KYOWA KIRIN

Results Presentation
Fiscal 2018

Kyowa Hakko Kirin Co., Ltd.

Agenda

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FY2018 Financial Review & FY2019 Forecasts
Outlook of the Mid-term Business Plan
Shareholder Returns Plan
R&D Review
Business Topics

President & COO **Masashi Miyamoto, Ph.D.**

Q&A

President & COO **Masashi Miyamoto, Ph.D.**
Executive Officer, Head of R&D Division **Mitsuo Satoh, Ph.D.**
Executive Officer, Head of Accounting Dept **Motohiko Kawaguchi**

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.

FY2018 Financial Review

Summary of the Consolidated Results

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	2017 Results	2018 Results	Changes	2018 Plan (30-Oct-2018)	Achieved Rate
Revenue	353.4	346.5	-6.8 (-2%)	335.0	103%
Core OP *[Margin]* OP: Operating Profit	57.7 *[16.3%]*	58.7 *[16.9%]*	+1.0 (+2%)	54.0 *[16.1%]*	109%
Profit	42.9	54.4	+11.5 (+27%)	52.0	105%

(Billion Yen / Rounded)

Consolidated: YoY Analysis 2017 vs 2018 -Profit-

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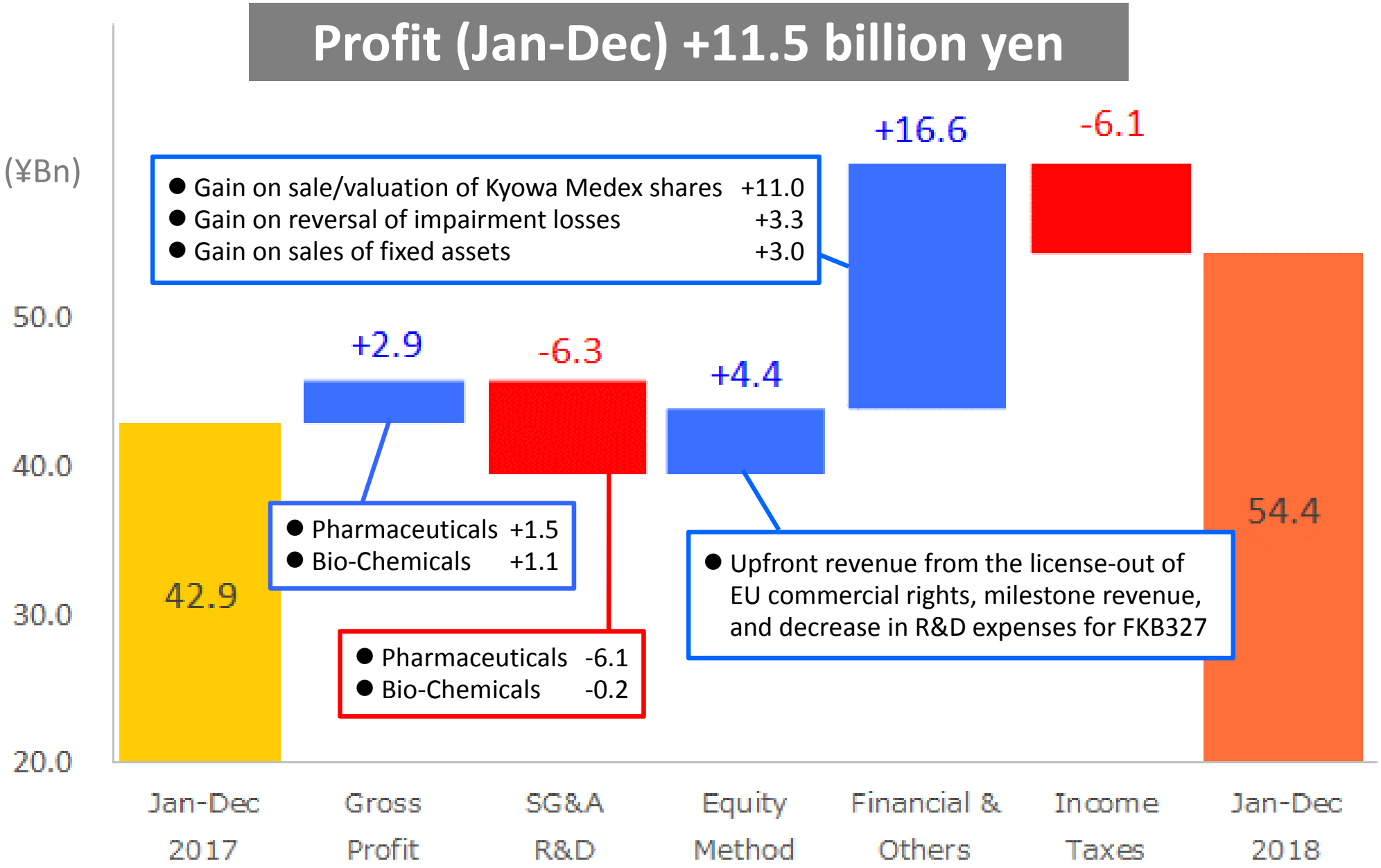

Summary of the Results by Segment

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- **Pharmaceuticals: Almost same as 2017 due to the higher overseas revenue & improved equity-method loss despite the higher expenses & lower domestic revenue.**
- **Bio-Chemicals: Core OP increased due to improved profitability despite the lower revenue.**

		2017 Results	2018 Results	Changes	2018 Plan (30-Oct-2018)	Changes
Pharma-ceuticals	Revenue	275.8	271.5	-4.3 (-2%)	262.0	104%
	Core OP *[Margin]*	50.5 *[18.3%]*	50.3 *[18.5%]*	-0.2 (-0%)	46.0 *[17.6%]*	109%
Bio-Chemicals	Revenue	81.1	78.2	-2.9 (-4%)	76.0	103%
	Core OP *[Margin]*	7.2 *[8.9%]*	8.1 *[10.4%]*	+0.9 (+13%)	8.0 *[10.5%]*	102%

(Billion Yen / Rounded)

