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Financial Briefing for the Second Quarter of the Fiscal Year Ended March 31, 2024 (Fiscal 2023)

Yasuo Takehana
President and COO

November 8, 2023

KISSEI PHARMACEUTICAL CO., LTD.

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Overview of the Financial Results for the Second Quarter of Fiscal 2023

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1. Consolidated Results

- ✓ **Net sales: ¥36,978 million (+12.5% YoY)**
- ✓ **Operating profit: ¥2,015 million**
  - Increased sales in the Pharmaceutical Business and other businesses

2. Pharmaceutical Business

✓**Net sales: ¥30,765 million (+10.1% YoY)**

- Key products: **Beova®,** a treatment for overactive bladder
- New products: **TAVNEOS®,** a treatment for MPA*1 and GPA*2 (restrictions of dosage period lifted in June 2023)

  CAROGRA®, a treatment for ulcerative colitis (restrictions of dosage period lifted in June 2023)

  TAVALISSE®, a treatment for chronic ITP*3 (launched in April 2023)

*1 Microscopic polyangiitis *2 Granulomatosis with polyangiitis *3 Idiopathic thrombocytopenic purpura

Overview of the Financial Results for the Second Quarter of Fiscal 2023

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3. Development pipeline

- **KORSUVA®** (treatment for uremic pruritis*): New Drug Application (NDA) approved (September 2023), preparations for launch underway
- **Rovatirelin** (treatment for spinocerebellar ataxia): NDA withdrawn, possibility of conducting additional trials currently under discussion

4. Overseas earnings

✓**Expand overseas earnings base through original products**

- **Linzagolix** (treatment for uterine fibroids)

  Europe: Launch of the drug as a treatment for uterine fibroids scheduled for fiscal 2024 via Theramex (marketing authorization application approved in June 2022)

* Indication: Improvement of pruritus in hemodialysis patients (limited to cases in which the effects of existing treatments are insufficient)

Consolidated Financial Results for the Second Quarter of Fiscal 2023

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(millions of yen)

	Second quarter of fiscal 2022		Second quarter of fiscal 2023			
	Result	Ratio to sales	Plan	Result	Ratio to net sales	YoY
Net sales	32,864	100.0 %	35,500	36,978	100.0 %	12.5 %
[Pharmaceutical Business]	[27,946]	[85.0 %]	[29,500]	[30,765]	[83.2 %]	[10.1 %]
Pharmaceuticals*1	23,550	71.7 %	25,000	26,420	71.4 %	12.2 %
Therapeutic and care foods	1,766	5.4 %	1,800	1,763	4.8 %	(0.1 %)
Technical fees*2	220	0.7 %	500	171	0.5 %	(22.2 %)
Other*3	2,410	7.3 %	2,200	2,410	6.5 %	0.0 %
Cost of sales	16,680	50.8 %	18,500	18,677	50.5 %	12.0 %
Gross profit	16,184	49.2 %	17,000	18,300	49.5 %	13.1 %
Selling, general and administrative expenses	16,810	51.1 %	16,100	16,284	44.0 %	(3.1 %)
[R&D expenses]	[5,200]	[15.8 %]	[4,500]	[4,499]	[12.2 %]	[(13.5 %)]
Operating profit (loss)	(625)	–	900	2,015	5.5 %	–
Ordinary profit	308	0.9 %	1,500	3,465	9.4 %	–
Quarterly profit*4	3,326	10.1 %	4,800	5,678	15.4 %	70.7 %
Comprehensive income	26			9,608		

*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 Refers to quarterly 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 2022

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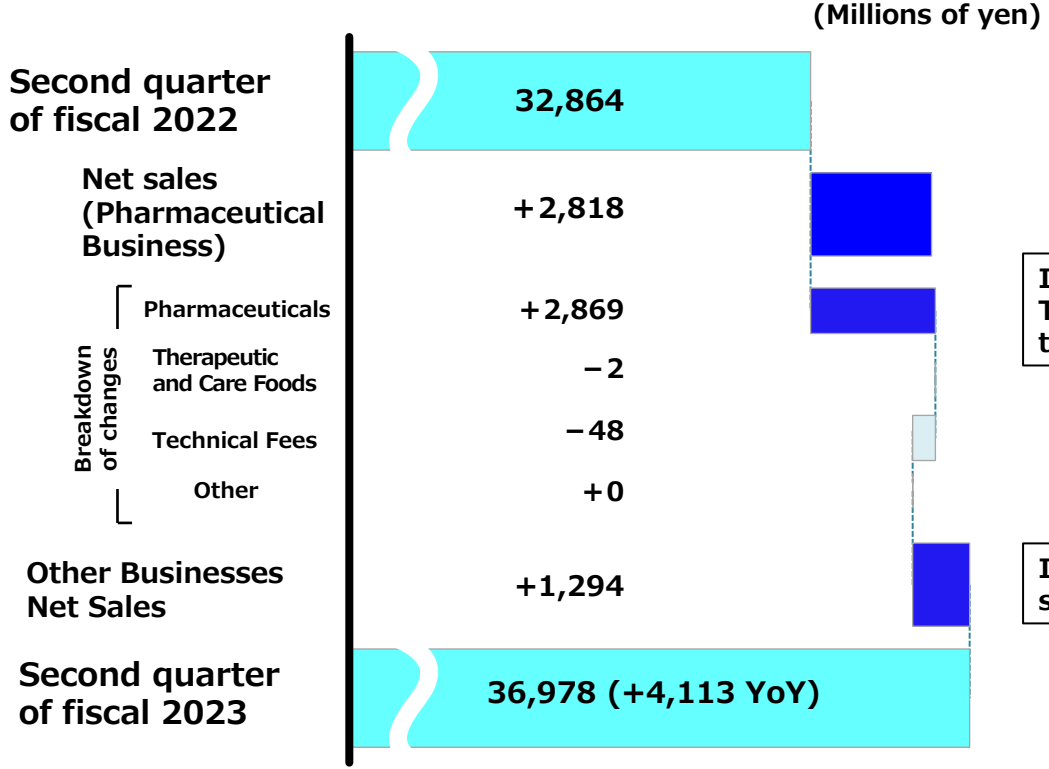
(Millions of yen)



Source of increase | Source of decrease

Increase in revenue from sales of Beova®, TAVNEOS®, and CAROGRA®, in addition to the launch of TAVALISSE®

Increase in revenue from information services, construction, and merchandising

Consolidated Quarterly Profit Attributable to Owners of Parent Compared with Second Quarter of Fiscal 2022

