



~ june

| TRIAL ID | TITLE | MAIN ELIGIBILITY |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BREAST | | |
| Adjuvant | | |
| Roche - BIG-04-11 / BO25126 Genentech-TOC4939g APHINITY | A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2- positive primary breast cancer-APHINITY | Invasive carcinoma, node + pts any pT except T0, for node negative tumor must be >1.0 cm or for tumors 0.5-1.0cm pts need to be grade 3 or ER and PR negative or age<35 yrs [pts with tumors 1.0cm or less will be limited to <10% of total], interval btwn Sx and randomization must be at least 3 wks but no more than 7 wks, LVEF≥55%, central confirmation of HER2. Exclusion: any prior ipsi and/or contralateral breast CA, any clinical T4 tumor including inflammatory, any node (-) tumor ≤0.5cm, any prior chemotherapy (neoadjuvant) |
| Amgen – 20060359 V-10-004 D-CARE | Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of Denosumab as Adjuvant Tx for Women with Early-Stage Breast Cancer at High Risk of Recurrence. <u>Only Open at the 3 Main Sites & BMC-South</u> Orange Park, Southside, St. Vincent's, BMC-S | Stage II or III Breast Cancer with a high risk of recurrence: Biopsy evidence of breast cancer in regional lymph nodes (N+); Tumor size > 5 cm (T3) or locally advance disease (T4); must be receiving or scheduled to receive standard of care adjuvant or neoadjuvant chemo and/or endocrine and/or HER-2 targeted therapy. Time between definitive surgery & randomization must be ≤ 8 wks. Time between start of neoadjuvant & randomization must be ≤ 4 wks. |
| Galena Biopharma – PH3-01 / RXIP1778 V-11-008 PRESENT | Prevention of Recurrence in Early Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment | invasive adenocarcinoma, surgical tx: total mastectomy OR BCS & axillary staging, node positive disease (pN1 or pN2), tumor stage T1-3, HER2 ICH 1+ or 2+ (2+ confirmed by FISH as negative), complete chemo neoadj, adj or both of at least 4 cycles, no more than 2mo +/-7days from last chemo/XRT to time of first tx, HLA-A2 or HLA-A3 haplotype (central test) Exclusionary: inflammatory CA, bilateral malignancy, prior DCIS, Stage T4, nodes clinical N2 or N3 or pN3, concurrent tx with invest agent |
| 1st, 2nd or 3rd Line Metastatic | | |
| Eisai-208 / v-10-008 | A Phase 2, Multicenter, Single-Arm, Open-Label Study of Eribulin Mesylate with Trastuzumab as First-Line Therapy for Locally Recurrent or Metastatic Human Epidermal Growth Factor Receptor Two Positive (HER 2 +) Breast Cancer | Breast adenocarcinoma, locally recurrent or metastatic with 1 measurable lesion of ≥1.5cm, 12 wks since (neo)adjuvant tx, prior endocrine therapy permitted, 1 prior tx herceptin/ lapatinib in metastatic setting allowed if not given w/ chemo |
| Genentech BO25734/TDM4997g TH3RESA | A Phase III Randomized, Multicenter, Two-Arm, Open-Label Trial to Evaluate the Efficacy of T-DM1 Compared w/ Treatment of Physician's Choice in Pts w/ <u>HER2-Positive Metastatic Breast Cancer</u> Who've Rec'd at Least 2 Prior Regimens of HER2-Directed Therapy <u>Only Open at: Orange Park, Southside, St. Vincent's, BMC-Beaches, North & South</u> | HER2 +, central testing required for study entry, disease progression on last regimen, prior tx with anthracycline, trastuzumab, taxane, lapatinib, and capecitabine in neoadj, adj, locally adv or recurrent/metastatic setting, documented progression after at least 2 regimens of HER2 directed tx, a min of 6 weeks prior trastuzumab, pts with documented toxicity to lapatinib can be eligible, LVEF≥ 50%. |

