**GOG 3015**: Genentech
Phase III C+T+Bevacizumab (anti-VEGF) ± Atezolizumab (anti PD-L1)
Stage III/IV

Open Cohort: Primary Surgery
*Neoadjuvant cohort closed*

For more details contact 1-877-UC-STUDY or ucstudy@uci.edu
GOG 3015: ATEZOLIZUMAB (anti PD-L1)
Primary Cytoreduction

**Figure 1: Study Schema for Patients in the Primary Tumor-Reductive Surgery Group**

- Previously-united epithelial ovarian, primary peritoneal, or fallopian tube cancer
- Stage III (sub-optimal/optimal with macroscopic residual), Stage IV, or patients with advanced disease treated in the neo-adjuvant setting
- ECOG PS 0-2

---

**Stratification variables:**
- Stage/debulking status
- ECOG PS
- PD-L1 IC0 versus IC1+
- Adjuvant/Neo-adjuvant

**Co-primary endpoint:** PFS and OS in all comers and Dx+ (IC 1+)

---

<table>
<thead>
<tr>
<th></th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
**UCI 17-111: On Target Lab**
Phase III, Randomized, Single Dose, Open-Label Study of OTL38 (Folate analog ligand + indole cyanine-like green dye) for Intra-operative Imaging of Folate Receptor Positive Ovarian Cancer

*Open to enrollment*
UCI 17-111: PHASE III OTL38
Folate analog ligand + indole cyanine-like green dye

Study Design

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCI 17-111</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
UCI 17-37: NuCana Phase II Open-Label Study of NUC-1031 (anti-neoplastic, DNA synthesis inhibitor) 
*Pending activation*

NRG-GY009: Phase II/III, PLD + Atezo vs PLD + Bev vs PLD + Atezo + Bev (chemo + anti-VEGF + anti-PD-1) 
*Open to Enrollment*
UCI 17-37: PHASE II NuCana (NUC-1031)
antineoplastic, DNA synthesis inhibitor

Study Design

<table>
<thead>
<tr>
<th></th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NuCana</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Pending</td>
</tr>
</tbody>
</table>
UCI 17-27: Phase 2, Single Arm, Two Period Study of Sodium Cridanimod (IFN inducer) in Conjunction with Progestin (anti-neoplastic, increases PrR and ER levels)

*No prior therapy with hormonal progestin agents*

**Enrollment on Hold** – reassessing eligibility criteria


*Cohort 1 (TMB group) on Hold*

**Enrollment only under Cohort 2**
UCI 17-27: Sodium Cridanimod
IFN-inducer

Recurrent or persistent endometrial carcinoma not amenable to surgical treatment or radiotherapy

Consent + Screening

Treatment Period 1: PrR + Progestin Monotherapy
- 160 mg PO QD
- CT/MRI 12 weeks post-Progestin Monotherapy
- No interruption of Progestin allowed

Radiographic evidence of disease control (SD, partial CR) will be treated per SOC

Radiographic PD moves to Treatment Period 2

Treatment Period 2: PrR - and PD post TP1
- Progestin monotherapy (160 mg PO QD) + Sodium Cridanimod (500 mg 2x/week)
- No interruption of progestin allowed

Follow Up:
1) 30 Day Safety Follow Up post-PD
2) SFU for 12 months

<table>
<thead>
<tr>
<th>Sodium Cridanimod/Progestin</th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Held</td>
</tr>
</tbody>
</table>
UCI 18-19: IBI308 (Anti-PD-1)

<table>
<thead>
<tr>
<th>Study Schema</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening Period</strong></td>
</tr>
<tr>
<td>Day-28 to Day -1</td>
</tr>
<tr>
<td>ICF, PE, LABs, Biopsies, Imaging, Evaluate all Subjects for Inclusion/Exclusion Criteria see Schedule of Events</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each Cycle=21 Days</td>
</tr>
<tr>
<td>IBI308 200 mg IV</td>
</tr>
<tr>
<td>Treat Until Intolerable Toxicity, Progression of Disease, Withdrawal of Consent, EOT.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cohort 1a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced/metastatic TMB-H cancers (TMB 10-15 mut /Mb)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cohort 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced/metastatic TMB-H cancers (TMB 15-20 mut /Mb)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cohort 1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced/metastatic TMB-H cancers (TMB&gt;20 mut /Mb)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cohort 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced/metastatic Endometrial cancer</td>
</tr>
</tbody>
</table>

| EOT±7 Days |

| Safety FU 30±7 Days |

---

<table>
<thead>
<tr>
<th>UCI 18-19</th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCI 18-19</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>Open</td>
</tr>
</tbody>
</table>
**Fertility-Preserving**

1A1, LVSI, 1A2, 1B1 (≤ 2 cm)

**GOG 278:** Physical function and QOL before and after non-radical surgical therapy (extra-fascial hysterectomy or cone biopsy with nodes)