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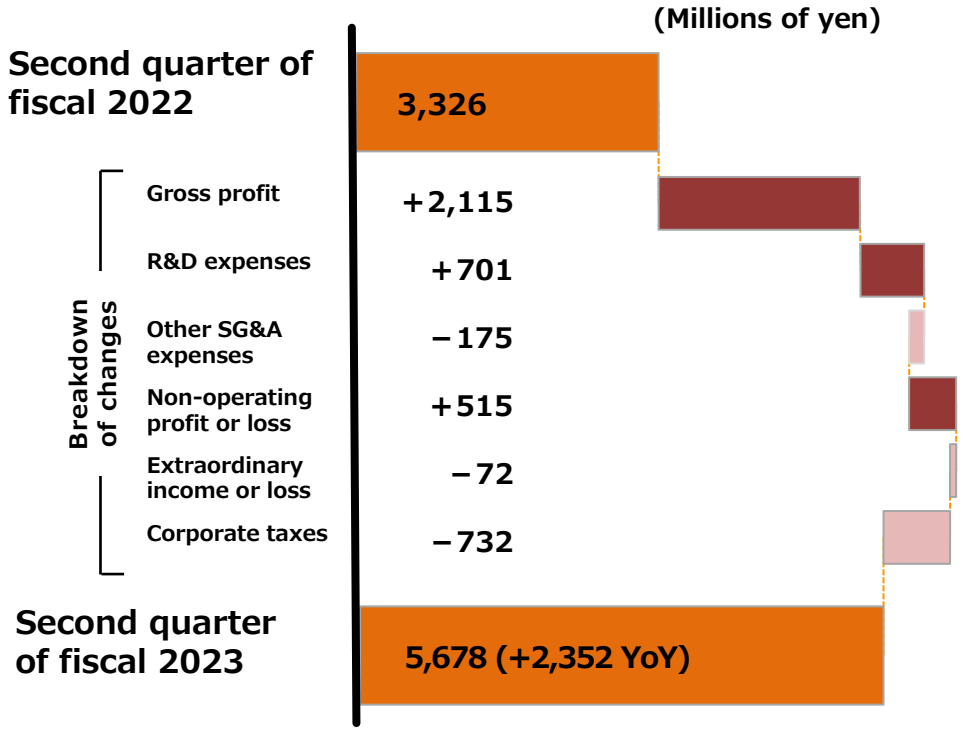

Source of increase	Source of decrease

Increase in revenue, primarily in the Pharmaceutical Business

Increase in the gain on sale of securities and gain on valuation of securities

Decrease in gain on sale of investment securities

Revised Plan for Fiscal 2023 (Consolidated)

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(millions of yen)

	Fiscal 2022		Fiscal 2023			
	Result	Ratio to net sales	Initial plan	Revised plan	Ratio to net sales	YoY
Net sales	67,493	100.0 %	74,500	77,500	100.0 %	14.8 %
[Pharmaceutical Business]	[56,243]	[83.3 %]	[62,500]	[65,000]	[83.9 %]	[15.6 %]
Pharmaceuticals	47,077	69.8 %	51,500	54,500	70.3 %	15.8 %
Therapeutic and Care Foods	3,461	5.1 %	3,600	3,600	4.6 %	4.0 %
Technical Fees	1,053	1.6 %	3,000	1,900	2.5 %	80.4 %
Other	4,650	6.9 %	4,400	5,000	6.5 %	7.5 %
Cost of sales	35,118	52.0 %	37,600	39,300	50.7 %	11.9 %
Gross profit	32,374	48.0 %	36,900	38,200	49.3 %	18.0 %
Selling, general and administrative expenses	33,503	49.6 %	32,700	33,200	42.8 %	(0.9 %)
[R&D expenses]	[10,391]	[15.4 %]	[9,200]	[9,400]	[12.1 %]	[(9.5 %)]
Operating profit (loss)	(1,129)	–	4,200	5,000	6.5 %	–
Ordinary profit	598	0.9 %	5,200	6,700	8.6 %	–
Profit attributable to owners of parent	10,528	15.6 %	10,600	10,000	12.9 %	(5.0 %)

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

Pharmaceutical Business | Toward Sustainable Growth

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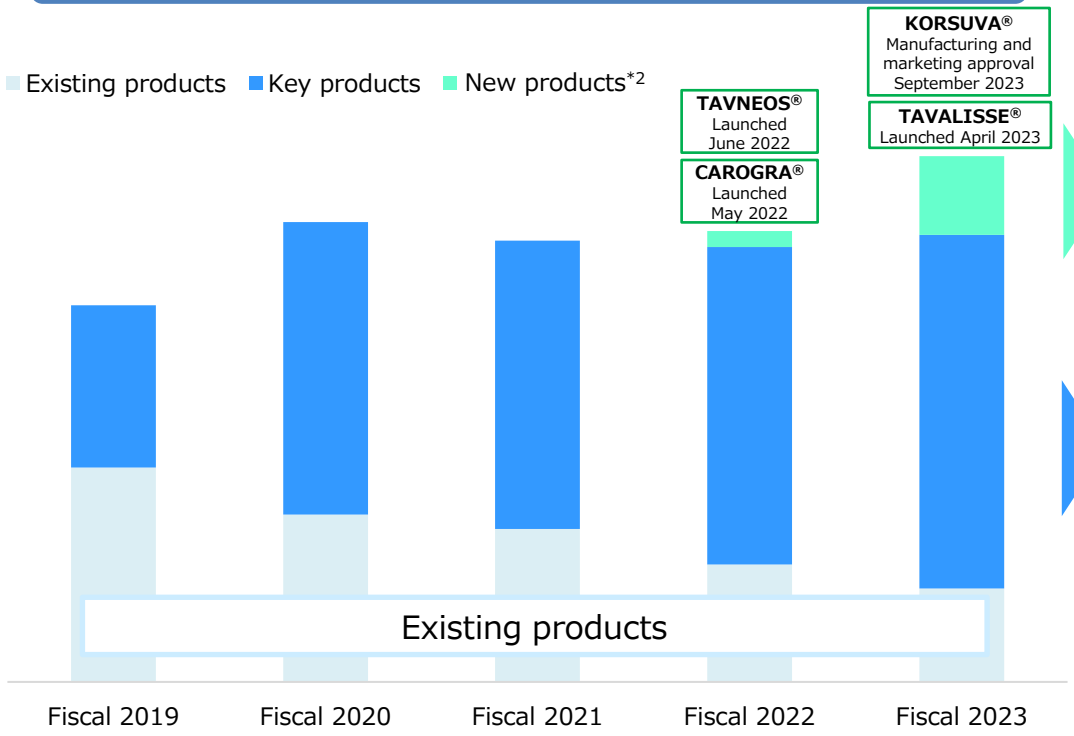
Net Sales for Pharmaceuticals*1



*1 Total domestic sales for the Company
*2 Total for drugs launched since the beginning of fiscal 2022 (TAVNEOS®, CAROGRA®, TAVALISSE®, KORSUVA®)

