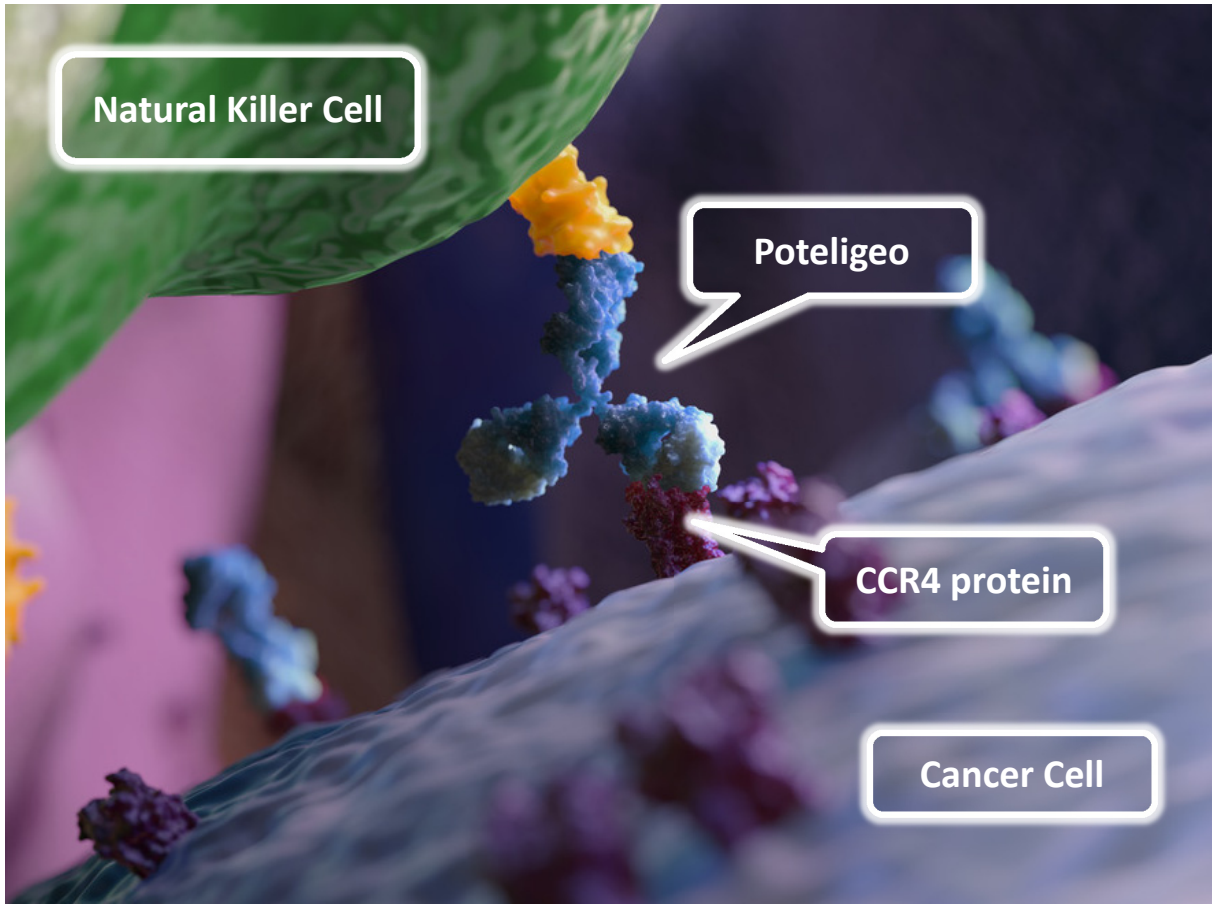
POTELIGEO® approved in the US

Product Information	
Brand name	POTELIGEO® injection
Generic name	mogamulizumab-kpkc
Indication	POTELIGEO is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy
Dosage and administration	1 mg/kg as an intravenous infusion over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle
Date of US approval	August 8th, 2018

POTELIGEO®: Mechanism of action



- Poteligeo is a defucosylated, humanized IgG1 kappa monoclonal antibody
- Poteligeo binds to CCR4[1], which is involved in the trafficking of lymphocytes to various organs
- Enhanced antibody-dependent cellular cytotoxicity (ADCC) activity of Poteligeo effectively depletes the target cells with CCR4 expression

[1]CCR4 is expressed on the surface of some T cell malignancies and is expressed on regulatory T-cells (Treg) and a subset of Th2 T-cells

POTELIGEO®: Research and Development History

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Related events

1996
Initiation of antibody formulation (Collaboration w/ Prof. Matsushima)

1999-2000
Research Reports:
CCR4 expression on T cell malignancy (Jones et al)
CCR4 expression on Th2 cells (Imai et al)

