

IMS-P25 **Research and Development of Novel Anti-Cancer Drug Mogamulizumab, Humanized Anti-CCR4 Antibody Using High ADCC POTELLIGENT® Technology, for Adult T-Cell Leukemia-Lymphoma**

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Mogamulizumab is a recombinant humanized monoclonal antibody targeting CC chemokine receptor 4 (CCR4). It has been approved as the first-in-class drug in Japan in March 2012 for the treatment of relapsed or refractory CCR4-positive adult T-cell Leukemia-Lymphoma (ATL). Currently, about 1,100 people a year develop ATL in Japan. Generally, combination chemotherapy such as mLSG15 is used, but no curative treatment has been established for ATL, except transplantation, which is actively being studied at present. For relapsed/refractory ATL, different types of chemotherapies are used based on the treatment of malignant lymphoma, but no effective treatment has been established. To provide the novel treatment for an unmet medical need of ATL, we carried out consistent research and development including target molecule validation, candidate antibody production, non-clinical study, translational study, and clinical trial in Japan. 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) and is also the world's first POTELLIGENT® antibody approved for marketing authorization. Mogamulizumab was also granted supplemental marketing authorization for the treatment of relapsed/refractory PTCL and CTCL in March 2014 in Japan and is being investigated world-wide in a number of clinical studies for other potential indications.