

Interim Term Financial Results Ended September 2020

November 6, 2020 KYORIN Holdings, Inc. President Yutaka Ogihara





- > Outline of Consolidated Financial Results
 - Trends of mainstay products
- > Consolidated Financial Forecast

- > Status of R&D Pipeline
- ➤ Initiative toward realization of the long-term vision "HOPE100"

Impact of COVID-19 on our Business



■ Promotion Activities etc.

- The spread of COVID-19 sets back sales progress
 - Patient's suppressive behavior to medical consultation diminishes KYORIN pharmaceutical's main products market(exp. Respiratory, ENT, Pediatrics)
 - Decrease of infected patients stagnated antimicrobial agent market
 - Voluntary restriction on MR activities results in delay in market penetration of the new drug groups

■R&D

 Work from home under the national sate of emergency affected some project, overall development schedule does not fall far behind

■ Production & Procurement

- No influence by COVID-19
 - Health check(ex. body temperature) and infection control keep production operation normal in every facilities
 - •For stable supply, procurement management(ex. Impact forecast) of materials enhanced



Outline of Consolidated Financial Results

Outline of Consolidated Financial Results for the Interim Term Ended September 2020



(Units : ¥billion)	Sep/19	Sep/20	Change	Change(%)	Change (forecast) Announced on May 12,2020
Net Sales	48.3	47.7	-0.6	-1.2	-5.1
Operating Income	0.8	1.5	+0.7	+91.7	-0.9
Ordinary Income	1.1	1.8	+0.7	+68.5	-0.8
Net Income	0.8	2.1	+1.3	+154.0	+0.2

^{*}We released a revision to our second-quarter financial results forecast on November 2, 2020 but these comparisons with the forecast show differences from the forecast announced on May 12, 2020.

Segment Sales and Breakdown of Gain and Loss



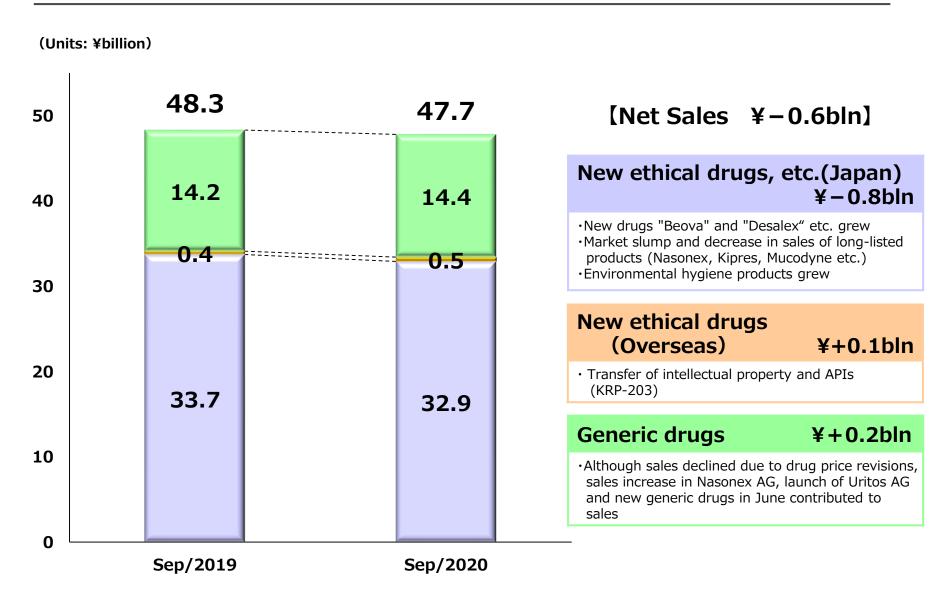
(Units: ¥billion)		Sep/19	Sep/20	Change	Change (%)	Change (forecast) Announced on May 12,2020
Sales		48.3	47.7	-0.6	-1.2	-5.1
	New ethical drugs, etc. (Japan)	33.7	32.9	-0.8	-2.6	-3.9
	New ethical drugs (Overseas)	0.4	0.5	+0.1	+35.1	+0.2
	Generic drugs	14.2	14.4	+0.2	+1.3	-1.2
Cost of	Sales	23.8	22.9	-0.9	-3.5	-
SG&A (R&D)		23.8 (5.2)	23.3 (5.2)	-0.5 (0)	-1.9 (+0.2)	(+0.4)
Operating Income		0.8	1.5	+0.7	+91.7	-0.9
Ordinary Income		1.1	1.8	+0.7	+68.5	-0.8
Net Inco	ome	0.8	2.1	+1.3	+154.0	+0.2