Growth Strategy

Continue to launch new products, mainly in rare diseases

- Launch four new products over a one and a half year period, including products to treat rare and designated intractable diseases
- Increase sales ratio of the products in the rare diseases field (TAVNEOS® and TAVALISSE®) (ratio has increased to 11% during fiscal 2023)

Expansion of sales of mainstay products, focusing on primary care

- Increase sales centered on OAB treatment Beova®
- Provide information using field-specific strategies, centered on urology and renal diseases and dialysis

Acquire overseas earnings base

Achieve sustainable growth

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

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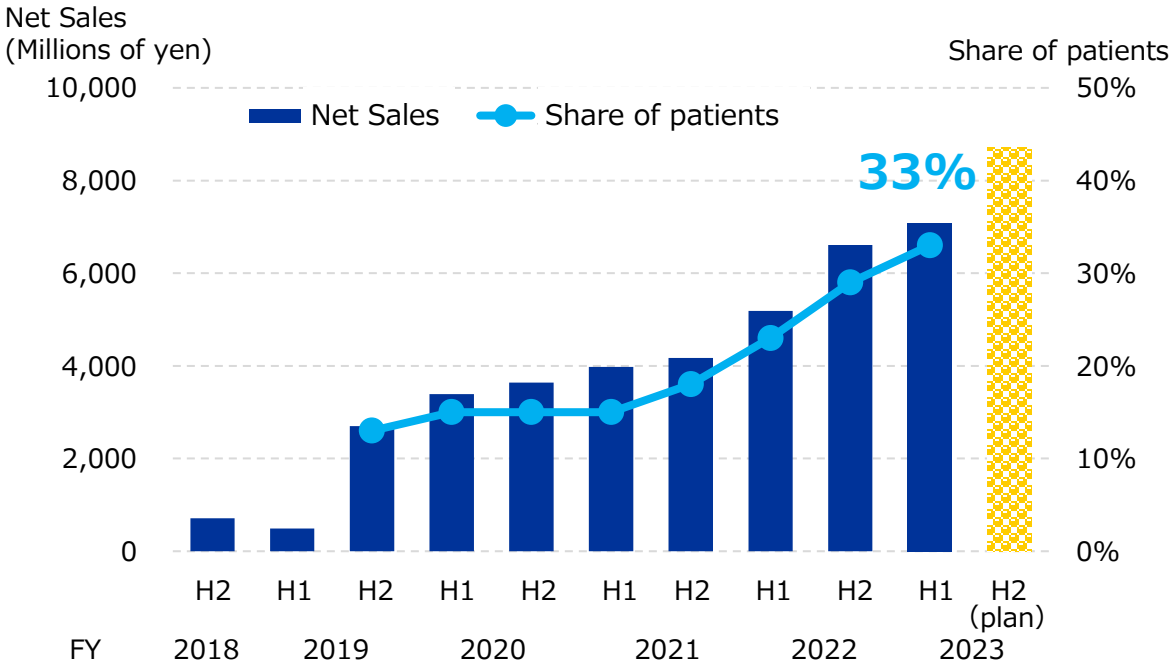
Net Sales (Sales by Kissei) and Share of Patients*1 (Two Companies)



Plan for fiscal 2023:

¥15.8 billion (+34.0% YoY)

*1 Share of patients receiving overactive bladder treatment. Compiled in-house based on JPM PATDY 2019/10-2023/8, Reprinted with permission, Copyright © 2023 IQVIA.

Status of Introduction of New Products to the Market | Dealing with Intractable Diseases

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	TAVNEOS®	TAVALISSE®	CAROGRA®
Common concepts	● These drugs offer new options to patients with designated intractable autoimmune diseases who have an inadequate response to or difficulty controlling their diseases with conventional treatments by utilizing different mechanisms of action. ● These drugs could solve the dilemma of choosing the efficacy of steroids (glucocorticoids) and having to face their side effects.		
Status	➢ **Began marketing activities via the Rare Diseases Project* in 2021, and are conducting activities to provide scientific information based on treatment needs and policies** ➢ **Products have been praised for meeting unmet needs, spread through the market is faster than anticipated**		

Provide new value faster to more patients who suffer from rare and intractable diseases

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

TAVNEOS® | Clinical Guidelines for ANCA-Associated Vasculitis 2023

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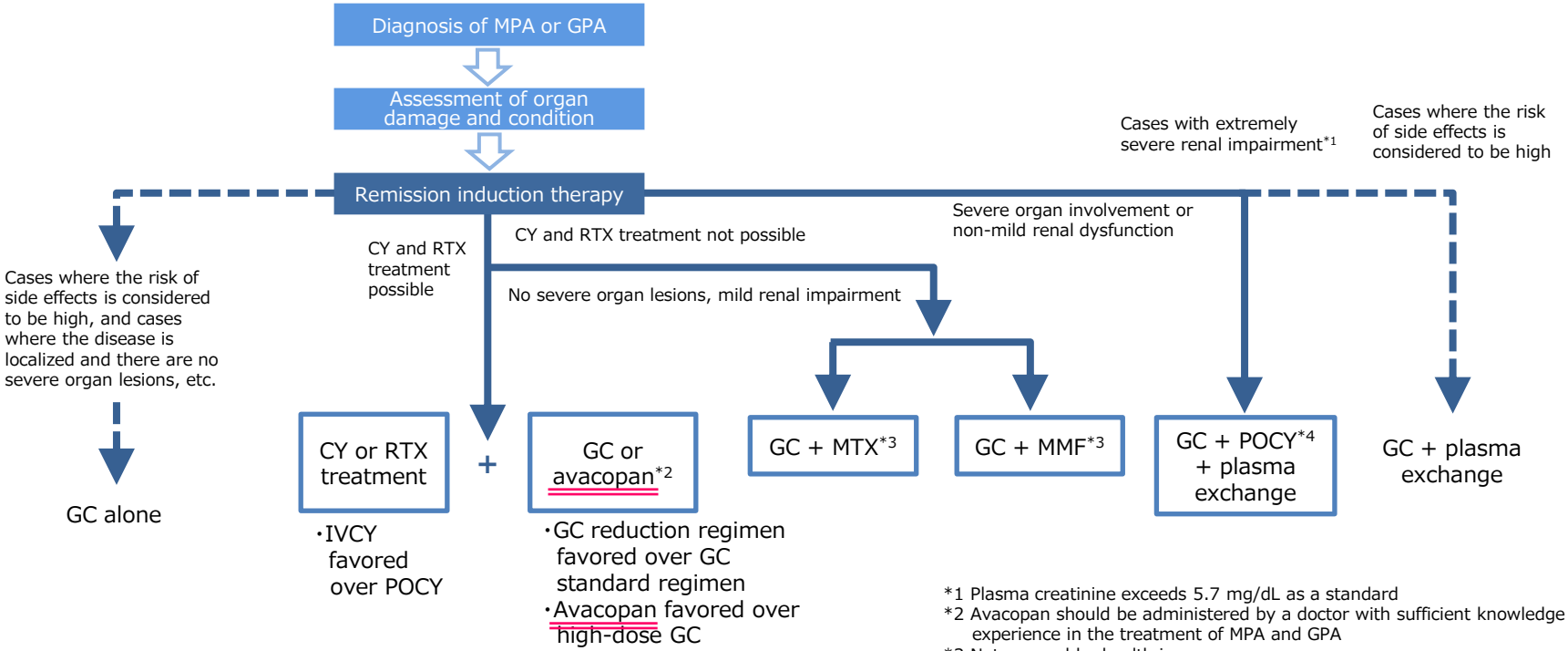
Treatment Regiment Options for MPA and GPA

