November 6, 2026 (Fri.)

KISSEI

80th Anniversary (1946–2026)

Fiscal Year Ending March 2027 (Fiscal 2026)

First-Half Financial Results Briefing

Keiji Miyazawa

Representative Director and President

**Building on 80 years of progress,
toward the next stage of growth.**

Strengthening existing businesses and developing new growth drivers

Three Key Messages for Today

We record losses related to TAVNEOS as lumpsum in 1H of the fiscal year

Loss on valuation of inventories and impairment losses

We continue to take all necessary actions with patient safety as the highest priority.

We maintain the capital allocation policy centered on growth investment and shareholder returns.

Maintaining Beyond 80's capital allocation policy and EPS and ROE targets.

We are working to achieve a P/B ratio exceeding 1.0 by increasing profitability and capital efficiency.

We focus on products and pipeline assets of the next drivers for growth.

Growth for five key products* Commercialization and expansion of indications for in-licensed products

We are advancing the development of original products while leveraging new in-licensing opportunities.

Drive growth during Beyond 80 period while advancing development for future growth

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* Beova, Yselty, KORSUVA, TAVALISSE, TOL

First-Half Results Summary

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Consolidated net sales	Operating profit	Pharmaceutical Business	R&D expenses
¥45.5 billion	¥1.6 billion	¥37.4 billion	¥7.3 billion
–¥0.3 billion YoY	+¥8.5 billion YoY	–¥0.9 billion YoY	–¥9.0 billion YoY

(Billions of yen)	Previous Interim Results	Current Interim Results	Increase/ Decrease
Net sales	45.8	45.5	–0.3
Pharmaceutical Business	38.3	37.4	–0.9
Domestic Pharmaceuticals*1	32.7	32.8	+0.1
Overseas Licensing*2	3.7	2.7	–1.0
Therapeutic and Care Foods	1.8	1.7	–0.1
Other Businesses	7.4	8.1	+0.6
Cost of sales	23.1	23.7	+0.6
Gross profit	22.6	21.7	–0.9
SG&A expenses	29.5	20.0	–9.5
R&D expenses	16.3	7.3	–9.0
Operating profit	(6.8)	1.6	+8.5
Ordinary profit	(5.6)	2.9	+8.5
Profit attributable to owners of parent	7.7	5.1	–2.5

First-Half Highlihts

Net sales

- Solid growth in our five key products and other factors helped offset decrease in sales of TAVNEOS

Operating profit

- Increased due to the absence of a large upfront payment made last year associated with an in-licensing agreement

Impacts on Profit attributable to owners of parent

- Recorded an extraordinary loss of ¥4.3 billion

(Loss on valuation of inventories: ¥2.1 billion; Impairment losses: ¥2.2 billion)

*1 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees
*2 Includes revenue from contracting fees related to out-licensing, milestone payments, running royalties, and pharmaceutical exports

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Full-Year Forecast: Changes from July

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(Billions of yen)	Previous Forecast (July)	Current Forecast (November)	Change from Previous Forecast (November–July)
Net sales	88.7	89.0	+0.3
Pharmaceutical Business	75.0	73.5	–1.5
Domestic Pharmaceuticals	64.7	64.5	–0.2
Overseas Licensing	6.6	5.4	–1.2
Therapeutic and Care Foods	3.7	3.6	–0.1
Other Businesses	13.7	15.5	+1.8
Cost of sales	46.6	47.3	+0.7
Gross profit	42.1	41.7	–0.4
SG&A expenses	40.1	39.2	–0.9
R&D expenses	14.3	14.3	0
Operating profit	2.0	2.5	+0.5
Ordinary profit	4.0	4.4	+0.4
Profit attributable to owners of parent	13.3	10.0	–3.3

Main Forcast Changes

Net sales

- Decline in TAVNEOS was mitigated by the five key products.
- Overseas export sales were temporarily decline.
- Sales in the Information Services Business increased.

Operating profit

- Operating profit exceeded the previous forecast.

Profit attributable to owners of parent

- Maintaining our policy of reducing investment securities, including cross-shareholdings.

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TAVNEOS | Current Status and Forecast Impact

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Patient safety is our highest priority. Therefore, we are committed to thorough communication with medical professionals and rigorous support for the appropriate use of the drug.

Regulatory Status

Domestic : administrative procedure status

Administrative procedures, including revocation of the marketing authorization, are underway.

*At this time, the revocation of the marketing authorization has not been decided.

- It was confirmed that there may be issues with the reliability of the review documents.
- It is difficult to determine that the therapeutic benefits outweigh the risks.

Status overseas

Europe: The marketing authorization revoked

U.S. : Hearing ongoing following recommendation to revoke the marketing authorization.

U.K. : Regulatory authority has indicated the intention to revoke the marketing authorization.

Support for Medical Professionals

New patients

- Avoid initiating treatment with the drug for new patients

Patients receiving drug treatment

- Consider discontinuing treatment or switching to an alternative therapy (in principle)
- Make decisions on a case-by-case basis based on clinical condition, treatment efficacy, alternative treatment options, and the impact of changing the treatment regimen
- If the drug is continued until switching to another therapy, continue its appropriate use in accordance with the Rapid Safety Communication (Blue Letter)

Impact on Forecasts

2H Sales Forecast: ¥600 million

1H results: ¥3.1 billion

Full-Year Sales Forecast：¥3.7 billion

Initial full-year sales forecast: ¥12.7 billion

Interim results include ¥4.3 billion in extraordinary losses

- Loss on valuation of inventories: ¥2.1 billion
- Impairment losses: ¥2.2 billion

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Five Key Products excluding TAVNEOS

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The five key products performed steadily and mitigated the decline in TAVNEOS.

1H FY2026 actual results (April–September 2026)

Beova
(Treatment for Overactive Bladder)

1H results	¥ 11.45 billion (99.6% of plan)
FY forecast	¥ 23.4 billion (108.6% YoY)

Achieved steady growth as the No. 1 share drug

Yselty
(Treatment for Uterine Fibroids)

1H results	¥ 0.25 billion (129.5% of plan)
FY forecast	¥ 0.7 billion (— YoY)

Market penetration accelerated

KORSUVA
(Treatment for Pruritus in Dialysis)

1H results	¥ 5.01 billion (106.7% of plan)
FY forecast	¥ 10.3 billion (127.6% YoY)

Sales grew as market penetration increased

TAVALISSE
(Treatment for Persistent and Chronic ITP*)

1H results	¥ 2.30 billion (100.2% of plan)
FY forecast	¥ 4.8 billion (128.4% YoY)

Sales grew as market penetration increased

P-TOL
(Treatment for Hyperphosphatemia)

1H results	¥ 2.05 billion (102.6% of plan)
FY forecast	¥ 3.9 billion (97.6% YoY)

A solid earnings base in the renal and dialysis field

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* Immune thrombocytopenia

Cash Allocation

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Capital Allocation Plan Upon Formulating Beyond 80 (Five-Year Period from Fiscal 2025 to Fiscal 2029)

Cash Inflows

Funding
Operating CF (before R&D expenses) ¥125.0 billion
Utilization of financial assets on hand ¥72.0 billion

Cash Outflows

Investment	
R&D	¥100.0 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

Capital Resources and Allocation Policy for the Remaining Three Years (Fiscal 2027–Fiscal 2029)

We will maintain a capital allocation policy centered on growth investment and shareholder returns.

To offset the shortfall in cash flows from operating activities resulting from the TAVNEOS situation, we will utilize available financial assets on hand.

We will secure the necessary funds and proceed with investment in key development candidates and shareholder returns

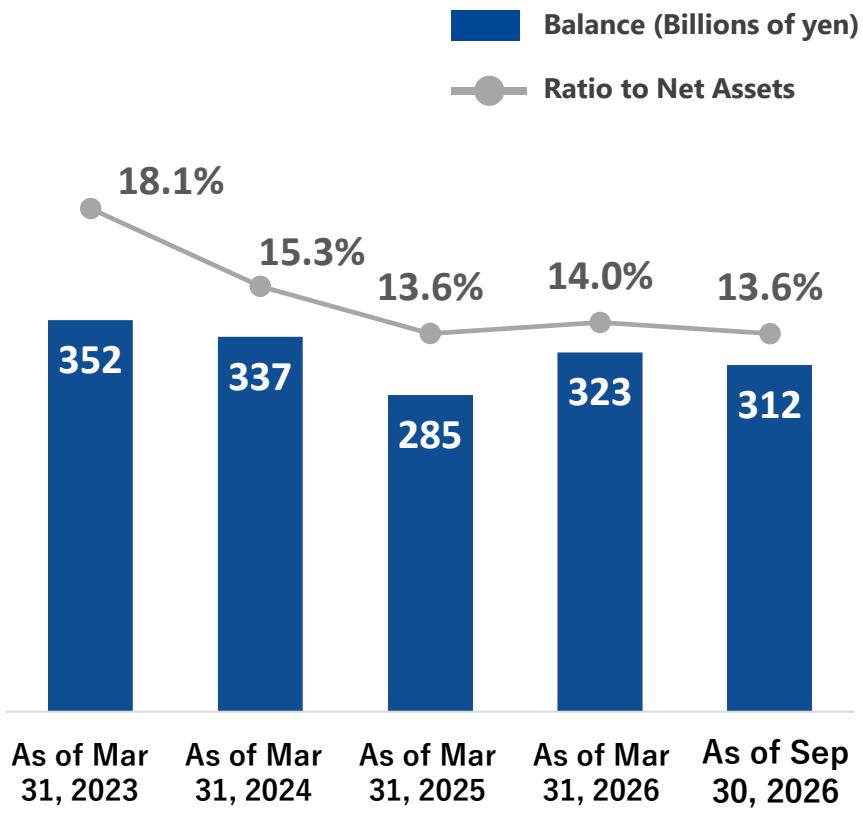
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Cross-shareholdings and Capital Efficiency | Trends and Targets

