Partial Revisions of Long-Term Business Plan 2031

April 9, 2025

KAKEN PHARMACEUTICAL CO., LTD.

Cautionary notes regarding forward-looking statement

- The performance forecasts described in this material are rational based on the information currently available and have been determined by the Company as reasonable.

- Considerable financial investment and a long development time are required before a new drug is launched. The Company carefully develop new drugs by confirming their efficacy and safety. There is a possibility that their development may be discontinued before completion, in such case where anticipated efficacy has not been proven or safety issues have been identified.

- The “Pipelines” are based on the current development plans. The status may change depending on their progress.

- The information about pharmaceutical products (including those in pipelines) included in this material is not intended as an advertisement or medical advice.

Agenda

1 Partial Revision of Long-Term Business Plan 2031

2 Research and Development
Introduction of Products Out-Licensed in FY2024 and FYARRO®

1 Partial Revision of Long-Term Business Plan 2031

Outlines of Long-term Business Plan 2031

■ 3 years has passed since the implementation in May 2022

VISION

1. A company that contributes to longer healthy life expectancy by developing and supplying innovative new drugs in a speedy manner.
2. A research-based pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics.

Strategies for achieving VISION

"3Xs"
-Three Transformations-

- 1st X **R&D** Transformation
- 2nd X **Overseas Expansion** Transformation
- 3rd X **Management Base** Transformation

Target KPIs

Target KPIs

Net Sales	¥100.0 billion
Operating Profit	¥28.5 billion
ROE	10% or higher
Overseas Sales Ratio	30% or higher

Investment and Shareholder Return Policy

Strategic Investment	◆¥200.0 billion or more over the 10 years of the plan
Shareholder Return	◆Dividend payout ratio: 30% or higher ◆Shareholder return ratio: 50% or higher

Progress on Long-term Business Plan 2031

1st X R&D Transformation | 2nd X Overseas Expansion Transformation | 3rd X Management Base Transformation

■ In-licensing, marketing alliances and pipelines are increasing steadily.

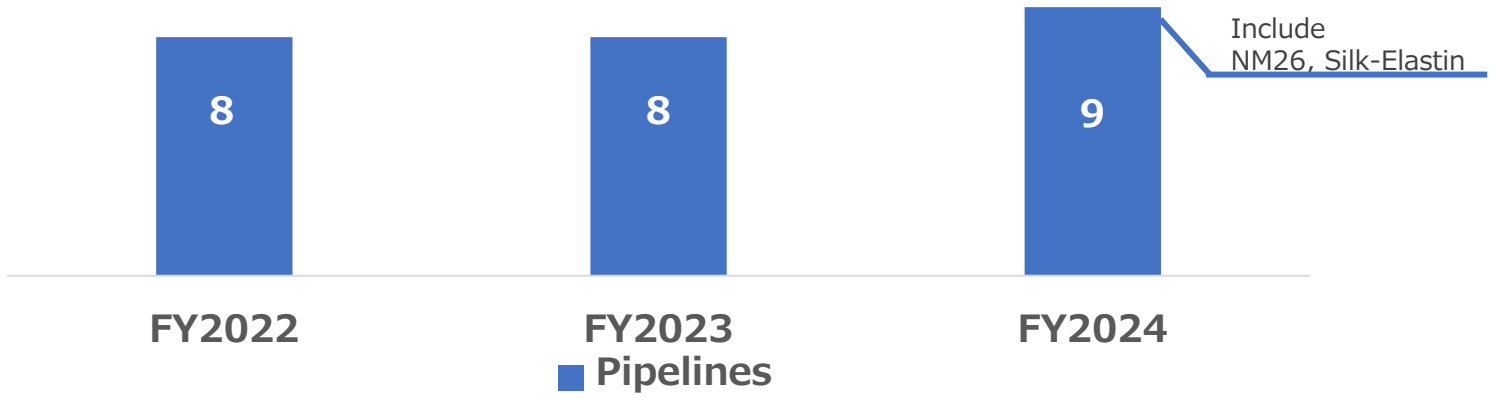
【 1st X **R&D Transformation】**

Progress on in-licensing and marketing alliances

In-licensed seven projects as of March 2025

FY2022	FY2023	FY2024
Tildacerfont	Marketing alliances from Eisai	ESK-001
Seladelpar	(Merislon®/Myonal®)	FYARRO®
		ND081
		Silk-Elastin

Pipelines *



*as of March 2025, see Appendix for more information

Achievements over the past three years

1st X R&D Transformation | 2nd X Overseas Expansion Transformation | 3rd X Management Base Transformation

■ Out-licensing and oversea expansion is also progressing steadily.

【 1st X **R&D Transformation**】

Out-licensing	✓ Entered into IP transfer and commercial option agreement for NM26. ✓ Entered into licensing agreement for STAT6 inhibitor. (Disposed treasury shares through a third-party allotment to JJDC.)

For more information, see Pg.29-30

<Reference>

■ IP transfer and commercial option agreement for NM26

Received an upfront payment of $86MM in total from Numab and Johnson & Johnson for the transfer of IP and licensing rights in FY2024.
Expects potential payments totaling up to $252.4MM in total for the achievement of certain regulatory and sales milestones as well as single to lower double-digit percent royalties on net sales in Asia.

■ License agreement for STAT6 inhibitors

Received an upfront payment of $30MM from Johnson & Johnson by granting an exclusive license for the worldwide development, manufacturing and commercialization of STAT6 program in FY2024.
Expect for success-based payments of up to $1,217.5MM based on development progress and sales milestones, as well as single to lower double-digit percent royalties on sales worldwide.

Achievements over the past three years

1st X R&D Transformation | 2nd X Overseas Expansion Transformation | 3rd X Management Base Transformation

■ Out-licensing and oversea expansion is also progressing steadily.

【 2nd X **Overseas Expansion Transformation】**

Overseas Expansion	✓ Acquisition of Aadi Subsidiary, Inc. in the US. ✓ Dong Wha Pharma filed for marketing authorization of "Sofpironium Bromide" in Korea. ✓ For marketing authorization of "efinaconazole", filed in Germany and obtained approval in Italy ✓ Entered Phase III clinical trial of "efinaconazole" in China by AIM

<Reference>

■ Acquisition of Aadi Subsidiary, Inc. in the US

For more information, see Pg.31-33

Entered into a stock purchase agreement for the acquisition of Aadi Subsidiary, Inc for $100MM, to make it a wholly-owned subsidiary, in December 2024 and completed the acquisition on March 26, 2025.

Expected effects from the acquisition

- A step towards building own sales structure overseas under the Overseas Expansion Transformation of Long-Term Business Plan 2031.
- Aadi obtains sales platform and know-hows for orphan drugs, which is critical for the success of KP-001 business in the US.
- Potential procurement of global products through synergies with Aadi, together with the sales of "FYARRO®"

Achievements over the past three years

1st X R&D Transformation | 2nd X Overseas Expansion Transformation | 3rd X **Management Base** Transformation

■ Establishment of management base is progressing.

【 3rd X **Management Base** Transformation】

Management Base	✓ Established a strong organizational foundation where flexibly respond to changes and be active as professionals. • Recruited mid-career professionals approximately six times more for the first three years of the Long-Term Business Plan 2031 (compared to FY2021). • Established new tiered training programs and reskilling opportunities (introduced online study services). • Improved working environment to enhance the work-life balance of employees. • Certified as Health and Productivity Management Outstanding Organization. ✓ Established foundation for medical information provision activities using digital technologies through renewal of the website for medical professionals.

