CLINICAL TRIALS OPEN LIST
(Updated 11/1/2013)

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Western Oncology Research Consortium (WORC) website: www.GoWORC.org
**BRAIN CANCER TRIALS**

Contact Research Nurse Chris Fountain at: 503-215-2691, christopher.fountain@providence.org

**ADU-623**  
Phase I Study of Safety and Immunogenicity of ADU-623, a live-attenuated *Listeria monocytogenes* vaccine (Δ*actA*/Δ*inlB*) expressing EGFRvIII and NY-ESO-1, in Patients with Treated and Recurrent WHO Grade III/IV Astrocytomas  
**Key Eligibility:**  
- Diagnosis of WHO Grade III or Grade IV astrocytic tumors that have completed radiation therapy, with temozolomide or with radiographic evidence of progression following radiation and chemotherapy treatment.  
- Performance status of 0-1 (KPS 70-100)  
For more information: NCT01967758

**Celldex ACT IV**  
An International, Randomized, Double-Blind, Controlled Study of Rindopepimut/GM-CSF with Adjuvant Temozolomide in Patients with Newly Diagnosed, Surgically Resected, EGFRvIII-positive Glioblastoma (The “ACT IV” Study)  
**Key Eligibility:**  
- Histologically confirmed, newly diagnosed, de novo glioblastoma including the following recognized variants of glioblastoma: small cell glioblastoma, giant cell glioblastoma, gliosarcoma and glioblastoma with oligodendrogial component (central pathologic review will be performed and histologic confirmation will be required prior to study entry).  
- Attempted surgical resection followed by conventional chemoradiation, consisting of radiotherapy at a minimally acceptable total dose of at least 90% of the planned radiation therapy dose (usually 60 Gy) and concomitant TMZ chemotherapy (75 mg/m² body surface area per day). Patients who received an incomplete course or lower dose of temozolomide may be eligible, provided all other entry criteria are met.  
For more information: NCT01480479

**T09-10644 (Tactical CTO)**  
Phase I Study of Oral Carboxyamidotriazole Ortate (CTO) Titrated as a Single Agent in Patients with Advanced or Metastatic Solid Tumors and Titrated in Combination Therapy with Temozol in Patients with Glioblastoma Multiforme or Other Recurrent Malignant Gliomas.  
**Key Eligibility:**  
- Patients must have histologically proven intracranial malignant glioblastoma multiforme  
- Patients must have shown unequivocal radiographic evidence for tumor progression by MRI scan to be performed within 14 days prior to registration and must be on a steroid dose that has been stable for at least 5 days. If the steroid dose is increased between the date of imaging and registration, a new baseline MRI scan is required.  
For more information: NCT01107522
**RTOG 1205**
Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma

**Key Eligibility:**
- Open at the following locations: Clackamas Radiation Oncology Center, Compass Oncology, PeaceHealth Southwest Medical Center, Providence Milwaukie Hospital, Providence Portland Medical Center, and Providence St. Vincent Medical Center. Credentialing required.
- Diagnosis of glioblastoma or variants (gliosarcoma, giant cell glioblastoma etc).
- Patients who did not have recent surgery for their glioblastoma must have shown unequivocal radiographic evidence for tumor progression by contrast-enhanced magnetic resonance imaging (MRI) scan (or computed tomography [CT] scan for patients with non-compatible devices) CT scan within 14 days prior to registration. Patients also must have passed an interval of 6 months or greater between completion of prior radiotherapy and registration; if patients have not passed an interval of at least 6 months, they may still be eligible given they meet certain criteria.

For more information: [NCT01730950](https://clinicaltrials.gov/show/NCT01730950)

**RTOG 1122**
Phase II Double-Blinded Placebo-Controlled Study of Bevacizumab With or Without AMG 386 in Patients With Recurrent Glioblastoma or Gliosarcoma

**Key Eligibility:**
- Unequivocal evidence of tumor progression on the previous treatment regimen
- Histologically proven diagnosis of glioblastoma or variants
- No Prior therapy with anti-VEGF targeted agents

For more information: [NCT01609790](https://clinicaltrials.gov/show/NCT01609790)

**BRAIN CANCER CONTROL AND PREVENTION TRIALS**
**URCC 0701**
A Study of the Effects of Exercise on Cancer-Related Fatigue

**Key Eligibility:**
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: [NCT00924651](https://clinicaltrials.gov/show/NCT00924651)
BREAST CANCER TRIALS
Contact Research Nurse Nikki Moxon at: 503-215-2619, nicole.moxon@providence.org

IMAGING

CTSU ALLIANCE A211201
Change in Mammographic Density with Metformin Use: A Companion Study to NCIC Study MA.32
Key Eligibility:
• Patients must be concurrently enrolling or previously enrolled to (CAN) or (NCIC) study MA.32 (CAN-NCIC-MA.32)
• Can be pre- or post-menopausal
• Must have hormone receptor-negative breast cancer

For more information: NCT01666171

EACRI MRI vs. BSGI
Study to Compare Breast Magnetic Resonance Imaging (Breast MRI) and Breast Specific Gamma Imaging (BSGI) in Women with a BIRADS (Breast Imaging Reporting and Data System) Score 4 or 5 as Determined by Mammogram or Ultrasound
Key Eligibility:
• Women ages 18 to 79 (inclusive)
• Suspicious mammographic or ultrasound finding or palpable abnormality or suspicious clinical finding without associated benign mammographic features scored as a BIRADS 4 or 5 that will require a biopsy (no longer than 6 weeks will elapse between abnormal mammogram findings and enrollment into this trial)

ADJUVANT THERAPY

NSABP B49
A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women With Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer
Key Eligibility:
• The tumor must be unilateral invasive adenocarcinoma of the breast on histologic examination
• The breast cancer must be HER2-negative
• Patients must have undergone either a total mastectomy or breast-conserving surgery (lumpectomy)

For more information: NCT01547741
SWOG S1207
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

Key Eligibility:
- Patients must not have inflammatory or metastatic breast cancer (stage IV disease). Patients with multifocal, multicentric and synchronous bilateral breast cancers are allowed.
- Patients must be high risk by belonging to one of the following risk groups:
  - Completion of adjuvant chemo with negative lymph nodes and tumor measuring ≥ 2 cm with an Oncotype DX recurrence score > 25.
  - Completion of adjuvant chemotherapy and 1-3 positive nodes with Oncotype DX recurrence score > 25.
  - Completion of adjuvant chemotherapy and 4 or more positive nodes (may be determined prior to or after chemotherapy).
  - Completion of neoadjuvant chemotherapy and 4 or more positive nodes (may be determined prior to or after chemotherapy).
- Patients must have completed either breast conserving surgery (and whole breast radiation) or total mastectomy, with negative margins and appropriate axillary staging.

