

News release

Final MINT Study Results Strengthen Real-World Evidence for Mogamulizumab (Poteligeo®) in patients with Mycosis Fungoides and Sézary Syndrome

- *Final analysis of 109 patients from 18 German centres demonstrates durable treatment outcomes in routine clinical practice.¹*
- *Median time-to-next-treatment (TTNT), the study's primary endpoint, was 14.9 months, alongside a 62.4% best overall response rate, 20.2-month overall median progression-free survival and improved quality of life from baseline reported in routine care.¹*
- *Exploratory analyses show meaningful responses in clinically relevant subgroups, including large cell transformation, folliculotropic mycosis fungoides and mogamulizumab-associated rash status, supporting individualised treatment for patients with mycosis fungoides and Sézary syndrome.¹*

Galashiels and Marlow, United Kingdom, 12 October, 2026 – Kyowa Kirin International plc, a wholly owned subsidiary of Kyowa Kirin Co., Ltd. (TSE:4151, Kyowa Kirin), today announced final results from the German MINT study evaluating mogamulizumab in patients with mycosis fungoides (MF) and Sézary Syndrome (SS). Presented at the European Organisation for Research and Treatment of Cancer Cutaneous Lymphoma Tumour Group (EORTC-CLTG) Annual Meeting 2026 in Berlin, Germany, the findings represent one of the largest real-world evaluations of mogamulizumab in Germany and add to the growing body of evidence supporting its use in routine clinical practice.¹⁻³

Conducted as a company-sponsored, multicentric, non-interventional, combined retro-prospective real-world study across 18 centres throughout Germany, MINT brought together cutaneous T-cell lymphoma (CTCL) specialists to evaluate treatment outcomes with mogamulizumab in a real-world setting, with time-to-next-treatment (TTNT) as the study's primary endpoint.¹ The study captured a broad and heterogeneous patient population, including clinically relevant subgroups such as patients with large cell transformation (LCT) and folliculotropic mycosis fungoides (fMF), and stratified by disease stage and mogamulizumab-associated rash (MAR) status, providing insights that complement evidence generated through controlled clinical studies.^{1,4}

MF and SS are forms of CTCL, a type of non-Hodgkin's lymphoma that manifests on the skin,⁵ though the disease can also involve the blood, lymph nodes and visceral organs.⁶ Symptoms can include persistent, itchy and scaly rashes, changes in skin colour and patches, plaques and/or tumours.⁷ These visible and often difficult-to-hide symptoms can make everyday activities harder and significantly affect patients' quality of life, including their work, relationships and social lives,⁸ and for some patients the disease can progress to affect long-term survival.⁹

"For patients living with mycosis fungoides and Sézary syndrome, understanding how treatments perform outside the controlled setting of clinical trials is critically important. The final MINT results demonstrate meaningful clinical outcomes across a broad patient population treated in routine practice and highlight the value of collaborative real-world research in helping clinicians make informed treatment decisions," said Professor Chalid Assaf, Director of the Department of Dermatology and Venereology, Helios Klinikum Krefeld, Health and Medical University Düsseldorf-Krefeld, Germany.

The final analysis included 109 patients, comprising 56 patients with MF and 53 patients with SS, with a median follow-up of 25.2 months.¹ The majority of patients had advanced disease when

they started treatment, with 83.5% at stage IIB or above.¹ The study demonstrated durable treatment outcomes, reporting a median TTNT of 14.9 months, a best overall response rate of 62.4%, and an overall median progression-free survival of 20.2 months.¹ Median overall survival was not estimable at the time of analysis due to the limited number of deaths observed, despite up to 71 months of follow-up in some cases.¹

Looking more closely at treatment response in clinically relevant patient subgroups, exploratory analyses reported best overall response rates of 54.5% in patients with LCT (n=11; 95% CI: 23.4–83.3) and 50.0% in patients with fMF (n=12; 95% CI: 21.1–78.9). Additional exploratory analyses by disease stage showed best overall response rates of 50% in patients with early-stage disease (n=18; 95% CI: 26.0–74.0) and 64.8% in patients with advanced stage disease (n=91; 95% CI: 54.1–74.6).¹⁰ Disease control rate was also reported in patients with MAR (n=47), at 95.7%.⁴

