

Interim Term Financial Results Ended September 2021

November 9, 2021 KYORIN Holdings, Inc. President Yutaka Ogihara





> Outline of Consolidated Financial Results

• Trends of mainstay products, Generic products

Consolidated Financial Forecast

Status of R&D Pipeline

Initiative toward realization of the long-term vision "HOPE100"



Outline of Consolidated Financial Results

Segment Sales and Breakdown of Gain and Loss



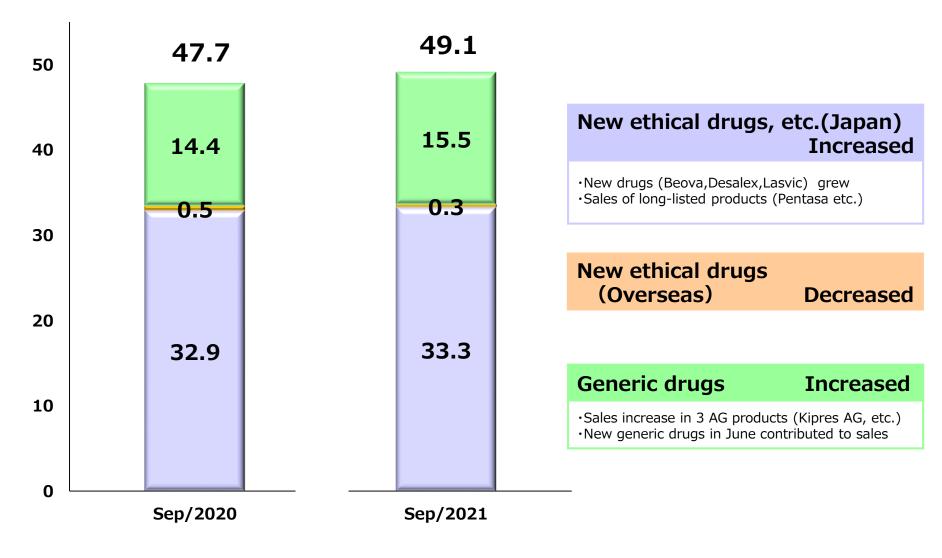
	(Units: ¥billion)	Sep/20	Sep/21	Change	Change (%)	Change (forecast) Announced on May 11,2021
Sales		47.7	49.1	n/a	n/a	+1.8
	New ethical drugs, etc. (Japan)	32.9	33.3	n/a	n/a	+1.4
	New ethical drugs(Overseas)	0.5	0.3	n/a	n/a	-0.2
	Generic drugs	14.4	15.5	n/a	n/a	+0.7
Cost of	Sales	22.9	26.7	n/a	n/a	-
SG&A (R&D)		23.3 (5.2)	22.4 (4.4)	n/a (-0.8)	-1.9 (-16.1)	_ (-0.5)
Operati	ing Income	1.5	-0.1	-1.6	-	+0.7
Ordina	ry Income	1.8	0.3	-1.5	-84.2	+0.9
Net Inc	come	2.1	0.1	-2.0	-94.3	+0.4

* From the beginning of the current term, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar.31,2020) etc. have been applied, and the revenue recognition standards for the previous second quarter is different from the current second quarter, the amount of increase / decrease compared to the second quarter and the Year on Year change rate (%) are not shown. There is no impact on operating loss, ordinary income, and net income.

Highlights of Business Performance: 1Net sales

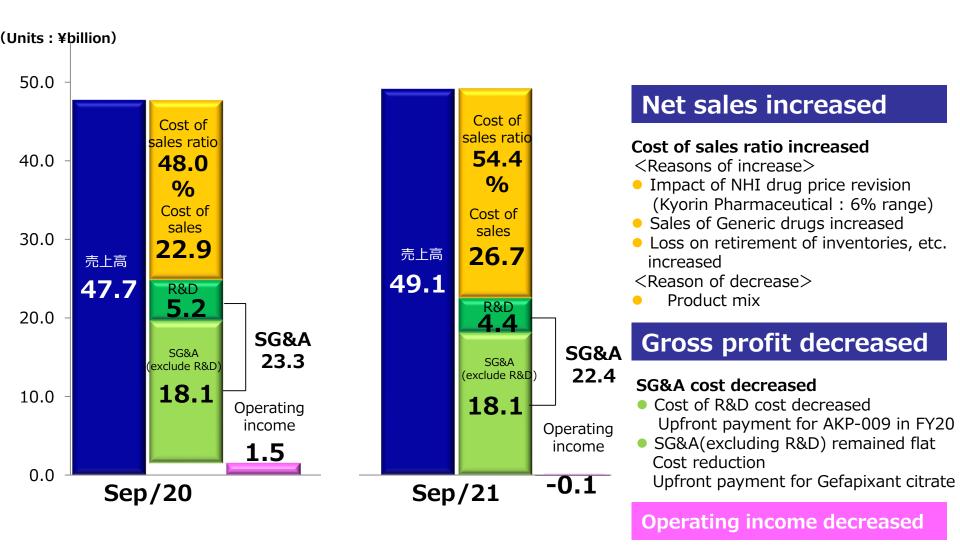


(Units: ¥billion)