2001
Initiation of research of CCR4-targeting antibody (Collaboration w/ Prof. Ueda)

2002-2004
Research Reports:
CCR4 expression on ATL (Yoshie et al)
CCR4 as a prognostic factor in ATL patients (Ishida et al)
Anti-tumor effect of defucosylated CCR4 antibody (Niwa et al)

2012
Approval in Japan

2017
Breakthrough Therapy Designation
Priority Review Designation

2018

Basic research | **Clinical Studies**

Clinical Development

Japan

- **2007- JPN** ATL Ph1 → **2009- JPN** ATL Ph2 → **2011.4** NDA → **2012.3** Approval
- **2010- JPN** PTCL Ph2 → **2014.3** Approval
- **2010- JPN** 1st ATL Ph2 → **2014.12** Approval

US

- **2009- US** PTCL/CTCL Ph1/2 → **2012- Global** CTCL Ph3 → **2017.11** BLA → **2018.8** Approval

Key development updates in 18Q3 (2)

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- **Discontinued development for mogamulizumab in combination with nivolumab for the treatment of solid tumors based on a collaboration agreement on immuno-oncology combination therapies with Ono Pharmaceutical**

Key development events in 2018 (after October)

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- **Initiation of the phase 2 clinical study of KHK4083 for the treatment of atopic dermatitis in Japan, the U.S., Canada, and Germany**

ClinicalTrials.gov identifier: NCT03703102

Note: Listed events were completed between October 1, 2018 and October 30, 2018.

Business Topics

Darbepoetin alfa Syringe [KKF]

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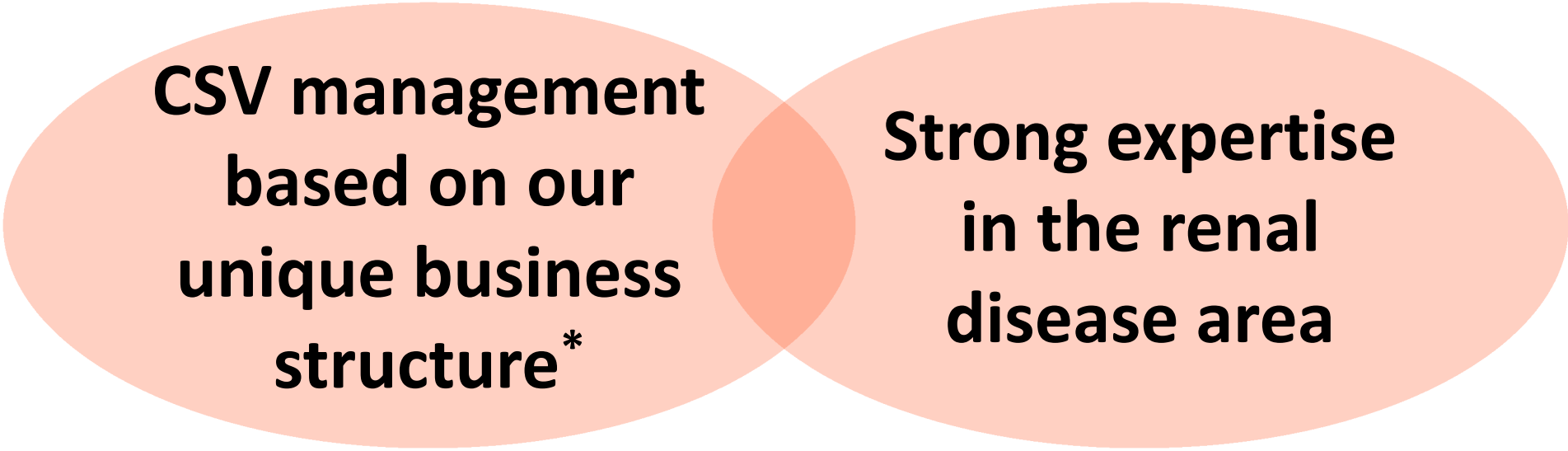
Darbepoetin alfa (authorized version of NESP)
Approved in Japan



- **Currently making preparations to ensure a steady supply**
  (Targeted retail availability: Third quarter of 2019)
- **Co-promotion by KHK and KKF****
  (KKF plans to deploy its sales forces)

* 2016-2020 mid-term business plan/Fourth strategic pillar: Contribution to health and well-being of people
** KKF: Kyowa Kirin Frontier Co., Ltd., a wholly owned subsidiary of KHK

Appendix

FOREX Information

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Average FOREX Rate

[Yen]