For more information: NCT01674140

NSABP B-47
A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

Key Eligibility:
- The tumor must be unilateral invasive adenocarcinoma of the breast on histologic examination, primary tumor must be pT1-3; ipsilateral nodes must be pN0, pN1 (pN1mi, pN1a, pN1b, pN1c), pN2a, pN2b, pN3a, or pN3b.
- HER2 status of the primary tumor must be evaluated prior to randomization; all testing performed must indicate that the tumor is HER2-low: IHC must be performed and the IHC staining results must indicate a score of 1+ (in situ hybridization [ISH] testing is not required) or 2+ (ISH must also be performed and must indicate that the tumor is HER2-low).
- The patient must have undergone either a total mastectomy or breast-conserving surgery (lumpectomy). (Patients who have had a nipple-sparing mastectomy are eligible.)

For more information: NCT01275677
NSABP B43
A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy.

Key Eligibility:
- Histologically confirmed ductal carcinoma in situ (DCIS) [Mixed DCIS and lobular carcinoma in situ (LCIS) allowed]
- HER2 receptor-positive as determined by central testing
- Must have undergone resection by lumpectomy and meet the following criteria: Margins of the resected specimen must be histologically free of DCIS (re-excision to obtain clear margins allowed), no more than 120 days since the last surgery for excision of DCIS (lumpectomy or re-excision of lumpectomy margins)

For more information: NCT00769379

RTOG 1005
A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation plus Sequential Boost for Early-Stage Breast Cancer

Key Eligibility:
- Pathologically proven diagnosis of breast cancer resected by lumpectomy and whole-breast irradiation (WBI) with boost without regional nodal irradiation planned
- Study entry must be within 50 days of whichever comes last: last surgery (breast or axilla) or last chemotherapy

For more information: NCT01349322

SWOG S1007
Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-responsive and Her2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.

Key Eligibility:
- Histologically confirmed invasive breast cancer meeting the following criteria: 1-3 node-positive disease (pN1mi, pN1a, pN1b, or pN1c) by sentinel node biopsy or axillary lymph node dissection. Positive estrogen receptor (ER) and/or progesterone receptor (PR) status. Considered positive if =>1% positive tumor nuclei in the sample on testing in the presence of expected reactivity of internal [normal epithelial elements] and external controls.
- Negative HER-2 as determined by IHC or non-amplified fluorescence in situ hybridization (FISH) for screening. If HER2 is 2+ by IHC, FISH must be performed and must not be positive (must be a ratio of <= 2.2). If IHC is 0 or 1+ by institutional standards, FISH is not required.
- Recurrence Score (RS) by Oncotype DX =<25

For more information: NCT01272037
FIRST LINE THERAPY
KATHERINE (NSABP B-50)
Phase III Trastuzumab Emantansine (T-DM1) vs. Traustuzumab when residual tumor present by path in breast or axillary lymph nodes after preoperative therapy.
Key Eligibility:
- HER2+ Breast Cancer
- Stage I-IV
- Completion of systemic treatment of at least 6 cycles with duration of at least 16 weeks including 9 weeks of Trastuzumab and taxane-based therapy

For more information: NCT01772472

E2108
A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer
Key Eligibility:
- Patients (male or female) must be older than 18 years and must have an intact primary (not recurrent) invasive carcinoma of the breast.
- Patients should have at least one organ system involved with distant metastatic disease. If only a single metastatic lesion is present, biopsy is mandatory.
- Patients must not have experienced disease progression since the start of systemic therapy, as evidenced by clinical and radiographic documentation of disease status before treatment and within 6 weeks prior to randomization, including: no new sites of disease, no enlargement of existing sites by 20% or more in longest diameter, and no symptomatic deterioration.

For more information: NCT01242800

SECOND(+) LINE THERAPY
EACRI OX40/SBRT
Phase I/II Study of Stereotactic Body Radiation Therapy to Metastatic Lesions in the Liver or Lung in Combination with Monoclonal Antibody to OX40 in Patients with Progressive Metastatic Breast Cancer After Systemic Therapy
Key Eligibility:
- Patients (male and female) with histologically confirmed breast cancer with clinical evidence of stage 4 disease. The patient must have measurable disease and at least one lesion in either liver or lung that is amenable to SBRT. Patients must have at least one site of disease that is evaluable and that will not be receiving SBRT.
- Patients with hormone receptor positive breast cancer must have received prior anti-hormonal therapy for metastatic disease and have progressed and patients with hormone receptor negative breast cancer must have received at least one prior chemotherapy regimen and progressed.

For more information: NCT01642290
BREAST CANCER CONTROL AND PREVENTION AND PREVENTION TRIALS

SWOG S0702
A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

Key Eligibility:
- Participants must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease
- All participants must be planning to receive zoledronic acid for metastatic bone disease within 30 days after registration
- Participants must not have a pre-existing diagnosis of ONJ

For more information: NCT00874211

URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651

SWOG 0812
Phase IIB Randomized Controlled Biomarker Modulation Study of Vitamin D in Premenopausal Women at High Risk for Breast Cancer

Key Eligibility:
- At an elevated risk of breast cancer, defined as meeting =>1 of the following criteria:
  - Diagnosis of resected ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) AND no evidence of invasive breast cancer at the time of study registration
  - Diagnosis of atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), a known deleterious mutation in BRCA1, BRCA2, PTEN, TP53 or have a Gail/CARE model risk at 5 years =>1.67% or lifetime risk =>20%

