News release

Kyowa Kirin Will Present New Rocatinlimab Phase 2b Data in Atopic Dermatitis at the American Academy of Dermatology Annual Meeting 2023

BEDMINSTER, NJ and TOKYO, March 17, 2023-Kyowa Kirin Co., Ltd. (TSE: 4151) today announces that data from the Phase 2b study of rocatinlimab (KHK4083/AMG 451), an investigational product in patients with moderate-to-severe atopic dermatitis will be presented in two posters at the upcoming American Academy of Dermatology (AAD) 2023 Annual Meeting to be held March 17-22, 2023, in New Orleans, Louisiana, USA.

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.

Often beginning in childhood, AD affects 15-20% of children and up to 10% of adults, making it the 15th most common nonfatal disease. AD is prevalent in countries globally, with approximately 1 in 3 people with AD worldwide classifying their disease as moderate to severe.

“We are pleased to share this additional data from the rocatinlimab Phase 2b study,” said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. “We hope that a better understanding of the physiological functions associated with OX40, in AD has the potential to lead to the creation of future treatment options for patients suffering from this disease.”

Title: Rocatinlimab demonstrates a significant reduction in IgE concentrations in addition to clinical efficacy measures in patients with moderate–severe atopic dermatitis (msAD) in a randomised, double-blind, placebo-controlled Phase 2 trial
Author: Emma Guttman-Yassky, MD, PhD., Camilla Chong, MD, DipPM, MFPM, Ehsanollah Esfandiari, MD, PhD.
Presentation: Friday, March 17th 2:55 pm CDT
Location: Ernest N. Morial Convention Center (Level 1, Hall E, Poster Center 2)

This double-blind, placebo-controlled Phase 2 trial (NCT03703102) randomized patients (n=274) 1:1:1:1:1 to subcutaneous rocatinlimab 150 or 600mg every 4 weeks (Q4W), 300 or 600mg every 2 weeks (Q2W) for 36 weeks, or placebo (Weeks 0–18; rocatinlimab 600mg Q2W Weeks 18–36), and a 20-week off-treatment follow-up period (Week 56).

Overall, 267 patients comprised the full analysis set; rocatinlimab: n=210 (78.7%), placebo: n=57 (21.3%). Rocatinlimab decreased mean serum IgE concentrations below baseline by Week 16($P \leq 0.0005$). These reductions continued to Week 36 and were maintained to Week 56.

In the placebo group, mean serum IgE concentrations increased to Week 16. After switching to 600mg Q2W at Week 18, concentrations decreased to Week 36 and continued to decrease below baseline to Week 56. Mean IgE reductions at Weeks 16, 36 and 56 were: -19.7%, -38.9%, -26.7% (150mg Q4W); -17.1%, -39.5%, -46.5% (600mg Q4W); -18.6%, -44.8%, -10.9% (300mg Q2W); -16.9%, -48.6%, -58.5% (600mg Q2W); 34.2%, -8.8%, -29.1% (placebo/600mg Q2W).

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.

Title: Rocatinlimab demonstrates improvements in patient-reported outcomes in adult patients with moderate–severe atopic dermatitis in a Phase 2 trial
Author: Eric Simpson, MD, MCR, Angela Williams PhD., Camilla Chong, MD, DipPM, MFPM, Ehsanollah Esfandiari, MD, PhD.
Presentation: Friday, March 17th 2:05pm CDT
Location: Ernest N. Morial Convention Center (Level 1, Hall E, Poster Center 2)

This Phase 2b, multicenter, double-blind, placebo-controlled trial, randomly assigned adult patients to subcutaneous rocatinlimab every 4 weeks (Q4W; 150 or 600mg) or every 2 weeks (300 or 600mg) or placebo, for 18 weeks, followed by an 18-week active treatment extension and a 20-week off-treatment follow-up (Week 56). Patient-reported outcomes (PROs) included pruritus and sleep disturbance (SD) scores, measured using a (Numerical Rating Scale (NRS), and the Dermatology Life Quality Index (DLQI). These were assessed at baseline to Week 16 and until Week 56.

Overall, 267 patients were randomized (rocatinlimab: n=210; placebo: n=57). From baseline to Week 16, percentage reductions in NRS-pruritus ($p \leq 0.029$) and NRS-SD scores ($p \leq 0.025$) were greater in the rocatinlimab groups compared with placebo. Improvement in pruritus and SD scores in the rocatinlimab groups was maintained until Week 56.

Greater reductions in DLQI scores in the rocatinlimab groups compared with placebo up to Week 16 (all $p<0.05$) were observed; scores continued to improve in the rocatinlimab groups to Week 36 and were maintained during the off-treatment period.

Treatment emergent adverse events (TEAEs) were reported for 175 of 216 (81.0%) subjects in rocatinlimab groups and 41 of 57 (71.9%) subjects in the placebo group in the initial 18-week double-blind treatment period. The most frequent TEAEs, reported in ≥ 10% of subjects in the combined rocatinlimab groups were nasopharyngitis, worsening of AD, pyrexia and chills. TEAEs of pyrexia and chills were mild to moderate in intensity and were mostly observed only after the first administration of rocatinlimab without resulting treatment discontinuation. There were no hypersensitivity reactions or deaths.

Along with Amgen, Kyowa Kirin is also co-sponsoring a symposium. **Uncovering the Critical Role of OX40 Signaling In Orchestrating Inflammation in Atopic Dermatitis** will be presented by Jonathan Silverberg, MD, PhD., MPH today from 12-1 PM CDT in Product Theater 1.

About rocatinlimab
Rocatinlimab (KHK4083/AMG451) an investigational, is a potential first-in-class, anti-OX40 monoclonal antibody that inhibits and reduces 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 US Research and La Jolla Institute for Immunology.

About Kyowa Kirin
Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a more than 70-year heritage, we apply cutting-edge science including expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com/.

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.