

CLINICAL TRIALS UPDATE



SUMMER 2008, VOL. 9, ISSUE 2

A Comprehensive Approach To Treating Melanoma



From left: James J. Mulé, PhD, Donald A. Adam, Jeffrey S. Weber, MD, PhD, and Vernon K. Sondak, MD.

Each year, nearly 60,000 people in the United States develop melanoma, the most serious type of skin cancer and one of the most common cancers in young adults. If melanoma is detected and treated early, a patient's chances of recovery are very good; however, undetected or untreated melanoma can grow deeper into the skin and spread. Once it spreads to other parts of the body it can be difficult to treat, and can be lethal.

Scientists and clinicians at Moffitt Cancer Center are exploring a number of immune-based therapies to treat melanoma, including the use of immune-modulating antibodies and tumor vaccines.

"Immune-based therapies for melanoma stem from early observations, years ago, that documented spontaneous regression of melanoma lesions without evidence of treatment," says James J. Mulé, PhD, a Moffitt researcher and executive vice president of Applied Science and Technology. "This regression suggested that some sort of immune response plays a role."

Funded by a \$20.4 million gift from philanthropist and melanoma survivor Donald A. Adam, Moffitt recently established a Comprehensive Melanoma Research Center (CMRC) to further examine this immune response role by conducting research in melanoma and translating scientific findings to cutting-edge patient treatments.

"The CMRC will take an 'all-arms' approach to treating this disease," says Jeffrey S. Weber, MD, PhD, director of the CMRC and member of Moffitt's Cutaneous Oncology Program. "We are looking at preclinical immunology, clinical immunology, antigen discovery, drug discovery, and clinical treatment to tackle this disease."

We're Here To Help

If you need assistance identifying the best physician for your patient or have questions about Moffitt Cancer Center's programs and services, call **1-888-MOFFITT (1-888-663-3488)**.

To determine if a Moffitt clinical trial is available for your patient, call **813-745-4106** or visit MOFFITT.org; click on the "Medical Professionals" tab and select "Active Clinical Trials."

Additionally, the National Institutes of Health has a Web site that focuses exclusively on clinical trials; visit www.clinicaltrials.gov.

Gene Therapy Tactic May Enhance Vaccine Efficacy



James J. Mulé, PhD

While several studies suggest that a vaccine has the potential to treat malignant melanoma or prevent its metastasis, the US Food and Drug Administration has not yet approved a melanoma vaccine. These vaccines contain one or more antigens that are unique to melanoma cells. Some also contain adjuvants to enhance their efficacy. Initial studies in patients showed that vaccines could trigger immunity from melanoma but not enough to cause disease regression.

Dr. Mulé currently is involved in a clinical trial using dendritic cells, which are powerful antigen-presenting cells, as the basis for a melanoma vaccine. Based on gene therapy, Dr. Mulé and his team will take dendritic cells from patients and grow them outside the body in the laboratory. They will then introduce into the dendritic cells a gene that encodes the CCL21 protein. CCL21, a chemokine that is normally expressed in secondary lymphoid organs, acts as a chemoattractant (a substance that elicits accumulation of cells) for several populations of immune cells. The administration of dendritic cells producing CCL21 can cause significant immune cell infiltration of the

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vaccination site and generate a local tumor-specific cellular immune response. Once the immune cells leave the vaccination site and distribute throughout the body, that response becomes systemic.

"In animal models," says Dr. Mulé, "this has led to significant regression of melanoma. It's a gene therapy trick to enhance the efficacy of the vaccine."

Dr. Mulé is involved in other clinical trials, including one in which patients are exposed to chemotherapy reagents that cause lymphopenia, a reduction in the number of lymphocytes circulating in the blood. In animal studies, researchers have found that vaccines are more effective after inducing lymphopenia.

Overcoming T-Cell Suppression

Dr. Weber is conducting clinical trials using monoclonal antibodies to overcome CTLA-4-mediated T-cell suppression to enhance the immune response against tumors. CTLA-4 (cytotoxic T lymphocyte antigen 4) is a key negative regulator of T cells and can restrict antitumor immune responses. Preclinical and early clinical trials of patients with advanced melanoma show that the monoclonal antibody ipilimumab used alone or in combination with chemotherapy or vaccines can promote antitumor activity. Dr. Weber says this antibody "worked like a charm" to boost immunity in those who received the melanoma vaccine,

especially in patients with high-risk resected melanoma. Studies are ongoing to see how well that improved immune response will translate into an increase in survival.