| TRIAL ID | TITLE | MAIN ELIGIBILITY |
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| COLORECTAL | | |
| 1st Line Metastatic | | |
| Genentech (ML25710) MAVERICC | A Randomized Phase 2 Study of Bevacizumab/mFOLFOX6 vs. Bevacizumab/FOLFIRI With Biomarker Stratification In Patients With Previously Untreated Metastatic Colorectal Cancer | Histologically confirmed CRC, measurable disease per RECIST 1.1, archival or fresh biopsy tissue available for submission. Exclusion: prior systemic treatment for metastatic CRC, adjuvant chemo completed <12mos prior, full dose anticoagulation, HTN (>150/100) |
| 2nd Line Metastatic | | |
| Lilly I4T-MC-JVBB | A Randomized, Double-Blind, Multicenter Phase 3 Study of Irinotecan, Folinic Acid, and 5-Fluorouracil (FOLFIRI) Plus Ramucirumab (IMC-1121B) Drug Product of Placebo in Patients with Metastatic Colorectal Carcinoma Progressive Following 1st-Line Combination Therapy with Bevacizumab, Oxaliplatin, and a Fluoropyrimidine | Metastatic CRC, received FOLFOX+bev 1st line & progressed on tx or within 6 mo last dose, measurable or non-measurable disease by RECIST, rec'd a minimum 2 doses of bevacizumab w/ 1st line tx |
| 3rd Line Metastatic | | |
| Oncothyreon PX-866-003 | Phase 1/2 study of PX-866 and Cetuximab – To determine the maximum tolerated dose (MTD) or recommended Phase 2 dose (RD) of PX-866 to be administered orally once per day in combination w/ cetuximab in patients with incurable metastatic colorectal carcinoma (CRC) or incurable progressive, recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). [phase 2 portion @ ICON] | Metastatic CRC or SCCHN pts with measurable disease per RECIST 1.1, CRC pts: progression after irinotecan and oxaliplatin for metastatic disease (or intolerance). Exclusionary: pts with prior cetuximab or KRAS mutant codon 12/13; cetuximab pts may cross over to PX-866 arm at progression with monitor approval. |
| GASTROESOPHAGEAL | | |
| 2nd or 3rd Line Metastatic | | |
| Lilly/v-10-007 I1Y-MC-JFBF | A phase 2 Indication Identification Study of LY2523355 in Patients with Ovarian, Non-Small Cell Lung , Prostate, Colorectal , Gastroesophageal Cancers, and Squamous Cell Carcinoma of the Head and Neck RE-OPENED ** EXCEPT COLORECTAL & NSCL PATIENTS ** | NSCLC: no more than 2 prior tx, at least 1 prior platinum regimen w/ taxane; Prostate: no more than 2 prior txs, prior regimen w/ docetaxel; Colorectal: at least 2 no more than 3 prior cytotoxic txs; GE: no more than 2 prior txs; SCCN: no more than 2 prior txs; Measurable disease per RECIST 1.1 required (except for prostate pts); ECOG 0-1 |
| HEAD & NECK | | |
| 1st Line & Beyond | | |
| Oncothyreon PX-866-003 | *** SEE STUDY LISTED UNDER COLON HEADING *** | *** SEE STUDY LISTED UNDER COLON HEADING *** |
| 2nd or 3rd Line Metastatic | | |
| Lilly/v-10-007 I1Y-MC-JFBF | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** |

