Real-World Observational Study of Mogamulizumab in Adult Patients with Mycosis Fungoides and Sézary Syndrome (PROSPER)

Poster Code: PCR223

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Background

- CTCLs are a rare and heterogeneous group of lymphomas characterized by skin involvement
- The most common types of CTCL are MF and SS; together they account for about two-thirds of all CTCLs[1]
- MF and SS can cause lifetime morbidity, being associated with chronic skin impairment with intractable itching, recurrent infections, disfiguring lesions, and sleep disturbance that can have a negative impact on HRQOL of patients and their caregivers[2]
- Mogamulizumab is a first-in-class, defucosylated humanized IgG1-kappa monoclonal antibody that selectively binds to CCR4 with enhanced antibody-dependent cellular cytotoxicity activity[3]
- MAVORIC was an open-label, international, randomized controlled phase 3 trial (NCT01728805) comparing mogamulizumab vs vorinostat in patients with MF or SS who have received at least one prior systemic therapy[4]
- 372 eligible patients were randomly assigned to receive mogamulizumab (n=186) or vorinostat (n=186). Mogamulizumab therapy resulted in significantly longer investigator-assessed PFS compared with vorinostat therapy (median 7.7 months [95% CI 5.7–10.3] in the mogamulizumab group vs 3.1 months [2.9–4.1] in the vorinostat group; hazard ratio 0.53, 95% CI 0.41–0.69; stratified log-rank $P<0.0001$)[4]
- The key secondary endpoints of the MAVORIC study included measurement of patient-reported pruritus experience and HRQOL using Skindex-29, FACT-G, ItchyQoL, and EQ-5D-3L. The symptoms, function, and overall HRQOL of patients with MF/SS favored mogamulizumab over vorinostat across all time points[5]
- A prospective study to collect information about the experiences of patients with MF/SS receiving mogamulizumab and of their caregivers in real-world clinical practice will provide additional insights into the impact of mogamulizumab treatment

Study Objectives

- The objectives of the PROSPER study (NCT05455931) are:
  - To describe the patient-reported changes in key signs and symptoms of disease as well as fatigue and HRQOL following initiation of mogamulizumab treatment
  - To assess change in the HRQOL of the patient's main caregiver
  - To describe treatment patterns in real-world clinical practice and associated patient-reported outcomes

Abbreviations

BFI, brief fatigue inventory; CarGOQoL, Caregiver Oncology Quality-of-Life questionnaire; CCR4, C-C chemokine receptor 4; CI, confidence interval; CTCL, cutaneous T-cell lymphoma; FACT-G, Functional Assessment of Cancer Therapy-Cancer; GVP, good pharmacovigilance practices; HRQOL, health-related quality of life; ISPE GPP, International Society for Pharmacoepidemiology Good Pharmacoepidemiology Practice; MF, mycosis fungoides; MF/SS CTCL-QOL, mycosis fungoides/Sézary syndrome cutaneous T-cell lymphoma quality of life; PFS, progression-free survival; PRO, patient-reported outcome; PROSPER, Prospective Research-based Observational Study of Poteligeo® Experience in the Real World in Adult Patients with Mycosis Fungoides and Sézary syndrome; Q1W, once every 1 week; Q12W, once every 12 weeks; Q4W, once every 4 weeks; SS, Sézary syndrome.

References

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Conflict of Interest Disclosures

AW, YZ, J-PR, RCR, KS, and **TT** are employees of Kyowa Kirin.

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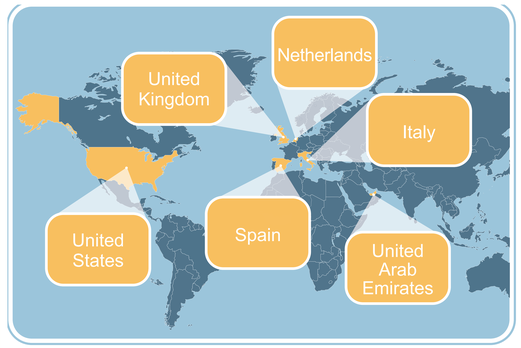
Study Design

