KISSEI

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

Yasuo Takehana
President and COO

November 9, 2022

KISSEI PHARMACEUTICAL CO., LTD.

Overview of the Fiscal 2022

1. Increase domestic sales

✓ Launched two new drug products in Japan

- May 2022: Launched alpha-4 integrin antagonist CAROGRA®, a treatment for ulcerative colitis
- June 2022: Launched selective complement C5a receptor antagonist TAVNEOS®, a treatment for microscopic polyangiitis and granulomatosis with polyangiitis

✓ Increased sales of key products

- August 2022: Completed shipping adjustments for selective beta-3 adrenoreceptor agonist Beova®, a treatment for overactive bladder

2. Strengthen earnings base overseas

✓ Established original product: GnRH receptor antagonist linzagolix

- July 2022: ObsEva SA, global licensee for linzagolix, except for Japan and certain Asian countries, returned its rights to the drug to Kissei and began corporate restructuring
- June 2022: A marketing authorization application was approved in Europe as a treatment for uterine fibroids, with plans to launch the drug in fiscal 2023 via Theramex
- August 2022: Temporarily withdrew the NDA submitted in the U.S. to reconsider the development strategy for the drug
- November 2022: Out-licensed linzagolix to Taiwan-based Synmosa Biopharma Corporation

3. Expand development pipeline

✓ Submitted applications for manufacturing and marketing approval

- April 2022: Submitted application for tyrosine kinase inhibitor fostamatinib, a treatment for chronic idiopathic thrombocytopenic purpura
- September 2022: Submitted application for kappa opioid receptor agonist difelikefalin, a treatment for pruritus in hemodialysis patients

✓ Began domestic Phase III clinical trials

- July 2022: Began Phase III clinical trials for GnRH receptor antagonist linzagolix, a treatment for uterine fibroids

4. Strengthen the management base to cope with the changes in the business environment

✓ Strengthened and enhanced governance

✓ Promoted ESG/SDGs

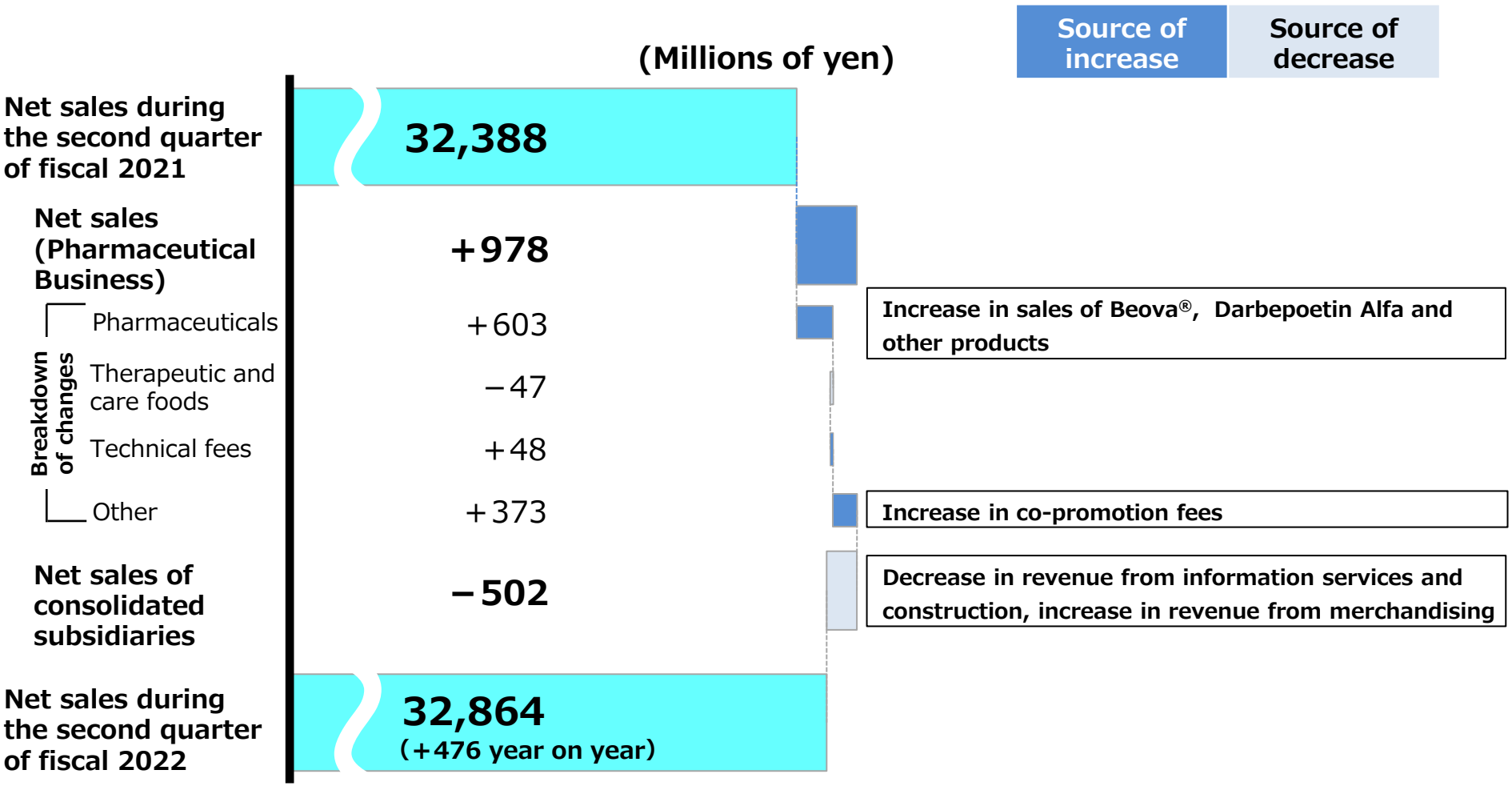
Consolidated Financial Results for the Second Quarter of Fiscal 2022

