

Results Presentation Fiscal 2024

協和キリン株式会社

 **KYOWA KIRIN**

Agenda

2021-2025 Medium Term Business Plan
 - FY2024 Review, FY2025 Plans -
 Capital Allocation, Shareholders Return
 Commercial Update
 R&D Update
 News Flow
 Q&A

President and Chief Executive Officer (CEO) **Masashi Miyamoto, Ph.D.**

Senior Managing Executive officer and Chief Medical Officer (CMO) **Takeyoshi Yamashita, Ph.D.**

Managing Executive Officer, Chief Financial Officer (CFO) **Motohiko Kawaguchi**

Managing Executive Officer, Chief International Business officer (CIBO) **Abdul Mullick, Ph.D.**

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but the actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

This document is used only for the purpose of providing the information to investors. Though it may contain the information concerning pharmaceutical products (including products under development), it is not for the purpose of promotion, advertising, or medical advice.

2021-2025 Medium Term Business Plan - FY2024 Review -

Provide pharmaceuticals for unmet medical needs

■ Formulated the Strategy for Achieving the Vision 2030 'Story for Vision 2030'

■ Maximize the value of global strategic products

- ✓ Steady growth of Crysvida and Poteligeo in North America and EMEA
- ✓ Expanded launched countries / regions for Crysvida to 52, and begun insurance reimbursement for adult XLH (England)

■ Continue to create groundbreaking new drugs

- ✓ Achieved the primary endpoint as well as all major secondary endpoints in the rocatinlimab Phase III clinical trial for atopic dermatitis (ROCKET HORIZON trial)
- ✓ Initiated a clinical trial for rocatinlimab targeting asthma and nodular prurigo
- ✓ Entered into a global strategic partnership agreement with Kura Oncology for the development and commercialization of ziftomenib
- ✓ Obtained approval for Lenmeldy for the treatment of early-onset metachromatic leukodystrophy in the United States and secured reimbursed in Benelux and Spain
- ✓ Entered clinical trials with multiple products, including ADCs

Reinforce human resources and structures that support the creation of Life-changing value

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Established CSCO and strengthened execution through the establishment of a CxO structure that encompasses all functions
- ✓ Articulated the desired vision of people and organizations that strongly promote global strategies and achieve the continuous creation of Life-changing Value as specific actions (KABEGOE Principals)
- ✓ Translated to a global research framework aimed at strengthening efforts in key areas and modalities
- ✓ Implemented a reorganization of business operations related to the Asia-Pacific region
- ✓ Joined PSCI (the Pharmaceutical Supply Chain Initiative)

Address patient-centric healthcare needs

■ Improvement of Access to medicine

- ✓ Continued disease awareness activities and the enhancement of patient support programs in North America, including transitional care for Crysvida from pediatric to adult patients
- ✓ Supported activities to expand MLD newborn screening in North America and Europe
- ✓ Published the global consensus 'Time to Act' aimed at improving the diagnosis and treatment of CTCL in collaboration with patient support organizations

■ Provide value that goes beyond pharmaceuticals

- ✓ Established Cowellnex Co., Ltd. as a joint venture with Kirin Holdings Company, aiming to create new value
- ✓ Clarification of challenges through the XLH Community Impact Survey (US)
- ✓ Established the Facebook online community 'Kurukotsu Voice' for XLH patients and their families (JP)

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Proceeded to establish the key products supply system with multiple production sites
- ✓ Continued the construction of a new active pharmaceutical ingredient (API) manufacturing building "HB7", scheduled for completion in March 2025
- ✓ Initiated the construction of a new biologics manufacturing plant in the US

■ Help to protect the global environment

- ✓ Reduced GHG emissions (Scope 1, 2) by 67% compared to 2019
- ✓ Initiated efforts to reduce GHG emissions (Scope 3)
- ✓ Received the Minister of the Environment Award at the Takasaki Plant and the Director-General of the Chugoku Bureau of Economy, Trade and Industry Award at the Ube Plant

Quantitative Summary of FY24 Results

(Billion Yen / Rounded)

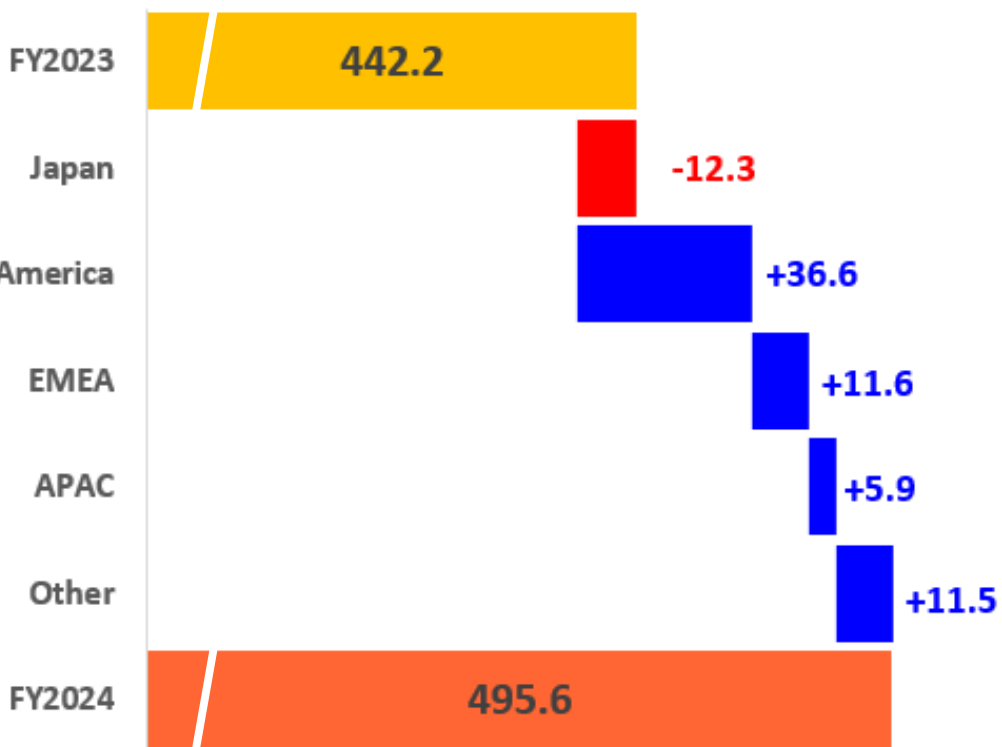
	FY2023 Results	FY2024 Results	Changes	2024 Revised Plans	Achieved
Revenue <i>[Overseas Ratio]</i>	442.2 <i>[65%]</i>	495.6 <i>[72%]</i>	+53.3 (+12%)	492.0 <i>[71%]</i>	101%
Gross Profit <i>[Gross Profit Margin]</i>	331.0 <i>[75%]</i>	362.9 <i>[73%]</i>	+31.9 (+10%)	364.0 <i>[74%]</i>	100%
SG&A <i>[SG&A Ratio]</i>	163.1 <i>[37%]</i>	167.5 <i>[34%]</i>	+4.5 (+3%)	168.0 <i>[34%]</i>	100%
R&D <i>[R&D Ratio]</i>	72.1 <i>[16%]</i>	103.5 <i>[21%]</i>	+31.4 (+44%)	105.0 <i>[21%]</i>	99%
Gain/Loss on Equity Method	0.9	3.5	+2.6 (+275%)	1.0	354%
Core Operating Profit <i>[Core OP Margin]</i>	96.8 <i>[22%]</i>	95.4 <i>[19%]</i>	-1.4 (-1%)	92.0 <i>[19%]</i>	104%
Profit	81.2	59.9	-21.3 (-26%)	68.0	88%
Return on Equity	10.2%	7.1%			
Dividend Payout Ratio ¹	35.5%	47.8%			

[FOREX]
 FY2023-Actual JPY140/USD
 FY2024-Actual JPY151/USD
 FY2024-Rev. Plan JPY151/USD

¹ Figures are based on Core-EPS (EPS calculated using “Core profit,” profit without other income/losses and related taxes).

FY23 vs FY24 -Revenue-

+53.3 billion yen
(incl. forex effect +24.4)



● **Japan -12.3**

Although Phozevel, Duvroq and Crysvita increased, revenue in Japan region decreased by 8% due mainly to negative impact by annual NHI price-cut and shrink in G-Lasta affected by competitive products.

● **North America +36.6 (incl. forex effect +12.1)**

Revenue in North America region increased by 27% with the growth of Crysvita (+24%) and Poteligeo (+38%).

● **EMEA +11.6 (incl. forex effect +6.9)**

Revenue in EMEA region increased by 16% with the growth of Crysvita (+47%) and Poteligeo (+19%) as well as the IP transfer of three established medicines (13.1) to Grünenthal-Med, the joint venture collaboration (JVC) with Grünenthal.*

*These three medicines are part of the portfolio of 13 brands, such as Abstral, which are marketed through Grünenthal-Med.

● **APAC +5.9 (incl. forex effect +2.2)**

APAC revenue increased by 17% driven by the growth of Crysvita and bulk transfer of inventory to DKSH, the partner in the business restructuring.

● **Other +11.5 (incl. forex effect +3.3)**

24% growth in the other revenue was due to the royalties of growing Fasentra (Benralizumab), upfront revenue from Boehringer Ingelheim, and new consolidation of Orchard.

FY23 vs FY24 -Revenue of Major Items in Japan-

(Billion Yen / Rounded)

Item	FY2023 Results	FY2024 Results	Changes	Reasons	2024 Rev. Plans	Achieved
Crysvita	10.5	11.7	+1.2(+12%)	Market penetration (Launched in Dec 2019)	12.9	91%
Poteligeo	1.9	1.8	-0.1 (-5%)		1.9	95%
Nesp + Nesp-AG ¹	17.1	14.2	-2.9 (-17%)	NHI price-cut & Biosimilars' penetration	14.4	99%
Nesp	3.2	2.6	-0.5 (-16%)		2.8	96%
Nesp-AG	14.0	11.6	-2.4 (-17%)		11.7	99%
Duvroq	9.9	12.7	+2.8 (+28%)	Market penetration (Launched in Aug 2020)	12.2	104%
Phozevel	-	4.7	+4.7 (- %)	Launched in Feb 2024	3.3	141%
Orkedia	10.6	10.4	-0.2 (-1%)		11.7	89%
G-Lasta	31.9	20.5	-11.4 (-36%)	NHI price-cut & Biosimilars' penetration	20.5	100%
Rituximab BS	9.0	7.8	-1.2 (-13%)	NHI price-cut	7.9	99%
Romiplate	12.0	13.9	+2.0 (+16%)	Market penetration	13.2	106%
Nourias	7.6	6.9	-0.6 (-8%)	Competitors' penetration	7.1	98%
Haruopi	4.5	4.6	+0.1 (+3%)	Market penetration	5.2	89%

1 AG stands for Authorized Generic. Official product name is Darbeopetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

* 2024 Revised Plan announced on August 1, 2024, there is no changes to the "Revenue of Major Items (Japan)"

FY23 vs FY24 -Revenue of Major Items outside Japan-

(Billion Yen / Rounded)

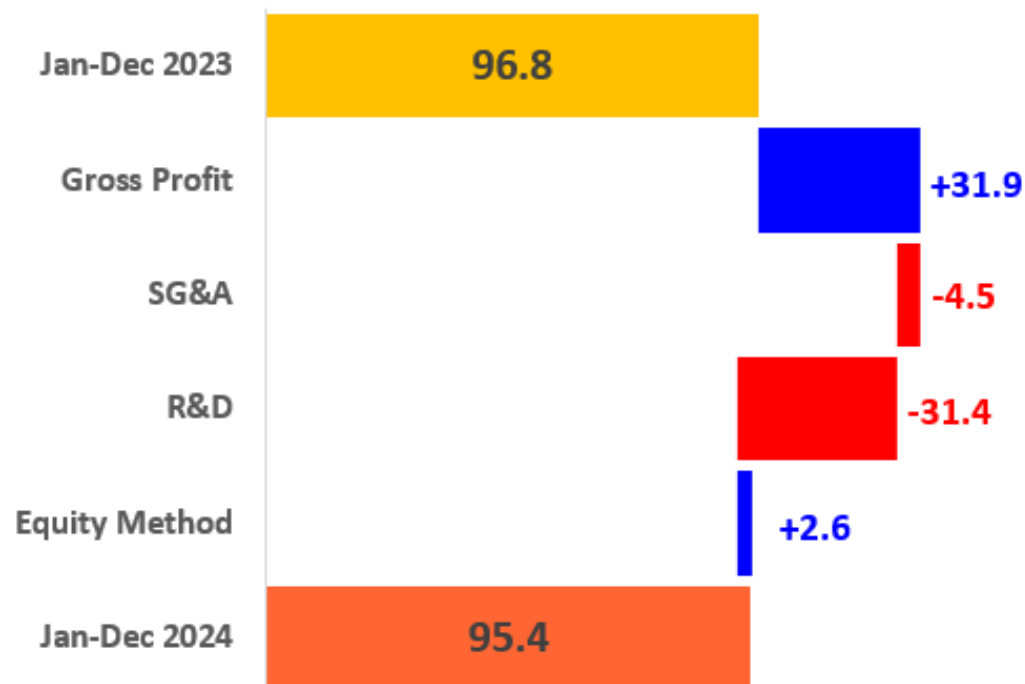
Item	FY2023 Results	FY2024 Results	Changes	Reasons	2024 Rev. Plans	Achieved
Crysvita	142.0	184.8	+42.8 (+30%)		187.8	98%
North America	105.2	130.0	+24.8 (+24%)	Market penetration		
EMEA	35.1	51.5	+16.4 (+47%)			
APAC	1.6	3.3	+1.7 (104%)			
Poteligeo	28.4	38.1	+9.7 (+34%)		34.8	110%
North America	21.5	29.7	+8.3 (+38%)	Market penetration	25.1	119%
EMEA	6.9	8.2	+1.3 (+19%)		9.3	89%
APAC	0.0	0.1	+0.1 (-%)		0.5	32%
Libmeldy / Lenmeldy	-	3.3	+3.3 (-%)	New consolidation of Orchard (FDA approval in Mar 2024)	4.9	67%
Nourianz	8.2	8.8	+0.5 (+6%)		9.1	96%
Nesp ¹	9.1	9.7	+0.6 (+7%)		10.7	91%
Gran ¹	6.9	5.4	-1.5 (-22%)	Business transfer to WinHealth in Oct 2024	7.2	76%
Tech-licensing	40.7	47.8	+7.1 (+18%)	Upfront revenue from Boehringer Ingelheim and growth of Fasenra	47.8	100%
Benralizumab Royalty ²	27.4	31.4	+4.0 (+15%)			

1 Shipments to partners (WinHealth and DKSH) after the restructuring of the APAC business (October 2024) are not included.

