

**Contribute to society through high-quality, innovative  
pharmaceutical products Serve society through our employees**

# **MEDIUM-TERM MANAGEMENT PLAN**

# **Beyond 80**

**- BEYOND 80 YEARS OF OUR FOUNDING,  
CHALLENGES AND CHANGES -**

**PERIOD: FISCAL 2025–FISCAL 2029**

# The Five-Years Mid-term Management Plan “PEGASUS”(fiscal years 2020 to 2024)

## Recap of PEGASUS: Results of Qualitative Goals



### Basic Policy

### Results

#### Increase domestic sales

- Commercialized seven products in Japan, including newly launched TAVNEOS®, KORSUVA®, TAVALISSE®, and CAROGRA®
- Entered rare and intractable diseases field, and strengthened presence in key fields (urology, renal diseases and dialysis)

#### Strengthen our overseas earnings base

- Regarding Linzagolix, the application for approval in the United States has been withdrawn, and the overseas commercialization scheme has been restructured. In Europe, it is set to be newly launched in September 2024. Additionally, in South Korea and Taiwan, development is being promoted by partner companies
- Outlicensed TAVALISSE® to South Korea and Taiwan. In South Korea, obtained marketing authorization through a partner company, and preparations for launch are underway.

#### Expand development pipeline

- Preparations are underway to initiate clinical trials for three drug discovery projects (CC-001-CC-003\*<sup>1</sup>)
- In-licensed the oncolytic virus Cretostimogene grenadenorepvec and the acute myeloid leukemia treatment drug Olutasidenib, we have strengthened our development pipeline in the field of rare and intractable diseases
- Drug discovery research has been strengthened through initiatives such as digital drug discovery capabilities, collaborative research with Reborna Biosciences, Inc., and the establishment of an information-gathering hub in the United States.

#### Strengthen the management base to cope with the changes in the business environment

- Enhanced quality control and stable supply system through organizational reforms and the construction of a new building for formulations
- Enhancing governance and sustainability promotion systems

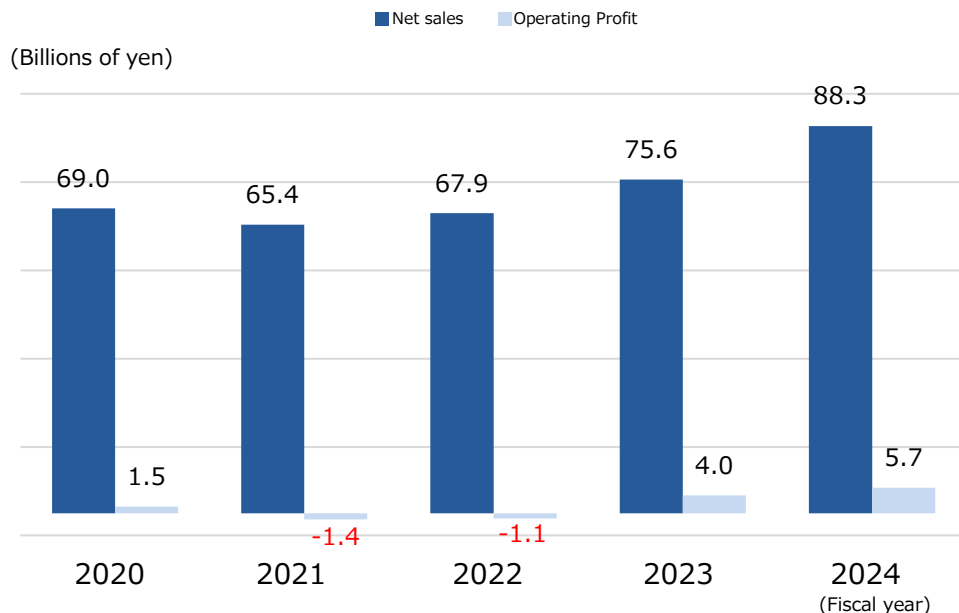
\*1 CC-001 (Graves' disease) 、 CC-002 (Overactive bladder, Interstitial cystitis Bladder pain syndrome) 、 CC-003 (Narcolepsy) \*2 Development code : CG0070

# The Five-Years Mid-term Management Plan “PEGASUS”(fiscal years 2020 to 2024)

## Recap of PEGASUS: Results of Financial Targets

**KISSEI**

- The expansion of Domestic pharmaceuticals has resulted in an update to the record-high sales
- Due to the restructuring of the overseas commercialization scheme for Linzagolix, the operating profit fell short



