KYOWA KIRIN

Results Presentation
Fiscal 2019 First Quarter

Kyowa Hakko Kirin Co., Ltd.

Agenda

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Financial Review

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Executive Officer, Director of Accounting Department

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.

Financial Review

Summary of the Consolidated Results

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(Billion Yen / Rounded)

	2018Q1 Results	2019Q1 Results	Changes	2019Q4 Plan (5-Feb-2019)	Progress
Revenue	66.5	75.8	+9.3 (+14%)	305.0	25%
Gross Profit *[Gross Profit margin]*	46.7 *[70%]*	56.1 *[74%]*	+9.4 (+20%)	224.0 *[73%]*	25%
Core OP *[Core OP margin]*	14.4 *[22%]*	17.3 *[23%]*	+2.9 (+20%)	53.0 *[17%]*	33%
Profit from continued operation	20.9	9.3	-11.6 (-55%)	37.0	25%
Profit from discontinued operation	1.1	-1.2	-2.3	31.0	n/a
Profit	22.0	8.1	-13.9 (-63%)	68.0	12%

YoY Analysis -Revenue-

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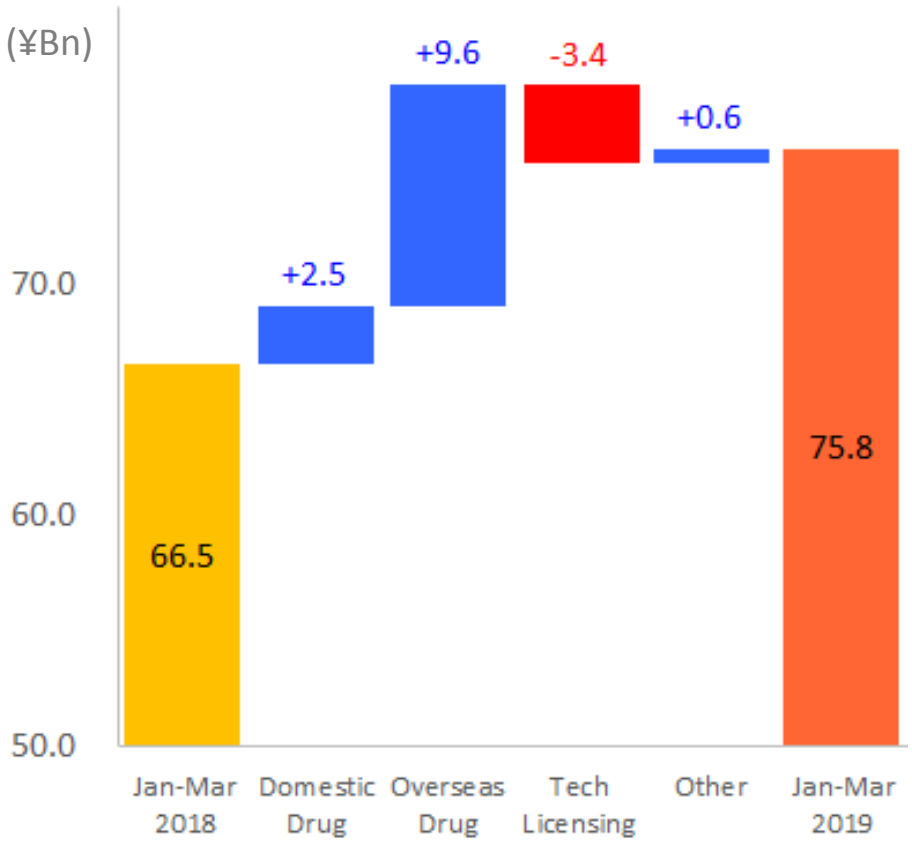
+9.3 billion yen (incl. forex effect -0.9)



● Domestic Drug +2.5

- **Positive:** New product line including Rituximab-BS (+1.5), Orkedia (+1.2), G-Lasta (+0.9), Dovobet (+0.4), Nouriast (+0.3) and Lumicef (+0.2) maintained steady growth. Patanol also increased due to the higher amount of pollen in the air (+0.8).
- **Negative:** There are negative impacts by the drug price revision in April 2018. In addition, Regpara (-1.7) dropped due to the presence of a competing product and switch to Orkedia. Long-listed products such as Allelock (-0.6), Coniel (-0.3) and Depakene (-0.2) decreased mainly due to the penetration of generic drugs.