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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 ending 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

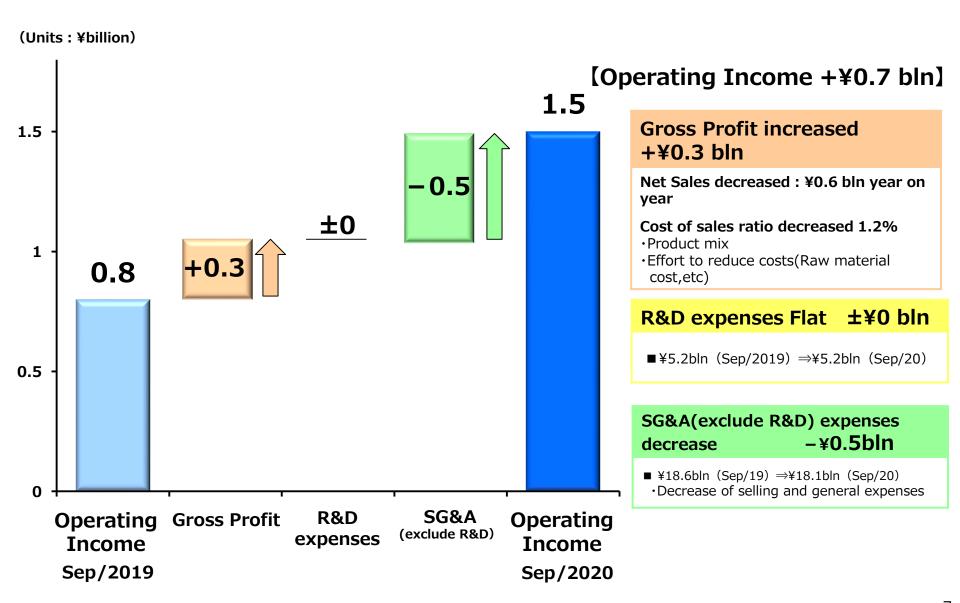




Highlights of Business Performance:

2Operating Income





Highlights of Business Performance : 3 Change (forecast)



(Units : ¥billion)		Sep/19	Sep/20	Change	Change(%)	Change (forecast) Announced on May 12,2020
Net S	ales	48.3	47.7	-0.6	-1.2	-5.1
	New ethical drugs, etc.(Japan)	33.7	32.9	-0.8	-2.6	-3.9
	New ethical drugs (Overseas)	0.4	0.5	+0.1	+35.1	+0.2
	Generic drugs	14.2	14.4	+0.2	+1.3	-1.2
Cost	of Sales	23.8	22.9	-0.9	-3.5	_
SG& (R&		23.8 (5.2)	23.3 (5.2)	-0.5 (0)	-1.9 (+0.2)	- (+0.4)
Oper	rating Income	0.8	1.5	+0.7	+91.7	-0.9
Ordinary Income		1.1	1.8	+0.7	+68.5	-0.8
Net 1	Income	0.8	2.1	+1.3	+154.0	+0.2

■ Difference from Original Forecast(May 12, 2020)

Net Sales: Market slump of main products and MR activity restraint led the delay in market penetration of new drug groups (Lasvic tablets, Desalex), and new ethical drugs, etc.(Japan) sales did not reach the forecast. Also General drugs sales were below the original forecast.

Operating Income: Due to cost reduction and restriction on activities, selling expenses (excluding R&D) decreased. But decrease of gross profit attributable to lower net sales could not be absorbed. As a result, original forecast fell short. R&D expenses increased due to a lump-sum contract payment associated with license agreements were not included in the initial forecast.

Net Sales: Due to the partial exemption of repayment obligation for long-term debt from JST(Japan Science and Technology Agency), debt exemption gain(¥1.1 bln) recorded and exceeded the initial forecast.

