St. Charles HEALTH SYSTEM

FEATURED TRIALS: JUNE 2019

Brief Title	Summary of Study	Key Features
BILIARY TRACT (Optimal-LEXICON)	Oral XERMELO plus 1st Line "Gem/Cis" Chemo for Locally advanced, unresectable, recurrent **or** MET Biliary Tract Cancer in patients with plans to initiate treatment.	Histo or Cyto confirmed; Naïve to tumor-directed therapy in locally advanced, unresectable, or MET setting. Prior t(x) w/ Chemo in adjuvant setting permitted if PD confirmed after 6 months of prior treatment.
BREAST **A171601** (PCRC, *DCP-001)*	To estimate the safety and tolerability (adverse event rate) of the combination of palbociclib and letrozole or fulvestrant	Age over 70 with estrogen receptor-positive, HER2-negative metastatic breast cancer.
DUCTAL CARCINOMA IN SITU (DCIS) **AFT-25: "COMET"**	Evaluating the clinical and quality of life outcomes for women with low risk DCIS: usual treatment vs. "close monitoring"	DCIS low or intermediate grade
BREAST **A011502: "ABC"** (PCRC, *DCP-001)*	A randomized phase III double blinded placebo trial of aspirin as adjuvant therapy for node-positive, HER2 negative	Node positive, HER2 negative, any ER/PR
BREAST **A011401: "BWEL"** (PCRC, *DCP-001)*	Evaluating the role of weight loss in adjuvant tx of overweight and obese women with breast cancer	BMI >27, ER/PR+ T0-3 N1-3 OR T3N0, OR ER/PR -
BREAST **S1418** (PCRC, *DCP-001)*	Pembrolizumab as adjuvant treatment in Triple-Negative patients	≥1cm residual disease or positive lymph node post neoadjuvant chemo
CERVICAL (Optimal-Agenus)	2nd Line -- Dual blockade AGEN 1884 Hum Mono G1 blocks CTLA-4 AGEN 2034 G4 blocks PD-1 binding	30 patients left; Relapse after 1st line plat double; Measurable D; no prior antibody/drug targeting T-cell co-reg, anti-PD1, anti-PDL-1 or Anti-CTLA-4.
COLON **S0820** (PCRC, *DCP-001)*	Eflornithine + Sulindac vs Placebo	Stage 0-3 CRC treated with resection alone or resection and chemo.
GENITOURINARY **Urothelial or Renal** (Optimal-NEKTAR)	1st Line + Conjugated Immunotherapy cytokine	Inoperable, Locally adv/met urothelial incl. renal pelvis, ureters, bladder, urethra with fresh b(x) @ screening. Renal will accept untreated patients.
Pancreatic (Optimal-Eli Lilly)	2nd Line; AM0010-PEGylated Recombinant. Human Interleukin-10 +/- SOC FOLFOX CT showing PD on 1st line; then randomize within 28 days	Hist d(x) of Panc Adenocarc (by PATH) Or Path-confirmed hist/cyt d(x) of panc origin with: a- mass in pancreas; or b-history of Panc Adenocarcinoma. No prior Platinum allowed
LYMPHOMA (Optimal-XYNOMIC)	4th + Line; Abexinostat- An oral HDAC-inhibitor. Prior trials show > 50% response.	G1-3a follicular lymphoma. Prior T(x) to include anti-CD20 antibody and cytotoxic therapy.
LUNG **A151216** (PCRC, *DCP-001)* "ALCHEMIST-SCREEN"	Following physician choice of std surgery, chemo, &/or radiation, Stdy tx: Sub-Stdy1 (***A081105***): erlotinib or observation for EGFR mutation. Sub-Stdy2 (***E4512***): crizotinib or observation for ALK mutation. Sub-Stdy3 (***EA5142***): nivolomab vs observation (for both PDL1 + or -)	IB (≥4 cm), II or IIIA non-squamous or squamous NSCLC; completely resected; Patients are eligible to be screened even with known local negative EGFR or ALK test

For more information, please contact one of our Research Coordinators
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LUNG - NSCLC "AEGEAN" (Astra Zeneca) Bill Martin-PI Jenn Dixon-Sub-I To start mid-Jun2019	Phase III, PBO-controlled. Neoadj/Adj Durvalumab for Resectable Stage IIA-Selected IIIB, squamous or non-squamous. Available SOC Chemo regimens for both durva and placebo arms include: a-Carboplatin + paclitaxel b-Cisplatin + gemcitabine c-Pemetrexed + cisplatin d-Pemetrexed + carboplatin Durvalumab-only provided by Sponsor	Arm 1: 1500 mg durvalumab plus platinum-based chemotherapy before surgery * 3-4, 21-day cycles. Then surgery, followed by up to 12, 28-day cycles of durvalumab. Arm 2: Placebo plus platinum-based chemotherapy before surgery followed by Placebo q4wks for up to 12 cycles post-surgery. EGFR and ALK mutations accepted, but capped @ 20%.
LUNG **EA5163** (PCRC, *DCP-001)* "First Line Pembro" Immunobiomarker signature driven analysis	First-line Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Post-progression in Advanced Non-squamous NSCLC (Stage IV + limited Stage IIIB) PD-L status must be >= 1%. Stratified by 1-49%; over 50%. ECOG 0-1 only.	***Arm 1*:** If 1st Line-Pembro 200 mg IV for 2 yrs or until progression.Then start 2nd line, w/Pemetrexed+Carbo for max 4 cycles; then pemetrexed alone q3wks until progression. ***Arm 2*:** If 1st line- Pembro 200 mg IV for 2 yrs or until progression. Then start 2nd line, w/Pembro + Pemetrexed for max 4 cycles; then continue as maint.dose until progression. ***Arm 3***: Induction is same as Arm 2. Maint. Phase is Pembro+ Pemetrexed for max 2 years or until progression, then pemetrexed alone until progression per Standard of Care.
LUNG **S1400/ LUNGMAP** (PCRC, *DCP-001)* "LUNG MAP BIOMARKER"	A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)	2 sub-protocols: (a) ***S1400F***= Durva + Trem in Anti-PD1/ PDL1 inhibitor resistant; and (b) ***S1900A***= LOH high and/or BRCA1/2 deleterious mutation.
MELANOMA **S1801**	Adjuvant Versus NeoAdjuvant (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma	Advanced Melanoma with BRAFV600E or BRAFV600K mutant; 1st line tx
MELANOMA **S1616** (PCRC, *DCP-001)*	Ipilimumab Vs Nivolumab + Ipilimumab	Advanced melanoma; prior therapy with a PD1 or PDL1 immunotherapy (ex. Opdivo or Keytruda)
PROSTATE (Optimal-HINOVA) Available July 2019	CRPC: Asymptomatic or mild symptoms. Untreated with AR or Androgen-biosynthesis inhibitors. Oral HC-1119= androgen receptor inhibitor	1:1 randomization to HC 1119 or Anzalutamide + HC Requires ongoing androgen deprivation therapy with a gonadotropin releasing hormone analogue or bilateral Orch.
RECTAL + ANAL	Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/ Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification	KRAS & NRAS Wild Type. No BRAF V600E exon 15 mutation. No prior t(x) w/ either cetuximab or pertuzumab. **Arm 1: TP; Arm 2: CETIRI**.

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