News release

Kyowa Kirin Announces Late-Breaking Abstract Presentation at the American Academy of Dermatology Annual Meeting 2025

Tokyo, Japan, February 27, 2025 -- Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that results of the Phase 3 ROCKET HORIZON trial of rocatinlimab, an investigational therapy targeting the OX40 receptor (OX40R) in patients with moderate-to-severe atopic dermatitis (AD), will be presented at the American Academy of Dermatology (AAD) 2025 Annual Meeting to be held in Orlando, Florida from March 7-11, 2025.

AD, a chronic, heterogeneous, inflammatory disease characterized by skin redness, pruritus, and pain, is driven by skin barrier disruption and T cell–dependent inflammatory pathways. Expansion of OX40R+ pathogenic T cells leads to T-cell imbalance, a root cause of inflammatory diseases including AD.

Title:	Rocatinlimab Significantly Improved Clinical Signs and Symptoms by Targeting OX40R+ T cells in Patients with Moderate-to-Severe Atopic Dermatitis: Results from the Phase 3 ROCKET HORIZON Trial
Presenter:	Emma Guttman-Yassky, MD, PhD
Date:	Saturday, March 8th
Time:	1-4 pm EST
Location:	Orange County Convention Center, Chapin Theater Level 2, Orlando, Fla.

ROCKET HORIZON and the ROCKET Phase 3 Program

ROCKET HORIZON is a Phase 3, randomized, placebo-controlled, double-blind trial assessing the efficacy, safety and tolerability of rocatinlimab monotherapy in adults with moderate to severe atopic dermatitis. The trial includes 726 adult patients who were randomized to receive rocatinlimab or placebo administered through a subcutaneous injection every four weeks for 24 weeks with a loading dose at week two. Key endpoints were assessed at week 16 and week 24. Co-primary endpoints for the trial are achievement of a Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™) score of 0 (clear) or 1 (almost clear) with a ≥ 2-point reduction from baseline at week 24 and achievement of ≥ 75% reduction from baseline in Eczema Area and Severity Index score (EASI-75) at week 24. (In the US, revised Investigator Global Assessment (rIGA) replaces vIGA as co-primary endpoint). Key secondary endpoints assess the

impact of rocatinlimab on itch, sleep, and quality of life as well as safety and tolerability.
ROCKET is a comprehensive, global Phase 3 clinical trial program comprised of eight studies intended to establish the safety and efficacy profile of rocatinlimab in adults and adolescents with moderate to severe atopic dermatitis (AD) as well as multiple dosing regimens.

About Moderate to Severe Atopic Dermatitis

Atopic dermatitis, the most common form of eczema, is a chronic inflammatory disease that causes excessively dry, itchy skin that can be painful. People with moderate to severe atopic dermatitis experience chronic symptoms, intensified by unpredictable flare-ups that can be painful and disruptive to everyday life. Almost half of these patients report severe itching, leading to repeated scratching which can cause the skin to thicken and become vulnerable to infection. Atopic dermatitis (all severities) affects 15-20% of children and up to 10% of adults. T-cell imbalance is a root cause of atopic dermatitis, contributing to clinical manifestations including the disease's recurring, unpredictable symptoms.

About Rocatinlimab

Rocatinlimab is an anti-OX40 human monoclonal antibody being investigated for the treatment of moderate to severe atopic dermatitis. Rocatinlimab has the potential to be the first and only T-cell rebalancing therapy that inhibits and reduces pathogenic T cells by targeting the OX40 receptor. OX40 is a co-stimulatory receptor responsible for driving systemic and local inflammatory responses in atopic dermatitis and other conditions. It has been reported that effector T cells expressing OX40 are present in the lesions of patients with atopic dermatitis and are critical in the disease pathophysiology.

Rocatinlimab is also being studied for moderate to severe uncontrolled asthma, prurigo nodularis and potentially other conditions where T-cell imbalance is a root cause of inflammation. The initial antibody was discovered in collaboration between Kyowa Kirin and La Jolla Institute for Immunology.

Rocatinlimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by the U.S. FDA or any other regulatory authority.

Amgen and Kyowa Kirin Collaboration

On June 1, 2021, Kyowa Kirin and Amgen entered into an agreement to jointly develop and commercialize rocatinlimab. Under the terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for KHK4083/AMG 451 for all markets globally, except Japan, where Kyowa Kirin will retain all rights. If approved, the companies will co-promote the asset in the United States and Kyowa Kirin has opt-in rights to co-promote in certain other markets including Europe and Asia.

About Kyowa Kirin

Kyowa Kirin aims to discover and deliver novel medicines and treatments with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, we have invested in drug discovery and biotechnology innovation for more than 70 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients with high unmet medical needs, such as bone & mineral, intractable hematological diseases/hemato oncology, and rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites us across the globe. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com.