Kyowa Kirin Announces Mogamulizumab Received Positive CHMP Opinion for the Treatment of Mycosis Fungoides and Sézary Syndrome

If approved, mogamulizumab would be the first biologic agent targeting CCR4 to be available for patients in Europe.

Tokyo, Japan, September 21, 2018 – Kyowa Hakko Kirin Co., Ltd., (Kyowa Kirin) announces today that the Committee for Medicinal Products for Human Use (CHMP), the European Medicines Agency's (EMA) scientific committee, has adopted a Positive Opinion recommending approval of the marketing authorisation of 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 CHMP's opinion is now being referred to the European Commission (EC), for a final decision on the grant of a marketing authorisation. This decision is expected by the end of 2018 and will apply to all 28 countries of the European Union, Norway, Iceland and Liechtenstein.

"At Kyowa Kirin we are fully committed to contributing to the health and wellbeing of patients across Europe who are living with mycosis fungoides and Sézary syndrome," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin. "I am happy about the CHMP's opinion which takes us one step closer to obtaining an EU marketing authorisation, launching mogamulizumab and to leaping forward to becoming a global specialty pharmaceutical company."

"Mycosis fungoides (MF) and Sézary syndrome (SS) can be disfiguring, debilitating, and even life-threatening, and there are limited treatment options for these rare lymphoma subtypes in Europe today," said Jeffrey S. Humphrey, MD, President of Kyowa Kirin Pharmaceutical Development, Inc. "MAVORIC, the pivotal Phase 3 trial of mogamulizumab, is the largest study of systemic therapy ever conducted in MF and SS. The study showed that mogamulizumab prolonged progression-free survival compared to vorinostat in patients with MF or SS. We will continue to work with the scientific community to advance the understanding of these complex diseases, and we look forward to working with health authorities to bring this important new option to Europe."

If mogamulizumab is approved, Kyowa Kirin International PLC, a Kyowa Hakko Kirin Group company, will be responsible for commercializing mogamulizumab in Europe.

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.

Mogamulizumab Regulatory Status in EU

The EMA's scientific committee, CHMP adopted a Positive Opinion recommending the approval of the marketing authorisation of mogamulizumab for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. The CHMP's recommendation is now being referred to the European Commission (EC), which is expected to render its final decision by the end of 2018. The EC typically adheres to the recommendation of the CHMP, but is not obligated to do so.

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 Mogamulizumab

Mogamulizumab 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). Mogamulizumab 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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