

Interim Term Financial Results

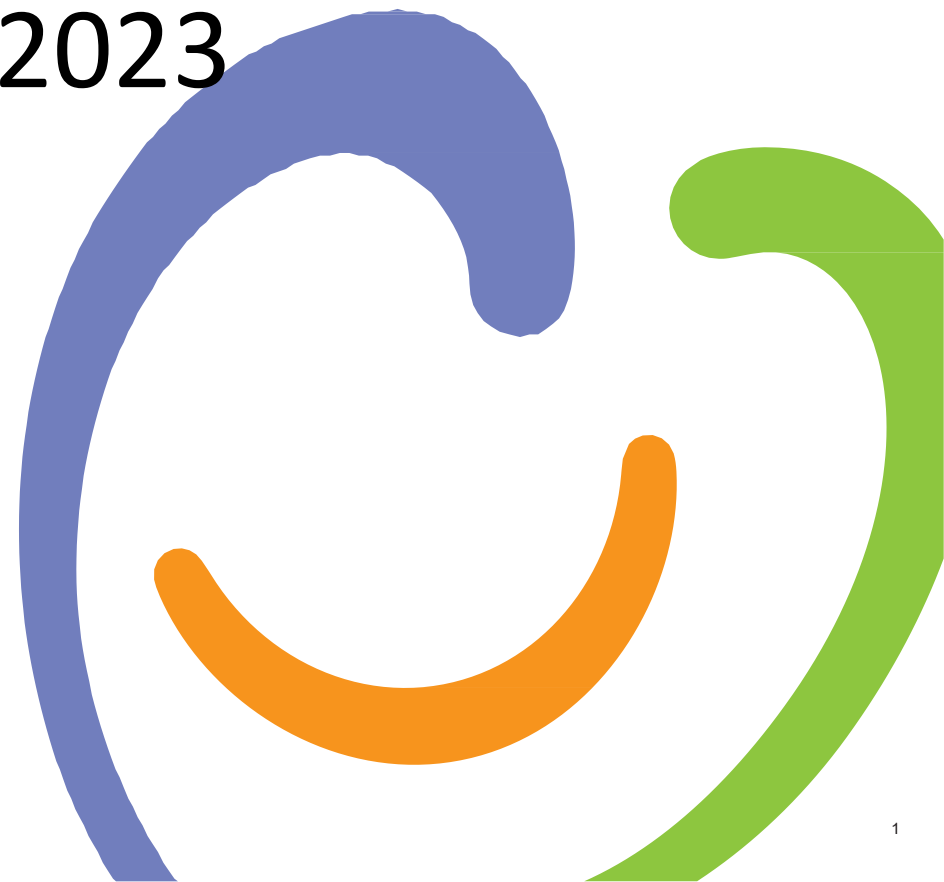
Ended September 2023

November 9 , 2023

KYORIN Pharmaceutical Co., Ltd.

Representative Director, President and CEO

Yutaka Ogihara





Outline of Consolidated Financial Results

Trends of mainstay products, generic product

Consolidated Financial Forecast

Status of R&D Pipeline

Overview of the Midium-term Vision “Vision 110 –Stage 1–”

Outline of Consolidated Financial Results

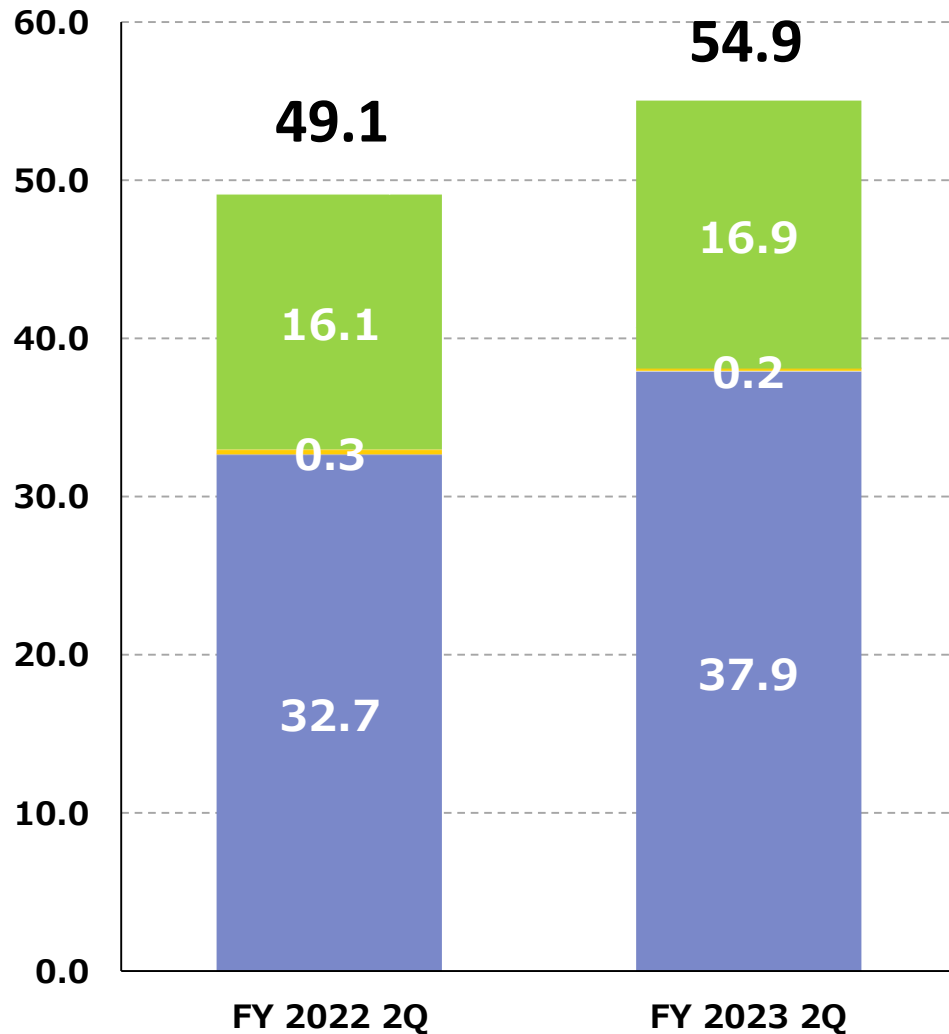
Breakdown of Gain and Loss for Second quarter of FY2023



(Units: JPY billions)

	FY2022 2Q	FY2023 2Q	Year-on-year		Vs forecast (announced on May 11, 2023)
			Change	Change (%)	Change
Net Sales	49.1	54.9	+5.8	+11.9	+ 1.2
New drugs, etc. (Japan)	32.7	37.9	+5.2	+16.0	+ 1.2
New drugs (Overseas)	0.3	0.2	-0.1	-46.5	0
Generic drugs	16.1	16.9	+0.8	+4.7	+ 0.2
Cost of sales	27.5	31.3	+3.8	+13.9	-
SG&A (R&D)	20.8 (4.5)	22.5 (3.8)	+1.7 (-0.7)	+8.0 (-14.6)	- (-0.9)
Operating profit	0.8	1.1	+0.3	+47.2	+ 0.5
Ordinary profit	1.2	1.4	+0.2	+18.4	+ 0.5
Profit attributable to owners of parent	1.2	1.8	+0.6	+41.4	+ 1.1

(Units: JPY billions)



[Net Sales +5.8 bln]

New drugs, etc. (Japan)

+ 5.2

- NHI drug price revision (KYORIN Pharm: 7% range)
- Mainstay drugs grew

New drugs (Overseas)

