

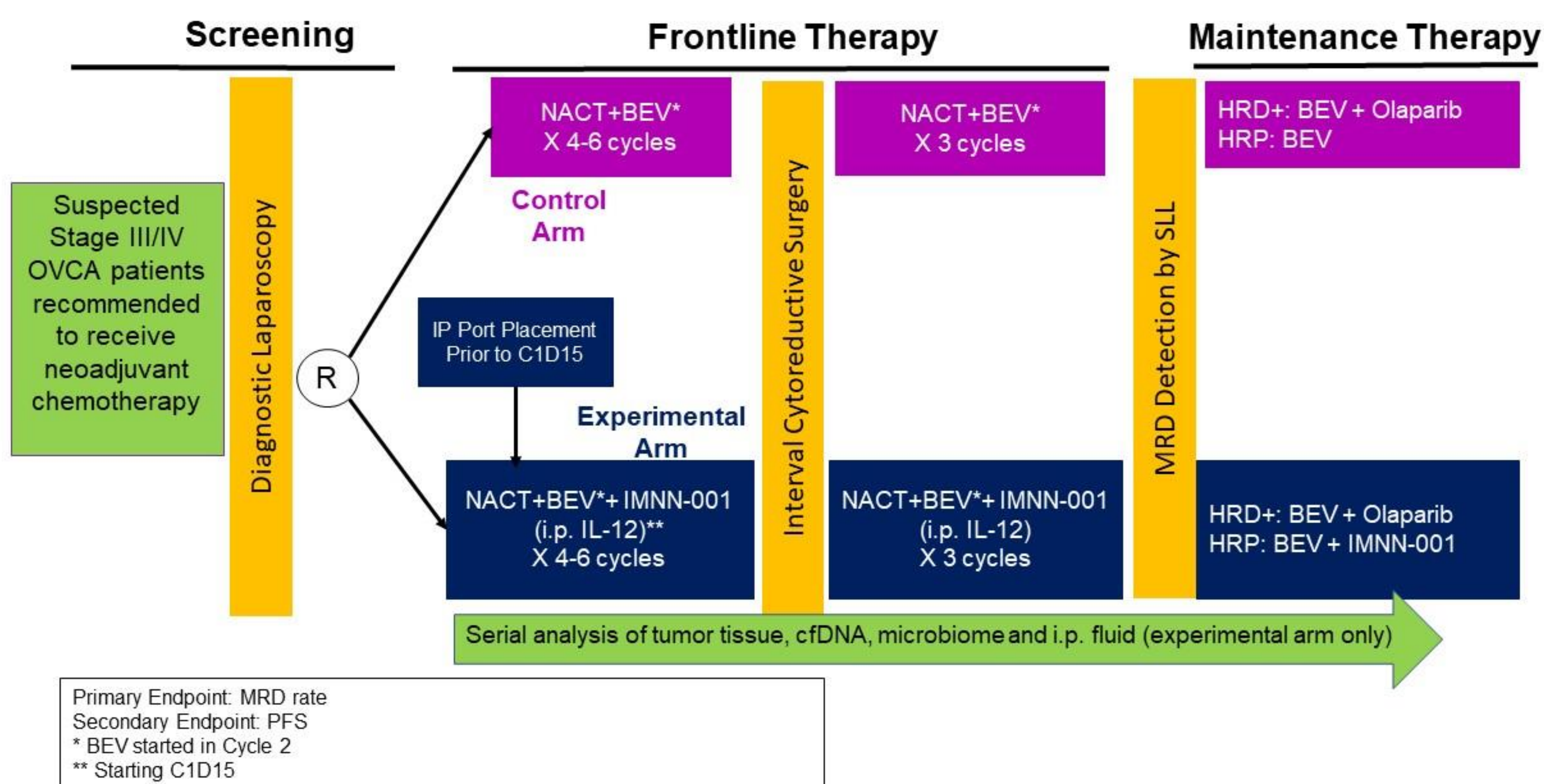
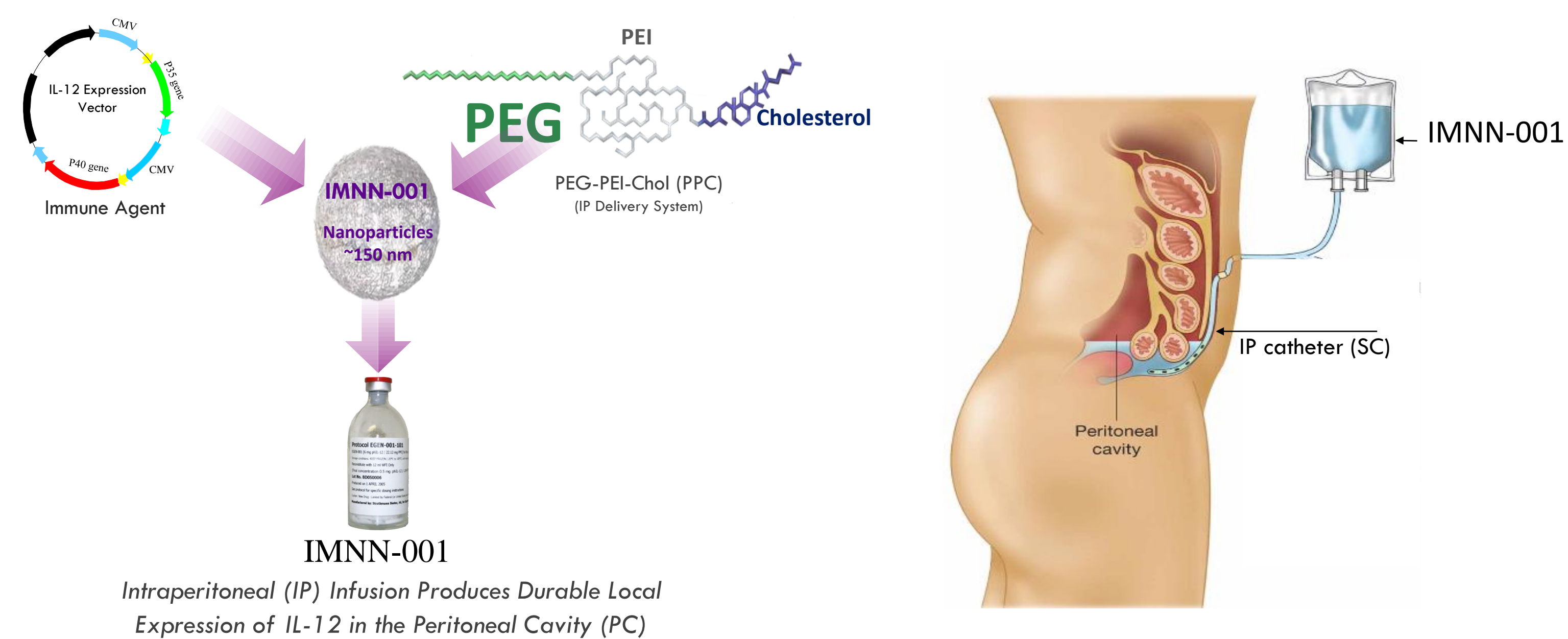
Abstract # TPS5633: A Phase II Study Evaluating the effect of IMNN-001 on Second Look Laparoscopy (SLL) when Administered in Combination with Bevacizumab (BEV) and Neoadjuvant Chemotherapy (NACT) in Patients Newly Diagnosed with Advanced Epithelial Ovarian Cancer (EOC)

