

Kyowa Hakko Kirin Announces Marketing Authorisation Application for Mogamulizumab Validated by European Medicines Agency

Tokyo, Japan, October 27th, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151 President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announces that its marketing authorisation application (MAA) for mogamulizumab, for the treatment of cutaneous T-cell lymphoma (CTCL) in adults who have received at least one prior systemic therapy, has been validated by the European Medicines Agency (EMA) and is now under review.

This MAA is based on the data from the MAJORIC (**M**ogamulizumab anti-CCR4 **A**ntibody **V**ersus **C**omparat**OR** **I**n **CTCL**) study, the largest global randomised clinical trial of systemic therapy in CTCL.

"This is a significant milestone for our subsidiary, Kyowa Kirin Pharmaceutical Development," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin. "I believe mogamulizumab has the potential to be an advance in therapy for patients with CTCL and we will keep working to make it available to patients as soon as possible."

Mogamulizumab was first approved in Japan 2012 for other haematological malignancies and in 2014 for use in CTCL. Kyowa Hakko Kirin has also initiated discussions with regulatory authorities concerning plans for marketing authorisation applications for mogamulizumab in CTCL in other countries.

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 humanised 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 MAJORIC

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

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 MF and 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.