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Notable abstracts featured at the meeting can be found on the following pages.

SAFETY AND EFFICACY OF LENALIDOMIDE (LEN), BORTEZOMIB (BZ), AND DEXAMETHASONE (DEX) IN PATIENTS (PTS) WITH NEWLY DIAGNOSED MULTIPLE MYELOMA (MM): A PHASE I/II STUDY.

[8520]

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Background

Single-agent Bz and Len/Dex are approved for pts with relapsed MM following >1 prior therapy. Len/Bz±Dex is active in relapsed/refractory MM, and Len/Dex and Bz/Dex are active in frontline MM. Primary objectives of this phase I/II study were to define the MTD and assess response rate to Len/Bz/Dex in previously untreated MM pts.

Methods

Pts received Len 15-25mg on d 1-14, Bz 1.0-1.3mg/m² on d 1, 4, 8, 11, and Dex 40/20mg (cycles 1-4/5-8) on day of and after Bz for up to eight 21-d cycles, initially at 4 planned dose levels (table). Dose escalation proceeded depending on dose-limiting toxicities (DLTs). Based on safety data, dose level 4M was added with a

reduced Dex starting dose (20/10mg). Toxicities were graded by NCI CTCAE v3.0. Pts with G>2 peripheral neuropathy (PN) were excluded. Responses were assessed by modified EBMT and Uniform Criteria. Pts with >PR could proceed to ASCT after >4 cycles.

Results

66 pts have been enrolled to date. Data are available on 53 pts (median age 58 yrs, 51% men, 68% IgG MM, 49% ISS Stage II/III): 33 in Phase I, including 17 at the maximum planned dose (dose level 4M), and 20 in Phase II (at max planned dose). Pts have received a median of 6 cycles; 16 (32%) have completed all 8 cycles, 14 have discontinued. Two DLTs of G3 hyperglycemia due to high-dose Dex were seen in dose level 4. Dose

reductions in cycle 2 and beyond have occurred for Len in 12 pts, Bz in 11 pts, and Dex in 18 pts, mostly in dose levels 1-4. Toxicities have been manageable, with no unexpected toxicities, no G4 PN, 2 DVTs, and no treatment-related mortality. Response rate (>PR) to date is 98% in 42 evaluable pts, including 52% CR/nCR/VGPR (table). After median follow-up of 4 months, median TTP, PFS, and OS have not been reached. Median stem cell collection in 7 pts was 11.5 x 10⁶ CD34+ cells/kg.

Conclusion

Len/Bz/Dex is very active and well tolerated in newly diagnosed MM pts. Phase II enrollment is almost complete. Updated response data will be presented. Responses by phase/dose level (subject to confirmation) ★