

# Kyowa Kirin to Regain Control of Rocatinlimab Development and Commercialization Program

February 2<sup>nd</sup>, 2026

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President and Chief Operating Officer (COO) Abdul Mullick, Ph.D.

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協和キリン株式会社

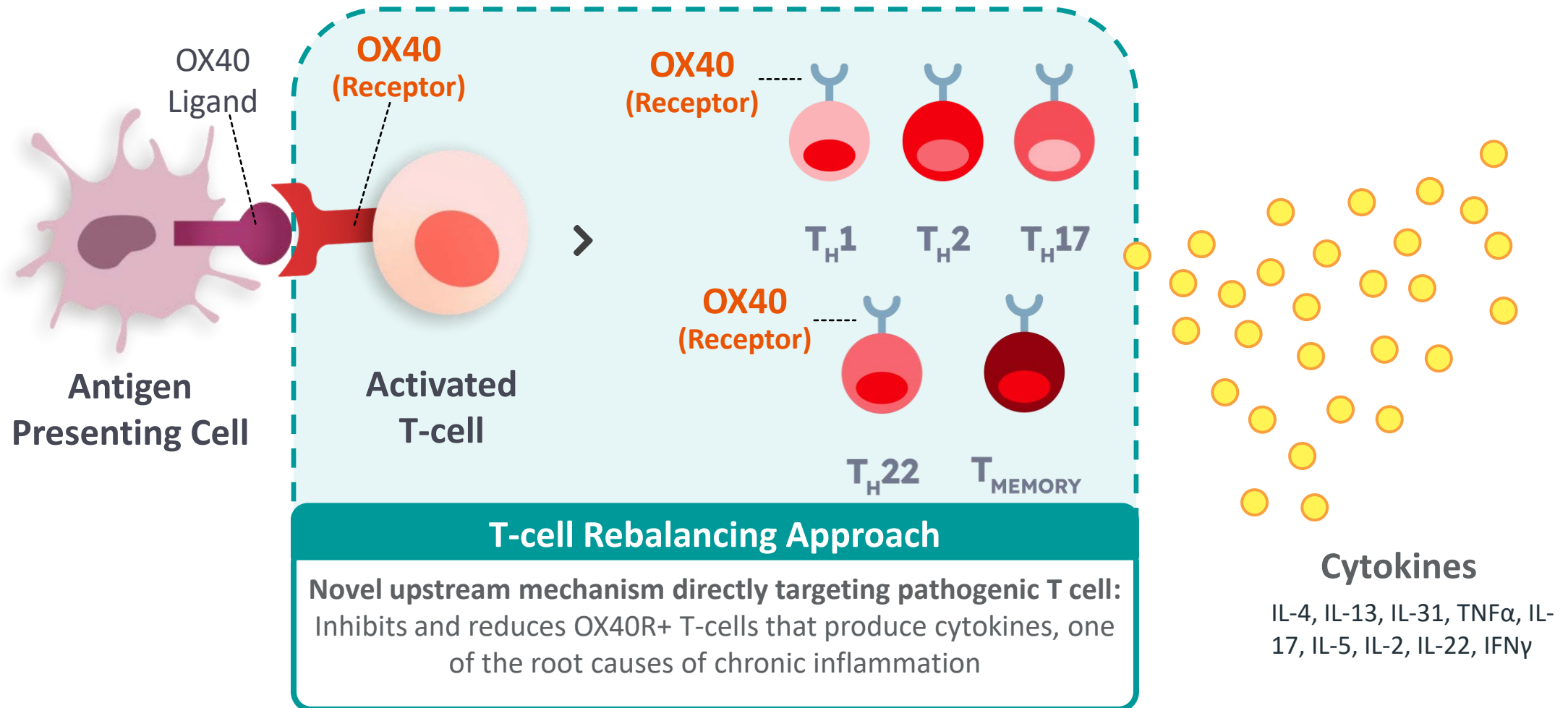
The logo for Kyowa Kirin, featuring the company name in a bold, sans-serif font. The 'K' is white and set within a white circle, while the rest of the text 'YOWA KIRIN' is white. The logo is positioned on an orange curved background element at the bottom right of the slide.

