

Financial Results **First-Half (Interim period) of Fiscal 2024**

November 8, 2024

KYORIN Pharmaceutical Co., Ltd.
Representative Director, President and CEO
Yutaka Ogihara



- **Outline of Consolidated Financial Results for Interim Period**
- **Trends of Mainstay Products, Generic Product**
- **Consolidated Financial Forecast**
- **Status of R&D Pipeline**
- **Initiatives toward Realization of Vision 110 –Stage 1–**

Outline of Consolidated Financial Results for Interim Period

Breakdown of Gain and Loss for interim period of FY2024

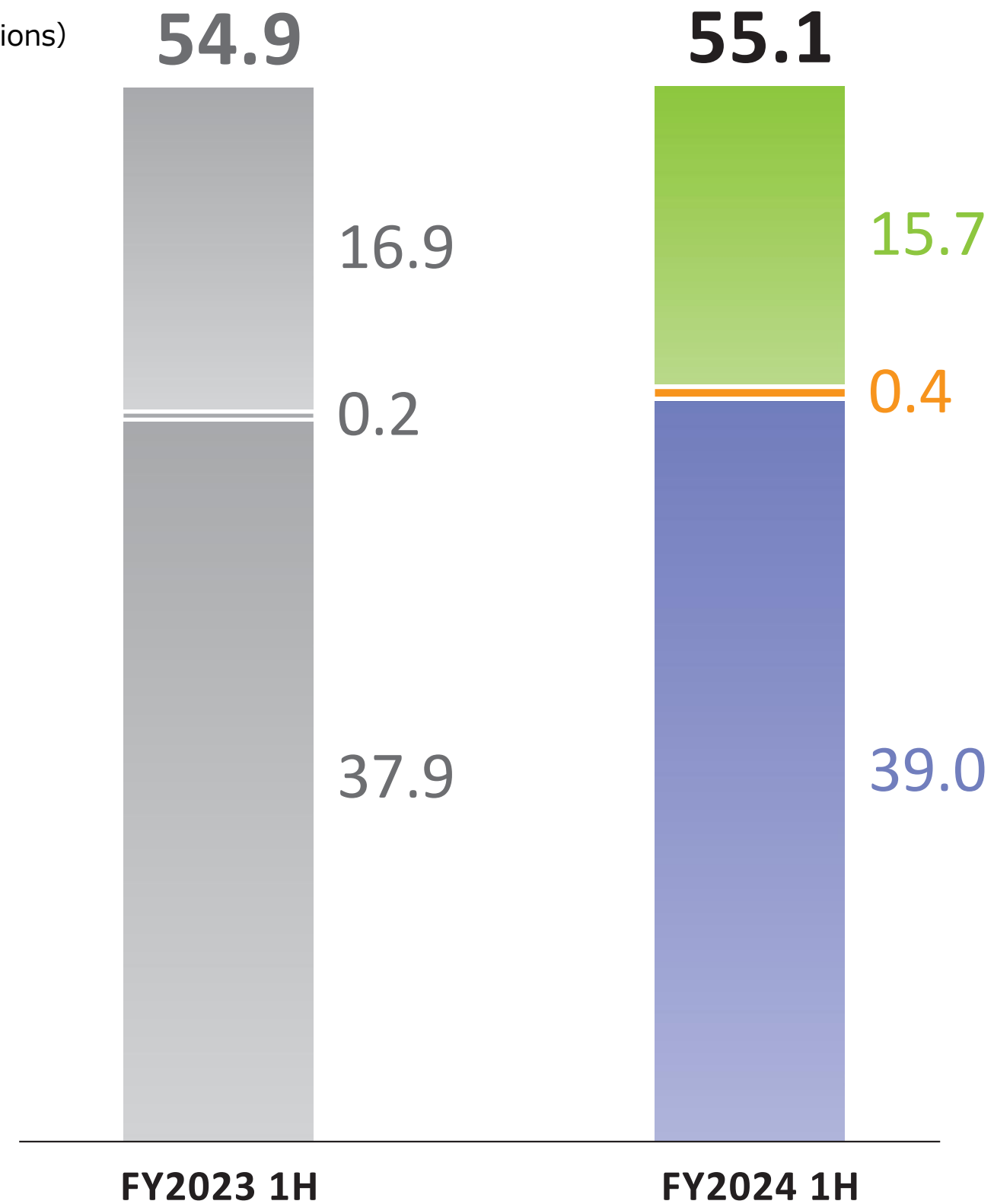


(Units: JPY billions)

	FY2023 1H	FY2024 1H	Year on year		Vs forecast (announced on May 10, 2024)
			Change	Change (%)	
Net sales	54.9	55.1	+0.2	+0.4	-1.8
New drugs, etc. (Japan)	37.9	39.0	+1.1	+3.0	-0.7
New drugs (Overseas)	0.2	0.4	+0.2	+153.8	+0.2
Generic drugs	16.9	15.7	-1.2	-7.2	-1.2
Cost of sales	31.1	31.6	+0.5	+1.5	—
Gross profit	23.8	23.6	-0.2	-1.1	—
SG&A (R&D)	22.5 (3.8)	22.0 (3.8)	-0.5 (0)	-2.2 (+0.0)	— (-0.6)
Operating profit	1.3	1.5	+0.2	+16.0	+0.5
Ordinary profit	1.6	2.1	+0.5	+29.9	+0.8
Profit attributable to owners of parent	1.9	1.3	-0.6	-33.6	+0.4

*Beginning with the interim period of FY2024, a change in accounting policy has been implemented, and figures for the interim period of FY2023 are presented after retroactive adjustment.

(Units: JPY billions)



[Net Sales +0.2]

New drugs, etc. (Japan) +1.1

Factor of increase

- New drugs grew (Beova, Lasvic, Desalex etc.)

Factor of decrease

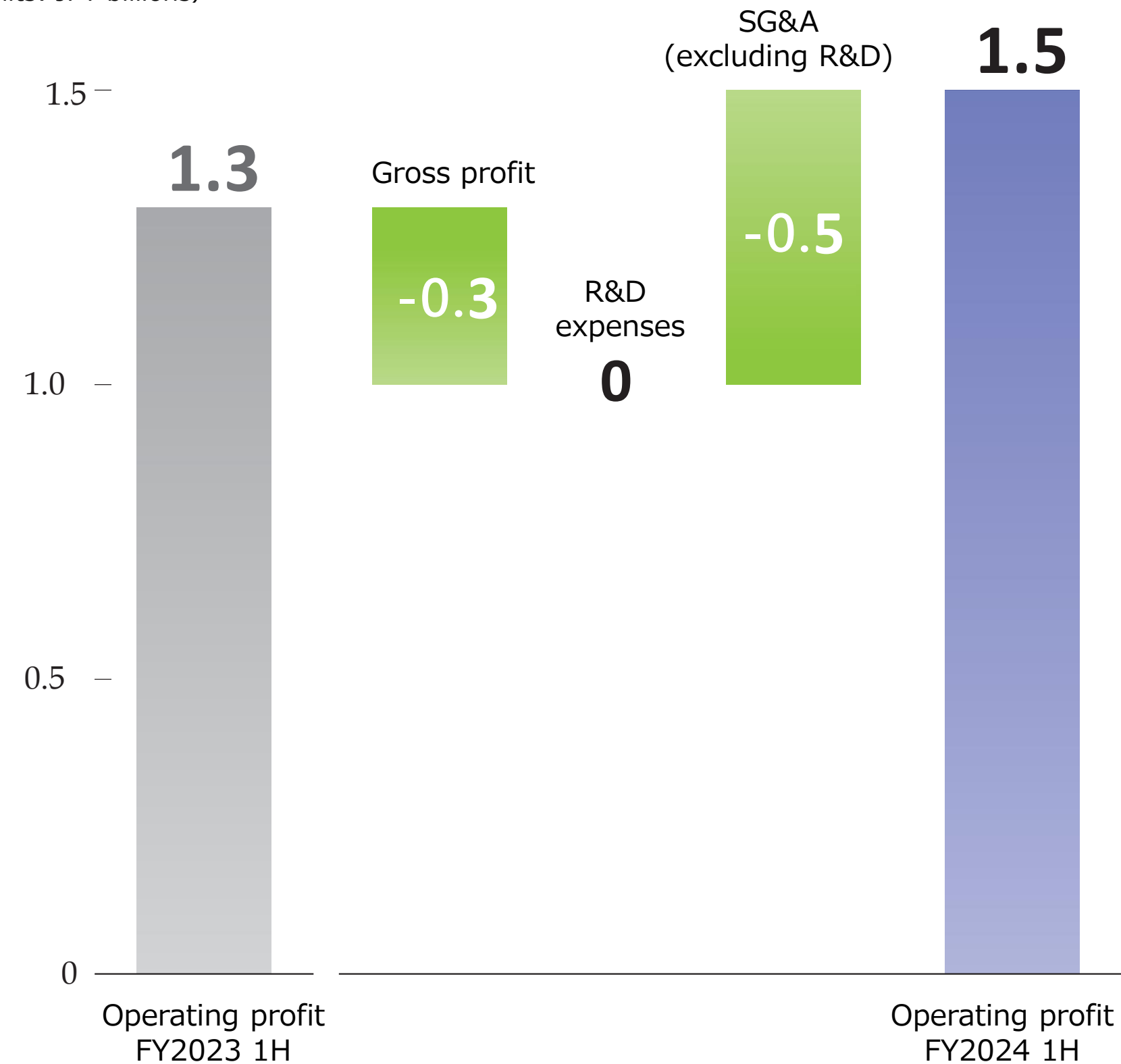
- Impact of NHI drug price revisions (Kyorin Pharmaceutical: 7% range)
- Decrease in sales of long-listed products (Kipres, Mucodyne etc.)

New drugs (Overseas) +0.2

Generic drugs -1.2

- Decrease in sales of AG etc.

