

| Trial Name                                    | Protocol # | PI                     | Study Team  | Enrolling sites   | Key Eligibility & Screening  | Treatment Arms   |
|---|------------|------------------------|---|---|--|--|
| <b>Neo-adjuvant/Adjuvant Trials</b>           |            |                        |   |   |  |  |
| Neo-adjuvant Pembro for Stage II Melanoma     | UPCC 09618 | Dr. Giorgos Karakousis | CRC: Faisha Salami<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles  | PCAM; MD Anderson; University of Louisville                             | clinical stage IIB/C resectable melanoma<br>uveal or mucosal melanoma not eligible<br>no other active malignancy except treated cutaneous SCC, BCC or carcinoma in situ<br>no active autoimmune disease requiring systemic treatment in prior 3 months   | 1 dose pembro + WLE/SLNBx + 1 yr pembro  |
| Neo-adjuvant Nivo for Stage III Melanoma      | UPCC 02619 | Dr. Tara Mitchell      | CRC: Shraya Divaker<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles | PCAM; Valley Forge; Lancaster General Health; Duke University           | clinical stage III resectable melanoma<br>uveal or mucosal melanoma not eligible<br>no other active malignancy except treated cutaneous SCC, BCC or carcinoma in situ<br>no active autoimmune disease requiring systemic treatment in prior 3 months<br>baseline research bx, if feasible<br>brain MRI at screening required   | 1 dose nivo + definitive Sx + randomized into arm after pathological response known<br>Arm A: if Path CR/nearCR, then 1 yr adjuvant nivo<br>Arm B: if <Path CR/near CR, then 1 yr adjuvant nivo<br>Arm C: if <Path CR/near CR, then 1 yr adjuvant ipi/nivo x 4 + nivo ≥ 1 yr |
| Neo-adjuvant Pembro for Merkel Cell Carcinoma | UPCC 01622 | Dr. John Miura         | CRC: Shraya Divaker<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles | PCAM  | clinical stage I-III MCC<br>Must have adequate tumor burden to yield 2-4 pre-operative research bx<br>ECOG PS 0 or 1<br>No active CNS metastases and/or carcinomatous meningitis; brain MRI required   | 1 dose of pembro + definitive Sx + 1 yr pembro   |
| Adjuvant mRNA vaccine for Melanoma            | UPCC 03623 | Dr. Ravi Amaravadi     | CRC: Shraya Divaker<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles | PCAM  | surgically resectable stage IIB, IIC, III, or IV cutaneous melanoma<br>uveal or mucosal melanoma not eligible<br>no prior systemic therapy or cancer vaccine<br>no evidence of disease at time of treatment start<br>no current or prior metastatic cancer<br>ECOG PS 0 or 1   | Definitive Sx<br>Arm A: pembro + mRNA vaccine q3wks for 9 cycles<br>Arm B: pembro + placebo vaccine q3wks for 9 cycles   |
| Adjuvant Cemiplimab for SCC                   | UPCC 04619 | Dr. Joanna Walker      | CRC: Sheridan Schwartz<br>CRN: Mollie Diehl                         | PCAM  | pathologic resected cSCC: primary lesion, primary with nodal involvement, or nodal metastasis with known primary<br>completion of curative intent post-op RT within 2-6 wks of randomization<br>non-cutaneous SCC not eligible<br>no other concurrent malignancy other than localized cSCC within 3 yrs of randomization<br>no hematologic malignancies<br>no history of distantly metastatic cSCC<br>no autoimmune diseases<br>no prior systemic anti-cancer immunotherapy for cSCC | Arm A: adjuvant cemiplimab up to 48 wks<br>Arm B: placebo up to 48 wks   |
| <b>Metastatic 1st Line Trials</b>             |            |                        |   |   |  |  |
| RADVAX for Metastatic Melanoma                | UPCC 05618 | Dr. Tara Mitchell      | CRC: Faisha Salami<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles  | PCAM; Valley Forge; Lancaster General Health; Huntsman Cancer Institute | histologically confirmed metastatic melanoma (includes CNS mets)<br>≥ 2 measurable lesions per RECIST 1.1<br>HFRT index lesion 1-7 cm<br>prior adjuvant αPD-1 allowed (4 wk washout)<br>prior adjuvant αCTLA4 excluded<br>CNS mets – symptomatic or require urgent local therapy are excluded  | Arm A: Ipi/Nivo<br>Arm B: Ipi/Nivo + radiation   |
| <b>Metastatic 1st/2nd Line Trials</b>         |            |                        |   |   |  |  |
| LIMIT for Metastatic Melanoma                 | UPCC 01620 | Dr. Ravi Amaravadi     | CRC: Faisha Salami<br>CRNs: Jennifer Tabita-Martinez & Lydia Giles  | PCAM  | unresectable stage III or IV melanoma<br>≥ 1 measurable site of disease by RECIST v.1.1 not previously irradiated<br>allowed for refractory pts per 3.2.4<br>treated brain mets allowed if > 2 wks post gamma knife, surgery or stable 2 months post whole brain RT<br>stable corticosteroid dose x 1 month or tapering off and reached 20 mg prednisone or equivalent   | Phase IB: Nivo + Ipi + HCQ: pts must be αPD-1 refractory<br>Phase IIC: Nivo + rela + HCQ: pts must be αPD-1 refractory   |

**Key**

ipi= ipilimumab  
nivo= nivolumab  
rela= relatlimab  
pembro= pembrolizumab  
HCQ= hydroxychloroquine