KISSEI

Financial Briefing for the Fiscal Year Ended March 31, 2023 (Fiscal 2022)

Yasuo Takehana
President and COO

May 10, 2023

KISSEI PHARMACEUTICAL CO., LTD.

Summary of Financial Results for Fiscal 2022

1. Consolidated results

✓ Plan for fiscal 2022: Operating profit ¥500 million ⇒ Result: Operating loss ¥1,129 million

- Revenue from technical fees deferred to the following fiscal year
- Net sales for the Pharmaceutical Business did not reach target; cost of sales ratio increased

2. Domestic sales

✓ Launched two new drug products in Japan

- May 2022: Launched CAROGRA®, a treatment for ulcerative colitis
- June 2022: Launched TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis

✓ Increased sales of key products

- August 2022: Completed shipping adjustments for Beova®, a treatment for overactive bladder

3. Development pipeline

- TAVALISSE® (treatment for chronic idiopathic thrombocytopenic purpura): Received marketing authorization approval (December 2022) and launched (April 2023)
- Difelikefalin (treatment for uremic pruritis): Submitted new drug application (NDA) (September 2022)

4. Overseas earnings

✓ Original product: linzagolix

- Europe: A marketing authorization application was approved (June 2022) as a treatment for uterine fibroids, with plans to launch the drug in fiscal 2023 via Theramex
- U.S.: Investigate partnering with other companies instead of handling development in-Company

Consolidated Financial Results for Fiscal 2022

(millions of yen)

	Fiscal 2021		Fiscal 2022			
	Result	Ratio to net sales	Forecast	Result	Ratio to net sales	YoY
Net sales	65,381	100.0%	68,500	67,493	100.0%	3.2%
[Pharmaceutical Business]	[54,147]	[82.8%]	[57,500]	[56,243]	[83.3%]	[3.9%]
Pharmaceuticals*1	45,792	70.0%	47,600	47,077	69.8%	2.8%
Therapeutic and care foods	3,568	5.5%	3,600	3,461	5.1%	(3.0)%
Technical Fees*2	518	0.8%	1,700	1,053	1.6%	103.4%
Other*3	4,268	6.5%	4,600	4,650	6.9%	8.9%
Cost of sales	34,143	52.2%	34,400	35,118	52.0%	2.9%
Gross profit	31,238	47.8%	34,100	32,374	48.0%	3.6%
Selling, general and administrative expenses	32,640	49.9%	33,600	33,503	49.6%	2.6%
[R&D expenses]	[10,363]	[15.9%]	[10,500]	[10,391]	[15.4%]	[0.3%]
Operating profit (loss)	(1,402)	–	500	(1,129)	–	–
Ordinary profit	562	0.9%	2,100	598	0.9%	6.4%
Profit*4	12,921	19.8%	10,800	10,528	15.6%	(18.5)%
Comprehensive income	(13,764)			(4,229)		

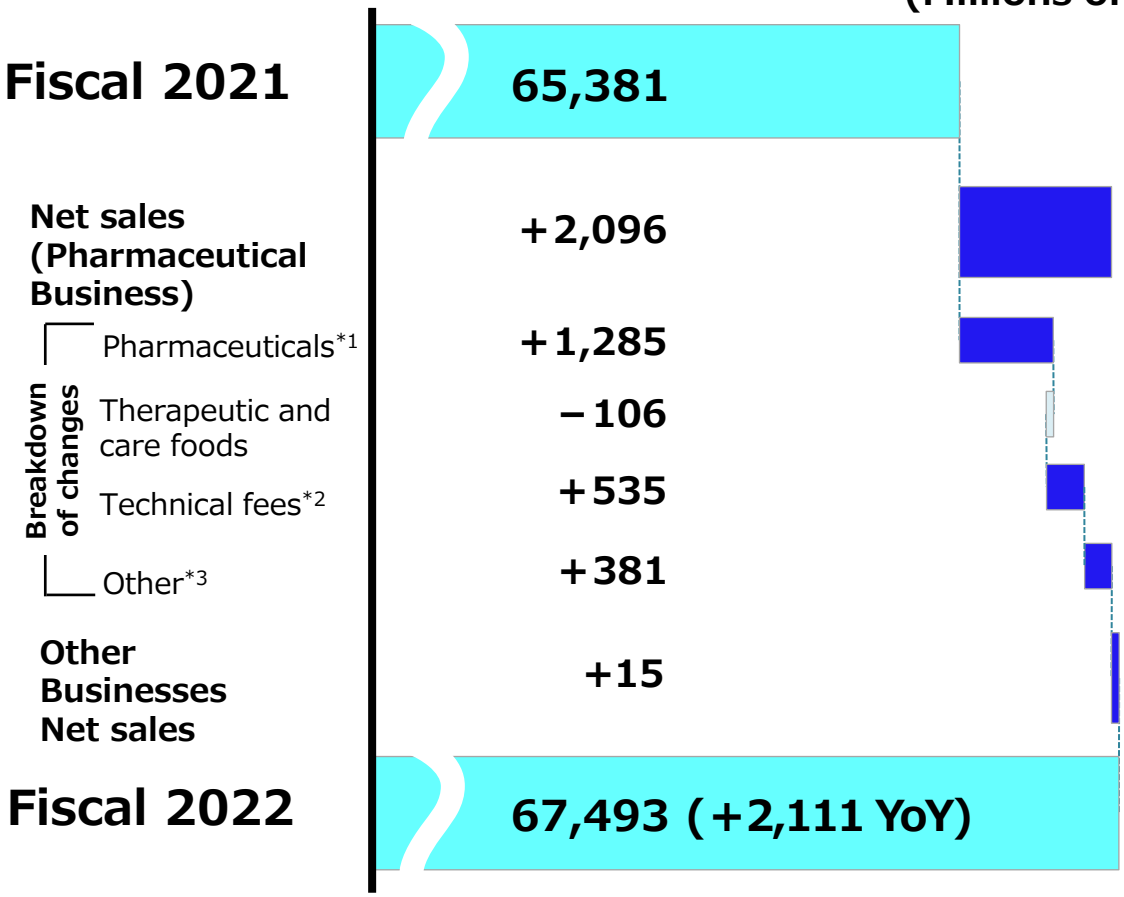
*1 Including active pharmaceutical ingredients (APIs) and bulk exports
*2 Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties
*3 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees
*4 Profit refers to profit attributable to owners of parent

Please refer to pages 2, 3, and 8 of the Supplementary Explanatory Materials on Financial Results

Consolidated Financial Results Compared with Fiscal 2021

(Millions of yen)