【Target KPIs】

Target KPIs	✓ Expected to achieve FY2026 KPIs two years ahead of schedule

Target KPIs for FY2026

Net Sales	¥80.0 billion	ROE	8% or higher
Operation Profit	¥18.0 billion	Overseas Sales Ratio	10% or higher

Analysis of the Current Status of the Long-Term Business Plan 2031

Analysis of the current status

Three years have passed since the formulation of the Long-Term Business Plan 2031. Need to respond to internal and external changes in the business environment.

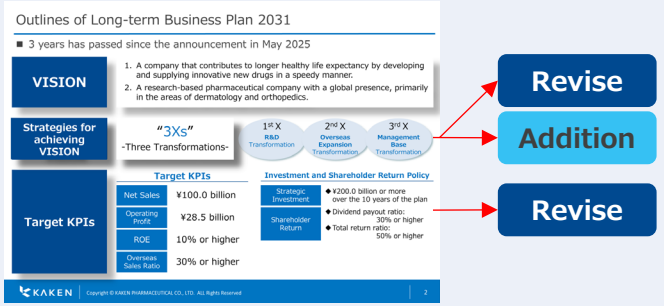
Changes in the business environment*

- Increase in number of in-licensed products and projects under development
- Early realization of derivation
- Progress in overseas expansion
- Progress on covering the patent cliff of Clenafin
- Impact of the "Elective Medical Care" system on long-term listed drug
- Soaring R&D costs
- Intensifying competition in the in-licensing and M&A market

* Positive impact and negative impact for the achievement of the long-term business plan.

As we announced at FY2024 2Q meeting,

we partially reviewed the Long-Term Business Plan 2031 due to changes in the business environment.



Long-Term Business Plan 2031 –Concept of the Revision-

Concept of the Revision

- **Increase strategic investment** for continuous launch of innovative new drugs to further increase corporate value.
- **Maintain financial discipline** taking into account increasing volatility and uncertainty in financial performance and cash flows.
- **Enhance shareholder return** for the stakeholders.

Major Items

A) Revision and addition to “3Xs” Three Transformations.

B) Revision of amount of strategic investment.

C) Revision of shareholder return policy.

D) Revision of cash flow allocation taking into account the financial discipline together with B) and C) above.

Long-Term Business Plan 2031 - Revision and Addition to Strategies -

■ Additional measures and revisions to further pursue Three Transformations

Items	Priority Measures of the Plan	Addition and Revision
1st x	➢ Secure pipelines capable of launching eight new products over the 10 years of the plan (maintain at least six pipelines in Phase I or later phases at any given time). ➢ Secure at least one new licensed products or new marketing alliance every year.	**Revision** ➢ Secure pipelines capable of launching eight new products over the 10 years of the plan (**maintain at least eight pipelines** in Phase I or later phases at any given time). ➢ Secure at least one new licensed products or new marketing alliance every year **expanding global products as target**.
2nd x	➢ overseas sales ratio of 25% or higher. • Expand global products. • Establish our own overseas development capabilities. • Establish global manufacturing and commercialization structure.	**Addition** ➢ Succession and stable operation of FYARRO® business. ➢ Consideration of European expansion policy. ➢ Procure products for overseas expansion in anticipation of synergies with Aadi.
3rd x	➢ Increase corporate value by establishing a strong organizational base that can flexibly respond to change and by improving operational efficiency.	**Addition, Specified** ➢ Actively recruit mid-career professionals with advanced expertise. ➢ Introduce Employee Stock Ownership Plan (J-ESOP). ➢ Maximize products value through optimizing medical information provision activities using Customer Relationship Management

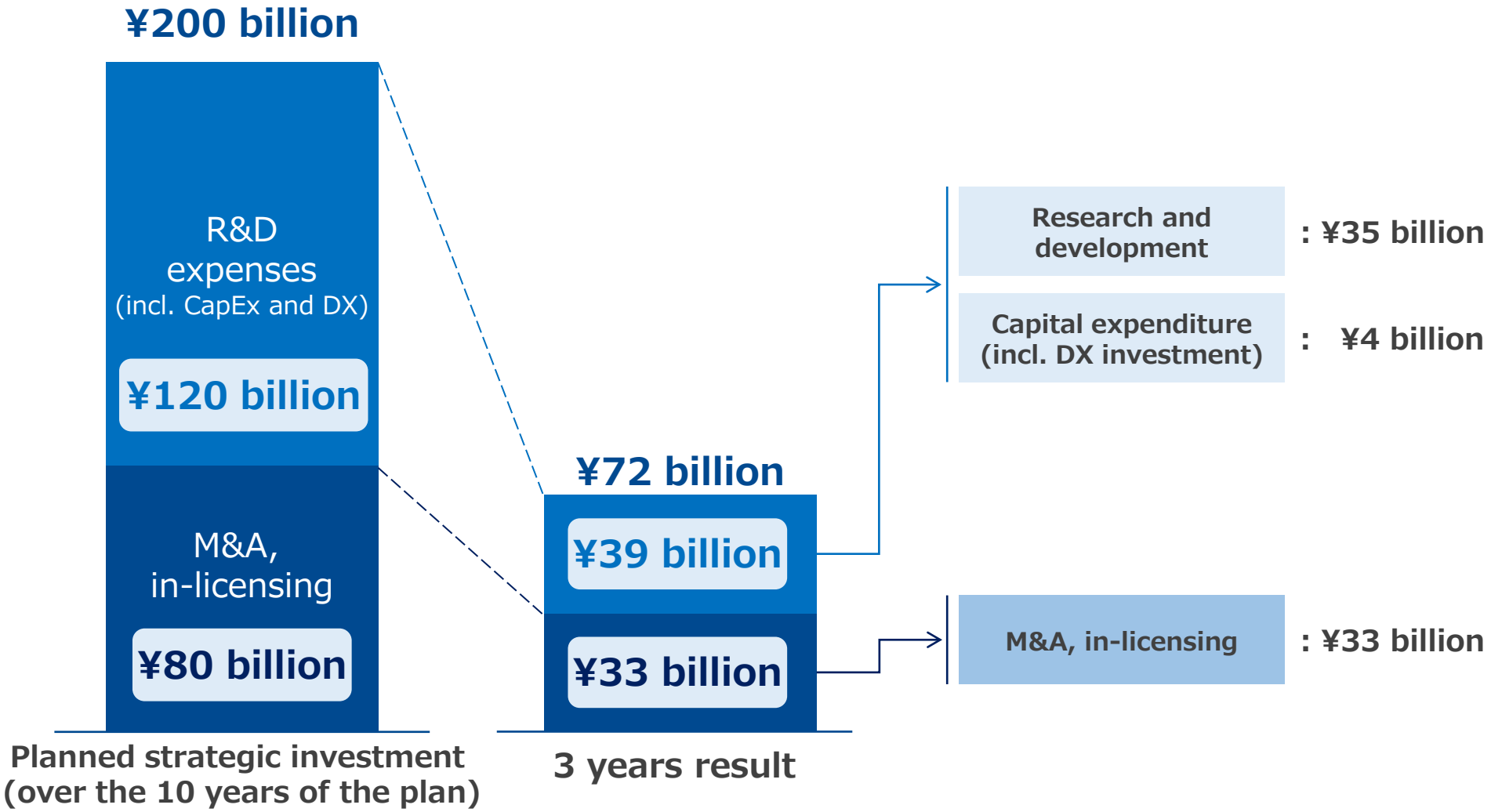
Long-Term Business Plan 2031 -Revision and addition of strategies-

■ Revision of strategic investment amount and shareholder return policy

Items	KPIs for FY2031	Revision and additions
Strategic Investment	➢ ¥200 billion or more over the 10 years of the plan	**Revision** ➢ **¥260 billion or more** over the 10 years of the plan
Shareholder Return Policy	➢ Dividend payout ratio: 30% or higher ➢ Shareholder return ratio: 50% or higher	**Revision** ➢ **Minimum of ¥190 per share dividend** of FY2024 taking into account dividend payout ratio of 30% or higher and shareholder return ratio of 50% or higher. ➢ Cumulative shareholder return of ¥50 billion or more for the next seven years.
Others		**Addition** ➢ Consider changing accounting standard to IFRS.

