UCI Chao Family Comprehensive Cancer Center

Gyn/Onc Clinical Trials

Solid Tumors					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	TBD	UCI 21-189:A Multicenter, Open-Label, Phase II Basket Study of MK-7684A, a Coformation of Vibostolimab (MK-7684) with Pembrolizumab (MK-3475), With or Without Other Anticancer Therapies in Participants with Selected Solid Tumors	MK7684+MK3475+/- other anticancer therapies	awaiting eligibilty documents	PRMC APPROVED
Tewari	Nirali Patel	UCI 20-110: A Phase Ib/II Study of TAK-981 Plus Pembrolizumab to Evaluate the Safety, Tolerability, and Antitumor Activity of the Combination in Patients with Select Advanced or Metastatic Solid Tumors	TAK-981 + Pembrolizumab	• histologically documented advanced nonsquamous NSCLC for which prior standard first in line treatment containing an anti-PD-(1/L1) has failed, CPI naive cervical cancer, CPI-naive MSS-CRC patients, unresectable stage III or IV cutaneous melanoma, Sqaumous NSCLC, SCLC, HNSCC, or treatment naive MSI-H/dMMR CRC. • have at least one radiologically measurable lesion based on RECIST version 1.1. • have recovered to grade 1 or baseline from all toxicity associated with previous therapy or have the toxicity established as squela.	OPEN TO ACCRUAL
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**

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Gyn/Onc Clinical Trials

Ovarian Platinum-Resistant Recurrence					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Kenya Gomez	NRG-GY021: A Phase II Randomized Trial of Olaparib versus Olaparib plus Tremelimumab in Patients in Platinum-Sensitive Recurrent Ovarian Cancer	PARP inhibitor ± anti-CTLA-4 immunotherapy	• platinum-sensitive, recurrent high-grade serous or high-grade endometrioid ovarian, primary peritoneal, or fallopian tube cancer. Other histologies eligible if known germline/somatic BRCA1/2 deleterious mutation. • no clinical or radiographic evidence of disease recurrence for > 6 months (or 182 days) after last receipt of platinum-based therapy. • may have received ≤ 1 non-platinum-based line of therapy in the recurrent setting	SUSPENDED
Tseng	Nirali Patel	GOG-3048: A Phase 1b/2, First-in-Human, Dose Escalation and Expansion Study of XMT-1536 In Patients with Solid Tumors Likely to Express NaPi2b	Antibody Drug Conjugate	• Histological diagnosis of high grade serous ovarian cancer, which includes fallopian tube, or primary peritoneal cancer, that is metastatic or recurrent. • One to 3 prior lines of systemic therapy for ovarian cancer including at least 1 prior line of a platinum-containing regimen. Patients must have platinum-resistant disease, defined as completing 4 or more cycles of platinum-based therapy and progressing within 6 months of last platinum-based therapy. • Patients with 4 lines of prior systemic therapy regardless of platinum sensitivity status may be enrolled at the Investigator's discretion and upon written approval by the Sponsor Medical Monitor. • Maintenance therapy, e.g., a PARP-inhibitor or bevacizumab given after a platinumcontaining regimen, will not count as a separate line of therapy.	OPEN TO ACCRUAL

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Ovarian Platinum-Resistant Recurrence					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Nirali Patel	UCI 20-157: A Phase II Study to Evaluate the Safety and Efficacy of EP0057 in Combination with Olaparib in Advanced Ovarian Cancer Patients	Lyophilis cake + PARP inhibitor	**Cohort 1 patients (Phase 2A and 2B)** must be/have: - PARP inhibitor naïve - Received no more than 1 prior line of therapy which must be platinum-based chemotherapy - Either: Stable disease (SD) following treatment with first line platinum based chemotherapy OR Primary platinum resistant disease defined by progressive disease (PD) within ≥1 and ≤ 6 months after completion of first line platinum-based chemotherapy **Cohort 2 patients (Phase 2A and 2B)** must have: - Received at least 1 prior lines of treatment, 1 of which must be platinum-based chemotherapy - Received a PARP inhibitor in the maintenance setting as their most recent treatment following a confirmed response by RECIST1.1 (CR or PR) to the last regimen which must be a platinum-based chemotherapy, with maintenance of response by PARP inhibitor lasting ≥6 months, with subsequent confirmed disease progression whilst receiving PARP inhibitor maintenance treatment as defined by RECIST v1.1 criteria	PRMC APPROVED