2 Sales royalties of Fasenra which has been marketed by AstraZeneca. Including our own estimation.

FY23 vs FY24 -Core OP-

**-1.4 billion yen
(incl. forex effect +8.6)**



- **Gross Profit +31.9 (incl. forex effect +21.3)**

Increased in conjunction with the 53.3 rise in revenue. COGs have increased due to the North America Crysvida Sales royalty after Apr 27, 2023. Hence, gross profit % declined YoY. (75% →73%) .

- **SG&A -4.5 (incl. forex effect -7.6)**

While the Crysvida commercial operation expenses are increased in North America, such as HR exp, decreased in Crysvida profit sharing expenses due to the North America Crysvida-related scheme change after Apr 27, 2023.

[Labor -10.4 / Sales promotion +11.6 (incl. Crysvida profit-share expenses +11.6)]

- **R&D -31.4 (incl. forex effect -5.3)**

Increased in clinical study costs of KHK4083, which is undergoing joint global Phase III clinical study, along with new consolidation of Orchard, resulted in significant increase of 44% (31.4), exceeding 100.0 billion yen in total R&D expenses. R&D expense ratio rose from 16% to 21%, an increase of 5 percentage points.

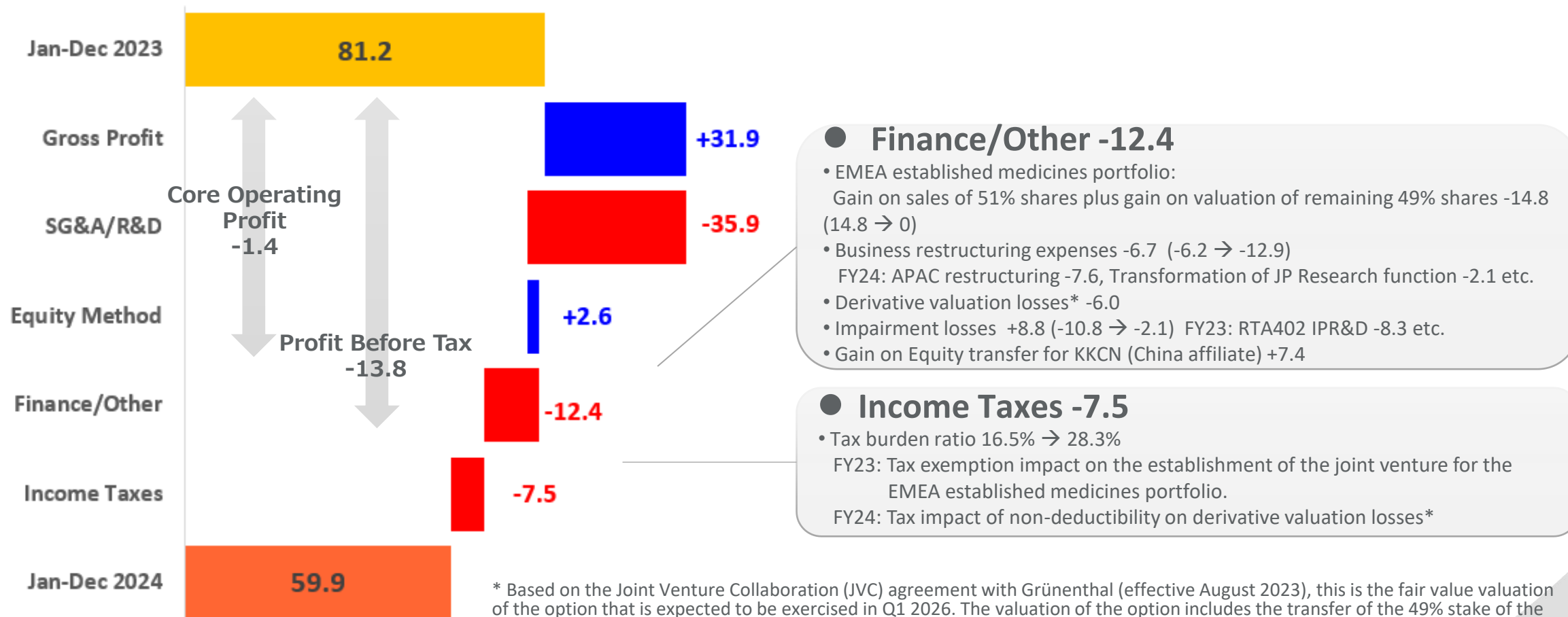
- **Gain/Loss on Equity Method +2.6 (incl. forex effect +0.2)**

Due to the recognition of inventory transfer gains related to the transfer of operation in certain countries within the European established pharmaceuticals business in the Joint Venture Collaboration with Grünenthal, along with the tax effect from FKB.

FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

FY23 vs FY24 -Profit-

Profit (Jan-Dec) -21.3 billion yen



* Based on the Joint Venture Collaboration (JVC) agreement with Grünenthal (effective August 2023), this is the fair value valuation of the option that is expected to be exercised in Q1 2026. The valuation of the option includes the transfer of the 49% stake of the JVC that includes the remaining operational assets of the business, as well as the transfer of the intellectual property to Grünenthal. The fair value assessment incorporates the compensation risks for lost profits related to out-of-stock products as well as any possible product Technical Transfer penalties.

2021-2025 Medium Term Business Plan

- FY2025 Plans -

Provide pharmaceuticals for unmet medical needs

■ Value creation and provision in disease areas that the company focuses on

- ✓ Application for approval of ziftomenib for monotherapy in the second-line treatment of AML in the US and advancement of clinical trials for first-line treatment, as well as the progress of clinical trials for KK2845
- ✓ Advancement of clinical trials for KK8123 with the same indications as Crysvisa
- ✓ Advancement of clinical trials for HSC-GT products such as OTL-203 and OTL-201

■ Value creation and provision through strategic partnering

- ✓ Efforts towards the US approval application and market launch of rocatinlimab for atopic dermatitis, as well as the advancement of clinical trials for asthma and prurigo nodularis
- ✓ Advancement of clinical trials for KHK4951, KK4277, KK2260, and KK2269

■ Continue to create groundbreaking new drugs

- ✓ Enhancement of capabilities in cell and gene therapy research and development
- ✓ Acceleration of research on advanced antibody technologies and continuation of pipeline development using those technologies

Reinforce human resources and structures that support the creation of Life-changing value

■ Cultivate human resources, Strengthen organizations, Build digital platforms, and Others

- ✓ Incorporation of the KABEGOE Principles into the talent management cycle, fostering KABEGOE Culture and accelerating talent development through penetration and establishment
- ✓ Establishment of a Chief Digital Transformation Officer (CDXO) and acceleration of value creation through operational transformation leveraging DX

Address patient-centric healthcare needs

■ Improvement of Access to medicine and Provide value that goes beyond pharmaceuticals

- ✓ Crysvisa: Continued efforts for disease awareness of XLH and TIO, patient support programs, and improving global access
- ✓ Poteligeo: Strive to enhance access for patients with Mycosis fungoides (MF) and Sezary syndrome (SS) through evidence-based approaches
- ✓ Continued support for activities to expand MLD newborn screening and reimbursed in North America and Europe
- ✓ Addressing the challenges through Patient Advocacy/Patient Engagement activities
- ✓ Efforts to address social issues related to health by Cowellnex Inc., a joint venture with Kirin Holdings

Retain the trust of society

■ Ensure stable supplies of high-quality pharmaceuticals

- ✓ Establishment of a stable production system and a resilient supply chain on a global scale
- ✓ The commencement of operations at the new active pharmaceutical ingredient (API) manufacturing building (HB7), the construction of a new biopharmaceutical plant in the United States and promotion of efforts to establish a global production network.

■ Help to protect the global environment

- ✓ Reduction in GHG emissions (Scope 1, 2) by 63% compared to 2019
- ✓ Promotion of the reduction of GHG emissions (Scope 3)

Quantitative Summary of FY25 Plans

(Billion Yen / Rounded)

	FY2023 Results	FY2024 Results	FY2025 Plans	Changes
Revenue <i>[Overseas Ratio]</i>	442.2 <i>[65%]</i>	495.6 <i>[72%]</i>	478.0 <i>[70%]</i>	-17.6 (-4%)
Gross Profit <i>[Gross Profit Margin]</i>	331.0 <i>[75%]</i>	362.9 <i>[73%]</i>	352.0 <i>[74%]</i>	-10.9 (-3%)
SG&A <i>[SG&A Ratio]</i>	163.1 <i>[37%]</i>	167.5 <i>[34%]</i>	166.0 <i>[35%]</i>	-1.5 (-1%)
R&D <i>[R&D Ratio]</i>	72.1 <i>[16%]</i>	103.5 <i>[21%]</i>	107.0 <i>[22%]</i>	+3.5 (+3%)
Gain/Loss on Equity Method	0.9	3.5	1.0	-2.5 (-72%)
Core Operating Profit <i>[Core OP Margin]</i>	96.8 <i>[22%]</i>	95.4 <i>[19%]</i>	80.0 <i>[17%]</i>	-15.4 (-16%)
Profit	81.2	59.9	57.0	-2.9 (-5%)
Return on Equity	10.2%	7.1%	6.6%	
Dividend Payout Ratio ¹	35.5%	47.8%	50.3%	

[FOREX]
 FY2023-Actual JPY140/USD
 FY2024-Actual JPY151/USD
 FY2025-Plan JPY145/USD

¹ Figures are based on Core-EPS (EPS calculated using "Core profit," profit without other income/losses and related taxes).

FY25 -Revenue of Major Items-

(Billion Yen / Rounded)

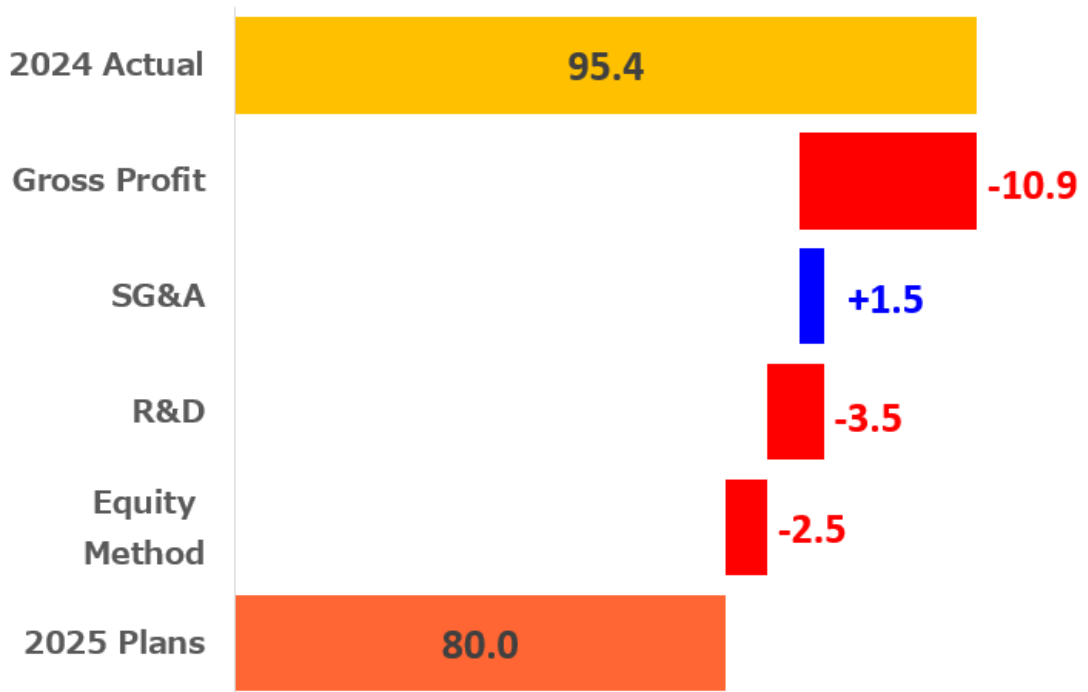
Item		FY2023 Results	FY2024 Results	FY2025 Plans	Changes	Reasons
Crysvita		152.4	196.6	210.2	+13.7 (+7%)	Market penetration
	JP	10.5	11.7	13.1	+1.3 (+11%)	
	NA	105.2	130.0			
	EMEA	35.1	51.5	197.1	+12.3 (+7%)	
	APAC	1.6	3.3			
Poteligeo		30.3	39.9	45.4	+5.5 (+14%)	Market penetration
	JP	1.9	1.8	1.9	+0.1 (+3%)	
	NA	21.5	29.7	34.1	+4.3 (+15%)	
	EMEA	6.9	8.2	9.2	+1.0 (+12%)	
	APAC	0.0	0.1	0.3	+0.2 (+98%)	
Libmeldy / Lenmeldy		-	3.3	6.9	+3.6 (+109%)	Market penetration (FDA approval in Mar 2024)
Phozevel	JP	-	4.7	8.9	+4.2 (+91%)	Market penetration (Launched in Feb 2024)
Duvroq	JP	9.9	12.7	15.5	+2.8 (+22%)	Market penetration
Nesp + Nesp-AG ¹	JP	17.1	14.2	11.6	-2.7 (-19%)	NHI price-cut & Biosimilars' penetration
G-Lasta	JP	31.9	20.5	17.0	-3.5 (-17%)	NHI price-cut & Biosimilars' penetration
Romiplate	JP	12.0	13.9	14.6	+0.7 (+5%)	Market penetration
Tech-licensing		41.9	48.8	52.3	+3.5 (+7%)	Growth of Fasentra
	Benralizumab Royalty 2	27.4	31.4			

© Kyowa Kirin Co., Ltd. 1 AG stands for Authorized Generic. Official product name is Darbepoetin Alfa [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

2 Sales royalties of Fasentra which has been marketed by AstraZeneca. Including our own estimation.

FY24 vs FY25 -Core OP-

**-15.4 billion yen
(incl. forex effect -4.4)**



● **Gross Profit -10.9**
 While Crysvida and Poteligeo are driving revenue growth primarily in North America, the total revenue is expected to decline by 17.6 (Japan -12.9, North America +16.6, EMEA -11.2, Other -10.0 (incl. the impact of the restructuring of APAC operations -18.0)) due to factors such as one-time revenue decreases in the EMEA region, the impact of the restructuring of APAC operations, the termination of the sales partnership for Dovobet in Japan, NHI price-cut, and FX impact (-11.4), leading to a decrease in gross profit.