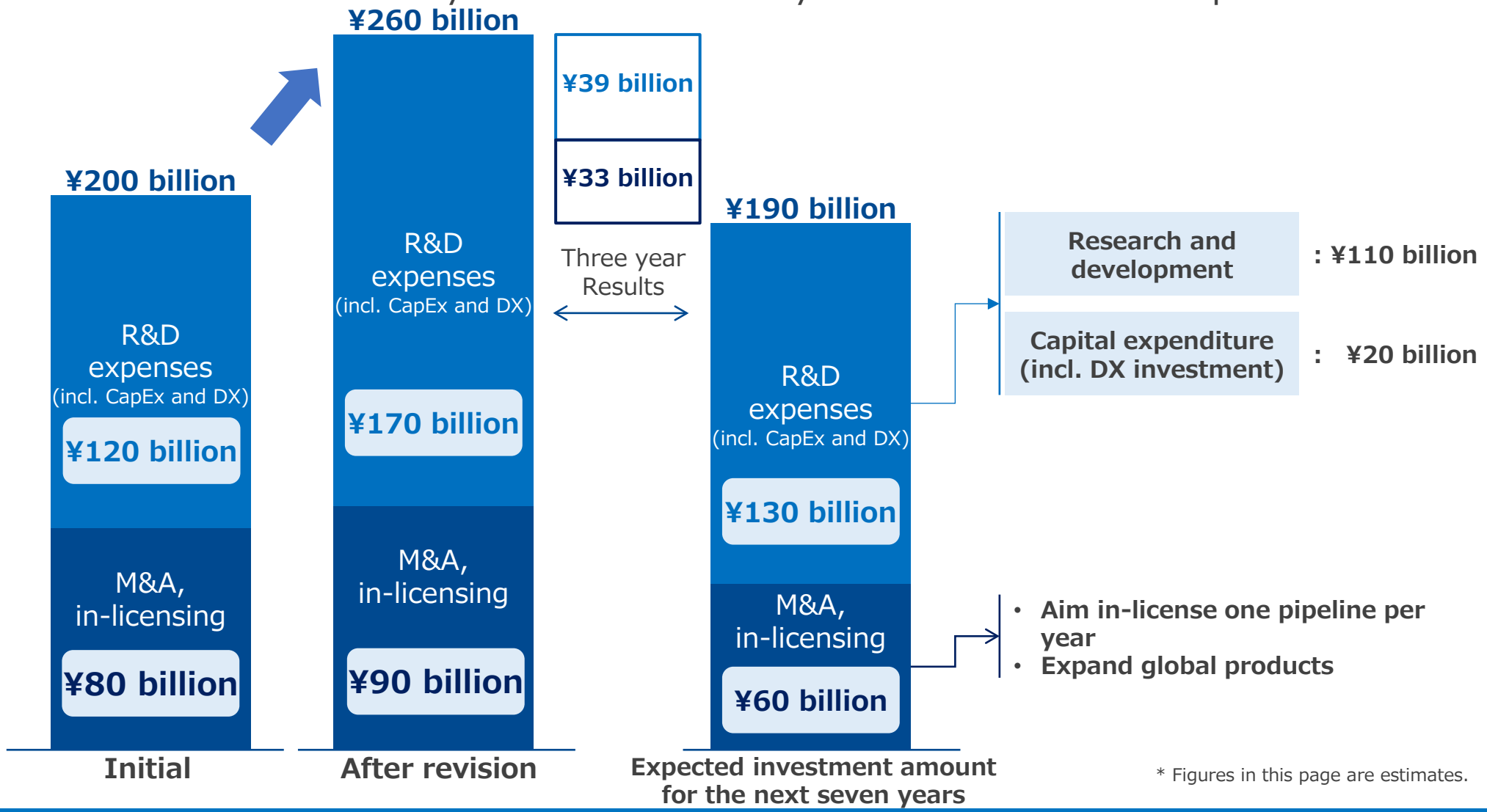
Progress on Strategic Investment

■ Spent approximately ¥72 billion in strategic investment for the past three years.



Revision of Amounts of Strategic Investments (by FY2031)

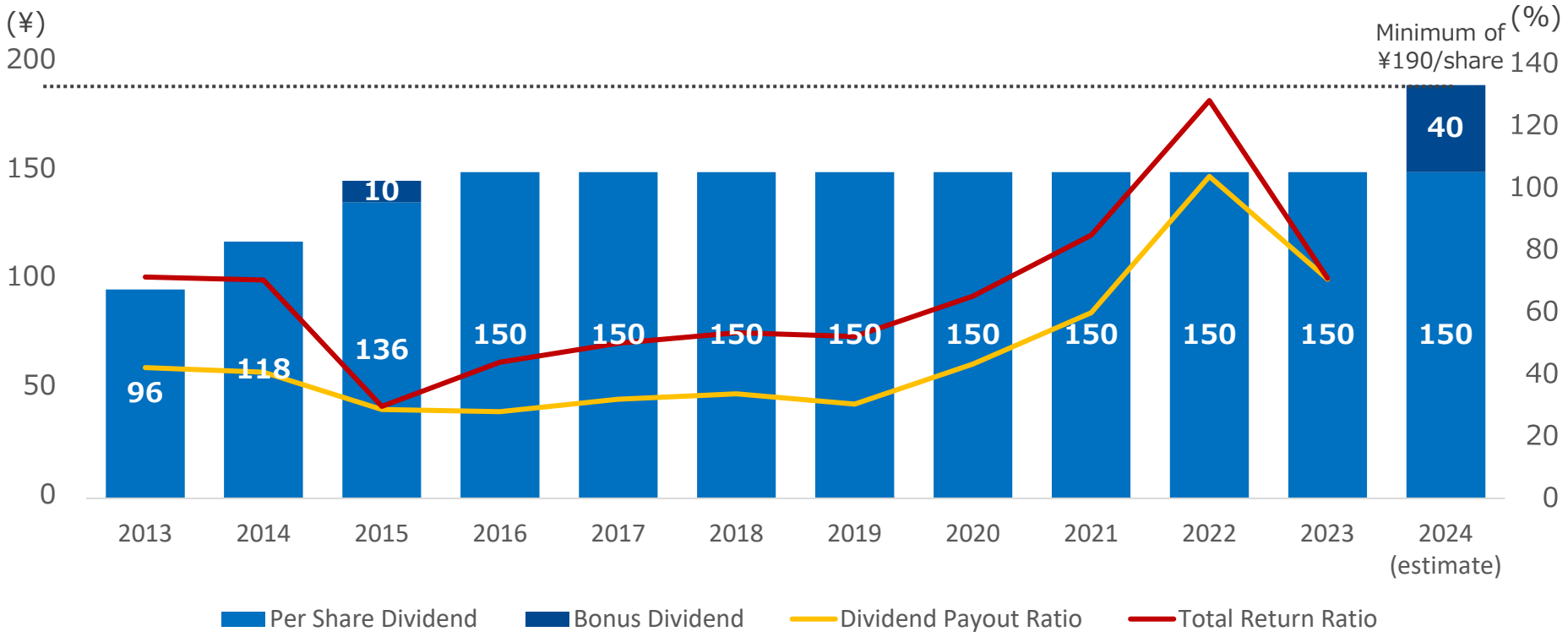
■ Allocate ¥260 billion by FY2031 increase by ¥60 billion from initial plan.



