Interim Term Financial Results Ended

September 2019

November 8 , 2019
KYORIN Holdings, Inc.
President Yutaka Ogihara

- **Outline of Consolidated Financial Results**
  - ・Trends of mainstay products
- **Consolidated Financial Results and Forecast**
- **Status of Development Pipeline**
- **Initiatives toward realization of the long-term vision “HOPE 100”**

Outline of Consolidated Financial Results

Outline of Consolidated Financial Results for the Interim Term Ended September 2019

(unit : ¥billion)	Sep/18	**Sep/19**	**Change**	**Change(%)**	**Change (forecast)** Announced on May 13, 2019
Net Sales	50.4	**48.3**	−2.1	−4.1	−3.8
Operating Income	2.9	**0.8**	−2.1	−72.5	−1.5
Ordinary Income	3.2	**1.1**	−2.1	−66.2	−1.4
Net Income	2.2	**0.8**	−1.4	−62.4	−1.1

We released a revision to our second-quarter financial results forecast on November 5, 2019 but these comparisons with the forecast show differences from the forecast announced on May 13, 2019.

Segment Sales and Breakdown of Gain and Loss

（unit : ¥billion）			Sep/18	Sep/19	Change	Change (%)	Change (forecast) Announced on May 13, 2019
Net Sales			50.4	**48.3**	**－2.1**	**－4.1**	－3.8
Ethical drugs business			47.6	45.5	－2.1	－4.4	－3.6
	Sales of new ethical drugs		34.0	31.3	－2.7	－7.9	－2.5
		Japan	33.4	30.9	－2.5	－7.4	－2.5
		Overseas	0.6	0.4	－0.2	－35.5	0
	Generic drugs		13.6	14.2	+0.6	+4.5	－1.1
Healthcare Business			2.8	2.8	0	+0.5	－0.1
Cost of Sales			23.8	**23.8**	**0**	**0**	－
SG&A			23.7	**23.8**	**+0.1**	**+0.1**	－
Operating Income			2.9	**0.8**	**－2.1**	**－72.5**	－1.5
Ordinary Income			3.2	**1.1**	**－2.1**	**－66.2**	－1.4
Net Income			2.2	**0.8**	**－1.4**	**－62.4**	－1.1

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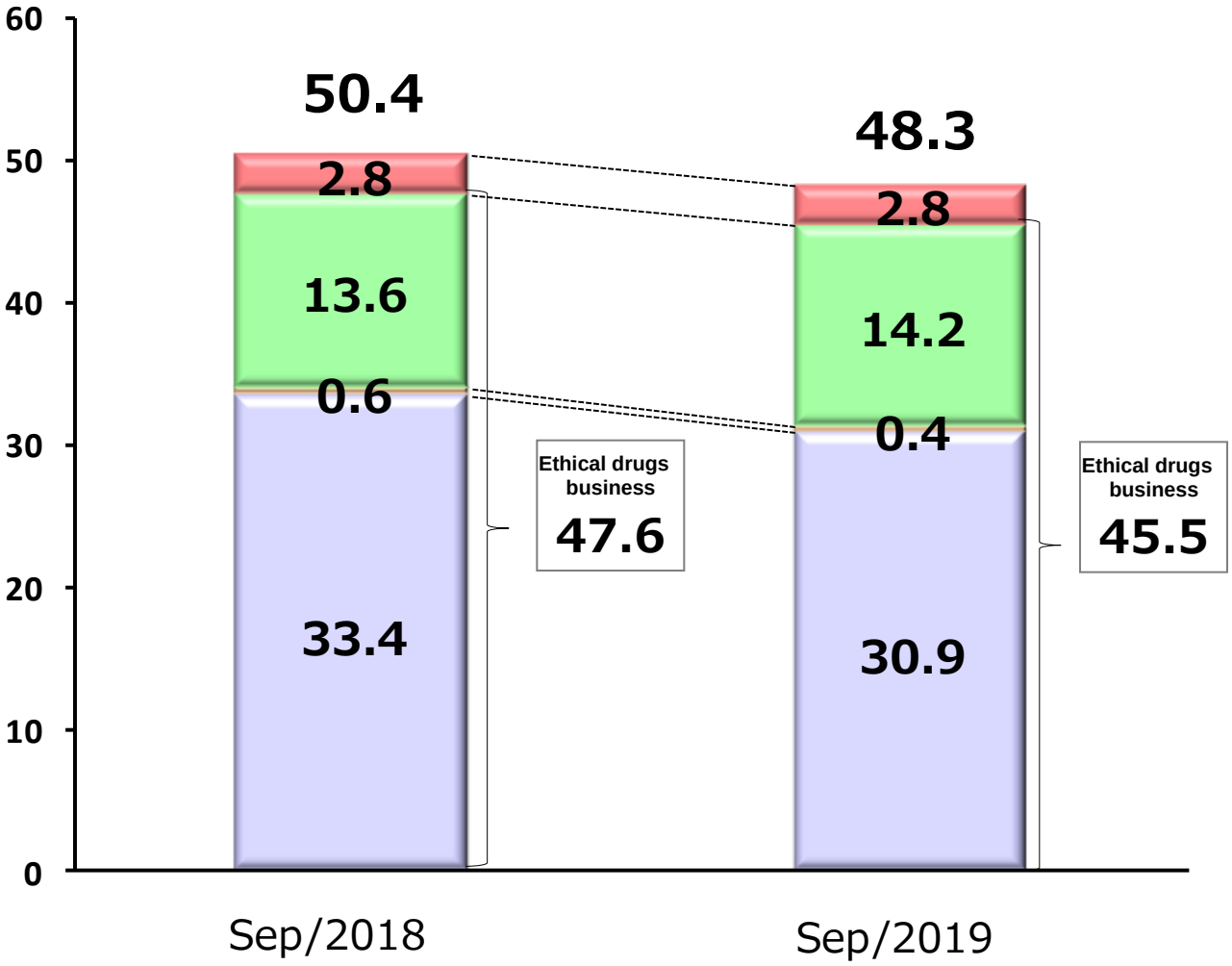
Highlights of Business Performance:①Net sales

（Units: ¥billion）



【 Net Sales ¥－2.1bin 】

New ethical drugs(Japan) ¥－2.5bin

- Growth in Flutiform, Beova and Nasonex sales
- Influence from the suspended supply of DESALEX
- Decreased in prescriptions of long-listed drugs.