Main Product Sales Update



		Sep/19	Sep/20	Change	Change(%)	Change (forecast) Announced on May 12,2020
	Flutiform (Combination drug for asthma treatment)	6.7	6.4	-0.3	-5.6	-0.6
	Desalex (Antiallergic Agent)	0	1.8	+1.8	1	-1.3
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	0.6	3.8	+3.2	+496.9	+0.3
	Lasvic tablets (New quinolone synthetic antibacterial agent)	-	0.2	+0.2	_	-1.2
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	6.8	6.4	-0.4	-6.0	+0.5
New ethical	Uritos (Kyorin) (Overactive bladder)	3.0	1.6	-1.4	-47.3	-0.2
drugs,etc. (Japan)	Nasonex (Spray type allergic rhinitis remedy)	2.7	0.6	-2.1	-76.4	0
	Kipres for adult (Leukotriene Receptor Antagonist)	2.4	1.7	-0.7	-30.5	-0.1
	for children	3.0	1.8	-1.2	-38.9	-0.4
	Mucodyne (Mucoregulant)	2.8	1.4	-1.4	-48.0	-0.8
	Milton (Disinfectant)	1.1	1.1	0	+0.9	0
	Rubysta (Disinfectant)	0.6	1.0	+0.4	+64.5	+0.4
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	5.4	4.5	-0.9	-16.8	-0.2
Generic drugs	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	0.4	0.9	+0.5	+142.8	0
	Imidafenacin tablets & OD "KYORIN"Overactive bladder)		0.3	+0.3	_	-0.1

^{*}We released a revision to our second-quarter financial results forecast on November 2, 2020 but these comparisons with the forecast show differences from the forecast announced on May 12, 2020.

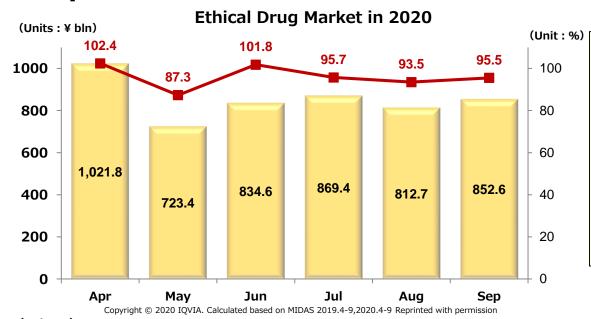


Trends of mainstay products and Generic drugs

Change of ethical drug market and number



of patients (First half of the fiscal year ending Mar.2021)



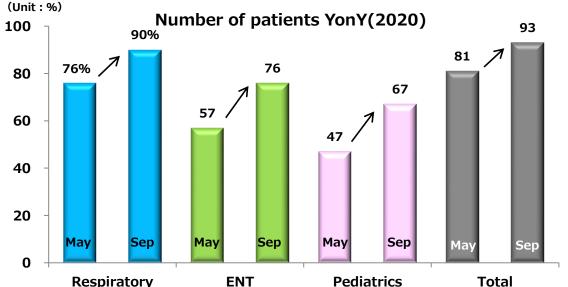
Status in first half 2020

■ Ethical drug market

·Market side gradually recovered

■ Patients

- •The number of patients decreased since the "state of emergency" issued in April. (Especially ENT, Pediatrics)
- After the release of the emergency at the end of May, it showed a recovery trend



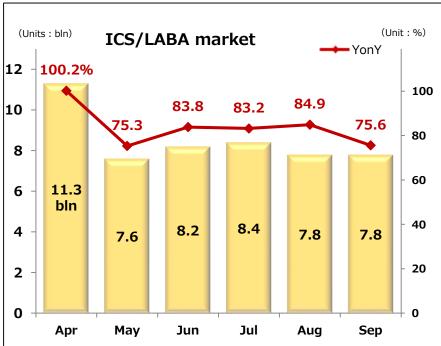
Forecast in second half 2020

■ Trend of market and patients

- Market and patient numbers are recovering to pre –COVID-19 spread
- Revised sales plan on the premise that certain impacts remain,

■ Main Product Flutiform (Anti-asthmatic)





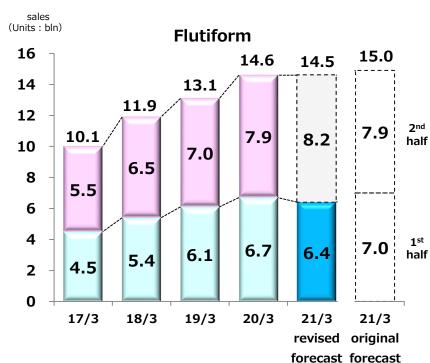
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■ICS/LABA market: Shrink 15.9%

460.8bln(FY19 first half) $\Rightarrow 451.1$ bln(FY20 first half) 100.8bln(FY19 first half)

