Journal of the National Comprehensive Cancer Network

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.

## 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.

### A Randomized Phase II Study of Single-Agent Dabrafenib (BRAFi) Versus Combination-Regimen Dabrafenib (BRAFi) and Trametinib (MEKi) in Patients With *BRAF* Mutation or *BRAF* Gene Fusion Defect in Thyroid Carcinoma

**Protocol Chair:** Manisha Shah, MD

**Institutional Principal Investigators:** Manisha Shah, MD; Naifa L. Busaidy, MD; Lori Wirth, MD; Jonas DeSouza, MD; and Greg Daniels, MD

**Condition:** Metastatic differentiated thyroid cancer

**Institutions:** The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute; Massachusetts General Hospital; The University of Texas MD Anderson Cancer Center; University of Chicago Medical Center; and UC San Diego Moores Cancer Center

This multi-institutional, randomized phase II trial is studying how well dabrafenib works with or without trametinib in treating patients with metastatic thyroid cancer that has *BRAF* mutations or fusions. Dabrafenib and trametinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether dabrafenib is more effective when given with or without trametinib in treating thyroid cancer.

Patients are randomized to either Arm A or Arm B. In Arm A, patients receive dabrafenib orally twice a day on days 1 through 28. Patients with disease progression may cross over to Arm B. Arm B will receive dabrafenib orally twice a day and trametinib orally once a day on days 1 through 28.

**Primary Objective:**

- Screen 2 different regimens, dabrafenib (BRAFi) as a single agent versus the combination regimen of dabrafenib (BRAFi) and trametinib (MEKi), and identify which regimen is more promising for subsequent testing in a phase III trial in patients with radioiodine-refractory *BRAF*-mutated differentiated thyroid cancer (DTC)

**Secondary Objectives:**

- Understand duration of objective response, progression-free survival, and overall survival for each treatment group
- Assess tolerability and adverse events of dabrafenib (BRAFi) as a single agent and the tolerability and adverse events of dabrafenib (BRAFi) and trametinib (MEKi) in combination, in patients with DTC
- Evaluate impact of experimental drugs on serum tumor marker thyroglobulin and its correlation with overall response rate
- Understand pharmacokinetics, pharmacogenetics, and pharmacodynamics of experimental drugs using serial tumor biopsies, tumor blocks, and peripheral blood

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**ClinicalTrials.gov Identifier:** NCT01723202