NRG Oncology Trial Evaluates Metformin for Improving the Treatment of Non-Small Cell Lung Cancer

The NRG-LU001 study is the first clinical trial to investigate whether the addition of the drug metformin can be well tolerated and improve progression-free survival for patients with locally advanced, non-small cell lung cancer (NSCLC) treated with standard concurrent chemoradiotherapy. Metformin is used in the treatment of millions of diabetic patients worldwide. The NRG-LU001 trial (Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin HCL in Locally Advanced NSCLC) opened for patient enrollment on August 25, 2014.

"Retrospective studies suggested that metformin may be able to improve the response of the epithelial tumors to cytotoxic therapy. Metformin modifies carbohydrate and lipid metabolism and mediates in cells a state of mild energy stress. This is shown to lead to inhibition of oncogenes and activation of molecular tumor suppressors," explains the study’s co-principal investigator (PI) Theodoros Tsakiridis, MD, PhD, FRCPC, a radiation oncologist at the Juravinski Cancer Center and a clinician scientist and associate professor in the departments of oncology, pathology and molecular medicine at McMaster University, Ontario, Canada.

Translational cancer biology research introduced the study of cancer metabolism into radiotherapy trials in lung cancer. Specifically, work from the laboratories of the LU001 investigators showed that metformin has anti-tumor and radio-sensitizing activity in NSCLC at safe concentrations for non-diabetic patients. “This work led to the NRG-LU001 study that will examine whether we can improve chemoradiotherapy responses with tolerated and economical modifiers of metabolism,” says co-PI Heath D. Skinner, MD, PhD, an assistant professor in the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center, Houston, TX.

NSCLC accounts for 85% of all new lung cancer cases diagnosed with at least 40% of patients diagnosed at an advanced stage, and a third with locally advanced disease. NSCLC exhibits a high degree of resistance to chemoradiotherapy treatment highlighting the need for improved cytotoxic therapies and patient outcomes in this disease.

One-hundred and sixty-eight patients will be enrolled into the trial at research sites in Canada and the United States. For more information visit NRG-LU001.

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.