# Skin Cancers: Epidemiologic/Correlative

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| Liu-Smith           | Liu-Smith       | UCI 18-05/Molecular epidemiology on gender difference in melanoma risk [UCIMC, Irvine and Newport] | N/A                | • Age > 18  
• Diagnosed with Melanoma under the age of 50              | Suspended        |
| Meyskens            | Meyskens        | UCI 09-17/Biology of Human Melanocytes and Keratinocytes [UCIMC]                  | N/A                | • Male babies  
• Foreskin available                                       | Open to Accrual  |
| Nelson              | Chang           | UCI 14-25/Plasma Exosome Concentration in Cancer Patients Undergoing Treatment [UCIMC and Newport] | Tracking the amount of circulating exosomes associated with tumor response to treatment or recurrence | • Age > 21  
• Histologically proven diagnosis of cancer.  
• Measurable tumor burden.  
• Exclusion: More than one malignant diagnosis, except for the basal cell epithelium of the skin | Open to Accrual  |
| Nelson              | Shim            |                                                                                   |                    |                                                             |                 |
| Nelson              | Chris           | UCI 16-01/Pathway Analyses for Individualized Network Therapeutics for Cancer [UCIMC] | Determine which biological pathways are turned on and turned off in tumor tissue | • Histologically proven diagnosis of cancer  
• Have available formalin fixed paraffin embedded tumor sample  
• Age > 21 | Open to Accrual  |
| Nelson              | Haymond         |                                                                                   |                    |                                                             |                 |
| Yamamoto            | Dorothy         | UCI 15-40/Prospective and Retrospective Study of Outcomes for Patients with Malignant Melanoma [UCIMC] | Collection of patient’s medical information to help researchers better understand the treatment and outcomes of melanoma patients | • Suspected or biopsy proven cutaneous melanoma  
• Exclusion: Patients whose final pathologic diagnosis does not reveal melanoma | Open to Accrual  |
| Yamamoto            | Chang           |                                                                                   |                    |                                                             |                 |

# Skin Cancers: Screening/Diagnostic

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| Kelly               | Ata Sharif      | UCI 11-30/Skin Imaging with Technologies in Development [Irvine]                  | N/A                | • Age > 7  
• Pt able to carry out study instructions                   | Open to Accrual  |
| Kelly               | & Mihaela Balu  | UCI 13-13/Pilot study on in-vivo non-invasive skin imaging using multiphoton microscopy and multispectral imaging [Irvine] | N/A                | • 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  
• Exclusion: Large amount of dark, coarse hair on the arms | Open to Accrual  |
| Kelly               | Dorothy         | 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 | • Age > 18  
• Normal appearing skin and a suspicious pigmented lesion  
• Exclusion: Self-reported history of photosensitivity  
• Exclusion: Self-reported history of vitiligo and/or other sun sensitive disease  
• Exclusion: Inaccessibility to lesion related to device: ears, toes, fingers, nailbeds, ankles, elbows, genitals | Open to Accrual  |

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| Linden/Kelly        | Dorothy        | 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 | • Age > 18  
• Normal appearing skin and a suspicious pigmented lesion  
• Exclusion: Self-reported history of photosensitivity  
• Exclusion: Self-reported history of vitiligo and/or other sun sensitive disease  
• Exclusion: Inaccessibility to lesion related to device: ears, toes, fingers, nailbeds, ankles, elbows, genitals | Open to Accrual  |

Chloe Thomas x456-6210    Dorothy Chang x509-2199
Cody Slicker x509-2710    Chang Shim x456-7242
Parvin Keshtmand x509-2739
September 2019
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| Fruehauf      | Chloe      | UCI 17-73/A Sequential 2-arm, Open-label Phase I Study to Evaluate the Effects of Encorafenib in Combination with Binimetinib on the Pharmacokinetics of Losartan, Midazolam, Caffeine, Omeprazole, and Dextromethorphan Administered in a Cocktail Approach an | Encorafenib BRAF kinase inhibitor and Binimetinib-MEK 1 and MEK 2 inhibitor | • Age > 18  
• Histologically confirmed diagnosis of locally advanced, unresectable or metastatic cutaneous melanoma or unknown primary melanoma American Joint Committee on Cancer (AJCC) Stage III, IIC or IV, or other BRAF V600 mutant advanced solid tumors  
• Presence of BRAF V600E and/or V600K mutation in tumor tissue  
• Evidence of measurable or non-measurable lesions (RECIST)  
• No prior treatment or progressed on or after other prior systemic therapy  
• Patient with other (non-melanoma) BRAF V600-mutant advanced solid tumors who has progressed on standard therapy or for whom there are no available standard therapies  
• Exclusion: Symptomatic brain metastasis. | Open to Accrual |
| Fruehauf      | TBD        | UCI 19-15/ A Phase II, Open-Label, Multicenter Trial of Encorafenib + Binimetinib Evaluating a Standard-dose and a High-dose Regimen in Patients with BRAFV600-Mutant Melanoma Brain Metastasis | Encorafenib BRAF kinase inhibitor and Binimetinib-MEK 1 and MEK 2 inhibitor | • Histologically confirmed diagnosis of melanoma  
• Presence of BRAF V600E mutation in tumor tissue determined by a local assay at any time prior to screening of by a central laboratory during screening  
• Metastatic disease to the brain with at least 1 parenchymal brain lesion greater than or equal to 0.5cm and less than or equal to 4 cm  
• Patients may have received no more than 1 prior line of checkpoint inhibitor therapy  
• Must not have had prior local treatment for brain metastasis, including whole brain radiation therapy, stereotactic radiosurgery or craniotomy | Pending |
| Fruehauf      | An         | UCI 18-109/ Establishing the 6-Month Total Cost-of-Care for the Treatment of First-Line Metastatic BRAF (+) Melanoma with Combination BRAF & MEK Inhibitors | BRAF inhibitor + MEK inhibitor or BRAF inhibitor + MEK1 inhibitor compared to BRAF kinase inhibitor + MEK inhibitor | • Age > 18  
• Stage IV BRAF V600 E/K Melanoma  
• First-line therapy | Open to Accrual |

