

Financial Results for Fiscal Year 2020

May 12, 2021
KYORIN Holdings, Inc.
Representative Director, President and Chief Executive Officer
Yutaka Ogihara





- >Outline of Consolidated Financial Results
- Trends of mainstay products
- > Consolidated Financial Forecast
- **>**Status of R&D Pipeline
- ➤Initiatives toward realization of the long-term vision "HOPE 100"
- Medium-Term Business Plan "HOPE 100-Stage3-"(Fiscal Year 2020~2023)

Impact of COVID-19 on our Business



■ Promotion Activities etc.

Although it is predicted the impact on sales activities will decrease after October 2020, promotion activities was affected by the state of emergency due to the arrival of the third wave

- •Patient's suppressive behavior to medical consultation diminishes KYORIN pharmaceutical's main products market(esp. Respiratory, ENT, Pediatrics)
- ·Hand washing, gargling, and wearing masks have reduced the number of patients suffering from infectious diseases, and the antibacterial agent market has been sluggish.
- •Although efforts were made to promote digitally, the market penetration of new drug groups was delayed due to MR visit restrictions esp. in hospitals.

■ R&D

Some project was affected, but overall development schedule does not fall far behind

■ Production & Procurement

As a result of strengthening procurement management of raw materials and other materials, there was no impact on stable supply



Outline of Consolidated Financial Results

Breakdown of Gain and Loss



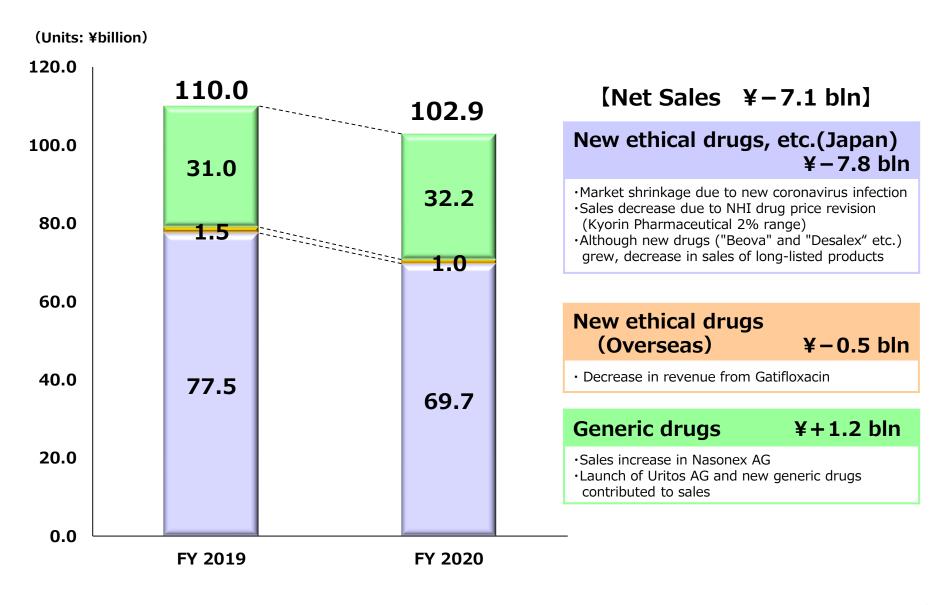
(Units: ¥billion)		FY 2019	FY 2020	Change	Change (%)
Sales		110.0	102.9	-7.1	-6.4
	New ethical drugs, etc. (Japan)	77.5	69.7	-7.8	-10.1
	New ethical drugs (Overseas)	1.5	1.0	-0.5	-33.2
	Generic drugs	31.0	32.2	+1.2	+3.9
Cost of	Sales	53.0	51.3	-1.7	-3.2
SG&A (R&D)		49.5 (11.0)	45.8 (9.7)	-3.7 (-1.3)	-7.4 (-11.7)
Operating Income		7.5	5.8	-1.7	-22.9
Ordinary Income		8.2	6.4	-1.8	-21.1
Net Inc	ome	6.1	6.1	0	-0.3

Change (forecast) Announced on Nov 5,2020
-5.1
-4.1
-0.1
-0.8
_
_
-2.0
-2.0
-1.1

The classification of reporting segment ("Prescription drugs business" and "Healthcare business") was consolidated to a single segment from the first quarter consolidated financial results for the fiscal year ended March 31, 2021. Along with this, the classification of sales was changed to combine the existing "New ethical drugs (Japan)" and "healthcare business" to "New ethical drugs, etc. (Japan)". There is no change in "New ethical drugs (overseas)" and "Generic drugs".

