

MERCY
FEBRUARY 2021

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
BILIARY TRACT				
S1815	Phase III randomized trial of Gemcitabine, Cisplatin and Nab-Paclitaxel vs Gemcitabine and Cisplatin in newly diagnosed, advanced biliary tract cancers	<p>≥ 18</p> <p>Confirmed intrahepatic or extrahepatic cholangiocarcinoma or gallbladder CA</p> <p>Unresectable disease</p> <p>No – prior systemic therapy for current metastatic CA, grade 2 or higher neuropathy</p>	Gemcitabine + Cisplatin + Nab-Paclitaxel vs Gemcitabine + Cisplatin	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
BREAST				
A011401 Breast Cancer <u>WE</u> ight <u>L</u> oss (BWEL study)	Randomized phase III trial evaluation the role of weight loss in adjuvant treatment of overweight and obese women with early <i>breast</i> cancer	<p>Dx < 12 months</p> <p>Stage II or III</p> <p>HER2 –</p> <p>ER/PR + or –</p> <p>≥ 18 (women)</p> <p>BMI ≥ 27</p> <p>Chemo/Rad/Surg complete > 21 days</p> <p>No – DMII with insulin/sulfonylurea</p>	Health education x 2 years vs Health education + weight loss intervention	Cooperative PROJECTED TO CLOSE 02/2021
CTG.MA.39	Randomized trial of regional radiotherapy in Biomarker low risk node positive breast cancer	<p>Invasive carcinoma of breast with no evidence of mets</p> <p>Tx by BCS (breast-conserving surgery) or mastectomy</p> <p>1-3 positive axillary nodes</p> <p>1-2+ axillary nodes</p> <p>ER ≥ 1% and HER2-</p> <p>Oncotype DX recurrence score <18</p> <p>NO – pT3 or pT4</p>	<p>Arm 1 – Group 1A</p> <p>Group 1B</p> <p>Arm 2 – Group 2A</p> <p>Group 2B</p> <p>See protocol for specific treatment</p>	Cooperative
EA1131	A Randomized Phase III Post-Operative trial of Platinum based chemotherapy VS Capecitabine in	<p>≥ 18</p> <p>ECOG 0-1</p> <p>Stage II or III</p>	<p>Arm A – closed to accrual</p> <p>Arm B – Cisplatin q3w x 4 cycles OR Carboplatin</p>	Cooperative IRB PENDING

MERCY
FEBRUARY 2021

	patients with residual Triple-Negative Breast Cancer following Neoadjuvant chemotherapy	ER-, PR-, HER2- Resection, Mastectomy or breast conserving surgery EXCLUDED – Carbo or Cisplatin as Neoadjuvant therapy RANDOMIZATION must occur within 24 weeks from surgery date	q3w x 4 cycles (12 weeks) Arm C – Capecitabine PO BID on days 1-14 q3w for a total of 6 cycles (16 weeks)	
NRG-BR003	Randomized phase II trial of adjuvant therapy comparing doxorubicin plus cyclophosphamide followed by weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive <i>Breast</i> Cancer	HER2 – ER/PR – ≥ 18 Mastectomy or lumpectomy Tumor unilateral No – T4 including inflammatory breast CA, Metastatic disease	AC IV q2w x 4 cycles → Paclitaxel IV qweek x 12 doses vs AC IV q2w x 4 cycles → Paclitaxel IV qweek x 12 doses + Carboplatin AUC5 IV q3w x 4 cycles	Cooperative
NRG-BR004	Randomized, double-blinded, phase III trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in 1 st line HER-2 Positive Metastatic Breast Cancer	≥ 18 ECOG 0-1 Locally recurrent, unresectable or metastatic HER-2+ NO – hx of cardiac disease (current or past) grade 2 neuropathy	Paclitaxel/Trastuzumab/Pertuzumab/Atezolizumab vs Paclitaxel/Trastuzumab/Pertuzumab/Placebo (see protocol for dosing schedule) until progression	Cooperative
S1418 Adjuvant	Randomized phase III trial to evaluate the efficacy and safety of MK-3475 as adjuvant therapy for triple receptor-negative <i>breast</i> cancer with ≥ 1 cm residual invasive cancer or positive lymph nodes after neoadjuvant chemotherapy	ER/PR/HER2 – (weekly ER or PR+ are eligible if no endocrine therapy) ≥ 18 Lymph node dissection after neoadjuvant chemotherapy Complete adjuvant chemotherapy prior to starting Pembrolizumab No – Metastatic disease	Observation vs MK-3475 (Pembrolizumab) IV q3w x 52 weeks	Cooperative <u>S1418 – BAHO sub-study permanently closed</u> STEP 1 Registration Temporarily Closed
PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
COLORECTAL				