Study findings have shown that inhibition of CTLA-4 can cause immune-related adverse events (IRAEs), including inflammatory responses such as rash, colitis and hepatitis. These IRAEs are associated with tumor regression in patients with metastatic melanoma and with prolonged time to relapse in those with high-risk resected melanoma.

"There appears to be a strong correlation between doing well and autoimmune side effects," says Dr. Weber. "People with inflammation of the pituitary or colitis seem to do best. These are very unusual findings in melanoma patients who haven't received anti-CTLA-4 antibodies."

Dr. Weber's clinical trials use ipilimumab as an adjuvant to surgery to treat high-risk melanoma patients, and also to treat those with metastatic melanoma that cannot be surgically removed. Early results show that patients undergoing this treatment sometimes have short-term disease progression followed by delayed regression or shrinkage of tumor. He also has observed that some patients evolve over a long period of time from a partial to a complete response with the treatment.

Dr. Weber is also involved in some early-stage clinical trials. One trial uses a dendritic cell melanoma vaccine to augment T-cell reactivity. Another trial involves the adaptive transfer of T cells derived from within the tumor, which has been shown to mediate tumor regression and long-lasting antitumor immunity in mouse models.

Small Molecules To Treat Melanoma

Other approaches to treating melanoma that do not exploit the immune system are being looked at in the CMRC. Investigators at Moffitt including Adil Daud, MD, have developed the idea of using small molecules approved for other cancers in combination with chemotherapy drugs and applying this approach to trials for melanoma. Dasatinib, a drug approved for breast cancer, is being tested in combination with a standard chemotherapy drug for melanoma, dacarbazine, to see if it would significantly add to the anticancer activity of the chemotherapy drug. Newer drugs including inhibitors of a cancer-related gene called MEK will also be tested by Dr. Weber, and a new recruit to the CMRC, Keiran Smalley, PhD, will perform assays to find out whether the target gene is affected by the drug.

Researchers Take Closer Look At Melanoma

Other Moffitt clinicians and researchers who are concentrating on discovering more about melanoma include the following:



Vernon K. Sondak,
MD

Vernon K. Sondak, MD, a surgical oncologist and leader of Moffitt's Cutaneous Oncology Program, is involved with a major national trial of adjuvant therapy with interferon, or biochemotherapy, an intensive treatment regimen that combines chemotherapy drugs with the active biological agents interleukin-2 and interferon. Nationally, this trial, SWOG S0008, enrolled over 400 patients with high-risk stage III melanoma. Along with pathologist **Jane L. Messina, MD**, and epidemiologist **Kathleen M. Egan, MPH, ScD**,

Dr. Sondak is also working on studies aimed at uncovering the factors that govern metastasis of primary melanoma tumors to the lymph nodes and beyond.

Dmitry Gabrilovich, MD, PhD, an immunologist, has been examining melanoma tumor mechanisms and the potential of immunotherapy for combating melanoma. His work is aimed at better understanding and demonstrating the factors that limit the effectiveness of immunotherapy, including those factors that prevent cytotoxic T cells from recognizing and eliminating tumors.

Prakash Chinnaiyan, MD, a radiation oncologist, is developing novel model systems for the therapeutic resistance of melanoma brain metastases. His hypothesis is that tumor stem cells have the plasticity to metastasize to the brain and may cause resistance to chemotherapy and radiation treatment.

Dana E. Rollison, PhD, an epidemiologist, is conducting a variety of studies aimed at unraveling independent risk factors for different types of skin cancer, including melanoma. In a current study, Dr. Rollison and colleagues are working toward establishing a clearer association between abnormal nevi and melanoma by examining telomere length in blood cells.

ILI Shows Promising Results For Recurrent Melanoma

A minimally invasive procedure to deliver chemotherapy drugs for malignant melanomas confined to a single extremity, isolated limb infusion (ILI) is catching on throughout the world and is being used at Moffitt Cancer Center with promising results.

ILI uses heated chemotherapy delivered directly into the affected extremity through small caliber catheters inserted in a patient's femoral artery and vein. The affected limb is "isolated" from the rest of the body by an occlusive tourniquet, which blocks the blood supply to the limb, keeping chemotherapy drugs from entering the bloodstream and affecting the rest of the body.