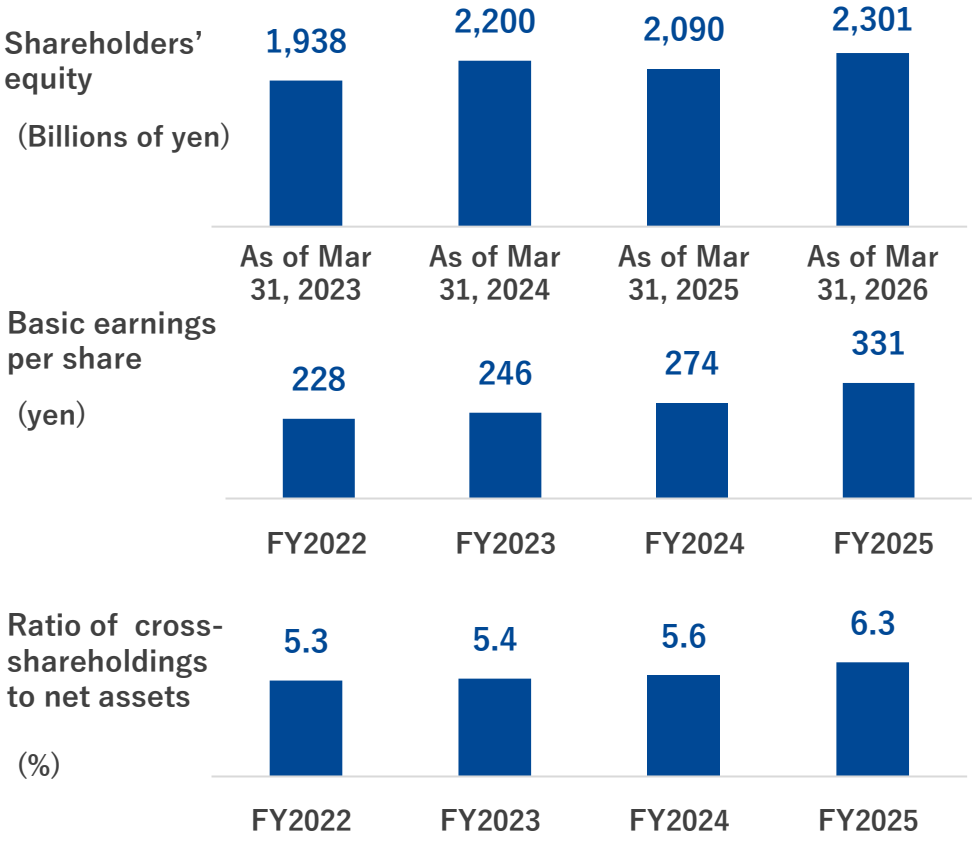
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Cross-Shareholdings and Ratio to Net Assets

As of Mar. 31, 2030: Ratio to Net Assets of 10% or Lower



Capital Efficiency Target



Fiscal 2029 Targets

Under ¥200.0 billion
As of Mar. 31, 2030

¥400 or higher
FY 2029

8% or higher
FY 2029

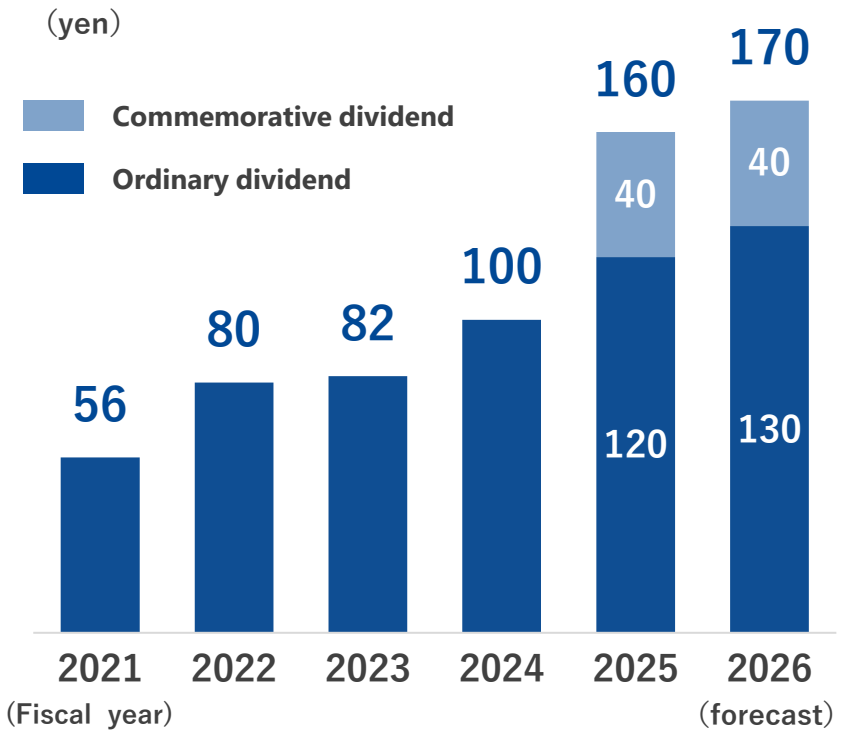
We will advance the restructuring of our earnings base and improve capital efficiency, aiming to achieve a P/B ratio of over 1.0.

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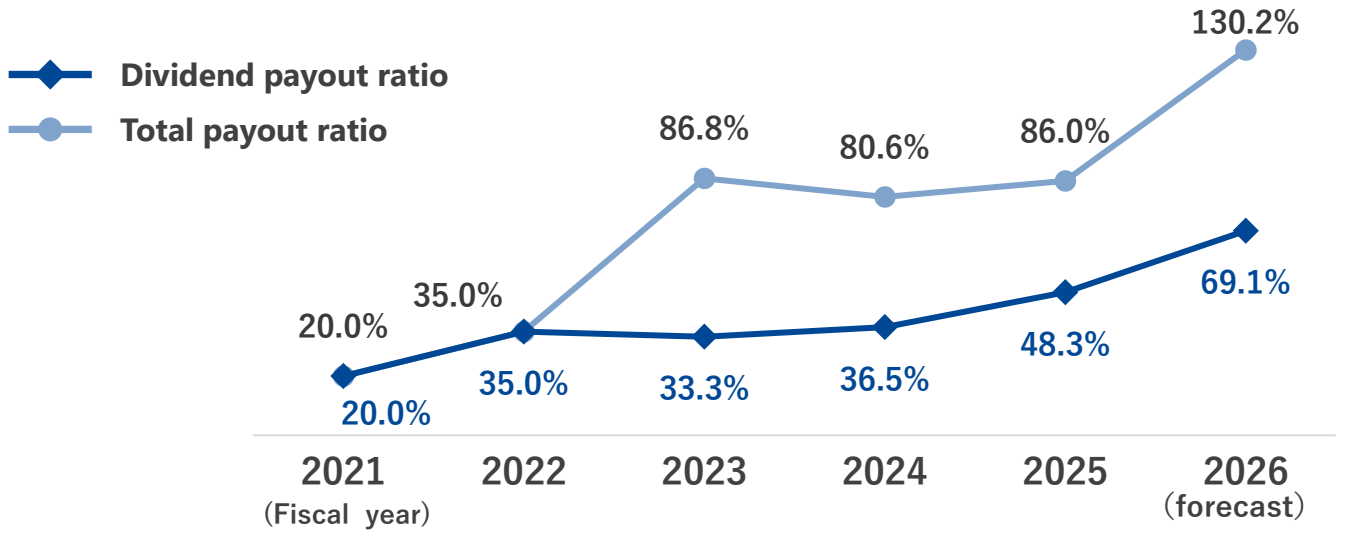
Shareholder Return | Continuation of the Policy

- Progressive dividend (ordinary dividend) continued, while aiming for a dividend payout ratio of 40% or higher
- Through acquisition and disposal of treasury shares,capital efficiency improved and shareholder returns increased

Annual dividend per share



Dividend payout ratio/Total payout ratio (consolidated)



Treasury shares purchased (number of shares)	—	—	**¥6.0 billion** (1,910,000 shares)	**¥5.3 billion** (1,400,000 shares)	**¥5.2 billion** (1,370,000 shares)	**¥6.0 billion** (1,300,000 shares)
Treasury shares canceled (number of shares)	—	—	**¥5.7 billion** (2,500,000 shares)	**¥4.0 billion** (1,400,000 shares)	**¥4.2 billion** (1,370,000 shares)	**¥4.3 billion** (1,300,000 shares)

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A Portfolio That Will Drive the Next Phase of Growth

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- Strengthen our current earnings base and foster growth during the Beyond80 period (through fiscal 2029) and beyond.

Key focus areas		Current earnings base	Beyond 80	Medium- to long-term
Urology		Beova	Cretostimogene* (High-risk、Medium-risk)	KSP-0576
Renal Diseases and Dialysis		P-TOL KORSUVA	—	—
Gynecology		Yselty (Uterine Fibroids)	Yselty (Endometriosis)	—
Rare and Intractable Diseases	Hematology	TAVALISSE	Olutasidenib	—
	Thyroid disease	—	Veligrotug	Elegrobart, KSP-0914
	CNS disorders	—	Rovatirelin	Matsupexole, KSP-0930

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* Cretostimogene grenadenorepvec

Thyroid | Realizing Value and Building a Sustanable pipeline

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We will advance domestic development of 2 treatments for thyroid eye disease (TED), proceeding with the development of veligrotug first.
Our goal is to provide treatment options with different dosage methods.

