Interim Term Financial Results Ended September 2022

November 10, 2022

KYORIN Holdings, Inc.

Representative Director, President and Chief Executive Officer

Yutaka Ogihara



Outline of Consolidated Financial Results

Trends of mainstay products, generic product

Consolidated Financial Forecast

Status of R&D Pipeline

Initiatives toward realization of the long-term vision "HOPE 100"



Outline of Consolidated Financial Results

Breakdown of Gain and Loss FY2022 2Q

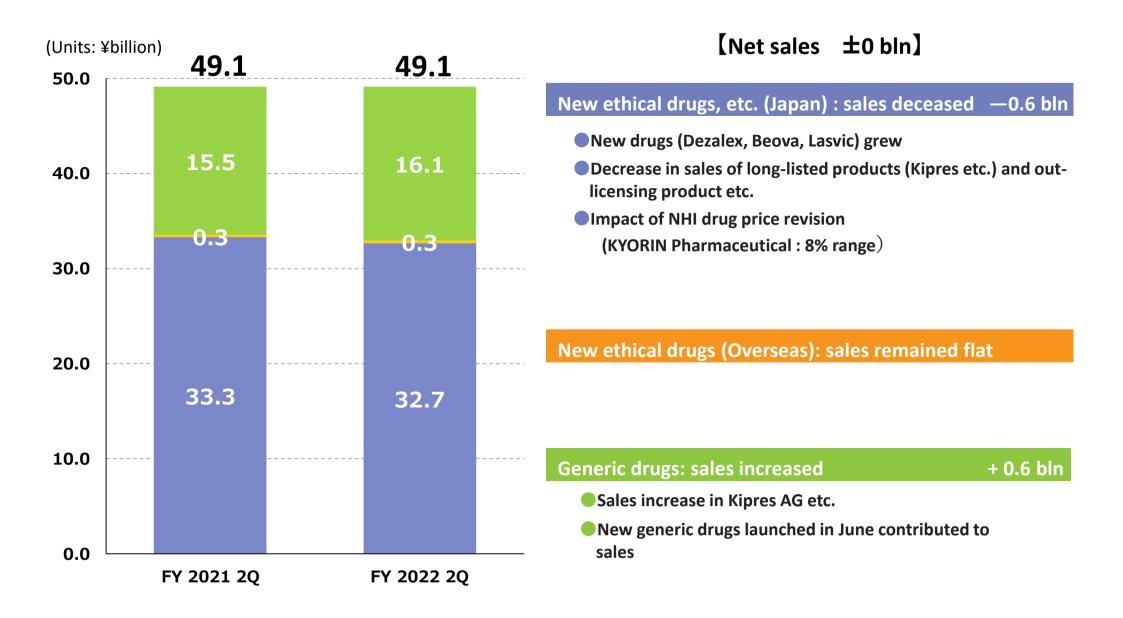


(Units: ¥billion)

		FY2021 2Q FY2022	Year-on-year		Vs forecast (announced on May 11, 2021)	
		(Apr-Sep)	2Q (Apr-Sep)	Change	Change (%)	Change
Net Sales		49.1	49.1	0	-0.0	-0.5
	New ethical drugs, etc. (Japan)	33.3	32.7	-0.6	-1.9	-0.7
	New ethical drugs (Overseas)	0.3	0.3	0	-8.6	0
	Generic drugs	15.5	16.1	+0.6	+4.2	+0.3
Cost of sales		26.7	27.5	+0.8	+2.8	_
SG&A (R&D)		22.4 (4.4)	20.8 (4.5)	-1.6 (+0.1)	-7.2 (+3.1)	_ (0)
Operating profit		-0.1	0.8	+0.9	_	+0.1
Ordinary profit		0.3	1.2	+0.9	+309.8	+0.2
Profit attribu	table to owners of	0.1	1.2	+1.1	+921.1	+0.5

