Gynecological Oncology Research Program

Women's Cancer Developmental Therapeutics (WCDT) Program

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Contact WCDT Program Nurse Navigator for patient referral or to request additional information.

Visit our website to request more information or send us a referral:
http://tinyurl.com/WCDTProgram

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Ovarian Cancer

A. Front Line

a. Front Line Maintenance

18-1337 GOG 3020-CO338-87 (ATHENA) A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Nivolumab and Rucaparib Combination Switch Maintenance following Front-Line Platinum-based Chemotherapy in Ovarian Cancer Patients (CLOVIS) *(NCT03522246) Local PI: Kian Behbakht, Study Coordinator: Anna Sweester*

- Newly diagnosed, histologically confirmed, advanced (FIGO stage III-IV), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Completed cytoreductive surgery, including at least a bilateral salpingo-oophorectomy and partial omentectomy, either prior to chemotherapy or following neoadjuvant chemotherapy
- Have received 4 to 8 cycles of first line platinum-doublet treatment per standard clinical practice, including a minimum of 4 cycles of platinum/taxane combination
- Patient must be randomized within 8 weeks of the first day of the last cycle of chemotherapy

- ECOG performance status of 0-1
- Successful establishment of an autologous epithelial ovarian, fallopian tube, or primary peritoneal cancer cell line by AIVITA Biomedical, Inc.
- Patients must previously have been staged as having Stage III (IP) or Stage IV (distant metastatic) ovarian, fallopian tube, or primary peritoneal cancer; have undergone surgical debulking, and have completed standard adjuvant chemotherapy, which may include IV and/or IP chemotherapy. Patients will be characterized as NED or non-NED per physical exam, CT and/or PET scans, and CA-125 levels
- Have undergone leukopheresis from which sufficient peripheral blood mononuclear cells were obtained to produce an investigational treatment
- Active central nervous system metastases at the time of treatment

18-2569 - A Phase II, Double-Blind, Randomized Trial of AVOVA-I (Autologous Dendritic Cells Loaded with Autologous Tumor Associated Antigens) vs. Autologous Peripheral Blood Mononuclear Cells (MC) in Patients with Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma After Primary Therapy
AIVITA (NCT02033616) PI: Bradley Corr, Study Coordinator: Jenna Buehler

- ECOG performance status of 0-1
- Successful establishment of an autologous epithelial ovarian, fallopian tube, or primary peritoneal cancer cell line by AIVITA Biomedical, Inc.
- Patients must previously have been staged as having Stage III (IP) or Stage IV (distant metastatic) ovarian, fallopian tube, or primary peritoneal cancer; have undergone surgical debulking, and have completed standard adjuvant chemotherapy, which may include IV and/or IP chemotherapy. Patients will be characterized as NED or non-NED per physical exam, CT and/or PET scans, and CA-125 levels
- Have undergone leukopheresis from which sufficient peripheral blood mononuclear cells were obtained to produce an investigational treatment
- Active central nervous system metastases at the time of treatment

B. Recurrent Disease Trials

a. Platinum-Resistant

16-0708 NRG GY005 - A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women With Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
GY005 (NCT02502266) PI: Behbakht, Study Coordinator: Jenna Buehler
Gyn Onc Cancer Research Team (Behbakht, Corr, Guntupalli, Lefkowits)

- No prior treatment affecting the VEGF/VEGFR pathway or the angiopoietin pathway in the recurrent setting
- No prior use of PARP-inhibitors
- No more than 3 prior treatment regimens (including primary therapy; no more than 1 prior non-platinum based therapy in the platinum-resistant/-refractory setting); hormonal therapies used as single agents (i.e. tamoxifen, aromatase inhibitors) will not count towards this line limit

18-0660 BP29889 – Hoffman-LaRoche; An Open-Label, Multicenter, Dose Escalation Phase IB Study with Expansion Cohorts to Evaluate the Safety, Pharmaconetics, Pharmacodynamics and Therapeutic Activity of RO7009789 (CD40 Agonistic Monoclonal Antibody) in Combination with Vanucizumab (ANTI-ANG2 AND ANTI-VEGF BI-SPECIFIC Monoclonal Antibody, PART I) OR BEVACIZUMAB (ANTI-VEGF MONOCLONAL ANTIBODY, PART II) in Patients with Metastatic Solid Tumors
(NCT02665416) Local PI: Antonio Jimeno/ Bradley Corr

- Part I: Histologically confirmed advanced/metastatic solid tumor (except prostate cancer and squamous non-small cell lung cancer [NSCLC])
- Part II: Histologically confirmed advanced/metastatic platinum-resistant ovarian carcinoma (aPROC), head and neck squamous cell carcinoma (HNSCC), or non-squamous NSCLC previously treated with anti-PD-L1/PD-1 inhibitor alone or in combination (e.g. atezolizumab, nivolumab, pembrolizumab, durvalumab, avelumab)
- Checkpoint inhibitor (CPI)- experienced patients must have experienced documented disease progression on or after PD-L1/PD-1 inhibitor therapy
- In CPI-experienced patients, the PD-L1/PD-1 inhibitor must have been part of the most recent systemic anticancer therapy administered prior to study enrollment
- No prior treatment with anti-programmed death (PD) 1 or anti-programmed death ligand (PD-L) 1 therapeutic antibody, vanucizumab, or compounds targeting cluster of differentiation (CD) 40
- Part II: No treatment targeting vascular endothelial growth factor (VEGF) or receptor within 12 months prior to enrollment

19-0591 A Phase 2, Randomized, Open-Label, 3-arm Study of Relacorilant in Combination With Nab-Paclitaxel for Patients With Recurrent Platinum-Resistant Ovarian Fallopian Tube, or Primary Peritoneal Cancer *(NCT03776812) PI: Bradley Corr, Study Coordinator: Anna Sweester*

