

## SF CAN Liver Task Force November 2020 Clinical Trials Newsletter

\*For CPMC trials: Enrollment to a clinical trial will only be considered when standard-of-care options are unavailable or if clinical trial participation is deemed necessary per patient care. Please contact [clinicalresearch@sutterhealth.org](mailto:clinicalresearch@sutterhealth.org) for more details on specific study statuses.

### UCSF Clinical Trials for Biliary Tract Cancer

#### First-Line Treatment

Title: SWOG-S1815 A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers

ClinicalTrials.gov ID: NCT03768414

Description: The purpose of this study is to compare overall survival (OS) in patients with untreated, advanced biliary cancers treated with gemcitabine and cisplatin (GC) versus those treated with gemcitabine, cisplatin, and nab-Paclitaxel (GCN).

Investigator: Robin K. Kelley, MD

Eligibility: Histologically or cytologically confirmed intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer; documented metastatic or locally advanced unresectable disease on computed tomography (CT) or magnetic resonance (MR) imaging; must not have received prior systemic therapy for the current metastatic or locally advanced biliary cancer; must not have received adjuvant therapy within 6 months prior to registration

Status: Active and open to enrollment

Contact: Alex Milloy (415) 502-3310: [Alexandra.Milloy@ucsf.edu](mailto:Alexandra.Milloy@ucsf.edu)

Title: A Phase 3 Randomized, Double Blind Study of Pembrolizumab (MK-3475) Plus Gemcitabine/Cisplatin Versus Placebo Plus Gemcitabine/Cisplatin for First-Line Advanced and/or Unresectable Biliary Tract Carcinoma (BTC) (MK-3475-966/KEYNOTE-966) (KEYNOTE-966)

Clinical trials.gov ID: NCT04003636

Description: This is a study of pembrolizumab plus gemcitabine/cisplatin versus placebo plus gemcitabine/cisplatin as first-line therapy in participants with advanced and/or unresectable biliary tract carcinoma.

Investigator: Robin K. Kelley, MD

Eligibility: Histologically confirmed diagnosis of advanced or unresectable biliary tract cancer and have measurable disease based on RECIST 1.1. Must not have received previous systemic therapy for advanced or unresectable biliary tract cancer with the exception of adjuvant therapy.

Status: Active and open to enrollment

Contact: Kelly Bauer (415) 514-5633, Email: [Kelly.Bauer@ucsf.edu](mailto:Kelly.Bauer@ucsf.edu)

#### Any Treatment beyond First-Line

Title: A Phase II Multicenter, Single Arm Study of Oral BGJ398 in Adult Patients with Advanced or Metastatic Cholangiocarcinoma with FGFR2 Gene Fusions or Other FGFR Genetic Alterations Who Failed or Are Intolerant to Platinum-based Chemotherapy

ClinicalTrials.gov ID: NCT02150967

Description: This is a multi-center, open label, single arm phase II study evaluating BGJ398 anti-tumor activity in advanced or metastatic cholangiocarcinoma patients with FGFR genetic alterations.

Investigator: Robin K. Kelley, MD

Eligibility: Histologically or cytologically confirmed cholangiocarcinoma. Patient must have received at least one prior regimen containing gemcitabine with or without cisplatin for advanced/ metastatic disease. Patient should have evidence of progressive disease following prior regimen, or if prior treatment discontinued due to toxicity must have continued evidence of measurable or evaluable disease.

Status: Active and open to enrollment

Enrollment update: Open only to cholangiocarcinoma patients with selected FGFR alterations. Please contact coordinator with possible candidates or for more information.