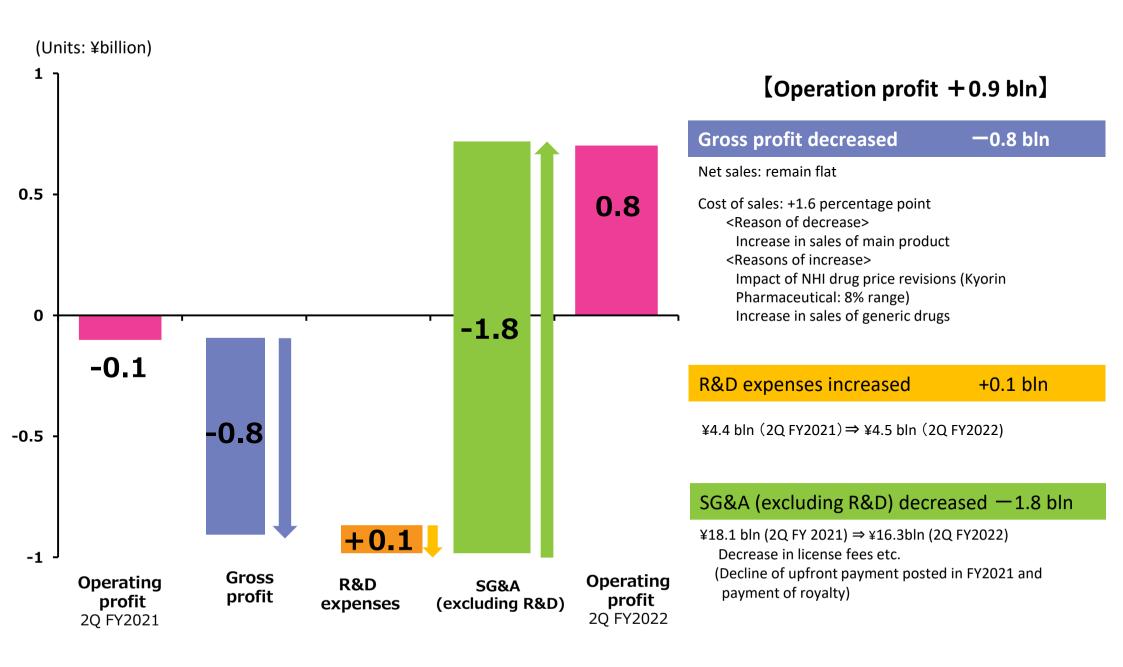
Highlights of Business Performance (1/3) YoY: Net Sales





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





Highlights of Business Performance (3/3) vs Forecast



(Units: ¥billion)

		FY2021 2Q (Apr-Sep)	FY2022 2Q	Year	-on-year	vs forecast (announced on May 11, 2022)
			(Apr-Sep)	Change	Change (%)	Change
Net Sales		49.1	49.1	0	-0.0	-0.5
	New ethical drugs, etc. (Japan)	33.3	32.7	-0.6	-1.9	-0.7
	New ethical drugs (Overseas)	0.3	0.3	0	-8.6	0
	Generic drugs	15.5	16.1	+0.6	+4.2	+0.3
Cost of sales		26.7	27.5	+0.8	+2.8	-
SG&A		22.4	20.8	-1.6	-7.2	_
(R&D)		(4.4)	(4.5)	(+0.1)	(+3.1)	(0)
Operating pr	ofit	-0.1	0.8	+0.9	_	+0.1
Ordinary pro	fit	0.3	1.2	+0.9	+309.8	+0.2
Profit attribu parent	itable to owners of	0.1	1.2	+1.1	+921.1	+0.5

[Difference from original Forecast (Announce on May 11, 2022)]

Net sales: Sales of new ethical drugs etc. (Japan) was lower than forecast and sales of generic drugs, mainly of AG exceeded forecast.

Operating profit: Gross profit was lower than forecast owing to less than expected sales in new ethical drugs etc. (Japan). On the other hand, operating profit was roughly in line with forecast owing to being lower then forecast for SG&A expenses (excluding R&D expenses).

Profit: Extraordinary profit of ¥1,319 mln (gain on insurance of ¥881 mln, income of compensation for damages of ¥393 mln, regarding a fire at Nishinihon delivery center)

Extraordinary loss of ¥678 mln (Impairment losses of ¥101 mln, provision for loss on liquidation of subsidiaries and associates of ¥561mln regarding dissolution of ActivX)

FY2022 2Q Main Product Sales Update



(Units: ¥billion)

