Kyowa Hakko Kirin Submits the Partial Change Approval Application of Mogamulizumab in Japan

Tokyo, Japan, November 30, 2017 — Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151 President and CEO: Nobuo Hanai; "Kyowa Hakko Kirin") today announces the submission of a supplemental application to remove the requirement for pre-treatment diagnostic testing and change the dosage and administration in patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL) * for mogamulizumab* (code name: KW-0761; brand name: POTELIGEO®) to the Ministry of Health, Labor and Welfare in Japan.

The application is supported by data from the MAVORIC (Mogamulizumab anti-CCR4 Antibody Versus ComparatOR In CTCL)* study, the largest global randomized clinical trial of systemic therapy in CTCL. The MAVORIC study did not require identification of CCR4 positive cells in patients before enrollment into the study. The application is intended to remove the requirement for diagnostic testing for CCR4 expression before administration of the drug for CTCL, which is required in the current approval of CTCL, and to change the dosage schedule for CTCL.

" We are happy to file the application of mogamulizumab in CTCL in Japan," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin. "We believe results of the MAVORIC study indicates mogamulizumab can help to treat CTCL in an expanded patient population."

Mogamulizumab currently has no approved indications outside of Japan, and has been recently submitted Marketing Authorization Application in EU and Biologics License Application in the US.

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 Mogamulizumab (KW-0761)

Mogamulizumab 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. Mogamulizumab 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 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.