Kyowa Kirin makes POTELIGEO® (mogamulizumab) available in Europe for the Treatment of Mycosis Fungoides and Sézary Syndrome, Two Rare Forms of Non-Hodgkin's Lymphoma with High Unmet Medical Need

POTELIGEO, the first approved therapy targeting CCR4, to treat rare cancers, mycosis fungoides and Sézary syndrome, now available in Germany

TOKYO, Japan, June 15, 2020– Kyowa Kirin Co., Ltd., (Kyowa Kirin) today announced commercial availability of POTELIGEO® (mogamulizumab) in Germany for the treatment of adult patients with the rare cancers, mycosis fungoides (MF) and Sézary syndrome (SS), who have received at least one prior systemic therapy.[1] POTELIGEO is a first-in-class humanised monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4),[2] a protein consistently expressed on cancerous cells seen in both MF and SS;[3,4,5] once POTELIGEO binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[6]

MF and SS are subtypes of cutaneous T-cell lymphoma (CTCL), a rare type of non-Hodgkin's lymphoma[7] that can affect the skin, blood, lymph nodes and internal organs.[8] CTCL is rare. For every 100,000 people, there are approximately 24cases of CTCL.[9] The annual incidence of MF in Europe is estimated to be between 1 in 110,000 to 1 in 350,000.[10] The annual incidence of SS is 1 in 10,000,000.[11] Together they represent approximately 65% of all cases of CTCL.[8] Individuals with this disease often suffer from disfiguring, itchy, painful and unpredictable skin symptoms, which can lead to further complications that can impact their life expectancy.[2,12] POTELIGEO, which demonstrates improvement in these skin and disease-related symptoms, as well as control of the disease, is expected to be available for prescription in Germany from 15th June 2020 [2]

"CTCL substantially deteriorates the quality of life for those living with the disease, as it has a profound and severe impact on daily function and social interactions" said Abdul Mullick, President of Kyowa Kirin International. "By making POTELIGEO available in Germany, we are helping meet the needs of physicians and patients to manage MF and SS more effectively. This milestone demonstrates the steady advances we are making as a company to fulfil the requests of patients suffering from diseases for which there are limited adequate treatments. We are continuing discussions with local health authorities across Europe in order to bring this treatment to more and more patients as quickly as possible".

Professor Chalid Assaf, Head of the Department of Dermatology, Helios Klinikum Krefeld, Germany said "POTELIGEO more than doubled the median progression-free survival of affected patients compared to vorinostat.[1] In particular, skin and blood responded significantly to the treatment, with lasting effects. The results are based on the MAVORIC study, the largest clinical trial to date on mycosis fungoides and Sézary syndrome."

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.[13,14] 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.[3,4,5] 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[3,15,16,17,18] which can resemble psoriasis or eczema.[13]

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.[8] 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, is linked with increased morbidity and an overall reduction in patient survival.[19,21,22]

Due to its likeness to more common skin conditions such as eczema and psoriasis,[13] CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.[23] It is critical for doctors to diagnose CTCL as early as possible as the patient's prognosis can be affected if the disease progresses to later stages.[24] Whilst most individuals that present with early stage do not progress to a more severe stage,[25] patients with advanced disease have significantly poorer outcomes with only around half of patients (52%) surviving for just 5 years.[19]

About POTELIGEO® (mogamulizumab)

POTELIGEO is a first-in-class humanised monoclonal antibody (mAb), designed to bind to CC chemokine receptor 4 (CCR4).[2] After POTELIGEO binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.[6] POTELIGEO uses Kyowa Kirin's proprietary POTELLIGENT® technology, which enhances the body's natural immune reaction to treatment, resulting in improved efficacy for killing cancer cells.[6]

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

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.[1] The European Medicines Agency's (EMA) decision was based on results of the MAVORIC trial, the largest study conducted in MF and SS,[2] and the first trial to compare systemic therapies using progression-free survival as a primary endpoint, which is a robust endpoint for a CTCL study, as it incorporates looking at disease progression in four different areas of the body (skin, blood, lymph nodes and internal organs).[2]

About the MAVORIC Trial

- The MAVORIC trial is the largest study conducted in MF and SS,[2] and the first trial to compare systemic therapies using 'progression-free survival' (PFS) as a primary endpoint, which is a robust endpoint for a CTCL study, as it incorporates looking at disease progression in four different areas of the body (skin, blood, lymph nodes and internal organs).[2]
- Secondary endpoints were overall response rate; duration of response (time from first achievement of an overall response to progression or death); the proportion of patients with an overall response in the crossover portion of the trial; assessment of quality of life; immunogenicity (immune response) and safety.[2]
- Results showed that:
    - People taking POTELIGEO experienced control over their disease for more than twice as long as those taking the comparator treatment, vorinostat* (PFS of 7.7 mths vs 3.1 mths) (HR=0.53, 95% CI: 0.41–0.69; p<0.0001).[2]
    - Overall significantly more patients responded to POTELIGEO than vorinostat* (Overall Response Rate [ORR] 28% versus 5%; Risk Ratio [RR]: 23.1; 95% CI 12.8-33.1, P<0.0001).[2]
    - Response to treatment lasted 43% longer in people taking POTELIGEO versus those taking vorinostat* (14.1 months versus 9.1 months).[2]
        - Significant involvement in the blood in MF/SS patients is linked to poorer predicted disease outcomes.[19,21,22]
    - More patients responded to POTELIGEO, across all studied MF/SS disease stages than with vorinostat.*[2] POTELIGEO has overall good tolerability with a manageable safety profile.[2,26]
    - The most common adverse reactions with POTELIGEOare constipation, diarrhoea, nausea, stomatitis, fatigue, oedema peripheral, pyrexia, infections, infusion related reactions, headache and drug eruption (including skin rash).[1].

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

Important Safety Information

Refer to the full Product Information for human medicinal products for full safety information: https://www.ema.europa.eu/en/medicines/human/EPAR/poteligeo#product-information-section

Kyowa Kirin International PLC, a Kyowa Kirin Group company, is responsible for commercialising POTELIGEO in Europe.

About Kyowa Kirin

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new values in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, the employees from 40 group companies across North America, EMEA and Asia/Oceania unite to champion the interests of patients and their caregivers in discovering solutions wherever there are unmet medical needs.

You can learn more about the EMEA business of Kyowa Kirin at:

Kyowa Kirin International

http://www.international.kyowa-kirin.com / www.kyowakirin.com

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