**KYOWA KIRIN**

# Kyowa Kirin will continue to advance rocatinlimab development to create Life-changing value that makes people smile

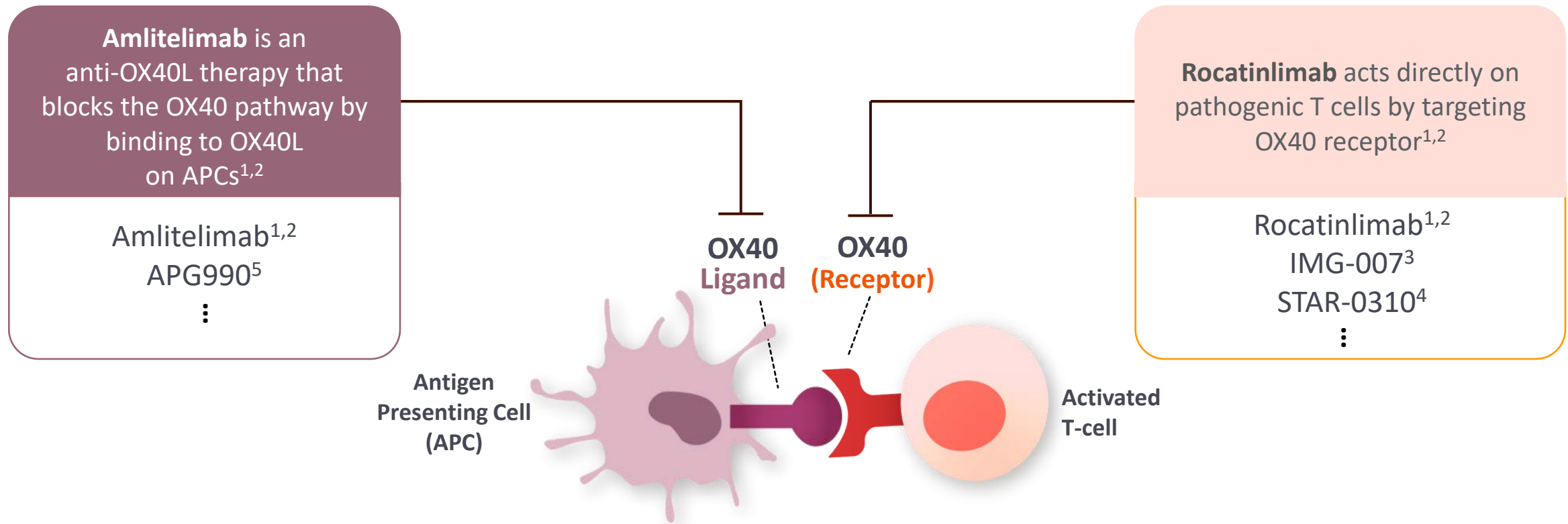
- Existing license and collaboration agreement will be terminated following Amgen's strategic portfolio prioritization, and Kyowa Kirin will regain control of the global rocatinlimab program
- Kyowa Kirin affirms commitment to developing rocatinlimab as a Life-changing differentiated asset with significant market potential
- Regulatory submissions are planned for the first half of 2026
- Amgen will provide transitional long-term manufacturing and supply of rocatinlimab to Kyowa Kirin
- All eight Phase 3 studies (ROCKET Program) successfully met their primary and key secondary endpoints. Of note, rocatinlimab demonstrated a significant improvement in the co-primary endpoint required for US regulatory submission, the revised Investigator's Global Assessment (rIGA) score of 0 or 1 (defined as achieving a vIGA-AD score of 0 [clear skin] or 1 [almost clear skin] with presence of only barely perceptible erythema) at week 24

# Rocatinlimab is a T-cell Rebalancing Therapy which directly targets a root cause of AD, activated pathogenic Effector and Memory T-cells



# At present, more than 10 assets related to OX40/OX40L are in clinical stage globally

OX40 signalling leads to the activation of downstream pathways that drive effector and memory T-cell differentiation, proliferation and survival<sup>1,2</sup>



Note: AD, atopic dermatitis; APC, antigen-presenting cell; OX40R, OX40 receptor; OX40L, OX40 ligand.

