# Financial Results First-Half (Interim period) of Fiscal 2025

**November 10, 2025** 

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





- Outline of Consolidated Financial Results for Interim Period
- **Consolidated Financial Forecast**
- Medium-Term Business Plan of "Vision 110 –Stage 1–"
  - Initiative for FY2025 First Half
  - Status of R&D Pipeline
  - Trends of Mainstay Products
- **Shareholder Returns**
- Reduction of Cross-Shareholdings



Outline of Consolidated Financial Results for Interim Period

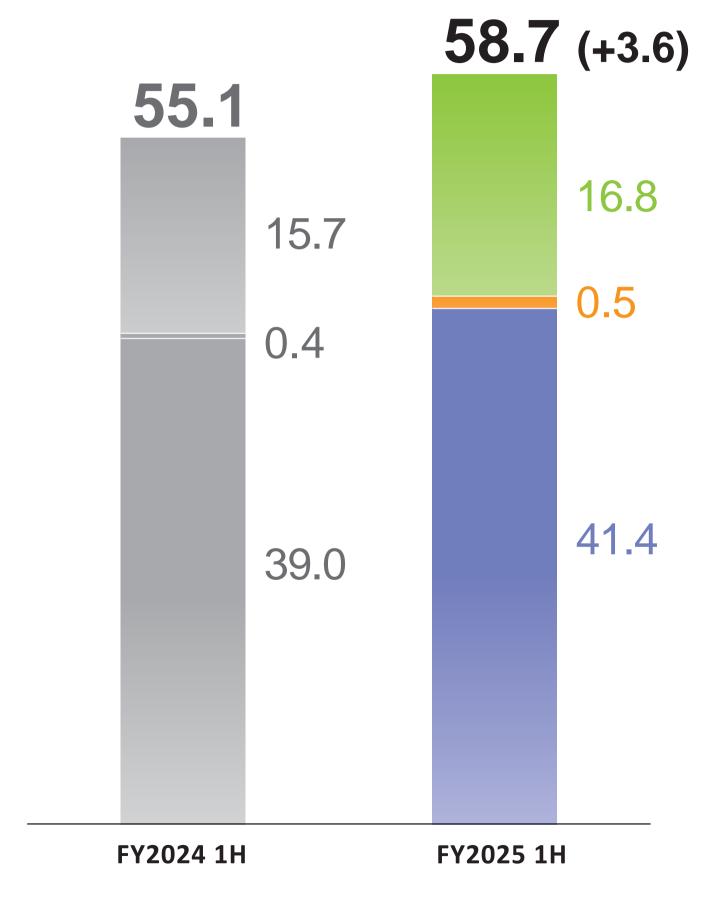


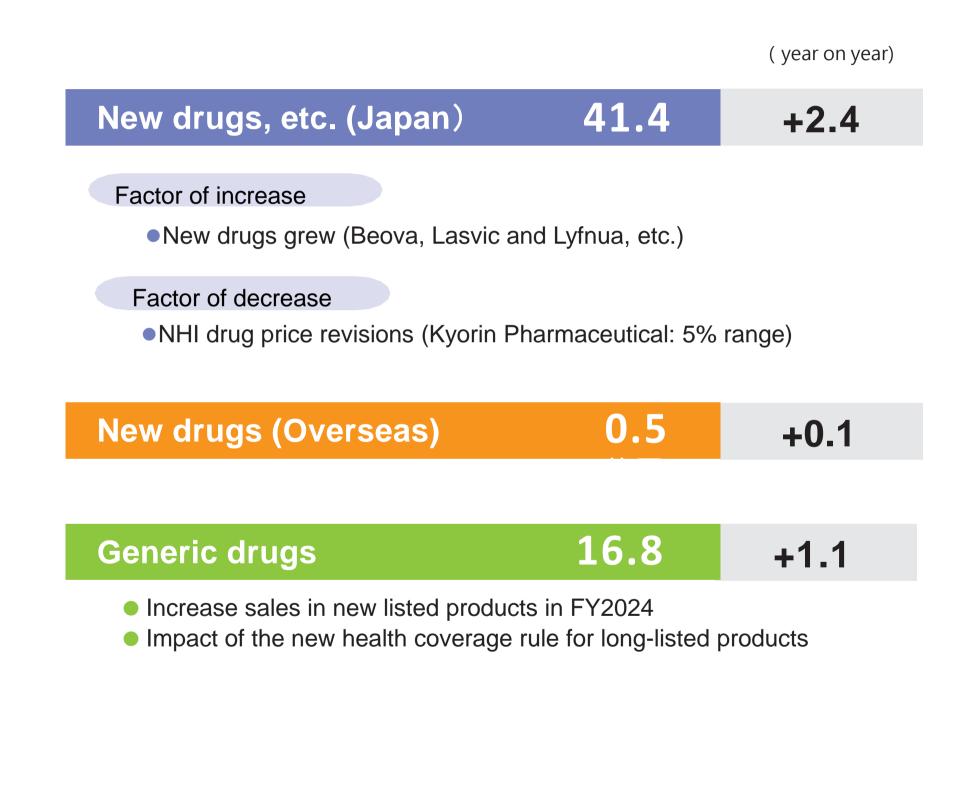
(Units: JPY billions)

					(Office, JP4 billions
		FY2024 1H	FY2025 1H	Year	on year
		F12024 IT	F12025 IT	Change	Change (%)
Net sales		55.1	58.7	+3.6	+6.5
	New drugs, etc. (Japan)	39.0	41.4	+2.4	+6.1
	New drugs (overseas)	0.4	0.5	+0.1	+18.8
	Generic drugs	15.7	16.8	+1.1	+7.2
Cost of sa	les	31.6	33.8	+2.2	+7.2
Gross pro	fit	23.6	24.9	+1.3	+5.7
SG&A		22.0	23.5	+1.5	+6.9
(R&D)		(3.8)	(5.4)	(+1.6)	(+41.6)
Operating	profit	1.5	1.4	-0.1	-12.0
Ordinary p	rofit	2.1	1.6	-0.5	-22.8
Profit attrib		1.3	1.5	+0.2	+19.0