	Total for the first half of fiscal 2021 (April 2021–September 2021)		Total for the first half of fiscal 2022 (April 2022–September 2022)			Year on year
	Amount (millions of yen)	Ratio to net sales	Plan (millions of yen)	Result (millions of yen)	Ratio to net sales	
Net sales	**32,388**	**100.0%**	**31,000**	**32,864**	**100.0%**	**1.5%**
[Pharmaceutical Business]	**[26,968]**	**[83.3%]**	**[25,500]**	**[27,946]**	**[85.0%]**	**[3.6%]**
Pharmaceuticals*1	22,947	70.8%	21,000	23,550	71.7%	2.6%
Therapeutic and care foods	1,813	5.6%	1,800	1,766	5.4%	(2.6)%
Technical fees*2	171	0.5%	300	220	0.7%	28.4%
Other*3	2,036	6.3%	2,400	2,410	7.3%	18.4%
Cost of sales	**16,924**	**52.3%**	**16,100**	**16,680**	**50.8%**	**(1.4)%**
Gross profit	**15,463**	**47.7%**	**14,900**	**16,184**	**49.2%**	**4.7%**
Selling, general and adminstrative expenses	**15,193**	**46.9%**	**16,200**	**16,810**	**51.1%**	**10.6%**
[R&D expenses]	**[4,168]**	**[12.9%]**	**[5,000]**	**[5,200]**	**[15.8%]**	**[24.8%]**
Operating profit	**270**	**0.8%**	**(1,300)**	**(625)**	**–**	**–**
Ordinary profit	**1,281**	**4.0%**	**(500)**	**308**	**0.9%**	**(75.9)%**
Quarterly profit*4	**5,666**	**17.5%**	**3,000**	**3,326**	**10.1%**	**(41.3)%**

