

	Adjuvant Merkel Cell Carcinoma Trials						
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status		
Gao	Parvin Keshtmand	EA6174/A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) To Standard of Care Observation in Completely Resected Merkel Cell Carcinoma	Pembrolizumab: Anti PD-1 Immunotherapy versus SOC	 Inclusion: Must have a histological confirmation of diagnosis of Merkel cell carcinoma (MCC), pathologic stages (AJCC version 8) I-IIIb Primary tumor must have negative margins Must treat within 112 days of surgical resection RT is allowed if completed 28 days prior to systemic tx or begins within 14 days of systemic tx Exclusion: Patients with distant metastatic disease (stage IV) 	Open to Accrual Accrual: 7/8		
Gao	Parvin Keshtmand	UCI 18-84/A Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of Adjuvant Avelumab (anti-PDL-1 Antibody) in Merkel Cell Carcinoma Patients with Clinically Detected Lymph Node Metastases [Orange]	PD-L1 Inhibitor	Inclusion: Histologically confirmed MCC metastases in clinically detected lymph node(s) Must have completed definitive treatment that included surgical removal of the clinically detected MCC metastases (with/without adjuvant radiation therapy as determined by the treating investigator). Must start the study treatment no more than 60 days from the last dose of RT (if administered) and no more than 120 days from the date of surgical removal of nodal metastases. Exclusion: Clinical or radiologic suspicion of residual MCC at the time of enrollment. Suspicion or known history of distant metastatic MCC, which is not classifiable as local recurrence or regional metastasis. Any prior systemic therapy (e.g. adjuvant, neo-adjuvant or concurrent use of chemotherapy, immunotherapy or an investigational agent) for MCC at any time Any prior intra-lesional MCC therapy within 180 days from Day 1 of study treatment	Accrual:6/7		



			Merkel Cell Carcinoma	Trials	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Yamamoto	Parvin Keshtmand	ETCTN 10057/ A Phase II Study of Talimogene Laherparepvec Followed by Talimogene Laherparepvec + Nivolumab in Refractory T Cell and NK Cell Lymphomas, Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma, and Other Rare Skin Tumors *Only enrolling to phase II (MCC)*	Tvec: replication in tumor tissue; normal cells are able to protect against talimogene laherparepvec infection as they contain intact antiviral defense mechanisms. Deletion of ICP47 prevents down-regulation of antigen presentation molecules and increases the expression of HSV US11 gene, which enhances viral replication in tumor cells. GM-CSF recruits and activates antigen presenting cells which can process and present tumor-derived antigens to promote an effector T-cell response.	Inclusion: • PD while on or within 6 months of completing prior PD1/ PD-L1 therapy • at least 1 cutaneous, subcutaneous, or nodal lesion that is suitable for intralesional injection, with or without the use of ultrasound • able and willing to undergo serial biopsies of injected lesion Exclusion: • Untreated central nervous system (CNS) involvement • Previous treatment with talimogene laherparepvec or other herpes virus based therapy	Open to Accrual Accrual: 1/3 Slot reservation required



		So	quamous Cell Carcinom	a Trials	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Fruehauf	Parvin Keshtmand	UCI 20-116/ A Randomized, Controlled, Open-Label, Phase II Study of Cemiplimab as a single agent and in Combination with RP1 in Patients with Advanced Cutaneous Squamous Cell Carcinoma	•RP1 (rHSV-1hGM-CSF/gibbon ape leukemia virus fusogenic glycoprotein	Exclusion:	Open to accrual Accrual: 0/5
Dayyani	Jasmine Balangue x509-2948	UCI 20-213/ Phase 1 First-in-Human (FIH) Study of Leukocyte Immunoglobulin-Like Receptor B2 (LILRB2) Inhibitor Monoclonal Antibody (mAb) JTX-8064, as Monotherapy and in Combination with a Programmed Cell Death Receptor-1 (PD-1) Inhibitor, in Adult Subjects with Advanced Refractory Solid Tumor Malignancies	JTX-8064 is a humanized mAb, consisting of 2 identical hingestabilized gamma 4 (IgG4, with the S228P mutation) heavy chains and 2 identical kappa (IgK) light chains, that specifically binds to human LILRB2 and is designed to block the interaction of LILRB2 with its known ligands, endogenous MHC I molecules and non-classical MHC I molecules. JTX-4014 is a fully human mAb consisting of 2 identical hingestabilized gamma 4 (IgG4, S228P) heavy chains and 2 identical kappa (IgK) light chains that specifically binds to and inhibits PD-1.	Skin cohort: 2L/3L cSCC; Subjects must have progressed on or after treatment with an anti-PD-(L)1 agent in their most recent prior line of therapy	Open to Accrual Accrual: 2/10