Proceeding with for Domestic Development First

Veligrotug

Expected indications
Active and Inactive TED*

- IV formulation currently available in the U.S.
- Domestic Phase III clinical trials in preparation
- Dosage schedule (U.S.): Five doses in three-week intervals 12 weeks from the initial to the final administration

Treatment Options with Different Modes of Administration

Elegrobart

Expected indications
Active and Inactive TED

- Subcutaneous formulation (suitable for self-administration)
- Topline results from overseas Phase III clinical trials for active and chronic TED have been released
- On track to submit a BLA to the U.S. FDA in Q1 2027

For more detailed data, please refer to the Appendix

Clinical Development of Allosteric Drug Discovery

KSP-0914

Expected indications
Graves' disease

- TSH receptor selective allosteric inhibitor
- Domestic Phase I clinical trials ongoing
- Expected to achieve rapid normalization of hormone levels and reduction of goiter size

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* Thyroid eye disease

Urology | Targeting New Unmet Medical Needs

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We will bolster Beova's established earning base while cultivating treatments that address unmet medical needs, including bladder cancer.

A Well-Established Base

Beova

Indications
Overactive Bladder

- A central base of earnings in the urology field
- Promote further market penetration

Future Growth Driver

Cretostimogene

Expected indications
BCG-unresponsive NMIBC (High and medium risk)

High risk

- Rolling submission in the U.S. underway
- Preparations for domestic New Drug Application underway

Medium risk

- Overseas Phase III clinical trials (PIVOT-006) in progress
- Domestic Phase II clinical trials to begin in September

For more detailed data, please refer to the Appendix

Pursuing Innovation

KSP-0576

Expected indications
Overactive Bladder, (IC/BPS)*

- TRPM8 inhibitor involved in bladder sensation
- Original product
- Domestic Phase I clinical trials ongoing

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* Interstitial cystitis / bladder pain syndrome

Renal and Dialysis | Further Market Penetration

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We will drive the market penetration of two key products to support the treatment and quality of life of patients undergoing dialysis.

Growth Driver

KORSUVA

Indications

Pruritus in Dialysis

- Help reduce pruritus and improve quality of life without creating a higher medication burden
- Progress being made in expanding prescriptions, driven by its distinct peripheral mechanism of action
- Promote identification of untreated patients through awareness-raising activities

Stable Source of Profit

P-TOL

Indications

Hyperphosphatemia

- Guideline revisions have led to stricter serum phosphorus control targets* and more individualized treatment
- A key product underpinning our presence in the dialysis field
- Promote appropriate use of P-TOL while increasing market penetration

*Targets for hemodialysis patients Source: Japanese Society for Dialysis Therapy, CKD-MBD Clinical Practice Guideline (2025 Revision, Statement 3.1.2)

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Yselty | Value Expansion and Overseas Growth

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- Promote growth by expanding the use of Yselty in Japan, through smooth market penetration and by increasing indications, while also expanding overseas.

Japan: Market Penetration

Indications

Uterine fibroids

Launched March 2026

129.5% of planned interim results

- The number of facilities that use and prescribe Yselty is rising steadily
- We will promote market penetration in anticipation of the lifting of the 14-day prescription limit for new drugs.

For more detailed data, please refer to the Appendix

Indication Expansion and Overseas Business

Expected indication

Endometriosis

- Domestic Phase III clinical trials ongoing
- Increase the target patient population and enhance product value
- NDA approval for the endometriosis indication already obtained in Europe.
- Aiming at expanding export sales in line with rincreasing, sales by partners

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Hematology | Addressing Unmet Medical Needs

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We will broaden the base of Kissei's business in hematology through the growth of TAVALISSE and the commercialization of Olutasidenib.

Earnings Base for Rare and Intractable Diseases Field

TAVALISSE

Indications

Persistent and chronic immune thrombocytopenia

- Our core product in rare and intractable diseases
- Interim analysis results from the post-marketing surveillance study in Japan were accepted at the 68th ASH* annual meeting and exposition.

Unmet Medical Needs

Olutasidenib

Expected indications

Relapsed/refractory IDH1 mutation positive acute myeloid leukemia (AML)

- NDA under review in Japan (May 2026)
- Marks entry into the cancer field
- Provides new treatment option for eligible patients

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* American Society of Hematology

CNS | Addressing Unmet Medical Needs

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We are making preparations for the Phase III clinical trial of Matsupexole.
This represents a significant milestone toward commercializing Kissei's drug discovery research.

Medium-Term Growth

Rovatirelin

Expected indications

Spinocerebellar Degeneration

- Additional Phase III trials are underway for the resubmission.
- Will verify efficacy and safety based on findings made to date

A Leading Candidate Among Kissei's Original Products

Matsupexole

Expected indications

Parkinson's disease

- Long-acting, non-ergot dopamine agonist
- Provide additional efficacy for patients whose symptoms are not adequately improved with L-DOPA treatment
- Primary endpoint achieved for late-stage Phase II clinical trials
- Preparations in progress for Phase III clinical trials

For more detailed data, please refer to the Appendix

Expectations for best-in-class potential

KSP-0930

Expected indications

Narcolepsy

- Original Product
- Orexin 2 receptor agonist
- Phase I clinical trials ongoing
- Non-clinical trials confirm lower likelihood of frequent urination

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Five Company-Discovered Programs Across Development Stages

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Nurture five in-house developed products across a range of development stages and translate them into sustainable growth.

P I	Preparing for P III	P III / Expand indications	Already launched
Next-generation themes	Core candidates	Label expansion	Launched product base
KSP-0914 Graves' disease	**Matsupexole** Parkinson's disease • Primary endpoint met in a late Phase II clinical trial • Preparing for Phase III clinical trials	**Yselty** Endometriosis • Conducting Phase III clinical trials in Japan • Enhancing product value through indication expansion	Uterine fibroids Launched in March 2026 • Creating value in the Women's Health field
KSP-0576 OAB / IC・BPS			
KSP-0930 Narcolepsy			

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Catalyst Calendar for 2026–2028

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Key Events

Period	Drug Name	Events
FY2026	Veligrotug	Initiation of Phase III clinical trial (planned)
FY2026	Yselty (endometriosis)	Announcement of topline data from Phase III clinical trials (planned)
FY2026	Matsupexole	Initiation of Phase III clinical trial (planned)
FY2027	Olutasidenib	Approval and launch (planned)
FY2027	Cretostimogene (high-risk NMIBC)	Filing for domestic approval (planned)
FY2027	Rovatirelin	Announcement of topline data from additional Phase III clinical trials (planned)
FY2027	Elegrobart	Consideration of a domestic development plan
FY2027–FY2028	KSP-0914 / KSP-0576 / KSP-0930	Phase I clinical trial results and decisions on advancement to the next phase (planned)

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Continuing Growth Investment and Rebuilding the Growth Plan

It would be difficult to offset the decline in TAVNEOS sales within the Beyond 80 period using only the growth of existing products and the current pipeline.

We will continue growth investment. By proactively utilizing financial assets, we will supplement the shortfall in operating cash flow from the next fiscal year onward.

Grow of existing products

- Increasing market penetration and sales of our five priority products
- Enhancing product value through expanded indications

Commercialize the Pipeline

- Continuing investment in in-house developed and in-licensed products
- Obtaining new approvals and launching products, as well as expanding indications

Add growth opportunities

- Expanding growth portfolio with utilizing new in-licensing.

Investment stance

- We assess the scientific and business potential, and emphasize the passion to realize value, competitive advantage through patient value, and sustainable earnings.
- We determine investment priorities based on the path to commercialization and the cost of capital.

Rebuild the growth plan for Beyond80 and beyond

- We review the levels and timing of achievement for net sales and operating profit before deducting R&D expenses.
- We also take into account the necessary R&D investment and the operating profit outlook that incorporates such investment.

Progress and future policy will be explained through the earnings presentation.

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Good to Great

Building a company that continues to make an ever-greater contribution to patients and society.

1 Act with Integrity

Put patient safety first and uphold our commitment to quality.

2 Turn Drug Discovery into New Medicines

Use the power of science to bring new treatment options to patients.

3 Help Our People Thrive

Support each employee’s sense of purpose and well-being at work and beyond, and encourage them to take on challenges and grow.

Think deeply. Take action. Deliver results.
Drive sustainable growth and create long-term value.



The forward-looking statements in these materials are based on Kissei's analysis of existing information and various trends As of November 2026. 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

Interim Financial Results for Fiscal 2026

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(millions of yen)	Interim results for fiscal 2025		Interim results for fiscal 2026			
	Results	Ratio to net sales	Initial forecast (July 2026)	Results	Ratio to net sales	YoY
Net sales	**45,831**	**100.0%**	**44,800**	**45,503**	**100.0%**	**(0.7%)**
Pharmaceutical Business	**38,347**	**83.7%**	**37,500**	**37,401**	**82.2%**	**(2.5%)**
Domestic Pharmaceuticals*1	32,766	71.5%	32,000	32,899	72.3%	0.4%
Overseas Licensing*2	3,775	8.3%	3,700	2,764	6.1%	(26.8%)
Therapeutic and Care Foods	1,806	3.9%	1,800	1,737	3.8%	(3.8%)
Other Businesses	**7,483**	**16.3%**	**7,300**	**8,102**	**17.8%**	**8.3%**
Cost of sales	**23,143**	**50.5%**	**23,500**	**23,793**	**52.3%**	**2.8%**
Gross profit	**22,688**	**49.5%**	**21,300**	**21,710**	**47.7%**	**(4.3%)**
Selling, general and administrative expenses	**29,525**	**64.4%**	**20,800**	**20,015**	**44.0%**	**(32.2%)**
R&D expenses	**16,328**	**35.6%**	**7,600**	**7,311**	**16.1%**	**(55.2%)**
Operating profit	**(6,837)**	**(14.9%)**	**500**	**1,694**	**3.7%**	**—**
Ordinary profit	**(5,622)**	**(12.3%)**	**1,700**	**2,923**	**6.4%**	**—**
Profit attributable to owners of parent	**7,784**	**17.0%**	**7,400**	**5,191**	**11.4%**	**(33.3%)**
[Comprehensive income]	(10,001)			(675)		