						(Offics: +Difficit)
		FY2021 2Q	FY2022 2Q (Apr-Sep)	Year-o	Year-on-year	
		(Apr-Sep)		Change	Change (%)	(announced on May 22, 2022) Change
	Flutiform (Combination drug for asthma treatment)	6.3	5.7	-0.6	-8.9	+0.1
	Desalex (Antiallergic Agent)	2.6	3.0	+0.4	+14.9	+0.1
	Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	4.3	5.5	+1.2	+26.6	-0.9
	Lasvic (New quinolone synthetic antibacterial agent)	0.8	1.0	+0.2	+17.1	-0.3
	Lyfnua (selective P2X3 receptor antagonist / chronic cough)	_	0.1	+0.1	_	-0.1
New ethical	Pentasa (Ulcerative colitis and Crohn's disease treatment)	7.1	6.5	-0.6	-8.0	+0.2
drugs, etc. (Japan)	Kipres (Leukotriene Receptor Antagonist)	3.6	2.7	-0.9	-23.9	-0.1
(Jupuil)	Mucodyne (Mucoregulant)	1.6	1.5	-0.1	-5.1	+0.1
	Nasonex (Spray type allergic rhinitis remedy)	0.7	0.6	-0.1	-9.8	+0.1
	Uritos (KYORIN) (Overactive bladder))	0.7	0.4	-0.3	-44.5	+0.1
	Milton (Disinfectant)	1.0	1.0	0	+0.0	0
	Rubysta (Disinfectant)	1.0	1.1	+0.1	+2.7	+0.1
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	5.1	5.4	+0.3	+5.4	+0.8
Generic drugs	Mometasone Nasal 50mg "KYORIN" Spray type allergic rhinitis remedy)	1.0	1.1	+0.1	+7.0	+0.1
91 NP3	Imidafenacin tablets & OD"KYORIN" (Overactive bladder)	0.4	0.4	0	-7.1	+0.2

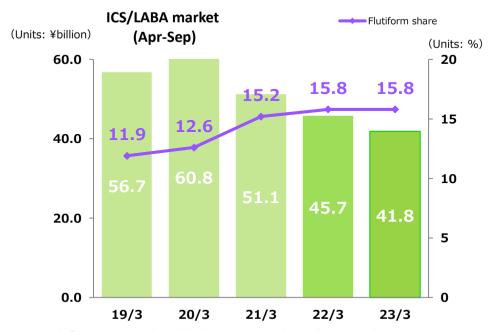


Trends of Mainstay Products and Generic Drugs

Flutiform (Anti-asthmatic)



12.0



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ICS/LABA market: Shrink 8.6%

¥45.7 bln (Apr-Sep 2021) ⇒ ¥41.8 bln (Apr-Sep 2022)*1

Impact of NHI drug price revision and expansion of triple therapy

Share of Flutiform sales

15.8% (Apr-Sep 2021)⇒ 15.8% (Apr-Sep 2022)*1

Rate of NHI drug price revision for Flutiform aerosol: – 6.97% (compared with Apr 2021)

► Medium to long-term market outlook

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

13.3

12.6

Second half

First half

14.6

Sales

13.1

(Units: ¥hillion)

15

Status in FY 2022 2Q

- Appeal the utility of aerosol formulations to suitable for patient with weak respiration
- Penetrate pediatric indications and increase market share
- Information activity accreting to "Practical guideline for Asthma management"

Effort for FY 2022

- Appeal the utility of aerosol formulations
- Penetrate pediatric indications and increase market share
- Increase market share (quantity basis)

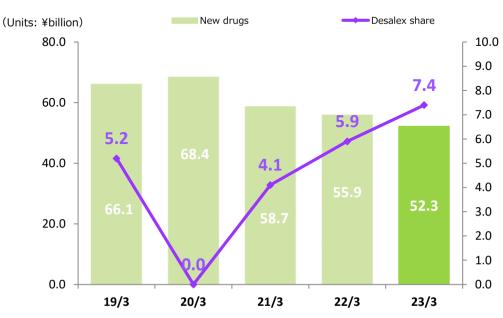
^{10 - 7.0 7.9 6.9 6.3 6.3 5.7 5.6 (}Forecast)

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Desalex (Antiallergic Agent)



Antihistamine market (Apr-Sep)



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Antihistamine Market: Shrink 6.4%

