IMNN-001 comprises a DNA plasmid encoding an interleukin-12 (IL-12) gene and a synthetic polymer facilitating plasmid delivery. IMNN-001 is designed to be delivered locally, offering the potential for cytokines to be expressed specifically in the tumor micro-environment with the goal of achieving increased efficacy while minimizing potential systemic toxicity. It has been shown to exhibit a favorable benefit/risk ratio when administered intraperitoneally (IP), in combination with intravenous platinum-taxane chemotherapy in women with advanced EOC in earlier Phase I & II studies. The 201-21-202 study (NCT05739981) is a multicenter, randomized, open-label phase II study with safety lead-in which hypothesizes the addition of IMNN-001 to neoadjuvant & adjuvant carboplatin-paclitaxel and bevacizumab (chemo + BEV) reduces the risk of histologically documented minimal residual disease (MRD) as determined by SLL by 50%.

**Purpose**

IMNN-001

**Patients and Methods**

Patients with newly diagnosed stage III and IV high grade serous EOC who are candidates for NACT will be enrolled into the trial. Initial safety lead-in will evaluate at least 6 patients randomized to the experimental arm. Upon confirmation of safety by the DSMB, a target of ~50 patients will be randomized 1:1 to receive either chemo + BEV with or without IMNN-001. Patients receive at least 4 cycles of NACT followed by interval cytoreductive surgery (ICS), and 3 additional adjuvant cycles of study treatments will be administered. BEV will be included with each cycle except cycle 1, the last cycle of NACT immediately preceding ICS, and the first cycle of adjuvant chemotherapy. In the experimental arm, IMNN-001 will be administered on C1D15 and continue weekly through the last cycle of adjuvant therapy. Following adjuvant therapy, all patients will undergo SLL with peritoneal washing and multiple biopsies. Pathologic detection of residual tumor in any biopsies or peritoneal cytology constitutes presence of MRD. All patients will receive maintenance therapy with Olaparib + BEV, IMNN-001 + BEV, or BEV alone based on their homologous recombination deficiency status and treatment randomization.

**Status**

The study is actively enrolling and is in the safety lead-in portion.

**Endpoints**

The primary endpoint is the rate of MRD at SLL. Secondary endpoints include progression-free survival, overall survival, objective response rate, chemotherapy response score, surgical response, and serologic response. All patients will be evaluated for safety.

**Contact / Collaborators**

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