(Billions of yen)			
Item	PEGASUS Final-Year Targets	Results	Difference
<b>Net sales</b>	<b>87.0</b>	<b>88.3</b>	<b>+1.3</b>
Pharmaceutical Business	75.0	75.2	+0.2
Domestic pharmaceuticals*1	57.0	63.9	+6.9
Overseas license*2	13.5	7.7	-5.8
Therapeutic and care foods	4.5	3.5	-1.0
Other Businesses	12.0	13.0	+1.0
<b>Operating Profit</b>	<b>9.0</b>	<b>5.7</b>	<b>-3.2</b>
<b>R&amp;D expenses</b>	<b>13.0</b>	<b>12.8</b>	<b>-0.2</b>
<b>ROE</b>	<b>5.0%</b>	<b>5.6%</b>	<b>+0.6%</b>

\*1 Including revenue from supply to domestic sales partners and co-promotion fees

\*2 Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports

# Toward Growth as an R&D-Oriented Pharmaceutical Company

KISSEI

Focus on unmet medical needs and provide new treatment options to patients around the world

## Domestic Operations

- ✓ Strengthen rare and intractable diseases field
- ✓ Strategies for the fields of urology, and renal diseases and dialysis

## Global Operations

- ✓ Out-licensing for original products (active pharmaceutical ingredient (API) and product supply)
- ✓ Sublicensing of in-licensed products

