

Rocatinlimab Clinical Program Discontinuation

March 4th , 2026

Representative Director, Chairman, and Chief Executive Officer

Representative Director, President, and Chief Operating Officer

Director, Executive Vice President, and Chief Medical Officer

Managing Executive Officer and Chief Financial Officer

Masashi Miyamoto

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Takeyoshi Yamashita

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 **KYOWA KIRIN**

Overview of Today's Presentation

- In late February, updated safety information from the global rocatinlimab clinical program, including the Phase 3 ROCKET program for moderate-to-severe atopic dermatitis was provided
- Following the planned joint safety evaluation meeting convened based on the latest data, Kyowa Kirin and Amgen concluded that potential risks may outweigh the benefits for patients enrolled in the studies
- On March 3, Kyowa Kirin decided to discontinue all clinical trials of rocatinlimab
- Detailed data from the studies are currently under review, and we will conduct a comprehensive data analysis and provide further updates once the analysis is completed
- No changes will be made to the mid- to long-term financial targets announced on February 9, 2026

Timeline of Events

- September 2025: Safety assessment of malignancies, including one case of Kaposi's sarcoma, showed no causal relationship with rocatinlimab
- January 2026: Rocatinlimab's benefit-risk assessment confirmed a favorable profile
- Late February 2026: Following the Joint Safety Assessment Committee meeting, Kyowa Kirin and Amgen concluded that the potential risks may outweigh the benefits

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

Although the overall number of malignancy cases across the program remains below expected background rates, the characteristics of these cases raised a plausible biological concern that could not be ruled out
- March 3rd, 2026: Kyowa Kirin decided to terminate all rocatinlimab clinical trials

Future Actions

- Clinical trial investigators and regulatory bodies are currently being informed
- All clinical trials will be formally terminated after participating patients complete their safety follow-up
- Kyowa Kirin and Amgen will collaborate to conduct a comprehensive data analysis and provide further updates once the analysis is completed
- The likelihood of resuming development is considered extremely low

Impact on Business Performance

- Short-term profit increase due to elimination of SG&A and R&D expenses related to rocatinlimab
- Certain negative profit impact expected in the medium to long term

■ Estimated Impact on Core Operating Profit

- 2026 : Approx. +¥20~30 billion
- 2027 : Approx. +¥30 billion
- 2028 : Approx. +¥10 billion
- 2029 onwards : Certain negative impact expected

■ Estimated Impact on Net Income for the Current Fiscal Year

- In addition to the impact on core operating profit, closing costs arising from the termination of the clinical trials will be recorded as “other expenses”

■ Revision of FY2026 Earnings Forecast

- Currently under review; revision to the earnings forecast will be disclosed at the time of the Q1 FY2026 earnings announcement

Impact on Mid- to Long-term Financial Targets and Future Management Policy

- No changes to the mid- to long-term financial targets announced in “Vision 2030 and beyond : Our Growth Story” published on February 9, 2026. These remain the targets we aim to achieve.

- Leveraging the following growth drivers, we aim to achieve ROE in the low-teens and a core operating margin of 30% in the early 2030s:
 - Continue robust growth of Crysvida and Poteligeo, with value maximization through lifecycle management initiatives
 - Achieve significant sales and profit growth from expansion of KOMZIFTI’s indication to AML*¹ first-line treatment
 - Advance the development and commercialization of pipeline assets in our focused disease areas, including KK8123, KK2845 and OTL-203
 - Strengthen resource allocation to focused disease areas and accelerate portfolio prioritization centered on delivering Life-changing Value
 - Improve profit margins through cost-structure optimization, including transformation into a more resilient organization through DX/AI initiatives
 - Actively pursue strategic investments to accelerate inorganic growth

*¹ For acute myeloid leukemia with menin dependency



- Contact for Inquiries Regarding This Material -

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