		Cutaneous Melanon	ma: Metastatic Unrese	ctable Previously Treated	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Moyers	Parvin Keshtmand	ETCTN 9466/ Phase I/II Study of Dabrafenib, Trametinib, and Navitoclax in BRAF Mutant Melanoma (Phase I and II) and Other Solid Tumors (Phase I Only) * Our site is only enrolling to phase II*		effective • Pts can also be tx naive	Accrual: 1/3
Fruehauf	Parvin Keshtmand	UCI 20-169/ A Phase IB, Open-Label, Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Activity of Belvarafenib as a Single Agent and in Combination with Either Cobimetinib or Cobimetinib Plus Atezolizumab in Patients with NRAS-Mutant Advanced Melanoma Who Have Received Anti-PD-1/PD-L1 Therapy		Inclusion: • Metastatic or unresectable stage III, previously treated w up to 2 lines of systemic therapy that included anti-PD-1 or anti-PD-L1 therapy (previous tx in adjuvant setting is also permitted) • NRAS mutation positive Exclusion: • HIV, HCV, HBV • Prior allogeneic stem cell or solid organ transplantation • Untreated or actively progressing CNS lesions	Open to Accrual Accrual: 0/5
Valerin	Parvin Keshtmand	UCI 20-174/ PVSRIPO with and without Immune Checkpoint Blockade in Advanced PD-1 Refractory Melanoma	PVSRIPO is a recombinant rhinovirus/polio virus chimera that may affect anti-tumor activity through two mechanisms: direct tumor cell killing and induction of a secondary anti-tumor immune response	Inclusion: • ≥ 2 measurable lesions (one of which must be injectable: visible or palpable cutaneous, subcutaneous or nodal melanoma lesion) • PD after ≥ 6w of tx w/ anti-PD-1/anti-PD-L1 therapy (including adjuvant tx) or BRAF-targeted therapy (if BRAF+) Exclusion: • Ocular melanoma is excluded • Symptomatic, untreated, or actively progressing CNS metastases	Open to Accrual Accrual: 0/5