- Patient's suppressive behavior to medical consultation by the spread of COVID-19
- Share of Flutiform sales: expand2.6%

12.6% (FY19 first half) \Rightarrow 15.2%(FY20 first half)* ¹ NHI price change 125aerosolized 120 for inhalation \blacktriangle 4.96% (Compared with Apr.2019)



■Status in first half 2020

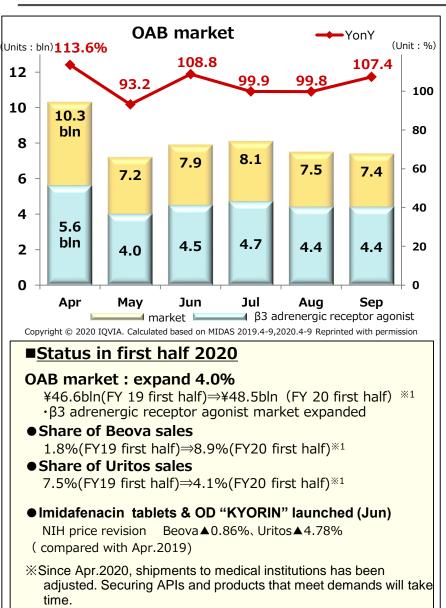
- Expand indications for pediatric asthma (June)
- ■Effort for FY 2020

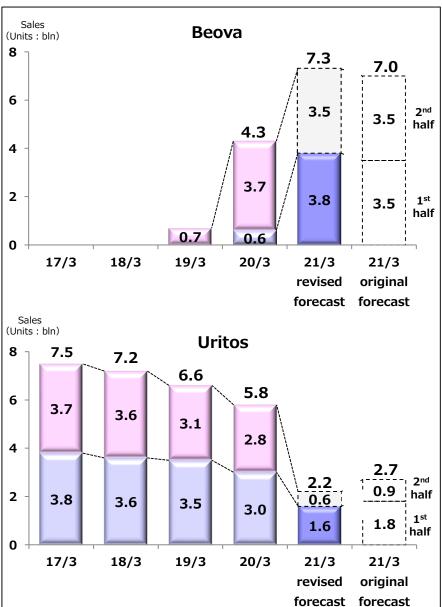
Establish the "First Choice for Asthma Treatment" Position

- In addition to real interviews, lectures on asthma management through Web
- Expand target facilities (internal medicine / pediatrics)
- ◆The second half year market to recover about 90% YoY Aim for 100% or more of the initial forecast

■ Main Product Beova/Uritos (OAB)

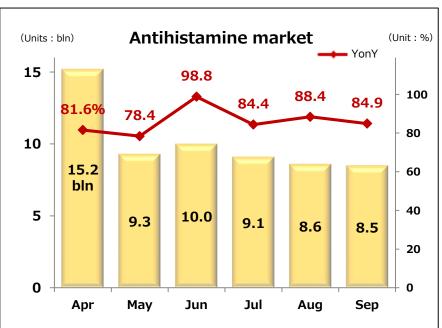






■ Main Product Desalex (Antiallergic Agent)





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■ Antihistamine market: shrink 14.7%

 $$\mp71.1$ bln(FY 19 first half)) \Rightarrow $$\pm60.7$ bln(FY 20 first half) $*1$

 Patient's suppressive behavior to medical consultation by the spread of COVID-19

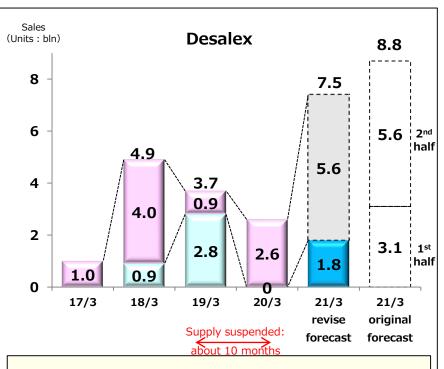
■ Share of Desalex sales

0%(FY 19 first half) ⇒ 4.0% (FY 20 first half) *1

- ◆ Dec. 18 single month: 6.3%^{*2}(Before supply suspension)
- Sep.20 single month: 4.6%^{*1} (After resuming supply)

 NHI price revision ▲4.73% (compared with Apr.2019)

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■Status in first half 2020

• Due to market shrinkage by patient's suppressive behavior, product dissemination was insufficient during the pollinosis season after resuming supply in November 2019.

