News release

Kyowa Kirin welcomes the decision that the National Institute for Health and Care Excellence (NICE) will revisit their appraisal of the innovative systemic treatment, POTELIGEO®▼(mogamulizumab), for adults living with two forms of ultra-rare non-Hodgkin lymphoma

NICE uphold appeal by Kyowa Kirin for POTELIGEO in the treatment of those living with certain ultra-rare blood cancers

London, England, 11 June 2021 – The National Institute for Health and Care Excellence (NICE) has upheld an appeal lodged by Kyowa Kirin, Lymphoma Action and Leukaemia Care, and the UK Cutaneous Lymphoma Group (UKCLG) as part of the Single Technology Appraisal for POTELIGEO® (mogamulizumab) for the treatment of adults with the ultra-rare blood cancers mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.[1]

The oral appeal hearing took place on 10 May 2021 in front of an independent Appeal Panel appointed by NICE. The Panel heard arguments from representatives of the appellants against the decision not to recommend POTELIGEO, as published in a Final Appraisal Document (FAD) on 4 March 2021.[2]

The parties involved in the appeal welcome this decision as it represents a significant and positive step forward for the cutaneous T-cell lymphoma (CTCL) community, where there is a high clinical unmet need. Kyowa Kirin remains committed to finding a solution for people living with SS or MF to have access to POTELIGEO and will continue discussions with NICE and NHS England to find a resolution.

Richard Johnson, Northern Cluster General Manager, responsible for the UK at Kyowa Kirin, commented: “The outcome of this appeal is an important step in enabling access to an innovative treatment for people with MF or SS who have few systemic treatment options. We remain committed to working with the patient and clinical community, as appropriate, and we are optimistic that future reconsideration of evidence by the Committee, could resolve the challenges with this appraisal. We strongly believe in the clinical and cost effectiveness of POTELIGEO and will continue a dialogue with NICE and NHS England.”

MF and SS are two forms of CTCL[3] which is a serious and potentially life-threatening form of cancer.[4] Additionally, there is a significant impact on quality of life for those caring for an individual living with CTCL.[5] CTCL is treatable but not curable and there is a clear unmet need for new treatment options.

Ropinder Gill, Chief Executive at Lymphoma Action commented: “We’re very grateful and pleased that the NICE Appeal Panel upheld the appeal around mogamulizumab on a number of grounds. This means that by relooking at aspects such as mogamulizumab’s cost effectiveness, there is an opportunity to make this treatment available to those people affected by skin lymphoma who have limited treatment options left. We are hopeful that NICE’s reassessment might bring parity with the SMC’s decision to make mogamulizumab available in Scotland.”

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;[6,7,8] once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[9]

Mogamulizumab has been shown to offer benefits to many patients with MF and SS.[10] The MAVORIC trial compared the efficacy of mogamulizumab with vorinostat in previously treated people with relapsed or refractory mycosis fungoides or Sézary syndrome, two types of Cutaneous T-cell lymphoma (CTCL).[10] Patients taking 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.[10] Levels of adverse events were similar between the two treatment groups.[10] The MAVORIC trial is the largest in CTCL; it enrolled a total of 372 patients across 61 sites in 11 countries (of which 16 sites were in Europe, including three in England).[10]

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

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.[11,12] 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.[6,7,8] When these cancerous T cells move to the skin, they can create a localised inflammatory immune skin response, commonly resulting in visible skin symptoms of red patches or plaques [6,13,14,15,16] which can resemble psoriasis or eczema.[11]

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

MF and SS can affect the skin, blood, lymph nodes (part of the body's immune system which is spread throughout the body) and internal organs.[17] All four areas of the body are used to assess disease stage[18,19] and clinically significant involvement of the blood, particularly in more advanced disease, is linked with increased morbidity and an overall reduction in patient survival.[18,20,21]

CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[22] It is critical 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 to a more severe stage,[24] patients with advanced disease have significantly poorer outcomes with only around half of patients (52%) surviving for just 5 years.[18]

CTCL is a ultra-rare disease that affects 0.7 per 100,000 patients across the UK.[25] The annual incidence of 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.[17]

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/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com.

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