Pharmaceuticals: YoY Analysis -Revenue-

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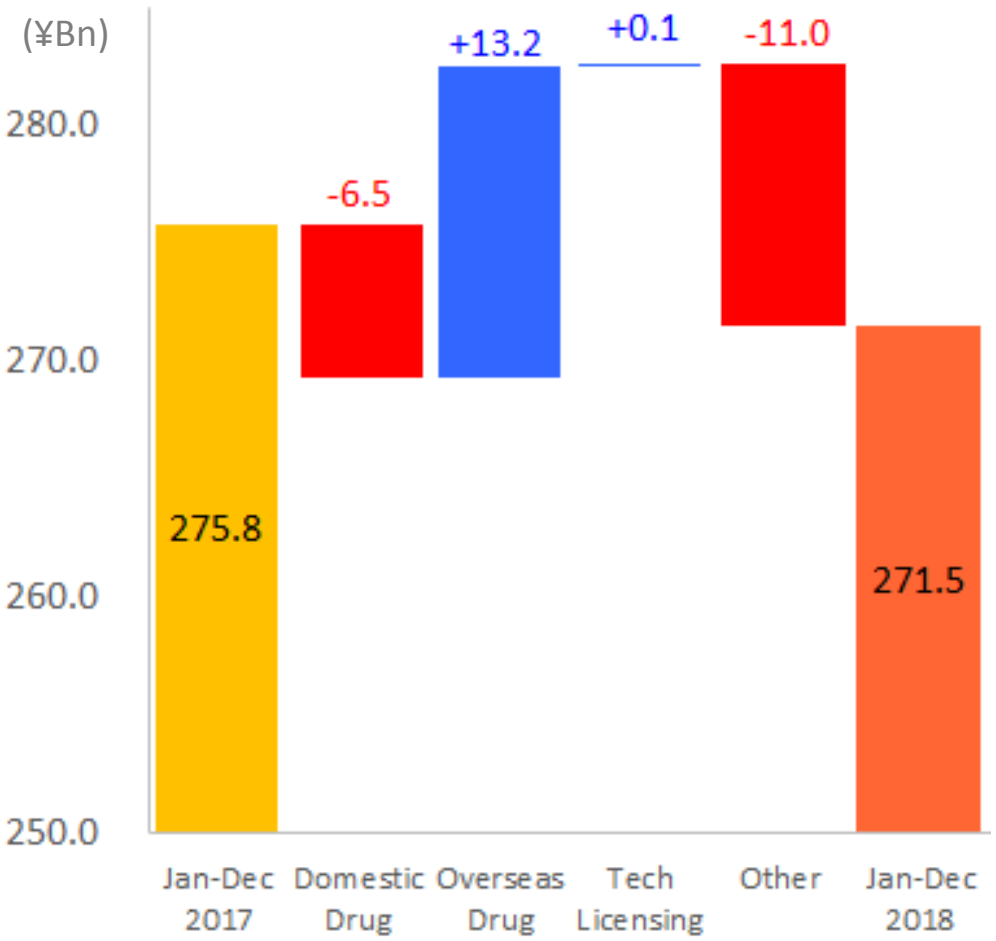
-4.3 billion yen
(incl. forex effect +0.9)



● Domestic Drug -6.5

- **Positive:** Rituximab-BS which was launched in Jan (+4.3), Orkedia which was released in May (+2.4), and the other new products such as G-Lasta (+2.6), Lumicef (+1.0), Nouriast (+0.9), Dovobet (+0.6) maintained strong growth.
- **Negative:** Regpara dropped due to the presence of a competing product (-5.3). Nesp declined due to the drug price cut (-2.6). Long-listed products including Allelock (-3.3), Coniel (-1.5), Asacol (-1.3), Depakene (-1.2) fell mainly due to the penetration of generic/competing drugs.

● Overseas Drug +13.2 (incl. forex effect +1.0)

- **EU/US:** Crysvita (+7.7) and POTELIGEO (+2.1) were launched in April and October, respectively. Abstral maintained steady growth (+0.8).
- **Asia:** Regpara (+1.0) & Nesp (+0.7) achieved favorable sales.

● Tech Licensing +0.1 (incl. forex effect -0.1)

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

● Others -11.0

- Mainly due to the deconsolidation of Kyowa Medex.

Pharmaceuticals: YoY Analysis -Core OP-

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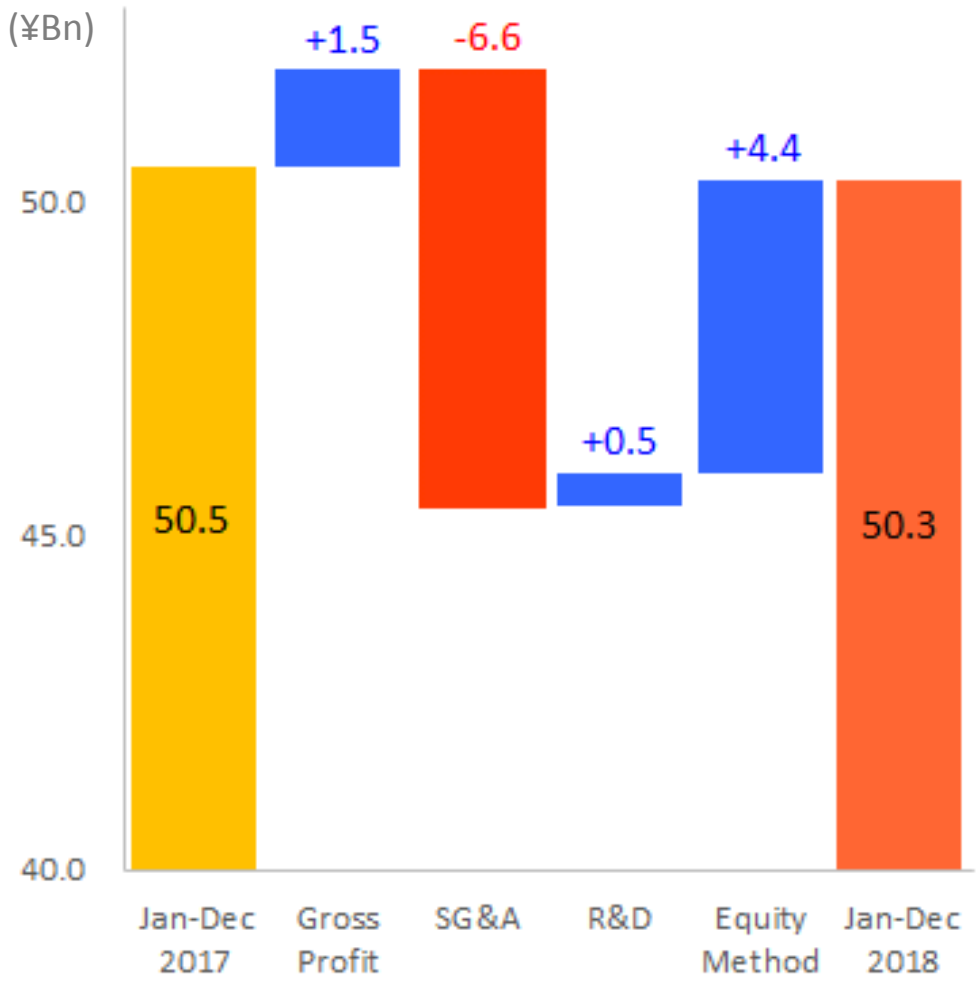
-0.2 billion yen
(incl. forex effect -0.2)



- **Gross Profit +1.5 (incl. forex effect +0.7)**
  - Increased due to the favorable overseas drug segment, despite the impact of the drug price cut and competitors/generics' penetration in Japan and the deconsolidation of Kyowa Medex.

- **SG&A -6.6 (incl. forex effect -0.8)**
  - Increased selling and launch readiness expenses for Crysvita & POTELIGEO in the EU/US.
    *Including profit sharing expenses in North America.

- **R&D +0.5 (incl. forex effect -0.1)**
  - **Positive:** KRN23 (Crysvita), KW-0761 (POTELIGEO)
  - **Negative:** RTA 402-Ph3, KHK4083-Ph2

- **Gain/Loss on Equity Method +4.4**
  - Upfront revenue from the license-out of EU commercial rights, milestone revenue, and decrease in R&D expenses for FKB327.