* Figures in this page are estimates.

Revision of Shareholder Return Policy

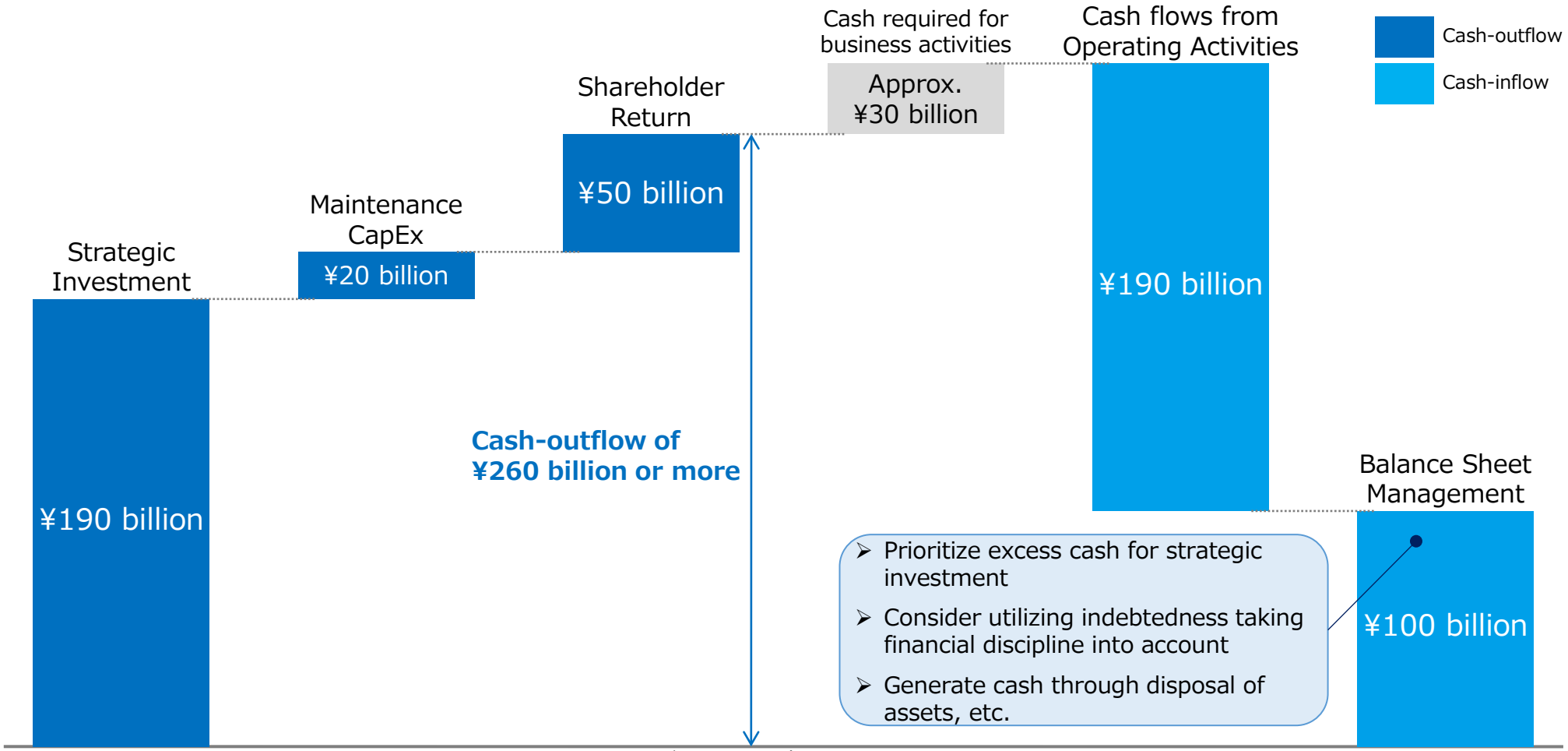
■ Minimum of ¥190 per share dividend taking into account dividend payout ratio of 30% or higher and shareholder return ratio of 50% or higher.



* Looking forward for adopting IFRS, the Company will not “calculate net income attributable to owners of the parent excluding the effect of one-time charges and other items related to strategic investments”.
* Two to one stock consolidation took place on October 1, 2015. Per share dividend prior to the period were adjusted taking into account the effect of the consolidation.

Revision of Image of Cash Flow Allocation (FY2025 – FY2031)

- Generate sources for strategic investment and shareholder return through operating cash flows and balance sheet management.