| TRIAL ID | TITLE | MAIN ELIGIBILITY |
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| LUNG CANCER (NON-SMALL CELL) | | |
| 1st Line Metastatic / Maintenance | | |
| Genentech GO27912 | A Phase II, Double blind, placebo controlled, randomized study evaluating the safety and efficacy of carboplatin/paclitaxel and carboplatin/paclitaxel/bevacizumab with and without GDC-0941 in patients with previously untreated advanced or recurrent NSCLC | Squamous or non squamous histology, Tumor tissue for biomarker testing, ECOG 0-1, Measurable disease per RECIST 1.1, FBG <135, HbA1c<7% [non-DM pts], FBG<160, HbA1c<8.5 [DM pts]. Exclusionary: documented EGFR/ALK gene mutation, no prior chemo for Stg IV NSCLC, type I or insulin dep type II DM, Bev exclusions apply for nonsq arms |
| 2nd / 3rd Line Metastatic | | |
| USO 10061 / I4T-MC-JVBA | A Randomized, Double-Blind, Phase 3 Study of Docetaxel and Ramucirumab versus Docetaxel and Placebo in the Treatment of Stage IV Non-Small Cell Lung Cancer Following Disease Progression after One Prior Platinum-Based Therapy | Pts w/ progression on 1 prior platinum regimen (adjuvant or neoadjuvant platinum based tx w/ progression w/in 6 mo.), prior bev (1st line/maintenance) allowed, measurable disease by RECIST 1.1; exclusion for pts w/ > 1 prior tx, pts w/ only prior erlotinib tx, pts on therapeutic anticoag (prophylactic low dose allowed w/ INR criteria) |
| Genentech OAM4971g | A Randomized, Phase III , multi-center, double blind, placebo-controlled study evaluating the safety and efficacy of MetMAB, a monovalent antibody antagonist to the Met receptor, in combination with Tarceva® (erlotinib) in patients with Met high incurable stage IIIB/IV non-small cell lung cancer (NSCLC) who have failed standard therapy for advanced or metastatic disease | Stage IIIB/IV NSCLC, Met diagnostic positive (by central test), radiographic evidence of disease (measurable not mandatory), prior tx w/ 1 prior platinum based treatment and no more than 1 additional tx. Exclusionary: >30 days exposure to EGFR inhibition agent, history of another malignancy w/in 3 years, symptomatic brain metastases. Washout for XRT is 7 days and surgery 14 days; screening ICF for met available |
| LUNG CANCER (SMALL CELL) | | |
| Treatment Naïve – Extensive Stage | | |
| BMS: CA184-156 | Randomized, Multicenter, Double-Blind, Phase 3 Trial Comparing the Efficacy of Ipilimumab Plus Etoposide/Platinum versus Placebo plus Etoposide/Platinum in Subjects with Newly Diagnosed Extensive-Stage Disease Small Cell Lung Cancer (ED SCLC) | SCLC histology or cytology confirmed, extensive stage disease (VALG), ECOG ≤1, Exclusionary: unstable CNS mets, prior systemic for lung cancer, prior XRT is allowed if performed at least 3 weeks prior, any immunotherapy for cancer or non-oncology vaccine therapy for infectious disease |
| LYMPHOMA | | |
| Untreated | | |
| Millennium / CO5013 | An Open-Label, Randomized, Phase 2 Study to Assess the Effectiveness of RCHOP With or Without VELCADE in Previously Untreated Patients with Non Germinal Center B-Cell-like Diffuse Large B-Cell Lymphoma | Treatment naïve DLBCL pts subclassified as non-GCB (path testing req'd), at least 1 measurable mass >1.5cm long axis and >1.0cm short axis, ECOG≤2, LVEF≥45%, Pts excluded for: CNS lymphoma, ≥grade 2 peripheral neuropathy [Local pathologist-Orange Park recently certified for local GCB path testing] |