Pharmaceuticals: Domestic Revenue of Major Items

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Item	2017 Results	2018 Results	Changes	Reason	2019 Plan	Changes
Nesp+AG*	56.3	53.7	-2.6(-5%)	Drug price cut	48.4	-10%
Regpara	18.5	13.3	-5.3(-28%)	A competitor's market penetration & shift to Orkedia	5.1	-62%
Orkedia	—	2.4	+2.4(—%)	Newly launched	9.5	+297%
Rituximab BS	—	4.3	+4.3(—%)	Newly launched	8.4	+95%
G-Lasta	18.1	20.7	+2.6(+14%)	Steady market penetration	22.8	+10%
Allelock	15.9	12.6	-3.3(-21%)	GE's market penetration & higher amount of pollen in the air	9.3	-26%
Patanol	12.8	13.4	+0.6(+4%)	Higher amount of pollen in the air	11.3	-16%
Nouriast	8.5	9.4	+0.9(+10%)	Steady market penetration	10.0	+7%
Technology licensing	2.4	2.7	+0.3(+15%)		4.4	+62%

(Billion yen / Rounded)

*Nesp-AG "Darbepoetin Alfa Injection Syringe [KKF]" is scheduled to be released in the 3Q of 2019 .

Pharmaceuticals: Overseas Revenue of Major Items

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Item	2017 Results	2018 Results	Changes	Reason	2019 Plan	Changes
Crysvita	—	7.7	+7.7(—%)	Newly launched	Undisclosed	—
POTELIGEO	—	2.1	+2.1(—%)	Newly launched	10.0	+378%
Abstral	11.9	12.8	+0.8(+7%)	Steady market penetration	12.3	-4%
Technology licensing	16.0	15.8	-0.2(-1%)		12.9	-18%
Including Fasenra royalty*	—	3.3	+3.3	Newly launched (by AstraZeneca)	Undisclosed	—-

(Billion yen / Rounded) *Sales royalties only, including KHK's own estimation.

Bio-Chemicals: YoY Analysis -Revenue-

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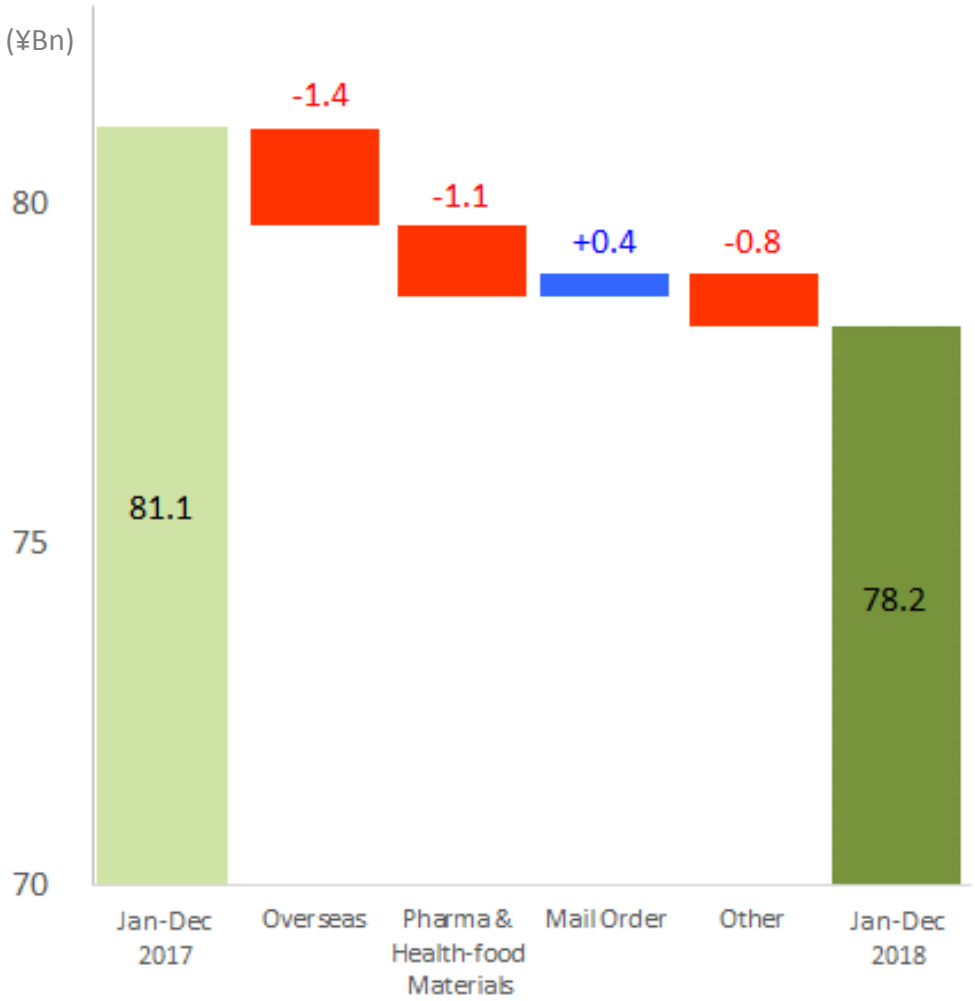
-2.9 billion yen
(incl. forex effect +0.2)



- **Overseas -1.4 (incl. forex effect +0.2)**
  - **Americas -0.8 (incl. forex effect -0.2)**
    Due to fiercer competition in certain products.
  - **Europe -0.7 (incl. forex effect +0.5):**
    Due to fiercer competition in certain products.
  - **Asia & others +0.0 (incl. forex effect -0.1)**

- **Pharma & Health-food Materials -1.1**
  - Declined due to the revamping of certain product lineups.

- **Mail Order +0.4**
  - Mainly “Arginine EX” and "Citrulline" increased.

- **Other -0.8**
  - Decreased mainly due to the transfer of the Plant Growth Regulator Business.