Source of increase | Source of decrease



・Increase due to launch of CAROGRA® and TAVNEOS®, and increased sales of Beova®

・Increase in co-promotion fees

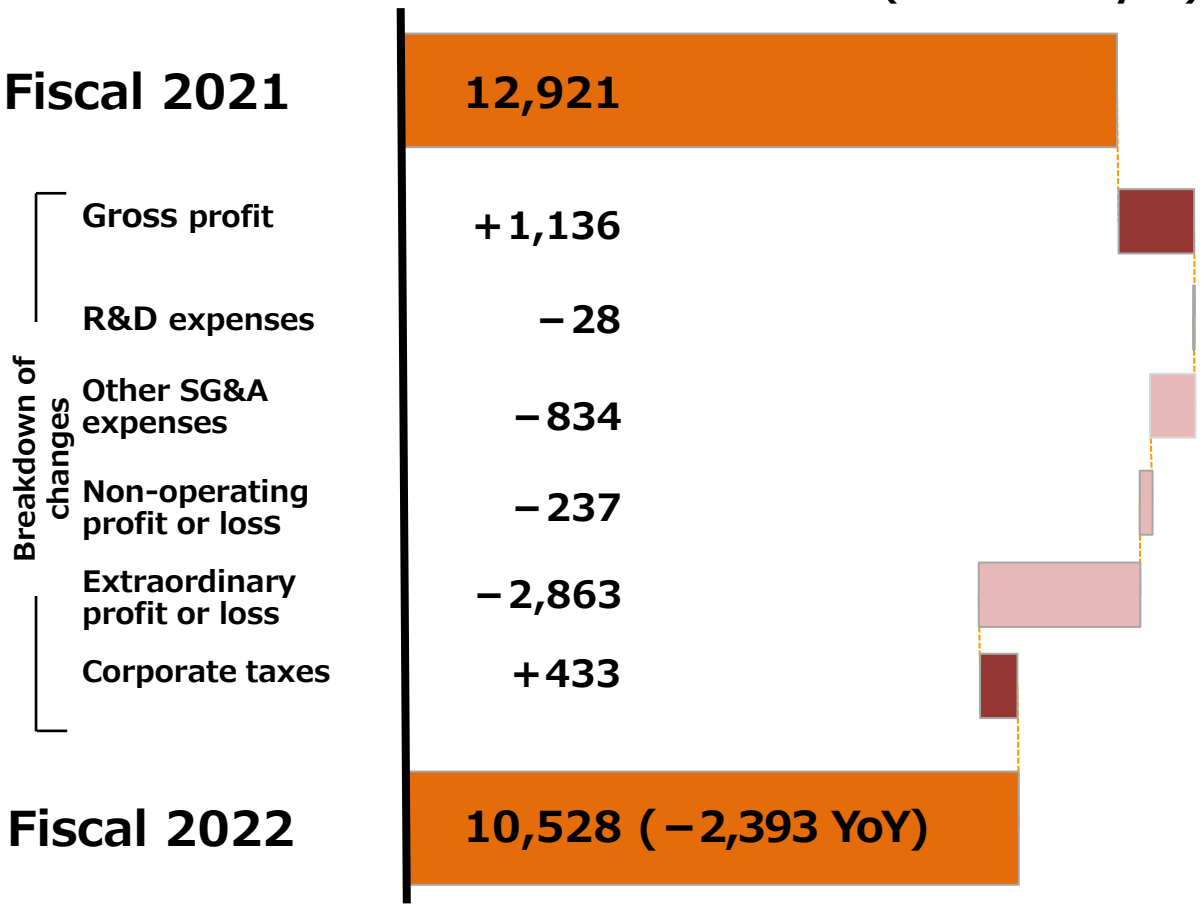
・Increase in revenue from information services and merchandising

*1 Including active pharmaceutical ingredients (API) and bulk exports
*2 Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties
*3 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees

Consolidated Profit Attributable to Owners of Parent Compared with Fiscal 2021

(Millions of yen)

Source of increase | Source of decrease



・Increase due to an increase in revenue in the Pharmaceutical Business

・Increase primarily in selling expenses

・Decrease in gain on sale of investment securities

Plan for Fiscal 2023 (Consolidated)

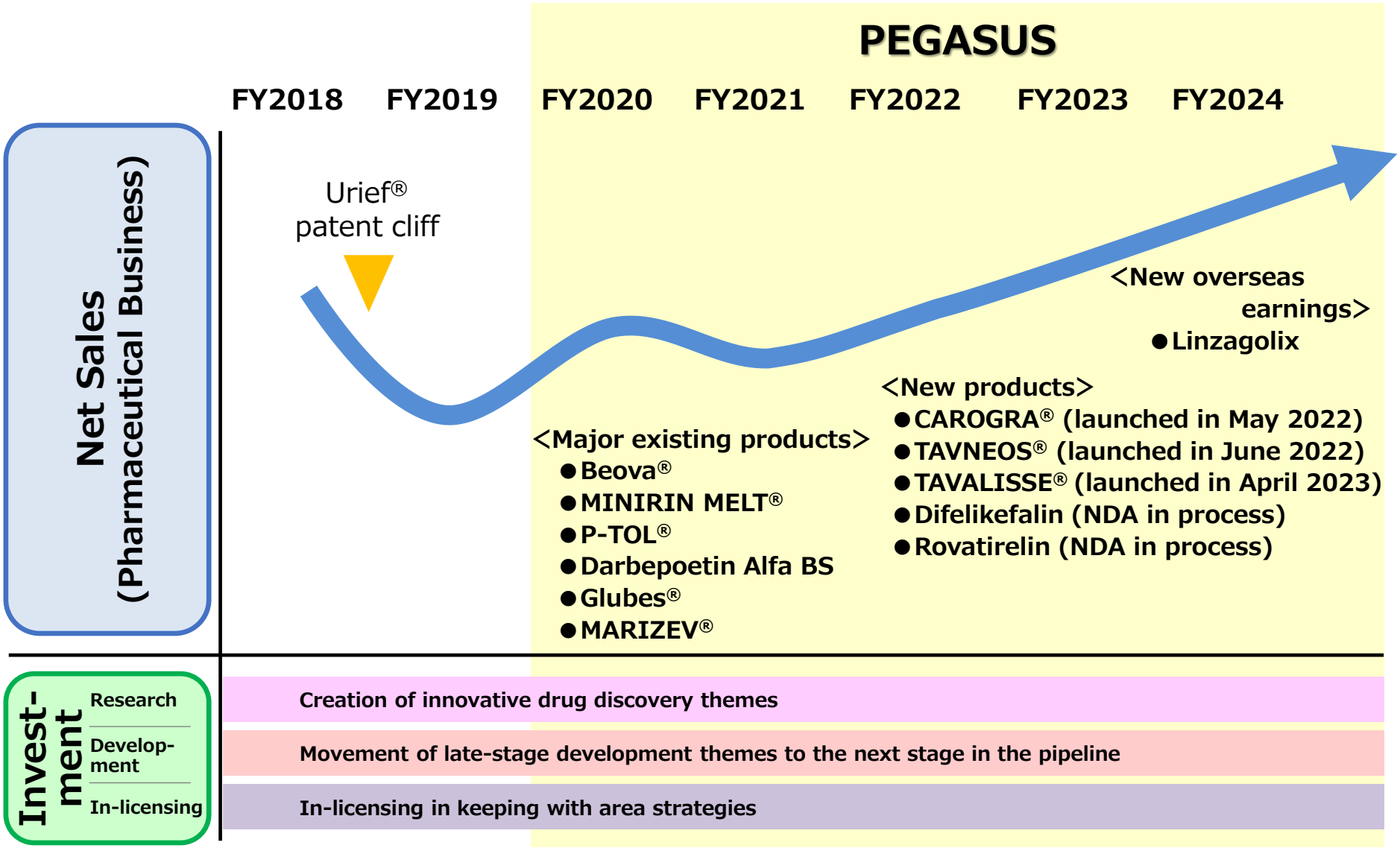
(millions of yen)