● Overseas Drug +9.6 (incl. forex effect -0.9)

- **EU/US:** Crysvita (+5.7) and Poteligeo (+2.4), launched last year, strongly penetrated into the market.
- **Asia:** Regpara (+0.5) achieved favorable sales in China and Korea. Neulasta/Peglasta (+0.5) increased due to the launch in Middle Eastern countries.

● Tech Licensing -3.4

- **Benralizumab:** Increased sales royalties were not able to offset the absence of milestone revenue booked last year.

Revenue of Major Items (Japan)

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(Billion yen / Rounded)

Item	2018Q1 Results	2019Q1 Results	Changes	Reason	2019Q4 Plan	Progress
Nesp+AG*	12.0	11.8	-0.2 (-2%)		48.4	24%
Regpara	3.6	1.8	-1.7 (-48%)	A competitor's market penetration & shift to Orkedia	5.1	36%
Orkedia	—	1.2	+1.2	Launched on May 2018	9.5	13%
Rituximab BS	0.3	1.8	+1.5 (+461%)	Launched on Jan 2018	8.4	22%
G-Lasta	4.3	5.3	+0.9 (+21%)	Steady market penetration	22.8	23%
Allelock	4.6	4.0	-0.6 (-13%)	Market penetration by generic drugs	9.3	43%
Patanol	7.7	8.5	+0.8 (+10%)	Higher amount of pollen in the air	11.3	75%
Nouriast	1.9	2.2	+0.3 (+14%)	Steady market penetration	10.0	22%
Technology licensing	1.1	0.9	-0.2 (-14%)		4.4	21%

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

Revenue of Major Items (Overseas)

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(Billion yen / Rounded)

Item	2018Q1 Results	2019Q1 Results	Changes	Reason	2019Q4 Plan	Progress
Crysvita*	—	5.7	+5.7	Launched on Apr 2018	Undisclosed	—
Poteligeo	—	2.4	+2.4	Launched on Oct 2018	10.0	24%
Abstral	3.4	3.1	-0.3 (-9%)		12.3	25%
Technology licensing	6.5	3.2	-3.3 (-50%)		12.9	25%

*In January, sales started in UK (England etc) at the list price of GBP2,992 per 10mg vial.
Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).

YoY Analysis -Core OP-

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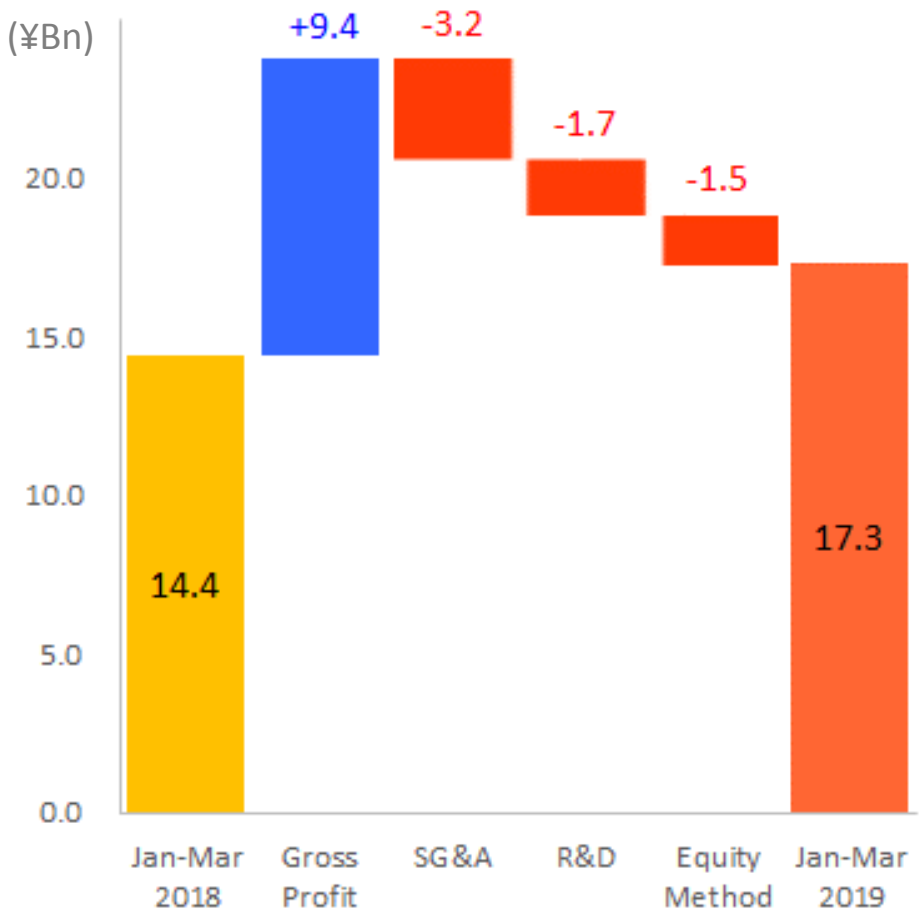
+2.9 billion yen (incl. forex effect +0.1)