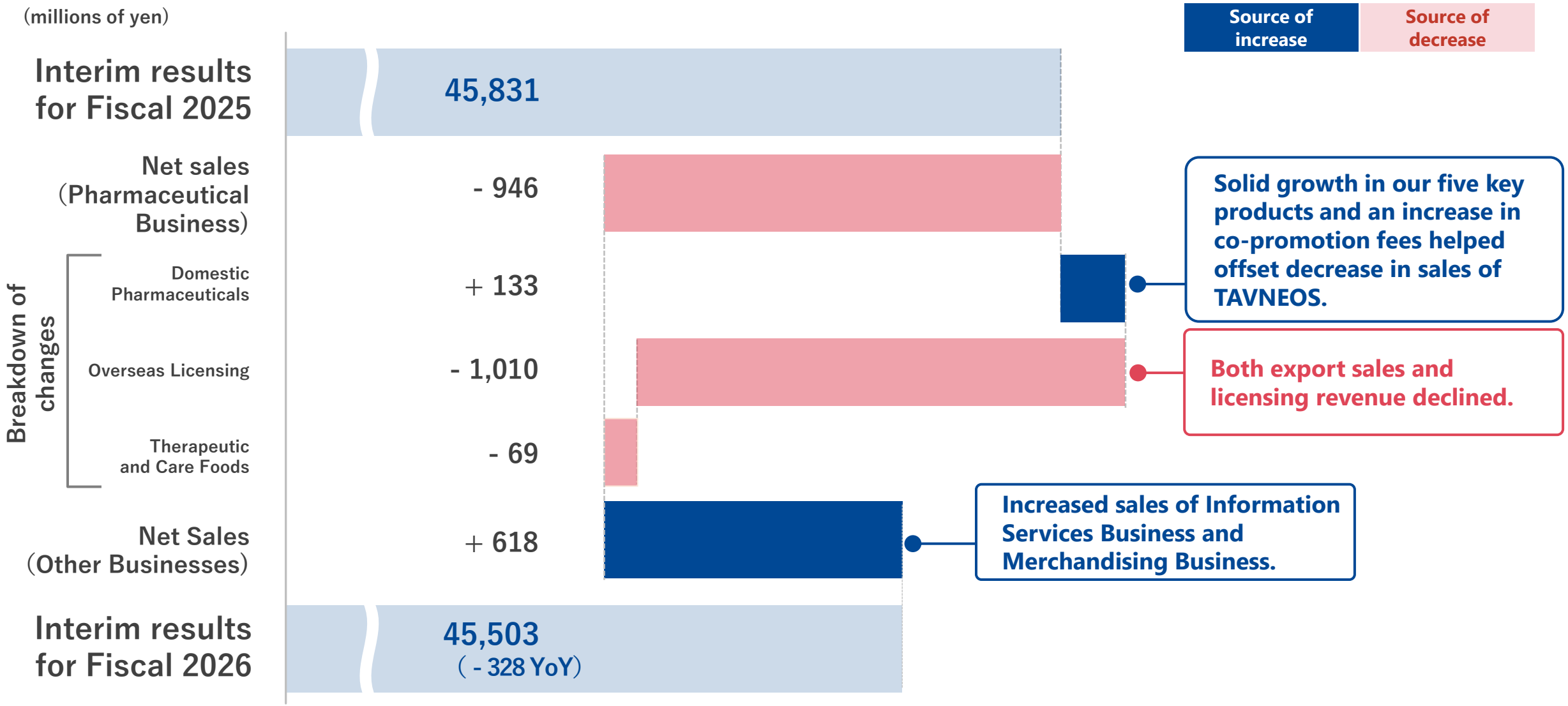
*1 Includes revenue from supply to domestic sales partners and revenue from co-promotion fees
*2 Includes revenue contracting fees related to out-licensing, milestone payments,running royalties, and pharmaceutical exports

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Net Sales Compared with Interim Results for Fiscal 2025

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(millions of yen)

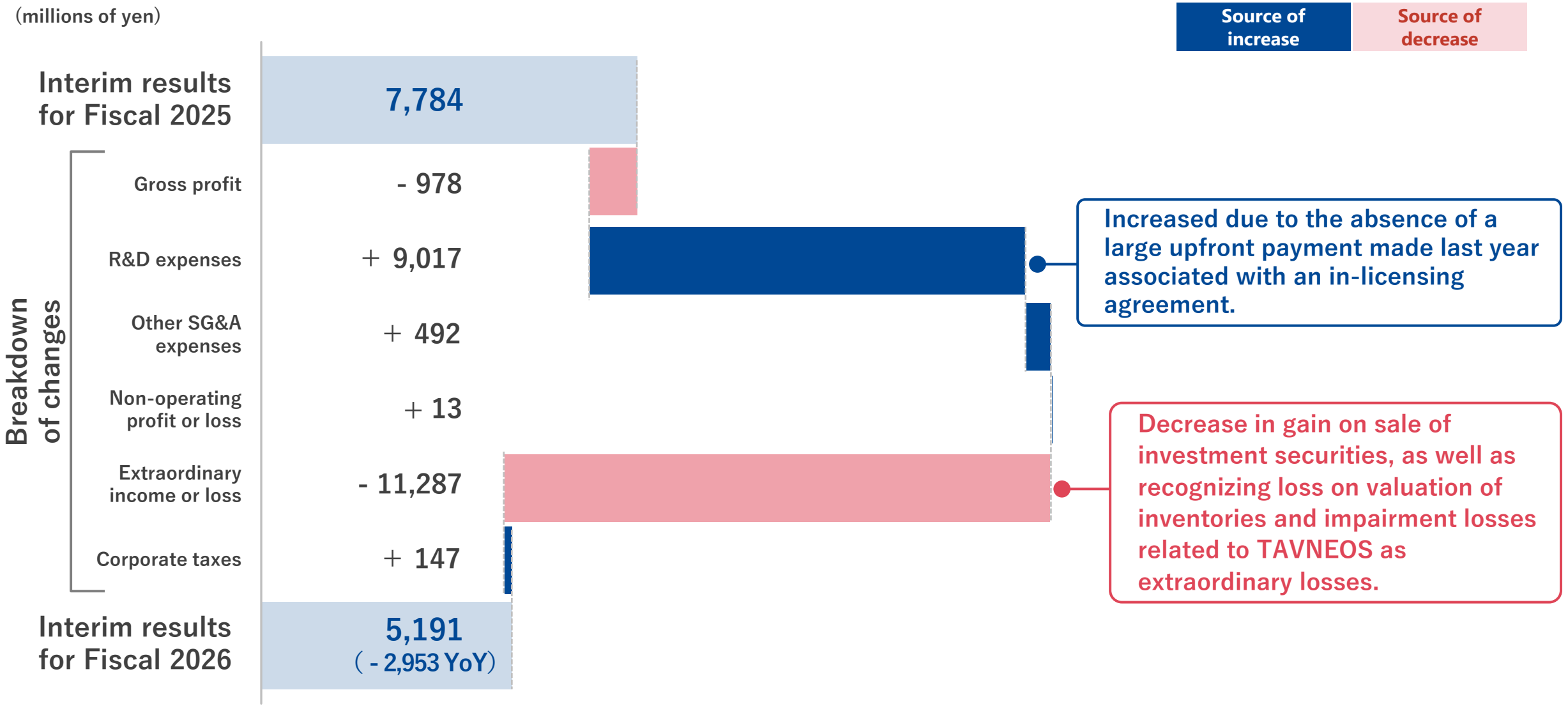


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Profit Attributable to Owners of Parent Compared with Interim Results for Fiscal 2025

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(millions of yen)



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Plan for Fiscal 2026:Latest forecast (November)

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(millions of yen)	Fiscal 2025		Fiscal 2026 Forecast			
	Results	Ratio to net sales	Initial forecast (July 2026)	Revised plan (November 2026)	Ratio to net sales	YoY
Net sales	97,406	100.0%	88,700	89,000	100.0%	(8.6%)
Pharmaceutical Business	77,950	80.0%	75,000	73,500	82.6%	(5.7%)
Domestic Pharmaceuticals	67,764	69.5%	64,700	64,500	72.5%	(4.8%)
Overseas Licensing	6,691	6.9%	6,600	5,400	6.1%	(19.3%)
Therapeutic and Care Foods	3,494	3.6%	3,700	3,600	4.0%	3.0%
Other Businesses	19,455	20.0%	13,700	15,500	17.4%	(20.3%)
Cost of sales	51,587	53.0%	46,600	47,300	53.1%	(8.3%)
Gross profit	45,818	47.0%	42,100	41,700	46.9%	(9.0%)
Selling, general and administrative expenses	48,745	50.0%	40,100	39,200	44.0%	(19.6%)
R&D expenses	22,521	23.1%	14,300	14,300	16.1%	(36.5%)
Operating profit	(2,927)	(3.0%)	2,000	2,500	2.8%	—
Ordinary profit	(1,162)	(1.2%)	4,000	4,400	4.9%	—
Profit attributable to owners of parent	13,779	14.1%	13,300	10,000	11.2%	(27.4%)

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R&D Pipeline (Out-Licensing)

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As of November 2026

■ : Changes from previous release (May 2025)