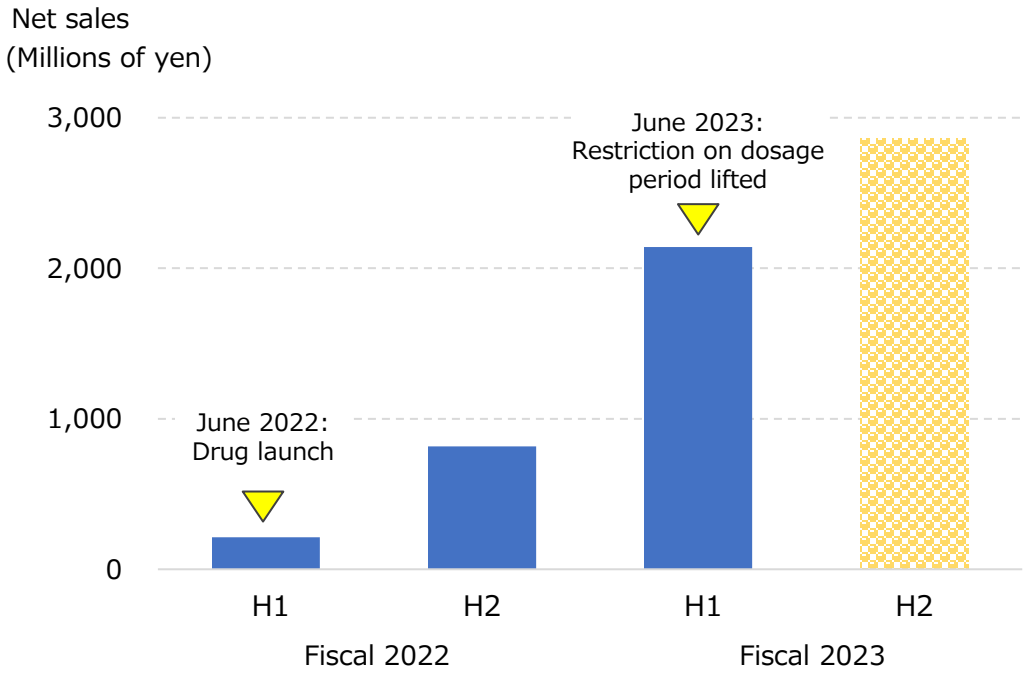


*1 Plasma creatinine exceeds 5.7 mg/dL as a standard
*2 Avacopan should be administered by a doctor with sufficient knowledge and experience in the treatment of MPA and GPA
*3 Not covered by health insurance
*4 There are cases where IVCY may be used instead of POCY

MPA: Microscopic polyangiitis
GPA: Granulomatosis with polyangiitis
CY: Cyclophosphamide
IVCY: Intravenously administered
POCY: Orally administered over oral cyclophosphamide
RTX: Rituximab
GC: Glucocorticoid
MTX: Methotrexate
MMF: Mycophenolate mofetil

Adapted from *Clinical Guidelines for ANCA-Associated Vasculitis 2023* (Diagnosis and Therapy, 2023/5)

TAVNEOS® | Status of Introduction to the Market



- June 2023: Restriction on dosage period lifted
- Target patients (initial goal): Patients who require remission induction therapy
- Number of target patients: Approx. 3,300 people per year (approx. 2,000 new patients + 1,300 patients with recurrences)*1*2

Estimated Number of Patients Treated
(as of September 2023)*3

Approx. **1,400** people

Plan for fiscal 2023:
¥5.0 billion (+385.9% YoY)

*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
*3 In-house total

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

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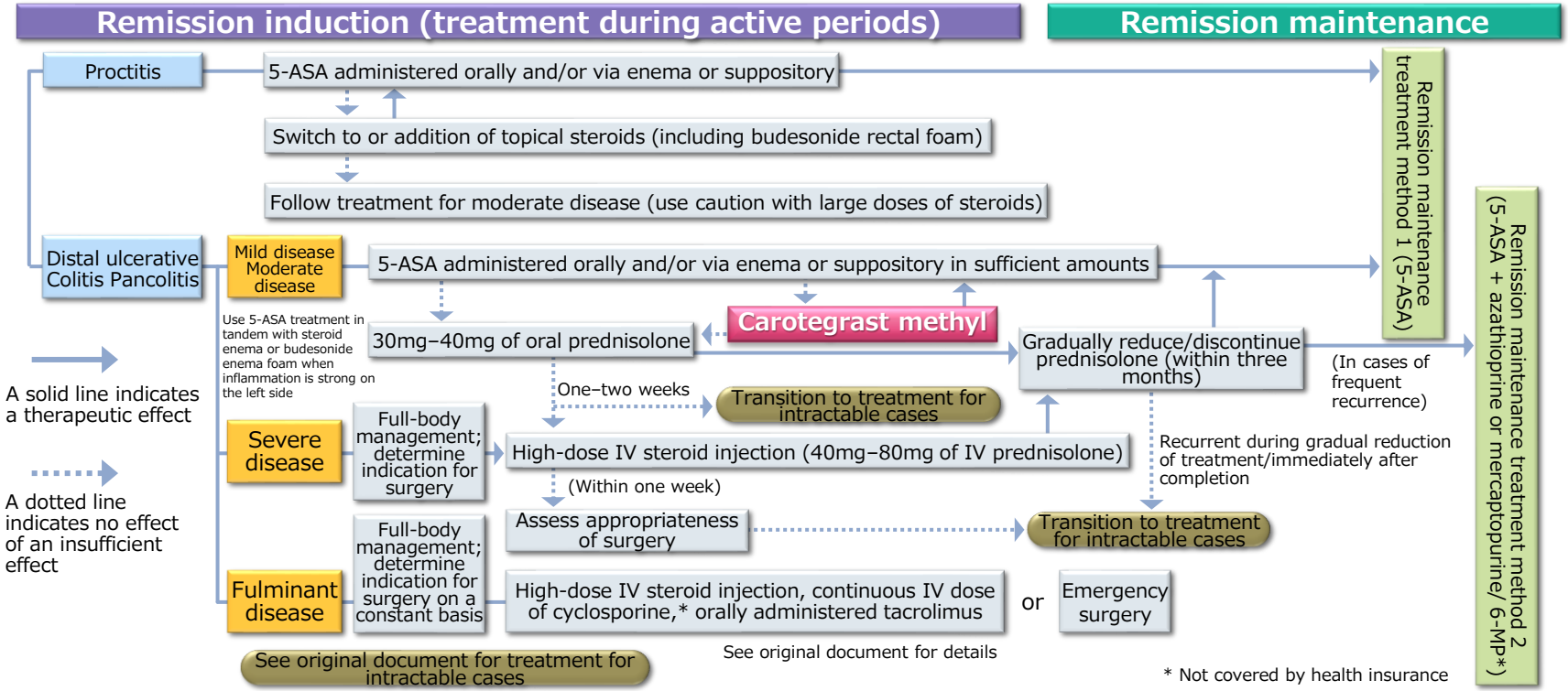
Ulcerative Colitis Flow Chart



