Results Trial in progress: there are no available results at time of submission.
Conclusions Trial in progress: there are no available conclusions at time of submission.

TP022/#1424 A PHASE I/II STUDY EVALUATING INTRAPERITONEAL GEN-1 IN COMBINATION WITH NEOADJUVANT CHEMOTHERAPY IN PATIENTS NEWLY DIAGNOSED WITH ADVANCED EPITHELIAL OVARIAN CANCER

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Objectives GEN-1, an IL-12 DNA plasmid formulated with a synthetic carrier is being evaluated with neoadjuvant platinum-taxane chemotherapy (NACT) in patients with advanced epithelial ovarian cancer. OVATION 2 is a multi-center, randomized, open-label phase I/II study evaluating the safety, anti-tumor activity, and immunological response to GEN-1 at a dose of 100 mg/m2 intraperitoneal (IP) actively enrolling at 20 centers in USA and Canada.
Methods Up to 130 patients will be randomized 1:1 to receive either NACT plus GEN-1 or NACT alone. The phase I portion will evaluate safety in at least 6 patients administered in 8 weekly infusions starting at cycle 1 week 2 in combination with three 21-day cycles of carboplatin AUC 6 with paclitaxel 175 mg/m2 (PC). Following interval cytoreductive surgery an additional 9 weekly GEN-1 IP infusions starting at cycle 4 week 1 with three 21-day cycles of PC. If no dose limiting toxicities are found, then the study will continue into the phase II portion. To evaluate biological activity a subgroup of patients will have tumor tissue at initial biopsy/laparoscopy collected and at interval cytoreductive surgery. Tissue will be analyzed for the density of CD8, FoxP3, IDO-1, PD-1, and PDL-1 cells. Blood, peritoneal fluid/wash will be collected before and after treatment in a subgroup of patients to quantify for levels of IFN-g. The primary endpoint is PFS.
Results Trial in progress: there are no available results at the time of submission.
Conclusions Trial in progress: there are no available conclusions at the time of submission.

TP023/#1560 A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO/PACLITAXEL-CONTROLLED STUDY OF BATIRAXCEPT IN COMBINATION WITH WEEKLY PACLITAXEL IN PATIENTS WITH PLATINUM-RESISTANT RECURRENT OVARIAN CANCER (GOG-3059/ENGOT OV-66)

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Objectives Introduction: The AXL receptor and its sole activating ligand, GAS6, are important drivers of metastasis and therapeutic resistance in human cancers. This signaling axis represents an attractive target for therapeutic intervention. The strong picomolar binding affinity between endogenous GAS6 and AXL and the promiscuity of small molecule AXL inhibitors have presented a barrier to specific and potent inhibition of AXL. Batiraxcept (AVB-S6–500) is a recombinant fusion protein with ~200-fold higher affinity for GAS6 than wild-type (WT) AXL. Batiraxcept binds GAS6, inhibiting its interaction with AXL thereby dramatically reducing AXL signaled invasion and migration of highly metastatic cells in vitro and inhibiting metastatic disease in nonclinical models of aggressive human cancers. The Phase 1b study showed no DLTs and established a RP2D of 15 mg/kg IV every 2 weeks with PAC/PLD. Longer PFS and OS times were observed in patients who had not been previously treated with bevacizumab (bev-naïve).
Methods High-grade serous PROC, who received 1–4 prior lines randomized (1:1) batiraxcept/PAC or placebo/PAC; stratified by last platinum regimen, prior lines, and prior bevacizumab. The primary endpoint is PFS by RECIST v1.1 assessed by the investigator with OS a secondary endpoint. The primary PFS analysis will be triggered when 130 PFS events occur in the bev-naïve; with an interim analysis of OS.