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.

Phase I Study of Afatinib With Postoperative Radiation Therapy for Intermediate- and High-Risk Squamous Cancer of the Head and Neck

Principal Investigator: Danielle Margalit, MD, MPH

Conditions: Squamous cell carcinoma of the head and neck

Institution: Dana-Farber Cancer Institute

This is an open-label, nonrandomized, 2-arm, 2-cohort phase I dose-escalation study to determine the maximum tolerated dose (MTD) and tolerability of (1) afatinib with radiation therapy (RT), and (2) afatinib with chemotherapy (docetaxel) and RT in the postoperative treatment of intermediate- and high-risk squamous cell carcinoma of the head and neck (SCCHN).

Afatinib has been studied in other clinical trials of participants with head and neck, lung, and breast cancers. This dose of afatinib has been studied in other research studies, but this is the first clinical trial to study afatinib in combination with RT.

Afatinib is a small molecule dual inhibitor of EGFR/HER2 receptor tyrosine kinases. Information from laboratory research studies suggests that this drug may help make head and neck cancer cells more sensitive to RT, and may also overcome common resistance mechanisms that limit the efficacy of antibody-based EGFR inhibitors.

The other therapy in this research study is RT or RT plus docetaxel. After surgery, RT is the standard treatment approach for intermediate-risk cancer; "intermediate risk" means that there is an intermediate risk that the disease may return. RT and chemotherapy is the standard treatment if you have high-risk disease; "high-risk disease" means that without additional therapy, there is a high risk that the disease may return. The high-risk arm of this study is closed. The study is currently accruing to the intermediate-risk arm of RT and afatinib.

Primary Objective:

- Establish the safety of afatinib when administered in combination with RT in participants with intermediate-risk SCCHN

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ClinicalTrials.gov Identifier: NCT01783587

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.

doi: 10.6004/jnccn.2017.0171