- Overview of consolidated results
  - consolidated results, and progress of the main products
- Consolidated Financial Results and Forecast
- Changes in Capital Policy
Overview of consolidated results
<table>
<thead>
<tr>
<th>(¥ billion)</th>
<th>First quarter Jun / 2017</th>
<th>First quarter Jun / 2018</th>
<th>YoY</th>
<th>Progress to Interim term forecast(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Change</td>
<td>change (%)</td>
</tr>
<tr>
<td>Net sales</td>
<td>26.5</td>
<td>25.1</td>
<td>−1.4</td>
<td>−5.0</td>
</tr>
<tr>
<td>Operating income</td>
<td>2.6</td>
<td>1.3</td>
<td>−1.3</td>
<td>−49.1</td>
</tr>
<tr>
<td>Ordinary income</td>
<td>2.8</td>
<td>1.6</td>
<td>−1.2</td>
<td>−43.1</td>
</tr>
<tr>
<td>Net income</td>
<td>2.4</td>
<td>1.1</td>
<td>−1.3</td>
<td>−55.0</td>
</tr>
</tbody>
</table>
Highlights of Business Performance ① (Sales)

Sales (Units: ¥ billion)

【Net Sales ¥ -1.4bln】

Healthcare Business ¥ +0.1bln
- Growth of RUBYSTA and Milton

Ethical Drugs Sales ¥ -1.4bln
- Generic drugs ¥ +0.6bln
  - Increase of MONTELKAST AG sales
  - Sales to other companies decreased

Ethical drug sales overseas ¥ -0.1bln
- Income related to Gatifloxacin decreased

Ethical drug sales in Japan ¥ -1.9bln
- Despite steady growth in Flutiform and Desalex sales
  - Decreased by the expiration of the patent for KIPRES.
<table>
<thead>
<tr>
<th>Product</th>
<th>Jun/2017</th>
<th>Jun/2018</th>
<th>change</th>
<th>change (%)</th>
<th>Progress to Interim term forecast (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flutiform</td>
<td>2.8</td>
<td>3.0</td>
<td>+0.2</td>
<td>+9.4</td>
<td>52.5%</td>
</tr>
<tr>
<td>(Combination drug for asthma treatment)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uritos (Kyorin)</td>
<td>1.9</td>
<td>1.7</td>
<td>-0.2</td>
<td>-8.8</td>
<td>50.1%</td>
</tr>
<tr>
<td>(Overactive bladder)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desalex (Antiallergic Agent)</td>
<td>0.5</td>
<td>1.5</td>
<td>+1.0</td>
<td>+230.8</td>
<td>48.6%</td>
</tr>
<tr>
<td>Kipres (LT receptor antagonist)</td>
<td>2.0</td>
<td>1.6</td>
<td>-0.4</td>
<td>-23.1</td>
<td>53.7%</td>
</tr>
<tr>
<td>For children</td>
<td>3.1</td>
<td>1.7</td>
<td>-1.4</td>
<td>-45.7</td>
<td>57.6%</td>
</tr>
<tr>
<td>Pentasa (Ulcerative colitis and Crohn’s disease treatment)</td>
<td>4.0</td>
<td>3.5</td>
<td>-0.5</td>
<td>-12.4</td>
<td>47.2%</td>
</tr>
<tr>
<td>Mucodyne (Mucoregulant)</td>
<td>2.1</td>
<td>1.7</td>
<td>-0.4</td>
<td>-22.5</td>
<td>51.4%</td>
</tr>
<tr>
<td>MONTELUKAST Tablets “KM”</td>
<td>2.7</td>
<td>3.3</td>
<td>+0.6</td>
<td>+21.9</td>
<td>68.1%</td>
</tr>
</tbody>
</table>
Highlights of Business Performance ② (Income)

[Operating Income ¥ − 1.4bln]

Gross Profit decreased
- Net Sales: decreased ¥1.4bln year on year
- Cost of sales ratio: Increased 2.6% year on year
  - Decreased in sales of drugs due to drug price revisions. (Kyorin Pharmaceutical drug price revision rate: 7% range)
  - Rising cost of sales ratio

R&D expenses is flat
- ¥2.5billion (FY2017Q1) ⇒ ¥2.5billion (FY2018Q1)

SG&A (excluding R&D) decreased
- Decrease of Labor costs
  - ¥9.5billion (FY2017Q1) ⇒ ¥9.4billion (FY2018Q1)

Progress to Interim term forecast (%)
- Operating Income: 69.5%
Forecast of Business Performance Second quarter
(Income)

【Operating Income ¥±0.5bln】

Gross Profit decreased
- Net Sales: decreased ¥0.6bln year on year
  - Despite steady growth in Flutiform and Desalex sales
- Cost of sales ratio: Increased about 1.5% year on year
  - Decrease in loss on retirement of inventories.

