

The following trials are currently being conducted at Moffitt Cancer Center. For additional information about these trials, please visit MOFFITT.org or call Cheryl Maker in the Clinical Research Department at (813) 745-4106 or e-mail cheryl.maker@moffitt.org.

Phase III

Random-Assignment Study of Hepatic Arterial Infusion of Melphalan With Venous Filtration Via Peripheral Hepatic Perfusion (PHP) (Delcath System) Versus Best Alternative Care for Ocular and Cutaneous Melanoma Metastatic to the Liver
MCC 15316, NCT00324727

Multicenter Selective Lymphadenectomy Trial II (MSLT-II): A Phase III Multicenter Randomized Trial of Sentinel Lymphadenectomy and Complete Lymph Node Dissection Versus Sentinel Lymphadenectomy Alone in Cutaneous Melanoma Patients With Molecular or Histopathological Evidence of Metastases in the Sentinel Node
MCC 14120, NCT00389571

Phase II

Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Lovastatin for Various Endpoints of Melanoma Pathobiology
MCC 15168, NCT00462280

Imatinib in Patients With Mucosal or Acral/Lentiginous Melanoma and Melanomas That Arise on Chronically Sun-Damaged Skin
MCC 15458, NCT00424515

Phase I/II

Dose Ranging Trial of MART-1/gp100/Tyrosinase/NY-ESO-1 Peptide Pulsed Dendritic Cells Matured Using Cytokines With Autologous Lymphocyte Infusion With Two Doses of Fludarabine for Patients With Chemotherapy-Naive Metastatic Melanoma
MCC 13649, NCT00313508

Open Label, Non-Randomized Dose Escalation Study to Evaluate the Safety, Tolerability, Immune Response and Clinical Response of Multiple

Doses of MKC1106-MT in Subjects With Advanced Melanoma
MCC 15453

Phase I

Dose-Ranging Trial of Adenovirus-CCL-21 Transduced MART-1/gp100 Peptide-Pulsed Dendritic Cells Matured Using Cytokines for Patients With Chemotherapy-Resistant Metastatic Melanoma
MCC 15280, NCT00798629

Trial of a Vaccine Combining Multiple Class I Peptides and Montanide ISA 51 VG With Escalating Doses of Anti-PD-1 Antibody MDX-1106 for Patients With Resected Stages IIIC/IV Melanoma
MCC 15651

Ipilimumab With PEG-Intron for Patients With High-Risk Resected Stages III/IV Melanoma
MCC 15654

Pilot

Trial of a Vaccine Combining Multiple Class I Peptides and Montanide ISA 51 VG With Escalating Doses of Anti-PD-1 Antibody MDX-1106 for Patients With Unresectable Stages III/IV Melanoma
MCC 15400

No phase specified

H. Lee Moffitt Cancer Center and Translational Genomics (TGen) Collaborative Melanoma Genome Project Protocol and Analysis Plan (Total Cancer Care Protocol)
MCC 15312

Predictors and Determinants of Nodal Metastasis in Localized Melanoma (Total Cancer Care Protocol)
MCC 15322

Use of Discarded Melanoma Tumor Specimens for Validation of Tumor Infiltrating Lymphocyte (TIL) Growth Procedures
MCC 15375

A Controlled Pilot Study of Oncovir Poly IC:LC and NY-ESO-1/gp100/MART-1 Peptides Emulsified

With Montanide ISA 51 With or Without One of Two Doses of CP 870,893 in the Treatment of Subjects With Resected Stage III or Stage IV Melanoma
MCC 15383

Ultrasound Evaluation of Lymph Nodes in Melanoma Patients, and the Prognostic Value for Detecting Metastatic Disease
MCC 15421

Adjuvant Immunotherapy With Anti-CTLA-4 Monoclonal Antibody (Ipilimumab) Versus Placebo

After Complete Resection of High-Risk Stage III Melanoma: A Randomized, Double-Blind Phase 3 Trial of the EORTC Melanoma Group
MCC 15597

Protocol CA184078: A Randomized, Parallel, 3-Arm Study to Characterize the Effect of Ipilimumab on the Pharmacokinetics of Chemotherapy and the Effect of Chemotherapy on the Pharmacokinetics of Ipilimumab in Subjects With Untreated Advanced Melanoma
MCC 15722

More information on the trials listed below is available at PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER. The PDQ Web site is accessible at www.cancer.gov. A searchable Web site developed by the National Library of Medicine is also available at clinicaltrials.gov.

Phase III

Randomized Adjuvant Study of High-Dose Interferon Alfa-2b Therapy in Patients With Stage II or III Melanoma
NCT00003641

Phase II

Depsipeptide (NSC 630176) in Advanced Malignant Melanoma
NCT00104884

Dasatinib in Patients With Stage III Unresectable or Stage IV Melanoma
NCT00436605

Imatinib Mesylate in Patients With Inoperable Stage III or IV Melanoma and Somatic Alterations of c-KIT
NCT00470470

Lymphodepleting Conditioning Comprising Fludarabine Phosphate and Cyclophosphamide Followed by Infusion of Autologous Anti-gp 100:154-162 T-Cell Receptor Gene-Engineered Lymphocytes in Patients With Metastatic Melanoma
NCT00509496

Lymphodepleting Conditioning Comprising Cyclophosphamide and Fludarabine Phosphate Followed by Autologous Anti-MART-1 F5 T-Cell Receptor Gene-Engineered Peripheral Blood

Lymphocytes and High-Dose Aldesleukin in Patients With Metastatic Melanoma
NCT00509288

Autologous Tumor-Infiltrating Lymphocytes and High-Dose Aldesleukin After Cyclophosphamide and Fludarabine Phosphate in Patients With Metastatic Melanoma
NCT00513604

Incorporating Pegylated Interferon in the Treatment for Children With High-Risk Melanoma
NCT00539591

Phase I/II

Nonmyeloablative Lymphocyte-Depleting Preparative Chemotherapy Comprising Cyclophosphamide and Fludarabine Followed by Allogeneic Tumor-Reactive Lymphocyte Cell Line DMF5 and High-Dose Aldesleukin in Patients With Refractory Metastatic Melanoma
NCT00537069

Cellular Adoptive Immunotherapy Comprising Autologous NY-ESO-1-Melanoma-Specific CD8+ T Cells With or Without Ipilimumab in Patients With Metastatic Melanoma
NCT00871481

Phase I

Sorafenib Tosylate in Combination With Regional Melphalan Via Normothermic Isolated Limb Infusion in Patients With Stage IIIB or IIIC Intransit Extremity Melanoma
NCT00565968