- 0.1

Generic drugs

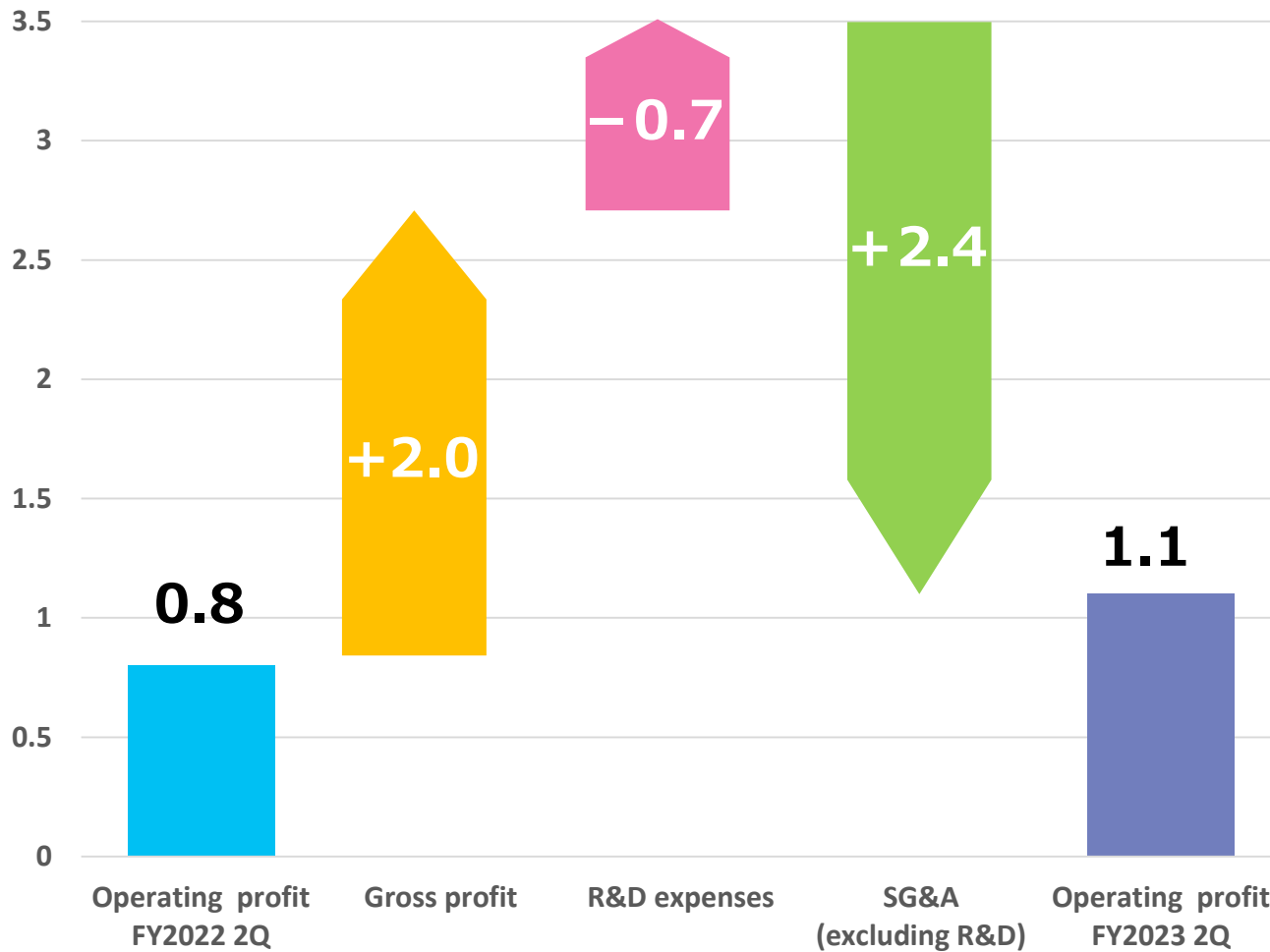
+ 0.8

- Increase in sales of Kipres AG
- New generic drugs launched in June 2023 contributed to sales

Highlights of Business Performance (2/3) YoY: Operating Profit



(Units: JPY billions)



[Operation profit +0.3 bln]

Gross profit +2.0

Net sales +5.8 bln

Cost of sales ratio +1.0 %pt

Factor of Decrease

Factor of Increase

New drugs (Beova, Lasvic etc) grew

NHI drug price revision (KYORIN Pharm: 7% range)

Sales increased in generic drugs

R&D expenses -0.7

4.5 (FY2022 2Q) ⇒ 3.8 (FY2023 2Q)

Decline of expenses regarding dissolution of ActivX

SG&A (excluding R&D) +2.4

16.3 (FY2022 2Q) ⇒ 18.7 (FY2023 2Q)

Increase in selling, personal expenses, depreciation expenses and license fees etc.

Highlights of Business Performance (3/3) vs Forecast



(Units: JPY billions)

	FY2022 2Q	FY2023 2Q	Year-on-year		vs forecast (announced on May 11, 2023)
			Change	Change (%)	Change
Net Sales	49.1	54.9	+5.8	+11.9	+ 1.2
New drugs, etc. (Japan)	32.7	37.9	+5.2	+16.0	+ 1.2
New drugs (Overseas)	0.3	0.2	-0.1	-46.5	0
Generic drugs	16.1	16.9	+0.8	+4.7	+ 0.2
Cost of sales	27.5	31.3	+3.8	+13.9	-
SG&A (R&D)	20.8 (4.5)	22.5 (3.8)	+1.7 (-0.7)	+8.0 (-14.6)	- (-0.9)
Operating profit	0.8	1.1	+0.3	+47.2	+ 0.5
Ordinary profit	1.2	1.4	+0.2	+18.4	+ 0.5
Profit attributable to owners of parent	1.2	1.8	+0.6	+41.4	+ 1.1

【Difference from the Forecast (Announced on May 11, 2023)】

Net sales: Net sales exceed the forecast due to increase in sales of mainstay products (Lasvic, Flutiform) and long-listed products.

Operating profit: Gross profit was lower than the forecast due to increase of cost of sales ratio while sales increased. SG&A expenses (R&D expenses) were lower than the forecast.

As a result, operating profit was higher than the forecast

Extraordinary profit: Recorded a gain on sale of investment securities of 969 million yen.

FY2023 2Q Mainstay Product Sales Update



(Units: JPY billions)

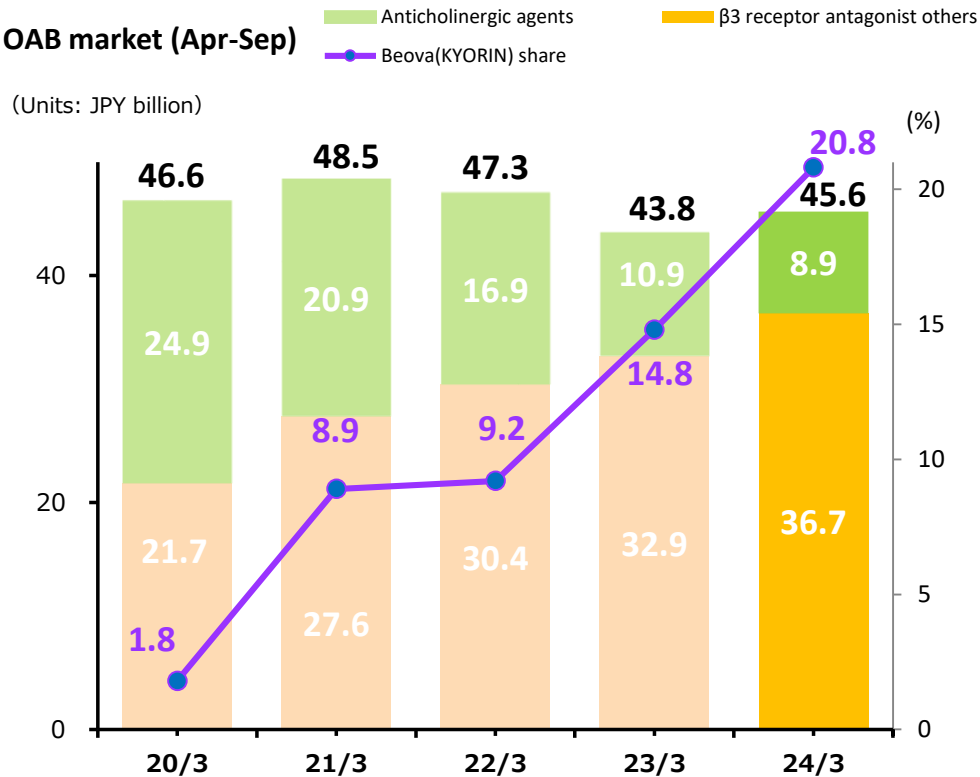
		FY2022 2Q	FY2023 2Q	Year-on-year		vs Forecast (announced on May 11, 2023) Change
				Change	Change (%)	
New drugs, etc. (Japan)	Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	5.5	8.3	+ 2.8	+ 50.8	- 0.5
	Lasvic (New quinolone synthetic antibacterial agent)	1.0	2.5	+ 1.5	+ 152.7	+ 1.1
	Lyfnua (Selective P2X3 receptor antagonist / chronic cough)	0.1	0.4	+ 0.3	+ 350.3	- 0.1
	Desalex (Antiallergic Agent)	3.0	3.1	+ 0.1	+ 3.8	- 0.1
	Flutiform (Combination drug for asthma treatment)	5.7	6.2	+ 0.5	+ 8.2	+ 0.7
	Pentasa (Ulcerative colitis and Crohn’s disease treatment)	6.5	6.1	- 0.4	- 6.9	+ 0.1
	Kipres (Leukotriene Receptor Antagonist)	2.7	2.6	- 0.1	- 3.3	+ 0.4
	Mucodyne (Mucoregulator)	1.5	2.0	+ 0.5	+ 30.7	+ 0.6
	Nasonex (Spray type allergic rhinitis remedy)	0.6	0.4	- 0.2	- 39.7	+ 0.1
	Uritos (KYORIN) (Therapeutic agent for overactive bladder)	0.4	0.3	- 0.1	- 26.9	+ 0.2
	Milton (Disinfectant)	1.0	1.0	0	- 7.6	0
	Rubysta (Disinfectant)	1.1	0.8	- 0.3	- 23.1	- 0.2
Generic drugs	Montelukast tablets “KM” (Leukotriene Receptor Antagonist)	5.4	5.8	+ 0.4	+ 7.1	+ 0.9
	Mometasone Nasal 50mg “KYORIN” (Spray type allergic rhinitis remedy)	1.1	0.9	- 0.2	- 17.0	0
	Imidafenacin tablets & OD “KYORIN” (Therapeutic agent for overactive bladder)	0.4	0.3	- 0.1	- 15.3	+ 0.1