		Cutaneous Melanor	ma: Metastatic Unrese	ctable Previously Treated	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Valerin	Parvin Keshtmand	UCI 21-40/ A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications	DF6002 is a monovalent human interleukin-12 (IL12)-constant fragment (Fc) fusion protein that binds to the IL12 receptor to stimulate interferon gamma (IFN22 secretion, proliferation of lymphocytes, and cytotoxicity of activated T cells and natural killer cells	Inclusion: Previously tx melanoma, NSCLC, small cell lung, head and neck squamous cell, urothelial, gastric, esophageal, cervical, hepatocellular, Merkel cell, cutaneous squamous cell carcinoma, renal cell, endometrial, triple negative breast cancer (TNBC), ovarian, and prostate cancers Exclusion: Prior treatment with rhIL2 or with any drug containing an IL2 or IL12 moiety •	Open to Accrual: 1/3 Slot request required prior to consenting
Chow	TBD	UCI 21-208/ AN OPEN-LABEL, MULTICENTER, PHASE I STUDY OF IGM-8444 AS A SINGLE AGENT AND IN COMBINATION IN SUBJECTS WITH RELAPSED AND/OR REFRACTORY SOLID CANCERS		Inclusion: -Patients who are either refractory to or intolerant of existing standard therapy or forwhom no effective further standard of care therapy exists -No more than three prior therapeutic regimens ("therapeutic" is defined as any cytotoxic, biologic, or targeted therapy [approved or investigational] with intent to treat the cancer) administered for the treatment of cancer in the advanced/metastatic setting Exclusion: - See protocol for cohort specific details	New
Ou	Celest Carrillo	UCI 21-38:An Open Label, First in Human (FIH), Phase I Trial of LVGN6051 as Single Agent and in Combination with Keytruda (Pembrolizumab) in Advanced or Metastatic Malignancy.	LVGN6051 is a humanized recombinant IgG1k that binds to CD137.	Inclusion: - Patients in the Phase 1b portion of the trial must have a histologically or cytologically confirmed melanoma, NSCLC, GI malignancy, or lymphoma that is metastatic or unresectable. GI malignancies may include colorectal, biliary tract, gastric/GE junction, pancreatic, small intestine, or esophageal cancers. One prior therapy for unresectable/metastatic disease, other than patients with melanoma who will receive LVGN6051 with the approved dose of pembrolizumab, is required. For patients with melanoma, this will have included either ipilimumab/nivolumab, an anti-PD-1 antibody, or agents targeting BRAF V600-activating mutations. No prior therapy for unresectable/metastatic disease is required in patients with melanoma who are assigned to LVGN6051 + pembrolizumab. Exclusion: - Prior exposure to immune-therapeutics with experience of ≥ Grade 3 drug-related toxicity or a toxicity requiring drug discontinuation. -Known active CNS metastasis and/or carcinomatous meningitis. Exception: Patients with previously treated brain metastases may be eligible for participation provided they are stable, have no evidence of new or enlarging brain metastases or cerebral edema, and are not using steroids for treatment of brain metastases at least 7 days before start of study treatment.	
Fruehauf	Parvin Keshtmand	UCI 18-64/An Open-Label, Multicenter, Phase I/II Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors	RP1 is a selectively replication competent HSV-1 Nivolumab	Inclusion: • Diagnosis of Stage IIIb-IV melanoma (ocular and mucosal allowed but no more than 10 patients each) Exclusion: • Prior treatment with an oncolytic therapy	Open to Acrrual Accrual: 0/5



		Resectable Melanom	a - Neoadjuvant + Surg	ery + Adjuvant Treatment	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Moyers	TBD	UCI 21-226/ An Open-Label, Randomized, Controlled Multi-Center Study of The Efficacy of Daromun (L19IL2 + L19TNF) Neoadjuvant Intratumoral Treatment Followed by Surgery and Adjuvant Therapy Versus Surgery and Adjuvant Therapy in Clinical Stage IIIB/C Melanoma Patients	L19IL2 and L19TNF are clinical- stage immunocytokines,	Inclusion: -Diagnosis of clinical stage IIIB and IIIC (AJCC v7) metastatic melanoma, eligible for complete surgical resection of all metastases -Measurable disease and must be candidate for intralesional therapy with at least one injectable cutaneous, subcutaneous, or nodal melanoma lesion (≥ 10 mm in longest diameter) or with multiple injectable lesions that in aggregate have a longest diameter of ≥ 10 mm. Exclusion: -Uveal melanoma or mucosal melanoma -Previous or concurrent cancer that is distinct in primary site or histology from the cancer being evaluated in this study except: cervical carcinoma in situ, treated basal cell carcinoma, superficial bladder tumors (Ta, Tis & T1), second primary melanoma in situ or any cancer curatively treated ≥ 5 years prior to study entry	New
Moyers	Parvin Keshtmand	S1801/A Phase II Randomized Study of Adjuvant Versus Neoadjuvant MK-3475 (Pembrolizumab) For Clinically Detectable Stage III-IV High Risk Melanoma	anti-PD-1	 Inclusion: must have resectable melanoma must have clinically detectable Stage III (clinically detectable N1b, N1c, N2b, N2c, N3b and N3c) or Stage IV resectable melanoma 	Open to Accrual Accrual: 3/4
		Cutaneous Melanoma	: Metastatic Unresecta	ble Not Previously Treated	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Moyers	Parvin Keshtmand	EA6141/ Randomized Phase II/III Study of Nivolumab Plus Ipilimumab Plus Sargramostim Versus Nivolumab Plus Ipilimumab in Patients With Unresectable Stage III or Stage IV Melanoma	blockade of the inhibitory effect of T-cell activation. Nivo: Inhibits the binding of PD-1 to	 Must have a known BRAF mutational status (WT or mutated) Exclusion: Prior tx w/ PD1 or PD-L1 in the adjuvant or metastatic setting Prior tx w/ ipilimumab in the metastatic setting 	Open to Accrual Accrual: 1/2