Generic name	Expected indications	Countries & Regions	Development stage						Development company
			Pre-IND	Phase I	Phase II	Phase III	NDA in process	NDA approved	
Linzagolix	Uterine fibroids	3countries*							Theramex (U.K.)
		South Korea							JW Pharmaceutical (South Korea)
	Endometriosis	Taiwan							Synmosa Biopharma (Taiwan)
		3countries*							Theramex (U.K.)
Silodosin	Dysuria associated with benign prostatic hyperplasia	Vietnam							Eisai (Japan)
Fostamatinib	Persistent and chronic ITP	Taiwan							Tai Tien Pharmaceuticals (Taiwan)

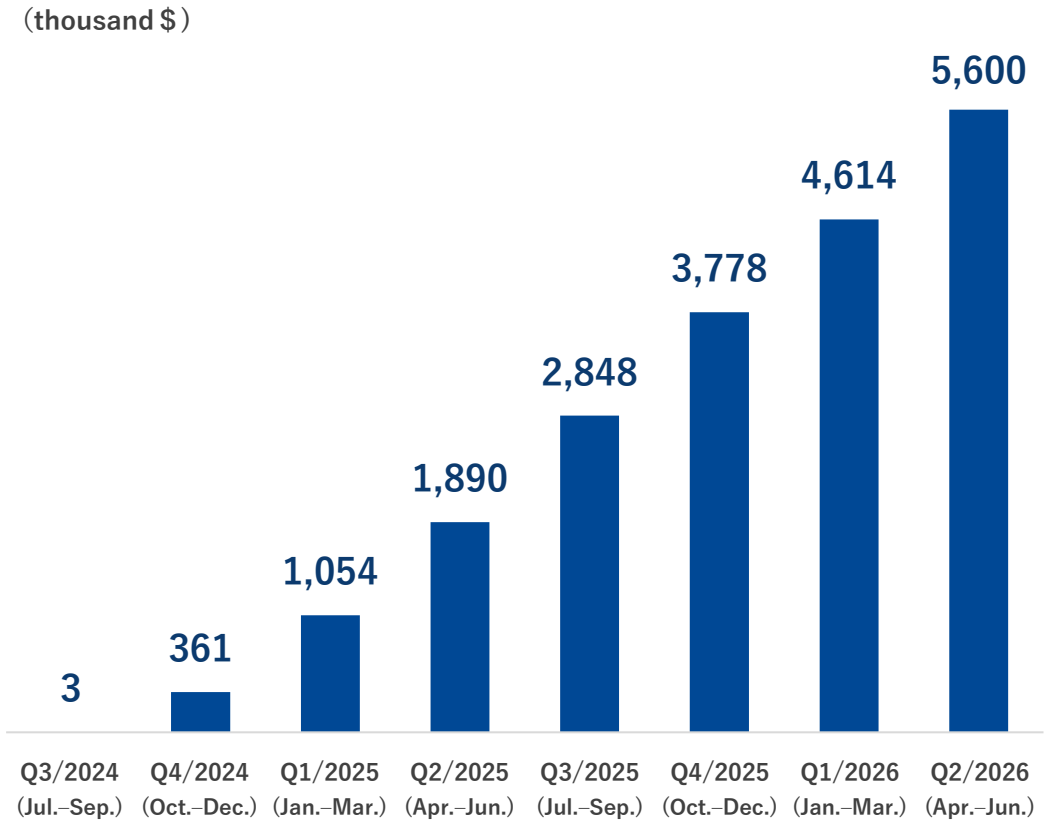
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*Brazil, Republic of South Africa, Mexico

Global Expansion for Yselty

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Sales of Yselty in Europe



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Europe and others (Theramex)

Countries of launch
(as of November 2026))
Germany, Spain, Poland, Italy, U.K, Belgium, Malta, Luxembourg

Canada (Searchlight Pharma)

- ☑ Entered into a license agreement in October 2025
- ☑ Under development as a treatment for uterine fibroids and endometriosis

South Korea (JW Pharmaceutical)

- ☑ Began Phase III clinical trials for the treatment of uterine fibroids in September 2025

Japan

- ☑ Launched for the treatment of uterine fibroids in Mach 2026
- ☑ Phase III clinical trials are ongoing for endometriosis

Taiwan (Synmosa Biopharma)

- ☑ Launched for the treatment of uterine fibroids in Mach 2026
- ☑ NDA for approval for the treatment of endometriosis

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R&D Pipeline (In-House) 1

KISSEI

As of November 2026

■ : Changes from previous release (May 2025)

Generic name / Development code	Expected indications	Development stage						Origin
		Pre-IND	Phase I	Phase II	Phase III	NDA in process	NDA approved	
Olutasidenib	Relapsed/refractory acute myeloid leukemia							In-licensed /Rigel
Linzagolix	Endometriosis							Kissei
Cretostimogene grenadenorepvec / CG0070	High-risk NMIBC							In-licensed /CG Oncology Global Phase III clinical trial
	Medium-risk NMIBC							In-licensed /CG Oncology
Rovatirelin / KPS-0373	Spinocerebellar degeneration							In-licensed /Shionogi
Matsupexole / KDT-3594	Parkinson's disease							Kissei

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R&D Pipeline (In-House) 2

KISSEI

As of November 2026

: Changes from previous release (May 2025)

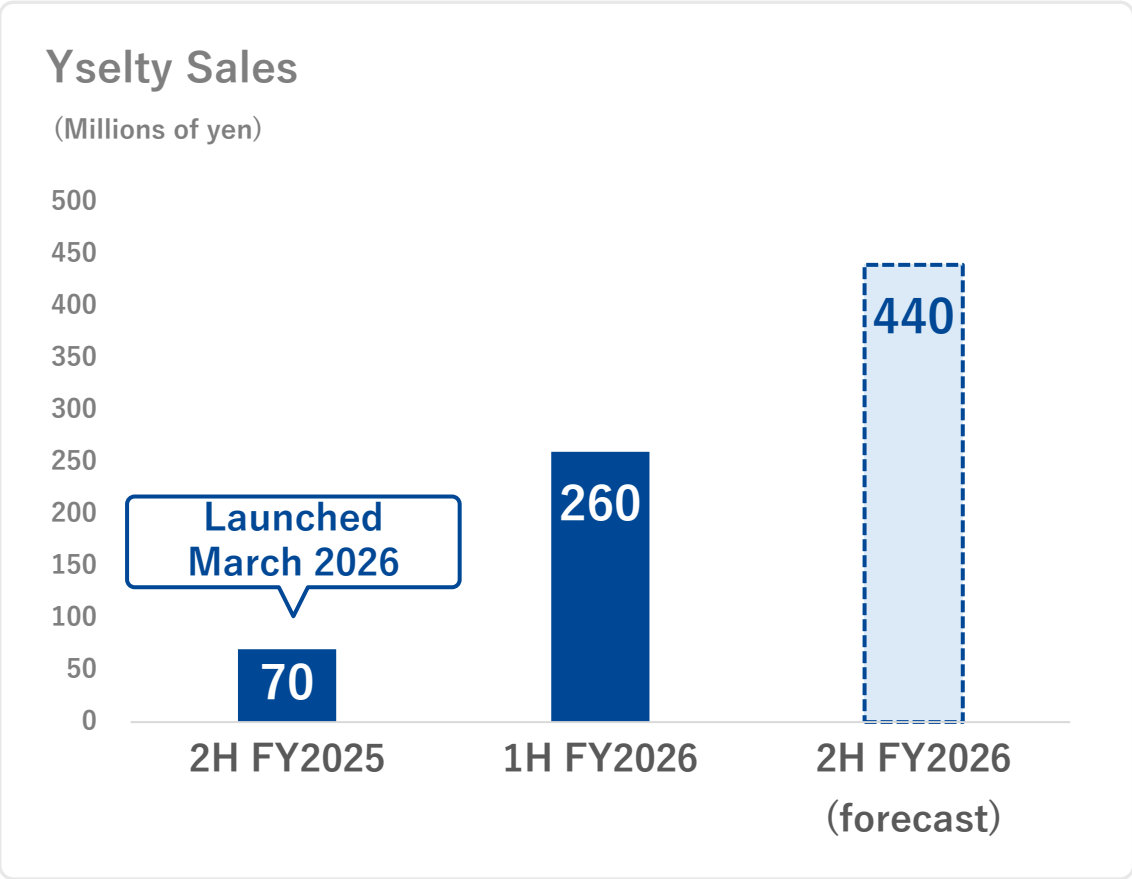
Generic name / Development code	Expected indications	Pre-IND	Phase I	Phase II	Phase III	NDA in process	NDA approved	Origin
KSP-0914	Graves' disease							Kissei
KSP-0576	Overactive bladder / interstitial cystitis and bladder pain syndrome							Kissei
KSP-0930	Narcolepsy							Kissei
Veligrotug	Active TED Inactive TED							In-licensed /Viridian
Elegrobart	Active TED Inactive TED							In-licensed /Viridian

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Yselty: Treatment for Uterine Fibroids | Marketing Strategy

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Increasing the number of facilities that use Yselty and promoting awareness of uterine fibroids to contribute to women's health and patient support.