R&D expenses decreased
- ¥7.2billion (FY2017 2Q)
  ⇒ ¥5.5billion (FY2018 2Q forecast)
  - Previous year: R & D expenses increased due to the development pipeline progress

SG&A(excluding R&D) increased
- ¥19.0billion (FY2017 2Q)
  ⇒ Roughly flat against the same period last year (FY2018 2Q forecast)
Consolidated Financial Results and Forecast
## Consolidated Financial Results Forecast
for the Year Ending March 31, 2019

<table>
<thead>
<tr>
<th>FY2017</th>
<th>FY2018 (Forecast)</th>
<th>Y/Y</th>
<th>Change</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net sales</strong></td>
<td>110.6</td>
<td><strong>114.4</strong></td>
<td>+3.8</td>
<td>+3.4</td>
</tr>
<tr>
<td>Ethical drugs business</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales of new ethical drugs</td>
<td>104.7</td>
<td>108.4</td>
<td>+3.7</td>
<td>+3.5</td>
</tr>
<tr>
<td>Japan</td>
<td>77.0</td>
<td>80.9</td>
<td>+3.9</td>
<td>+5.0</td>
</tr>
<tr>
<td>Overseas</td>
<td>27.7</td>
<td>27.4</td>
<td>-0.3</td>
<td>-0.9</td>
</tr>
<tr>
<td>Generic drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare Business</td>
<td>5.9</td>
<td>6.0</td>
<td>+0.1</td>
<td>+1.1</td>
</tr>
<tr>
<td>Operating Income</td>
<td>8.8</td>
<td><strong>8.6</strong></td>
<td>-0.2</td>
<td>-2.5</td>
</tr>
<tr>
<td>Ordinary Income</td>
<td>9.3</td>
<td><strong>9.2</strong></td>
<td>-0.1</td>
<td>-1.6</td>
</tr>
<tr>
<td>Net Income</td>
<td>6.6</td>
<td><strong>6.6</strong></td>
<td>0</td>
<td>+0.4</td>
</tr>
</tbody>
</table>

(for reference: year on year)

1. Increase sales of our main products Flutiform and Desalex, and increase sales of Nasonex.
2. Reduction of gross operating income: The cost rate is up by about 4 point.
3. Reduction of selling, general and administrative expenses (SGA): R&D cost is reduced (forecast a reduction of 2.6 billion yen from the previous year, to 11.6 billion yen). The rate of SGA (excluding R&D cost) has declined by about 1% from the previous year.
4. Method of depreciation: Expect a change from the declining-balance method to the straight-line method.
## Forecast of Mainstay Product Sales

(Units: ¥ billion)

<table>
<thead>
<tr>
<th>Product</th>
<th>FY2017</th>
<th>FY2018 (forecast)</th>
<th>Y/Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Change</td>
</tr>
<tr>
<td>Flutiform (Combination drug for asthma treatment)</td>
<td>11.9</td>
<td>12.3</td>
<td>+0.4</td>
</tr>
<tr>
<td>Uritos (Kyorin) (Overactive bladder)</td>
<td>7.2</td>
<td>6.8</td>
<td>−0.4</td>
</tr>
<tr>
<td>Desalex (Antiallergic Agent)</td>
<td>4.9</td>
<td>8.1</td>
<td>+3.2</td>
</tr>
<tr>
<td>Kipres for adult (LT receptor antagonist)</td>
<td>8.3</td>
<td>6.0</td>
<td>−2.3</td>
</tr>
<tr>
<td>Kipres for children (LT receptor antagonist)</td>
<td>10.5</td>
<td>7.2</td>
<td>−3.3</td>
</tr>
<tr>
<td>Pentasa (Ulcerative colitis and Crohn’s disease treatment)</td>
<td>15.3</td>
<td>14.5</td>
<td>−0.8</td>
</tr>
<tr>
<td>Mucodyne (Mucoregulant)</td>
<td>8.7</td>
<td>7.2</td>
<td>−1.5</td>
</tr>
<tr>
<td>Nasonex (Spray type allergic rhinitis remedy)</td>
<td>−</td>
<td>10.1</td>
<td>+10.1</td>
</tr>
<tr>
<td>MONTELUKAST Tablets “KM”</td>
<td>11.7</td>
<td>9.8</td>
<td>−1.9</td>
</tr>
</tbody>
</table>
Changes in Capital Policy
Changes in Capital Policy

Before the change

- While maintaining the sound financial base, we adopt the capital policy ensuring both growth investment and stable return to shareholders.
  As for the return to shareholders, we aim for “stable dividends” on a basis of the present dividend standard.

