UCI Chao Family Comprehensive Cancer Center

Gyn/Onc Clinical Trials

Solid Tumors					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Nirali Patel	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	MK7684A + Pembrolizumab +/- other anticancer therapies	• Cohort A1: participants with cervical cancer whose tumor express PD-L1 (CPS ≥1) • Cohort A2: participants with cervical cancer whose tumor does not express PD-L1 (CPS ≥1) • Cohort B1: participants with endometrial cancer whose tumors are dMMR as determined by the central laboratory • Cohort B2: participants with endometrial cancer whose tumors are pMMR as determined by the central laboratory • Cohort I: Ovarian cancer • HIV-infected participants must have well controlled HIV on ART • Has an ECOG Performance Status of either 0 or 1, as assessed within 7 days before starting study intervention.	OPEN TO ACCRUAL

Gyn/Onc Clinical Trials

Solid Tumors					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tewari	Nirali Patel	UCI 22-77: Phase I First-in-Human Study to Explore the Safety, Tolerability and Pharmacokinetics of AMG 794 in Subjects with Claudin 6-Positive Advanced/Metastatic Non-Squamous Non-Small Cell Lung Cancer or Epithelial Ovarian Cancerand Other Malignant Solid Tumor Indications	AMG794 half-life extended (HLE) BiTE molecule targeting CLDN6	Inclusion: • Subjects with histologically or cytologically documented malignant solid tumor diseases expressing CLDN6 including but not limited to NSCLC, EOC, testicular germ cell cancer, uterine endometrial cancer, or triple negative breast cancer, that is metastatic or unresectable at screening time point. Subjects should have exhausted available SOC systemic therapy or should not be candidates for such available therapy. • For dose expansion cohorts: Subjects with at least 1 measurable lesion ≥ 10 mm which has not undergone biopsy within 3 months of screening scan. This lesion cannot be biopsied at any time during the study. Exclusion: • History of other malignancy within the past 2 years, with the following exceptions: - Malignancy treated with curative intent and with no known active disease present for ≥ 2 years before enrollment and understood to be at low risk for recurrence by the treating physician. - Adequately treated cervical carcinoma in situ without evidence of disease. - Adequately treated breast ductal carcinoma in situ without evidence of disease.	ENROLLMENT HOLD

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Solid Tumors					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
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 (small molecule inhibitor of SUMOylation) + Pembrolizumab	• Have histologically or cytologically documented, advanced (metastatic and/or unresectable) cancer • CPI-naive cervical cancer (squamous cell carcinoma, adenosquamous or adenocarcinoma of cervix) patients for whom prior standard first line treatment has failed and who has received no more than 1 prior systemic line of therapy for recurrent or Stage IVB cervical cancer • Measurable disease per RECIST, (non-nodal lesions >10 mm and lymph nodes >15mm) • ECOG 0 to 1	Open to Accrual - COHORT B WAITLIST ONLY
Tewari	Nirali Patel	UCI 22-78: A Phase I Study of KSQ-4279 Alone and in Combination in Patients with Advanced Solid Tumors	KSQ-4279(small molecule inhibitor of USP1) +/- Olaparib or Carboplatin	• Deleterious mutation (germline or somatic) in at least 1 of the following genes involved in the HRR pathway • Histologically diagnosed recurrent or persistent high grade serous ovarian cancer (including primary peritoneal and/or fallopian tube cancer) • Received prior platinum-based chemotherapy – Note: Patients may have platinum-sensitive or resistant disease	Open to Accrual

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Tewari	Nirali Patel	UCI 22-42: Phase I/II, Open-label Dose Escalation and Dose Expansion Study of TransCon TLR7/8 Agonist, Alone or in Combination with Pembrolizumab in Participants with Locally Advanced or Metastatic Solid Tumor Malignancies	TransCon Toll like receptor (TLR) 7/8 agonist	• Participants must have histologically confirmed locally advanced, recurrent or metastatic solid tumor malignancies that cannot be treated with curative intent (surgery or radiotherapy). - Patients in neoadjuvant cohorts are exempt. • At least 2 lesions of measurable disease per RECIST 1.1, unless specified otherwise in the selection criteria – at least 1 lesion that is safely accessible for intratumoral injection and 1 lesion that is not injected (at least initially). • Lesion(s) to be injected must be measurable and greater than or equal to 15 mm in the longest diameter at initial selection.	Pending Activation

Gyn/Onc Clinical Trials

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Cervical Recurrence/Metastatic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Ovarian Platinum-Resistant Recurrence					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Ovarian Platinum-Sensitive Reccurence					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Tseng	Nirali Patel	GOG-3049: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Upifitamab Rilsodotin (XMT-1536) as Post-Platinum Maintenance Therapy for Participants with Recurrent, Platinum-Sensitive Ovarian Cancer (UP-NEXT)	XMT-1536 (Antibody Drug Conjugate)	Inclusion: • Participant must have a histological diagnosis of high grade serous ovarian cancer, which includes fallopian tube and primary peritoneal cancer, that is metastatic or recurrent. • Participant must have platinum-sensitive recurrent disease, defined as having achieved either a partial or complete response to 4 or more cycles in their penultimate platinum-containing regimen and their disease progressing more than 6 months after completion of the last dose of platinum containing therapy in the penultimate regimen. • Participant must have had 4 to 8 cycles of platinum-based chemotherapy in 2nd to 4th line setting in their most recent treatment regimen. Exclusion: • Participant has received prior treatment with mirvetuximab soravtansine or another ADC containing an auristatin or maytansinoid payload. • Participant has received bevacizumab in combination with last platinum-based regimen or plans to receive maintenance therapy outside the study intervention.	OPEN TO ACCRUAL
Recurrent/Persistent Ovarian/Endometrial					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Endometrial Recurrent/Uterine Carcinoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**

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Gyn/Onc Clinical Trials

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**
Vulvar					
Tewari	Nirali Patel	NRG-GY024: Gronigen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial	Cisplatin + Radiotherapy	Histological confirmed primary SCC of the vulva - T1 tumor, not encroaching urethra/vagina/anus - Depth of invasion > 1mm - Tumor diameter < 4cm - Unifocal tumor - No enlarged (>1.5cm) or suspicious inguinofemoral lymph nodes at imaging (CT/MRI/ultrasound) - Possibility to obtain informed consent - Metastatic sentinel lymph node; size of metastasis > 2mm and / or extracapsular extension, or - Metastatic sentinel lymph node: more than 1 SN with metastasis ≤ 2mm; ECOG 0,1,2	OPEN TO ACCURAL

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