Highlights of Business Performance : 2 Operating Income





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Highlights of Business Performance: ③Change (forecast)



	(Units : ¥billion)	Sep/20	Sep/21	Change	Change(%)	Change (forecast) Announced on May 11,2021
Net S	ales	47.7	49.1	n/a	n/a	+1.8
	New ethical drugs, etc.(Japan)	32.9	33.3	n/a	n/a	+1.4
	New ethical drugs (Overseas)	0.5	0.3	n/a	n/a	-0.2
	Generic drugs	14.4	15.5	n/a	n/a	+0.7
Cost	of Sales	22.9	26.7	n/a	n/a	_
SG& (R8		23.3 (5.2)	22.4 (4.4)	n/a (-0.8)	-1.9 (16.1)	_ (-0.5)
Ореі	ating Income	1.5	-0.1	-1.6	_	+0.7
Ordinary Income		1.8	0.3	-1.5	-84.2	+0.9
Net	Income	2.1	0.1	-2.0	-94.3	+0.4

■ Difference from Original Forecast(May 11, 2021)

Net Sales : Though New drug groups (Flutiform etc.) did not reach the forecast, Long-listed products (Pentasa, Kipres etc.) and Generic drugs sales were strong.

Operating Income : Gross profit also exceeded forecast as sales of new ethical drugs, etc. (Japan) and Generic drugs exceeded expectations. R & D expenses were lower than initially expected, but SG&A expenses (excluding R&D) exceeded expectations. As a result, SG & A expenses as a whole remained almost as expected, operating income exceeded expectations.



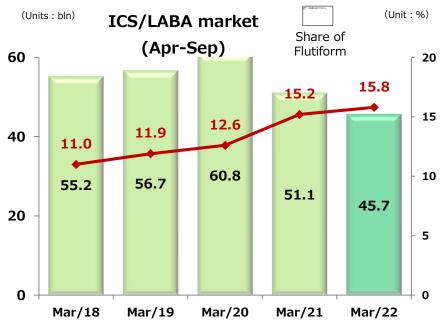
(Units : ¥billion)

		Sep/20	Sep/21	Change	Change(%)	Change (forecast) Announced on May 11,2021
	Flutiform (Combination drug for asthma treatment)	6.4	6.3	-0.1	-1.2	-0.3
	Desalex (Antiallergic Agent)	1.8	2.6	+0.8	+42.9	-0.2
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	3.8	4.3	+0.5	+14.9	+0.2
	Lasvic tablets (New quinolone synthetic antibacterial agent)	0.2	0.8	+0.6	+431.3	-0.3
New ethical	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.4	7.1	+0.7	+12.0	+1.1
drugs,etc. (Japan)	Uritos (Kyorin) (Overactive bladder)	1.6	0.7	-0.9	- 57.0	+0.2
(Japan)	Nasonex (Spray type allergic rhinitis remedy)	0.6	0.7	+0.1	+11.6	+0.2
	Kipres (Leukotriene Receptor Antagonist)	3.5	3.6	+0.1	+1.6	+0.6
	Mucodyne (Mucoregulant)	1.4	1.6	+0.2	+10.8	+0.4
	Milton (Disinfectant)	1.1	1.0	-0.1	- 5.9	-0.1
	Rubysta (Disinfectant)	1.0	1.0	0	-0.8	0
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	4.5	5.1	+0.6	+13.2	+1.1
Generic drugs	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	0.9	1.0	+0.1	+13.7	0
	Imidafenacin tablets & OD "KYORIN"Overactive bladder)	0.3	0.4	+0.1	+18.1	0



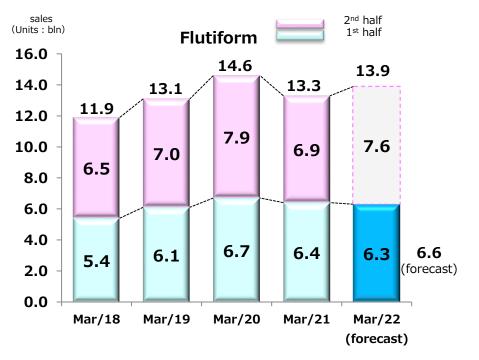
Trends of mainstay products and Generic drugs

Main Product Flutiform (Anti-asthmatic)



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Kvorin

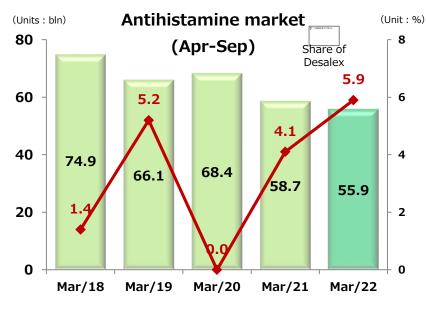
Status in first half 2021

- Proactively developed web seminar and briefing
- Competition with triple therapy
- ■Effort for FY 2021