For more information: NCT01097278
ORAL, HEAD, AND NECK CANCER TRIALS
Contact Research Nurse Brenda Fisher at: 503-215-2613, brenda.fisher@providence.org

Head and Neck
RTOG 0920
A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer
Key Eligibility:
- Histologically confirmed squamous cell carcinoma of the head and neck
- Surgical resection of the primary tumor with curative intent within the past 7 weeks
- Surgical pathology demonstrating intermediate risk of recurrence

For more information: NCT01311063

Salivary Gland
RTOG 1008
A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors
Key Eligibility:
- Pathologically proven diagnosis of malignant major salivary gland tumor
- Surgical resection with curative intent within 8 weeks prior to registration

For more information: NCT01220583

ORAL, HEAD, AND NECK CANCER CONTROL AND PREVENTION TRIALS
MDACC 2010-0547
A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer
Key Eligibility:
- Diagnosis of head/neck cancer
- Received bilateral radiation therapy and subsequently developed grade 2 or 3 xerostomia

For more information: NCT01141231
GASTROINTESTINAL CANCER TRIALS

Contact Research Nurse Yue-Yun To at: 503-215-2855, yue-yun.to@providence.org
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HEPATOCELLULAR

RTOG 1112
Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma

Key Eligibility:
• Unresectable hepatocellular carcinoma
• Child pugh A
• BCLC stage B or C

For more information: NCT01730937

COLON (STAGE I/II/III) – RESECTED

CALGB 80702
A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer

Key Eligibility:
• Histologically confirmed adenocarcinoma of the colon
• Patients must have already-resected stage III disease
• No rectal cancer

For more information: NCT01150045

COLON/RECTAL (STAGE IV)

MDACC 2009-0288
Comparative Study of Oncologist Recommended, Home-Based Exercise Program and Relaxation Training for Physical Functioning and Symptom Control in Colon Cancer Patients

Key Eligibility:
• Diagnosis of colon cancer, Stage IV or recurrent disease, unresectable disease
• Not exercising at a moderate-vigorous intensity for =>150 minutes per week or at a vigorous intensity for >20 minutes on =>3 days per week.
• No symptomatic bone metastases

For more information: NCT00985400
Biothera BT-CL-PGG-CRC1031
A Phase 3 Open-Label, Randomized, Multicenter Study of Imprime PGG® in Combination with Cetuximab (Erbitux®) in Subjects with Recurrent or Progressive KRAS Wild Type Colorectal Cancer

Key Eligibility:
- Recurrent or metastatic carcinoma of the colon or rectum with documented histological or cytological confirmation
- KRAS wildtype
- Have received at least 2 prior chemotherapeutic regimens for colorectal cancer

For more information: NCT01309126

BILE DUCT
DELTIC UL2011.1
Drug-Eluting Bead, Irinotecan (DEBIRI) Therapy of Unresectable intrahepatic cholangiocarcinoma (ICC) with Concomitant Systemic Gemcitabine and Cisplatin (Gem-Cis)

Key Eligibility:
- Histological evidence of intrahepatic cholangiocarcinoma, deemed unresectable
- Liver-dominant disease defined as ≥80% of the subject’s total amount of malignant disease (tumor burden) that is confined to the liver.
- Liver tumor volume is less than 70% of entire volume of liver

For more information: NCT01648023

ESOPHAGEAL
RTOG 1010
Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

Key Eligibility:
- Pathologically confirmed primary adenocarcinoma of the esophagus meeting the following criteria: Involvement of mid (up to 25 cm), distal, or esophagogastric junction.
- HER2 positive only
- T1, N1-2 or T2-3, N0-2 disease

For more information: NCT01196390

CALGB 80803 - Opening soon
Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer

Key Eligibility:
- Surgically resectable, histologically confirmed esophageal adenocarcinoma, including Siewart GE junction adenocarcinomas Types 1 and 2
- T1N1-3M0 or T2-4NanyM0 as determined by EUS and PET/CT
- No evidence of distant metastases

For more information: NCT01333033
SWOG 1201
A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer
Key Eligibility:
- Unresectable advanced or metastatic histologically or cytologically confirmed adenocarcinoma of the esophagus, stomach, or gastroesophageal junction (GEJ)
- HER-2 negative
For more information: NCT01498289

PANCREATIC
EACRI CRIT
Phase 1 Trial of Chemoimmunotherapy and Hypofractionated Radiation Therapy for Borderline Resectable and Locally Advanced Pancreatic Adenocarcinoma
Key Eligibility:
- Pancreatic adenocarcinoma proven by cytology or biopsy
- Locally advanced, unresectable disease with absence of distant metastatic disease OR borderline resectable disease
For more information: NCT01903083

RTOG 0848
A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma
Key Eligibility:
- Histologic proof of primary head of pancreas invasive adenocarcinoma managed with a potentially curative resection
- Enrollment must occur 21-56 days after surgical resection of the pancreas
For more information: NCT01013649

ACOSOG Z5041
A Phase II Study of Preoperative Gemcitabine and Erlotinib Plus Pancreatectomy and Postoperative Gemcitabine and Erlotinib for Patients with Operable Pancreatic Adenocarcinoma
Key Eligibility:
- Cytologic or histologic proof of adenocarcinoma of the pancreatic head or uncinate process
- Localized, potentially resectable tumors
For more information: NCT00733746
**RECTAL (STAGE II/III)**

**NCCTG N1048**
A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

**Key Eligibility:**
- Rectal adenocarcinoma, measurable or clinically evaluable disease
- Candidate for sphincter-sparing surgical resection prior to neoadjuvant therapy
- Preoperative proctoscopy with distal end of tumor tissue evident between 5 and 12 cm from the anal verge

For more information: [NCT01515787](https://clinicaltrials.gov/ct2/show/NCT01515787)

**HEPATOCELLULAR CARCINOMA**

**BMS CA209040**
A Phase I Dose Escalation Study to Investigate the Safety, Immunoregulatory Activity, Pharmacokinetics, and Preliminary Antitumor Activity of Anti-Programmed-Death-1 (PD-1) Antibody (BMS-936558) in Advanced Hepatocellular Carcinoma in Subjects with or without Chronic Viral Hepatitis