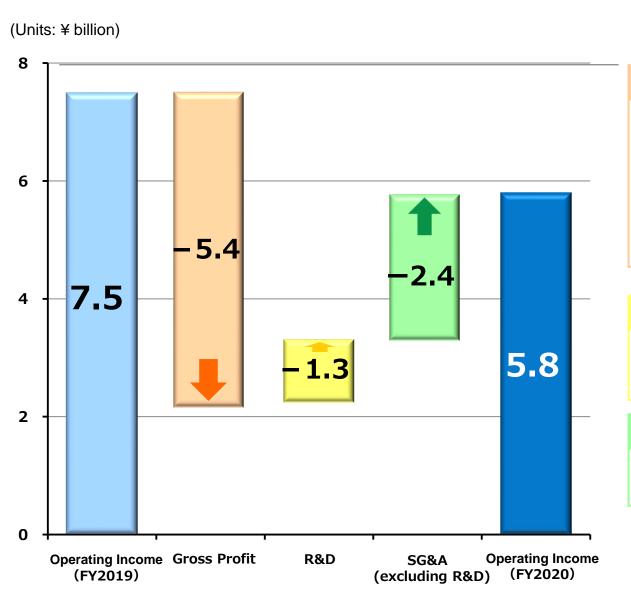
Highlights of Business Performance: 1 Net sales





Highlights of Business Performance 2 (Income)





[Operating Income ¥ – 1.7 bln]

Gross Profit

-¥5.4 bln

Net Sales:

Decreased ¥7.1bln year on year

Cost of sales ratio:

Increased 1.7% year on year

- ·Impact of NHI price revision
- ·Increase in generic sales ratio

R&D expenses

-1.3 bln

 $\pm 11.0 \, \text{bln}(\text{FY2019}) \Rightarrow \pm 9.7 \, \text{bln}(\text{FY2020})$

 Development project progress and development discontinuation (Ad-SGE-REIC, etc.)

SG&A(excluding R&D) -2.4 bln

 ± 38.5 bln(FY2019) $\Rightarrow \pm 36.1$ bln(FY2020)

Mainly reduction of selling, personnel and general expenses

Highlights of Business Performance 3



(Change: Revised forecast)

(Units : ¥billion)		FY 2019	FY 2020	Change	Change(%)
Net s	Sales	110.0	102.9	-7.1	-6.4
	New ethical drugs, etc.(Japan)	77.5	69.7	-7.8	-10.1
	New ethical drugs (Overseas)	1.5	1.0	-0.5	-33.2
	Generic drugs	31.0	32.2	+1.2	+3.9
Cost	t of Sales	53.0	51.3	-1.7	-3.2
SG8 (R8	A &D)	49.5 (11.0)	45.8 (9.7)	-3.7 (-1.3)	-7.4 (-11.7)
Operating Income		7.5	5.8	-1.7	-22.9
Ordinary Income		8.2	6.4	-1.8	-21.1
Net	Income	6.1	6.1	0	-0.3

Change (Forecast)
Announced in Nov 5,2020
-5.1
-4.1
-0.1
-0.8
_
_
-2.0
-2.0
-1.1

■ Difference from Revised Forecast(Nov 5, 2020)

Net Sales: Despite efforts to promote digitally, the arrival of the third wave of COVID-19 delayed the penetration of new drug groups into the market, and sales of generic drugs were lower than expected.

Operating Income: SG & A expenses decreased due to efforts to reduce costs and refraining from activities. On the other hand, operating income was lower than expected because of gross profit decrease caused by unmet sales goal.