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| LYMPHOMA continued... | | |
| Relapsed | | |
| GSK OFB114612 | Phase II Open-Label Study of Ofatumumab & Bendamustine Followed by Maintenance Ofatumumab for Indolent B-cell Non-Hodgkin's Lymphoma (B-NHL) Which Has Relapsed after Rituximab Therapy | Small lymphocytic, lymphoplasmacytic, marginal zone and follicular lymphomas (GR 1,2,3a), CD20+ pathology, + response to rituximab (PR/CR) lasting 6 mo from completion of tx, measurable disease [2 lesions ≥ 1.5 cm LD or 1 lesion ≥ 2.0 cm], ECOG 0-2 Exclusionary: previous bendamustine, RIT w/in 6 months, previous allogeneic SC transplant, CNS involvement |
| V-10-027 / PIX 306 | A Randomized, Single-Blind, Multicenter Study Comparing Pixantrone + Rituximab with an Investigator's Choice of Single Agent Rituximab or Gemcitabine + Rituximab in Non-Stem Cell Transplant Eligible Patients with Aggressive B-cell Non-Hodgkins Lymphoma Who Have Relapsed after Therapy wit CHOP-R or an Equivalent Regimen | DLBCL or DLBCL transformed from FL, bone core bx within 8wks randomization, received 1 but no more than 3 prior therapies, received RCHOP or equivalent previously w/ confirmed PR or CR, > 1 measurable (≥ 1.5 cm short axis) nodal site (not previously irradiated), ECOG 0-2, LVEF $\geq 45\%$; pts are excluded w/ CNS or leptomeningeal lymphoma involvement |
| Relapsed / Refractory | | |
| Pfizer B1931008-1273 | An Open-Label, Randomized, Phase 3 Study of Inotuzumab Ozogamicin Administered in Combination with Rituxumab Compared to Defined Investigator's Choice Therapy in Subjects with Relapsed or Refractory CD22-Positive Aggressive Non-Hodgkin Lymphoma Who Are Not Candidates for Intensive High-Dose Chemotherapy | CD20 and CD22+ aggressive NHL [DLBCL, transformed indolent, mediastinal LG B-cell], req'd prior tx w/ rituximab, up to 3 prior cytotoxic regimens allowed, at least 1 measurabel lesion ≥ 1.0 cm in 2 perpendicular dimensions w/ product ≥ 2.25 cm. Exclusionary: LVEF $<50\%$, ECOG 4, QTcF interval >470 msec. 28d washout prior chemo,prior CD22 antibodies or radioimmunotx 6mo washout |
| USO 11107/ SGNoo-001 Seattle Genentics | Screening protocol to detect tumor antigen expression required for enrollment on clinical research protocols of antibody-directed therapy | Failed, refused or been deemed ineligible for standard therapy, Measurable disease; Screening protocol expanded to include NHL pts, testing available starting 3-19-12. Treatment protocol available end March with brentuximab vedotin for CD30+ pts. |
| MULTIPLE MYELOMA | | |
| 1st Line / Phase III (Randomized) | | |
| BMS: CA204-006 | A Phase 3, Randomized, Open Label Trial of Lenalidomide/dexamethasone With or Without Elotuzumab in Ist Line Multiple Myeloma | Newly diagnosed ,untreated, symptomatic, MM; not candidates for high-dose therapy plus SCT AND; Measureable disease: serum IgG, IgA, IgM M-protein ≥ 0.5 g/dL or serum IgD M-protein ≥ 0.05 g/dL or ≥ 200 mg urinary M-protein excretion/24- hr |
| Relapsed Refractory / Phase II | | |
| BMS: CA204-009 | A Phase 2, Randomized Study of Bortezomib/dexamethasone With or Without Elotuzumab in Subjects With Relapsed/Refractory Multiple Myeloma | MM w/ documented prog by IMWG criteria druing most recent tx, ECOG ≤ 2 , measurable disease. Exclusionary: MGUS, smoldering, waldenstroms macroglobulinemia, active plasma cell leukemia, significant cardiac disease, HepA/B/C, HIV, uncontrolled DM, refractory/intolerant to bortezomib. Washout req'd for prior therapies. |