¥55.9 bln(Apr-Sep 2021) ⇒ ¥52.3 bln(Apr-Sep 2022)*1

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

Share of Desalex sales

5.9% (Apr-Sep 2021) \Rightarrow 7.4% (Apr-Sep 2022)*1

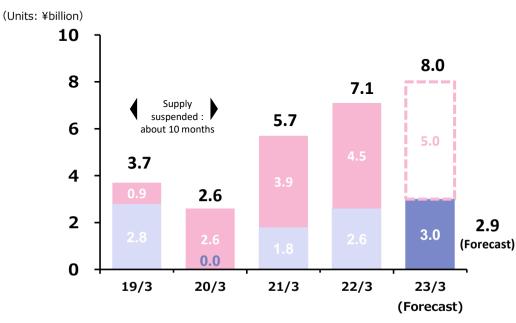
- Dec 2018 single month: 6.3%*2 (Before supply suspension)
- Sep 2022 single month: 7.5%*2

[Rate of NHI drug price revision: -9.62% (compared with Apr 2021)

Medium to long-term market outlook

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





Status in FY 2022 2Q

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

Effort for FY 2022

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

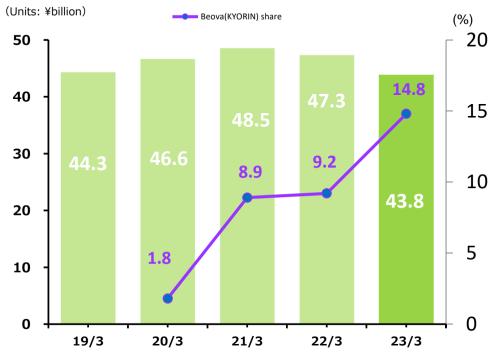
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Beova (OAB)



OAB market (Apr-Sep)



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OAB market: Shrink 7.4%

¥47.3bln (Apr-Sep 2021) ⇒ ¥43.8bln (Apr-Sep 2022)*

- Market shrink due to impact of NHI drug price revision and launch for generic drug Market expansion β3 adrenergic receptor (+8.3%)
- Share of Beova (KYORIN) sales: Expand 1.6%

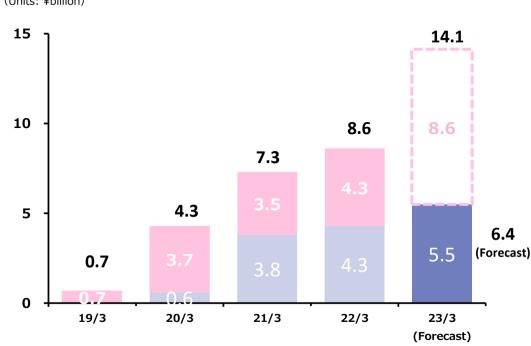
9.2% (Apr-Sep 2021) ⇒ 14.8% (Apr-Sep 2022)*

Rate of NHI drug price revision: -4.57% (compared with Apr 2021)

Medium to long-term market outlook

Shrinking market due to NHI drug price revision and launch generic drug Market expansion for $\beta 3$ adrenergic receptor





Status in FY2022 2Q

- End of restrictions on shipment in August 1, 2022
- Focus on providing information
- Provide information in urology with Zymso

Effort for FY2022

Aim to establish evaluation of Beova as first line treatment for OAB

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End of Restrictions on Shipment: August 2022

Statue of Beova in market of OAB

- Number of new costumers expand as our plan
- Achieved No.1*1 for rate of acquiring prescriptions in new patients
- Expansion of market share for forecast sales proceed as expected

Decrease in sale forecast (2Q)

Forecast: 6.4bln ven Actual: 5.5bln ven

In consideration of the recent issue for stable supplies, we expected to have mass order from medical institute and wholesalers after endo of restrictions on shipment. However they have much more inventory than expected, so that the sales was decline than forecast

Market share of Beova in OAB [Target in FY 2022: 18%]

Mar 2022 (single month) : 11.9% ► Sept 2022 (single month) : 16.4%*2

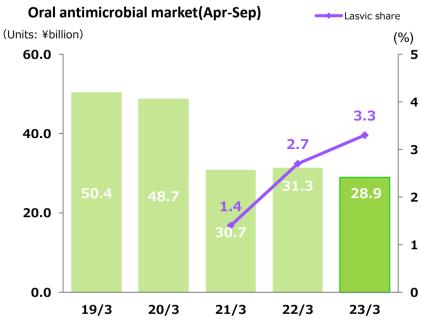
Aim to No.1 in Market of OAB

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Lasvic (New quinolone synthetic antibacterial agent)





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Oral antimicrobial market: Shrink 7.6%