Jonathan Zager,
MD

"The tourniquet enables us to use a high dose of chemotherapy, isolate the extremity, and prevent chemotherapy drugs from entering the systemic circulation," says Jonathan Zager, MD, a surgical oncologist in Moffitt's Cutaneous Oncology Program who performs the procedure. Slightly elevating the temperature of the limb is thought to increase the drugs' efficacy.

ILI is used to treat unresectable or recurrent extremity melanoma or in-transit melanoma confined to a single limb. It can also be used to treat unresectable extremity sarcoma. Outcomes are very good, with an overall response rate of around 60 to 65 percent, says Dr. Zager. A major advantage of ILI is that it can be repeated several times.

Moffitt is in the early stages of planning multicenter clinical trials of ILI to "tweak the procedure's toxicity rate and efficacy rate."

High-Priority Studies At Moffitt - Phase I & I/II

Solid Tumors

MCC#14689: Phase I dose-escalation, pharmacokinetic and pharmacodynamic evaluation of intravenous LY2275796 (antisense oligonucleotide inhibits production of the human eukaryotic translation initiation factor-4E protein) in patients with advanced cancer.

MCC#14886: Phase I study of combination therapy of temozolomide, valproic acid and radiation therapy in subjects with advanced cancers that have metastasized to the brain.

MCC#14963: Combination phase I open-label dose-escalation study of concomitant administration of BIBW 2992 (inhibitor of EGFR & HER2 tyrosine kinases) with BIBF 1120 (inhibitor of VEGFR-2 tyrosine kinase) in patients with advanced solid tumors.

MCC#14984: Phase I trial evaluating the epidermal growth factor receptor inhibitor erlotinib in combination with the SRC kinase inhibitor dasatinib for patients with recurrent non-small cell lung cancer.

MCC#15002: Phase I open-label, dose-escalation, safety, pharmacokinetic and pharmacodynamic study of CNF2024 (heat shock protein 90 inhibitor) as a single-agent treatment in subjects with HER2- advanced breast cancer or in combination with trastuzumab in subjects with HER2+ advanced breast cancer.

MCC#15038: Phase I study of ALT-801 (recombinant humanized soluble single chain TCR cytokine fusion protein) chain in patients with progressive metastatic malignancies.

MCC#15041: Phase I trial of an SRC kinase inhibitor, dasatinib, in combination with paclitaxel and carboplatin in patients with advanced or recurrent ovarian, peritoneal and tubal cancer.

MCC#15208: Phase I dose-escalation study with sorafenib administered continuously in combination with docetaxel administered once every three weeks in patients with advanced solid tumors.

MCC#15256: Phase I/II study of dasatinib and dacarbazine in patients with metastatic melanoma.

MCC#15267: Phase I study of 1-methyl-D-tryptophan (inhibitor of the enzyme IDO) in patients with advanced malignancies.

MCC#15278: Phase I dose-escalation study of LY2090314 (inhibitor of GSK-3) in patients with advanced or metastatic cancer in combination with pemetrexed and carboplatin.

MCC#15296: Phase I dose-escalation study of daily oral OSI-930 (PDGFR inhibitor) and erlotinib (Tarceva) in patients with advanced solid tumors.

Hematologic Malignancies

MCC#13643: Phase I trial of bortezomib (PS-341; NSC 681239) and flavopiridol (NSC 649890) in patients with recurrent or refractory indolent B-cell neoplasms.

MCC#14606: Phase I study of the safety and pharmacokinetics of escalating intravenous doses of the proteasome inhibitor carfilzomib in patients with hematological malignancies: four-week cycle.

MCC#14796: Phase I dose-escalation study of R11577 (Tipifarnib) plus PS-341 (bortezomib) in relapsed or refractory acute leukemias.

MCC#14862: Phase I study of CPX-351 (cytarabine: daunorubicin) liposome injection in patients with advanced hematologic malignancies.

MCC#14954: Phase I study of triciribine phosphate monohydrate (AKT inhibitor) (TCN-PM, VD0002) in adult patients with advanced hematologic malignancies.

MCC#15149: Open-label phase I study of the safety of perifosine in combination with lenalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma.

MCC#15219: Phase I, multicenter, open-label, dose-escalation study with HuLuc63 (humanized anti-CS1 monoclonal IgG1 antibody) in subjects with advanced multiple myeloma.

MCC#15220: Phase I sequential cohort, dose-escalation trial to determine the safety, tolerability, and maximum tolerated dose of weekly administration of GRN 163L (a telomerase inhibitor) in patients with refractory or relapsed multiple myeloma.