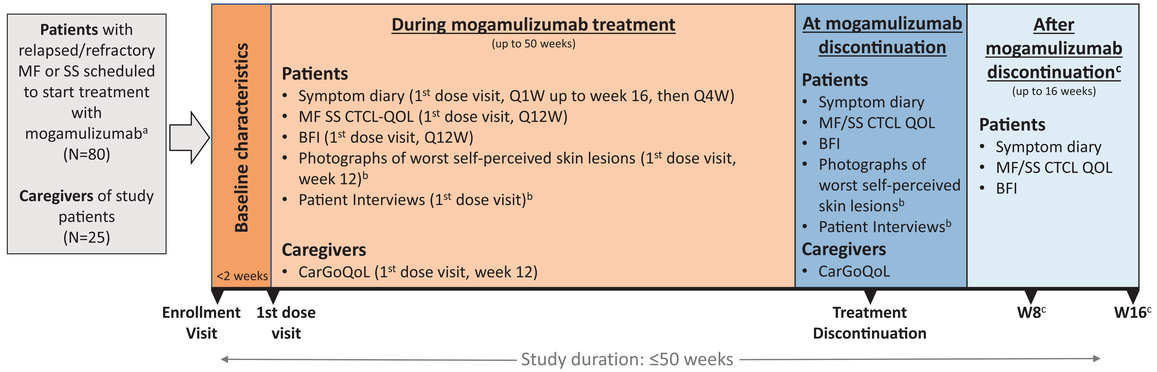
- PROSPER is a prospective, observational, noninterventional, international, multicenter, mixed-methods study that will involve integration of quantitative and qualitative data in patients with MF/SS treated with mogamulizumab
- The study was designed with input from patients and caregivers to focus on patient-relevant outcome measures[6]
- The study is being conducted in 6 countries: Italy, Netherlands, Spain, United Arab Emirates, United Kingdom, and United States of America (**Figure 1**)

Figure 1. Locations of Study Countries



- Target study size is 80 patients and approximately 25 primary caregivers, who were followed for up to 50 weeks (**Figure 2**)
- The investigators will prospectively enroll all patients with MF/SS who are scheduled to initiate mogamulizumab within the reimbursed indication and fulfill all selection criteria
- Disease stage must be known at the start of mogamulizumab treatment
- Patients will be treated according to institutional standards of care, and any changes in mogamulizumab dosing or schedule will be documented (along with the reasons for the change)
- The patients' main caregivers will also be invited to participate in the study
- Patients will be followed up for up to 50 weeks from study enrollment whilst being treated with mogamulizumab and up to 16 weeks after discontinuation if not commencing a new systemic therapy (**Figure 2**)
- The study will be conducted in compliance with ISPE GPP guidelines, the ethical principles arising from the Declaration of Helsinki, the European Union GVP, European and national laws in terms of data protection, and all current local regulations
- Before any protocol-specified procedures are carried out, the investigator or qualified designee will ensure that the patient is given full and adequate oral and written information about the nature, purpose, and possible risks and benefits of the study

Figure 2. PROSPER Study Design



[a] Per the approved indication in patient's country and reimbursement.
[b] Optional for patients.
[c] If a patient discontinues mogamulizumab before the end of the 50-week study period, data will continue to be collected at point of treatment discontinuation, 8 and 16 weeks after treatment discontinuation, or until they begin a new systemic therapy.

Conclusions

- The PROSPER study will provide novel insights into the impact of mogamulizumab treatment on symptoms and the patient experience among patients with MF and SS as well as their caregivers in the real-world setting
- The trial is currently enrolling and will collect data from 2022 through 2024

Outcome Measures

- Patient-reported data will be collected using a bespoke designed symptom diary, the BFI, and MF/SS CTCL-QOL questionnaire
- Medical records entered into an electronic data capture system
- One-on-one interviews
- Patient-provided photographs of the worst perceived lesion
- Caregivers will complete the CarGOQoL questionnaire
- Patient-reported data will be collected either through electronic diaries or paper forms

Study Population

- Key eligibility criteria are shown in **Table 1**

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Patient	**Patient**
• Confirmed diagnosis of MF/SS • Completed disease staging at enrollment • Scheduled to receive mogamulizumab • Age ≥18 years • Willing and able to complete a symptom diary and PRO questionnaires • Willing and able to provide written consent	• Unable to participate in all aspects of the study • Currently participating in an interventional clinical trial
Caregiver	**Caregiver**
• Main caregiver of study participant • Willing and able to provide written consent	

Study Variables

- Data to be collected during the study are summarized in **Table 2**

Table 2. Study Variables Collected From the Following Sources During Study Period

Collected by investigator	Collected by patient			Collected by patient's main caregiver
Medical records	**Symptom diary**	**PRO questionnaire**	**Other (optional)**	**CarGOQoL**
• Demographic data • MF/SS history • Other relevant medical history • MF/SS treatment history • Blood involvement (including flow cytometry results) • Mogamulizumab treatment • Concomitant medications • Safety assessments	• Worst skin pain score in past 24 h[a] • Worst skin itch score in past 24 h[a] • Worst skin flaking score in past 24 h[a] • Worst skin redness score in past 24 h[a] • Frequency of difficulty regulating body temperature in past 7 days • Frequency of sleep problems in past 7 days	• BFI • MF/SS CTCL-QOL	• One-on-one interviews • Photographs of patient's worst self-perceived skin lesion area	• Caregiver age and gender • Relationship with patient • CarGOQoL

[a] Worst score within 24 hours of diary entry.

Data Analyses

- Statistical analyses will be mainly descriptive. No formal hypothesis testing will be performed
- Quantitative data will be analyzed for both the treatment and posttreatment period using descriptive statistics
- Thematic analyses of qualitative data will be conducted using the Framework approach
- Qualitative data will be mixed with quantitative data in order to provide additional depth and context to the results derived from the quantitative data analyses