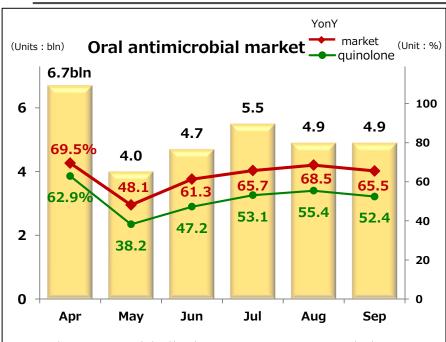
■Effort for FY2020

Promoting "high effect", "less drowsiness", and "easy to use"

- No. 1 prescription acquisition rate in otolaryngology
- Focus on acquiring prescriptions in internal medicine
- ◆ Due to market recovery, the second half year market is to be about 90% of the previous year Aim for a share of >10% through web lectures etc.

■ Main Product Lasvic (Oral new quinolone synthetic antibacterial agent)





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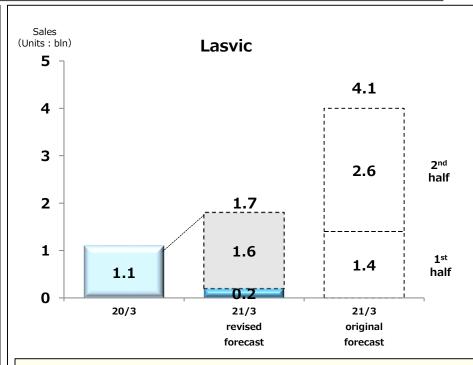
■ Oral antimicrobial market: shrink36.9%

448.7bln (FY 19 first half) $\Rightarrow 430.7$ bln (FY 20 first half) 11

- In addition to curbing medical consultations, preventing infection (washing hands, gargling, wearing masks, etc.) has reduced the number of infectious diseases, and the market shrunk significantly
- Share of Lasvic sales 1.4% (FY 20 first half)**1

 NHI price revision ▲2.2% (compared with Jan.2020)

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■Status in first half 2020

• The shrinking market and voluntary restraint of MR activities led insufficient to disseminate the product.

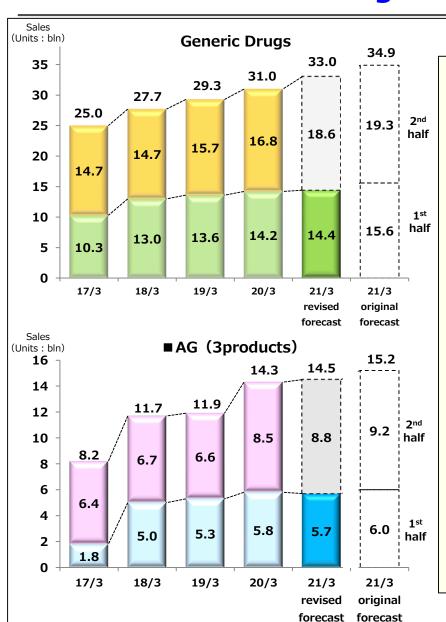
■Effort for FY2020

Promote proper use and product dissemination

- Increase prescriptions and achieve a market share of >3% by improving product understanding through web lectures.
- ◆The second half market :about 50% YoY
- **♦**Injection (KRP-AM1977Y) to be approved & launched in FY2020

■ Status of Generic Drugs





■Status in first half 2020

Action for an authorized generic drug(AG)

- Montelukast AG (for Adult) Keep >50% share in GE market (¥4.5bln)
- Mometasone AG expanded (¥0.9bln)
- Imidafenacin AG launched (Jun) (¥0.3bln)

GE drugs released in Jun 2020 (7ingredients 13items)

Memantine hydrochloride OD, Levocetirizine hydrochloride tablets, Dutasteride Capsules AV etc.