Bio-Chemicals: YoY Analysis -Core OP-

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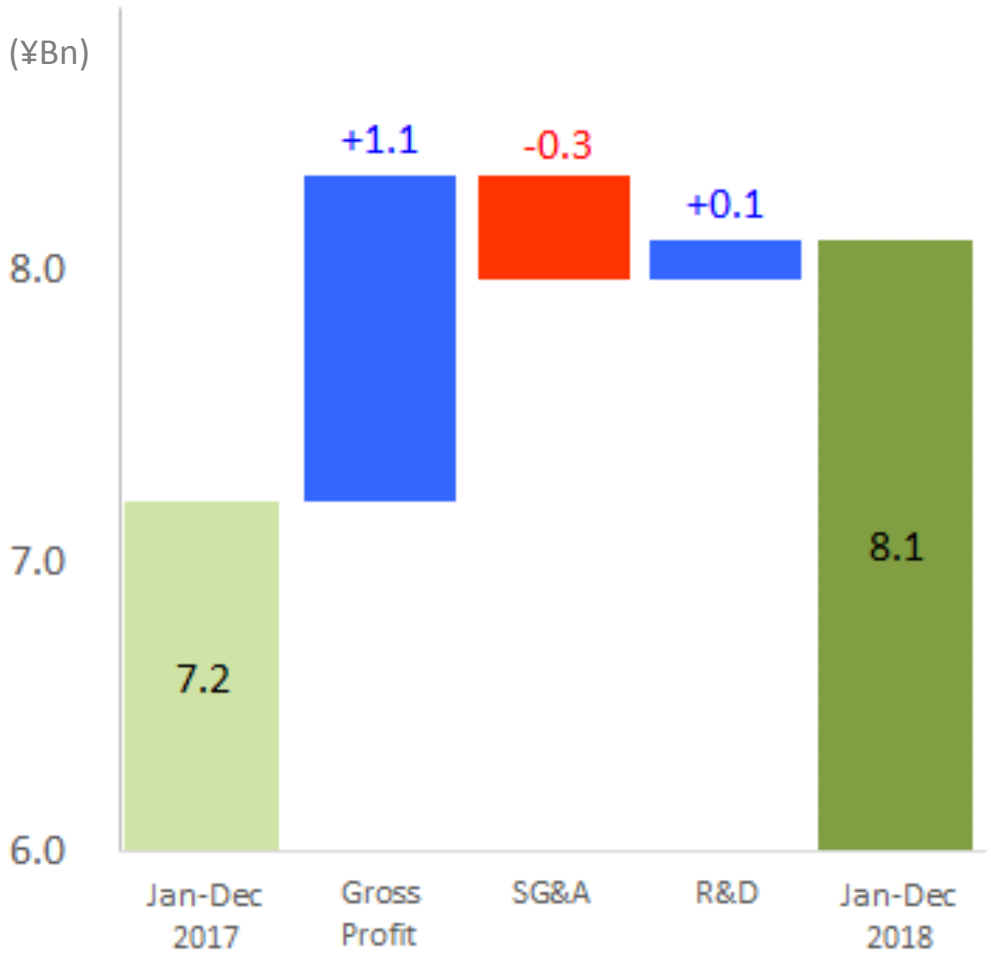
+0.9 billion yen
(incl. forex effect +0.0)



- **Gross Profit +1.1 (incl. forex effect +0.1)**
  - Manufacturing costs decreased by an increase in the overseas production.

- **SG&A -0.3 (incl. forex effect -0.0)**
  - Increased advertisement aimed at expanding the mail order business.

Aim for further leaps forward as a GSP

Aim for further leaps forward as a GSP

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Achievement of the important targets in the FY2016-2020 Mid-term Business Plan (-2018)

- Leaping forward to ES/US market
- Proactive investment for R&D
- Global Management
- Creating shared value

2016

- US KRN23 Designated Breakthrough Therapy
- JPN LUMICEF Launched

2017

- EU/US Crysvita Submission
- EU/US POTELIGEO Submission
- US KW-0761 Designated Breakthrough Therapy
- JPN ORKEDIA Submission

2018

- EU/US Crysvita Approval/ Launched
- US POTELIGEO Launched
- EU POTELIGEO Approval
- EU Hulio Launched
- JPN RTA 402 Designated "Sakigake"/Ph3
- JPN ORKEDIA Launched

2019

Leaping forward for GSP

Aim for Further Leaps Forward as a GSP

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External environment

- Japan: Fundamental revision to the drug pricing system, changes in the environment surrounding MR activities
- US: Uncertainty surrounding the healthcare policy
- Europe: Changes to the market environment due to the withdrawal of the United Kingdom from the EU

Strategic issues (2019 -)

- Maximize the value of the global strategic products
- Promote the market penetration of new drugs in Japan
- Create value directed at future growth
- Strengthen global governance

Aim for further leaps forward as a GSP, and take the necessary actions

◆Establish the "One Kyowa Kirin" structure

◆Reform business structure of KHK group

Establish the “One Kyowa Kirin” Structure

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Newly establish North America as an independent region, and start a management structure based on a matrix of regional axis X functional axis

Global management structure from April 2019

Reform Business Structure of KHK Group

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Maximize the corporate value of Kyowa Hakko Bio, and focus our resources on Pharma business

Kirin Holdings

Kyowa Hakko Kirin Group

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Kyowa Hakko Bio

Increase business speed in the health and well-being domain

Leaping forward as a GSP

Further synergies with Kirin

Reform Business Structure of KHK Group

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◆**Quickly shift to a global business model, and strengthen the business foundation in Japan**

→ Solicitation of voluntary retirement

FY2019 Forecast

FY2019 Consolidated Plan

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	2018 Results	2019 Plan	Change
Revenue	346.5	305.0	-41.6 (-12%)
Pharmaceuticals	271.5		+33.5 (+12%)
Core OP [Margin]	58.7 [16.9%]	53.0 [17.4%]	-5.7 (-10%)
Pharmaceuticals	50.3 [18.5%]		+2.7 (+5%)
Profit	54.4	68.0	+13.6 (+25%)

(Billion Yen / Rounded)

Consolidated: YoY Analysis 2018 vs 2019 -Profit-

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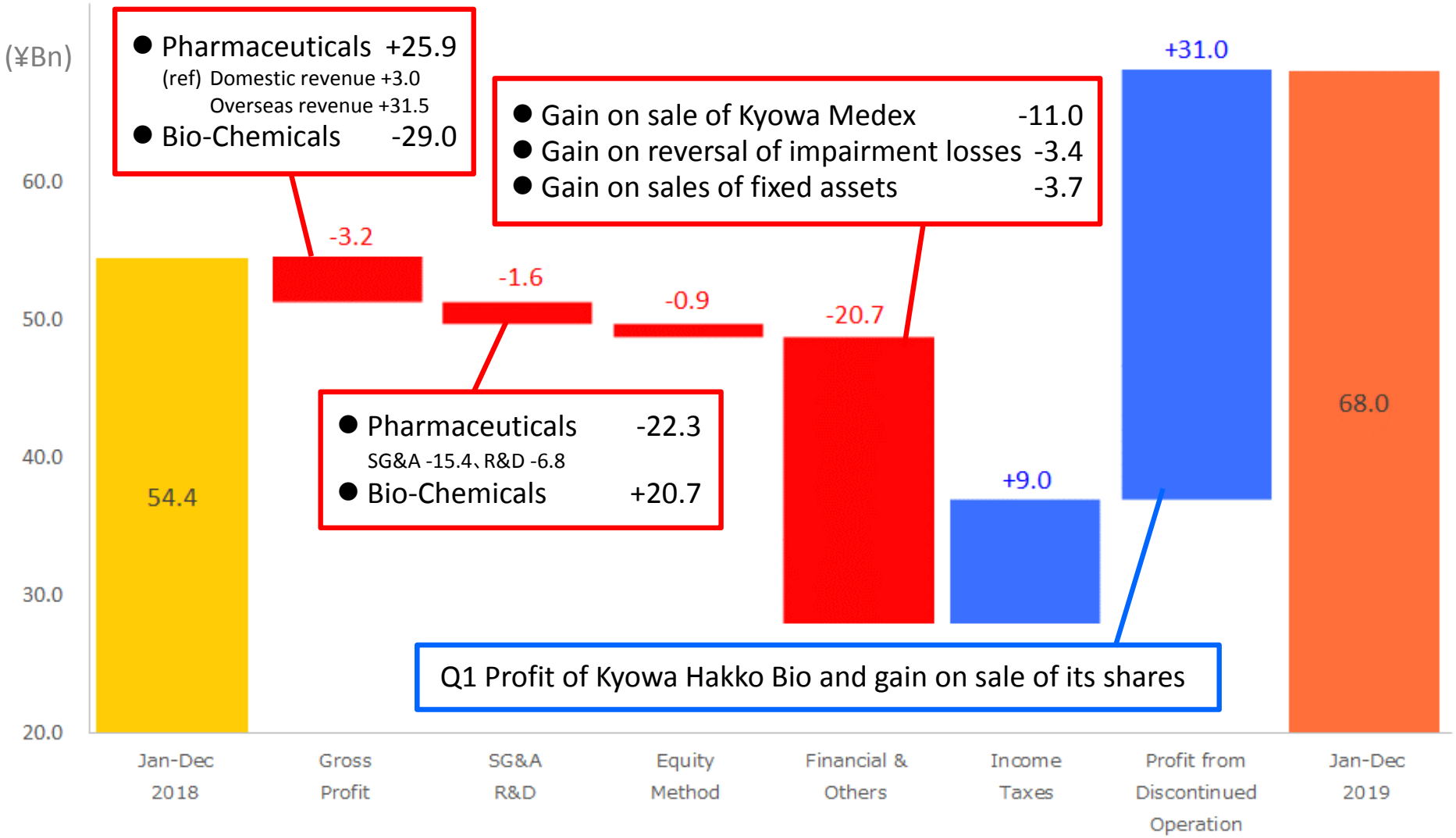
Profit (Jan-Dec) +13.6 billion yen



