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News release

New Post Hoc Analysis from MAVORIC Trial Sheds Light on the Burden of Cutaneous T-Cell Lymphoma on Health-Related Quality of Life

Findings presented at the 65th annual American Society of Haematology meeting in San Diego, CA.

Tokyo, Japan, 11 December 2023 – Kyowa Kirin International (KKI), a wholly owned subsidiary of Kyowa Kirin Co. Ltd**,** today announced health-related quality of life (HRQL) findings from a post hoc analysis of the MAVORIC trial in patients with mycosis fungoides (MF) or Sézary syndrome (SS), two subtypes of cutaneous T-cell lymphoma (CTCL).

Researchers analysed baseline data collected prior to initiation of study treatment and found the symptoms of advanced MF/SS affected HRQL across all domains, with poorer HRQL associated with being younger in age, female, having moderate or severe itching, and impaired function as measured by the Eastern Cooperative Oncology Group performance status (ECOG PS).

"CTCL is a chronic, life-long condition. Understanding how symptoms impact an individual physically, emotionally as well as in their daily life is critical," said Susan Thornton, Chief Executive Officer, Cutaneous Lymphoma Foundation and one of the study authors. "The data provide new insights into the burdens of living with CTCL, and the patient characteristics associated with a poorer quality of life - important factors to consider when developing a care plan for a patient."

Cutaneous T-cell lymphoma is a rare form of non-Hodgkin's lymphoma that most prominently affects the skin, presenting as patches, plaques, tumours or erythroderma (reddening of the skin), and may be associated with severe pruritus (itching). In advanced cases, the disease may spread to the lymph nodes, blood, and/or viscera.

To determine the impact of CTCL on HRQL, researchers analysed data collected at baseline from 372 MAVORIC trial participants using Skindex-29, which evaluates the effect of skin disease on HRQL; the ItchyQol, which is a pruritus-specific measure of HRQL; and the Functional Assessment of Cancer Therapy – General (FACT-G), which measures HRQL in people with cancer. The findings were analysed at the individual question level and scored according to instrument guidelines. Bivariate analysis (t-tests and ANOVA) was used to identify demographic and medical history variables that had a relationship with HRQL. LASSO (least absolute shrinkage and selection operator) regression analysis was used to identify factors that may drive poor HRQL.

Results show the symptoms of advanced MF/SS affected HRQL across all domains with worse scores seen in Symptoms for Skindex-29, Well-being for FACT-G and Functioning for ItchyQoL. In bivariate analysis, a worse total score across all three HRQL measures were related to being younger, female, having moderate or severe pruritis, ECOG performance status 1 or 2, and higher mSWAT (Modified Severity-Weighted Assessment Tool) scores. In multivariate analysis, worse HRQL was associated with being younger, female, moderate or severe pruritus and impaired function (as measured by ECOG PS). Researchers concluded that assessing a patient's disease concerns may help guide treatment goals and therapeutic choice.

About MAVORIC

MAVORIC (Mogamulizumab anti-CCR4 Antibody Versus Comparator In CTCL) was an international, open label, Phase 3, randomised controlled trial that evaluated the safety and efficacy of Poteligeo® (mogamulizumab) versus vorinostat in patients with relapsed or refractory MF or SS (stage IB–IVB) previously treated with at least one systemic therapy. The study population (n=372) had a mean age of 63 years (SD 13.0). Fifty-five percent of patients had MF, 45% SS, and 77% had advanced disease (stage IIB–IV). The disease involved the skin in all patients and the blood and/or nodes in 66%. ECOG performance status was stage 0, 1, and 2 in 56%, 43%, and <1% of patients, respectively.

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]

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.[5,6] 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.[7]

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.[8,9] 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 [1,10,11,12,13] which can resemble psoriasis or eczema in the early stages of the disease.[8] 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 [10] and is typically indolent, characterised by skin symptoms including patches or plaques, skin redness and tumours.[14] SS is much rarer, accounting for around 5% of CTCLs,[15] and is more aggressive,[8] with high levels of blood involvement.[16] It can cause severe itching, erythroderma, intense scaling of the skin and frequent hair loss.[10]

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.[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, has been linked with increased morbidity and an overall reduction in patient survival.[14,16,20]

CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[21] 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.[22] Whilst most individuals that present with early stage disease do not progress more severely,[23] patients with advanced disease have significantly poorer outcomes with only around half of patients (52%) surviving for just 5 years.[18] CTCL is an ultra-rare disease that affects 0.7 per 100,000 patients across the UK.[24] The annual incidence of MF in Europe is estimated to be between 1 in 110,000 to 1 in 350,000.[25] The annual incidence of SS is 1 in 10,000,000.[26] 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, innovation, and integrity.

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