- **Gross Profit +9.4 (incl. forex effect -0.5)**
  - Increased in conjunction with the rise in the revenue. Gross profit margin up by 4 points, from 70% to 74%.

- **SG&A -3.2 (incl. forex effect +0,6)**
  - Increased selling and launch readiness expenses in the EU/US. *Including Crysvita's profit sharing expenses in North America.

- **R&D -1.7 (incl. forex effect +0.1)**
  - **Negative:** KHK4083 (P2 initiated in Oct 2018), RTA402 (P3 initiated in May 2018), KW-6356 (P2 initiated in Nov 2018), etc.

- **Gain/Loss on Equity Method -1.5**
  - Decreased due to the absence of FKB327-related revenue from the license-out of EU commercial rights and the achieved development milestone booked last year.

YoY Analysis -Profit-

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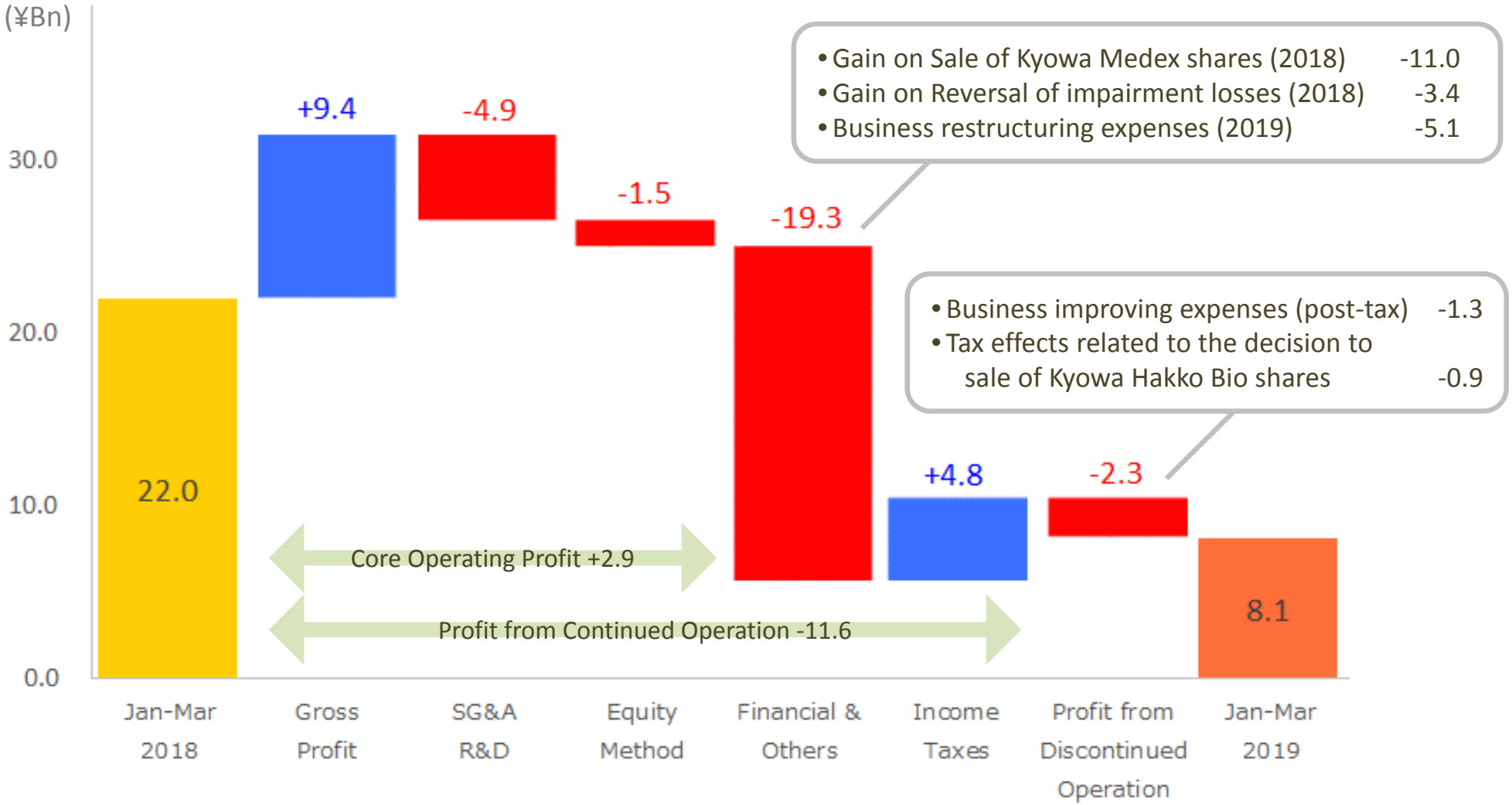
Profit (Jan-Mar) -13.9 billion yen