MERCY
FEBRUARY 2021

<p>A021502 Adjuvant</p>	<p>Randomized trial of standard chemotherapy alone or combined with Atezolizumab as adjuvant therapy for patients with stage III <i>colon</i> cancer and deficient DNA mismatch repair</p>	<p>≥ 18 Stage III adenocarcinoma DNA mismatch Tumor resected No - prior therapy, rectal involvement, metastatic disease at time of registration</p>	<p>mFOLFOX6 IV x 12 cycles (6m) + atezolizumab x 25 cycles (12m) vs mFOLFOX6 x 12 cycles (6m) 1 cycle = 14 days *survival status 5-8y</p>	<p>Cooperative</p>
<p>A021703 (SOLARIS)</p>	<p>Randomized double-blind phase III trial of Vitamin D3 supplementation in patients with previously untreated metastatic colorectal cancer</p>	<p>≥ 18 ECOG 0-1 No prior tx for metastatic disease EXCLUDED – calcium, vitamin D, thiazide diuretics, oral corticosteroids</p>	<p>Arm 1 – FOLFOX6 or FOLFIRI + Bevacizumab + high dose Vit D3 Arm 2 – FOLFOX6 or FOLFIRI + Bevacizumab + Standard dose Vit D3</p>	<p>Cooperative</p>
<p>NRG-GI002</p>	<p>Phase II clinical trial platform of sensitization utilizing total neoadjuvant therapy in <i>rectal</i> cancer</p>	<p>≥ 18 Rectal adenocarcinoma, stage II or III + distal location or bulky or high risk of mets or not a candidate for sphincter-sparing surgical resection Able to swallow PO med No – metastatic disease, neuropathy grade 2, active bowel disease, colon cancer, pelvic radiation</p>	<p>mFOLFOX6 q2w x 8 cycles followed by RT + capecitabine PO bid on RT days vs mFOLFOX6 q2w x 8 cycles followed by RT + capecitabine PO BID on RT days + veliparib PO BID vs mFOLFOX 6 q2w x 8 cycles followed by RT + capecitabine PO BID on RT days + MK-3475 IV (pembrolizumab) q3w x 6 cycles starting D1 of RT</p>	<p>Cooperative TEMPORARY SUSPENSION 05/13/2019</p>
<p>NRG-GI004/SWOG S1610 Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT)</p>	<p>A randomized phase III study of mFOLFOX6/Bevacizumab combination chemotherapy with or without Atezolizumab or Atezolizumab monotherapy in the 1st line treatment of patients with deficient DNA mismatch repair (dMMR) metastatic <i>colorectal</i> cancer</p>	<p>≥ 18 Tumor determined to be mismatch-repair deficient No – previous chemo or systemic therapy for mets colorectal cancer</p>	<p>mFOLFOX6 until disease progression. Discontinue oxaliplatin after C10. Vs Atezolizumab monotherapy until disease progression or up to and including max of 48 cycles vs mFOLFOX6 until disease progression.</p>	<p>Cooperative Request approval from NCI CIRB upon patient eligibility. Temporarily closed 6/4/2020</p>
<p>NRG-GI005 Circulating tumor Or DNA as a predictive</p>	<p>Phase II/III study of circulating tumor DNA as a predictive biomarker in adjuvant chemotherapy in patients with stage IIA colon cancer</p>	<p>≥ 18 ECOG 0-1 Stage II of colon (T3,N0,M0) Tumor resection within 14-60 days of</p>	<p>SOC(surveillance) → samples analyzed retrospectively for ctDNA status Vs Assay-directed therapy → samples analyzed prospectively for</p>	<p>Cooperative Temporarily Suspended</p>