Establish the "First Choice for Asthma Treatment Position

- Appeal the utility of the aerosol formulations
 To get understanding and permeate the significance of administration to patients with cough symptoms
- Penetrate pediatric indications and increase market share
- Provide information according to "Practical guideline for Asthma management"

Main Product Desalex (Antiallergic Agent)



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■ Antihistamine market : shrink 4.7%

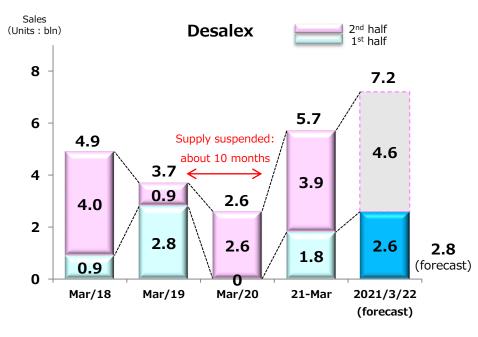
- ± 58.7 bln(FY20 first half)) $\Rightarrow \pm 55.9$ bln(FY21 first half) $^{\times 1}$
- Market shrinking due to NHI drug price revision and launch of Generic drugs etc.

■ Share of Desalex sales

- 4.1%(FY20 first half) \Rightarrow 5.9% (FY21 first half)^{\times 1}
- Dec. 18 single month : 6.3% *2 (Before supply suspension)
- Sep.21 single month : 6.2%^{*1}

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[NHI price revision ▲8.3% (compared with Ap,2020) ]
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Status in first half 2021

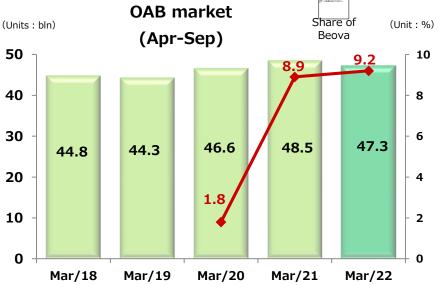
- Amount of pollen dispersed in spring was lower than usual
- Accelerated effort for skin disease in internal medicine and expanded adoption in medical institutions

Effort for FY2021

- Aim to be No. 1 prescription in otolaryngology
- Focus on acquiring prescriptions in internal medicine

Main Product Beova/Uritos (OAB)





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■Status in first half 2021

OAB market : expand 2.5%

¥48.5bln(FY20 first half)⇒¥47.3bln (FY21 first half) *1 ⋅β3 adrenergic receptor agonist market expanded

Share of Beova sales

8.9%(FY20 first half)⇒9.2%(FY21 first half)*1

Share of Uritos sales

4.1%(FY20 first half)⇒1.7%(FY21 first half)*1

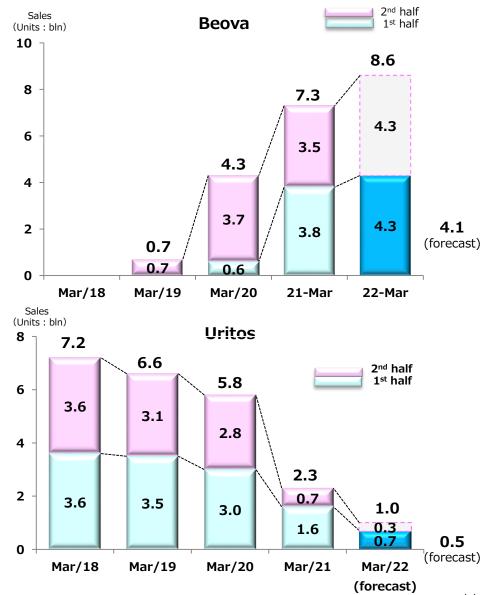
[NIH price revision Beova▲3.8%,Uritos▲6.6% (compared with Apr.2020)]

Effort for FY2021

- Aim to contribute to urology together with Zymso *1
- After clearing shipping adjustment *, aim for the top share soon

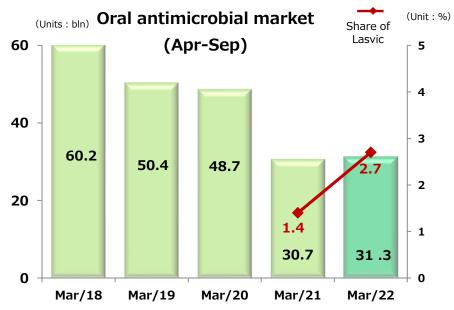
%. At each OEM manufacturer, they are working to expand facilities and launch new manufacturing sites. Shipment adjustments are expected to be lifted during FY2022

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■ Main Product Lasvic (New quinolone synthetic antibacterial agent)