## CMC/ Manufacturing

- ✓ CMC system for supplying high-quality pharmaceuticals

## Development

- ✓ Addressing a variety of diseases and modalities

## Drug Discovery Research

- ✓ Deepening small molecule drug discovery
- ✓ Promotion of open innovation

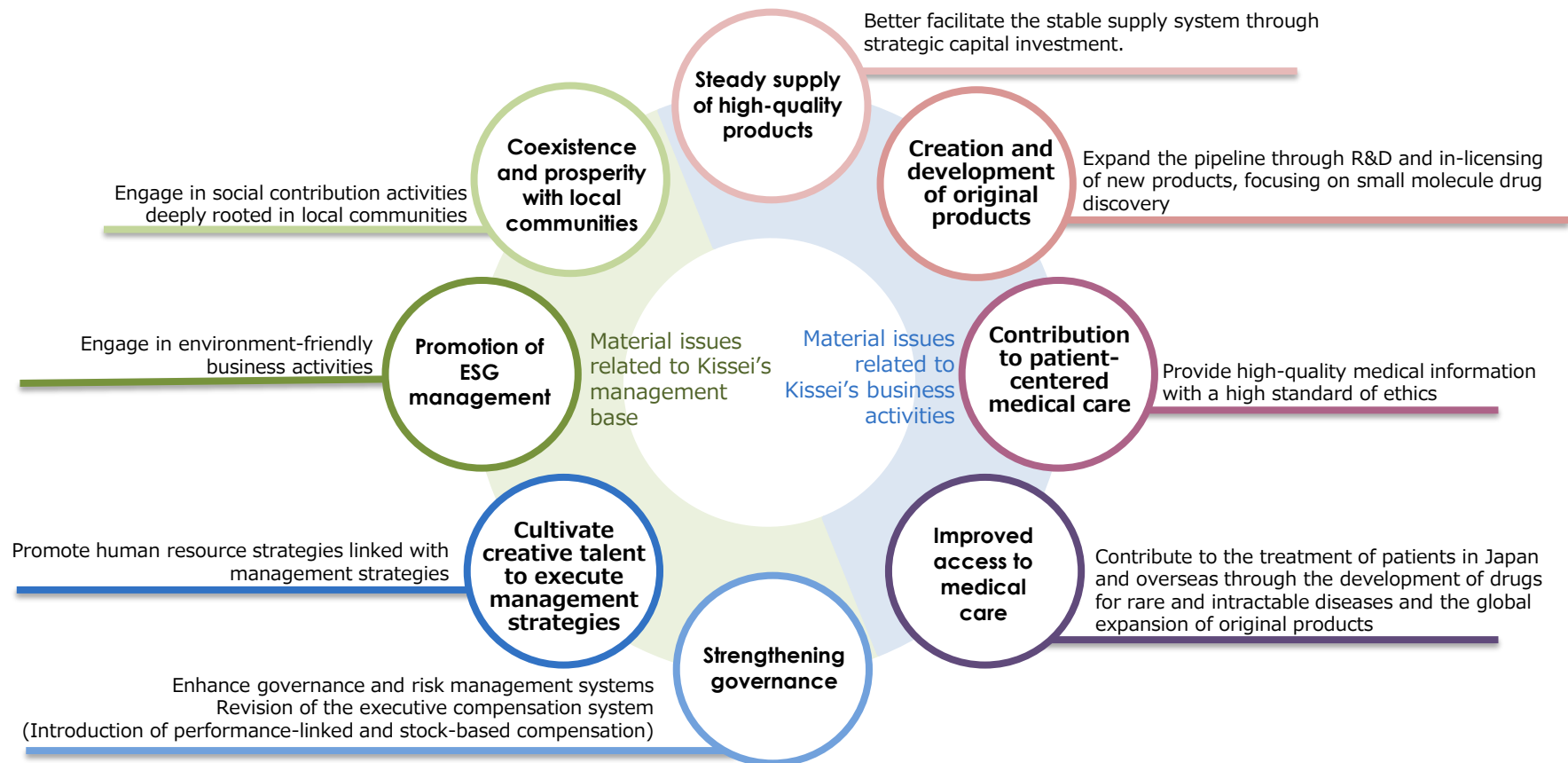
## In-Licensing

- ✓ Target all modalities
- ✓ Utilize financial assets

PEGASUSを通じて獲得した事業基盤と強み

# Kissei's 8 Material Issues For Achieving the Management Philosophy

**KISSEI**



# Our Vision and the Positioning of Beyond 80

**KISSEI**

Transition from patent cliff to growth phase

P/B ratio	0.79
ROE	5.6%
Basic earnings per share	274 yen
Net sales	¥88.3 billion
Operating profit before R&D expenses	¥18.6 billion

Growth investment toward future sustainable growth

P/B ratio	1.0 or higher
ROE	8% or higher
Basic earnings per share	400 yen Or higher
Net sales	¥110.0 billion or higher
Operating profit before R&D expenses	¥29.0 billion or higher

Growth as an R&D-oriented pharmaceutical company

- Expansion of business through the continuous launch of innovative products
- Strengthening the research and development pipeline with a focus on drug discovery
- Establishment of a new overseas revenue base through global development
- Contribution to the realization of a decarbonized and circular society

ROE	10% or higher
10-year average growth rate (CAGR)	Net sales 5% or higher
	Operating profit before R&D expenses 10% or higher

**PEGASUS**  
Fiscal 2020–Fiscal 2024

**Beyond 80**  
Fiscal 2025–Fiscal 2029

**Fiscal 2030–Fiscal 2034**

©80th anniversary (2026)

# Beyond 80—Growth Strategy

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Investment in future growth to increase the profitability of our core business, to  
**raise our P/B ratio over 1.0 at an early stage**

## 1. Invest in Future Growth

- ✓ Engage in aggressive growth investment focused on R&D, IT, and facilities
- ✓ Reduce shareholders' equity and strengthen shareholder returns

## 2. Expand drug discovery themes and acquire growth drivers

- ✓ Begin early development of CC-001–CC-003
- ✓ Promote in-licensing that matches growth strategies for each field
- ✓ Promote drug discovery research focused on small molecules

## 3. Expand and grow domestic pharmaceuticals

- ✓ Launch of four products to market with six indications
- ✓ Expand the market for the four new drugs launched under the PEGASUS
- ✓ Enhance information provision system for rare and intractable diseases

## 4. Increase overseas licensing income

- ✓ Promote global development and expand for Linzagolix (Yselty®)
- ✓ Out-license drug discovery themes at an early stage

## Fiscal 2029

ROE

**8% or higher**

Net sales

**¥110.0 billion  
or higher**

Operating profit  
before R&D  
expenses

**¥29.0 billion  
or higher**

Shareholders'  
equity

**Under  
¥200.0 billion**

Basic earnings  
per share

**¥400 or higher**

Ratio of cross-  
shareholdings to  
net assets

**10% or lower**

Clinical  
Development  
Themes

**10 projects or more**

# Numerical Targets

**KISSEI**

Item	Fiscal 2024	Beyond 80 (Fiscal 2029)
<b>Net sales</b>	<b>¥88.3 billion</b>	<b>¥110.0 billion or higher</b>
Non-consolidated net sales	¥75.2 billion	¥95.0 billion or higher
Domestic pharmaceuticals* <sup>1</sup>	¥63.9 billion	¥80.5 billion or higher
Overseas license* <sup>2</sup>	¥7.7 billion	¥10.0 billion or higher
Therapeutic and care foods	¥3.5 billion	¥4.5 billion or higher
Other (consolidated subsidiaries)	¥13.0 billion	¥15.0 billion or higher
<b>Operating profit before R&amp;D expenses</b>	<b>¥18.6 billion</b>	<b>¥29.0 billion or higher</b>
<b>ROE</b>	<b>5.6%</b>	<b>8.0% or higher</b>

\*1 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees

\*2 Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports



# Growth Investment (Cash Allocation)

KISSEI

We will step up investments for future growth and actively return profits to shareholders.