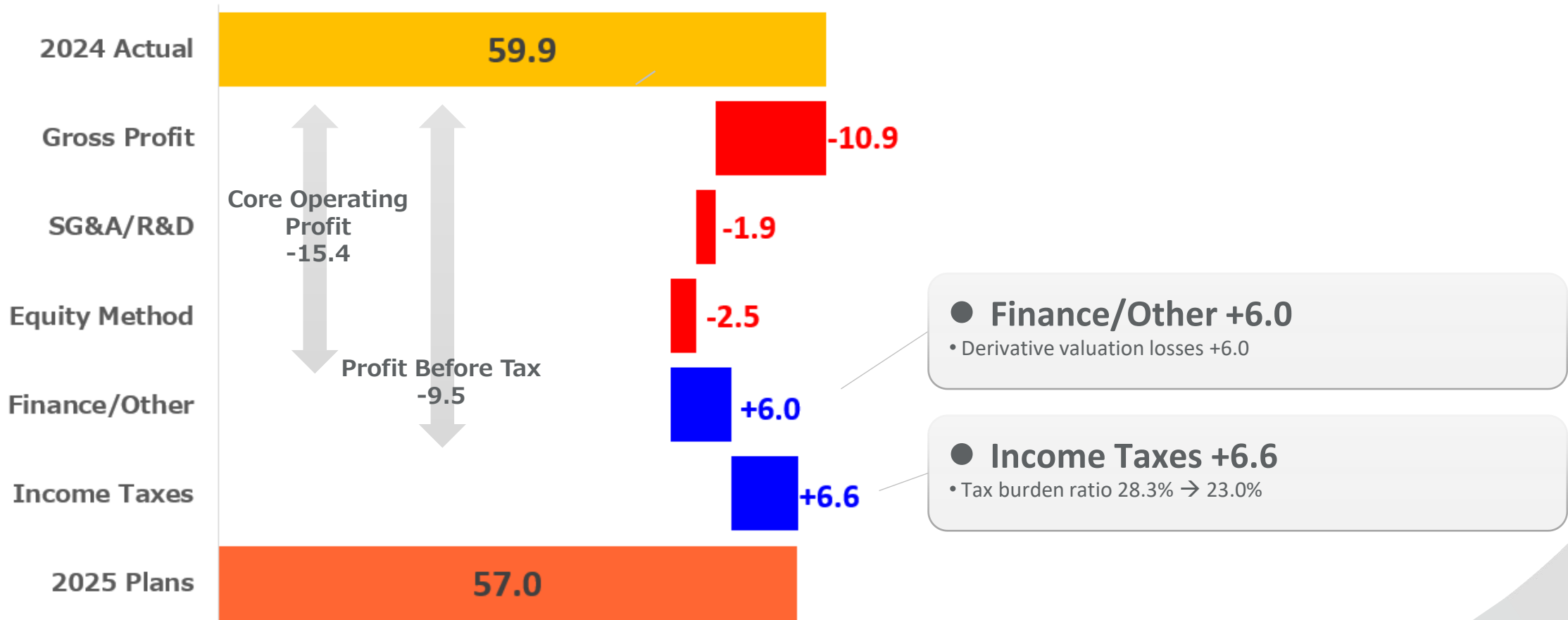
● **SG&A +1.5**
 A decrease of 1.5 billion is expected due to the restructuring impact in the APAC region, despite anticipated increases in launch readiness costs related to ziftomenib and KHK4083, as well as rising labor costs due to inflation.

● **R&D -3.5**
 R&D investment will continue at a high level exceeding 100.0, centered on KHK4083, which is undergoing joint global Phase III clinical study. The R&D expense ratio is expected to increase from 20.9% to 22.4%, a rise of 1.5 percentage points.

● **Gain/Loss on Equity Method -2.5**
 A decrease of 2.5 is anticipated due to the removal of inventory transfer gains from the established pharmaceuticals business in the Joint Venture Collaboration with Grünenthal that occurred FY24, along with the elimination of tax effect from FKB.
FKB; Fujifilm Kyowa Kirin Biologics Co., Ltd.

FY24 vs FY25 -Profit-

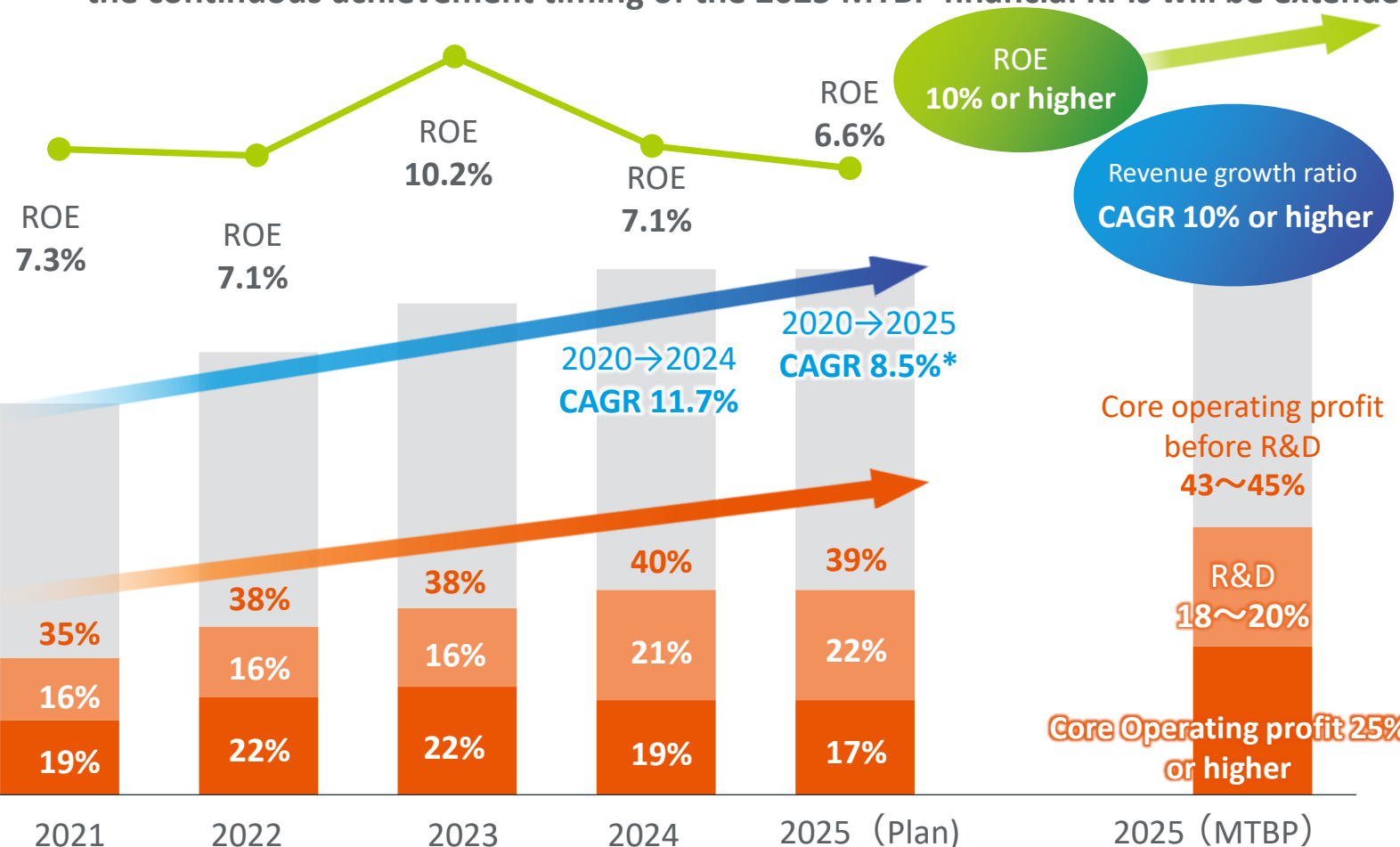
Profit (Jan-Dec) -2.9 billion yen



2021-2025 Medium Term Business Plan

- Revision of Financial KPI -

- Although 2023 achieved record profits and “10% of ROE”, 2024 and 2025 (plan) are expected to miss financial KPIs due to increased R&D investment.
- Due to the restructuring of our business model to adapt to environmental changes, the continuous achievement timing of the 2025 MTBP financial KPIs will be extended to 2026 or beyond.



2025 MTBP financial KPIs
Achievement timing will be 2026 or beyond

- +
- Steady growth in Crysvita sales
 - Collaboration with Amgen on KHK4083
 - Depreciation of Yen

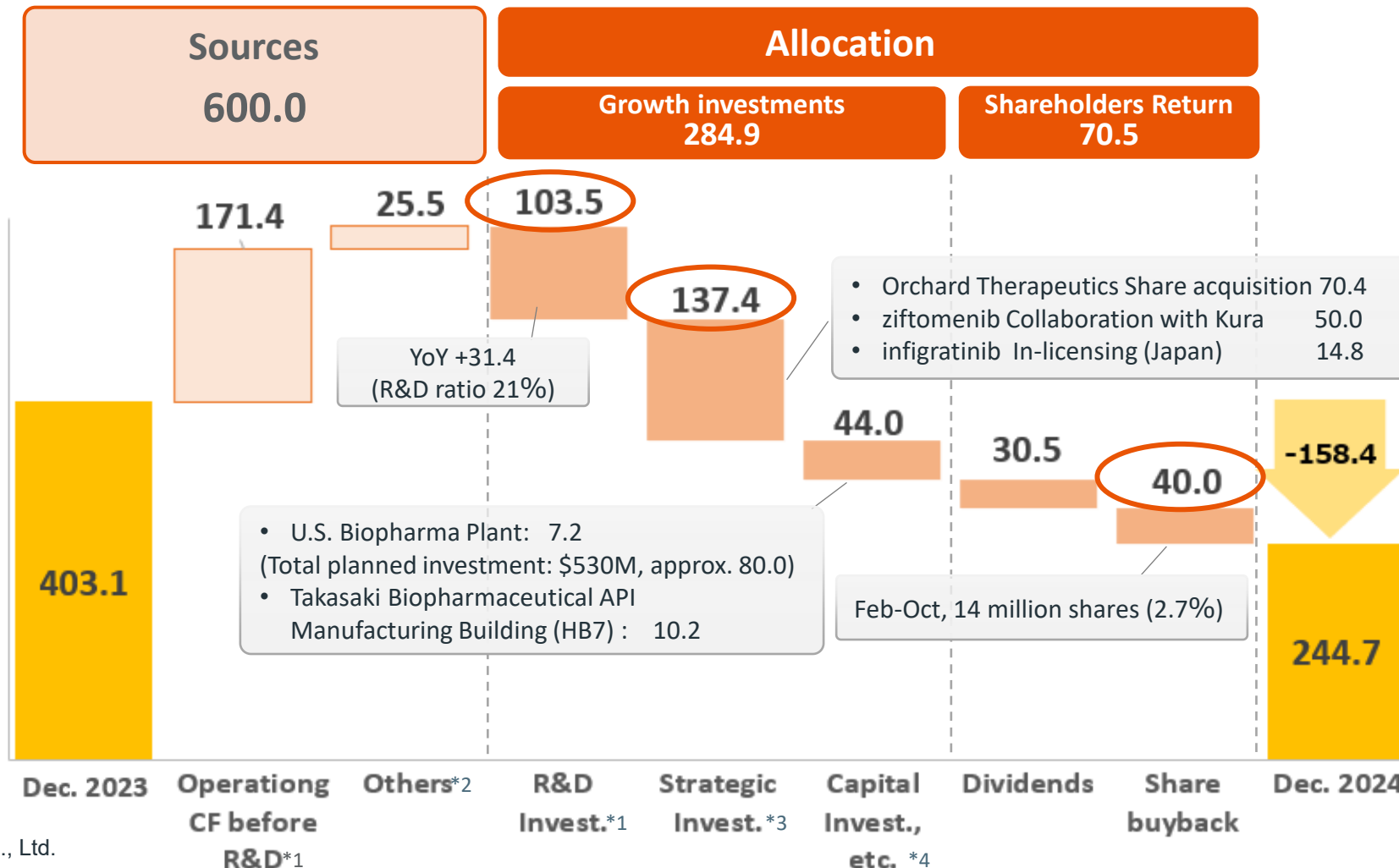
-
- Short term financial impact on Orchard acquisition
 - Increasing investment in KHK4083 development
 - Depreciation of Drug price environment (Japan, Europe, and China)
 - Unlaunched new products (discontinued pipelines, Nourianz in Europe)

Capital Allocation, Shareholders Return

FY2024 Capital Allocation

- Investment and Shareholder Returns for Sustainable Growth -

- ✓ Strategic investments, such as the acquisition of Orchard Therapeutics, ziftomenib, and significantly increased R&D spending, along with aggressive shareholder returns including share buyback, support sustainable growth.