Net Income: Due to the partial exemption of repayment obligation for long-term debt from JST(Japan Science and Technology Agency), debt exemption gain etc. totally ¥1.9 bln was recorded as an extraordinary income.

Main Product Sales Update



		FY 2019	FY 2020	Change	Change(%)	
	Flutiform (Combination drug for asthma treatment)	14.6	13.3	-1.3	-9.0	
	Desalex (Antiallergic Agent)	2.6	5.7	+3.1	+120.7	
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	4.3	7.3	+3.0	+70.2	
	Lasvic tablets (New quinolone synthetic antibacterial agent)	1.1	0.9	-0.2	-19.6	
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	13.3	12.8	-0.5	-4.3	
New ethical	Uritos (Kyorin) (Overactive bladder)	5.8	2.3	-3.5	-60.1	
drugs,etc. (Japan)	Nasonex (Spray type allergic rhinitis remedy)	6.0	2.8	-3.2	-54.0	
	Kipres for adult (Leukotriene Receptor Antagonist)	5.3	3.9	-1.4	-25.4	
	for children	6.5	4.4	-2.1	-33.0	Ī
	Mucodyne (Mucoregulant)	5.8	3.3	-2.5	-43.4	Ī
	Milton (Disinfectant)	2.4	2.1	-0.3	-10.2	Ī
	Rubysta (Disinfectant)	1.5	2.0	+0.5	+34.9	
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	11.5	10.8	-0.7	-6.1	
Generic drugs	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	2.8	3.8	+1.0	+37.0	
	Imidafenacin tablets & OD "KYORIN" Overactive bladder)	_	0.7	+0.7	_	

Change				
(forecast)				
Announced on Nov 5,2020				
-1.2				
-1.8				
0				
-0.9				
+0.3				
+0.1				
+0.4				
+0.1				
+0.1				
0				
-0.2				
-0.1				
+0.6				
+0.3				
-0.1				

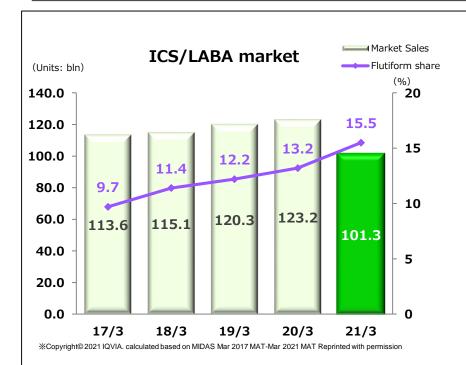


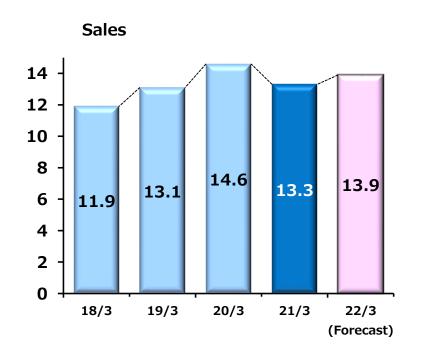
Trends of mainstay products and Generic drugs

■ Mainstay product

Flutiform (Anti-asthmatic)







■ICS/LABA market: Shrink 18%

 $$123.2bln(FY2019) \Rightarrow $101.3bln(FY2020) *1$

- Patient's suppressive behavior to medical consultation by the spread of COVID-19
- Generic for a competitive product launched
- **Share of Flutiform sales : expand2.3%** 13.2% (FY2019) ⇒ 15.5%(FY2020)* ¹
- Medium to long-term market outlook

 Market shrinks due to annual NHI drug price revision and GE launch impact

■Status in FY 2020

• Expand indications for pediatric asthma (June 2020)