■Effort for FY2020

Promotion of AG strategy

● Aim to achieve a market share of more than 50% for each AG product in GE market

Expand sales of new launches

● To be released in Dec 2020(2ingredients 4items)
Pregabalin OD Tablets 25/75/150mg,LoreAce Combination
Tablets



Consolidated Financial Forecast

Consolidated Financial Forecast in FY2020



(Units : ¥billion)		FY 2020 (revised		Yo	ρΥ	FY2020 (Original	Versus the revised forecast
	(Offics: #Difficit)	112013	forecast)	Change	Change(%)	forecast)	Change
Net sale	Net sales		108.0	-2.0	-1.8	115.5	-7.5
	New ethical drugs, etc.(Japan)	77.5	73.8	-3.7	-4.8	79.7	-5.9
	New ethical drugs (Overseas)	1.5	1.1	-0.4	-26.2	1.0	+0.1
	Generic drugs	31.0	33.0	+2.0	+6.6	34.9	-1.9
Operat	ing Income	7.5	7.8	+0.3	+4.0	9.7	-1.9
Ordinary Income		8.2	8.4	+0.2	+2.7	10.2	-1.8
Net In	come	6.1	7.2	+1.1	+17.1	7.6	-0.4

■ Main factors behind revision of forecast

Net sales: New ethical drugs, etc.(Japan) and Generic drugs revised downward based on the result of the first half and sales reduction

by COVID-19.

Operation income: Gross profit will be decreased due to a fall in sales. Selling and SG&A expenses(excluding R&D) will be reduced. R&D expenses

will be increased ¥0.4bln due to a lump-sum contract payment associated with license agreements for the development of

candidate products (¥9.6bln⇒¥10.0bln).

Net income: Due to the partial exemption of repayment obligation for long-term debt from JST(Japan Science and Technology Agency), debt

exemption gain(¥1.1 bln) was recorded as extraordinary profit.

■ Main factors in YoY change

Net sales: While in New ethical drugs, etc.(Japan), "Beova", "Desalex", "Lasvic" etc. grow, sales for Nasonex, Uritos and long-listed products

will decrease mainly due to a decline in the number of prescription. In Generic drugs, sales are expected to rise chiefly reflecting the

release of Mometason AG and Imidafenacin AG.

Operating income: Although gross profit will decrease due to a fall in net sales, the cost of sales ratio is expected to decline

(the cost of sales ratio: down about 0.5%)

Operating income expected to increase thanks to decrease in R&D expenses (¥11.0bln⇒¥10.0bln) and SG&A(excluding R&D)

Forecast of Mainstay Products Sales



(Units : ¥billion)		FY2019	FY2020 (Revised	Yo	YoY		Versus the revised forecast
			forecast)	Change	Change(%)	forecast)	Change
	Flutiform (Combination drug for asthma treatment)	14.6	14.5	-0.1	-0.5	15.0	-0.5
	Desalex (Antiallergic Agent)	2.6	7.5	+4.9	+191.1	8.8	-1.3
	Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	4.3	7.3	+3.0	+70.6	7.0	+0.3
	Lasvic tablets (New quinolone synthetic antibacterial agent)	1.1	1.7	+0.6	+63.8	4.1	-2.4
New	Pentasa (Ulcerative colitis and Crohn's disease treatment)	13.3	12.5	-0.8	-6.1	11.7	+0.8
ethical drugs,etc.	Uritos (Kyorin) (Overactive bladder)	5.8	2.2	-3.6	-61.1	2.7	-0.5
(Japan)	Nasonex (Spray type allergic rhinitis remedy)	6.0	2.4	-3.6	- 59.6	2.6	-0.2
	Kipres for adult (Leukotriene Receptor Antagonist)	5.3	3.8	-1.5	-26.5	4.2	-0.4
	for children	6.5	4.3	-2.2	-32.7	5.3	-1.0
	Mucodyne (Mucoregulant)	5.8	3.3	-2.5	-41.1	4.9	-1.6
	Milton (Disinfectant)	2.4	2.3	-0.1	-2.1	2.2	+0.1
	Rubysta (Disinfectant)	1.5	2.1	+0.6	+45.6	1.4	+0.7
	Montelukast tablets "KM" (Leukotriene Receptor Antagonist)	11.5	10.2	-1.3	-10.9	10.7	-0.5
Generic drugs	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	2.8	3.5	+0.7	+ 26.5	3.5	0
	Imidafenacin tablets & OD "KYORIN" (Overactive bladder)	_	0.8	+0.8	_	1.0	-0.2

Shareholder Returns



Basic Policy

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

Dividend

	FY2018	FY2019	FY2020 (forecast)
Dividend per	¥75	¥75	¥75
Share	(Interim ¥30)	(Interim ¥30)	(Interim ¥30)

^{*} There is no change in the dividend forecast (¥75/year) announced on May 12, 2020.