MERCY
FEBRUARY 2021

<u>B</u> iomarker in <u>A</u> djuvant chemotherapy (COBRA)		randomization NO – hx colon ca, metastatic disease, prior therapy	the detection of ct DNA to guide adjuvant chemotherapy decision → ctDNA detected FOLFOX or CAPOX OR ctDNA not detected Active surveillance	12/28/2020
S0820 <u>P</u> reventing <u>A</u> denomas of the <u>C</u> olon and with <u>E</u> flornithine and <u>S</u> ulindac (PACES)	A double blind placebo-controlled trial of Eflornithine and Sulindac to prevent recurrence of high risk adenomas and secondary primary colorectal cancers in patients with stage 0-III <i>colon or rectal</i> cancer, phase III	≥ 18 Treatment per SOC with resection alone or in combo with chemoXRT 180-456 post resection with no evidence of disease Able to swallow PO med No – NSAIDs, no anticoagulants, GI ulcer	Eflornithine placebo + Sulindac placebo x 3 years vs Eflornithine and Sulindac placebo vs Eflornithine placebo + sulindac vs Eflornithine and Sulindac	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
HEAD AND NECK				
EA3161	Phase II/III Randomized study of maintenance Nivolumab vs Observation if Patients with Locally Advance, Intermediate Risk HPV Positive Oropharyngeal Cancer	≥ 18 ECOG 0-1 OPCA that is p16-positive by immunohistochemistry with smoking status Measurable disease	Cisplatin weekly during RT x 7 weeks → Nivolumab for 12 cycles → LTFU vs Cisplatin weekly during RT x 7 weeks → Observation → Progression → Nivolumab for 12 cycles → LTFU	Cooperative
NRG-HN004	Randomized Phase II/III trial of radiotherapy with concurrent MED14736 (Durvalumab) vs radiotherapy with concurrent Cetuximab in patients with locoregionally advanced head and neck cancer with a contraindication to Cisplatin	≥ 18 Must have contraindication of cisplatin No prior radiation, immunotherapy, chemotherapy, distant mets	Arm 1: IMRT + Cetuximab vs Arm 2: IMRT + Durvalubam	Cooperative
RTOG-1008	A randomized phase II/phase III study of adjuvant concurrent radiation and chemotherapy versus radiation alone in resected high-risk malignant salivary	Malignant major/minor salivary gland tumor of the H/N of histologic subtypes (see protocol) ≥ 18	Cisplatin 40mg/m ² x 7 doses with concurrent radiation vs radiation alone	Cooperative Request Approval from

	gland tumors	No – residual macroscopic disease		MMC IRB
--	--------------	-----------------------------------	--	----------------

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
LEUKEMIA (Chronic Lymphocytic CLL)				
EA9161	A Randomized Phase III study of the addition of Venetoclax to Ibrutinib and Obinutuzumab VS Ibrutinib and Obinutuzumab in untreated younger patients with Chronic Lymphocytic Leukemia (CLL)	≥ 18 and < 70 ECOG 0-2 No prior chemotherapy for CLL or SLL	Arm A – Ibrutinib PO daily, IV Obinutuzumab x 6 cycles, Venetoclax Cycle 3-14 PO daily Arm B – Ibrutinib C1-19 PO daily, Obinutuzumab IV x 6 cycles	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
LUNG				
ALCHEMIST* A151216 SCREENING TRIAL FOR A081105, E4512	Adjuvant <i>lung</i> cancer enrichment marker identification and sequencing trial	Resectable non-small cell lung cancer Suspected clinical stage of IIIA, IIA, IIB, large IB (≥4cm) ≥ 18 No – neoadjuvant therapy for this lung ca, treatment with targeting EGRF mutation, ALK rearrangement, PD1/PD-L1/CTLA-4. Recurrence of lung ca after prior resection	Site must have A151216 and the two treatment trials A081105 and E4512 IRB approved before registering patients to A151216. A081105 – PERMANENTLY CLOSED	Cooperative
*E4512	Randomized phase III trial for surgically resected early stage <i>non-small cell lung</i> cancer: crizotinib vs observation for patients with tumors harboring the anaplastic lymphoma kinase (ALK) fusion protein	≥ 18 Registered for A151216 Complete surgical resection of stage IB, II or non-squamous IIIA and have negative margins Positive for translocation inversion events	Crizotinib 250mg PO BID until recurrence up to 2 years vs Observation	Cooperative