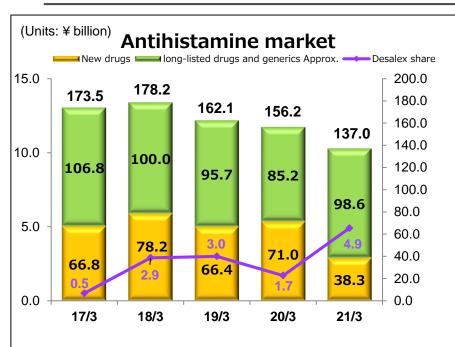
■Effort for FY 2021

- Appeal the utility of the aerosol formulations
 To understand and permeate the significance of administration to patients with cough symptoms
- Aim to penetrate pediatric indications and increase market share

Mainstay product

Desalex (Antiallergic Agent)





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■ Antihistamine market: shrink 12%

¥156.2bln (FY2019) ⇒ ¥137.0 bln (FY2020) *1

- Patient's suppressive behavior to medical consultation by the spread of COVID-19
- Market of aged 12 or over: 110 billion yen

■ Share of Desalex sales

1.7% (FY2019) ⇒ 4.9% (FY2020) *1

•Dec 2018: 6.3% (before supply suspended)

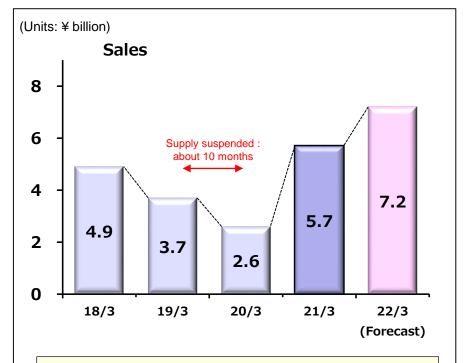
•Mar 2021: 6.7%*2 (after supply resumed)

■ Medium to long-term market outlook

Market shrinks due to annual NHI drug price revision and GE launch impact

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■Status of FY2020

 Worked on recovery to market share before supply stop through real interviews and webinars and achieved its goal in March 2021

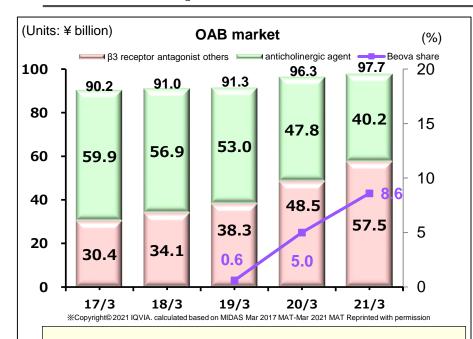
■Effort for FY2021

- Realization of prescription acquisition rate No.1 in otolaryngology
- Focus on expanding the number of general internal medicine clinics and acquiring prescriptions

■ Mainstay product

Beova / Uritos (Therapeutic agent for overactive bladder)





■OAB market: expand 1.5%

 $$96.3bln(FY2019) \Rightarrow $97.7(FY2020) \%1$

•β3 receptor agonist market :expand 18.9% (compared with 17/3)

■Share of Beova and Uritos

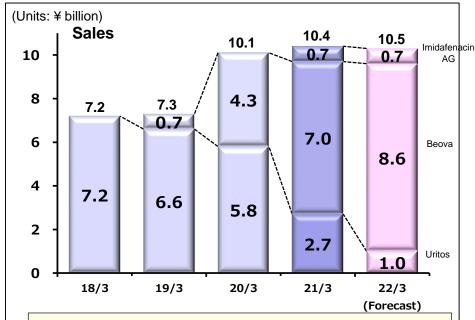
•Share of Beova sales

5.0% (FY2019) ⇒ 8.6% (FY2020) *2

Share of Uritos sales

7.0% (FY2019) \Rightarrow 3.0% (FY2020) \times^2

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■Status of FY2020

● Launched Imidafenacin AG (June 2020)

■Effort of FY2021

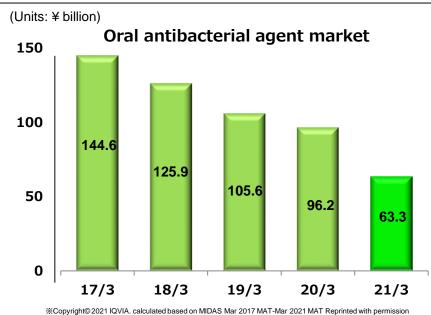
- Aim to contribute to urology together with Zymso *1
- After clearing shipping adjustment *2, aim for the top share soon %1: Refer to P29
- *2: At each OEM manufacturer, they are working to expand facilities and launch new manufacturing sites.