	Fiscal 2022		Fiscal 2023 Forecast			
	Result	Ratio to net sales	Full year	Ratio to net sales	YoY	First half
Net sales	67,493	100.0%	74,500	100.0%	10.4%	35,500
[Pharmaceutical Business]	[56,243]	[83.3%]	[62,500]	[83.9%]	[11.1%]	[29,500]
Pharmaceutical products	47,077	69.8%	51,500	69.1%	9.4%	25,000
Therapeutic and care foods	3,461	5.1%	3,600	4.8%	4.0%	1,800
Technical fees	1,053	1.6%	3,000	4.0%	184.7%	500
Other	4,650	6.9%	4,400	5.9%	(5.4)%	2,200
Cost of sales	35,118	52.0%	37,600	50.5%	7.1%	18,500
Gross profit	32,374	48.0%	36,900	49.5%	14.0%	17,000
Selling, general and adminstrative expenses	33,503	49.6%	32,700	43.9%	(2.4)%	16,100
[R&D expenses]	[10,391]	[15.4%]	[9,200]	[12.3%]	[(11.5)%]	[4,500]
Operating profit (loss)	(1,129)	–	4,200	5.6%	–	900
Ordinary profit	598	0.9%	5,200	7.0%	768.4%	1,500
Profit*1	10,528	15.6%	10,600	14.2%	0.7%	4,800

*1 Profit refers to profit attributable to owners of parent

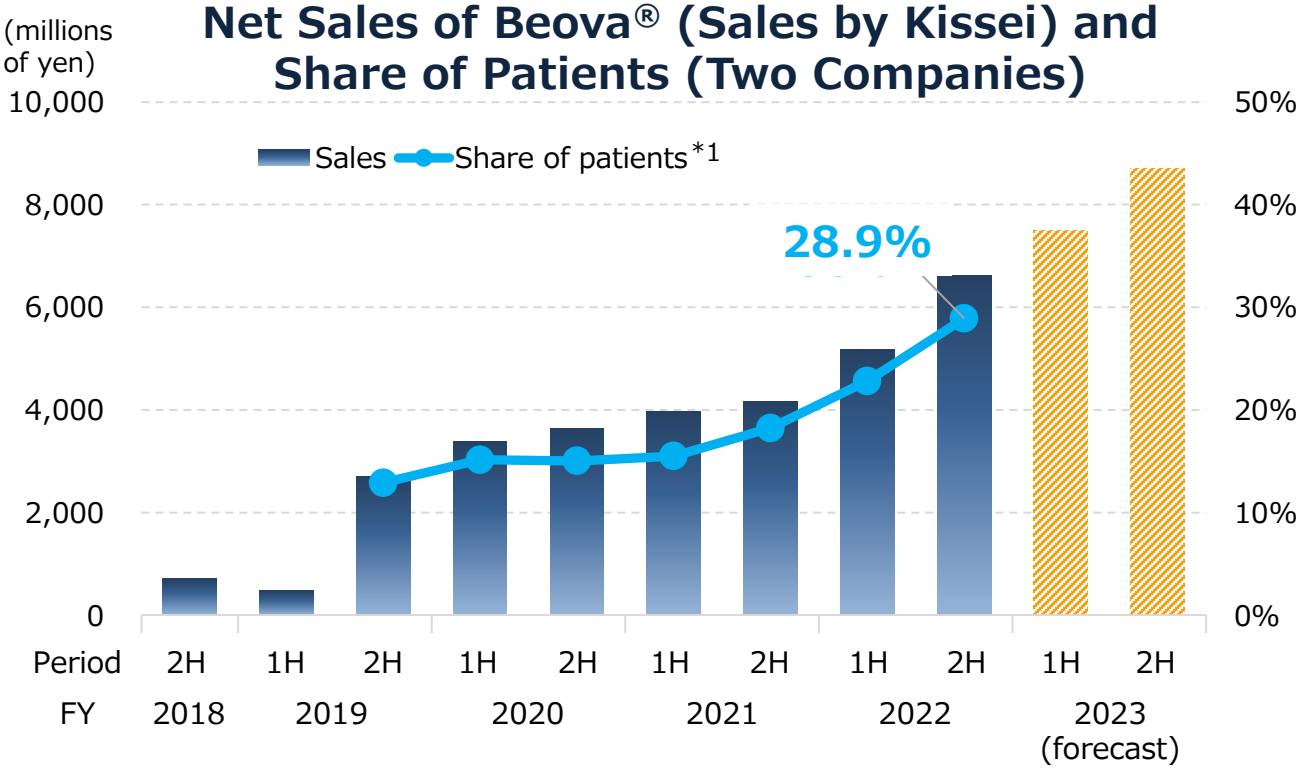
Please refer to pages 2, 3, and 8 of the Supplementary Explanatory Materials on Financial Results

Outlook for the Pharmaceutical Business



Beova®: Becoming the Most-Prescribed Treatment for Overactive Bladder

Net Sales of Beova® (Sales by Kissei) and Share of Patients (Two Companies)



Sales forecast for fiscal 2023: ¥16.2 billion (+37% YoY)

Beova® is administered to about 40%*2 of patients beginning treatment for OAB, with net sales and the share of patients on a steady rise.

Position Beova® as a beta-3 agonist with high efficacy and safety and the No. 1 treatment for overactive bladder

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*1 Share of patients receiving overactive bladder treatment (beta-3 adrenoreceptor agonists, anticholinergic drugs, etc.)

