### Skin

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<th>Protocol #/Title</th>
<th>Mechanism</th>
<th>Primary In/Ex Criteria</th>
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</thead>
<tbody>
<tr>
<td>Pinter-Brown</td>
<td>Cody Slicker</td>
<td>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)</td>
<td>An oligonucleotide inhibitor of microRNA miR-155-5p</td>
<td>• Intolerant, R/R, biopsy-proven DLBCL, including transformed disease</td>
<td>Suspended</td>
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<td>• Previously treated with at least two prior therapies for DLBCL including with any anti-CD20 monoclonal antibody and chemotherapy with curative intent</td>
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<td>• Ineligible for hematopoietic stem cell transplant, OR have failed transplant and must be at least 4 months post-transplant</td>
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<td>• Stage 1</td>
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<tr>
<td>Merkel</td>
<td>Gao Paveen Keshtmand</td>
<td>EA6174/A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) To Standard of Care Observation in Completely Resected Merkel Cell Carcinoma</td>
<td>Pembrolizumab: Anti PD-1 Immunotherapy versus SOC</td>
<td>• Must have a histological confirmation of diagnosis of Merkel cell carcinoma (MCC), pathologic stages (AJCC version 8) I-IIIb</td>
<td>Open to Accrual</td>
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<td>• Primary tumor must have negative margins</td>
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<td>• Must treat within 116 days of surgical resection</td>
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<td>• Patients with distant metastatic disease (stage IV)</td>
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<td>• RT is allowed if completed 28 days prior to systemic tx or begins within 14 days of systemic tx</td>
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<td>Gao TBD</td>
<td>UCI 19-91/A Phase Ib/Ii Study of AST-008 Combined with Pembrolizumab in Patients with Advanced Solid Tumors</td>
<td>INC: advanced inoperable histologically diagnosed solid tumor; At least one tumor lesion amenable to repeated IT injection via palpation or ultrasound; EXC: Previous severe hypersensitivity reaction to treatment with pembrolizumab or another anti-PD(L)1 monoclonal antibody; Known hypersensitivity to any phosphorothioate oligonucleotide, or previous exposure to a TLR9 agonist drug</td>
<td>PRMC approved</td>
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Chloe Thomas x456-6210
Dorothy Chang x509-2199
Cody Slicker x509-2710
Chang Shim x456-7242
Parvin Keshtmand x509-2739
Kim Inocencio x456-8549
Julie Nguyen x456-5956

feb 2020
Ejadi 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

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

Ejadi 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

- 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

Ejadi Keshtmand

S1616: A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC732442) of Ipilimumab alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent

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
- Stage 3-4
- 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-PD-1 or anti-PD-L1 agents prior to progression
- must not have had prior treatment with ipilimumab or other CTLA-4 antagonists

Open to Accrual

Cutaneous Melanoma: Resectable

Cutaneous Melanoma: Metastatic Unresectable Previously Treated

Cutaneous Melanoma: Metastatic Unresectable Not Previously Treated

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feb 2020
Fruehauf
Chloe Thomas
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 and Encorafenib BRAF kinase inhibitor and Binimetinib-MEK 1 and MEK 2 inhibitor
- Age > 18
- Histologically confirmed diagnosis of locally advanced, resectable or metastatic cutaneous melanoma or unknown primary melanoma
- American Joint Committee on Cancer (AJCC) Stage IIIB, IIIC 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
Parvin Keshtmand
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 and Encorafenib BRAF kinase inhibitor and Binimetinib-MEK 1 and MEK 2 inhibitor
- Histologically confirmed diagnosis of melanoma
- Presence of BRAFV600 mutation in tumor tissue determined by a local assay at any time prior to screening or 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.

Open to Accrual

**Miscellaneous & Phase 1 Clinical Trials**

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<tr>
<td>Ejadi</td>
<td>Gandhar Katre</td>
<td>UCI 19-38: A Phase IA/II, Open-Label First-in-Human Study of the Safety, Tolerability, and Feasibility of Gene-Edited Autologous NeoTCR-T Cells (NeoTCR-P1) Administered as a Single Agent or in Combination with Anti-PD-1 to Patients with Locally Advanced or Metastatic Solid Tumors</td>
<td>NeoTCR-P1 and anti-PD-1</td>
<td>16-46</td>
<td>on hold</td>
</tr>
<tr>
<td>Abi-Jaoudeh</td>
<td>TBD</td>
<td>UCI 18-100/Radiation-Emitting SIR-Spheres in Non-Resectable (RESiN) Liver Tumor Patient Study [UCIMC]</td>
<td>N/A</td>
<td>Patients receiving SIR-Spheres therapy to the liver for the first time. 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).</td>
<td>Open to accrual</td>
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<tr>
<td>Ou</td>
<td>Kim Inocencio</td>
<td>UCI 19-64: A Phase (II) Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors</td>
<td>MCLA-128 inhibits phosphorylation of HER3 and the downstream serine/threonine kinase Akt, inhibits HER2/HER3 dimerization, shows ADCC activity independent of FcyR receptor phenotype, and lacks CDC activity.</td>
<td>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 Ex: Symptomatic or unstable brain mets leptomeningeal mets NYHA Class III or IV congestive heart failure or LVEF &lt;50% or history of significant cardiac disease, unstable angina, congestive heart failure, myocardial infarction, or ventricular arrhythmia requiring medication.</td>
<td>Open to Accrual</td>
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**Skin Cancers: Epidemiologic/Correlative**

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<td>Liu-Smith</td>
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<td>UCI 18-05/Molecular epidemiology on gender difference in melanoma risk [UCIMC, Irvine and Newport]</td>
<td>N/A</td>
<td>Age ≥ 18</td>
<td>Suspended</td>
</tr>
<tr>
<td>Meyskens</td>
<td>Meyskens</td>
<td>UCI 09-17/Biology of Human Melanocytes and Keratinocytes [UCIMC]</td>
<td>N/A</td>
<td>Male babies</td>
<td>Open to Accrual</td>
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| Nelson              | Chang Shim     | 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 epithelioma of the skin | Suspended    |
| Nelson              | Chris Raymond  | UCI 16-01/(PAINT) 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 |
| Yannamoto           | Dorothy Chang  | 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 |

### 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               | 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                                                                       | • 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 |
| Linden/Kelly        | Dorothy Chang  | 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: Inaccessibility to lesion related to device: ears, toes, fingers, nailbeds, ankles, elbows, genitals | Open to Accrual |