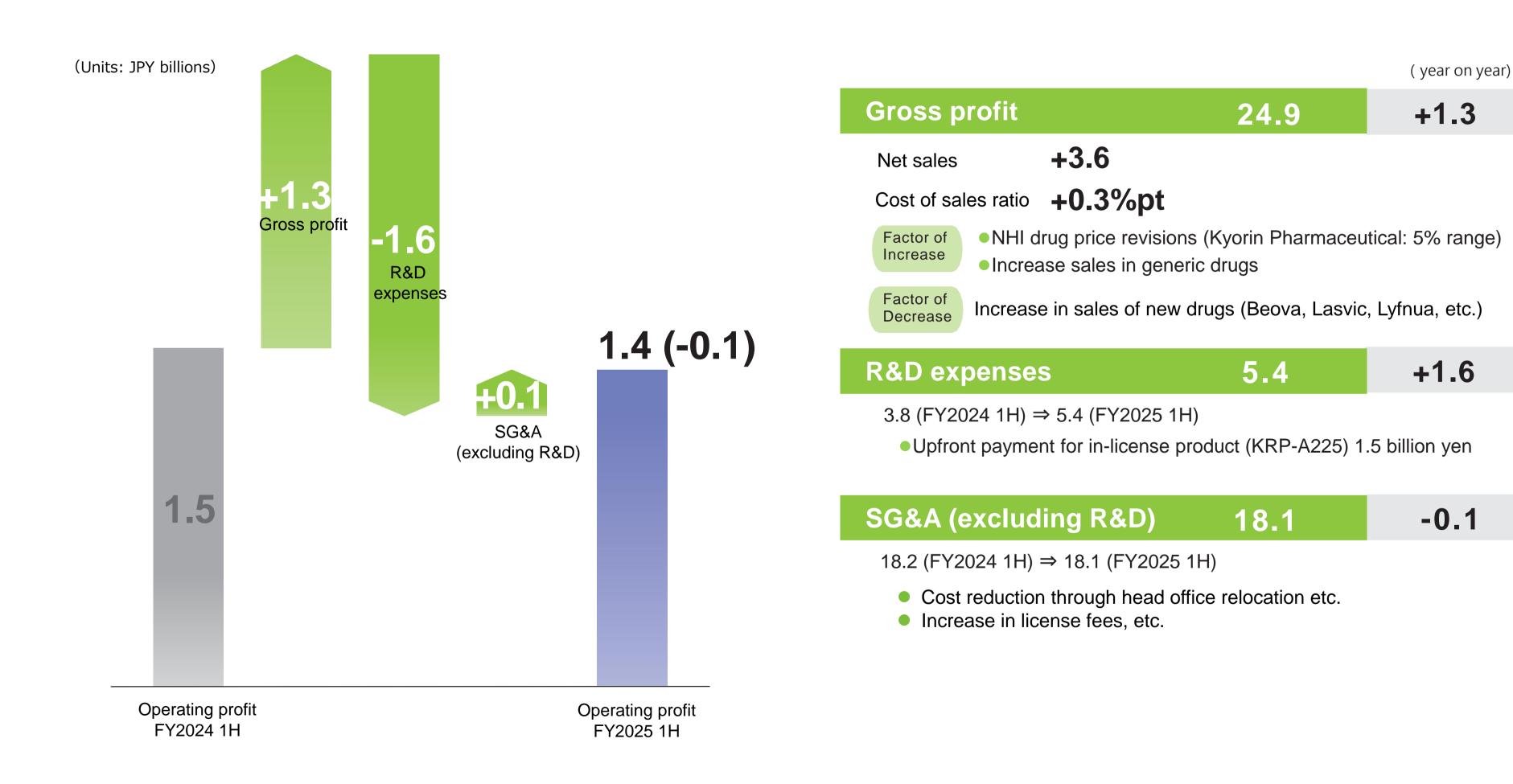


(Units: JPY billions)









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



(Units: JPY billions)

		FY2025 1H	TV2025 411	Vs.	forecast
		(forecast)	FY2025 1H	Change	Achievement rate (%)
Net sales		57.4	58.7	+1.3	102.3
	New drugs, etc. (Japan)	40.7	41.4	+0.7	101.7
	New drugs (overseas)	0.1	0.5	+0.4	504.1
	Generic drugs	16.5	16.8	+0.3	102.0
Cost of sal	les		33.8	<u>—</u>	
Gross prof	it		24.9		
SG&A			23.5		
(R&D)		(4.3)	(5.4)	(+1.1)	(126.6)
Operating	profit	1.7	1.4	-0.3	80.2
Ordinary p	rofit	1.8	1.6	-0.2	87.9
Profit attrib		1.4	1.5	+0.1	106.7

#### Difference from the Forecast announced on May 12, 2025

Net sales:Interim forecasts were exceeded due to the growth of new drugs such as Beova and income related to Gatifloxacin.

Operating profit: R&D expenses included a upfront payment of 1.5 billion yen associated with KRP-A225, resulting in a shortfall of 0.3 billion yen. Profit attributable to owners of parent: Extraordinary income included a 0.4 billion yen gain on the sale of investment securities, etc.

Nasal 50mg

"KYORIN"



(Units: JPY billions)

			ΓV000Ε 411	Year on year		
		FY2024 1H	FY2025 1H	Change	Change (%)	
	Beova (KYORIN)	10.4	12.3	+1.9	+17.5	
	Lasvic	3.0	3.5	+0.5	+19.0	
	Lyfnua	0.4	0.5	+0.1	+9.9	
	Desalex	3.4	3.7	+0.3	+8.1	
New Drugs,	Flutiform 6.4		6.3	-0.1	-1.1	
etc. (Japan)	Pentasa	6.2	6.3	+0.1	+1.4	
(Japan)	Kipres	1.8	0.9	-0.9	-48.9	
	Mucodyne	1.5	2.0	+0.5	+30.2	
	Milton	0.9	0.9	0	+0.5	
	Rubysta	0.6	0.4	-0.2	-31.6	
		1	ı			
Generic	Montelukast tablets"KM"	5.0	4.4	-0.6	-12.8	
Drugs	Mometasone Nasal 50mg	0.7	1.1	+0.4	+58.6	

1.1

+0.4

+58.6

0.7

FY2025 1H	Vs. f	orecast
(Forecast) announced on May 12, 2025	Change	Achievement rate (%)
11.6	+0.7	105.8
3.7	-0.2	95.2
0.5	0	93.2
3.6	+0.1	101.8
6.2	+0.1	101.8
5.9	+0.4	106.2
0.8	+0.1	117.2
2.2	-0.2	90.1
0.9	0	103.8
0.5	-0.1	81.6

4.9	-0.5	89.7
0.8	+0.3	140.0



**Consolidated Financial Forecast** 

### Consolidated Financial Forecast for FY2025 \*remain unchanged



(Units: JPY billions)

		FY2024	FY2025	Year-	on-year
		(Actual)	(Forecast)	Change	Change (%)
Net sales		130.1	127.0	-3.1	-2.4
	New drugs, etc. (Japan)	84.2	89.0	+4.8	+5.8
	New drugs (overseas)	8.9	0.2	-8.7	-97.7
	Generic drugs	37.1	37.7	+0.6	+1.7
Cost of sale	es	70.6		_	_
SG&A		47.0	_	_	<del>_</del>
(R&D)		(10.5)	(10.4)	(-0.1)	(-1.1)
Operating p	orofit	12.6	6.1	-6.5	-51.5
Ordinary pr	ofit	13.2	6.3	-6.9	-52.3
Profit attribution	utable to owners	9.1	4.8	-4.3	-47.2



(Units: JPY billions)

		FY2024	FY2025	Year-c	n-year
		Actual	Forecast	Change	Change (%)
	Beova (KYORIN)	22.1	25.1	+3.0	+13.7
	Lasvic	7.8	8.5	+0.7	+8.3
	Lyfnua	0.9	1.1	+0.2	+20.4
	Desalex	9.6	10.1	+0.5	+5.0
New Drugs,	Flutiform	13.7	13.2	-0.5	-3.9
etc. (Japan)	Pentasa	12.2	11.6	-0.6	-4.7
	Kipres	3.5	2.1	-1.4	-40.0
	Mucodyne	3.6	5.2	+1.6	+45.8
	Milton	1.8	1.8	0	-2.3
	Rubysta	1.1	1.0	-0.1	-9.7
	Montelukast tablets "KM"	12.0	11.3	-0.7	-5.6
Generic Drugs	Mometasone Nasal 50mg "KYORIN"	4.1	4.3	+0.2	+4.5



Medium-Term Business Plan of "Vision 110 –Stage 1–" Initiatives for FY2025 First Half