*2

Urology Area Strategy

Spreading awareness

▶ Promote awareness of urology conditions through public lectures, websites, and materials for patients

Provision of Information

▶ Propose appropriate treatments for three conditions and communicate benefits to patients

▶ Kissei's medical representatives (MRs) in urology praised highly by doctors*1

Provide appropriate drug treatments to patients suffering from lower urinary tract symptoms (LUTS)

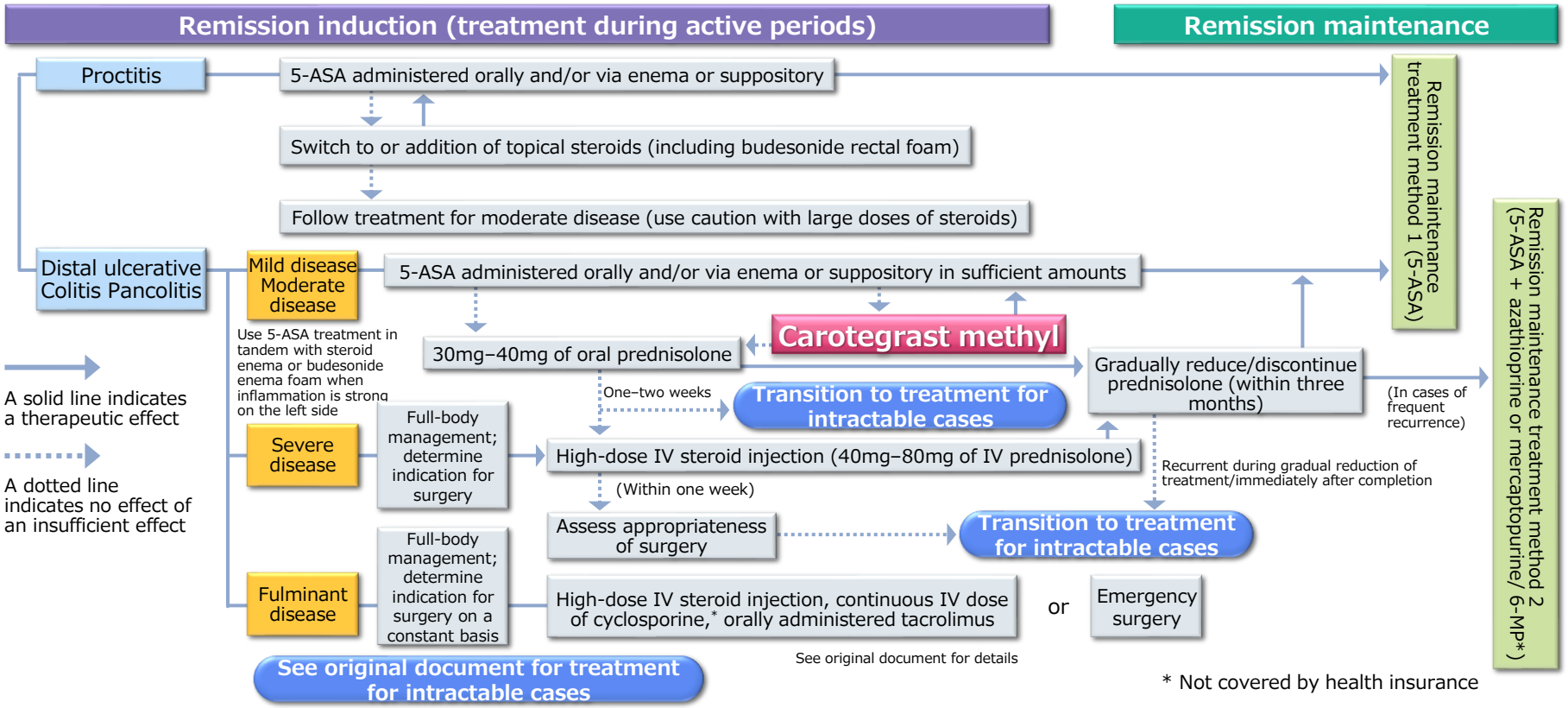
	Beova®	MINIRIN MELT®	Urief®
Indications	▶Overactive bladder (OAB)	▶Nocturia due to nocturnal polyuria	▶Benign prostatic hyperplasia(BPH)
Positioned in treatment guidelines	▶Grade A recommendation*2 *2 *Clinical Guidelines for Overactive Bladder Syndrome* (3rd edition, 2022)	▶ Grade A recommendation for men*3 *3 *Clinical Guidelines for Nocturia* (2nd edition, 2020)	▶Grade A recommendation*4 *4 *"Clinical Guidelines for Lower Urinary Tract Symptoms in Males with Benign Prostatic Hyperplasia," (2017)*

Kissei Pharmaceutical is the only pharmaceutical company that offers drugs to treat three conditions: OAB, nocturia, and BPH.

*1 Ranked 2nd in urology in a 2023 survey regarding MRs requested by doctors, published in MIX Online

CAROGRA®: Diagnostic Criteria and Treatment Guidelines for Ulcerative Colitis/Crohn's Disease

Ulcerative Colitis Flow Chart



Partially adapted from page 17 of an assigned research report for Investigation and Research on Intractable Inflammatory Bowel Disease (Hisamatsu Group) as part of the Research Program on Rare and Intractable Diseases, funded by the Ministry of Health, Labour and Welfare's Health, Labor and Welfare Sciences Research Grants system, fiscal 2022

- **CAROGRA® (Carotegrast methyl) is clearly positioned within the revised 2023 treatment guidelines**
- **June 2023: Two-week restriction on dosage period to be lifted**

▶ **Sales forecast for fiscal 2023: ¥1.4 billion (+180% YoY)**

TAVNEOS®: Positioning

Provide a new option to treat ANCA-associated vasculitis as the standard alternative to steroids

Post-launch period

Positioning in accordance with ADVOCATE trial evidence

TAVNEOS® + immunosuppressive agent + low-dosage, short-term corticosteroids

Corticosteroids

TAVNEOS®

Cyclophosphamide or rituximab, etc. → Azathioprine, etc.

Targets:

- **Initial goal of remission induction treatment through a combination of low-dosage, short-term corticosteroids and an immunosuppressive agent**
- Number of target patients amounts to approx. 3,300 per year (approx. 2,000 new patients + 1,300 patients with recurrences)*1, *2

Future

Work with medical experts to build product based on post-launch evidence

TAVNEOS® + immunosuppressive agent (potentially non-steroid)

TAVNEOS®

Cyclophosphamide or rituximab, etc. → Azathioprine, etc.