Shipment adjustments are expected to be lifted during FY2022

Mainstay product

Lasvic (New quinolone synthetic antibacterial agent)



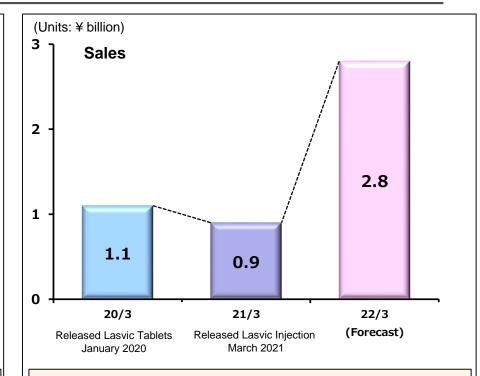


- Oral antibacterial agent market: Shrink 34% ¥96.2bln(FY2019)⇒¥63.3bln(FY2020)^{×1}
- The number of patients from infectious diseases has decreased by washing hands, gargling, and wearing masks
- Share of Lasvic
- Share of Lasvic sales 1.9% (FY2020) *1
- Promotion of proper use of antibacterial agents against AMR

■ Medium to long-term market outlook

The market for oral antibacterial agents in respiratory and otolaryngology is expected to shrink significantly compared to before COVID-19.

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■ Status of FY2020

• Launched Lasvic IV drip infusion kit (Mar 2021)

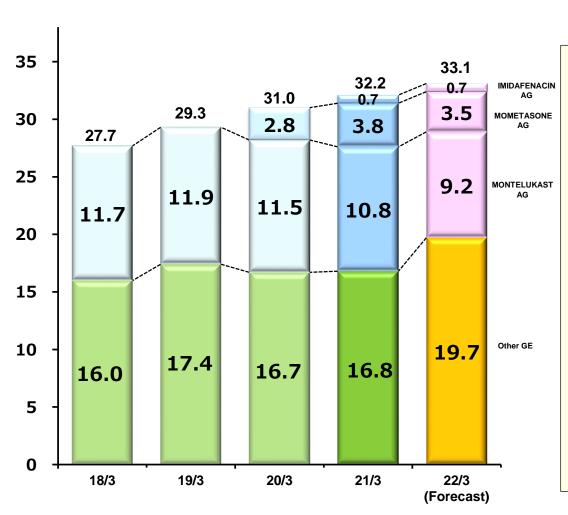
■Effort of FY2021

- Appeal 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



(Units: ¥ billion)



■Status of FY2020

- Released of Imidafenacin AG(June)
- Montelukast AG, Mometasone AG, Imidafenacin AG maintain the market share of more than 50% in the GE market
- Released in June 2020: 7 ingredients 13 items Levocetirizine hydrochloride tablets 2.5mg/5mg, DS0.5%
 - Memantine hydrochloride OD5mg/10gm/20mg, etc.
- Released in Dec 2020: 2 ingredients 4 items
 Pregabalin OD Tablets 25/75/150mg,
 LoreAce Combination Tablets

■Effort for FY2021

 Expand sales of strategic products and Supplementary Items

Contribution of launched items in FY2020 through the year Release in June 2021: 5 items

Promotion of AG strategy

Aim to maintain market share of more than 50% for Montelukast AG, Mometasone AG and Imidafenacin AG in the GE market



Consolidated Financial Forecast

Consolidated Financial Forecast for the Year Ending March 31, 2022



(Units: ¥ billion)