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® | Status of Market Introduction

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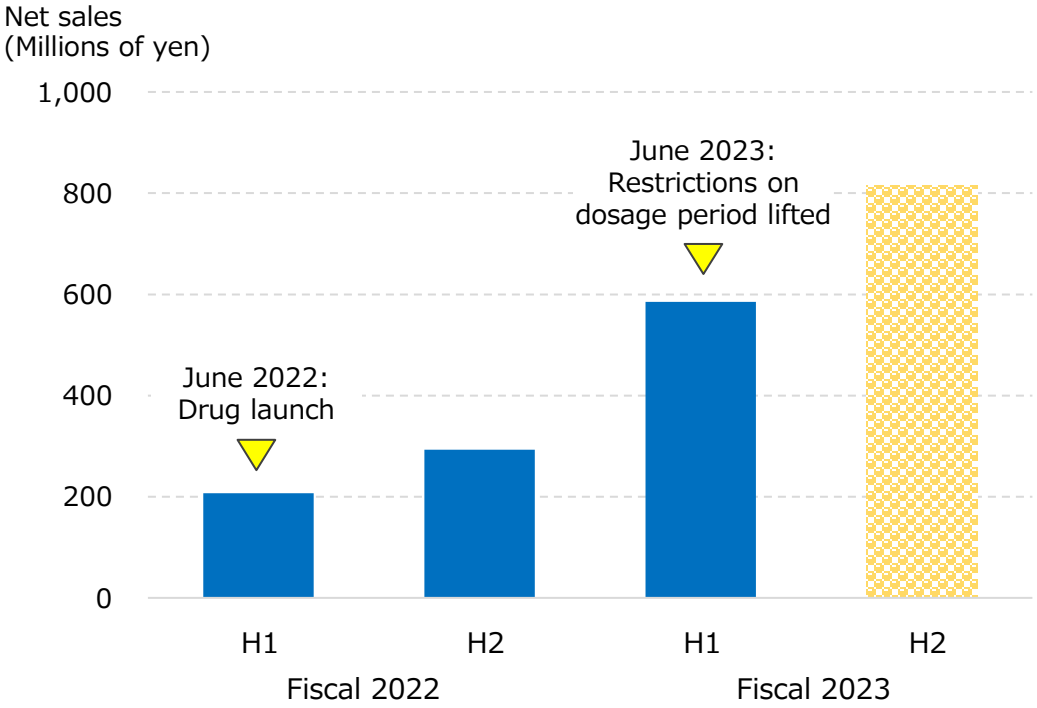

- June 2023: Restrictions on dosage period lifted

Number of Patients Treated (as of September 30, 2023)*1

Approx. **3,300** people

Plan for fiscal 2023:

¥1.4 billion (+180.0% YoY)

*1 In-house total

TAVALISSE® | Positioning

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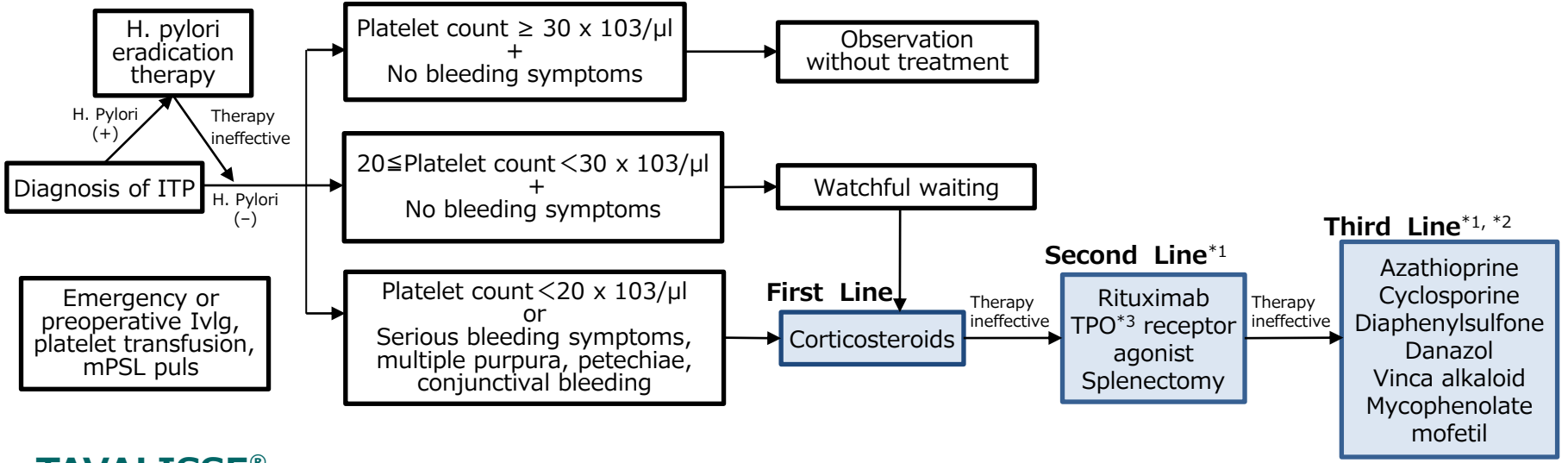
Position drug as a second-line treatment as an orally administered drug with a novel mechanism of action that inhibits platelet destruction associated with ITP