(Units: JPY billions)



[Operating Profit +0.2]

Gross Profit

-0.3

Net Sales +0.2

Cost of sales ratio +0.7 %pt

Factor of Decrease | Increase in sales of new drugs (Beova, Lasvic etc.)
Improve in a ratio of new drugs

Factor of Increase | Impact of NHI drug price revisions (Kyorin Pharmaceutical: 7% range)
Impact of exchange fluctuation

R&D Expenses

0

3.8 (FY2023 1H) ⇒ 3.8 (FY2024 1H)

SG&A (excluding R&D)

-0.5

18.7 (FY2023 1H) ⇒ 18.2 (FY2024 1H)

- Decrease in selling expenses, personnel expenses, and depreciation expenses
- Increase in license fees etc.

Highlights of Business Performance (3/3) YoY: Vs Forecast



	FY2023 1H	FY2024 1H	Year on year		Vs forecast (announced on May 10, 2024)
			Change	Change (%)	Change
Net Sales	54.9	55.1	+0.2	+0.4	-1.8
New drugs, etc. (Japan)	37.9	39.0	+1.1	+3.0	-0.7
New drugs (Overseas)	0.2	0.4	+0.2	+153.8	+0.2
Generic drugs	16.9	15.7	-1.2	-7.2	-1.2
Cost of sales	31.1	31.6	+0.5	+1.5	-
Gross profit	23.8	23.6	-0.2	-1.1	-
SG&A (R&D)	22.5 (3.8)	22.0 (3.8)	-0.5 (0)	-2.2 (+0.0)	- (-0.6)
Operating profit	1.3	1.5	+0.2	+16.0	+0.5
Ordinary profit	1.6	2.1	+0.5	+29.9	+0.8
Profit attributable to owners of parent	1.9	1.3	-0.6	-33.6	+0.4

Difference from the Forecast announced on May 10, 2024

Net sales: While sales of the new drugs (Beova, Lasvic, Flutiform) exceeded projections, overall revenue fell below expectations due to underperformance in sales of long-listed products (Kipres etc.) and generic drugs including AG.

Operating profit: Although net sales were below expectations, SG&A expenses (including R&D expenses) were lower than projected, resulting in operating profit exceeding expectations.

Mainstay Product Sales Update



(Units: JPY billions)

		FY2023 1H	FY2024 1H	Year on year		Vs forecast (announced on May 10, 2024) Change
				Change	Change (%)	
New Drugs, etc. (Japan)	Beova (KYORIN)	8.3	10.4	+2.1	+26.4	+0.1
	Lasvic	2.5	3.0	+0.5	+19.8	+0.2
	Lyfnua	0.4	0.4	0	+7.6	-0.2
	Desalex	3.1	3.4	+0.3	+8.3	-0.2
	Flutiform	6.2	6.4	+0.2	+3.1	+0.4
	Pentasa	6.1	6.2	+0.1	+1.4	+0.5
	Kipres	2.6	1.8	-0.8	-30.2	-0.3
	Mucodyne	2.0	1.5	-0.5	-23.2	-0.4
	Uritos (KYORIN)	0.3	0.2	-0.1	-25.7	+0.1
	Milton	1.0	0.9	-0.1	-3.7	0
	Rubysta	0.8	0.6	-0.2	-26.5	-0.2
Generic Drugs	Montelukast tablets“KM”	5.8	5.0	-0.8	-12.5	-0.1
	Mometasone Nasal 50mg “KYORIN”	0.9	0.7	-0.2	-24.0	-0.3
	Imidafenacin tablets & OD “KYORIN”	0.3	0.3	0	-10.7	+0.1

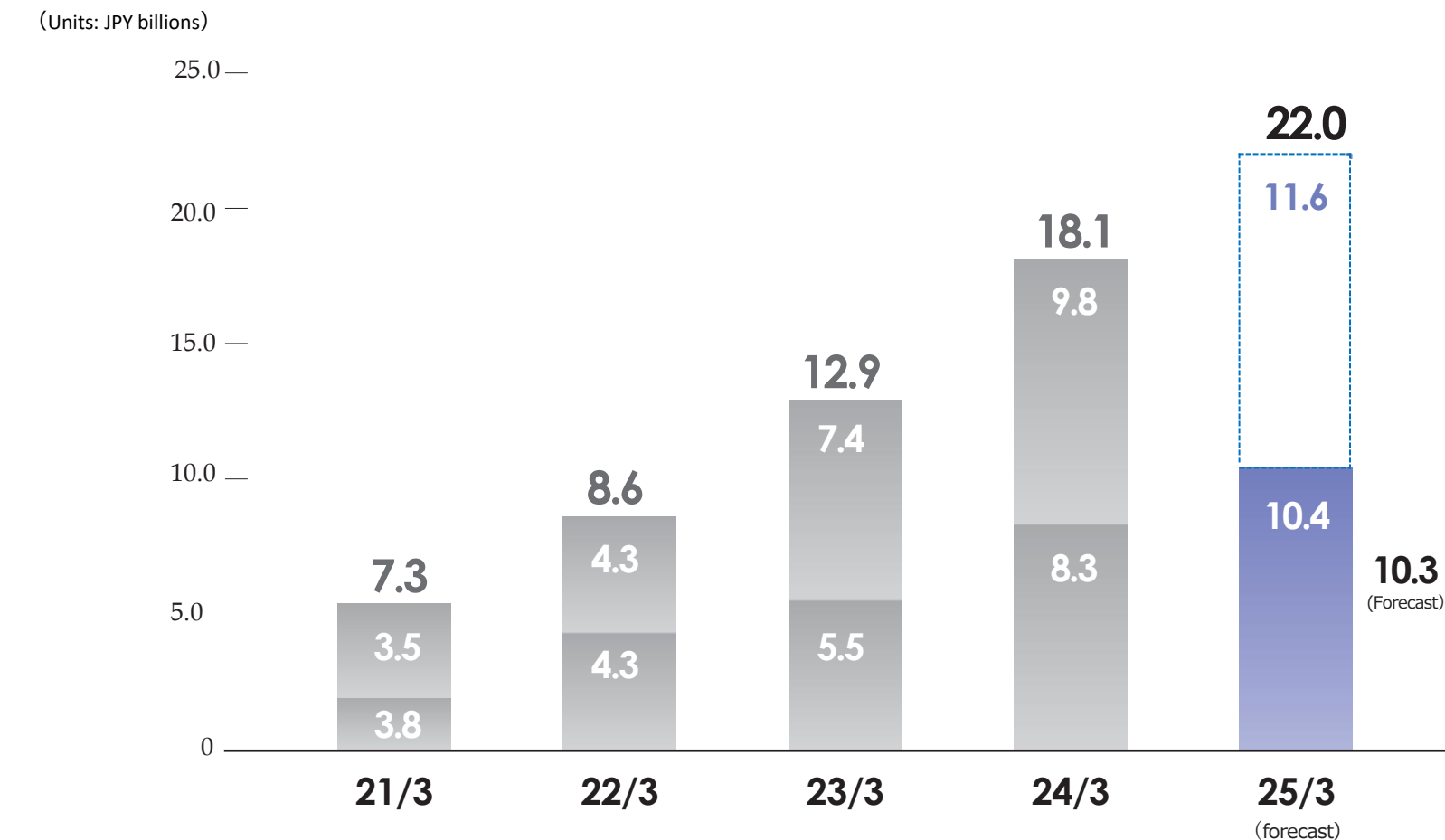
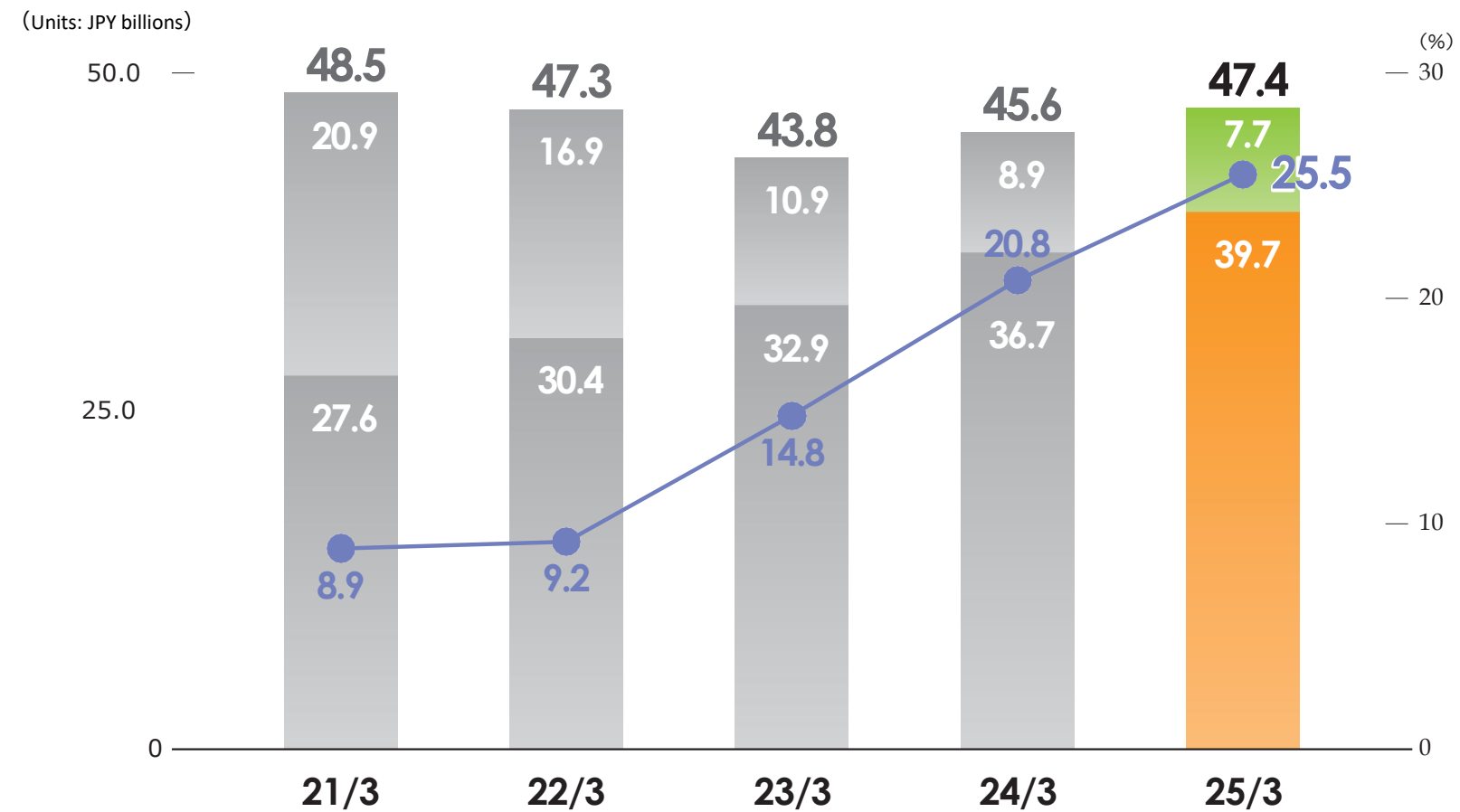
Trends of Mainstay Products, Generic Product