**Key Eligibility:**
- Unresectable hepatocellular carcinoma
- Histological confirmation of hepatocellular carcinoma.
- Child pugh A or B7

For more information: [NCT01658878](https://clinicaltrials.gov/ct2/show/NCT01658878)

**GASTROINTESTINAL CANCER CONTROL AND PREVENTION TRIALS**

**SWOG 0702**
A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

**Key Eligibility:**
- Participants must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease
- All participants must be planning to receive zoledronic acid for metastatic bone disease within 30 days after registration
- Participants must not have a pre-existing diagnosis of ONJ

For more information: [NCT00874211](https://clinicaltrials.gov/ct2/show/NCT00874211)
URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651
GENITOURINARY CANCER TRIALS

Contact Research Nurse Scot Lary at: 503-215-2604, john.lary@providence.org

PROSTATE
RTOG 0815
A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer

Key Eligibility:
- Histologically confirmed adenocarcinoma of the prostate diagnosed within the past 6 months and at intermediate-risk for recurrence by meeting =>1 of the following criteria:
  - Gleason score 7
  - PSA >10, and <= 20 ng/mL, Clinical stage T2b or T2c disease
- If patients have all 3 intermediate-risk factors then no more than 50% of the biopsy cores can be positive for cancer

For more information: NCT00936390

EACRI OX40 PROSTATE
Phase Ib Study of Monoclonal Antibody to OX40, Cyclophosphamide (CTX) and Radiation in Patients with Progressive Metastatic Prostate Cancer After Systemic Therapy

Key Eligibility:
- Patients with measurable or evaluable metastatic adenocarcinoma of the prostate. Either histologic or cytologic diagnosis is acceptable
- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1, or 2
- Confirmed radiographic and/or PSA progression (using PCWG2 definitions) after at least one androgen ablation regimen and docetaxel
- At least one bone metastatic lesion amenable to radiation

For more information: NCT01303705

RTOG 0924
Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial

Key Eligibility:
- Histologically or cytologically proven diagnosis of prostatic adenocarcinoma within 180 days of registration at moderate- to high-risk for recurrence as determined by one of the following:
  - Gleason score 7-10 + T1c-T2b (palpation) + prostate-specific antigen (PSA) <50 ng/mL
  - Gleason score 6 + T2c-T4 (palpation) or > 50% (positive) biopsies + PSA < 50 ng/ml
  - Gleason score 6 + T1c-T2b (palpation) + PSA > 20 ng/ml
- Clinically negative lymph nodes as established by imaging (pelvic and/or abdominal CT or MR), (but not by nodal sampling, or dissection) within 90 days prior to registration

For more information: NCT01368588
CALGB 90203
Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer

Key Eligibility:
- Open at the following locations: Clackamas Radiation Oncology Center, Compass Oncology, PeaceHealth Southwest Medical Center, Providence Alaska Medical Center, Providence Milwaukie Hospital, Providence Newberg Medical Center, Providence Portland Medical Center, Providence St. Vincent Medical Center, Providence Willamette Falls Medical Center
- Histologically confirmed adenocarcinoma of the prostate (No small cell, neuroendocrine, or transitional cell carcinoma accepted)
- Clinically localized, stage T1-3 (High-risk disease, meeting 1 of the following criteria: 1. Probability of biochemical progression-free survival at 5 years after surgery < 60% by Kattan nomogram prediction, 2. Biopsy Gleason score 8 to 10

For more information: NCT00430183

RENAI
XL184–308
A Phase 3, Randomized, Controlled Study of Cabozantinib (XL184) vs Everolimus in Subjects with Metastatic Renal Cell Carcinoma that has Progressed after Prior VEGFR Tyrosine Kinase Inhibitor Therapy

Key Eligibility:
- Documented histological or cytological diagnosis of renal cell cancer with a clear-cell component.
- Measurable disease
- Karnofsky Performance Status (KPS) score of ≥ 70%

For more information: NCT01865747

PROMETHEUS PROCLAIM
Proleukin® Observational Registry to Evaluate the Treatment Patterns and Clinical Response in Malignancy

Key Eligibility:
- Planned to receive at least one course of HD IL-2 and must receive at least one dose of HD IL-2

For more information: NCT01415167
Argos ADAPT AGS-003-007
An International Phase III Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)

Key Eligibility:
- Advanced measurable metastatic disease that can be monitored throughout the course of the study participation per RECIST
- Candidates for a first-line therapy initiating with sunitinib with time from diagnosis to treatment < 1 year
- Scheduled for unilateral or partial nephrectomy at which time, tumor tissue will be collected

For more information: NCT01582672

Cytokine Working Group/Univ. of Pittsburgh IIT11PLK01
Inhibiting the Systemic Autophagic Syndrome – A Phase II Study of Hydroxychloroquine and Aldesleukin in Renal Cell Carcinoma Patients (RCC). A Gytokine Working Group (CWG) Study

Key Eligibility:
- Histologically confirmed metastatic renal cell carcinoma with predominantly clear cell histology and with measurable disease.
- Karnofsky PS ≥ 80%
- No prior IL-2

For more information: NCT01550367

GENINTOURINARY CANCER CONTROL AND PREVENTION TRIALS
URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651
GYNECOLOGIC CANCER TRIALS

Contact Research Nurse Brenda Fisher at: 503-215-2613, brenda.fisher@providence.org

Epithelial Ovarian

CANVAS Temporarily Closed

Placebo controlled trial of Cvac (Autologous Dendritic cells pulsed with Recombinant Human Fusion Protein [Mucin 1-Glutathione S-Transferase] coupled to Oxidized Polymannose) as Maintenance treatment in patients with Epithelial Ovarian Cancer (EOC) in complete remission following first-line chemotherapy

Key Eligibility:
- Females, 18 years or older
- A confirmed diagnosis of Stage III or IV epithelial ovarian, primary peritoneal, or fallopian tube cancer
- Undergone optimal debulking surgery
- Eligible for standard platinum and taxane first-line chemotherapy
- Mucin 1-positive tumor as determined by central immunohistopathology
- Adequate renal, liver and bone marrow function

