# Financial Results

Ended March 2023

May 12, 2023
KYORIN Pharmaceutical Co., Ltd.
Representative Director, President and CEO
Yutaka Ogihara





## **Outline of Consolidated Financial Results**

Trends of mainstay products, generic product

**Consolidated Financial Forecast** 

**Status of R&D Pipeline** 

Overview of the Long-term Vision "HOPE 100 –Stage 3–"

New Long-term Vision "Vision 110" (FY2023-FY2032) and Medium-term Business Plan "Vision 110 – Stage 1–" (FY2023-FY2025)



# **Outline of Consolidated Financial Results**

# Breakdown of Gain and Loss FY2022



(Units: JPY billions)

|                          |                            | FY2021            | FY2021 <b>FY2022</b> |                    | Year-on-year    |              |
|--------------------------|----------------------------|-------------------|----------------------|--------------------|-----------------|--------------|
|                          |                            |                   |                      | Change             | Change (%)      | Change       |
| Net Sales                |                            | 105.5             | 113.3                | +7.8               | +7.3            | + 1.3        |
|                          | New drugs, etc.<br>(Japan) | 69.7              | 74.8                 | +5.1               | +7.2            | +0.3         |
|                          | New drugs (Overseas)       | 1.0               | 0.3                  | -0.7               | -70.1           | -0.4         |
|                          | Generic drugs              | 34.8              | 38.2                 | +3.4               | +9.8            | +1.5         |
| Cost of sales            |                            | 56.1              | 63.1                 | +7.0               | +12.5           | -            |
| SG&A<br>(R&D)            |                            | <b>44.4</b> (8.9) | <b>45.0</b> (10.9)   | <b>+0.6</b> (+2.0) | +1.4<br>(+22.5) | <b>-</b> (0) |
| Operating profit         |                            | 5.0               | 5.1                  | +0.1               | +2.3            | -0.4         |
| Ordinary<br>profit       |                            | 5.6               | 5.8                  | +0.2               | +4.6            | -0.2         |
| Profit attribu<br>parent | table to owners of         | 3.9               | 4.7                  | +0.8               | +20.1           | +0.2         |

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





#### [Net Sales 113.3]

New drugs, etc. (Japan): sales increased

+5.1

[Factors of increase]

- New drugs (Beova, Dezalex, Lasvic) grew
- Increase in sales of out-licensing product (Beova)

[Factor of decrease]

Decrease in sales of long-listed products

New drugs (Overseas): sales decreased

-0.7

Decline in the income of lump-sum payment of out licensing product

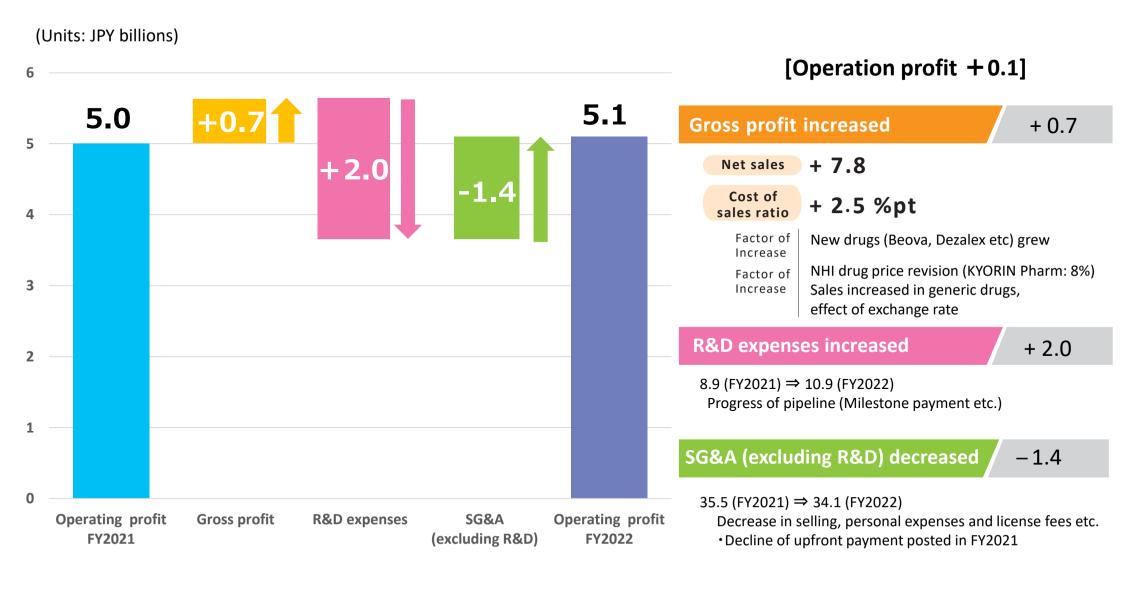
Generic drugs: sales increased

+3.4

- Increase in sales of Kipres AG and Nasonex AG etc.
- New generic drugs launched in FY2022 contributed to sales