[Mainstay products] Beova (Therapeutic agent for OAB)



OAB market (Apr-Sep)
 Anticholinergic agents
 β3 receptor antagonist
 Beova (KYORIN) share

Sales 2H
1H



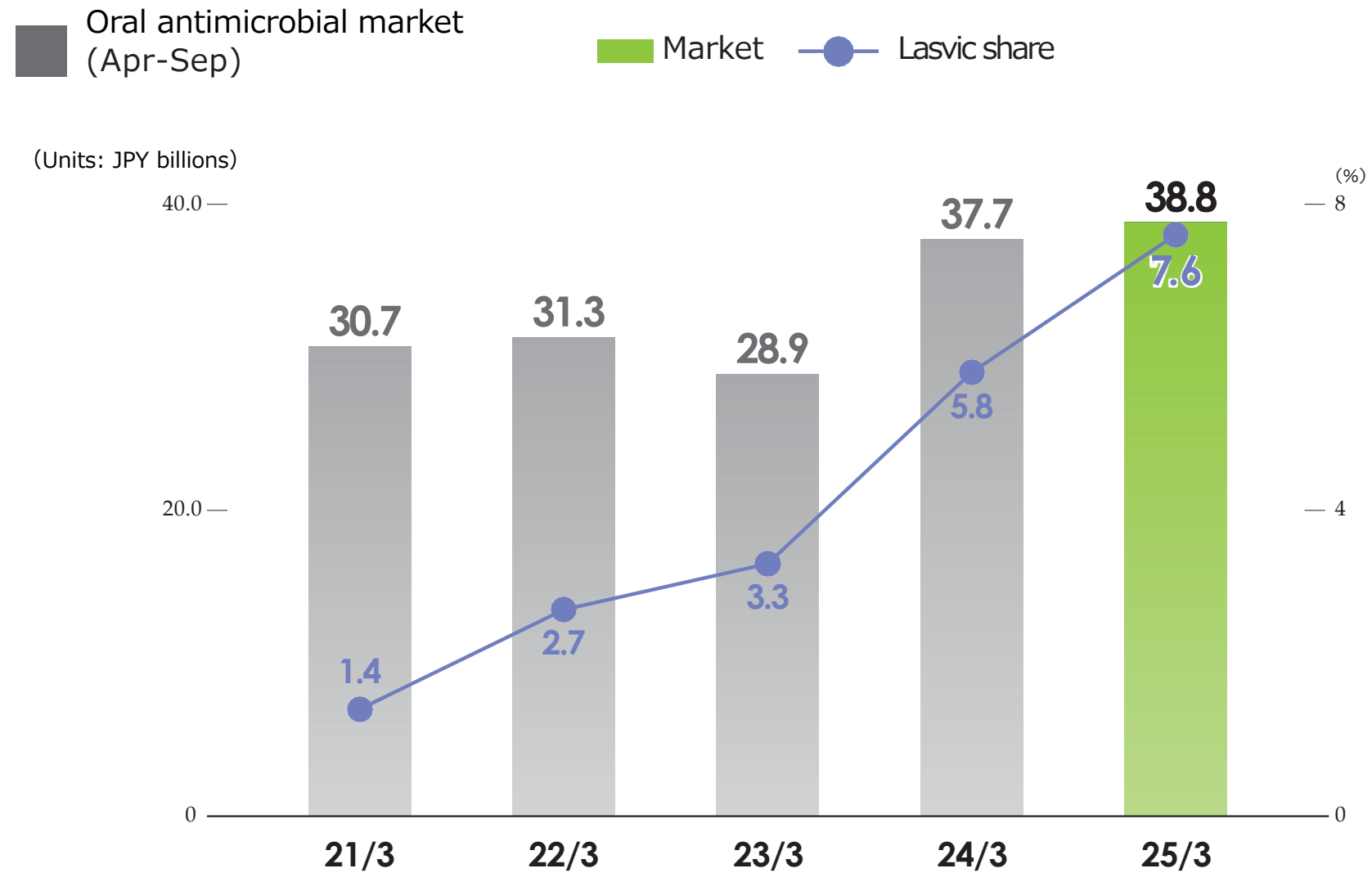
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	Market	OAB market: +3.9%* Market expansion of β3 adrenergic receptor
	Medium to long-term market outlook	The number of OAB patients tend to increase Market is forecast to remain flat due to impact of NHI drug price revision and launch generic drug Market expansion for β3 adrenergic receptor.

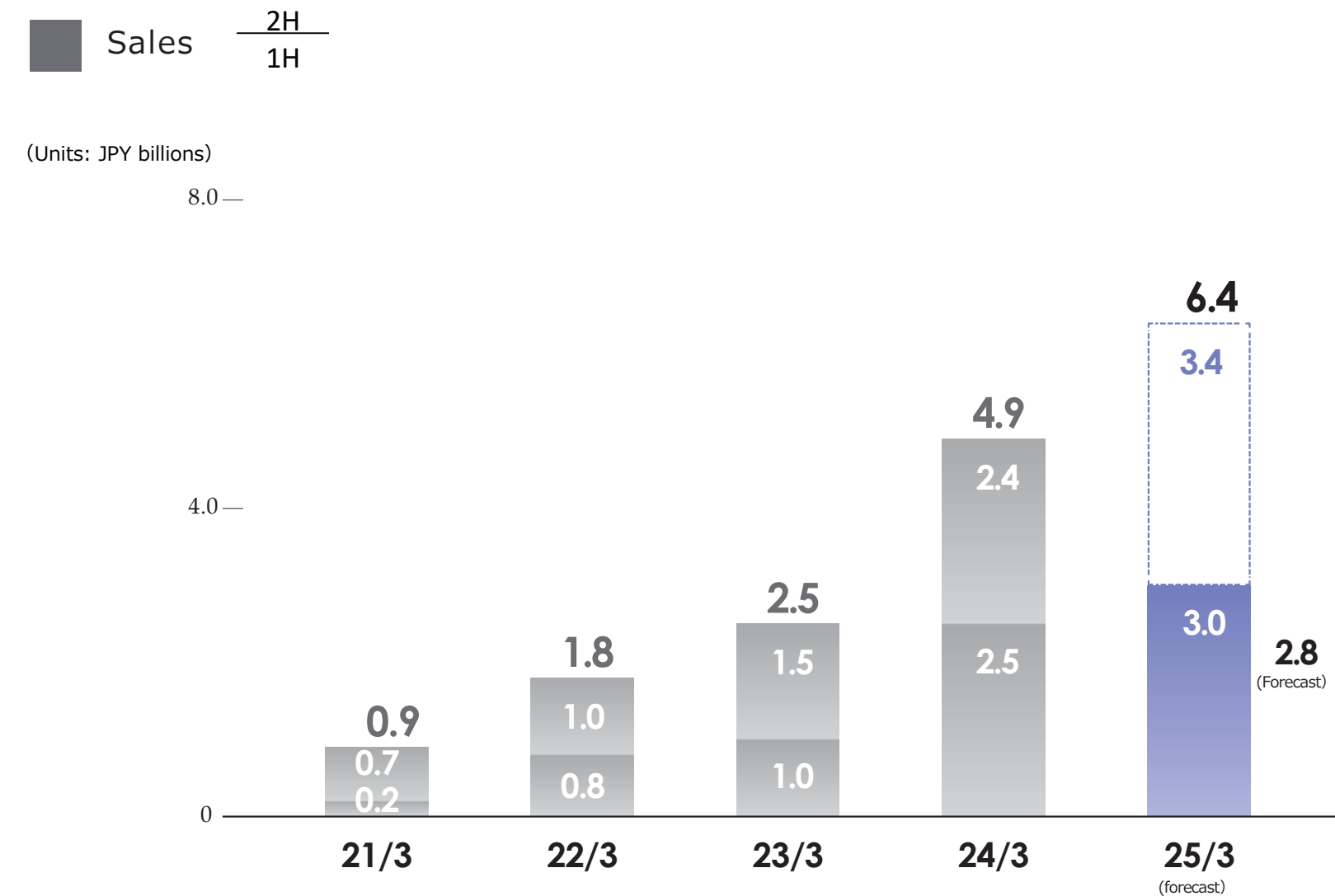
	Status FY2024 1H	● Customer coverage, prescription amount per customer and a rate of acquisition rate of new prescription, sales share progress as expected.
	Initiative FY2024	● Understanding the characteristics of Beova and promoting real-world evidence in urology and general internal medicine ● DTC (Direct to Consumer): Initiative to encourage medical consultation

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[Mainstay products] Lasvic (New quinolone synthetic antibacterial agent)



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Market	Oral antimicrobial market: +2.8% (NQ market: -4.5%)*
Medium to long-term market outlook	Expect to tend to decrease in oral antimicrobial market due to prevent infection/appropriate use against AMR

