US Food and Drug Administration Grants Breakthrough Therapy Designation for Mogamulizumab for the treatment of Mycosis Fungoides and Sézary Syndrome

Tokyo, Japan, August 25th, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo; 4151 President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announced that U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation status to their investigational product, mogamulizumab which is being developed for the treatment of Mycosis Fungoides (MF) and Sézary Syndrome (SS), in adult patients who have received at least one prior systemic therapy. Mycosis Fungoides and Sézary Syndrome are the most common subtypes of cutaneous T-cell lymphoma (CTCL).

"We are excited to hear mogamulizumab received such a valuable designation." said Mitsuo Satoh, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Hakko Kirin. "We will keep on making effort to provide this antibody to patients with these conditions worldwide."

Breakthrough Therapy Designation was granted based on the data from the MAVORIC (**M**ogamulizumab anti-CCR4 **A**ntibody **V**ersus Comparat**OR I**n **C**TCL) study. This global study is the largest randomized trial in CTCL. Kyowa Hakko Kirin is working with investigators on the future presentation and publication of clinical trial results.

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and regulatory review of therapies for serious or life-threatening conditions and whose preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. Under the designation, the FDA provides intensive guidance, organizational commitment involving senior managers, and eligibility for rolling and priority review of the marketing application; this process is intended to ensure that safe and effective therapies for serious conditions are approved and available to patients faster than through conventional approval pathways.

Kyowa Hakko Kirin has also initiated discussions with other regulatory authorities concerning plans for marketing authorization 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 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 MAVORIC

MAVORIC is a Phase 3 open-label, multi-center, randomized study of mogamulizumab versus vorinostat in patients with MF and SS 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.

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.