NRG Oncology Launches Phase III Study Evaluating Radiotherapy in Addition to Chemotherapy for Patients with Inoperable, Localized Intrahepatic Cholangiocarcinoma

Philadelphia—Cancer that develops in the small bile duct branches inside the liver, known as intrahepatic cholangiocarcinoma (IHC), is most often not treated with surgery because of the advanced stage of the disease at the time of diagnosis. Today, NRG Oncology announces the activation of NRG-GI001, a trial enrolling patients with inoperable, localized IHC to evaluate the value of adding liver-directed radiotherapy (RT) to the standard treatment for IHC of gemcitabine/cisplatin chemotherapy.

“Though a fairly rare gastrointestinal malignancy, intrahepatic cholangiocarcinoma is on the increase in the United States and Asia and is a disease with very dismal prognosis,” says the trial Principal Investigator Theodore Hong, MD, the director of gastrointestinal service in the Department of Radiation Oncology at Massachusetts General Hospital, in Boston. “Results of small, single-institution studies and of collaborative work between investigators at Massachusetts General Hospital and MD Anderson Cancer Center have suggested that radiation therapy is beneficial to patients with IHC. However, this is the first trial to formally test the benefit of liver-directed radiation therapy in this patient population.”

The trial’s objectives are to evaluate the addition of liver-directed radiation therapy to chemotherapy with respect to overall survival and cancer control. The 182 patients to be enrolled in the NRG-GI001 trial will receive 3 cycles of gemcitabine/cisplatin chemotherapy and then will have their cancer re-staged after 3 cycles. Only patients whose cancer has not progressed after the 3 cycles will go on to be randomized to either continue gemcitabine/cisplatin (Arm 2) or receive radiation therapy and gemcitabine/cisplatin (Arm 1) followed by treatment maintenance gemcitabine chemotherapy.

“Patients are re-staged after three cycles of chemotherapy to confirm that they still have localized disease amenable to radiation prior to randomization to ensure the appropriate patients are evaluated for radiation,” says Hong.

For more information, visit NRG-GI001.

www.nrgoncology.org

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research strengths of the National Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group and the Gynecologic Oncology Group. The research organization seeks to carry clinical trials with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types. NRG Oncology’s extensive research organization is comprised of multidisciplinary investigators including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians and encompasses more than 1300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.