R&D Review

Key development updates in 19Q1

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

- **Initiation of the phase 2 clinical study of KHK7791 for the treatment of hyperphosphatemia under maintenance dialysis in Japan**

KHK7791: Phase 3 Study Results (conducted by Ardelyx in the US)

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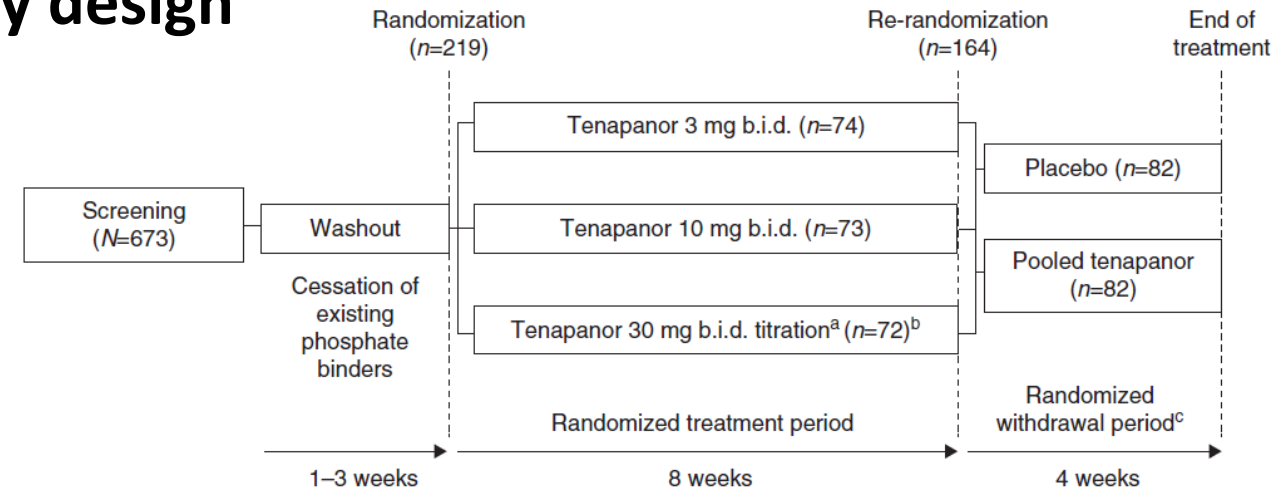
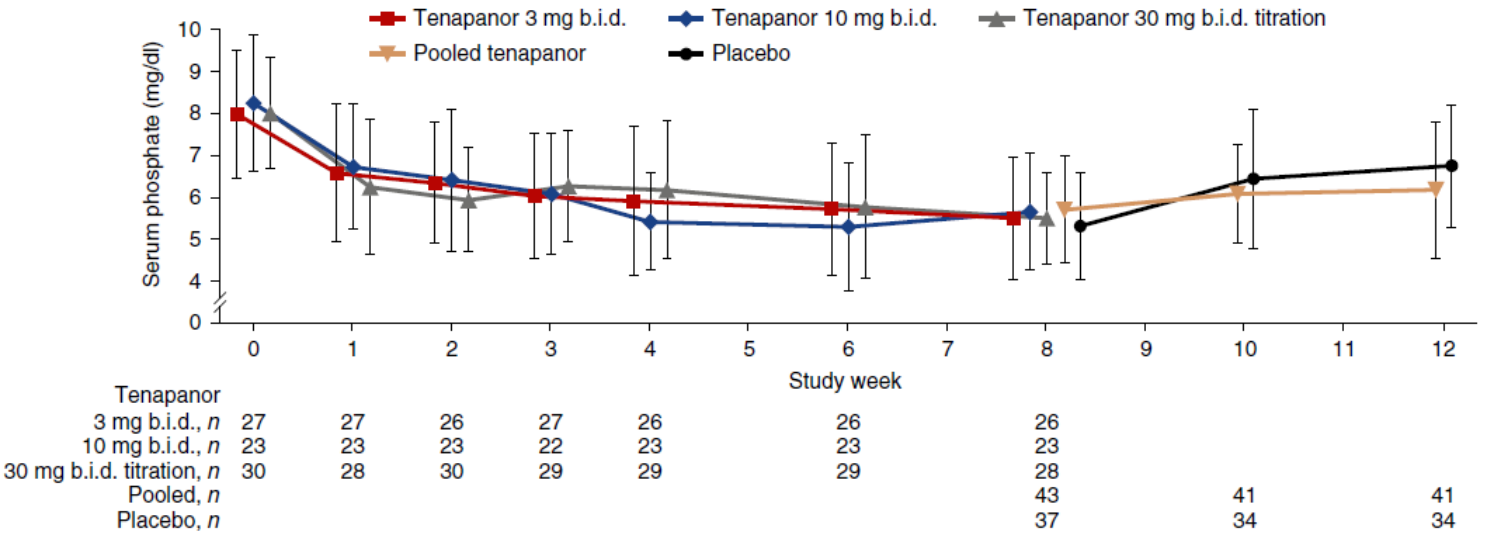
- **Study design**

