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

Updated March 14, 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 Wallace
Gyn Onc Cancer Research Team (Behbakht, Corr, Guntupalli, Lefkowits)

- 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 Maintence 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

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, 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

17-1511 NRG GY009 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 Wallace
Gyn Onc Cancer Research Team (Behbakht, Corr, Guntupalli, Lefkowits)

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

17-2451 GCT1021-01 Genmab A/S First-in-human, open label, dose-escalation trial with expansion cohorts to evaluate safety of Axl-specific antibody-drug conjugate (HuMax-AXL-ADC) in patients with solid tumors

GCT1021-01 (NCT02988817) PI: Victor Villalobos Study Coordinator: Siobhan Collins

- prior regimens (including primary tx) allowed, no doxil allowed
- Measurable disease per RECIST
- ECOG 0-1
- No clinically significant cardiovascular disease, including unstable angina or acute MI within 6 months

- Stable, asymptomatic brain mets are allowed
- No > grade 2 peripheral neuropathy
- Resistance to at least on platinum-based therapy
- Failing at least one treatment regimen containing a taxane
- Patients with primary platinum refractory disease are excluded
- Failure of at least 2 prior treatment regimens containing systemic therapy, but not more than 5 for recurrent disease

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

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

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 Wallace
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 (Corr?)

- 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.

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