¥31.3bln (Apr-Sep 2021) ⇒ ¥28.9bln (Apr-Sep 2022)*

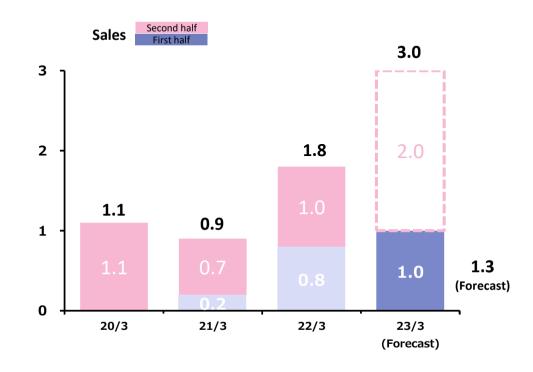
Reducing the number of patients due to infection prevention measure result to shrink market.

Share of Lasvic sales:

2.7% (Apr-Sep 2021) ⇒ 3.3% (Apr-Sep 2022)*
Rate of NHI drug price revision: -3.18% (compared with Apr 2021)

Medium to long-term market outlook

Expect to tend to remain flat in oral antimicrobial due to NHI drug price revision and prevent infection/appropriate use against AMR



> Status in FY2022 2Q

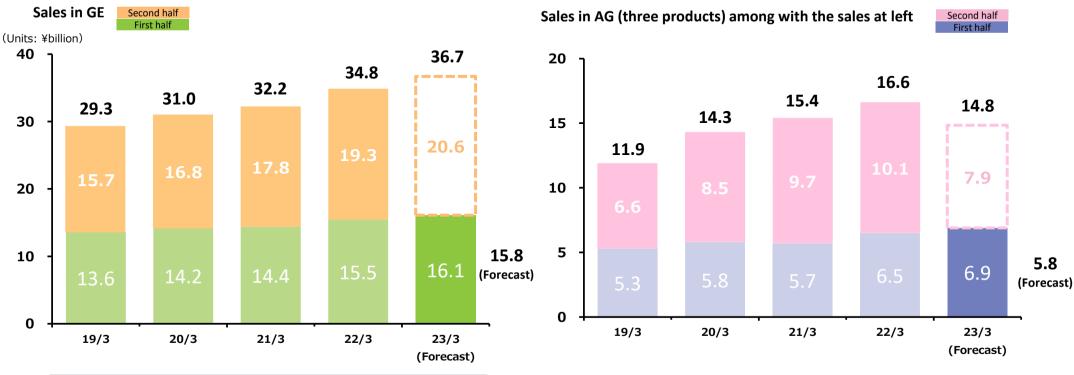
Expand prescriptions in old people/patients with disease

Effort for FY2022

- Aim to be first line treatment for old people/patients with disease
- Targeting to provide information
- Clarify target disease/medical case to provid information

Status of Generic Drugs





- > Status in FY2022 2Q
- Montelukast AG, Mometasone AG, Imidafenacin AG maintain the market share of more than 50% in the GE market
- Released in June 2022: 2 ingredients 5 items
 ○Febuxostat tablets 10mg/20mg/40mg
 ○Duloxetine Capsules 20mg/30mg

Effort for FY2022

- Expand sales of strategic products
- Steady launch for new products and sales growth
 Released in December 2022: 2 ingredients 3 items
 - ○Ramelteon Tablets 8mg
 - **OEsomeprazole Capsules 10mg/20mg**
- Promotion of AG strategy Aim to maintain market share of more than 50% for AG products in the GE market



Consolidated Financial Forecast FY2022

Consolidated Financial Forecast FY2022



(Unit: ¥billion)

		FV2024	EV2024 EV2022		-on-year
		FY2021	FY2022	Change	Change (%)
Net Sales		105.5	112.0	+6.5	+6.1
	New ethical drugs, etc. (Japan)	69.7	74.5	+4.8	+6.8
	New ethical drugs (Overseas)	1.0	0.7	-0.3	- 32.2
	Generic drugs	34.8	36.7	+1.9	+5.5
Cost of sales		56.1	-	-	-
SG&A (R&D)		44.4 (8.9)	- (10.9)	- (+2.0)	- (+22.5)
Operating profit		5.0	5.5	+0.5	+9.8
Ordinary profit		5.6	6.0	+0.4	+7.7
Profit attribution of parent	utable to owners	3.9	4.5	+0.6	+14.4

*The results forecasts for the full year announced on May 11, 2022 remain unchanged

[Key factors for Increase/decrease (Year-on-Year)]

Net sales: The sales of new ethical drugs (Japan) are expected to increase due to expansion in sales of new drugs by end of shipping adjustment in August 2022. For GE, AG and new products launched in FY2022 expected to contribute in sales increase.