MCC#15224: Phase I clinical trial of oral vorinostat (MK-0683) in combination with bortezomib in patients with advanced multiple myeloma.

MCC#15229: Phase I study of SGN (anti-huCD40 mAb), lenalidomide (Revlimid, CC-5013), and dexamethasone in patients with relapsed or refractory multiple myeloma.

MCC#15243: Phase I dose-escalation study of the safety, pharmacokinetics and pharmacodynamics of XL019 (JAK-2 inhibitor) administered to subjects with myeloproliferative disorders.

MCC#15244: Phase I dose-escalation study of the safety, pharmacokinetics, pharmacodynamics of XL228 (BCR-ABL tyrosine kinase inhibitor) administered intravenously to subjects with chronic myeloid leukemia (CML) or Philadelphia-chromosome-positive acute lymphocytic leukemia (Ph+ ALL).

MCC#15261: Phase Ib open-label, multicenter, dose-escalating clinical study of the safety, tolerability and pharmacokinetic and pharmacodynamic profiles of SNS-595 (DNA-PK signaling in the S phase and induces apoptosis and a G₂ phase arrest of the cell cycle) injection in combination with cytarabine in patients with relapsed or refractory acute myeloid leukemia.

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Select Clinical Trials At Moffitt Cancer Center



Following is a sampling of current clinical trials at Moffitt Cancer Center. Approximately 200 therapeutic trials are open for accrual in patient care programs. For more information, call 813-745-4106.

For a complete listing of active clinical trials at Moffitt, visit MOFFITT.org.

The mission of the H. Lee Moffitt Cancer Center & Research Institute is to contribute to the prevention and cure of cancer.

Blood & Marrow Transplantation

MCC#14955: Phase II trial of autologous peripheral blood hematopoietic cell transplantation followed by dendritic cell p53 vaccination and adoptive T-cell transfer in patients with limited-stage small cell lung cancer (SCLC).

Eligibility: Patients with histologically confirmed SCLC who presented with limited stage (LS) at diagnosis. LS is defined as tumor confined to the hemithorax of origin, the mediastinum, and the supraclavicular nodes, which can be encompassed within a tolerable radiation therapy port. Measurable disease at the time of initial therapy. (Patients will have re-staging of disease after completion of standard chemoradiotherapy.)

Contact: Jennifer Barolo, 813-745-2721.

MCC#15009: Phase II trial of Pentostatin and targeted busulfan as a novel reduced-intensity regimen for allogeneic hematopoietic stem cell transplantation using laboratory-guided (CD4-guided) immunosuppression.

Eligibility: Age: ≥ 18 yrs of age, or younger with parental consent. HLA A, B, C, DRB1, DQB1, 10/10 or 9/10 allele sequence-matched related donor or unrelated donor available. Histologically confirmed diagnosis.

Contact: Dawn Garrett, 813-745-7227.

Breast

MCC#14662: Phase II trial of suberoylanilide hydroxamic acid (SAHA, vorinostat) in combination with tamoxifen for patients with advanced breast cancer who have failed prior antihormonal therapy.

Eligibility: Progression on treatment with any aromatase inhibitor for metastatic disease; recurrence while on adjuvant aromatase inhibitors or within 12 months of completion; recurrence after having completed

adjuvant tamoxifen for at least 12 months; patients who are not candidates for or are intolerant of aromatase inhibitor treatment; prior chemotherapy is not required, but patients may have had three prior chemotherapy regimens in the metastatic setting.

Contact: Mira Mensura Lacevic, MD, 813-745-8304.

MCC#14812: Neoadjuvant intratumoral injection of dendritic cells in breast cancer: translation of biotechnology into the clinic.

Eligibility: Histological diagnosis of invasive breast cancer. Primary tumor estimated by mammography/ultrasound or palpation to be 3 cm or larger and/or palpable axillary nodes larger than 1 cm. Tumor stains for survivin and/or CEA. Tumor must be localized by exam or ultrasound to allow tumor injection.

Contact: Angela Stephens, BS, CCRP, 813-745-1807.

Cutaneous

MCC#15179: A phase II, multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of bevacizumab in combination with carboplatin and paclitaxel chemotherapy for the first-line treatment of patients with metastatic melanoma.

Eligibility: Stage IV metastatic melanoma, histologically confirmed with measurable or nonmeasurable disease (including mucosal melanoma). No prior treatment for metastatic disease with chemotherapy or biologic therapy (adjuvant systemic therapy is acceptable).