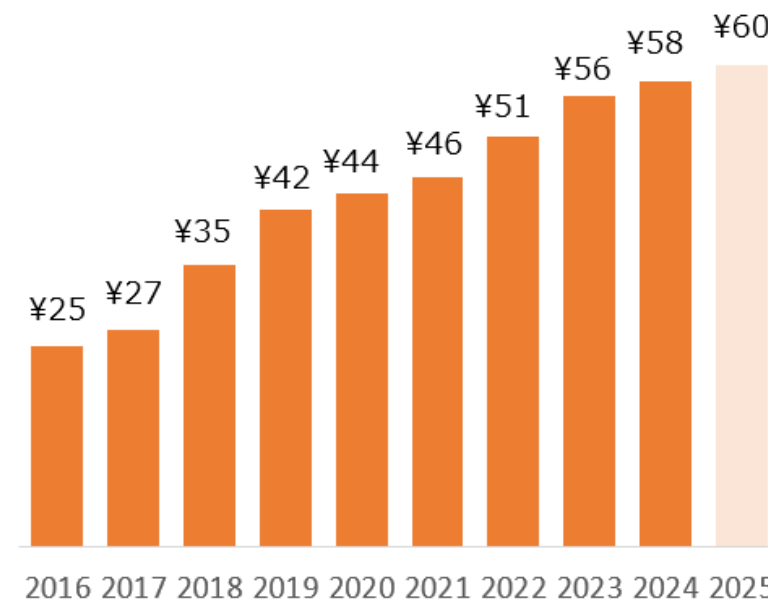


*1 P/L-based
 *2 Mainly recovering investments through asset sales.
 *3 Licensing-in and M&A investments to strengthen the portfolio, and Investment in science and technology to create new strengths.
 *4 Capital Investments (acceptance-based), Intangible Asset Investments (excluding *3), etc.

Shareholders Return

- ✓ FY24 dividend is **58 yen**, and FY25 to be **60 yen** (plan)
 - ✓ Plans **9-year consecutive rises** since FY17
 - ✓ FY21-25 weighted average payout ratio is **42.6%** (plan)
- (Mid-term guidance for payout ratio “Targeting sustained dividend hikes with 40%”)

Year	Dividend (yen)			Payout Ratio ^{*1}	Return on Equity
	Interim	Year-end			
2016	12.50	12.50	25.00	44.9%	5.3%
2017	12.50	14.50	27.00	34.4%	7.2%
2018	15.00	20.00	35.00	35.2%	8.6%
2019 ^{*2}	20.00	22.00	42.00	33.7%	10.1%
2020	22.00	22.00	44.00	50.3%	6.8%
2021	23.00	23.00	46.00	43.2%	7.3%
2022	24.00	27.00	51.00	38.9%	7.1%
2023	27.00	29.00	56.00	35.5%	10.2%
2024 ^{*3*4}	29.00	29.00	58.00	47.8%	7.1%
2025 Plan	30.00	29.00	60.00	50.3%	6.6%



*1 Payout ratio for FY2021/beyond are payout ratios against the Core EPS that is calculated based on the Core Earnings (= Profit - Other income/losses - Related income taxes)

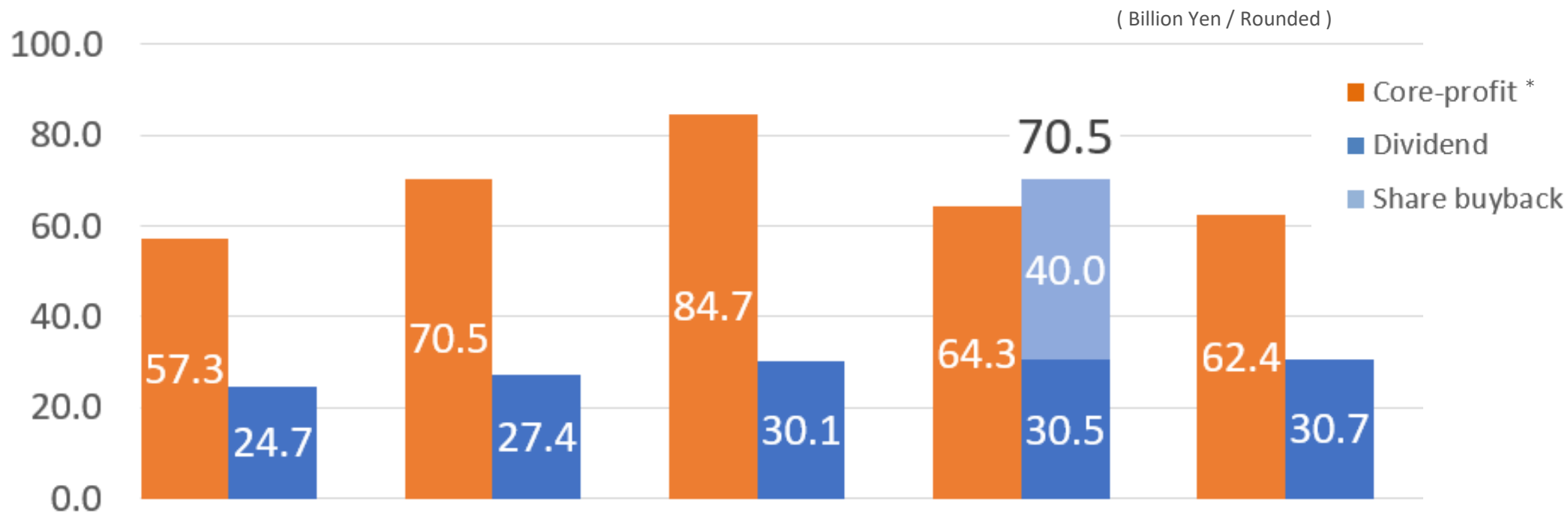
*2 Buyback of 10.7M own shares (¥22.6B) executed on February 6, 2019. Total return ratio for FY2019 is 67.3%.

*3 Buyback of 14.366M own shares (¥40.0B) executed from Feb to Oct 2024. Total return ratio for FY2024 is 109.6%.

*4 Year-end dividend of 29 yen/share will be submitted to the 102nd Ordinary General Meeting of Shareholders to be held on March 19, 2025.

Share buyback and cancellation of treasury shares

- ✓ To improve capital efficiency and shareholder returns, the company implemented its largest-ever share buyback and cancellation of 40.0 billion (14 million shares, 2.7%) from February to October 2024.
- ✓ Total return ratio for FY2024 is 109.6%



	2021	2022	2023	2024	2025(Plan)
Dividend (Yen/share)	46.0	51.0	56.0	58.0	60.0
Payout ratio	43.2%	38.9%	35.5%	47.8%	50.3%
Total return ratio	43.2%	38.9%	35.5%	109.6%	50.3%

Commercial Update

2024 Review & 2025 Key Actions

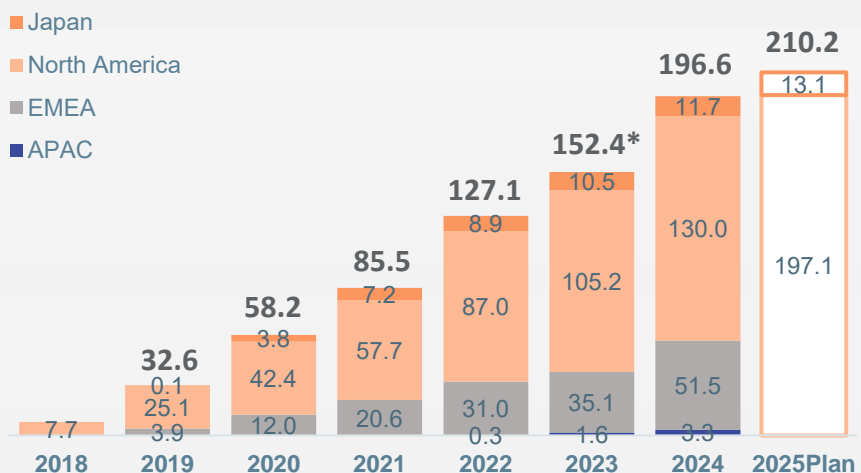
2024 Review

- NA: Sales revenue increased by 24% year-on-year YTD due to:
The number of new patients has remained at a high level throughout the year, mainly among adults.
Strengthened patient support programs and collaboration with specialty pharmacies.
- EMEA: Sales revenue increased by 47% year-on-year YTD due to:
Started the insurance reimbursement indicated for adult XLH in UK.
Penetrated among adult XLH patients in Germany, France, the UK, Italy, and Spain, etc.
And continue to growth in the pediatric market.
- Japan
Strengthened promotional activities by the dedicated personnel team.

2025 Key Actions

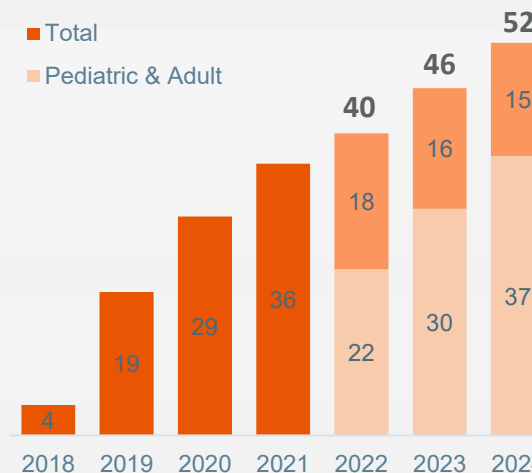
- Strengthen evidence-based marketing activities.
- North America:
Strengthening promotional activities. Further market penetration through disease awareness initiatives and patient support programs..
- EMEA:
Continue to focus on geographical & indication expansion. Increase market penetration in adult XLH.
- Japan:
Further strengthening of promotional activities by dedicated personnel, and enhancement of disease awareness activities for patients.

Sales Revenue
(Billion Yen)



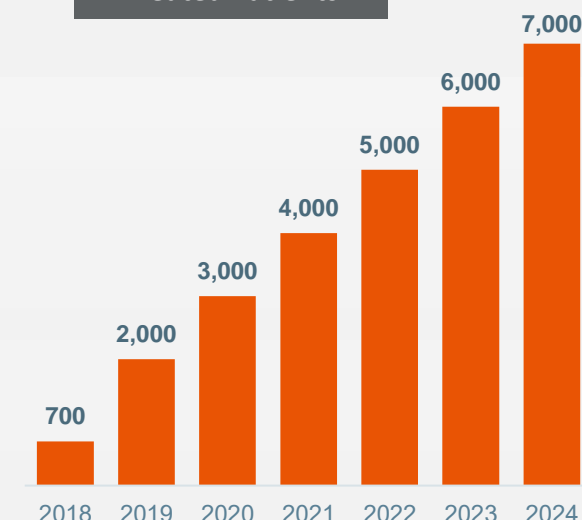
*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

Launched Countries / Regions (XLH)



*Excludes Latin America and Turkey, where Ultragenyx records sales.

Treated Patients



*The numbers of treated patients is an approximate number based on our calculations.

2024 Review & 2025 Key Actions

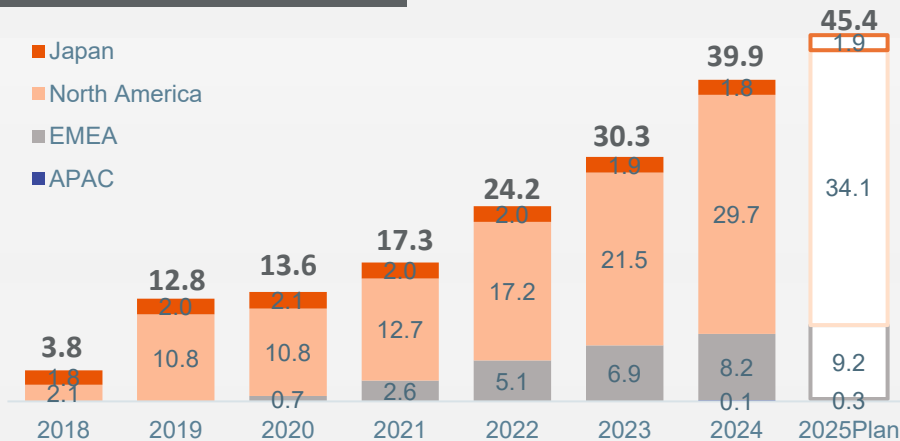
2024 Review

- NA : Sales revenue increased by 38% year-on-year YTD due to:
 - Continue to expand evidence-based promotional activities to focus not only on cases with predominantly blood involvement, but also on early-stage cases with predominantly skin compartment.
 - Sales force expansion and promotional activities focused on medical facilities with high potential for use based on data analysis.
- EMEA : Sales revenue increased by 19% year-on-year YTD due to:
 - Geographic expansion
 - Increase in the number of new patients in early cases with predominantly skin compartment.

2025 Key Actions

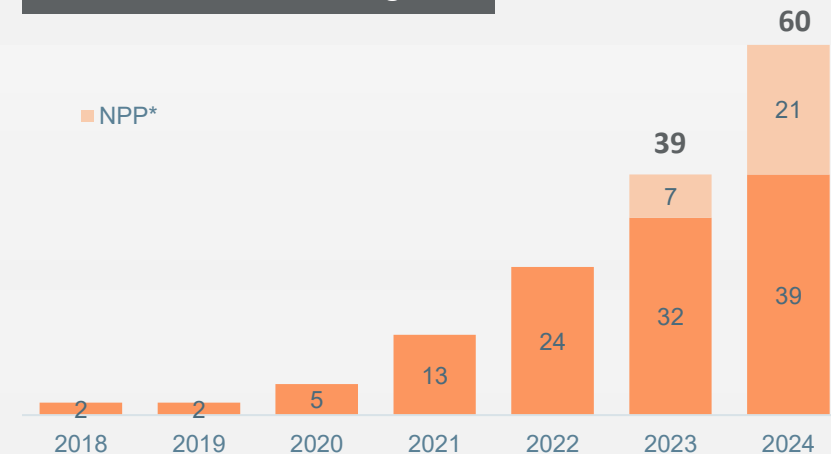
- Global :
 - Evidence-based promotion activities will continue to expand, addressing both cases with predominantly blood involvement and early-stage cases with predominantly skin compartment.
- NA & EMEA :
 - Increasing access to medical facilities through the strengthening of the sales organization.
 - Continuing evidence-based disease awareness activities.
- NA :
 - Further development in promotional activities focused on medical facilities with a high potential for use based on data analysis, leveraging AI based technology.

Sales Revenue (Billion Yen)



*Revenue from EAP (Early Access Program) is not included in sales until FY2022, and is included in sales from FY2023 onwards as it is insignificant in monetary terms.

Launched Countries / Regions



*Named Patient Program: The program that provides unapproved medications to patients with specific medical conditions who are not eligible for clinical trials or for whom other treatments have proven ineffective.

