GI Phase I Clinical Trial Portfolio

Study Number	Disease Status	Slot Availability	Study Title	Basic Eligibility
HCC Studies				
Eisai H3B-6527-G000-101	Advanced, unresectable, or recurrent HCC/ICC TUMORS MUST EXPRESS FGF19 [FOUNDATION, ETC.]	Open and Enrolling	An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced HCC **FGFR ORAL PILL (MONOTHERAPY)**	1. Child Pugh A 2. Failed/Intolerant to Sorafenib 3. No clinically significant ascites **4. Be tumor- FGF19-positive as determined by a Sponsor-designated laboratory prior to enrollment** 5. Requires Biopsy
Sanofi ACT15377	Unresectable HCC (excluding fibrolamellar and mixed hepatocellular/cholangiocarcinoma). Radiology diagnosed HCC. Child Pugh Class A.	Slots Strictly Allocated - Must Request Prior	A Phase 1/2 open-label, multi-center, safety, preliminary efficacy and pharmacokinetic (PK) study of isatuximab (SAR650984) in combination with atezolizumab or isatuximab alone in patients with advanced malignancies	1. Stage C disease, or BCLC Stage B disease not amenable to locoregional therapy or refractory to locoregional therapy, and not amenable to a curative treatment approach 2. PD during or after treatment with either sorafenib or lenvatinib, or intolerance to the therapy
Cholangio Studies				
Incyte 54828 (FGFR)	Cholangiocarcinoma	Slots Strictly Allocated - Must Request Prior	A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies **FGFR ORAL PILL (MONOTHERAPY)**	1. Must have FGFR translocation by Foundation Mecidine, Caris, etc. 2. Must be amendable to biopsy
Eisai H3B-6527-G000-101	Advanced, unresectable, or recurrent HCC/ICC TUMORS MUST EXPRESS FGF19 [FOUNDATION, ETC.]	Open and Enrolling	An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced HCC **FGFR ORAL PILL (MONOTHERAPY)**	1. Child Pugh A 2. Failed/Intolerant to Sorafenib 3. No clinically significant ascites **4. Be tumor- FGF19-positive as determined by a Sponsor-designated laboratory prior to enrollment** 5. Requires Biopsy

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Esophageal/Gastroesophageal Studies				
Adjuvant				
BMS CA209-577	Stage II or Stage III adeno or squamous carcinoma of the esophagus or gastroesophageal junction	Open and Enrolling	A Randomized, Multicenter, Double Blind, Phase III Study of Nivolumab or Placebo in Subjects with Resected Lower Esophageal, or Gastroesophageal Junction Cancer	1. Must complete pre-operative chemoradiotherapy and surgery prior to enrollment 2. Subject must have complete resection (R0), have been surgically rendered free of disease with negative margins on resected specimens defined as no vital tumor present within 1 mm of the proximal, distal, or circumferential resection margins. Subject must have residual pathologic disease, non-pathologic complete response (nonpCR) of their EC or GEJ, with at least ypN1 or ypT1 listed in the pathology report of resected specimens.
1L - Metastatic				
BMS CA224-060	Histologically- or cytologically-confirmed diagnosis of unresectable, locally advanced, or metastatic GC or GEJ adenocarcinoma	Open and Enrolling	**RANDOMIZED** Study of Relatlimab in Combination with Nivolumab with Chemotherapy Versus Nivolumab with Chemotherapy in Patients with Gastric or GEJ **FOLFOX+OPDIVO** **FOLFOX+OPDIVO+LAG3**	1. Participant must be previously untreated with systemic treatment given as primary therapy for unresectable, locally advanced, or metastatic gastric or GEJ adenocarcinoma
Metastatic				
Metastatic - Squamous Cell				
Genentech - Roche BP40234	Recurrent or metastatic esophageal cancer (Squamous)	Open and Enrolling	PHASE II STUDY TO EVALUATE THE THERAPEUTIC ACTIVITY OF RO6874281, AN IMMUNOCYTOKINE, CONSISTING OF INTERLEUKIN-2 VARIANT (IL-2V) TARGETING FIBROBLAST ACTIVATION PROTEIN-A (FAP), IN COMBINATION WITH ATEZOLIZUMAB, IN PARTICIPANTS WITH ADVANCED AND/OR METASTATIC SOLID TUMORS	1. Experienced progression or intolerance while receiving > 1 line of standard therapy 2. Must be amendable to biopsy

