

Kyowa Kirin Presents New Data for Mogamulizumab from Its Lead Program in Cutaneous T-cell Lymphoma (CTCL) at ASCO

- *Quality of life and patient health outcomes data from the pivotal MAVORIC trial is being reported for the first time*

Tokyo, Japan, June 4, 2018 – Kyowa Hakko Kirin Co., Ltd., (Kyowa Kirin) announces that additional analyses from the pivotal MAVORIC trial are being presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO), June 1-5, Chicago. MAVORIC was the open-label randomized multi-center phase 3 trial evaluated mogamulizumab versus vorinostat for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. MF and SS are the most common subtypes of cutaneous T-cell lymphoma (CTCL).

Presentation title at the 2018 ASCO Annual Congress:

Quality of life in cutaneous T-cell lymphoma subjects treated with anti-CCR4 monoclonal antibody mogamulizumab versus vorinostat: results from the Phase 3 MAVORIC trial
[Abstract #7577; Poster #214; Monday, June 4, 8:00-11:30AM CDT]

Progression free survival (PFS) was the primary endpoint; the results that demonstrated mogamulizumab had a clinically relevant and statistically significant increase in progression free survival over vorinostat have already been presented. Infusion reaction and rash were the most common adverse events associated with mogamulizumab. QOL measurements were secondary endpoints and included Skindex-29 (SDX-29), Functional Assessment of Cancer Therapy-General (FACT-G) and EuroQol-5D. SDX-29 and FACT-G were reported in ASCO.

“Quality of life may be severely impacted in patients living with CTCL, and the MAVORIC study included evaluation of the effect of both treatments on a range of QOL instruments,” said Jeffrey S. Humphrey, M.D., President of Kyowa Kirin Development. “We are encouraged by the QOL data and look forward to working with investigators and patient advocates to further understand how mogamulizumab might help patients with MF and SS.”

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. Mogamulizumab is an investigational product currently under review at FDA and EMA.

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.

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 was conducted in the U.S., Europe, Japan and Australia, and randomized 372 patients to receive either mogamulizumab or vorinostat.