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





# Highlights of Business Performance (3/3) vs Forecast



(Units: 1PY billions)

|                |                            | FY2021        | FY2022         | Year-on-year     |                   | vs forecast<br>(announced on May 11, 2022) |
|----------------|----------------------------|---------------|----------------|------------------|-------------------|--|
|                |                            |               |                | Change           | Change (%)        | Change                                     |
| Net Sales      |                            | 105.5         | 113.3          | + 7.8            | + 7.3             | + 1.3                                      |
|                | New drugs, etc.<br>(Japan) | 69.7          | 74.8           | + 5.1            | + 7.2             | + 0.3                                      |
|                | New drugs (Overseas)       | 1.0           | 0.3            | -0.7             | -70.1             | -0.4                                       |
|                | Generic drugs              | 34.8          | 38.2           | + 3.4            | + 9.8             | +1.5                                       |
| Cost of sales  |                            | 56.1          | 63.1           | + 7.0            | + 12.5            | -  |
| SG&A<br>(R&D)  |                            | 44.4<br>(8.9) | 45.0<br>(10.9) | + 0.6<br>(+ 2.0) | + 1.4<br>(+ 22.5) | _<br>(0)                                   |
| Operating pro  | ofit                       | 5.0           | 5.1            | + 0.1            | + 2.3             | -0.4                                       |
| Ordinary pro   | fit                        | 5.6           | 5.8            | + 0.2            | + 4.6             | -0.2                                       |
| Profit attribu | table to owners of         | 3.9           | 4.7            | + 0.8            | + 20.1            | + 2.0                                      |

#### [Difference from the Forecast (Announced on May 11, 2022)]

Net sales: Sales of new drugs etc. (Japan) and generic drugs exceeded forecast due to increase in sales of Desalex, Nasonex, Kipres AG accompanying high volume of Airborne pollen. Operating profit: Gross profit was lower than forecast due to increase of cost of sales ratio, since sales in new drugs came lower than estimated and sales in generic drugs were increased. SG&A expenses were lower than forecast. As a result, operating profit was slightly lower than forecast. R&D expenses were ¥10.9 bln.

Profit: Extraordinary profit of ¥1,979 mln (gain on insurance of ¥881 mln, income of compensation for damages of ¥401 mln, regarding a fire at Nishinihon delivery center, gain on sale of investment securities ¥685 mln)

Extraordinary loss of ¥900 mln (Impairment losses of ¥110 mln, provision for loss on liquidation of subsidiaries and associates of ¥605 mln regarding dissolution of ActivX)<sub>17</sub>

# FY2022 Main Product Sales Update



(Units: JPY billions)

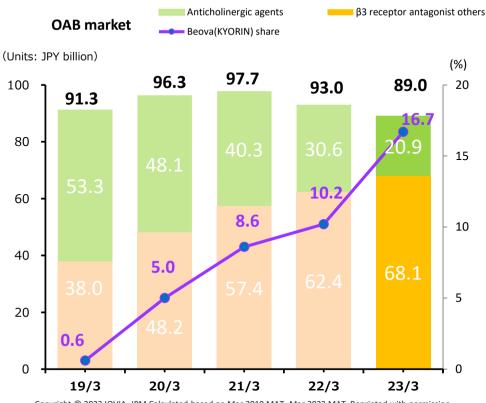
|                  |  |        |                      |        |              | (Offics: JFT billions)             |
|------------------|--|--------|----------------------|--------|--------------|------------------------------------|
|                  |  | FV2021 | FY2021 <b>FY2022</b> |        | Year-on-year |                                    |
|                  |  | FY2021 | 112022               | Change | Change (%)   | (announced on May 11, 2022) Change |
|                  | Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics ) | 8.6    | 12.9                 | +4.3   | + 49.8       | -1.2                               |
|                  | Lasvic (New quinolone synthetic antibacterial agent)                             | 1.8    | 2.5                  | +0.7   | +35.0        | -0.5                               |
|                  | Lyfnua (selective P2X3 receptor antagonist / chronic cough)                      | _      | 0.2                  | +0.2   | _            | -0.3                               |
|                  | Desalex (Antiallergic Agent)   | 7.1    | 8.5                  | +1.4   | +20.6        | + 0.5                              |
|                  | Flutiform (Combination drug for asthma treatment)                                | 12.6   | 12.0                 | -0.6   | -4.8         | 0                                  |
| New drugs,       | Pentasa (Ulcerative colitis and Crohn's disease treatment)                       | 14.0   | 12.8                 | -1.2   | -8.4         | +0.3                               |
| etc. (Japan)     | Kipres<br>(Leukotriene Receptor Antagonist)                                      | 8.4    | 6.6                  | -1.8   | -21.7        | -0.2                               |
|                  | Mucodyne<br>(Mucoregulator)  | 3.5    | 3.5                  | 0      | +1.5         | +0.6                               |
|                  | Nasonex<br>(Spray type allergic rhinitis remedy)                                 | 2.4    | 2.5                  | +0.1   | +4.1         | +0.7                               |
|                  | Uritos (KYORIN) (Therapeutic agent for overactive bladder)                       | 1.3    | 0.7                  | -0.6   | <b>-44.2</b> | 0                                  |
|                  | Milton<br>(Disinfectant)   | 2.1    | 2.0                  | -0.1   | -2.4         | 0                                  |
|                  | Rubysta<br>(Disinfectant)  | 2.1    | 2.1                  | 0      | -0.7         | +0.1                               |
|                  |  |        |                      |        |              |                                    |
|                  | Montelukast tablets "KM" (Leukotriene Receptor Antagonist)                       | 12.2   | 13.3                 | +1.1   | +9.5         | + 2.6                              |
| Generic<br>drugs | Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)             | 3.6    | 4.7                  | +1.1   | + 28.5       | + 1.1                              |
| - 0-             | Imidafenacin tablets & OD"KYORIN" (Therapeutic agent for overactive bladder)     | 0.8    | 0.7                  | -0.1   | -9.9         | + 0.2                              |