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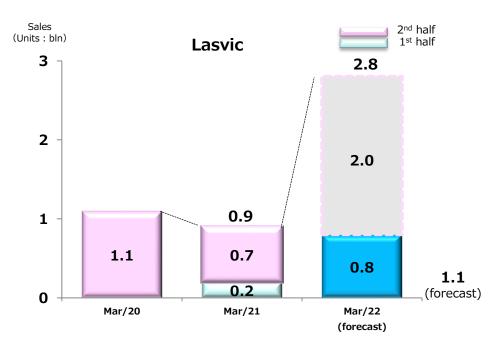
■ Oral antimicrobial market : expand 1.7%

- 430.7bln (FY 20 first half) \Rightarrow 431.3bln (FY 21 first half)^{*1}
- Prevent infection (washing hands, gargling, wearing masks, etc.) has continued to reduce the number of infectious diseases, and the market remained flat

■ Share of Lasvic sales

1.4% (FY 20 first half) \Rightarrow 2.7%(FY 21 first half)^{*1} [NHI price revision \blacktriangle 2.2% (compared with Apr.2020)]

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■<u>Status in first half 2021</u>

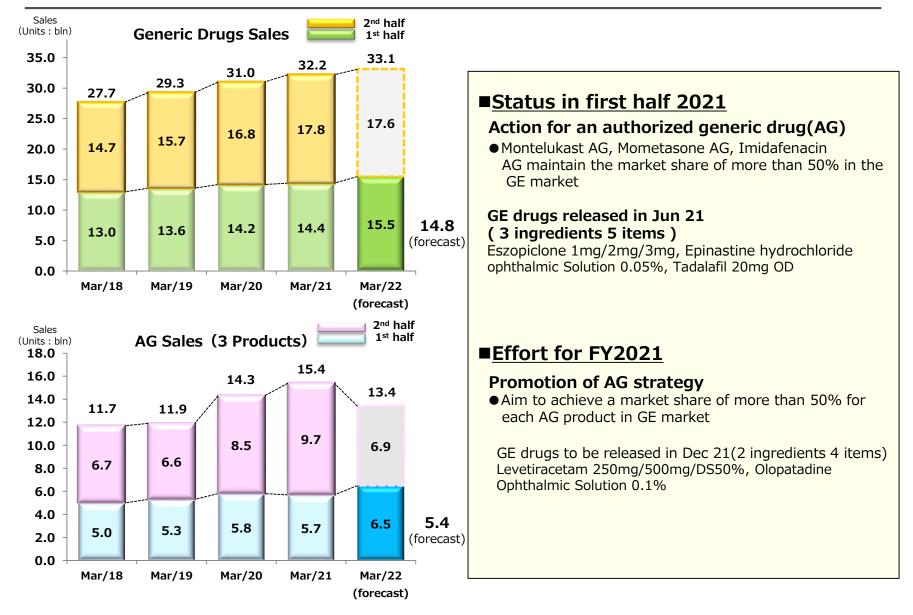
- Actively provide solution (Prevention, Diagnosis, Medication)in the infection field
- Continue cognitive activities for diseases and AMR through web seminar

■Effort for FY2021

- Appeal that both dosage forms can cover respiratory infections
- Increase in-hospital and outpatient treatment options Tablets: Aim to maximize product penetration Injection: Aim for early adoption and widespread use

Status of Generic Drugs







Consolidated Financial Forecast

Consolidated Financial Forecast in FY2021



		5/2020	FY2021	Y/Y	/
	(Units : ¥billion)	FY2020	(forecast)	Change	Change(%)
Net sales		102.9	102.6	n/a	n/a
	New ethical drugs, etc.(Japan)	69.7	68.6	n/a	n/a
	New ethical drugs (Overseas)	1.0	0.8	n/a	n/a
	Generic drugs	32.2	33.1	n/a	n/a
Cost of	Sales	51.3	_	_	_
SG&A		45.8	-		_
(R&D)		(9.7)	(9.2)	(-0.5)	(-5.2)
Operati	ng Income	5.8	3.3	-2.5	-43.0
Ordinar	y Income	6.4	3.8	-2.6	-41.1
Net Inco	ome	6.1	2.7	-3.4	-56.0

%The results forecasts for the full year announced on May 11, 2021 remain unchanged

Net Sales: Although sales of main products (Desalex, Lasvic, etc.) will grow, sales of new ethical drugs (Japan) are expected to decrease due to NHI drug price revisions (Kyorin Pharmaceutical 6% range). Meanwhile, GE's sales are expected to increase **Operating Income:** Gross profit decrease due to a decrease in sales. Despite efforts to reduce SG & A expenses (including R&D expenses), profits are expected to decline due to investment costs to expand the development pipeline Cost of sales ratio: Increase about 3.5 points, SG&A expenses ratio (excluding R&D expenses): Decrease about 1 point, R&D: Decrease ± 0.5 bln (± 9.7 bln $\Rightarrow \pm 9.2$ bln)

* From the beginning of the current term, "Accounting Standards for Revenue Recognition" (ASBJ Statement No. 29, Mar.31,2020) etc. have been applied, and the revenue recognition standards for the previous second quarter is different from the current second quarter, the amount of increase / decrease compared to the second quarter and the Year on Year change rate (%) are not shown. There is no impact on operating loss, ordinary income, and net income.