Contact: Sue Rivers, RN, 813-745-3558.

MCC#15168: A randomized, double-blind, placebo-controlled phase II clinical trial of lovastatin for various endpoints of melanoma pathobiology.

Eligibility: A history of melanoma <4 mm in Breslow's thickness, with no evidence of regional nodal involvement (sentinel node biopsy strongly encouraged if the lesion is >1 mm or ulcerated). Presence of at least 2 clinically atypical nevi (fulfilling criteria listed below) in locations that can be easily biopsied. Exclusion criteria: Patients with untreated melanoma of any stage or locally advanced (>4 mm) or metastatic (stage III or IV) melanoma.

Contact: Sue Rivers, RN, 813-745-3558.

Gastrointestinal

MCC#15223: A randomized phase II/III study of TNFerade biologic with 5-FU and radiation therapy for first-line treatment of unresectable locally advanced pancreatic cancer.

Eligibility: Patients with unresectable, locally advanced adenocarcinoma of the pancreas who have not received previous treatment for pancreatic cancer. Patients who have been surgically explored and deemed unresectable on that basis are eligible, provided other entry criteria are met. No metastatic (stage IV) disease (including involvement of the colon, adrenals, or kidney, or radiographic evidence of peritoneal seeding).

Contact: Tiffany Campos, 813-745-8358.

MCC#15260: A phase II study of AZD6244 in advanced or metastatic hepatocellular carcinoma.

Eligibility: Patients must have either: (1) histologically or cytologically confirmed hepatocellular carcinoma, or (2) serum alpha fetoprotein greater than 1000 ng/dL with characteristic imaging findings coupled with chronic hepatitis and/or cirrhosis. Eligible patients must have either metastatic disease (including any proven lymph node metastases) or localized disease not amenable to potentially curative transplant/locoregional/surgical therapy. No prior systemic chemotherapy, sorafenib, therapeutic antibody or experimental systemic therapy.

Contact: Tiffany Campos, 813-745-8358.

CLINICAL TRIALS UPDATE

is produced by H. Lee Moffitt Cancer Center & Research Institute

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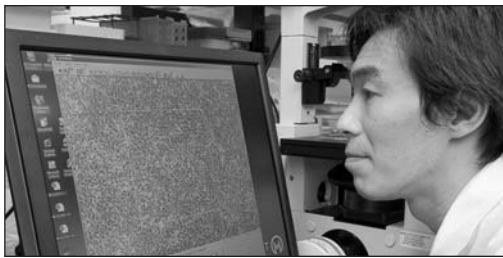
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Genitourinary

MCC#15205: Phase II randomized, double-blinded study to estimate the efficacy and evaluate the safety and tolerability of sorafenib in combination with AMG 386 or placebo as first-line therapy for patients with metastatic clear cell carcinoma of the kidney.

Eligibility: Must have measurable disease with at least one measurable lesion per RECIST guidelines. Renal function with creatinine less than or equal to $2.0 \times$ ULN.

Contact: Marla Davis, RN, 813-745-3543.

MCC#15406: Cancer and Leukemia Group B (CALGB) 90203: a randomized phase III study of radical prostatectomy alone versus estramustine and docetaxel before radical prostatectomy for patients with high-risk localized disease.

Eligibility: No prior treatment for prostate cancer including prior surgery (excluding TURP), pelvic lymph dissection, radiation therapy, or chemotherapy. Patients may have received up to 3 months of androgen deprivation therapy (LHRH agonists, antiandrogens, or both) prior to being enrolled on the study. Must have clinical stage T1-T3a and no radiographic evidence or metastatic disease.

Contact: Marla Davis, RN, 813-745-3543.

Gynecologic

MCC#14889: A phase II randomized trial of BAY 43-9006, a novel Raf kinase inhibitor, versus BAY 43-9006 plus paclitaxel/carboplatin in women with recurrent platinum-sensitive epithelial ovarian, peritoneal or fallopian tube cancer.

Eligibility: Recurrent platinum-sensitive epithelial ovarian cancer, primary peritoneal or fallopian tube cancer. Must have had prior platinum-based therapy but no more than 2 regimens. Prior hormonal therapy is allowed. Measurable disease by RECIST criteria and not in a previously irradiated field.

Contact: Sierra Theodore, RN, 813-745-7272.

