Kyowa Hakko Kirin Announces Preliminary Results from Pivotal Phase 2 Study of Mogamulizumab (KW-0761) in Patients with Relapsed or Refractory Adult T-cell Leukemia-Lymphoma

Tokyo, June 6th, 2016 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo; 4151 President and CEO: Nobuo Hanai; "Kyowa Hakko Kirin") announced the preliminary results today from the pivotal Phase 2 study of mogamulizumab (Code name: KW-0761) for the treatment of Adult T-cell Leukemia-Lymphoma (ATL).

"We are very pleased to announce that we have completed the largest, prospective randomized clinical trial for relapsed/refractory ATL and that the preliminary results of this pivotal Phase 2 study showed potential of mogamulizumab for the treatment of relapsed/refractory ATL, where no standard of care exists" said Yoichi Sato, Managing Executive Officer, Vice President, Head of Research and Development Division of Kyowa Hakko Kirin.

Study Design

Patients from the USA, EU, and Latin America with aggressive relapsed or refractory ATL were randomized 2:1 to treatment with mogamulizumab or to 1 of 3 investigator choice (IC) regimens (Gem/Ox, DHAP or pralatrexate). Patients in the IC arm were permitted to cross-over to treatment with mogamulizumab after progression. Overall Response Rate (ORR; confirmed and unconfirmed) was assessed by the treating investigator (IA) and through blinded assessment by independent review (IR).

Study Results

71 patients were randomized (47 to mogamulizumab, 24 to IC). In the mogamulizumab treated group, unconfirmed ORR was 28% (13/47) by IR and 34% (16/47) by IA, while in the IC group, unconfirmed ORR was 8% (2/24) by IR and 0/24 by IA. Confirmed ORR (response maintained at successive evaluations approximately 8 weeks apart) for mogamulizumab was 11% by IR and 15% by IA, while there were no confirmed responses in the IC group. 18 out of 24 patients in the IC arm crossed over to mogamulizumab and 3 patients (17%) responded (1 of the responses was confirmed). The median duration of confirmed response for mogamulizumab was 5.0 months by IR and 5.5 months by IA. One patient had a response lasting more than 9 months. The frequently observed treatment-emergent, adverse events in the mogamulizumab arm included infusion reactions (46.8%), rash/drug eruption (19.1%) and infections (51.1%). The safety data collected from this study were similar to what has previously been documented.

These data from the study were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 5th, 2016.

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 mAb directed against CC chemokine receptor 4 (CCR4), which is frequently expressed on leukemic cells of certain hematologic malignancies including ATL. Mogamulizumab was produced using Kyowa Hakko Kirin's proprietary POTELLIGENT® platform, which is associated with enhanced antibody-dependent cellular cytotoxicity (ADCC), and was launched in Japan in May 2012 for the treatment of patients with relapsed or refractory CCR4-positive ATL under the trade name POTELIGEO®. The drug was approved for indication expansion and was granted marketing authorization in Japan for the treatment of patients with relapsed or refractory CCR4-positive, peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) in March 2014, and with chemotherapy-naive CCR4-positive ATL in December 2014.

About Adult T-cell Leukemia-Lymphoma (ATL)

ATL is a disease entity within the category of mature T- and NK-cell neoplasms, according to the classification by the World Health Organization. It is an extremely aggressive T lymphocytic malignancy that originates in T-cells infected with the human T-lymphotropic virus-1(HTLV-1). ATL has a very distinct epidemiology and geographic distribution, primarily involving areas of Japan, the Caribbean Basin, parts of South America, the Middle East and sub-Saharan Africa, where HTLV-1 infection is endemic. In non-endemic regions such as North America and Europe, HTLV-1 infection is mainly found in immigrants from endemic areas, their offspring or sexual contacts. Treatment regimens for ATL have not been standardized, especially in the relapsed/refractory setting, representing a large unmet medical need in this patient population.