Forecast of Mainstay Products Sales



	(Units : ¥billion)	FY2020	FY2021	Ye	ρΥ
		(Actual)	(Forecast)	Change	Change(%)
	Flutiform (Combination drug for asthma treatment)	13.3	13.9	+0.6	+4.8
	Desalex (Antiallergic Agent)	5.7	7.2	+1.5	+27.2
	Beova(Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	7.3	8.6	+1.3	+18.3
	Lasvic (New quinolone synthetic antibacterial agent)	0.9	2.8	+1.9	+229.0
New ethical	Pentasa (Ulcerative colitis and Crohn's disease treatment)	12.8	11.7	-1.1	-7.8
drugs,etc. (Japan)	Uritos (Kyorin) (Overactive bladder)	2.3	1.0	-1.3	- 56.3
	Nasonex (Spray type allergic rhinitis remedy)	2.8	1.8	-1.0	- 33.7
	Kipres (Leukotriene Receptor Antagonist)	8.3	6.9	-1.4	-16.1
	Mucodyne (Mucoregulant)	3.3	2.9	-0.4	-9.6
	Milton (Disinfectant)	2.1	2.2	+0.1	+5.6
	Rubysta (Disinfectant)	2.0	2.1	+0.1	+8.3
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	10.8	9.2	-1.6	- 14.2
Generic drugs	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	3.8	3.5	-0.3	-6.4
	Imidafenacin tablets & OD "KYORIN"(Overactive bladder)	0.7	0.7	0	+5.9

%The results forecasts for the full year announced on May 11, 2021 remain unchanged



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

Revision of Dividend Level

In consideration of dramatic changes in the business environment, rising demand for growth investments such as expansion of development pipelines, investment in facilities, we lowered the level of DOE while maintaining the capital policy

Dividend

	FY2019	FY2020	FY2021 (Plan)
Dividend per	¥75	¥75	¥52
Share	(Interim ¥30)	(Interim ¥30)	(Interim ¥20)

* There is no change in the dividend plan (¥52/year) announced on May 11, 2021.

The interim dividend of ¥20 was resolved by the Board of Directors on November 8, 2021 17



KYORIN Holdings,Inc. (Head Office: Chiyoda-ku Tokyo Japan, hereafter "KYORIN") received on July 9, 2021 the results of the initial assessment of its compliance with the listing standards of the new market segments to be introduced on April 4, 2022 from the Tokyo Stock Exchange (hereafter the "TSE"), and confirmed its compliance with the listing standards for the "Prime Market".

Based on these results, at the Board of Directors Meeting held on November 8, 2021, KYORIN resolved to select the new market segment "Prime Market" as its listing market (Press release on November 8, 2021)

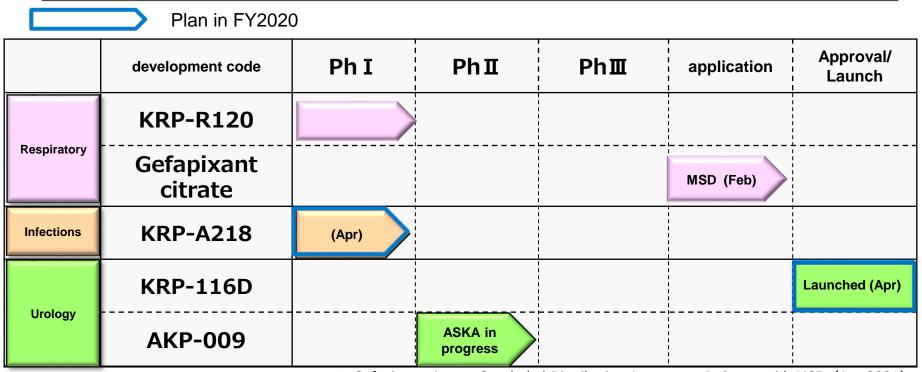
Hence, KYORIN will follow the prescribed procedures related to the application for the selection of the new market segment, in accordance with the schedule set by the TSE.



Status of R&D Pipeline

Drug R&D Pipeline: Progress



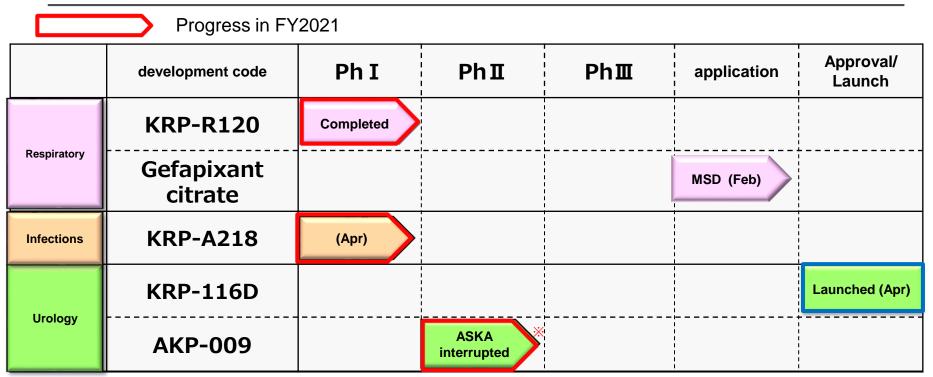


% Gefapixant citrate: Concluded Distribution Agreement in Japan with MSD (Apr 2021)

