Kyowa Kirin Announces Top-line Data from Rocatinlimab Phase 3 ROCKET HORIZON Trial for Adults with Moderate to Severe Atopic Dermatitis

- **Rocatinlimab Met Co-Primary Endpoints of vIGA-AD™ 0/1 with a ≥ 2-Point Reduction from Baseline, EASI-75, and All Key Secondary Endpoints**
- **HORIZON is the First of Eight Phase 3 Trials in the ROCKET Program**

Tokyo, Japan, September 25, 2024 -- Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced top-line results of the Phase 3 ROCKET HORIZON trial of rocatinlimab, an investigational therapy targeting the OX40 receptor. HORIZON met its co-primary endpoints: 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 [19.3% rocatinlimab vs. 6.6% placebo (12.8% difference, p<0.001)] and achievement of ≥ 75% reduction from baseline in Eczema Area and Severity Index score (EASI-75) [32.8% rocatinlimab vs. 13.7% placebo (19.1% difference, p<0.001)], both at week 24. The trial also met the revised Investigator Global Assessment (rIGA 0/1) *, a more stringent measure of efficacy than vIGA 0/1 based on a narrower definition of 1 (almost clear), at week 24 [16.4% rocatinlimab vs. 4.9% placebo (11.5% difference, p<0.001)].

HORIZON is a Phase 3, 24-week, randomized, placebo-controlled, double-blind study to assess the efficacy, safety and tolerability of rocatinlimab monotherapy in adults with moderate to severe atopic dermatitis (eczema). HORIZON is one of eight studies in the global ROCKET Phase 3 clinical trial program.

The study also reached statistically significant differences from placebo for all key secondary endpoints, which include measurements of skin clearance (vIGA 0/1 and EASI-75 at week 16 and EASI-90 at week 24), the Pruritus Numeric Rating Scale, Atopic Dermatitis Skin Pain Scale, Dermatology Quality of Life Index, and severity scores of hand atopic dermatitis and facial atopic dermatitis.

Overall safety findings in ROCKET HORIZON were comparable to those seen in the Phase 2b study. [1]

* rIGA 0/1 defined as achieving vIGA-AD 1 response with presence of only barely perceptible erythema or vIGA-AD 0 response and ≥ 2-point reduction from baseline

"We are very pleased to have achieved statistically significant efficacy results over placebo which are consistent for co-primary endpoints and all key secondary endpoints. We look forward to further demonstrating that rocatinlimab, a potential T-cell rebalancing therapy, may help patients with moderate to severe atopic dermatitis as a new therapeutic option. We anticipate getting additional data from the ROCKET program and fully understanding the value rocatinlimab can deliver to patients." said Takeyoshi Yamashita, Ph.D., senior managing executive officer and chief medical officer at Kyowa Kirin.

Detailed results of HORIZON will be provided at a future medical congress. Amgen and Kyowa Kirin plan to review HORIZON and forthcoming results from the other seven studies in the ROCKET program as part of ongoing discussions with global regulatory authorities.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

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.[2] 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.[3,4] People with moderate to severe atopic dermatitis experience chronic symptoms, intensified by unpredictable flare-ups that can be painful and disruptive to everyday life.[4] Almost half of these patients report severe itching, leading to repeated scratching which can cause the skin to thicken and become vulnerable to infection.[5,6,7] Atopic dermatitis (all severities) affects 15-20% of children and up to 10% of adults.[8] T-cell imbalance is a root cause of atopic dermatitis, contributing to clinical manifestations including the disease's recurring, unpredictable symptoms.[9]

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.[9] 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.[10,11]

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.

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