## Breast

<table>
<thead>
<tr>
<th>Primary Site</th>
<th>Sponsor/Study ID NCT #</th>
<th>Protocol Description</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast HER2+ MBC third line</td>
<td>PUMA-NER-1301 NALA NCT01808573</td>
<td>A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients with Her2+ Metastatic Breast Cancer Who Have Received Two or More Prior Her2-Directed Regimens in the Metastatic Setting (NALA)</td>
<td>• Histologically confirmed MBC; stage IV • HER2+ (IHC3+ or FISH+), by central lab • Prior tx w/ two (2) HER2-directed regimens for MBC • &gt;1 measurable metastatic lesion by RECIST v1.1 • LVEF &gt;50% by MUGA or ECHO; • ECOG status of 0 or 1 • No prior treatment w/ capecitabine, neratinib, lapatinib, • No prior HER2 directed TKI • No cumulative exposure to anthracyclines • No active CNS metastases • No active uncontrolled cardiac disease</td>
</tr>
<tr>
<td>HER2 – Metastatic or Locally Advanced Unresectable BRCA Associated Breast Cancer</td>
<td>AbbVie M12-914 NCT02163694</td>
<td>A Phase 3 Randomized, Placebo-Controlled Trial of Carboplatin and Paclitaxel With or Without the PARP Inhibitor Veliparib (ABT-888) in HER2-Negative Metastatic or Locally Advanced Unresectable BRCA-Associated Breast Cancer</td>
<td>• Histologically confirmed breast cancer advanced or metastatic • Suspected deleterious or deleterious BRCA1 or BRCA2 germline mutation • HER2 negative • Measurable or non-measurable disease • ECOG 0-2 • 1st, 2nd or 3rd line</td>
</tr>
<tr>
<td>Genetic Registry</td>
<td>City of Hope National Medical Center 96144 GENETICS STUDY</td>
<td>Molecular Genetic Studies of Cancer Patients and Their Relatives</td>
<td>• Personal History of family history of cancer suggestive of presence of an inherited predisposition • In a group known or suspected to have increased risk of carrying genetic alteration or of sustaining exposure that would place them at risk of cancer • Willing historian to provide information or access</td>
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## Gastrointestinal

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| Liver | MDS Nordion | Treatment of Unresectable Hepatocellular Carcinoma with TheraSphere® (Yttrium-90 Glass Microspheres): An HDE Treatment Protocol | • Hepatocellular carcinoma of the liver  
• ECOG PS score of ≤ 2 with a life expectancy of > 3 months  
• > 4 weeks since prior RT or surgery  
• > 1 month post other chemotherapy.  
• Excludes contraindications to angiography and selective visceral catheterization  
• Excludes extra-hepatic disease representing an imminent life-threatening outcome or active infection |
|---|---|---|---|
| Pancreas | AstraZenca | A Phase III, Randomized, Double Blind, Placebo Controlled, Multicentre Study of Maintenance Olaparib Monotherapy in Patients with gBRCA Mutated Metastatic Pancreatic Cancer whose Disease Has Not Progressed on First Line Platinum Based Chemotherapy | • Histologic/pathologic confirmation pancreatic adenocarcinoma  
• Receiving initial chemotherapy for metastatic disease and without evidence of disease progression on treatment  
• 1st Line with platinum-based regimen received a minimum of 16 weeks of continuous platinum treatment with no evidence of progression  
• Documented mutation in gBRACA1 or gBRACA2 that is predicted to be deleterious or suspected deleterious  
• ECOG performance status 0-1 |
| Met. Colorectal | BTG International Inc. | A Phase III Clinical Trial Evaluating TheraSphere® in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy | • ECOG PS 0-1 through screening to first treatment on study  
• Unresectable metastatic disease to the liver with disease progression in the liver with oxaliplatin or irinotecan based 1st line chemotherapy  
• No prior external beam radiation treatment to liver or any prior intra-arterial liver directed therapy  
• No clinically evident ascites  
• Tumor replacement <50% of total liver volume |