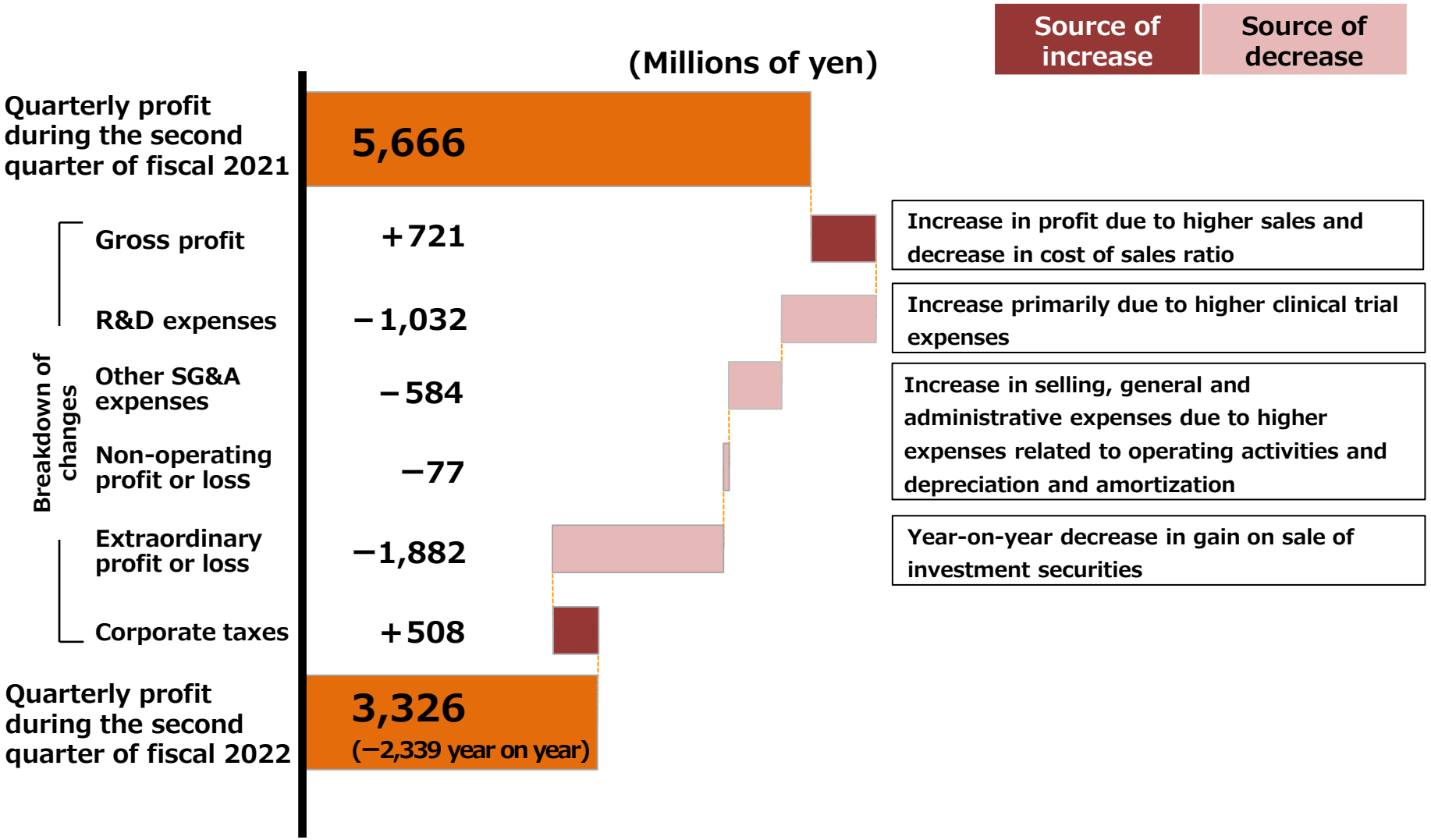
*1 Including active pharmaceutical ingredients (APIs) and bulk exports
*2 Total amount of contracting fees related to out-licensing, milestone payments, and running royalties
*3 Includes amounts from supply to domestic sales partners and co-promotion fees
*4 Quarterly profit refers to quarterly profit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

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

Consolidated Net Sales Compared with the Second Quarter of Fiscal 2021



Consolidated Quarterly Profit Attributable to Owners of Parent Compared with Second Quarter of Fiscal 2021



Revised Plan for Fiscal 2022 (Consolidated)

	Fiscal 2021 results		Fiscal 2022 plan			Year on year
	Amount (millions of yen)	Ratio to net sales	Initial plan (millions of yen)	Revised plan (millions of yen)	Ratio to net sales	
Net sales	**65,381**	**100.0%**	**68,000**	**68,500**	**100.0%**	**4.8%**
[Pharmaceutical Business]	**[54,147]**	**[82.8%]**	**[57,000]**	**[57,500]**	**[83.9%]**	**[6.2%]**
Pharmaceuticals	45,792	70.0%	44,700	47,600	69.5%	3.9%
Therapeutic and care foods	3,568	5.5%	3,600	3,600	5.3%	0.9%
Technical fees	518	0.8%	4,200	1,700	2.5%	228.1%
Other	4,268	6.5%	4,500	4,600	6.7%	7.8%
Cost of sales	**34,143**	**52.2%**	**33,700**	**34,400**	**50.2%**	**0.8%**
Gross profit	**31,238**	**47.8%**	**34,300**	**34,100**	**49.8%**	**9.2%**
Selling, general and adminstrative expenses	**32,640**	**49.9%**	**31,500**	**33,600**	**49.1%**	**2.9%**
[R&D expenses]	**[10,363]**	**[15.9%]**	**[9,000]**	**[10,500]**	**[15.3%]**	**[1.3%]**
Operating profit	**(1,402)**	**–**	**2,800**	**500**	**0.7%**	**–**
Ordinary profit	**562**	**0.9%**	**4,400**	**2,100**	**3.1%**	**273.7%**
Quarterly profit*1	**12,921**	**19.8%**	**10,000**	**10,800**	**15.8%**	**(16.4)%**