**Cutaneous Melanoma: Metastatic Unresectable Previously Treated**

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| Ejadi         | Parvin     | S1616: A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipiilumab (NSC732442) of Ipiilumab alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent | Nivolumab (anti-PD1) and anti-PD-L1 monoclonal antibody and anti-PD-1 | • pathologically confirmed melanoma that is either Stage IV or unresectable Stage III  
• must have had prior treatment with anti-PD1 or anti-PD-L1 agents and had documented disease progression  
• must have had prior treatment with anti-PD1 or anti-PD-L1 agents and had documented disease progression  
• must not have achieved a partial or complete response to the anti-PD1 or anti-PD-L1 agents prior to progression  
• must not have had prior treatment with ipilimumab or other CTLA-4 antagonists | Open to Accrual |
| Ejadi         | Parvin     | S1801: A Phase II Randomized Study of Adjuvant Versus Neoadjuvant MK-3475 (Pembrolizumab) For Clinically Detectable Stage III-IV High Risk Melanoma | Pembrolizumab (anti-PD-1) | • must have resectable melanoma  
• have clinically detectable Stage III [clinically detectable N1b, N1c, N2b, N2c, N3b and N3c] or Stage IV resectable melanoma | Open to Accrual |
### Skin

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| Pinter-Brown| Cody Slicker | UCI 16-46/A Phase I dose-ranging study to investigate the safety, tolerability and pharmacokinetics of MRG-106 following local intratumoral, subcutaneous, and intravenous administration in subjects with various lymphomas and leukemias [UCIMC] | An oligonucleotide inhibitor of microRNA miR-155-5p | • Intolerant, R/R, biopsy-proven DLBCL, including transformed disease  
• Previously treated with at least two prior therapies for DLBCL including with any anti-CD20 monoclonal antibody and chemotherapy with curative intent  
• Ineligible for hematopoietic stem cell transplant, OR have failed transplant and must be at least 4 months post-transplant | Open to Accrual |
| Ejadi        | Chloe Thomas | UCI 18-84/A Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of Adjuvant Avelumab (anti-PD-L1 Antibody) in Merkel Cell Carcinoma Patients with Clinically Detected Lymph Node Metastases [Orange] | PD-L1 Inhibitor | • Age ≥ 18 years  
• 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).  
• Estimated life expectancy greater than 3 years.  
• 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.  
• Exclusion: Suspicion or known history of distant metastatic MCC, which is not classifiable as local recurrence or regional metastasis.  
• Exclusion: Any prior systemic therapy (e.g. adjuvant, neo-adjuvant or concurrent use of chemotherapy, immunotherapy or an investigational agent) for MCC at any time  
• Exclusion: Any prior intra-lesional MCC therapy within 180 days from Day 1 of study treatment  
• Exclusion: Previous malignant disease (other than Merkel cell carcinoma) diagnosed within 3 years from Day 1 of study treatment that could interfere with study endpoints or put patient safety at risk. | Open to Accrual |
| Gao          | Chloe Thomas | 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 | • 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  
• Patients with all macroscopic Merkel cell carcinoma (either identified by physical exam or imaging) have been completely resected by surgery within 8 weeks before registration. | Open to Accrual |

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### Miscellaneous & Phase 1 Clinical Trials

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| Abi-Jaoudeh  | TBD       | UCI 18-100/Radiation-Emitting SIR-Spheres in Non-Resectable (RESiN) Liver Tumor Patient Study [UCIMC] | N/A       | • Age ≥ 18  
• Patients receiving SIR-Spheres therapy to the liver for the first time.  
• Provision of written informed consent.  
• Exclusion: Prior completion of Y90 therapy to the liver (SIR-Spheres, TheraSpheres, or any other liver-targeted therapy involving the use of radiation-emitting spheres). | Pending      |
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<th>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</th>
<th>MCLA-128 inhibits phosphorylation of HER3 and the downstream serine/threonine kinase Akt, inhibits HER2:HER3 dimerization, shows ADCC activity independent of FcR receptor phenotype, and lacks CDC activity.</th>
<th>At least one measurable lesion • Able to provide baseline mandatory tumor biopsy • Must have received prior standard therapy appropriate for their tumor type and stage of disease, or would be unlikely to tolerate or derive clinically meaningful benefit from appropriate SOC therapy • Locally-advanced unresectable or metastatic solid tumor malignancy with documented NRG1 gene fusion, identified through molecular assays</th>
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<td>UCI 19-74: A Phase I Open-Label, Multicenter, Dose-Escalation Study of PRN1371, a FGFR1-4 Kinase Inhibitor, in Adult Patients with Advanced Solid Tumors, followed by an Expansion Cohort in Patients with FGFR1,2,3 or 4 Genetic Alterations</td>
<td>Pending</td>
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