	Cutaneous Melanoma: Metastatic Unresectable Not Previously Treated							
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status			
Fruehauf	Parvin Keshtmand	Safety of UV1 Vaccination in Combination with Nivolumab and Ipilimumab as First-line Treatment of Patients with Unresectable or Metastatic Melanoma (UV1-202)	UV1 is a therapeutic cancer vaccine consisting of 3 synthetically-produced peptides covering an epitope rich sequence within the active site of the human telomerase reverse transcriptase (hTERT). The mode of action of UV1 is to activate the immune system to induce T cells that recognize hTERT. The efficacy of the vaccine is thought to be mediated through these T cells.	Inclusion: - Histologically confirmed diagnosis of unresectable stage IIIB-D or unresectable stage IV malignant melanoma. Patient must have at least 1 measurable lesion at Screening according to the RECIST 1.1 criteria. - ECOG ps of 0 or 1 - Eligible for combination treatment with nivolumab and ipilimumab Exclusion: - Known brain metastases or leptomeningeal metastases. - Uveal or ocular melanoma - History of New York Heart Association class 3-4 congestive heart failure or history of MI within 6 months of starting study treatment - Known history of human immunodeficiency virus (HIV) (HIV 1/2 antibodies) - History of or active hepatitis B (hepatitis B surface antigen reactive) or active hepatitis C (hepatitis C virus antibody) - Prior systemic treatment for unresectable stage IIIB-D or unresectable stage IV malignant melanoma. Prior systemic BRAF/MEK inhibitors or immunotherapy as neoadjuvant or adjuvant or other setting treatment of stage I-IIIA, resectable IIIB-D, or resectable IV if patient progressed earlier than 6 months after last dose of such treatment				



			Adjuvant Melanor	na	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Fruehauf	Baoan Huynh	UCI 20-57/ A Phase III, Randomized, Open-Label Study of Adjuvant Immunotherapy with Bempegaldesleukin Combined with Nivolumab versus Nivolumab after Complete Resection of Melanoma in Participants at High Risk for Recurrence (PIVOT-12)	prodrug of a conjugated cancer immunotherapy cytokine that exerts its biological activity by binding to the IL-2 receptor and subsequent activation of effector T cells.	Inclusion: • Stage IIIA (LN metastasis > 1 mm [i.e., at least one LN metastasis measuring > 1 mm at greatest diameter]), IIIB/C/D, or IV (M1a/b/c/d) cutaneous melanoma by AJCC (8th edition) at study entry that has been completely surgically resected within 12 weeks prior to randomization. • Have PD-L1 expression classification (≥ 1%, < 1%, indeterminate, or not evaluable) prior to randomization (by central lab review). • Documented left ventricular ejection fraction (LVEF) > 45% Exclusion: • History of ocular/uveal melanoma or mucosal melanoma • Prior tx w/ interferon, talimogene laherparepvec (Imylgic®), IL-2 directed therapy, anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody (including ipilimumab or any other antibody or drug specifically targeting T cell co stimulation or checkpoint pathways). • Need for > 2 antihypertensive medications for management of hypertension (including diuretics). • HCV, HBV, HIV positive • History of leptomeningeal disease	Suspended by sponsor Accrual: 8/12
		Miscel	laneous & Phase 1 Cl	inical Trials	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Ou	Keagan Buttigieg x456-7429	UCI 19-64/ A Phase I/II Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors	kinase Akt, inhibits HER2:HER3 dimerization, shows ADCC activity independent of FcyR receptor phenotype, and lacks CDC activity.		Open to Accrual Accrual: 4/7