New ethical drugs (overseas) ¥－0.2bin

- Decrease of Gatifloxacin sales

Generic drugs ¥＋0.6bin

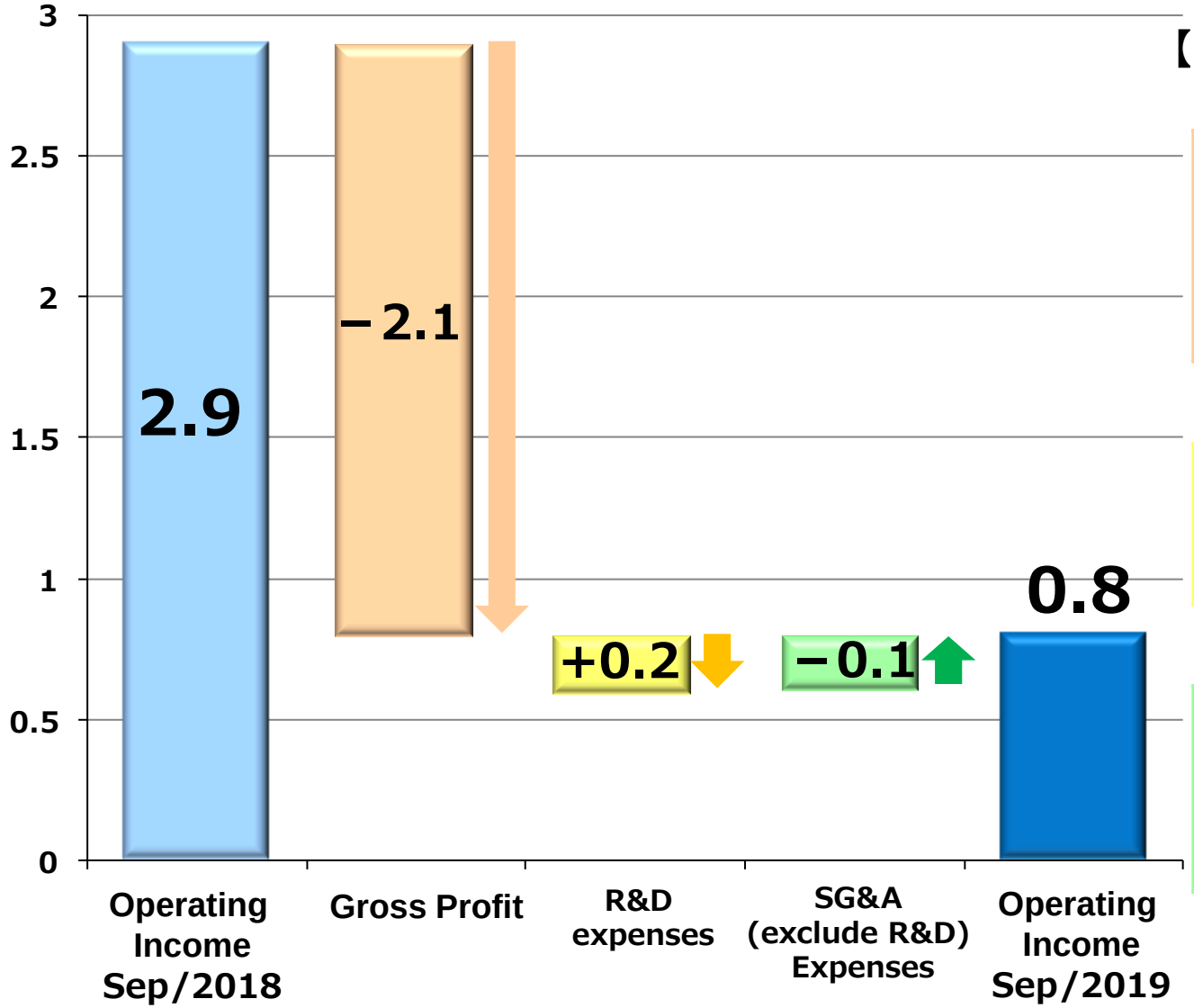
- Increase of MONTELKAST AG and MOMETASONE AG sales
- Increase in sales of generic drugs released in fiscal 2018

Healthcare Business ¥±0

- Growth of RUBYSTA

Highlights of Business Performance : ②Operating Income

（Units: ¥billion）



【 Operating Income－￥2.1bin 】

Gross Profit decreased

Net Sales decreased ¥2.1billion year on year.
Cost of sales ratio increased 2.0%.
- Product mix
- Fall in lump-sum revenue

R&D expenses increased

■ ￥5.0bin （Sep/2018）⇒￥5.2bin （Sep/2019）

SG&A (exclude R&D) Expenses decreased

- Decrease of Selling costs.
  ￥18.7bin （Sep/2018）⇒￥18.6bin （Sep/2019）

Highlights of Business Performance

:③Change (forecast)

(unit : ¥billion)			Sep/18	Sep/19	Change	Change (%)	Change (forecast) Announced on May 13, 2019
Net Sales			50.4	**48.3**	**−2.1**	**−4.1**	−3.8
Ethical drugs business			47.6	45.5	−2.1	−4.4	−3.6
	Sales of new ethical drugs		34.0	31.3	−2.7	−7.9	−2.5
		Japan	33.4	30.9	−2.5	−7.4	−2.5
		Overseas	0.6	0.4	−0.2	−35.5	0
	Generic drugs		13.6	14.2	+0.6	+4.5	−1.1
Healthcare Business			2.8	2.8	0	+0.5	−0.1
Cost of Sales			23.8	**23.8**	**0**	**0**	−
SG&A			23.7	**23.8**	**+0.1**	**+0.1**	−
Operating Income			2.9	**0.8**	**−2.1**	**−72.5**	−1.5
Ordinary Income			3.2	**1.1**	**−2.1**	**−66.2**	−1.4
Net Income			2.2	**0.8**	**−1.4**	**−62.4**	−1.1

■ **Net Sales and Operating Income: Difference from Original Forecast**

Net Sales : **In new ethical drugs (Japan), results remained largely favorable for mainstay products. However, net sales fell short of projections mainly because the supply of DESALEX was determined to resume in November and the production / marketing approval of Lasvic Tablets, which had been ready for release, was postponed to September.**

Operating Income: Profit was lower than the initial forecast, reflecting a decline in gross profit mainly attributable to lower-than-projected net sales, despite efforts for the reduction of selling, general and administrative expenses.

Main Product Sales Update

(unit : ¥billion)	Sep/18	**Sep/19**	Change	Change(%)	**Change (forecast)** Announced on May 13, 2019
Flutiform (Combination drug for asthma treatment)	6.1	**6.7**	+0.6	+10.3	+0.1
Desalex (Antiallergic Agent)	2.8	**0**	−2.8	−	−1.8
Kipres for adult (Leukotriene Receptor Antagonist)	2.9	**2.4**	−0.5	−15.4	+0.2
for children	3.3	**3.0**	−0.3	−9.6	+0.3
Nasonex (Spray type allergic rhinitis remedy)	1.3	**2.7**	+1.4	+110.3	−0.4
Uritos (Kyorin) (Therapeutic agent for overactive bladder)	3.5	**3.0**	−0.5	−12.9	−0.1
Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	−	**0.6**	+0.6	−	−0.1
Pentasa (Ulcerative colitis and Crohn's disease treatment)	7.1	**6.8**	−0.3	−5.4	+0.5
Mucodyne (Mucoregulant)	3.1	**2.8**	−0.3	−9.7	+0.1
MONTELUKAST Tablets "KM" (LT receptor antagonist)	5.3	**5.4**	+0.1	+2.5	0
Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	−	**0.4**	+0.4	−	−
Milton (Disinfectant)	1.1	**1.1**	0	−1.1	−0.1