TAVNEOS® + low-dosage, short-term corticosteroids (potentially without immunosuppressive agents)

Corticosteroids

TAVNEOS®

Utilize other drugs to maintain remission in patients

Remission induction using other drugs → **TAVNEOS®** or Patients undergoing remission maintenance treatment switch to TAVNEOS®

Targets: Almost all patients that require drugs for treatment (approx. 14,000 people*1)

*1 Fiscal 2021 Report on Public Health Administration and Services: Number of patients receiving medical expense payments for designated intractable diseases (as of the end of March 2022)
*2 Calculations derived from *Rheumatology* 2011; 50, 1916-1920, *Arthritis Res Ther.* 2015; 17, 305, and *J Rheumatol.* 2018; 45(4), 521-528

TAVNEOS®: Current Status and Outlook

Provide a new option to treat ANCA-associated vasculitis as the standard alternative to steroids

Estimated Number of Patients Treated*1

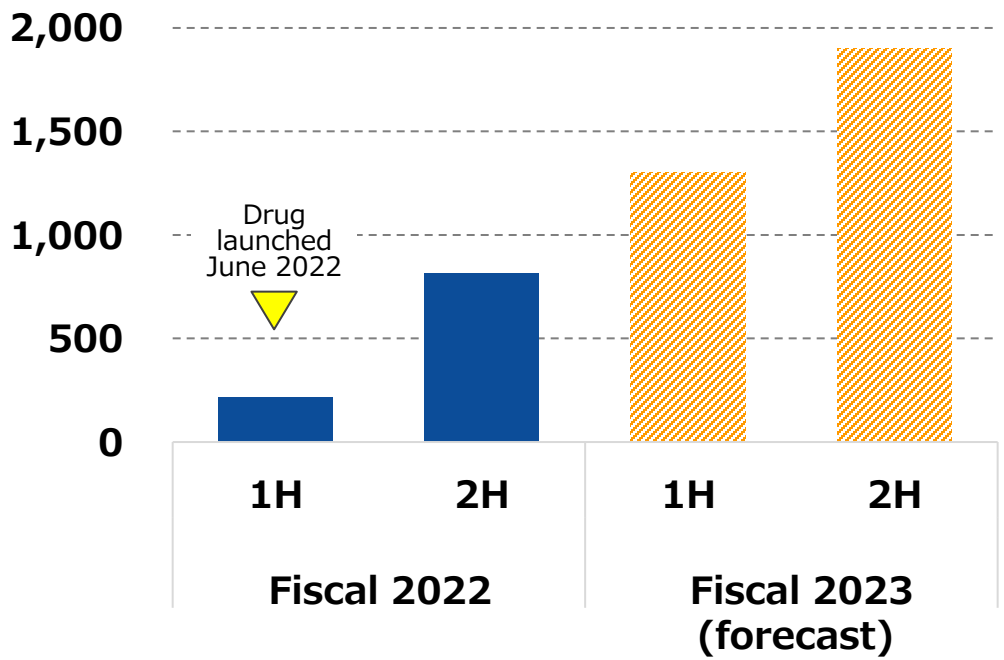
Approx. 580

Prescriptions*2

About 80% remission induction rate among patients receiving the drug since launch

Net sales

(millions of yen)



June 2023: Two-week restriction on dosage period to be lifted

Sales forecast for fiscal 2023: ¥3.2 billion (+211% YoY)

*1 In-house total based on sales volume performance for 6 months after launch
*2 In-house total

TAVALISSE®: Overview

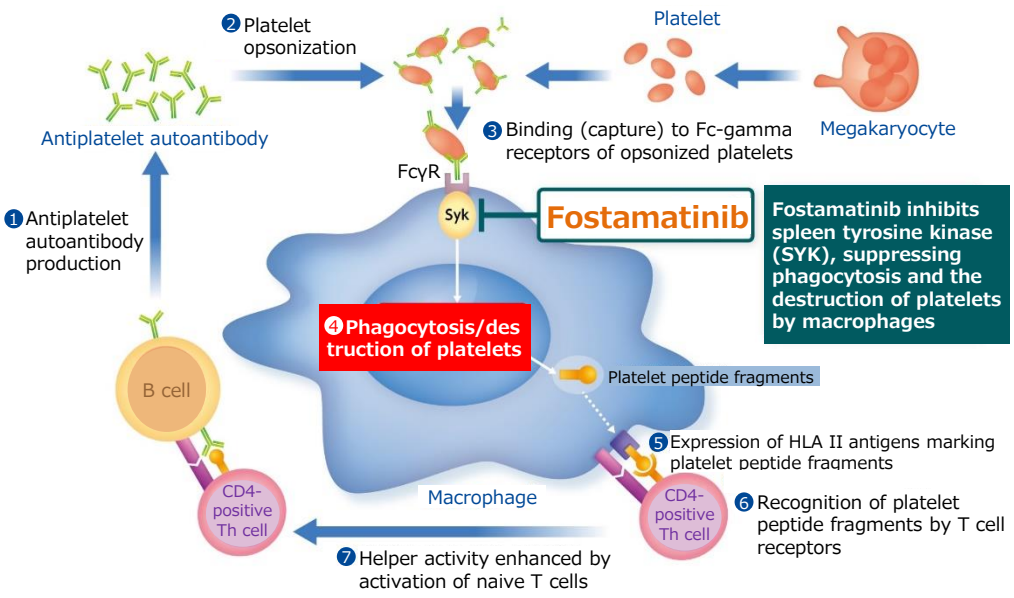
Date of launch: April 6, 2023

Indications
Chronic idiopathic thrombocytopenic purpura (ITP*1)

Drug Price
¥4,188.0 per tablet (100 mg),
¥6,226.8 per tablet (150 mg)

Dosage and Administration
Typical initial adult dosage of fostamatinib is 100mg administered orally twice a day. If platelet counts have not increased to the target level by four weeks after administrating the initial dose and there are no safety issues, the dose should be increased to 150mg twice a day. The dosage may be adjusted according to the patient's platelet count and symptoms. The maximum dose is 150mg twice a day.

Mechanism of Action



- SYK*2 inhibitor that can be used to treat chronic ITP, a rare disease, with a novel mechanism of action that has effects similar to those of causative therapy, suppressing phagocytosis and platelet destruction
- Provides a new treatment option for patients who have had an insufficient response to previous treatments

  Main symptoms of ITP: petechiae, nosebleeds, and gum bleeding, and intracerebral bleeding and gastrointestinal bleeding in severe cases
- Number of patients with ITP (designated intractable disease) in Japan: 16,972*3

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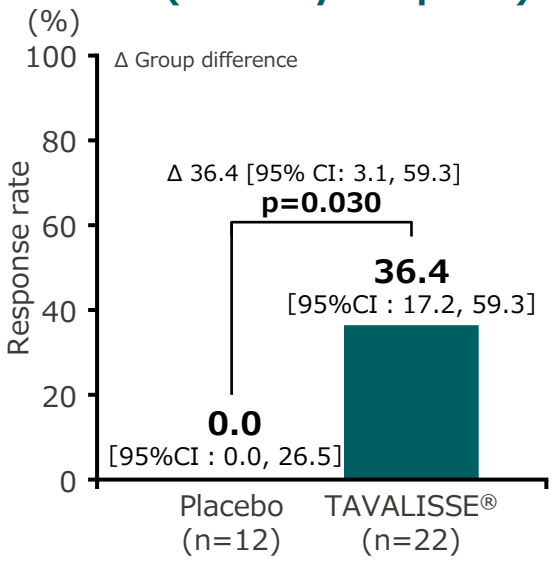
*1 ITP: Idiopathic thrombocytopenic purpura
*2 SYK: Spleen tyrosine kinase
*3 Fiscal 2021 Public Health Administration Report; patients receiving medical expense payments for designated intractable diseases

