

Kyowa Hakko Kirin Announces FDA Acceptance for Filing and Priority Review Designation of Mogamulizumab's Biologics License Application

Tokyo, Japan, November 28, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151 President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announces that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for mogamulizumab to treat Cutaneous T-cell Lymphoma (CTCL) in patients who have received at least one prior systemic therapy, and has granted Priority Review status.

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

The FDA has granted mogamulizumab Priority Review status, which is available to drugs that would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The Prescription Drug User Fee Act (PDUFA) action date for the BLA is June 4, 2018.

"I am delighted that the FDA accepted the BLA for mogamulizumab with Priority Review and this is another significant achievement 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. "We will keep working with Regulatory Authorities such as FDA to make it available to patients with CTCL in the US as soon as possible."

Mogamulizumab was first approved in Japan in 2012 for other hematological malignancies and in 2014 for use in CTCL. FDA has granted Breakthrough Therapy Designation status to mogamulizumab for the treatment of Mycosis Fungoides (MF) and Sézary Syndrome (SS), in patients who have received at least one prior systemic therapy. MF and SS are the most common subtypes of CTCL.

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).

About MAJORIC

MAJORIC is a Phase 3 open-label, multi-center, randomized study of mogamulizumab versus active comparator in patients with MF and SS who have failed at least one prior systemic treatment. The study was conducted in the US, Europe, Japan and Australia, and randomized 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.