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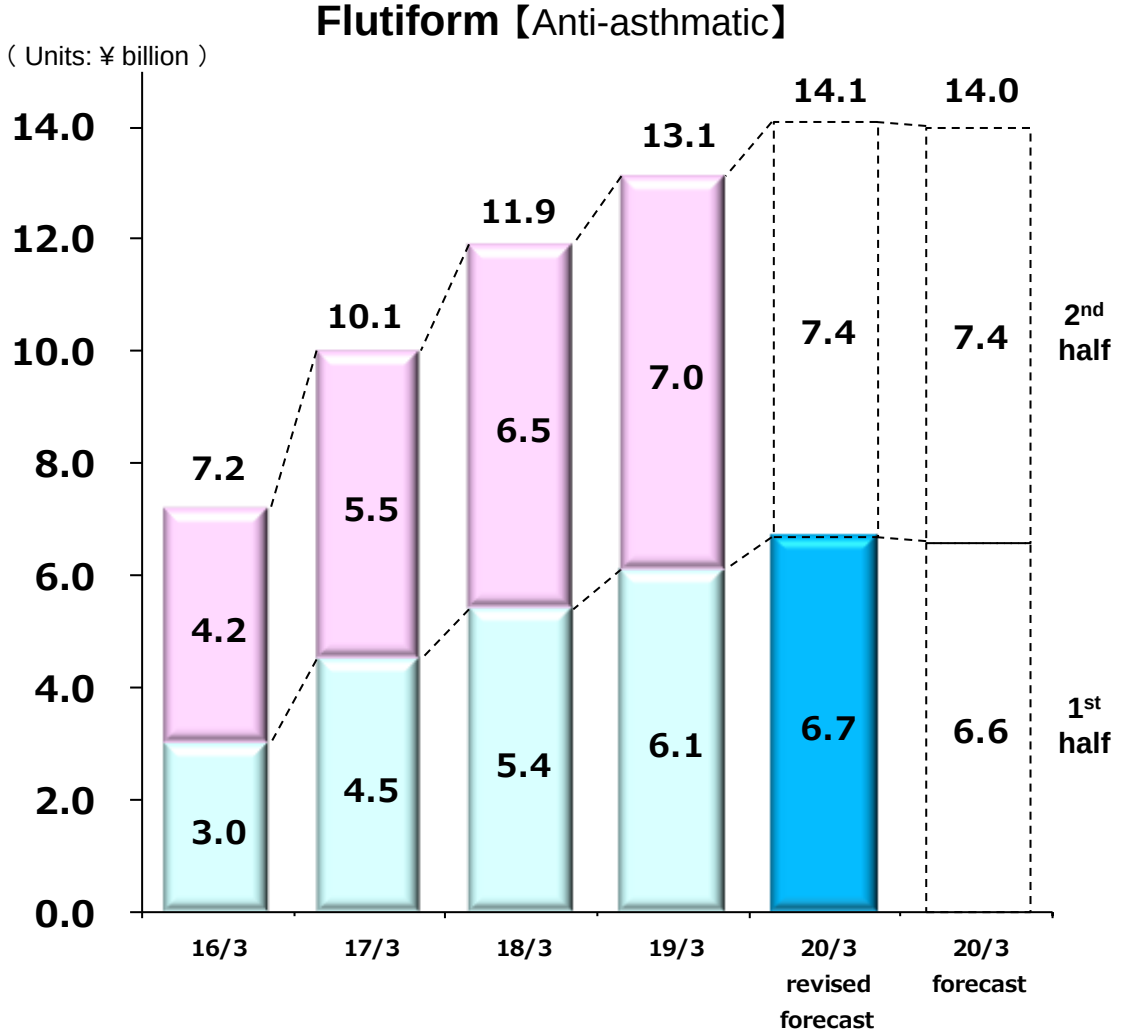
Trends of mainstay products and Generic drugs

■ Respiratory/Otolaryngology



■ Status in first half 2019

- **ICS/LABA market：expand 7.2%**
  ¥56.7bln（FY18 first half）⇒ ¥60.8bln（FY19 first half） ※1
- **share of Flutiform sales**
  11.9%（FY18 first half ）⇒ 12.6%（FY19 first half ）※2

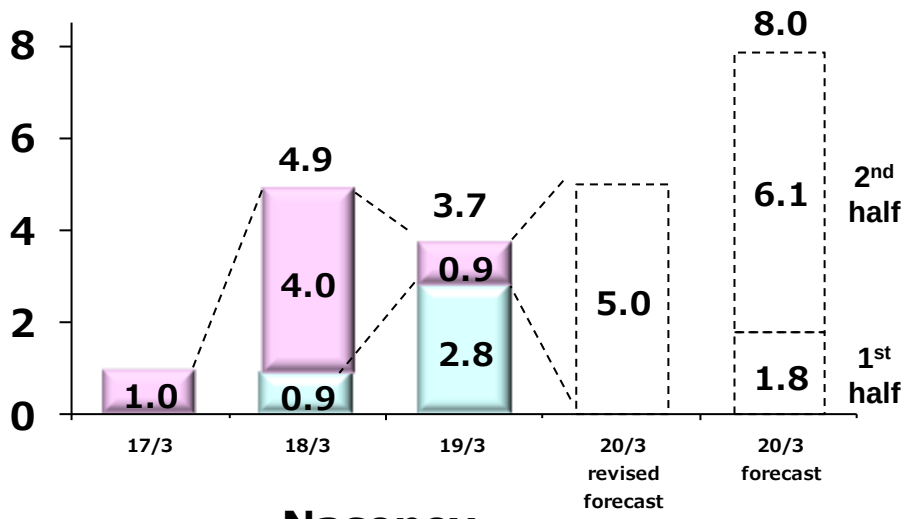
■ effort for FY2019

- **Secure the positioning of a first-line drug for the treatment of asthma**
  - ・Attract attention to the clinical impact from a patient with symptoms
  - ・The agent spreads into the overall lung, including central and peripheral areas.
  - ・Easy to use for inhalation

■ Respiratory/Otolaryngology

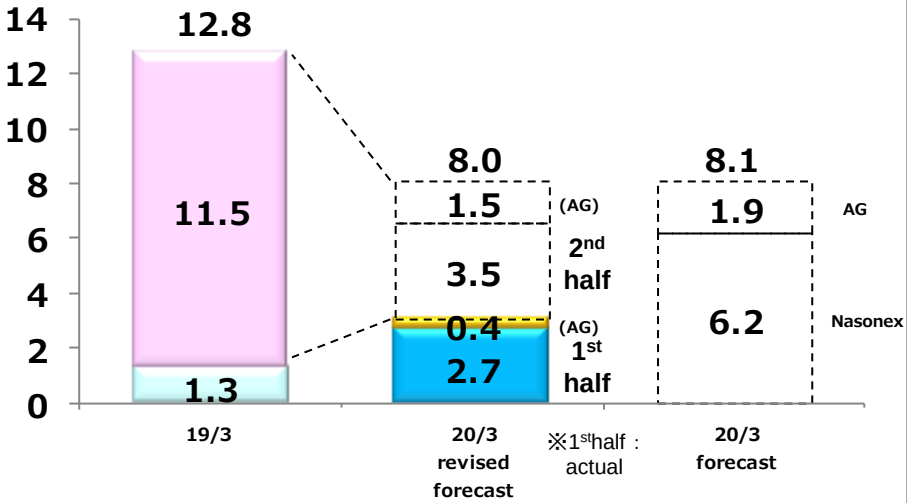
（Units: ¥ billion）

Desalex(Antiallergic Agent)



Nasonex Spray type allergic rhinitis remedy)

（Units: ¥ billion）



Desalex

Resumption of supply

■ **MSD has completed the pharmaceutical procedures**

・Acquired certification as an overseas manufacturer of drug substance storage facilities.

・Acquired approval for changes to the production/marketing approval document.

◆Efforts will be made to ensure the resumption of supply and the securing of inventories considered necessary for stable supply thereafter.