For more information: NCT01521143

GOG 0258

A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma

Key Eligibility:
- Open at the following locations: Clackamas Radiation Oncology Center, Compass Oncology, PeaceHealth Southwest Medical Center, Providence Portland Medical Center, Providence St. Vincent Medical Center
- Histologically confirmed endometrial carcinoma, including the following cell types (Clear cell carcinoma, Serous papillary carcinoma, Undifferentiated carcinoma)
- Surgical stage III or IVA disease per FIGO2009 staging criteria. Surgical stage I or II endometrial clear cell or serous papillary carcinoma with positive peritoneal cytology per FIGO 2009 staging criteria
- Has undergone optimal surgical debulking that included a hysterectomy and bilateral salpingo-oophorectomy within the past 8 weeks (Residual tumor after surgery (any single site) ≤ 2 cm in maximum dimension)

For more information: NCT00942357
GYNECOLOGIC CANCER CONTROL AND PREVENTION TRIALS

URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:

- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651
HEMATOLOGIC CANCER TRIALS

Contact Research Nurse Laurie Delanty at: 503-216-3067 or 503-215-2492, laurie.delanty@providence.org

LYMPHOMA

BMS CA186-017
A Phase 1b, Open-label, Multicenter Study of Urelumab (BMS-663513) in Combination with Rituximab in Subjects with relapsed / refractory B-Cell Malignancies

Key Eligibility:
- Relapsed/refractory CD20+ B Cell malignancies (DLBCL, FL, MZL, Mantle Cell, Burkitts, CLL, SLL)
- Up to 4 prior therapies allowed
- FL and DLBCL patients must have one tumor site that can be biopsied by fine needle aspiration (FNA). The tumor site must not have received radiation therapy).

For more information: NCT01775631

SWOG S1001
A Phase II Trial of PET-Directed Therapy for Limited Stage Diffuse Large B-Cell Lymphoma (DLBCL)

Key Eligibility:
- DLBCL, stage I or II, CD 20+ non-bulky disease – biopsy proven
- IF stage 1 or 2 based on CT, but upstaged to 3 or 4 on FDG-PET are also eligible
- No prior chemotherapy or radiation therapy

For more information: NCT01359592

LEUKEMIA - ACUTE MYELOID

ECOG E2906 – OPENING SOON
A phase 3 randomized trial of Clofarabine as Induction and post-remission therapy vs. standard Daunorubicin and Cytosine Arabinoside and intermediate dose Cytosine Arabinoside post-remission therapy, followed by Decitabine Maintenance vs. observation in newly diagnosed Acute Myeloid Leukemia (AML) in older adults (age greater than or equal to 60 years)

Key Eligibility:
- Circulating blasts > 109/L, no blastic transformation of chronic myelogenous leukemia
- No APL or CNS involvement or prior MDS therapy (Decitabine, Cytarabine, Azactidine
- Candidate for intensive chemo based on peripheral blood or bone marrow aspirate < 2 wks

For more information: NCT01041703
Celator CTLR0310-301
Phase III, Multicenter, randomized trial of CPD351 (Cytarabine:Daunorubicin) Liposome injection vrs Cytarabine and Daunorubicin in patients 60-75 years of age with untreated high risk (secondary) AML
Key Eligibility:
- Bone marrow documentation of MDS prior to AML or CMML and Fish/cytogenetic link to MDS
- No APL, CNS, History of Wilson’s Dz, copper metabolism disorder
- Cumulative anthracycline exposure > 368 mg/m² excluded

For more information: NCT01696084

SWOG S1203
Randomized, Phase III trial of Cytarabine and Daunorubicin Hydrochloride or Idarubicin and Cytarabine with or without Vorinostat in treating younger patients with previously untreated Acute Myeloid Leukemia
Key Eligibility:
- Newly diagnosed and < 60 yrs of age
- No induction chemo for AML or MDS or valproic acid use
- No APL, FAB, M3 or blastic transformation of CML
- Inpatient chemotherapy with option of allogeneic transplant following induction or consolidation

For more information: NCT01802333

LEUKEMIA - CHRONIC MYELOID
BMS CA186-017 TEMPORARILY CLOSED; WILL RE-OPEN ON OCTOBER 21ST
A Phase 1b, Open-label, Multicenter Study of Urelumab (BMS-663513) in Combination with Rituximab in Subjects with relapsed / refractory B-Cell Malignancies
Key Eligibility:
- Relapsed/refractory CD20+ B Cell malignancies (DLBCL, FL, CLL)
- Up to 4 prior therapies allowed
- FL and DLBCL patients must have one tumor site that can be biopsied by fine needle aspiration (FNA). The tumor site must not have received radiation therapy.

For more information: NCT01775631
**MYELODYSPLASTIC SYNDROMES/CHRONIC MYELOMONOCYTIC LEUKEMIA**

**SWOG S1117**

A Randomized Phase II Study of Azacitidine in Combination With Lenalidomide vs. Azacitidine Alone vs. Azacitiditine in Combination With Vorinostat for Higher-Risk Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML)

**Key Eligibility:**
- Refractory anemia with 5-20% myeloblasts in marrow or (CMML) 10-19% myeloblasts in marrow or 5-19% in blood
- No prior Lenalidomide, Azacitidine, Vorinostat, Decitabine, chemo or RT <= 12 months
- No prior stem cell or bone marrow transplantation at any time

For more information: [NCT01522976](https://clinicaltrials.gov/ct2/show/NCT01522976)

**FOLLICULAR LYMPHOMA**

**ROCHE-GNE BO21223**  *(THIS TRIAL WILL CLOSE IN NOVEMBER 2013.)*

A multicenter, Phase III, open-label, randomized study in previously untreated patients with advanced indolent non-Hodgkin’s lymphoma evaluating the benefit of GA101 (RO5072759) plus chemotherapy compared with rituximab plus chemotherapy followed by GA101 or rituximab maintenance therapy in responders