# **Trends of Mainstay Products and Generic Drugs**

# [Mainstay products] Beova (Therapeutic agent for OAB)





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#### OAB market: Shrink 4.3%

93.0 (Mar 2022 MAT) ⇒ 89.0 (Mar 2023 MAT)\*

- NHI drug price revision and launch for generic drug
- Market expansion of β3 adrenergic receptor (+9.1%)

#### Share of Beova (KYORIN) sales: Expand 6.5%pt

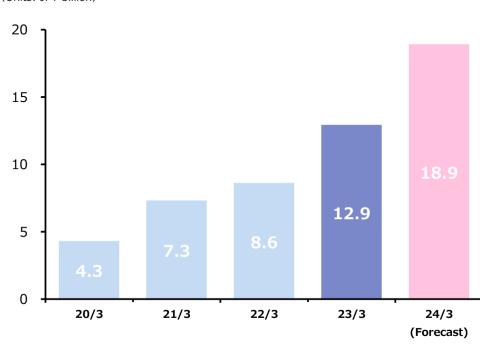
10.2% (Mar 2022 MAT) ⇒ 16.7% (Mar 2023 MAT)\*

#### Medium to long-term market outlook

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

#### Sales

(Units: 1PY billion)



#### Status in FY2022

NHI drug price revision in Apr 2022: - 4.6%

- End of restrictions on shipment in Aug 2022
- Focus on providing information
- Patients acquisition rate of OAB agents: No.1 (for Vibegron)

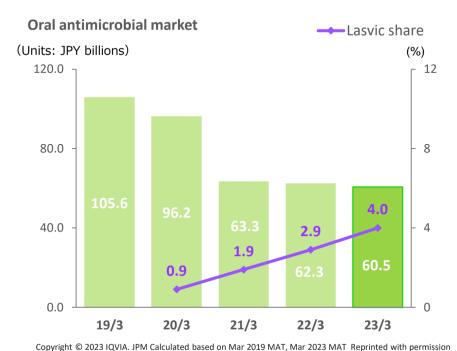
#### Effort for FY2023

NHI drug price revision in Apr 2023: - 4.6%

- Promotion to expand patients acquisition rate of OAB agents
- Aim to establish evaluation of Beova as first line treatment for OAB

# [Mainstay products] Lasvic (New quinolone synthetic antibacterial agent) Kyorin 🔾

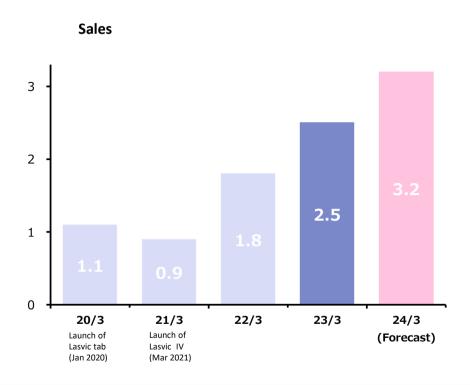




#### Oral antimicrobial market: Shrink 2.9%

- 62.3 (Mar 2022 MAT) ⇒ 60.5 (Mar 2023 MAT)\*
  - Reducing the number of patients due to infection prevention measure result to shrink market.
- Share of Lasvic sales: Expand 1.1 %pt
- 2.9% (Mar 2022 MAT)  $\Rightarrow$  4.0% (Mar 2023 MAT)\*
- Medium to long-term market outlook

Expect to tend to remain flat in oral antimicrobial market for respiratory and otolaryngology



#### Status in FY2022

NHI drug price revision in Apr 2022: - 3.2% (oral), - 0.9% (iv)

 Expand prescriptions in elderly or patients with underlying disease in infection disease

#### Effort for FY2023

NHI drug price revision in Apr 2023: - 5.3% (oral), - 0% (iv)

- Aim to be first line treatment for old people/patients with disease
- Strive for improving the recognition as the drug recommended by the guideline
- Aim to be No.1 share in new guinolone market

# [Mainstay products] Lyfnua (Cough treatment)



The number of estimated patients

Chronic chough patients

2,500 K

**RCC/UCC** patients

400 K ~ 500 K

Definition of Refractory/Unexplained Chronic Cough

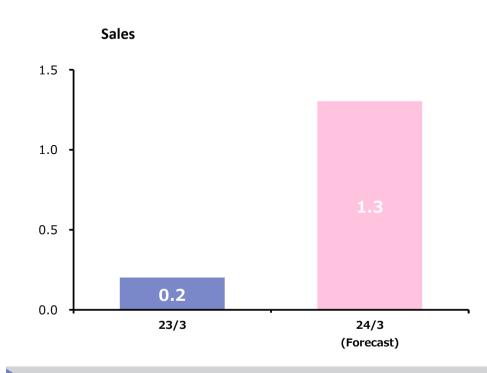
#### RCC/UCC

# Refractory chronic cough

Chronic cough despite the appropriate treatment of primary disease, Asthma, GERD, UACS etc.