Trends of Mainstay Products and Generic Drugs

[Mainstay products] Beova (Therapeutic agent for OAB)



OAB market (Apr-Sep)



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OAB market: Expansion of 4.2%

43.8bln (Apr-Sep, 2022) ⇒ 45.6 bln (Apr-Sep, 2023)*

- Market expansion of beta3 adrenergic receptor

Share of Beova (KYORIN) +6.0 %pt

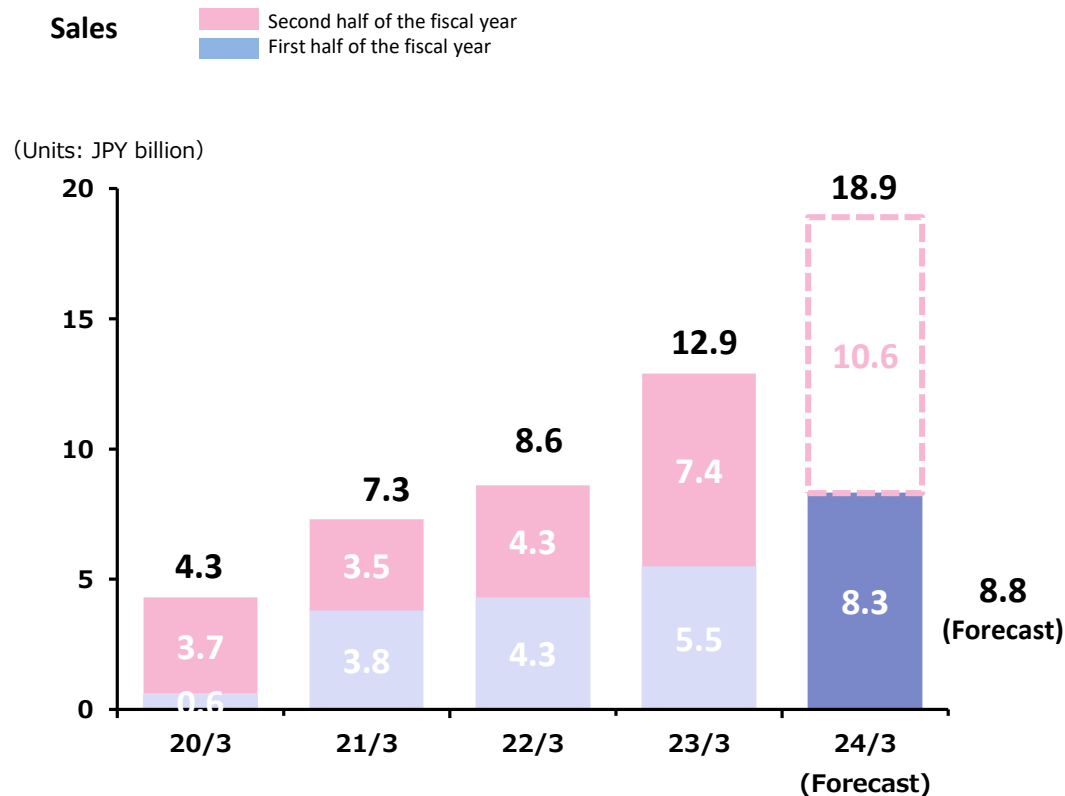
14.8% (Apr-Sep, 2022) ⇒ 20.8% (Apr-Sep, 2023)*

[NHI drug price revision: Beova -4.62% (Apr 2023)]

Medium to long-term market outlook

Market expansion for beta3 adrenergic receptor, while shrinking market for OAB market due to NHI drug price revision and launch generic drug

Sales



Status in FY2023 2Q

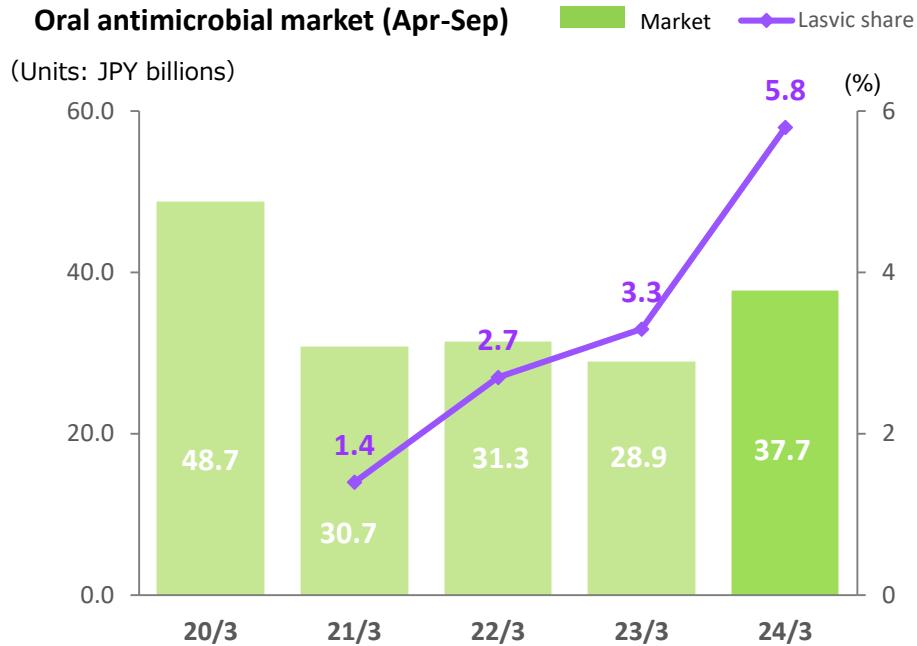
- Rate of new patients acquisition, swiching rate from existing drug
- Increased market share in number of patients prescribed