**Key Eligibility:**
- Stage III or IV disease, or Stage II bulky disease
- Histologically documented, CD20+, indolent B-cell NHL consisting of follicular lymphoma (Grades 1-3a)
- Must have (1): Bulky disease >= 7 cm, B symptoms, symptomatic extranodal dx, cytopenias, >= 3 nodal site involvement (diameter >= 3 cm) or symptomatic splenic enlargement

For more information: [NCT01332968](https://clinicaltrials.gov/ct2/show/NCT01332968)

**MANTLE CELL LYMPHOMA**

**E1411**

Intergroup randomized phase 2 four arm study in patients >= 60 years with previously untreated Mantle Cell Lymphoma of therapy with Arm A: Rituximab, Bendamustine Hydrochloride, and Bortezomib followed by Rituximab Consolidation; Arm B: Rituximab, Bendamustine, Bortezomib followed by Rituximab consolidation; Arm C: Rituximab, Bendamustine followed by Lenalidomide and Rituximab consolidation or Arm D: Rituximab, Bendamustine, Bortezomib followed by Lenalidomide and Rituximab consolidation

**Key Eligibility:**
- Stage III/IV or bulky stage II
- Age >= 60 yrs with measureable disease and no CNS involvement
- If randomized to Arms C or D, and proceed onto Arms G or H, they will register into the mandatory RevAssist program
- No prior chemotherapy

For more information: [NCT01415752](https://clinicaltrials.gov/ct2/show/NCT01415752)
MULTIPLE MYELOMA – NEWLY DIAGNOSED
SWOG S1211 TEMPORARILY CLOSED
Bortezomib, Dexamethasone, and Lenalidomide with or without Elotuzumab in treating patients with newly diagnosed high risk multiple myeloma

Key Eligibility:
• Patients must have newly diagnosed active multiple myeloma (MM)
• Patients with non-secretory MM or known amyloidosis are not eligible
• Patients must have measurable disease within 28 days prior to registration

For more information: NCT01668719

ECOG E3A06
A Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic Smoldering Multiple Myeloma

Key Eligibility:
• Diagnosis of smoldering multiple myeloma (MM) meeting the following criteria: asymptomatic high-risk disease; bone marrow plasmacytosis with ≥ 10% plasma cells or sheet of plasma cells by bone marrow aspiration and/or biopsy; abnormal serum free-light chain (FLC) ratio (< 0.125 or > 8.0) by serum FLC assay; no baseline bone lesions or plasmacytomas; no monoclonal gammopathy of undetermined significance; no immediate need for chemotherapy
• M protein > 1.0 serum, > 10% plastma cells, abn serum FLC ration
• No bone lesions, plasmacytomas or monoclonal gammopathy
• No immediate need for treatment
• Bone marrow biopsy MUST be completed at Providence Portland Medical Center (due to processing requirements). Study treatment can then resume with original provider/clinic.

For more information: NCT01169337

HEMATOLOGIC CANCER CONTROL AND PREVENTION AND PREVENTION TRIALS
SWOG S0702
A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

Key Eligibility:
• Participants must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease
• All participants must be planning to receive zoledronic acid for metastatic bone disease within 30 disease after registration
• Participants must not have a pre-existing diagnosis of ONJ

For more information: NCT00874211
URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue
Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651

URCC 10055
Assessment of the Cognitive Function in Breast Cancer and Lymphoma Patients Pre-Treatment, Post-Treatment, and at 3 Month Follow-up
Key Eligibility:
- Participants must have a diagnosis of invasive breast cancer (stage I-IIIc) or intermediate or high-grade lymphoma
- Participants must be chemotherapy naïve
- Participants must be scheduled to begin a course of chemotherapy (oral chemotherapy is acceptable). Previous or concurrent treatment with hormones or biological response modifiers is acceptable

For more information: NCT01382082
LUNG CANCER TRIALS

Contact Research Nurse Brenda Fisher at: 503-215-2613, brenda.fisher@providence.org

NON-SMALL CELL LUNG CANCER

SURGICAL

CALGB 140503
A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (<=2 cm) Peripheral Non-Small Cell Lung Cancer

Key Eligibility:
- Suspected or proven Non-Small Cell Lung Cancer (NSCLC), meeting both preoperative and intraoperative criteria: Preoperative criteria, Peripheral lung nodule =<2 cm by CT scan. Center of the tumor must be located in the outer third of the lung in either the transverse, coronal, or sagittal plan. Tumor location must be suitable for either lobar or sublobar resection (wedge resection or segmentectomy). No pure ground opacities or pathologically confirmed N1 or N2 disease. Intraoperative criteria: Histologically confirmed NSCLC.
- Confirmation of N0 status by frozen section examination of nodal levels 4, 7, and 10 on the right side and 5, 6, 7, and 10 on the left side* Levels 4 and 7 nodes may be sampled by mediastinoscopy or at the time of thoracotomy or video-assisted thoracoscopic surgery (VATS) exploration* [Note: *Nodes previously sampled by mediastinoscopy either immediately prior to or within 6 weeks of the definitive surgical procedure (thoracotomy or VATS) do not need to be resampled]

For more information: NCT00499330

ADJUVANT

UbiVac DRibble
Randomized Phase II Trial of Cyclophosphamide with Allogeneic Non-small Cell Lung Cancer (NSCLC) DRibble Vaccine alone or with Granulocyte-Macrophage Colony-Stimulating Factor or Imiquimod for Adjuvant Treatment of Definitively-Treated Stage IIIA or IIIB NSCLC

Key Eligibility:
- Completed curative intent treatment for stage IIIA or IIIB NSCLC
- Archived tissue required for eligibility

For more information: NCT01909752

FIRST LINE STAGE IV

CRAB RAD001
Phase I Dose Escalation Study of Everolimus, Pemetrexed, Carboplatin, and Bevacizumab in Stage IV Non-Squamous Non-Small Cell Lung Cancer

Key Eligibility:
- Lung DLCO >80%
- Treated brain mets allowed

For more information: NCT01700400
SWOG 0819
A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab With or Without Concurrent Cetuximab in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC)

Key Eligibility:
- Open at the following locations: Clackamas Radiation Oncology Center, Compass Oncology, PeaceHealth Southwest Medical Center, Providence Milwaukie Hospital, Providence Newberg Medical Center, Providence Portland Medical Center, Providence St. Vincent Medical Center, Providence Willamette Falls Medical Center
- Histologically or cytologically confirmed non-small cell lung cancer (NSCLC)
- Newly diagnosed stage IV disease OR recurrent disease after prior surgery and/or irradiation. NO prior chemotherapy for any stage NSCLC

For more information: NCT00946712

SECOND LINE STAGE IV
BI 1200.125 (12-122B)
A randomized, open-label Phase III trial of afatinib versus erlotinib in patients with advanced squamous cell carcinoma of the lung as second-line therapy following first-line platinum-based chemotherapy

Key Eligibility:
- Diagnosis of advanced stage NSCLC considered to be squamous histology, including mixed histology, in the opinion of the investigator, and eligible for EGFR-directed therapy in 2nd line setting. (tissue either fresh or archived available.)