◆ The interim dividend of ¥30 was resolved by the Board of Directors on November 5th



Status of R&D Pipeline

Drug Development Pipeline



Schedule in FY2020 (As of May 12 announcement)

	Development Code	Ph I	PhⅡ	PhⅢ	Application	Approval/ Launch
	Ad-SGE-REIC	End of the I	PhI / PhII PhII Start 2018/6			
Respir atory	KRP-108P				2019/7	Expected launch in FY 2020
	KRP-R120	Expected clinical trial in FY 2020	1 1 1 1 1 1	1 1 1 1 1 1 1		
Infection	KRP-AM1977Y				2019/10	Expected launch in FY 2020
Urology	KRP-116D		 		2020/3	Expected launch in FY 2020

(Licensing development)

Development Code	Licensee	Development Stage	Characteristics
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	Under Licensing activity	Ph I	Sphingosine-1-Phosphate Receptor Agonist Therapy area: GvHD

Drug Development Pipeline



Schedule in 2020 ×F	Progress in 2020 (as of Nov.5)
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	Development Code	Ph I	PhⅡ	PhⅢ	Application	Approval/ Launch
Respir	KRP-108P				2019/7	Approved in June
atory	KRP-R120	2020/7				
Infection	KRP-AM1977Y				2019/10	Expected launch in FY 2020
Urology	KRP-116D				2020/3	Expected launch in FY 2020

(Licensing development) **Development Code** Licenser **Development Stage** Comments •Novel androgen receptor modulator with the potential to exhibit prostatic ASKA **AKP-009**^{*} Ph II shrinkage and to improve urinary function for Benign Prostatic Hyperplasia Pharmaceutical · Joint development and commercialization rights within Japan (Sep.2020) **Development Code** Licensee Comments **Development Stage** •FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit FPR2 agonist **BMS** Ph I anti-inflammatory action. program Therapy area: Non-disclosure Sphingosine-1-Phosphate Receptor Agonist **KRP-203**** Priothera Ph I Target: AML patients undergoing HSCT · Assignment of intellectual properties and drug substances(Sep.2020) Compound for Sensorineural • OTO-6XX (Otonomy's Development Code) **Nonclinical** Otonomy Hearing Loss[™] ·License Agreement (Aug.2020)

Development pipeline aiming for approval in FY2020



Combination drug for asthma treatment "KRP-108P"

■Approved (Jun.2020)

Study results: PhIII study confirmed non-inferiority to control drug (fluticasone / salmeterol combination)

Efficacy and safety for patients with bronchial asthma aged ≥ 5 , < 16 years confirmed

Disease name : Bronchial asthma in children

Dosage/Administration: Two inhalations (puffs) of Fultiform (50/5 µg), twice daily

New quinolone synthetic antibacterial agent"KRP-AM1977Y"

Aim for approval in second half 2020

■ Application submitted (Oct.2019)

Study results: PhIII study verified efficacy and safety against community-acquired pneumonia, secondary

infections of chronic respiratory lesions etc.

Disease name : Respiratory tract infection

Dosage/Administration in Ph3 study:

Intravenous administration of 150mg once daily (Double dose on the starting day)

Therapeutic agent for interstitial cystitis "KRP-116D"

Aim for approval in second half 2020

■ Application submitted (Mar.2020)

**Under development for handling unapproved drugs and off-label drugs

Study results: Confirmed the superiority and safety compared to placebo in PhⅢ study

XIts superiority compared to placebo proved for the first time worldwide

Disease name : interstitial cystitis

Dosage/Administration in PhⅢ study: one intravesical instillation of 50mL once every two weeks



