CHOA Clinical Trial Master List

HEPATOCELLULAR CARCINOMA

TaiRx CVM004: A Phase 2, Open-Label Study with Orally Administered CVM-1118 and Sorafenib in Subjects with Advanced Hepatocellular Carcinoma	
Sponsor: TaiRX	Therapy Line: **1st line Advanced-Stage** Drug Classification: **anti-vascular mimicry agent**
Principal Investigator: David Ellison, MD	**CRC:**
Basic Enrollment Information Criteria: Pathologically or cytologically-confirmed, advanced-stage hepatocellular carcinoma without prior systemic treatment and Child-Pugh liver function class A appropriate for treatment with sorafenib. Measurable disease according to the Response Evaluation Criteria in Solid Tumors (RECIST v.1.1). ECOG performance status of 0-1. **Exclusion Criteria:** Major surgery (other than diagnostic surgery) or radiation therapy within 28 days of starting study treatment. Systemic anticancer therapy (e.g., chemotherapy, hormonal, investigational, biological therapies) within 28 days (or fewer than 5 half-lives, whichever is shorter) of starting study treatment except for ongoing hormonal therapy administered for control of a second cancer (e.g., breast or prostate cancer). Other known active cancer(s) likely to require treatment in the next two (2) years or likely to impact the assessment of any study endpoints. Receipt of a CYP3A4 inducer less than 28 days or 5 half-lives of the CYP3A4 inducer prior to the first day of sorafenib administration. Known CNS metastases unless appropriately treated and neurologically stable for ≥ 4 weeks.	

NON-SMALL CELL LUNG CANCER

ARMO Cypress 01: A Randomized Phase 2 Trial of AM0010 in Combination with Pembrolizumab vs. Pembrolizumab Alone as First-line Therapy in Patients with Metastatic Non-Small Cell Lung Cancer whose Tumors Have High PD-L1 Expression	
Sponsor: Armo Biosciences ****contract negotiations****	Therapy Line: **1st Line** Drug Classification: **Long-acting form of recombinant human Interleukin 10**
Principal Investigator: Brian M. Lingerfelt, MD	**CRC:**
Basic Enrollment Information Criteria: Patients must have histologically or cytologically confirmed WT NSCLC that is stage IV / metastatic or recurrent (progression after surgery or radiation or chemo-radiation treatment for loco-regional disease). Patients must be naïve to therapy for the advanced stage of the disease. Previous neoadjuvant or adjuvant therapy is allowed for patients who successfully underwent complete radical surgery and ONLY if the last treatment was administered more than 12 months prior to the start of the trial treatment. Patients with tumor tissue high expression of PD-L1 as defined by Tumor Proportion Score (TPS) ≥ 50% and as determined by an FDAapproved test. PD-L1 IHC 22C3 pharmDx assay is mandatory. Patients without known EGFR or EML4-ALK mutation. (ECOG) performance status of 0 or 1. **Exclusion Criteria:** Patients with life expectancy of < 3 months. Patients with no history of tobacco use. Patients with other active malignancies requiring concurrent intervention. Patients with previous malignancies (except non-melanoma skin cancers and the following in situ cancers: bladder, gastric, colon, cervical/dysplasia, endometrial, melanoma, or breast) are excluded unless a complete remission was achieved at least 2 years prior to trial entry AND no additional therapy is required or anticipated to be required during the trial period. Patients that have received pembrolizumab. Patients that have received therapy with anti-PD-1, anti-PD-L1, anti- PD-L-2, anti-CD-137, and/or anti CTLA-4 antibodies (including ipilimumab or any other antibody or drug specifically targeting T cell co-stimulation or checkpoint pathways).	