CHOA Clinical Trial Master List

UPCOMING CLINICAL TRIALS

COLORECTAL

POLAR-M: A Phase 3, double-blind, multicenter, placebo-controlled study of PledOx used on top of modified FOLFOX6 (5-FU/FA and Oxaliplatin) to prevent chemotherapy induced peripheral neuropathy (CIPN) in patients with first-line metastatic colorectal cancer	
Sponsor: Pled Pharma ****Delayed until September/October, per sponsor**** ****FOLFOX +/- Avastin Allowed****	Therapy Line: **1st Line Metastatic** Drug Classification:
Principal Investigator: James M. Orcutt, MD	**CRC:**
Basic Enrollment Information Criteria: Metastatic (stage IV) CRC, pathologically confirmed adenocarcinoma of the colon or rectum. No prior systemic chemotherapy (within the previous 12 months) and/or biologic/targeted therapy for metastatic CRC. Patient indicated for at least 3 months of oxaliplatin-based chemotherapy (without any pre-planned treatment breaks) and without any clinically observed neurological disorders. ECOG performance status of 0 or 1. Adequate renal function: creatinine clearance >50 cc/min using the Cockroft andGault formula or measured. **Exclusion Criteria**: Any grade of neuropathy from any cause. Any prior oxaliplatin-based chemotherapy <1 year before the randomization. Any evidence of severe or uncontrolled systemic diseases (e.g., unstable or uncompensated respiratory, cardiac, unresolved bowel obstruction, hepatic or renal disease). Known hypersensitivity to any of the components of mFOLFOX6 and, if applicable, biological therapies to be used in conjunction with the chemotherapy regimen or any of the excipients of these products.	

MULTIPLE MYELOMA

Amgen 20170596: An Open-label Phase 4 Study of Carfilzomib (Kyprolis) Plus Dexamethasone To Assess Tolerability and Adherence in Subjects With Relapsed or Refractory Multiple Myeloma at US Community Oncology Centers	
Sponsor: Amgen ****Contract negatiations****	Therapy Line: **Relapsed/Refractory** Drug Classification:
Principal Investigator: George F. Geils, Jr., MD	**CRC:**
Basic Enrollment Information Criteria: Relapsed MM after last treatment or refractory while receiving non-proteasome Inhibitor therapy. Measurable disease with at least 1 of the following assessed within 21 days prior to enrollment: • immunoglobulin G (IgG) MM: serum monoclonal protein (M-protein) level ≥ 1.0 g/dL • IgA, IgD, IgE multiple myeloma: serum M-protein level ≥ 0.5 g/dL • urine M-protein ≥ 200 mg per 24 hours • in subjects without detectable serum or urine M-protein, serum free light chain (SFLC) ≥ 100 mg/L (involved light chain) and an abnormal serum kappa lambda ratio. (ECOG PS) of 0 to 1. Subjects must have at least partial response (PR) to at least 1 line of prior therapy. Subjects must have received at least 1 but not more than 3 prior lines of therapy for MM (induction therapy followed by stem cell transplant and consolidation/maintenance therapy will be considered as 1 line of therapy. **Exclusion Criteria**: Waldenström macroglobulinemia. Multiple myeloma of IgM subtype. POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes). History of plasma cell leukemia. Myelodysplastic syndrome. History of other malignancy within the past 5 years. Immunotherapy within 21 days prior to enrollment. Chemotherapy with approved anticancer therapeutic within 21 days prior to enrollment.	