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

Outline of New 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

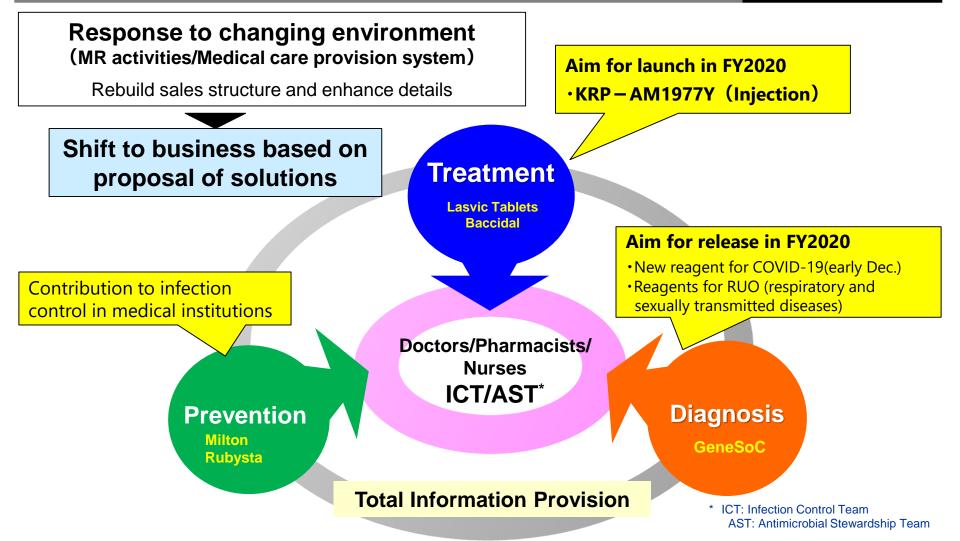
Organization Strategy Aim to be the No. 1 company as Best worthwhileness place of work

Performance Targets

- Growth potential and profitability
- Capital policy and shareholder returns

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

Solution Provision Activities in Infection Domain



Establish a group-wide sales structure to make Kyorin's unique contribution to health care workers.

Interstitial lung disease "KRP-R120"



Clinical trial of KRP-R120 (Started Ph1 study)

- Contract: license to develop and commercialize in Japan with aTyr pharma (USA) (Jan.2020)
- **Development status:** Ph1 study (started in Jul.2020)
- Therapy area: Interstitial lung disease (pulmonary sarcoidosis etc.)

 ※ Developing as a therapeutic drug for rare diseases with low treatment satisfaction

■ Mode of action

Suppress the excessive activation of immune cells by binding to Neuropilin-2 receptor **Aim for first-in-class launch

■ Characteristics

A fusion protein comprised of the immuno-modulatory domain of histidyl tRNA synthetase fused to the FC region of a human antibody, is a selective modulator of Neuropilin-2 that downregulates the innate and adaptive immune response in inflammatory disease states.

By making a fusion protein drug, the blood stability of the protein can be improved and it became possible to extend the half-life

※ In USA, aTyr is conducting a P1b / 2a clinical trial for pulmonary sarcoidosis

Treatment agent for BPH "AKP-009"



Joint Development and Commercialization Agreement for a treatment agent for Benign Prostatic Hyperplasia with ASKA Pharmaceutical

■ Contract: Sep.2020 (Press release 30/Sep)

■ Contract contents

- We were granted the joint development and commercialization rights within Japan
 Contract terms
 - Development will be jointly carried out by both companies
 - •KYORIN makes an upfront and milestone payments according to its progress from development to launch

AKP-009 (Novel androgen receptor modulator)

<Development Concept>

Potential to exhibit prostatic shrinkage and to improve urinary function for Benign Prostatic Hyperplasia

Development status

●Ph2a study (Conducted by ASKA Pharmaceutical, Started in Dec.2019)

Study: Randomized, double-blind, parallel-group comparative study with placebo as a control

Disease name : Benign Prostatic Hyperplasia

(Scheduled indications: Dysuria associated with benign prostatic hyperplasia)

(Primary endpoint) Safety & efficacy

Rate of change from baseline in prostate volume at 12 weeks of administration

Active partnering activities



License agreement with Otonomy, Inc. (USA) regarding novel candidate compound

■ Mode of action

It helps improve hearing function in patients with sensorineural hearing loss by regenerating cochlear hair cells to replace cells damaged due to noise exposure or aging

■ License agreement

KYORIN granted Otonomy a global exclusive license to develop, manufacture and commercialize the therapeutic agent (Aug.2020)

- <Agreement terms>
- •Eligible to receive up-front payment and milestone payments from development to launch
- •Eligible to receive royalties and sales milestone payments based on net sales

■ Otonomy

The company pioneered the application of drug delivery technology to the ear in order to develop products that achieve sustained drug exposure from a single local administration.

Assignment of Intellectual Properties and drug substances regarding Immunomodulator KRP-203 to Priothera

- Mode of Action Sphingosine-1-Phosphate Receptor Agonist
- Asset purchase agreement in Sep.2020
- <Agreement terms>
- Assignment of the KRP-203 assets such as intellectual rights and drug substance for development and sales
- ·Kyorin receives considerations including ordinary shares issued by Priothera

■ Priothera

Drug discovery venture company with strengths in developing sphingosine 1 phosphate receptor