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| MYELODYSPLASTIC SYNDROME | | |
| Relapsed / Refractory / Intolerant | | |
| Onconova 04-21 | A Phase III, Multi-Center, Randomized, Controlled Study to Assess the Efficacy & Safety of ON01910.Na Administered as a 72-hour Continuous Intravenous Infusion Every Other Wk in Myelodysplastic Syndrome Pts w/ Excess Blasts Relapsing after, or Refractory to, or Intolerant to Azacitidine or Decitabine | MDS confirmed w/in 6 weeks pr to entry (WHO/FAB classification), one cytopenia, progression OR failure to achieve CR/PR OR relapse OR intolerance to azacitidine/decitabine w/in past 2 yrs, ECOG 0-2 Exclusionary: hyponatremia (<130mEq/L), ascites req paracentesis, HTN ≥160/110mmHg, prior low dose cytarabine w/in 2 yrs |
| Thrombocytopenia (AML or MDS) | | |
| GSK - ASPIRE TRC114968 ON HOLD Until MAY / JUNE | A Three-part Study of Eltrombopag in Thrombocytopenic Subjects with Myelodysplastic Syndromes or Acute Myeloid Leukemia (Part 1: open-label, Part 2: randomized, double-blind, Part 3: extension). ASPIRE: A Study of EltromboPag In Myelodysplastic SyndRomes and Acute Myeloid Leukemia | MDS or AML dx (≤50% bone marrow blasts) , Gr4 thrombo-cytopenia (PLT<25) or requirement for transfusions, in last 4 wks pts must have had PLT transfusion, symptomatic bleeding or PLT<10; prior systemic treatment washout 4 weeks, supportive care tx allowed. Exclusionary: MDS IPSS low or int-1 risk, history of tx with TPO-R agonists, QTc>480msec or >510 with BBB, palpable spleen >16cm, thrombophilic risk factors, HIV, liver cirrhosis |
| NON-LYMPHOMATOUS MALIGNANCIES | | |
| Failed, Refused, or Deemed Ineligible for Standard Therapy | | |
| USO 11107/ SGN00-001 Seattle Genentics | Screening protocol to detect tumor antigen expression required for enrollment on clinical research protocols of antibody-directed therapy | Failed, refused or been deemed ineligible for standard therapy, Measurable disease Exclusionary: Primary diagnosis lymphoma or CNS |
| USO 10328/ SGN35-013 Seattle Genentics | A Phase 2, open-label, single-arm study of brentuximab vedotin in patients with CD30-positive nonlymphomatous malignancies | CD30+ positive determined by SGN00-001, failed, refused or been deemed ineligible for standard tx, Measurable disease (Solid tumor-at least one resectable lesion ≥10mm LD). Exclusionary: Primary diagnosis lymphoma or CNS malignancy, hx invasive primary malignancy not treated or in remission for at least 3 yrs |
| OVARIAN | | |
| 2nd or 3rd Line Metastatic | | |
| Lilly/v-10-007 I1Y-MC-JFBF | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** |
| PANCREATIC | | |
| Opens With 1st Potential Patient, 1st Line | | |
| Pharmacyclics- PCYC-1001 | Phase II Study of Coagulation Factor VIIa Inhibitor PCI-27483 in Pancreatic Cancer Patients Receiving Treatment w/ Gemcitabine | Locally advanced pts diagnosed ≤ 3 mos prior to enrollment; metastatic pts diagnosed ≤ 2 mos prior, normal baseline coagulation, pts eligible 4 wks post non curative surgery ECOG 0-1 |