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

Expansion of development pipeline through in-licensing

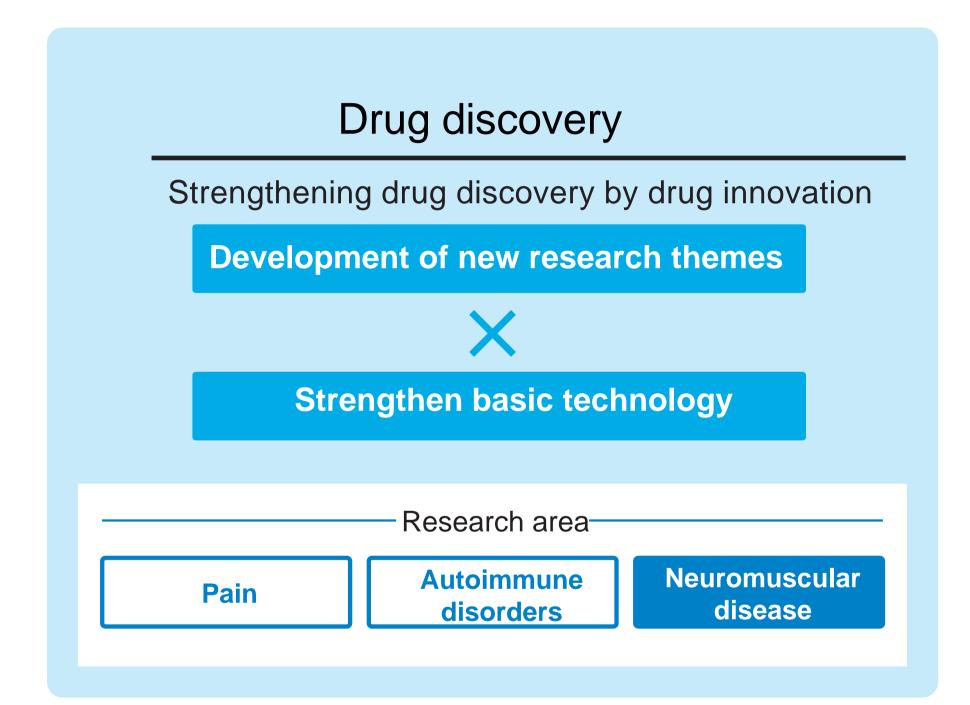
Maximization of the ratio of new drugs

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





Newly establishing Neuromuscular Disorders as a drug discovery research area

#### Neuromuscular disease

A general term for diseases that cause motor impairment (movement disorders) due to a lesion/pathology in the nerves themselves (such as the brain, spinal cord, and peripheral nerves) or in the muscles themselves.

- Amyotrophic Lateral Sclerosis (ALS)
- Parkinson's Disease (PD)
- Myasthenia Gravis (MG)
- Multiple Sclerosis (MS)
- Muscular Dystrophy
- Hereditary Neuropathies, etc.

**Etiology / Causes** Genetic mutations, autoimmunity, aging, environmental factors, etc.

Expansion of development pipeline through in-licensing



Stage1 Target

At least six in-licensing items

FY2025 Initiatives Obtain at least two in-licensed assets (including marketed products) demonstrating high potential for rapid revenue generation

FY2025 Actual for first half

KRP-A225 (HB2198, new drug candidate for SLE, etc.): September 2025, Hinge Bio Inc.



### Target disease: Systemic Lupus Erythematosus - SLE

Overview	<ul> <li>An autoimmune disease where immune abnormalities lead to the production of autoantibodies, damaging organs</li> <li>Excessively produced autoantibodies form immune complexes, which deposit in tissues, leading to inflammation</li> <li>A designated intractable disease in Japan</li> </ul>
Symptoms	<ul> <li>Most patients exhibit systemic, skin, and joint symptoms</li> <li>Other symptoms are diverse, including visceral symptoms such as lupus nephritis, and vascular symptoms.</li> <li>The specific symptoms and combinations vary from person to person</li> </ul>
Number of patients	Estimated prevalence: Approximately 60,000 to 100,000 people  Number of medical certificate holders (for designated intractable disease): 66,307 (FY 2023)  Prevalence rate: 20 to 150 per 100,000 people*
Current treatments	●Steroids ●Immunosuppressants ●Immunomodulatory drugs ●Biologics



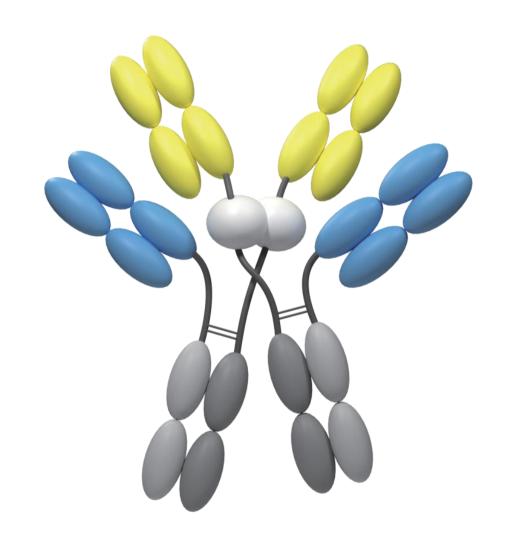
\* Guideline for the management of systemic lupus erythematosus 2019

A significant unmet need for new therapeutic options remains



#### **Overview of KRP-A225**

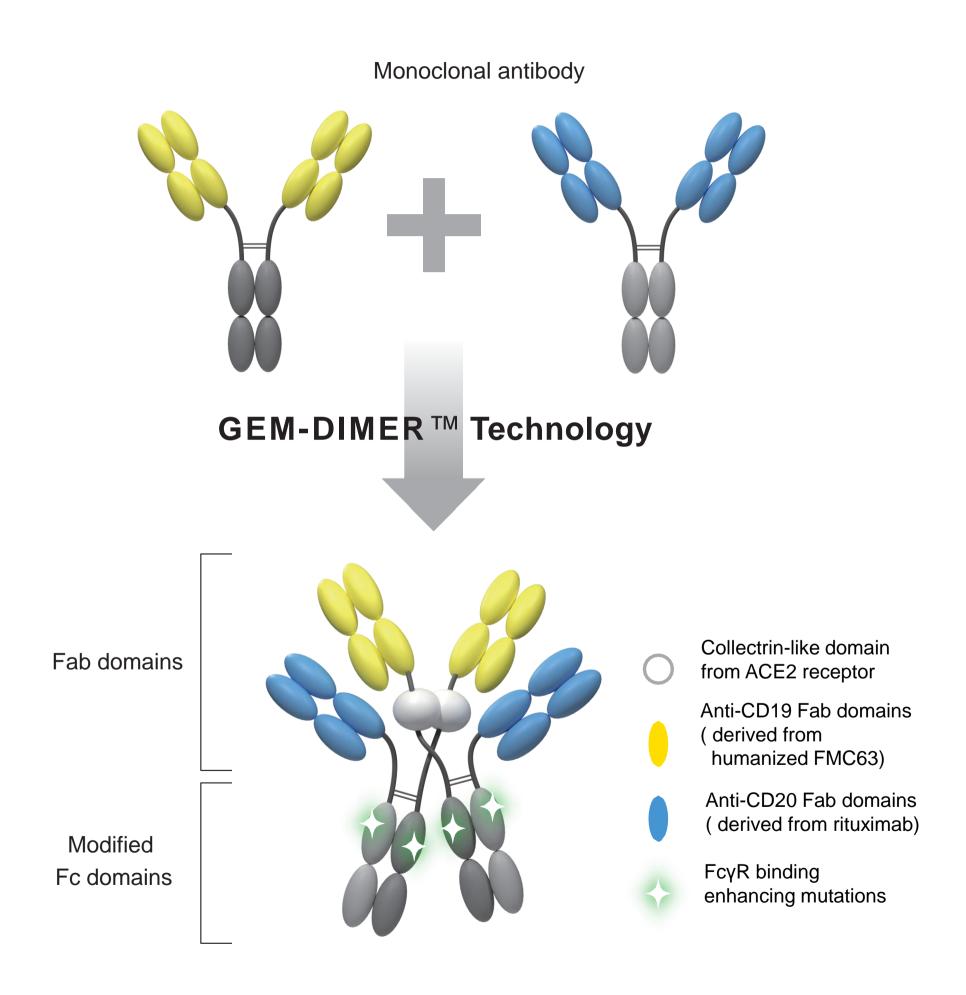
Target disease	Systemic Lupus Erythematosus (SLE), etc.
MoA	B cell depletion by a humanized bispecific antibody targeting CD19 and CD20
Patients	Moderate to severe patients
Formulation	Iv infusion
Development status	Phase 1 trial in preparation (targeted to start in 2025)
Future direction	The next steps will be determined based on the results of the Phase 1 trial conducted by Hinge Bio