TAVALISSE®: Clinical Trial Results

Results of domestic Phase III clinical trial (R788-1301)

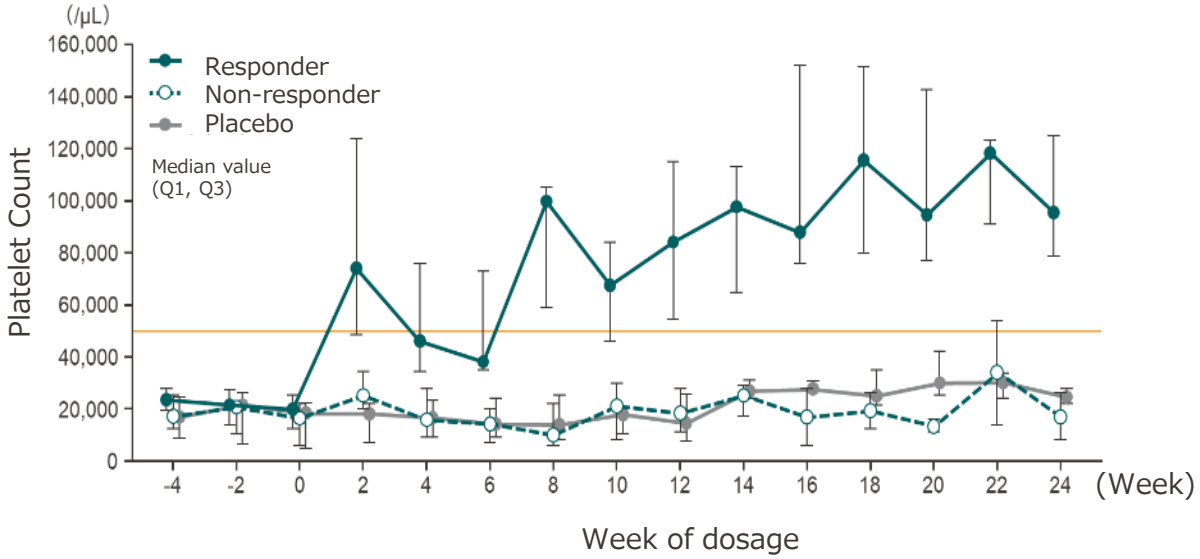
First Period (Double-Blind Test)

Stable platelet response*1 (Primary endpoint)



P-value: Fisher's exact test

Platelet Count for Responders*2 and Non-Responders (Subgroup Analysis of Secondary Endpoint)

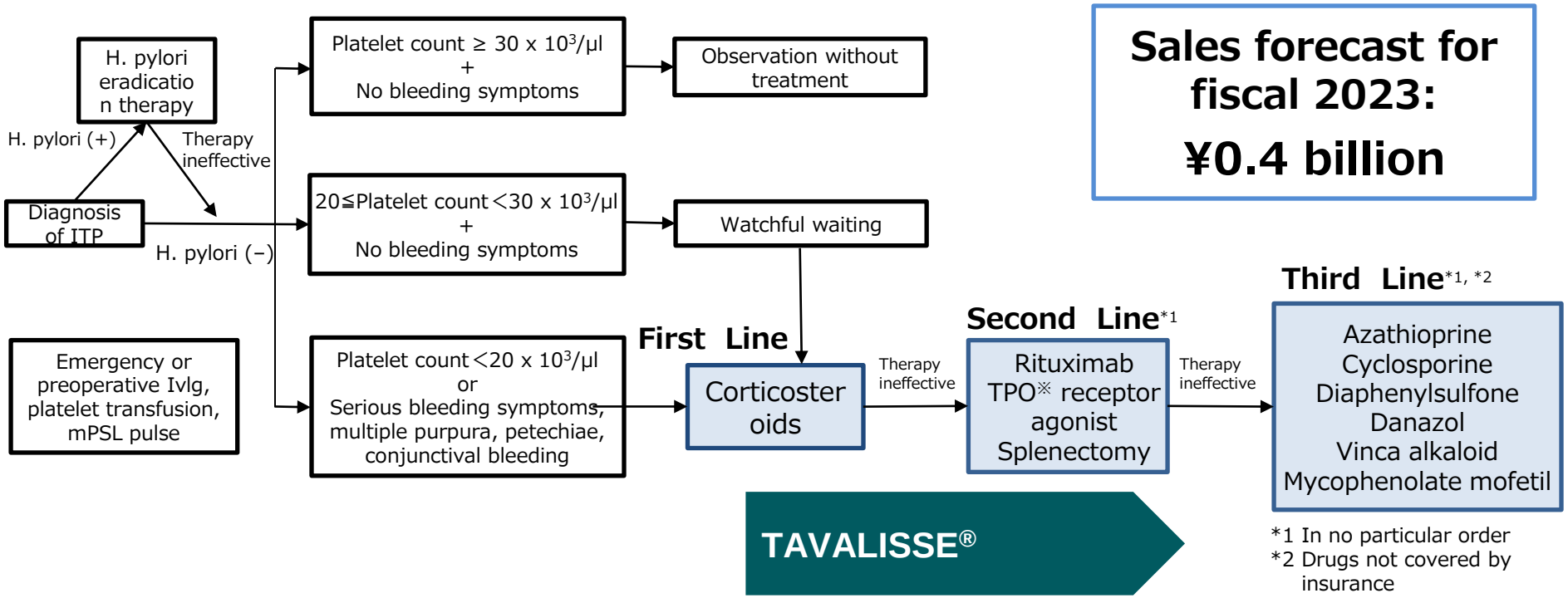


*1 Stable platelet response: Platelet count of 50,000/μl or higher at four or more of the six hospital visits from weeks 14 to 24
*2 Responder: Patients who achieved a stable platelet response (primary endpoint)

Data from domestic Phase III clinical trials of the drug in patients with idiopathic thrombocytopenic purpura, submitted as part of the application for marketing authorization approval
Kuwana M et al.: *Br J Haematol.* DOI: https://doi.org/10.1111/bjh.18582, 2022 (Study funded by Kissei Pharmaceutical Co., Ltd.; authors include those who have received consulting fees from Kissei Pharmaceutical Co., Ltd., and employees of Kissei Pharmaceutical Co., Ltd.)