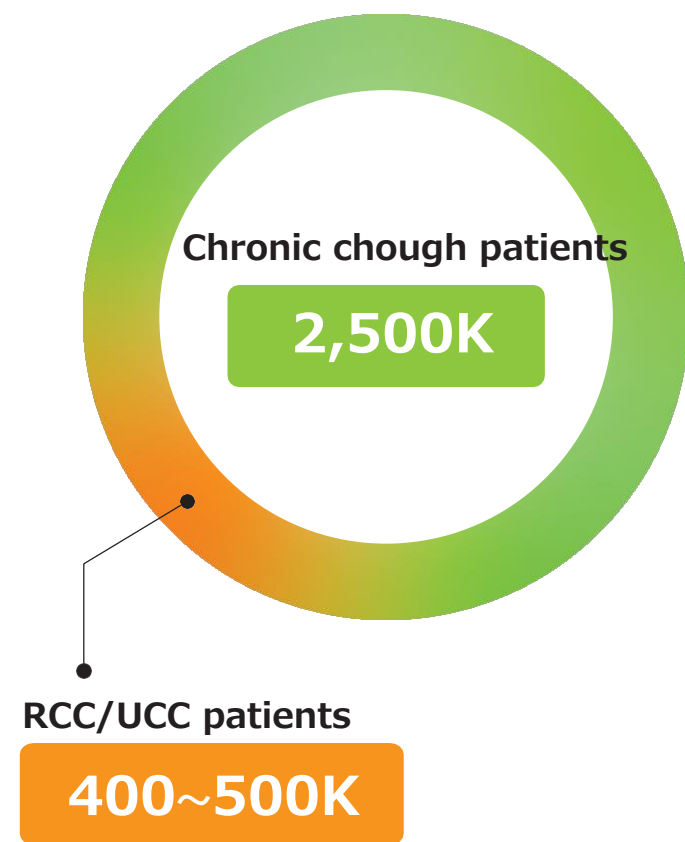
Status FY2024 1H	<ul style="list-style-type: none"> Achieved No.1 growth rate in oral NQ market Tablet: +115% (yoy), iv: +170% (yoy) Being listed in clinical guidelines was recognized
Initiative FY2024	<ul style="list-style-type: none"> Promotion for the first choice for the elderly/patients with respiratory infection Growth in number of medical institutions with prescriptions of Lasvic (internal medicine/otorhinolaryngology)

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[Mainstay products] Lyfnua (Cough treatment)

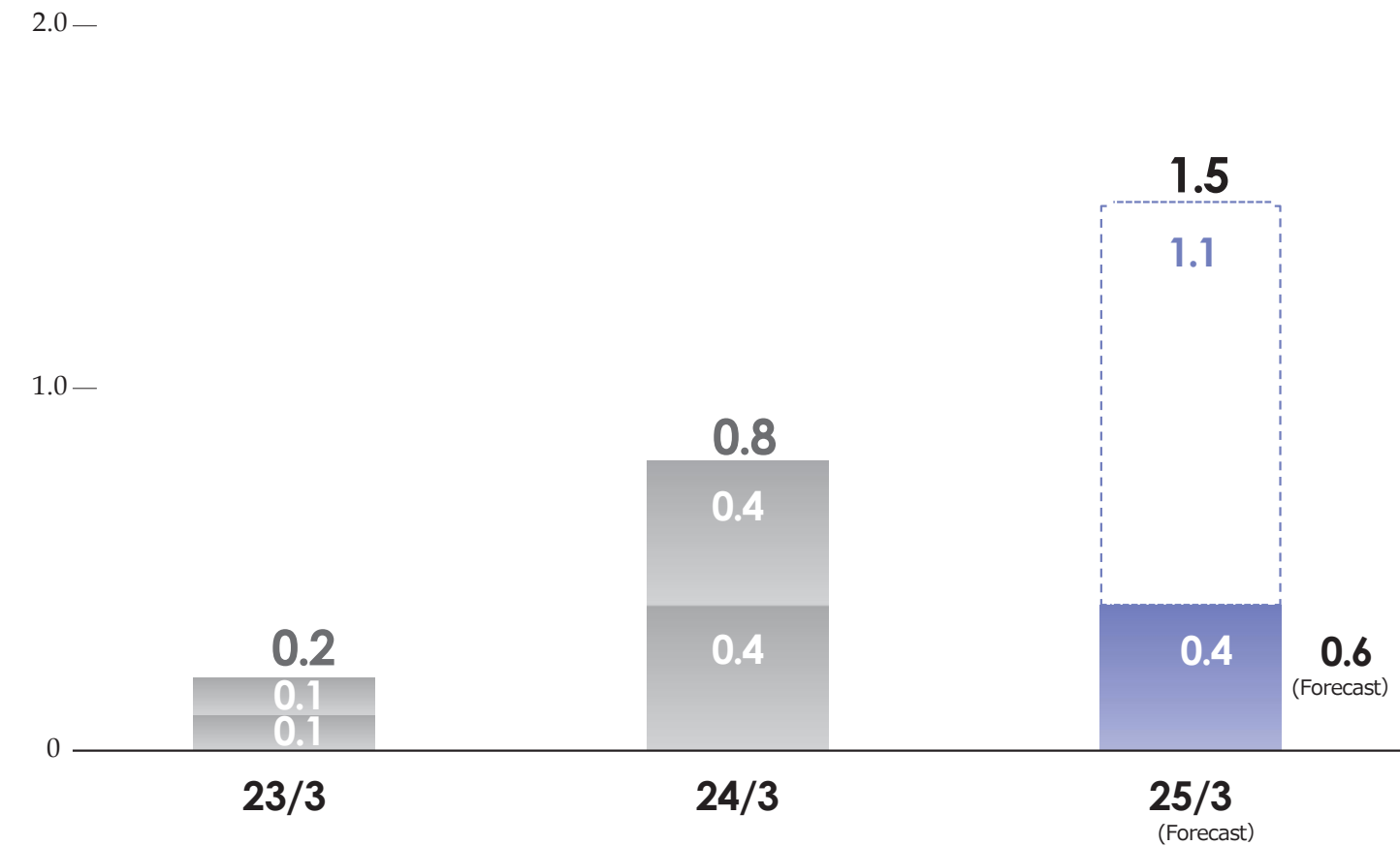


■ The number of estimated patients



■ Sales $\frac{2H}{1H}$

(Units: JPY billions)



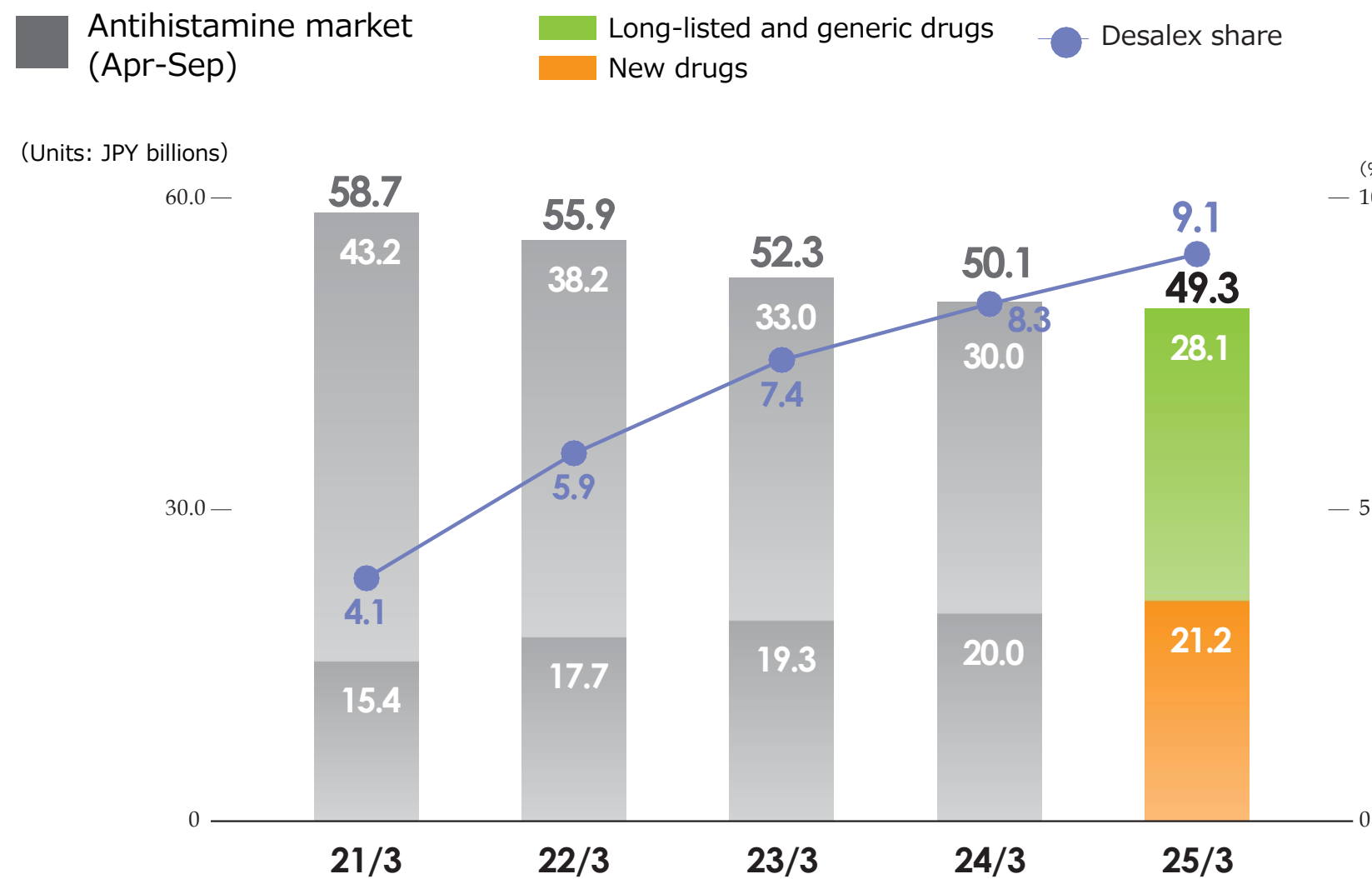
Status
FY2024 1H

- Target cases have not been clearly identified due to the ambiguity in the definition of RCC/UCC
- Shorter than expected due to concern about adverse events and the early perceived effectiveness