Outlook of Mid-term Business Plan

Forecast for Achieving the Targets in the Mid-term Business Plan

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◎

- Global strategic products: Launch the global strategic products (Crysvita, Poteligeo) in Europe and the US
- Launch new products in Japan (Lumicef, Orkedia, Rituximab-BS)
- BS business: Start sales of Hulio in Europe

✕

- Global strategic products: Delay compared to the fastest market launch plan assumed when formulating the Mid-term Business Plan, and delay in submitting the application for KW-6002
- Advance allocation of SG&A expenses directed at expanding the earnings and maximizing the value of the global strategic products (establish and enhance the global sales system, etc.)
- BS business: Start of sales has been delayed from the timing assumed when formulating the Mid-term Business Plan
- Negative impact on the recent performance as a result of the structural reforms to the businesses (KHB, KMX)

Achieving Core OP of 100 billion yen will be carried over to the next Mid-term Business Plan

Forecast for Achieving the Targets in the Mid-term Business Plan

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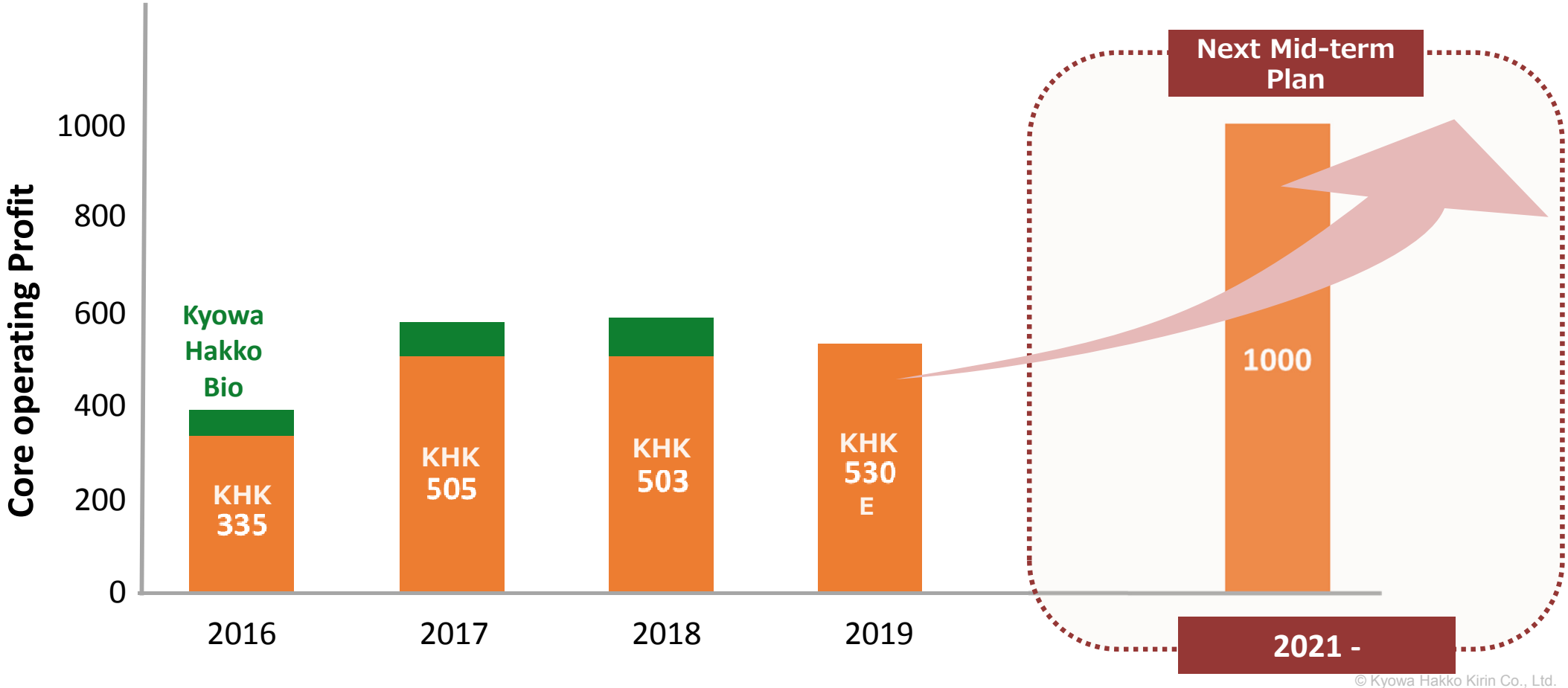
By definitely maximizing the value of the three global strategic products, aim to achieve the management targets of "core operating profit of 100 billion yen", "ROE of at least 10%" and "Percentage of overseas sales of 50%" early in the 2020s



Shareholder Returns Plan

Repurchase and Cancellation of Treasury Shares

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-Repurchase-

- Objective: Improvement of Capital Efficiency and Further Enhancement of Returns to Shareholders
- Date: February 6th, 2019
- Number: Up to 10,700,000 shares
- Amount: Up to JPY 27 billion
- Procedure: Tokyo Stock Exchange Trading Network system for Off-Auction Own Shares Repurchase Trading (ToSTNeT-3)

-Cancellation-

- Purpose: Dispelling the Concern of Future Dilution
- Date: February 19th, 2019 (planned)
- Number: Number of Shares repurchased + 25,783,555 shares