*1 Quarterly profit refers to quarterly profit

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

Clinical Guidelines for Overactive Bladder Syndrome: Beova®

Third edition of *Clinical Guidelines for Overactive Bladder Syndrome*
(issued September 2022):
Vibegron (Beova®) listed as a Grade A
recommended treatment for overactive bladder
(Other Grade A recommended treatments include mirabegron and imidafenacin)

Notable Points from the Description of Vibegron (Beova®)*1

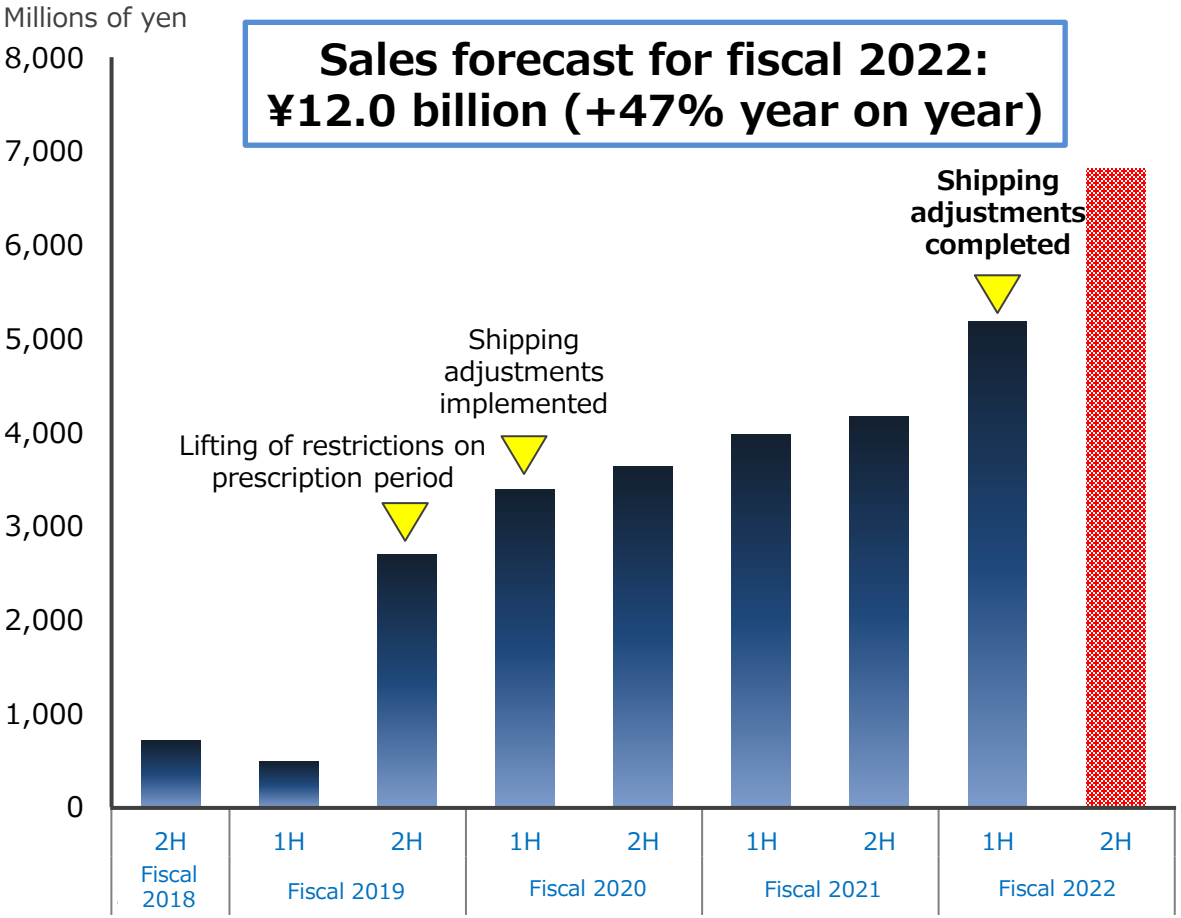
- Shows efficacy in treating overactive bladder symptoms and raising quality of life, with minimal side effects
- Post hoc analysis of the domestic Phase III study confirmed the drug's use as a treatment for nocturia and urgency incontinence in elderly patients aged 65 and over and demonstrated the drug to have minimal influence on cardiovascular parameters (level 2 in both treatment cases)
- High continuation rate
- Almost no drug interactions