**HEMATOLOGY**

**ANEMIA**
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<tbody>
<tr>
<td><strong>MULTIPLE MYELOMA</strong></td>
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<tr>
<td><strong>LYMPHOMA</strong></td>
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<tr>
<td><strong>CHRONIC LYMPHOCYTIC LEUKEMIA</strong></td>
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**Newly Dx or Relapsed or Refractory CLL**
- Sponsor: TG Therapeutics
- UTX-TGR-304 NCT02656303
  - Protocol: A Phase 3, Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with TGR-1202 Compared to Obinutuzumab in Combination with Chlorambucil in Patients with Chronic Lymphocytic Lymphoma
- Eligibility: 
  - ECOG PS $\leq 2$
  - B-cell CLL that warrants treatment consistent with accepted IWCLL criteria for initiation of therapy
  - Massive, progressive, or symptomatic splenomegaly or lymphadenopathy
  - No prior therapy with obinutuzumab and/or chlorambucil

**CLL, PD while on UTX-TGR-304**
- Sponsor: TG Therapeutics
- UTX-TGR-204 NCT02612311
  - Protocol: A multi-center, open-label, study to evaluate the safety and efficacy of Ublituximab (TG-1101) in combination with TGR-1202 for patients previously enrolled in protocol UTX-TGR-304
- Eligibility: 
  - ECOG PS $\leq 2$
  - After confirmed progression receiving treatment and randomized onto Arms B, C, or D while on UTX-TGR-304

| General Oncology | | |
|------------------|------------------------|----------------------|-------------|
| General Oncology                      | LCI Senior Exercise Project/ SPP-2014-38-LCI | Senior Adult Cancer Treatment Optimization of Performance Project (Pilot study) | 70 years or older at time of cancer diagnosis  
Understand and adhere to study related assessments/procedures  
No prior cancer treatment  
Scheduled to start cytotoxic chemotherapy and/or radiation therapy  
No restriction on tumor stage |
|-------------------------------------|---------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------------------------------------------------|

**LUNG**

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Stage IV Non-Squamous NSCLC</td>
<td>Roche</td>
<td>GO29431 NCT02409342</td>
<td>A Phase III, open-label, randomized study of MPDL3280A (Anti-PDL1 Antibody) compared with Cisplatin or Carboplatin + Pemetrexed for PD-L1–selected chemotherapy naïve patients with stage IV non-squamous-non-small cell lung cancer</td>
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</tbody>
</table>
ECOG PS: 0 or 1  
Histologically or cytologically confirmed stage IV non-squamous NSCLC  
No prior chemo treatment for Stage IV unless patient had previously detected EGFR or ALK. Previous targeted therapy for those is allowed.  
Treated stable brain mets is allowed  
Tumor PD-L1 expression (TC3 or IC3) determined by an IHC assay performed by central laboratory on previous archival tumor tissue or tissue obtained from biopsy at screening |
### IIIA, II or IB Resected Non-Squamous NSCLC

<table>
<thead>
<tr>
<th>NCI</th>
<th>A151216</th>
<th>ALCHEMIST</th>
<th>NCT02194738</th>
<th>Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)</th>
<th><strong>This is the pre-registration study which randomizes to either A081105 or E4512</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A151216</td>
<td></td>
<td>• ECOG PS: 0 or 1</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>ALCHEMIST</td>
<td></td>
<td>• No neoadjuvant (chemo or radio-therapy) for this lung cancer</td>
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<td></td>
<td></td>
<td>NCT02194738</td>
<td></td>
<td>• No prior treatment with agents targeting EGFR mutation or ALK rearrangement</td>
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<td></td>
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<td></td>
<td>• No pure squamous carcinoma</td>
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<td></td>
<td></td>
<td>• Pre-surgical: Suspected clinical stage of IIIA, II or large IB (defined as size ≥4cm)</td>
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<td></td>
<td>• Post-surgical: Pathologic stage IIIA, II or IB (defined as size ≥4 cm)</td>
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<td>• Patients may be receiving adjuvant chemotherapy at the time of registration.</td>
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<td>• Adequate FFPE tissue for central EGRF and ALK genotyping for all patients, include those already locally tested.</td>
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<td>• Complete resection.</td>
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</tr>
</tbody>
</table>

### IIIA, II or IB Resected Non-Squamous NSCLC

<table>
<thead>
<tr>
<th>NCI</th>
<th>A081105</th>
<th>ALCHEMIST</th>
<th>NCT029193282</th>
<th>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 center (NSCLC)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A081105</td>
<td></td>
<td>• ECOG PS: 0 or 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ALCHEMIST</td>
<td></td>
<td>• Registered to A151216 with result of EGFR exon 19 deletion or L858R mutation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NCT029193282</td>
<td></td>
<td>• Completely resected stage IB (≥4 cm), II, or IIIA non-squamous NSCLC with negative margins</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Patients with known resistant mutations in the EGFR TK domain (T790M) are not eligible.</td>
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<td>• Patients that are both EGFR mutant and ALK rearrangements will be registered to A081105</td>
</tr>
</tbody>
</table>