MCC#14920: A phase II trial of Avastin in combination with docetaxel in patients with recurrence of epithelial carcinoma of the ovary/fallopian tube/peritoneum with 12 months of platinum therapy.

Eligibility: Recurrent epithelial ovarian, peritoneal serous or fallopian tube cancer within 12 months of platinum therapy. Measurable disease by RECIST criteria or elevated CA-125 greater than 70.

Contact: Sierra Theodore, RN, 813-745-7272.

MCC#15041: A phase I trial of an SRC kinase inhibitor, dasatinib, in combination with paclitaxel and carboplatin in patients with advanced or recurrent ovarian, peritoneal, and tubal cancer.

Eligibility: Stage III or IV or recurrent epithelial ovarian, peritoneal, or tubal cancer. Measurable disease by RECIST criteria. No chemotherapy, radiotherapy, biologic, hormonal, or investigational drug therapy within 28 days prior to study entry. Up to 3 prior cytotoxic chemotherapeutic regimens, including prior treatment with carboplatin and paclitaxel, are acceptable.

Contact: Luz Diez, RN, 813-745-8380.

Head & Neck

MCC#15266: An open-label single-arm trial investigating zalutumumab, a human monoclonal anti-EGF receptor antibody, in combination with best supportive care, in patients with noncurable squamous cell carcinoma of the head and neck who have failed standard platinum-based chemotherapy.

Eligibility: Failure to at least one standard platinum-based chemotherapy. Measurable disease defined as one or more target lesions according to RECIST guidelines.

Contact: Marla Davis, RN, 813-745-3543.

MCC#15305: A phase II study of AZD6244 in iodine-131 refractory papillary thyroid carcinoma and papillary thyroid carcinoma with follicular elements.

Eligibility: Patients must have confirmed papillary thyroid cancer and papillary thyroid cancer with follicular elements that is no longer amenable to radioactive iodine therapy or curative surgical resection. Tumors are no longer iodine avid. There is no limit on the number of patient's prior therapies, except no treatments with TKIs that target RET or RAF nor with MEK inhibitors.

Contact: Marla Davis, RN, 813-745-3543.

Malignant Hematology

MCC#14496: A multicenter, phase II study of maintenance azacitidine in elderly patients with acute myeloid leukemia in complete remission after induction therapy.

Eligibility: One or two rounds of consolidation are necessary. No more than 12 weeks from last consolidation. Blast count of at least 20%.

Contact: Tera Uliano, RN, 813-745-1706.

MCC#14844: Mechanism and response of thymoglobulin in patients with myelodysplastic syndrome (MDS).

Eligibility: For MDS patients, entails 4 days inpatient stay, with blood tests done for follow-up.

Contact: Tera Uliano, RN, 813-745-1706.

MCC#15276: A pilot study of oral dasatinib in subjects with higher-risk MDS.

Eligibility: For MDS patients, entails oral medication given with blood tests done at certain intervals.

Contact: Rick Santana, 813-745-2071.

Neuro-Oncology

MCC#15272: A phase II multicenter exploratory study evaluating the treatment effect of surgery plus Gliadel[®] wafer in patients with metastatic brain cancer (GLIA-001).

Eligibility: Primary diagnosis of non-small cell lung cancer, breast, melanoma, renal, colon, or unknown primary cancer and have single brain metastasis for which surgical resection is planned OR an intraoperative diagnosis of metastatic brain tumor in a patient with a single lesion. 18 years of age, KPS >70%, life expectancy >12 weeks; RPA status of 1 or 2.

Contact: Shirley Entis, RN, CNN©, CCRP, OCN, 813-745-3929.

MCC#15412: Phase I/II study of the poly (ADP-ribose) polymerase-1 (PARP-1) inhibitor BSI-201 in patients with newly diagnosed glioma (NABTT 0703) pending.

Eligibility: Phase I: 18 years of age, KPS >60%, histologically proven supratentorial malignant glioma. Must have received at least 80% of planned TMZ and radiation therapy with no grade 3 or 4 toxicity attributed to TMZ; at least 28 days but no more than 49 days prior to starting treatment on this study; and must have gadolinium MRI or contrast CT scan within 28 days of starting treatment.

Contact: Shirley Entis, RN, CNN©, CCRP, OCN, 813-745-3929.

MCC#15356: A phase II study of R(-)-gossypol (Ascenta's AT-101) in recurrent glioblastoma multiforme (NABTT 0702).