## PEGASUS (Fiscal 2020–Fiscal 2024)

Funding	投資先
Operating CF (before R&D expenses) ¥56.0 billion	R&D ¥77.0billion
Utilization of financial assets on hand ¥77.0 billion	IT investment ¥13.0billion
	Production facilities, other investments ¥14.0billion
	Stable dividends ¥16.0 billion Share buybacks ¥13.0billion

Total: ¥133.0 billion



## Beyond 80 (Fiscal 2025–Fiscal 2029)

Funding	Investment
Operating CF (before R&D expenses) ¥125.0 billion	R&D ¥100.0 billion
Utilization of financial assets on hand ¥72.0 billion	IT investment ¥20.0 billion
	Capital Investment ¥20.0 billion
	Stable dividends ¥27.0 billion Share buybacks ¥30.0 billion

Total: ¥197.0 billion

# Promotion of Growth Investments for the Future

**KISSEI**

Beyond 80 (Fiscal 2025–Fiscal 2029)

Investment	Main Investment	Outcomes
R&D Investment    ¥100.0 billion	<ul style="list-style-type: none"><li>● Promotion of drug discovery research</li><li>● Advancement of clinical development themes</li><li>● In-licensing</li></ul>	<ul style="list-style-type: none"><li>● Revenue expansion through continuous drug launches</li><li>● Acquisition of new growth drivers</li><li>● Expansion of research and development pipeline</li></ul>
IT Investment    ¥20.0 billion	<ul style="list-style-type: none"><li>● Renewal of ERP system</li><li>● Strengthening of security</li></ul>	<ul style="list-style-type: none"><li>● Promotion of DX (Digital Transformation) and productivity improvement</li><li>● Strengthening Business Continuity Systems through Cybersecurity Measures</li></ul>
Capital Investment    ¥20.0 billion	<ul style="list-style-type: none"><li>● Research facilities</li><li>● Manufacturing facilities</li><li>● ESG investment</li></ul>	<ul style="list-style-type: none"><li>● Establishment of a stable supply system</li><li>● Strengthening of drug discovery research framework</li><li>● Improvement of work engagement</li><li>● Promotion of environmental management</li></ul>

# Capital Policy : Reduction of Equity Capital and Enhancement of Shareholder Returns

KISSEI

## Stable Dividends

- ◆ Progressive dividend (ordinary dividend)  
Over the period of Beyond 80  
**¥27.0 billion**

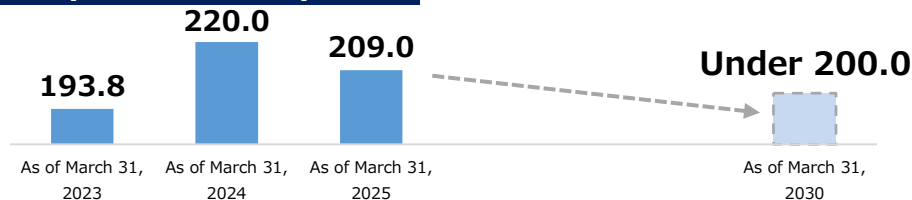
## Higher Capital Efficiency

- ◆ Flexible share buybacks  
Over the period of Beyond 80  
**¥30.0 billion**

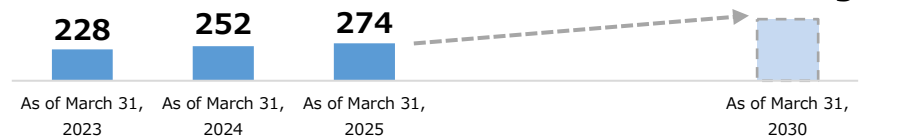
## Beyond 80

- Dividend payout ratio : 40% or higher
- Shareholders' Equity : Under 200.0 billion
- Basic earnings per share : 400 yen or higher
- Cross-Shareholdings : 10% or Lower  
(Ratio to Net Assets)

