News Release

AMGEN AND KYOWA KIRIN PROVIDE TOP-LINE RESULTS FROM ROCATINLIMAB PHASE 3 IGNITE STUDY IN ADULTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

Ongoing Studies are Evaluating Long-Term Maintenance and Durability

THOUSAND OAKS, Calif., and TOKYO (March 8, 2025) – Amgen (NASDAQ:AMGN) and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151) today announced new results from the ongoing ROCKET Phase 3 clinical trial program evaluating rocatinlimab, an investigational T-cell rebalancing therapy targeting the OX40 receptor, in moderate to severe atopic dermatitis (AD).

The IGNITE study, which evaluated two dose strengths of rocatinlimab, met its co-primary endpoints and all key secondary endpoints, achieving statistical significance for both rocatinlimab dose strengths versus placebo. IGNITE was a 24-week, randomized, placebo-controlled, double-blind study to assess the efficacy, safety and tolerability of rocatinlimab monotherapy every 4 weeks in 769 adults with moderate to severe AD, including patients previously treated with a biologic or systemic Janus kinase (JAK) inhibitor medication.

At week 24, 42.3% of patients in the higher dose group achieved ≥75% reduction from baseline in Eczema Area and Severity Index score (EASI-75), a 29.5% difference vs. placebo ($p < 0.001$). In the lower dose group, 36.3% of patients achieved EASI-75, a 23.4% difference vs. placebo ($p < 0.001$).

In the higher dose group, 23.6% of patients achieved a validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD™) score of 0 (clear) or 1 (almost clear) with a ≥2-point reduction from baseline (vIGA-AD 0/1) at week 24, representing a 14.9% difference vs. placebo ($p < 0.001$). In the lower dose group, 19.1% of patients achieved this endpoint, a 10.3% difference vs. placebo ($p = 0.002$).

In addition, IGNITE met the endpoint of revised Investigator's Global Assessment (rIGA™) score of 0/1 with a ≥2-point reduction from baseline, a more stringent measure of efficacy than vIGA-AD 0/1. At week 24, 22.7% of patients in the higher dose group achieved this endpoint, a 14.4% difference vs. placebo ($p < 0.001$). In the lower dose group, 16.3% of patients achieved this endpoint, an 8.0% difference vs. placebo ($p = 0.01$).

Across ROCKET program results to date, safety findings were generally consistent with the safety profile of rocatinlimab previously observed. The most frequent treatment-emergent adverse events (≥5%) with higher observed proportion in rocatinlimab groups were pyrexia, chills and headache. A higher number of patients receiving rocatinlimab vs. placebo experienced gastrointestinal ulceration events, with an overall incidence of less than 1%.[1]

"Many patients with moderate to severe atopic dermatitis struggle with chronic, life-disrupting symptoms," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "Even with currently available therapies, they may fail to reach or maintain treatment goals. We're pleased with ROCKET program results to date, which support the potential of rocatinlimab as a new treatment option."

"Looking ahead, the ASCEND trial will explore the effects of rocatinlimab beyond 24 weeks, including maintenance of clinical response with continued treatment or withdrawal, and the ASTRO and ORBIT trials will evaluate rocatinlimab in adolescent patients," said Takeyoshi Yamashita, Ph.D., senior managing executive officer and chief medical officer at Kyowa Kirin. "These findings will help define the full profile of rocatinlimab and its potential to inhibit and reduce pathogenic T cells."

The ROCKET program is also informed by the results of the SHUTTLE and VOYAGER studies. The SHUTTLE study, which evaluated two dose strengths of rocatinlimab in combination with topical corticosteroids (TCS) and/or topical calcineurin inhibitors (TCI) in 746 adults using the same co-primary endpoints as IGNITE, met its co-primary endpoints and all key secondary endpoints, achieving statistical significance for both rocatinlimab dose strengths plus TCS/TCI versus placebo plus TCS/TCI at week 24.

For EASI-75, 52.3% of patients in SHUTTLE's higher dose group achieved the endpoint, a 28.7% difference vs. placebo ($p < 0.001$), while 54.1% of patients in the lower dose group achieved the endpoint, a 30.4% difference vs. placebo ($p<0.001$).

For vIGA-AD 0/1, 26.1% of SHUTTLE patients in the higher dose group achieved the endpoint, a 13.8% difference vs. placebo ($p<0.001$). In the lower dose group, 25.8% of patients achieved the endpoint, a 13.5% difference vs. placebo ($p<0.001$).

For rIGA 0/1, 23.3% of SHUTTLE patients in the higher dose group achieved the endpoint, an 11.5% difference vs. placebo ($p<0.001$). In the lower dose group, 22.7% of patients achieved the endpoint, a 10.9% difference vs. placebo ($p = 0.002$). The higher rocatinlimab dose used in IGNITE and SHUTTLE was identical to the dose used in HORIZON.

The VOYAGER study successfully demonstrated that rocatinlimab does not interfere with responses to tetanus and meningococcal vaccinations.

HORIZON, top-line results of which were previously shared, will be presented as a late-breaking abstract at the 2025 American Academy of Dermatology Annual Meeting.

Results from IGNITE, SHUTTLE and VOYAGER will be presented at upcoming congresses or published in peer-reviewed journals.

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

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.[3] 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.[3,7]

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.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, YouTube and Threads.

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.

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.

References

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