# Unexplained chronic cough

Cough without identify primary disease, despite the thorough diagnostic evaluation is preformed.



#### Status in FY2022

- Enhancement of better understanding for product characteristic to respiratory specialists
- Strive to promote in university hospitals or core hospitals Issue: Difficult to diagnosis and recognize the patients of RCC/UCC

#### Effort for FY2023

Dismantling of prescription limitation on May

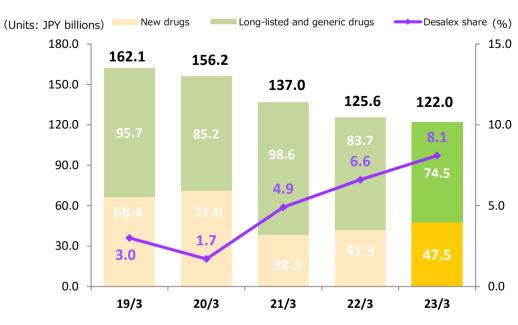
- Appealing that Lyfnua is the only drug which has indication for refractory chronic cough
- Growth of prescriptions for the patients with chlonic cough despite treatment
- Spread of understanding from Dr to Dr

GERD: gastroesophageal reflux disease UAUS: upper airway cough syndrome

# [Mainstay products] Desalex (Antiallergic Agent)



#### **Antihistamine market**



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#### Antihistamine Market: Shrink 2.8%

125.6 (Mar 2022 MAT)  $\Rightarrow$  122.0 (Mar 2023 MAT)\*1

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

#### Share of Desalex sales: Expand 1.5 %pt

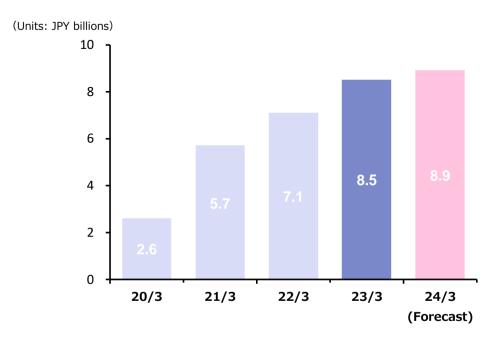
6.6% (Mar 2022 MAT)  $\Rightarrow$  8.1% (Mar 2023 MAT)\*1

Dec 2018 single month: 6.3% (Before supply suspension)
 ⇒ 10.0% \*2 (Mar 2023 single month)

#### Medium to long-term market outlook

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

#### Sales



#### > Status in FY 2022

NHI drug price revision in Apr 2022: - 9.6%

Appealing as effective and usability drug
 Usability: less sleepiness, no-limitation for drive, administration with or without meals

#### Effort for FY 2023

NHI drug price revision in Apr 2023: - 9.1%

Aim to be first line treatment as effective and usability drug

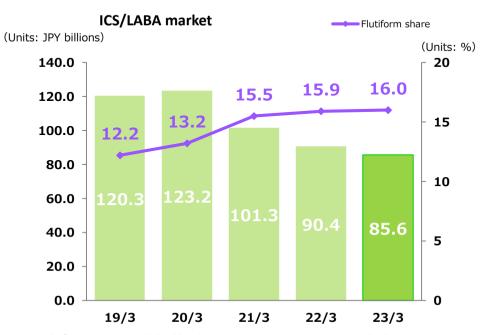
• Aim to be No.1 prescription in otolaryngology

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# [Mainstay products] Flutiform (Anti-asthmatic)





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#### ICS/LABA market: Shrink 5.4%

90.4 (Mar 2022 MAT) ⇒ 85.6 (Mar 2023 MAT)\*1

- Impact of NHI drug price revision and expansion of triple therapy
- Launch of GE in competing product

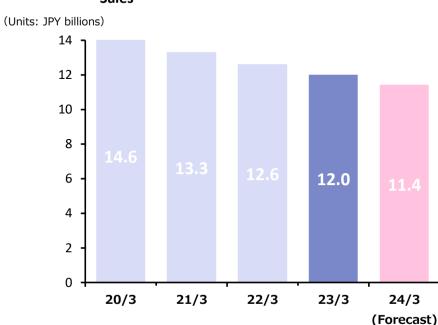
#### Share of Flutiform sales: Expand 0.1 %pt

15.9% (Mar 2022 MAT) ⇒ 16.0% (Mar 2023 MAT)\*1

#### Medium to long-term market outlook

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

#### Sales



#### Status in FY 2022

NHI drug price revision in Apr 2022: - 6.2%

- Appeal the utility of aerosol formulations to suitable for patient with weak inspiration
- Increase market share on a volume-basis 17.3% (Mar 2022 single month) ⇒ 17.8% (Mar 2023 single month)

