443 OPEN-LABEL, PHASE 2 STUDY TO ASSESS THE SAFETY OF MOGAMULIZUMAB AT 2 MG/KG Q4W MAINTENANCE DOSING IN PATIENTS WITH RELAPSED/REFRACTORY MF/SS SUBTYPES OF CTCL

Karen Dwyer, Roland Meier, Matthew Hruska, Floyd Fox, Takahiro Ito. *Kyowa Kirin, Inc., Princeton, NJ, USA*

Background Mogamulizumab is approved in the United States, Japan, and the European Union for patients with relapsed/refractory mycosis fungoides (MF)/Sézary syndrome (SS) who have received at least one prior systemic therapy. The approved dose and schedule of mogamulizumab induction therapy are 1 mg/kg administered intravenously (IV) on Days 1, 8, 15, and 22 of the first 28-day cycle (figure 1). After induction, patients continue with 1 mg/kg IV on Days 1 and 15 of subsequent cycles. Patients must return to a clinic for administration, which can be inconvenient for patients with inadequate support systems or lack of accessibility. Additional clinic visits can also impact patient care when unforeseen circumstances, such as the COVID-19 pandemic, limit access to treatment. Limiting the number of clinic visits needed for infusion should also decrease the risk of possible exposure to nosocomial infections. This study's purpose is to evaluate the safety, tolerability, and pharmacokinetics of mogamulizumab in patients receiving standard induction treatment followed by 2 mg/kg every 4 weeks in subsequent cycles. Data from this study will be combined with data from previous studies using modeling and simulation methods to understand how every-4-week dosing compares to every-2-week dosing in terms of exposure, safety, and activity profiles. By extending the treatment interval of mogamulizumab, patients with MF/SS will have fewer clinic visits and reduced risk of exposure to nosocomial infections.

Methods This is a phase 2, open-label, multicenter, international study of mogamulizumab in adult patients with relapsed/refractory MF/SS who have failed at least one prior course of systemic therapy. All patients will receive mogamulizumab induction therapy. Therapy will then be administered as a 2 mg/kg IV infusion on day 1 of each subsequent 28-day cycle (figure 2). The primary objective is to evaluate the safety and tolerability of mogamulizumab 2 mg/kg administered every 4 weeks by observing the percentage of patients experiencing treatment-emergent adverse events. Secondary objectives include characterization and evaluation of mogamulizumab's pharmacokinetic profile, immunogenicity, anti-tumor activity (global composite response and response by compartment), and pharmacodynamic profile. A maximum of 33 patients will be enrolled in this clinical trial. The study consists of a 28-day screening period followed by a treatment period of up to 2 years from Cycle 1. No dose adjustment or modification is planned or permitted. Patients will be treated until disease progression or unacceptable toxicity or upon reaching 2 years from first dose.

Abstract 443 Figure 1 Approved mogamulizumab dosing: 1 mg/kg every 2 weeks following induction

Abstract 443 Figure 2 Study mogamulizumab dosing: 2 mg/kg every 4 weeks following induction

Acknowledgements The study was sponsored by Kyowa Kirin. Medical writing assistance was provided by Jonathan Mitchell, PharmD, of MedVal Scientific Information Services (Princeton, NJ, USA) and funded by Kyowa Kirin, Inc. (Princeton, NJ, USA).

Trial Registration ClinicalTrials.gov identifier: NCT04745234

Ethics Approval This study has been approved by the Advarra Institutional Review Board (Approval MOD00923851). Participants will be informed that their participation is voluntary and will be required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local regulations, ICH guidelines, requirements of the Health Insurance Portability and Accountability Act of 1996, where applicable, and the IRB/EC or study center.

http://dx.doi.org/10.1136/jitc-2021-SITC2021.443