

A Phase I Study of Mogamulizumab in Combination with Brentuximab Vedotin in Previously Treated Mycosis Fungoides and Sézary Syndrome

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INTRODUCTION

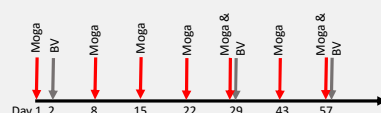
- The prognosis for patients with advanced-stage Mycosis Fungoides (MF) and Sézary syndrome (SS) is poor and more effective and well-tolerated treatments are needed.
- Mogamulizumab (Moga) is an anti-CCR4 monoclonal antibody that has excellent efficacy in the blood compartment and is approved for patients with MF and SS after one prior therapy.¹
- Brentuximab vedotin (BV) is a CD30-targeted antibody drug conjugate that is highly effective in skin and nodal compartments and is approved for patients with CD30-positive MF after one prior therapy.²
- We are conducting a phase I study of Moga in combination with BV in MF/SS (NCT05414500).

AIMS

- Primary: To determine safety, tolerability and recommended doses of BV and Moga given in combination for patients with relapsed / refractory (R/R) MF and SS.

- Secondary: To determine the efficacy of this combination.

ADMINISTRATION SCHEDULE



METHODS

- This is a single center phase I dose de-escalation study of BV and Moga in MF/SS.
- Key inclusion criteria:
 - Stage II-IV MF/SS
 - ≥ 1 prior systemic therapy
 - ≥ 1% CD30 positivity on most recent biopsy
 - No prior BV or Moga (unless prior BV > 6 months prior to study enrollment)
- 3 doses of BV will be explored in combination with standard dose of Moga
- If no DLTs at Dose Level 1 (n = 3), proceed to expansion cohort (n = 6).
- Treatment duration = 12 28-day cycles

CONCLUSIONS

- The recommended dose of BV given in combination with standard-dose Moga is 1.8 mg/kg every 3 weeks.
- Treatment was well-tolerated and AEs were in keeping with known side effect profiles of each drug.
- Enrollment to an expansion cohort at Dose Level 1 is ongoing.
- Moga + BV is a promising combination, particularly for those with both blood involvement and high burden of skin and/or nodal disease.

RESULTS

PATIENT CHARACTERISTICS

	n = 4
Age (median, range)	53.5 (47-57)
% male	50
Stage	IIA (1 pt), IIB (2 pts), IIIB (1 pt)
Prior lines of therapy (median, range)	1.5 (1-3)
Large cell transformation (%)	75

TREATMENT-RELATED AEs*

	Grade 1-2 (%)	Grade 3-4 (%)
Rash	75	0
Peripheral neuropathy	75	0
Diarrhea	50	0
Myalgia	50	0
GERD	50	0
Fatigue	50	0

* Occurring in >1 participant.

GLOBAL RESPONSE RATES³



- All enrolled patients completed the DLT evaluation period with no DLTs.
- No de-escalation was triggered and enrollment proceeded to an expansion cohort at Dose Level 1 (BV at 1.8 mg/kg and Moga at 1 mg/kg).
- Treatment was well-tolerated and all AEs were Grade 1-2 in severity.
- Only one serious AE occurred (grade 2 fever, related to skin infection).
- 3 patients completed all 12 cycles of therapy. 1 patient completed 9 cycles before coming off study for progression.
- Best global responses were 3 PR and 1 SD.

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CONTACT INFORMATION

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