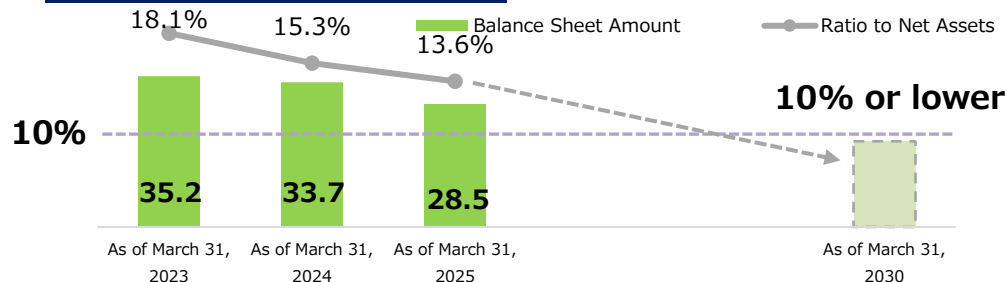
## Shareholders' Equity (Billions of Yen)



## Basic earnings per share (Yen)



## Cross-Shareholdings (Billions of Yen)



# Expand Drug Discovery Themes and Acquire Growth Drivers

**KISSEI**

Continuous drug discovery  
and expansion of the pipeline

## A faster, more efficient drug discovery process

- Strengthening and utilization of the technological foundation for small molecule drug discovery
- Business innovation for medicinal chemists and efficiency improvement of analysis and purification processes through standardization and automation
- Shorten compound creation periods for drug discovery projects
- Promote open innovation

## Utilization of digital technology and promotion of open innovation

Establishment of the Boston Open Innovation Office

Introduction of ChromaJean's analysis and preparative purification platform

Introduction of AI drug discovery platform Makaya™, produced by Iktos

Full-scale operation of the DAIIA-produced AI drug discovery tool

Collaborative research with Reborna on RNA-targeted drug discovery

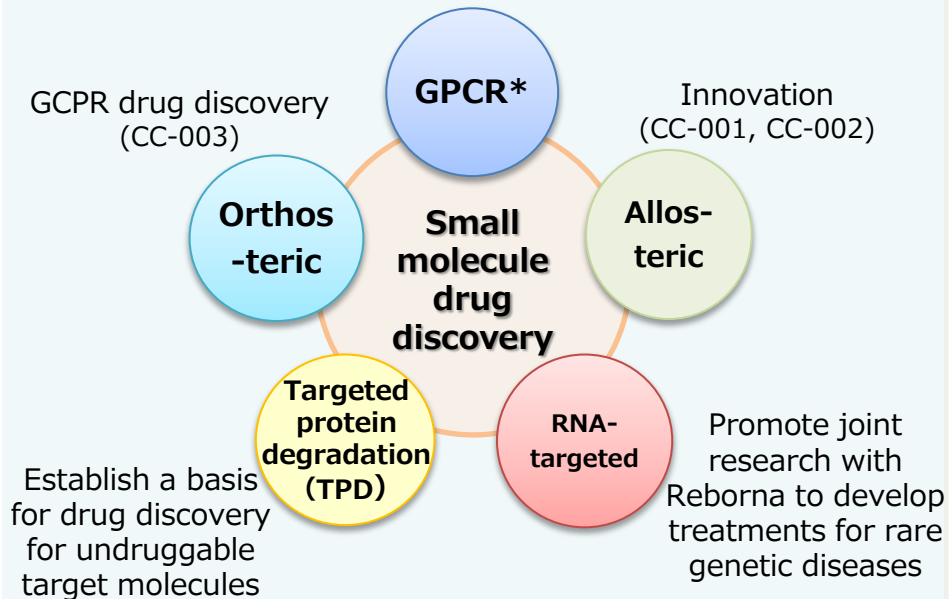
# Expand Drug Discovery Themes and Acquire Growth Drivers

KISSEI

Expand the development pipeline by promoting small molecule-focused drug discovery research

