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	TBD	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.	PRMC APPROVED

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	Kenya Gomez	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

Gyn/Onc Clinical Trials

Ovarian Platinum-Resistant Recurrence					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tseng	Kenya Gomez	**ETCTN-10150**: A Randomized Phase II Study of Bevacizumab and Either Weekly Anetumab Ravtansine or Weekly Paclitaxel in Platinum-Resistant or Platinum Refractory Ovarian Cancer	Antibody Drug Conjugate or Chemo + Anti-VEGF	• Histologically or cytologically confirmed high grade serous or high grade endometroid ovarian, fallopian tube, primary peritoneal cancer. • Must have platinum resistant (platinum-free interval < 6 months) or platinum refractory disease as per GCIC criteria. • ECOG performance status ≤2. •Prior use of weekly paclitaxel or bevacizumab in the platinum resistant (disease progression within 6 months of platinum based chemotherapy)/refractory (disease progression during or following the 3 months of the first line platinum based chemotherapy) setting is EXCLUSIONARY.	OPEN TO ACCRUAL
Tewari	TBD	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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Gyn/Onc Clinical Trials

Ovarian Platinum-Resistant Recurrence					
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
Tewari	Kenya Gomez	GOG-3018: The OVAL Study: A Randomized, Controlled, Double-Arm, Double-Blind, Multi-Center Study of Ofranergene Obadenovec (VB-111) Combined with Paclitaxel vs. Paclitaxel Combined with Placebo for the Treatment of Recurrent Platinum-Resistant Ovarian Ca	Chemo ± Gene/Immunotherapy	• Platinum-resistant disease, defined as a CT confirmed progressive disease within 90 to 180 days from completion of a minimum of 4 platinum therapy cycles • Patients must have no evidence of rectosigmoid involvement by pelvic examination, bowel involvement on CT, or clinical symptoms of bowel obstruction	OPEN TO ACCRUAL

Gyn/Onc Clinical Trials

Recurrent/Persistent Ovarian/Endometrial					
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	SUSPENDED
Tewari	Kenya Gomez	UCI 20-111: A Phase 1A/B Study to Evaluate the Safety and Tolerability of ETC-1922159 as a Single Agent and in Combination with Pembrolizumab in Advanced Solid Tumours	PORCN inhibitor	• Has histologically or cytologically confirmed, advanced or metastatic, or unresectable solid malignancies at Screening, for whom no approved treatment option or standard of care is available (for Part B dose expansion segment only, refractory, intolerant or not suitable to available treatment at Screening according to the treating physician). • Has evaluable or measurable disease as determined by RECIST Version 1.1 • Groups 2b and 2c only (MSS-ovarian and MSS-endometrial cancer): Has advanced or metastatic disease for which further conventional therapy, e.g., platinum-based chemotherapy, is not suitable according to the treating physician. Has MSS tumour as determined by IHC, PCR or NGS.	OPEN TO ACCRUAL

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Gyn/Onc Clinical Trials

Endometrial Recurrent/Uterine Carcinoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	TBD	UCI 20-203: Phase II, Open Label, Single Arm, Efficacy and Safety Study of the WEE1 Inhibitor ZN-c3 as Second Line Oral Therapy in Adult Women with Recurrent or Persistent Uterine Serous Carcinoma	WEE1 inhibition	• Histologically or cytologically confirmed recurrent or persistent USC as confirmed at the local study site. Uterine carcinomas (except for carcinosarcomas which are excluded) that have any component that is considered serous will be considered eligible. • Measurable disease • Treatment with at least 1 prior platinum-based chemotherapy regimen for management of advanced or metastatic USC.	OPEN TO ACCRUAL
Tewari	Kenya Gomez	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

Gyn/Onc Clinical Trials

Cervix Recurrent and Metastatic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Kenya Gomez	UCI 20-88: A Phase 1b Study of ASP1951, a GITR Agonistic Antibody, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors	GITR Agonostic Antibody	• Subject has locally-advanced (unresectable) or metastatic solid tumor malignancy (no limit to the number of prior treatment regimens) that is confirmed by available pathology records or current biopsy as well as the following: • Subject in the escalation cohort has received all standard therapies (unless the therapy is contraindicated or intolerable) felt to provide clinical benefit in the opinion of the treating investigator for his/her specific tumor type. • Subject in an expansion cohort has received at least 1 standard therapy for his/her specific tumor type. • Subject has at least 1 measurable lesion per RECIST •Performance Status of 0, 1 or 2.	OPEN TO ACCRUAL
Uterine					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	TBD	UCI 20-203: Phase II, Open Label, Single Arm, Efficacy and Safety Study of the WEE1 Inhibitor ZN-c3 as Second Line Oral Therapy in Adult Women with Recurrent or Persistent Uterine Serous Carcinoma	WEE1 inhibition	• Histologically or cytologically confirmed recurrent or persistent USC as confirmed at the local study site. Uterine carcinomas (except for carcinosarcomas which are excluded) that have any component that is considered serous will be considered eligible. • Measurable disease • Treatment with at least 1 prior platinum-based chemotherapy regimen for management of advanced or metastatic USC.	OPEN TO ACCRUAL

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NonTreatment Trials					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
O'Brien	Mashal Chhotani	NCICOVID: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study	Data collection, blood collection and Imaging	• Tested positive for COVID-19 ≤ 14 days or will be tested. • Belongs to one of the following cohorts: - being treated for cancer ≤ 6 weeks - received allogenic stem cell transplant or CAR-T - being treated for Graft vs. Host - received autologus bone marrow transplant ≤ 2 years	OPEN TO ACCRUAL
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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