### IIIA, II or IB Resected Non-Squamous NSCLC

<table>
<thead>
<tr>
<th>NCI</th>
<th>E4512</th>
<th>ALCHEMIST</th>
<th>NCT02201992</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>E4512</td>
<td></td>
<td>• ECOG PS: 0 or 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ALCHEMIST</td>
<td></td>
<td>• Pre-registered to A151216</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NCT02201992</td>
<td></td>
<td>• Completely resected stage IB (≥4 cm), II, or IIIA non-squamous NSCLC with negative margins</td>
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<tr>
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<td>• Positive for translocation or inversion events involving the ALK gene locus</td>
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<td>• No prior treatment with crizotinib or another ALK inhibitor</td>
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<td></td>
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<td></td>
<td>• No known interstitial fibrosis or interstitial lung disease.</td>
</tr>
</tbody>
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| IIA, II or IB Resected Non-Squamous NSCLC | Mirati 265-109 Phase 2, Parallel-Arm Study of MGCD265 in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Activating Genetic Alterations in Mesenchymal-Epithelial Transition Factor | • ECOG PS 0-2  
• Tumor tissue and/or ctDNA  
• No prior positive test for EGFR mutation or ALK gene rearrangement  
• No prior treatment with small molecule or antibody inhibitor of MET or HGF |
| Resected Stage IB-IIIA NSCLC | Roche GO29527 NCT02486718 A Phase III, open label, randomized study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 Antibody) compared with best supportive care following adjuvant cisplatin based chemotherapy in PD-L1 selected patients with completely resected stage IB-IIIA non-small-cell lung cancer. | • ECOG PS 0 or 1  
• Histological or cytological diagnosis of Stage IB (tumors greater than or equal 4cm)- IIIA (T2-3, NO, T1-3, N1, T1-3, N2)  
• Tumor PD-L1 expression of TC3 or IC3 performed by central lab  
• No prior treatment with systemic chemotherapy  
• No segmentectomy or wedge resection |
| Met. Squamous NSCLC 1st Line | Merck & Co. MK3475-407 NCT02775435 A Randomized, Double-Blind, Phase III Study of Carboplatin-Paclitaxel/Nab-Paclitaxel Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-407) | • ECOG PS: 0-1  
• Stage IV Squamous NSCLC  
• Creatinine or calculated CrCl (≤1.5 X upper limit of normal (ULN) OR ≥60 mL/min for subjects with creatinine levels > 1.5 X institutional ULN  
• No radiation therapy to lung > 30 Gy w/in 6 mths of 1st dose of trial treatment  
• Completed palliative radiotherapy < 7 days of 1st dose of trial treatment |
| SCLC | Pharma Mar PM1183-C-003-14 Atlantis NCT02566993 Phase III randomized clinical trial of Lurbinectedtin (PM01183)/ Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as treatment in patients with Small Cell Lung Cancer (SCLC) who failed one prior platinum-containing line | • ECOG PS ≤ 2  
• Histologically or cytologically confirmed limited or extensive SCLC  
• 4 weeks since completion whole brain RT and two weeks since PCI completion  
• No more than one prior chemotherapy containing regimen and not treated with PM01183, topotecan or anthracyclines |
## Metastatic or Locally Advanced Solid Tumors

**EMD Serono**  
EMR200647-001  
NCT02517398  
A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0011359C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications  
- Life expectancy ≥ 12 weeks  
- ECOG performance status of 0 to 1  
- Beyond this further cohort inclusion/exclusion is site specific.

