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Global Registry Data Show Meaningful Overall Survival Benefit in Patients with Advanced Cutaneous T-cell Lymphoma (CTCL) treated with POTELIGEO (mogamulizumab)

- **The PROCLIPI study, one of the largest studies to date in cutaneous T-cell lymphoma (CTCL), is a prospective, observational, multicentre international registry spanning 19 countries and includes over 2,000 patients, collects data to develop prognostic indices for CTCL**[1]
- **An analysis of 371 patients observed meaningful overall survival (OS) benefit for patients with advanced mycosis fungoides (MF) and Sézary syndrome (SS) treated with POTELIGEO (mogamulizumab)**[1,2,3]
- **Findings align with earlier survival signals and highlight how global collaboration can generate meaningful evidence in rare conditions such as MF and SS**[4,5]
- **Results were presented at this year's European Organisation for Research and Treatment of Cancer - Cutaneous Lymphoma Tumour Group (EORTC-CLTG) Annual Meeting in Athens, Greece**[2]

Galashiels and Marlow, and Birmingham, United Kingdom, 22 October 2025 — Kyowa Kirin International (KKI), a wholly owned subsidiary of Kyowa Kirin Co., Ltd. (TSE:4151, Kyowa Kirin), a Japan-based global specialty pharmaceutical company, and the University Hospitals Birmingham NHS Foundation Trust, today announced new overall survival (OS) insights from the PROCLIPI (PROgnostic Cutaneous Lymphoma International Prognostic Index) Study aligning with previous findings that suggest mogamulizumab may offer meaningful OS benefit for patients living with mycosis fungoides (MF) and Sézary syndrome (SS), two rare conditions and subtypes of cutaneous T-cell lymphoma (CTCL).[2]

Key findings[2]**:**

- For patients with advanced-stage MF and SS (n=371), the median overall survival from the onset of treatment was higher for patients treated with mogamulizumab (n=72) at 64 months compared with those not receiving mogamulizumab (n=175) at 54 months ($p<0.01$).
- Patients treated with mogamulizumab showed a trend toward improved OS compared to those not receiving mogamulizumab across risk-stratified groups according to the new Cutaneous Lymphoma International Prognostic Index (CLIPI).
- For a subset of patients with SS (n=96), the median OS is around 6.5 years for patients treated with mogamulizumab (n=46) compared with around 3 years for systemic treatment but not mogamulizumab (n=50) ($p<0.01$).

This research was presented as part of the Scientific Proceedings at this year's European Organisation for Research and Treatment of Cancer Cutaneous Lymphoma Tumour Group (EORTC-CLTG) Annual Meeting in Athens, Greece.[2] The data contributes to a growing body of evidence suggesting potential OS benefits with mogamulizumab, [4,5] highlighting the importance of collaboration across the CTCL community in advancing understanding of survival outcomes and helping to shape the future of patient care.

"The PROCLIPI Study demonstrates the power of global collaboration in rare diseases. By bringing together data from across the world, we can generate insights that simply wouldn't be possible in isolation," says Professor Julia Scarisbrick, Chief Investigator of the PROCLIPI Study and Honorary Professor of Dermatology, University Hospitals Birmingham NHS Foundation Trust. "*We are proud to coordinate this initiative as we're working to build rigorous scientific evidence while giving patients and their families a better understanding of what long-term survival looks like."*

The PROCLIPI Study, now in its tenth year, aims to develop prognostic indices for MF and SS. The study collects comprehensive data, including clinical, haematological, pathological, imaging, treatment with responses, quality of life and survival data.[1] Recently, a new prognostic index (CLIPI) for advanced CTCL was published to enable precise patient risk stratification.[6]

"For those of us in the CTCL community, survival isn't just about numbers on a chart - it's about being able to spend more time with our families, plan for the future, and live life with dignity", says Susan Thornton, CEO, Cutaneous Lymphoma Foundation*. "That's why initiatives like PROCLIPI are important, as the data collected reflects real lived experiences and can help inform future improvements in care for patients."*

The independent international PROCLIPI Study aligns with Kyowa Kirin International's commitment to generating real-world insights that advance the understanding of CTCL and turn these clinical insights into meaningful improvements in access, policy, and patient care.

