Penn Medicine

MELANOMA & CUTANEOUS MALIGNANCIES CLINICAL TRIALS

TARA MILLER MELANOMA CENTER

Trial Name	Protocol #	PI	Study Team	Enrolling sites	Key Eligibility & Screening	Treatment Arms
Neo-adjuvant/Adjuvant Trials						
Neo-adjuvant Pembro for Merkel Cell Carcinoma	UPCC 01622	Dr. John Miura	CRC: Shraya Divaker CRNs: Jennifer Tabita-Martinez & Lydia Giles	HUP; Valley Forge; Lancaster General Health; Duke University	clinical stage I-III MCC Must have adequate tumor burden to yield 2-4 pre-operative research bx ECOG PS 0 or 1 No active CNS metastases and/or carcinomatous meningitis; brain MRI required	1 dose of pembro + definitive Sx + 1 yr pembro
Locally Advanced Trials						
Intralesional Cemplimab for Early Stage cSCC	UPCC 06625	Dr. Joanna Walker	CRC: Marie DeMarco	HUP (Derm Clinic)	histologically confirmed invasive stage I cSCC (> 1 cm-≤2.0 cm (longest diameter)) located in either the HN, hand, or pre-tibial surface eligible for Mohs surgical resection resection	Arm A: intralesional cemiplimab 5 mg qw x6 cycles
					No cSCC or BCC lesion >2.0 cm (diameter) not surgically removed during the screening period No history of metastatic cSCC, including distant (M1) or nodal (N1-N3) cSCC within 5 years	Arm B: Mohs surgery
Metastatic 1st Line Trials						
RADVAX for Metastatic Melanoma	UPCC 05618	Dr. Tara Mitchell	CRC: Carrie Bosse CRNs: Jennifer Tabita-Martinez & Lydia Giles	HUP; Valley Forge; Lancaster General Health; Huntsman Cancer Institute	histologically confirmed metastatic melanoma (includes CNS mets) ≥ 2 measurable lesions per RECIST 1.1 HFRT index lesion 1-7 cm prior adjuvant αCTLA4 excluded	Arm A: Ipi/Nivo
					CNS mets – symptomatic or require urgent local therapy are excluded	Arm B: Ipi/Nivo + radiation
Metastatic 2nd Line Trials						
LIMIT for Metastatic Melanoma	UPCC 01620	Dr. Ravi Amaravadi	CRC: Carrie Bosse CRNs: Jennifer Tabita-Martinez & Lydia Giles	HUP	unresectable stage III or IV melanoma ≥ 1 measurable site of disease by RECIST v.1.1 not previously irradiated allowed for refractory pts per 3.2.4 treated brain mets allowed if > 2 wks post gamma knife, surgery or stable 2 months post whole brain RT stable corticosteroid dose x 1 month or tapering off and reached 20 mg prednisone or equivalent	Phase IIC: Nivo + Rela + HCQ (pts must be αPD-1 refractory)
Linnaeus GPER agonist for metastatic melanoma	UPC 06224	Dr. Tara Mitchell	CRC: Carrie Bosse CRNs: Jennifer Tabita-Martinez & Lydia Giles	HUP	unresectable stage III or IV cutaneous melanoma with measurable disease by RECIST 1.1 2 copies fully function form of GPER protein-coding sequence	Arm A: LNS8801 125 mg daily up to 2 yrs
					progressed on or after at least one PD-1 inhibiotor, applied as monotherapy or in combination with others no blue nevus subtype, mucosal, acral lentiginous, or uveal/ocular/chorodial melanoma	Arm B: LNS8801 125 mg daily + pembro 200 mg IV q3wks **or** 400 mg IV q6wks up to 2 yrs
					no history of allogeneic tissue/solid organ transplant	Arm C: Physician's Choice (chemotherapy: darcarbazine, temozolomide or immunotherapy: pembro, nivo/rela, or ipi/nivo)
Immatics T cell receptor for metastatic melanoma	UPCC 01625	Dr. Tara Mitchell	CRC: Shraya Divakar CRNs: Emily Marcuson (CTT), Jennifer Tabita-Martinez & Lydia Giles	HUP	unresectable stage III or IV melanoma with measurable disease by RECIST 1.1 HLA type: HLA-A*02:01 positive progressed on or after at least one PD-1 inhibiotor, applied as monotherapy or in combination with others	Arm A: IMA203
					pathologically confirmed cutaneous melanoma, no mucosal, uveal, or unknown primary no history of other malignancies within last 3 years except BCC, SCC, or carcinoma in situ) no active brain or CNS disease	Arm B: Physician's choice (lifileucel, nivo/rela, nivo, pembro, ipi, or chemo)
Expanded access program for TIL therapy	UPCC 02625	Dr. Tara Mitchell	CRC: Shraya Divakar CRNs: Emily Marcuson (CTT), Jennifer Tabita-Martinez & Lydia Giles	HUP (inpatient)	eligible for lifileucel therapy have lifileucel product manufactured but did not meet commerical release criteria	Cyclophosphamide for 2 days + Fludarabine for 5 days + lifileucel (TIL) infusion + IL-2 BID x6 doses
Pending Trials						
Pfizer MEK1/2 Inhibitor for metastatic melanoma	UPCC 05625	Dr. Ravi Amaravadi	CRC: Carrie Bosse CRNs: Jennifer Tabita-Martinez & Lydia Giles	HUP	unresectable stage III or IV melanoma with measurable disease by RECIST 1.1 BRAF V600E or V600K mutation	Phase IA: monotherapy (PF-07799544)
					progressed following prior treatment, no other available treatment options can have active brain or CNS disease	Phase IB: combination therapy (PF-07799544 + PF-07799933)

Key

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

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