J Am Soc Nephrol. 2019 Apr;30(4):641-652.

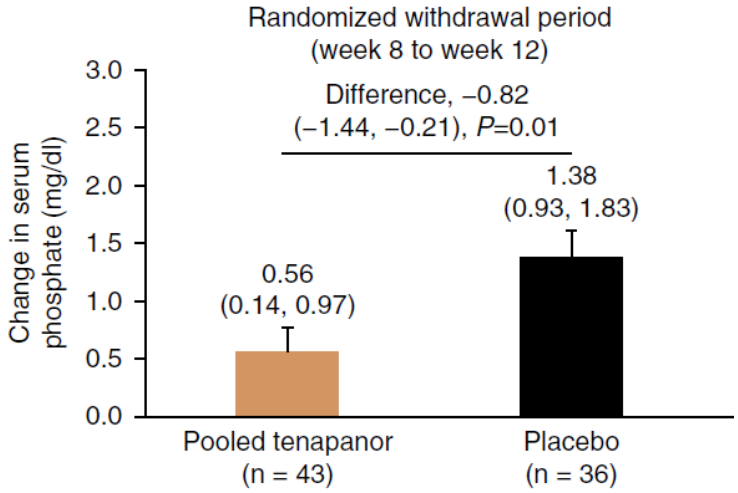


- **Efficacy result**

Serum phosphate levels



Change in serum phosphate levels during randomized withdrawal period



KHK7791: Phase 2 Study Design

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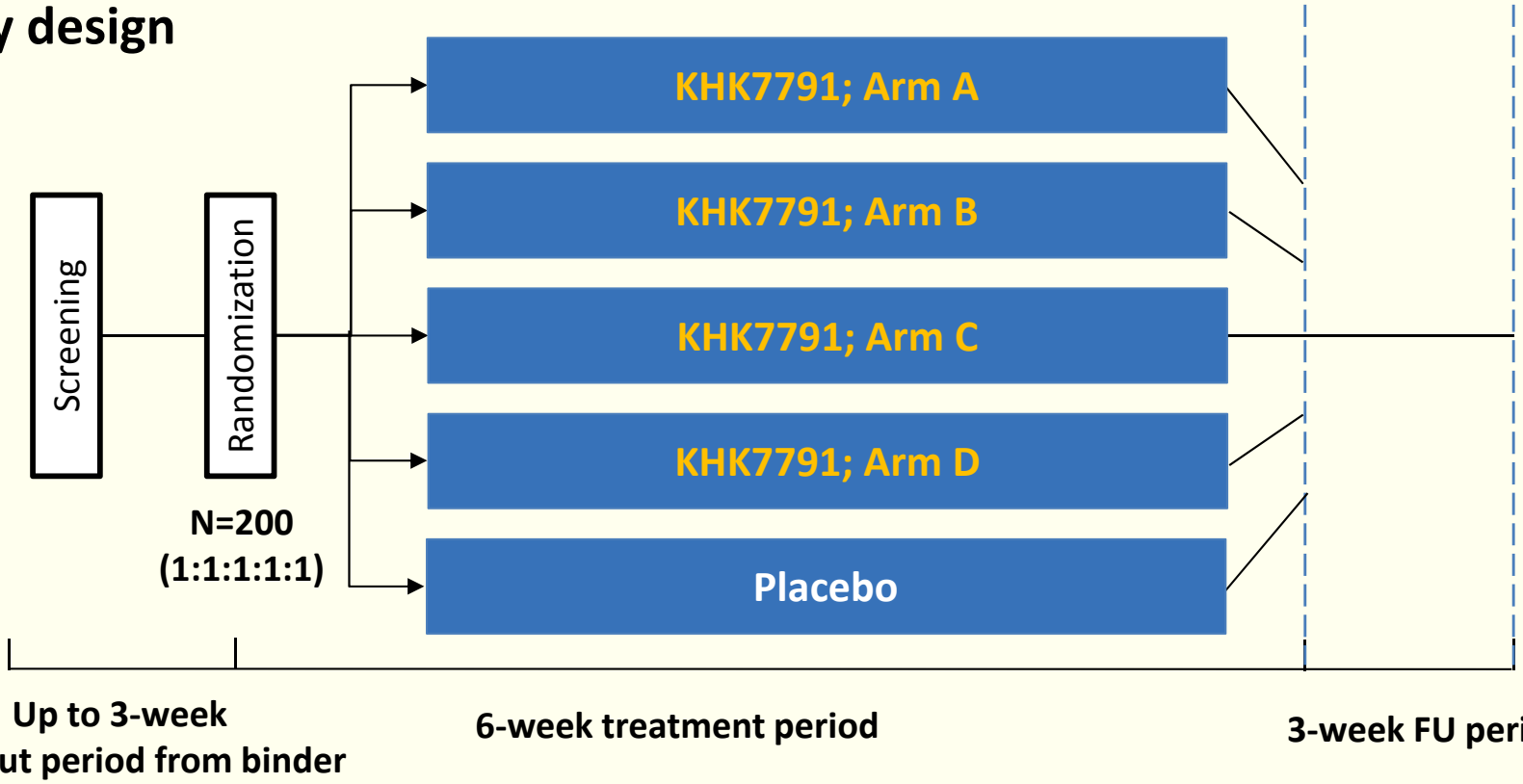
Dose-finding Study of KHK7791 in Hyperphosphatemia Patients

ClinicalTrials.gov Identifier: NCT03864458

☐ Study design



☐ Primary endpoint: To investigate the clinically recommended dose by comparing changes in serum phosphorus levels from baseline values at Week 6

In addition to the above, two other Phase 2 studies are underway
（ClinicalTrials.gov Identifier: NCT03831607, NCT03864445）

Key development events in 2019 (after April)

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- **Resubmission of application for approval of istradefylline for the treatment of Parkinson's disease in the U.S.**

Note: Listed event was completed between April 1, 2019 and May 7, 2019.