Operating profit: Gross profit increased although impact on NIH drug price revisions. Operating profit are expected to increase according to decrease SG&A expenses (excluding R&D expenses) but R&D expenses are increased.

Cost of sales ratio: Increase about 0.5 percentage points SG&A expenses(excluding R&D expenses): decrease about 2 percentage points

Forecast of Mainstay Products Sales



		FY2021 FY2022		Year-o	n-year ⁽
		F12021	(Forecast)	Change	Change (%)
	Flutiform (Combination drug for asthma treatment)	12.6	12.0	-0.6	- 4.6
	Desalex (Antiallergic Agent)	7.1	8.0	+0.9	+13.6
	Beova(KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics)	8.6	14.1	+5.5	+64.4
	Lasvic (New quinolone synthetic antibacterial agent)	1.8	3.0	+1.2	+65.8
	Lyfnua (Selective P2X3 receptor antagonist/chronic cough)	-	0.5	+0.5	-
New ethical drugs, etc.	Pentasa (Ulcerative colitis and Crohn's disease treatment)	14.0	12.5	— 1.5	- 9.9
(Japan)	Kipres (Leukotriene Receptor Antagonist)	8.4	6.8	— 1.6	— 18.5
	Mucodyne (Mucoregulant)	3.5	2.9	-0.6	-14.1
	Nasonex (Spray type allergic rhinitis remedy)	2.4	1.8	-0.6	-23.3
	Uritos (KYORIN) (Overactive bladder))	1.3	0.7	-0.6	-40.4
	Milton (Disinfectant)	2.1	2.0	-0.1	+0.4
	Rubysta (Disinfectant)	2.1	2.0	-0.1	-0.1
	Montagest to blots "IVNA"	1			
	Montercast tablets "KM" (Leukotriene Receptor Antagonist)	12.2	10.7	— 1.5	—11.7
Generic drugs	Mometasone Nasal 50mg "KYORIN" Spray type allergic rhinitis remedy)	3.6	3.6	0	+0.1
	Imidafenacin tablets & OD"KYORIN" (Overactive bladder)	0.8	0.5	-0.3	-26.3

^{**}The results forecasts for the full year announced on May 11, 2022 remain unchanged

Shareholders Returns



Capital Policy

- While maintaining the sound financial base, we aim to improve the capital efficiency through growth investment and returns to shareholders
- We will maintain stable dividends taking DOE (Dividend on Equity ratio)
 into account

Dividend

	FY2020	FY2021	FY2022 (Forecast)
Dividend per	¥75	¥52	¥52
share (Yen)	(Interim ¥30)	(Interim ¥20)	(Interim ¥20)

XThe year-end dividend of 52 yen remain unchanged in the fiscal year ended March 2023

OThe year-half dividend of 20 yen have been decided at in the Board Meeting scheduled in November 9, 2022

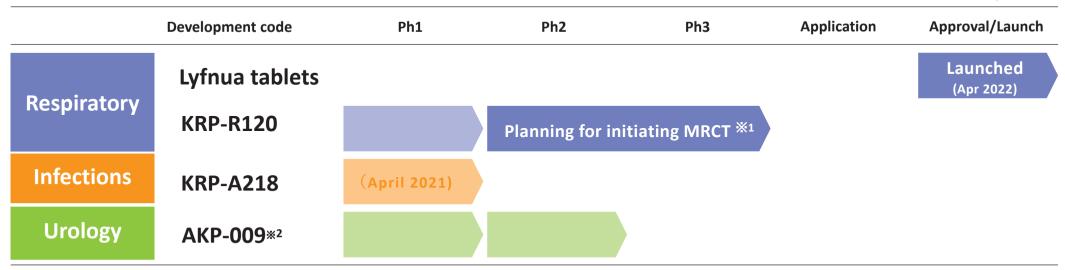


Status of R&D Pipeline

Plan of R&D Pipeline in FY2022



As of May 11, 2022



^{※1} MRCT: Multi-Regional Clinical Trials

Plan in FY2022

[Licensed Compound]