R&D Update

News Flow of Development Pipeline Products

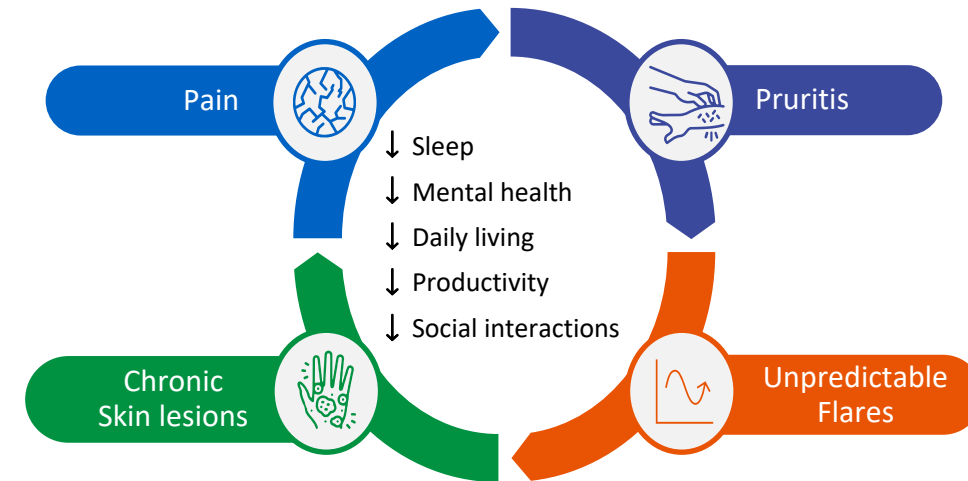
As of Feb. 6th, 2025

Products	Diseases under development	Events	Status/Schedule
rocatinlimab KHK4083/AMG 451	Moderate to severe atopic dermatitis	ROCKET HORIZON (P3) Detailed data	1H 2025
		ROCKET SHUTTLE (P3) Topline data ROCKET IGNITE (P3) Topline data	Q2 2025
	Prurigo Nodularis	P3	In progress
	Moderate to severe asthma	P2	In progress
ziftomenib	AML (1L combo/2L+ combo)	KOMET-007 (P1a, P1b) P1a data presentation	Dec. 2024
	AML (2L+ mono)	KOMET-001 (P2) Topline data	Feb. 2025
	AML (1L combo)	KOMET-017 (P3) initiation	2H 2025
OTL-203	MPS-IA (Hurler Syndrome)	Registrational study (Equivalent to P3 study)	In progress
KK8398 infigratinib	Achondroplasia	P3	Preparation underway
KHK4951 tivozanib eyedrop	DME	P2	In progress
	nAMD	P2	In progress
OTL-201	MPS-IIIA (Sanfilippo syndrome typeA)	PoC study (Equivalent to P1-2 study)	In progress
KK4277	SLE, CLE	P1	In progress
KK2260	Advanced or metastatic solid tumors	P1	In progress
KK2269	Advanced or metastatic solid tumors	P1	In progress
KK2845	AML	P1	In progress
KK8123	XLH	P1 initiation	Nov. 2024

Atopic Dermatitis (AD) is a chronic and heterogeneous inflammatory skin disease that imparts a significant burden on patients and caregivers



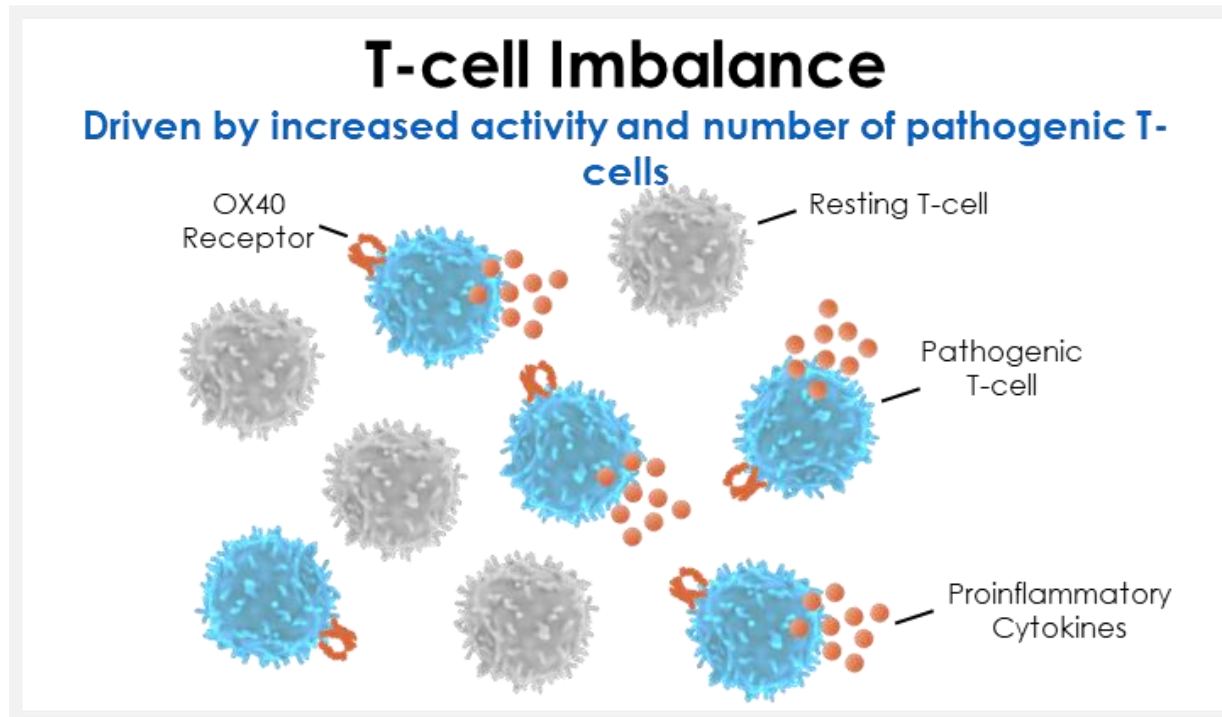
- AD causes excessively dry, itchy skin that can be painful
- Repeated scratching can cause the skin to thicken, harden or become vulnerable to infection
- Clinical manifestations of AD are heterogenous in intensity and distribution, and are driven by complex networks of immune pathways
- Chronic symptoms of moderate-to-severe AD can negatively impact sleep, mental health, daily living, productivity, and social interactions, leading to an overall decrease in quality of life



As a result of these factors, a significant burden is placed on patients and their families and there is an ongoing unmet medical need

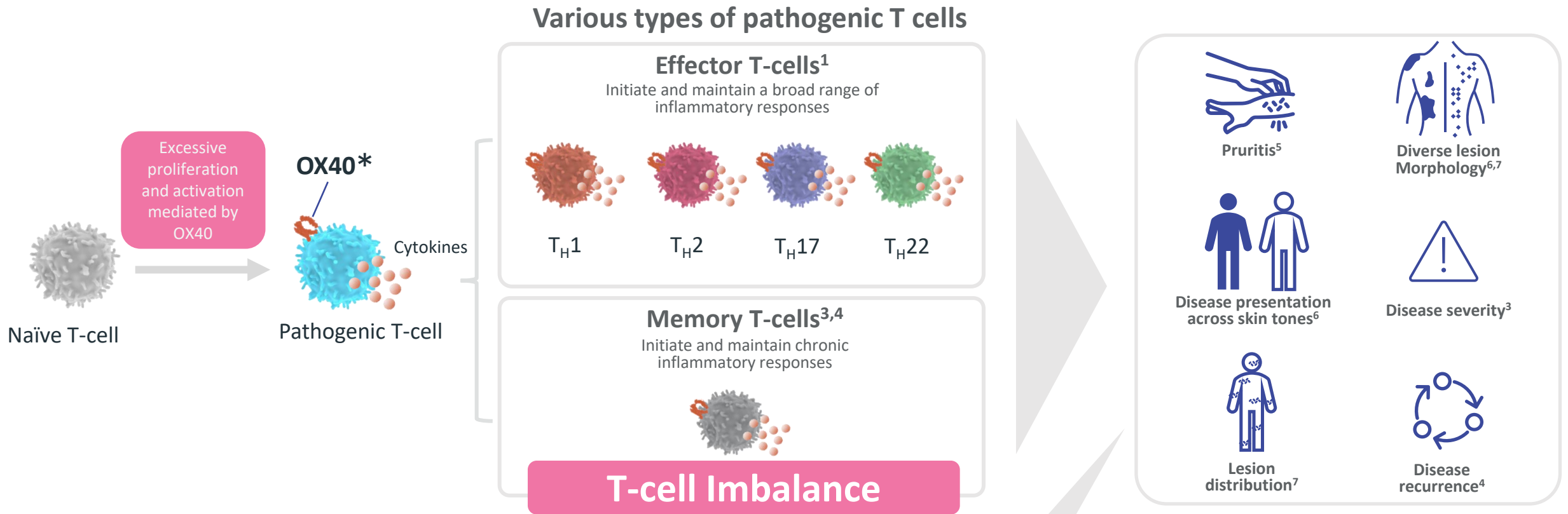
T-cell imbalance is considered as a root cause of inflammatory diseases

T-cell Imbalance – a root cause of inflammatory diseases



- Atopic dermatitis is thought to be caused in part by **T-cell imbalance** due to the increase and enhanced activation of pathogenic T cells
- **T-cell imbalance** is one of the root causes of various inflammatory diseases

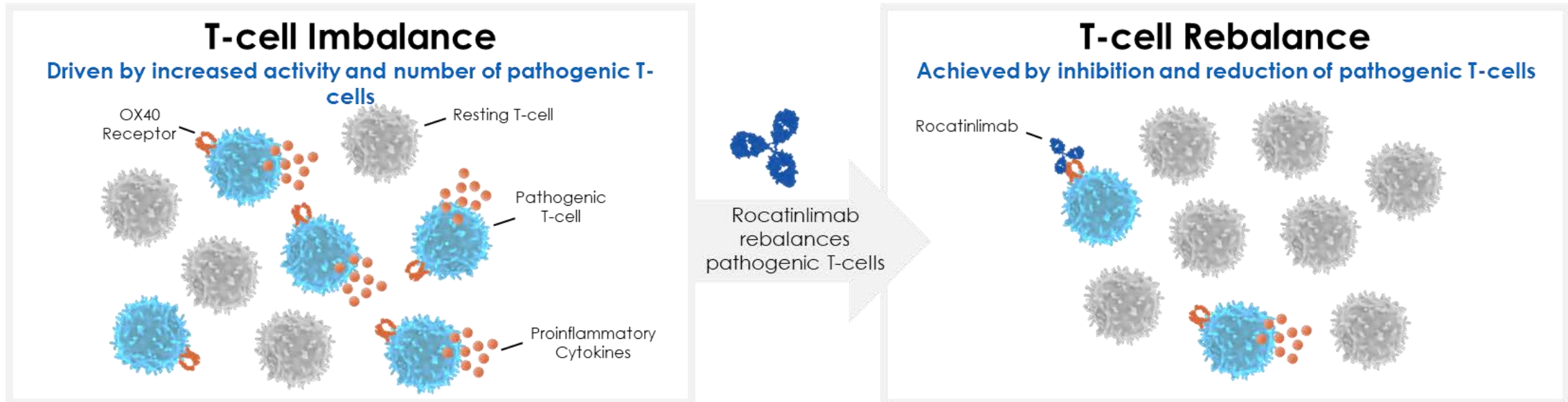
An imbalance in multiple pathogenic T-cell Types contributes to AD Chronicity and Heterogeneity^{1,2}



Cytokines released by pathogenic effector T-cells drive the heterogeneous clinical presentation of AD, while pathogenic memory T-cells drive disease persistence and chronicity^{1,3-5,8}

AD = atopic dermatitis. T_H = T helper.
 *OX40 is expressed transiently on T cells when these become activated, and is distinct from its ligand, OX40L. 1. Fania L, et al. *Int J Mol Sci.* 2022;23:2684. 2. Sadrolashrafi K, et al. *Cells.* 2024;13(7):587. 3. Czarnowicki T, et al. *Allergy.* 2017;72:366-372. 4. Carlier TDB, et al. *J Autoimmun.* 2021;120:102634. 5. Croft M, et al. *Am J Clin Dermatol.* 2024;25(3):447-461. 6. Bissonnette R, et al. *J Clin Med.* 2023;12:3805. 7. Yew YK, et al. *J Am Acad Dermatol.* 2019;80:390-401. 8. Chen L, et al. *Cell Mol Immunol.* 2020;17:64-75.

T-cell Rebalance – Aiming for broad and sustained therapeutic effects by addressing a root cause of inflammatory diseases

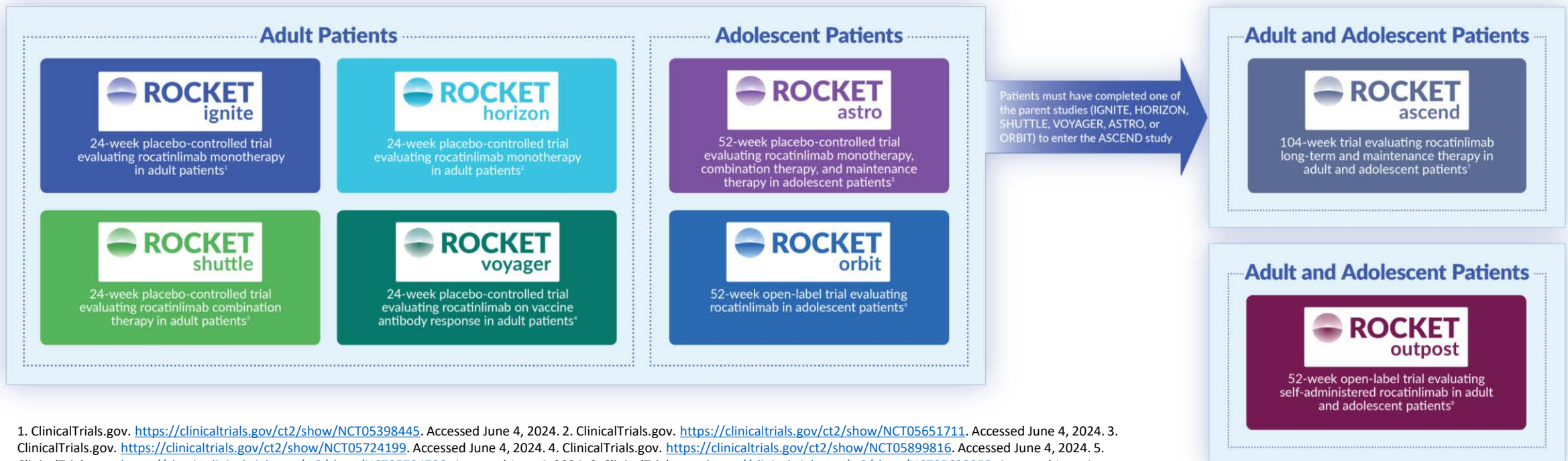


- Directly targeting pathogenic T-cells via OX40 with rocatinlimab is a novel approach, and has potential to address **T-cell imbalance**, a root cause of inflammatory disease
- Rocatinlimab, unlike cytokine inhibitors and other OX40 pathway blockers, is believed to inhibit the function and reduce pathogenic T-cells leading to **T-cell rebalance**
- Rocatinlimab is thought to act on memory T-cells that contribute to the chronicity of inflammation, **potentially leading to sustained symptom control and disease modification**

Rocatinlimab is currently under clinical investigation. Its efficacy and safety have not been evaluated by any health authority.