Business Topics

Maximizing the value of Benralizumab

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Agreed to grant AstraZeneca exclusive development and commercialization rights for all indications, including the already agreed to rights for asthma and COPD, in Asia, including Japan

- **With this new agreement, AstraZeneca now possesses global rights to all of the indications for benralizumab**
- **Through this agreement, it is expected that the value of benralizumab will be maximized by AstraZeneca handling the product strategy for all indications globally**

Appendix

FOREX Information

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Average FOREX Rate

[Yen]

Currency	2018Q1 Results	2019Q1 Results	Changes	2019Q4 Plan
USD/JPY	110	110	—	110
GBP/JPY	152	143	-9	145

FOREX Effect (YoY)

[Billion Yen]

Segment	Currency	Revenue	Core OP
Pharmaceuticals	USD	—	—
	GBP	-0.7	+0.3

Key progress in development (2019 Q1)

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Note: Listed events were completed between January 1st ,2019 and March 31st, 2019.

Month	Generic name Code	Indication	Country/region	Event
Jan.	Burosumab KRN23	XLH[1]	**JP** US EU etc	Filed
Feb.	Tenapanor KHK7791	Hyperphosphatemia under maintenance dialysis	**JP** US EU etc	Initiated Phase 2 study
Mar.	Istradefylline KW-6002	Parkinson's disease	JP **US** EU etc	Filed

[1]Filed indications are FGF23-related hypophosphatemic rickets and osteomalacia

Key progress in development (after April)

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Note: Listed events were completed between April 1st, 2019 and May 7th, 2019.

Month	Generic name Code	Indication	Country/region	Event
Apr.	Istradefylline KW-6002	Parkinson's disease	JP **US** EU etc	Accepted resubmission
Apr.	Evocalcet KHK7580	Hypercalcemia In patients with parathyroid carcinoma or primary hyperparathyroidism	**JP** US EU etc	Filed additional indications

Submission plan of major pipeline

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As of March 31st, 2019

Generic name Code	Indication	Country/region	2019	2020	2021~
Burosumab KRN23	XLH (adult)[1]	EU	Submission	+	
Burosumab KRN23	XLH[2]	JP	Filed	+	
Burosumab KRN23	XLH	KR	Submission	+	
Evocalcet KHK7580	PHPT	JP	Submission	+	
Istradefylline KW-6002	Parkinson's disease	US	Filed	+	
Romiplostim AMG531	Aplastic anemia	JP	+		
Romiplostim AMG531	Aplastic anemia	KR	Submission	+	
Romiplostim AMG531	ITP	CN		Submission	+
Brodalumab KHK4827	Psoriasis	AS	Submission / +		
Brodalumab KHK4827	Axial spondyloarthritis	JP, AS	Phase 3	Submission / +	
Mogamulizumab KW-0761	HAM	JP	Phase 3	Submission / +	

+ Estimated time of regulatory decisions
Completed
On going
Planned

[1]Jointly developed with Ultragenyx
[2]Filed indications are FGF23-related hypophosphatemic rickets and osteomalacia
AS: Asia, CN: China, EU: Europe, JP: Japan, KR: Korea, US: United States

Development plan of major pipeline

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As of March 31st, 2019

Generic name Code	Indication	Country/region	2019	2020	2021~
Bardoxolone methyl RTA 402	Diabetic kidney disease	JP	Phase 3		
Bleselumab ASKP1240	Recurrence of FSGS in de novo kidney transplant[1]	US	Phase 2		
Entinostat KHK2375	Breast cancer	JP	Phase 2		
Evocalcet KHK7580	SHPT	AS	FPI	Phase 3	
KHK4083	Atopic dermatitis	JP US EU	Phase 2		Phase 3
KW-6356	Parkinson's disease	JP	Phase 2		Phase 3
Tenapanor KHK7791	Hyperphosphatemia under maintenance dialysis	JP	FPI	Phase 2	Phase 3

Completed
On going
Planned

[1]Jointly developed with Astellas
AS: Asia, EU: Europe, JP: Japan, US: United States

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.

List of acronyms

BS	Biosimilar
COPD	Chronic Obstructive Pulmonary Disease
FSGS	Focal Segmental Glomerulosclerosis
HAM	HTLV-1 Associated Myelopathy
ITP	Idiopathic (immune) Thrombocytopenic Purpura
PHPT	Primary Hyperparathyroidism
SHPT	Secondary Hyperparathyroidism
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.

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