The OVATION-2 Study

A Phase 1/2 Study Evaluating the Dosing, Safety, Efficacy, and Biological Activity of Intraperitoneal GEN-1 (IL-12 Plasmid Formulated With PEG-PEI-Cholesterol Lipopolymer) Administered in Combination With Neoadjuvant Chemotherapy (NACT) in Patients Newly Diagnosed With Advanced Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

While the standard of care for stage 3 and 4 ovarian cancer treatment can be successful, the current five-year survival rate still remains low, at less than 50%, with a relapse rate of 70%. There is a significant unmet need for more robust treatment options for ovarian cancer patients and their loved ones.

The study is based on the findings from the recently published OVATION trial that can found in Clinical Cancer Research.[1]

OVATION-2 is a randomized, open label, multicenter trial to evaluate the safety, dosing, efficacy, and biological activity of intraperitoneal GEN-1 immunotherapy plus NACT, compared to NACT alone in newly diagnosed patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer.

PROTOCOL INFORMATION

PROTOCOL NUMBER:
201-17-201
(NCT03393884)

PHASE: 1/2

ENROLLING:
130 subjects with newly diagnosed advanced ovarian cancer

RANDOMIZATION:
Randomly assigned 1:1 to receive either NACT plus GEN-1 or NACT alone

GEN-1 THE INVESTIGATIONAL DRUG

- Human IL-12 plasmid (phIL-12-005) is formulated with lipopolymer PEG-PEI-Cholesterol (PPC) in 10% lactose; classified as a biologic (non-viral gene therapeutic)
- Infusion into abdominal cavity via an intraperitoneal catheter
- Dose: 100 mg/m^2

STUDY DESIGN AND TREATMENT SCHEDULE:

- **NACT:** paclitaxel 175 mg/m^2 IV over 3 hours followed by carboplatin AUC 6 IV over 1 hour on Day 1; repeated every 3 weeks for 6 cycles [3 cycles chemo + surgery + 3 more cycles chemo]
- **GEN-1:** 100 mg/m^2 IP will be administered on Days 8 and 15 of first NACT cycle and then on Days 1, 8, and 15 of the subsequent five 21-day NACT cycles for a total of 17 treatments (when given same day as NACT, GEN-1 should be given 30 minutes to 3 hours after completion of NACT infusions)
- **Interval debulking surgery:** will take place after 3 cycles of NACT or placebo

KEY INCLUSION CRITERIA

- A suspected histologic diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma and confirmation per pretreatment biopsies by laparoscopy, or interventional radiology or CT / Ultrasound guided core biopsy. Histologic documentation of the original primary tumor is required via the pathology report.
- An International Federation of Gynecology and Obstetrics (FIGO) of III or IV.
- The following histologic epithelial cell types are eligible: High grade serous adenocarcinoma, endometrioid adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, or adenocarcinoma not otherwise specified (N.O.S.).
- Hormonal therapy directed at the malignant tumor must be discontinued at least one week prior to first treatment. Continuation of hormone replacement therapy is permitted.
- Performance status score of 0, 1, or 2 by Eastern Cooperative Group (ECOG) criteria.

KEY EXCLUSION CRITERIA

- Subjects with other invasive malignancies are excluded if there is any evidence of the invasive malignancy being present within the last 3 years.
- Prior radiotherapy to any portion of the abdominal cavity or pelvis are excluded.
- Subjects who have received prior chemotherapy for any abdominal or pelvic tumor are excluded.
- Receiving treatment for active autoimmune disease.
- Oral or parenteral corticosteroids within 2 weeks of study entry or who have a clinical requirement for ongoing systemic immunosuppressive therapy such as chronic steroid use not related to chemotherapy administration.

[1] Thaker PH, Bradley WH, Leath CA, et al. Gen-1 in combination with neoadjuvant chemotherapy for patients with advanced epithelial ovarian cancer: A phase I dose-escalation study. *Clinical Cancer Research*. 2021;27(20):5536-5545. doi:10.1158/1078-0432.ccr-21-0360

Contact our Clinical Trial Information Center at 609-482-2472 to learn more.

Scan this code for more information.

20211013–US–ENG–PI–WEB–201-17-201–V1.0