

Cabozantinib shows significant first-line activity for differentiated thyroid cancer

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Results of a new phase II clinical trial indicate that cabozantinib offers an active therapy option for patients with differentiated thyroid cancer (DTC) that has progressed following surgery and treatment with radioactive iodine (RAI). Thirty-four of 35 patients in the trial experienced a reduction in tumor size following treatment with the targeted kinase inhibitor, and more than half experienced reductions in excess of 30 percent. The study will be presented today in an online news briefing and at the 2018 Multidisciplinary Head and Neck Cancers Symposium in Scottsdale, Arizona.

"The recent introduction of targeted therapy with kinase inhibitors for [patients](#) with advanced thyroid [cancer](#) created a possible path to control the cancers of patients we previously could treat only with supportive care. Our trial shows that cabozantinib also is an active agent and could significantly improve the care of patients with advanced disease," said Marcia S. Brose, MD, PhD, an associate professor in the Department of Otorhinolaryngology: Head and Neck surgery and the director of the Center for Rare Cancers and Personalized Therapy at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Five years ago, there were no federally approved curative options for RAI-refractory differentiated [thyroid cancer](#). Two [kinase inhibitors](#) have come to market for advanced DTC in the years since, but responses to these agents are not durable and when patients progress they need additional therapeutic options.

"While prior agents that attack the vascular endothelial growth factor (VEGF) receptor have been active in advanced DTC, patients on these therapies eventually progress or are unable to tolerate the drug," explained Dr. Brose. "Our positive trial results indicate that cabozantinib offers an additional option to shrink patients' tumors and provide an additional progression-free period."

NCT02041260 is a single-arm, open-label phase II study of cabozantinib in the first-line setting for metastatic, RAI-refractory, unresectable or locally-advanced thyroid carcinoma. Thirty-five patients were enrolled between March 2014 and August 2017. Patients in the trial were administered 60 mg of oral cabozantinib each day. Median time on the study was 35 weeks (range 3-197), and 16 patients remain enrolled as of February 6, 2018.

Most patients had papillary histology (63%), followed by poorly differentiated (29%) and Hürthle cell (9%) carcinomas. Patients had not received prior kinase inhibitor therapy. Median patient age was 65 years (range 45-84), and 49 percent of the enrolled patients were male.

Thirty-four of the 35 patients experienced tumor shrinkage. Partial response (i.e., greater than 30%) was achieved in 19 of the 35 patients (with short follow-up for four patients enrolled at the end of the study), for an overall response rate of 54 percent. Duration of partial responses ranged from 11 weeks to more than 174 weeks. Stable disease was achieved in 15 patients, with duration of stability ranging from eight weeks to more than 142 weeks. Cancer progressed in six patients, with a median time to progression of 35 weeks (range 8-40).

Cabozantinib was well-tolerated, although dose interruptions and dose adjustments were needed for the majority of patients (23 of 35) at some point on treatment. Treatment-related adverse events of any grade were experienced by all patients (100%). The most common adverse events

attributable to cabozantinib included hyperglycemia (28 patients, 80%), diarrhea (27, 77%), malaise/fatigue (26, 74%) and weight loss (25, 71%). The majority of these adverse events were grades 1 and 2. Grade 3 or higher [adverse events](#) that occurred in more than one patient included hypertension (5 patients, 14%), increased lipase (3, 9%), weight loss (2, 6%), pulmonary embolism (2, 6%) and hyponatremia (2, 6%).

More information: The abstract, "A Phase II Trial of Cabozantinib for the Treatment of Radioiodine (RAI)-refractory Differentiated Thyroid Carcinoma (DTC) in the First-line Setting," will be presented in detail during the Oral Abstract Session at the 2018 Multidisciplinary Head and Neck Cancers Symposium in Scottsdale, Arizona.

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