#### Effort for FY 2023

NHI drug price revision in Apr 2023: - 6.1%

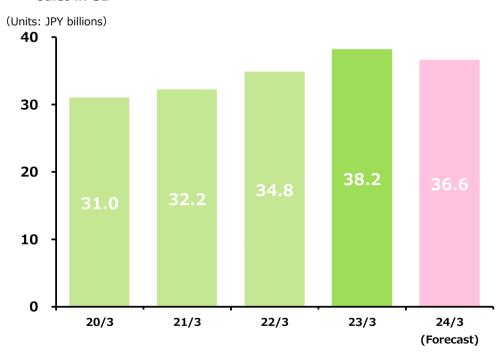
- Appeal the utility and easy-to-use of aerosol formulation
   Elderly patients and those have inflammations of small airways in asthma
- Aim to sustainable growth

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# **Status of Generic Drugs**



#### Sales in GE



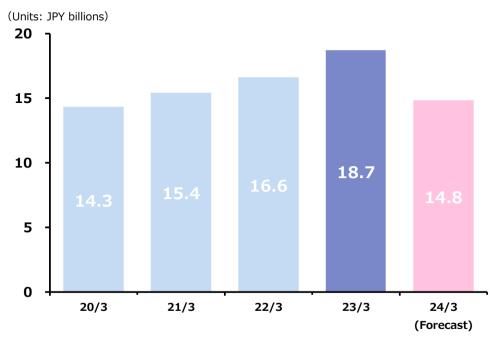
#### > Status in FY2022

- Increased market share for strategic products
- Launched new products

Jun 2022
O Febuxostat tablets 10mg/20mg/40mg
O Duloxetine Capsules 20mg/30mg

Dec 2022
Ramelteon Tablets 8mg
O Esomeprazole Capsules 10mg/20mg

#### Sales in AG (three products) among with the sales at left



#### Effort for FY2023

- Expand sales of strategic products
- Strive for stable supplyOptimization of manufacturing and order plan
- Launch new products

June 2023 Eplerenome tablets 25mg/50mg/100mg
Fluticason FR Nasal Solution 27.5µg 50/120
Azilsaltan OD tablets 20mg/40mg



# **Consolidated Financial Forecast FY2023**

#### **Consolidated Financial Forecast FY2022**



(Unit: JPY billion)

|                              |                            |                |            | Year        | -on-year       |
|------------------------------|----------------------------|----------------|------------|-------------|----------------|
|                              |                            | FY2022         | FY2023     | Change      | Change (%)     |
| Net Sales                    |                            | 113.3          | 116.2      | + 2.9       | + 2.6          |
|                              | New drugs, etc.<br>(Japan) | 74.8           | 79.1       | + 4.3       | + 5.8          |
|                              | New drugs<br>(Overseas)    | 0.3            | 0.4        | + 0.1       | + 29.6         |
|                              | Generic drugs              | 38.2           | 36.6       | -1.6        | -4.2           |
| Cost of sales                | 5                          | 63.1           | -          | -           | -              |
| SG&A (R&D)                   |                            | 45.0<br>(10.9) | -<br>(9.6) | -<br>(-1.3) | -<br>( – 12.0) |
| Operating p                  | rofit                      | 5.1            | 6.0        | + 0.9       | + 17.1         |
| Ordinary pro                 | ofit                       | 5.8            | 6.5        | + 0.7       | + 11.5         |
| Profit attribution of parent | utable to owners           | 4.7            | 4.9        | + 0.2       | + 3.7          |

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

Net sales: The sales of new drugs (Japan) are expected to increase due to expansion in sales of mainstay products, Beova, Lyfnua and Lasvic etc. The sales of generic are expected to decrease due to decline of sales in AG etc. Net sales are expected to increase.

Operating profit: Gross profit are expected to increased although impact on NHI drug price revisions. Operating profit are expected to increase despite increase SG&A expenses.

Cost of sales ratio: approx. −1.5%pt. SG&A expenses (excluding R&D expenses): approx. +2%pt. R&D expenses: −1.3 (from 10.9 to 9.6 billion yen)

# **Forecast of Mainstay Products Sales**



(Unit: JPY billions)

|                  |   | FY2022 | FY2023     | Year-on-year |               |
|------------------|---|--------|------------|--------------|---------------|
|                  |   | F12022 | (Forecast) | Change       | Change (%)    |
|                  | Beova (KYORIN) (β3 adrenergic receptor agonist overactive bladder therapeutics) | 12.9   | 18.9       | + 6.0        | + 46.8        |
|                  | Lasvic (New quinolone synthetic antibacterial agent)                            | 2.5    | 3.2        | + 0.7        | + 32.6        |
|                  | Lyfnua (Selective P2X3 receptor antagonist / chronic cough)                     | 0.2    | 1.3        | + 1.1        | + 595.4       |
|                  | Desalex (Antiallergic Agent)  | 8.5    | 8.9        | + 0.4        | + 4.6         |
|                  | Flutiform (Combination drug for asthma treatment)                               | 12.0   | 11.4       | -0.6         | -4.2          |
| New drugs,       | Pentasa (Ulcerative colitis and Crohn's disease treatment)                      | 12.8   | 11.8       | -1.0         | <b>-</b> 7.0  |
| etc. (Japan)     | Kipres<br>(Leukotriene Receptor Antagonist)                                     | 6.6    | 5.3        | -1.3         | -19.2         |
|                  | Mucodyne<br>(Mucoregulator)   | 3.5    | 3.0        | -0.5         | -12.5         |
|                  | Nasonex (Spray type allergic rhinitis remedy)                                   | 2.5    | 1.2        | -1.3         | <b>– 49.6</b> |
|                  | Uritos (KYORIN) (Therapeutic agent for overactive bladder)                      | 0.7    | 0.2        | -0.5         | - 58.9        |
|                  | Milton (Disinfectant)   | 2.0    | 1.9        | -0.1         | -1.0          |
|                  | Rubysta (Disinfectant)  | 2.1    | 2.1        | 0            | + 3.0         |
|                  | Nantaugest to blots (IVNA))   |        |            | į            |               |
|                  | Montercast tablets "KM"  (Leukotriene Receptor Antagonist)                      | 13.3   | 11.0       | -2.3         | -16.7         |
| Generic<br>drugs | Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)            | 4.7    | 3.4        | -1.3         | - 26.6        |
|                  | Imidafenacin tablets & OD"KYORIN" (Therapeutic agent for overactive bladder)    | 0.7    | 0.4        | -0.3         | -30.7         |