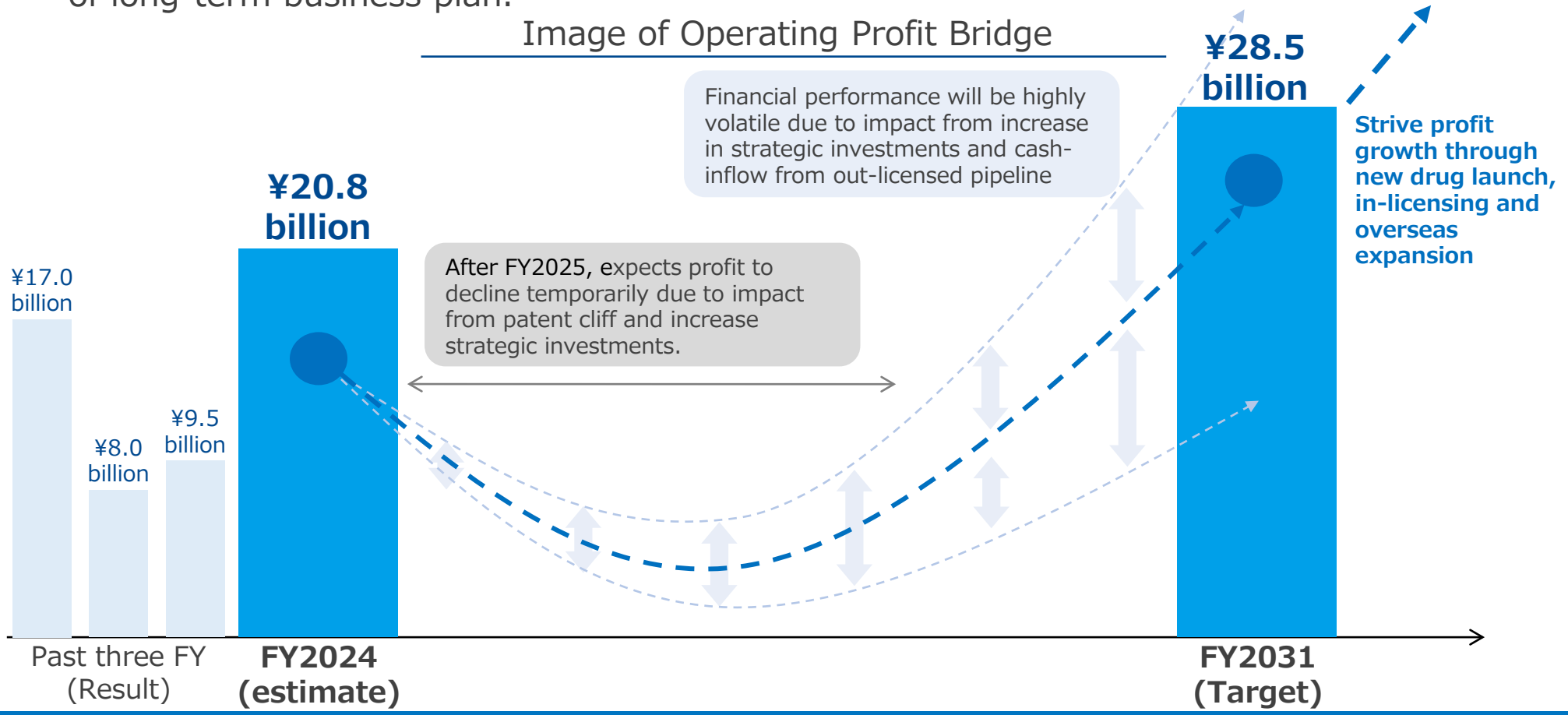


* Figures in this page are estimates.
* Cash flows from operating activities exclude R&D investment and one-time fees for in-licensing.

Image of Financial Performance for the Period of Long-Term Business Plan 2031

- Expects profit to decline temporarily due to impact from “Clenafin®” patent cliff.
- Financial performance will be highly volatile due to impact from patent cliff, increase in strategic investments and cash-inflow from out-licensed pipeline.
- Realize profit growth through execution of strategic investments in Three Transformation of long-term business plan.

Image of Operating Profit Bridge



2 Research and Development
Introduction of Products Out-Licensed in FY2024 and FYARRO®

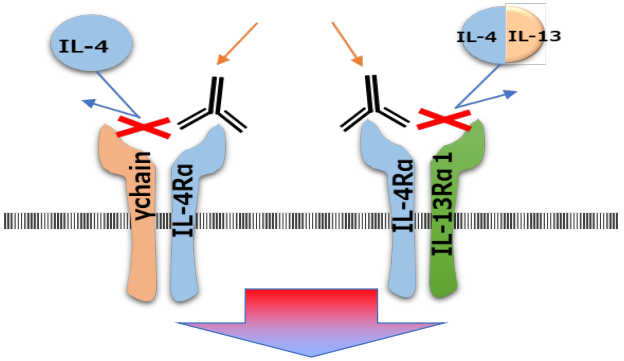
Research and Development

- NM26, a bi-specific antibody for the treatment of atomic dermatitis
- Expectation for STAT 6 inhibitor

- FYARRO®, treatment for perivascular epithelioid cell tumors

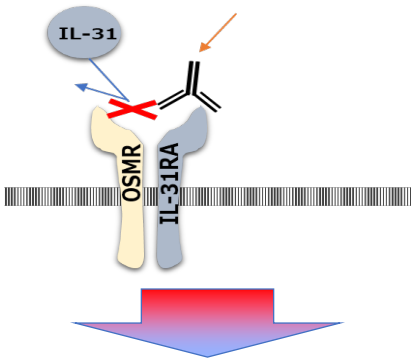
Antibody Therapeutics for Atopic Dermatitis

Anti IL-4RA Antibody



Impairment of skin barrier function and exacerbation of chronic inflammation

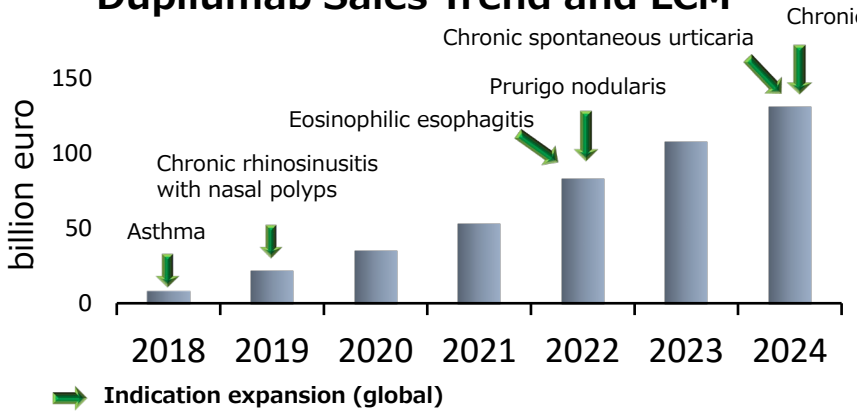
Anti IL-31RA Antibody



Pruritus

(*Illustration: Kaken Pharmaceutical*)

Dupilumab Sales Trend and LCM



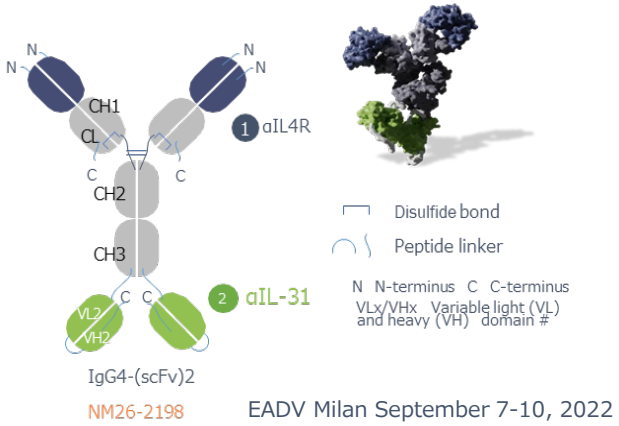
- ✓ Dupilumab sales in 2024 exceeded ¥2 trillion.
- ✓ Appropriate label expansions based on targeted mechanisms contributed to sales growth.

(Source: Created based on materials disclosed on Sanofi's official website)

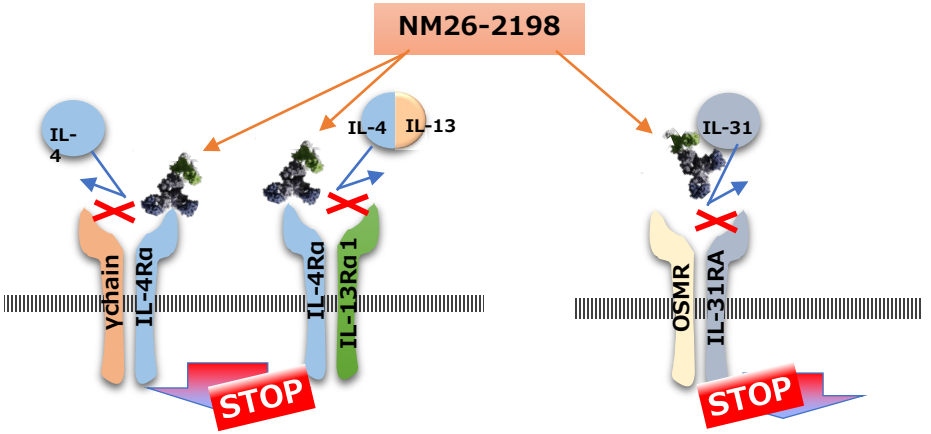
IL-4Rα and **IL-31RA** are promising targets for atopic dermatitis

NM26, A Bi-specific Antibody for the Treatment of Atopic Dermatitis

- A bi-specific antibody targeting IL-4Rα and IL-31 simultaneously.
- Controls both IL-4/IL-13 signaling inhibition and IL-31 neutralization with a single agent.
- NM26-2198 blocks the primary symptoms of atopic dermatitis with just one antibody.



