SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

OVATION 2 Study

Society of Gynecologic Oncology

A Phase I/II Study Evaluating Intraperitoneal GEN-1 in Combination with Neoadjuvant Chemotherapy in Patients with Newly Diagnosed Advanced Epithelial Ovarian Cancer (EOC)

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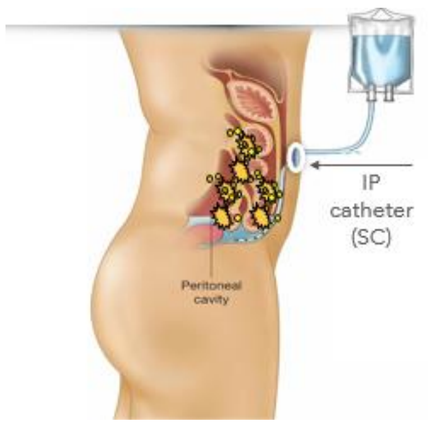
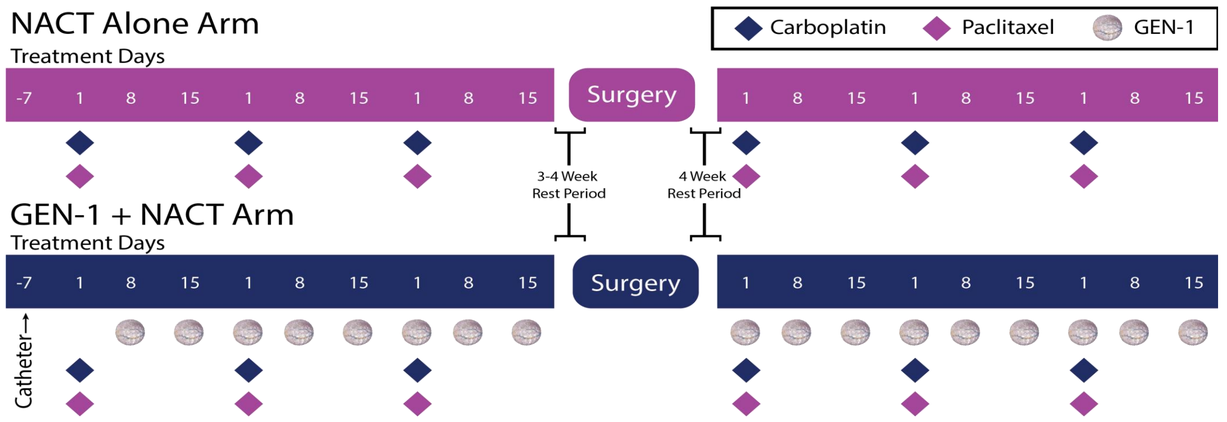
GEN-1 BACKGROUND

GEN-1 is an IL-12 plasma vector encased in a nanoparticle delivery system. The encasement enables cell transfection followed by persistent, local secretion of IL-12 at therapeutic levels, providing efficacy by recruiting an anti-cancer immune response. This delivery system is designed for local administration which avoids the toxicities associated with systemic recombinant IL-12 GEN-1 is administered through a subcutaneously implanted intraperitoneal (IP) catheter.



STUDY DESIGN AND METHODS

- **Up to 130 patients with newly diagnosed stage IIIC or IV EOC will be randomized 1:1 to receive NACT plus GEN-1 or NACT alone.**
- **Subjects on both treatment arms will receive a total of six cycles of carboplatin AUC 6 with paclitaxel 175 mg/m² every 21 days. Three cycles occur prior to interval debulking surgery (IDS) then another three cycles follow IDS.**
- **Subject randomized to the GEN-1 + NACT treatment arm will receive 8 weekly GEN-1 IP infusions at a dose of 100 mg/m² starting at Cycle 1 Day 8. Following IDS, an additional 9 weekly GEN-1 IP infusions at a dose of 100 mg/m² will be administered.**



KEY ELIGIBILITY CRITERIA

Inclusion Criteria

- ☑Histological diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma
- ☑FIGO staging of III or IV
- ☑Adequate bone marrow, renal, hepatic, and neurological function
- ☑Free of active infection 4 weeks prior to study entry
- ☑Free of hormonal therapy directed at the tumor (1 week prior to study entry)
- ☑Performance status score of 0, 1, or 2 based on ECOG criteria

Exclusion Criteria

- ☒Prior GEN-1 treatment
- ☒History of allergic reaction to compounds (or similar compounds) used in study
- ☒Corticosteroids within 2 weeks prior to study or ongoing immunosuppressive therapy required
- ☒Other malignancies
- ☒Hepatitis
- ☒Prior chemotherapy or radiotherapy to the abdominal cavity or pelvis
- ☒Central nervous system disease within 6 months prior to study

ENDPOINTS

Primary
- Safety & Phase II dose
- Progression Free Survival

Secondary
- Overall Survival
- Objective Response Rate
- Pathological Response
- Serological Response (CA-125)

All subjects are being evaluated for safety

TRANSLATIONAL DATA

- Immunohistochemistry analysis to determine the biological activity of GEN-1 on tumor tissue will be evaluated in a subgroup of patients in the control arm (NACT alone) and experimental arm (NACT + GEN-1) at the initial biopsy/laparoscopy and at IDS. Tumor tissue will be analyzed for frequency of CD8+, FoxP3, IDO-1, PD-1, and PDL-1.
- A subgroup of patients from both treatment arms will have blood and peritoneal fluid/washings collected before and after treatment to quantify levels of IFN-γ.
- All consenting subjects will have blood collected prior to Cycle 1 Day 1 for a gene expression and immune repertoire.

CURRENT STUDY STATUS

Phase I
- Completed in Q2 2020
- Data Safety Monitoring Board confirmed no dose limiting toxicities were found & 100 mg/m² is the recommended Phase II dose
- Reduced target enrollment to 110

Phase II
- Ongoing, actively recruiting eligible subjects across 25 sites throughout the US and Canada
- ⅓ of subject recruitment has been completed
- PFS endpoint results anticipated in Q1 2023
- OS endpoint results anticipated in 3Q 2024 (*corrected*)

CONTACT INFORMATION AND DISCLOSURES

Trial in Progress Poster ID: 11024

NCT03393884 on https://www.clinicaltrials.gov/

For questions, please contact Lauren Musso at lmusso@celsion.com

K. Anwer, N. Borys, and L. Musso are employees of Celsion Corporation. P.H. Thaker is a consultant for Celsion Corporation.

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