

Kyowa Hakko Kirin Receives the Partial Change Approval of POTELIGEO® in Japan

Tokyo, Japan, August 21, 2018 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151 President and COO: Masashi Miyamoto; "Kyowa Hakko Kirin") today announces that it has obtained the partial change approval for POTELIGEO® (code name: KW-0761; generic name: mogamulizumab) from the Ministry of Health, Labor and Welfare in Japan. The approved partial change includes removing the requirement for pre-treatment diagnostic testing, and changing the dosage and administration in patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL)*

The approval is based on data from the MAVORIC (Mogamulizumab anti-CCR4 Antibody Versus ComparatOR In CTCL) study, the largest global randomized clinical trial of systemic therapy in CTCL. In the MAVORIC study, identification of CCR4 positive cells in patients before enrollment into the study was not required and the enrolled patients were treated with mogamulizumab 1.0 mg/kg intravenously on a weekly basis for the first 28-day cycle, then on days 1 and 15 of subsequent cycles. With the partial change approval, the requirement for diagnostic testing for CCR4 expression will be unnecessary and the dosage schedule will be changed for CTCL in Japan.

“ With this approval, I believe POTELIGEO is more helpful for patients with relapsed or refractory cutaneous T-cell lymphoma and healthcare professionals in Japan,” said Mitsuo Satoh Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin, "Kyowa Hakko Kirin is dedicated to using advanced science and research methodologies to contribute to patients with unmet medical needs.”

On August 8, POTELIGEO was approved for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy by the U.S. Food and Drug Administration (FDA). The marketing authorization application for mogamulizumab is currently under review by the European Medicines Agency (EMA) 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.

About CTCL (Cutaneous T-cell Lymphoma)

CTCL is a rare type of non-Hodgkin's T-cell lymphoma. The two most common types of CTCL are mycosis fungoides (MF) and Sézary syndrome (SS), and depending on the stage, the disease may involve skin, blood, lymph nodes, and viscera. In advanced stage CTCL is associated with significant morbidity and mortality.

About POTELIGEO (KW-0761)

POTELIGEO is a humanized monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4), which is frequently expressed on leukemic cells of certain hematologic 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). It was approved first in Japan for treatment of relapsed or refractory CCR4 positive adult T cell lymphoma (ATL) in March 2012 (brand name: POTELIGEO®). In addition, mogamulizumab received approvals in Japan for an additional indication for relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) in March 2014 and for chemotherapy-naïve CCR4-positive adult T-cell leukemia-lymphoma (ATL) in December 2014.

About MAVORIC

MAVORIC is a Phase 3 open-label, multi-centre, randomized study of mogamulizumab versus Vorinostat, active comparator in patients with CTCL who have failed at least one prior systemic treatment. The study was the largest comparative trial in patients with CTCL conducted in the US, Europe, Japan and Australia, and randomized 372 patients.