Dividend Plan

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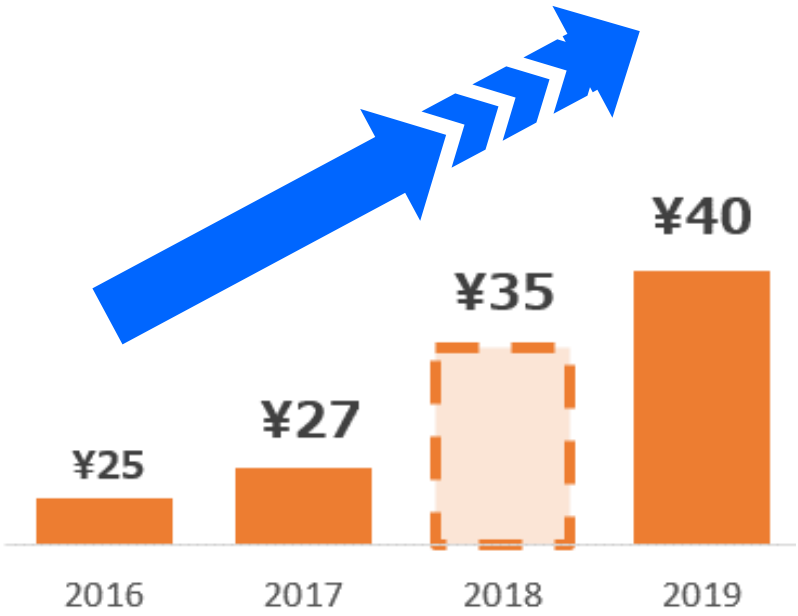
- 2018 full-year dividend will be **increased by 8 yen to 35 yen**.
- 2019 full-year dividend is planned to be further **increased by 5 yen to 40 yen**.
- The subsequent dividend is aimed to be **continually increased based on a payout ratio of 40%**.

Year	Dividend (yen)			Payout Ratio	ROE*
	Interim	Year-end			
2016	12.50	12.50	25.00	44.9%	5.3%
2017	12.50	14.50	27.00	34.4%	7.2%
2018	15.00	20.00	35.00	35.2%	8.6%
2019 (Plan)	20.00	20.00	40.00	31.7%	10.5%

*ROE: Return On Equity



[Basic policy for profit distribution]

Along with working to enhance retained earnings, such as preparing for future business developments, provide a stable dividend while comprehensively considering factors including the consolidated business results and dividend payout ratio.

- **Stock Repurchase /** Flexibly acquire treasury stock based on the market environment and financial situation.
- **Retained Earnings /** Allocate to investments that will lead to new growth, such as R&D, capital investments and development pipeline enhancements which will contribute to increased corporate value in the future..
- **Dividend /** Based on the consolidated dividend payout ratio of 40% set forth in the Mid-term Business Plan, aim to stably and continually increase the dividend level in accordance with the growth in profits.

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	Dec.	Approved (BN: Crysvita)

[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 December 31, 2018.

Key development events in 2018 (2)

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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	Nov.	Approved[1] (BN: Poteligeo)
KHK4083	Atopic dermatitis	U.S., Europe, Japan	Oct.	Initiated phase 2 study
KW-6356	Parkinson's disease	Japan	Nov.	Initiated phase 2 study

Discontinued programs in 2018：

- Development of mogamulizumab in combination therapy for the treatment of solid tumor

[1]Approved indications are MF and SS
BN: brand name
Note: Listed events were completed between January 1, 2018 and December 31, 2018.

Key development updates in 18Q4 (1)

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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 Europe**

ClinicalTrials.gov identifier: NCT03703102

KHK4083: Phase 1 Study Result (Atopic Dermatitis)

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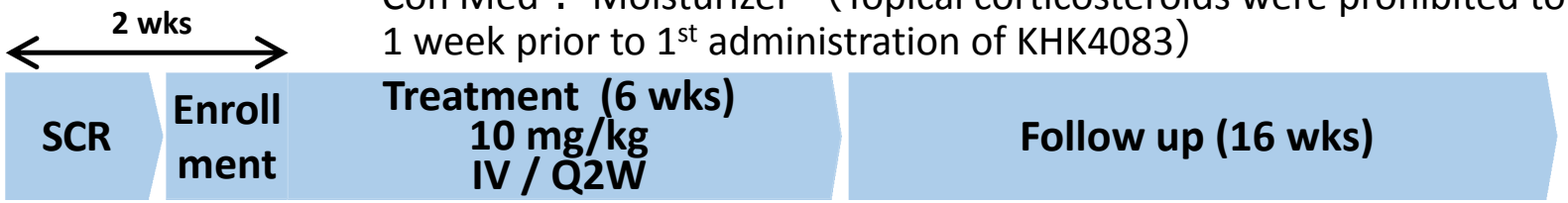
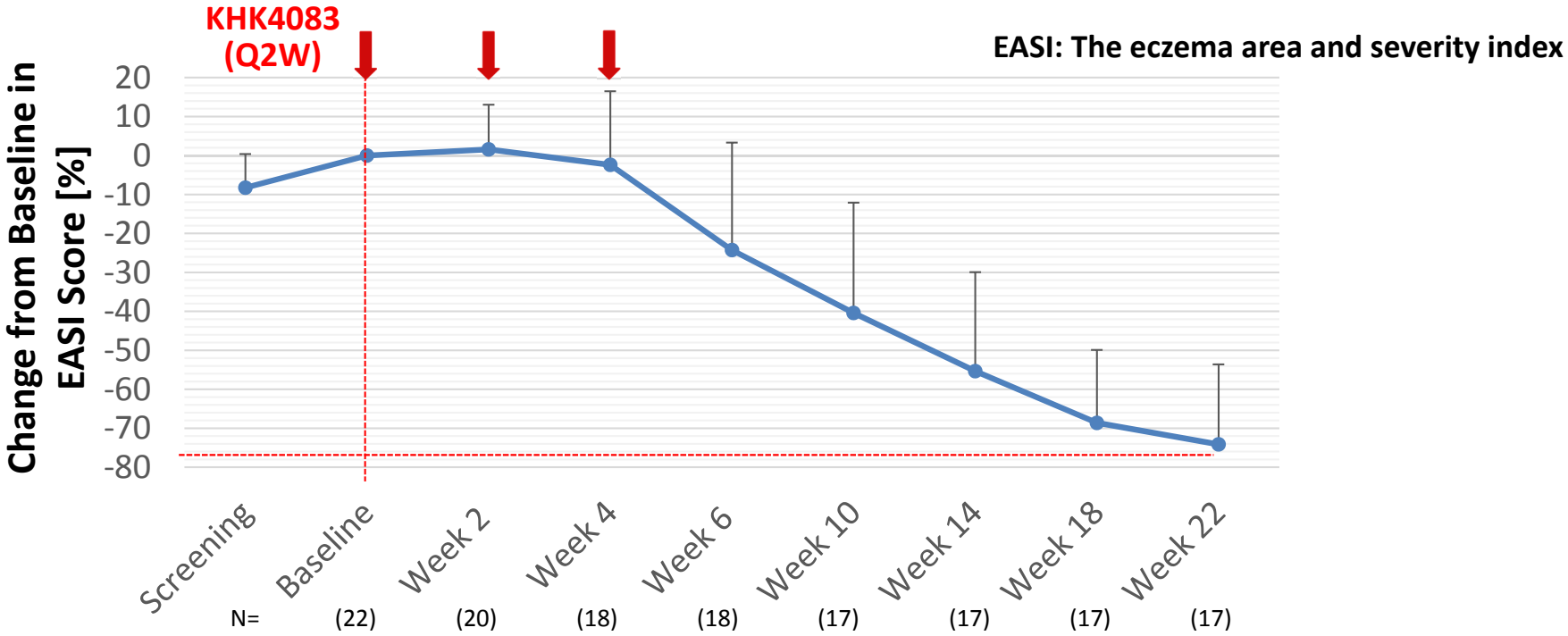
ClinicalTrials.gov Identifier: NCT03096223