## 【Small Molecule Drug Discovery】

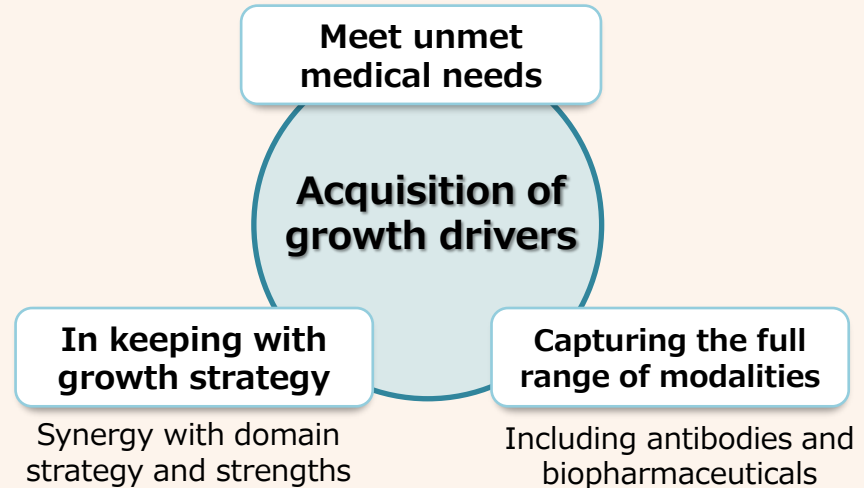
Expertise cultivated for over 30 years  
(Silodosin, Linzagolix, Matsupevole)



\* G protein-coupled receptor

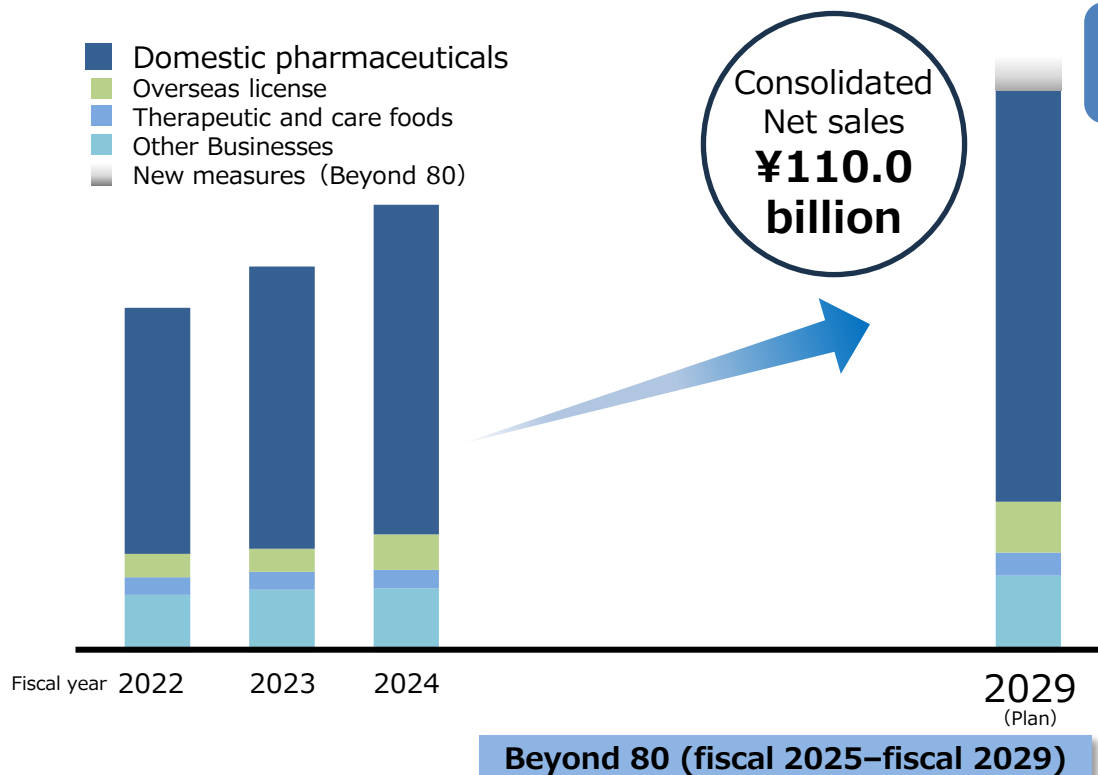
## 【In-Licensing】

Disease areas with no treatment options or low satisfaction with existing treatments.