■ **the date of resumption of supply: November 18,2019(estimate)**

■Status in first half 2019

◆**Antihistamine market： expand 3.4%**

¥68.8bin（FY18 first half） ⇒ ¥71.1bin （FY19 first half） ※1

■ effort for FY2019

◆We will strive to spread the product among users by spotlighting its clinical effects, interactions and safety again. Through such efforts, we will increase the number of cases in which the product is adopted while also reviving treatments.

Nasonex

■Status in first half 2019

◆**Spray type allergic rhinitis remedy market : expand 1.3%**

¥15.5bin（FY18 first half） ⇒ ¥15.7bin （FY19 first half） ※1

◆share of Nasonex sales

36.4% （FY18 first half） ⇒ 31.7% （FY19 first half） ※2

●**Released Mometasone Nasal（AG）:August 2019**

■ effort for FY2019

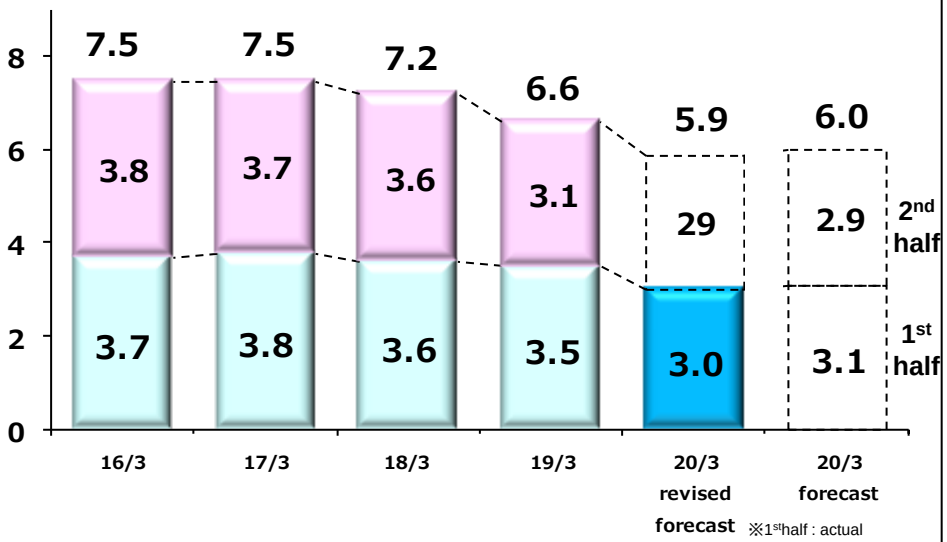
◆With a focus on ear and nose treatments, we will propose the proper use of DESALEX and KIPRES (Montelukast KM) based on symptoms. In doing so, we will continue to provide optimal rhinitis treatments in response to needs

■Urology

OAB market

（Units: ¥ billion）

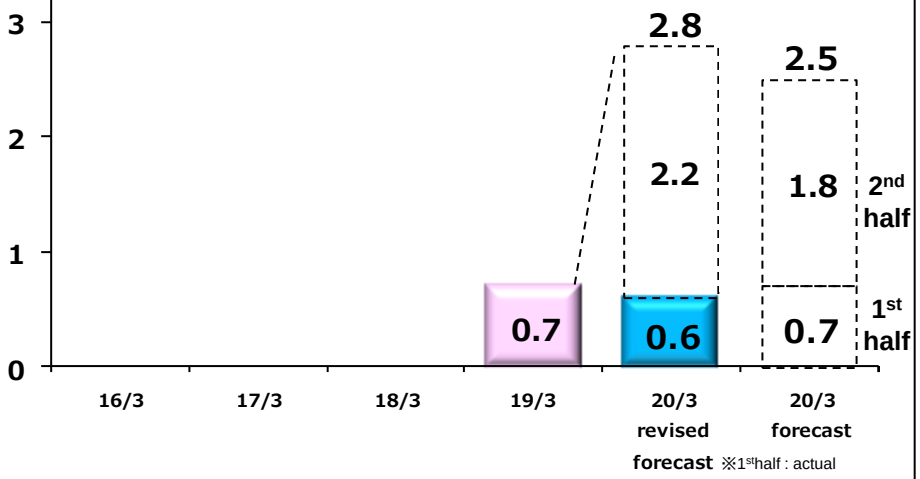
Uritos（Overactive bladder）



※1stHalf : actual

（Units: ¥ billion）

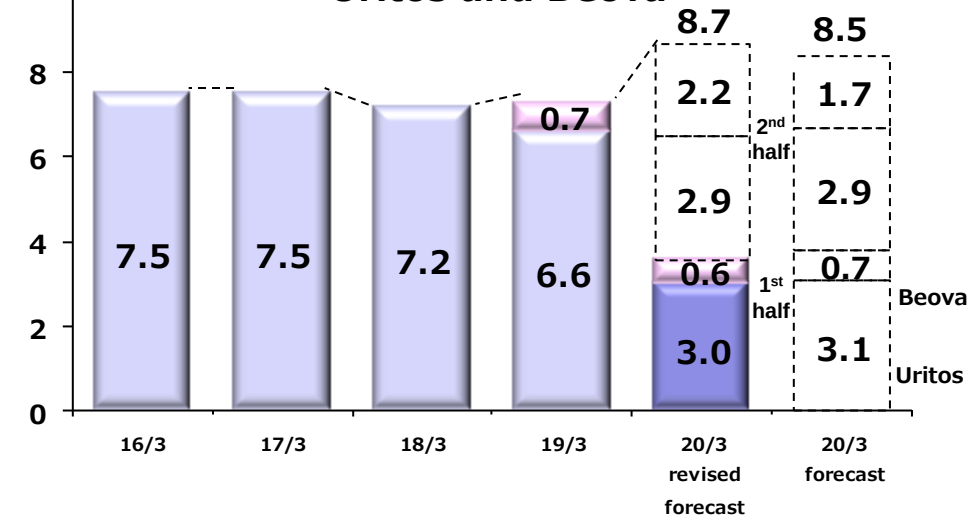
Beova（Overactive bladder）



※1stHalf : actual

（Units: ¥ billion）

Uritos and Beova



■Status in first half 2019

◆ **OAB market expand：5.2%**

44.3bln（FY18 first half） ⇒ 46.6bln（FY19 first half）※1

◆**share of Uritos sales**

8.6%（FY18 first half） ⇒ 7.5%（FY19 first half）※2

◆ **share of Beova sales**

1.8%（FY19 first half）※2

■effort for FY2019

◆**Uritos：Succeeded in acceptable product positioning (OAB patients with nocturia)**