- **Study Design**

  - Target：Moderate to Severe Atopic Dermatitis Subjects
  - Con Med： Moisturizer （Topical corticosteroids were prohibited to use 1 week prior to 1st administration of KHK4083）



- **% Change from Baseline in EASI Score** **(without data of subjects who received rescue treatment)**



Change of EASI score from baseline to W22 was -74.12%

Continuous improvement of EASI score was observed even after last treatment of KHK4083

KHK4083: Phase 2 Study Design (Atopic Dermatitis)

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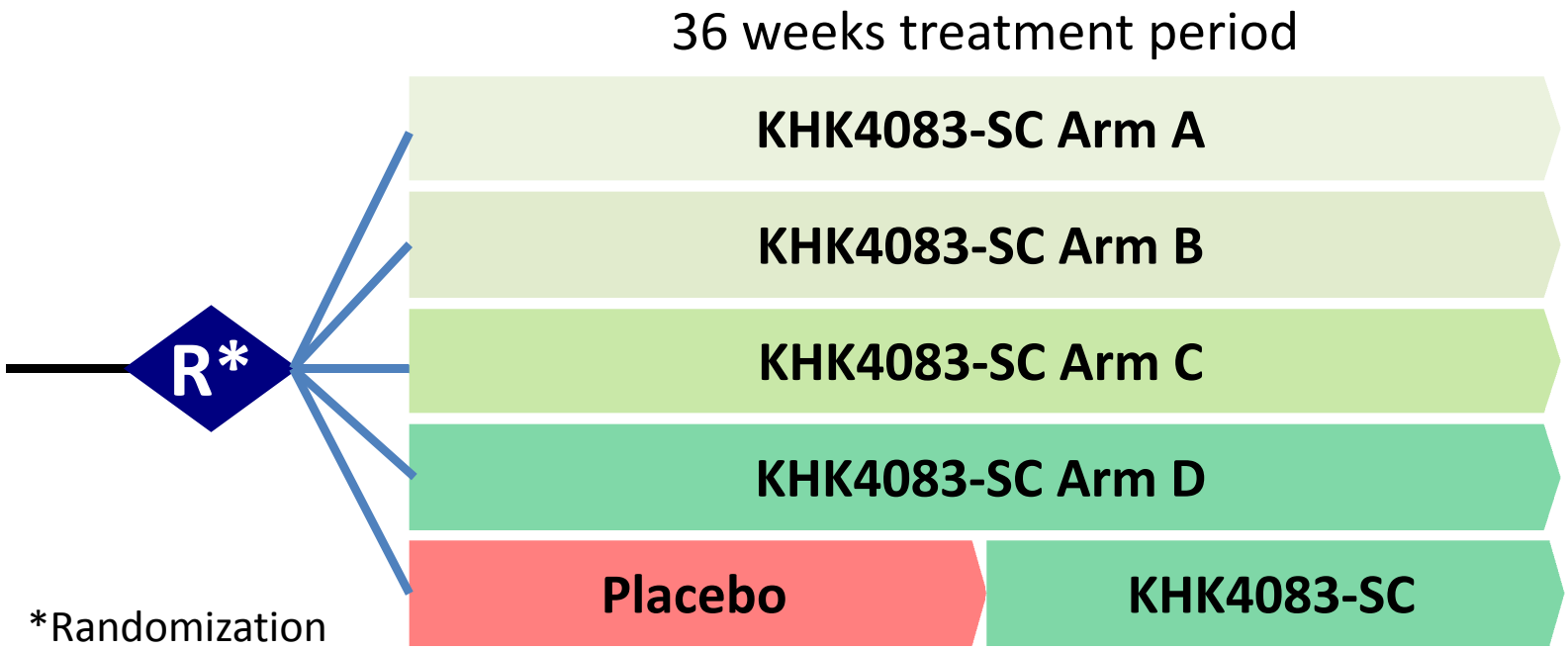
ClinicalTrials.gov Identifier: NCT03703102

- Double-blind, Placebo-Controlled study for subjects with moderate to severe atopic dermatitis



- Primary Endpoint: % change from baseline to Week16 in EASI score
- Estimated Enrollment: 250 participants

Key development updates in 18Q4 (2)

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- **Initiation of the phase 2b clinical study of KW-6356 for the treatment of Parkinson's disease in Japan**

ClinicalTrials.gov identifier: NCT03703570

KW-6356: Phase 2a Study Result (Parkinson's disease)

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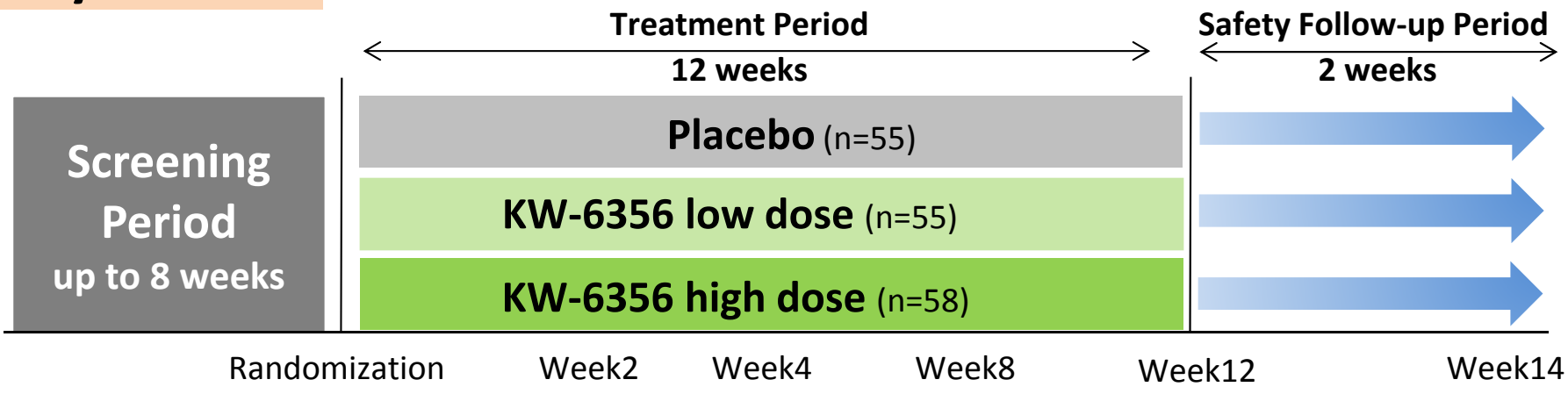
ClinicalTrials.gov Identifier: NCT02939391

Study schema



Primary endpoint; change from baseline in MDS-UPDRS* part III score at Week12

	LS mean	95% CI	Difference (KW-6356 - placebo)	95% CI
Placebo	-3.14	-4.97, -1.30		
KW-6356 low dose	-5.37	-7.25, -3.48	**-2.23**	-4.86, 0.40
KW-6356 high dose	-4.76	-6.55, -2.96	**-1.62**	-4.19, 0.94

Both KW-6356 groups showed a greater reduction in score compared with the placebo group.