Development will be advanced in collaboration with Hinge Bio, aiming for the earliest possible market launch





A humanized bispecific antibody that features a dimeric structure of a full-length IgG antibody, generated using Hinge Bio's proprietary GEM-DIMER™ technology.

It targets the CD19 and CD20 molecules, which have clinically validated efficacy against SLE, and is expected to achieve rapid and potent B-cell depletion in the circulating blood and lymphoid tissues.

"Superdimerization" is mediated by an ACE2 receptor-derived collectrin-like domain.

The high-affinity modified Fc region is expected to enhance immune effector functions such as ADCC (Antibody-Dependent Cellular Cytotoxicity), ADCP (Antibody-Dependent Cellular Phagocytosis), and CDC (Complement-Dependent Cytotoxicity)

The antibody can be manufactured using standard antibody drug manufacturing processes.



# **Status of R&D Pipeline**



- No statistically significant difference was achieved in the primary endpoint
- Clinical benefit was observed across multiple study efficacy parameters

### **EFZO-FIT Study**

Titles	Efficacy and Safety of Intravenous Efzofitimod in Patients With Pulmonary Sarcoidosis  Others*  Nominal p- value		● Steroid free at week 48  Efzofitimod 5mg/kg: 52.6% Placebo: 40.2%   p = 0.0919		
Study Design	<ul> <li>Randomized, Double-Blind, Placebo-Controlled Parallel         Assignment Study</li> <li>Efzofitimod 3mg/kg or 5mg/kg of Efzofitimod or placebo         dosed intravenously once a month</li> </ul>		<ul> <li>Change from baseline in KSQ-lung</li> <li>Efzofitimod 5mg/kg: 10.36 Placebo: 6.19  p = 0.0479</li> <li>Steroid free and KSQ-lung improvement</li> </ul>		
Primary Outcome Measures	<ul> <li>Change from baseline in mean daily oral corticosteroid (OCS) dose at week 48</li> <li>Efzofitimod 5mg/kg: -7.9% Placebo: -7.1% p = 0.3313</li> </ul>	Safety	Efzofitimod 5mg/kg: 29.5% Placebo: 14.4   p = 0.0199  Safe and well-tolerated		

\*The statistical analysis plan was designed on a hierarchical assessment basis.

Therefore, since the primary endpoint was not met, all subsequent statistical testing is reported as nominal findings.

The path forward will be determined following a discussion with aTyr

### Results was reported by the Principal Investigator\* at the 70th Congress of Japan Audiological Society

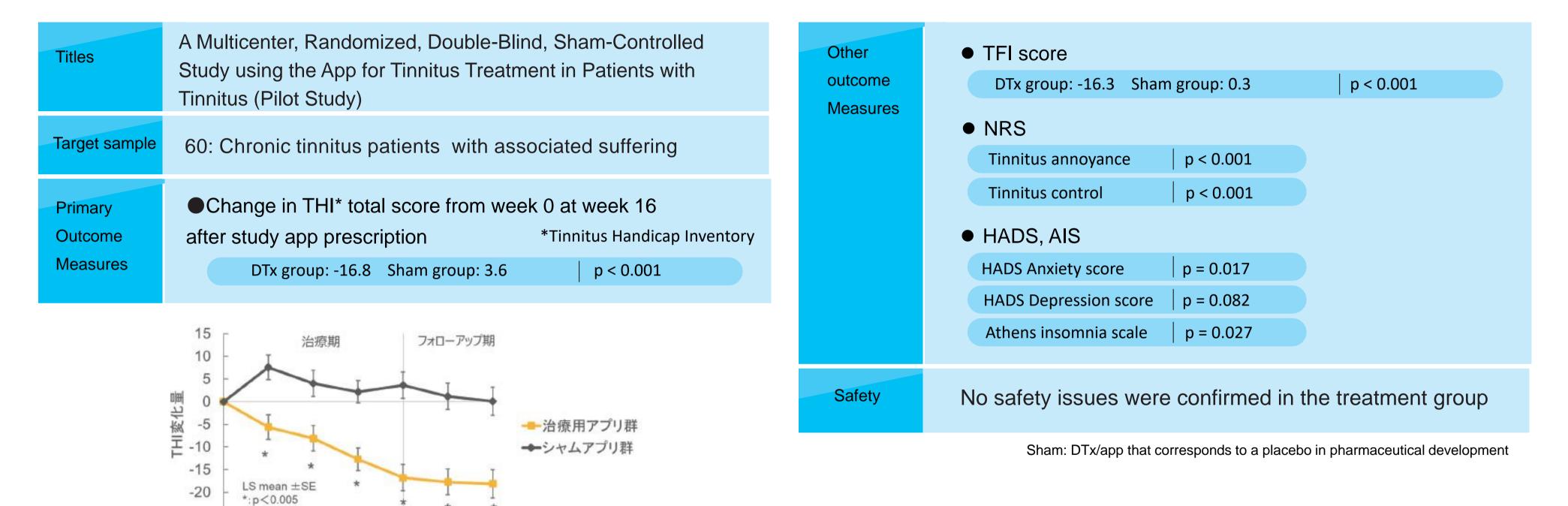


\*Professor Koichiro Wasano (Department of Otorhinolaryngology, Head and Neck Surgery, Tokai University School of Medicine)

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### Primary endpoint showed a statistically significant improvement



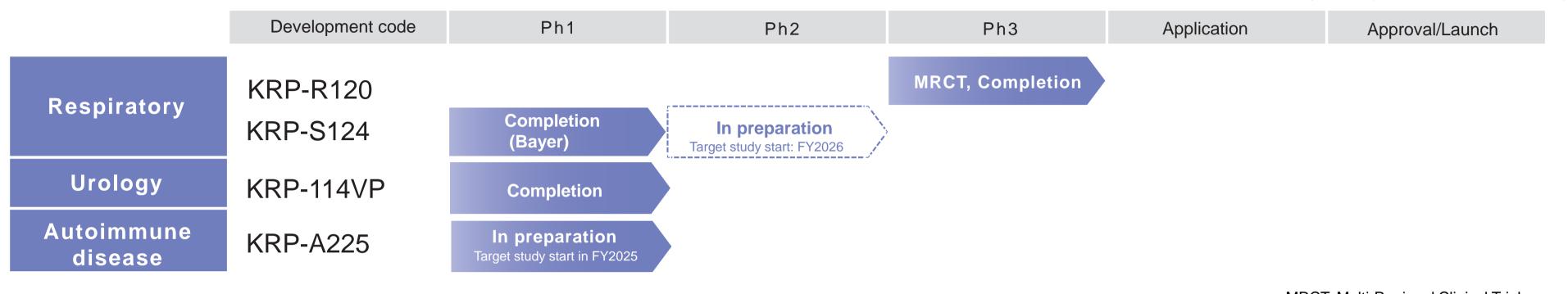
Aim to initiate the pivotal trial in the first half of FY2026

