| Short Name/Protocol # | Disease | Treatment | | |
|---|---|--|--|--|
| | Device study LUNG STUDIES | NovoTTF-100M device (150kHz output frequency) | | |
| | Phase 3/Brain mets from NSCLC | Novo 1 1F-100M device (150kHz output frequency) | | |
| | New diagnosis of brain metastases with 1 inoperable brain metastasis or 2-10 brain metastases, amenable to SRS. | Patients may continue on systemic therapy while receiving TTFields. | | |
| | • Largest tumor volume < 10 cc.; longest tumor diameter < 3 cm; Cumulative volume of all tumors ≤ 15 cc | Patients on the supportive care arm can crossover to the device arm after second intracranial failure | | |
| Metis EF-25 | At least one measurable lesion | • Following first progression in the brain, patients may be offered salvage therapy based on local practice such as resection, repeat SRS or WBRT. | | |
| (Novocure) | Karnofsky performance status (KPS) ≥ 70 Leptomeningeal metastasis is exclusionary. | | | |
| | Leptomeningeal metastasis is exclusionary. Patients that have received WBRT or prior SRS for their brain metastases will be ineligible for this study. | | | |
| | Exclusion: Patients who are known to have somatic tumor mutations in the following genes, for which targeted agents are available that directly affect the treatment of brain | | | |
| | metastasis: Anaplastic lymphoma kinase (ALK), epidermal growth factor receptor (EGFR), ROS-1 proto-oncogene, and proto-oncogene B-RAF | | | |
| | Stage IIIB, IIIC or Stage IV NSCLC disease at the time of randomization | A total of approximately 590 eligible subjects will be randomized to DS-1062a arm or docetaxel arm in a 1:1 ratio (295/arm) | | |
| DS1062-A-U301 | Progression following PD-1/PD-L1 following or in combination with platinum-based treatment Subjects with Actionable genomic mutations must have received targeted therapy for the mutation | ARM 1: DS-1062a 6.0 mg/kg IV q 3 weeks | | |
| Tropion | No mixed SCLC and NSCLC histology | ARM 2: Docetaxel 75mg/m2 IV q 3 weeks | | |
| (Daiichi-Sankyo) | Two minded delice and ridelice instology | | | |
| | | | | |
| | Stage I to II NSCLC - T1 - T3N0M0 | Double Blind, randomized 1:1 Durvalumab 1500mg IV Q 4 wks | | |
| PACIFIC-4 | Medically inoperable or operable & refusing surgery or choosing SBRT **SBRT as definitive tx during treatment period | up to 24 months | | |
| D9103C00001 | ECOG 0 – 2 | Or Or | | |
| (Astra Zeneca) | All comers for histology and PDL-1 Status | Placebo IV Q 4 wks up to 24 months | | |
| | Patients with ultra-central tumors are not eligible | | | |
| | Patients with T1a/b – recruitment closed Patients with T1a/b – recruitment closed Patients with T1a/b | | | |
| | Phase 3/newly diagnosed untreated LS- SCLC Untreated Stage I-III LS-SCLC with at least 1 measurable lesion | Group A: Platinum doublet + Pembro with standard thoracic BID RT or QD RT followed by Pembro + olaparib placebo Group B: Platinum doublet + pembro w/ BID RT or QD RT followed by pembro plus Olaparib | | |
| MK 7339-013 | ECOG 0-1 | Group C: Platinum doublet + pembro placebo with BID RT or QD RT followed by pembro placebo plus olaparib placebo | | |
| KEYLYNK (Merck) | Tumor tissue required, fresh preferred over archival | Standard thoracic RT (45 Gy in 30 twice-daily fractions over 3 weeks) | | |
| (WICICK) | Life expectancy at least 6 months | Once-daily RT (60 to 66 Gy in 33 daily fractions over 6 weeks) | | |
| | BREAST STUDIES | | | |
| | Cohort A: TNBC – locally advanced or Metastatic | Treatments | | |
| TDY 540.02 | No prior chemo or systemic therapy for locally adv. or mets TNBC setting | TNBC: IPI-549 PO + Front line therapy | | |
| IPI-549-03 (Infinity | -Measurable disease per RECIST 1.1 FOOG 0.1 | (Atezolizumab + Nab-paclitaxel) | | |
| Pharmaceuticals) | -ECOG 0-1 -Screening biopsy required | | | |
| , | Cohort B: RCC – Closed | | | |
| | Locally advanced unresectable or Metastatic Triple Negative Breast Cancer | 1:1 randomized | | |
| | Cohort 1 | Trilaciclib/placebo solution as a 30-minute IV infusion followed by Gemcitabine and Carboplatin | | |
| | • 1 st line advanced or metastatic | The dose of trilaciclib will not be modified and will remain at 240 mg/m2 throughout the study. | | |
| | No prior Pd-1/PD-L1 any setting | • Cohort 1: Any PD-L1 Status, First-line, PD-1/PD-L1 Inhibitor-Naïve Population | | |
| G1T28-208 – PRESERVE 2 | • ≥ 6 months since curative tx Cohort 2 (Closed to enrollment) | • <u>Cohort 2</u> : PD-L1 + Status, Second-line, Previously Treated with a PD-1/PD-L1 Inhibitor-(Closed to enrollment) | | |
