

Targeted therapy sorafenib shows success in advanced differentiated thyroid cancer patients

June 2 2013

The kidney and liver cancer drug sorafenib holds metastatic thyroid cancer at bay for nearly twice as long as a placebo, according to results of a randomized phase III trial, which will be presented today by a researcher from the Abramson Cancer Center and the Perelman School of Medicine at the University of Pennsylvania in a plenary session during the American Society of Clinical Oncology's annual meeting (Abstract #4).

If approved for use in thyroid cancer patients by the Food and Drug Administration, sorafenib (Nexavar), a kinase inhibitor that mediates tumor cell division and growth of <u>tumor blood vessels</u>, would be the first effective agent for this patient population. Thyroid cancer is highly curable through surgery and radioactive iodine treatment, but about 10 percent of the 60,000 patients who are diagnosed with the disease each year fail to respond to standard therapies, with tumors eventually appearing in the lymph nodes, bones, lungs, and other sites. The only other drug for advanced thyroid cancer, doxorubicin, which was approved in 1974, is not used because it is highly toxic and is not effective.

"Until we began using sorafenib, we had no medical options for these patients who suffered due to progression of their disease," said Marcia S. Brose, MD, PhD, an assistant professor of Otolaryngology and <u>Head and</u> <u>Neck Surgery</u> and Hematology/Oncology, who led the study, which is



known as DECISION. "Now, we can give patients hope – a breakthrough medication that can stop the progression of the disease for 5 months. This trial is the first step in a promising series of clinical trials to identify new drugs that are shifting the horizon for patients with advanced thyroid cancer."

Of the 417 metastatic thyroid cancer patients studied in the multicenter, international trial, 207 were randomized to take sorafenib, an oral drug, and 210 to a placebo arm. Twelve percent of patients experienced <u>tumor</u> <u>shrinkage</u> in the sorafenib arm, compared to 0.5 percent of patients taking a placebo. Importantly, the therapy also appeared to thwart disease progression even among many of those whose tumors did not regress: 42 patients who took sorafenib had stable disease after six months, compared to 33 percent of those in the placebo group.

Among patients taking sorafenib, median progression-free survival was 10.8 months, compared to 5.8 months among the placebo group. Patients taking the placebo were allowed to cross over into the sorafenib arm once their disease progressed; 70 percent of them did so. Overall survival data is not yet available.

The most common adverse events observed among patients taking sorafenib included hand-foot skin reaction, diarrhea, alopecia, rash, fatigue, weight loss and hypertension, all of which are consistent with findings from previous trials of the drug for its approved indications.

Brose will present her team's findings in the ASCO press conference at 7:30 a.m. CT on Sunday, June 2 in Room E353a, McCormick Place in Chicago. She will also present the findings of the trial in a plenary session 3:20 p.m. on Sunday in N Hall B1 of McCormick Place.

Provided by University of Pennsylvania School of Medicine



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