



## AMGEN AND KYOWA KIRIN ANNOUNCE TOP-LINE RESULTS FROM ROCATINLIMAB PHASE 3 ASCEND LONG-TERM EXTENSION STUDY IN ADULTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

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THOUSAND OAKS, Calif. and TOKYO, Sept. 8, 2025 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and Kyowa Kirin Co., Ltd. (TSE: 4151) today announced preliminary top-line results from the ASCEND study evaluating rocatinlimab, an investigational T-cell rebalancing therapy targeting the OX40 receptor, in adults and adolescents with moderate to severe atopic dermatitis (AD).

The ongoing ASCEND study, which includes approximately 2,600 patients, is designed to evaluate the long-term safety and efficacy of rocatinlimab (150 mg and 300 mg) administered every four or eight weeks in individuals who completed a previous ROCKET program trial (IGNITE, HORIZON, SHUTTLE, ASTRO, ORBIT or VOYAGER). This analysis focused on adults who completed the first 24 weeks of therapy in a previous ROCKET trial and continued in ASCEND for an additional 32 weeks.

The primary endpoint of the study was to evaluate the long-term safety of rocatinlimab and is descriptive in nature. The most frequent treatment-emergent adverse events (AEs) in adults ( $\geq 5$  per 100 patient-years in any of the rocatinlimab groups and greater than placebo), included upper respiratory infections (including nasopharyngitis and pharyngitis), aphthous ulcers, headache, influenza, cough and rhinitis, which were observed in previous ROCKET trials. The discontinuation rate due to AEs was low across the adult rocatinlimab treated cohorts.

Across the Phase 3 ROCKET program including ASCEND, the incidence of gastrointestinal ulceration events with rocatinlimab to date is less than 1 per 100 patient-years. The ASCEND study is ongoing and continues to evaluate the long-term safety and efficacy of rocatinlimab up to 104 weeks in adult and adolescent patients with moderate to severe AD.

The secondary endpoints of the study were evaluated in adults who achieved a clinical response (EASI 75 or vIGA-AD 0/1 without rescue use at week 24) in either the HORIZON or IGNITE trials and were re-randomized in the ASCEND study. The majority of patients in this sub-population, who continued receiving rocatinlimab monotherapy either with Q4W or Q8W dosing, reported continued therapeutic benefit at one year of treatment across measures of improvement in skin clearance, itch, disease extent and severity.

"Atopic dermatitis is a heterogeneous disease where many patients still lack adequate control with current therapies," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "These findings add to our understanding of the role OX40 inhibition can play in addressing the underlying drivers of this chronic disease and provide further information on rocatinlimab's durability of response and long-term safety profile, which we will continue to monitor."

"People with moderate to severe atopic dermatitis are looking for new options to help them achieve and sustain their treatment goals," said Takeyoshi Yamashita, Ph.D., Chief Medical Officer, Kyowa Kirin. "These results mark an important milestone in furthering our understanding of rocatinlimab. The findings from ASCEND characterize rocatinlimab's ongoing therapeutic benefit at one-year of treatment in adult patients with moderate to severe AD, with possible maintenance dosing as infrequently as every eight weeks, following initial 24-week dosing, an approach that may lessen the ongoing burden of treatment. We look forward to sharing further updates."

Amgen and Kyowa Kirin plan to share full results at an upcoming congress or in a peer-reviewed publication.

### About the ASCEND Study and ROCKET Phase 3 Program

The ongoing ASCEND study will continue to evaluate the long-term safety and efficacy of rocatinlimab in adult and adolescent patients with moderate to severe AD for up to two and a half years (inclusive of time in parent studies).

ASCEND is part of the larger ROCKET Phase 3 clinical program. ROCKET is a comprehensive, global Phase 3 clinical program composed of eight studies intended to establish the safety and efficacy profile of multiple dosing regimens of rocatinlimab in adults and adolescents with moderate to severe AD as well as multiple dosing regimens.

### About Moderate to Severe Atopic Dermatitis

Atopic dermatitis, the most common form of eczema<sup>1</sup>, is a chronic inflammatory disease that causes excessively dry, itchy skin that can be painful.<sup>2</sup> People with moderate to severe atopic dermatitis experience chronic symptoms, intensified by unpredictable flare-ups that can be painful and disruptive to everyday life.<sup>3</sup> 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.<sup>4,5</sup> Atopic dermatitis (all severities) affects 15-20% of children and up to 10% of adults.<sup>5</sup> T-cell imbalance is a root cause of atopic dermatitis, contributing to clinical manifestations including the disease's recurring, unpredictable symptoms.<sup>6</sup>

### About Rocatinlimab

Rocatinlimab is an anti-OX40 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 effector and memory 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.<sup>3</sup> 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.<sup>3,6</sup>

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](https://www.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 leads the development, manufacturing, and commercialization for rocatinlimab 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 BeOne Medicines Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), 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 our 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 our 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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our 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 our products and global economic conditions, including those resulting from geopolitical relations and government actions. In addition, sales of our 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, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, 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 our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant

problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our 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 we have acquired, may not be successful. There can be no guarantee that we 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. We 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 our information technology systems could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our sustainability objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our 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. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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