Eligibility: KPS >60%; at least 18 years of age, measurable contrast-enhancing progressive or recurrent glioblastoma by MRI or CT imaging within 14 days of starting treatment. Must have received no more than 2 prior treatments.

Contact: Shirley Entis, RN, CNN©, CCRP, OCN, 813-745-3929.

Radiation Oncology

MCC#14729: A randomized phase III trial of concurrent accelerated radiation and cisplatin versus concurrent accelerated radiation, cisplatin, and cetuximab (C225) [followed by surgery for selected patients] for stage III and IV head and neck carcinomas.

Eligibility: Patients with squamous cell carcinoma of the oropharynx, hypopharynx, or larynx; selected stage III-IV disease (T2, N2-3, M0; T3-4, any N, M0).

Contact: Bonnie Sauder, RN, 813-745-3574.

MCC#15303: A pilot study to validate metallic markers for image-guided radiation therapy for breast cancer treatment.

Eligibility: Pathologically confirmed invasive adenocarcinoma or intraductal carcinoma of the breast. Stage 0, I or II unilateral breast cancer. Surgical treatment with lumpectomy. Pathologic tumor size < 5 cm. Axillary nodal sampling for all invasive cancer. Successful placement of intraparenchymal metallic markers at last breast surgery.

Contact: Mimi Renaldo, 813-745-2279.

MCC#14799: A phase III trial comparing conventional adjuvant temozolomide with dose-intensive temozolomide in patients with newly diagnosed glioblastoma.

Eligibility: Histopathologically confirmed glioblastoma (WHO grade IV) confirmed by central tissue evaluation. Tumor must have supratentorial component. Tumor tissue block must be available for analysis.

Contact: Shirley Entis, RN, CNN®, CCRP, OCN, 813-745-3929.

Sarcoma

MCC#14497: Combination of external beam radiation with intratumoral injection of dendritic cells as neoadjuvant treatment of high-risk soft-tissue sarcoma patients.

Eligibility: Intermediate- or high-grade sarcoma only. Must have musculo-skeletal tumor > 5 cm in diameter located in the extremities, trunk or chest wall. Patient is not a candidate for neoadjuvant chemotherapy. Metastatic disease is an exclusion criterion.

Contact: Robin Szekely, RN, 813-745-7280 or robin.szekely@moffitt.org.

Senior Adult Oncology

MCC#12839: CRASH Score: design and validation.

Eligibility: Must be 70 years or older, any chemotherapy regimen, any tumor site other than leukemia, and may be first-, second-, third-, or fourth-line therapy.

Contact: Ivette Boler, RN, pager: 813-201-4412.

MCC#14915: Support of the caregiver of the older cancer patient undergoing chemotherapy.

Eligibility: Patient must be 70 years or older, have a primary diagnosis of non-Hodgkin's lymphoma or early-stage cancer of the large bowel, be able to provide informed consent, be able to complete English language questionnaires, and be scheduled for chemotherapeutic treatment at Moffitt Cancer Center. Caregiver must be the designated caregiver of a patient 70 years or older who is scheduled for chemotherapy, able to provide informed consent, and able to complete English language questionnaires.

Contact: Mishu Popa, MD, PhD, 813-745-1972.

MCC#14914: Health and personal resources in older cancer patients undergoing chemotherapy.

Eligibility: Must be 65 years or older, able to provide informed consent, able to complete English language questionnaires, and scheduled for chemotherapeutic treatment at Moffitt Cancer Center.

Contact: Gail Tiffenberg, pager: 813-256-5203.

Thoracic

MCC#15005: Randomized phase III multicenter trial of RRM1 & ERCC1 directed customized chemotherapy versus standard of care for first-line treatment of patients with advanced non-small cell lung cancer.

Eligibility: Patients must have untreated, advanced (stage IIIB with malignant pleural effusion or IV) non-small cell lung cancer. Patients must have an ECOG PS of 0 or 1. Prior RT allowed; however, completion must be at least 7 days prior to initiation of chemotherapy. Prior chemotherapy (given in adjuvant or neoadjuvant form prior to or after surgical resection) allowed with last dose \geq 12 months. Patients must have had a prior biopsy or are willing to undergo a biopsy for customization of chemotherapy.

Contact: Amanda Sweeney, 813-745-1457.

MCC#15206: A randomized phase II trial using dendritic cells transduced with an adenoviral vector containing the p53 gene to immunize patients with extensive-stage small cell lung cancer in combination with chemotherapy with or without all-trans retinoic acid.