Со	mpound/Code	Licensee	Stage	Features
	KRP-203	Priothera	Ph1	 Sphingosine-1-Phosphate receptor Agonist Target: AML patients undergoing HSCT Assignment of IP and drug substances (Sep. 2020)

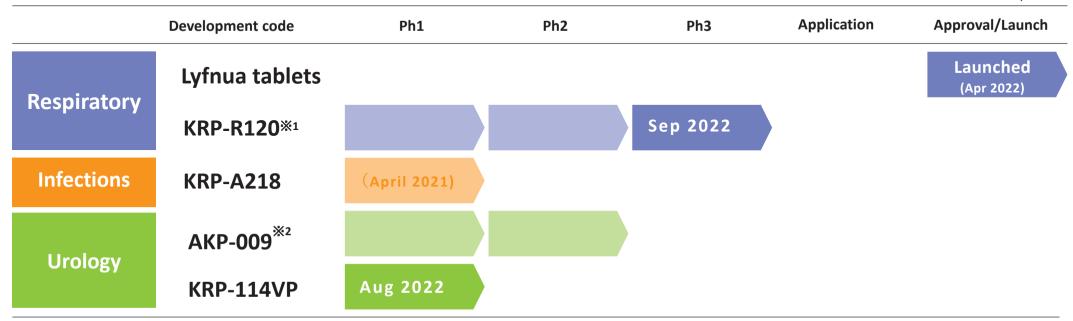
[□] Compound for sensorineural healing loss was removed from the list since Otonomy (licensee) decided to discontinue the program for strategic reasons

X2 Additional Ph1 study to confirm the maximum effect at a higher dose has been completed (ASKA)

Status of R&D Pipeline in FY2022



As of Nov 9, 2022



^{¾1 Ph1b/2a study has been completed in USA (aTyr)}

[Licensed Compound]

Compound/Code	Licensee	Stage	Features
KRP-203	Priothera	Ph1	 Sphingosine-1-Phosphate receptor Agonist Target: AML patients undergoing HSCT Assignment of IP and drug substances (Sep. 2020)

X2 Additional Ph1 study to confirm the maximum effect at a higher dose has been completed (ASKA)



Multi-Regional Clinical Trials (Phase 3 study)

Titles	Efficacy and Safety of Intravenous Efzofitimod in Patients With Pulmonary Sarcoidosis
Study Design	Randomized, Double-Blind, Placebo-Controlled Parallel Assignment Study
Outcome Measures	 [Primary Outcome Measures] Change from baseline in mean daily oral corticosteroid (OCS) dose post-taper [Secondary Outcome Measures] Annual rate of change in absolute value of Forced vital capacity (FVC) Percent change from baseline in mean daily OCS dose post-taper Change from baseline in King's Sarcoidosis Questionnaire (KSQ)-Lung score
Estimated Enrollment	264

GMAC (Genetically Modified Adipocyte)



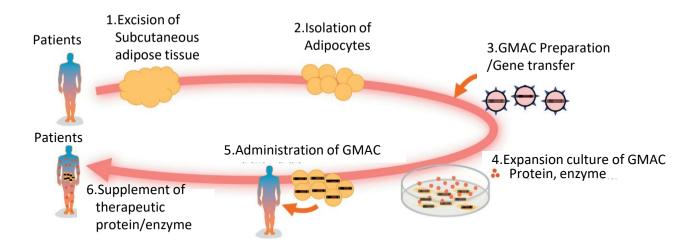
Status

Joint development and license agreement with CellGenTech (June 2022)

Non-clinilcal study is ongoing

Target disease

Fabry disease



Feature

- GMAC is the genetically modified human adipocytes with an ability to produce enzyme or protein for treatment in patients
- Adipocytes have a high ability of protein secretion, a long life span and a low risk of tumorigenesis
- Possibility of supplement insufficient enzyme over years by one dose (Contribution to improving QOL)

<Fabry disease>

- O Progressive hereditary disorder which occurred due to gene mutation in the gene encoding α -galactocidase, a type of lysosome hydrolase
- O Current treatment: Enzyme replacement therapy (Intravenous infusion once every two weeks
- O Estimated patients in Japan: approx. 1700





Initiative toward Realization of the Long-term Vision "HOPE 100"



