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Application Seeking Approval for Additional Indication for ATL, PTCL and CTCL of Mogamulizumab

Tokyo, Japan, July 19 2013 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that it has been filed an application to Japan's Ministry of Health, Labour and Welfare ("MHLW") seeking approval for additional indication for untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL), relapsed CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) of Mogamulizumab (brand name: POTELIGEO® Injection 20 mg).

Mogamulizumab is a novel, humanized monoclonal antibody directed against CC chemokine receptor 4 (CCR4), which is over-expressed on various malignant T cells, including ATL, PTCL and CTCL cells. Engineered by Kyowa Hakko Kirin's unique POTELLIGENT® Technology, the antibody is designed to kill its target cells through potent antibody-dependent cellular cytotoxicity (ADCC). Clinical studies of Mogamulizumab in patients with untreated CCR4-positive ATL, relapsed CCR4-positive PTCL and CTCL in Japan met their primary endpoint, which allowed Kyowa Hakko Kirin to file an application. Mogamulizumab was also granted orphan drug designations for the treatment of CCR4-positive ATL in August 2010, PTCL and CTCL in March 2013 by the MHLW.

Mogamulizumab was launched in Japan with the brand name "POTELIGIO® Injection 20 mg" on May 29, 2012 for the treatment of patients with relapsed or refractory CCR4-positive ATL and is being investigated world-wide in a number of clinical studies for other potential indications.

Kyowa Hakko Kirin is committed to developing innovative therapeutics for treatment of a wide range of diseases with unmet medical needs, including lymphomas such as ATL, PTCL and CTCL, and contributing to the improvement of patients' quality of life (QOL).

Overview of Phase II Clinical Study for untreated ATL in Japan

Objective	Evaluate the efficacy, safety and pharmacokinetics of mLSG15 + Mogamulizumab or mLSG15 in patients with untreated CCR4-positive ATL. Mogamulizumab: 1.0 mg/kg/2wks for eight times in patients

Primary Endpoint	Efficacy (complete response rate, ORR), safety, pharmacokinetics
Efficacy	Efficacy was assessed in 53 patients (mLSG15 + Mogamulizumab: 29 patients, mLSG15: 24 patients) <Complete response rate> mLSG15 + Mogamulizumab: 52% (95%CI; 33-71%)(15/29) mLSG15: 33% (95%CI; 16-55%)(8/24) <ORR> mLSG15 + Mogamulizumab: 86% (95%CI; 68-96%)(25/29) mLSG15: 75% (95%CI; 53-90%)(18/24) Add-on effects of Mogamulizumab were found on mLSG15 therapy in complete response rate and ORR
Safety	Safety was assessed in 53 patients Common adverse events might cause by mLSG15 therapy in patients, add-on therapy of Mogamulizumab was found to be well tolerated at this dose level on mLSG15 therapy.

Overview of Phase II Clinical Study for PTCL and CTCL in Japan

Objective	Evaluate the efficacy, safety and pharmacokinetics of Mogamulizumab at 1.0 mg/kg weekly for eight weeks in patients with CCR4-positive relapsed PTCL and CTCL.
Primary Endpoint	Efficacy (ORR), safety, pharmacokinetics
Efficacy	Efficacy was assessed in 37 patients (PTCL: 29 patients, CTCL: 8 patients) <ORR> 35% (95% CI; 20-53%)(13/37) (complete response in 5 patients, partial response in 8 patients) <ORR for PTCL> 34% (95% CI; 18-54%)(10/29) (complete response in 5 patients, partial response in 5 patients) <ORR for CTCL> 38% (95% CI; 9-76%)(3/8) (partial response in 3 patients)
Safety	Safety was assessed in 37 patients Mogamulizumab was found to be well tolerated at this dose level.

ENDS

About CCR4 (CC chemokine receptor 4)

CCR4 is one of the chemokine receptors involved in leukocyte migration, selectively expressed in type 2 helper T (Th2) cells and regulatory T (Treg) cells. CCR4 is also shown to be over-expressed in certain hematological malignancies.

About adult T-cell leukemia-lymphoma (ATL)

ATL is a peripheral T-cell malignancy and the retrovirus HTLV-1 is thought to be involved in its onset. Estimates show that around 1,150 new cases occur every year in Japan. ATL is generally treated with combination chemotherapy, such as mLSG15, but there are currently no therapeutic methods with the potential of providing a cure for ATL, although researchers are actively looking into other methods than transplantation. For relapsed/refractory cases, various chemotherapy regimens based on malignant lymphoma therapies are currently used, but an effective treatment method has yet to be established.

About Peripheral T-Cell Lymphoma (PTCL)

Non-Hodgkin lymphomas account for the majority of malignant lymphoma cases and can be broadly divided into disease of B-cell origin and disease of T/natural killer (NK)-cell origin. Disease of T/NK-cell origin can be classified according to the main lesion site into nodal, extranodal, cutaneous, and leukemic disease. PTCL is a general term describing nodal and extranodal disease of T/NK-cell origin.

About Cutaneous T-Cell Lymphoma (CTCL)

CTCL is a rare, low grade type of non-Hodgkin's lymphoma. CTCL is one of the most common forms of T-cell lymphoma. The two most common types of CTCL are mycosis fungoides (MF) and Sezary syndrome (SS). MF does not look the same in all patients and may present as skin patches, plaques, and tumors. SS is an advanced form of MF and includes the presence of malignant lymphocytes in the blood.

About POTELLIGENT®

POTELLIGENT® is Kyowa Hakko Kirin's unique technology for the production of antibodies with enhanced ADCC activity. This technique enables production of antibodies with a reduced amount of fucose in their carbohydrate structure. Non-clinical studies have demonstrated that antibodies produced using this technology killed target cells more efficiently than conventional antibodies and exhibited stronger antitumor effects. For more information, please visit www.POTELLIGENT.com.

About antibody-dependent cellular cytotoxicity (ADCC)

ADCC is one of the body's immune responses, initiated by binding of an antibody to its antigen on target cells, followed by lysis of the antibody-bound target cells by effector cells such as natural killer cells. ADCC is known to be one of the modes of action of therapeutic antibodies.

Orphan drug designation

A drug must meet the following three conditions in order to be granted an orphan drug designation in Japan.

1) The number of patients who may use the drug is less than 50,000 in Japan.

2) There are high medical needs for the drug (There is no appropriate alternative drug/treatment, or high efficacy or safety is expected compared with existing products).

3) There is high possibility of development (There should be a theoretical rationale for the use of the drug for the target disease, and the development plan should be appropriate). For designated orphan drugs, measures to support the research and development activities are taken (The orphan drug and orphan medical device research and development promotion program).

About mLSG15 therapy

The mLSG15 therapy is one of standard chemotherapies for ATL patients. The mLSG15 therapy generally consists of six courses. A course is the combination of the following three therapies, VCAP therapy (V: Vincristine Sulfate, C: Cyclophosphamide Hydrate, A: Doxorubicin Hydrochloride, P: Prednisolone), AMP therapy (A: Doxorubicin Hydrochloride, M: Ranimustine, P: Prednisolone) and VECP therapy (V: Vindesine Sulfate, E: Etoposide, C: Carboplatin, P: Prednisolone), which are administered at one week interval in turns. ATL patients are administrated cytarabine, methotrexate, and prednisolone intraspinally before the start of VCAP therapy of the 2,4,6 course (Intraspinal administration is to inject directly in and around the area of the spinal cord with anti-cancer agents to prevent relapsing cancer from these sites by distributing anti-cancer drugs to the brain and spinal cord). According to patient's conditions, the reduction of the number of courses and doses of medicine may be done.