	Jilio. + D					
Y/Y		Y/Y	FY2021	FY2020		
ange(%)	Change	Change	(forecast)	F12020		
n/a	r	n/a	102.6	102.9		Net sales
n/a	r	n/a	68.6	69.7	New ethical drugs, etc.(Japan)	Jaics
n/a	r	n/a	0.8	1.0	New ethical drugs (Overseas)	
n/a	r	n/a	33.1	32.2	Generic drugs	
_		_	_	51.3	Sales	Cost of
_		_	_	45.8		SG&A
-5.2)	(-5	(-0.5)	(9.2)	(9.7)		(R&D)
-43.0	-43	-2.5	3.3	5.8	ng Income	Operati
-41.1	-41	-2.8	3.8	6.4	y Income	Ordinar
-56.0	-56	-3.4	2.7	6.1	ome	Net Inco
	-	-2.8	3.8	45.8 (9.7) 5.8 6.4	ng Income y Income	SG&A (R&D) Operati Ordinar

Apply the "Accounting Standards for Revenue Recognition" from the fiscal year ending March 31, 2022, and the consolidated earnings forecast for the fiscal year ending March 31, 2022 incorporates these changes.

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 ⇒¥9.2 bln)





(Units : ¥billion)		FY2020	FY2021	YoY		
		(Actual)	(Forecast)	Change	Change(%)	
	Flutiform (Combination drug for asthma treatment)	13.3	13.3 13.9		+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	

Shareholder 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

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 will lower the level of DOE while maintaining the capital policy

Dividends	FY2018	FY2019	FY2020※
Dividend per share (Yen)	¥75 (Year-end ¥45)	¥75 (Year-end ¥45)	¥75 (Year-end ¥45)
Consolidated payout ratio	72.6%	70.9%	71.1%

FY2021 (forecast)				
¥52 (Year-end ¥32)				
112.0%				



Status of R&D pipeline

Drug R&D Pipeline: Progress in FY2020



Progress in FY	2020

	development code	Ph I	PhⅡ	PhⅢ	application	Approval/ Launch
Doonington	KRP-108P					Pediatric Indication (Jun)
Respiratory	KRP-R120	(Jul)				
Infections	KRP-AM1977Y					Launched (Mar)
Unabani	KRP-116D					Approved (Feb)
Urology	AKP-009]	ASKA in progress			

ullet Gefapixant citrate: MSD : Ph ${\ensuremath{\mathbb{I}}}$ Concluded a momorandum of understanding for sales collaboration. (May 2019)

[Licensed Compound / Program]

Licensed Compound / Frogram 2					
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			

Drug R&D Pipeline: Progress in FY2021





Progress in FY2021

	development code	Ph I	PhⅡ	PhⅢ	application	Approval / Launch
Respiratory	KRP-R120					
	Gefapixant citrate				MSD(2021)	
Infections	KRP-A218	(Apr)			 	
	KRP-116D				 	Launched (Apr)
Urology	AKP-009		ASKA in progress			

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

[Licensed Compound / 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	



Progress of Medium-Term Business Plan "HOPE 100-Stage 3-" (Fiscal Year 2020~2023)

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



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



Response to changing environment (MR activities/Medical care provision system)

Rebuild sales structure and enhance details

"Lasvic IV Drip Infusion Kit 150mg" launched (Mar)

- Contribute to respiratory and ENT infection along with tablets
- "KRP-A218"(Rhinovirus)Ph I
- ·Expand pipeline in infection medicines

Shift to business based on proposal of solutions

Treatment

Lasvic
Tablets/Injection
Baccidal Tablets
etc.

Contribution to infection control in medical institutions

Doctors/Pharmacists/Nurses ICT/AST*

GeneSoC

Aim to launch IVD, Reagent for extracting nucleic acid, GeneSoC mini

Prevention

Milton Rubysta etc.

