Kyowa Hakko Kirin Announces FDA Notification of PDUFA Action Date Extension for Mogamulizumab

Tokyo, Japan, May 30, 2018 –Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151 President and COO: Masashi Miyamoto, "Kyowa Hakko Kirin") announced today that it has been notified that the U.S. Food and Drug Administration (FDA) is extending its review of the Biologics License Application (BLA) for mogamulizumab for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. In a notice received from the FDA, the Prescription Drug User Fee Act (PDUFA) target action date has been extended to September 4, 2018.

During the review, Kyowa Hakko Kirin submitted additional documentation related to the manufacturing section of the BLA, and FDA subsequently decided that it constituted a major amendment requiring a 3 month extension to the original target action date, to provide time to complete review of the submission.

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 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 (cutaneous T-cell lymphoma). Mogamulizumab was produced using Kyowa Hakko Kirin's proprietary POTELLIGENT® platform, which is associated with enhanced antibody-dependent cellular cytotoxicity (ADCC).

In August 2017, the FDA announced that mogamulizumab has been granted Breakthrough Therapy designation status for the treatment of MF and SS in adult patients who have received at least one prior systemic therapy. In late November 2017, the FDA accepted the BLA for filing and granted mogamulizumab Priority Review.

About Mycosis Fungoides (MF) and Sézary Syndrome (SS)

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