◆**Beova：The limits on prescription periods were removed (December 2019)**

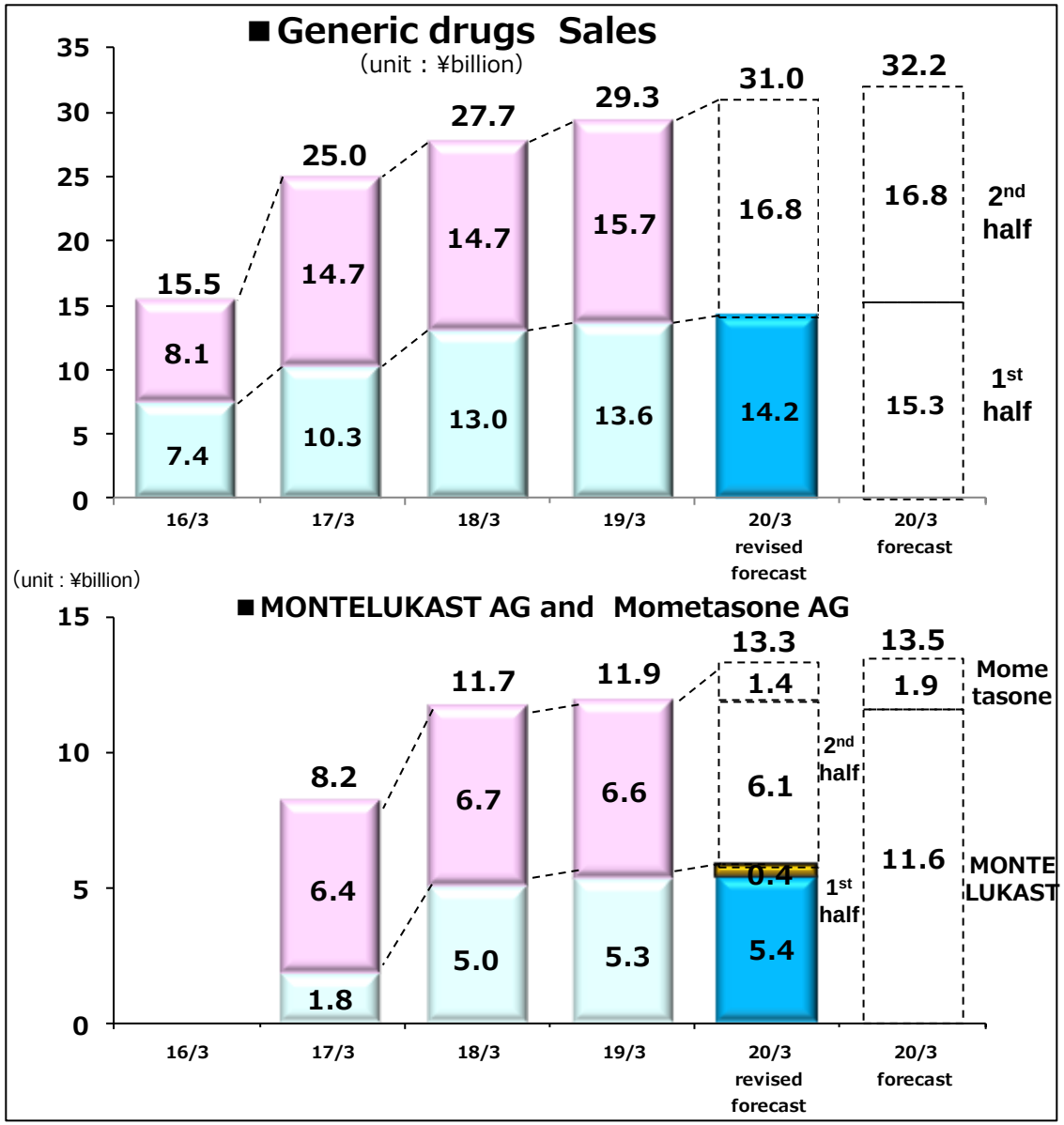
【Popularize the drug to make sure it is chosen as a first-line medicine for OAB treatment】

・The treatment may be applied to different types of OAB patients.

・Clinical effects, interactions and safety are featured.

・Increase the number of medical organizations that use the drug for prescriptions and the number of treatments with the drug, with an eye on removing the limit on prescription periods.

■Status of Generic Drugs



■ Status in first half 2019

◆ Promotion of AG strategy

- MONTELUKAST AG ￥5.4bin(＋￥0.1bln)
- Mometasone AG ￥0.4bin(＋￥0.4bln)
- Acquired production/marketing approval for IMIDAFENACIN (Uritos) AG.

◆ Generic drugs released in June 2019

Silodosin tablets 2mg / 4mg, OD 2mg / 4mg
Mecobalamin tablets 500μg

■ Effort for FY2019

- **Actions for an authorized generic drug (AG)**
  - ・Aim to achieve a large market share of more than 50% for MONTELUKAST AG in the GE market

Consolidated Financial Results and Forecast

Consolidated Financial Results Forecast for the Year Ending March 31, 2020

※The results forecasts for the fiscal year ending March 31, 2020 announced on May 13, 2019 are revised.

(unit : ¥billion)

			FY2018	FY2019 (revised forecast)	Y/Y Change	Y/Y Change(%)	FY2019 (original forecast)	Versus the revised forecast
Net sales			113.6	**109.4**	−4.2	−3.7	114.1	−4.7
Ethical drugs business			107.9	103.4	−4.5	−4.1	108.0	−4.6
	Sales of new ethical drugs		78.5	72.4	−6.1	−7.8	75.8	−3.4
		Japan	77.7	71.0	−6.7	−8.6	74.4	−3.4
		Overseas	0.8	1.4	+0.6	+68.7	1.3	+0.1
	Generic drugs		29.3	31.0	+1.7	+5.7	32.2	−1.2
Healthcare Business			5.8	5.9	+0.1	+2.4	6.1	−0.2
Operating Income			9.0	**6.5**	−2.5	−27.6	9.1	−2.6
Ordinary Income			9.4	**7.1**	−2.3	−24.8	9.6	−2.5
Net Income			6.9	**5.4**	−1.5	−21.4	7.1	−1.7

■Main factors behind revision of forecast

Net sales : we revised forecast of the sales because reviewed the sales of DESALEX Tablets 5 mg that was determined to resume supply in November and Lasvic Tablets 75 mg that was given the marketing approval in September with a result of taking financial results in the first half.

Operating income : Gross profit decreased due to a fall in net sales and rise in the cost of sale ratio (approximately 0.5 point). With respect to selling expenses and research and development expenses, certain reductions were made to initial projections.

■ Main factors in year-on-year change

Net sales : In new ethical drugs (Japan), sales of new drugs such as Beova, DESALEX and Lasvic Tablets will increase. However, net sales are expected to decline mainly due to a decline in the number of prescriptions with Nosonex and long-listed drugs . In generic drugs, sales are expected to rise, chiefly reflecting the release of MOMETASONE AG.

Operating income : Gross profit will decrease due to a fall in net sales, although the cost of sales ratio is expected to decline. （the cost of sales ratio : down about 0.5points）
increase SG & A expenses（ SG&A ratio (excluding R&D expenses) ：up about 2points. Decrease R&D expenses ¥0.2bln : ¥10.8bln→¥10.6bln

Forecast of Mainstay Product Sales

※The results forecasts for the fiscal year ending March 31, 2020 announced on May 13, 2019 are revised.

