Cancer Research Consortium of West Michigan
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FAST FACTS

S1815 - A PHASE III RANDOMIZED TRIAL OF GEMCITABINE, CISPLATIN, AND NAB-PACLITAXEL VERSUS GEMCITABINE AND CISPLATIN IN NEWLY DIAGNOSED, ADVANCED BILIARY TRACT CANCERS

ELIGIBILITY CRITERIA

1. Disease Related Criteria
    a. Patients must have histologically or cytologically confirmed intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer. NOTE: Pathology report must be uploaded in Rave. Histology report must be consistent with an adenocarcinoma with pancreaticobiliary primary assuming there are no pancreatic lesions and other primaries are ruled out per local standard.
    b. Patients must have documented metastatic or locally advanced unresectable disease on CT or MR imaging CT scans or MRIs used to assess measurable disease as defined in Section 10.1. must have been completed within 28 days prior to registration. CT scans or MRIs used to assess non-measurable disease must have been completed within 42 days prior to registration. All disease must be assessed and documented on the Baseline Tumor Assessment Form.
    c. Patient must not have a current diagnosis of ampullary cancer.

2. Prior/Concurrent Therapy Criteria
    a. Patients must not have received prior systemic therapy for the current metastatic or locally advanced biliary cancer.
    b. Patient must not have received adjuvant therapy within 6 months prior to registration.

3. Clinical/Laboratory Criteria
    a. Patients must have a complete medical history and physical exam within 28 days prior to registration.
    b. Patients must be ≥ 18 years of age.
    c. Patients must have a Zubrod Performance Status of 0 or 1. (See Section 10.4)
    d. Patients must not have a history of peripheral neuropathy of Grade 2 or greater by Common Terminology Criteria for Adverse Events (CTCAE) 5.0. In CTCAE version 5.0 Grade 2 sensory neuropathy is defined as "moderate symptoms; limiting instrumental activities of daily living (ADLs)"
    e. Patients must have adequate bone marrow function as evidenced by all of the following: ANC ≥ 1,500/mcL; platelets ≥ 100,000/mcL; Hemoglobin ≥ 8 g/dL, and serum albumin ≥ 2.8 g/dL. These results must be obtained within 28 days prior to registration.
    f. Patients must have adequate hepatic function as evidenced by the following: total bilirubin ≤ 1.5 x institutional upper limit of normal (IULN) (except patients with Gilbert's Syndrome, who must have a direct bilirubin < 1.5 mg/dL), and SGOT (AST) and SGPT (ALT) ≤ 8 x IULN. These results must be obtained within 28 days prior to registration.
    g. Patients must have adequate renal function as evidenced by ONE of the following: serum creatinine ≤ IULN OR calculated creatinine clearance ≥ 60 mL/min. This serum creatinine result must have been obtained within 28 days prior to registration.

Calculated creatinine clearance = $\frac{(140 - \text{age}) \times \text{wt*} (\text{kg}) \times 0.85 \text{ (if female)}}{72 \text{ Creatinine**} (\text{mg/dl})}$

* The kilogram weight is the patient's actual body weight with an upper limit of 140% of the IB IBW.

** Actual lab serum creatinine value with a minimum of 0.8 mg/dL

h. Patients must have CA19-9 obtained within 42 days prior to registration.

i. Patients must have sodium, potassium, bicarbonate, chloride, BUN, calcium, total protein, magnesium, and alkaline phosphatase obtained within 28 days prior to registration.

j. Patients must not have an active infection requiring systemic therapy.

k. No other prior malignancy is allowed except for the following: adequately treated basal cell or squamous cell skin cancer, *in situ* cervical cancer, adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease free for two years.

l. Patients must not be pregnant or nursing. Women/men of reproductive potential must have agreed to use an effective contraceptive method. A woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation. However, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures.

4. Specimen Submission Criteria

a. Sites must seek additional patient consent for the future use of specimens as described in Section 15.1

SCHEMA