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

*1 In no particular order
*2 Drugs not covered by insurance
*3 Thrmbopoietin

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

TAVALISSE® | Status of Introduction to the Market

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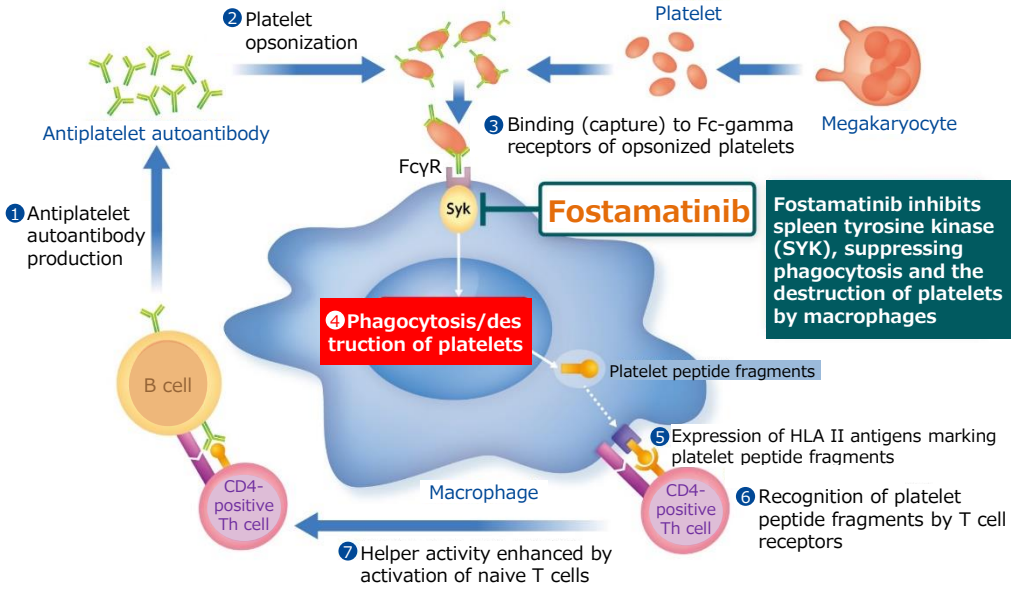
- Date of launch: April 6, 2023
- TAVALISSE® utilizes a novel mechanism of action, offering new treatment options and assistance in cases where conventional treatments prove insufficient. As a result, the number of facilities administering the drug and the number of patients receiving the drug have increased beyond expectations



Plan for Fiscal 2023:
¥0.7 billion

KORSUVA® | Product Overview

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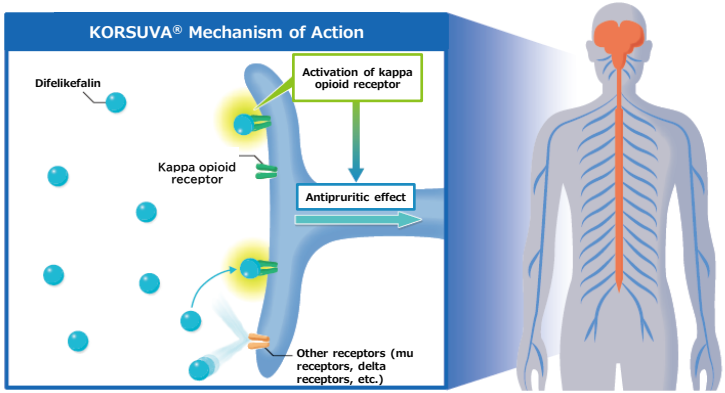
September 25, 2023: Acquired manufacturing and marketing approval in Japan

Product Name	KORSUVA® IV injection syringe for dialysis 17.5μg, 25.0μg, and 35.0μg
Generic Name	Difelikefalin acetate (JAN)
Indications	Improvement of pruritus in hemodialysis patients (limited to cases in which the effects of existing treatments are insufficient)
Dosage and Administration	Normally, inject difelikefalin with the below table dosage to adults into the venous side of the dialysis circuit during return transfusion at the end of dialysis three times a week.

Dry weight	Dosage
Under 45 kg	17.5 μg
45 kg or higher but under 65 kg	25.0 μg
65 kg or higher but under 85 kg	35.0 μg
85 kg or higher	42.5 μg

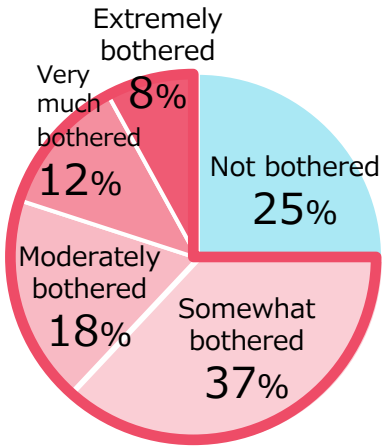
Mechanism of Action	Helps ease itching (pruritis) by acting upon kappa opioid receptors
Overseas Status of Approval and Drug Launch	Drug is approved in 39 countries/regions and has been launched in nine of these countries/regions. Main countries of sale include the United States (as KORSUVA™) and European countries such as Austria, Germany, Sweden, France, Finland, the Netherlands, Switzerland (as Kapruvia®)



Based on A. Albert-Vartanian, et al., *J Clin Pharm Ther.*, 2016; 41: 371-382.

KORSUVA® | About Uremic Pruritis in Dialysis Patients

- **Approximately 70% of patients undergoing dialysis experience pruritis, of which 30% experience severe pruritis.*1**
- **Percentage of patients suffering from pruritis: 75%*2**



- **Severe and prolonged pruritis can lead to a drop in a patient's quality of life, as well as the following negative effects*2**
  - **Sleep deprivation**
  - **Depression**
  - **Fainting and dizziness**
  - **Fatigue**

*1 I. Narita, et al. *Kidney Int*., 2006 May; 69(9):1626-32
*2 Adapted from N. Sukul, et al., *Kidney Med*., 2020 Nov. 21; 3(1):42-53. "Dialysis Outcomes and Practice Patterns Study " (data for Japan)

