GI Hepatobiliary

- **Hepatocellular Carcinoma**
  - **Localized**
    - No Prior Therapy
      - 1st line
        - IRB #2377
          A humanitarian device exemption use protocol of TheraSphere for treatment of unresectable Hepatocellular Carcinoma
        - IRB 11974
          SOLACE: A Randomized Controlled Trial of Transcatheter Arterial Chemoembolization with Drug-Eluting Beads (DEB-TACE) Versus Sorafenib in the Treatment of Unresectable, Locally-Advanced Hepatocellular Carcinoma
        - IRB #15077
          9785-CL-3021: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Enzalutamide in Subjects with Advanced Hepatocellular Carcinoma
      - 2nd line
        - IRB #11746
          I4T-MC-JVDE: Randomized, Double-Blind, Placebo-Controlled Study of Ramucirumab and Best Supportive Care (BSC) Versus Placebo as Second-Line Treatment in Patients With Locally-Advanced Hepatocellular Carcinoma and Elevated Baseline Alpha-Fetoprotein (AFP) Following First-Line Therapy with Sorafenib
        - IRB #15816
          A Phase II Study of Pembrolizumab (MK-3475) as Monotherapy in Subjects with Previously Systemically Treated Advanced Hepatocellular Carcinoma (KEYNOTE-224)
        - IRB# 15077
          9785-CL-3021: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Ramucirumab and Best Supportive Care (BSC) Versus Placebo as Second-Line Treatment in Patients With Locally-Advanced Hepatocellular Carcinoma and Elevated Baseline Alpha-Fetoprotein (AFP) Following First-Line Therapy with Sorafenib
  - Prior Therapy
    - 1st or 2nd Line
      - IRB# 16255
        INCB 54828-202: A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

- **Cholangiocarcinoma**
  - 1st or 2nd Line
    - IRB# 16255
      INCB 54828-202: A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

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