Reason of the Changes in Capital Policy

◇ Considering the perspective of the recovery of the corporate earnings caused by the implementation of our key strategies.
◇ Taking into consideration the current capital market conditions and the financial situation of the Company, we decided to change the policy from capital accumulation to capital efficiency improvement.
◇ We aim to continue this new shareholder return policy unless there is a special change in the business environment.

Changes in Capital Policy and Shareholder Return Policy

Basic idea

- Please note that there is no change in our business strategy towards the realization of the medium-term business plan “HOPE100-Stage 2-”, and we will continue to make our best efforts to achieve our target figures in that business plan by investing for continuous growth.
- We aim to further improve the shareholder's value and increase efficiency of capital to strengthen the return to shareholders by strengthening shareholder return taking DOE (shareholders' equity dividend rate) into account.
Shareholder Returns

Basic Policy (After the change)

- 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.

<table>
<thead>
<tr>
<th>Dividends</th>
<th>FY2017</th>
<th>FY2018 (original forecast)</th>
<th>FY2018 (revise forecast)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend per share (Yen)</td>
<td>¥58 (Year-end ¥38)</td>
<td>¥58 (Year-end ¥38)</td>
<td>¥75 (Year-end ¥45)</td>
</tr>
<tr>
<td>Consolidated payout ratio(%)</td>
<td>65.9%</td>
<td>65.7%</td>
<td>84.9%</td>
</tr>
</tbody>
</table>

※ We revised the dividend forecast for the fiscal year ended March 2007, which was announced on May 10, 18, to July 31, 18.
## Drug Development Pipeline:
### Progress in FY2017, schedule of FY2018

<table>
<thead>
<tr>
<th>Compound/Code</th>
<th>Licensee</th>
<th>Stage</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FPR2 agonist program</strong></td>
<td>BMS</td>
<td>Ph I</td>
<td>FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area: Non-disclosure</td>
</tr>
<tr>
<td><strong>KRP-203</strong></td>
<td>Derivation activity restart</td>
<td>Ph I</td>
<td>Sphingosine-1-Phosphate Receptor Agonist. Therapy area: GvHD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, kyorin receive the return of development rights.</td>
</tr>
</tbody>
</table>

### Approval/Launch

<table>
<thead>
<tr>
<th>Compound/Code</th>
<th>Approval/Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad-SGE-REIC</td>
<td></td>
</tr>
<tr>
<td>KRP-108P</td>
<td></td>
</tr>
<tr>
<td>KRP-AM1977X</td>
<td>FY19 Expected Release</td>
</tr>
<tr>
<td>KRP-AM1977Y</td>
<td>FY18 Expected Release</td>
</tr>
<tr>
<td>KRP-114V</td>
<td>2017/9</td>
</tr>
<tr>
<td>KRP-116D</td>
<td>2017/9</td>
</tr>
<tr>
<td>KRP-N118 (SK-1404)</td>
<td>2017/9</td>
</tr>
</tbody>
</table>

### Schedule and Progress

- **Respiratory**
  - Ad-SGE-REIC: End of the Ph I/Ph II, Ph II start, 2017/6
  - KRP-108P: 2017/6
- **Infections**
  - KRP-AM1977Y: 2017/4
- **Urological**
  - KRP-114V: 2017/9
  - KRP-116D: 2017/9
  - KRP-N118 (SK-1404): Ph II start

※ For KRP-AM 1977 X, additional nonclinical studies are required and will be carried out.
Accelerate regrowth with new drug group and new products

- Maximize the dissemination of Flutiform, Desalex, PENTASA Granules, Uritos and Nasonex.
- Launch and disseminate KRP-114V and KRP-1977X.