## **Shareholders Returns**



# Capital Policy

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

#### Dividend

|                             | FY2020                       | FY2021                       | FY2022                       | FY2023<br>(Forecast)      |
|-----------------------------|------------------------------|------------------------------|------------------------------|---------------------------|
| Dividend per<br>share (Yen) | <b>¥75</b><br>(Year-end ¥45) | <b>¥52</b><br>(Year-end ¥32) | <b>¥52</b><br>(Year-end ¥32) | <b>¥52</b> (Year-end ¥32) |
| Consolidated payout ratio   | 70.9%                        | 76.9%                        | 64.0%                        | 61.7%                     |

OThe year-end dividend of 32 yen have been decided at in the Board Meeting scheduled in May 22, 2023



# **Status of R&D Pipeline**

# **Status of R&D Pipeline in FY2022**



|             | Development code | Ph1           | Ph2                 | Ph3    | Application | Approval/Launch |
|-------------|------------------|---------------|---------------------|--------|-------------|-----------------|
| Respiratory | KRP-R120         |               |                     | MRCT*1 |             |                 |
| Infections  | KRP-A218         | (April 2021)  |                     |        |             |                 |
| Urology     | AKP-009*2        |               | (Completed by Aska) |        |             |                 |
|             | KRP-114VP        | (August 2022) |                     |        |             |                 |

<sup>\*1</sup> MRCT: Multi-Regional Clinical Trials

#### [ Licensed Compound ]

| Compound/Code | Licensee  | Stage | Features   |
|---------------|-----------|-------|--|
| KRP-203       | Priothera | Ph3   | <ul> <li>Sphingosine-1-Phosphate receptor Agonist</li> <li>Target: AML patients undergoing HSCT</li> <li>Assignment of IP and drug substances (Sep. 2020)</li> </ul> |

<sup>\*2</sup> Additional Ph1 study to confirm the maximum effect at a higher dose has been completed (ASKA)

# Plan of R&D Pipeline in FY2023



|             | Development code | Ph1           | Ph2                 | Ph3    | Application | Approval/Launch |
|-------------|------------------|---------------|---------------------|--------|-------------|-----------------|
| Respiratory | KRP-R120         |               |                     | MRCT*1 | •           |                 |
| Infections  | KRP-A218         | (April 2021)  |                     |        |             |                 |
| Urology     | AKP-009*2        |               | (Completed by Aska) |        |             |                 |
|             | KRP-114VP        | (August 2022) |                     |        |             |                 |

<sup>\*1</sup> MRCT: Multi-Regional Clinical Trials

#### [ Licensed Compound ]

| Compound/Code | Licensee  | Stage | Features   |
|---------------|-----------|-------|--|
| KRP-203       | Priothera | Ph3   | <ul> <li>Sphingosine-1-Phosphate receptor Agonist</li> <li>Target: AML patients undergoing HSCT</li> <li>Assignment of IP and drug substances (Sep. 2020)</li> </ul> |

## [ DTx development ]

| Compound/Code | Proposed Indication | Features                              |
|---------------|---------------------|---------------------------------------|
| KRP-DT123     | Tinnitus            | Specified clinical trial is scheduled |

<sup>\*2</sup> Ph1 study under preparation (ASKA)



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

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



#### **Long-Term Vision [HOPE100]**

#### Statement

The Kyorin Group will promote diversified healthcare business expansion and by 2023 be recognized both within and outside as a company that supports sound and healthy lifestyles.

| Stage 1<br>FY2010-FY2015  | <b>Stage 2</b><br>FY2016-FY2019  | Stage 3<br>FY2020-FY2023(2022)                                       |  |
|---|--|--|--|
| Statement  Business organization, the building of a system to promote each business, and the enhancement of the driving force of each business  | Statement  Making reforms (changes and innovations)  and achieving continuous growth in an effort  to realize our long-term vision | Statement Realization of growth trend through pursuit of originality |  |
| Vision in Stage 3  Aim to become a globally recognized compand creation of innovative new drugs. To this end, drugs business, GE business, infection-related integrated manner to widely support people's | expand the new business in an  | Diagnosis business  New drugs business  GF business                  |  |

Renovated our structure and formulate a new long-term vision in FY2023, the 100th anniversary of our founding