# Expand and Grow Domestic Pharmaceuticals

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## Sustainable Expansion of Domestic Pharmaceutical Products

- Maximize sales of key products
  - ✓ Beova®, TAVNEOS®, KORSUVA®, TAVALISSE®, CAROGRA®
- Develop the products scheduled for launch over Beyond 80 as growth drivers (four products with six indications)
  - ✓ Linzagolix (Uterine fibroids, Endometriosis)
  - ✓ Cretostimogene grenadenorepvec (High-risk/Medium-risk Non-muscle-invasive bladder cancer)
  - ✓ Rovatirelin (Spinocerebellar degeneration)
  - ✓ Olutasidenib (IDH1 mutation-positive relapsed/refractory AML)

# Expand and Grow Domestic Pharmaceuticals

**KISSEI**

## Major Products

Field	Product	Fiscal 2025 (forecast) (Millions of yen)	Ideal Outcome
Urology	Beova®	20,400	Beova® becomes a first-line treatment for OAB* <sup>1</sup> , capturing a 50% share of patients in fiscal 2025
Rare and Intractable Diseases	TAVNEOS®	11,400	TAVNEOS® becomes the standard treatment for ANCA-associated vasculitis* <sup>2</sup> , replacing steroid treatments
Renal Diseases and Dialysis	KORSUVA®	7,100	KORSUVA® becomes the first choice for second-line treatment of pruritis in dialysis patients thanks to its ease of use and high efficacy
Rare and Intractable Diseases	TAVALISSE®	3,700	TAVALISSE® becomes a second-line treatment option for chronic ITP* <sup>3</sup>
Rare and Intractable Diseases	CAROGRA®	1,400	CAROGRA® becomes the first choice for treatment in cases where patients have an inadequate response to oral 5-ASA* <sup>4</sup>

\*1 Overactive bladder   \*2 Microscopic polyangiitis, granulomatosis with polyangiitis   \*3 Idiopathic thrombocytopenic purpura   \*4 5-aminosalicylic acid

# Expand and Grow Domestic Pharmaceuticals



## Products to be Launched over Beyond 80 (Four Products with Six Indications)

Field	Product name /Development code	Expected indications	Estimated number of domestic patients	Notable features
Gynecology	Linzagolix/KLH-2109	Uterine fibroids	Approx. 3.5–7.0 million*1	Linzagolix is Kissei's first original drug since silodosin. Linzagolix may serve as a new treatment option as the number of target patients increases with each year.
		Endometriosis	Approx. 1.34 million to 2.68 million*1	
Rare and Intractable Diseases	Cretostimogene grenadenorepvec/CG0070	High-risk Non-muscle invasive bladder cancer	Approx. 7,000*2	Local administration of the drug is expected to serve as a bladder-sparing [treatment/alternative] for patients who would otherwise require radical cystectomy.
		Medium-risk Non-muscle invasive bladder cancer (NMIBC)		
Rare and Intractable Diseases	Rovatisrelin/KPS-0373	Spinocerebellar degeneration	Approx. 37,000*3	Rovatisrelin is highly demanded by patients, and it is expected to improve satisfaction with treatment.
Rare and Intractable Diseases	Olutasidenib	IDH1 mutation-positive relapsed/refractory AML	Approx. 240–360*4	Olutasidenib features a good remission rate and a long remission period, and enables treatment that does not require blood transfusions.

\*1 "The Frontline of Endometriosis Treatment" (Tokyo: Igaku-Shoin, 2008)., "Medical Clinics of Uterine Diseases and Endometriosis" (Nihon Rinsho, 2009). (Japanese only)

\*2 According to the cancer statistics put forth by the National Cancer Center Japan's Cancer Information Service, of the new bladder cancer patients in Japan each year (23,230), 70% (16,261) had NMIBC, of which 30% (4,878) had carcinoma in situ. Of these patients, 49% (2,389) had received ineffective Bacillus Calmette-Guérin (BCG) treatment or suffered a relapse.

\*3 Number of recipients of a certificate for receiving medical expense assistance for designated intractable diseases provided by the Japan Intractable Diseases Information Center (as of March 31, 2024).