Statement

Realize growth trend by pursuing Kyorin's originality

Business Strategy

- Shift to business based on the proposal of solutions and accelerate the growth of new drug groups
- Enhance pipeline to support medium-term growth
- Strengthen drug discovery capability to realize the creation of innovative new drugs
- Improve cost competitiveness
- Expand overseas revenue

Organization Strategy

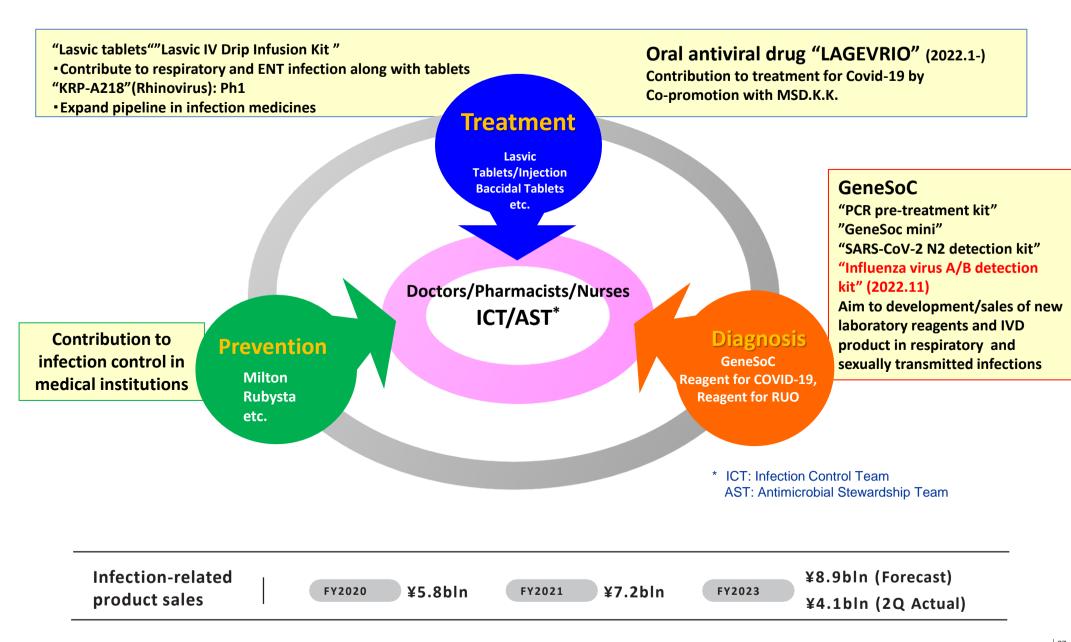
Aim to be the No. 1 company for career fulfillment

Performance Targets

- Growth potential and profitability
- Capital policy and shareholder returns

Solution Provision Activities in Infection Domain





Accelerate the growth of new drug groups



Treatment of chronic cough Lyfnua Tablets 45 mg

Launch: April 21, 2022

Status in FY2022 2Q

- Enhancement of better understanding for product characteristic to respiratory specialists
- Acceptance of product in university hospitals or core hospitals progress as planed

Plan in FY2022

- Clarification for positioning of product
- Enhancement of better understanding for product characteristic to respiratory specialists
- Aim to increase number of prescribing physicians in university hospitals or core hospitals



Development of Digital Therapeutics in Otolaryngology Field



Background

Expand product portfolio including new treatment option for strengthen competitiveness in otolaryngology area, aiming "Establish strong presence in priority area (respiratory, otolaryngology and urology)"



Purpose

- Challenge to unmet medical needs
 Patient satisfaction with treatment in otolaryngology is low
- New treatment options to patients

Service regarding digital x healthcare/medical care are attaching attention

Health care system for digital healthcare are being established

Collaboration Research and Sales Agreement for development of Digital Therapeutics

(November 2022)

SUSMED

Know-how of clinical development for DTx, negotiation experience with PMDA and success clinical trial of digital therapeutics for insomnia

KYORIN

Knowledge and know-how of clinical development, human network in otolaryngology field



Start of Construction of the Takaoka New Plant

Strengthen the supply capacity as the production of drugs increased



(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 m², Total floor area about 21,091 m²
Groundbreaking	September 2022
Completion	October 2023 (Scheduled)
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

Building Production System Supplies Stably and at Low Cost



Business strategy in FY 2022

Increase the "Speed"

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