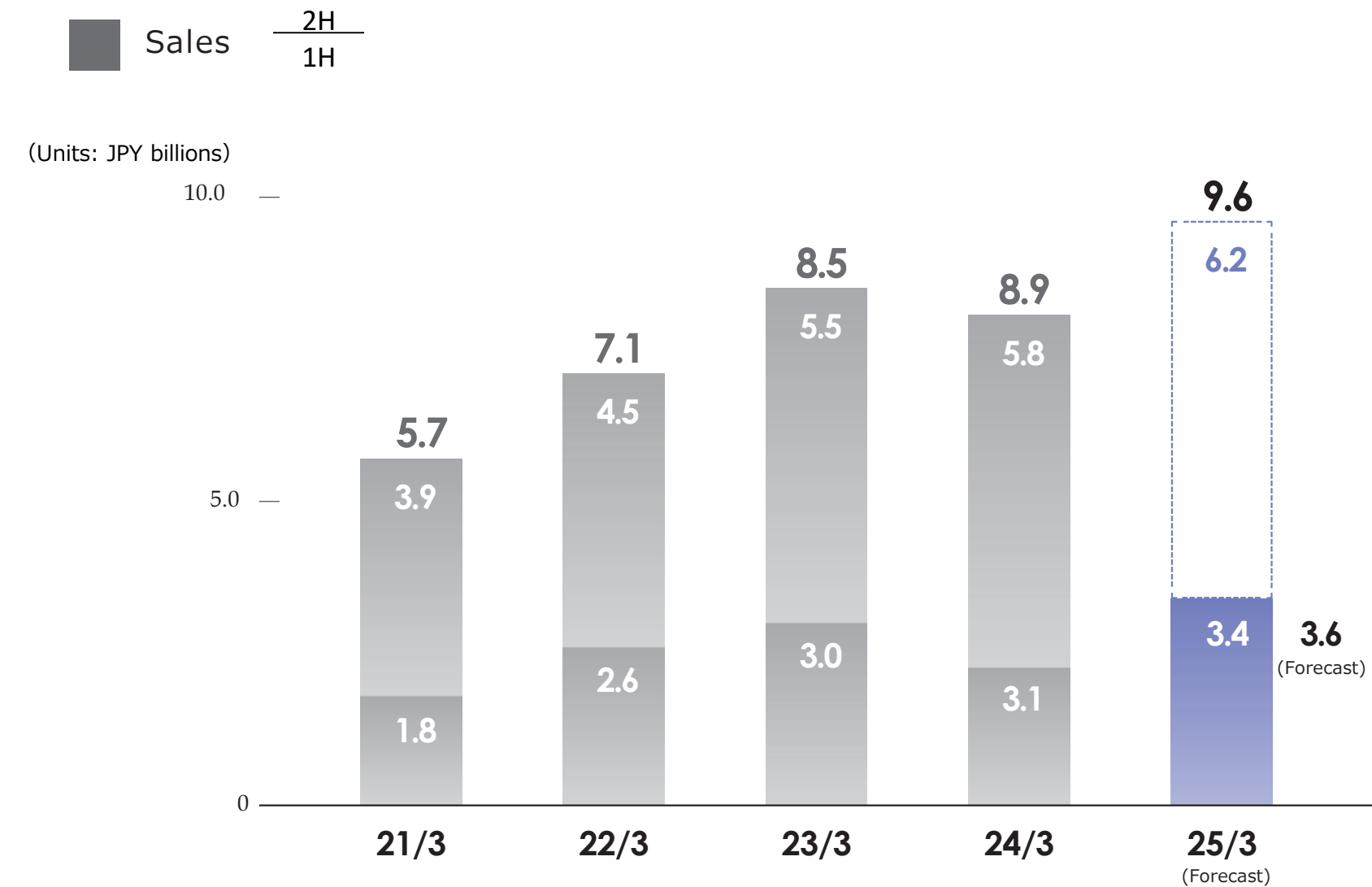
Initiative
FY2024

- Enhancement of better understanding for product characteristic (suppressing cough caused by nerve hypersensitivity)
- Initiative to extend the patient's period of taking drug (appealing effectiveness/safety including long-term data)
- Target in 2nd-Half of FY2024, Customer coverage GP: 9,700, HP: 1,700

[Mainstay products] Desalex (Antiallergic Agent)



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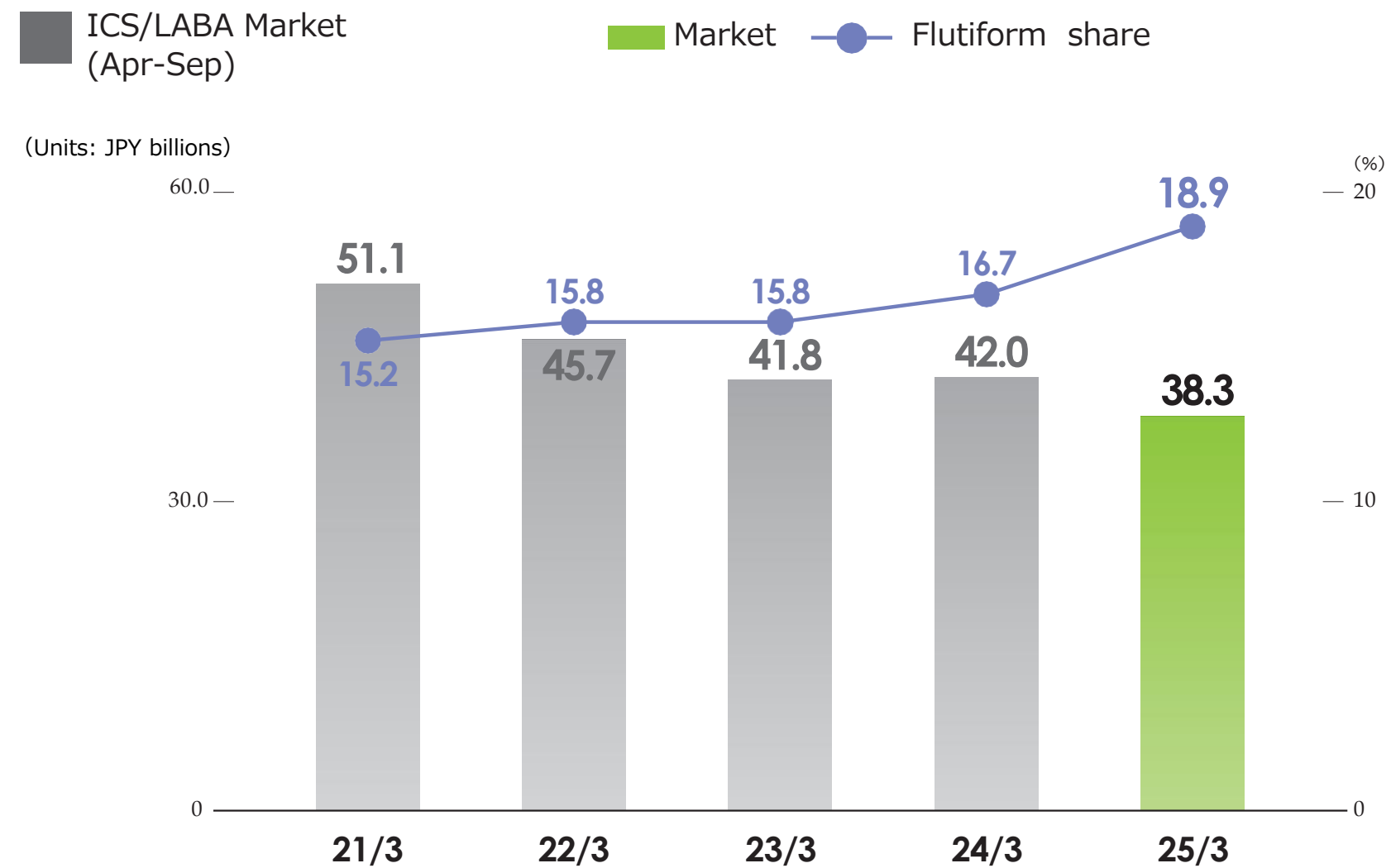


Market	Antihistamine market: -1.6%* Impact of NHI drug price revisions etc.
Medium to long-term market outlook	Number of patients tend to increase. Shrinking market due to NHI drug price revision and launch generic drug.

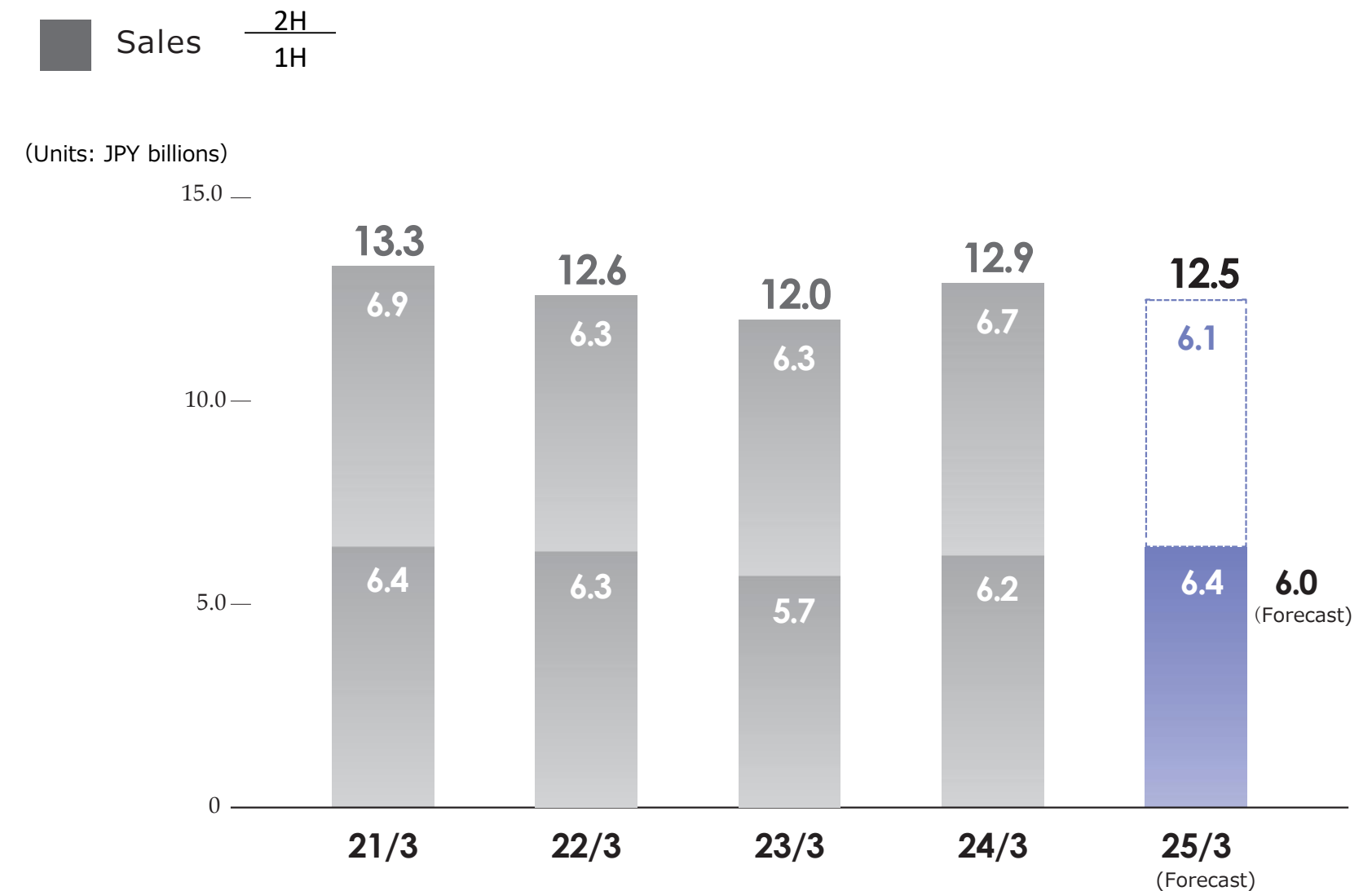
Status FY2024 1H	<ul style="list-style-type: none"> Sales growth remained high Strengthen promotion for skin disorders in the summer to increase the number of patients with prescriptions
Initiative FY2024	<ul style="list-style-type: none"> Aiming to achieve the No.1 prescription rate in otolaryngology. Aiming to be first line treatment appealing as effective and usability drug Usability: less sleepiness, no limitation for drive, administration with or without