EADV Milan September 7-10, 2022



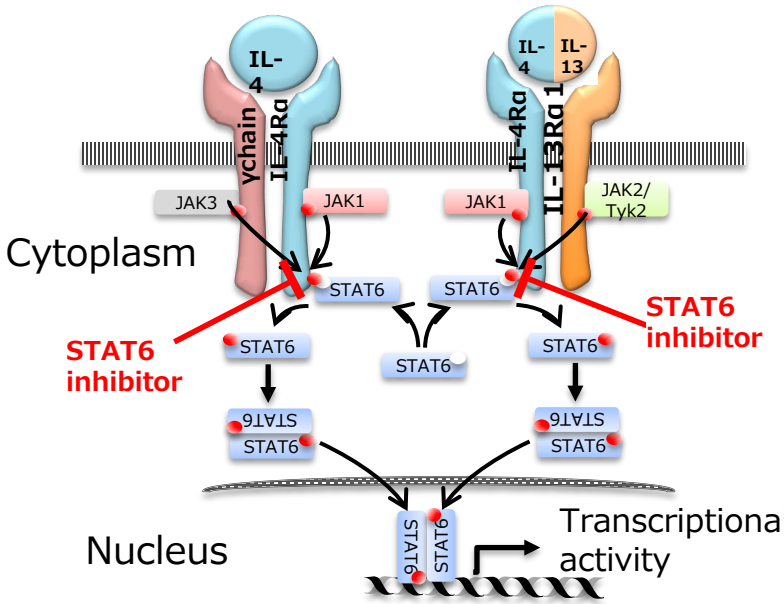
Impairment of skin barrier function and exacerbation of chronic inflammation

Pruritus

(*Illustration: Kaken Pharmaceutical*)

NM26-2198 blocks the primary symptoms of atopic dermatitis with a single antibody

Expectations for STAT6 Inhibitors



(*Illustration: Kaken Pharmaceutical*)

STAT6: Master transcription factor of IL-4/IL-13 signaling

STAT6 plays multiple roles:

- Promotes Th2 cell differentiation (immune response)
- Stimulates IgE production (via B cells)
- Involved in airway hyperresponsiveness (asthma/allergy)

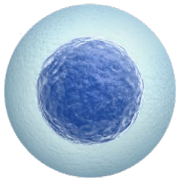
STAT6 inhibitors are expected to be therapeutic agents for a broad range of type 2 inflammatory diseases

Differences Between Dupilumab and STAT6 Inhibitors

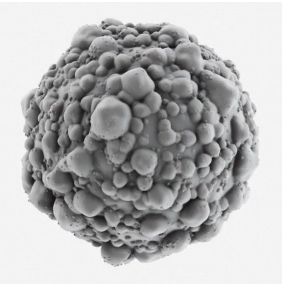
	Dupilumab (Antibody)	STAT6 Inhibitor
Target:	Blocks extracellular IL-4Rα	Inhibits intracellular signal transduction
Scope:	Specific to IL-4/IL-13	Broad inhibition of STAT6-related signals
Administration:	Subcutaneous injection	Oral administration

Primary Perivascular Epithelioid Cell Tumor (PEComa)

- Malignant PEComa: A rare cancer classified as a soft tissue sarcoma.
- "PEC" refers to the perivascular epithelioid cells that compose the tumor.
- Sarcomas: Rare cancers that arise in bones and soft tissues such as fat, blood vessels, muscles, and nerves.
- Malignant PEComas are highly aggressive and can metastasize.
- Early-stage tumors may be surgically removed.
- Locally advanced or metastatic PEComas cannot be surgically removed or have spread to other parts of the body.



Normal cells

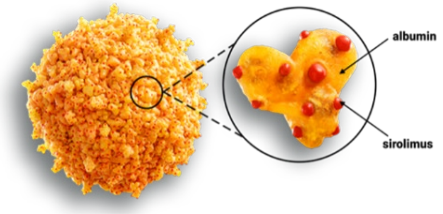


PEComa cells

(*Source: Aadi website*)

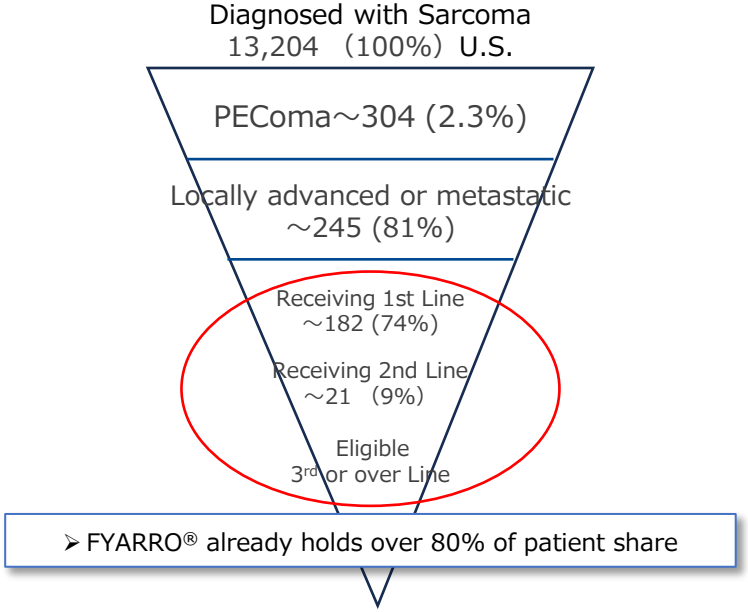
FYARRO®

- FDA-approved in November 2021, launched in the U.S. in February 2022.
- 100 mg/m² intravenous injection on Day 1 and Day 8 of a 3-week cycle.
- Active ingredient: Sirolimus, an mTOR inhibitor, suppresses genes involved in excessive cell proliferation.
- Utilizes nanoparticle technology to enhance sirolimus delivery to tumors and boost mTOR inhibition.
- Commands over 80% U.S. patient share, with a stable market outlook.



