Highlights of the NCCN Oncology Research Program

The NCCN Oncology Research Program (ORP) strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. Since the program's establishment in 1999, the NCCN ORP has brought millions of dollars in research grants to investigators at NCCN Member Institutions. Research grants are provided to NCCN through collaborations with pharmaceutical and biotechnology companies; these grants are in turn used to support scientifically meritorious cancer research efforts.

NCCN ORP studies typically explore new avenues of clinical investigation and seek answers to important cancer-related questions. All studies are approved and funded through a scientific peer-review process and are overseen by the ORP.

An NCCN study funded through the grant mechanism is highlighted below.

Randomized Phase II Trial of Osimertinib With or Without Local Consolidation Therapy for Patients With *EGFR*-Mutant Metastatic NSCLC (NORTHSTAR)

Principal Investigator: Daniel Gomez, MD

Conditions: Malignant neoplasms of respiratory and intrathoracic organs, non-small cell lung cancer

Institution: The University of Texas MD Anderson Cancer Center

This randomized phase II trial will investigate whether local consolidation therapy (LCT; surgery, radiation therapy, or a combination of radiation therapy and surgery) after osimertinib treatment can help control *EGFR*-mutant metastatic non-small cell lung cancer (NSCLC) compared with continued treatment with osimertinib alone. The safety of this treatment will also be studied. Osimertinib is FDA-approved and commercially available for the treatment of NSCLC. It is considered investigational to perform surgery and/or radiation therapy after osimertinib treatment in patients with NSCLC. Up to 143 participants will be enrolled in this multicenter study.

Primary Objective:

- Progression-free survival (PFS; time frame: start of induction osimertinib up to 22 months)

Secondary Objectives:

- Time to appearance of new metastases, progression of target lesions, and progression of nontarget lesions (time frame: start of induction osimertinib to development of a new lesion, up to 22 months)
- Adverse events of osimertinib with and without LCT (time frame: start of induction osimertinib to development of a new lesion, up to 22 months)
- Determine overall survival (OS; time frame: start of induction osimertinib to death, up to 22 months)
- Determine whether osimertinib plus LCT improves PFS compared with osimertinib alone in the subgroup of patients with oligometastatic NSCLC (up to 3 metastases) (time frame: induction of osimertinib, up to 22 months)
- Determine whether osimertinib plus LCT improves OS compared with osimertinib alone (time frame: induction up to 22 months)
- Determine if there is a difference in survival outcomes or toxicity by radiation treatment modality (protons vs photons) (time frame: start of radiation therapy up to 22 months)

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ClinicalTrials.gov Identifier: NCT03410043

The goal of the Highlights of the NCCN Oncology Research Program (ORP) is to provide readers with more information on the ORP, including studies currently accruing patients.

For more information on specific trials, including patient selection criteria, please use the contact information listed with each study.

For more information on the NCCN ORP, including a complete detailing of the clinical studies currently underway at NCCN Member Institutions, please access the NCCN ORP pages at NCCN.org/clinical_trials/clinicians.asp.

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