		involving the ALK gene locus No – uncontrolled Afib		
BDX-00146 Biodesix	An observational study assessing the clinical effectiveness of the Veristrat® test and validating immunotherapy tests in subjects with <i>non-small cell lung cancer</i>	≥ 18 Dx NSCLC EGFR mutation negative or UNK	None – assess the physician’s clinical practice patterns while using the Veristrat test in subjects with NSCLC	Pharmaceutical
EA5163/S1709	Randomized, Phase III study of firstline immunotherapy alone or in combination with chemotherapy in indication/maintenance or postprogression in advanced nonsquamous non-small cell lung cancer (NSCLS) with immunobiomarker signature-driven analysis	≥ 18 Stage IV NSCLC T4NX Stage IIIB with nodule in ipsilateral lung lobe are eligible if they are not chemo/radiation therapy PD-L1 ≥ 1% NO – prior chemo or immunotherapy, EGFF mutations (except exon 20), BRAF or ALK, ROS1 are excluded, symptomatic brain mets	Arm A: MK-3475 (Pembrolizumab) followed by 2 nd line Pemetrexed/Carboplatin Arm B: MK-3475 (Pembrolizumab) followed by 2 nd line MK-3475 (Pembrolizumab) Pemetrexed/Carboplatin Arm C: MK-3475 (Pembrolizumab) Pemetresec/Carboplatin induction followed by Pemetresec/MK-3475 maintenance	Cooperative
EA5181	Randomized Phase III trial of MED14736 (durvalumab) as concurrent and consolidative therapy or consolidative therapy alone for unresectable Stage III NSCLC	≥ 18 ECOG 0-1 Newly dx stage III A/B/C unresectable and confirmed with biopsy Body weight > 30kg PTFs and Lung V20 ≤ 35%	Arm A – Platinum doublet chemotherapy (see protocol for specific choices) plus concurrent TRT Durvaluban IV on days 1, 15, 29 of concurrent chemo/radiation Arm B – Platinum doublet chemotherapy as above pluse concurrent TRT Step 2 – consolidative durvalumab Arm C – Patient from both arms of Step 1 will proceed to Step 2, consolidative durvalumab and	Cooperative

MERCY
FEBRUARY 2021

			radiations. 1500mg IV q4w for up to 1 year (12 cycles)	
LUNGMAP	A master protocol to evaluate biomarker-driven therapies and immunotherapies in previously-treated non-small cell lung cancer (Lung-MAP screening study)	≥ 18 Stage IV or recurrent Screened at progression on prior treatment At least 1 line of systemic therapy for any stage	None – patients with successful biomarker profiling are eligible to register to a sub-study.	Cooperative
LUNGMAP S1900A Biomarker Driven			Rucaparib	Cooperative Temporarily closed 7/16/2020
MIRATI 516-005	A Randomized Phase III Study of Sitravatinib in combination with Nivolumab vs Docetaxel in patients with advance non-squamous non-small cell lung cancer with disease progression on or after platinum-based chemotherapy in combination with checkpoint inhibitor therapy	≥ 18 Duration of treatment on prior therapy at least 4 months Non-squamous with mets or unresectable ECOG 0-1	Nivolumab 240 q2w OR 480mg q4w (PI discretion) + Sitravatinib 100 mg qd PO VS. Docetaxel 75mg/m ²	Pharmaceutical
OSU BLCIO	<u>Beating Lung Cancer in Ohio</u>	≥ 18 Stage IV NSCLC No – treatment for advance lung cancer for over 1 month before enrollment	Monthly phone calls about QOL	Cooperative
S1827	MRI Brain Surveillance Alone Versus	≥ 18	ARM 1: PCI with conventional or	Cooperative

MERCY
FEBRUARY 2021

	MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)	ECOG 0-2 No evidence or hx of brain metastases or leptomeningeal disease	hippocampal avoidance PCI using IMRT vs ARM 2 Surveillance	
--	--	---	--	--

