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

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Ongoing Studies are Evaluating Long-Term Maintenance and Durability

THOUSAND OAKS, Calif., and TOKYO, March 8, 2025 /PRNewswire/ -- 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.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), Amgen's acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on Amgen's acquisition-related expenses going forward), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on Amgen's business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends

toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for Amgen's manufacturing activities, the distribution of Amgen's products, the commercialization of Amgen's product candidates, and Amgen's clinical trial operations, and any such events may have a material adverse effect on Amgen's product development, product sales, business and results of operations. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology Amgen has acquired, may not be successful. There can be no guarantee that Amgen will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. Amgen may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of Amgen's information technology systems could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business and operations may be negatively affected by the failure, or perceived failure, of achieving its environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect Amgen's business and operations. Global economic conditions may magnify certain risks that affect Amgen's business. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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