Effort for FY2023

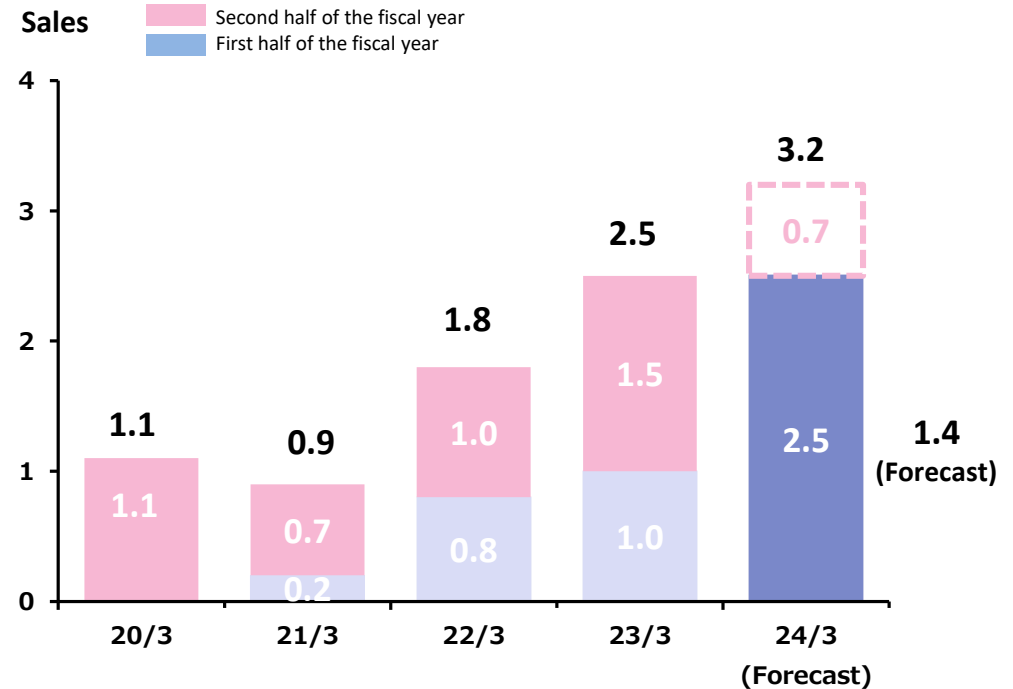
- Promote initiatives using real-world-data
- Strengthening initiatives for being No.1 in OAB market
- Aim to establish evaluation of Beova as first line treatment for OAB

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



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Oral antimicrobial market: Expansion of 30.7%

28.9 bln (Apr-Sep 2022) ⇒ 37.7 bln (Apr-Sep 2023)*

- Classified Covid-19 to the Category V caused market expansion

Share of Lasvic sales: + 2.5 %pt

3.3% (Apr-Sep 2022) ⇒ 5.8% (Apr-Sep 2023)*

[NHI drug price revision: -5.26% (Apr 2023, oral)]

Medium to long-term market outlook

- Expect to tend to decrease in oral antimicrobial market due to NHI drug price revision and prevent infection/appropriate use against AMR
- National action plan on AMR set a target of 30% reduction by FY2027, compared to FY2020 levels, in the use of NQ agents

Status in FY2023 2Q

- Growth rate of No.1 in expansion of oral new quinolone market
- Listed in guidelines as a recommended drug

Effort for FY2023

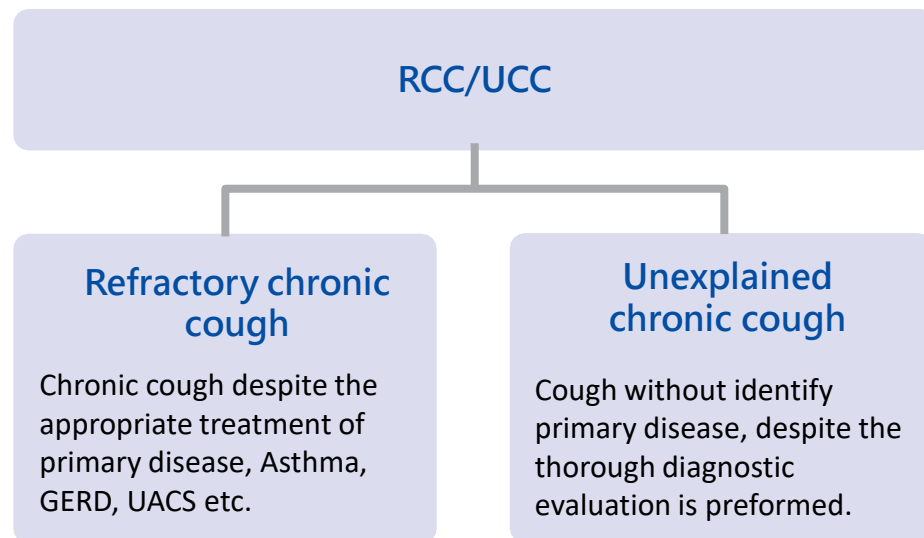
- Focus on providing information to target medical facilities/doctors
- Aim to be first line treatment for elderly people/patients with underlying disease

The number of estimated patients

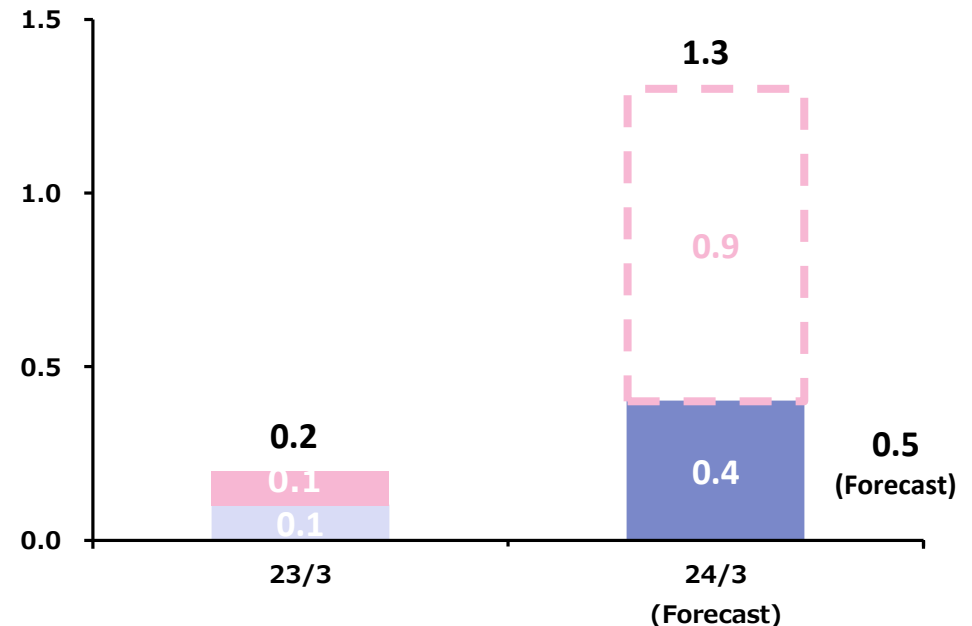
Chronic cough patients
2,500 K

RCC/UCC patients
400 K ~ 500 K

Definition of Refractory/Unexplained Chronic Cough



GERD: gastroesophageal reflux disease
UAUS: upper airway cough syndrome



Status in FY2023 2Q

- Dismantling of prescription limitation on May 1, 2023
- Period of taking drug was shorter than expected

Effort for FY2023

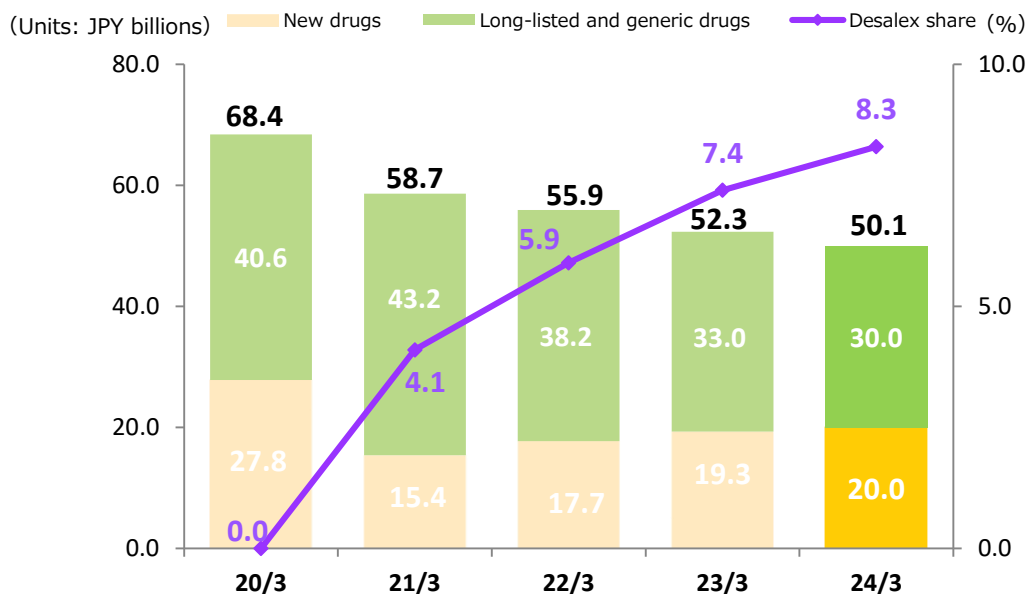
- Enhancement of better understanding for product characteristic
- Initiative to extend the patient's period of taking drug
- Appealing that Lyfnua is the only drug which has indication for refractory chronic cough

Evaluation of Cost effectiveness resulted in downward NHI drug price revision on November 1, 2023 (from 203.20 yen to 187.50 yen).