Contact: Maxine Hamilton (415) 476-3755: [Maxine.Hamilton@ucsf.edu](mailto:Maxine.Hamilton@ucsf.edu)

## **UCSF Clinical Trials for Solid Tumors**

### **Any Treatment beyond First-Line**

Title: A Phase 1/1b Study of TPST-1120 as a Single Agent and in Combination with Systemic Anti-Cancer Therapies in Subjects with Advanced Solid Tumors

ClinicalTrials.gov ID: NCT03829436

Description: This is a phase 1/1b open label, multicenter dose escalation and dose expansion study to investigate the safety, tolerability and anti-tumor activity of TPST-1120, a small molecule selective antagonist of PPAR $\alpha$  (peroxisome proliferator activated receptor alpha) as monotherapy and in combination with other systemic anticancer agents including nivolumab, an anti-PD1 antibody, docetaxel, a cytotoxic chemotherapeutic agent and cetuximab, an anti-EGFR antibody in subjects with advanced solid tumors.

Investigator: Pamela Munster, MD

Eligibility: Have at least one measurable lesion per RECIST v1.1; ECOG performance status of 0-1 at enrollment; progressive disease or previously untreated tumors for which no standard therapy exists or are treatment naïve at time of study entry are eligible. For patients with cholangiocarcinoma: must have progressed or have a history of intolerance to a platinum-containing regimen and received no more than 5 prior systemic therapies. For patients with HCC: Child-Pugh class A; any viral status (HBV, HCV, or none) is eligible but co-infection of hepatitis B and hepatitis C or hepatitis B and hepatitis D will be excluded.

Status: Active and open to enrollment

Contact: Lily Stander (415) 535-4084; [Lily.Stander@ucsf.edu](mailto:Lily.Stander@ucsf.edu)

## **UCSF Clinical Trials in Development**

### **Any Treatment beyond First-Line**

Title: Expanded Access Study of TAS-120 in Patients with Advanced Cholangiocarcinoma Harboring FGFR2 Gene Arrangements

ClinicalTrials.gov ID: NCT04507503

Description: This is an open-label study to provide expanded access to TAS-120 prior to its commercial availability for patients with Advanced Cholangiocarcinoma Harboring FGFR2 Gene Rearrangements who have failed standard therapy or who are unable to tolerate standard therapy.

Investigator: Robin K. Kelley, MD

Eligibility: Histologically confirmed locally advanced, or metastatic, or recurrent unresectable cholangiocarcinoma harboring FGFR2 gene rearrangements, failed standard therapy or standard therapy is not tolerated, have measurable or non-measurable lesion(s), ECOG performance status of 0 or 1.

Status: Activation by mid-November 2020

Contact: Kelly Bauer (415) 514-5633, Email: [Kelly.Bauer@ucsf.edu](mailto:Kelly.Bauer@ucsf.edu)

## **CPMC Clinical Trials for Liver Cancer**

### **Adjuvant Treatment**

Title: A Study of Nivolumab in Patients with Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation (CheckMate 9DX)

Clinical trials.gov ID: NCT03383458

Description: This study will investigate if nivolumab will improve recurrence-free survival (RFS) compared to placebo in participants with HCC who have undergone complete resection or have achieved a complete response after local ablation, and who are at high risk of recurrence.

Investigator: Ari Baron, MD

Eligibility: First diagnosis of HCC who have undergone a curative resection or ablation; non-viral related-HCC, or if they have HBV-HCC, or HCV-HCC; Child Pugh score 5 or 6

Status: Active and open to enrollment

Contact: [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)

### **Any Treatment beyond First-Line**

Title: A Study of Ramucirumab (LY3009806) Versus Placebo in Participants With Hepatocellular Carcinoma and Elevated Baseline Alpha-Fetoprotein (REACH-2)

Clinical trials.gov ID: NCT02435433

Description: The purpose of this study is to evaluate the safety and efficacy of ramucirumab in participants with hepatocellular carcinoma (HCC) and elevated baseline alpha-fetoprotein. Participants will be randomized to ramucirumab or placebo in a 2:1 ratio (Main Global Cohort and China Maximized Extended Enrollment [ME2] Cohort). Participants may also receive ramucirumab if eligible to be enrolled in Open-Label Expansion (OLE) Cohort.

Investigator: Ari Baron, MD

Eligibility: Subjects 18 years and older with a diagnosis of HCC based on histopathologic findings, or a diagnosis of cirrhosis and a tumor with classical HCC imaging characteristics, and BCLC stage C or stage B not amenable to locoregional therapy.