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[Mainstay products] Flutiform (Anti-asthmatic)



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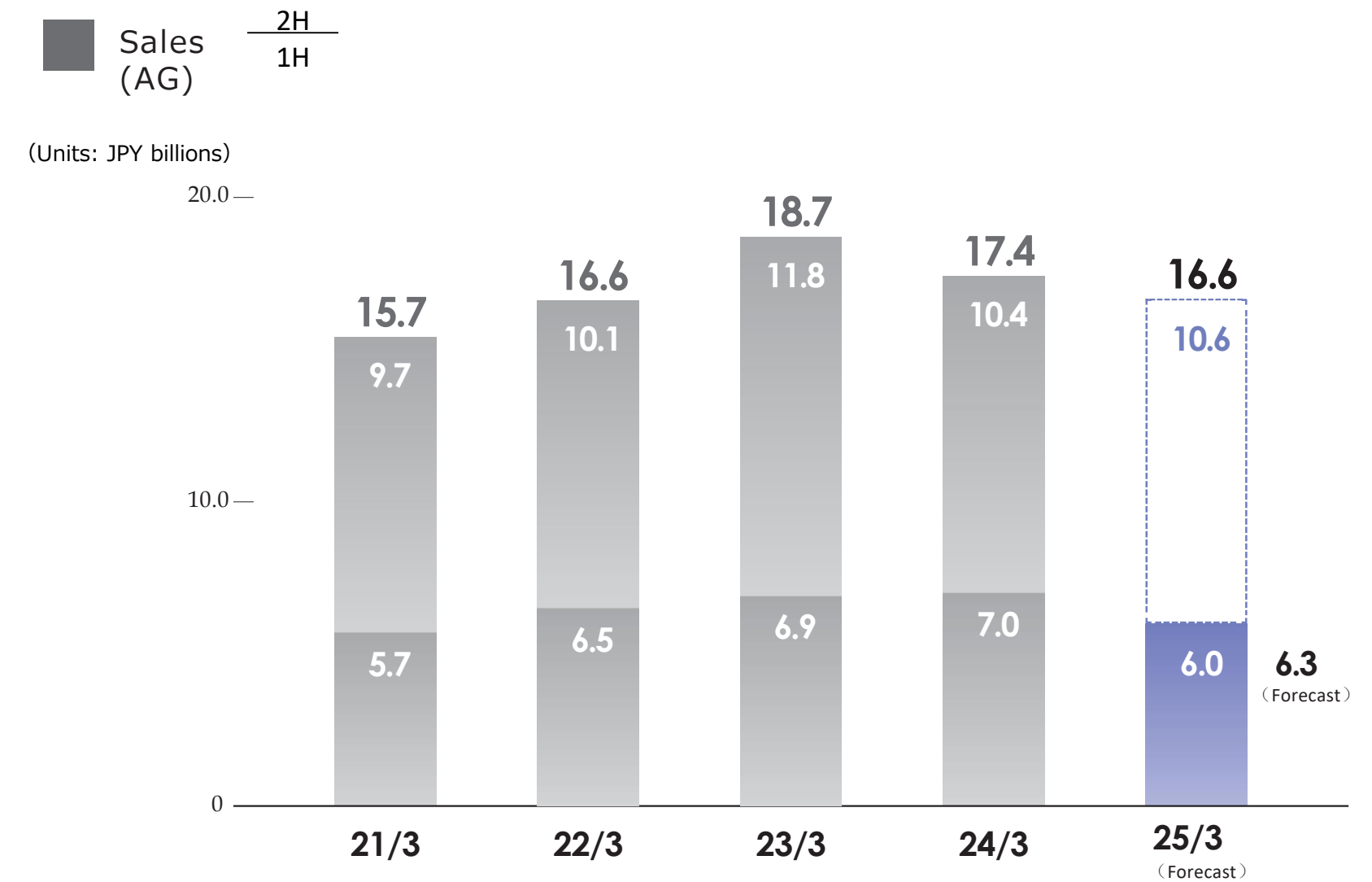
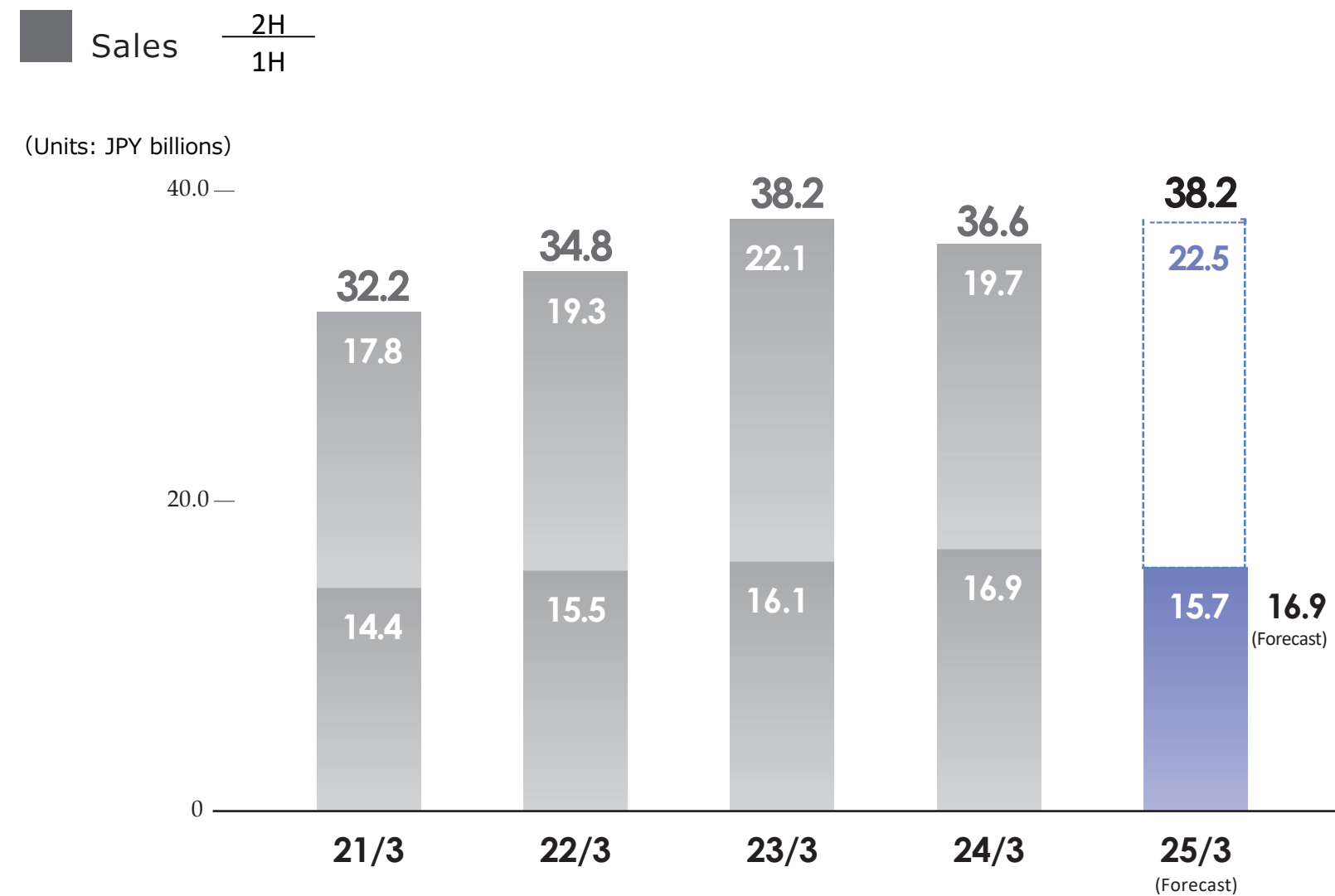


Market	ICS/LABA market: -8.7%* Return the additional amount of PMP (the price maintenance premium) for competing product, and promote to switch to GE
Medium to long-term market outlook	Shrinking market due to NHI drug price revision.

