

CANCER INSTITUTE CLINICAL TRIALS
May 8, 2019

AMYLOIDOSIS

SWOG S1702 NCT03499808	A Phase II Study of Isatuximab (SAR650984) (NSC-79145) for Patients with Previously Treated AL Amyloidosis
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BILIARY TRACT CANCERS

SWOG S1815 NCT03768414	A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel vs Gemcitabine and Cisplatin in Newly Diagnosed Advanced Biliary Tract Cancers
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BREAST - Neoadjuvant

Alliance A011106 (ALTERNATE) NCT01953588 Temp. Susp. Effective 05/09/19	ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study
Alliance A011202 NCT01901094 Temp. Susp.	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy
DFCI 16-052 PELOPS NCT02764541	PELOPS: Palbociclib and Endocrine Therapy for Lobular Breast Cancer Preoperative Study: A Randomized Phase II Study of Palbociclib With Endocrine Therapy vs. Endocrine Therapy Alone for Invasive Lobular Carcinoma and Invasive Ductal Carcinoma
ECOG-ACRIN EA1131 NCT02445391	Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy

BREAST – DCIS

AFT-25 COMET NCT02926911	Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low Risk DCIS: A Phase III Prospective Randomized Trial
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BREAST - Adjuvant Triple Negative

Alliance A211601 NCT03609021	Evaluation of Mammographic Breast Density Effect of Aspirin: A companion study to Alliance Study A011502
NRG BR003 NCT02488967	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Invasive Breast Cancer
EA1131 NCT02445391	A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy
SWOG S1418 NCT02954874 DTL Required	A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for triple Receptor-Negative Breast Cancer with \geq 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) after Neoadjuvant Chemotherapy

BREAST - Adjuvant HR positive

Alliance A011401 NCT02750826	Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer
Alliance A011502 NCT02927249	A randomized phase III double blinded placebo-controlled trial of aspirin as adjuvant therapy for node-positive, HER2 negative breast cancer: the ABC trial
DFCI 18-124 ATOP NCT03587740	Adjuvant Ado-Trastuzumab Emtansine (T-DM1) for Older Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer
SWOG S1207 NCT01674140 Closes to accrual 05/01/19	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor Positive and HER2/NEU Negative Breast Cancer

BREAST - Adjuvant XRT

CCTG MA.39 NCT03488693	A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
NSABP B-51 NCT01872975	A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy
SWOG S1706 NCT03598257	A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy alone for Inflammatory Breast Cancer

Breast – Metastatic

NRG-BR004 NCT 03199885 DTL Required	A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer
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BREAST - Locally Advanced/Metastatic

HER2+/HR+

DFCI 17-318 NCT03289039	A Phase 2 Study of Neratinib With or Without Fulvestrant in HER2-Positive, ER-Positive Metastatic Breast Cancer
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ER+/HER2-

A171601 NCT03633331	A Phase II Trial Assessing the tolerability of Palbociclib in combination with letrozole or fulvestrant in patients aged 70 and older with estrogen receptor positive, HER-2 negative metastatic breast cancer
DFCI 17-101 PACE NCT03147287	Palbociclib After CDK and Endocrine Therapy (PACE): A Randomized Phase II Study of Fulvestrant, Palbociclib, and Avelumab for Endocrine Pre-Treated ER+/HER2- Metastatic Breast Cancer

TRIPLE NEGATIVE

DFCI 17-512 NCT03414684	A Randomized Phase 2 Trial of Carboplatin With or Without Nivolumab in First- or Second-Line Metastatic Triple-Negative Breast Cancer
SWOG S1416 NCT02595905	Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer"

RADIATION

DFCI 16-304 NCT03422003	Study of Radiation Fractionation on Patient Outcomes After Breast Reconstruction (FABREC) for Invasive Breast Carcinoma
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CHILDREN'S ONCOLOGY GROUP REGISTRY

APEC14B1 (Patients 25 or younger)	Project EveryChild: A Registry, Eligibility Screening, Biology and Outcome Registry
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COLORECTAL