Cutaneous T-cell lymphoma is a rare disease[7], and innovation in this environment can be challenging due to the rarity of this disease.[8] Yet despite these challenges, mounting evidence continues to emerge[4,5] to help strengthen our collective understanding of potential treatment benefits.

"These insights into improved overall survival for patients living with CTCL mark an important step forward, providing a stronger clinical evidence base and reinforcing the value of international networks in rare disease research," says Dr Nick Kronfeld, Head of Medical Affairs, Kyowa Kirin International*. "By working alongside scientific and patient communities in CTCL, we can gain a better understanding of real-world outcomes, enabling us to bring life-changing value to patients and families, not just today but over the long term."*

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Note to editors

- The OS data from the PROCLIPI Study was presented as an oral presentation during the EORTC CTCL Annual Group Meeting 2025.[2] KKI did not sponsor the PROCLIPI study or OS analysis.
- The median OS for patients (n=72) receiving mogamulizumab compared to those not receiving mogamulizumab (n=175) was 64 months versus 54 months.[2]
- Median OS data amongst risk stratifications according to CLIPI: [2,6]
    - Low-risk: 67 months vs. 'not reached' for mogamulizumab versus those who had not received mogamulizumab
    - Medium-risk: 64 vs. 48 months for mogamulizumab versus those who had not received mogamulizumab

- High-risk: 26 vs. 13 months for mogamulizumab and for those who had not received mogamulizumab

About Kyowa Kirin

Kyowa Kirin aims to discover novel medicines 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 affected by severe and rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions – Japan, Asia Pacific, North America, and EMEA/International.

You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com

About University Hospitals Birmingham NHS Foundation Trust

University Hospitals Birmingham NHS Foundation Trust (UHB) is one of the largest teaching hospital trusts in England, serving a regional, national and international population.

The Trust provides high-quality acute and specialist care across four main hospital sites, Queen Elizabeth Hospital Birmingham, Heartlands Hospital, Good Hope Hospital, and Solihull Hospital, as well as a range of community services.

With over 25,000 staff and approximately 2,700 beds, UHB delivers care to more than 2.2 million patients annually. It is a regional centre for trauma, burns, neurosciences, cancer, and military medicine - proudly hosting the Royal Centre for Defence Medicine.

UHB is also a leader in clinical research and innovation, home to the NIHR Birmingham Biomedical Research Centre and the Institute of Translational Medicine.

Guided by its 2024-2029 strategy, Building Healthier Lives, UHB is committed to improving health and wellbeing, shaping an equitable and sustainable future, and creating excellent experiences for patients and staff. The Trust's core values, Kind, Connected, and Bold, underpin its mission to deliver compassionate care, foster collaboration, and drive innovation across all services. For more information, visit www.uhb.nhs.uk.

About PROCLIPI

PROCLIPI is the PROgnostic Cutaneous Lymphoma International Prognostic Index Study with the main aim to produce a prognostic index in mycosis fungoides (MF) and Sezary syndrome (SS). The study prospectively collects clinical, haematological, pathological, imaging, treatment with responses, quality of life and survival data using careful predefined datasets. Patients are subject to a central review to confirm diagnosis. PROCLIPI opened in 2015 and recruitment has been strong with to date over 2,000 patients recruited from 52 Centres from 19 countries across 6 continents.[1] This trial was registered at www.ClinicalTrials.gov NCT02848274.[3]

About MF and SS

MF and SS are two subtypes of CTCL, which is itself a rare form of non-Hodgkin's lymphoma that presents and persists in the skin.[7] 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.[9]

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.[10] These cancerous T cells consistently express a protein called CCR4, which enables them to move from the blood to the skin.[11-13] 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.[14] Later, for some patients, skin involvement may evolve to include tumours or reddening of the majority of the skin's surface (erythroderma).

MF—the most common CTCL subtype—accounts for approximately 60% of all CTCLs[15] 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,[16] and is more aggressive,[14] with high levels of blood involvement.[16] It can cause severe itching, erythroderma, intense scaling of the skin and hair loss.[14] CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[14]

About Poteligeo (mogamulizumab)

Mogamulizumab is a first-in-class humanised monoclonal antibody directed against CC-chemokine receptor 4 (CCR4), a protein consistently expressed on cancerous cells seen in both MF and SS. [11-13] Once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[17]

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