

For Patients with cHCC-CC

EA2205 Available Through ECOG-ACRIN Cancer Research Group

A Randomized Phase II Trial Evaluating Chemotherapy vs Chemotherapy plus Bevacizumab and Atezolizumab in Advanced Combined Hepatocellular Carcinoma-Cholangiocarcinoma

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age \geq 18 years, ECOG PS 0-1, Child Pugh class A, adequate lab values, measurable disease per protocol
- Must have histologically confirmed diagnosis of combined hepatocellular carcinoma-cholangiocarcinoma (cHCC-CC) based on 2019 WHO classification, including the classical type and intermediate cell carcinoma
- Must have unresectable/metastatic disease
- No prior history of systemic therapy for cHCC-CC
- Patients with prior locoregional therapy are eligible per protocol
- Must not have new/progressive brain metastases (active brain metastases) or leptomeningeal disease
- No prior allogenic bone marrow/solid organ transplant
- No history of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis
- No active/history of autoimmune disease or immune deficiency per protocol; no active tuberculosis
- Must not have received prior treatment with immune checkpoint blockade therapies
- Must not be on treatment with systemic immunosuppressive medication within 2 weeks of randomization, or anticipate the need for systemic immunosuppressive medication during the study (exceptions per protocol)
- No inadequately controlled arterial hypertension; must not have significant vascular disease within 6 months of randomization
- No evidence of bleeding diathesis/significant coagulopathy
- No history of abdominal/tracheoesophageal fistula, GI perforation or intra-abdominal abscess within 6 months of randomization
- No uncontrolled tumor-related pain
- No uncontrolled pleural/pericardial effusion or ascites requiring recurrent drainage procedures

Treatment Plan

See Section 5.0 for Complete Treatment Details

Arm A:

- Atezolizumab 1200 mg IV day 1 followed by
- Bevacizumab 15 mg/kg day 1
- Gemcitabine 1000 mg/m² IV days 1 and 8
- Cisplatin 25 mg/m² IV days 1 and 8
- Repeat cycles every 21 days until progression or unacceptable toxicity
- *NOTE: a safety lead-in phase on Arm A will enroll an initial 6 patients to assess for dose limiting toxicities (refer to Section 5.1.3 for details)*

Arm B:

- Gemcitabine 1000 mg/m² IV days 1 and 8
- Cisplatin 25 mg/m² IV days 1 and 8
- Repeat cycles every 21 days until progression or unacceptable toxicity

All patients will be followed for response until progression and for survival for 3 years from the date of end of treatment visit

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN), <https://open.ctsu.org>

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

Please Enroll Your Eligible Patients!

Study Chair:

David Hsieh, MD

Co-Chair:

Muhammad Beg, MD

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Schema