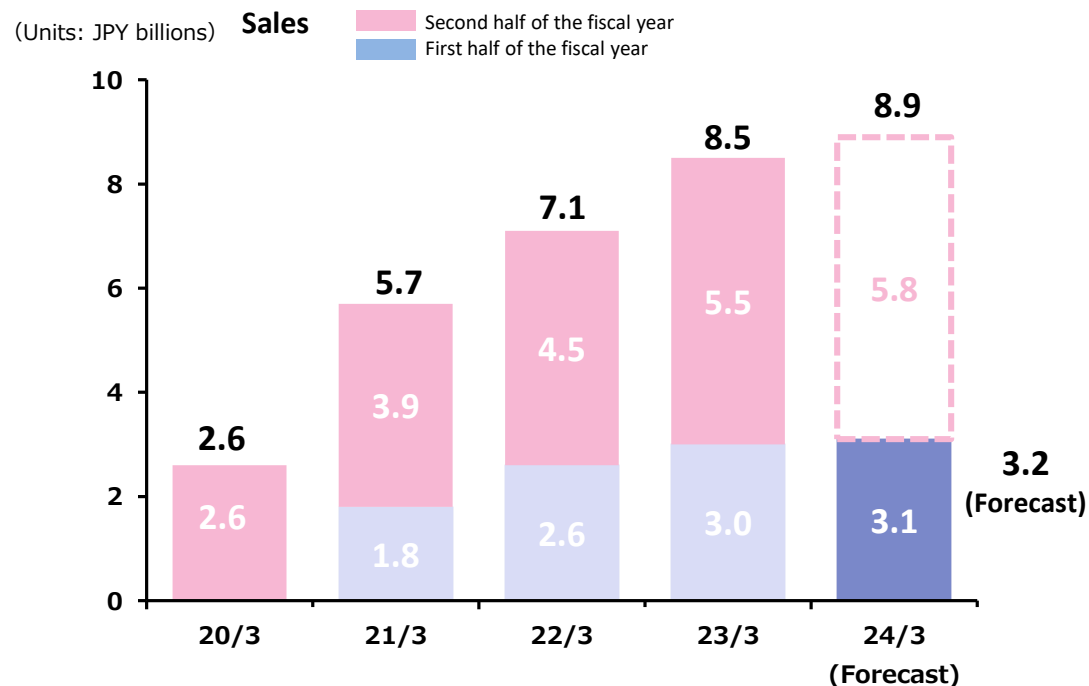
[Mainstay products] Desalex (Antiallergic Agent)



Antihistamine market (Apr-Sep)



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Antihistamine Market: Shrink of 4.3%

52.3bln (Apr-Sep 2022) ⇒ 50.1 (Apr-Sep 2023)*¹

- Shrinking market due to NHI drug price revision and launch generic drug but new drugs grew

Share of Desalex sales: +0.9%pt

7.4% (Apr-Sep 2022) ⇒ 8.3% (Apr-Sep 2023)*¹

[NHI drug price revision: -9.09% (Apr 2023)]

Medium to long-term market outlook

Shrinking market due to NHI drug price revision and launch generic drug

Status in FY 2023 2Q

- Prescription in otolaryngology: No.2
- Focus on acquiring prescriptions in internal medicine
- Enhancement of corroboration with KAKEN Pharmaceutical in dermatology

Effort for FY 2023

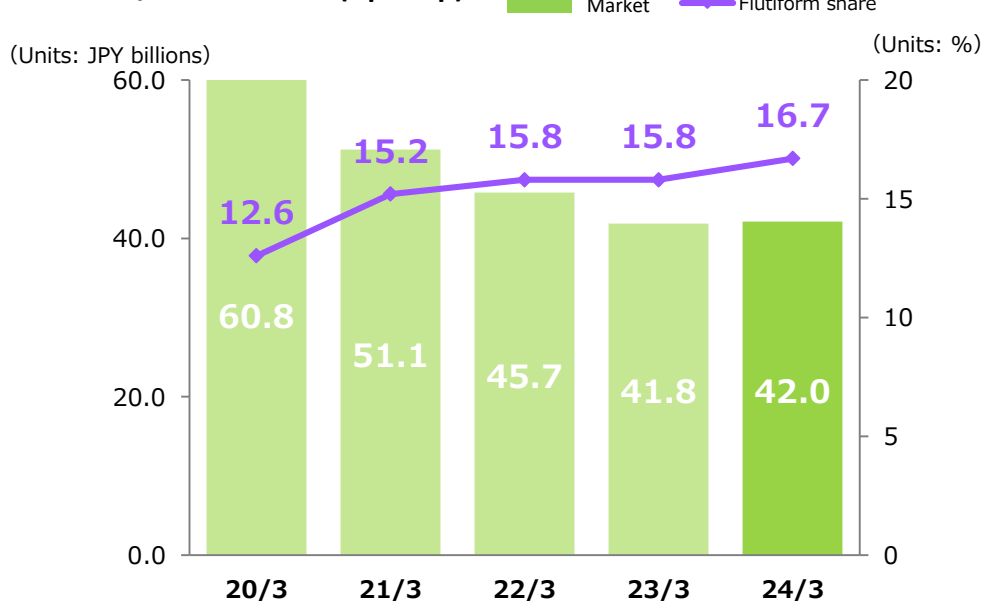
- Aim to be No.1 prescription in otolaryngology
- Aim to be first line treatment appealing as effective and usability drug
Usability: less sleepiness, no-limitation for drive, administration with or without

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[Mainstay products] Flutiform (Anti-asthmatic)



ICS/LABA market (Apr-Sep)



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ICS/LABA market: Remain flat

41.8 bln (Apr-Sep 2022) ⇒ 42.0 bln (Apr-Sep 2023)*¹

● Market remained flat although impact of NHI drug price revision and expansion of triple therapy

Share of Flutiform sales: +0.9 %pt

15.8% (Apr-Sep 2022) ⇒ 16.7% (Apr-Sep 2023)*¹

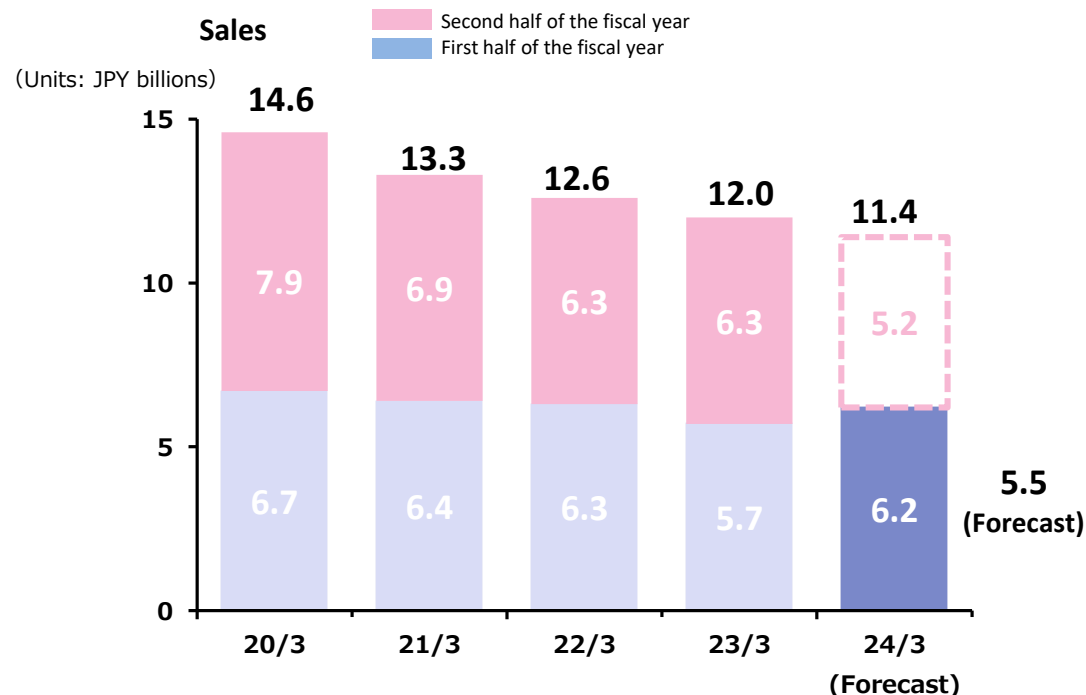
[NHI drug price revision for Flutiform 125 aerosol 120 puffs : -6.25% (Apr 2023)]