		Skin Ca	ncers: Epidemiologic	:/Correlative	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Meyskens	Meyskens	UCI 09-17/Biology of Human Melanocytes and Keratinocytes [UCIMC]	N/A	Male babies Foreskin available	Open to Accrual Accrual: 700/800
Yamamoto	Jennifer Chen	UCI 15-40/Prospective and Retrospective Study of Outcomes for Patients with Malignant Melanoma [UCIMC]	N/A	 Suspected or biopsy proven cutaneous melanoma Exclusion: Patients whose final pathologic diagnosis does not reveal melanoma 	Open to Accrual Accrual: 383/5000
		Skin	Cancers: Screening/[Diagnostic	
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Kelly	Ata Sharif	UCI 11-30/Skin Imaging with Technologies in Development [Irvine]	N/A	 Inclusion: Age > 7 Pt able to carry out study instructions 	Open to Accrual Accrual: 551/750
Kelly	Ata Sharif & Mihaela Balu	UCI 13-13/Pilot study on in-vivo non-invasive skin imaging using multiphoton microscopy and multispectral imaging [Irvine]	N/A	 Inclusion: Age > 45 Female Skin type scale I to III Exclusion: History of skin cancer, including squamous or basal cell carcinoma at the treatment site or history of malignant melanoma Large amount of dark, coarse hair on the arms 	Open to Accrual Accrual: 201/250
Yamamoto	Erin Torrison	UCI 19-135/DecisionDx-Melanoma Impact on Sentinel Lymph Node Biopsy Decisions and Clinical Outcomes (DECIDE) [UCIMC and Irvine]	Patients who have newly diagnosed invasive cutaneous melanoma, are being considered for sentinel lymph node biopsy, and are undergoing DecisionDx-Melanoma GEP testing to inform this decision.	Inclusion: Invasive cutaneous melanoma diagnosed within past 2 months Being tested with the DecisionDx-Melanoma 31-GEP test as part of their clinical care Pts being considered for sentinel lymph node biopsy Exclusion: Stage III or IV disease Exclusion: Patients with a melanoma diagnosed in the same anatomical region in the last 5 years	Open to Accrual Accrual: 27/40



	Skin Cancers: Screening/Diagnostic							
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status			
Linden	Erin Torrison	UCI 14-05/ (mAID) Multicenter Diagnostic Imaging Study for the Melanoma Advanced Imaging Dermatoscope [UCIMC and Irvine]	The Melanoma Advanced Imaging Dermatoscope (mAID) manufactured RGB hyperspectral imaging of the lesion in 21 different colors	 Inclusion: Age > 18 Normal appearing skin and a suspicious pigmented lesion Exclusion: Self-reported history of photosensitivity Self-reported history of vitiligo and/or other sun sensitive disease Inaccessibility to lesion related to device: ears, toes, fingers, nailbeds, ankles, 	Suspended Accrual: 106/120			
Yamamoto	TBD	UCI 21-106/ A Phase II Open-Label, Dose-Finding Study to Determine the Optimal Dose for Lymph Node Visualization Using ASP5354 in Participants with Breast Cancer or Melanoma Undergoing Sentinel Lymph Node Biopsy		elbows. Inclusion:	IRB initial approval Accrual: 0/20			
			Other					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status			
Jakowatz	Erin Torrison	UCI 21-35/Outcomes of Cutaneous Melanoma Patients Clinically Tested DecisionDx - Melanoma (CONNECTION)		 Inclusion: Patients clinically tested with DecisionDx®-Melanoma between January 1, 2013 and December 31, 2017 Exclusion: • 	Open to Accrual Accrual: 1/56			