

News release

EMBARGOED UNTIL: 10 pm JST/8 am EST

Kyowa Kirin Announces Discontinuation of Rocatinlimab Clinical Trials

TOKYO AND PRINCETON, Japan and the U.S., 3 March 2026 — Kyowa Kirin Co., Ltd. (TSE:4151, Kyowa Kirin), a Japan-based global specialty pharmaceutical company, today announced the discontinuation of all ongoing clinical trials for rocatinlimab, an investigational anti-OX40 monoclonal antibody being evaluated for potential indications in moderate-to-severe atopic dermatitis, prurigo nodularis, and moderate-to-severe asthma.

This decision was informed by a recent planned safety update from the global rocatinlimab clinical program. Based on this update, Kyowa Kirin and Amgen have concluded that the potential risks may outweigh the benefits for the studied patient populations. This determination reflects the totality of emerging safety information, including previously reported safety risks.

The most recent safety review conducted over the last several weeks identified emerging concerns of malignancies with possible viral or immune-related links. This included one new confirmed case and one suspected case of Kaposi's sarcoma, in addition to the previously confirmed case, suggesting a potential mechanistic link to OX40 pathway modulation. While the overall number of malignancy cases across the program remains below expected background rates, the characteristics of these cases raise a plausible biological concern that cannot be excluded.

“This is deeply disappointing news, as we had hoped to bring a safe and effective treatment to patients. Rocatinlimab has demonstrated durable and clinically meaningful efficacy in moderate-to-severe atopic dermatitis in the ROCKET program. However, the safety profile has evolved, and as patient safety remains our highest priority, we have taken this decisive and cautious step,” said Abdul Mullick, Ph.D., President and Chief Operating Officer of Kyowa Kirin. “Although this outcome is not what we hoped for, our work has not been in vain. The knowledge gained from the program will contribute meaningfully to the broader understanding of the OX40 pathway and future research efforts.”

Both companies are currently notifying clinical trial investigators and regulatory authorities. After trial participants complete required safety follow-up visits, all studies will be formally terminated. The companies will work together to conduct a comprehensive analysis of the full dataset and are committed to providing further updates once data assessments are complete.

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/haemato-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: www.KyowaKirin.com

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CONTACT:

Stacey Minton, stacey.minton@kyowakirin.com (Media, Global)

Hiroki Nakamura, hiroki.nakamura.fp@kyowakirin.com (Media, Japan)

Susan Thiele, susan.thiele.38@kyowakirin.com (Media, U.S.)

Ryohei Kawai, ryouhei.kawai.jh@kyowakirin.com (Investors)