News release

Kyowa Kirin Will Present Phase 2b Post-hoc Analysis and Symposium at the American Academy of Dermatology Annual Meeting 2024

Princeton, NJ and TOKYO, March 8, 2024- Kyowa Kirin Co., Ltd. (TSE: 4151) today announces that post-hoc analysis data from the Phase 2b study of rocatinlimab (AMG 451/KHK4083), an investigational product currently being evaluated for the treatment of patients with moderate-to-severe atopic dermatitis (msAD), will be presented at the American Academy of Dermatology (AAD) 2024 Annual Meeting to be held in San Diego from March 8-12, 2024.
Atopic Dermatitis (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; the relative contribution of different inflammatory pathways in driving disease can vary across populations and within individuals over time.

Patients with msAD continue to need additional treatment options due to ongoing symptoms like pruritis and scratching. Thus, there remains a need for therapeutic options that can deliver benefits across a heterogeneous AD patient population.

e-poster: Rocatinlimab Significantly Improves Clinical Responses in Patients with Moderate-to-Severe Atopic Dermatitis by Week 2 in a Randomized Double-Blind Placebo-Controlled Phase 2b Study, will be available starting Friday, March 8th
Author: Emma Guttman- Yassky, MD, PhD *et al*

A multicenter, randomized, double-blind, placebo-controlled Phase 2b trial (NCT03703102) evaluated rocatinlimab for msAD. Primary endpoint achievement (Week 16 Eczema Area and Severity Index [EASI]) has been presented. Randomized patients (1:1:1:1:1) received subcutaneous rocatinlimab 150mg/600mg every 4 weeks (Q4W) or 300mg/600mg every 2 weeks (Q2W) for 36 weeks, or placebo (Weeks 0–18) followed by rocatinlimab (600mg Q2W Weeks 18–36). All cohorts had 20-week off-treatment follow-up.

The current post-hoc analysis (267 patients; rocatinlimab: n=210, placebo: n=57) of the phase 2b study evaluated EASI and pNRS between baseline and week 16 to investigate early clinical response. Difference in least squares mean of percent change from baseline between rocatinlimab cohorts and placebo were assessed. The post hoc analysis showed statistically significant improvement in pNRS scores for patients in the treatment arms compared to placebo.

Pruritis improved with rocatinlimab by Week 2 in all cohorts (−18.40% to −21.96%; p≤0.018) except 600mg Q4W (−9.66%; p=0.208), and in all cohorts by Week 4 (−15.70% to −27.19%; p≤0.045); EASI improvements *vs.* placebo were significant in all rocatinlimab cohorts by Week 6 (−20.50% to −32.13%; p≤0.001), and the 300mg & 600mg Q2W cohorts by Week 2 (−13.27% and −13.66%; p≤0.028). Further improvements *vs.* placebo continued to Week 16; improvements *vs.* baseline continued in all active cohorts to Week 36 and were maintained for 20 weeks off-treatment.

Adverse events reported were generally similar between rocatinlimab groups. Common adverse events during the double-blind period included fever, chills, headache, aphthous ulcers and nausea.

An Amgen & Kyowa Kirin co-sponsored symposium:
From Heterogeneity Comes New Insights: Exploring the role of T Cells and OX40 in Atopic Dermatitis
Presenters: Chih-ho Hong, MD, Clinical Assistant Professor at the University of British Columbia
Raj Chovatiya, MD, PhD, Assistant Professor of Dermatology at the Northwestern University Feinberg School of Medicine in Chicago, Illinois
Date: Saturday, March 9th, 11:15 am
Location: Exhibit Hall, Theater 2

About rocatinlimab
Rocatinlimab (AMG 451/KHK4083), an investigational product, is a potential first-in-class anti-OX40 monoclonal antibody that is being studied for its ability to inhibit and reduce the number of OX40+ pathogenic T cells responsible for driving systemic and local AD inflammatory responses.
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. The initial antibody was discovered in collaboration between Kyowa Kirin and La Jolla Institute for Immunology.

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.