Keys to increasing the number of facilities using Yselty

- ☑ Lifting of the prescription period restrictions (scheduled for April 2027)
- ☑ Increasing awareness of Yselty's product profile among gynecology clinics/hospitals
- ☑ Target adoption rate for the 2H FY 2026*: 45%

Keys to promoting awareness

- ☑ Joint seminars with government agencies and related academic societies
- ☑ Spreading information through social media
- ☑ Public lectures

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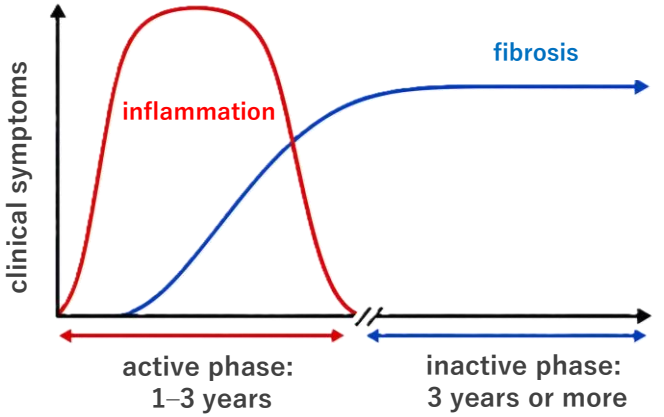
* Percentage of gynecology clinics/hospitals that use Yselty

Status of Veligrotug and Elegrobart

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The total estimated patient population for active and inactive TED is approximately 35,000.

- Approximately 9,000 patients have active TED.
- Approximately 26,000 patients have inactive TED.



Veligrotug

Overview of approved use in the U.S.

Administration route	Intravenous administration
Dosage schedule	5 doses at 3-week intervals; each infusion takes 30 minutes.

Elegrobart

Dosing regimen in overseas clinical trials

Administration route	Self-administered subcutaneous injection
Dosage schedule	6 doses at 4-week intervals or 3 doses at 8-week intervals.

☑ By developing two drugs with different routes of administration in Japan, we aim to expand future treatment options.

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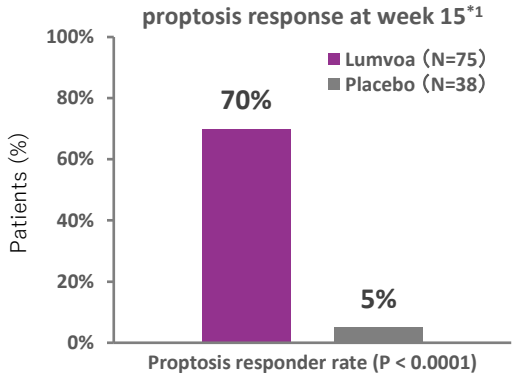
(Reference)Journal of the Endocrine Society 2024; 8:1-8 Prevalence, Incidence, and Clinical Characteristics of Thyroid Eye Disease in Japan (Issue 1)
Diagnostic criteria and treatment guidelines for Graves' disease with malignant exophthalmos (thyroid eye disease) 2023 (Draft version 3), Journal of the Endocrine Society, Volume 8, Issue 1, January 2024, bvad148

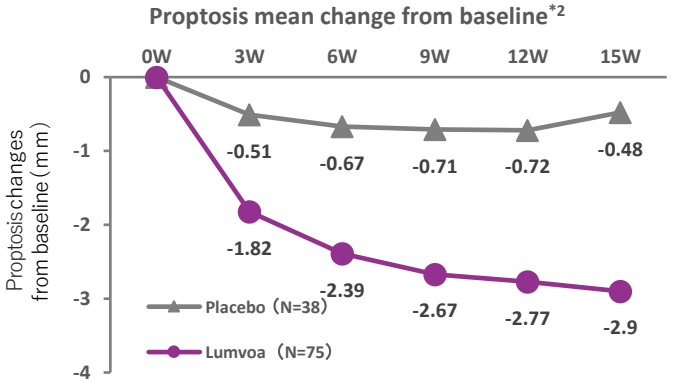
Veligrotug (Lumvoa™) | Clinical trial results

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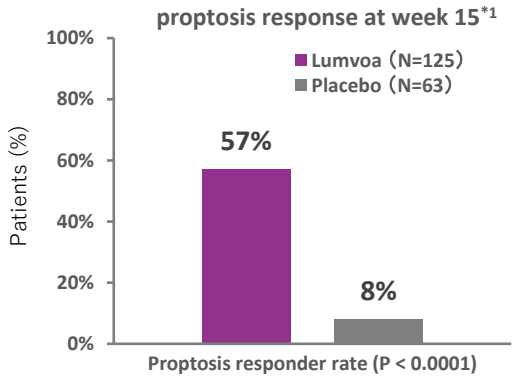
- A potential promising and significant new treatment option for patients with thyroid eye disease.
- U.S. FDA approval obtained in June 2026 / Domestic Phase III trial preparation ongoing.

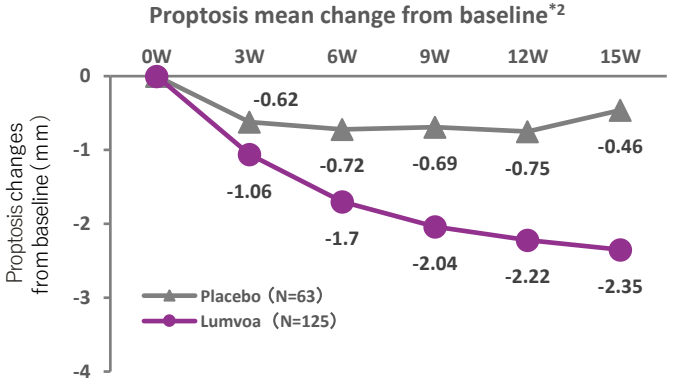
Efficacy (Hertel exophthalmometry) Active TED : THRIVE





Efficacy (Hertel exophthalmometry) Chronic TED : THRIVE-2





Safety Adverse reactions occurring in 5% or more of patients with active or chronic TED (at week 15)

Adverse Reactions	Lumvoa (N=200)		Placebo (N=101)	
	N	%	N	%
Muscle spasms	79	40%	7	7%
Headache	34	17%	14	14%
Hearing impairment*3	29	15%	6	6%
Hyperglycemia*4	25	13%	5	5%
Fatigue*5	25	13%	11	11%
Diarrhea	22	11%	7	7%
Ear discomfort*6	19	10%	3	3%
Infusion-related reaction	18	9%	2	2%
Nausea	15	8%	6	6%
Nasopharyngitis	14	7%	1	1%
Blood creatine phosphokinase increased	12	6%	1	1%
Dry skin	12	6%	2	2%
Hypertension	11	6%	5	5%
Menstrual disorders*7,8	24	24/82 (29%)	2	2/33 (6%)

*1 Proptosis responder rate at week 15 was defined as the percentage of patients with a ≥2-mm reduction in proptosis in the study eye from baseline, without deterioration in proptosis (≥2-mm increase) in the non-study eye.

*2 Change in proptosis of -2 mm or greater was considered a clinically meaningful change.

*3 Hearing impairment includes tinnitus, hypoacusis, deafness, and autophony.

*4 Hyperglycemia includes blood glucose increased, glucose tolerance impaired, glycosylated hemoglobin increased, diabetes mellitus, glucose urine present, and impaired fasting glucose. *5 Fatigue includes asthenia. *6 Ear discomfort includes ear feels clogged or blocked, ear plugging, sensation of ear pressure, and ear popping. *7 Menstrual disorders include amenorrhea, menstruation irregular, dysmenorrhea, menstruation delayed, intermenstrual bleeding, and menstrual disorder, 8 Reported as percentage of menstruating women

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(Reference) Viridian's presentation materials dated June 29, 2026 https://s203.q4cdn.com/807813999/files/doc_events/2026/06/v2/LUMVOA-Approval-Call-Presentation_FINAL-1.pdf

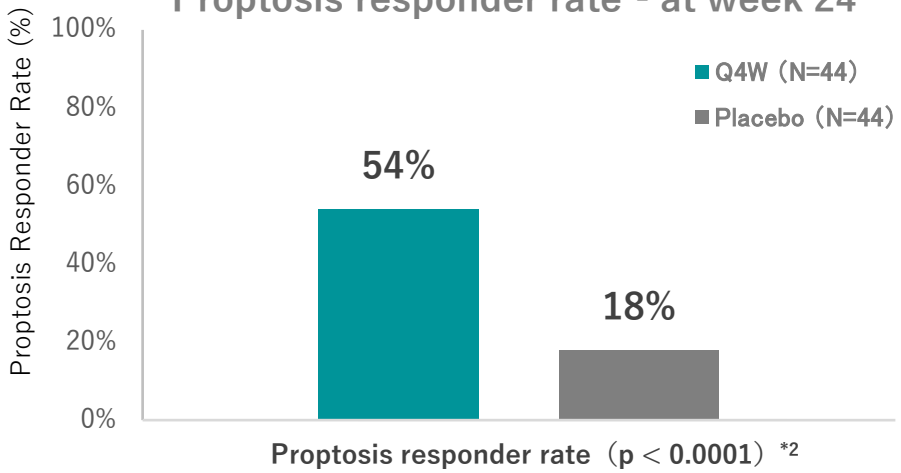
Lumvoa (veligrotug-vvze) prescribing information. Lumvoa trademark is the property of Viridian Therapeutics, Inc.

