CLINICAL TRIALS & ENROLLMENT SUMMARY Updated 6/21/2024

Trial	Inclusion/Exclusion	Study Arms	Locations
FALLOPIAN TUBE/OVARIAN/PRIMARY PERITONEAL			
Front-line			
NRG-CC008 A Non-Randomized Prospective Clinical Trial Comparing the non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk]	**Inclusion:** - Women ≥35 and ≤50 years of age - Documented *BRCA1* mutation - Defers RRSO (BLS cohort only) - At least one intact ovary + fallopian tube (prior hyst allowed if did not include bilateral salpx; prior tubal ligation allowed if one intact ovary and FT are present **Exclusion:** - Prior history of ovca (incl LMP), perit ca, or FT ca - Abnormal TVUS or CA-125 suspicious for occult or gross pelvic malignancy or neoplasm within past 180 days	After discussion and consult with GynOnc, patients choose between study groups: BS Cohort – bilateral salpingectomy ± hysterectomy (can receive bilateral oophorectomy at any time) BSO Cohort – bilateral salipingo-oophorectomy ± hysterectomy	**Providence** **OHSU** **Legacy**
GY019 A randomized phase 3, 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	**Inclusion:** - Newly dx stage II-IV LGSOC - Nonaberrant p53 - Undergone attempt at maximal cytoreduction (optimal and suboptimal allowed) **Exclusion:** - NACT or Neoadjuvant RT - Prior hormone therapy for disease	Arm 1: carbo/taxol x6 cycles-> letrozole daily maintenance Arm 2: letrozole daily	**Providence** **Legacy**
Platinum-Sensitive Recurrence			
GLORIOSA PhIII study to evaluate the safety and efficacy of mirvetuximab soravtansine as maintenance therapy in platinum sensitive ovarian cancer with high folate receptor-alpha expression	**Inclusion:** - High grade serous histology - FOLRa positivity >=75% membraine staining at 2+ intensity - BRCA germline and somatic testing. If positive need to receive prior PARPi - Minimum of 4 cycles of chemo w/ recurrence **Exclusion:** - Endometrioid, clear cell, mucinous, sarcomatous histology - More than 1 prior line of therapy	Arm 1: Mirvetuximab soravtansine 6mg/kg + bev 15mgk/d q21 days Arm 2: Bev 15mg/kg q21 days	**OHSU**
Platinum-Resistant Recurrence			
GOG3086 REFRaME-01/ENGOT-OV79 Phase II/III study evaluating efficacy and safety of luveltamab tazevibulin vs. Chemo in platinum resistant, FOLRa positive OvCa	**Inclusion:** - Platinum resistant up to 3 prior regimens - TPS>=25% FOLRa expression - Measurable disease	Arm 1: luvelta (4.3mg/kg or 5.2mg/kg) q3 weeks Arm 2: investigator's choice chemo	**Providence**

	- High grade serous histology **Exclusion:** - Primary platinum refractory - Prior FOLRa ADC or ADC containing tubulin inhibitor				
ROSELLA/ GOG-3073 PhIII study of relacorilant in combination with nab-paclitaxel vs. Nab-paclitaxel alone in platinum resistant OvCa	**Inclusion:** - High grade serous histology - Meausrable disease - At least 1 but <= 3 prior lines **Exclusion:** - Low grade endometrioid, clear cell, mucinous, sarcomatous histology - Had not received prior bev	Arm 1: nab-paclitaxel 80mg/m2 D1, 8,15 q28 days + relacorilant 150mg PO daily Arm 2: nab-paclitaxel 100mg/m2 D1,8,15 q28 days	**OHSU**		
GOG 3082 / ACR-368 Ph1b/2 study to evaluate efficacy and safety of ACR-368 monotherapy or in combination with ultralow dose gemcitabine in platinum resistant ovarian, endometrial and urothelial carcinoma	**Inclusion:** - High grade serous histology - Received at least 1 prior but <6 - Prior bev unless contraindicated **Exclusion:** - Non-epithelial, clear cell, mucinous, germ cell, low grade serous - Clinically meaningful ascites	Oncosignature positive: ACR-368 (prexasertib) monotherapy IV q14 days Oncosignature negative: Prexasertib + ultra low dose gemcitabine IV q14 days	**OHSU**		
Endometrial					
Front-line					
Genentech C044195 Phase II single arm study of giredestrant in grade 1 endometrial cancer	**Inclusion:** - Grade 1 endometrioid histology - MRI w/ <50% myometrial invasion - MRI or CT no metastatic disease **Exclusion:** - Non-endometrioid histology - Prior tx for endometrial cancer	Single arm: giredestrant 30mg oral daily D1-28 of each q28 cycle x6 cycles=> choose to discontinue for additional 18 cycles or stop	**Providence**		
XPORT-EC-042 PhIII study of selinexor in maintenance therapy after systemic therapy for p53 wt advanced of recurrent endometrial carcinoma	**Inclusion:** - Endometrioid, serous, undifferentiated, carcinosarcoma histology - TP53wt by NGS - Completed single line at least 12 week of platinum therapy (not including adjuvant or neoadjuvant for Stage I-III disease), achieved CR or PR **Exclusion:** - Uterine sarcomas, clear cell, small cell, neuroendocrine	Arm 1: selinexor 60mg oral tablets once week D1, 8, 15, 22 q28d cycle Arm 2: placebo	**Providence**		