TTNT is an important measure in real-world clinical practice as it reflects both disease control and the duration of clinical benefit before a patient requires an alternative treatment approach. The study reported a median TTNT of 12.0 months in patients with MF and 20.2 months in patients with SS.⁴ Patients also experienced improvements in quality of life, with median Skindex-29 scores improving by 38.5% from 49.1 at treatment initiation (n=21) to 30.2 at Month 12 (n=7).¹

“MINT provides valuable real-world evidence from Germany on the use of mogamulizumab across the heterogeneous population of patients with mycosis fungoides and Sézary syndrome, including clinically relevant subgroups that are often underrepresented in clinical trials. By evaluating time-to-next-treatment as a clinically meaningful outcome, the study offers practical insights that can support CTCL specialists in making informed, individualised treatment decisions,” said Dr. Azeem Danish, Medical Affairs Director, DACH, Kyowa Kirin.

The investigators concluded that, in a real-world setting, mogamulizumab demonstrated a safety profile comparable to that observed in the pivotal Phase 3 MAVORIC study, while providing clinical benefits in treatment response and quality of life for patients with MF and SS.^{1,5} Grade 3 or higher treatment-related adverse events were reported in 38.5% of patients, most commonly drug eruption and lymphopenia.¹ Serious treatment-related adverse events leading to discontinuation occurred in 22.0% of patients.¹

Kyowa Kirin has supported the generation of real-world evidence in CTCL through collaborations with investigators and treatment centres across Europe. The MINT study contributes to a growing evidence base exploring outcomes in patients treated with mogamulizumab in routine clinical practice¹⁻³ and reflects a shared commitment between investigators and industry to advancing understanding of rare cancers and improving care for patients living with CTCL.

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About the MINT Study

MINT (Mogamulizumab In a Non-interventional study to evaluate the safety and outcome in mycosis fungoides and Sézary syndrome Treatment) is a German multicentric, non-interventional, retro-prospective real-world study evaluating the effectiveness and tolerability of mogamulizumab in patients with mycosis fungoides (MF) and Sézary Syndrome (SS). Data were collected from patient medical records across 18 study sites in Germany. The primary endpoint was time-to-next-treatment, with secondary endpoints including response rate, progression-free survival, overall survival, quality of life and tolerability.¹

About Kyowa Kirin

Kyowa Kirin aims to discover novel medicines with life-changing value. As a global specialty pharmaceutical company, we have invested in drug discovery and biotechnology innovation for more than 75 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by severe and rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our three regions: JAPAC, North America, and EMEA.

You can learn more about the business of Kyowa Kirin at: <https://kyowakirininternational.com/>

About mycosis fungoides (MF) and Sézary Syndrome (SS)

MF and SS are two subtypes of cutaneous T-cell lymphoma (CTCL), which is itself a rare form of non-Hodgkin's lymphoma that presents and persists in the skin.⁵ CTCL is treatable, but is not generally considered to be curable, and there has been a clear unmet need for novel treatment options. As well as the obvious impact of symptoms upon patients, there can be significant erosions to quality of life for those caring for an individual living with CTCL.¹¹

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.⁹ These cancerous T cells consistently express a protein called CCR4, which enables them to move from the blood to the skin.¹²⁻¹⁴ When these cancerous T cells move to the skin, this results in the visible early skin symptoms of red patches or plaques which can resemble psoriasis or eczema in the early stages of the disease.⁷ Later, for some patients, skin involvement may evolve to include tumours or reddening of the majority of the skin's surface (erythroderma).⁷

MF—the most common CTCL subtype—accounts for approximately 60% of all CTCLs¹⁵ and is typically indolent, characterised by skin symptoms including patches or plaques, skin redness and tumours. SS is much rarer, accounting for around 5% of CTCLs,⁶ and is more aggressive,⁷ with high levels of blood involvement.⁶ It can cause severe itching, erythroderma, intense scaling of the skin and hair loss.⁷ CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.¹⁶

About POTELIGEO® (mogamulizumab)

Mogamulizumab is a first-in-class humanised monoclonal antibody (mAb) directed against CC-chemokine receptor 4 (CCR4), a protein consistently expressed on cancerous cells seen in both mycosis fungoides and Sézary syndrome.¹²⁻¹⁴ Once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.¹⁷

About POTELIGEO® (mogamulizumab) in Plain Language

Mogamulizumab is a monoclonal antibody designed to recognise and attach to CCR4, a protein commonly found on certain cancerous cells in mycosis fungoides and Sézary syndrome. By targeting these cells, it helps the body's immune system identify and destroy them.

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