（Units: ¥ billion）

	FY2018	FY2019 (revised forecast)	Y/Y		FY2019 (original forecast)	Versus the revised forecast
			Change	Change(%)		Change
Flutiform (Combination drug for asthma treatment)	13.1	**14.1**	+1.0	+8.0	**14.0**	+0.1
Desalex (Antiallergic Agent)	3.7	**5.0**	+1.3	+34.4	**8.0**	−3.0
Kipres for adult (Leukotriene Receptor Antagonist)	6.2	**4.7**	−1.5	−24.5	**4.5**	+0.2
for children	7.6	**6.3**	−1.3	−17.4	**6.1**	+0.2
Nasonex （Spray type allergic rhinitis remedy）	12.8	**6.2**	−6.6	−51.4	**6.2**	0
Uritos（Kyorin） (Therapeutic agent for overactive bladder)	6.6	**5.9**	−0.7	−10.7	**6.0**	−0.1
Beova (β3 adrenergic receptor agonist overactive bladder therapeutics)	0.7	**2.8**	+2.1	+278.6	**2.5**	+0.3
Pentasa (Ulcerative colitis and Crohn's disease treatment)	13.5	**12.7**	−0.8	−6.3	**12.0**	+0.7
Mucodyne （Mucoregulant）	6.8	**6.1**	−0.7	−9.6	**6.0**	+0.1
MONTELUKAST Tablets "KM" （LT receptor antagonist）	11.9	**11.5**	−0.4	−3.3	**11.6**	−0.1
Mometasone Nasal 50mg "KYORIN" （Spray type allergic rhinitis remedy）	0	**1.8**	+1.8	−	**1.9**	−0.1
Milton (Disinfectant)	2.2	**2.2**	0	+1.4	**2.3**	−0.1

Shareholder Returns

Basic 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 per share for fiscal 2019 (estimate): ¥75 (including interim dividend of ¥30)

Dividends

	FY2017	FY2018	FY2019 (forecast)
Dividend per share (Yen)	¥58 (interim ¥20)	¥75 (interim ¥30)	¥75 (interim ¥30)

Status of development pipeline

Drug Development Pipeline:
schedule in FY2019

shedule in FY19 [May 13, 2019]

	development code	Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	application	Approval/	Launch
Respiratory	Ad-SGE-REIC	End of the Ph Ⅰ／Ph Ⅱ	Ph Ⅱ Start 2018/6				
	KRP-108P			2017/6	Preparation	Expecting to create an Application in FY19	
Infections	KRP-AM1977X				2017/4		FY19 Expected Release
	KRP-AM1977Y				Preparation	Expecting to create an Application in FY19	
Urological	KRP-116D			2017/3	Preparation	Expecting to create an Application in FY19	
	KRP-N118 (SK-1404)		Ph Ⅱ Start2018/8				

※ MK-7264, a drug for chronic coughing: MSD is working on Phase III development. Concluded a memorandum of understanding for sales collaboration（2019/5）.

【 Licensing development】

開発コード	導出先	開発段階	特徴
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	Implementing licensing activities	**Ph Ⅰ**	Sphingosine-1-Phosphate Receptor Agonist Therapy area　GvHD
	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, Kyorin receive the return of development rights.		

Drug Development Pipeline:

Progress in FY2019 2Q and schedule in FY2019

shedule in FY19　　progress in FY19 2Q [November 7,2019]

	development code	Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	application	Approval/	Launch
Respiratory	Ad-SGE-REIC	End of the Ph Ⅰ／Ph Ⅱ	Ph Ⅱ Start 2018/6				
	KRP-108P			2017/6	2019/7	Application	
Infections	KRP-AM1977X				2017/4	2019/9	FY19 Expected Release
	KRP-AM1977Y				2019/10	Application	
Urological	KRP-116D			2017/3	Preparation	Expecting to create an Application in FY19	
	KRP-N118 (SK-1404)		Ph Ⅱ Start2018/8				

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KRP-203	Implementing licensing activities	**Ph Ⅰ**	Sphingosine-1-Phosphate Receptor Agonist Therapy area　GvHD
	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, Kyorin receive the return of development rights.		

Initiatives toward realization of the long-term vision “HOPE 100”

For continuous growth（Refinement of pharmaceutical Business）

Kyorin 健康はキョーリンの願いです。

Medium-term management plan “HOPE100－Stage 2－” （2016-2019）

＜Drug Discovery＞

■Initiatives for first-in-class New drug discovery

・Establishment of system for continual generation of innovative new drugs

＜New Drug Business＞

■ Increase in the Ratio of New Drugs Group

・Make the four new drugs (including those developed in-house) the driving force

＜ Generic Drugs Business ＞

■Promotion of Generic Drugs Business by Making the Most of Its Characteristics

・promotion of AG strategy

＜ New businesses ＞

■ Development of the diagnostic business and establishment of a foundation

Progress in FY2019

◆FPR2 Agonist Program

: Presented three themes at two overseas academic conferences.

◆KRP-116D

: Presented two themes at two academic conferences.

◆ Lasvic tablets

: Production/marketing approval acquired Expected Release in FY2019

◆KRP-AM1977Y

: Applied for production / marketing approval（October）

◆Beova

: It will be removed the limit on prescription periods （December 1）

◆Desalex

: Resumption of supply is estimated on November 18

◆ Flutiform

: Applied for production / marketing approval for KRP-108P（August）

◆ Mometasone Nasal Released AG(August)

◆ Acquired production / marketing approval for **IMIDAFENACIN (Uritos)AG**（August）

◆Microchannel-based Genetic Measurement Device 「GeneSoC®」, special-purpose measurement chip

To be released on November 11.

FPR2 Agonist Program

BMS and Kyorin have given a total of three presentations on this FPR2 agonist (development code: BMS-986235/LAR-1219) at 2 academic conferences

American Chemical Society National Meeting (San Diego)

■ Aug. 28, 2019:Poster presentation

Discovery of clinical candidate, BMS-986235/LAR-1219, design and optimization of selective 4-phenylpyrrolidinone FPR2 agonist

■ Aug. 28, 2019:Oral presentation

Discovery of clinical candidate, BMS-986235/LAR-1219: Selective FPR2 agonist for prevention of heart failure

European Society of Cardiology Congress (Paris, France)

■ Sept. 1, 2019:Oral presentation

A selective small-molecule formyl peptide receptor 2 agonist promotes a pro-resolution macrophage phenotype and improves left ventricular structure-function relationships post myocardial infarction

Summary of oral presentation at ACS

- Discovery of a conformationally constrained urea followed by optimization of FPR2 potency and selectivity, let to the identification of a highly potent and selective FPR2 agonist with excellent PK and ADME properties.

- Significant improvements of remodeling and functional endpoints observed in a mouse heart failure model

- First example of efficacy in a heart failure model with daily oral dosing of a selective, small molecule FPR2 agonist

- BMS-986235/LAR-1219 is currently in Phase 1 clinical trials.

<Drug Discovery>

Therapeutic agent for interstitial cystitis "KRP-116D"

(Name of Ingredient: Dimethyl Sulfoxide)

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Status of Development

●Phase 3 study (completed) **◆ Application in preparation**

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

Study type: multicenter, randomized, double-blinded, placebo-controlled, parallel group, comparative study
Disease name: interstitial cystitis
Primary endpoint: O'Leary & Sant interstitial cystitis symptom index (ICSI)
Secondary endpoints: O'Leary & Sant interstitial cystitis problem index (ICPI), voiding symptoms, and safety, etc.
Number of cases: 96
Dosage and Administration, usage: one intravesical instillation of 50 mL once every two weeks
Remarks: designated orphan drug

Study results

This phase 3 study confirmed the superiority and safety of this compound compared to placebo (Its superiority compared to placebo could be proven for the first time worldwide)

Presentations at academic conferences related to this phase 3 study

Name of academic conference: The 26th Japanese Continence Society (Sept. 12 to 14, 2019)
[Topic] Therapeutic effects of KRP-116D (50% dimetyl sulfoxide) in Japanese patients with interstitial cystitis