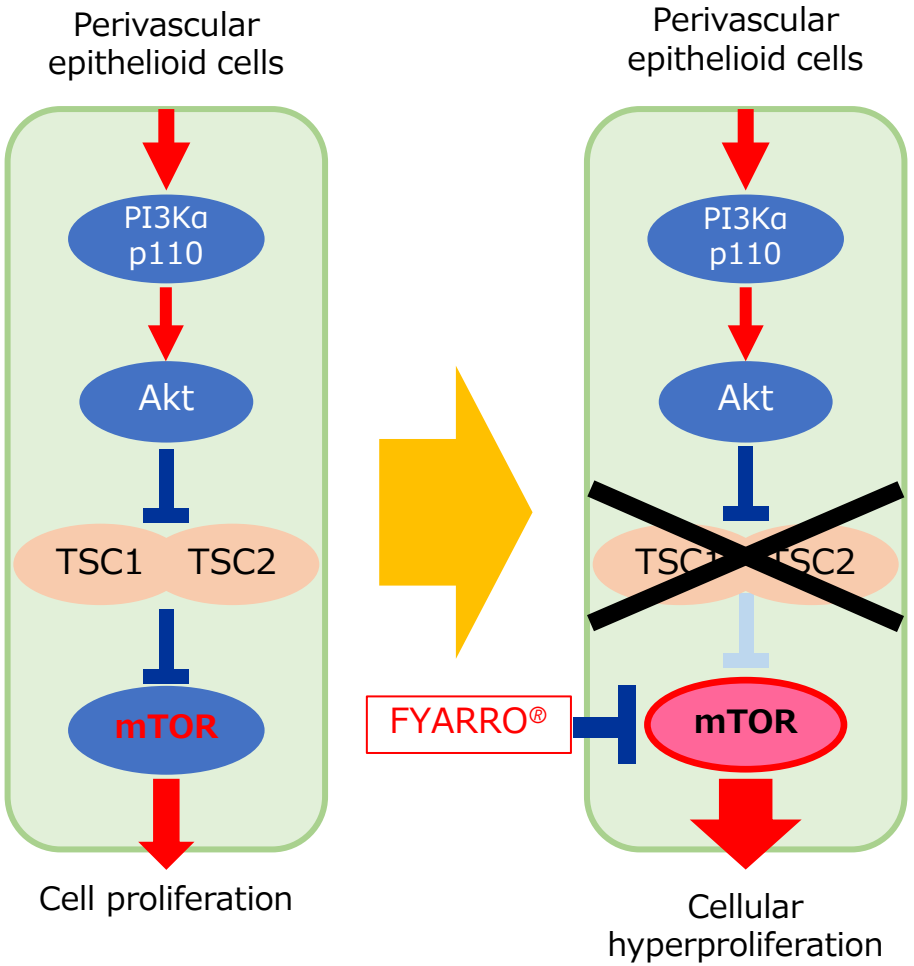
Source; FYARRO® web page (Aadi Bioscience, Inc.)

Epidemiology & FYARRO® Usage



Soource： FYARRO® tracking Pulse- Wave 6（March 2024）

Genetic Mutations and FYARRO® Mechanism of Action in PEComa



Cause of PEComa: Often involves mutations in TSC1 or TSC2 genes, leading to overactivation of the mTOR pathway, promoting tumor growth and angiogenesis.

Mechanism of FYARRO®:

- Inhibits mTOR, thereby suppressing PEComa cell proliferation and angiogenesis
- Particularly effective in cases involving TSC1/TSC2 mutations

Synergy with KP-001

- mTOR, the target of FYARRO®, is downstream of PI3Kα, the target of KP-001
- As PEComa is a rare disease, FYARRO®'s distribution network and marketing strategy can be leveraged for KP-001's U.S. market expansion

Appendix

Pipelines

* as of Nov 8, 2024, includes preparation stage of clinical trials

■ In-house discovered and in-licensed projects

Development Code	Development Stage *	Therapeutic Area	Planned Indication	Remarks
KAR	P III	Dermatology	Head lice	In-licensed from Arbor Pharmaceuticals, LLC Product name in the US: Sklice®
KP-001	P III	Plastic Surgery, Pediatrics, Dermatology	Refractory vascular malformations	—
KC-8025 (Seladelpar)	P III	Gastroenterology, Hepatology, Internal Medicine	primary biliary cholangitis	In-licensed from CymaBay Therapeutics, Inc. CymaBay was acquired by Gilead Sciences, Inc. in February 2024
KP-483	P I	---	Solid Tumors (immuno-oncology)	Product discovered in-house
KP-910	P I	Neurology, Orthopedics, Pain Medicine	Peripheral neuropathic pain	Product discovered in-house
Tildacerfont	P I	Pediatrics, Internal Medicine	congenital adrenal hyperplasia	In-licensed from Spruce Biosciences, Inc.
KP-001 (US)	P I	Plastic Surgery, Pediatrics, Dermatology	Refractory vascular malformations	Consulting with FDA on P III plan

Pipelines

* as of Nov 8, 2024

■ Status of pipeline with a commercial option agreement in Japan

Product	Planned Indication	Development Stage	Remarks
NM26	Atopic dermatitis	P I	Clinical trial underway after IP transfer to J&J

■ Status of pipeline for which license agreements have been executed (medical devices)

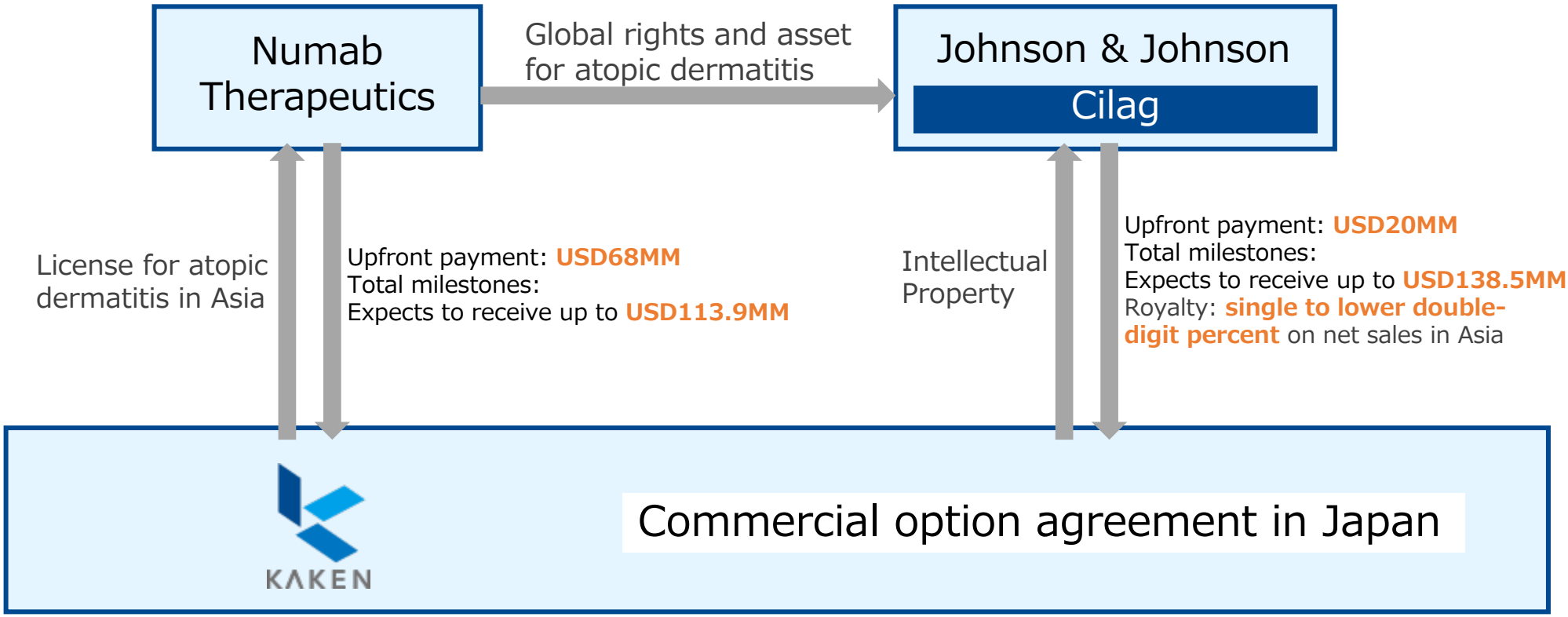
Application Name	Intended use or effect	Development Stage	Remarks
Silk-Elastin Wound Healing Sheet	Wound treatment	Filed	Manufacturing and marketing approval is under review after submission by the licensor, Sanyo Chemical Industries, Ltd.