Amir A. Jazaeri¹, Rachel N. Grisham², Stephanie Gaillard³, Jeffrey A. How¹, Sebastien Hazard⁴, Lauren Musso⁴, Chrisann Kyi²

¹University of Texas, MD Anderson Cancer Center; ²Memorial Sloan Kettering Cancer Center; ³Johns Hopkins Medicine; ⁴Imunon, Inc.

Purpose

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 multi-center, 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%.

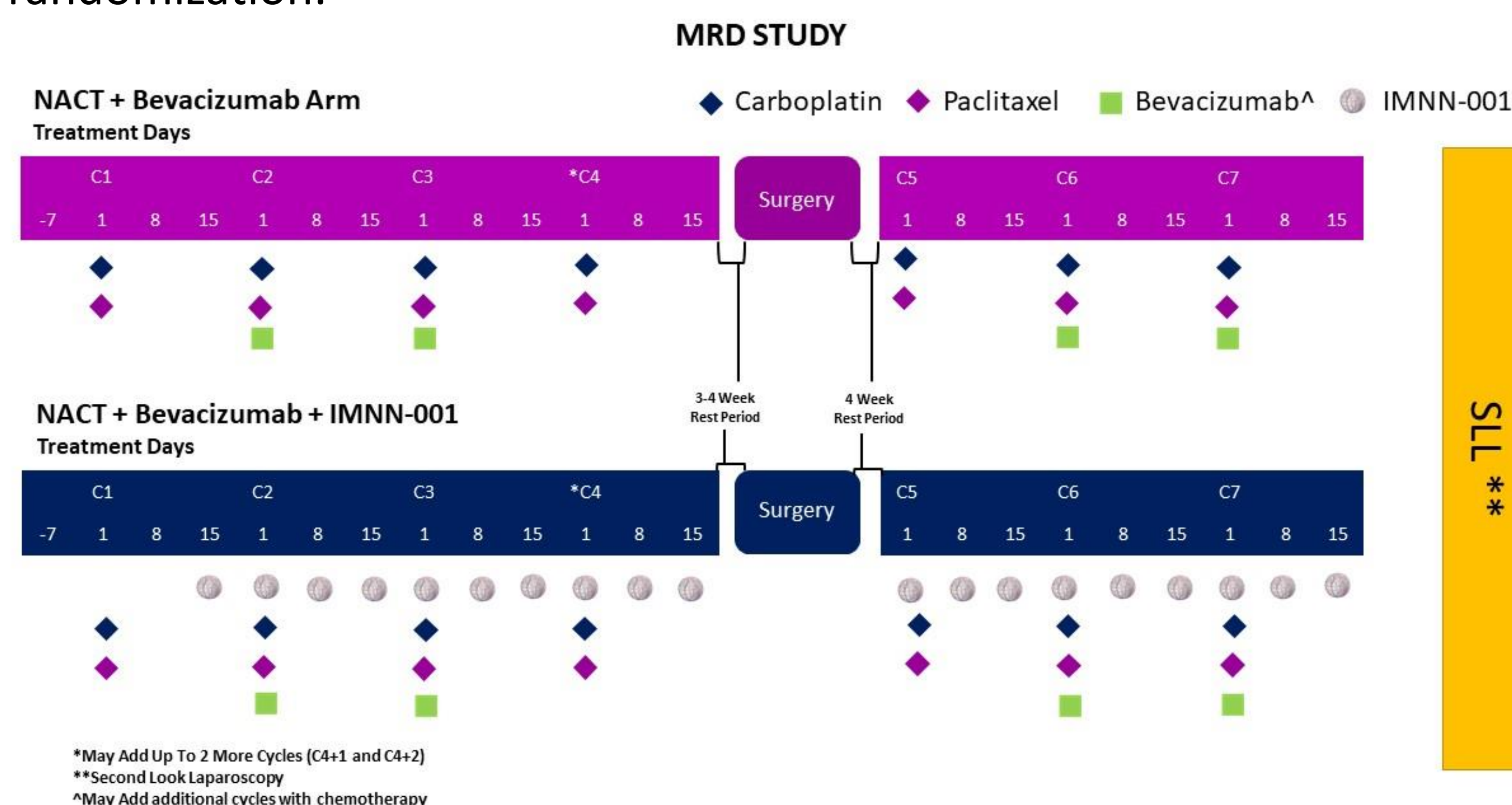


Translational

All subjects will undergo biospecimen collection and organoid preparation prior to treatment, at the time of ICS and SLL for comprehensive longitudinal genomic, circulating tumor DNA, immune, and microbiome profiling. Subjects in the experimental arm will also undergo peritoneal lavage and collection of fluid and cells for assessment of the peritoneal tumor environment.

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

For additional information, visit Imunon.com or contact Amir Jazaeri, MD at AAJazaeri@mdanderson.org.



Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from ASCO® or the author of this poster.