MELVIN AND BREN SIMON COMPREHENSIVE CANCER CENTER

Indiana University

Simon Comprehensive Cancer Center

Clinical Trials

Gynecology Oncology

Open to Enrollment

Ovarian

★ • ***NRG-GY019*** *[NCT04095364]*
Carbo/Taxol/Letrozole vs. Letrozole alone in adjuvant setting
1. Newly Diagnosed
2. Stage II-IV, low grade serous carcinoma
3. Upfront cytoreductive surgery required
4. Bilateral salping-oophorectomy required

• ***GOG-3078*** *[NCT05445778]*
MIRV+Bev vs. Bev alone as maintance therapy s/p 2nd line treatment (see IC 3)
1. FRa positivity positivity (≥ 75% of tumor membrane staining at ≥ 2+ intensity) is required
2. Prior PARP required - if BRCA+
3. must have or plan to complete platinum-based triplet therapy in the second line (recurrent PSOC)

★ • ***NRG-CC008*** *[NCT04251052]*
BSO vs. BLS surgical procedure in RRSO setting
1. A positive CLIA-approved BRCA1 mutation
2. Patient MUST be 35-50 years of age
3. Patient is undergoing RRSO
4. At least 1 intact ovary or fallopian tube is in situ at time of counseling

• ***GOG-3076*** *[NCT05281417]*
Olvi-vec+Carbo/Taxol/Bev vs. Carbo/Taxol/Bev in Platinum Resistant/Refractory setting
1. High grade serous, endometrioid, or clear cell ovarian cancer
2. Minimum of 3 piror lines (including first line)
3. Last dose of platinum-based line therapy is 3-15 months prior to consent
4. Received prior Bevaizumab
5. No bowel Obstruction within 3 months of study treatment
6. No contrainidcations for IP catheter placement
7. No prior Virus-based therapy or cytolytic virus therapy of any type

Cervical

• ***STAR-IIT*** *[NCT04068753]*
Niraparib+Dostarlimab s/p recurrence or PD (see IC 2)
1. *Histologicallly proven* Recurrent or Progressive
2. *At least 1 prior line of systemic therapy (chemotherapy with radition does not count)*
3. *Prior Pembrolizumab is allowed, but cannot have had immune realted AEs or progression from Pembro treatment*

• ***GOG-3091 (VB-C-04)*** *[NCT06099418]*
VB10.16 + Atezolizumab vs. VB10.16 + Placebo
1. Persistant recurrent or metastatic squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma
   a. **PD-L1+** (confirmed by central testing)
   b. **HPV16+** (confirmed by central testing)
2. MUST have confirmed disease progression *during or after* 1st line Pembro + platinum-containing chemo +/- Bev
   a. must receive at least 4 cycles of Pembro
   b. NO more than 1 prior line of systemic therapy
3. No prior administration of thearaputic HPV16 vaccine
4. No Radiaiton within 14 days of C1D1 of study treatment

Endometrial

• ***NRG-GY026*** *[NCT05256225]*
Carbo/Taxol vs. Carbo/Taxol/Herceptin Hylecta vs. Carbo/Taxol/PHESGO in adjuvant setting (1st line treatment)
1. *Stage IA-IVB, endometrial Serous Carcinoma or Carcinosarcoma*
2. *HER2+ via IHC or ISH testing by loal pathology (NGS testing is allowed)*
3. *Must be chemo-naive & no prior radiation treatment*
4. *Must provide 1 FFPE Tissue Block for enrollment*

★ • ***NRG-CC010*** *[NCT0564631]*
SLN Mapping vs. Bilateral Pelvic Lymphadenctomy in upfront surgerical setting
1. *Histologically proven endometrial cancer*
2. *Clinically Stage 1*
3. *Plan to undergo laproscopic or robotic hysterectomy & lymphatic assessment*
4. *No prior Progestin-containing therapies allowed (IUD is acceptable)*
5. *No prior Radiation to pelvis, groin or lower extremities*

• ***GOG-3089*** *[NCT05797831]*
Maintanence Navtemadlin s/p Carbo/Taxol with response (see IC 3)
1. Advanced or Recurrent Endomtrial Cancer
   a. **Excludes**: Sarcomas or Small-cell carcinomas w/ neuroendocrine differentiation
2. TP53 wild-type
3. 1st line treatment includes:
   a. Stage I-III = adjuvant chemotherapy +/- immunotherapy *or* surgery alone followed by relapse
   b. Primary Stage IV = taxane-platinum therapy w/ debulking (R0 or R1) *or* received imunotherapy/endocrine therapy alone followed by relapse
4. Must complete a 2nd line treatment of Taxane-Platinum combo chemotherapy (maximum of 6 cycles) w/ CR or PR per RECIST v 1.1
5. Oral drug - must be able to swallow pills without difficulty & must begin study maintance therapy w/in 6 weeks of completing 2nd line treatment

★ • ***NRG-GY025*** *[NCT05112601]*
Nivolumab+Ipilimumab vs. Nivolumab alone s/p recurrence
1. Recurrent Endometrial cancer
   a. **Excludes:** serous carcinoma or carcinosarcoma
2. MMR deficient
3. *Must have received 1-2 prior lines of systemic therapy*
   a. *If immunotherapy is given, must have a complete response f/b disease progression/recurrence after a 12 month or more diesease-free interval*
4. No active autoimmune disease or history of autoimmune that might recur
5. No prior therapy with CTLA-4 inhibitor or an other antibody/drug specifically targeting T-cell co-stimulation or immune checkpoint pathway

For Questions, please contact:

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★ *Open at IU Schwarz Cancer Center*