Patients With Relapsed/Refractory Multiple Myeloma: Results From the Phase 2 Study O-12-M1

**BACKGROUND**

- Patients with multiple myeloma (MM) that relapses after conventional treatment have limited therapeutic options for long-term disease control.

**OBJECTIVES**

- To provide an update of PFS and OS for melflufen and dex in patients with RRMM, including those still participating in long-term follow-up and those who were alive at their protocol-specified end-of-study visit, in an extended long-term follow-up amendment in the O-12-M1 phase 2 study.

**METHODOLOGY**

- Phase 2 studies are more advanced in studies and are more applicable to real-world scenarios. A phase 2 study in a small group of patients is more likely to result in a phase 3 study.

**RESULTS**

- **Median PFS**, 5.7 months
- **Overall response rate**, 31%
- **Median progression-free survival (PFS)**, 5.7 months
- **Median OS** for all patients (ITT), 13.6 months
- **Median OS** for all patients with PD, 4.7 months
- **Median TTNT** of 7.9 months in the updated post hoc analysis
- **OS subgroup analysis** showed that 12 patients with a PFS ≥ 12 months had a TTNT of 11.2 months (95% CI, 9.1-13.3)

**CONCLUSIONS**

- Melflufen plus dexamethasone demonstrated sustained long-term benefit in patients with heavily pre-treated RRMM that relapsed on conventional therapy including bortezomib and lenalidomide.
- Median OS, 20.7 months
- Median OS, 47.2 months for patients achieving SD as best response, suggesting sustained clinical benefit despite a limited OS benefit in patients achieving a response
- Melflufen plus dexamethasone showed a median TTNT of 7.9 months in the updated post hoc analysis

**REFERENCES**


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**DISCLAIMERS**

- The authors declare no conflicts of interest.
- All authors have read and approved the final manuscript.

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