Currency	2017Q3 Results	2018Q3 Results	Changes	2018Q4 Plan
USD/JPY	112	109	-3	110
EUR/JPY	124	131	+7	130
GBP/JPY	142	149	+7	150

2018Q3 FOREX Effect (YoY)

[Billion Yen]

Segment	Currency	Revenue	Core OP
Pharmaceuticals	USD	-0.2	-0.1
	EUR	+0.0	+0.0
	GBP	+1.3	-0.2
Bio-Chemicals	USD	-0.3	-0.2
	EUR	+0.6	+0.3

Burosumab： Collaboration with Ultragenyx (summary)

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	KHK group	Ultragenyx
U.S.A Canada	●Books sales ●Splits profits in half with Ultragenyx for first 5 years ●After 5 years, pays mid to high 20% range sales royalty to Ultragenyx	●Splits profits in half with KHK for first 5 years ●After 5 years, receives mid to high 20% range sales royalty from KKI
Europe	●Books sales ●Pay up to 10% sales royalty to Ultragenyx	●Receives up to 10% sales royalty from KKI
Latin America	●Receives low single-digit sales royalty from Ultragenyx	●Books sales ●Pays low single-digit sales royalty to KHK
Turkey	●Receives up to 20% sales royalty from Ultragenyx ●Retains an option to take over commercialization rights after a certain period	●Books sales ●Pays up to 20% sales royalty to KKI
Asia (incl. Japan) ROW	●Books sales	

* KHK supplies commercial product in all regions.

Development schedule of major pipeline

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As of September 30
+：Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2018	2019	2020~
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Phase 3		
Benralizumab[1] KHK4563	COPD	U.S., Europe		TBD	
		Japan		TBD	
Brodalumab KHK4827	Psoriasis	Asia		Submission / +	
	Axial spondyloarthritis	Japan, Korea, Taiwan	Phase 3		Submission
Burosumab[2] KRN23	XLH	Europe	Approved (Pediatric)	+ (Adult)	
		U.S.	Approved		
		Japan	Submission	+	
Entinostat KHK2375	Breast cancer	Japan	Phase 2		
Istradefylline KW-6002	Parkinson's disease	U.S.	Submission	+	
Mogamulizumab KW-0761	CTCL	U.S	Approved[3]		
		Europe	+		
Romiplostim AMG531	Aplastic anemia	Japan	Filed	+	
		Korea		Submission	+
	ITP	China		Submission	+

[1]NDA holder is AstraZeneca [2]Jointly developed with Ultragenyx [3]Approved indications are MF and SS

Development schedule of major pipeline (cont.)

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As of September 30

Code	Indication	Country/ region	2018	2019	2020~
Bleselumab ASKP1240[4]	Recurrence of FSGS in de novo kidney transplant	U.S.	Phase 2		
KHK4083	Ulcerative colitis	U.S., Europe	Phase 2		
	Atopic dermatitis	U.S., Europe, Japan	Phase 2		
KW-6356	Parkinson's disease	Japan	Phase 2		

[4]Jointly developed with Astellas Pharma Inc

Progress in products under the alliances with partners

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Product	Indication	Country/ region	Month	Event
Dovobet Gel	• Psoriasis	Japan	Feb.	Approved
			Jun.	Launched
Rituximab BS Intravenous Infusion [KHK]	• CD20 positive, B-cell non Hodgkin's lymphoma • CD20 positive, B-cell lymphoma under immunosuppressed condition • Wegener's Granulomatosis, microscopic polyangiitis	Japan	Jan.	Launched

Note: Listed events were completed between January 1, 2018 and September 30, 2018.

Biosimilar product development

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As of September 30

Development code	Reference bio medical product		Country/region	Development stage		
	Generic name	Brand name		Phase 2	Phase 3	Application
FKB327[2]	Adalimumab	HUMIRA	U.S., others			
FKB238[3]	Bevacizumab	Avastin	U.S., Europe, others			
Not disclosed	Not disclosed	Not disclosed	Not disclosed (Target product determined)			

1

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

ClinialTrials.gov identifier: [1] NCT02810457

[2] Already approved in EU

[3] Development is currently conducted by Centus Biotherapeutics Limited.

List of acronyms

BS	Biosimilar
COPD	Chronic Obstructive Pulmonary Disease
CTCL	Cutaneous T-Cell Lymphoma
CKD	Chronic Kidney Disease
DKD	Diabetic Kidney Disease
ESRD	End Stage Renal Disease
FSGS	Focal Segmental Glomerulosclerosis
ITP	Idiopathic (immune) Thrombocytopenic Purpura
MF	Mycosis Fungoides
PTCL	Peripheral T-Cell Lymphoma
SS	Sézary Syndrome
XLH	X-linked Hypophosphatemia

KYOWA KIRIN

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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