Status: Temporary enrollment hold

Contact: [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)

## **CPMC Clinical Trials for Biliary Tract Cancer**

### **First-Line Treatment**

Title: Phase 3 Study of BJJ398 (Oral Infigratinib) in First Line Cholangiocarcinoma With FGFR2 Gene Fusions/Translocations (PROOF)

Clinicaltrials.gov ID: NCT03773302

Description: Infigratinib is an oral medication which selectively binds to fibroblast growth factor receptor (FGFR)-2 and is being developed to treat participants with FGFR-2 mutated cholangiocarcinoma. The purpose of the study is to evaluate the efficacy and safety of the investigational agent oral Infigratinib vs standard of care chemotherapy (gemcitabine plus cisplatin) in first-line treatment of participants with unresectable or metastatic cholangiocarcinoma with FGFR-2 gene fusions/translocations.

Investigator: Ari Baron, MD

Eligibility: Patients 18 y/o and older, with histologically or cytologically confirmed non-resectable, recurrent, or metastatic cholangiocarcinoma and documented FGFR-2 gene fusions/translocations.

Status: Active and open to enrollment

Contact: [Clinicalresearch@sutterhealth.org](mailto:Clinicalresearch@sutterhealth.org)

Title: Durvalumab or Placebo in Combination With Gemcitabine/Cisplatin in Patients With 1st Line Advanced Biliary Tract Cancer (TOPAZ-1)

Clinicaltrials.gov ID: NCT03875235

Description: A Phase III Randomized, Double-Blind Placebo Controlled, Multi-Regional, International Study of Durvalumab in Combination with Gemcitabine Plus Cisplatin Versus Placebo in Combination with Gemcitabine Plus Cisplatin for Patients With First-Line Advanced Biliary Tract Cancers

Investigator: Ari Baron, MD

Eligibility: Histologically confirmed, unresectable advanced or metastatic biliary tract, including cholangiocarcinoma (intrahepatic or extrahepatic) and gallbladder carcinoma.

Status: Active and open to enrollment

Contact: [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)

## **CPMC Clinical Trials for Solid Tumors**

### **Any Treatment beyond First-Line**

Title: Molecular Analysis for Therapy Choice (MATCH)

Clinicaltrials.gov ID: NCT02465060

Description: This phase II trial studies how well treatment that is directed by genetic testing works in patients with solid tumors or lymphomas that have progressed following at least one line of standard treatment or for which no agreed upon treatment approach exists.

Investigator: NCI - National Cancer Institute

Eligibility: Subjects, 18 y/o and older, who have histologically documented solid tumors or histologically confirmed diagnosis of lymphoma or multiple myeloma requiring therapy and that has progressed following at least one line of standard systemic therapy and/or for whose disease no standard treatment exists that has been shown to prolong survival.

Status: Active and open to enrollment

Contact: [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)

Title: Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer (TAPUR)

Clinicaltrials.gov ID: NCT02693535

Description: This study is a non-randomized clinical trial that aims to describe the safety and efficacy of commercially available, targeted anticancer drugs prescribed for treatment of patients with advanced cancer that has a potentially actionable genomic variant

Eligibility: Subjects with histologically-proven locally advanced or metastatic solid tumor, multiple myeloma or B cell non-Hodgkin lymphoma who are no longer benefiting from standard anti-cancer treatment or for whom, in the opinion of the treating physician, no such treatment is available or indicated. Must have measurable and evaluable disease per RECIST v1.1 and have a tumor genomic profile for which single agent treatment with one of the FDA approved targeted anti-cancer drugs included in this study has potential clinical benefit based on the criteria described in protocol

Status: Active and open to enrollment

Contact: [ClinicalResearch@sutterhealth.org](mailto:ClinicalResearch@sutterhealth.org)

### **Kaiser Clinical Trials for Liver Cancer**

\*\*\*No active hepatobiliary trials at the moment.