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News release

Kyowa Kirin demonstrates commitment to real-world evidence for POTELIGEO® (mogamulizumab) at EORTC 2023.

Systemic therapy approved for second-line treatment of adults with mycosis fungoides (MF) or Sézary syndrome (SS) demonstrates effectiveness in routine clinical practice.

Tokyo, Japan, 21 September 2023 – Kyowa Kirin International (KKI), a wholly owned subsidiary of Kyowa Kirin Co. Ltd, today announced the acceptance of an extensive programme of data to the annual meeting of the European Organisation for Research and Treatment of Cancer's Cutaneous Lymphoma Tumour Group (EORTC-CLTG), taking place from the 21st – 23rd of September 2023 in Leiden, the Netherlands.

Four studies across a range of European countries, the USA and the UAE, aim to collect robust evidence in a real-world clinical setting for Poteligeo® (mogamulizumab), the first-in-class humanised monoclonal antibody (mAb) therapy approved in Europe for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.

Danie du Plessis, Executive Vice President of International Medical Affairs, Kyowa Kirin, commented: *"The studies presented at EORTC-CLTG demonstrate our long-term commitment to expand the evidence base for the effectiveness of mogamulizumab in real-world settings. Our ongoing research programme in CTCL extends across a wide geographic area, recognising the patient perspective, clinical endpoints and the diversity of healthcare systems, all part of our ambition to improve outcomes for those affected by mycosis fungoides and Sézary syndrome."*

Data from OMEGA (France) represents the first published real-world evidence generated by KKI regarding the effectiveness of mogamulizumab. OMEGA, a completed, retrospective, real-world, non-interventional observational study, described real-world effectiveness and tolerability of mogamulizumab in patients with MF and SS.

Alongside the data from OMEGA, interim data from two of the other studies – MINT (Germany) and MIBERIC (Spain and Portugal) – support the effectiveness of mogamulizumab in real-world clinical practices and are in line with efficacy and safety data demonstrated in global clinical trials. Across all three trials no new safety signals were seen. The fourth study – PROSPER (USA, UAE, Spain, Italy, Netherlands, UK) – is 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.

Professor Chalid Assaf, Director of the Department of Dermatology, HELIOS Klinikum Krefeld, and lead author of the MINT study, commented: "*CTCL can have a severely detrimental impact on patients' health-related quality of life, with sometimes far-reaching consequences for those living with the disease as well as their families. The real-world evidence being generated by Kyowa Kirin raises the standard of information available to those involved in treating mycosis fungoides and Sézary syndrome helping to inform decisions that support optimal patient care."*

Table 1. Overview of mogamulizumab study programme for presentation at EORTC-CLTG

Trial Name and Presentation Type	Lead Author	Abstract Title
OMEGA (*oral abstract*)	Prof. Marie Beylot-Barry, Bordeaux Institute of Oncology, France	*Efficacy and tolerability of mogamulizumab in patients with Mycosis Fungoides or Sézary syndrome. Retrospective and real-world data from centres of the French Study Group of Cutaneous Lymphoma*

MINT (*oral abstract*)	Prof. Chalid Assaf, Helios Hospital, Germany	*Mogamulizumab in patients with mycosis fungoides or Sézary syndrome: Interim analysis of the German non-interventional MINT study*
MIBERIC (*poster*)	Prof. Pablo Ortiz Romero, Hospital Universitario 12 de Octubre, Spain	*Real-world effectiveness of mogamulizumab in patients with Sézary syndrome or mycosis fungoides in Spain and Portugal: The MIBERIC study*
PROSPER (*poster*)	Prof. Julia Scarisbrick, University Hospital Birmingham, United Kingdom	*A Real-World International Observational Study of Mogamulizumab in Adult Patients with Mycosis Fungoides and Sézary Syndrome (PROSPER study NCT05455931) – UK*

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 MF and SS;[1,2,3] once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[4]

The MAVORIC trial compared the efficacy of mogamulizumab with vorinostat in previously treated patients with relapsed or refractory mycosis fungoides or Sézary syndrome; the best-studied subtypes of cutaneous T-cell lymphoma (CTCL).[5] Patients receiving mogamulizumab experienced control over their disease for more than twice as long as those taking the comparator treatment, vorinostat*[1] (7.7 months vs 3.1 months of median progression free survival), the primary endpoint of the trial.[5] Frequencies of adverse events were similar between the two treatment groups.[5]

The MAVORIC trial is the largest trial of systemic treatments in CTCL and enrolled a total of 372 patients across 61 sites in 11 countries (of which 16 sites were in Europe, including three in England).[5]

About Mycosis Fungoides (MF) and Sézary Syndrome (SS)

MF and SS are two subtypes of CTCL,[5] which is itself a rare form of non-Hodgkin lymphoma that presents and persists in the skin.[6,7] 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.[8]

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.[9,10] These cancerous T cells consistently express a protein called CC-chemokine receptor 4 (CCR4), which enables them to move from the blood to the skin.[1,2,3] When these cancerous T cells move to the skin this results in the visible early skin symptoms of red patches or plaques [1,11,12,13,14] which can resemble psoriasis or eczema in the early stages of the disease.[9] Later, for some patients, skin involvement may evolve to include tumours or reddening of the majority of the skin surface (erythroderma).

MF – the most common CTCL subtype – accounts for approximately 60% of all CTCLs[11] and is typically indolent, characterised by skin symptoms including patches or plaques, skin redness and tumours.[15] SS is much rarer, accounting for around 5% of CTCLs,[16] and is more aggressive,[9] with high levels of blood involvement.[17] It can cause severe itching, erythroderma, intense scaling of the skin and frequent hair loss.[11]

MF and SS, while presenting in skin, can for some patients also affect the blood, lymph nodes (part of the body's immune system which is spread throughout the body) and internal organs.[18] All four areas of the body are used to assess disease stage[19,20] and clinically significant involvement of the blood, particularly in more advanced disease, has been linked with increased morbidity and an overall reduction in patient survival.[15, 19,21,]

CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[22] Therefore, it is important for doctors to consider CTCL as an early differential diagnosis as the patient's prognosis can be affected if the disease progresses to later stages.[23] Whilst most individuals that present with early stage disease do not progress more severely,[24] patients with advanced disease have significantly poorer outcomes with only around half of patients (52%) surviving for just 5 years.[19] CTCL is an ultra-rare disease that affects 0.7 per 100,000 patients across the UK.[25] The annual incidence of

*[1] Vorinostat is a USA FDA-licensed existing treatment for MF and SS and is currently unlicensed in the EU

MF in Europe is estimated to be between 1 in 110,000 to 1 in 350,000.[26] The annual incidence of SS is 1 in 10,000,000.[27] Together they represent approximately 65% of all cases of CTCL.[18]

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan based Global Specialty Pharmaceutical Company with a more than 70-year heritage, the company applies cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork, innovation, and integrity.

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