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Cervical Recurrence/Metastatic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Nirali Patel	GOG-3024: A Phase 1b/II Open-label Trial of Tisotumab Vedotin Monotherapy and in Combination with other agents in subjects with recurrent or Stage IVB Cervical Cancer	Tisotumab Vedotin + Carboplatin + Pembrolizumab +/- Bevacizumab	Arm H must be/have: -Must have squamous, adenosquamous or adenocarcinonma of the cervix and must not have received prior systemic therapy for recurrent or stage IVB cervical cancer - Must have recovered from all AEs due to previous systemic therapies to grade 1 - Measurable disease per RECIST - No clinically relevant bilateral hydronephrosis which cannot be alleviated by uteral stents or percutaneous drainage - Prior anti-PD-1, anti-PD-L1, or anti-PD-L2 treatment	OPEN TO ACCRUAL

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Ovarian Platinum-Resistant Recurrence

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Gyn/Onc Clinical Trials

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Cappuccini	Kenya Gomez	GOG-3059: A Phase III, Randomized, Double-Blind, Adaptive, Placebo/Paclitaxel-Controlled Study of AVB-56-500 in Combination with Paclitaxel in Patients with Platinum-Resistant Recurrent Ovarian Cancer	Paclitaxel ± AVB-500	• Histologically confirmed and documented recurrent ovarian, fallopian tube, or peritoneal cancer. Only patients with high-grade serous adenocarcinoma histology are eligible. •Patietnts with primary platinum-refractory disease (defined as progression during or within 4 weeks after completion of the first platinum regimen) are not eligible. • ECOG of 0 to 1. • Platinum-resistant disease (defined as progression within ≤ 6 months from completion of most recent platinum-containing regimen and calculated from the date of the last administered dose of platinum therapy). •Must have received at least 1 but not more than 4 prior therapy regimens since ovarian cancer diagnosis.	OPEN TO ACCRUAL
Recurrent/Persistent Ovarian/Endometrial					

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PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Cappuccini	Kenya Gomez	NRG-GY014: A Phase II Study of Tazemetostat in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma	EZH2 inhibitor	• Recurrent or persistent ovarian endometrioid or clear cell carcinoma (primary ovarian tumor must be at least 50% endometrioid or clear cell) OR recurrent or persistent endometrioid endometrial adenocarcinoma (MMR status required for recurrent endometrial cancer) • 1-3 lines of prior lines of cytotoxic therapy	OPEN TO ACCRUAL
Endometrial Recurrent/Uterine Carcinoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Parajuli	TBD	UCI 20-60: A Phase Ia/Ib Study of LY3484356 Administered as Monotherapy and in Combination with Abemaciclib to Patients with ER+, HER2- Locally Advanced or Metastatic Breast Cancer and Other Select Non-Breast Cancers	Non-covalent oral SERD	• Locally advanced unrectable endometrial cancer • Up to 3 lines of treatment in advanced/metastatic setting and progression while on endocrine therapy	OPEN TO ACCRUAL
Tewari	Nirali Patel	NRG-GY018: A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in addition to Paclitaxel and Carboplatin for Measurable Stage III or IVa, Stage IVb or Recurrent Endometrial Cancer	Chemo ± anti-PD-1 immunotherapy	• Measurable stage III, measurable stage IVA, stage IVB (with or without measurable disease) or recurrent (with or without measurable disease) endometrial cancer. • MMR IHC testing • No prior chemo, anti-PD-1/anti-PD-L1, or anti-CTLA-4	OPEN TO ACCRUAL
Cervix Newly Diagnosed					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Rare Cancers					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Bota	Mehir Tharani	SWOG S1609: DART (Ipi + Nivo)- Choriocarcinoma, vulvar cancer, clear cell cervical cancer, small cell carcinoma of the ovary (hypercalcemic type), and PD-LI amplified tumors	Anti-CTL4 immunotherapy + Anti PD1 immunotherapy	• Histologically confirmed rare cancer, must be able to submit specimens • Must have progressed on at least one prior line • No prior malignancy w/some exceptions	OPEN TO ACCURAL
Bota	Manisha Dandekar	ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)	Precision Medicine	• Any solid tumor, lymphoma (cancer in the cells of the immune system), or myeloma (cancer in the bone or soft tissue) that has returned or gotten worse after standard systemic therapy (oral or intravenous) OR a type of cancer for which no standard treatm	OPEN TO ACCURAL

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