An article under submission

### Status of R&D Pipeline



\*Updated (As of November, 7 2025)



MRCT: Multi-Regional Clinical Trials

DTx	Development code	Research/Developmen	t Pivotal tria	I	Application	Approval/Launch
Otolaryngology	KRP-DT123		In preparation  Target study start: FY:	/		
Respiratory	KRP-DC125		In preparation Target study start: FY:			
	Compound/Code	Licensee	Stage	Features		
Licensed Compound	KRP-M223*	Novartis	Pre-clinical		(2 antagonist llergic and inflammatory diseas	ses involving mast cells
	KRP-203	Priothera	Ph3	●Target: A	ine-1-Phosphate receptor Ago ML patients undergoing HSCT ent of IP and drug substances	Γ



Compound/Code	Origin	Stage	Target disease	Features
BDT272	BIODOL Therapeutics	Ph1 (In France)	Pain	<ul> <li>Press release on Jan 2025</li> <li>FLT3 inhibitor</li> <li>Patient market of 23 million (Japan)</li> </ul>

Based on the results of the Phase 1 trial, the decision on whether to transition to a licensing agreement will be made within FY2025.

Compound/Code	Origin	Stage	Target disease	Features
CYR-064	Cyrano Therapeutics	Ph2 (In USA)	Post-viral loss of smell	<ul> <li>Press release on Feb 2025</li> <li>PDE inhibitor</li> <li>Patient market of 1 million (Kyorin estimated)</li> </ul>

Based on the results of the Phase 2 trial, the decision on whether to transition to a licensing agreement will be made within FY2025.

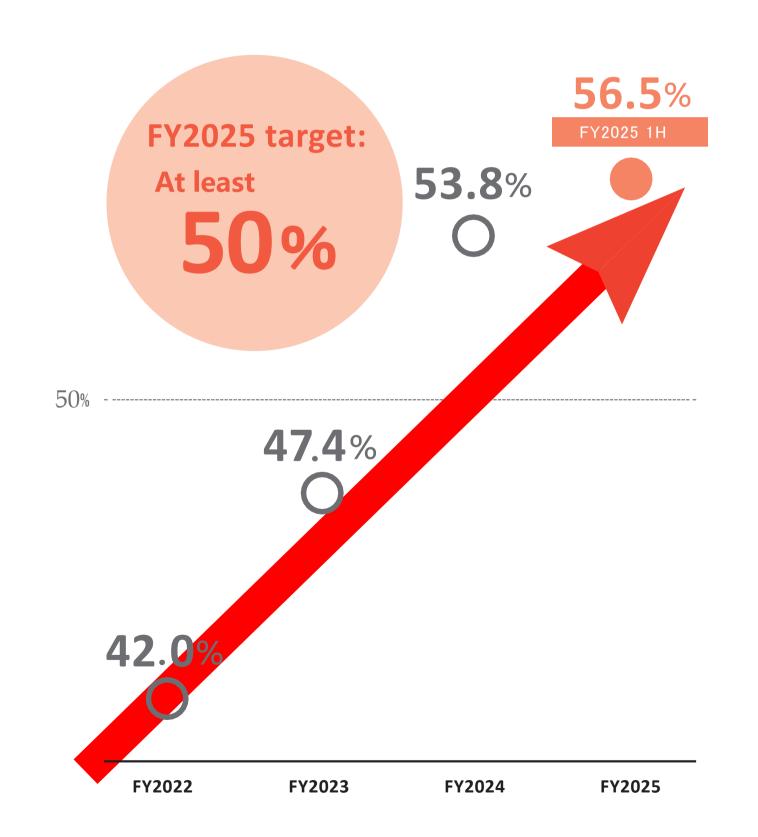


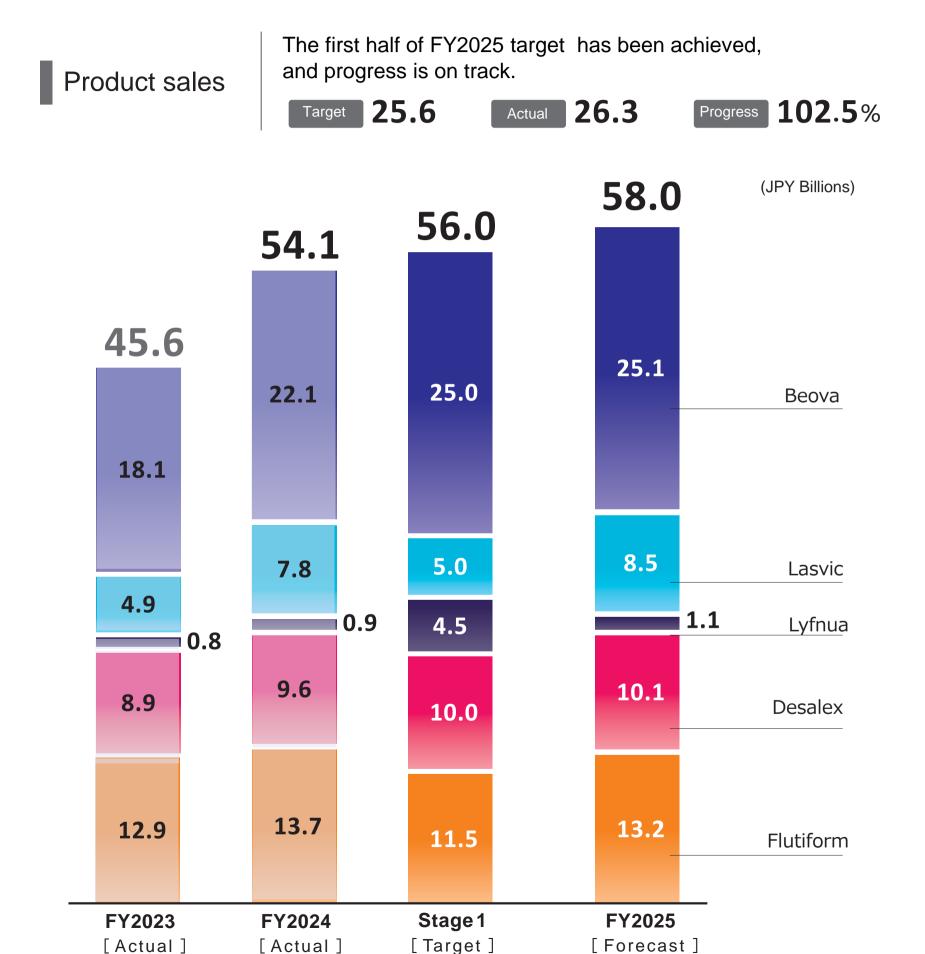
# Maximization of the ratio of new drugs