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Study Number	Disease Status	Slot Availability	Study Title	Basic Eligibility
Colon Studies				
2nd Line				
BMS CV202-103 (CRX2)	Metastatic CRC previously treated with one line of oxaliplatin-based systemic therapy in the metastatic setting or progression on or within 6 months of adjuvant oxaliplatin based chemotherapy.	Open and Enrolling	RANDOMIZED A Phase Ib/II Study of BMS-813160 in Combination with Chemotherapy or Nivolumab in patients with Advanced Solid Tumors **FOLFIRI + CRX2 (ORAL MEDICATION)** **FOLFIRI ALONE**	1. Must be amendable to biopsy X2
2nd or 3rd Line				
BMS CA021-002 (ICOS)	Participant must have non-resectable metastatic disease	Slot Request Required	A Phase 1/2 Dose Escalation and Combination Cohort Study to Evaluate the Safety and Tolerability, Pharmacokinetics, and Efficacy of BMS-986226 (anti-ICOS mAb) Alone or in Combination with Nivolumab or Ipilimumab in Patients with Advanced Solid Tumors	1. Biopsiable disease - Willing to undergo 2 mandatory tumor biopsies 2. Participants must have received at least 1, but no more than 3, prior systemic therapies for metastatic and/or unresectable disease
Greater than 1st Line - KRAS Wild Type				
Checkpoint REFMAL 449	KRAS wild-type adenocarcinoma of the colon or rectum that is metastatic and/or unresectable	Slots Strictly Allocated - Must Request Prior	A Phase 1/2 Open label, saftey, pharmacokinetic and efficacy study of ascending doses of Oral CK-101 in Patients with Advanced Cancer known as SCRI study REFMAL 449	1. Any refractory solid tumor setting where targeting EGFR may be reasonable 2. Ability to swallow pills
Pancreatic Studies				
1st Line - Unresectable, locally advanced				
Silenseed SLSG12D-P2	Unresectable, locally advanced pancreatic cancer - stage III defined as T4, N (any) and M0	Open and Enrolling	RANDOMIZED Phase 2 - Loder Treatment [VIA EUS] in Combination with Gem+Abraxane vs. Gem+Abraxane Alone WORKING WITH DR. LIGRESTI'S GROUP TO PERFORM PROCEDURES	1. Have a target tumor that is accessible for intratumoral administration by EUS as determined by the radiologist/gastroenterologist performing the EUS intratumoral administration. EXCLUSION: Subjects with resectable and borderline resectable pancreatic cancer
1st Line				
BMS CV202-103 (CRX2)	Metastatic pancreatic previously untreated or recurring systemically after surgery or > 6 months post neoadjuvant/adjuvant therapy.	Open and Enrolling	RANDOMIZED A Phase Ib/II Study of BMS-813160 in Combination with Chemotherapy or Nivolumab in patients with Advanced Solid Tumors **GEM/ABRAXANE + CRX (ORAL DRUG)** **GEM/ABRAXANE + CRX (ORAL DRUG) + OPDIVO** **GEM/ABRAXANE ALONE**	1. Must be amendable to biopsy X2
Greater than 1st Line				
Checkpoint REFMAL 449	Locally advanced, unresectable or metastatic pancreatic cancer	Slots Strictly Allocated	A Phase 1/2 Open label, saftey, pharmacokinetic and efficacy study of ascending doses of Oral CK-101 in Patients with Advanced Cancer known as SCRI study REFMAL 449	1. Any refractory solid tumor setting where targeting EGFR may be reasonable 2. Ability to swallow pills