1. Croft, et al. Am J Clin Dermatol 2024;25:447-461; 2. Le AM, et al. Pharmaceutics 2022;14:2753; 3. Shen Y, et al. Br J Dermatol 2024;191(Suppl 2); 4. Biris N, et al. Presented at EAACI 2024. Poster D1.343; 5. Wong M et al. RAD 2025., Kyowa Kirin internal search

# Kyowa Kirin has absolute conviction in rocatinlimab's science and excited to advance Rocatinlimab program to the next chapter

Efficacy and safety of rocatinlimab for the treatment of moderate-to-severe atopic dermatitis in ROCKET-IGNITE and ROCKET-HORIZON: two global, double-blind, placebo-controlled, randomised phase 3 clinical trials

*Lancet 2026; 407: 53-66*

An anti-OX40 antibody to treat moderate-to-severe atopic dermatitis: a multicentre, double-blind, placebo-controlled phase 2b study

*Lancet 2023; 401: 204-14*

Antagonist OX40 mAb discovery project initiated based on proposal from Dr. Croft at La Jolla Institute (LJI)

rocatinlimab precursor discovered

Activity of rocatinlimab confirmed

Pre-clinical studies initiated

1st IND for rocatinlimab

**ROCKET**  
Rocatinlimab in Eczema Trials  
Partnership with Amgen Initiation of Ph3 AD ROCKET Program

Global Ph2b data Published in the Lancet

Global Ph3 mono-therapy data Published in the Lancet

Kyowa Kirin regain control of the global program

Rocatinlimab was discovered and advanced by Kyowa Kirin scientists, drawing on our deep expertise in immunology and antibody engineering

**KYOWA KIRIN**

La Jolla Institute  
FOR IMMUNOLOGY

Life Without Disease<sup>®</sup>

# Moderate-to-Severe Atopic Dermatitis (msAD) is a chronic, heterogeneous inflammatory skin disease that imposes a substantial burden on patients and caregivers



Many patients strive to find relief, and hope for new treatment options

## Impact of Moderate-to-Severe AD:

### Skin Symptoms

Excessively dry, itchy, and painful skin  
Repeated scratching can lead to thickened, hardened skin and increased infection risk

### Sleep Disruption

Chronic symptoms negatively impacts sleep in **up to 80% of children and 90% of adults**

### Mental Health

Adults are **twice as likely** to experience depression and anxiety

### Daily Life

Reduced productivity, limited social interactions and an overall decrease in Quality of Life

**Despite existing therapies, many patients with moderate-to-severe AD continue to experience inadequate disease control<sup>1,2,3</sup>**

1. Lio P, et al. *J Drugs Dermatol*. 2023;22:119-131. 2. Eichenfield LF, et al. *SKIN J Cutaneous Med*. 2024;8(6):s462. 3. Hongbo Y, et al. *J Invest Dermatol*. 2005;125:659-664.

## Current treatment options often fail to provide sufficient depth and durability of symptom improvement<sup>1-3</sup>

- Due to the heterogeneous pathogenesis of AD, no one therapy shows consistent efficacy across diverse patient populations.
- Only 10 - 15% of eligible patients are currently receiving biologic treatment<sup>4</sup>, indicating considerable opportunity for growth in the msAD market.
- More than 50% of patients receiving systemic therapies discontinue treatment within a year<sup>5</sup>.
- Treatment goals have evolved from "short-term symptom control" to "long-term disease control", and ultimately toward "*disease modification*".

**There remains an urgent need for new therapies with novel mechanisms of action to expand treatment options for patients with moderate-to-severe AD**

1. Lio P, et al. *J Drugs Dermatol*. 2023;22:119-131. 2. Eichenfield LF, et al. *SKIN J Cutaneous Med*. 2024;8(6):s462. 3. Hongbo Y, et al. *J Invest Dermatol*. 2005;125:659-664. 4. IQVIA analysis: Closing in: Novel oral immunotherapies are taking on the biologics [\[LINK\]](#), 5. Kyowa Kirin/Amgen internal data on file

# For patients with Atopic Dermatitis, Unmet Medical Needs (UMN) still exist

- *There remain significant unmet medical needs in AD. Few patients are able to continue existing advanced treatments over the long term. Patients are eagerly waiting for innovative new options.*
- *I welcome new drug candidates with novel mechanism of actions that have the potential to deliver unique value that other therapies are not able to provide.*



**Professor Kenji Kabashima**

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## COI Disclosure

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The following conflicts of interest (COI) should be disclosed in relation to this material.

- Receives consulting fees from Kyowa Kirin Co., Ltd.

# Strong Growth Expected in the msAD Markets Driven by increasing penetration of biologics and the introduction of novel therapies



## Atopic Dermatitis Market Overview



## Atopic Dermatitis Market Outlook

Estimated U.S. AD patient 12y+ population

>23 million

Biologic penetration in the U.S.