Ratio of new drugs

Exceeding the FY2025 target





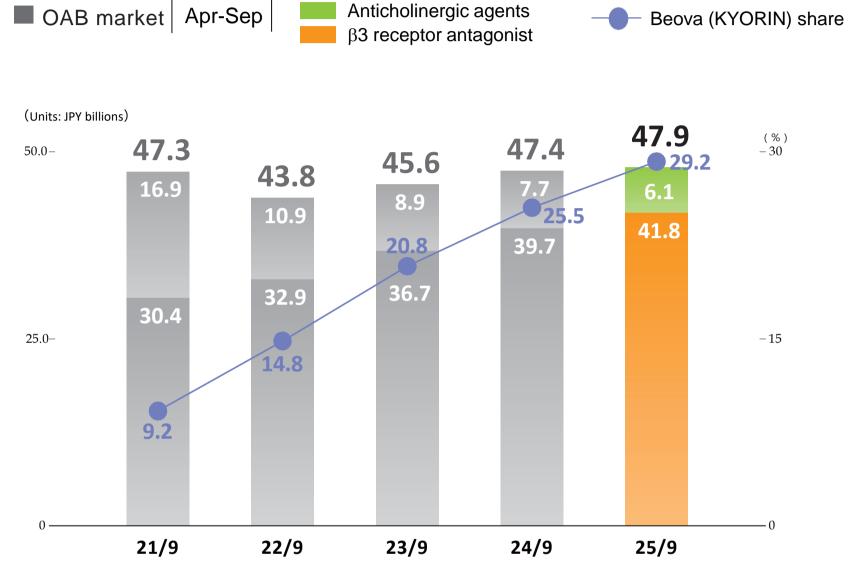
[Forecast]



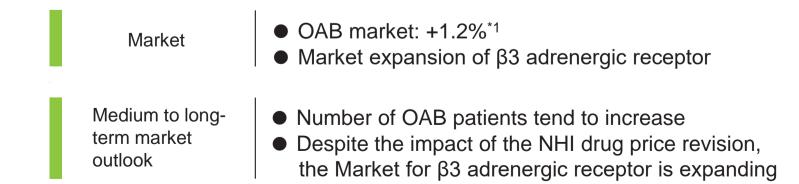
# **Trends of Mainstay Products**

### [Mainstay products] Beova (Therapeutic agent for OAB)



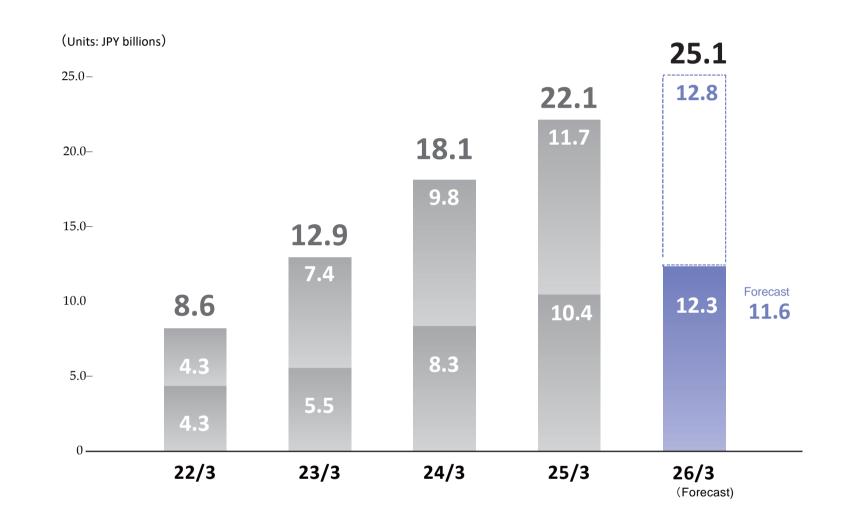


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Sales 2H 1H



Status in FY2025 1H No.1 in OAB market sale\*2

No.1 share of OAB patients and rate of new patients acquisition\*2
 [NHI drug price revision: -4.32% (Apr 2025)]

Initiative FY2025 Expand patient share in general internal medicine

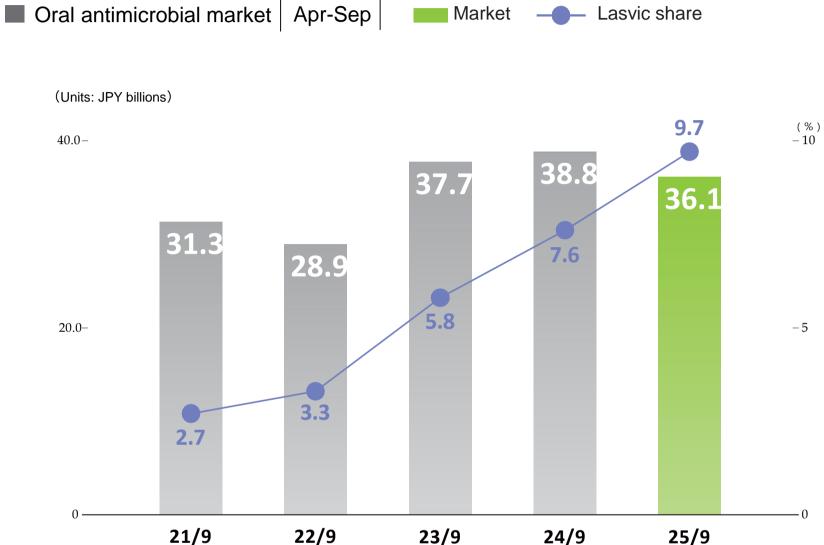
• Enhance the consultation rate and generate consultation opportunities in urology

DTC: initiative to encourage medical consultation

<sup>\*2</sup> Combined total with partner company Copyright©2025 IQVIA. Calculated based on JPM Apr-Sep 2025, reprinted with permission Calculated based on IQVIA Rx.Sep 2025, reprinted with permission

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





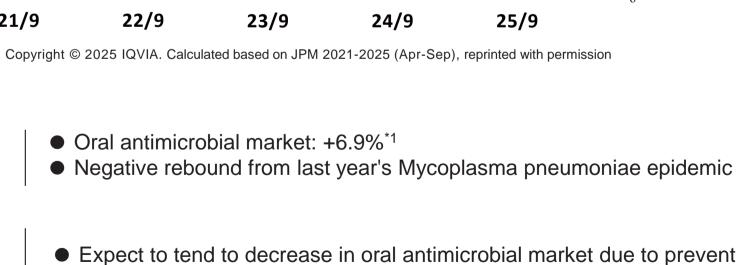
infection/appropriate use against AMR

Market

Medium to long-

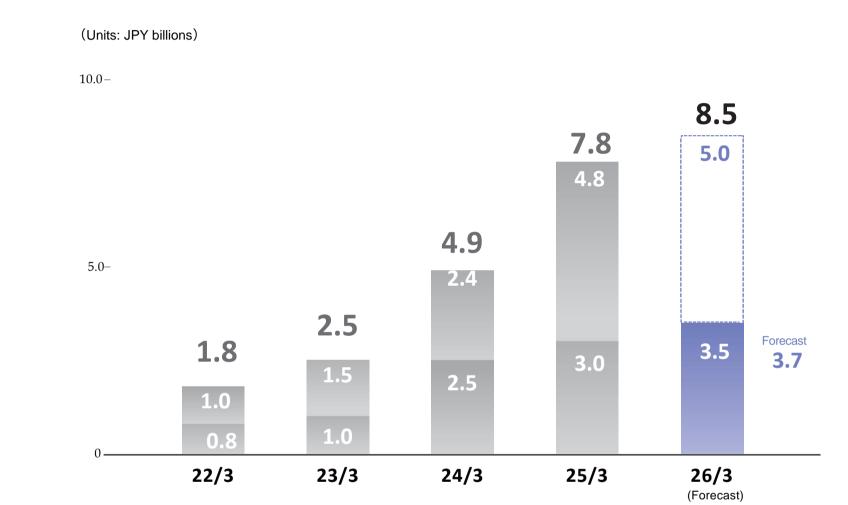
term market

outlook



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Achieved No.1 of sales share in oral NQ market\*1
 [NHI drug price revision: -6.21% (tab), 0.00% (iv) (Apr 2025)]