[Licensed Compound	d / Program 】		
Compound/Code	Licensee	Stage	Features
FPR2 agonist program	BMS	Ph I	 FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure
KRP-203	Priothera	Ph I	 Sphingosine-1-Phosphate Receptor Agonist Target: AML patients undergoing HSCT Assignment of intellectual properties and drug substances(Sep.2020)
Compound for Sensorineural Hearing Loss	Otonomy	Non-clinical	 ·「OTO-6XX」 (Otonomy's Development Code) License Agreement (Aug.2020)

Drug R&D Pipeline: Progress





%ASKA started an additional Ph I study to confirm the maximum effect at a higher dose

Compound/Code	Licensee	Stage	Features
FPR2 agonist program	BMS	Ph I	 FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure
KRP-203	Priothera	Ph I	 Sphingosine-1-Phosphate Receptor Agonist Target: AML patients undergoing HSCT Assignment of intellectual properties and drug substances(Sep.2020)
Compound for Sensorineural Hearing Loss	Otonomy	Non-clinical	• [OTO-6XX] (Otonomy's Development Code) • License Agreement (Aug.2020)



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

Overview of Medium-Term Business Plan Kyorin 🖓 "HOPE 100-Stage 3-"

Statement : Realize growth trend by pursuing Kyorin's originality

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

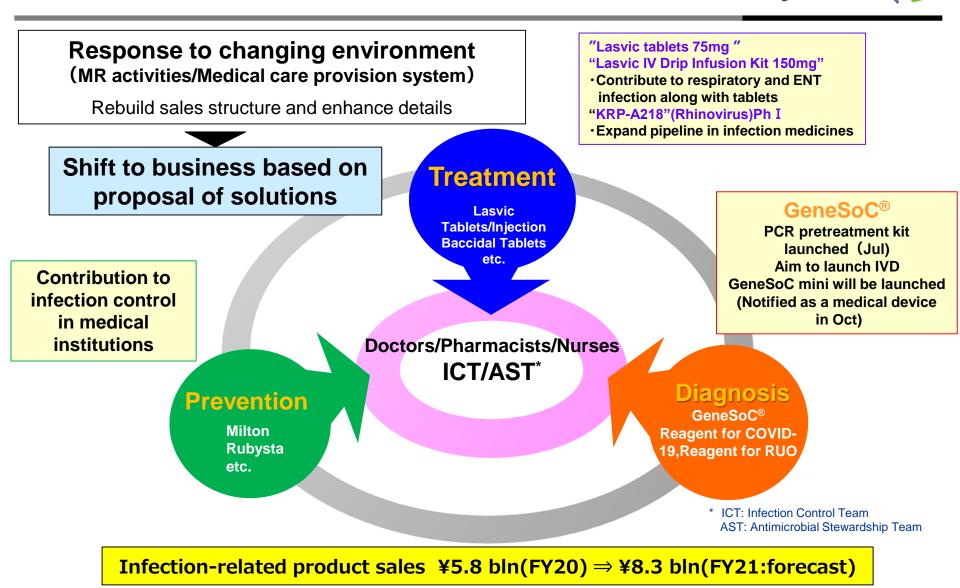
Organization Strategy

 \cdot Aim to be the No. 1 company for career fulfillment

Performance Targets

- ·Growth potential and profitability
- ·Capital policy and shareholder returns

Shift to business based on the proposal of solutions Solution Provision Activities in Infection Domain



Kyorin's unique contribution to health care workers in the infection fields

Kyorin

Effort in diagnosis business

"Genetic Analyzer GeneSoC[®] mini Launch: End of Nov

Kyorin

	GeneSoC [®] mini	GeneSoC®
Aspect	Diameter 10.5cm/Height 15.5cm	Width 62cm/Depth 29cm//Height 15.4cm
Notification	General medical device	Laboratory equipment
Principle	RT-PCR	RT-PCR
Specimen/Test	1	1~4
Detecting time	5~15 min	5~15 min
Price (with Tax)	¥1,152,800	¥3,278,000 (Body+1 Unit)
Weight	0.65kg (Body)	4kg (Body) + 1kg (Unit)

Characteristics of GeneSoC[®] mini : Lightweight · Compact/Rapid/Low price

Promote the use as a POCT * compatible device and develop reagents as IVD (in-vitro diagnostic drug) aiming to contribute to the proper use of antimicrobial drugs