Medium to long-term market outlook

Market growth expected flat although NHI drug price revision and launch generic drug

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Sales



Status in FY 2023 2Q

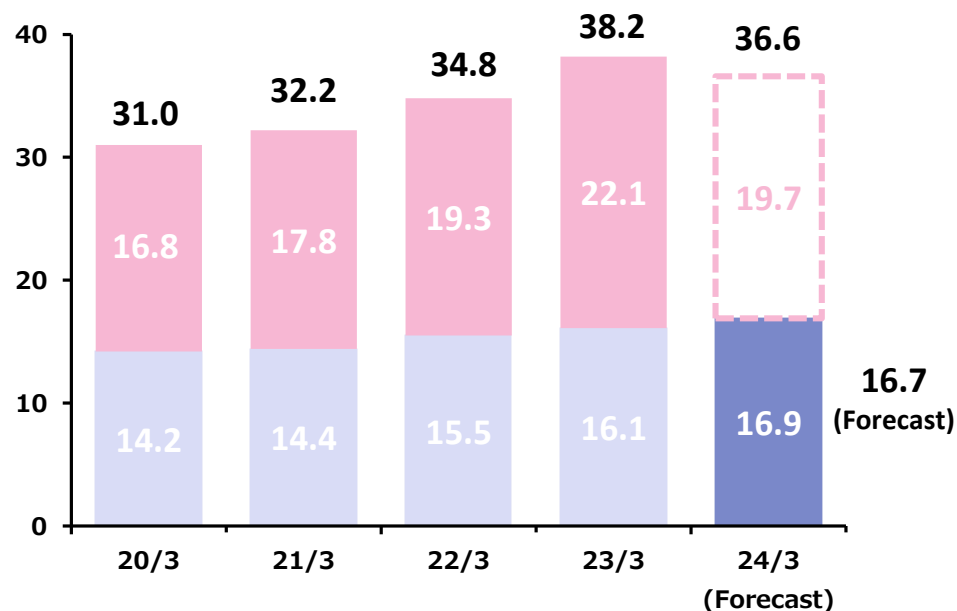
- Classified Covid-19 to the Category V caused patients seeing doctors
- Appealing a position of Flutiform on treatment for Asthma based on the guideline

Effort for FY 2023

- Expansion market share in terms of volume
- Appeal the utility and easy-to-use of aerosol formulation

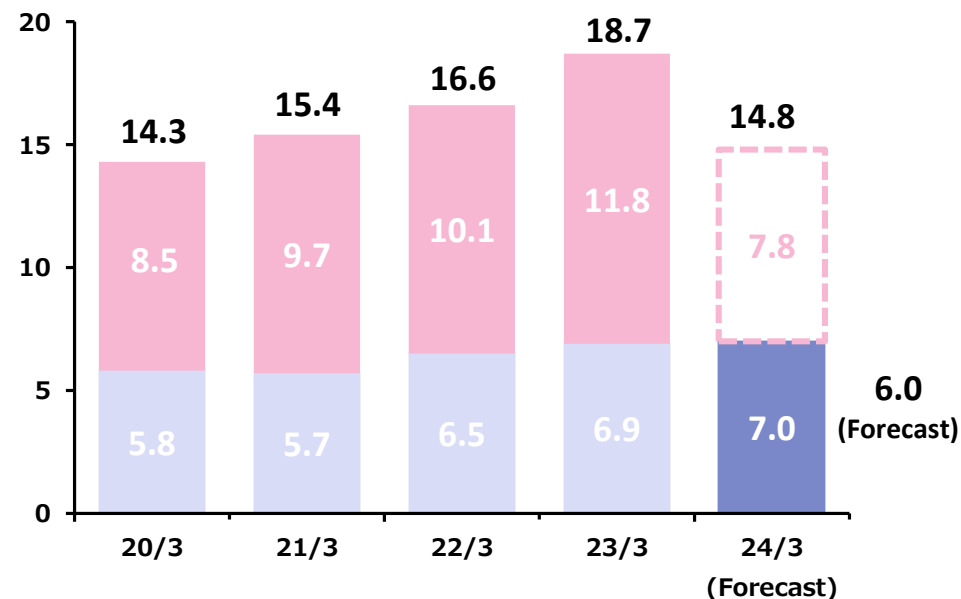
Sales

(Units: JPY billions)



Sales in AG (three products) among with the sales at left

(Units: JPY billions)



Status in FY2022 2Q

AG initiatives

- Keep market share of 50% in GE for Montelukast AG, Mometasone AG, Imidafenacin AG

[New products launched in June 2023]

Eplerenone tablets 25mg/50mg/100mg

Fluticasone FR Nasal Solution 27.5µg 56/120 puffs

Azilsartan OD tablets 10mg/20mg/40mg

Effort for FY2023

- Expand sales of strategic products
- Strive for stable supply for new products
- Promote initiatives for AG, Keep market share of 50% in GE for each products

Consolidated Financial Forecast FY2023

Consolidated Financial Forecast FY2023



(Unit: JPY billion)

	FY2022	FY2023	Year-on-year	
			Change	Change (%)
Net Sales	113.3	116.2	+ 2.9	+ 2.6
New drugs, etc. (Japan)	74.8	79.1	+ 4.3	+ 5.8
New drugs (Overseas)	0.3	0.4	+ 0.1	+ 29.6
Generic drugs	38.2	36.6	- 1.6	- 4.2
Cost of sales	63.1	-	-	-
SG&A (R&D)	45.0 (10.9)	- (9.6)	- (- 1.3)	- (- 12.0)
Operating profit	5.1	6.0	+ 0.9	+ 17.1
Ordinary profit	5.8	6.5	+ 0.7	+ 11.5
Profit attributable to owners of parent	4.7	4.9	+ 0.2	+ 3.7

[The full-year forecast remain unchanged]

Business results for the full fiscal year remains unclear, although net sales, operating profit and profit exceed the forecast.

Forecast of Mainstay Products Sales



(Unit: JPY billions)

		FY2022	FY2023 (Forecast)	Year-on-year	
				Change	Change (%)
New drugs, etc. (Japan)	Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	12.9	18.9	+ 6.0	+ 46.8
	Lasvic (New quinolone synthetic antibacterial agent)	2.5	3.2	+ 0.7	+ 32.6
	Lyfnua (Selective P2X3 receptor antagonist / chronic cough)	0.2	1.3	+ 1.1	+ 595.4
	Desalex (Antiallergic Agent)	8.5	8.9	+ 0.4	+ 4.6
	Flutiform (Combination drug for asthma treatment)	12.0	11.4	- 0.6	- 4.2
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	12.8	11.8	- 1.0	- 7.0
	Kipres (Leukotriene Receptor Antagonist)	6.6	5.3	- 1.3	- 19.2
	Mucodyne (Mucoregulator)	3.5	3.0	- 0.5	- 12.5
	Nasonex (Spray type allergic rhinitis remedy)	2.5	1.2	- 1.3	- 49.6
	Uritos (KYORIN) (Therapeutic agent for overactive bladder)	0.7	0.2	- 0.5	- 58.9
	Milton (Disinfectant)	2.0	1.9	- 0.1	- 1.0
Rubysta (Disinfectant)	2.1	2.1	0	+ 3.0	
Generic drugs	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	13.3	11.0	- 2.3	- 16.7
	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	4.7	3.4	- 1.3	- 26.6
	Imidafenacin tablets & OD"KYORIN" (Therapeutic agent for overactive bladder)	0.7	0.4	- 0.3	- 30.7

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 the sound financial base.
- Maintain stable dividends taking DOE (Dividend on Equity) ratio into account

Dividend

	FY2021	FY2022	FY2023 (Forecast)*
Dividend per share (Yen)	¥52 (interim dividend of ¥20)	¥52 (interim dividend of ¥20)	¥52 (interim dividend of ¥20)