| (G1 Therapeutics) | Both cohorts | | | |
| (====================================== | Tissue required | | | |
| | • ECOG 0-1 | | | |
| | No prior gemcitabine | | | |
| <u> </u> | • Optional tumor biopsies done at Screening and between C1D17 – C1D20 Phase 3 - ER+, HER2- locally advanced (not amenable to curative treatment by surgery) or metastatic Breast Cancer, who have been treated with an AI, alone or | Open Label – randomized 1:1 | | |
| | in combination with a CDK4/6 inhibitor. | Arm A – Imlunestrant PO daily | | |
| | Key Inclusion Criteria: | Imlunestrant is an oral SERD. | | |
| | Have a diagnosis of ER+, HER2- breast cancer | Arm B – Investigator choice of: | | |
| EMPED 2 | Locally advanced (not amenable to curative treatment by surgery) or metastatic disease and progression on or after only 1 line of therapy with an AI, alone or in combination with a CDK4/6 inhibitor. | Fulvestrant or Exemestane Arm C- Imlunestrant PO daily+ | | |
| EMBER-3 J2J-OX-JZLC | Combination with a CDK4/6 inhibitor. ECOG of 0 or 1 | Arm C- inhunestrant PO dany+ Abemaciclib PO BID | | |
| (Eli Lilly) | Key Exclusion Criteria: | | | |
| (======;) | • prior chemotherapy (except for neoadjuvant/adjuvant chemotherapy), fulvestrant , any investigational-ER-directed therapy (including SERDs and non-SERDs), any | | | |
| | PI3K-, mTOR-, or AKT-inhibitor | | | |
| | • Inflammatory breast cancer | | | |
| | • wide-field radiotherapy ≤4 weeks (defined as involving ≥25% of the bone marrow), or limited field radiation for palliation ≤1 week prior to randomization. | | | |
| | Locally advanced unresectable or Metastatic Triple Negative Breast Cancer | Treatment Phase (21-day Cycles) Survival Follow-Up Phase Combination (by 16, 12-day cycle) Combination (by 16, 12-day cycle) Phase Combination (by 16, 12-day cycle) Survival Follow-Up Phase Combination (by 16, 12-day cycle) Treatment Phase (21-day Cycles) | | |
| | Histologically documented hormone receptor negative and HER2 negative | Treatment Table 200 Page 100 P | | |
| G1T28-213 | Measurable disease per RECIST 1.1 2 prior lines of systemic therapy, at least one in the metastatic setting | Doug 1 Septembry 21 days Septembry 21 days | | |
| (G1 Therapeutics) | ECOG 0-1 2 prior lines of systemic therapy, at least one in the metastatic setting ECOG 0-1 | Hacebo CH, De CVCLY 2.1 days - Placebo CH - | | |
| (31 Incrapouties) | Exclusions | Sacituzumab Govitecan-hxiy DC=dicontinued. PD=progressive disease: PI=Principal Investigator: WD=withdraw | | |
| | Patients with known brain mets at enrollment | 10mg/kg days 1, 8 every 21 days | | |
| | Bone-only disease I VARIOUS STUDIES TO STUDIES | The dose of Trilaciclib will not be modified and will remain at 240 mg/m2 throughout the study | | |
| LYMPHOMA STUDIES | | | | |

| XPORT-DLBCL- 30 (Karyopharm) | Phase 2/3 Relapsed Refractory DLBCL (pts not intended for ASCT or CAR-T) • pathologically confirmed de novo DLBCL or DLBCL transformed from previously diagnosed indolent lymphoma (eg, FL) • Have received at least 1 but no more than 2 previous systemic regimens for DLBCL tx • measurable disease per Lugano • ECOG ≤ 2 • primary refractory disease defined as no response or relapse within 3 months after ending 1 st -line tx will be allowed on study (up to 20% of enrolled patients in each Phase) Newly Diagnosed, previously untreated, high-intermediate and high risk DLBCL | Treatment Phase 2: Selinexor + R-GDP Treatment Phase 3: Selinexor or placebo + R-GDP Experimental Arm: 6 cycles |
|---|---|--|
| MOR208C310 FRONT-MIND | ≤ 28 days from pathologic diagnosis to start of treatment (C1D1) Biopsy proven CD20 positive p DLBCL ECOG 0-2 Thromboembolic event Prophylaxis required No known CNS involvement | R-CHOP + Tafasitamab + lenalidomide (D1) (Days 1, 8, 15) (D1-10) Control Arm: 6 cycles R-CHOP + Tafasitamab placebo + lenalidomide Placebo (D1) (Days 1, 8, 15) (D1-10) |
| TRANSFORM-2 M20-178 (AbbVie) | Relapsed or refractory Myelofibrosis (resistant to a JAK-2 inhibitor) • Previously treated with JAK-2 inhibitor therapy who have measurable splenomegaly and are not candidates for allogeneic-stem cell transplantation. | Arm A – Exp. group: ruxolitinib 10mg BID + navitoclax 100/200 mg QD Arm B - Control group: Best available therapy, options include ruxolitinib, hydroxyurea, PEG-interferon-α2, or danazol and fedratinib (where approved for relapsed/refractory MF). |
| | COLORECTAL CANCER | |