Rocatinlimab – Phase 3 the ROCKET Program

- Composed of eight global studies enrolling adult and adolescent moderate – severe AD patients
- To date, over 3,300 patients have been enrolled with seven studies having completed enrollment
- Studies were designed to examine long-term sustained efficacy and safety



1. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05398445>. Accessed June 4, 2024. 2. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05651711>. Accessed June 4, 2024. 3. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05724199>. Accessed June 4, 2024. 4. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05899816>. Accessed June 4, 2024. 5. ClinicalTrials.gov. <https://classic.clinicaltrials.gov/ct2/show/NCT05704738>. Accessed June 4, 2024. 6. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05633355>. Accessed June 4, 2024. 7. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT05882877>. Accessed June 4, 2024. 8. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT06224192>. Accessed June 4, 2024.

Rocatinlimab - Future Plans



24-week placebo-controlled trial evaluating rocatinlimab monotherapy in adult patients

Detailed data are planned to be presented in 1H 2025



24-week placebo-controlled trial evaluating rocatinlimab monotherapy in adult patients



24-week placebo-controlled trial evaluating rocatinlimab combination therapy in adult patients

Topline data are to be disclosed in Q2 2025



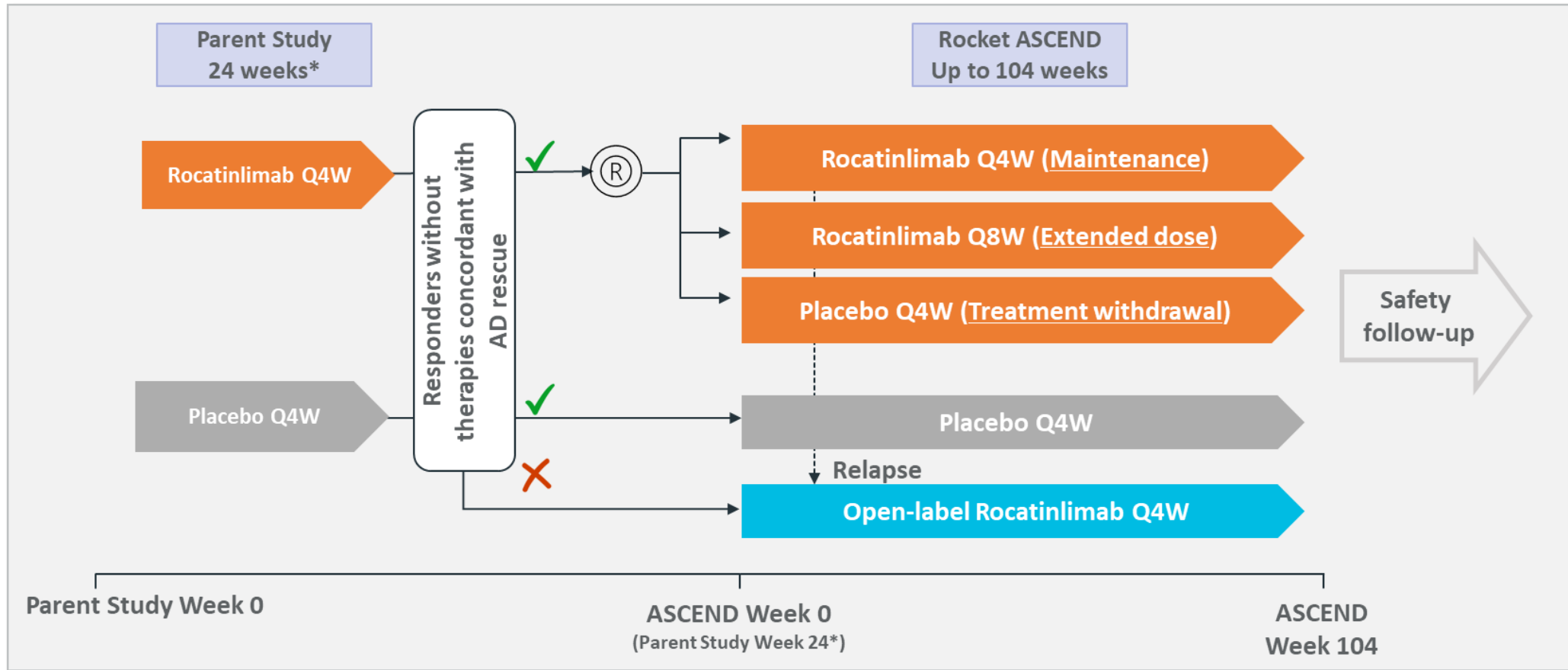
*Interim data



Data readout is anticipated in 2H 2025

Current plan for regulatory submission is 2025/2026

ROCKET ASCEND Study Design Includes Adult Patients in Monotherapy Trials*

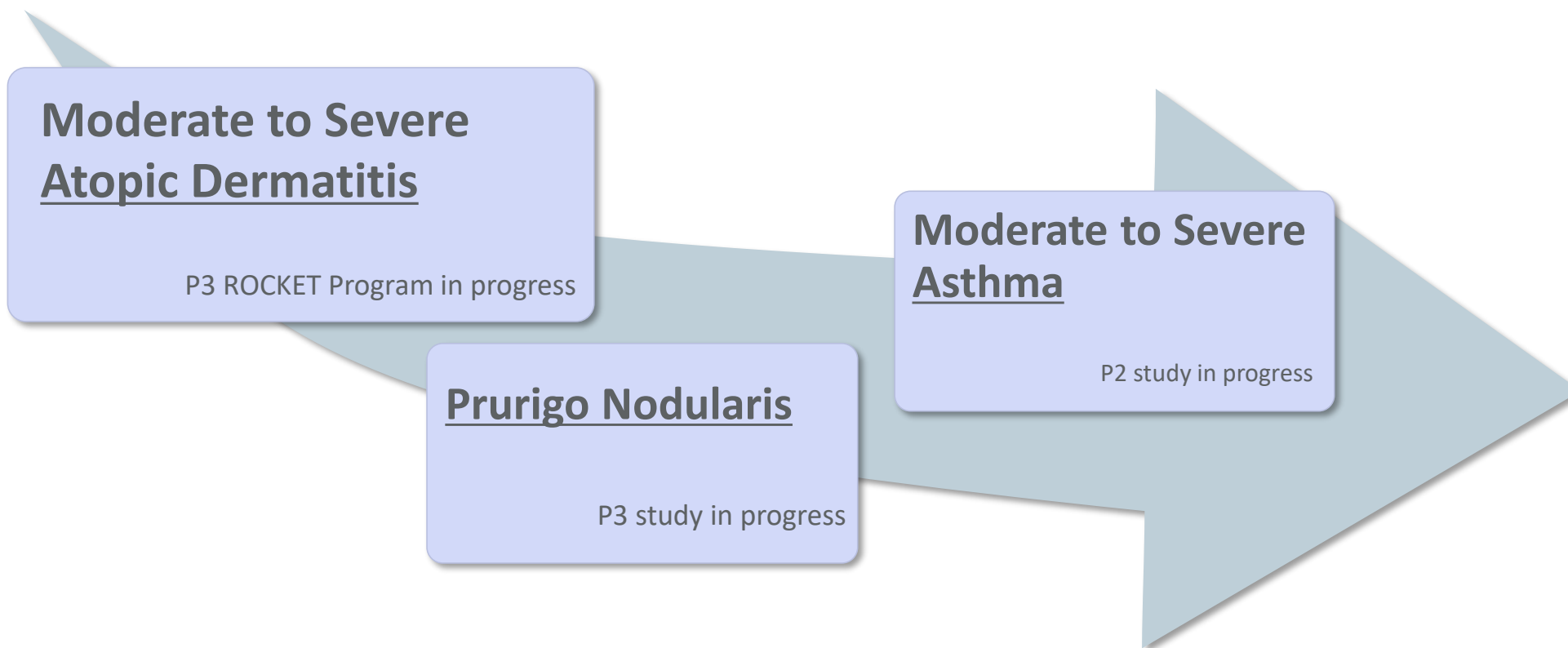


Designed to evaluate the safety and efficacy beyond 24 weeks, including off-treatment durability of efficacy

*The figure above illustrates, as an example, the trial content for patients transitioning from two trials, HORIZON and IGNITE, to the ASCEND trial. For more detail on full ASCEND design visit [ClinicalTrials.gov \(https://clinicaltrials.gov/study/NCT05882877\)](https://clinicaltrials.gov/study/NCT05882877)

Anti-OX40* antibody – Potential new treatment option for multiple inflammatory diseases

Future expansion into indications where "T-cell rebalancing" is expected to lead to reduced disease activity



We will continue our efforts to deliver Life-changing value to more patients in the future

Overview of ziftomenib

- Selective Oral Small Molecule Menin Inhibitor
- Target Disease: Menin-dependent AML (NPM1 gene mutations and KMT2A gene rearrangements)
 - Up to 50% of AML cases are estimated to be menin-dependent (including NPM1 gene mutations and KMT2A gene rearrangements)
 - NPM1 gene mutation is one of the most common AML mutations, acting as a driver mutation via the menin pathway. It is observed in 30%-35% of cases.
 - AML with NPM1 gene mutations shows poor prognosis in relapsed/refractory AML and is attracting attention as a target for new treatments
- The only investigational therapy to receive Breakthrough Therapy Designation from the FDA for treatment of R/R NPM1-mutated AML
- Mechanism of Action: Inducing leukocyte blast differentiation by inhibiting the binding of menin and KMT2A (MLL)
- On November 21, 2024, announced entering into a global strategic collaboration with U.S.-based Kura Oncology for the development and commercialization of this product

Plan to submit New Drug Application (NDA) to the FDA for ziftomenib for the treatment of relapsed/refractory NPM1-mutant AML in Q2 2025

ASH2024 Presentation Overview - KOMET-007 P1a (Dose escalation)

■ Newly Diagnosed (1L) combination with 7+3

● Efficacy

	NPM1-m	KMT2A-r
ORR	100%	83%
MRD negativity	76%	75%

- Safety No dose-limiting toxicities, QTc prolongation, or severe myelosuppression observed
Differentiation syndrome manageable at 2% (Grade 3)

■ R/R (2L+) combination with ven+aza

● Efficacy

	NPM1-m (Prior to ven)
ORR	68% (50%)
CRC	50% (36%)

- Safety No dose-limiting toxicities or QTc prolongation observed
Differentiation syndrome manageable at 8% (all Grade 2 or 3)

Demonstrated both good tolerability and promising clinical activity

Ziftomenib KOMET-001 Study Phase 2 Results

- Target Disease: R/R NPM1-Mutated AML
- Results: Primary endpoints (CR¹ and CRh²) were achieved, and safety and tolerability were consistent with previous reports.
- More detailed data presentation is scheduled at an upcoming medical conference in Q2 2025.

Future Plans

- 2L+ Monotherapy: Approval application to be submitted in Q2 2025
- 1L Combination: Phase 3 KOMET-017 is planned to start in 2H 2025
 - Consists of two trials: KOMET-017-IC and KOMET-017-NIC³
 - Randomized placebo-controlled trial (ziftomenib + standard of care vs. placebo + standard of care).

1. Complete response; 2. CR with partial hematological recovery ; 3. IC = intensive combination, NIC = non-intensive combination.

HSC-GT : Progress of OTL-203 development

Target Disease : MPS-IH - Disease snapshot

- Multisystemic neurometabolic condition affecting cognition, growth and skeletal function
- Diagnosed during first 2 years of life; life-expectancy up to 10 yrs.
- Current standard of care: Allogeneic HSCT w/ or w/o ERT as bridging/chronic therapy, both of which have significant limitations
- Incidence: ~1:100,000 live births; Hurler syndrome accounts for 60%¹
- NBS established in some geographies, including U.S.



