A Phase I/2 Study of Selinexor, Carfilzomib, and Dexamethasone (SKd) in Relapsed / Refractory Multiple Myeloma (RRMM)

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Key Inclusion / Exclusion criteria

- Relapsed or refractory multiple myeloma (RRMM)
- Age ≥ 18 years
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- Bone marrow biopsy showing > = 10% plasma cells
- Adequate organ function

Key Inclusion / Exclusion criteria

- Myeloma (MM)
- Involvement of central nervous system (CNS) not treated with prior carfilzomib
- Adequate organ function

Dose Schedule

- SKd (Day 1, 8, 15, and 22)
- Twice weekly (BIW) per carfilzomib's label
- Carfilzomib 56 or 70 mg/m

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SKd Patient Characteristics

- As of October 1, 2019, 14 patients have been evaluable (2 patients with ongoing ORR with selinexor 80 mg/m2 k filzomib 56 mg/m2)
- SKd dose at study entry: 100 mg PO S, 56 mg/m2 K
- Median Age: 55.3 years (18-78)
- Majority of patients were male (10/14) (71.4)
- Median prior regimens: 1-2 (71.4) 3 (28.6)

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SKd Treatment-related adverse events ≥ 2 Patients (as of Oct 1, 2019)

- Adverse events (AE) were recorded in all patients
- AE included grade 3/4 events

Summary and Conclusions

- Selinexor, once-weekly, can be safely combined with once-weekly carfilzomib and low-dose dexamethasone
- The RP2D of SKd is once-weekly selinexor 80 mg + carfilzomib 56 mg/m

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References


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