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Bortezomib in relapsed or refractory mantle cell lymphoma (MCL): Results of the PINNACLE study.

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BACKGROUND

Bortezomib (VELCADE, Vc), a novel proteasome inhibitor, is approved in relapsed multiple myeloma and has shown activity in MCL in phase 2 NHL studies.

METHODS

Patients (pts) with relapsed or refractory MCL with a maximum of 2 prior therapies received Vc 1.3 mg/m² i.v. on d 1, 4, 8, and 11 of a 21-d cycle for up to 1y. Full accrual (155 pts) was completed in this multicenter, phase 2 study. Primary

endpoint was TTP, secondary endpoints included RR and duration of response (DOR). Response (International Workshop Criteria) was assessed by the investigators and separately by the sponsor using central radiology review.

RESULTS

Data are available for 154 pts. Baseline characteristics included median age 65y, 81% male, 28% KPS < 90%, 35% LDH > normal, 43% IPI ≥ 3, 74% stage IV MCL. 90% of pts had prior intensive therapy (e.g. Hyper CVAD, CHOP, EPOCH), 96%

had prior rituximab, and 14% had prior stem cell transplant. Median duration of Vc treatment was 4 cycles. 138 pts were evaluable for response. By investigator assessment, RR was 35% (CR + CRu = 8%) and median DOR was 9.2 mo. Median TTP was 5.5 mo (all patients, n = 154). Using central radiology review RR was 31% (CR + CRu = 7%), median DOR was 4.6 mo and median TTP was 4.1 mo. With median follow-up of 10 mo, median survival has not been reached. The most common non-hematologic AEs were

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Palonosetron (PALO) + dexamethasone (DEX) for prevention of chemotherapy (CT)-induced nausea and vomiting (CINV) in patients receiving multiple-day cisplatin CT for germ cell cancer.

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BACKGROUND:

Fractionated cisplatin is highly emetogenic; despite 5HT₃ receptor antagonists + DEX, patients still experience acute and delayed CINV. PALO, a novel 5HT₃ antagonist, is superior to conventional 5HT₃ antagonists in protecting patients from emesis with a 0.25-mg IV dose prior to single-day CT. To assess the efficacy and safety of PALO in 40 patients with germ

cell tumors receiving multiple-day cisplatin-based CT, a phase II multicenter study is being conducted.

METHODS:

Adult men receiving 5-day cisplatin-based (20 mg/m²/d) CT received PALO 0.25 mg IV 30 min before CT on days 1, 3, and 5 and DEX 20 mg qd (po or IV 30 min before CT) on days 1-2; 8 mg po bid on days 6-7; and 4 mg po bid on day 8.

Rescue medication was allowed at investigator discretion. Endpoints included emetic episodes (EE), nausea intensity, and rescue use, recorded in diaries for 9 consecutive 24-h periods. Interference with functioning due to nausea on a 4-point scale (none, a little bit, quite a bit, very much) was assessed with the validated Osoba nausea module on days 1, 5, and 10; safety was assessed

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