FOR MEDICAL MEDIA

News release

Kyowa Kirin announces positive interim real-world data for mogamulizumab (Poteligeo®) in cutaneous T-cell lymphoma at EORTC-CLTG 2024

Interim real-world data reinforces effectiveness and tolerability of mogamulizumab for mycosis fungoides (MF) or Sézary Syndrome (SS) in routine clinical practice

Galashiels and Marlow, United Kingdom., 8 October 2024 – Kyowa Kirin International (KKI), a wholly owned subsidiary of Kyowa Kirin Co., Ltd. (TSE:4151, Kyowa Kirin), today announced it will present interim findings from three real-world studies in cutaneous T-cell lymphoma (CTCL) at the annual meeting of the European Organisation for Research and Treatment of Cancer's Cutaneous Lymphoma Tumour Group (EORTC-CLTG), taking place from 9th–11th of October 2024 in Lausanne, Switzerland.

The three studies include participants from Europe, the United States (US) and the United Arab Emirates (UAE), and aim to collect evidence in the real-world clinical setting for mogamulizumab. Mogamulizumab is a first-in-class humanised monoclonal antibody (mAb) therapy approved in Europe and the United Arab Emirates for the treatment of adult patients with MF or SS who have received at least one prior systemic therapy.[1] In the United States and Switzerland, mogamulizumab is approved for the treatment of adult patients with relapsed or refractory MF or SS who have received at least one prior systemic therapy.[2,3]

"For most patients, treatment of CTCL aims to prolong time to disease progression, reduce the burden of disease and preserve or enhance quality of life," said Professor Emmanuella Guenova, chief physician of dermatology and venereology at Lausanne University Hospital and chair of the EORTC-CLTG 2024 Annual Meeting. "The real-world evidence being established by Kyowa Kirin is invaluable information for physicians to understand response to treatment in the real world as they determine the best path forwards for their patients."

This will be the second interim analyses from these studies:

- MINT (Germany) and MIBERIC (Spain and Portugal) – study the effectiveness and tolerability of mogamulizumab in real-world clinical practices and are broadly in line with efficacy and safety data demonstrated in global clinical trials. Across both studies, no new safety signals were seen.
- PROSPER (US, UAE, Spain, Italy, Netherlands, UK) – an ongoing study investigating the impact of mogamulizumab in patients with MF and SS from the patient perspective, assessing symptoms and health-related quality of life, as well as impact on their primary care partners, also in the real-world clinical setting. Patients receiving mogamulizumab experienced improvements in skin symptoms (pain, itch, flaking and redness), sleep problems and body temperature within four weeks and improvements in patient-reported fatigue and health-related quality of life within 24 weeks.

"The studies being presented at EORTC-CLTG build on our presentations at last year's annual meeting and reinforce our commitment to providing the community with a wide breadth of real-world data to inform clinical decision-making and hopefully improve patient outcomes," said Dr Nicholas Kronfeld, Senior Vice President, Head of Medical Affairs, Kyowa Kirin International. "Our ongoing research programme in CTCL reinforces mogamulizumab's clinical utility across a diverse range of patient profiles and healthcare systems."

Kyowa Kirin is committed to sharing scientific knowledge at EORTC-CTLG 2024, with three accepted abstracts to be presented.

Table 1. Overview of Kyowa Kirin presentations at EORTC-CTLG 2024 Annual Meeting

Trial Name and Presentation Type	Presenting author	Abstract Title	Timing
MINT (*oral*)	Prof. Chalid Assaf, Helios Hospital, Germany	Mogamulizumab in patients with mycosis fungoides or Sézary syndrome: Update on the German non-interventional MINT study	18:30–19:30, Wednesday, October 9th
MIBERIC (*oral*)	Prof. Pablo Ortiz Romero, Hospital Universitario 12 de Octubre, Spain	Real-world effectiveness of mogamulizumab in Spain and Portugal: Second interim analysis of the MIBERIC study	18:30–19:30, Wednesday, October 9th
PROSPER (*oral*)	Prof. Julia Scarisbrick, University Hospital Birmingham, United Kingdom	Patient-reported symptoms and HRQL of MF and SS patients receiving mogamulizumab over 24 weeks: interim results from the PROSPER study	15:25–16:25, Thursday, October 10th

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.[4-6] Once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[7]

About MF and SS
MF and SS are two subtypes of CTCL,[8] which is itself a rare form of non-Hodgkin's lymphoma that presents and persists in the skin.[9,10] 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.[12,13] These cancerous T cells consistently express a protein called CCR4, which enables them to move from the blood to the skin.[4-6] 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.[4,12,14-17] 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 and is typically indolent,[10] characterised by skin symptoms including patches or plaques, skin redness and tumours.[18] SS is much rarer, accounting for around 5% of CTCLs,[19] and is more aggressive,[12] with high levels of blood involvement.[20] It can cause severe itching, erythroderma, intense scaling of the skin and frequent hair loss.[14,21] CTCL can take on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[22]

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.