GOG-3069 A Phase 2 study of alpelisib and fulvestrant for PIK3CA-mutated estrogen receptor (ER)-positive endometrioid endometrial cancers	**Inclusion:** - Advanced (Stage III or IV), persistent, recurrent - Endometrioid histology with ER+ and PIK3CA mutation - Measurable disease - Prior adjuvant chemotherapy okay (only one line) - No diagnosis of DM I and DMII must be well controlled - No more than 3 prior lines	Single arm: alpelisib 300mg QD (oral) + fulvestrant (IM) q4 weeks (loading requires q2 weeks x2)	**Legacy**
Metastatic/Recurrent			
GY026 A phase II/III study of paclitaxel/carboplatin alone or combined with either trastuzumab and hyaluronidase-oysk (HERCEPTIN HYLECTA) or pertuzumab trastruzumab and hyaluronidase-zzfx (PHESGO) in HER2 positive, stage I-IV endometrial serous carcinoma or carcinosarcoma	**Inclusion:** - Stage IA-IVB upfront HER2+ endometrial serous carcinoma or carcinosarcoma - Less than 10% nonserous histology allowed - Non-operative patients allowed **Exclusion** - Neoadjuvant chemotherapy - Pelvic EBRT (vaginal brachytherapy ok)	Arm 1: Carbo (AUC 5)/Taxol Arm 2: Carbo (AUC5)/Taxol/subq trastuzumab Arm 3: Carbo (AUC 5)/Taxol/sub trastuzumab and pertuzumab	**OHSU** **Providence** **Legacy**
GOG 3082 / ACR-368 Ph1b/2 study to evaluate efficacy and safety of ACR-368 monotherapy or in combination with ultralow dose gemcitabine in platinum resistant ovarian, endometrial and urothelial carcinoma	**Inclusion:** - High grade endometrial adenocarcinoma including carcinosarcoma - No more than 3 prior lines in recurrent setting - Failed prior PDl1 inhibitor **Exclusion:** - Low grade histology	Oncosignature positive: ACR-368 (prexasertib) monotherapy IV q14 days Oncosignature negative: Prexasertib + ultra low dose gemcitabine IV q14 days	**OHSU**
AFT-50 A phase IB/II multi-cohort study of targeted agents with atezolizumab for patients with recurrent or persistent endometrial cancer	**Inclusion:** - Recurrent or persistent dz after at least 1, but no more than 2, prior lines of therapy (hormone therapy not counted) - Measurable disease **Exclusion:** - Squamous, sarcoma histology - Synchronous primaries	Based on Foundation testing, will be assigned to targeted therapy + atezolizumab: Cohort 1: + Bev (unmatched) Cohort 2: + Ipatasertib (PIK3CA/AKT/PTEN altered) Cohort 3: + talazoparib (LOH high) Cohort 4: + Trastuzumab (ERBB2/HER2 amp) Cohort 5: +tiragolumab (MSI-H, TMB >=10mut/mb)	**Providence**
ZN-C3-004/GOG3065/Teton	**Inclusion:**	Single arm: ZN-c3 (azenosertib) taken orally with food	**Providence**

