Durvalumab With Gemcitabine and Cisplatin for the Treatment of High-Risk Resectable Liver Cancer Before Surgery

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically or cytologically confirmed intrahepatic cholangiocarcinoma (iCCA) that is resectable by imaging evaluation. Choice of staging modality is left up to the discretion of the treatment team; we favor high-quality CT scan of the chest/abdomen/pelvis with liver or biliary protocol. Eligibility will be confirmed through central imaging review. * Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded for non-nodal lesions and short axis for nodal lesions) as \>= 10 mm (\>= 1 cm) with CT scan, MRI, or calipers by clinical exam. * Patients must be an acceptable risk surgical candidate at the time of enrollment, as determined by a board-certified surgeon with expertise in hepatobiliary surgery. * High-risk iCCA is defined as the presence of any of these factors: * Tumor size \> 5 cm. * Multifocality or satellitosis limited to the same lobe. * Vascular invasion. * Suspected or confirmed (via biopsy) regional lymph node metastases. * Suspected is defined as lymph nodes that are deemed suspicious for metastasis based on large size (criteria vary per anatomical location; 6-10 mm for abdominal and 8-10 mm for pelvic), enhancement pattern, and shape. These may also include lymph nodes that display fludeoxyglucose F 18 (FDG)-avidity on positron emission tomography (PET) scan, if obtained, in the course of disease work-up (not mandatory). * CA 19-9 \> 200 U/mL. * Patients are treatment naïve for iCCA. * Age \>= 18 years. Because no dosing or adverse event data are currently available on the use of durvalumab (MEDI4736) in combination with cisplatin and gemcitabine in patients \< 18 years of age, children are excluded from this study. * Body weight \> 30 kg. * Eastern Cooperative Oncology Group (ECOG) performance status =\< 1 (Karnofsky \>= 70%). * Leukocytes \>= 3,000/mcL. * Hemoglobin \>= 9.0 g/dL. * Absolute neutrophil count \>= 1,500/mcL. * Platelets \>= 100,000/mcL. * Neuropathy grade =\< 1 by CTCAE. * Albumin \>= 2.8 g/dL. * Serum bilirubin =\< 1.5 x institutional upper limit of normal (ULN). * Aspartate aminotransferase (AST)(serum glutamic oxaloacetic transaminase \[SGOT\]) / alanine aminotransferase (ALT)(serum glutamic pyruvic transaminase \[SGPT\]) =\< 3 × institutional ULN. * Serum creatinine =\< 1.5 x institutional ULN. * Measured creatinine clearance \> 60 mL/min or glomerular filtration rate (GFR) \>= 60 mL/min/1.73 m\^2 (by the Cockcroft-Gault equation). * Evidence of post-menopausal status or negative urinary or serum pregnancy test for female pre-menopausal patients. Women will be considered post-menopausal if they have been amenorrheic for 12 months without an alternative medical cause. The following age-specific requirements apply: * Women \< 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinizing hormone and follicle-stimulating hormone levels in the post-menopausal range for the institution or underwent surgical sterilization (bilateral oophorectomy or hysterectomy). * Women \>= 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of all exogenous hormonal treatments, had radiation-induced menopause with last menses \> 1 year ago, had chemotherapy-induced menopause with last menses \> 1 year ago, or underwent surgical sterilization (bilateral oophorectomy, bilateral salpingectomy or hysterectomy). * Life expectancy \>= 12 weeks. * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load. * Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression. * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. If non-protocol anticancer agents for non-study indications is required concurrently with the protocol therapy, the case should be discussed and approved by the study chair and the sponsor (Cancer Therapy Evaluation Program \[CTEP\]). * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better. * Ability to understand and the willingness to sign a written informed consent document. Legally authorized representatives may sign and give informed consent or behalf of study participants.

Exclusion Criteria:

* Potential trial participants should have recovered from clinically significant adverse events of their most recent therapy/intervention prior to enrollment. * Major surgical procedure (as defined by the Investigator) within 14 days prior to the first dose of durvalumab. Note: Local surgery of isolated lesions for palliative intent or biliary stents is acceptable. * Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab. The following are exceptions to this criterion: * Intranasal, inhaled, topical steroids, or local steroid injections (e.g., intra articular injection). * Systemic corticosteroids at physiologic doses not to exceed \<\<10 mg/day\>\> of prednisone or its equivalent. * Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication). * Receipt of live attenuated vaccine within 30 days prior to the first dose of durvalumab. Note: Patients, if enrolled, should not receive live vaccine whilst receiving durvalumab and up to 30 days after the last dose of durvalumab. * Patients who are receiving any other investigational agents. * History of allergic reactions attributed to compounds of similar chemical or biologic composition to durvalumab, gemcitabine, cisplatin, or other platinum-containing compounds. * Patients with uncontrolled intercurrent illness or any other significant condition(s) that would make this protocol unreasonably hazardous. * Pregnant women are excluded from this study because durvalumab (MEDI4736) is an anti-PD-L1 monoclonal antibody agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with durvalumab, breastfeeding should be discontinued if the mother is treated with durvalumab. These potential risks may also apply to other agents used in this study. Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for 6 months after durvalumab administration. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 6 months after completion of durvalumab. * Patients with active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease \[e.g., colitis or Crohn's disease\], diverticulitis \[with the exception of diverticulosis\], systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome \[granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc.\]). The following are exceptions to this criterion: * Patients with vitiligo or alopecia. * Patients with hypothyroidism (e.g. following Hashimoto syndrome) stable on hormone replacement. * Any chronic skin condition that does not require systemic therapy. * Patients without active disease in the last 5 years may be included but only after consultation with the study physician. * Patients with celiac disease controlled by diet alone. * Active infection including tuberculosis (clinical evaluation that includes clinical history, physical examination and radiographic findings, and tuberculosis \[TB\] testing in line with local practice), hepatitis B (known positive HBV surface antigen (HBsAg) result), or hepatitis C. Patients with a past or resolved HBV infection (defined as the presence of hepatitis B core antibody \[anti-HBc\] and absence of HBsAg) are eligible. Patients positive for hepatitis C (HCV) antibody are eligible only if polymerase chain reaction is negative for HCV RNA. * History of allogenic organ transplantation. * Patients with a prior or concurrent malignancy whose natural history or treatment has the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.

Conditions & Interventions

Interventions:
PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, DRUG: Cisplatin, PROCEDURE: Computed Tomography, BIOLOGICAL: Durvalumab, DRUG: Gemcitabine, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Resection
Conditions:
Resectable Intrahepatic Cholangiocarcinoma

More Information

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