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
LUNG SMALL CELL				
IPSEN MM-398-01-03-04 (RESILIENT)	A Randomized, open label phase 3 Study of Irinotecan Liposome Injection (ONIVYDE) versus Topotecan in patients with Small Cell Lung Cancer who have progressed on or after platinum-based 1 st line therapy. (RESILIENT)	≥ 18 ECOG 0-1 Life expectancy > 12 weeks Progression on or after 1 st line platinum-based chemotherapy	Arm A: Irinotecan liposome injection vs Arm B: IV Topotecan	Pharmaceutical SPONSOR APPROVAL NEEDED TO SCREEN 1/2021
NRG-LU005	Limited Stage Small Cell Lung Cancer. A Phase II/III Randomized study of Chemoradiation VS Chemoradiation + Atezolizumab	≥ 18 ECOG 0-2 Proven dx within 60 days prior to registration EXCLUDED – metastatic disease Cytologically positive pleural or pericardial fluid are not eligible	Arm 1 – Standard CRT + Platinum/etoposide chemotherapy (Cisplatin preferred) q3w for 3 cycle Arm 2 – Standard CRT plus platinum/etoposide chemotherapy (Cisplatin preferred) q3w x 3 cycles _ Atezolizumab IV q3w x 1 year	Cooperative
S1929	Phase II Randomized Study of Maintenance Atezolizumab versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)	≥ 18 ECOG 0-2 Cardiac class 2B or better Complete at least 1 cycle frontline induction treatment with platinum plus etoposide plus atezolizumab prior to Step 1 Excluded – mixed histology	ARM A: Atezolizumab 1200mg IV q21 day cycle VS. ARM B: Takazoarub 100 mcg plus Atezolizumab 1200mg IV q21 day cycle	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
LYMPHOMA				
A051701	Randomized Phase II/III Study of	≥ 18	R (chemo) VS R (chemo) +	Cooperative

MERCY
FEBRUARY 2021

	Venetodax (ABT199) plus cheoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas	ECOG 0-2 Diffuse Large BCell or High grade BCell High grade with MYC and BCL2 (Double hit) or DLBCL or High Grade with MYC and BCL2 (Double expressing)	Venetoclax RCHOP with DEL or DA-EPOCH-R with DHL	Temporarily Suspended 9/28/2020
S1826	Phase III, Randomized study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in patients (age >= 12 years) with Newly Diagnosed Advance Stage Classical Hodgkin Lymphoma	Stage III or IV classical Hodgkin Lymphoma Measurable disease ≥ 1.5cm No prior tx ECOG 0-2	Nivolumab + AVD (Cycles 1-6) vs Brentuximab Vedotin + AVD (Cycles 1-6)	Cooperative
S1608	Randomized phase II trial in early relapsing or refractory <i>follicular lymphoma</i>	Grade I, II, IIIa follicular lymphoma at initial dx and at relapse ≥ 18 See prior/concurrent therapy criteria	TGR-1202 800mg PO + Obinutuzumab 1000mg IV qcycle x 12 vs Lenalidomide 20mg PO + Obinutuzumab 1000mg IV qcycle x 12 vs CHOP PO qcycle x 6 + Obinutuzumab 1000mg IV qcycle x 12 *1 cycle = 28 days	Cooperative Request approval from NCI CIRB

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
MELANOMA				
EA6141	Randomized phase II/III study of Nivolumab plus Ipilimumab plus Sargramostim vs Nivolumag plus Ipilimumab in patients with unresectable stage III or stage IV melanoma	≥ 18 BRAF mutational status of tumor, wild type or mutated Unresectable stage III or IV No – pior Ipil and/or anti PD-1/PD-L1 agent in metastatic setting, No hx diverticulitis (diverticulosis ok), autoimmune disease	Cycle 1-4; Nivolumab IV, + Ipilimumab IV + Sargramostim SC Cycle 5- x 2 years or progression; Nivolumab IV + Sargramostin SC vs Cycle 1-4 Nivolumab IV +, Ipilimumab IV. Cycle 5 – x 2 years or progression; Nivolumab IV	Cooperative
S1801	Phase II randomized study of adjuvant vs neoadjuvant MK-3475 (pembrolizumab) for clinically detectable stage III-IV high-risk melanoma	≥ 18 Resectable melanoma. Stage III (N1b, N1c, N2b, N2c, N3b, N3c) or Stage IV No – previous neoadjuvant tx, prior non-immunotherapy adjuvant therapy.	Adjuvant → Surgery → Resection → Adjuvant Pembrolizumab → Adjuvant MK-3475 200mg IV q3w x 18 doses vs Neoadjuvant → MK3475 q3w x 3 doses → surgery	Cooperative

			→ surgical resection → adjuvant Pembrolizumab → Adjuvant MK3475 200mg IV q3w x 15 doses	
--	--	--	---	--

