	OVARIAN	CERVICAL	ENDOMETRIAL
Front line	**NRG-GY019: (Van Le/Lorraine Balletta)** 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 **Brief Eligibility: Inclusion** • Stage II-IV • Patients must have undergone a bilateral salpingo-oophorectomy • No prior chemo or radiation for this disease • must be within ≤8 weeks of primary cytoreductive surgery at time of randomization.		**NWU-02-01: (Clark/Lorraine Balletta)** Randomized phase II open-label pre-surgical window of opportunity study, comparing megestrol acetate to megestrol acetate and metformin ER. **Brief Eligibility:** • Participants with EIN on an endometrial biopsy or dilation and curettage specimen who have not had any prior treatment • Must be a candidate and accepting of surgical management of EIN with planned hysterectomy or IUD placement. • Registration required w/in 3 months of dx biopsy • Women with alcohol and tobacco use or abuse are ineligible **NRG-GY026: (Van Le/Tamara Pfeffer)** A Phase II/III study of paclitaxel/carboplatin alone or combined with either trastuzumab and (HERCEPTIN HYLECTA) or (PHESGO) in HER2 positive, stage I-IV endometrial Serous, clear cell, endometrioid, mixed epithelial, dedifferentiated/ undifferentiated), Carcinosarcoma **(only stage III & IV open)** **Brief Eligibility**: • HER2+ status (Local testing) • Stage IA-IVB, non-recurrent, chemo-naïve • For (stage I), tumor must be into the myometrium. • Patients must be within 8 wks of primary surgery (or endometrial biopsy in patients who never undergo hysterectomy) at the time of study registration • Treated brain mets are eligible if follow-up after CNS directed therapy shows no evidence of progression. • Trial excludes prior radiation therapy **NRG-GY032: (Olivia Lara/Tamara Pfeffer)** A Phase II Study of Tailored Adjuvant Therapy in Polemutated And p53-WILDTYPE/NSMP Early-Stage Endometrial Cancer (Rainbo Blue & Taper)

Relapsed/ Refractory	**GOG-3078/IMGN853-0421/GLORIOSA- (Van Le, Lorraine Balletta)** Mirvetuximab soravtansine in combination with bevacizumab vs bevacizumab alone **Brief Eligibility: Inclusion** • high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer • Confirmation of high FRα expression • relapsed after 1 line (first line) of platinum-based chemotherapy & must be platinum-sensitive • Must have received no less than 4 & no greater than 8 cycles of platinum-based triplet therapy in the second line, to include no less than 3 cycles of bevacizumab in combination with platinum-based chemotherapy **Exclusion:** • Endometrioid, clear cell, mucinous, or sarcomatous histology or mixed tumors containing any of the above histologies • more than one line of prior chemotherapy before current/planned triplet therapy **LCCC1818-ATL:** A Phase 1 Study of Autologous Activated T-cells Targeting the B7-H3 Antigen in Subjects with Recurrent Epithelial Ovarian Cancer **(Dr. Van Le / Catherine Cheng SC)** **LCCC 2152- Phase 1 Ovarian High Grade Serous Carcinoma Car-T trial for platinum resistant patients, opened yesterday (Dr. Van Le/ Hannah Ratzlaff)** **NOT OPEN YET:** **IMGN-151-1001: (Van Le, Lorraine Balletta)** A Phase 1, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGN151 (anti-FR& antibody-drug conjugate) in Adult Patients with Recurrent Endometrial Cancer and Recurrent, High-Grade Serous Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers		**LCCC2036: (Bae-Jump/Lorraine Balletta):** **Phase 1 Clinical Trial of ONC201 and Atezolizumab in Obesity-Driven Endometrial Cancer.** **Brief Eligibilty:** • Histologically confirmed metastatic or recurrent EC Carcinosarcoma, endometrioid, serous, clear cell, adeno-squamous and mixed histologies. • Subjects must have measurable disease. • Must have radiographic disease progression after at least 1 line of systemic cytotoxic therapy for metastatic disease or with progression within 12 months of completing adjuvant chemotherapy. • Patients must have no prior treatment with ONC201 or CD137 agonists (including anti−CTLA-4) and anti−PD-L1 therapeutic antibodies. (prior Pembro IS ALLOWED) **NRG-GY028 : (Olivia Lara/Melissa Flores)** A Phase IB and Randomized Phase II trial of Megestrol Acetate with or without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer (Transferring from Phase I to GynOnc) **NOT OPEN YET:** **IMGN-151-1001: (Van Le, Lorraine Balletta)** A Phase 1, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGN151 (anti-FR& antibody-drug conjugate) in Adult Patients with Recurrent Endometrial Cancer and Recurrent, High-Grade Serous Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers

Pending			
Translational	**MASCOT:** Manufacturing and Analysis of Stem Cells for Ovarian Cancer Treatment **(VBJ/Luz) ON HOLD**		**LCCC2054**: Obesity, Frailty, and Age-Related Responses to Surgery and Treatment in Endometrial Cancer Patients **(Buckingham/Luz)** **SISTER**: The Social Interventions for Support during Treatment for Endometrial Cancer and Recurrence (SISTER) Study **(Bae-Jump /Luz)** **MICROBIOME:** Impact of the Uterine and Gut Microbiomes in Endometrial Cancer Development and Treatment (**Bae-Jump/Luz)**
Other Trials with a GYN arm	**TAPUR: (Phase I pod- Shetal Patel/Olivia Gorman)** Phase II non-randomized study prescribing targeted therapies to patients with advanced cancer whose solid tumor harbors a genomic variant known to be a drug target or to predict sensitivity to a drug. **(Shetal Patel PI/ Melissa Flores)** **NCI10486: (Phase 1 pod-Shetal Patel PI/ Melissa Flores)** Phase 2 Trial of the Combination of the BET inhibitor, ZEN003694 (ZEN-3694), and the PARP Inhibitor Talazoparib, in Patients with Molecularly-Selected Solid Tumors (ComBET) **NX-1607-101 (Phase I pod -Weiss / Melissa Flores)** A Phase 1a, Dose Escalation, Safety and Tolerability Study of NX-1607, a Casitas B-lineage lymphoma proto-oncogene (CBL-B) inhibitor, in Adults with Advanced Malignancies, with Phase 1b Expansion in Select Tumor Types **Mirati 849-001 (Phase I pod-Elizabeth Schwabe/Dr. Weiss):** Phase 1/2 of MRTX849 a KRAS G12C Mutation targeting agent for Advanced Solid Tumors **ACR-368-201:(GU Pod-Milowsky/Robert Morton)** Phase 1b/2 study to evaluate the efficacy and safety of ACR-368 as monotherapy or in combination with ultralow dose gemcitabine in participants with platinum-resistant ovarian carcinoma, endometrial adenocarcinoma, and urothelial carcinoma based on Acrivon's OncoSignature® test status**.** **1042-CLN01: (Phase I pod-Siddharth/Olivia Gorman)** Phase 1 First-in-Human Dose Escalation and Expansion Study to Assess Safety and Tolerability of Intravenous Administration of ICVB-1042 in Patients With Advanced Solid Tumors		