PhII study in women with recurrent or persistent uterine serous carcinoma	- Recurrent or persistent uterine serous carcinoma (or at least 5% for mixed histology) - Prior platinum, PDL1 inhibitor required - Prior HER2 targeted required for HER2+ - Measurable disease **Exclusion:** - Prior WEE1, ATR, CHK1/2 inhibitor		
Cervical			
Early Stage			
GOG 3043 ROCC A randomized controlled trial of robotic versus open radical hysterectomy for cervical cancer	**Inclusion:** - Newly diagnosed FIGO 2018 IA2, IB1, IB2 radiographic evidence of definite parametrial, vaginal, lymph node, or distant metastases. - Uterine size less than 12 cm	**Arm 1** Open radical hysterectomy +/- BSO with lymph node assessment **Arm 2** Robotic radical hysterectomy +/- BSO with lymph node assessment	**Providence**
Metastatic/Recurrent			
Phase 1, Multicenter, Open-Label Study of SQZ-AAC-HPV as Monotherapy and in Combination With Immune Checkpoint Inhibitors in HLA-A*02+ Patients With HPV16+ Recurrent, Locally Advanced or Metastatic Solid Tumors **SQZ-AAC-HPV:** activating antigen carrier cell therapy, a therapeutic vaccine engineered from red blood cells manufactured with immunogenic epitopes of HPV16.	**Inclusion:** - HPV16+ incurable or metastatic solid tumors that have progressed after >/=1 standard therapy, or has a tumor where no standard therapy exists - HLA-A*02+ - At least 1 measurable lesion (RECIST 1.1) - Lesion that can be biopsied at baseline and cycle 2 **Exclusion:** - Systemic treatment with either corticosteroids (>10 mg of prednisone or the equivalent per day) or other immunosuppressive medications within 14 days prior to Cycle 1 Day 1 - Patients with active, known, or suspected autoimmune disease may not be eligible and should be discussed with the Sponsor - History of interstitial lung disease requiring steroids	**All cohorts:** Blood collection for manufacture of autologous SQZ-AAC-HPV **Cohort 1:** SQZ-AAC-HPV monotherapy dose escalation HPV + ipilimumab **Cohort 2a:** SQZ-AAC-HPV + nivolumab **Cohort 2a:** SQZ-AAC-HPV + nivolumab + ipilimumab on	**OHSU**
INSTITUTIONAL PHASE 1/MULTI-INDICATION TRIALS			

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Updated 6/21/2024

- **EAY191-N4** A randomized trial of selumetinib and olaparib or selumetinib alone in patients with recurrent or persistent RA pathway mutant ovarian and endometrial cancers Target mutations: KRAS, NRAS, HRAS. BRAF, MEK1, MEK2, or inactivating mutations in NF1 - **EAY1910-E5**: A randomized Ph II study of AMG510 (sotorasib) with or without panitumumab in advanced solid tumors Target mutations: KRAS G12 targets - EAY191-A3: Palbociclib and binimetinib in RAS mutant cancers Target mutations: KRAS, NRAS, non-BRAF V600E aMOIs or rare RAG fusions - SGNDV-005: A PhII study or disitamab vedotin in platinum resistant ovarian cancers Target mutation: HER2 at least 1+	**Providence**
- AZD9574/ Certis1: A study of AZD9574 as monotherapy or in combination in advanced solid tumors Target mutations: BRCA1/2, PALB2, RAD51C/D, HER2 - FONTANA: A PhI/IIa study for AZD5335 single agent FOLRa TOP1 inhibitor in platinum resistant ovarian cancer Target mutation: none - PMV: A study of PC14586 in combination with pembrolizumab Target mutation: p53 Y220C target - FOG-001 A study of single agent direct inhibitor of b-catenin Target mutation: wnt pathway mutations APC loss, CTNNB1 gain, RNF42 and RSP03 etc. - AZD3470 PRIMROSE: PRMT5 inhibitor for patients with MTAP loss - Incyte IIT axatilimab in combination with retifanlimab and paclitaxel	**OHSU**