* The year-end dividend of 52 yen announce on May 11, 2023 remain unchanged

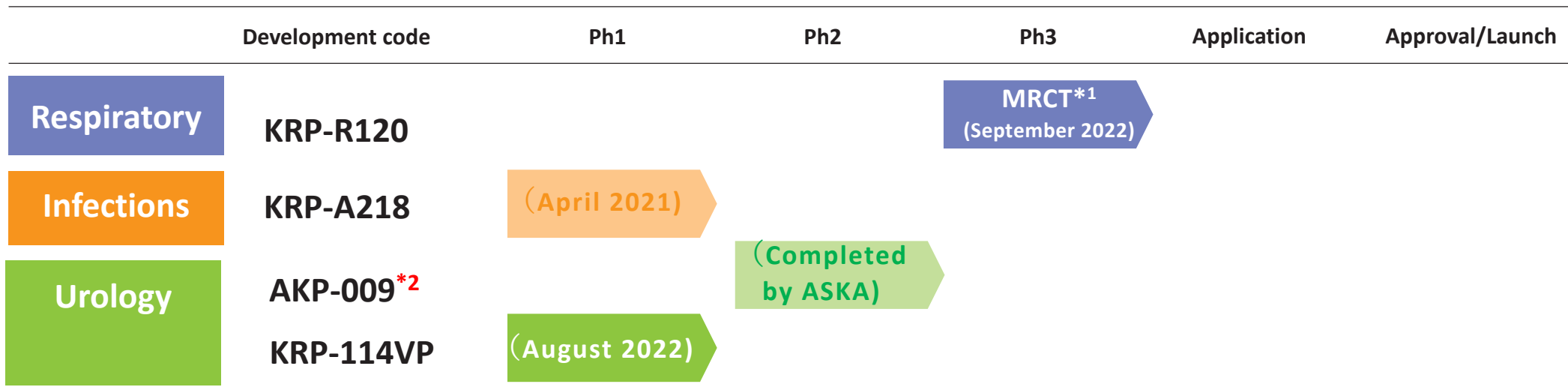
○The interim dividend of 20 yen have been decided at in the Board Meeting scheduled in November 8, 2023.

Status of R&D Pipeline

Status of R&D Pipeline in FY2023



Updated



*1 MRCT: Multi-Regional Clinical Trials

*2 Ph1 trial is being conducted again (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	● Specified clinical trial (September 2023)

Start of the specified clinical trial using the DTx for tinnitus

Title

A Multicenter, Randomized, Double-Blind, Sham-Controlled Study using the App for Tinnitus Treatment in Patients with Tinnitus (Pilot Study).

Primary outcome

Change in THI total score from week 0 at week 16 after study app prescription

THI: Tinnitus handicap inventory

Subjects

Chronic tinnitus with associated suffering (18 years to 75 years old)

Enrollment (Estimated)

60

(Contact for scientific/public queries: Tokai University Hospital)

Initiative toward Realization of the Midium-term Vision “Vision 110 -Stage1-”

Vision 110

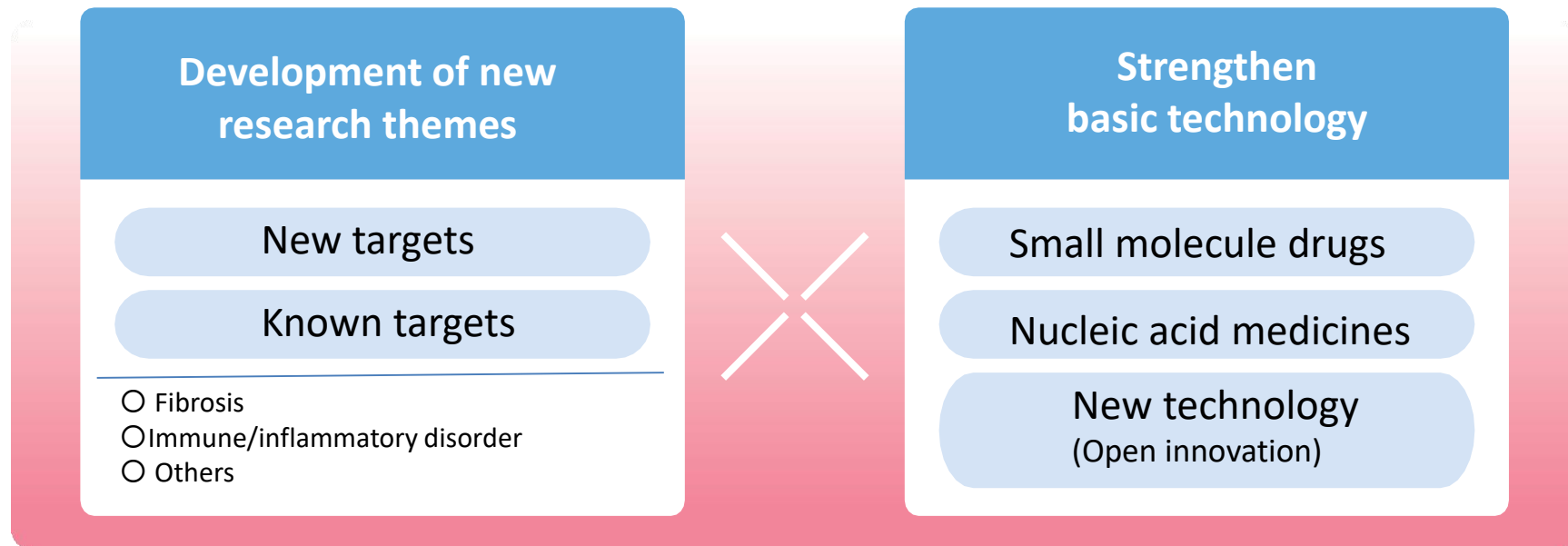
Stage 1

1. Strengthening drug discovery capability to create high-value new drugs that meet medical needs
2. Expansion of development pipeline through in-licensing
3. Maximization of the ratio of new drugs
4. Promoting healthcare-related businesses that have synergies with the new drugs business
5. Building a sustainable corporate foundation

● Strategic image

	Stage 1	Stage 2-3
New drugs business	<p>Drug Discovery</p> <p>Strengthen the drug discovery capability to create high-value new drugs that meet medical needs ○Try for drug innovation through new drug discovery strategies</p> <p>Reorganization</p> <p>Creation of new drugs from long-term perspective</p>	»»
	<p>Development</p> <p>Expansion of development pipeline through in-licensing ○Significantly strengthen in-licensing ability ○Promote DTx development</p> <p>Investment of resource</p> <p>Enhancement of development pipeline</p>	»»
	<p>Marketing, SCM, Reliability Assurance</p> <p>Maximization of the ratio of new drugs ○Maximize the extension of new drugs ○Ensure the stable supply of high-quality drugs</p> <p>Driving force of revenue</p> <p>Maximization of profitability</p>	»»
Healthcare-related business	<p>GE business</p> <p>○Achieve sustainable growth in the generic drugs business ○Strengthen production capacity for drugs and reduce manufacturing costs</p>	»»
	<p>Other business</p> <p>○Promote infectious disease-related business</p>	»»

