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# Targeted therapies show initial effectiveness in subset of papillary thyroid cancer

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Two immunotherapy drugs currently approved by the U.S. Food and Drug Administration (FDA) for the treatment of melanoma also show promise for treating a rare but aggressive form of papillary thyroid cancer.

Up to 44 percent of papillary thyroid cancer patients have a B-raf mutation that can be specifically targeted by existing cancer drugs.

The B-raf gene belongs to a class of genes known as "oncogenes," which send signals to normal cells that cause them become cancerous. B-raf gene mutations have known roles in the development of many human cancers including melanoma, lung and thyroid cancer.

In a randomized, phase 2 multi-center clinical study, led by Manisha Shah, MD of The Ohio State University Comprehensive Cancer Center - Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC - James), investigators tested the effectiveness of the targeted therapy drug, dabrafenib (pronounced "da bRAF e nib" and marketed as Tafinlar), given alone compared with the same drug given in combination with trametinib (pronounced "tra ME ti nib", marketed at MeKinist) to treat a subset of advanced papillary thyroid cancer patients with B-raf mutations.

Initial data shows that both dabrafenib alone and combined dabrafenib/trametinib therapy are well tolerated by patients, resulting in a 50 to 54 percent response rate among the patients advanced BRAF-

mutated papillary thyroid cancer participating in the trial.

The OSUCCC - James team presented their findings (Abstract No. 6022) today at the American Association of Clinical Oncology (ASCO) annual meeting in Chicago.

"This is an entirely new approach to treating a disease that has limited treatment options. There is no clear 'winner' between single- and dual-agent targeted therapy yet but the good news is that both therapy approaches resulted in positive outcomes for patients, and that gives us more treatment options to help patients with this disease," says Shah, a medical oncologist and researcher with the OSUCCC - James Translational Therapeutics Research Program. "Targeted therapy has the potential to change the standard of care for patients affected by this rare but aggressive form of thyroid cancer."

Researchers will continue to follow patients on this trial to determine if dabrafenib alone or dabrafenib given in combination with trametinib is more effective long term.

## Study Design and Methods

For this OSUCCC - James-designed and led study, oncologists recruited 53 patients with progressive B-raf-mutated progressive papillary thyroid cancer. Patient median age was 63 and all received treatment at Ohio State, Massachusetts General Hospital, MD Anderson, University of California - San Diego or University of Chicago. Patients were randomized to receive twice daily dabrafenib alone or dabrafenib given in combination with once-a-day trametinib. All drugs are administered orally. Patients who experienced disease progression on dabrafenib alone were able to cross over into the combination treatment arm.