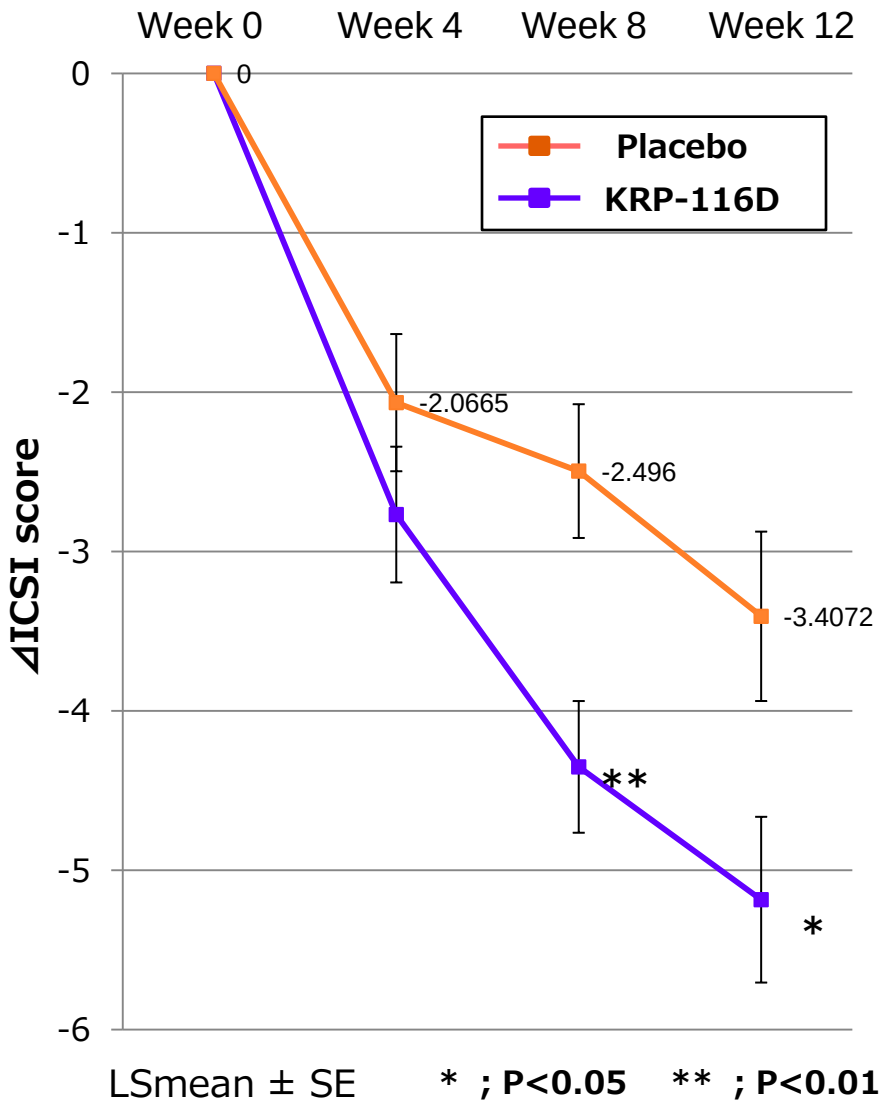
Name of academic conference: ICS2019 (Sept. 3 to 6, 2019)
[Topic] A randomized, double-blinded, placebo-controlled multicenter trial on the efficacy and safety of the intravesical instillation of KRP-116D (50% dimetyl sulfoxide) in Japanese patients with interstitial cystitis/bladder pain syndrome

<Drug Discovery>

Efficacy endpoints (ICSI, bladder diary)

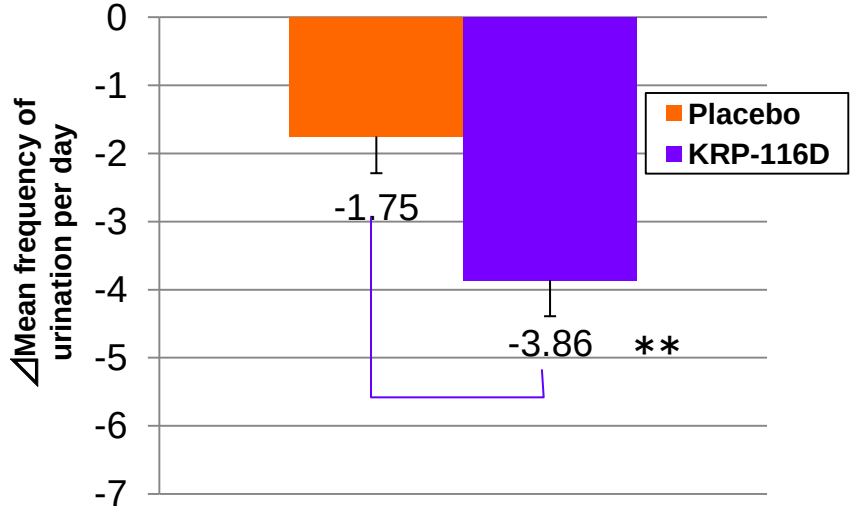
Changes from baseline

Changes in ICSI over time (primary endpoint)

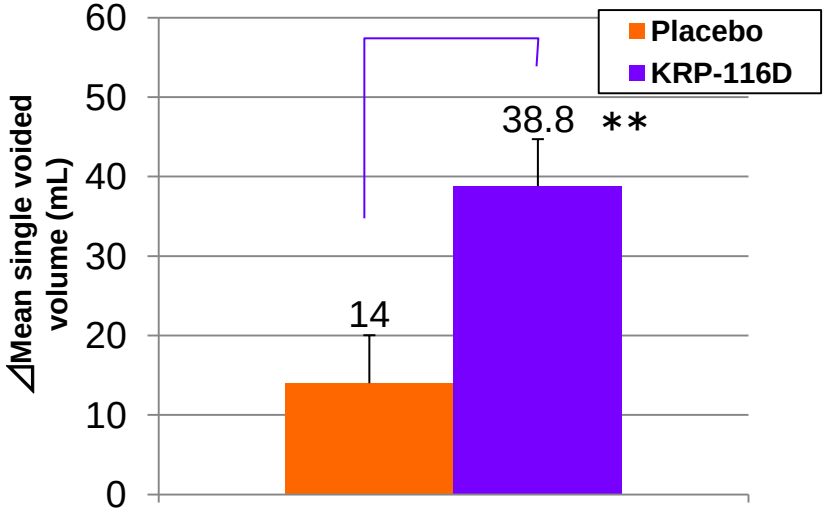


Bladder diary (after 12 weeks) (secondary endpoints)

Mean frequency of urination per day



Mean single voided volume



Overview of study results

■ Regarding the primary endpoint (ICSI) the superiority of KRP-116D compared to placebo could be verified, and thus the goal of this study was achieved

■ The efficacy of KRP-116D was confirmed for all endpoints, including subjective and objective endpoints

■ The incidence of adverse events for which a causal relationship could not be denied was 59.2% in the KRP-116D group, and 27.7% in the placebo group, and no serious adverse reactions were observed

<New Drug Business>

"KRP-AM1977X" and "KRP-AM1977Y"

- **Generic name: lascufloxacin hydrochloride**
- **Abbreviation: LSFX**
- **Classification: quinolone antimicrobial**

[Aim of the development of this drug]

Our aim was to develop a new therapeutic agent that is effective for treatment of pneumonia, etc., and with low risks regarding safety and tolerance

- To strengthen antibacterial activity against bacteria that cause respiratory tract and ENT infections (particularly aerobic Gram-positive bacteria and anaerobic bacteria)
- Improve its transfer to tissues of the lung, ear, nose and throat
- Exerts sufficient antibacterial activity at the therapeutic target, and impedes the expression of resistant bacteria, while suppressing systemic exposure