## NSCLC Unknown EGFR status

**Biodesix**  
BDX-00146  
No NCT #  
An Observational Study Assessing the Clinical Effectiveness of VeriStrat® and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer  
- EGFR mutation status wildtype or unknown  
- If prior treatment then documented disease progression prior to VeriStrat

### GENITOURINARY

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</tr>
</thead>
</table>
| **Non-metastatic CRPC**       | Bayer HealthCare Pharmaceuticals Inc.  
ARAMIS 17712  
NCT02200614 | A Phase III multinational randomized, double-blind, placebo-controlled efficacy and safety study of ODM-201 in men with high-risk non-metastatic castration-resistant prostate cancer | • Histologically or cytologically confirmed adenocarcinoma of prostate without neuroendocrine differentiation or small cell features  
• CRPC with 3 rising PSA levels at least 1 week apart during ADT. History of antiandrogen use, most recent PSA must be at least 4 weeks after antiandrogen withdrawal  
• ECOG PS: 0 to 1  
• Castrate level of serum testosterone (< 1.7 nmol/l [50 ng/dl]) on GnRH agonist or antagonist therapy or after bilateral orchiectomy. Patients who have not undergone bilateral orchiectomy must continue GnRH therapy during the study |
| **Met. Hormone Sensitive Prostate Cancer** | Bayer HealthCare Pharmaceuticals Inc.  
ARASENS 17777  
NCT02799602 | A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer | • ECOG PS: 0 to 1  
• Histologically or cytologically confirmed adenocarcinoma of prostate  
• Metastatic disease documented either by a positive bone scan, or for soft tissue or visceral metastases, either by contrast-enhanced CT abdominal/pelvic/chest MRI  
• None of the following within 6 months before randomization: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, congestive heart failure  
• No prior treatment with second-generation AR inhibitors such as enzalutamide, ARN-509, ODM-201, other investigational AR inhibitors, or CYP17 enzyme inhibitor as antineoplastic treatment |
| Metastatic CRPC | Clovis Oncology, Inc. | A Multicenter, Open-label Phase 2 Study of Rucaparib in patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency | • ECOG PS: 0 to 1
• Histologically or cytologically confirmed adenocarcinoma or poorly differentiated carcinoma of prostate
• Castrate level of serum testosterone of $\leq 50$ ng/dL (1.73 nM). For patients currently being treated with LHRH agonists therapy must be continued throughout the study
• Have a deleterious mutation in BRCA1/2 or ATM, or molecular evidence of other homologous recombination deficiency
• No prior treatment with any PARP inhibitor, mitoxantrone, cyclophosphamide or any platinum-based chemotherapy |
|---|---|---|---|
| Metastatic CRPC | F. Hoffman-La Roche Ltd | A Phase III, multicenter, randomized study of Atezolizumab (Anti-PD-L1 antibody) in combination with Enzalutamide vs. Enzalutamide alone in patients with metastatic castration-resistant prostate cancer after failure of an androgen synthesis inhibitor and failure of, eligibility for, or refusal of a taxane regimen | • ECOG PS: 0 to 1
• Progressive disease prior to screening by PSA or imagine per PCWG3 criteria
• One prior regimen of a taxane-containing regimen or refusal or ineligibility of a taxane-containing regimen along
• One prior regimen of an androgen synthesis inhibitor
• Tumor specimen from a site not irradiated for PD-L1 status testing via central pathology |
| Metastatic CRPC | Clovis Oncology, Inc. | Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician’s Choice of Therapy for Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency | • ECOG PS: 0 or 1
• Surgically or medically castrated, with serum testosterone levels of $\leq 50$ ng/dL (1.73 nM)
• Have a deleterious mutation in a BRCA1/2 or ATM gene
• Eligible for treatment with physician’s choice of comparator treatment
• PD after treatment with one prior next-generation AR-targeted therapy for castration-resistant disease |
| Metastatic CRPC | F. Hoffman-La Roche Ltd | A phase III, randomized, double-blind, placebo-controlled, multicenter trial testing Ipatasertib plus Abiraterone plus prednisone/prednisolone, relative to placebo plus Abiraterone plus prednisone/prednisolone in patients with asymptomatic or mildly symptomatic, metastatic castrate resistant prostate cancer with PTEN diagnostic positive tumors | • Histologically confirmed prostate adenocarcinoma without neuroendocrine differentiation or small-cell features
• Consent to provide FFPE tissue block
• Valid PTEN IHC result (central testing)
• Metastatic disease documented by bone lesion on bone scan or soft tissue disease by CT or MRI
• Asymptomatic or mildly symptomatic form of prostate cancer
• Progress disease defined using at least one; a) two rising PSA levels $\geq 1$ ng/mL measured $\geq 1$ week apart b) radiographic evidence of disease progression in soft tissue |
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