---

**RH-Nodes**

GOG 92 Sedlis Criteria

**GOG 263:** Phase III– adjuvant RT vs chemoRT
Intermediate risk stage I/IIA s/p RH-nodes

GOG 109 Peters Criteria

**GOG 724:** Phase III chemoRT +/- adjuvant chemoRx
High-risk early stage s/p RH-nodes

---

**Recurrent & Metastatic**

1st Line Therapy

**UCI 18-32:** Phase III Randomized, Double-Blind, Pembrolizumab (anti-PD-1) + Chemotherapy +/- Bevacizumab (anti-VEGF) Vs. Chemotherapy + Placebo +/- Bevacizumab

2nd Line Therapy

**GOG 3016:** Regeneron
Phase III physician’s choice ChemoRx vs Anti-PD-1 (REG2810)
GOG 278 – Fertility Preservation

SCHEMA (06/03/2013)

Women with IA1-IB1 (≤2cm) carcinoma of the cervix who have been consented for surgery will be approached for study participation. Pre-entry cone biopsy/LEEP (depth of invasion ≤10mm)

Study Entry

Pre-operative QOL Study Survey

Fertility Preservation Group:
Carcinoma with pelvic lymphadenectomy
(If the lateral margins were positive on the first cone biopsy/LEEP, patients must have a second cone biopsy/LEEP at the time of the pelvic lymphadenectomy)

No Wish for Future Fertility Group:
Simple hysterectomy with pelvic lymphadenectomy (If the lateral margins were positive on the first cone biopsy/LEEP, patients must have a second cone biopsy/LEEP prior to hysterectomy)

If depth of invasion (sum of the pre and post entry biopsies) ≤10 mm, only ECC is required.

If any of the following criteria are met, patient will be followed for survival only:
• Depth of invasion (sum of the pre and post entry biopsies) >10 mm
• Positive pelvic lymph nodes on final pathology
• Adjuvant therapy required

If depth of invasion (sum of the pre and post entry biopsies) ≤10 mm, proceed to hysterectomy.

Post-Operative
Follow-up Visits and QOL Study Surveys
4-6 weeks Post-Op and every 6 months (6, 12, 18, 24, 30, 36) for three years

1. QOL Study Survey includes: Bladder and Bowel Function Items, Female Functioning Index and PROMIS Items, QLQ-Gyn Cancer Lymphadenectomy Questionnaire, Functional Assessment Cancer Therapy FACT-G, and Impact of Events Scale (IES). Patients in the Fertility Preservation Group will also complete the Reproductive Items (ICF & RCS) in addition to the items above. See section 7.4 for additional information regarding the QOL Study Survey.

<table>
<thead>
<tr>
<th>Fertility QoL</th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
GOG 263 – Sedlis Rad Hyst-Nodes

SCHEMATIC:
- Post-operative Stage I-IIA cancer of cervix with intermediate risk factors (IRF)
- Squamous cell carcinoma, adenosquamous carcinoma or adenocarcinoma histology
- GOG performance status 0-2

- Baseline Quality of Life Assessment
- Smoking History Questionnaire

RANDOMIZE:
- Stratification factors: IRF, performance status, radiation modality, cooperative group

Regimen I (control arm)
- Radiation Therapy:
  - (External pelvic standard radiation or IMRT)

Regimen II (CRT arm)
- Concurrent Cisplatin and Radiation Therapy
  - (External pelvic standard radiation or IMRT)
  - Cisplatin 40mg/m² (max=70mg) IV over 1-2 hours weekly x 6 cycles with radiation therapy

Regimen II (CRT arm) Schedule

<table>
<thead>
<tr>
<th>Cycle</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>1</td>
<td>8</td>
<td>15</td>
<td>22</td>
<td>29</td>
<td>36</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X**</td>
</tr>
<tr>
<td>Radiation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedlis RH-nodes</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
### GOG 724 – Peters Rad Hyst-Nodes

#### Schema (8/21/14)

<table>
<thead>
<tr>
<th>STRATIFY</th>
<th>RANDOMIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intention To Use Brachytherapy</strong></td>
<td><strong>Arm 1</strong></td>
</tr>
<tr>
<td>1. No</td>
<td>Concurrent weekly cisplatin and RT ± brachytherapy</td>
</tr>
<tr>
<td>2. Yes</td>
<td>Versus</td>
</tr>
<tr>
<td><strong>RT Modality</strong></td>
<td><strong>Arm 2</strong></td>
</tr>
<tr>
<td>1. Standard RT</td>
<td>Concurrent weekly cisplatin and RT ± brachytherapy</td>
</tr>
<tr>
<td>2. IMRT</td>
<td>FOLLOWED BY</td>
</tr>
<tr>
<td><strong>Radiation Therapy Dose</strong></td>
<td>Carboplatin and paclitaxel</td>
</tr>
<tr>
<td>1. 45 Gy</td>
<td></td>
</tr>
<tr>
<td>2. 50.4 Gy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peters RH-nodes</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
KEYNOTE-826
1L Cervical – MK-3475 + paclitaxel + cisplatin or carboplatin (± bevacizumab)

