

News release

New Real World Evidence Underlines Benefits of POTELIGEO®▼ (mogamulizumab) Treatment for Cutaneous T-cell Lymphoma (CTCL) Patients

Patients responded better to treatment with POTELIGEO in real life, compared to data from the pivotal Phase 3 MAVORIC trial¹

GALASHIELS, UK 14 October 2021 – Kyowa Kirin International PLC (Kyowa Kirin), a wholly owned subsidiary of Kyowa Kirin Co., Ltd., today announced a new study of real world data showing higher response rates than previously seen in people living with cutaneous T-cell lymphoma (CTCL) treated with POTELIGEO® (mogamulizumab). The findings, from a retrospective observational study of French CTCL patients, showed that the best overall response rate in the real-life study was 58.5 per cent, compared to 35 per cent seen in the MAVORIC trial.^{1,2} The MAVORIC study was the pivotal Phase 3 trial that investigated treatment with POTELIGEO® compared to an active comparator^a in previously treated adult patients with mycosis fungoides (MF) and Sézary syndrome (SS), two types of CTCL.

Professor Martine Bagot of Saint-Louis Hospital, Université de Paris, France said: “The purpose of the study was to assess, for the first time, the efficacy and safety of mogamulizumab in a real-life setting. We saw a higher response in the real-life study compared to the MAVORIC trial results. The increase was also seen in both the MF and SS patient groups, compared to MAVORIC. As both the real world data and MAVORIC recruited a broadly similar set of patients, this new data underlines the value of mogamulizumab in treating these CTCL patients, whose disease causes a severe impact on their functioning, emotional and social wellbeing.”

Data was collected and analysed from medical records of 124 MF and SS patients treated with POTELIGEO between February 2014 and March 2020, from 14 specialist treatment centres in France. The best overall response rate (ORR) seen in the real-life study was 47.0% in MF patients and 68.3% in SS patients. In contrast, the ORR^b in MAVORIC was 21% and 37%, respectively.^{1,2} Of the 124 patients who received POTELIGEO treatment in the study, 44% were MF patients and 56% were SS patients. This compares to 56% and 44% in MAVORIC, respectively. In the real-life study, 49.6% of patients were at disease stage IVA1, compared to 39% in MAVORIC.^{1,2}

POTELIGEO was also shown to have a favourable safety profile, in the real life study the most common drug-related treatment-emergent adverse events (TEAEs) were lymphopenia and asthenia. Commonly occurring TEAEs seen in both the real life study and MAVORIC were rash and infusion-related reactions.^{1,2}

Abdul Mullick, President of Kyowa Kirin International, said: “Kyowa Kirin is committed to improving outcomes for patients with rare diseases, whose needs are often underserved. It’s heartening to see this new real world data, which reinforces what we’ve seen previously in clinical trials. Kyowa Kirin is dedicated to improve the lives of patients with CTCL, which is a chronic, debilitating disease and to deliver on our purpose, to make people smile.”

MF and SS are subtypes of CTCL, a rare type of non-Hodgkin's lymphoma that can affect the skin, blood, lymph nodes and internal organs.³ It is associated with disfiguring skin lesions, intractable itching, sleep disturbance, and psychosocial problems, CTCL has a serious negative effect on quality of life.⁴

The new data was presented at a poster session at the EORTC meeting in Marseille, France, which is being held on 14-16 October 2021.

^a The comparator in the MAVORIC trial was vorinostat, a histone deacetylase inhibitor (HDACi) and FDA-approved standard of care option for treatment of CTCL that is licensed in the US for the treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent or recurrent disease on or following two systemic therapies. Vorinostat is not licensed for use in Europe.

^b MAVORIC ORR included only those patients with confirmed global response at two (or more) successive evaluations at least 8 weeks apart).

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

Cutaneous T-cell lymphoma (CTCL) is a cancer of white blood cells (lymphocytes) that presents in the skin.⁵ CTCLs are rare, serious and potentially life-threatening forms of non-Hodgkin lymphoma (NHL).² Malignant T cells in CTCL circulate in the blood and migrate to the skin⁶ causing lesions and itching.⁷

The annual incidence of CTCL in Europe is around 5.2 new cases per 100,000 population⁸ and it affects around 240 people per million in the region at any one time.⁵ The two best-studied types of CTCL are mycosis fungoides (MF) and Sézary syndrome (SS).⁹ Together, MF and SS account for around two thirds of all CTCLs.^{10,11}

- MF accounts for approximately 60% of all CTCLs,¹⁰ is typically indolent and is characterised by skin symptoms including patches or plaques, skin redness and tumours.¹²
- SS is much rarer, accounting for around 5% of CTCLs,⁶ and is more aggressive¹³ with high levels of blood involvement by definition.¹⁰ It causes very severe itching, total body redness (erythroderma), intense scaling of the skin and frequent hair loss.⁷

It can typically take between three and six years from CTCL disease onset for a patient to be diagnosed, in some cases it can take decades.^{10,12} This is sometimes due to the fact that CTCL presents very similarly to

other benign skin conditions (e.g. eczema and psoriasis)⁷; this can mean many patients experience a long, frustrating journey before diagnosis.

CTCL can be very distressing for patients and has a significant negative life-long impact upon many aspects of a patient's life.^{12,14} CTCL causes chronic skin impairment with itching, pain, recurrent infections, and disfiguring skin lesions, as well as sleep disturbance and psychosocial problems.^{9,12} Even in the early stages of CTCL, the disease can affect patients' ability to meet the needs of their family, interfere with their job, and limit normal daily activities.¹⁴

About POTELIGEO (mogamulizumab) and the MAVORIC Trial

Malignant T lymphocytes in MF and SS, consistently express a molecule called CC chemokine receptor 4 (CCR4).² POTELIGEO is a humanised monoclonal antibody that selectively binds to CCR4-expressing cells¹⁵ and helps destroy them by harnessing the body's immune system.² POTELIGEO is a systemic therapy, administered by intravenous infusion weekly for the first five weeks, then subsequently every two weeks.¹⁵ The registrational Phase 3 MAVORIC trial was the largest randomised study of systemic therapy in CTCL. It evaluated the safety and efficacy of POTELIGEO versus vorinostat in patients who had failed at least one previous systemic therapy.²

Following a positive opinion from Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), the European Commission (EC) granted marketing authorisation for POTELIGEO in November 2018 for the treatment of adult patients with MF or SS who have received at least one prior systemic therapy.¹⁵

Important Prescribing information and Safety Information

Refer to the full Summary of Product Characteristics (SmPC) for prescribing information and the full safety information: <https://www.ema.europa.eu/en/medicines/human/EPAR/poteligeo#product-information-section>

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 heritage of 70+ -years, we apply 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/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com/>

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