RTOG initiates a phase I trial testing the therapy ganitumab for locally advanced pancreatic cancer

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Over 17,000 patients will have been diagnosed with locally-advanced pancreatic cancer in the United States in 2011. Surgery is not a treatment option for these patients whose tumor has grown beyond the pancreas to surrounding vital structures. In the past 20 years, numerous treatment regimens have been evaluated for locally-advanced pancreatic cancer with high-dose chemotherapy followed by chemoradiation being the current standard approach. However, the median survival time of these patients remains generally less than 12 months.

Ganitumab is a fully-human monoclonal antibody antagonist of the insulin-like growth factor-1 receptor, (IGF-1R). From preclinical studies, IGF-1R has been shown to play a significant role in tumor cell growth and in tumor cell's resistance to both chemotherapy and radiation treatment. The investigational drug ganitumab is thought to interrupt the process that changes normal cells into cancer, thereby stopping the abnormal growth behavior of a tumor and making it more amenable to chemoradiation treatment.

"Ganitumab is a therapy under investigation that has shown promising results in early-phase trials for patients with metastatic pancreatic cancer ," says Christopher Crane, MD, Professor of Radiation Oncology at MD Anderson Cancer Center and principal investigator for the RTOG 1102 trial, Houston, "Collecting information about the best drug dose and safety of administering ganitumab with chemoradiation is critical to

further evaluating the efficacy of this treatment regimen for patients with locally-advanced disease," explains Crane.

Up to 42 study participants at institutions across the United States will be enrolled in the trial and will receive 2 months of induction (high-dose) chemotherapy with gemcitabine and ganitumab to provide early systemic treatment and also to select the study participants most likely to benefit from chemoradiation. Previous RTOG studies, such as RTOG 0411, have shown no increase in toxicity during chemoradiation when induction chemotherapy is first administered.

Following induction chemotherapy, study participants will receive ganitumab—first investigating doses of 12mg/kg and, if tolerated, subsequently 20 mg/kg—along with standard chemoradiation treatment. Upon treatment completion, participants will continue to receive maintenance doses of gemcitabine and ganitumab until tumor progression.

According to Walter Curran, MD, RTOG Group Chair and Executive Director of the Winship Cancer Institute of Emory University in Atlanta, "Amgen is conducting a phase III trial of ganitumab in metastatic pancreatic cancer. If trial results for treatment of metastatic disease are positive, moving forward with a randomized phase II trial for patients with locally advanced disease would be indicated. In this scenario, the RTOG 1102 trial results will expedite further evaluation of this targeted therapy."

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