

Kyowa Hakko Kirin Announces Results of Phase 3 Clinical Study of Mogamulizumab (KW-0761) in Patients with Cutaneous T-cell Lymphoma at the American Society of Hematology 2017

Tokyo, Japan, December 11, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that the results of the Global Phase 3 study (MAVORIC: **Mogamulizumab anti-CCR4 Antibody Versus ComparatOR In CTCL**) investigating the use of mogamulizumab (KW-0761) in patients with cutaneous T-cell lymphoma (CTCL) will be presented at the Annual Meeting of American Society of Hematology 2017.

The American Society of Hematology 2017 Oral Presentation 817:

Title: *Anti-CCR4 Monoclonal Antibody, Mogamulizumab, Demonstrates Significant Improvement in PFS Compared to Vorinostat in Patients with Previously Treated Cutaneous T-Cell Lymphoma (CTCL): Results from the Phase III MAVORIC Study*

MAVORIC is a phase 3 open-label, multi-center, randomized study of mogamulizumab versus vorinostat in patients with CTCL who have failed at least one prior systemic treatment. The study was conducted in the US, Europe, Japan and Australia, and randomized 372 patients to receive either the investigational monoclonal antibody, mogamulizumab, or vorinostat. The primary endpoint was investigator-assessed Progression-free Survival (PFS), and the key secondary endpoints included overall response rate (ORR).

In the study, the patients who received mogamulizumab had significantly better PFS compared to vorinostat with a median PFS of 7.7 months for mogamulizumab and 3.1 months for vorinostat ($p < 0.0001$). Global ORR was significantly improved in the patients randomized to mogamulizumab at 28.0% vs 4.8% for vorinostat ($p < 0.0001$). Patient-reported outcomes, as measured by the Skindex-29 and FACT-G, showed significantly greater symptom reduction and improved functional status in favor of mogamulizumab vs vorinostat ($p < 0.05$).

The most common treatment-emergent adverse events (TEAEs) that were more frequent in the mogamulizumab arm included infusion-related reactions (33.2%, vs 0.5% in the vorinostat arm) and drug rash (23.9% vs 0.5%). Common TEAEs reported more often with vorinostat included diarrhea (23.4%, vs 61.8% in the vorinostat arm) nausea (15.2% vs 42.5%), thrombocytopenia (11.4% vs 30.6%), dysgeusia (3.3% vs 29.0%), and increased blood creatinine (3.3% vs 28.0%).

In conclusion, mogamulizumab demonstrated significant PFS and ORR improvement compared to vorinostat in patients with previously treated CTCL.

"We are delighted with the finding from the MAVORIC study which is the largest, global randomized phase 3 clinical study ever conducted in patients with CTCL," said Jeffrey S. Humphrey, MD., Chief Medical Officer and President of Kyowa Kirin Pharmaceutical Development, Inc. "We look forward to having the data reviewed by regulatory agencies in the near future and to providing mogamulizumab to patients with CTCL if approved."

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 MAVORIC

MAVORIC is a Phase 3 open-label, multi-center, randomized study of mogamulizumab versus vorinostat, active comparator, in patients with mycosis fungoides (MF) and Sézary syndrome (SS) who have failed at least one prior systemic treatment. The study was the largest comparative trial in patients with MF and SS conducted in the US, Europe, Japan and Australia, and randomized 372 patients.

About Mogamulizumab

Mogamulizumab is an investigational 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).

About Cutaneous T-cell Lymphoma (CTCL)

CTCL is a rare type of non-Hodgkin's lymphoma which is characterized by localization of malignant T lymphocytes to the skin. The two most common types of CTCL are mycosis MF and SS, and depending on the stage, the disease may involve skin, blood, lymph nodes, viscera and other organs.