15- 20%

Projected sales growth

Over 15%

AT\*-treated # of Patients in U.S.\*\*

400-450K

2026

800-850K

2030 and beyond

6 therapies launched to date

- Dupixent
- Adbry
- Rinvoq
- Cibinqo
- Nemluvio
- Ebglyss

- Rocatinlimab
- Amlitelimab
- Zumilokibart
- Temtokibart
- Rezpegaldesl eukin

~75% anticipated increase in AT treated population from 6 to 10+ products launched based on similarities with psoriasis market

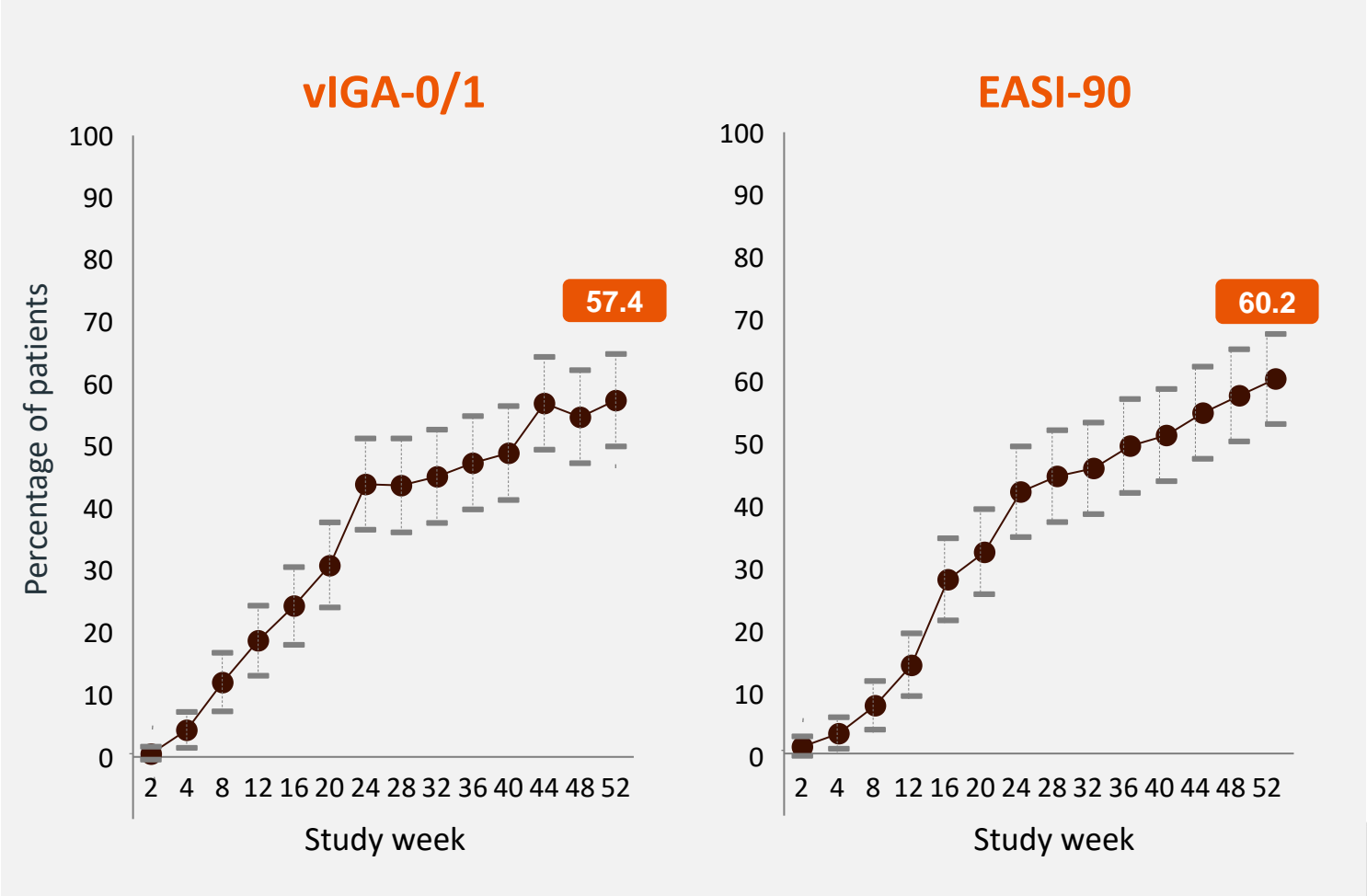
SOURCE: National Eczema Association; Asthma and Allergy Foundation of America; US Census Data; WHO, CDC, analyst research. FDA labels; corporate presentations; Clinicaltrials.gov; Allergy& Asthma Network; Datamonitor; Chan et al., J Am Acad Dermatol (2025); Hanifin et al., Dermatitis (2007); Silverberg et al., J Allergy Clin Immunol (2013); Datamonitor; Therapeutic Categories Outlook, TD Cowen (2024); Gorritz et al., J Derm Treat (2022); Heratizadeh et al., J Eur Acad Dermatol Venereol (2024); Lio et al., J Drugs Dermatol (2023); Fuxench et al., J Inv Dermatol(2019); Boytsov et al., J Derm Treat (2022); \* Advanced Therapy, \*\* Based on L.E.K. epidemiology assessment

