

Gynecological Oncology Research Program

Women's Cancer Developmental Therapeutics (WCDT) Program

WCDT Program Nurse Navigator	Brandi Welker	720-848-9302	Brandi.Welker@uchealth.org
Gyn Onc Research Team Manager	Gwen Wade	720-848-2538	Gwendolyn.Wade@ucdenver.edu
MOTT (Molecular Oncology) previously "T3" Research Team Manager	Courtney Newbold	720-848-0653	Courtney.Newbold@ucdenver.edu
Phase I Research Team New Patient Intake Coordinator	Amanda Lark	720-848-0678	Amanda.Lark@ucdenver.edu
	Amanda Siedem	720-848-0052	Amanda.Siedem@ucdenver.edu

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>

Updated: May 21, 2019

Ovarian Cancer

A. Front Line

a. Front Line Newly Diagnosed

16-2745 Phase 3 GOG 3015/Roche YO39523 A Study of Atezolizumab (PD-L1 binder) Versus Placebo in Combination with Paclitaxel (taxane chemotherapy), Carboplatin (platinum), and Bevacizumab (VEGF inhibitor) in Participants With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

(NCT03038100) PI: Behbakht, Study Coordinator: Jenna Buehler

Gyn Onc Cancer Research Team (Behbakht, Corr, Guntupalli, Lefkowitz)

- Atezolizumab/placebo with paclitaxel, carboplatin, and bevacizumab
- Allows for primary cytoreductive surgery or interval debulking surgery (must be within 42 days of surgery)
- Stage III or IV
- Neoadjuvant is closed, only frontline surgery arm available as of 6/7/18

b. 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) (NCT03038100) 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

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: Jennifer Wallace

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

17-1511 NRG GY009 A Randomized Phase II/III of PLD (anthracycline) and Atezolizumab (PD-L1 binder) vs plus PLD/Bev/Atezo vs PLD/Bev for Platinum Resistant Ovarian

GY009 (NCT02839707) PI: Behbakht Study Coordinator: Jenna Buehler

Gyn Onc Cancer Research Team (Behbakht, Corr, Guntupalli, Lefkowitz)

- 1-2 Prior regimens (including primary treatment) allowed
- Measureable or evaluable disease allowed

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

Endometrial Cancer

A. Endometrial

a. 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

b. Stage III/IV Recurrent or Persistent

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

Cervical/Vulvar Cancers

A. Cervical

a. Recurrent

17-0948 A Phase 1 Trial of MK-7684 (TIGIT binder) as Monotherapy and in Combination with Pembrolizumab (PD-1 inhibitor) in Subjects with Advanced Solid Tumors

Merck TIGIT MK7684 (NCT02964013), PI Jimeno, Study Coordinator: Amanda Kupniewski
Phase I Research Team/Clinic Anschutz (Diamond/Corr)

- Locally advanced and unresectable or metastatic
- Any receptor status, including TNBC
- Must have received standard of care therapy, ≤ 3 lines
- No prior PD1/PD-L1 therapy
- Measurable disease
- Stable brain mets allowed

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

a. 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: Olivia Pearson

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: 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.

Gyn Onc Providers	Location	Cell	Email
Kian Behbakht, MD	Anschutz & Lone Tree	303-918-6476	Kian.Behbakht@ucdenver.edu
Bradley Corr, MD	Anschutz	215-688-3604	Bradley.Corr@ucdenver.edu
Saketh Guntupalli, MD	Anschutz & Lone Tree	713-294-1841	Saketh.Guntupalli@ucdenver.edu
Carolyn Lefkowits, MD	Anschutz	617-823-5750	Carolyn.Lefkowits@ucdenver.edu

Gyn-Onc CRCs	Office	Pager	Email
Wade, Gwen – Manager	720-848-2538	303-266-4705	Gwendolyn.Wade@ucdenver.edu
Kissane, Becky - Supervisor	720-848-7202	303-266-3213	Rebecca.Kissane@ucdenver.edu
Buehler, Jenna	720-848-0661	303-266-5152	Jenna.Buehler@ucdenver.edu
Sweetser, Anna	720-848-0701	303-266-5152	Anna.Sweetser@ucdenver.edu
Ob/Gyn/Surgery CRCs: Alyse Brennecke Dina Flink Anna	303-724-8467		Alyse.Brennecke@ucdenver.edu
MOTT CRCs	Office	Pager	Email
Closson-Niese, Tate	720-848-0669	303-266-1829	Tate.Closson-Niese@ucdenver.edu
Draper, Lauren	720-848-7341	303-266-1084	Lauren.Draper@ucdenver.edu
Pearson, Olivia	720-848-9382	303-266-1277	Olivia.Pearson@ucdenver.edu
Phase I CRCs	Office	Pager	Email
Lark, Amanda	720-848-0678		Amanda.Lark@ucdenver.edu
Siedem, Amanda	720-848-0052		Amanda.Siedem@ucdenver.edu
Kupniewski, Amanda	720-848-0643	303-266-4156	Amanda.Kupniewski@ucdenver.edu
O'Hern, Matthew	720-848-0523	303-266-1790	Matthew.Ohern@ucdenver.edu
Bouley, Alleah	720-848-8846	303-266-5105	Alleah.bouley@ucdenver.edu
Rippke, Sarah	720-848-0685	303-266-1710	Sarah.Rippke@ucdenver.edu
Wells, Tara RN	720-848-0755	303-266-1654	Tara.Wells@ucdenver.edu
Phase I On Call		303-266-2328	
Radiation CRCs	Office	Pager	Email
Withrow, Suzanne - Supervisor	720-848-0593	303-266-6227	Suzanne.Withrow@ucdenver.edu
Santangelo, Tess	720-848-9398	303-266-5454	Tess.Santangelo@ucdenver.edu
Schaefer, Chelsea	720-848-0608	303-266-3662	Chelsea.Schaefer@ucdenver.edu
Swing, Robin – Manager	720-848-0607	303-266-7223	Robyn.Swing@ucdenver.edu