

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:](https://medschool.cuanschutz.edu/colorado-cancer-center/clinical-trials/women's-cancer-developmental-therapeutic-program)

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Updated: July 1, 2020

Ovarian Cancer

A. Front Line

a. Front Line

19-2797 NRG-GY019 A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients With Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (NCT04095364) PI: Bradley Corr, Study Coordinator: Jenna Buehler

- Patients must have newly diagnosed, stage II-IV low-grade serous carcinoma (invasive micropapillary serous carcinoma or invasive grade I serous carcinoma) of the ovary or peritoneum. Tumors must be assessed for nuclear p53 staining
- Patients must have undergone an attempt at maximal upfront cytoreductive surgery, with either optimal (< 1 cm diameter residual disease/nodule) or suboptimal residual disease (> 1 cm diameter residual disease/nodule) status allowed
- Patients must have undergone a bilateral salpingo-oophorectomy
- (ECOG) performance status of 0, 1 or 2 within 14 days prior to registration
- Patients must be within =< 8 weeks of primary cytoreductive surgery prior to initial randomization

- Patients may not have received neoadjuvant chemotherapy or radiotherapy for the treatment of this disease
- Patients may not have received previous hormonal therapy for the treatment of this disease

b. Front Line Maintenance

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, Lefkowitz)

- 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, Pharmacokinetics, 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: Jenna Buehler

- History of high grade serous or endometrioid epithelial ovarian, primary peritoneal, or fallopian tube cancer or ovarian carcinosarcoma
- 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. Platinum Sensitive

19-0457 Phase 1 Dose Escalation and Expansion Cohort of Carboplatin and Gemcitabine With or Without M6620 (VX-970) in First or Second Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer

(NCT02627443) PI: Bradley Corr, Study Coordinator: Jenna Buehler

- Histologically confirmed high grade serous or endometrioid ovarian, peritoneal or fallopian tube malignancy that is metastatic and for which curative measures do not exist
- Patients must have measurable disease
- Patients enrolled in the expansion cohort will be required to have archival tumor tissue available for analysis and be willing to have a tumor biopsy at baseline
- Must have platinum sensitive disease and be in their first or second platinum sensitive recurrence
- ECOG \leq 2
- Cannot have prior exposure to gemcitabine

c. *Regardless of Platinum status*

Radiation

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

19-0556 A Randomized Phase II Study of Anti-PD-1 and Limited Metastatic Site Radiation Therapy Versus Anti-PD-1 Alone for Patients With Microsatellite Instability-high (MSI-H) and Mismatch Repair Deficient (dMMR) Metastatic Solid Tumors (NCT04001101) PI:

Christine Fisher, Study Coordinator: Jillian Welker

- ECOG 0 or 1
- Unresectable or metastatic MSI-H/dMMR tumors eligible to receive pembrolizumab according to FDA-approved indications:
- Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
- Confirmation from medical or gynecologic oncology that the patient is eligible to receive pembrolizumab per FDA-approved indication.
- At least one site of disease amenable to radiation therapy per the acceptable dosing regimens outlined in section 6.2, and at least one additional site of measurable disease suitable for out-of-field response assessment.
- Cannot have active collagen vascular disease (CVD), specifically systemic lupus erythematosus or scleroderma. Patients with a history of CVD without evidence of active disease are eligible for enrollment at the discretion of the study PI.
- Cannot have had prior treatment with immune checkpoint inhibitor

Endometrial Cancer

A. *Endometrial*

a. Primary Stage III/IV or Recurrent

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

19-0207 An Open-Label, Multicenter, Phase 1b/2 Study of Rebastinib (DCC-2036) in Combination with Paclitaxel to Assess Safety, Tolerability, and Pharmacokinetics in Patients with Advanced or Metastatic Solid Tumors

Deciphera (NCT03601897) PI: Jennifer Diamond, Study Coordinator: Kari Corby

Part 2, Cohort 4: Endometrial Cancer

- Histologically confirmed adenocarcinoma of the endometrium.
- Received at least one prior line of platinum-based therapy in the recurrent, metastatic, or high-risk disease setting, or, for patients with known microsatellite instability-high (MSI-H) or mismatch repair deficiency, progressed after a regimen including an anti-PD1 agent.
- At least one measurable lesion according to RECIST Version 1.1.
- ECOG PS of ≤ 2
- Able to provide an archival tumor tissue sample

b. Recurrent/Persistent

Radiation

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)

- 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

19-0556 A Randomized Phase II Study of Anti-PD-1 and Limited Metastatic Site Radiation Therapy Versus Anti-PD-1 Alone for Patients With Microsatellite Instability-high (MSI-H) and Mismatch Repair Deficient (dMMR) Metastatic Solid Tumors (NCT04001101) PI:

Christine Fisher, Study Coordinator: Jillian Welker

- ECOG 0 or 1
- Unresectable or metastatic MSI-H/dMMR tumors eligible to receive pembrolizumab according to FDA-approved indications:
- Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
- Confirmation from medical or gynecologic oncology that the patient is eligible to receive pembrolizumab per FDA-approved indication.

- At least one site of disease amenable to radiation therapy per the acceptable dosing regimens outlined in section 6.2, and at least one additional site of measurable disease suitable for out-of-field response assessment.
- Cannot have active collagen vascular disease (CVD), specifically systemic lupus erythematosus or scleroderma. Patients with a history of CVD without evidence of active disease are eligible for enrollment at the discretion of the study PI.
- Cannot have had prior treatment with immune checkpoint inhibitor

c. 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. Newly Diagnosed

19-1151 Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently With Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer

(NCT03738228) PI: Bradley Corr, Study Coordinator: Jenna Buehler

- Patients with histologically confirmed newly diagnosed advanced cervical cancer (squamous cell carcinoma, adenocarcinoma, and adenosquamous cell carcinoma)
- ECOG PS of ≤2
- Patients who have received prior radiation therapy to the pelvis or abdominal cavity, PALN radiation, or previous therapy of any kind for this malignancy or pelvic, PALN, or abdominal radiation for any prior malignancy are not eligible
- Patients with PALN nodal metastasis above the T12/L1 interspace are not eligible
- Patients who had a radical hysterectomy with positive PALNs are not eligible
- Patients previously treated with systemic anticancer therapy (e.g., chemotherapy, targeted therapy, immunotherapy) within 3 years prior to entering the study are not eligible

B. 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

All GYN Cancers

A. Multiple Subtypes

a. Any Line

20-0360 – NRG-GYN022 Assessment of Carboplatin Clearance Predictors: A PK Study on NCI-Sponsored Clinical Trials or Standard of Care (NCT03997370) PI: Bradley Corr, Study Coordinator: Megan Khu

- Any patients who will receive treatment with intravenous carboplatin (any AUC, any cycle) on a National Cancer Institute (NCI)-sponsored National Clinical Trial Network (NCTN)-, Experimental Therapeutics Clinical Trials Network (ETCTN)-, trial, local trial, or through standard of care
- No prior history of allergic reactions to computed tomography (CT) contrast, iodine or shellfish, or history of anaphylactic reaction to any food item
- No recent (last 6 months) episodes of acute kidney injury, have sickle cell disease, or have current indwelling nephrostomy tubes

b. Newly Diagnosed

17-2198 UM1 10132:a AZD1775 + radiotherapy + cisplatin (NCT03345784) 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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