Contacts for Kyowa Kirin Co., Ltd.
Media
Stacey Minton
Email: Stacey.Minton@kyowakirin.com

References

[1] European Medicines Agency. Summary of Product Characteristics, Poteligeo, 2023 Available from: https://www.ema.europa.eu/en/documents/product-information/poteligeo-epar-product-information_en.pdf#:~:text=POTELIGEO%20is%20indicated%20for%20the%20treatment%20of%20adult. Last accessed: October 2024.
[2] United States Food and Drug Administration (U.S. FDA). Highlights of prescribing information, Poteligeo, 2018. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761051s000lbl.pdf#:~:text=POTELIGEO%20is%20indicated%20for%20the%20treatment%20of%20adult. Last accessed: October 2024.
[3] Swissmedic. Public Summary SwissPAR, Poteligeo, 2021. Available from: https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/public-summary-swiss-par/public-summary-swiss-par-poteligeo.html#:~:text=Medicinal%20product%20for%20second-line%20treatment%20in%20adults%20with. Last accessed: October 2024.
[4] Ferenczi K, et al. Increased CCR4 expression in cutaneous T cell lymphoma. J Invest Dermatol. 2002;119:1405-10.
[5] Yoshie O, et al. Frequent Expression of CCR4 in Adult T-Cell Leukemia and Human T-cell Leukemia Virus Type 1-transformed T cells. Blood. 2002;99(5):1505-11.
[6] Ishida T, et al. Clinical Significance of CCR4 Expression in Adult T-cell Leukemia/Lymphoma: Its Close Association With Skin Involvement and Unfavorable Outcome. Clin Cancer Res. 2003;9:3625-34.
[7] Duvic M, et al. Mogamulizumab for the treatment of cutaneous T-cell lymphoma: recent advances and clinical potential. Ther Adv Hematol. 2016;7(3):171-174.
[8] Kim YH, Bagot M, Pinter-Brown L, et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2018;19(9):1192-1204.
[9] National Organization for Rare Disorders: Cutaneous T-Cell Lymphomas. Available from: https://rarediseases.org/rare-diseases/cutaneous-t-cell-lymphomas/. Last Accessed: October 2024.
[10] Willemze R, et al. The 2018 update of the WHO-EORTC classification for primary cutaneous lymphomas. Blood. 2019;133(16):1703-1714.
[11] Williams et al (2020) – Health state utilities associated with caring for an individual with CTCL. Journal of Medical Economics. 2020; 23(10):1142-1150.
[12] Cutaneous Lymphoma Foundation, Lymphoma Action and Lymphoma Coalition Europe. Cutaneous lymphoma – a patient's guide. 2019. Available from: https://lymphomacoalition.org/wp-content/uploads/Cutaneous_lymphoma_-_patients_guide_-.pdf. Last accessed: October 2024.
[13] Mariani M, Lang R, Binda E, et al. Dominance of CCL22 over CCL17 in induction of chemokine receptor CCR4 desensitization and internalization on human Th2 cells. Eur J Immunol. 2004;34(1):231-240.
[14] Wilcox RA. Cutaneous T-cell lymphoma: 2016 update on diagnosis, risk-stratification, and management. Am J Hematol. 2016;91(1):151-65.
[15] Ni X, Jorgensen JL, Goswami M, et al. Reduction of regulatory T cells by Mogamulizumab, a defucosylated anti-CC chemokine receptor 4 antibody, in patients with aggressive/refractory mycosis fungoides and Sézary syndrome. Clin Cancer Res. 2014; 21(2):274-85.
[16] Kakinuma T, Sugaya M, Nakamura K, et al. Thymus and activation-regulated chemokine (TARC/CCL17) in mycosis fungoides: serum TARC levels reflect the disease activity of mycosis fungoides. J Am Acad Dermatol. 2003;48(1):23-30.
[17] Girardi M, Heald PW, Wilson LD. The Pathogenesis of Mycosis Fungoides. NEJM. 2004;350(19):1978-88.
[18] Scarisbrick, J, et al. The PROCLIPI international registry of early-stage mycosis fungoides identifies substantial diagnostic delay in most patients. Br J Dermatol. 2019;181(20):350-357.
[19] Trautinger F, et al. European Organisation for Research and Treatment of Cancer consensus recommendations for the treatment of mycosisfungoides/Sézary syndrome - Update 2017. European Journal of Cancer. 2017;77:57-74.
[20] Scarisbrick JJ, Whittaker, S, Evans, AV, et al. Prognostic significance of tumor burden in the blood of patients with erythrodermic primary cutaneous T-cell lymphoma. Blood. 2001;97(3):624-30.

[21] Demierre M-F, et al. Significant impact of cutaneous T-cell lymphoma on patients' quality of life. Cancer. 2006;107(10):2504-2511.
[22] CL Foundation: A Patient's Guide. Available from: https://www.clfoundation.org/sites/default/files/2018-04/a_patients_guide.pdf. Last Accessed: October 2024.