*POCT : Point of Care Testing (Examine beside the subjects and promptly make use of the results in medical treatment) 23

Enhance pipeline to support medium-term growth Kyorin ())

Interstitial cystitis "Zymso Intravesical Solution 50%" Launched : Apr 2021

As a new treatment, Zymso contributes to patient treatment and better QOL

Indication : Improvement of symptoms of interstitial cystitis (Hunner type) (chronic pelvic pain, pressure and discomfort associated with the bladder, lower urinary tract symptoms such as increased urgency or pollakiuria)



- **Characteristics:** First therapeutic agent for interstitial cystitis
 - Exhibits anti-inflammatory effect, shows sedative and analgesic effects on inflammation in the bladder

"Gefapixant Citrate" a Treatment for Chronic Cough

MSD's drug application (Feb), KYORIN's Exclusive distribution rights (Apr)

Target	Refractory chronic cough (RCC) or unexplained chronic cough (UCC)
treatment:	(Reported that the prevalence of chronic cough in Japan is about 2% among Japanese
	16 years and older) Fujimura, Allergology International. 2012; 61: 573-581

Characteristics: Currently, there is no therapeutic drug with the indication or effect of RCC and UCC, and Gefapixant is expected as a new treatment option



aTyr社 ATYR1923 Ph 1b/2a Study

Trial Design

Design	 Randomized (2:1), double-blind, placebo-controlled, multiple ascending dose 24 week study: 6monthly IV dose of ATYR1923 being tested at 1.0, 3.0, 5.0 mg/kg Forced steroid taper to 5.0 mg by week 8; amendment to allow
	taper to 0 mg at week 16 in responders
Population	• 37 histologically confirmed pulmonary sarcoidosis patients
Endpoints	 [Primary Endpoint] Safety and tolerability of multiple ascending IV ATYR1923 doses [Secondary Endpoint] Steroid-sparing effect Immunogenicity Pharmacokinetics(PK) Exploratory : Lung function (FVC and other PFTs); sarcoidosis symptom scores and quality of life scales; inflammatory and sarcoidosis biomarkers; FDG-PET/CT imaging

Reference : ATYR Pharma Conference Call and Webcast(Sep 13, 2021)

Enhance pipeline to support medium-term growth Pulmonary sarcoidosis treatment "KRP-R120"



Primary Endpoint

• The trial met its endpoint : Safe and well-tolerated

Secondary Endpoint

- 58% overall steroid reduction from baseline and 22% relative reduction in steroid utilization post taper in the 5.0mg/kg treatment group
- 33% of patients able to taper completely off steroids in the 5.0mg/kg treatment group
- 3.3% absolute improvement in lung function as measured by FVC% predicted at week 24 in the 5.0mg/kg treatment group
- Dose-dependent clinically meaningful improvement in all sarcoidosis symptom measures in the 5.0mg/kg treatment group
- Dose-dependent improvement on inflammatory biomarkers including IL-6, MCP-1, IFN-γ, IP-10 and TNFα as well as sarcoidosis markers ACE, IL-2Ra and SAA with tightest control in the 5.0mg/kg treatment group

Reference : ATYR Pharma Conference Call and Webcast(Sep 13, 2021)

Kyorin is initiating investigation to proceed to the next stage of development such as MRCT together with aTyr

Treatment agent for BPH "AKP-009"



Development Outline

- **PhIa study** (Randomized, double-blind, parallel-group comparative study with placebo as a control)
- Target treatment : Benign Prostatic Hyperplasia patients
- Number : About 100
- Frequency of administration : Once a day
- **Primary endpoint** : Safety & efficacy(Rate of change from baseline in prostate volume

at 12 weeks of administration)

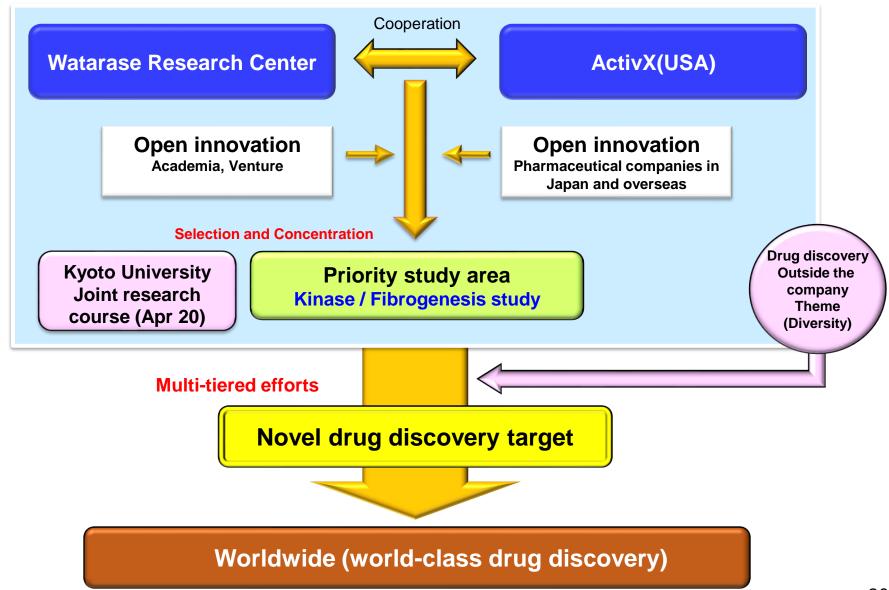
Development Result

No statistically significant dose correlation was found, and no significant difference was found for each active group compared to the placebo group

Next Step

Based on the results of the PhIIa study, it is necessary to conduct clinical study at a higher dose in order to confirm the maximum effect, and Aska Pharmaceutical started an additional PhI study in September.

