MM-005: Phase 1 Trial of Pomalidomide, Bortezomib, and Low-Dose Dexamethasone (PVD) in Lenalidomide-Refractory–Exposed Myeloma

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INTRODUCTION

- Pomalidomide (POM) is a distinct oral IMiDs® immunomodulatory agent
- Combination treatment (Tx) with immunomodulatory agents and proteasome inhibitors has demonstrated clinical activity in early phase trials in myeloma
- POM or DEX, per protocol

METHODS

- MM-005 is a phase 1, multicenter, open-label, dose-escalation study (Figure 1)
- A secondary objective examined giving BORT subcutaneously (SC) instead of IV
- POM: 4 mg (D1-14)
- BORT: 1.3 mg/m2 (days 1, 4, 8, 11) for cycles 1-8; days 1 and 8 for cycle 9 and beyond

RESULTS

- 28 pts have been enrolled (Table 1)
- POM: 4 mg (D1-14)
- BORT: 1.3 mg/m2 (IV)
- DEX: 10 mg DEX administered for pts aged > 75 years

OBJECTIVES

- Pts must not be refractory to BORT (1.3 mg/m2 twice weekly)
- Measurable disease by M protein serum (≥ 0.5 g/dL) or urine protein (≥ 10 mg/dL)

ADVERSE EVENTS

- No DLTs have been observed in the first 6 pts treated in the SC cohort
- Discontinued 10 (83) 9 (90) 3 (50) 22 (79)
- On treatment 2 (17) 1 (10) 3 (50) 6 (21)

CONCLUSIONS

- POM was well tolerated in lenalidomide-refractory and BORT-exposed pts, with no DLTs observed due to treatment-related AEs reported in any cohort to date
- Making data from MM-005 with SC BORT show efficacy and safety profile similar to those of PVD with SC BORT
- Additional SC cohort to include an additional cohort of pts receiving SC BORT to verify these findings
- POM exposure does not appear to be affected by BORT administration route (oral vs. SC)

REFERENCES