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

Tokyo, Japan, April 7, 2017 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today the Global Phase 3 study (MAVORIC: **M**ogamulizumab anti-CCR4 **A**ntibody **V**ersus Comparat**OR** **I**n **C**TCL) investigating the use of mogamulizumab (KW-0761) in patients with cutaneous T-cell lymphoma (CTCL) met its primary endpoint of progression free survival.

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 is conducted in the US, Europe, Japan and Australia, and randomized 372 patients to receive either mogamulizumab or vorinostat. The top-line results demonstrated a statistically significant improvement in progression free survival in the mogamulizumab arm compared to the control (vorinostat) arm, and tolerable safety profile of mogamulizumab.

Kyowa Hakko Kirin will complete a full evaluation of the data from the MAVORIC study and work with investigators on the future presentation and publication of results. Kyowa Hakko Kirin plans to initiate discussions with global regulatory authorities in 2017 about plans for pursuing marketing authorizations for mogamulizumab in CTCL.

“We are delighted with the positive results from the MAVORIC study which is the largest, global randomized phase 3 clinical study ever conducted in patients with CTCL.” said Mitsuo Satoh, Executive Officer, Vice President, Head of Research and Development Division of Kyowa Hakko Kirin.
“We look forward to reviewing the data with regulatory agencies in the near future.” said Stephen Letrent, Pharm.D, Ph.D, Senior Vice President, Kyowa Kirin Pharmaceutical Development.

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 Mogamulizumab
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). Mogamulizumab was first granted marketing authorization in Japan in March 2012 for the treatment of patients with relapsed or refractory CCR4-positive Adult T-cell Leukemia-Lymphoma (ATL) under the trade name POTELIGEO®. The drug was subsequently granted marketing authorization in Japan for the treatment of patients with relapsed or refractory CCR4-positive, peripheral T-cell lymphoma (PTCL) and CTCL in March 2014, and with chemotherapy-naive CCR4-positive ATL in December 2014.

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 fungoides (MF) and Sézary syndrome (SS), and depending on the stage, the disease may involve skin, blood, lymph nodes, viscera and other organs.