- History of high grade serous or endometrioid epithelial ovarian, primary peritoneal, or fallopian tube cancer or ovarian carsinosarcoma
- Received at least one line of therapy with progression within 6 months after platinum-based therapy, persistent disease at the completion of primary platinum-therapy, or PD during platinum-based therapy. Patients with platinum resistance (progression after first-line) chemotherapy) are considered eligible
- Measurable or non-measurable disease by RECIST 1.1
- Previously irradiated lesions are not allowed as measurable disease, unless there is documented evidence of progression in the lesions
- Up to 2 prior chemotherapeutic or myelosuppressive regimens for recurrent disease (not including maintenance therapy such as single-agent bevacizumab)
- Appropriate to treat with nab-paclitaxel
- ECOG 0-1

b. Regardless of Platinum status

17-1333 PH 1 of SBRT for Patients with Limited Locoregional Recurrences of Ovarian and Uterine Serous Carcinoma
SBRT (NCT03325634) PI: Fisher, Study Coordinator: Chelsea Schaefer
Radiation Oncology Research Team (Fisher, Rabinovitch)

- Diagnosis of primary ovarian cancer of any histology (patients with diagnoses of fallopian tube and primary peritoneal cancer are also eligible), or primary uterine cancer of papillary serous histology
- Initial oligorecurrence defined as first recurrence after initial standard of care surgery and chemotherapy with 3 or less sites of disease or

- Subsequent oligorecurrence limited to 3 or less sites of disease or
- Oligoprogressive disease defined as 3 or less sites of active disease in the setting of otherwise controlled additional systemic disease.
- Systemic Therapy allowed, no limit on prior lines

Endometrial Cancer

A. Endometrial

a. Primary Stage III/IV or Recurrent

18-2281 NRG GY012 A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent, or Metastatic Endometrial Cancer
(NCT03660826) PI: Kian Behbakht, Study Coordinator: Jenna Buehler & Anna Sweester

- Must have recurrent or persistent endometrial carcinoma, which is refractory to curative therapy or established treatments. Histologic confirmation of the original primary tumor is required
- Patients must have measurable disease was defined by RESIST 1.1 or non-measurable (detectable) disease
- Patients must have had at least one prior chemotherapy regimen, no more than 2 prior cytotoxic regimens
- Patients cannot have current signs or symptoms of bowel obstruction, or in the preceding 3 months
- Cannot have history of gastrointestinal perforation
- Cannot have clear cell or carcinosarcoma histology

19-0507 A Phase 3 Randomized, Open-Label, Study of Pembrolizumab (MK-3475) Plus Lenvatinib (E7080/MK-7902) Versus Chemotherapy for First-line Treatment of Advanced or Recurrent Endometrial Carcinoma (LEAP-001)
(NCT03884101) PI: Bradley Corr, Study Coordinator: Jenna Buehler

- Must have Stage III or IV, or recurrent histologically-confirmed endometrial carcinoma
- Measurable or non-measurable but radiographically apparent, per RECIST 1.1
- May have received prior chemotherapy only if administered concurrently with radiation; may have received prior radiation; and may have received prior hormonal therapy, provided it was discontinued $\geq$ week prior to randomization
- Has provided archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion that was not previously irradiated
- ECOG 0-1
- Carcinosarcoma, endometrial leiomyosarcoma or other high grad sarcomas, or endometrial stromal sarcomas are not eligible

b. Primary Stage III/IV or Recurrent – Maintenance

18-0567 A Phase II, randomized, double-blind, study of the use of Rucaparib vs placebo maintenance therapy in metastatic and recurrent endometrial cancer: *(NCT03617679)*
Local PI: Bradley Corr, Study Coordinator: Anna Tayebnejad

- Maintenance therapy to initiate 4-8 weeks from last cycle day 1. Must have CR or PR (as determined by RESIST 1.1) at completion of last therapy
- Primary Stage III/IV or recurrent endometrial cancer
- Patients have received at least one prior chemotherapy regimen and no more than two prior cytotoxic regimens (including hormonal therapy)
- Primary chemotherapy regimen must have consisted of at least 4 completed cycles and no more than 8 completed cycles

Cervical/Vulvar Cancers

A. Cervical

a. Recurrent

16-0493 NRG GY006 A Randomized Phase II Trial of Radiation Therapy and Cisplatin (platinum) Alone or in Combination with Intravenous Triapine (ribonucleotide reductase inhibitor) in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer
(NCT02466971) PI: Behbakht Study Coordinator: Jenna Buehler
Radiation Oncology Research Team (Fisher, Rabinovitch)

- Cannot have had a hysterectomy

B. Vulvar

a. Recurrent/Persistent

15-2301 A Clinical Trial of Pembrolizumab (MK-3475) Evaluating Predictive Biomarkers in Subjects With Advanced Solid Tumors (KEYNOTE 158)
(NCT02628067) PI: Lindsay Davis, Study Coordinator: Tate Closson-Niese
Molecular Oncology Research Team

- Vulvar or Cervical Squamous Cell Carcinoma
- No known mutation
- ECOG 0 or 1
- No prior treatment with PD-1/PD-L1/PD-L2

All GYN Cancers

A. *Cervical, upper vaginal, and uterine*

a. *Newly Diagnosed*

17-2198 UM1 10132:a AZD1775 + radiotherapy + cisplatin
*(NCT*03345784*) PI: Corr, Study Coordinator: Alleah Bouley*
Phase I Research Team (Corr)

- Newly diagnosed Cervical, upper vaginal and uterine cancer that is planned to receive radiation and cisplatin

There are additional Phase I all comer trials available, please contact the Nurse Navigator for assistance.

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