Status FY2024 1H	<ul style="list-style-type: none"> Increasing trend in terms of volume Synergy effects with Lyfnua promotion for "cough"
Initiative FY2024	<ul style="list-style-type: none"> Expansion market share in terms of volume Appeal the utility and easy to use of aerosol formulation

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Status of Generic Drugs



Status
FY2024 1H

- Decrease in the sales of AG
- New products launched in June 2024: ZONISAMIDE OD Tablets TRE 25mg, 50mg
- Acquire the products (products succession)

Initiative
FY2024

- Expand sales of new products and mainstay products.
- Increase in the sales to other companies.

Status (AG)
FY2024 1H

- Restrictions on shipment although improve the shipping volume: Montelukast AG
- Keep market share of 50% in AG

 **Consolidated Financial Forecast**

(Units: JPY billions)

	FY2023	FY2024	Year on year	
			Change	Change (%)
Net sales	119.5	123.4	+3.9	+3.2
New drugs, etc. (Japan)	82.6	84.7	+2.1	+2.6
New drugs (Overseas)	0.4	0.4	0	+3.6
Generic drugs	36.6	38.2	+1.6	+4.5
Cost of sales	67.9	—	—	—
SG&A (R&D)	45.4 (8.0)	— (8.5)	— (+0.5)	— (+6.0)
Operating profit	6.2	6.5	+0.3	+4.3
Ordinary profit	6.8	6.9	+0.1	+1.1
Profit attributable to owners of parent	5.5	5.0	-0.5	-8.7

No Revision to Initial Forecast

Operating profit and profit progressed above expectations for first-half; however, temporary variances, such as unspent SG&A expenses, have occurred, and thus the initial forecast remains unchanged.

*Beginning with the interim period of FY2024, a change in accounting policy has been implemented, and figures for the interim period of FY2023 are presented after retroactive adjustment.

Forecast of Mainstay Products Sales



(Units: JPY billions)

		FY2023 (Actual)	FY2024 (Forecast)	Year on year	
				Change	Change (%)
New Drugs, etc. (Japan)	Beova (KYORIN)	18.1	22.0	+3.9	+21.6
	Lasvic	4.9	6.4	+1.5	+29.8
	Lyfnua	0.8	1.5	+0.7	+86.3
	Desalex	8.9	9.6	+0.7	+8.5
	Flutiform	12.9	12.5	-0.4	-2.6
	Pentasa	12.3	11.6	-0.7	-5.0
	Kipres	7.0	5.3	-1.7	-23.5
	Mucodyne	4.2	4.3	+0.1	+2.6
	Uritos (KYORIN)	0.5	0.3	-0.2	-34.7
	Milton	1.9	1.9	0	-2.1
	Rubysta	1.5	1.5	0	+1.8
Generic Drugs	Montelukast tablets "KM"	12.3	11.8	-0.5	-3.9
	Mometasone Nasal 50mg "KYORIN"	4.5	4.3	-0.2	-3.4
	Imidafenacin tablets & OD "KYORIN"	0.6	0.5	-0.1	-12.5

Capital Policy

- Increase capital efficiency through investment for growth and shareholder returns, with a constant awareness of the cost of capital and return on capital, while maintaining a sound financial base
- Maintain stable dividends taking DOE (Dividend on Equity ratio) into account

Dividend

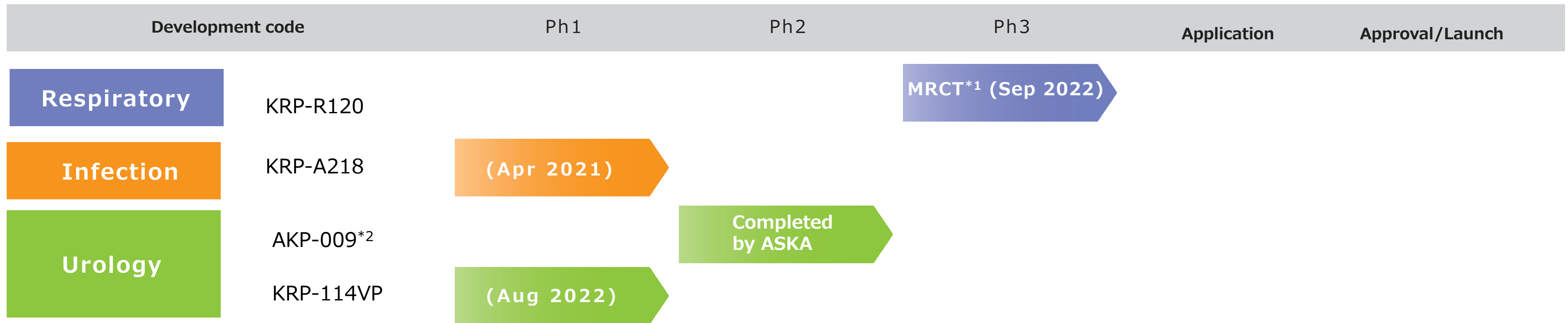
	FY2022	FY2023	FY2024 (Forecast)
Dividend per share (Yen)	¥52 (Interim term ¥20)	¥52 (Interim term ¥20)	¥52 (Interim term ¥20)

- * The year-end dividend of 52 yen announce on May 10, 2024 remain unchanged
- The interim dividend of 20 yen have been decided at in the Board Meeting scheduled in November 7, 2024



Status of R&D Pipeline

As of 2024/11/7



*1 MRCT: Multi-Regional Clinical Trials

*2 Next step following the result of Ph1 trial is under consideration (ASKA Pharmaceutical)

[Licensed Compound]

Compound/Code	Licensee	Stage	Features
KRP-203	Priothera	Ph3	<ul style="list-style-type: none"> ● Sphingosine-1-Phosphate receptor Agonist ● Target: AML patients undergoing HSCT ● Assignment of IP and drug substances (Sep 2020)

[DTx development]

Compound/Code	Proposed Indication	Features
KRP-DT123	Tinnitus	<ul style="list-style-type: none"> ● Specified clinical trial (Sep 2023)

 **Initiatives toward Realization of Vision110 –Stage1–**

Vision 110

— Stage 1 —

Strengthening drug discovery capability to create high-value new drugs that meet medical needs

Expansion of development pipeline through in-licensing

Maximization of the ratio of new drugs

Promoting healthcare-related businesses that have synergies with the new drugs business

Building a sustainable corporate foundation

Strengthening drug discovery capability to create high-value new drugs that meet medical needs/ Expansion of development pipeline through in-licensing



[Drug discovery]

Strengthening drug discovery by drug innovation

In-house/collaborative research,
collaboration with external organization

Development of
new research themes

New targets

Known targets:
Creating value through
technological innovation

Strengthen basic technology

Small molecule drugs:
Continuous technological enhancement

Nucleic acid medicines:
Establishment of basic technology

New technology (Open innovation)

Research area: Fibrosis/Pain/Autoimmune disorders

Drug candidate

[Incubations]

Identifying products and technologies
that lead to future growth

Companies

Ventures

Academia

Research support

Investment

[In-licensing]

Development pipeline
through in-licensing

Expand the scope of modality and
therapeutic area

Speedy assessment and acquisition of
in-licensing

Promote and expand DTx development

Increase of
investment

Organizational reform
Human resource

Expanding the development pipeline

Development, application
and approval

High-value new drugs that meet medical needs

At least six in-licensing items
[Target in Stage1]

Acquiring option rights for future implementation
Capital alliance, M&A etc.



Disclosure two agreements for Incubations

KYORIN and Veneno Technologies conclude Joint Research Agreement For Functional DRPs

January 22, 2024

Veneno Technologies Co. Ltd.

Option Agreement for drug discovery of extracellular vesicles derived from airway epithelial cells

August 2, 2024

EVERMed Inc.

Implement a program to obtain functional Disulfide-Rich Peptides (DRPs) for selected target membrane proteins by using Veneno's next-generation peptide discovery technology called "PERISS".

Secure the option to acquire the license for the development and commercialization of EM-001. It is under examination for possibility of a candidate a good candidate for the treatment of respiratory diseases.



■ DRPs

DRPs are a general term for peptides with multiple disulfide bonds in the molecule. It is known to have low immunogenicity due to its compact and stable structure.

■ PERISS

PERISS is a high-throughput screening technology based on evolutionary molecular engineering that enables the discovery of DRPs acting on membrane proteins.



■ EM-001

Extracellular vesicle derived from airway epithelial cells and expected to function in suppression of cell aging and fibrosis, and in normalization of traits by transport of enclosing complex. Phase 1 study is planned by EVERMed and the Jikei University School of Medicine.

In addition to the above, we have signed contracts for multiple projects.

Maximization of the ratio of new drugs



<h2>Beova®</h2>	<p>FY2025 Goal</p> <ul style="list-style-type: none"> No.1 sales as Beova in OAB market by FY2023 Achievement Achieving 50% share of OAB patients 	<p>24.1H</p> <p>New patients acquisition rate : 51.0%*1 Patient share: 39.9% (as Beova)*2 (FY2023 1H: 31.7%)</p>
	<p>FY2024 Status</p> <ul style="list-style-type: none"> Aiming for 50% share of new OAB patients Promoting product characteristics and Real-World Evidence DTC: initiative to encourage medical consultation → Aiming for 45% share of OAB patients 	
<h2>Lasvic®</h2>	<p>FY2025 Goal</p> <ul style="list-style-type: none"> No.1 sales in oral NQ market by FY2023 Achievement Achieving 40% market share in NQ market 	<p>24.1H</p> <p>Market share in NQ: 32.1%*2 (FY2023 1H: 22.7%)</p> <p>231H</p>
	<p>FY2024 Status</p> <ul style="list-style-type: none"> First-line antibacterial agent for elderly or patients with underlying disease in respiratory infection Growth in number of medical institution with prescription of Lasvic (internal medicine/otorhinolaryngology) 	
<h2>Lyfnua®</h2>	<p>FY2025 Goal</p> <ul style="list-style-type: none"> Customer coverage in 2nd half of FY2025 GP Approx. 10,000 HP Approx. 2,000 Aim to being a first-line treatment for the patients with chronic cough despite treatment 	<p>24.1H</p> <p>Customer coverage GP: Approx. 6,300 HP: Approx. 1,300</p>
	<p>FY2024 Status</p> <ul style="list-style-type: none"> Enhancement of better understanding for product characteristic (Suppressing cough caused by nerve hypersensitivity) Initiative to extend the patient's period of taking drug (appealing effectiveness/safety including long-term data) Customer coverage in 2nd half of FY2024 GP : 9,700, HP : 1,700 -Practical Guidelines for Asthma Management 2024 (published in Jul 2024) -Asthma Prevention and Management Guidelines 2024 (published in Oct 2024) -The JRS Guidelines for the Management of Cough and Sputum (upcoming) Propose new options in line with the guidelines to secure prescriptions, aiming to increase the number of prescribing institution and the quantity per facility 	