Engl J Med 2021; 385:1929-1940 DOI: 10.1056/NEJMoa2106596

Progress of “HURCULES” Registrational Study (equivalent to P3)

- Study Overview: A multicenter, randomized, active-controlled clinical trial to evaluate the efficacy and safety of OTL-203 in patients with MPS-IH compared to standard treatment with allogeneic hematopoietic stem cell transplantation (HSCT)
- Subject enrollment has progressed faster than planned and is nearing completion
 - Evidence of the urgent medical need in MPS-IH
- Primary endpoint analysis measured 2-year mark post-treatment ; data, if positive, to be used to support regulatory submissions
- **The current anticipated application timeline is for 2028, with potential U.S. approval planned in 2029 assuming priority review**

News Flow in 2024

Year-to-date Key News Flow

Category	Date	Headline
SP	Jan 5	Out-licensed the exclusive and worldwide rights to Boehringer Ingelheim of developing first-in-class treatment for fibro-inflammatory diseases.
SI	Jan 24	Completion of share acquisition of Orchard Therapeutics plc, UK biopharmaceutical company
R&D	Feb 6	First Patient Randomized in Registrational Trial of OTL-203 for MPS-I Hurler Syndrome
R&D	Feb 6	First Patient Enrolled in the Phase2 Clinical Trial Evaluating Tivozanib Eye Drop for Diabetic Macular Edema
SI	Feb 7	Conclusion of Agreement with BridgeBio Pharma for an Exclusive License on Infigratinib in Skeletal Dysplasias in Japan
Finance	Feb 7	Acquisition of Own Shares and Cancellation of Treasury Shares
MKT	Feb 19	Launch of PHOZEVEL [®] Tablets for Improvement of Hyperphosphatemia in Chronic Kidney Disease Patients on Dialysis (Japan)
R&D	Mar 11	Presented the post-hoc analysis data from the Phase 2b study of rocatinlimab (AMG 451/KHK4083) at American Academy of Dermatology (AAD) 2024 Annual Meeting
R&D	Mar 19	Receives FDA Approval of OTL-200 (Lenmeldy) for the treatment of children with early-onset—metachromatic leukodystrophy (MLD)

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP; strategic partnering MKT; marketing MGMT; management

Year-to-date Key News Flow

Category	Date	Headline
ESG	May 14	Announced the Publication of a Patient-focused Global Consensus Statement for Improving Diagnosis and Care in Cutaneous T-Cell Lymphoma (Kyowa Kirin, Inc.)
LCM	May 17	Approval for Partial Change of Approved Indication of G-Lasta [®] for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation in Japan
SCM	Jun 10	Announced Establishing New Biologics Manufacturing Plant in North Carolina, in the United States
LCM	Jun 28	Application for Additional Formulation of “LUMICEF [®] Subcutaneous Injection 210 mg Pen” in Japan
MKT	Jul 1	Announced Global Progress toward Advancing Newborn Screening for MLD (Orchard Therapeutics)
ESG	Jul 29	Joined the Pharmaceutical Supply Chain Initiative (PSCI)
SCM	Aug 1	Restructuring of APAC Region Business and Change in Kyowa Kirin China Pharmaceutical Co., LTD
R&D	Aug 1	Transition to a Research Organization to Realize Our Vision toward 2030, and Introduction of a Voluntary Retirement Program

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP: strategic partnering MKT; marketing MGMT; management

Year-to-date Key News Flow

Category	Date	Headline
MKT	Sep 19	Presented new research on the real-world experiences of people living with XLH and the impact of Crysvita treatment at American Society for Bone and Mineral Research (ASBMR) 2024 annual meeting
R&D	Sep 25	Announced Top-line Data from rocatinlimab Phase 3 ROCKET HORIZON Trial for Adults with Moderate to Severe Atopic Dermatitis
R&D	Oct 24	A Faculty Member of the School of Life Science and Technology, Institute of Science Tokyo has been Appointed as a Researcher through the Cross-Appointment System
MGMT	Oct 31	Notice Regarding Changes of Representative Directors
LCM	Nov 1	Transfer of sales from Kyowa Kirin to LEO Pharma following the termination of the distribution and co-promotion agreement for the psoriasis treatment products Dovobet Ointment, Gel, and Foam (Japan)
SI	Nov 21	Entered into a global strategic collaboration with Kura Oncology to develop and commercialize ziftomenib which is the oral menin inhibitor targeting acute leukemia
R&D	Dec 9	Reported positive combination data from the Phase 1 dose escalation study KOMET-007 for ziftomenib at the American Society of Hematology (ASH) Annual Meeting with Kura Oncology
MGMT	Dec 24	Announcement of the establishment of the Chief Digital Transformation Officer (CDXO) and related executive personnel changes
Updates after the previous earnings announcement		

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP; strategic partnering MKT; marketing MGMT; management

Year-to-date Key News Flow

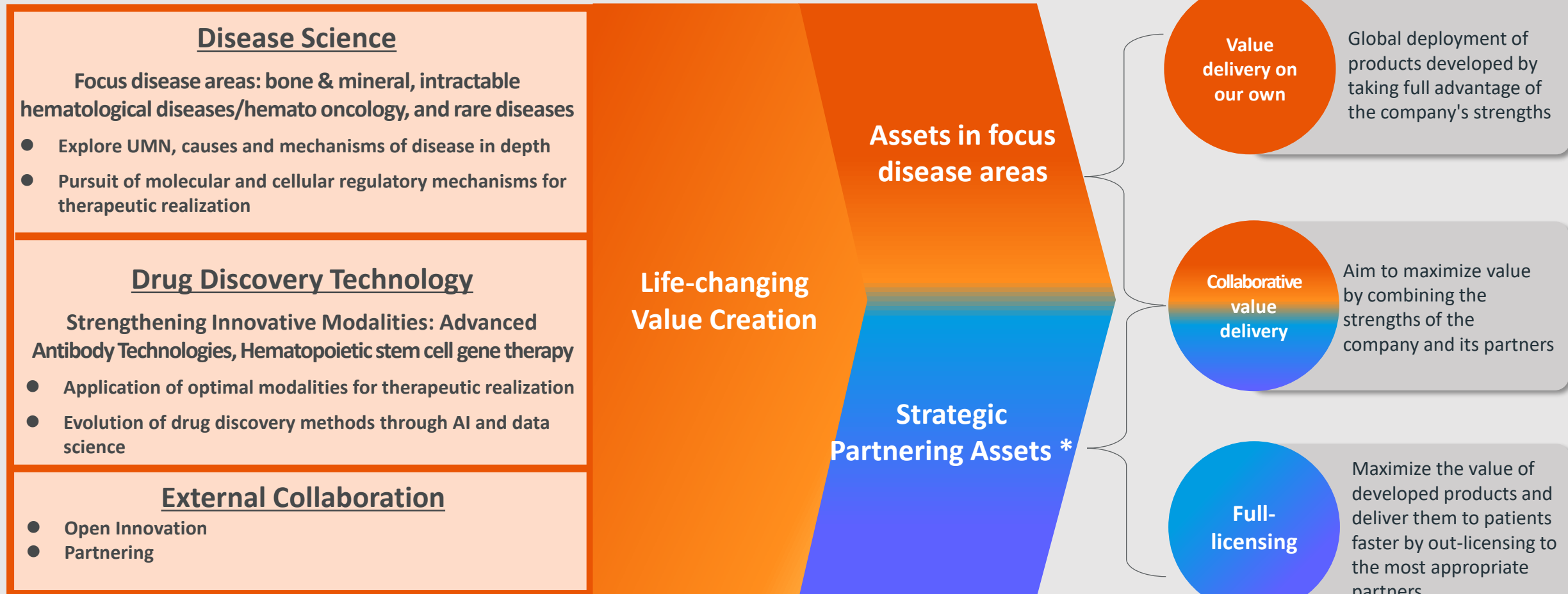
Category	Date	Headline
R&D	Jan 20	Received the 7th Prime Minister’s Award for the Japan Medical Research and Development Grand Prize, recognizing the accomplishment of developing mogalizumab featuring our proprietary Potelligent technology and achieving success in the development of the first antibody drug for cancer originating in Japan.(Japan)
R&D	Feb 6	Announced positive topline data from the KOMET-001 trial, which evaluated ziftomenib as a monotherapy for R/R NPM1-m AML
Updates after the previous earnings announcement		

ESG: environmental, social, and governance; LCM: lifecycle management; R&D: research and development; SCM: supply chain management; SI: strategic investment; SP; strategic partnering MKT; marketing MGMT; management

Appendix

Story for Vision 2030

Strategies for creating and delivering life-changing value



*Assets outside of the disease areas of focus are designated as strategic partnering assets, and value maximization is achieved through collaboration with partners.

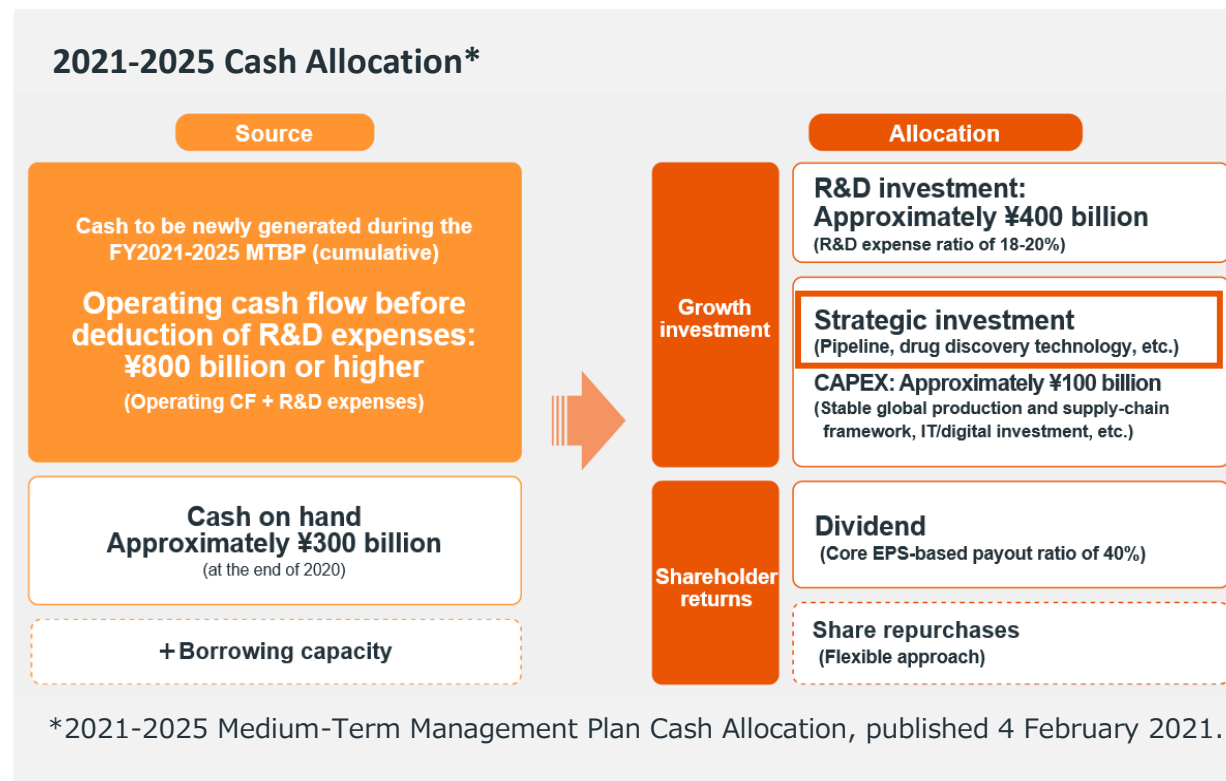
Strategic Investment ~ For successful creation and delivery of life-changing value

Licensing-in and M&A investments to strengthen the portfolio

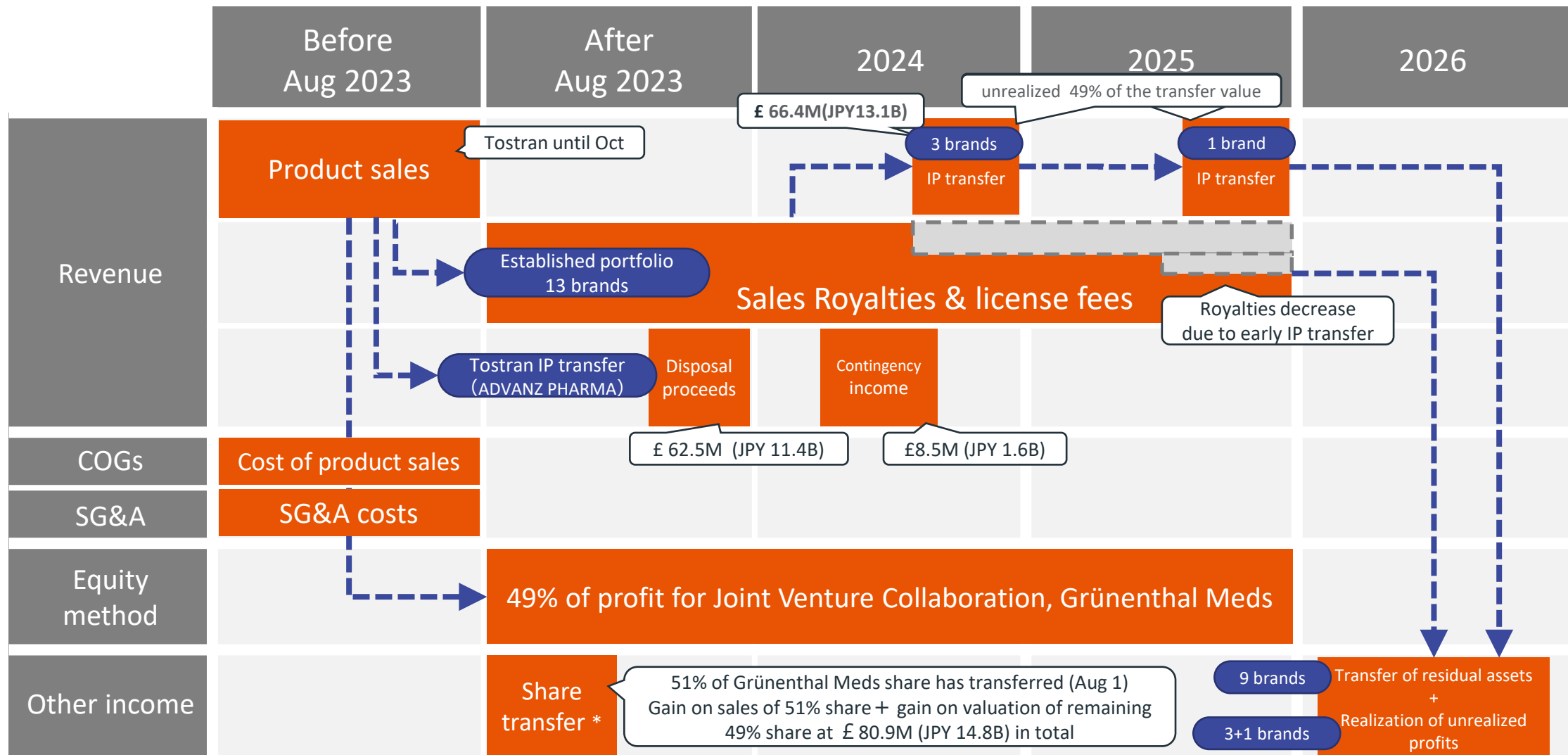
- Priority will be given to the focus disease areas
 - bone & mineral
 - intractable hematological diseases/hemato oncology
 - rare diseases

Investment in science and technology to create new strengths

- Investments aimed at acquiring new drug discovery technologies and early pipelines and accelerating cooperation and collaborations
- VC investment and CVC activities for exploring and accessing information.