Diagnosis

GeneSoC Reagent for COVID-19,Reagent for RUO

> * ICT: Infection Control Team AST: Antimicrobial Stewardship Team

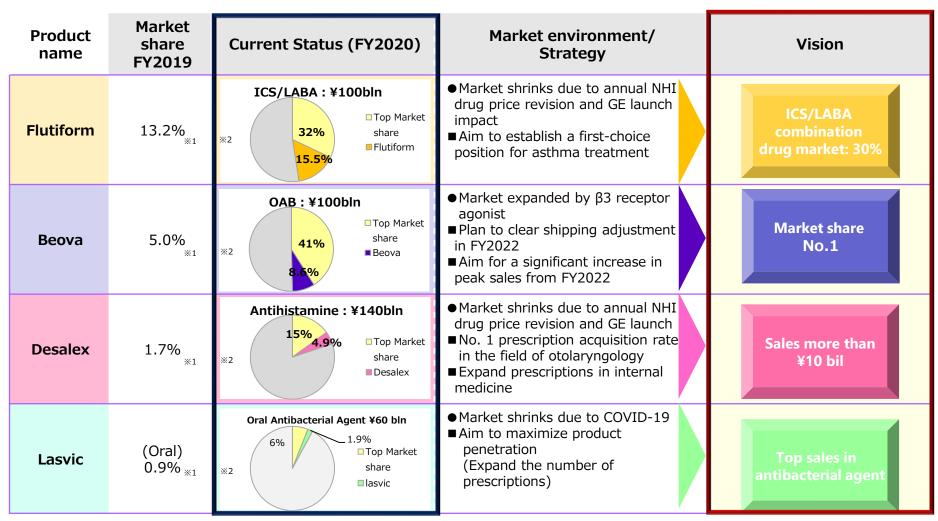
Infection-related product sales ¥5.8 bln(FY2020) ⇒ ¥8.3 bln(FY2021)

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





Medium-term management plan "HOPE100 – Stage 3 – " Accelerate new drugs group as much as possible

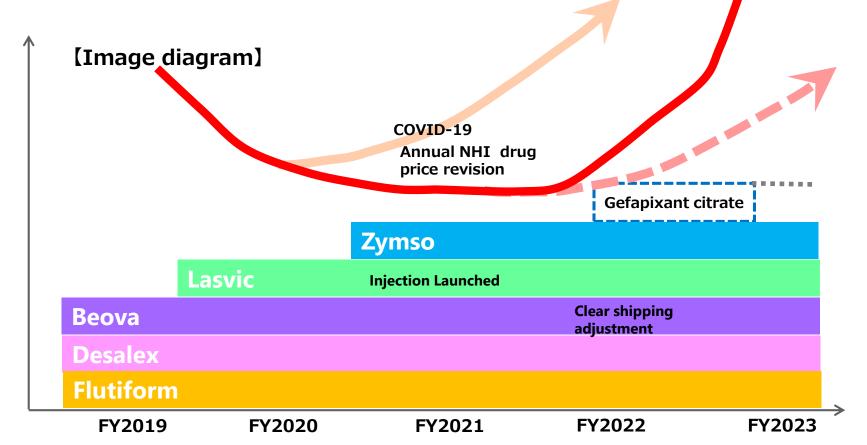




New Growth

Accelerate growth of new drug groups

- Maximize the spread of Flutiform and Desalex
- Establish Lasvic's position as a quinolone for respiratory and otolaryngological infections
- Accelerate growth of Beova (after clearing shipping adjustment in FY2022)
- Acquire Gefapixant citrate



New quinolone synthetic antibacterial agent "Lasvic"



Lasvic Tablets 75mg

Launched in Jan 2020

■ Indication

Pharyngitis, stomatitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory disease, middle ear infection, sinusitis

■ Dosage and Administration

The usual oral dosage for adults is 75mg of lascufloxacin once daily.

■ Development background

Narrow down the treatment target to respiratory and otolaryngological infections, strengthen antibacterial activity against major causative bacteria including Gram-positive bacteria and anaerobic bacteria

Lasvic tablets was developed with a concept different from the conventional one, improving organizational migration.

Lasvic Intravenous Drip Infusion Kit

Launched in Mar 2021

■ Indication

Pneumonia, lung abscess, secondary infection of chronic respiratory disease

■ Dosage and Administration

The usual dosage for adults is 300 mg of lascufloxacin on the first day of administration and 150 mg once daily on the second and subsequent days of administration.