For more information: NCT01523587

AT13387-05
A Study of HSP90 Inhibitor AT13387 Alone or in Combination with Crizotinib in the Treatment of Non-small Cell Lung Cancer (NSCLC)

Key Eligibility:
- Have a histologically or cytologically confirmed NSCLC that is ALK+ or has other mutations or rearrangements that are potentially sensitive to crizotinib and have been receiving or have received crizotinib.
- Good cardiac function (QTc <450msec and LVEF >/=50%) and has not had greater than grade 2 visual disturbance while receiving crizotinib treatment.

For more information: NCT01712217
Lilly I4C-MC-JTBC
A Randomized, Open-Label Phase 2 Study Evaluating LY2875358 Plus Erlotinib and LY2875358 Monotherapy in MET Diagnostic Positive NSCLC Patients with Acquired Resistance to Erlotinib
Key Eligibility:
- Molecular evidence of an activating EGFRmt known to be associated with EGFR TKI drug sensitivity or show clinical benefit ≥ or equal to 6 months on erlotinib.
- MET positive tissue and able to undergo biopsy after showing erlotinib progression.
For more information: NCT01900652

SMALL CELL LUNG CANCER (SCLC)
BMS CA 184-156
Randomized, Multicenter, Double-Blind, Phase 3 Trial Comparing the Efficacy of Ipilimumab plus Etoposide/Platinum versus Etoposide/Platinum in Subjects with Newly Diagnosed Extensive-Stage Disease Small Cell Lung Cancer
Key Eligibility:
- Subjects with extensive SCLC documented by histology or cytology from brushing, washing or needle aspiration of a defined lesion but not from sputum cytology alone
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
For more information: NCT01450761

MESOTHELIOMA
CALGB 30901
Randomized phase II study of maintenance pemetrexed versus observation for patients with malignant pleural mesothelioma without progression after first-line chemotherapy
Key Eligibility:
- Histologically confirmed malignant pleural mesothelioma meeting 1 of the following cell types: Epithelial, Sarcomatoid, Mixed type and with complete, partial or stable disease after completion of 4 cycles of first line platinum plus pemetrexed.
For more information: NCT01085630
LUNG CANCER CONTROL AND PREVENTION TRIALS
SWOG 0702
A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

Key Eligibility:
- Participants must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease
- All participants must be planning to receive zoledronic acid for metastatic bone disease within 30 disease after registration
- Participants must not have a pre-existing diagnosis of ONJ

For more information: NCT00874211

URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651
**MELANOMA TRIALS**

Contact Research Nurse Chris Fountain at: 503-215-2691, [christopher.fountain@providence.org](mailto:christopher.fountain@providence.org)

**BMS CA209067**
A Phase 3, Randomized, Double-Blind Study of Nivolumab Monotherapy or Nivolumab Combined with Ipilimumab Versus Ipilimumab Monotherapy in Subjects with Previously Untreated Unresectable or Metastatic Melanoma

**Key Eligibility:**
- Histologically confirmed Stage III (unresectable) or Stage IV melanoma
- Measurable disease by CT or MRI per RECIST 1.1 criteria
- Archival or fresh tissue for PDL-1 expression used for stratification
- No prior treatment for metastatic disease

For more information: [NCT01844505](https://clinicaltrials.gov/ct2/show/NCT01844505)

**Viralytics VLA-007**
A Phase 2 Study of the Efficacy and Safety of Intratumoral CAVATAKTM (Coxsackievirus A21, CVA21) in Patients with Stage IIIc and Stage IV Malignant Melanoma

**Key Eligibility:**
- Histologically confirmed Stage III (unresectable) or Stage IV melanoma.
- Measurable disease by CT or clinical measurements per RECIST 1.1 criteria.
- Treatment naïve or progressed on 1 prior therapy
- Visceral metastasis not greater than 10 cm and no more than 3 visceral lesions (excluding lung lesions)

For more information: [NCT01227551](https://clinicaltrials.gov/ct2/show/NCT01227551)

**GSK BRF115532**
A phase III randomized double blind study of dabrafenib (GSK2118436) in COMBInation with trametinib (GSK1120212) versus two placebos in the ADjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after

**Key Eligibility:**
- Completely resected histologically confirmed high-risk Stage IIIa, IIIb or IIIc
- Must be surgically rendered free of disease no more than 12 weeks before randomization
- BRAF V600E/K mutation positive
- No prior systemic anti-cancer treatment (chemotherapy, immunotherapy, biologic therapy, vaccine therapy, or investigational treatment) or radiotherapy for melanoma allowed.

For more information: [NCT01682083](https://clinicaltrials.gov/ct2/show/NCT01682083)
**Alliance A091201**
Randomized Phase II Study Comparing the MET Inhibitor Cabozantinib to Temozolomide/Dacarbazine in Ocular Melanoma

**Key Eligibility:**
- Prior therapies allowed, except for those treatments directed toward, or with activity against, c-Met or VEGF/R, and the chemotherapy agents temozolomide and dacarbazine
- Patients must have experienced disease progression on their prior therapy in the opinion of the treating investigator.