P/L Impact on EMEA established medicines portfolio



* Grünenthal owns a 51 percent majority share in the Joint Venture Collaboration, while Kyowa Kirin International plc owns a 49 percent share. Grünenthal will have the option to fully acquire the remaining 49 percent share, including intellectual property (IP) of 13 → 9 brands, via exercising an option in Q1, 2026

P/L Impact on Restructuring of APAC business

		Country / region	Until September 2024	October 2024 onwards
Revenue	Divest (Established medicines portfolio)	CN	Sales to market <small>In addition to sales to market, KR/TW Inventory transfer to partner occurred (JPY 5.4B) at the end of September,</small>	Sales to Partner
	Partnering (Established medicines portfolio & Global products)	CN/HK/MO/ MY/SG/TH /KR/TW		Sales to Partner
	Continuation of in-house (Global products)	KR/TW/AU		Sales to market
COGs		ALL	COGs	COGs
SG&A	Divest / Partnering	CN/HK/MO/ MY/SG/TH /KR/TW	SG&A	
	Continuation of in-house (Global products)	KR/TW/AU		SG&A
Other income / expenses			Gain on sales of shares Business restructuring expenses	Business restructuring expenses

Accounting treatment of share acquisition of Orchard Therapeutics (Finalized)

- ✓ Completed the share acquisition on January 24, 2024, and started consolidation from the February 2024
- ✓ Recognized intangible assets of \$208M (JPY 30.8B) and goodwill of \$230M (JPY 34.1B)
- ✓ Intangible assets will be amortized over 20 years (19 years for Libmeldy/Lenmeldy)

(Unit: Million USD)

<p>【Breakdown of Intangible \$208M (JPY 30.8B)】</p> <ul style="list-style-type: none"> • Libmeldy/Lenmeldy \$118M (JPY 17.5B) • OTL-203 \$90M (JPY 13.3B) <p>【Annual amortization amount】</p> <ul style="list-style-type: none"> • Libmeldy/Lenmeldy \$6M /year ⇒ Amortization started from Feb 2024 • OTL-203 \$4M /year ⇒ To be amortized after market launch 	←	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;">Other assets 122</td> <td style="text-align: center; padding: 5px;">Other liabilities 91</td> </tr> <tr> <td style="text-align: center; padding: 5px;">Intangible assets 208</td> <td rowspan="3" style="text-align: center; padding: 5px;">Acquisition costs 478</td> </tr> <tr> <td style="text-align: center; padding: 5px;">Goodwill 230</td> </tr> <tr> <td style="text-align: center; padding: 5px;">Other Expenses 9</td> </tr> </table>	Other assets 122	Other liabilities 91	Intangible assets 208	Acquisition costs 478	Goodwill 230	Other Expenses 9
	Other assets 122	Other liabilities 91						
	Intangible assets 208	Acquisition costs 478						
	Goodwill 230							
Other Expenses 9								

✓ The acquisition costs above (\$478 million) include amounts for options, Restricted Stock Units and other instruments which are paid by Orchard. The acquisition costs under business combination accounting is \$386 million (approximately 57.1 billion yen)

Main Development Pipeline Products (P2-P3)

As of Feb. 6th, 2025

	Diseases under development ^{*1}		Planned Approval Year ^{*2}	Development status	Total addressable market ^{*3}	No. of Patients ^{*4}
Rocatinlimab KHK4083/AMG 451	Moderate to severe Atopic Dermatitis		2026/2027	P3 (Global)	★★★★★	16M
	Prurigo nodularis		TBD	P3 (Global)	★★★★	1M
	Moderate to severe Asthma		TBD	P2 (Global)	★★★★★	13.5M
Infigratinib	Achondroplasia		TBD	P3 (Japan)	★	6K
Ziftomenib	AML (NPM1-m or KMT2A-r)	R/R	2025 (Mono)	P2 (US, EU)	★★★★	20K
		1L	TBD	P1 (US)		
KHK4951 tivozanib eyedrop	nAMD		TBD	P2 (JP, US)	★★★★	2,600K
	DME		TBD	P2 (JP, US)	★★★★	3,400K
OTL-203	MPS-IA (Hurler Syndrome)		2029/2030	Registrational study ^{*5} (US, EU)	★	(1 in 100K live births) ^{*6}
OTL-201	MPS-IIIA (Sanfilippo syndrome typeA)		TBD	Proof-of-concept study ^{*7}	★	(~1 in 100K live births)








^{*1} Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities. ^{*2} Expected year of first approval. ^{*3} Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in ^{*1}, not projected sales or the Company's targets. **Colored areas represent estimates for global, and the rest are for Japan.** ★: less than ¥50Bn. ★★: ¥50Bn-¥100Bn. ★★★: Over ¥100Bn-¥500Bn. ★★★★: Over ¥500Bn-¥1Tn. ★★★★★: Over ¥1Tn. ^{*4} Total number of estimated patients by Kyowa Kirin. **Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan.** ^{*5} Equivalent to P3 study. ^{*6} "1 in 100k live birth" is estimated incidence for all of MPS-I, of which approximately 60 percent of patients have the Hurler subtype. ^{*7} Equivalent to P1/2 study.

Main Development Pipeline Products (P1)

	Diseases under development ^{*1}	Development status	Modality, technology
KK4277	SLE, CLE	P1 (JP, Asia)	Antibody, POTELLIGENT [®]
KK2260	Advanced or metastatic solid tumors	P1 (JP: in progress, US: in preparation)	Antibody, REGULGENT [™]
KK2269	Advanced or metastatic solid tumors	P1 (JP, US)	Antibody, REGULGENT [™]
KK2845	AML	P1 (JP)	Antibody-Drug Conjugate
KK8123	XLH	P1 (US, EU)	Antibody

^{*1} Expected indications as of the date of this document; indications may ultimately differ to expectations due status of approvals from regulatory authorities

Main Development Pipeline Products: Future plans

Product	Target Disease	Development Status	2025	2026	2027	+
rocatinlimab (KHK4083/AMG 451)	Moderate to severe Atopic Dermatitis 	IGNITE	P3	Q2 Topline data		
		HORIZON		Detailed data presentation in 1H		
		SHUTTLE		Q2 Topline data		
		ASTRO		 2H Topline data		
		ORBIT				
		VOYAGER		Completed		
		ASCEND		 2H Interim Data		
		OUTPOST				
	Prurigo Nodularis	P3				
	Moderate to severe asthma	P2				

Main Development Pipeline Products: Future plans

Products	Target	Development Status		2025	2026	2027	+
ziftomenib	AML	KOMET-001 2L+ Mono	P2 ¹ (NPM1-r)	Topline Data reported			
	ALL		P1a ² (KMT2A-r)	Ongoing			
			P1a ² (non NPM1-m / KMT2A-r AML)	Ongoing			
	AML	KOMET-007 1L, 2L+ Combinations with cytarabine + daunorubicin (7+3), and venetoclax + azacitidine	P1a/P1b ³				
		KOMET-008 2L+ Combination with gilteritinib, FLAG-IDA, LDAC	P1a ²				
		KOMET-017 1L Combinations with cytarabine + daunorubicin (7+3), and venetoclax + azacitidine	P3				

1. Patients Remain On Study in Follow-Up; 2. Dose-Escalation Now Dosing Patients; 3. Dose-Validation Now Enrolling

Main Development Pipeline Products: Future plans

Product	Target Disease	Phase	2025	2026	2027	+
KHK4951 tivozanib	nAMD	P2				
	DME	P2				
KK4277	SLE, CLE	P1				
KK2260	Advanced or metastatic solid tumors	P1				
KK2269	Advanced or metastatic solid tumors	P1				
KK2845	R/R AML	P1	In progress			
KK8123	XLH	P1				

FOREX Information

Average FOREX Rates (yen)

	FY2023	FY2024	Changes	FY2025 Plans
USD	140	151	+11	145
GBP	174	193	+19	190
EUR	151	164	+13	160

FY24 FOREX Impacts (vs FY23, billion yen)

	Revenue	Core OP
USD	+14.8	+4.9
GBP	+2.5	-0.0
EUR	+4.1	+2.2

FY25 FOREX Sensitivities (vs FY25 Plan, billion yen)

	Changes	Revenue	Core OP
USD	+1 yen	+1.6	+0.5
GBP	+1 yen	+0.1	-0.0
EUR	+1 yen	+0.3	+0.2

Ziftomenib - Collaboration with Kura -

	US	ex- US
Development	<ul style="list-style-type: none"> • Kura leads development • Share global development cost • Kura funds development costs (~2028) 	<ul style="list-style-type: none"> • Kyowa Kirin leads development
Commercialization	<ul style="list-style-type: none"> • Kura books sales • 50/50 profit share 	<ul style="list-style-type: none"> • Kyowa Kirin commercializes and books sales
Sales Royalties		<ul style="list-style-type: none"> • Double-digit royalty to Kura
Commercial supply	<ul style="list-style-type: none"> • Kura supplies 	<ul style="list-style-type: none"> • Kura supplies

Kyowa Kirin makes a \$330 million up-front payment and future contingent milestone payments potentially worth up to \$1,161 million in total, including \$420 million in near-term milestone payments and \$228M opt-in right for solid tumors, as well as royalty payments on future global sales to Kura.

KHK4083/AMG 451 - Collaboration with Amgen -

	US	Europe & Asia (ex. JP)	JP
Development	<ul style="list-style-type: none"> • Amgen leads development • Share development cost 	<ul style="list-style-type: none"> • Amgen leads development • Share development cost 	<ul style="list-style-type: none"> • Kyowa Kirin leads development
Commercialization	<ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin co-promotes and shares promotion cost 	<ul style="list-style-type: none"> • Amgen commercializes and books sales • Kyowa Kirin has opt-in rights for co-promotion 	<ul style="list-style-type: none"> • Kyowa Kirin commercializes and books sales
Sales Royalties	<ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin 	<ul style="list-style-type: none"> • Double-digit royalty to Kyowa Kirin 	
Commercial supply	<ul style="list-style-type: none"> • Amgen supplies 	<ul style="list-style-type: none"> • Amgen supplies 	<ul style="list-style-type: none"> • Kyowa Kirin supplies

Amgen makes a \$400 million up-front payment (done) and future contingent milestone payments potentially worth up to an additional \$850 million, as well as royalty payments on future global sales, to Kyowa Kirin.

Crysvita - Collaboration with Ultragenyx -

Economic Terms

US & Canada

- Kyowa Kirin books sales
- 50/50 profit share for 5 years from the U.S. launch
 - Supply price: 35% of net sales through 2022, 30% thereafter (No impact on the sales royalties stated below)
- After 5 years (April 27, 2023-), Kyowa Kirin pays tiered sales royalties in mid-high 20% range to Ultragenyx
 - *Ultragenyx has sold 30% of its royalty interest, subject to a 1.45x cap, to OMERS Capital Markets

Europe

- Kyowa Kirin books sales
- Kyowa Kirin pays sales royalties in up to 10% range to Ultragenyx
 - *Ultragenyx has sold its royalty interest, subject to a 1.9x or 2.5x cap depending on when the cap is achieved, to Royalty Pharma

Latin America

- Ultragenyx books sales
- Kyowa Kirin receives low single-digit sales royalties from Ultragenyx
- Supply price: 35% of net sales through 2022, 30% thereafter

Turkey

- Ultragenyx books sales
- Kyowa Kirin receives sales royalties in up to 20% range from Ultragenyx

Asia & Others

- Kyowa Kirin books sales
 - * Kyowa Kirin supplies commercial products in all territories.

Estimated Patient Numbers

Disease	Country/ Region	Incidence	Prevalence*	Reference
PTCL	JP		2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
CTCL	JP		2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
	US	1,500 / y		SEER Data (2001-2007)
XLH	JP	1:20,000	Adult: 5,000 Ped: 1,000	Estimate based on reported prevalence of 1 in 20,000 people; Nationwide survey of fibroblast growth factor 23 (FGF23)-related hypophosphatemic diseases in Japan: prevalence, biochemical data and treatment. (Endo I et al., Endocr J., 2015)
	EU	1:20,000	Adult: 12,000 Ped: 3,000	Estimate based on reported prevalence of 1 in 20,000 people
	US	1:20,000	Adult: 12,000 Ped: 3,000	Estimate based on reported prevalence of 1 in 20,000 people; New perspectives on the biology and treatment of X-linked hypophosphatemic rickets. (Carpenter TO, Pediatr Clin North Am., 1997)
TIO	JP		30	2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
	US		500-1,000	Survey by Ultragenyx Pharmaceutical
AD	JP, NA, EU		30,000,000	Study by Decision Resources
nAMD	JP, US		2,300,000	Study by Decision Resources
MLD	Global	1:40,000-160,000		https://medlineplus.gov/genetics/condition/metachromatic-leukodystrophy/#frequency
MPS-IH	Global	1:100,000		Puckett et al. 2021 Orphanet J Rare Dis 16:241: US NBS data (MPS-I incidence derived from NBS data in Table 3)
MPS-IIIA	Global	1:100,000		Trinity Partners research report 2013 based on literature and KOL feedback

*Prevalence represents the estimated patient number per the entire population of each country or region.

List of Acronyms

AD	Atopic Dermatitis
AG	Authorized Generic
APAC	Asia-Pacific
AML	Acute myeloid leukemia
BS	Biosimilar
DME	Diabetic Macular Edema
EMEA	Europe, the Middle East and Africa
JP	Japan
LCM	Lifecycle Management
MDS	Myelodysplastic syndromes
MLD	Metachromatic Leukodystrophy
MPS-IH	Mucopolysaccharidosis type I, Hurler syndrome
MPS-IIIA	Mucopolysaccharidosis type IIIA, Sanfilippo syndrome type A
NA	North America
nAMD	neovascular Age-related Macular Degeneration
PD	Parkinson's Disease
PE	Preeclampsia
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia



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