■ Development background

The treatment target was defined as respiratory disease and developed as an injection that can be used for Pneumonia, lung abscess, secondary infection of chronic respiratory disease

Respond and contribute to treatment needs for respiratory and otolaryngological infections with two dosage forms (tablets and injections)

Interstitial cystitis "Zymso® Intravesical Solution 50%" Kyorin (



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)

Dosage and Administration

The usual dosage for adults is 50 mL of 50% (w / w) dimethyl sulfoxide solution per vial (27g as dimethyl sulfoxide) instilled into the bladder 6 times at 2-week intervals

Product characteristics

- **1** First therapeutic agent for interstitial cystitis
- 2 Exhibits anti-inflammatory effect, shows sedative and analgesic effects on inflammation in the bladder
- 3 In domestic Phase III clinical trials, no serious side effects were observed



Launch

Launched in April 21, 2021

Patients

About 4,500

(Survey in 2015 by Society of Interstitial Cystitis of Japan)

About 17,000

(Survey in 2019 by M3, Inc)

As a new treatment option Zymso contributes to patient treatment and quality of life improvement

"Gefapixant Citrate" a Treatment for Chronic Cough



Agreement with MSD

Date of agreement: Apr 2021 (Press release Apr 26, 2021) Essence of agreement: Exclusive distribution rights in Japan

Development status

Application submitted by MSD in Feb 2021

Target Treatment

Refractory chronic cough (RCC) or unexplained chronic cough (UCC) (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

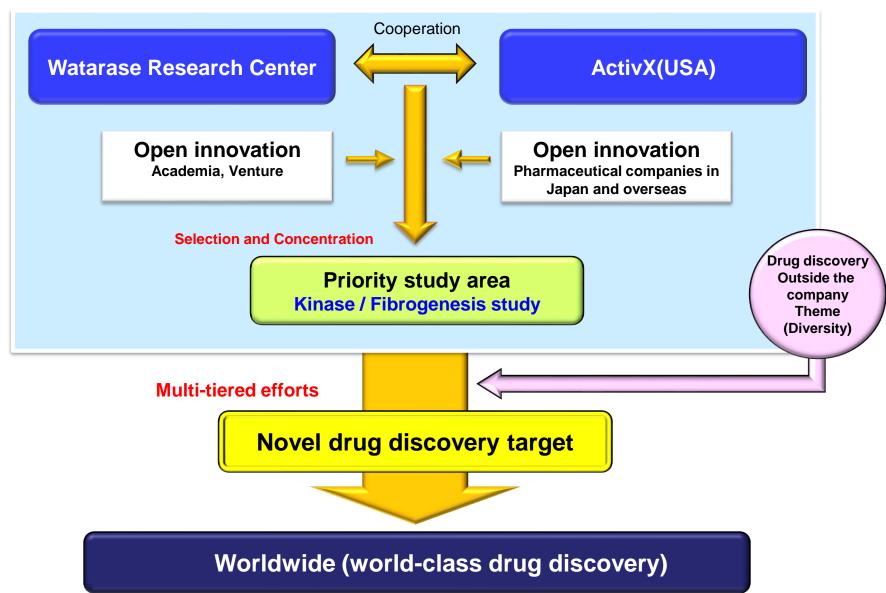
Mode of Action

By inhibiting the binding of extracellular ATP and P2X3 receptor, Gefapixant suppresses C fiber activation and suppresses cough

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

Strengthen drug discovery capability to Kyo 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

Reform cost structure through intra-group optimization



Improve cost competitiveness at KYORIN Pharmaceutical Group Facilities Co., Ltd

- Control outsourcing expenses by equalizing the manufacturing capabilities of each factory
- ◆ Facilitate efficient operation through the flexible transfer of employees among factories
- Use existing facilities more effectively







Expected effects of reorganization: Total cost reduction approximately 1,000 million yen by 2023.

Achieved ahead of schedule in FY2020



Aim to realize new factory construction (Takaoka, Toyama) to expand production capacity



Example 2021 Rey point of Business Strategy in FY 2021

Increase
Business speed
and
Cost competitiveness

Disclaimer



These forecast performance figures are based on information currently available to the Company and may include uncertain factors or risk that affect our future performance. Accordingly, actual business results may materially differ from the forecasted figures due to various factors in the future.