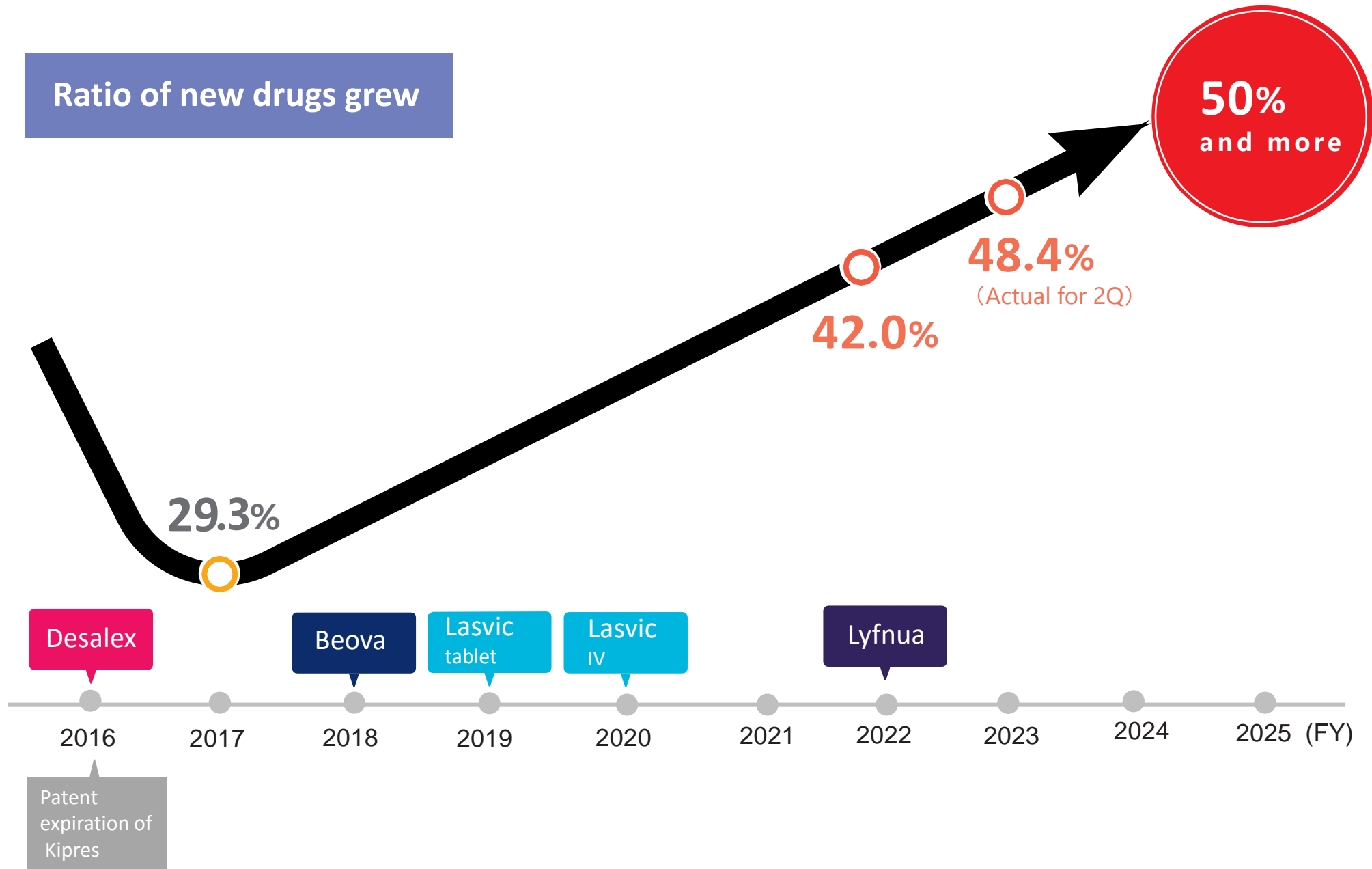
Try for drug innovation through new drug discovery strategies



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

Products	Aimed status	Goal at FY2025	Sales (JPY billions)																												
Beova®	First-line treatment for OAB	<ul style="list-style-type: none"> No.1 in OAB market as Beova in FY2023 50% of patient's share 	<table border="1"> <caption>Sales Breakdown (JPY billions)</caption> <thead> <tr> <th>Year</th> <th>Orange</th> <th>Pink</th> <th>Dark Pink</th> <th>Light Blue</th> <th>Dark Blue</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>FY2022 (Actual)</td> <td>12.0</td> <td>8.5</td> <td>0.2</td> <td>2.5</td> <td>12.9</td> <td>36.1</td> </tr> <tr> <td>FY2023 (Forecast)</td> <td>11.4</td> <td>8.9</td> <td>1.3</td> <td>3.2</td> <td>18.9</td> <td>43.7</td> </tr> <tr> <td>FY2025 (Targeted)</td> <td>11.5</td> <td>10.0</td> <td>4.5</td> <td>5.0</td> <td>25.0</td> <td>56.0</td> </tr> </tbody> </table>	Year	Orange	Pink	Dark Pink	Light Blue	Dark Blue	Total	FY2022 (Actual)	12.0	8.5	0.2	2.5	12.9	36.1	FY2023 (Forecast)	11.4	8.9	1.3	3.2	18.9	43.7	FY2025 (Targeted)	11.5	10.0	4.5	5.0	25.0	56.0
Year	Orange	Pink		Dark Pink	Light Blue	Dark Blue	Total																								
FY2022 (Actual)	12.0	8.5		0.2	2.5	12.9	36.1																								
FY2023 (Forecast)	11.4	8.9		1.3	3.2	18.9	43.7																								
FY2025 (Targeted)	11.5	10.0		4.5	5.0	25.0	56.0																								
Lasvic®	First-choice antibacterial agent for elderly or patients with underlying disease in respiratory infection	<ul style="list-style-type: none"> No.1 in oral new quinolone market in FY2023 40% share of new quinolone market in FY2025 as Lasvic 																													
Lyfnua®	Only one treatment for chronic cough	<ul style="list-style-type: none"> FY2025 approx. 10,000 of GP approx. 2,000 of HP 																													
Dezalex®	Effective and easy-to-use drug	<ul style="list-style-type: none"> Sales of 10 billion yen in FY2025 																													
Fultiform®	Aerosol for patients with weak inspiration	<ul style="list-style-type: none"> Sustainable growth on volume-basis to FY2025 with CAGR of low single digit % 																													

Ratio of new drugs grew



Beova®

Status



Aimed status

By FY2025

Goal

● New patients acquisition rate : No.1

(End of September 2023: 43.4%*¹, as Beova)

● Switching rate from existing drugs: No.1

(End of September 2023: 35.9%*¹, as Beova)

Patients share of OAB market (as Beova)

FY2022: 25.7%*² => FY2023 Apr-Sep.: 32.5*², as Beova)

Initiatives for Second half of the year

Promote initiatives using real-world-data

First-line treatment for OAB

- No.1 in OAB market as Beova in FY2023
- 50% of patients' share of OAB market

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Lasvic®

NQ: New quinolone

Status

- Classified Covid-19 to the Category V caused market expansion
(Oral NQ market: +150%, year on year)
- Listed in guidelines as a recommended drug
- Growth rate of No.1 in expansion of oral NQ market

Initiatives

GP: Promotion to internal medicine/otorhinolaryngology

HP: More opportunities for promotion of products

(Number of adaption increased: +120%, year on year)

Market share in oral NQ market

FY2022: 17.3%* => FY2023 Apr-Sep.: 22.7%* (FY2023 forecast: 25%)



Aimed status

First-choice antibacterial agent for elderly or patients with underlying disease in respiratory infection

By FY2025

Goal

- No.1 sales in oral NQ market by FY2023
- 40% share of NQ market as Lasvic

Lyfnua®

Status

- Dismantling of prescription on May 1, 2023
- Number of customers in FY2023 2Q
 - GP Target achieved
 - HP Target not achieved
- Lower sales than the forecast ⇒ Period of taking drug was shorter than expected

Initiatives for second half of the year

- Enhancement of better understanding for product characteristic (adverse event on target)
 - Initiative to extend the patient's period of taking drug (appealing effectiveness/safety including long-term data)
- Target number of customers in second half of FY2023 GP: 7,200 HP: 1,800



Aimed status

By FY2025

Goal

Only one treatment for chronic cough

- Number of customers in FY2025
 - GP Approx. 10,000
 - HP Approx. 2,000

Aim to being a first-line treatment for the patients with chronic cough despite treatment

Construction of the Takaoka New Plant

Strengthen the supply capacity as the production of drugs increased



Takaoka plant (Toyama) as of October 11, 2023

【Outline of the Takaoka Plant】

Location	IC Park 8, Takaoka-City, Toyama
Site Area	42,457 m ²
Building	Three floors, Building area about 7,262 m ² , Total floor area about 21,091 m ²
Groundbreaking	September 2022
Operation	April 2024 (Scheduled)
Investment	About 10 billion yen

- Production function of Inami which manufactures GE are transferred to Takaoka
- Product capacity of approximately two billion tablets (More than twice of Inami Plant)
- Significantly reduce CO₂ emissions, actively utilize LNG and renewable energy

Proceeding with construction toward operation in April 2024

Reform of management group structure and new initiatives

Reform of R&D
systems

Expand of
development pipeline

Maximize the
expansion of sales
growth in new drugs

Improve cost
competitiveness

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