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| PROSTATE | | |
| 1st Line | | |
| EFC11784 FIRSTANA | Randomized, Open Label Multi-Center Study comparing cabazitaxel at 25 mg/m ² and at 20 mg/m ² in Combination with Prednisone Every 3 Weeks to Docetaxel in Combination with Prednisone in Patients with Hormone Refractory Metastatic Prostate Cancer not Pretreated with Chemotherapy Only Open at: Orange Park, Southside, St. Vincent's, BMC-N, BMC-S, BMC-Beaches & St. Augustine | Prostate adenocarcinoma, progressive disease on hormonal therapy, effective castration, if pt on LHRH agonist continue; washout 6wks bicalutamide/nilutamide, 4 wks flutamide, megestrol or other HT. Exclusion: prior chemotherapy (provenge is allowed), whole pelvic XRT or XRT to >30% bone marrow, peripheral neuropathy >GR2 |
| 2nd / 3rd Line Metastatic | | |
| EFC11785 PROSELICA | Randomized, Open Label Multi-Center Study comparing cabazitaxel at 20 mg/m ² and at 25 mg/m ² in Combination with Prednisone Every 3 Weeks to the Treatment of Hormone Refractory Metastatic Prostate Cancer Treated with a Docetaxel-Containing Regimen Only Open at: Orange Park, Southside, St. Vincent's, BMC-N, BMC-S, BMC-Beaches & St. Augustine | Prostate adenocarcinoma resistant to HT and previously treated with docetaxel, pt must have progressed during or w/in 6mo after docetaxel; measurable or non measurable disease allowed; ECOG 0-2. Exclusion: prior mitoxantrone or cabazitaxel, XRT to >30% bone marrow. |
| Lilly/v-10-007 11Y-MC-JFBF | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** |
| Registry | | |
| Dendreon Corp. P10-3/ PROCEED | A Registry of Sipuleucel-T Therapy in Men with Advanced Prostate Cancer | Subjects >18 years of age with advanced prostate cancer who will receive sipuleucel-T (enrollment required prior to first leukapheresis procedure) |
| RENAL | | |
| 2nd Line | | |
| ECOG - CALGB 90802 | Randomized Phase III Trial Comparing Everolimus Plus Placebo versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment w/ Tyrosine Kinase Inhibitors | Prior tx w/ 1 VEGFR TKI, no prior systemic tx w/ bevacizumab, no prior mTOR therapies (temsirolimus, everolimus etc), prior tx washout 4 weeks, measurable disease by RECIST, no active brain mets |
| SOLID TUMORS | | |
| 2nd or 3rd Line Metastatic | | |
| Lilly/v-10-007 11Y-MC-JFBF | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** | *** SEE STUDY LISTED UNDER GASTROESOPHAGEL *** |
| Any Line | | |
| Merck ZOSTER V212-011 | A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy | Pts w/ STM or HM and receiving immunosuppressive chemo that does not include rituximab, or 50 years of age or older with a HM, not in remission, regardless of chemotherapy; prior history of varicella or documented antibodies to VZV. Exclusion: HZ within 1 year of enrollment, prior varicella or zoster vaccine, receiving long-term antiviral prophylaxis (>4wks) |
| SUPPORTIVE CARE | | |
| Any Line | | |
| Merck ZOSTER V212-011 | *** SEE STUDY LISTED UNDER SOLID TUMORS *** | *** SEE STUDY LISTED UNDER SOLID TUMORS *** |

OPENING SOON!!!

Please contact your research coordinator regarding the trial's status or to refer potential patients for screening.

Bristol-Myers Squibb – CA184-104: *Randomized, Multicenter, Double-Blind, Phase 3 Trial Comparing the Efficacy of Ipilimumab in Addition to Paclitaxel and Carboplatin versus Placebo in Addition to Paclitaxel and Carboplatin in Subjects with Stage IV/Recurrent Non Small Cell Lung Cancer (NSCLC) [squamous]*

GlaxoSmithKline – TRC112765 (PHASE II): *A Randomized, Blinded, Placebo-controlled, Two-Phase, Sequential Cohort, Dose Finding Study to Assess the Safety and Efficacy of an Oral Thrombopoietin Receptor Agonist, Eltrombopag (SB-497115-GR), Administered to Patients with Solid Tumors Receiving Gemcitabine monotherapy or Gemcitabine Plus Carboplatin or Cisplatin Chemotherapy*