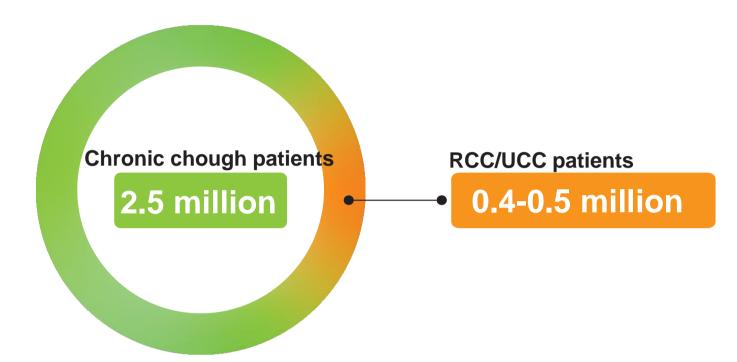
Initiative FY2025

- Promote treatment and therapeutic drug selection in accordance with each guideline
- Clearly define the distinctiveness and novel positioning of Lasvic
- HP: Expand new adoptions at university hospitals and key regional hospitals.
- GP: Promote prescription recommendations to diseases targeted for AMR action (\*\*xrhinosinusitis\*, tonsillitis\*, pharyngolaryngitis\*, acute bronchitis\*) and pneumonia.

### [Mainstay products] Lyfnua (Cough treatment)



■ The number of estimated patients



■ JRS Guidelines for the Management for Cough and Sputum



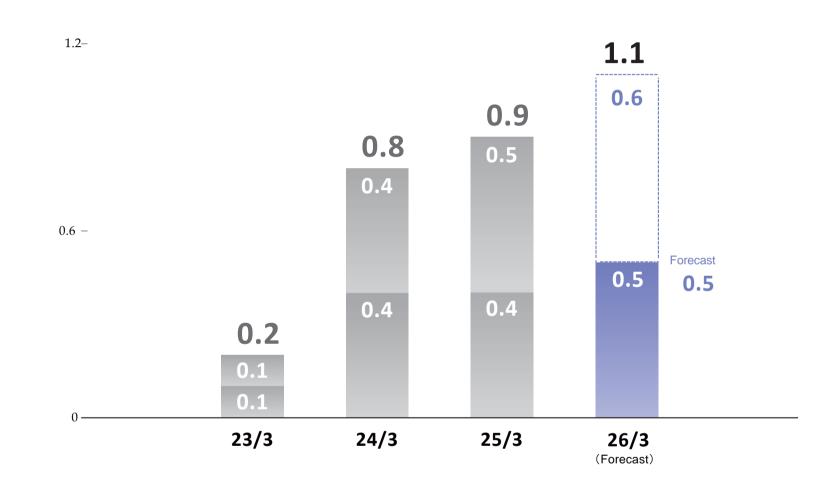
#### **Revision Point**

- Clearly state the recommendation levels for cough and sputum treatment
- The importance of Cough Hypersensitivity (CHS)
- Detailed explanation of refractory chronic cough

Partial modification of the JRS Guidelines for the Management for cough and Sputum 2025. p.xv Medical Review

P2X3 receptor antagonists for the management of persistent and chronic cough in adults, described on flowchart





Status in FY2025 1H

- The guideline was published in April 2025
- Due to the early onset of efficacy and taste-related adverse events, the persistence is short.

[NHI drug price revision: 0.0 % (Apr 2025)]

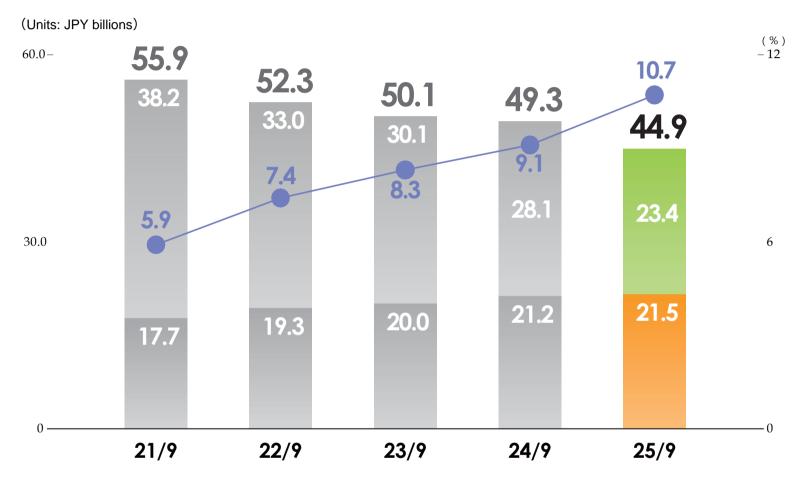
Initiative FY2025

- Utilized Practical guideline and new evidences
- Enhancement of better understanding for product characteristic (suppressing cough caused by nerve hypersensitivity)
- Initiative to extend the patient's period of taking drug (Promotion of proper medication counseling)

### [Mainstay products] Desalex (Antiallergic Agent)







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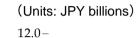
Market

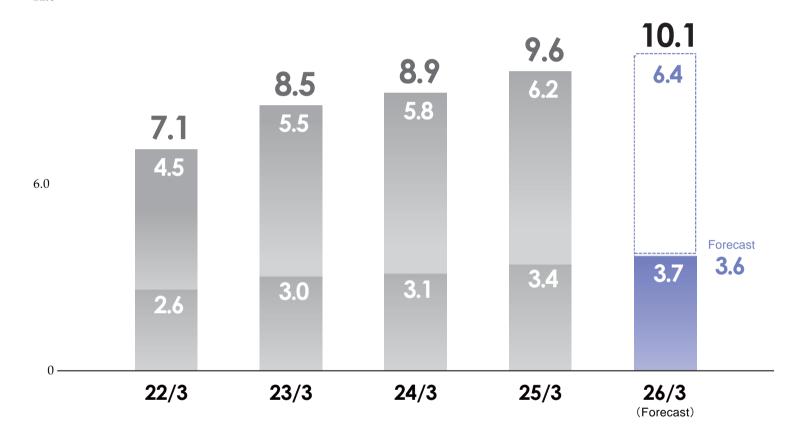
• Antihistamine market: -8.7%\*

Medium to longterm market and particular and generic drugs.