KORSUVA® | Domestic Phase III Clinical Trial ～ NRS Score ～

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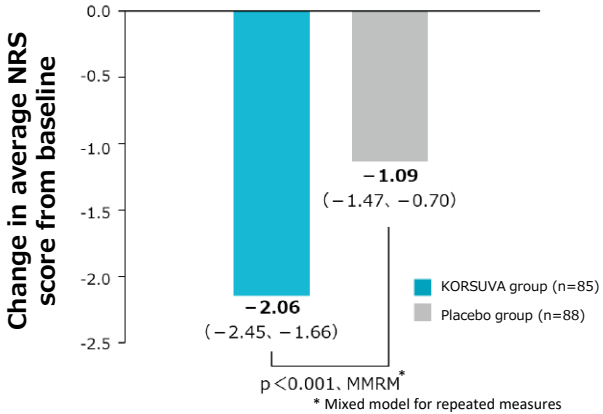
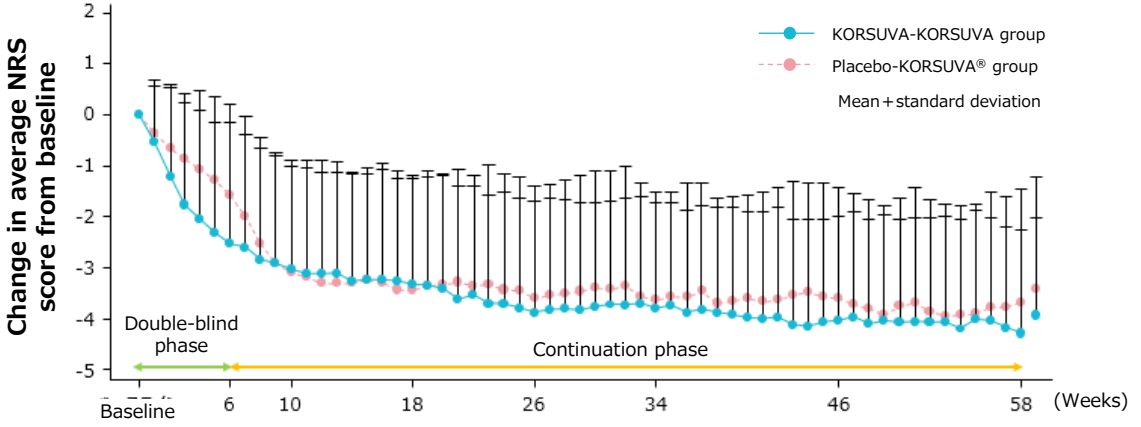
Design: Double-blind, placebo-controlled, multicenter, randomized, parallel-group comparative study (double-blind phase) followed by a multicenter, open-label study (continuation phase)
Participants: Hemodialysis patients with previously treated pruritus
Dosage: Based on dry weight (see right table)
Dosage period and method: Six-week double-blind phase (three times a week, 18 times total), followed by a 52-week continuation phase (three times a week, 156 times total); drug is administered via intravenous bolus injection into the venous line of the dialysis circuit at the end of each dialysis treatment
Primary endpoint: Change in the Numerical Rating Scale (NRS) score for itching at week four

Dry weight	Dosage	
	KORSUVA group	Placebo group
Less than 45 kg	17.5 μg	0.0 μg
Over 45 kg but less than 65 kg	25.0 μg	0.0 μg
Over 65 kg but less than 85 kg	35.0 μg	0.0 μg
Over 85 kg	42.5 μg	0.0 μg

■ Primary endpoint: Change in NRS Score (double-blind phase at week four)



■ Primary endpoint (other evaluation variables): Change in NSR score (double-blind phase + continuation phase)



Difference between groups:
-0.97
95% CI(-1.52, -0.42)

Baseline NRS score (mean ± standard deviation)
KORSUVA group: 6.57 ± 1.29
Placebo group: 6.40 ± 1.28

(Weeks)		Baseline	6	10	18	26	34	46	58
n	KORSUVA- KORSUVA group	81	81	81	76	69	67	66	58
	Placebo-KORSUVA group	83	83	77	70	67	63	57	50

Change from baseline was measured using the NRS scores for itching.

In-Company data from Phase III clinical trials (MR13A9-5). NDA approved September 25, 2023, CTD2.7.6.14.

KORSUVA® | Domestic Phase III Clinical Trial ～ Quality of Life Score ～

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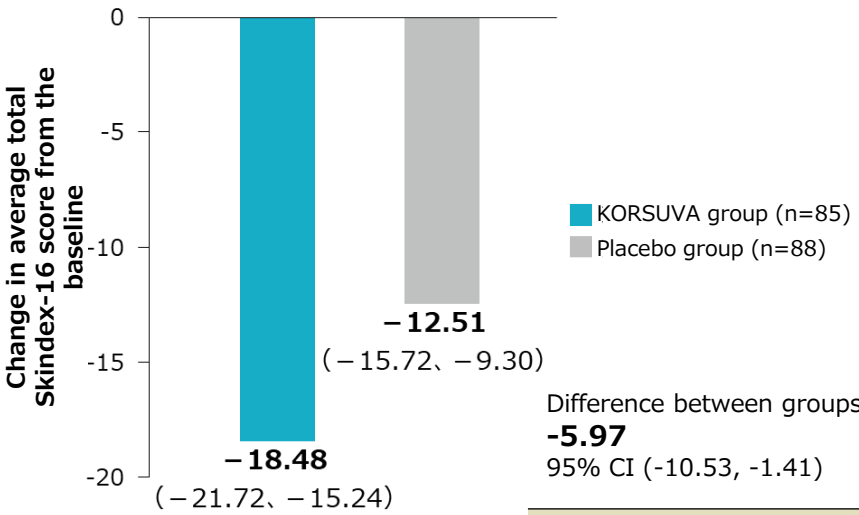
Total Skindex-16 Score

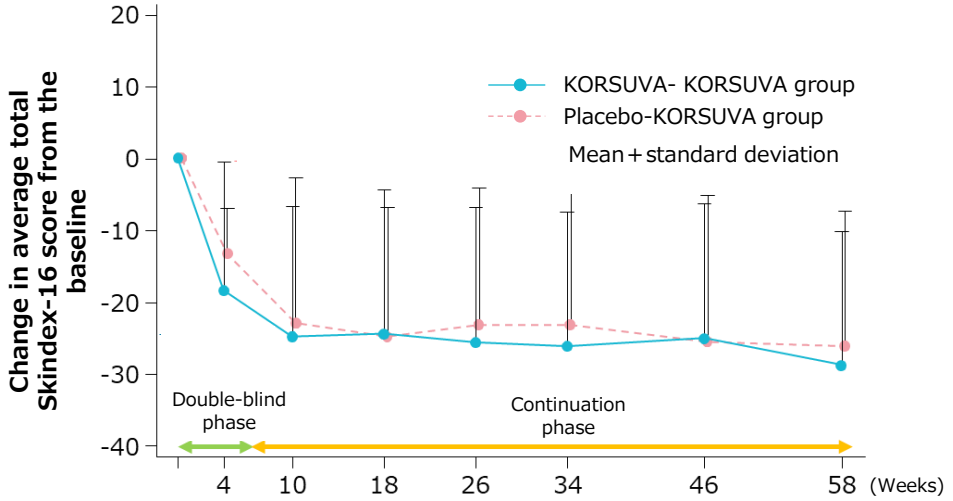
■ Secondary endpoint: Change in total Skindex-16 score (double-blind phase, final assessment)



Difference between groups:
-5.97
95% CI (-10.53, -1.41)

Baseline total Skindex-16 score Mean ± standard deviation
KORSUVA group: 38.9 ± 17.7
Placebo group: 38.9 ± 17.5

■ Secondary endpoint: Change in total Skindex-16 score (double-blind phase + continuation phase)



(Weeks)		Baseline	4	10	18	26	34	46	58
n	KORSUVA-KORSUVA group	81	81	80	76	70	67	66	64
	Placebo-KORSUVA group	83	83	78	73	69	64	58	53

Change from baseline was measured using total Skindex-16 scores.