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
MULTIPLE MYELOMA				
EAA181	Effective quadruplet utilization after treatment evaluation (EQUATE): A Randomized phase 3 trial for newly diagnosed multiple myeloma not intended for early autologous transplantation	≥ 18 ECOG 0-2, 3 allowed if d/t pain Ineligible for stem cell transplantation or willing to delay until first relapse or later	Step 1: Induction – 9 cycles ARM A: Drd = daratumumab, lenalidomide, dexamethasone Verses ARM B: 9 cycles and maintenance (until disease progression) Btz = Bortezomib + Drd	Cooperative IRB PENDING
Sanofi OBS16577	A prospective, non-interventional, multinational, observational study with isatuximab in patients with relapsed and/or refractory multiple myeloma (RRMM)	≥ 18 Must have received 1 prior line of therapy Patients who will be receiving isatuximab	Observation Baseline – up to 4 weeks prior Treatment observation period – q3m up to 30 days after treatment d/c Follow-up – 30 days after	Pharmaceutical

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
MYELOYDYSPLASTIC (MDS)				
ECOG NHLBI-MDS	National Myelodysplastic Syndromes (MDS) Study	≥ 18 Suspected MDS or MDS/MPN overlap disorders OR dx w/ denovo or therapy-related MDS	Observational study with specimen acquisition	Cooperative Physician training required

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
NEUROPATHY				

MERCY
FEBRUARY 2021

A221805	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study			Cooperative IRB PENDING
----------------	--	--	--	-----------------------------------

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
PANCREAS				
EA2186	A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)	ECOG 0-2 ≥ 70 years of age	ARM A: Gemcitabine/Nab-Paclitaxel ARM B: Fluorouracil, Leucovorin, Liposomal	Cooperative IRB PENDING

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
PROSTATE				
S1802	Phase III randomized trial of standard systemic therapy (SST) versus standard systemic therapy plus definitive treatment (surgery or radiation) of the primary tumor in metastatic prostate cancer	≥ 18 Adenocarcinoma (small cell or squamous cell not eligible) Intact prostate, no prior local therapy No – brain mets	Standard Systemic Therapy (SST) prior to randomization. Randomized to SST only (NCCN guidelines) or ST and definitive treatment (physician's choice or radical prostatectomy or radiation therapy to the primary tumor)	Cooperative

PROTOCOL	TITLE	Key ELIGIBILITY	TREATMENT	SPONSOR
SOLID TUMORS				
2018-01	Blood sample collection to evaluate	≥ 18	None – evaluate biomarkers	Pharmaceutical

MERCY
FEBRUARY 2021

	biomarkers in subjects with untreated solid tumors	Untreated primary malignancy of breast, lung, colorectal, prostate, bladder, uterine, kidney/renal pelvis, pancreatic, liver, stomach, ovarian or esophageal CA NO – previous CA dx x 5 yrs any treatment of primary malignancy or sites of metastases	associated with cancer as potential targets for diagnostic assays and to support subsequent assay development activities	
--	--	--	--	--

PROTOCOL	TITLE			SPONSOR
RARE OR UNKNOWN	ACTIVE	TEMORARY CLOSURE		Cooperative
S1609	11 – Sarcomatoid carcinoma of lung	4 – undifferentiated carcinoma of gastrointestinal (GI) tract		
	12 – Bronchoalveolar carcinoma lung OR Adenocarcinoma in situ, minimally invasive adenocarcinoma, lepidic predominant adenocarcinoma, or invasive mucinous adenocarcinoma	11 – Sarcomatoid carcinoma of lung		
	19 – Spindle cell carcinoma of kidney, pelvis, ureter	18 – Squamous cell variants of the genitourinary (GU) system		
	27 – Dermoid tumors	29 – Malignant giant cell tumors		
	38 – Perivascular epithelioid cell tumor (PECom)			
	40 – Peritoneal mesothelioma	40 – Peritoneal mesothelioma		
	41 – Basal cell carcinoma	46 – Clear cell ovarian cancer		
	46-Clear cell ovarian cancer	51 (3-4) – Angiosarcoma		

MERCY
 FEBRUARY 2021

	47 – Gestational trophoblastic disease	53 – Treat-emergent small-cell neuroendocrine prostate cancer		
	49 – Small cell carcinoma of the ovary, hypercalcemic type			
	50 – PD-L1 amplified tumors			
	51 (2-19) - Angiosarcoma 51 (3-4) – Temp closed			