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PHASE I STUDY OF MIRVETUXIMAB SORAVTANSINE (MIRV) AND RUCAPARIB FOR RECURRENT ENDOMETRIAL, OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER

ORAL FEATURED POSTERS

Lecture Title:

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Objectives: To estimate the maximally tolerated dose (MTD) and toxicities associated with MIRV and rucaparib.

Methods: Patients had to be folate receptor α (FRα) positive by IHC (≥25% of tumor staining at ≥2+ intensity). Using a 3+3 design patients received MIRV (4-6 mg/kg IV every 3 weeks) and rucaparib PO BID (400-600 mg) depending on the dose level.

Results: >100 patients were screened for FRα expression; 21 have been enrolle, , 16 with ovarian and 5 with endometrial cancer. Median age was 64.5, with 3 (range 1-9) prior lines of treatment. 6 patients completed DL2 (5/500), however, 2 DLTs (grade 3 fatigue), let us to establish the RP2D at DL1 (MIRV 5 mg/kg IV every 3 weeks and rucaparib 400 mg PO BID). Treatment related toxicities (all grades) occurring in ≥25% of patients included fatigue (73%), nausea (67%), blurred vision (60%), anemia (47%), anorexia (47%), mucositis (40%), ALT/AST elevated (40%), dry eyes (33%), vomiting (27%), thrombocytopenia (27%), weight loss (27%), leukopenia (27%), dysgeusia (27%). Grade ≥3 toxicities were fatigue (20%), pneumonitis (13%), anemia (13%), diarrhea (7%), cataract (7%), lymphopenia (7%), thrombocytopenia (7%), weight loss (7%), hypokalemia (7%). Sixteen patients are currently evaluable for response; 6 (37.5%) with PR, 8 (50%) SD, 2 (12.5%) PD; ORR 33% (4/12) in ovarian cancer and 50% (2/4) in endometrial cancer. Median PFS is 6.3 months with 95%CI (0.7, 13.8) months.

Conclusions: Combination rucaparib and MIRV was tolerable with mostly manageable side effects and encouraging activity in this heavily pretreated population (including prior PARPi) of both endometrial and ovarian cancer.