Elegrobart ｜REVEAL-1（Active TED）

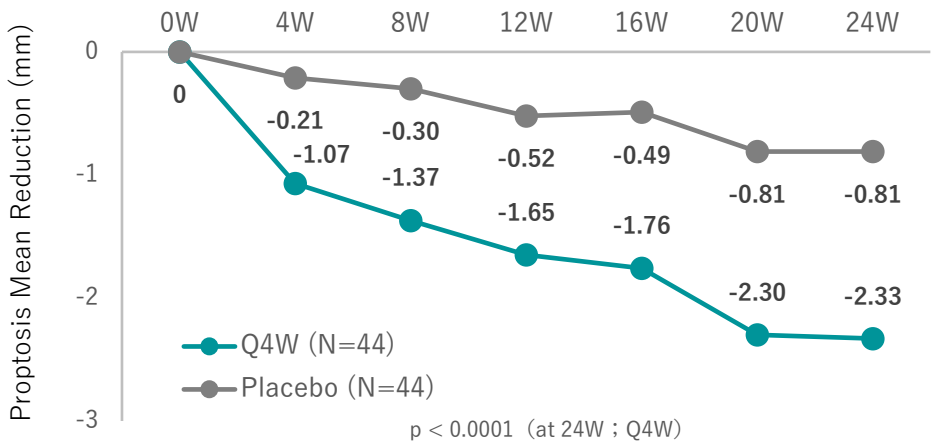
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Efficacy (Hertel exophthalmometry)

Proptosis responder rate*1 at week 24



Proptosis mean change from baseline



Safety AEs occurring at ≥10% frequency in any arm through week 24

Adverse event	Elegrobart (Q4W) n=44, n(%)	Placebo n=44, n(%)
Muscle spasms	18 (41%)	3 (7%)
Injection site reactions (ISR)*3,4	15 (34%)	7 (16%)
Headache	7 (16%)	3 (7%)
Ear discomfort	7 (16%)	1 (2%)
Alopecia	7 (16%)	1 (2%)
Diarrhea	6 (14%)	2 (5%)
Hearing impairment*3,5	6 (14%)	1 (2%)
Hyperglycemia*3	5 (11%)	1 (2%)
Injection related reactions (IRR)*3	5 (11%)	2 (5%)
Menstrual disorders*3,6	5 / 17 (29%)	1 / 20 (5%)

*1 Participants with ≥2 mm reduction in proptosis from baseline in study eye, without deterioration in fellow eye (≥2 mm increase),

*2 Statistically significant. Key secondary endpoints below Q4W “CAS Reduction to 0 or 1” in the prespecified testing hierarchy and other secondary endpoints are nominally significant if below the statistically significant threshold of 0.025.

*3 Includes multiple terms aggregated using standard sets of MedDRA terms; *4 All ISRs were Grade 1 except for one Grade 2 in Q8W arm (erythema), and majority of ISRs were erythema; *5 All hearing impairment events in the treatment arms were tinnitus with no reductions in hearing. There was one hypoacusis event in placebo arm; *6 Reported as percentage of menstruating women.

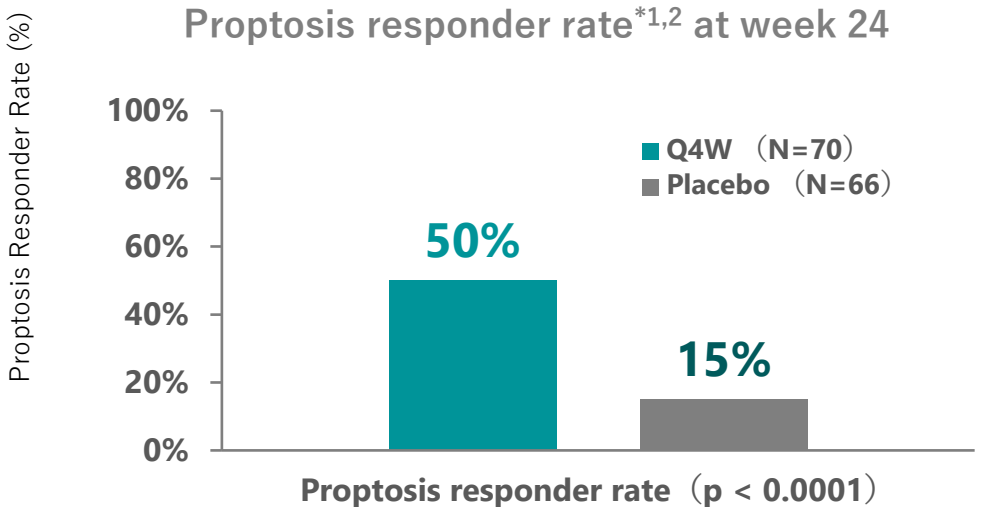
(Reference) Viridian presentation materials dated March 30, 2026
https://s203.q4cdn.com/807813999/files/doc_events/2026/Mar/REVEAL-1-Topline-Readout-Presentation_Final-PDF.pdf

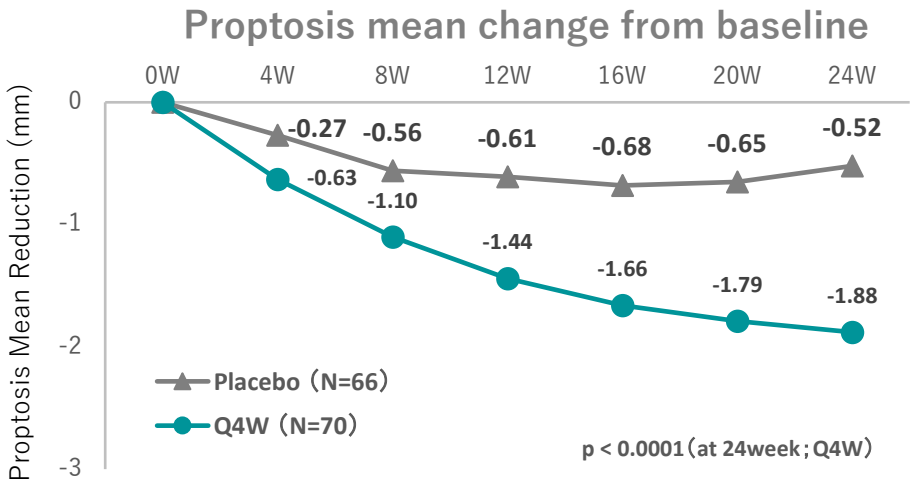
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Elegrobart ｜ REVEAL-2（Chronic TED）

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Efficacy(Hertel exophthalmometry)





Safety AEs occurring at ≥10% frequency in any arm through week 24

Adverse event	Elegrobart (Q4W) n=70, n(%)	Placebo n=66, n(%)
Muscle spasms	15 (21%)	7 (11%)
Injection site reactions (ISR)[3,4]	16 (23%)	18 (27%)
Hyperglycemia[3]	12 (17%)	1 (2%)
Headache	7 (10%)	3 (5%)
Hearing impairment[3,5]	5 (7%)	2 (3%)
Diarrhea	3 (4%)	1 (2%)
Nasopharyngitis	3 (4%)	4 (6%)
Alopecia	2 (3%)	5 (8%)
Menstrual disorders[3,6]	11 / 30 (37%)	2 / 24 (8%)

*1 Measured by exophthalmometry, *2 Participants with ≥2 mm reduction in proptosis from baseline in study eye, without deterioration in fellow eye (≥2 mm increase),*3 Includes multiple terms aggregated using standard sets of MedDRA terms; *4 All ISRs were mild (Grade 1) except for 4 moderate (Grade 2) (3 in Q8W arm & 1 in placebo arm); most common ISR was erythema; *5 Among participants that experienced hearing impairment AEs, the majority reported tinnitus; *6 Reported as percentage of menstruating women

(Reference) Viridian presentation materials dated May 5, 2026
https://s203.q4cdn.com/807813999/files/doc_presentation/2026/REVEAL-2-Topline-Readout-Presentation_FINAL.pdf

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Cretostimogene Grenadenorepvec:Development Strategy

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Development program spanning a wide range of patients with medium-risk and high-risk non-muscle-invasive bladder cancer (NMIBC)

Number of new patients with bladder cancer: Approx. 24,000 people/year*

High risk (40%)

Approx. 7,000 people/year*
(BCG-unresponsive: Approx. 2,000 people/year*)
T1 disease, high-grade disease, or carcinoma in situ (CIS), including concomitant CIS

BOND-003
(Global Phase III Clinical Trial)

Medium risk (30%)

Approx. 5,000 people/year*
Neither low risk nor high risk

September 2026
Submission of domestic clinical trial notification

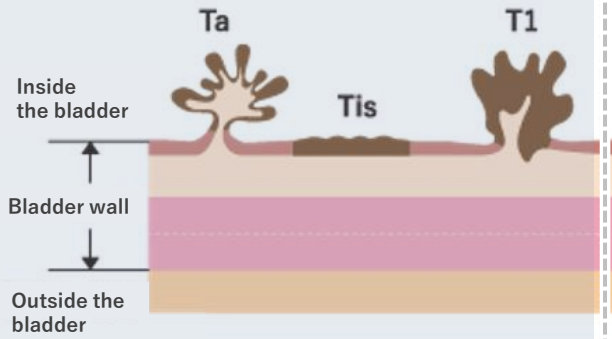
PIVOT-006
(U.S. Phase III Clinical Trial)

CG1201
(Domestic Phase II Clinical Trial)

Low risk

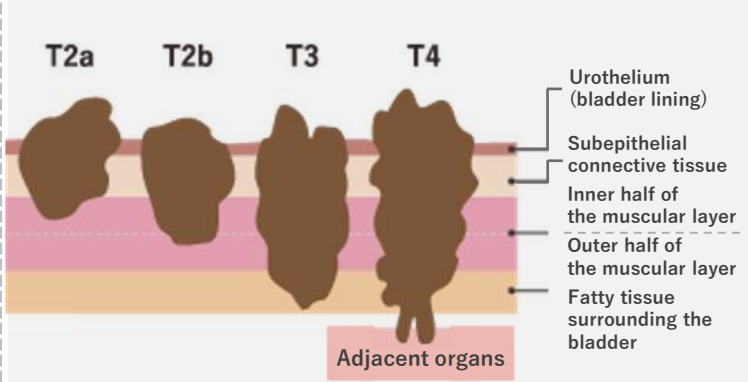
Meets all the following criteria:
solitary tumor (a single tumor within the bladder), primary tumor (first occurrence of bladder cancer), tumor size <3 cm, Ta disease, low-grade disease, no concomitant CIS.

