News release

Kyowa Kirin to Regain Control of Rocatinlimab Development and Commercialization Program, Demonstrating Strong Commitment to Address High Unmet Medical Need in Atopic Dermatitis

- ***Kyowa Kirin affirms commitment to developing rocatinlimab as a life changing differentiated asset with significant market potential.***
- ***Rocatinlimab's novel approach as an investigational, T-cell rebalancing therapy directly targeting the OX40 receptor expressed on pathogenic T-cells shows potential to deliver long-term disease control in patients with moderate-to-severe atopic dermatitis (msAD).***
- ***Regulatory submission is planned first half of 2026***

TOKYO AND PRINCETON, Japan and the U.S., 30 January 2026 -- Kyowa Kirin Co., Ltd. (TSE:4151, Kyowa Kirin), a Japan-based global specialty pharmaceutical company, announced the termination of the current rocatinlimab development and commercialization collaboration with Amgen. Kyowa Kirin will control of the global rocatinlimab program, including regulatory filings and future commercialization. This business decision is the result of a strategic portfolio prioritization by Amgen. The companies are initiating a smooth and orderly transition of the program, with a focus on ensuring continuity for participants currently enrolled in clinical trial programs. Amgen, who has partnered with Kyowa Kirin on numerous investigational therapies over 41 years, will continue to manufacture rocatinlimab.

"Kyowa Kirin is confident in the potential of rocatinlimab to address critical unmet needs for patients with moderate-to-severe atopic dermatitis, who are looking for new long-lasting options that may address the chronic nature of unpredictable flares," said Abdul Mullick, Ph.D., President and Chief Operating Officer of Kyowa Kirin. "Rocatinlimab's science and its highly differentiated mechanism of action targeting the OX40 receptor make it a potentially unique treatment option. We are excited to build on the strong clinical program we have established and apply our extensive clinical and commercial expertise to help make patients smile with what is a key strategic priority for Kyowa Kirin going forward."

In November 2025, landmark findings from the Phase 3 ROCKET-IGNITE and ROCKET-HORIZON studies in nearly 1,500 adults with msAD were published in The Lancet[1]. Both studies evaluated rocatinlimab monotherapy and met all co-primary and key secondary endpoints, including the US regulatory submission requirement, the revised Investigator's Global Assessment (rIGA) score of 0/1 (defined as achieving a vIGA-AD score of 0 [clear skin] or 1 [almost clear skin] with only presence of barely perceptible erythema and ≥2-point reduction from baseline.) For the more stringent rIGA score of 0 or 1 endpoint, patients with a score of 1 could not have any induration, papulation, or lichenification. Previously announced topline results from the primary analysis of the long-term safety extension study, ASCEND, demonstrated the potential for long-term therapeutic effect and extended dosing. The most frequent treatment-emergent adverse events (AEs) in adults (≥ 5 per 100 patient-years in any of the rocatinlimab groups and greater than placebo), included upper respiratory infections (including nasopharyngitis and pharyngitis), aphthous ulcers, headache, influenza, cough and rhinitis, which were

observed in previous ROCKET trials. Results from this trial will be presented at an upcoming medical conference.

Rocatinlimab was discovered and advanced by Kyowa Kirin, drawing on the company's deep expertise in immunology and antibody engineering. It reflects the strength of the company's internal R&D capabilities and long-term investment in science that targets the underlying drivers of chronic inflammatory disease, not just its symptoms. The Phase 3 ROCKET program is a comprehensive clinical development program in atopic dermatitis, which consists of eight pivotal studies, evaluating both long-term efficacy and safety. The program includes diverse patient populations, including adults and adolescents, systemic treatment–naïve patients, as well as those previously treated with biologics and JAK inhibitors, underscoring its potential as a meaningful treatment option for people living with atopic dermatitis across a broad range of clinical scenarios.

"Based on the data available to date, rocatinlimab has demonstrated a generally favorable benefit–risk profile across its Phase 3 clinical program, in which more than 3,300 patients with moderate-to-severe atopic dermatitis have been enrolled," said Takeyoshi Yamashita, Ph.D., Executive Vice President and Chief Medical Officer of Kyowa Kirin. "The potential to provide a meaningful and sustained clinical response may be important, particularly for patients who continue to experience symptoms despite existing therapies. We will continue to evaluate rocatinlimab's clinical profile as development progresses and look forward to presenting additional data from the program at future medical congresses."

The company plans to file for regulatory approval in the U.S. first, followed by Japan, before expanding to other markets across the world as appropriate.

Reference :

1. Emma Guttman-Yassky, Kenji Kabashima, Margitta Worm, et al. 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. The Lancet. 2026; 407 (10523): 53-66, ISSN 0140-6736.

About Rocatinlimab

Rocatinlimab is an anti-OX40 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 effector and memory 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 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.

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/haemato-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: www.KyowaKirin.com