Strengthen drug discovery capability to Kyorin realize the creation of innovative new drugs



"KPR-A218" a Treatment for Rhinovirus infection



Development background

Discovered from Kinase research by Watarase Drug Discovery Center and ActivX in the United States

Development status

Started Ph I in Apr 2021 in England

Target Treatment

Rhinovirus infection at risk of aggravation

Rhinovirus is known as the causative virus of the common cold, but the risk of developing a lower respiratory tract infection is becoming recognized as a medical issue in immunocompromised patients.

Mode of Action

An antiviral drug that targets host molecules and suppresses viral growth in the body

• Expected to be widely effective against many rhinovirus serotypes (types of surface antigens)

• Less generate resistant virus by mutant strain

"Discovery for Lung Diseases" course at Graduate School of Kyoto University (Phase 2)

Kyorin

Purpose of Joint Research

A joint research course "Discovery for Lung Disease" was established in 2017 at the Graduate School of Medicine, Kyoto University. The joint research was extended for three years in 2020, aiming to create innovative therapeutic drugs originating in Japan, by integrating the pathological research and basic research capabilities of the Kyoto University Graduate School with the drug discovery capabilities of Kyorin Pharmaceutical, and identifying various factors that are deeply involved in the pathophysiology of respiratory disease, and proceed with the search for new targets through validation research on the potential as drug discovery targets

- Research on the pathophysiology of organ fibrosis processes such as pulmonary fibrosis based on both technologies (continued from phase 1)
- Promote patient stratification research with a view to clinical application in collaboration with the Department of Respiratory Medicine, Kyoto University, for candidate compounds for new drug discovery targets (Phase 2)

Outline of Joint Research

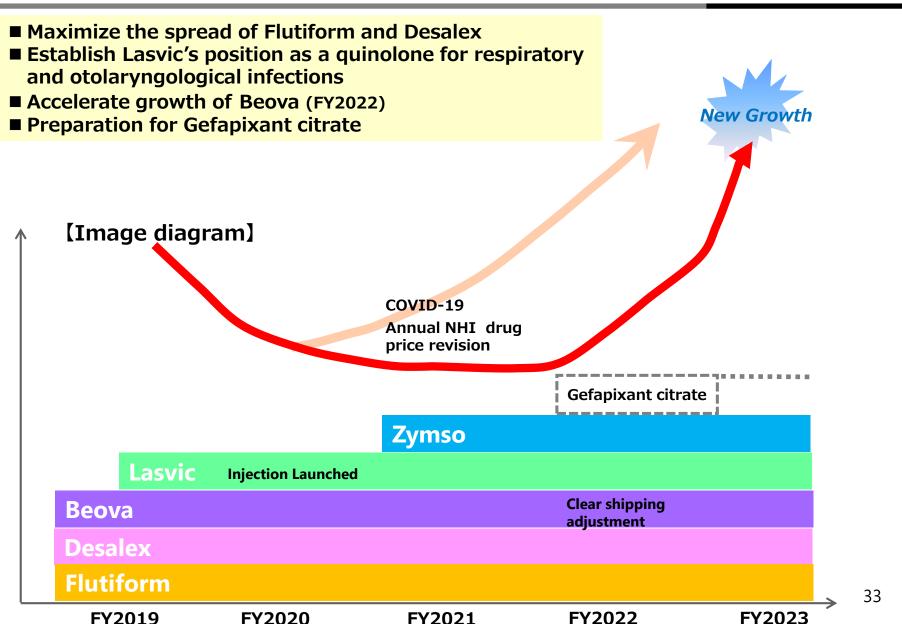
- Place : Graduate school of Medicine, Kyoto University
- Name: Discovery for Lung Disease Course

Faculty: Associate Professor Shimpei Gotoh (Ex assistant professor, iPS group leader, Department of Respiratory Medicine, Graduate School of Kyoto University)
 Assistant Professor Masayasu Toyomoto (Ex assistant professor, Department of Anatomy and Developmental biology, Graduate School of Kyoto University)
 Terms : April 1, 2021 – March 31, 2023

Contributions : About ¥200 Million / 3 years

Shift to business based on the proposal of solutions and accelerate the growth of new drug groups

Accelerate growth of new drug groups



Kyorin

Kyorin 🕗

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