# Rocatinlimab delivers progressive increases in the proportion of patients achieving deep responses through Week 52

ROCKET-ORBIT Topline: 52-week Open Label Adolescent Trial\*



- Safety results are consistent with those observed in the ROCKET 24-week and 56-week adult trials.
- The most frequent TEAE in ROCKET-ORBIT were headache, pyrexia, aphthous ulcer, upper respiratory tract infection, and nasopharyngitis.
- Low discontinuation rate due to adverse events.



AD = atopic dermatitis; AU = aphthous ulcers; vIGA-AD = Validated Investigator's Global Assessment for Atopic Dermatitis; EASI = Eczema Area and Severity Index; TEAE = Treatment-Emergent Adverse Event

# A Robust Launch Readiness Upon Regulatory Approval

## **Kyowa Kirin has established operations in Japan, U.S., and Europe with proven track records**

- Japan: Strong track record in dermatology
- U.S. and Europe: Excellent core teams across Sales, Marketing, Market Access, Medical, Patient Support; proven success with Crysvita and Poteligeo

## **U.S. Dermatology Launch Preparation**

- Multi-year preparation for co-promotion with Amgen
- Core functional teams already in place
- Continued investment to ensure readiness for potential approval and launch

## **Robust Manufacturing Capabilities Established**

- Combines Amgen's world-class manufacturing capability with Kyowa Kirin's global supply infrastructure to ensure stable and reliable product supply

# This transition will allow Kyowa Kirin to bring Rocatinlimab with the highest priority and urgency to patients around the world

Item	Original Agreement	After Original Agreement Termination
<b>Market Authorization Holder</b>	Amgen	Kyowa Kirin
<b>Manufacturing</b>	Amgen	Amgen will provide transitional long-term manufacturing and supply of rocatinlimab to Kyowa Kirin
<b>Development</b>	Led by Amgen	Led by Kyowa Kirin with certain transition services from Amgen
<b>Commercialization</b>	Japan: Kyowa Kirin US: Amgen (Kyowa Kirin co-promotion) Europe/Asia: Amgen (Kyowa Kirin retains co-promotion rights)	Japan & US: Kyowa Kirin Europe/Asia: Kyowa Kirin explores all options

# Impact on P&L: Short-term cost increase, but substantially beneficial over the mid to long term

Item	Original Agreement	After Original Agreement Termination
Revenue	Kyowa Kirin receives double-digit % royalty	Kyowa Kirin records sales revenue
COGS	—	Amgen supplies products at an agreed-upon price
SG&A Expenses	Shared equally by both companies	100% borne by Kyowa Kirin
R&D Expenses	Shared equally by both companies	100% borne by Kyowa Kirin Service fee payment to Amgen for transition support (FY2026-2027)

## Future Prospects

**Peak Sales Potential**

Over ¥200 billion

**Profit Contribution Timing**

2028

# Rocatinlimab: Pioneering a Novel Treatment Paradigm Through T-cell Rebalance

- Directly targets a root cause of inflammation and chronicity to potentially achieve deeper and durable improvement
- Potential to expand to other inflammatory diseases with significant unmet need

## Moderate-to-Severe Atopic Dermatitis

 Patients **16 million**
 Existing Market Size **JPY 1 trillion~**



P3 Study (ROCKET program) ongoing



## Prurigo Nodularis

 Patients **1 million**
 Existing Market Size **JPY 0.5-1 trillion**



P3 Study Enrollment Complete

## Moderate-to-Severe Asthma

 Patients **13.5 million**
 Existing Market Size **JPY 1 trillion~**



P2 Study Enrollment Complete

**Kyowa Kirin is fully committed to bringing rocatinlimab to patients worldwide with the highest priority and urgency**

**This is a catalyst for accelerated growth and the gateway to our next chapter**

**KYOWA KIRIN**