Stage 2

Stage 3

Stage 1



# 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

# **Look-back of Stage 3: Strategy/Organization**



# Strategy

|   | Solution-based marketing activities   |  |  |  |  |
|---|---|--|--|--|--|
| 1 | Shift to business based on the proposal of solutions and accelerate the growth of new drug groups | Ratio of new drugs Projected: at least 50% Actual: 42.0% (FY2022)  Launched FY2020: Lasvic IV  FY2021: Zymso  FY2022: Lyfnua  LCM FY2020: Flutiform (additional indication n pediatric patients)                                     |  |  |  |
| 2 | Enhance pipeline to support medium-term growth  | In-license  FY2020: AKP-009  FY2021: Lyfnua (MSD), Lagevrio (co-promotion agreement with MSD)  FY2022: Agent for Fabry disease (CellGen Tech)  FY2022: DTx in otolaryngology (SUSMED)  FY2022: KRP-114VP (Ph1 in pediatric patients) |  |  |  |
| 3 | Strengthen drug discovery capability to realize the creation of innovative new drugs              | In-house FY2021: KRP-A218 FY2021: FPR2 program (discontinued)  • ActivX (Dissolution in FY2022)  |  |  |  |
| 4 | Improve cost competitiveness  | <ul> <li>GE drugs: launched 6 ingredients (average for the past 3 years)</li> <li>Construction of Takaoka new plant (The operation is scheduled in Apr 2024)</li> </ul>  |  |  |  |
| 5 | Expand overseas revenue   | Out-license  FY2020: KRP-203 (Priothera), hearing-loss (Otonomy), Vibegron (Eisai) FY2021: Lascufloxacin (Nanjing Neiwa Faith) FY2022: Vibegron (Sumitomo Pharma)  |  |  |  |

# Organization

|  | Aim to be the No. 1 company for career fulfillment | <ul><li>Flexible working style</li><li>Initiatives for health management</li></ul> |
|--|--|--|
|--|--|--|



# Performance to realize sustainable growth

Growth potential Net Sales

Profitability Operating profit before deduction of R&D expenses

CAGR at least 5%

At least 20% of net sales

+1.0%

14.2%

<Negative Factors>

Revision of the NHI drug price

Annual NHI drug price revisions, applied to items with an average deviation rate of "exceed 0.625 times"

COVID-19 pandemic caused:

- Suppression by patients of visiting medical institutions
- Shrink market of mainstay products

Markets of mainstay products

(year on year) FY2020 85.4%\*

FY2020 85.4% FY2021 95.0%\*

FY2022 97.3%\*

# Shareholders returns

Aiming for stable divisions

Taking into increase by demand for funds for investment for growth, including the expansion of the development pipeline and capital expenditure, we have lowered the DOE

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# Our Issue

New drugs business (core business)

- Continued the development of new drugs
- Expansion of development pipeline
- Growth of new drugs

Helthcare-related business

- Growth in GE business
- Stable supply of products, stable procurement of API
- Enhancement of the duagnostics business

**Corporate foundation** 

- Cost competitiveness
- Environmental issues, compliance, and governance, etc.



New long-term vision "Vision 110" (FY2023-FY2032) and medium-term business plan "Vision 110 –Stage 1 –" (FY2023-FY2025)



# Long-term Vision



Vision for 110<sup>th</sup> anniversary

[Our goal]

A company that contributes broadly to people's health by comprehensively developing healthcare-related businesses, with a core focus on the new drug business, which continuously provides high-value new drugs that meet medical needs

[Term]

10 years: FY2023 - FY2032

Medium-term business plan

Stage 1

FY2023 - FY2025

Stage 2

FY2026 - FY2029

Stage 3

FY2030 - FY2032



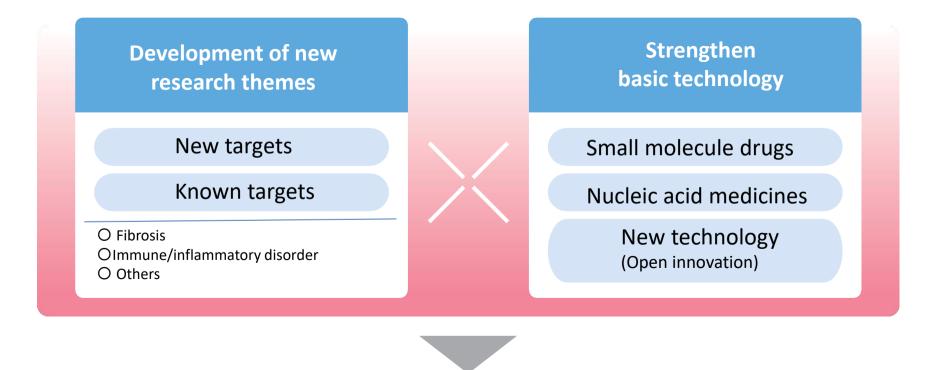


- 1. Strengthening drug discovery capability to create high-value new drugs that meet medical needs
- 2. Expansion of development pipeline through in-licensing
- 3. Maximization of the ratio of new drugs
- 4. Promoting healthcare-related businesses that have synergies with the new drugs business
- 5. Building a sustainable corporate foundation