TAVALISSE®: Positioning

Position drug as a second-line treatment as an orally administered drug with a novel mechanism of action that inhibits platelet destruction associated with ITP



Sales forecast for fiscal 2023:

¥0.4 billion

TAVALISSE® utilizes a novel mechanism of action to inhibit platelet destruction in a manner similar to steroids

- Patients with an insufficient response to or who are unable to tolerate other treatments
- Patients who need to maintain or reduce steroid dosage
- Patients deemed suitable for an orally administered second-line treatment

※ Thrombopoietin

Kashiwagi Hirokazu et al, *Jpn J Clin Hematol*. 2019; 60(8), 877-896. (partially adapted)

Introduce New Products to the Market, Focusing on Rare Diseases

TAVNEOS® **TAVALISSE®**

Smooth provision of new drugs to medical sites through collaboration between the Rare Diseases Project* and MRs

*A department responsible for planning marketing strategies in the rare disease area, collecting information nationwide, and providing specialized and advanced information

CAROGRA®

Establishment of drug positioning through co-promotion with EA Pharma

▶Three products with a common concept

- Drugs that target designated intractable diseases for which steroids are used as a treatment strategy to help solve the dilemma of choosing between the efficacy of steroids and facing their side effects
- New treatment options aimed at inducing or maintaining remission by helping taper off steroids (TAVNEOS®, TAVALISSE®) or delaying steroid use (CAROGRA®)
- Information provision that leads to optimal treatment plans put forth based on medical experts' treatment strategies

Provide new value to patients suffering from rare and intractable diseases

New Drug Development (In-Company)

Generic name / Development code	Expected indications	Development stage: Phase I	Phase II	Phase III	NDA in process	Development classification
Rovatirelin / KPS-0373	Spinocerebellar ataxia					In-licensed / Shionogi
Difelikefalin / MR13A9	Pruritus in hemodialysis patients					In-licensed / Co-development with Maruishi Pharmaceutical
CG0070	Non-muscle-invasive bladder cancer					In-licensed / CG Oncology Joint global Phase III clinical trial
Linzagolix / KLH-2109	Uterine fibroids					Original product
	Endometriosis					Original product
KDT-3594	Parkinson’s disease					Original product
KSP-0243	Ulcerative colitis					Original product

Difelikefalin: Overview

◆ **Expected indication: Pruritus in hemodialysis patients (improvement of symptoms when existing treatments are inadequate)**

- Licenser: Maruishi Pharmaceutical Co., Ltd. (via Cara Therapeutics, Inc., originator of the drug)
- Domestic development: Primary endpoint achieved in Phase III clinical trials, NDA submitted in September 2022 by Maruishi Pharmaceutical
- Launch status overseas: Launched in April 2022 in the U.S. and in November 2022 in Austria and Germany by CSL Vifor

Characteristics:

- Helps ease itching (pruritis) by selectively activating kappa opioid receptors, which improves disruptions in opioid balance, one of the causes of pruritus in hemodialysis patients
- Administered intravenously via a prefilled syringe formulation three times a week after dialysis sessions, and can be administered reliably without having to take medication
- Expected to have few instances of insomnia and other central nervous system side effects due to low possibility of crossing the blood-brain barrier

Number of domestic patients:

- Approximately 350,000 patients undergoing hemodialysis in Japan[*1]
- 75% of hemodialysis patients complain of pruritus and 38% have moderate or severe pruritus[*2]

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*1 *2020 Annual Dialysis Data Report*, JSDT Renal Data Registry, December 31, 2021
*2 *Clin J Am Soc Nephrol.* 2017 Dec 7; 12(12): 2000–2007

Difelikefalin: Clinical Trial Results

Domestic Phase II clinical trial

Design: Placebo-controlled double-blind comparative study

Participants: Hemodialysis patients with previously treated pruritus*1

Dosages: Difelikefalin (0.25μg/kg, 0.5μg/kg, and 1.0μg/kg) or placebo

Dosage period and method: Eight weeks, administered intravenously three times a week at the end of each dialysis session

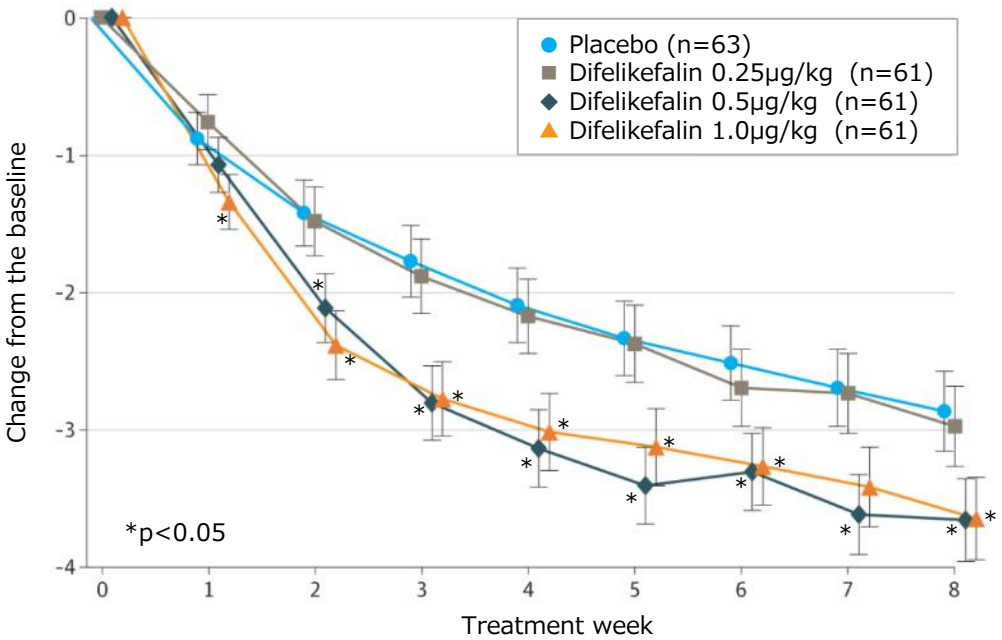
Primary endpoint: Change in the Worst Itching Intensity Numerical Rating Scale (NRS) score*2 at week eight)

Pre-screening	Eight-week double-blind treatment	Follow-up period
	Placebo Difelikefalin 0.25μg/kg Difelikefalin 0.5μg/kg Difelikefalin 1.0μg/kg	

Summary of Results

- A statistically significant difference was observed between the placebo group and the 0.5μg/kg and 1.0μg/kg groups of difelikefalin, achieving the primary endpoint.
- Secondary endpoints, including quality of life scores, also showed efficacy of the drug compared with the placebo group.
- The incidence of adverse events and side effects increased depending on the dosage. No side effects of insomnia were observed, and results in terms of safety were favorable.
- The clinically recommended dose should be set at 0.5μg/kg, and the drug has been advanced to Phase III clinical trials.

Change in NRS score



*1 Patients experiencing a certain level of itching or higher even after treatment with moisturizing agents or topical steroids
*2 An 11-point scale evaluating itching ranging from 0 (no itching) to 10 (maximum itching)

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Narita I, et al. *JAMA Netw Open.* 2022 May 2;5(5):e2210339.