| BESPOKE 20-041-NCP (Natera) Registry Study | Patients that have undergone surgery for stage I, II or III colorectal cancer & oligometastatic Stage IV colorectal cancer Planning or undergone surgical resection of adenocarcinoma of the colon or rectum Pathologic stage I, II or III disease Stage IV with oligometastatic disease eligible for curative intent resection or ablation, and clinically eligible for adjuvant chemotherapy or immunotherapy ECOG performance status ≤ 2 Clinically eligible for chemotherapy | Observational Study: Data will be collected for patients who have undergone surgery for stage I, II, III, & IV colorectal cancer (CRC) and will provide whole blood samples for routine care SIGNATERA testing. Patients will receive SIGNATERA test results and may be recommended for adjuvant chemotherapy or observation by their treating healthcare provider. Optional future research testing done via Natera test. |
| | SOLID TUMORS | |
| SGNLVA-005 (SeaGen) | Unresectable LA or Met solid tumors ECOG ≤ 1 Measurable disease per RECIST 1.1 Prior PDL-1 treatment CPRC (castrate resistant prostate cancer) Histologic adenocarcinoma of prostate Metastatic CRPC No more than one prior 2 nd gen anti-androgen for mCPRC No prior chemo in mCPRC Measurable or non-measurable disease Melanoma Must have histologically or cytologically confirmed cutaneous malignant melanoma; Subjects with mucosal, acral, or uveal melanoma are excluded. | *Currently only 2 cohorts open Cohort 1: SCLC (closed) Cohort 2: NSCLC-squamous (closed) Cohort 3: NSCLC-nonsquamous (closed) Cohort 4: HNSCC (closed) Cohort 5: Esophoogeal squamous closed) Cohort 6: Gastric and GEJ adenocarcinoma (closed) Cohort 7: CRPC (OPEN) Cohort 8: Melanoma (OPEN) |
| | Must have locally advanced unresectable or metastatic stage disease; Must have measurable disease: Must have progressive disease following anti-PD(L)1 therapy: Prior ipilimumab therapy is allowed; Patients that were treated with curative intent and are planning to undergo standard-of-care follow-up/monitoring for cancer recurrence At least one blood sample (Landmark sample) collected 4-12 weeks after completion of primary treatment | Ladiratuzumab Vedotin Observational Study: |
| 02-MX-003 ORACLE (Guardant Health) | Have a single primary qualifying cancer: Primary Cohorts: Muscle invasive carcinoma of the bladder, ureter, or renal pelvis (stage II-III) Non-small cell lung cancer (stage II-III) Invasive breast carcinoma (T1-4/N0-3/M0 at presentation) who completed preop chemotherapy, underwent surgical resection, & have pathological evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes Exploratory Cohorts: Cutaneous melanoma (stage IIb-III or resectable stage IV) Esophageal or gastroesophageal junction carcinoma (stage II-III) Gastric adenocarcinoma (stage II-III) Surgically resected pancreatic adenocarcinoma Invasive squamous cell carcinoma of the head and neck (stage I-III) High risk epithelial ovarian or Fallopian tube carcinoma High risk endometrial carcinoma | ORACLE is a multi-center, prospective observational study for patients with solid tumors treated with curative intent. The study goal is to determine how well a simple blood test identifying presence of circulating tumor DNA (ctDNA) predicts cancer recurrence after curative intent treatment. Blood samples will be collected at the patient's standard-of-care follow-up visits. Results of testing will not be made available to research staff, physicians, or patients. |
| | High risk renal cell carcinoma | |
| | Advanced RCC patients that have progressed after prior Anti-PD-1/L1 therapy | Experimental Arm: |
| MK6482-011 (Merck) | 2nd or 3rd line treatment post anti PD-1/L1 therapy (at least 2 doses) 1 prior anti-PD-1/L1 therapy for locally advanced or metastatic RCC locally advanced/metastatic RCC with clear cell component Measurable disease per RECIST 1.1 No intermittent or supplemental oxygen requirement | Belzutifan + Lenvatinib Control Arm: Cabozatinib |

| MYELODYSPLASTIC SYNDROME (MDS) | | | | |
|---|--|--|--|--|
| STIMULUS-MDS CMBG543B1US01 (Novartis) | Intermediate, high or very high risk myelodysplastic syndrome (MDS) Confirmed dx of MDS intermediate, high, or very high risk per PISS-R criteria ECOG 0-2 Not eligible for SCT No prior to exposure to TIM-3 therapy (prior checkpoint inhibitor allowed if >than 4 months prior to enrollment No more than 1 prior ccle of HMA No prior chemotherapy | Treatment: Sabatolimab (MBG453) + HMA of choice (Decitabine IV or Azacitabine IV) | | |