*Movement Disorder Society-Unified Parkinson's Disease Rating Scale

KW-6356: Study design of phase 2b clinical study

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ClinicalTrials.gov Identifier: NCT03703570

A multicenter, randomized, double-blind, placebo-controlled phase 2b study to evaluate the efficacy and safety of KW-6356 in patients with Parkinson's disease* on treatment with Levodopa-containing preparations

Primary endpoint: % change from baseline in MDS-UPDRS part III score
Estimate enrollment: 486 participants

*Parkinson's disease patients in Stages 2 to 4 on the Modified Hoehn and Yahr Scale, and MDS-UPDRS part III score of ≧15

Key development events in 2019 (after January)

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- **Application for approval of Burosumab (KRN23) for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Japan**

Note: Listed event was completed between January 1, 2019 and February 4, 2019.

Business Topics

Enhance the lineup and pipeline of renal products

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Strengthen the renal business in Japan based on the healthcare needs

2018

- **March: Received approval for Orkedia; Received priority review designation for RTA 402**
- **May: Initiated Ph3 clinical study in Japan for RTA 402 targeting diabetic kidney disease**
- **August: Received approval for Darbepoetin Alfa Injection Syringe [KKF]**
- **November: Concluded a strategic commercialization deal in Japan for daprodustat (GSK)**

Product lineup/R&D pipeline (Nephrology area)

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Renal function deterioration — CKD Disease Progression

CKD/not on dialysis（Stage 3-5） — ESRD/on dialysis

Primary disease Comorbidity

- High blood pressure: Coniel（1991） Coversyl（1998）
- Diabetes: Onglyza（2013）
- RTA 402

Complication

- Anemia: NESP（2007） Darbepoetin alfa「KKF」（2019 E）; daprodustat
- CKD-MBD: Regpara（2008） Orkedia（2018）; ROCALTROL（2001）; PHOSBLOCK（2003）; tenapanor

Products | R&D pipeline

Commercialization agreement for HP-3000

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- **Commercialization agreement for HP-3000 in Japan, a potential new Transdermal Patch for Parkinson's Disease developed by Hisamitsu Pharmaceutical**

Appendix

FOREX Information

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Average FOREX Rate

[Yen]

Currency	2017 Results	2018 Results	Changes	2019 Plan
USD/JPY	112	110	-2	110
EUR/JPY	126	131	+5	130
GBP/JPY	144	148	+4	145

2018 FOREX Effect (YoY)

[Billion Yen]

Segment	Currency	Revenue	Core OP
Pharmaceuticals	USD	-0.3	-0.1
	EUR	+0.1	+0.0
	GBP	+1.0	-0.1
Bio-Chemicals	USD	-0.3	-0.2
	EUR	+0.5	+0.3

Currency Fluctuation Sensitivity for FY2019

Impact in case of 1yen appreciation from the plan

Currency	Impact on Revenue	Impact on Core OP
USD	-0.45 billion yen	-0.31 billion yen
GBP	-0.31 billion yen	+0.11 billion yen

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 Oceania Middle East	●Books sales	

* KHK supplies commercial product in all regions.

Development schedule of major pipeline - review

KYOWA KIRIN

As of December 31, 2018
+ : Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2018	2019	2020~
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	✓ FPI	Phase 3	
Benralizumab[1] KHK4563	COPD	U.S., Europe		TBD	
		Japan		TBD	
Brodalumab KHK4827	Psoriasis	Asia	✓ Filed / Approved	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	✓ Approved[3]		
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 - review (cont.)

KYOWA KIRIN

As of December 31, 2018

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	✓ FPI	Phase 2	
KW-6356	Parkinson's disease	Japan	✓ FPI	Phase 2	

[4]Jointly developed with Astellas Pharma Inc

Development schedule of major pipeline

KYOWA KIRIN

As of December 31, 2018
+ : Estimated time of regulatory decisions

Generic name Code	Indication	Country/ region	2019	2020	2021~
Bardoxolone methyl RTA 402	Diabetic kidney disease	Japan	Phase 3		
Bleselumab ASKP1240[1]	Recurrence of FSGS in de novo kidney transplant	U.S., Europe	Phase 2		Phase 3
Brodalumab KHK4827	Psoriasis	Asia	Submission / +		
	Axial spondyloarthritis	Japan, Korea, Taiwan	Phase 3	Submission / +	
Burosumab[2] KRN23	XLH (adult)	Europe	Submission	+	
	XLH[3]	Japan	Submission / +		
Entinostat KHK2375	Breast cancer	Japan	Phase 2		
Evocalcet KHK7580	PHPT	Japan	Submission	+	
	SHPT	Asia	Phase 3		
Istradefylline KW-6002	Parkinson's disease	U.S.	Submission / +		
Mogamulizumab KW-0761	HAM	Japan	Submission	+	
Romiplostim AMG531	Aplastic anemia	Japan	+		
		Korea	Submission	+	
	ITP	China	Submission	+	

[1]Jointly developed with Astellas [2]Jointly developed with Ultragenyx
[3]Filed indications are FGF23-related hypophosphatemic rickets and osteomalacia

Development schedule of major pipeline (cont.)

KYOWA KIRIN

As of December 31, 2018

Code	Indication	Country/ region	2019	2020	2021~
KHK4083	Ulcerative colitis	U.S., Europe	Phase 2		Phase 3
	Atopic dermatitis	U.S., Europe, Japan	Phase 2		Phase 3
KHK7791	Hyperphosphatemia in CKD	Japan	Phase 2		Phase 3
KW-6356	Parkinson's disease	Japan	Phase 2		Phase 3
ME-401	B cell malignancy	Japan	Phase 1	Phase 3	

Progress in products under the alliances with partners

KYOWA KIRIN

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 December 31, 2018.

Biosimilar product development

KYOWA KIRIN

As of December 31, 2018

Development code	Reference bio medical product		Country/region	Development stage		
	Generic name	Brand name		Phase 2	Phase 3	Application
FKB327[1]	Adalimumab	HUMIRA	U.S., others			
FKB238[2]	Bevacizumab	Avastin	U.S., Europe, others			
Not disclosed	Not disclosed	Not disclosed	Not disclosed (Target product determined)			

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

ClinialTrials.gov identifier: [2] NCT02810457

[1] Already approved in EU. FKB327 has been sold by Mylan in EU (Brand Name: Hulio).

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

List of acronyms

KYOWA KIRIN

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
HAM	HTLV-1 Associated Myelopathy
ITP	Idiopathic (immune) Thrombocytopenic Purpura
MF	Mycosis Fungoides
PHPT	Primary Hyperparathyroidism
SHPT	Secondary Hyperparathyroidism
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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