■ Status of out-licensed products overseas

Generic name (domestic sales name)	Planned Indication	Development Stage	Out-licensed to(Developing country)
Efinaconazole (Clenafin)	Onychomycosis	Filed	Almirall S.A. (Europe)
Efinaconazole (Clenafin)	Onychomycosis	P III	AIM (China)
Sofpironium bromide (Ecclock)	Primary axillary hyperhidrosis	Filed	Dong-Wha Pharm Co., Ltd. (Korea)

<Reference> IP Transfer and Commercial Option Agreement for NM26

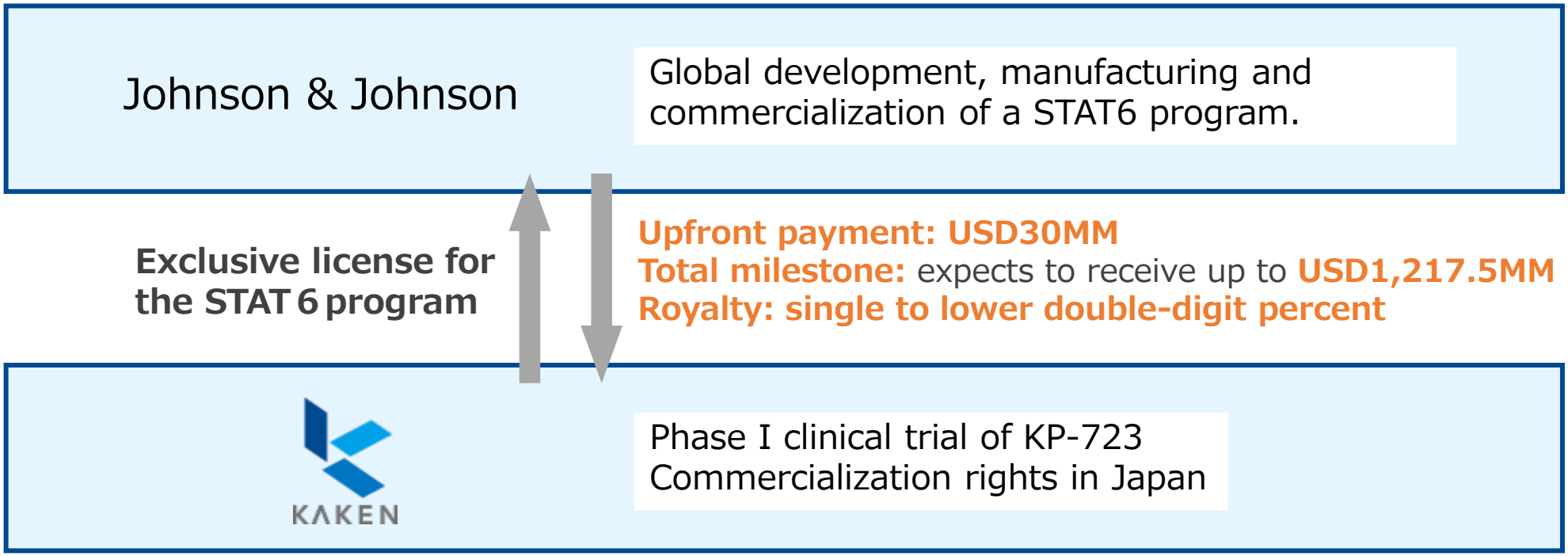
- Entered into an IP Transfer and Commercial Option Agreement for NM26 on May 28, 2024.
- NM26-2198 is a bi-specific antibody for the treatment of atopic dermatitis which has been co-developed with Numab Therapeutics.
- Kaken expects to receive milestone payment and royalties in accordance with the progress of development and the achievement of sales targets.



※ For more information, see the news release on May 29, 2024.

<Reference> License Agreement for STAT6 Inhibitor

- Entered into a license agreement with Johnson & Johnson for STAT6 inhibitors on December 26, 2024.
- Kaken will advance KP-723 to the completion of Phase I clinical trials, after which Johnson & Johnson will conduct the worldwide clinical development and commercialization.
- Kaken expects to receive milestone payment and royalties in accordance with the progress of development and the achievement of sales targets.



※ For more information, see the news release on December 26, 2024.

<Reference> Acquisition of Aadi Subsidiary, Inc. in the US

- Entered into a stock purchase agreement for the acquisition of Aadi Subsidiary, Inc for $100MM, to make it a wholly-owned subsidiary, in December 2024 and completed the acquisition on March 26, 2025.

KAKEN

KP-001, a pipeline possible to expand globally

aadi bioscience

US company who markets prescription drug for rare cancer (FYARRO®)

Hi-tech products : FYARRO®

Expected effects from the acquisition

- A step towards building own sales structure overseas under the Overseas Expansion Transformation of Long-Term Business Plan 2031.
- Aadi obtains sales platform and know-hows for orphan drugs, which is critical for the success of KP-001 business in the US.
- Potential procurement of global products through synergies with Aadi, together with the sales of "FYARRO®"

※ For more information, see the news release on December 26, 2024, and March 27, 2025.

<Reference> Acquisition of Aadi Subsidiary, Inc.

■ Detail of the acquisition

Target Company	• Aadi Subsidiary, Inc. (hereinafter, “Aadi”) (Changed its name to **Aadi Bioscience, Inc.** on March 26, 2025.)
Head Office	• Morristown, New Jersey
Target for Acquisition	• 100% of issued shares for Aadi. (Products and pipelines other than “FYARRO®” is not subject to transfer.)
Purpose of Acquisition	• To build our own sales structure in the US market. • Acquire Aadi’s orphan drug sales platform and sales know-how.
Business	• Marketing authorization for FYARRO®, prescription drug for rare disease.

<Reference> About Aadi Bioscience, Inc.

- Description of Aadi Bioscience, Inc.

  Aadi Bioscience, Inc. (now Whitehawk Therapeutics, Inc.) was founded in 2007, with the aim of “developing new cancer treatments using mTOR inhibitors”. The company’s missions was to provide safe and effective treatment options, particularly for patients with rare and intractable cancers.

- Background of Development of FYARRO®

  Founder Dr. Neil Desai focused on the importance of the mTOR pathway in cancer treatment and developed an mTOR inhibitor called “nab-sirolimus (FYARRO®)” that utilizes nab technology (nanoparticle albumin binding technology) with the aim of developing an effective therapeutic drug.

- Marketing of FYARRO®

  FYARRO® was approved by FDA in November 2021 as a treatment for perivascular epithelioid cell tumors (PEComa) and has been sold by Aadi Subsidiary, Inc., a subsidiary of Aadi Bioscience, Inc. since February 2022.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