*1 Excerpted and adapted from the third edition of *Clinical Guidelines for Overactive Bladder Syndrome*

Sales of Beova®

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

Half-year net sales for Beova® (based on financial results)



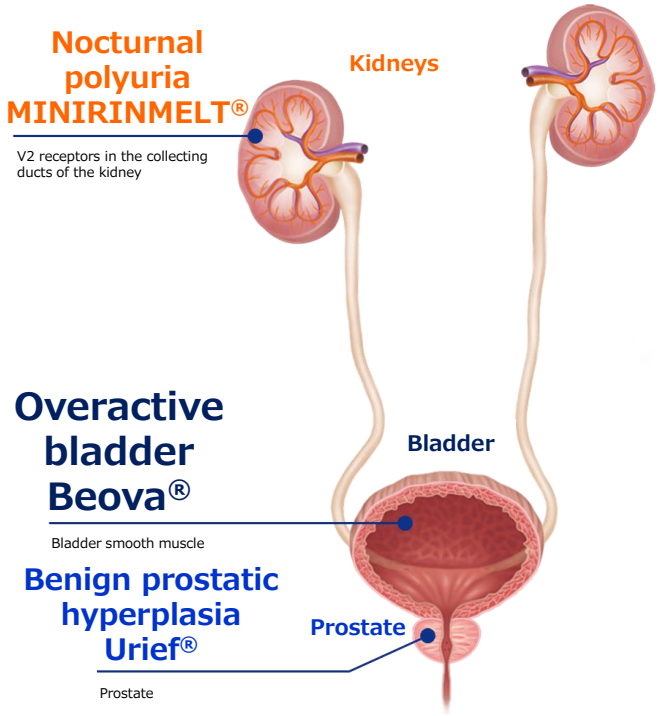


Image shows male organs

Product Overview: TAVNEOS®

Date of launch: June 7, 2022

Indications

Microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)

Dosage and Administration

Typical adult dosage is 30 mg twice daily orally after breakfast and dinner

Overview of TAVNEOS®

- First-in-class, orally administered agent that selectively blocks the complement C5a receptor, which is closely related to MPA and GPA
- Results of the ADVOCATE trial, a global Phase III clinical trial that included participation from Japan, were published in the February 18, 2021, edition of *the New England Journal of Medicine*
- Granted orphan drug designation in Japan (re-assessment period: 10 years)
- There are 10,681 patients suffering from MPA and 3,196 suffering from GPA in Japan as of March 31, 2021, for a total of approximately 14,000 patients*1
- Launched in the U.S., Germany, and Austria
- NDA approved in the European Union, Canada, the U.K., and Switzerland
- Drug price (Japan): ¥1,403.9 per capsule (¥8,423.4 per day)

Microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)

Onset of MPA and GPA is related to antineutrophil cytoplasmic antibodies (ANCAs), and they are classified as types of ANCA-associated vasculitis (AAV). AAV is a severe and intractable disease characterized by damage to blood vessels caused by inflammation, leading to ischemia, kidney damage due to necrosis, and a variety of other organ disorders.

