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Kyowa Hakko Kirin announces results of Phase 3 trial of patients with Cutaneous T-cell Lymphoma

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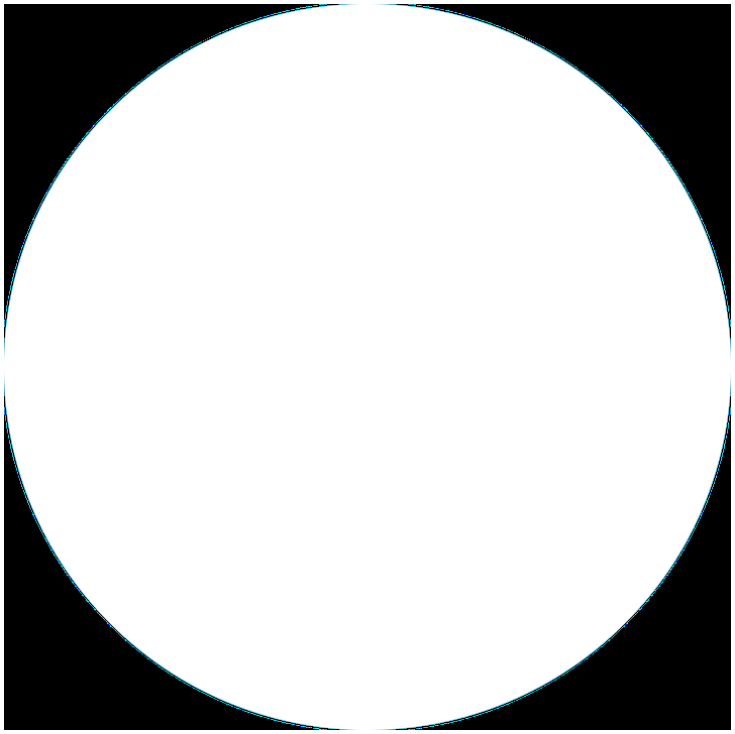
MAVORIC study (Mogamulizumab anti-CCR4 Antibody Versus ComparatOR In CTCL) investigating the use of mogamulizumab in patients with cutaneous T-cell lymphoma (CTCL) have been published in Lancet Oncology.



Kyowa Hakko Kirin Co., Ltd., (Kyowa Kirin) has announced that results of the global Phase 3 MAVORIC study (Mogamulizumab anti-CCR4 Antibody Versus ComparatOR In CTCL) investigating the use of mogamulizumab in patients with cutaneous T-cell lymphoma (CTCL) have been published in *Lancet Oncology.*

MAVORIC was the open-label randomized multi-center phase 3 trial that 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 CTCL.

MAVORIC is the first pivotal trial to use progression free survival (PFS) as a primary endpoint and the largest randomized study to compare systemic therapies in CTCL. Secondary endpoints included proportion of patients achieving an overall response (ORR), duration of response (DOR) and safety. It was the pivotal study included in the Biologics License Application (BLA) that was recently approved by the U.S. Food and Drug Administration (FDA).

"Progression-free survival captures the duration of disease control with treatment based on the composite response assessment of each disease compartment, skin, blood, lymph nodes, and viscera, and may more broadly reflect the overall

impact of new therapies," said Youn Kim, lead investigator and Professor of Dermatology/Medicine and Director of the Multidisciplinary Cutaneous Lymphoma Program at Stanford University School of Medicine and Stanford Cancer Institute. "Progression-free survival is more informative about the duration of overall clinical benefit for patients with a chronic course as in CTCL compared to using the overall response rate as a primary endpoint."

In MAVORIC, 372 patients across 61 centers in 11 countries were randomized 1:1 to mogamulizumab or vorinostat and stratified by CTCL subtype (MF or SS) and disease stage (IB/II or III/IV). Once enrolled, patients received either mogamulizumab 1.0 mg/kg or vorinostat 400 mg and each treatment cycle was 28 days. Patients on vorinostat who demonstrated confirmed disease progression or experienced intolerable toxicity after two cycles, despite dose reduction and appropriate management of side effects, could cross over to treatment with mogamulizumab.

The results showed that mogamulizumab demonstrated significantly superior PFS at a median of 7.7 months [95% CI, 5.7, 10.3] compared to 3.1 months with vorinostat [95% CI, 2.9, 4.1; hazard ratio 0.53, 95% CI 0.41– 0.6969; p<0.0001]. In addition to meeting the primary endpoint, ORR [28%; 95% CI, 21.6, 35.0 vs. 4.8%; 95% CI, 2.2, 9.0], median DOR [14.1 months, IQR 8.4-19.2 vs. 9.1 months (IQR 5.6 – not estimable)] and response by disease compartment were higher for patients assigned to mogamulizumab than for patients assigned to vorinostat. The safety profile of mogamulizumab was consistent with previous studies and the most common adverse events of any grade included infusion-related reactions (33%) and drug rash (24%). Infusion-related reactions were manageable and mostly limited to early infusions. Grade 3–4 adverse events were reported in 75 (41%) of 184 patients in the mogamulizumab group and 76 (41%) of 186 patients in the vorinostat group. The most common serious adverse events were pyrexia in eight (4%) patients and cellulitis in five (3%) patients in the mogamulizumab group; and cellulitis in six (3%) patients, pulmonary embolism in six (3%) patients, and sepsis in five (3%) patients in the vorinostat group.

"Mycosis fungoides and Sézary syndrome can be debilitating for patients and complex to treat and manage for healthcare professionals," said Jeffrey S. Humphrey, MD, Chief Medical Officer and President of Kyowa Kirin Pharmaceutical Development, Inc. "We are encouraged that these findings underscore the viability of mogamulizumab as a new treatment option for patients living with MF or 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.