\*4 Number of patients [with relapsed/refractory AML that is IDH1 mutation-positive] calculated by taking the number of AML patients in Japan (13,000 according to the Ministry of Health, Labor and Welfare 2023 Patient Survey), multiplied by the number of patients that are IDH1 mutation positive (6–9% of patients, according to NCCN Guidelines 2025 V1), then multiplied by the number of patients with relapsed/refractory cases (approx 40% according to Blood (2015) 126 (3): 319–27.)  
(13,000×a×b= Approx. 360)

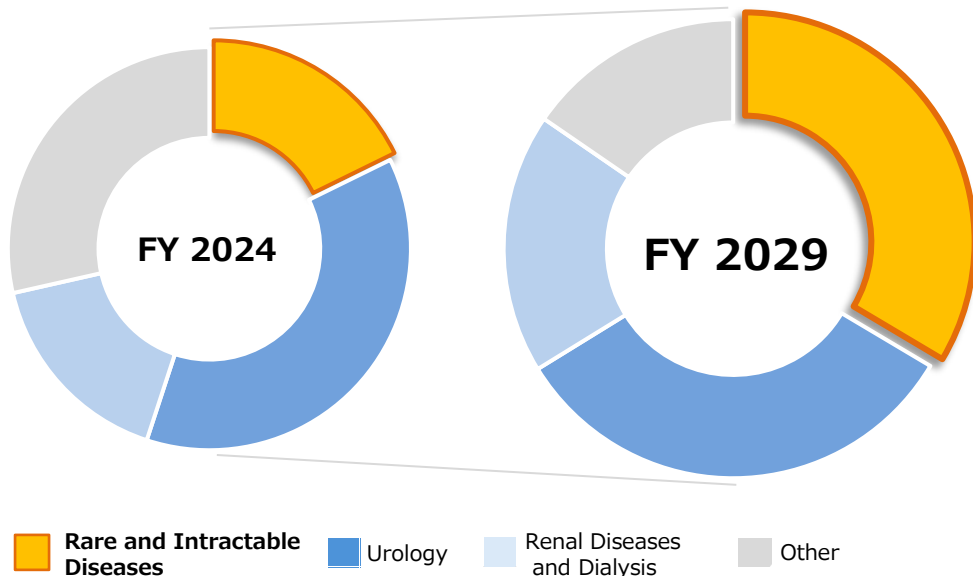


# Expand and Grow Domestic Pharmaceuticals

**KISSEI**

Final Year of PEGASUS

Final Year of Beyond 80



## Expansion of rare diseases and difficult illnesses field and development of domain strategy

- Expand the product lineup in the field of rare diseases and intractable diseases from 3 projects to 6 projects\*, and increase the scale of the business
- Strengthen the organization with a view to entering the oncology field
- Developing a strategy in the fields of urology, and renal diseases and dialysis leveraging our corporate presence
- Improving medical access through disease awareness and other means

\* TAVNEOS®, TAVALISSE®, CAROGRA®, Cretostimogene grenadenorepvec, Rovatirelin, Olutasidenib



# Increase overseas licensing income

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## Promote Global Development and Business Expansion for Linzagolix

### ■ Countries where Linzagolix is available (as of March 2025)

Germany, Spain, Poland, Italy, the U.K, Belgium

### ■ Benefits of prescribing Linzagolix

- ✓ Flexibility—can be used with or without add-back therapy
- ✓ Quick effect—rapid improvement of symptoms
- ✓ Effective in cases where other treatments are inadequate
- ✓ Effective in shrinking fibroids

## Strengthening the overseas revenue base

- Achieving the licensing out of new innovative products
- Sublicensing of in-licensed products (mainly in Asia)

Work with global companies to promote global development  
Increase the number of countries set for launch and expand business



### Overseas license\*

¥7.7 billion  
(Fiscal 2024)

▶ **¥10.0 billion  
or higher  
(Fiscal 2029)**

\* Includes revenue contracting fees related to out-licensing, milestone payments, running royalties, and exports

# New Drug Development (Out-Licensing) **KISSEI**

			Development stage						(As of May 2025)	
Generic name	Expected indications	Countries and regions	Phase			Preparation to submit application	NDA in process	NDA approved	Preparation for launch	Partner company
			I	II	III					
Linzagolix	Uterine fibroids	4 countries*1	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>			Theramex
		Taiwan	<div></div>	<div></div>	<div></div>	<div></div>			Synmosa Biopharma	
	Endometriosis	Europe	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>		Theramex	
Fostamatinib	Chronic ITP*2	South Korea	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>		JW Pharmaceutical
Silodosin	Dysuria associated with BPH*3	Vietnam, other countries	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>			Eisai

\*1 Switzerland, Brazil, Israel, South Africa

\*2 Idiopathic thrombocytopenic purpura

\*3 Benign prostatic hyperplasia



The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends as of May 2025. Actual results may differ from forecasts due to risks and uncertainties that may affect business. Although drug information, including information pertaining to drugs under development, is reported in these materials, the contents are not intended as marketing or medical advice.