*1 Number of patients receiving medical expense payments for designated intractable diseases (fiscal 2020)

Status of Activities: TAVNEOS®

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

【Positioning】

Positioning in accordance with ADVOCATE trial evidence (Initial launch)

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

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

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®

Target patients:
- ✓ **Almost all patients that require drugs for treatment**

Sales forecast for fiscal 2022: ¥0.8 billion

Sales:
- Sales exceeding initial plans
- Adopted by approximately 60% of facilities staffed with medical experts

Activities:
- Used follow-ups conducted after each prescription to collect and provide information on proper drug use
- Developed activities for providing highly specialized drug information to medical experts, made possible through cooperation between the Rare Diseases Project team and medical representatives (MRs)
- Began providing information on a website dedicated to TAVNEOS® made for medical professionals (some sections membership only)
- Launched a website with information related to ANCA-associated vasculitis, aimed at the general public and patients and their families

Indications: Microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)

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*1 Number of patients receiving medical expense payments for designated intractable diseases (fiscal 2020)
*2 Calculations derived from *Rheumatology* 2011_50_1916-1920, *Arthritis Res Ther.* 2015_17_305, and *J Rheumatol.* 2018_45(4)_521-528

Product Overview: CAROGRA®

Date of launch: May 30, 2022

Indications

Moderate ulcerative colitis (limited to those patients who had inadequate response to 5-aminosalicylic acid (5-ASA))

Dosage and Administration

Typical adult dosage of carotegrast methyl is 960 mg administered orally after a meal three times a day

Overview of CAROGRA®

- Small molecule compound originated by EA Pharma Co., Ltd. (formerly Ajinomoto Pharmaceuticals Co., Ltd.), as the world's first alpha-4 integrin antagonist available in an orally administered dosage
- Results of Phase III clinical trial AJM300/CT3 were published in the March 30, 2022, edition of *the Lancet Gastroenterology & Hepatology*
- Approximately 220,000 patients suffer from ulcerative colitis in Japan[*1]
- Provided as a new treatment option for patients with an inadequate response to 5-ASA, the standard form of treatment
- Drug price: ¥200.0 per tablet (¥4,800.0 per day)
- Distribution in Japan by Kissei Pharmaceutical, with co-promotion by EA Pharma

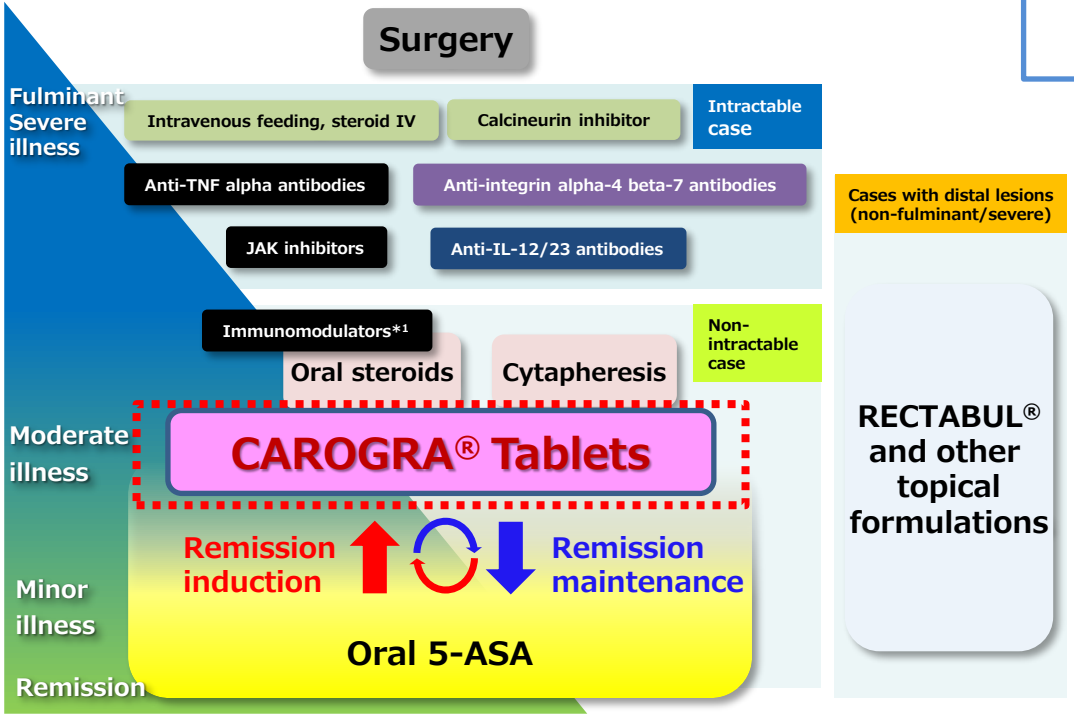
Marketing: Kissei Pharmaceutical Co., Ltd.
Manufacturing and marketing: EA Pharma Co., Ltd.

