

Kyowa Kirin Announces POTELIGEO® Receives Marketing Authorisation in Europe for the Treatment of Mycosis Fungoides and Sézary Syndrome

POTELIGEO will be the first biologic agent targeting CCR4 to be available for patients in Europe.

Tokyo, Japan 26th November, 2018 – Kyowa Hakko Kirin Co., Ltd., (Kyowa Kirin) announces today that it has received a European Commission decision granting a marketing authorisation to POTELIGEO® (Generic name: mogamulizumab), a humanised monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4), for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.

MF and SS are the two most common subtypes of cutaneous T-cell lymphoma (CTCL), a rare type of non-Hodgkin's lymphoma.

The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP), adopted a Positive Opinion recommending approval of the marketing authorisation for POTELIGEO in September 2018.

The European Marketing Authorisation is valid in the 28 countries of the European Union and in Norway, Iceland and Liechtenstein. Kyowa Kirin plans to launch POTELIGEO in various markets in Europe from 2019. Kyowa Kirin International PLC, a Kyowa Hakko Kirin Group company, is responsible for commercialising POTELIGEO in Europe.

“With this approval, now there is a new option for the patients with mycosis fungoides (MF) or Sézary syndrome (SS) across Europe,” said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Kirin. “I’m delighted about the European Commission’s decision which is strategically important for us to realise our mid-term business plan and our goal as a global specialty pharmaceutical company.”

Tom Stratford, CEO of Kyowa Kirin International, said: “Mycosis fungoides (MF) and Sézary syndrome (SS) are horrible conditions which patients literally wear on their skin. The granting of this marketing authorisation is encouraging news for those across Europe who live with these conditions every day and we look forward to making POTELIGEO available for patients and clinicians across Europe.”

“POTELIGEO offers a new approach to tackling the underlying disease pathophysiology of mycosis fungoides (MF) and Sézary syndrome (SS). By targeting CCR4-expressing T cells in blood and skin we could have a new option to manage patient symptoms.” Said Professor Martine Bagot, Head of the Department Dermatology in Hospital Saint Louis, Paris.

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About Kyowa Kirin

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realise its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.

Kyowa Kirin International PLC is a wholly owned subsidiary of Kyowa Hakko Kirin and is a rapidly growing specialty pharmaceutical company engaged in the development and commercialization of prescription medicines for the treatment of unmet therapeutic needs in Europe and the United States. Kyowa Kirin International is headquartered in Scotland.

You can learn more about the business at: www.kyowa-kirin.com.

About POTELIGEO

POTELIGEO is a humanised monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4), which is frequently expressed on leukaemic cells of certain haematologic malignancies including CTCL (cutaneous T-cell lymphoma). POTELIGEO was produced using Kyowa Hakko Kirin's proprietary POTELLIGENT® platform, which is associated with enhanced antibody-dependent cellular cytotoxicity (ADCC).

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

MF and SS are the two most common subtypes of CTCL, a rare type of non-Hodgkin's lymphoma, which is characterised by CCR4 related localisation of malignant T lymphocytes to the skin, and depending on the stage, the disease may involve skin, blood, lymph nodes, and viscera.

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