Lasvic tablets 75mg: Received marketing approval in Sept. 2019

◆Indications: Pharyngeal laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, secondary infection of chronic respiratory lesions, otitis media, and sinusitis

◆Dosage and Administration: 75mg orally once daily

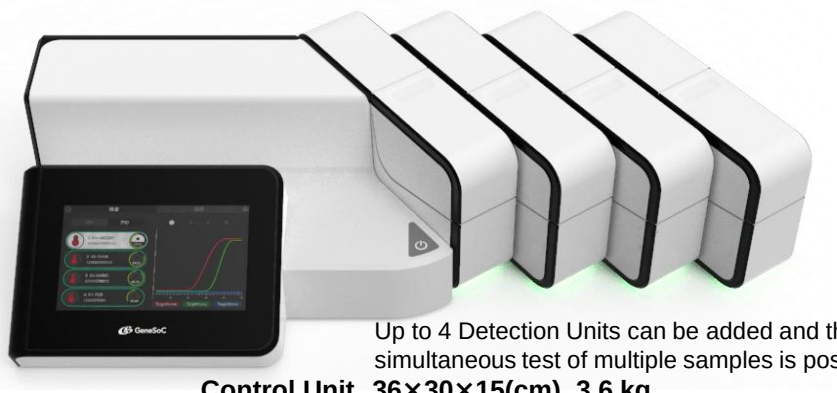
KRP-AM1977Y: Application was submitted in Oct. 2019

◆Diseases included in the phase 3 study: Community-acquired pneumonia, secondary infection of chronic respiratory lesions, aspiration pneumonia, pulmonary suppuration, and lung abscess

◆Dosage and Administration in the phase 3 study: Intravenous administration of 150mg once daily (administration of double dose on the starting day of administration)

Microchannel-based Genetic Measurement Device「GeneSoC®」

Microfluidic Real-Time PCR System
GeneSoC®



Up to 4 Detection Units can be added and the simultaneous test of multiple samples is possible

Control Unit 36×30×15(cm), 3.6 kg

Characteristics

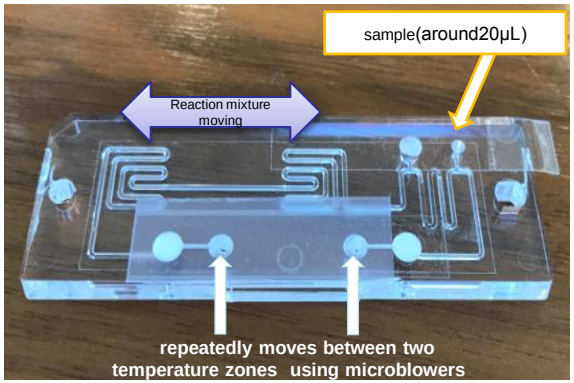
GeneSoC : Gene Sensor on a Chip

- Rapid detection of genes based on the technology of ultrafast quantitative PCR* (5-15 minutes)
- High-sensitivity detection is possible with a trace amount of the sample immediately after infection
- A compact, desktop PCR device eyeing POCT*

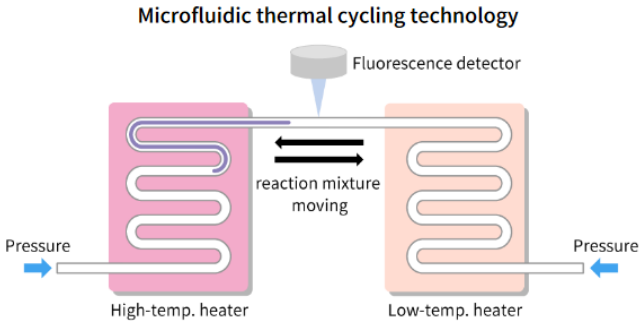
Identification of pathogenic bacteria of infection by POCT and improvement of treatment with the choice of an appropriate antibacterial agent

※1 PCR (Polymerase Chain Reaction): A technique of selectively amplifying DNA arrangements.
※2 POCT (Point of Care Testing): Testing carried out by a healthcare worker at a patient's bedside.

- To be released on November 11 (as laboratory equipment)
  - Microchannel-based Genetic Measurement Device「GeneSoC®」, special-purpose measurement chip
  - Dedicated analytical reagents will be released gradually.
- Aim to launch dedicated in-vitro diagnostics kits in 2021 after filing application as a medical device.



Measurement chip 7.6×2.6(cm)



In GeneSoC®, a small volume of reaction mixture repeatedly moves between two temperature zones in a short microchannel for thermal cycling using microblowers. With our technology, nucleic acid amplification occurs faster, with a more compact instrument, and less power consumption.

Our group's efforts in the field of infectious diseases

Kyorin
健康はキョーリンの願いです。

Microchannel-based Genetic Measurement Device「GeneSoC®」

※ To be released on November 11 (as laboratory equipment)

Diagnostic equipment and diagnostics

Diagnosis

Treatment

Prevention

Ethical drugs

※ Production/marketing approval acquired / Not listed in the drug pricing standard

Oral Quinolone Antibacterial Agent **「Lasvic® tablets 75mg」**

「KRP-AM1977Y」

broad-spectrum antibiotic **「Baccidal tablets」**

Multi-purpose disinfectant cleaner
「RUBYSTA®」

Disinfectant
「Milton」

Aim to establish a business model of infectious diseases about Prevention, Diagnosis and Treatment.


Kyorin

November 7, 2019

NEWS RELEASE

Company:	KYORIN Holdings, Inc.
Representative:	Yutaka Ogihara Representative Director, President (Securities Code: 4569, TSE 1st Sec.)
Contact:	Yoshinori Tanifuji Director, Corporate Planning
Telephone:	(0)3-3525-4707

KYORIN and JEIL Signed License Agreement for Vibegron in Korea

KYORIN Holdings, Inc. today announced that its wholly owned subsidiary of KYORIN Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo, President & CEO: Shigeru Ogihara, "Kyorin") signed a license agreement with JEIL Pharmaceutical Co., Ltd. (Head office: Seoul, Korea, President & CEO: Suk Je, Sung, "JEIL") to grant to JEIL an exclusive license to develop, manufacture and commercialize vibegron, an overactive bladder (OAB) therapeutic agent, in Korea.

Vibegron is a novel once-daily β3-adrenergic receptor agonist that was discovered by Merck & Co., Inc., Kenilworth, N.J., U.S.A., known as MSD outside the United States and Canada ("Merck"). It acts selectively on the bladder's β3-adrenergic receptor, relaxes the bladder and enhances the urine collection, and consequently improves the symptoms of urgency, urinary frequency and urge urinary incontinence associated with OAB.

Kyorin acquired from Merck an exclusive license to develop, manufacture and commercialize vibegron in Japan in July 2014 and later expanded the license territory to certain other Asian countries[1] in April 2017. In Japan, Kyorin developed this agent with Kissei Pharmaceutical Co., Ltd. under a co-development and co-marketing agreement entered into as of March 2016, and the companies have been co-marketing the same under the brand name of "Beova® Tablets 50mg" since November 2018.

Kyorin is committed to prevailing vibegron into Japanese market and contributing to improve the QOL of patients suffering from OAB symptoms. The partnership with JEIL will allow Kyorin to promote the penetration of vibegron in the Korean market as well and accelerate its global business expansion.

The impact of this transaction is reflected in the revised financial forecast for the fiscal year ending March 31, 2020 announced today.