[The ratio of the new drugs group should increase as follows]

- Flutiform, DESELEX expands
- Nezonex released on August 1
- Progress in R&D pipeline

Ratio of new drug group (%)
Approach to Drug Discovery and Status of R&D Pipeline

Kyorin Holdings, Inc.
August 8, 2018

Shigeru Ogihara, Senior Executive Director
(Senior Executive Director and General Manager, Discovery Research HQs, Kyorin Pharmaceutical Co., Ltd)
➤ Approach to first-in-class drug discovery through “selection and concentration” scheme: Focus on fibrosis research

➤ Status of R&D pipeline
Approach to “First-in-class” Drug Discovery

WRC: Watarase Research Center

Open Innovation
Academia and Ventures

Open Innovation
Global and Domestic Pharma Companies

Research Focuses
- Fibrosis
- Kinase

Unique Drug Target

World-class Drug Discovery

Partnership

External drug discovery programs

Multi-layered approach

Selection and Concentration
Organ Fibrosis

- Functional damage of organs by excessive accumulation of collagens and so on
- Cause of the onset is not clear, and progression is irreversible.
- Development of effective drugs is required.

Skin (scleroderma: 20k)
Lung (IPF: 13k)
Liver (NASH: 7 million)
Pancreas (Chronic pancreatitis: 44k)
Kidney (Diabetic nephritis: 2.8 million)
Bone marrow: (Myelofibrosis: 1.5k)

Estimated number of patients in Japan (as of Jan 2018)

a: Datamonitor Healthcare
b: Japan Intractable Diseases Information Center
c: Disease guidelines
Outline of Organ Fibrosis

For organ fibrosis, there are common causes and factors irrespective of organ and organ specific ones.

**Organ specific**

**Lung**
- Virus infections
- Alveolar epithelial cell damage

**Liver**
- Virus infections
- Fatty liver
- Hepatocellular injury
- Activation of stellate cells

**Kidney**
- Chronic kidney diseases
- Renal tubular cell injury
- Activation of mesangial cells

**Bone marrow**
- Hematopoietic stem cell gene mutation
- Megakaryocyte / monocyte-derived humoral factor

**Common**
- Inflammatory cell infiltration
- Growth of myofibroblasts
- Macrophage activation
- ECM over deposition

**Organ-specific dysfunction**
- TGF-β
- PDGF-bb
- LPA
- CTGF
- VEGF
- FGF
- IL-1β
- IL-10
Drug Discovery for Pulmonary Fibrosis

Pathology
Stage

Specific causes/factors
Early cell damage
Dysfunction of cells

Common causes/factors
Fibrotic factor production
Progress of fibrosis

Type 2 alveolar epithelial cells

Macrophage
Fibroblasts

Cells involved

Molecular Target

● Novel target A
● Novel target B
<Kyoto Univ.>

● Novel target C (Nucleic acid drug)
● Novel target D
● Novel target E

Aim for radical treatment for early onset cases
Aim for suppression of severe symptoms in progressive fibrosis
Status of R&D Pipeline
# Status of R&D Pipeline

## Highlights in FY2018

### As of July 31, 2018

<table>
<thead>
<tr>
<th>Projects</th>
<th>Ph1</th>
<th>Ph2</th>
<th>Ph3</th>
<th>NDA</th>
<th>Appr/Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ad-SGE-REIC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gene therapy (MPM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-108P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma combo. inhaler</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Infections</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-AM1977X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroquinolone</td>
<td></td>
<td>October</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-AM1977Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroquinolone</td>
<td></td>
<td>October</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Urology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-114V</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OAB treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-116D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KRP-N118</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(SK-1404)</td>
<td></td>
<td>October</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nocturia treatment</td>
<td></td>
<td>October</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Status of out-licensing items

- Additional non-clinical studies for KRP-AM1977X ongoing

<table>
<thead>
<tr>
<th>Projects</th>
<th>Licensed to</th>
<th>Stage</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPR2 agonists</td>
<td>BMS</td>
<td>Ph1</td>
<td>FPR2 agonist: Mainly suppresses the migration of neutrophils and shows anti-inflammatory action</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Target disease: Undisclosed</td>
</tr>
<tr>
<td>KRP-203</td>
<td>Re-start of out-licensing</td>
<td>Ph1</td>
<td>S1P receptor agonist</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Target disease: GvHD</td>
</tr>
</tbody>
</table>

Novartis ceased the development from the strategic viewpoint and returned development rights to Kyorin.
Outline of Ad-SGE-REIC

Expression of REIC protein in various cancer cells

Expression of REIC in normal and cancer cells

It has been confirmed that expression of REIC protein is downregulated in various cancer cells.
Ad-SGE-REIC is a gene therapy product in which the cancer-suppressing gene REIC/Dkk-3 discovered in Okayama Univ is mounted on an adenoviral vector as a therapeutic gene.

**Selective cytotoxicity against cancer cells**
By forcibly expressing REIC in cancer cells, selective cell death (apoptosis) of cancer cells is induced.