*1 "Basic Knowledge for the Treatment of Ulcerative Colitis That Everyone Needs to Know," (revised March 2020) produced by the Research Group for Intractable Inflammatory Bowel Disease as part of the Research Program on Rare and Intractable Diseases, funded by the Ministry of Health, Labour and Welfare's Health, Labour and Welfare Sciences Research Grants system

Status of Activities: CAROGRA®

Position CAROGRA® as the first choice for patients with an inadequate response to orally administered 5-ASA

【Positioning】



Sales forecast for fiscal 2022: ¥0.6 billion

Sales:

- Sales drastically exceeding initial plans
- Adopted by approximately 30% of facilities staffed with medical experts

Activities:

- Confirmed treatment policies of medical experts while promoting CAROGRA®'s characteristics and positioning
- Worked in collaboration with EA Pharma Co., Ltd., to expand activities to provide drug information
- Thorough spread of information on proper use using our CAROGRA® Tablet Management Period Support System
  - Administration period: six months maximum
  - Period of time before readministration: eight weeks or longer
  - Possible side effect: progressive multifocal leukoencephalopathy (PML)

*1 Used in cases of steroid dependency or as a remission maintenance drug

New Drug Development (In-Company)

Generic name / Development code	Expected indications	Development stage				Development classification
		Phase I	Phase II	Phase III	NDA in process	
Rovatirelin / KPS-0373	Spinocerebellar ataxia					In-licensed / Shionogi & Co., Ltd.
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura*					In-licensed / Rigel Pharmaceuticals, Inc. (US)
Difelikefalin / MR13A9	Pruritus in hemodialysis patients					In-licensed / Maruishi Pharmaceutical Co., Ltd.
CG0070	Non-muscle-invasive bladder cancer					In-licensed / CG Oncology, Inc. (US) 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 2022

New Drug Development (Out-Licensing)

Generic name / Development code	Expected indications	Countries and regions	Development stage	Partner company
Linzagolix / KLH-2109	Uterine fibroids	Europe	Phase III	Theramex
		China	Clinical trials under preparation	Bio Genuine
		Taiwan	Phase I	Synmosa Biopharma
	Endometriosis	Europe and US	Phase II	Theramex (Europe)
		China	Clinical trials under preparation	Bio Genuine
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam, other countries	NDA in process	Eisai Co., Ltd
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura	South Korea	Preparation to submit application	JW Pharmaceutical
		Hong Kong	Phase I	Inmagene Biopharmaceuticals
		China, other countries	Clinical trials under preparation	Inmagene Biopharmaceuticals
KDT-3594	Parkinson's disease	China, other countries	Phase II	Affamed Therapeutics Limited

Development stage: Clinical trials under preparation | Phase I | Phase II | Phase III | Preparation to submit application | NDA in process | NDA approved

■ Changes from May 2022

Small molecule tyrosine kinase (SYK)*1 inhibitor

Fostamatinib

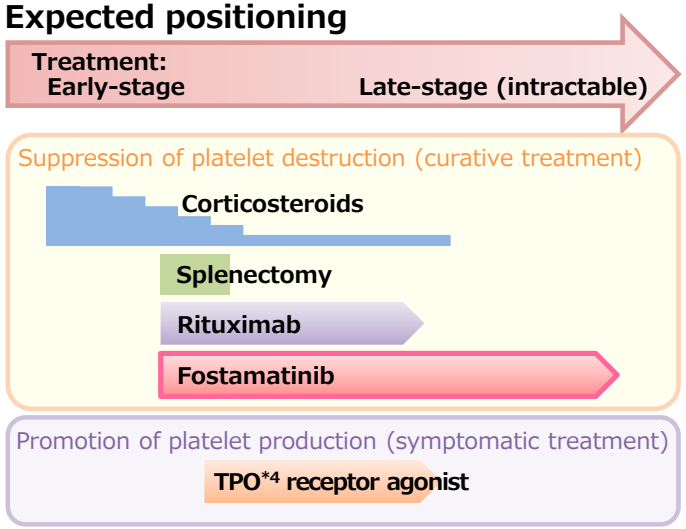
Expected indication: Chronic idiopathic thrombocytopenic purpura (ITP)*2

- Acquired development and marketing rights in Japan, China, South Korea, and Taiwan from U.S.-based Rigel Pharmaceuticals, Inc., in October 2018, and submitted NDA in Japan in April 2022
- SYK inhibitor that can be used to treat 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
- Granted orphan drug designation in Japan in February 2020, with a re-assessment period of 10 years
- Number of patients with ITP (designated intractable disease) in Japan: 18,793*3