| Strategic image        |  | Stage 1  | Stage 2-3 |  |
|------------------------|--|--|-----------|--|
|                        | Drug Discovery                           | Strengthen the drug discovery capability to create high-value new drugs that meet medical needs  O Try for drug innovation through new drug discovery strategies |           |  |
|                        | Reorganization                           | Creation of new drugs from long-term perspective   |           |  |
| New drugs<br>business  | Development                              | Expansion of development pipeline through in-licensing OSignificantly strengthen in-licensing ability OPromote DTx development                                   |           |  |
| business               | Investment of resource                   | Enhancement of development pipeline  |           |  |
|                        | Marketing, SCM,<br>Reliability Assurance | Maximization of the ratio of new drugs  OMaximize the extension of new drugs  OEnsure the stable supply of high-quality drugs                                    |           |  |
|                        | Driving force of revenue                 | Maximization of profitability  |           |  |
|                        |  |  |           |  |
| Healthcare-<br>related | GE business                              | OAchieve sustainable growth in the generic drugs business OStrengthen production capacity for drugs and reduce manufacturing costs                               |           |  |
| business               | Other business                           | OPromote infectious disease-related business   |           |  |



## Try for drug innovation through new drug discovery strategies



Drug discovery capability to create high-value new drugs that meet medical needs

#### 2. Expansion of development pipeline through in-licensing



Strengthen the foundation of new drug business by enhancement of in-licensing and alliance function and expansion of development pipeline

**Expand the scope of modality** and therapeutic area Increase of Organizational reform **Speedy assessment and** investment Human resource acquisition of in-licensing **Promote and expand DTx** development

**Target** 

At least 6 in-licensing items (each 1 item in early/late stage per year)

# 3. Maximization of the ratio of new drugs



| Products               | Aimed status  | Goal at FY2025   | Sales (JP          | Y billions)    |
|------------------------|---|--|--------------------|----------------|
| Beova®                 | First-line treatment for OAB  | <ul> <li>No.1 in OAB market as Beova in FY2023</li> <li>50% of patient's share</li> </ul>  |                    | 56.0           |
| Lasvic <sup>®</sup>    | First-choice antibacterial agent for elderly or patients with underlying disease in respiratory infection | <ul> <li>No.1 in oral new quinolone<br/>market in FY2023</li> <li>No.1 in new quinolone market<br/>in FY2025 for tablets/iv</li> </ul> | 36.1               | 25.0           |
| <b>Lyfnua</b> ®        | Only one treatment for chronic cough  | <ul> <li>FY2025         <ul> <li>approx. 10,000 of GP</li> <li>approx. 2,000 of HP</li> </ul> </li> </ul>                              | 12.9<br>2.5<br>0.2 | <b>5.0 4.5</b> |
| Dezalex®               | Effective and easy-<br>to-use drug  | Sales of 10 billion yen in FY2025  | 8.5                | 10.0           |
| Fultiform <sup>®</sup> | Aerosol for patients with weak inspiration  | <ul> <li>Sustainable growth on volume-<br/>basis to FY2025 with CAGR of<br/>low single digit %</li> </ul>                              | FY2022             | FY2025         |



# Achieve sustainable growth in the generic drugs business

- Enhance an ability of drug development and accelerate growth business
- Strive to stable supply by enhancement of manufacturing and SCM structure
- Develop of low cost system along business environment

Strengthen production capacity for drugs and reduce manufacturing costs

- Maximize manufacturing ability by operation at Takaoka plant and optimization each plants
- Improve reliability and stable manufacturing by raise the level of GMP
- Cost reduction by improvement activities

Promote infectious diseaserelated business

- Develop of diagnostics business for future with enhancement in IVD area.
- Spared of Rubysta and Milton brand

# 5. Building a sustainable corporate foundation



| Improve cost competitiveness                                  | Cost optimization along business environment   |
|---|--|
| Enhance human capital   | <ul> <li>Human resource development for people leading Vision 110</li> <li>Revision of human resource system to improve career fulfillment</li> <li>Promote work-style reforms to meet divers of values</li> <li>Promote initiatives the Health Management</li> </ul>  |
| Respond to environmental issues, compliance, governance, etc. | <ul> <li>Set target of cutting CO2 emissions in 2030 and commit proactively to approach it</li> <li>Abide by all low, regulation, codes of conduct, and the spirit thereof and act with high ethical standard</li> <li>Strengthen corporate governance</li> <li>Appropriate actions to stakeholders</li> </ul> |



# ■ Performance targets (consolidated basis)

| Growth potential | "Net sales" CAGR  | At least 2%  |
|------------------|---|--------------|
| Profitability    | Operating profit before deduction of R&D expenses (operating profit + R&D expenses) | At least 16% |

# Improve the company value according to meet high profitability by executing the medium business plan

- Maximize the ratio of new drugs and optimize cost competition
- Increase of R&D expenses (strengthen the drug discovery capability, expand of development pipeline
- Expand capital investments
- Enhance human capital



# Capital policy and shareholder returns

Our capital policy is to improve capital efficiency through investment for growth and shareholder returns, while maintaining a sound financial base.

Regarding shareholder returns, we will continue stable dividends, taking into account the dividend on equity ratio (DOE).



# Reform of management group structure and new initiatives

Reform of R&D systems

**Expand of development pipeline** 

Maximize the expansion of sales growth in new drugs

Improve cost competitiveness

## **Disclaimer**



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