**Activation of anticancer immunity**
By differentiation induction of dendritic cells and cytotoxic T cells (CTL cells), activation of anticancer immunity is induced.

It is expected that the REIC proteins are forcibly expressed in tumor cells, resulting in the direct effect on the cancer lesion spreading in the thoracic cavity of malignant pleural mesothelioma and the indirect effect on the remote lesion due to the activation of anticancer immunity.
(1) Increase in cancer antigen-specific cytotoxic T cells was confirmed both in the tumor treated with the product and in the spleen.

(2) Increase in cancer antigen-specific cytotoxic T cells and anti-tumor effect were confirmed in the tumor in untreated side.

It was confirmed that Ad-SGE-REIC shows anticancer effect locally in the product-treated tumor and systemically via activation of anticancer immunity by induction of antigen-specific cytotoxic T cells.

Strain: E.G7-OVA

* Igaku no ayumi 2018; 265(5); 422-428.
# Development status of Ad-SGE-REIC

## Ph1/2

<table>
<thead>
<tr>
<th>Study period</th>
<th>July 2015～</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>Japanese MPM patient with standard treatment ineffective or without appropriate treatment</td>
</tr>
</tbody>
</table>
| Objects      | Primary endpoint: Safety, Estimation of maximum tolerated dose  
Secondary endpoint: Efficacy |
| Administration | Local administration to pleural tumors |
| Dose         | Level 1: $3 \times 10^{11}$ vp  
Level 2: $1 \times 10^{12}$ vp  
Level 3: $3 \times 10^{12}$ vp |
| No. of cases | 13 |

MPM: Malignant pleural mesothelioma

**Objectives of Ph 1/2 achieved and Ph2 started.**

## Ph2

<table>
<thead>
<tr>
<th>Study period</th>
<th>July 2018～</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>Patients with MPM in the second treatment</td>
</tr>
</tbody>
</table>
| Objects      | Primary endpoint: Efficacy (PFS)  
Secondary endpoint: Efficacy (ORR, OS), Safety, etc.  
PFS: Progression-free survival  
ORR: Overall response rate  
OS: Overall survival |
| Administration | Local administration to pleural tumors |
| Dose         | $3 \times 10^{12}$ vp |
| No. of cases | 30 (targeted) |

- Completed responses to Cartagena Act and Clinical Trial Notification submission
- Joining in the Master Key Project
- Promote development by industry-government-academia collaboration (JST, Okayama Univ., Momotaro Gene)
Expansion of product line-up in urology field

Causes of frequent urination and incontinence

Overactive Bladder (OAB)
- Uritos® (anticholinergic)
- KRP-114V (β3 agonist)

Nocturia
- KRP-N118 (vasopressin V2 Agonist)

And for Interstitial cystitis
- KRP-116D under development

Offer treatment options for urination trouble

(Tips)
- No. of OAB patients
  10.4 million (≥40 y/o) ※1
- No. of nocturia patients
  45 million (once/night), 8.5 million (≥3 times/night)※2

Outline of KRP-N118

◆ Indication: Nocturia caused by night polyuria
◆ MOA: Antidiuretic effect by promoting water re-absorption from renal collecting tubule by vasopressin V2 receptor agonistic action
◆ Dosage: Once daily before bedtime, oral dissolution tablets
◆ Features

- A small molecular compound, expecting a possibility of alleviating the variation of effects among individuals by improving oral absorbability.
- It is expected that it can be used by elderly people who have reduced renal function as this compound was mainly excreted via liver.
- By excreting promptly from the blood, the effect is exerted only during sleep, there is a possibility that side effects can be reduced.
## Development status of KRP-203

**GvHD**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Targeted</th>
<th>Recruited</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td><strong>Ph1b</strong></td>
<td>10</td>
<td>10</td>
<td>Methotrexate + Ciclosporin</td>
</tr>
<tr>
<td>Part 1</td>
<td>10</td>
<td>10</td>
<td>Methotrexate + Ciclosporin</td>
</tr>
</tbody>
</table>
| **Part 2** | 20       | Terminated | **KRP-203 low dose** Methotrexate + Ciclosporin  
|           |          |           | **KRP-203 high dose** Methotrexate + tacrolimus |

- Novartis ceased Ph1b before the completion of scheduled cases due to development strategy reasons.
- In addition to the GvHD preventive effect, an effect of suppressing the recurrence of the blood tumor and the improvement of the survival rate were newly found. (patent filed)

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**Re-start of out-licensing**