New Drug Development (Out-Licensing)

Generic name / Development code	Expected indications	Countries and regions	Development stage							Partner company
			Clinical trials under preparation	Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	NDA approved	
Linzagolix / KLH-2109	Uterine fibroids	Europe								Theramex
		China								Bio Genuine
		Taiwan								Synmosa Biopharma
	Endometri-osis	Europe								Theramex
		China								Bio Genuine
Silodosin	Dysuria associated with BPH*1	Vietnam, other countries								Eisai
Fostamatinib / R788	Chronic ITP*2	South Korea								JW Pharmaceutical
		China, other countries								Inmagene Biopharmaceuticals
KDT-3594	Parkinson's disease	China, Other countries								AffaMed Therapeutics

- Linzagolix
  - Europe: Scheduled for launch in fiscal 2023
  - U.S.: Investigate partnering with other companies instead of handling launch in-Company

Changes from November 2022

*1 benign prostatic hyperplasia
*2 idiopathic thrombocytopenic purpura

Enhance Drug Discovery Research

What: Commitment to the concept of drug discovery

- Modality: Focus on small molecule drug discovery
- Targets: Find targets that leverage the advantages of small molecules
- Mechanism of action: Discover unprecedented new use cases

- **Co-create using the latest technology from outside the Company**
- **Utilize digital technology**

How: Innovation in compound creation technology

- Boost drug design capabilities
- Shorten the compound discovery period
- Strengthen the proprietary assessment system and assessment capabilities

Expand development pipeline

Basic Policy on the Distribution of Profits

◆ Financial Strategy

Regarding profit attributable to owners of parent, our goal is to achieve an ROE of 5.0% or higher.

We will secure net income through the effective use of cross-shareholdings and other financial assets and actively expand and bolster capital investment. This includes investment in R&D (drug discovery research, milestone payments for existing development themes, introduction of new development themes, enhancing R&D facilities, etc.), strategic ICT investments (DX, etc.), and production facilities.

◆ Basic Policy on the Distribution of Profits

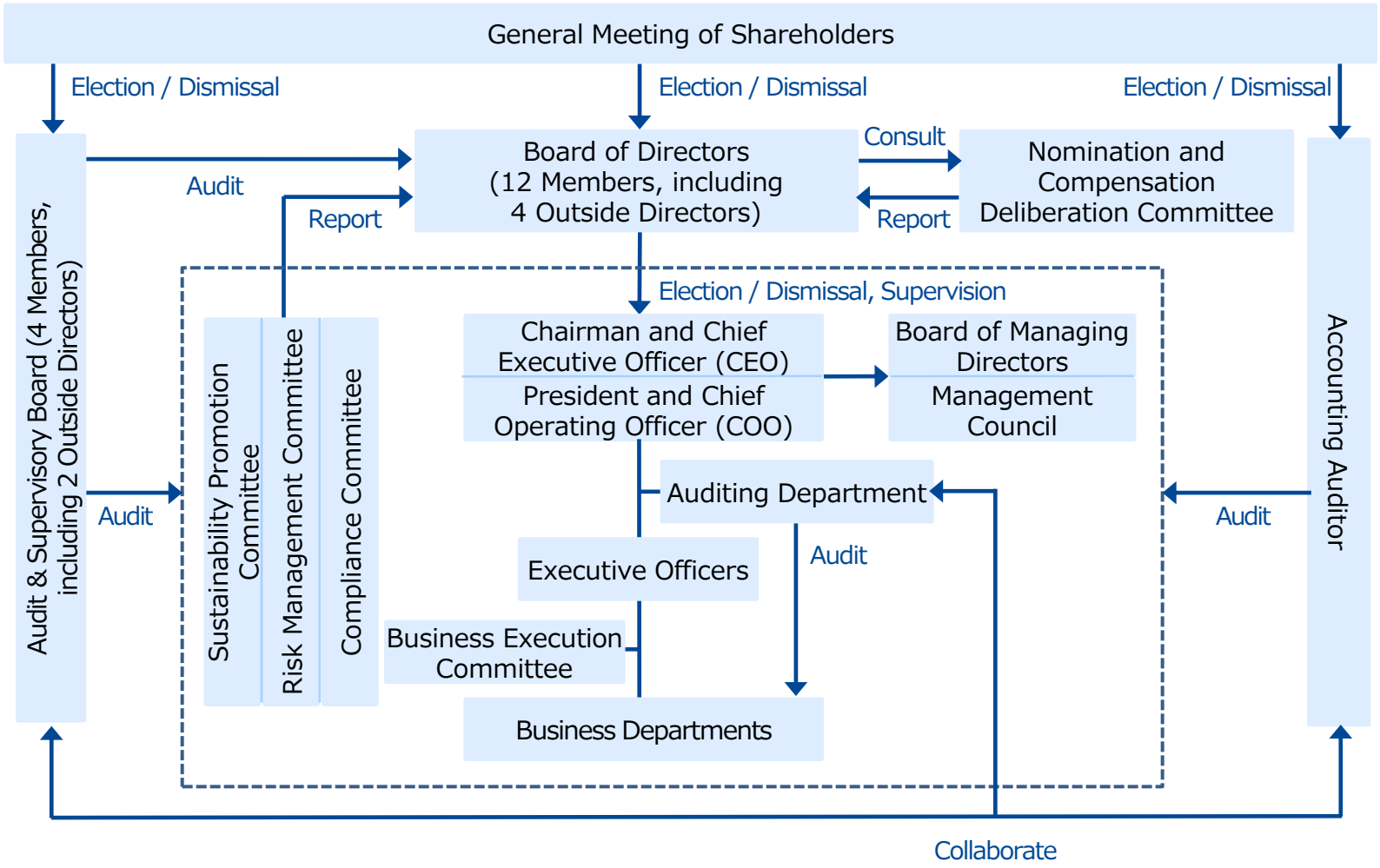
As a company listed on the Prime Market, we aim to secure a solid management base while providing stable, consistent returns to shareholders.

◆ Purchase and Disposal of Treasury Stock

Improve capital efficiency and expand shareholder returns

	Fiscal 2018	Fiscal 2019	Fiscal 2020	Fiscal 2021	Fiscal 2022	Fiscal 2023 Forecast
Annual dividend per share	¥50	¥52	¥54	¥56	¥80	¥82
Dividend payout ratio (consolidated)	42.6%	86.2%	47.7%	20.0%	35.0%	35.7%
Treasury stock purchased (No. of shares)			¥1.3 billion (0.6 M shares)			¥6.0 billion (2.0 M shares)
Disposal of treasury stock (No. of shares)						(2.5 M shares)

Corporate Governance Bodies and Internal Control System



The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends as of May 2023. 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.