Timeline of NDA Approval and Drug Launch:

April 2018	NDA approved in the U.S., launched in May 2018
January 2020	NDA approved in the European Union, launched in July 2020 in Germany and the U.K., followed by France, Italy, Norway, Spain, and the Czech Republic
November 2020	NDA approved in Canada
August 2021	NDA approved in Israel
April 2022	**Application for manufacturing and marketing approval submitted in Japan (currently under review)**

Expected positioning



*1 SYK: Spleen tyrosine kinase
*2 ITP: Idiopathic thrombocytopenic purpura
*3 Number of patients receiving medical expense payments for designated intractable diseases (fiscal 2020)
*4 Thrombopoietin

Treatment for uremic pruritis

Difelikefalin (Generic Name)

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
- Overseas development: NDA approved in the U.S. in August 2021 (submitted by Cara Therapeutics)
  NDA approved in the European Union in April 2022 (submitted by Vifor Fresenius Medical Care Renal Pharma Ltd.)

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, 2020
*2 *Clin J Am Soc Nephrol.* 2017 Dec 7; 12(12): 2000–2007

Promoting the Basic Strategies of "PEGASUS"

Increase Domestic Sales, Strengthen Our Overseas Earnings Base

Domestic: Continued introduction of new drugs in key areas

<Domestic available-for-sale pharmaceutical products>

Renal Diseases and Dialysis
- P-TOL®
- Epoietin Alfa BS
- Darbepoetin Alfa BS
- UPASITA® (co-promotion)

Urology
- Beova®
- MINIRINMELT® , etc.
- Urief®

Rare Diseases
- TAVNEOS® (launched in June 2022)

Gastroenterology
- CAROGRA® (launched in May 2022)
- RECTABUL® (co-promotion)

Diabetes
- Glubes®
- MARIZEV®

<Domestic development>

Renal diseases and dialysis
- Difelikefalin (NDA submitted September 2022)

Rare and intractable diseases
- Fostamatinib (NDA filed April 2022)
- Rovatirelin (NDA filed December 2021)
- CG0070 (undergoing joint international Phase III clinical trials)
- KDT-3594 (Phase II clinical trials)

Gastroenterology
- KSP-0243 (undergoing Phase II clinical trials)

Obstetrics / Gynecology
- Linzagolix (undergoing Phase III clinical trials)

Overseas: Launch Kissei-developed drugs globally

<Overseas expansion>

- Launch linzagolix in Europe (fiscal 2023)
- Develop linzagolix in Asian regions
- Re-evaluate U.S. development strategy for linzagolix
- Expand drugs discovered by Kissei overseas

Achieve continuous growth

(Note) Blue: Products scheduled to be launched during "**PEGASUS**"

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

Drug Discovery Research

Pursue speed and quality

Creation of innovative new drugs that impact treatment

Strengthen Our Management Base, Contribute to the SDGs Using Our Material Issues

<Management Philosophy>

Contribute to society through high-quality, innovative pharmaceutical products

Serve society through our employees

Material issues related to Kissei's business activities

Development and provision of products useful to society

- Development of innovative products (drugs, foods)
- Contribution to scientific technology

Steady supply of high-quality products

- Quality control and steady supply and procurement

Communication with medical professionals and patients

- Promotion of proper product usage (drugs, foods)
- Improvement of customer satisfaction and provision of patient support

Material issues related to Kissei's management base

Strengthening and enhancement of governance

- Strengthening of governance
- Risk management
- Compliance

Creation of a fulfilling workplace environment

- Human resource cultivation
- Promotion of diversity and gender equality
- Enhancement of workplace environments

Environmental initiatives

- Waste management and resource recycling
- Initiatives toward biodiversity
- Climate change countermeasures

Social contribution as a good corporate citizen

- Participation in social contribution activities

Value created

Economic value

- Expansion of stable profits
- Stable and sustainable return of profits to shareholders

Social value

- Creation and provision of innovative pharmaceutical products and treatment solutions
- Higher quality of life for patients and their families
- Provision of proper drug and medical information
- Rewarding work environment and skill development opportunities
- Lower environmental load
- Contributions to local communities

Fulfill social responsibilities and grow as an R&D-oriented pharmaceutical company

The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends as of November 2022. 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.