Characterization and Outcomes of Mogamulizumab-Associated Skin Reactions in Patients With MF/SS From the Phase 3 MAVORIC Trial

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Background of Study

- Mogamulizumab is an anti-CCR4 antibody approved by the FDA and EMA for the treatment of patients with relapsed or refractory (R/R) peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL) based on results from the phase 3, open-label, randomized, international trial that enrolled the safety and efficacy of mogamulizumab versus vorinostat in patients with PTCL or CTCL after systemic therapy

Methodology/Methods

- In MAVORIC, 372 patients were randomized 1:1 to receive either intravenous mogamulizumab at 1.0 mg/kg once weekly for Cycle 1 (28 days) and then on days 1 and 15 of subsequent cycles or oral vorinostat at 400 mg daily (Table 1)

Table 1. Management of Drug Rash in MAVORIC

<table>
<thead>
<tr>
<th>Grade</th>
<th>No Rash</th>
<th>With Drug Rash</th>
<th>Without Drug Rash</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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<td>0</td>
<td>0</td>
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<td>2</td>
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<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

- Results

- Among the 44 patients who experienced mogamulizumab-associated rash during MAVORIC, 59% (26/44) were ≥65 years of age, and more patients with SS (56.8 [25/44]) than MF (43.2% [19/44]) experienced drug rash

- Median (Q1, Q3) duration of exposure to mogamulizumab was 165 days (78, 200) for patients with MF and 185 days (85, 463) in patients with SS

- No rash was observed before day 30

- Central review assessed rashes as granulomatous, histiocytic spongiotic, lichenoid, eosinophilic, or psoriasiform with no clear predominant histological pattern

- Immunohistochemistry on TCR gene rearrangement was often required to differentiate genetic etiology from disease

- No trend toward increased incidence of drug rash was observed among the consented modifications (Table 2) or immediate prior therapy used by patients in MAVORIC (Figure 2A, Table 2).

- Among patients with MF, the proportion of responders with drug rash did not differ significantly from responders without rash (P=0.31); the proportion of SS responders with drug rash was significantly higher than responders without rash (P<0.02) (Figure 3A and B)

- Initial drug rash occurred after response in 17% (34/198) of patients who experienced both

- Overall, the median (Q1, Q3) time to onset of drug rash was 106 days (53, 254) (Figure 4)

- Conclusions

- Mogamulizumab-associated rashes displayed heterogeneous histopathology without predominant features

- Correlation of rash with clinical features via biopsy is advised to differentiate drug rash from disease progression

- Patients with SS were associated with a higher rate of drug rash than patients with MF

- After resolution of initial drug rash, 80% of patients were able to continue mogamulizumab for ≥6 months

- Nurse involvement in evaluation, identification, and management of mogamulizumab-associated rash may prevent premature treatment discontinuation

- Acknowledgements

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

References


The study was sponsored by Kyowa Kirin, Inc.

Presented at the Dermatology Nurses’ Association (DNA) 39th Annual Convention; April 21-23, 2021; Virtual Convention.

ClinicalTrials.gov identifier: NCT01728805