Eligibility: Must have a diagnosis of extensive stage small cell lung cancer. Must have completed first-line chemotherapy: 4-6 cycles of a standard platinum/etoposide regimen. Randomization must occur 4 weeks after the last dose of first-line chemotherapy. If randomized to vaccine, apheresis must occur 6 weeks after last dose of first-line chemotherapy.

Contact: Robin Szekely, RN, 813-745-7280 or robin.szekely@moffitt.org.

MCC#15294: Safety and efficacy (phase II) study of concurrent cetuximab plus conformal thoracic radiotherapy in (poor prognosis) patients with inoperable or unresectable, locally advanced non-small cell lung cancer (LA-NSCLC).

Eligibility: Patients must have histologically or cytologically confirmed inoperable or unresectable, locally advanced non-small cell lung cancer. Patients with stages IIA through IIIA will be eligible if they are not considered to be candidates for possible resection. Patients with stage IIIB without significant pleural effusion are also eligible. Age \geq 70 OR ECOG PS = 2 OR weight loss \geq 5% in the preceding 3 months at the time of registration

to be eligible for participation. Patients must have measurable disease by RECIST criteria and can have no evidence of distant metastasis. No prior thoracic RT or EGFR pathway targeting therapy.

Contact: Aaron Becker, RN, BA, CCRC, 813-745-4679.

Cancer Prevention/Early Detection For High-Risk Populations

MCC#13342: Randomized placebo-controlled adjuvant study of prevention of prostate cancer recurrence after radical prostatectomy by soy protein isolate.

Eligibility: Surgery less than 4 months ago at start of intervention, undetectable PSA after removal of catheter. Must meet one or more of the following criteria: preoperative PSA >20 ng/mL; Gleason sum 8, 9 or 10; seminal vesicle invasion; positive surgical margins: established not focal; extracapsular extension: established not focal; positive (pelvic) lymph nodes.

Contact: Tiffany Smith, 813-745-6250 or 813-507-1320.

MCC#13930: Natural history of HPV infection in men: the HIM study.

Eligibility: Healthy men 18-70 years old will be followed every 6 months for 4 years. Study participants will undergo interviews, a physical exam, and laboratory analysis for HPV. Information collected in this study will be useful in answering fundamental questions relative to the natural history of male HPV infection. Participants will receive compensation for their time.

Contact: Martha Abrahamsen, MPH, 813-745-6055 or The HPV Research Clinic, 813-745-6996.

MCC#15008: Phase II, randomized, double-blind, multicenter study of Polyphenon E in men with high-grade prostatic intraepithelial neoplasia (HGPIN).

Eligibility: Men aged 30-80 with biopsy-proven HGPIN in the last 3 months. No history of prostate or other cancer (other than non-melanoma skin cancer). No history of liver disease. Ability to take study drug and comply with scheduled monthly visits for 1 year.

Contact: Theresa Crocker, MS, RD, LD/N, 813-745-6046.

Health Outcomes And Behavior

MCC#13615: Translating basic learning research into enhanced cue exposure therapy for smoking cessation.

Eligibility: Patients who want to quit smoking, ages 18 to 60, smoking more than 15 cigarettes per day, can speak and read English well. Not currently enrolled in any formal smoking cessation treatment or using medication to quit smoking. Must not be pregnant or breastfeeding, no heart disease, and no uncontrolled hypertension.

Contact: Marina Unrod, PhD, 813-745-5498.

MCC#14456: Impact of gynecologic cancer on women's health: a prospective study.

Eligibility: Participants must be at least 18 years of age and have been diagnosed with a gynecologic cancer. Participants must be able to read and speak English and be able to provide informed consent. Eligible participants will have been diagnosed with a gynecologic cancer but will not have started treatment.

Contact: Chi-Chi Schickel, 1-800-456-3434, ext. 3430, or e-mail mary.schickel@moffitt.org.

MCC#15198: Symptom measurement and interrelationships during chemotherapy for gynecologic cancer.

Eligibility: Patients must be 18 years or older, able to speak and read English, and diagnosed with a gynecologic cancer. They must be free of psychiatric or neurological disorders that would interfere with study participation, and be able to provide informed consent. Eligible patients will have been off chemotherapy for at least 8 weeks, and be currently scheduled for at least 3 cycles of platinum-based IV chemotherapy at Moffitt Cancer Center.

Contact: Heather Jim, PhD, 1-800-456-3434, ext. 6369, or Heather.Jim@moffitt.org.