In-Company data from Phase III clinical trials (MR13A9-5). NDA approved September 25, 2023, CTD2.7.6.14.

New Drug Development (In-Company)

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Product name / Generic name / Development code	Expected indications	Development stage: Phase I	Phase II	Phase III	NDA in process	NDA approved	Development classification
KORSUVA®/ 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

■ Changes from May 2023
KORSUVA® (uremic pruritis in dialysis patients*) NDA in process --> NDA approved
Rovatirelin (spinocerebellar ataxia) NDA in process --> NDA withdrawn, discussions into the possibility of additional clinical trials underway (removed from table)
* Indications: pruritus in hemodialysis patients (limited to the improvement of symptoms when conventional treatments are inadequate)

New Drug Development (Out-Licensing)

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Development stage

Generic name / Development code	Expected indications	Countries and regions	Clinical trials under preparation	Phase I	Phase II	Phase III	Preparation to submit application	NDA in process	NDA approved	Partner company
Linzagolix / KLH-2109	Uterine fibroids	Europe								Theramex
		China								Bio Genuine
		Taiwan								Synmosa Biopharma
	Endometriosis	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

■ Changes from May 2023
Linzagolix (endometriosis) Phase I clinical trials --> Phase III clinical trials (China)

*1 Benign prostatic hyperplasia
*2 Idiopathic thrombocytopenic purpura

Improving the Quality and Speed of Drug Discovery Research through DX

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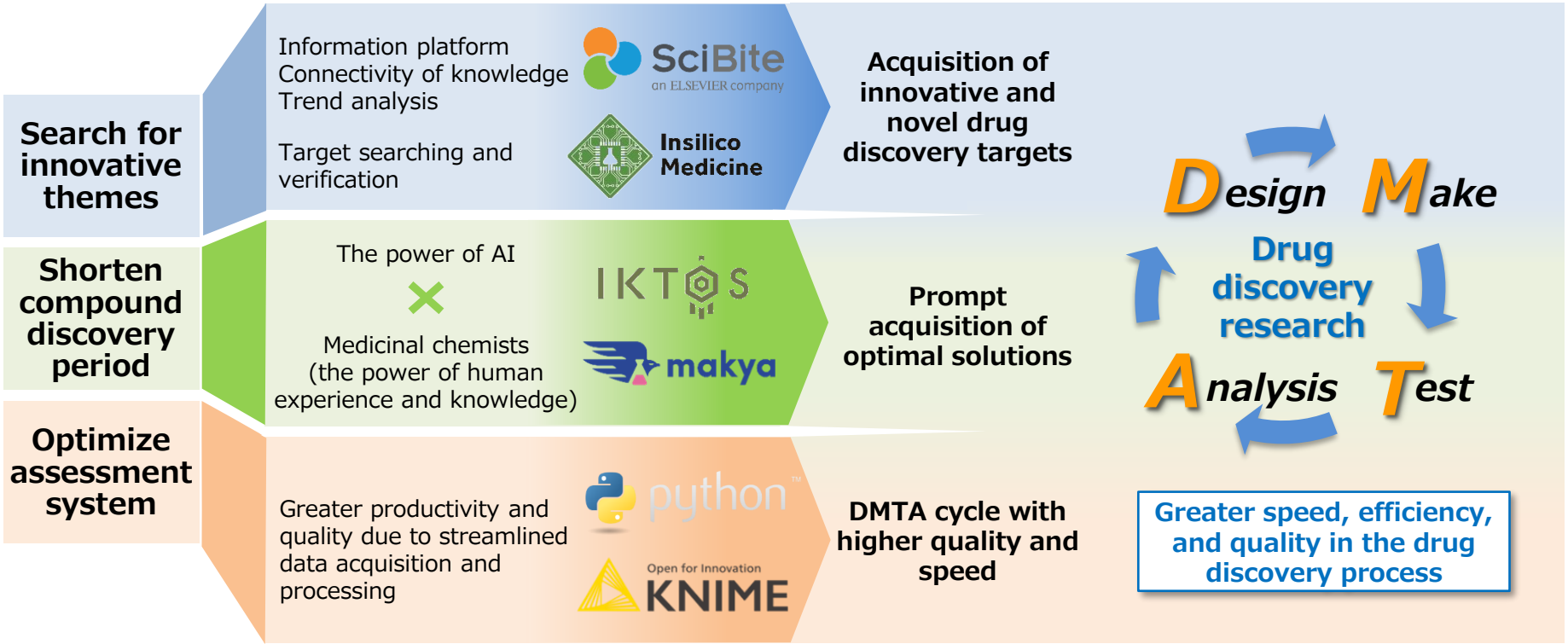

Efforts to Increase Corporate Value

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Past investments have enabled us to transition to a growth phase.
We will continue investments toward stable future growth.

- ✓ Improve corporate value and realize a sustainable society
- ✓ Conduct management mindful of the cost of capital and stock price

Business Strategy		Management Base		Shareholder Returns
Enhance drug discovery research	Expand pipeline	Enhance human capital	Enhance governance	Continue stable dividends
Promote DX	Increase production	Protect the environment	Promote compliance	Purchase treasury shares

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

Appendix

Indicator for Assessing Improvement of Pruritis

Numerical Rating Scale (NRS) Score for Itching

Patients rate their itching on an 11-point scale ranging from 0 (no itch) to 10 (worst imaginable itch).
This assessment method is based on the rating scale used widely in pain-related fields.

Adapted from Phan NQ, et al. *Acta Derm Venereol*., 2012 ; 92 : 502-507

Quality of Life Assessment Score

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Skindex-16 Score

Patients reflect on their skin symptoms over the past week and complete a 16-item assessment, rating how bothered they were regarding each item on a scale of 0 (never bothered) to 6 (always bothered).
Over the past week, how often did you feel bothered regarding each of the following items?

1. Skin itching
2. Burning or stinging sensation in the skin
3. Skin pain
4. Skin irritation
5. Persistent, recurrent, or worsening skin symptoms
6. Worry over skin symptoms worsening, spreading further, leaving marks, or reappearing unpredictably
7. Concern over skin appearance
8. Frustration over skin symptoms
9. Embarrassment over skin symptoms
10. Annoyance over skin symptoms
11. Depression over skin symptoms
12. Changes in social relationships (with family, friends, etc.) due to skin symptoms
13. Loss of desire to be with people due to skin symptoms
14. Difficulty showing love and affection openly due to skin symptoms
15. Impact on daily activities from skin symptoms
16. Difficulty working or doing enjoyable activities due to skin symptoms

The assessment is divided into three subscales: symptom (items 1 to 4), emotional (items 5 to 11), and functional (items 12-16). For each item, patients provide a score along a seven-point scale ranging from 0 (never bothered) and 6 (always bothered).

Adapted from Y. Higaki, et al. *J Dermatol.*, 2002; 29: 693-698