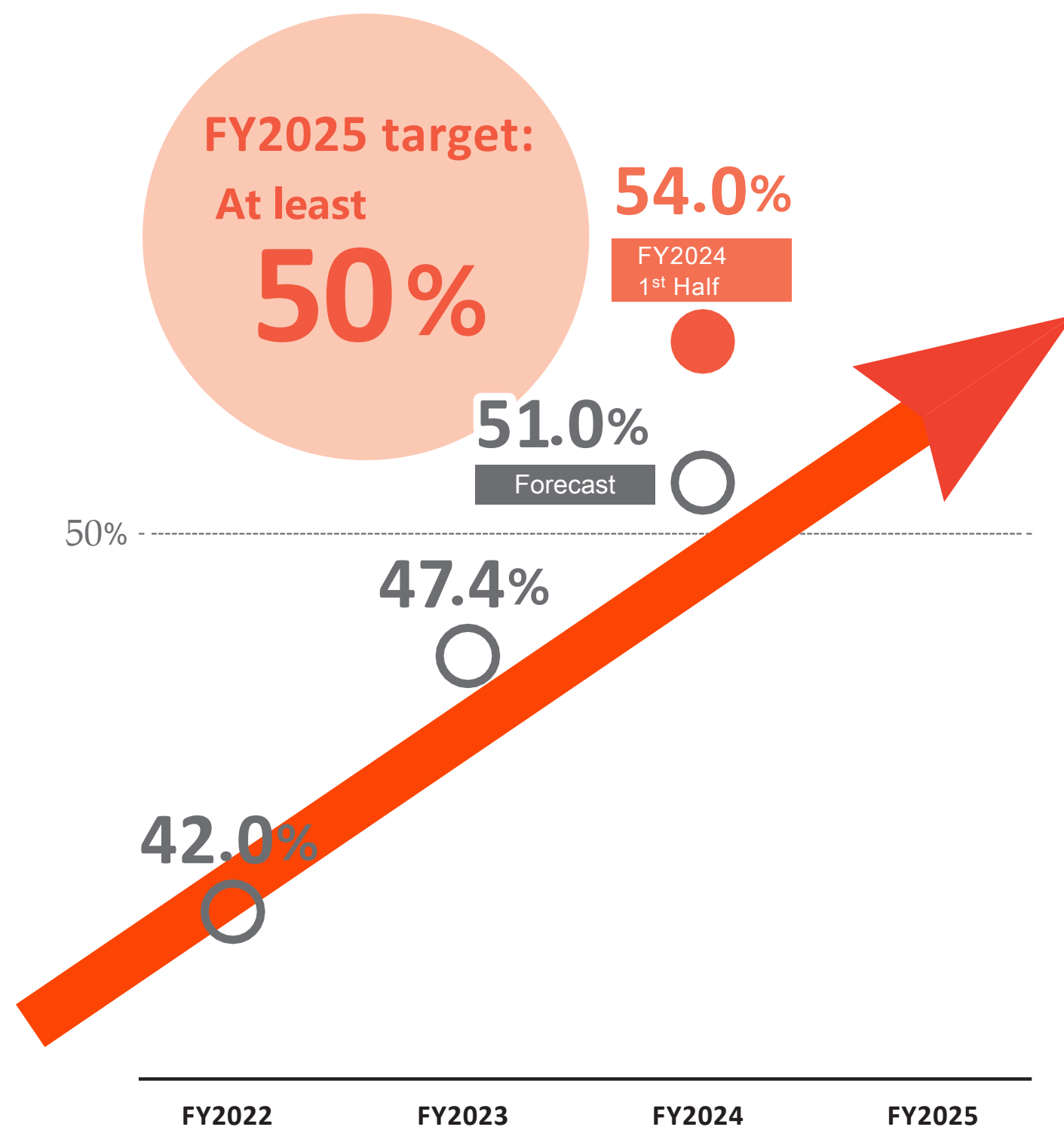
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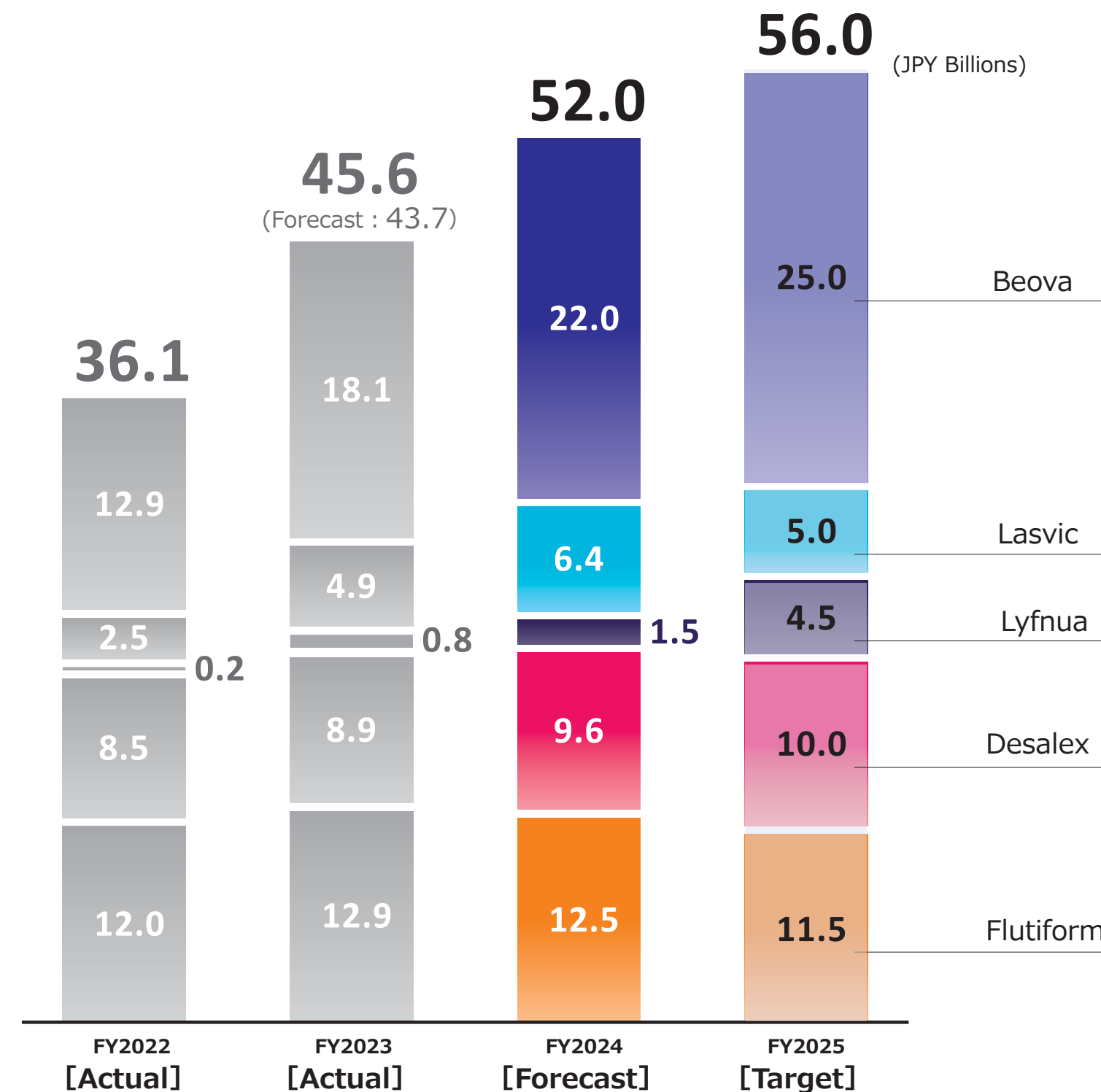
Maximization of the ratio of new drugs



Ratio of new drugs | Exceeding the FY2025 target



Product sales | Achieved the first-half plan, with sales progressing smoothly.



Vision 110

Stage 1

	Initiatives in FY2024	Status in 1 st Half of FY2024
Strengthening drug discovery capability to create high-value new drugs that meet medical needs	<ul style="list-style-type: none"> Promoting in-house research activities and acquisition of external technologies Expanding R&D pipeline 	<ul style="list-style-type: none"> Creation of new drug candidate (in-house) Promotion of new drug discovery themes
Expansion of development pipeline through in-licensing	<ul style="list-style-type: none"> Acquisition of in-licensed products 	<ul style="list-style-type: none"> Multiple in-licensed products, <i>in progress</i>
Maximization of the ratio of new drugs	<ul style="list-style-type: none"> Promotion of proliferation of new drugs 	<ul style="list-style-type: none"> Ratio of new drugs: 54% (forecast 51%) Plan in 1H 2024: 233 JPY Billion Actual: 236 JPY Billion (101.3%)
Promoting healthcare-related businesses that have synergies with the new drugs business	<ul style="list-style-type: none"> Promotion of solution-based marketing activities Sales in infection-related products <small>FY2024 Forecast</small> 11.2 billion yen Full-operation of Takaoka plant Establish production increase structure of Mucodyne 	<ul style="list-style-type: none"> Sales in infection-related products <small>FY2024 1H</small> 5.0 billion yen Launched GeneSoC mini2 Enhancement of promotion by MR Shipment of Mucodyne and Amlodipine
Building a sustainable corporate foundation	<ul style="list-style-type: none"> Operational efficiency and cost reduction 	<ul style="list-style-type: none"> Operational efficiency and cost reduction

Accomplish reform of drug discovery

Expand of development pipeline

Maximize the expansion of sales

Improve cost competitiveness

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Kyorin 