For more information: [NCT01835145](https://clinicaltrials.gov/ct2/show/NCT01835145)

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**E1609**
A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon α-2b for Resected High-risk Melanoma

**Key Eligibility:**
- Diagnosis of melanoma of a cutaneous origin or unknown primary.
- No ocular melanoma or melanoma of mucosal origin.
- Resected Stage IIIB, IIIC, or IV (M1a or M1b) disease

For more information: [NCT01274338](https://clinicaltrials.gov/ct2/show/NCT01274338)

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**EACRI SBRT/IL-2**
Phase II Randomized Study of High Dose Interleukin-2 Versus Stereotactic Body Radiation (SBRT) and High Dose Interleukin-2 (IL-2) in Patients with Metastatic Melanoma

**Key Eligibility:**
- Histological confirmation of melanoma will be required by previous biopsy or cytology.
- Tumors amenable to SBRT in lungs, mediastinum, chest wall, bones (other than long bones), or liver (inclusive of immediately adjacent masses), 1 – 3 foci; no minimum size, but none greater than 7 cm. Patients may have other metastases but only a maximum of 3 will be treated.
- ECOG performance status of 0-1.

For more information: [NCT01416831](https://clinicaltrials.gov/ct2/show/NCT01416831)
IL-2 SELECT BIOSPECIMEN COLLECTION
The High-Dose Aldesleukin (IL-2) “SELECT” Trial: A Prospective Tissue Collection Protocol to Investigate Predictive Models of Response to High Dose IL-2 Treatment in Patients with Advanced Melanoma

Key Eligibility:
- Patients must have histologically confirmed malignant melanoma that is metastatic or unresectable.
- Patients must be eligible to receive high-dose IL-2 per institutional guidelines.
- Patients must have a tissue block available with adequate tumor to perform RNA extraction and DASL analysis (Patients with only a previous fine needle aspirate are ineligible for enrollment).

For more information: NCT01288963

PROMETHEUS 12PLK01
A Multi-Center Study of High Dose Aldesleukin (Interleukin-2) + Vemurafenib Therapy in Patients with BRAFV600 Mutation Positive Metastatic Melanoma

Key Eligibility:
- Confirmed and measurable metastatic melanoma with the BRAF V600E mutation.
- Patients with at least one metastatic melanoma lesion accessible for biopsy prior to vemurafenib treatment if no archived tissue is available.
- Meet the requirements for HD IL-2 therapy per institutional guidelines.
- Meet the requirements for vemurafenib therapy per institutional guidelines.

For more information: NCT01683188

BMS CA209037
A Randomized, Open-Label Phase 3 Trial of BMS-936558 versus Investigator’s Choice in Advanced (Unresectable or Metastatic) Melanoma Patients Progressing Post Anti-CTLA-4 Therapy

Key Eligibility:
- Histologically confirmed Stage III (unresectable) or Stage IV melanoma.
- Measurable disease by CT or MRI per RECIST 1.1 criteria.
- A pre-treatment fresh core or excision tumor biopsy (no punch biopsies) must be provided for PD-L1 status determination prior to randomization and for exploratory biomarker analyses
- Prior ipilimumab and BRAF inhibitor treatment ( unless wild type )

For more information: NCT01721746
MELANOMA CANCER CONTROL AND PREVENTION
SWOG 0702
A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment

Key Eligibility:
- Participants must have bone metastasis from multiple myeloma, solid tumors, or other malignancy for which intravenous bisphosphonate has clinical indications in the treatment of metastatic bone disease
- All participants must be planning to receive zoledronic acid for metastatic bone disease within 30 days after registration
- Participants must not have a pre-existing diagnosis of ONJ

For more information: NCT00874211

URCC 0701
A Study of the Effects of Exercise on Cancer-Related Fatigue

Key Eligibility:
- Participants must have a primary diagnosis of cancer other than leukemia, with no distant metastasis
- Participants must be chemotherapy naïve
- Participants must be starting chemotherapy treatments for cancer and be scheduled for at least 6 weeks of treatments with treatment cycles of either 2 or 3 or 4 weeks. Oral chemotherapy is acceptable

For more information: NCT00924651
PHASE I TRIALS FOR MULTIPLE CANCER TYPES

Contact Research Nurse Scot Lary at: 503-215-2604, john.lary@providence.org

T09-10644 (Tactical CTO)
A Phase I Study of Oral Carboxyamidotriazole Orotate (CTO) Titrated as a Single Agent in Patients with Advanced or Metastatic Solid Tumors and Titrated in Combination Therapy with Temodar® in Patients with Glioblastoma Multiforme

Key Eligibility:
- For current phase of study: Patients must have histologically-confirmed advanced or metastatic solid tumors that are refractory after standard therapy, or for which no standard therapy exists.
- ECOG status of 0-2
- For upcoming phase of study: Patients must have histologically proven intracranial malignant glioblastoma multiforme

For more information: NCT01107522

BMS CA223-001
A Phase I Dose Escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-KIR (BMS-986015) Administered in Combination with Anti-PD-1 (BMS-936558) in Advanced Refractory Solid Tumors

Key Eligibility:
- Subjects must have histologic or cytologic confirmation of a solid malignancy that is advanced (metastatic and/or unresectable)
- Measurable disease
- ECOG status of 0 or 1

For more information: NCT01714739

SWOG S1221
Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib in Patients with BRAF Mutant Cancer

Key Eligibility:
- For current phase of study: Patients must have BRAFV600 mutant metastatic cancer irrespective of the histology or prior therapy. For upcoming phase of study: Patients must have Stage IIIIC or IV melanoma with BRAFV600 mutation
- Must have locally advanced unresectable Stage IIIIC or metastatic Stage IV cancer with either progression to prior therapy or a newly diagnosed cancer that does not have an available treatment with curative intent.
- May have received prior systemic therapy (chemotherapy, immunotherapy, biologic therapy, or combination regimens). Patients progressing on a prior BRAF inhibitor-based therapy are eligible.

For more information: NCT01902173
BMS CA224-020 Opening Soon
A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination with Anti-PD-1 Monoclonal Antibody Nivolumab, BMS-936558) in Advanced Solid Tumors

Key Eligibility:
• Subjects must have histologic or cytologic confirmation of a solid malignancy that is advanced (metastatic and/or unresectable)
• Measurable disease
• ECOG status of 0 or 1