• Antihistamine market: -8.7%\*









- Sales increased steadily
- No.1 prescribing share in Otolaryngology\*2
   [NHI drug price revision: -9.16% (Apr 2025)]

Initiative FY2025

- Promote prescribing to Otolaryngology and Internal Medicine
- Aim to establish a position as a drug that combines both efficacy and ease of use

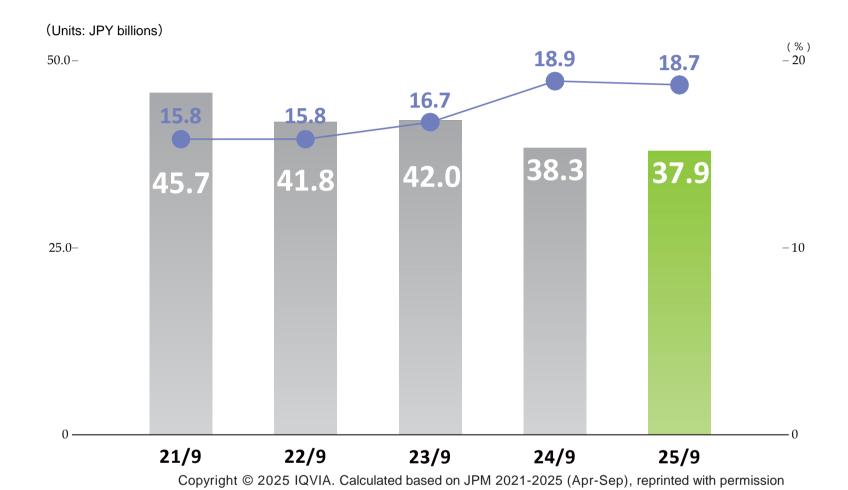
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### [Mainstay products] Flutiform (Anti-asthmatic)







Market

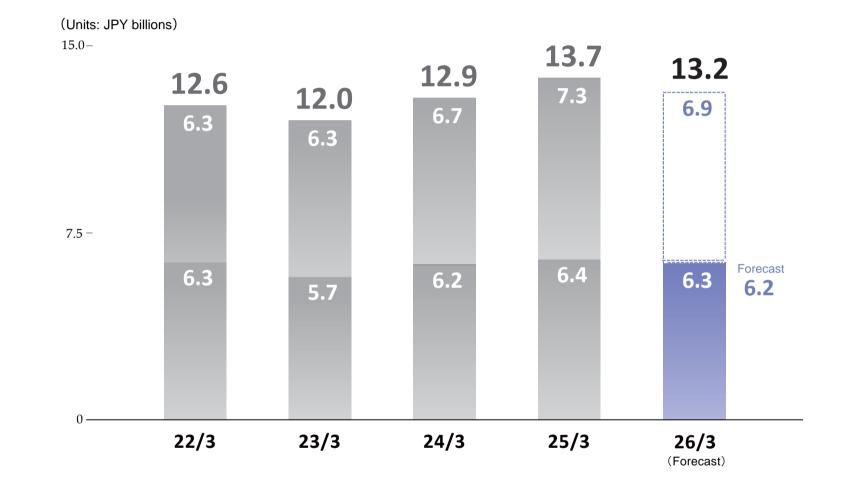
Medium to long-term market outlook

● ICS/LABA market: -1.1%\*1

 Increase to seek treatment after Covid-19, and promote to switch to generic drugs

 While the number of patients continues to increase, the market is forecast to remain flat due to the NHI drug price revision and generic drugs

Sales 2H 1H



Status in FY2025 1H

● Sales increased steadily, 3% year-on-year increase in volume.

• Market share in terms of volume:

18.6% (Sep 2024) to 19.3% (Sep 2025) \*2 [NHI drug price revision: -5.59% (Apr 2025)]

Initiative FY2025  Appeal to the utility of the aerosol formulation as suitable for patients with weak inspiratory force

Expand prescriptions through synergy with Lyfnua promotion activities

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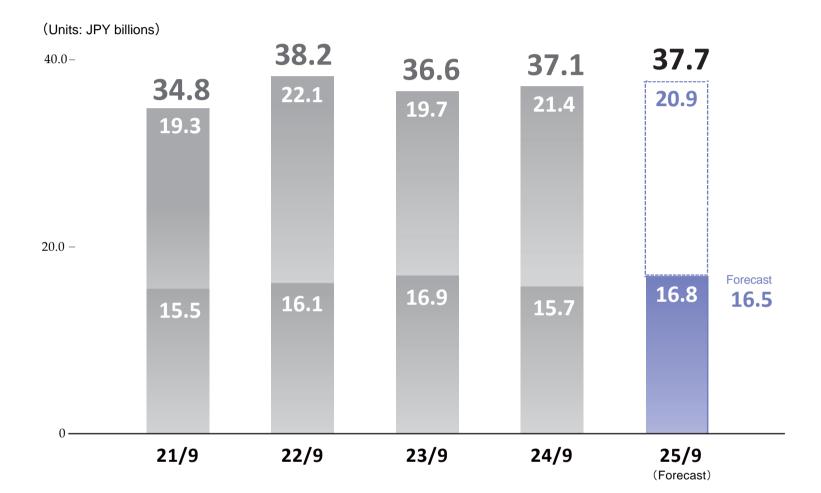


# Promoting healthcare-related businesses that have synergies with the new drugs business

### Status of Generic Drugs

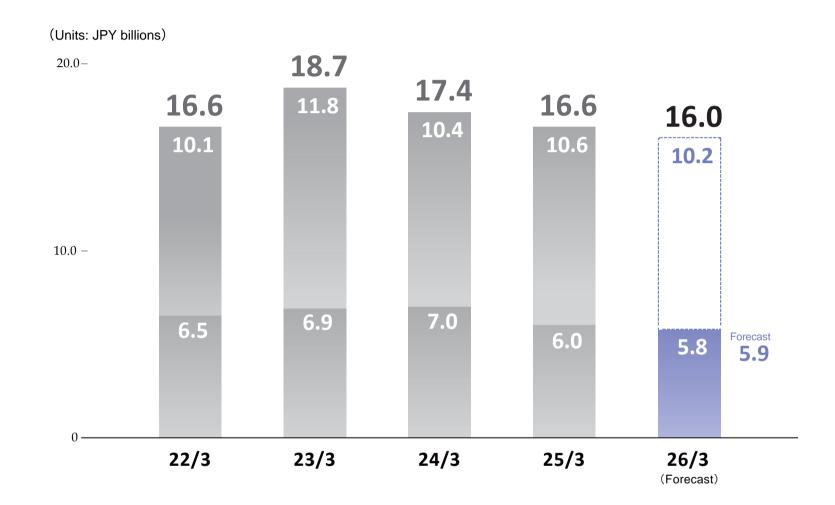






Status in FY2025 1H

- Quantity growth driven by the impact of the new health coverage rule for long-listed products
- Expansion of sales for products added to the new listed products in FY2024 and key focus items
- Sales decline in AG due to the drug price revision, etc.



Status (AG) in FY2025 1H

- Sales decline due to the drug price revision, etc.
- Keep market share of 50% in AG



### **Shareholder Returns**



Capital Policy

Maintain a stable dividends, taking DOE (Dividend on Equity ratio) into account

#### Dividend

	FY2023	FY2024	FY2025	
	Interim period	Interim period	Interim period	
Interim dividend per share (Yen)	20 yen (Annual dividend of 52 yen)	20 yen  (Annual dividend of 57 yen, which includes special dividend of 5 yen)	20 yen (Annual dividend of 57 yen)	

- OThe interim dividend of 20 yen have been decided at in the Board Meeting scheduled in November 7, 2025
- OThe year-end dividend of 57 yen announce on May 12, 2025 remain unchanged



Reduction of Cross-shareholdings



**Reduction Target** 

The ratio of Cross-shareholding to net assets to be less than 10% by 2030

- One stock was reduced in the first half of FY2025
- Aim to reduce the ratio of cross-shareholding to net assets to less than 10% ahead of schedule

	Mar 2022	Mar 2023	Mar 2024	Mar 2025	Sep 2025	change
Total of holdings	25	21	20	20	19	-1
Listed	14	12	11	11	10	-1
Unlisted	11	9	9	9	9	0

Ref. The ratio of cross-shareholding to net assets as of the end of September 2025: 11.9%



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