Key eligibility criteria:
- Persistent, recurrent or metastatic cervical cancer
- No prior systemic chemotherapy
- Prior radiation ± radiosensitizing chemotherapy allowed
- ECOG PS 0, 1

Randomization:
1:1

Randomized:
- pembrolizumab
  - paclitaxel +
  - cisplatin or carboplatin +
  - (± bevacizumab)
  - N=300
- placebo
  - paclitaxel +
  - cisplatin or carboplatin +
  - (± bevacizumab)
  - N=300

Patients treated until:
- Disease progression
- Unacceptable toxicity

Primary Objectives:
- Progression-free survival (PFS)
- Overall survival (OS)

Stratification factors:
- Metastatic at diagnosis (yes vs. no)
- Bevacizumab use (yes vs. no)
- PD-L1 status by CPS (<1 vs. 1 to <10 vs. ≥10)

Study Treatments administered Q3W (Day 1 of each cycle):
- Pembrolizumab 200 mg or Placebo by IV infusion
- Paclitaxel 175 mg/m² by IV infusion
- Cisplatin 50 mg/m² or Carboplatin AUC 5 by IV infusion
  - (± bevacizumab 15 mg/kg by IV infusion)

Abbreviations: AUC = area under concentration-time curve; CPS = combined positive score; ECOG = Eastern Cooperative Oncology Group; IV = intravenous; PD-L1 = programmed cell death ligand 1; PFS = progression-free survival; OS = overall survival

Figure 1  Study Diagram

<table>
<thead>
<tr>
<th></th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCI 18-32</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
GOG Partners 3016: Anti-PD-1

**Study Population:** Cervical cancer, with progression or recurrence within 6 months of last dose of platinum therapy that was used to treat metastatic, persistent, or recurrent disease

**Screening, Randomization, and Stratification (N = 414):**
- Randomization – 1:1
- Stratification – Squamous versus adenocarcinoma/adenosquamous

**Experimental Therapy**
- REGN2810
- 250 mg IV Q3W

**Control Therapy, Investigator’s Choice**
- Any of the following, given IV Q3W:
  - Paclitaxel 300 mg/m² on Day 1
  - Topotecan 1.5 mg/m² on Days 1-5
  - Gemcitabine 1000 mg/m² on Days 1 and 8

**Duration of Treatment:**
- Treatment until PD, unacceptable toxicity, or until 48 weeks (8 cycles, each 6 weeks)
- Response assessments Q12W
- Option for treatment beyond PD with REGN2810
- Option for retreatment for patients who complete 8 cycles and then experience PD in post-treatment follow up

**Post-Treatment Follow-up:**
- For safety, progression events, and OS

**Study Endpoints:**
- Primary: OS
- Key Secondary: PFS, ORR

<table>
<thead>
<tr>
<th></th>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>REG2810</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
GOG 279: Phase II CDDP+GEM with IMRT (chemo + IMRT)
Previously untreated

<table>
<thead>
<tr>
<th>Active</th>
<th>Accrual</th>
<th>Screening</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Open</td>
</tr>
</tbody>
</table>
GOG 279: CDDP+GEM with IMRT

Chemo + IMRT

Local advanced squamous cell carcinoma of the vulva, T2 or T3 primary tumors (N0-3, M0) not amenable to surgical resection by standard radical vulvectomy

Patient registration

Resectable Lymph Nodes
Patients will undergo a pre-treatment inguinal-femoral lymph node dissection or sentinel lymph node biopsy

LN (-)
No radiation vs 45 Gy to groin(s) and low pelvis; 64 Gy to vulva
Gemcitabine 50 mg/m² + Cisplatin 40mg/m² administered weekly throughout radiation therapy

Clinical/Radiographic assessment 6-8 weeks after chemoradiation
Complete Clinical Response
Local, core biopsies of tumor bed to confirm complete pathologic

No Complete Clinical Response
Surgical resection of residual disease or additional chemoradiation

Unresectable Lymph Nodes

LN (+)
50 Gy to groin(s) and low pelvis with groin boost to 60 Gy to involved sides if
> 3 LN (+) or
extra capsular extension or
close positive margin
64 Gy to vulva
Gemcitabine 50 mg/m² + Cisplatin 40mg/m² administered weekly throughout radiation therapy

Radiation 64 Gy to vulva and unresectable groin(s) and 50 Gy to non-malignant groin and low pelvis
Gemcitabine 50 mg/m² + Cisplatin 40mg/m² administered weekly throughout radiation therapy

FNA of clinical or radiographic residual 6-8 weeks after chemoradiation
Target excision of (+) LNs
PHASE I & BASKET TRIALS

**SWOG-S1609**: DART (Ipi + Nivo)
(Anti CTLA-4 + Anti-PD-1)

Cohort: Choriocarcinoma