Non-muscle-invasive bladder cancer 75%



Ta	**Non-invasive papillary carcinoma** Confined to the urothelium (bladder lining) Protrudes into the bladder cavity
Tis	**Carcinoma in situ (CIS)** Confined to bladder lining Grows as a flat lesion along bladder lining
T1	Extends into the subepithelial connective tissue

Muscle-invasive bladder cancer 25%



T2a	Confined to the inner half of the muscular layer
T2b	Invades beyond the inner half of the muscular layer
T3	Extends into the fatty tissue surrounding the bladder **T3a** Microscopic invasion of the tissue surrounding the bladder **T3b** Macroscopically visible extravesical tumor
T4	Extends to adjacent organs **T4a** Involves the prostate, seminal vesicles, uterus, or vagina **T4b** Involves the pelvic or abdominal wall

*Sources: National Cancer Center Japan Cancer Information Service, Cancer Statistics (2021); Bladder Cancer Clinical Practice Guidelines 2019; Int J Urol. 2023 Dec;30(12):1155-1163; BJUI Compass. 2023 Nov 3;5(2):269-280; Int J Urol. 2023 May;30(5):473-481.

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Cretostimogene Grenadenorepvec: Single-Arm Phase III Clinical Trial (BOND-003 Cohort C)


Articles

Intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer with carcinoma in situ (BOND-003 Cohort C): a single-arm, phase 3 trial

Summary

Background There are few bladder-sparing treatment options for high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer that are effective and have a manageable adverse event profile. Cretostimogene grenadenorepvec (formerly, cretostimogene) is an oncolytic immunotherapy with dual mechanisms of action—it replicates in and lyses cancer cells with retinoblastoma–E2F pathway alterations and amplifies the immune response. We evaluated the response and safety/tolerability of cretostimogene in patients with high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer.

Methods BOND-003 Cohort C is a single-arm, international, phase 3 study done in 41 centres (community practices and academic centres) located in North America, Asia, and Australia. Sites were selected through a study team-led qualification process that evaluated feasibility, protocol alignment, operational capabilities, and regulatory readiness, as applicable. We enrolled patients aged at least 18 years with Eastern Cooperative Oncology Group performance status of 0–2 and pathologically confirmed, high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer with carcinoma in situ, with or without resected high-grade Ta or T1 disease. Patients received intravesical cretostimogene (1×10¹¹ viral particles per 0·1 mL per week) as 6-week induction followed by maintenance; re-induction was permitted for persistent disease at 3 months. The primary endpoint was centrally confirmed complete response at any time in patients who received at least one dose of cretostimogene and completed the 3-month assessment; safety was assessed in those who received at least one dose of cretostimogene. This trial is registered with ClinicalTrials.gov (NCT04452591) and is ongoing.

Findings Between Oct 9, 2020, and Aug 3, 2023, 165 patients were assessed for eligibility; 115 patients were enrolled in the study and 112 received cretostimogene. 83 (74%) were male and 29 (26%) were female; median age was 74·0 years (IQR 68·5–79·5). As of June 23, 2025, after a median follow-up of 25·3 months (IQR 22·1–31·3), complete response at any time was observed in 83 (75% [95% CI 66·3–83·2]) of 110 patients. 71 (63%) of 112 patients had at least one treatment-related adverse event, the most common being bladder spasm in 28 (25%) patients, pollakiuria in 25 (22%) patients, and micturition urgency in 23 (21%) patients; there were no grade 5 or 4 treatment-related adverse events and no treatment-related discontinuations or deaths. Two (2%) patients had serious treatment-related adverse events (one non-infective cystitis and one urinary bladder haemorrhage, both grade 2).

Interpretation Cretostimogene showed clinically meaningful anti-tumour response, with an adverse event profile characterised predominantly by low-grade, transient events. Cretostimogene shows promise as an innovative bladder-sparing treatment for high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer with carcinoma in situ.

Funding CG Oncology.

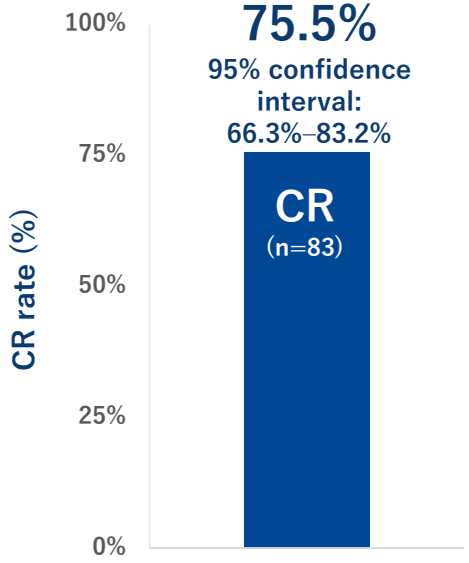
Introduction

Correspondence to:

- Study Design: Single-arm, open-label trial (international collaborative Phase III trial)
- Target patients: Patients with BCG-unresponsive NMIBC with carcinoma in situ
- Administration Method: Intravesical administration once a week for six weeks (once a week for three weeks after six months)
- Primary Endpoint: Complete response (CR) rate at either 3 or 6 months (centrally confirmed)

BOND-003 (Cohort C)

Primary endpoint* (n=110)



Key Efficacy Endpoints Other Than the Primary Endpoint (n=110)

- ☑ At 24 months, 96.4% of patients remained free from progression to MIBC (muscle-invasive bladder cancer) or mUC (metastatic urothelial carcinoma).
- ☑ By month 24, 83.6% of responding patients had avoided radical cystectomy (bladder removal).
- ☑ All complete responses were confirmed by central review.

Assessment point	CR rate (%) (95% confidence interval)	Kaplan-Meier estimate (%) (95% confidence interval)
12 months	46.4% (51/110 patients) (36.8-56.2)	50.7% (40.9-59.8)
24 months	41.8% (46/110 patients) (32.5-51.6)	42.4% (32.7-51.7)

Safety Profile (n=112)

Number of treatment-related adverse events	71	63.4%
Main adverse events		
Bladder spasms	28	25.0%
Pollakiuria	25	22.3%
Urgency	23	20.5%
Dysuria	21	18.8%
Hematuria	15	13.4%
Serious treatment-related adverse effects	2	1.8%
Treatment-related discontinuations	0	0.0%

* Analysis population: Efficacy analysis set / Data cutoff: June 23, 2025

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Matsupexole | Results of Late-Stage Phase II Clinical Trial

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KDT1203 Trial (Patients with Advanced Parkinson's Disease)

- Matsupexole demonstrated a statistically significant improvement compared to placebo regarding the primary endpoint, change from baseline in the total MDS-UPDRS score for Part II and Part III (on period) at 17 weeks of treatment
- At 17 weeks, treatment discontinuation due to adverse events was 6.7% in the Matsupexole group and 3.4% in the placebo group.

Study Design

Randomized, double-blind, placebo-controlled, parallel-group comparative dose escalation study

Participants

Patients with advanced Parkinson's disease receiving treatment in combination with L-DOPA

Administration Method

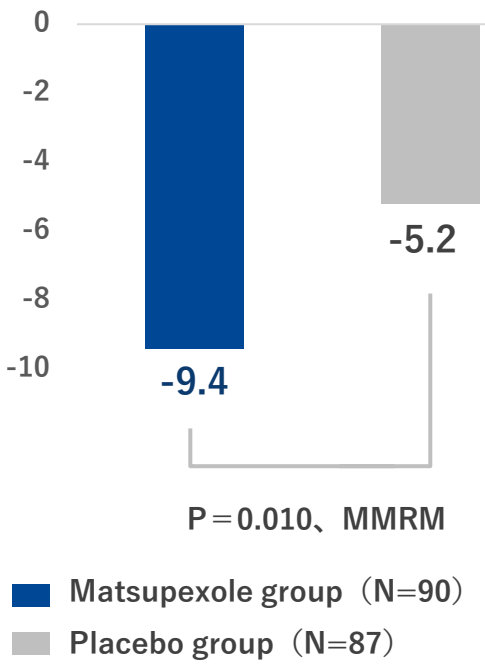
Administered once daily, gradually increasing dosage

Primary Endpoint

Change from baseline in the total MDS-UPDRS score for Part II and Part III (on period) at 17 weeks of treatment

Primary Endpoint

(analysis population:Full Analysis Set)



Safety Profile

（analysis population:Safety Set）

	Matsupexole (N=90)	Placebo (N=88)
Number of treatment-related adverse events	26（28.9%）	21（23.9%）
Main adverse events	Occurring at 5% or more for either group	
Excessive daytime sleepiness	7（7.8%）	5（5.7%）
Constipation	8（8.9%）	1（1.1%）
Nausea	2（2.2%）	6（6.8%）
Serious treatment-related adverse effects	0（0.0%）	1（1.1%）
Treatment-related discontinuations	6（6.7%）	3（3.4%）

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Sustainability and Sustainable Management

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August 2026 marked the 80th anniversary of Kissei Pharmaceutical.
We will continue to promote sustainable management through environmental initiatives, social contribution, and human resource development.

Environment







Top left: Selection to the CDP A-List

Top right: Building equipped with energy-saving and energy-generating systems

Bottom Left: Use of renewable energy

- ☑ Reduction of GHG emissions
- ☑ Efficient use of water resources
- ☑ Waste reduction

Society







Top left: Kanzawa Medical Research Foundation

Top right: Matsumoto Yamaga Football Club

Bottom left: Seiji Ozawa Matsumoto Festival

- ☑ Support for young career researchers
- ☑ Promotion of culture and sports
- ☑ Provision of learning opportunities for students and children

Human Capital

2026
健康経営優良法人
KENKO Investment for Health
大規模法人部門

- ☑ Enhancing R&D talent
- ☑ Strengthening frontline management capabilities
- ☑ Development of next-generation leaders
- ☑ Promotion of health management

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