A021502 NCT02912559 DTL Required	Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair
NRG-GI002 NCT02921256	A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer
NRG-GI004 NCT02997228 DTL Required	NRG-GI004/SWOG-S1610: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer

GENITOURINARY

A031501 NCT03244384	Phase III randomized “Adjuvant study of MK-3475 (pembrolizumab) in muscle invasive and locally advanced urothelial carcinoma” (AMBASSADOR) versus observation
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GYN

NRG GY005 NCT02502266 DTL Required	A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS)
NRG GY009 NCT02839707	A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer
NRG GY012 NCT03660826	A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer.
NRG-GY014 NCT03348631	A Phase II Study of Tazemetostat (EPZ-6438) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma

LEUKEMIA - Untreated/Newly Diagnosed

A041701 NCT03701308 DTL Required	A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy
A041702 (NCT 03737981)	A Randomized Phase III Trial of Ibrutinib Plus Obintuzumab versus Ibrutinib Plus Venetoclax and Obintuzumab in Untreated Older Patients (≥ 70) Years of Age) with Chronic Lymphocytic Leukemia (CLL)
SWOG S1612 NCT03092674 Temp. closed to accrual	A Randomized Phase II/III Trial of "Novel Therapeutics" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older
ECOG E1910 NCT02516423	A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL Negative B-lineage Acute Lymphoblastic Leukemia in Adults

LUNG CANCER - Screening Adjuvant

Alliance A151216 (ALCHEMIST) NCT02194738	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial
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LUNG CANCER – Neo-Adjuvant

AFT-16 NCT03102242	Phase II Trial of Induction Immunotherapy With Atezolizumab for Patients With Unresectable Stage IIIA and IIIB NSCLC Eligible for Chemoradiotherapy With Curative Intent
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LUNG CANCER - Adjuvant

Alliance A081105 (ALCHEMIST) NCT02193282	Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)
ECOG E4512 (ALCHEMIST) NCT02201992	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein
ECOG EA5142 (ALCHEMIST) NCT02595944 DTL Required	Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) – A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers

LUNG CANCER – 1ST Line Metastatic

ECOG EA5163 NCT03793179	INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis
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LUNG CANCER - 2nd Line Metastatic

LUNGMAP NCT02154490	A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)
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LYMPHOMA - Relapsed

UTX-TGR-205 UNITY NCT02793583	A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 With or Without Bendamustine and TGR-1202 Alone in Patients With Previously Treated Non-Hodgkin's Lymphoma
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MELANOMA - Locally Advanced/Metastatic

ECOG-ACRIN EA6141 NCT02339571 Temp. closed to accrual	Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma
SWOG S1320 NCT02196181	A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma



MELANOMA – Adjuvant

SWOG S1801 NCT03698019	A Phase II Randomized Study of Adjuvant vs. Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma
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MULTIPLE TUMOR TYPES

ECOG EAY131 (MATCH) NCT# 02465060	Molecular Analysis for Therapy Choice (MATCH)
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MYELOMA - Relapsed/Refractory

Alliance A061202 NCT02004275	A Phase I/II Study of Pomalidomide, Dexamethasone and Ixazomib VS. Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Relapsing on Lenalidomide as Part of First Line Therapy
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PREVENTION

AFT-28 CANVAS NCT02744092	Direct Oral Anticoagulants (DOACs) vs. LMWH +/- Warfarin for VTE in Cancer: A Randomized Effectiveness Trial (CANVAS Trial)
A221701 NCT03839940	Phase III Placebo-Controlled Trial to Evaluate Dexamethasone Use for Everolimus-Induced Oral Stomatitis: Prevention versus Early Treatment Approaches

PROSTATE

AFT-19 NCT03009981	A Phase 3 Study of Androgen Annihilation in High-Risk Biochemically Relapsed Prostate Cancer
SWOG S1802 NCT03678025	S1802 Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer
NRG-GU006 NCT03371719	A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy With or Without Enhanced Anti-Androgen Therapy With Apalutamide in Recurrent Prostate Cancer

RARE TUMORS

SWOG S1609 NCT02834013	DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors
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RENAL

ECOG-ACRIN EA8143 NCT03055013 DTL Required	A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)
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