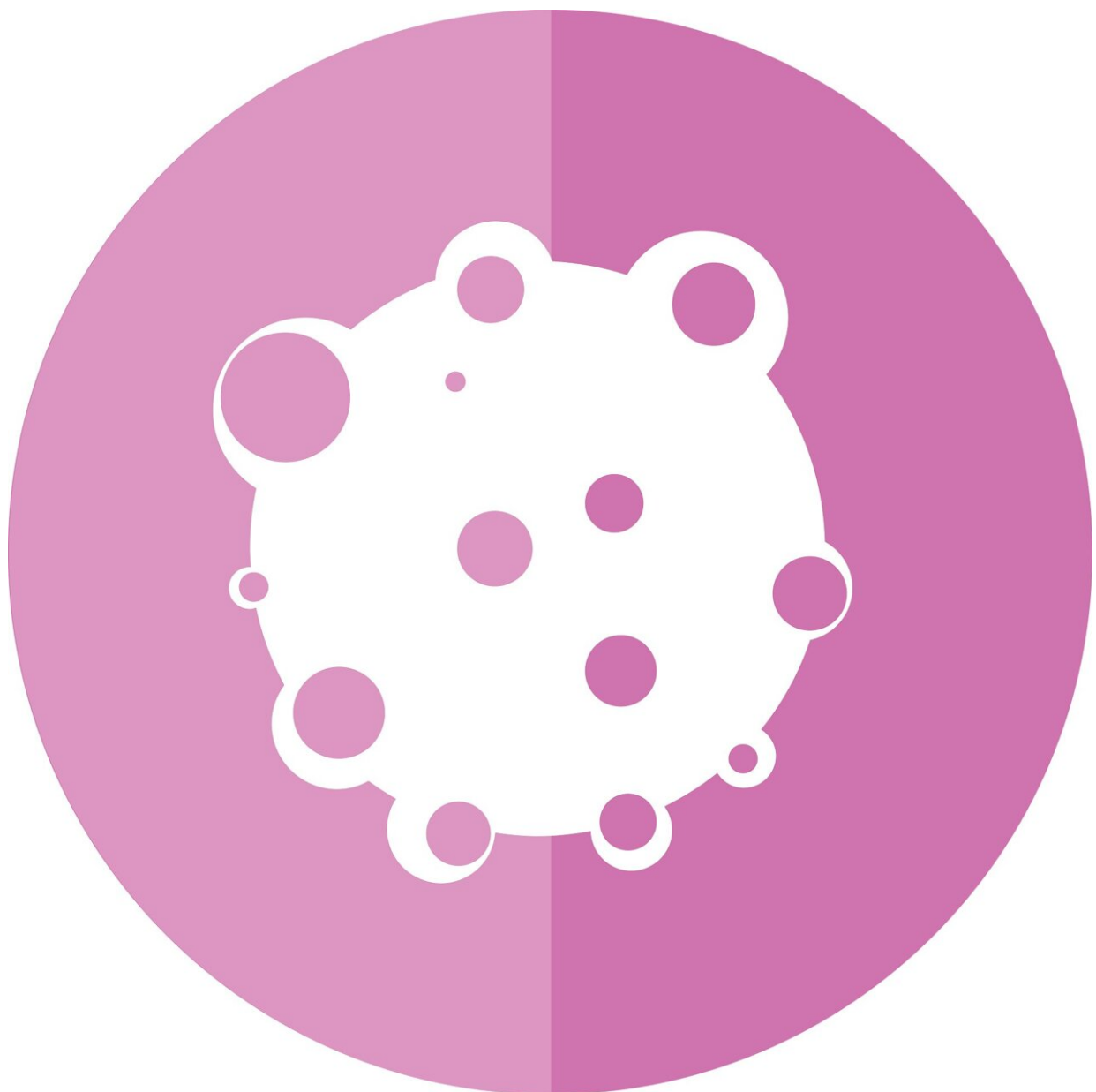


Clinical trial shows promising results for patients with advanced neuroendocrine tumors

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The Alliance for Clinical Trials in Oncology today announced that an independent Data and Safety Monitoring Board (DSMB) determined that the phase III CABINET (A021602) pivotal trial met its primary endpoint at an interim analysis in both of the trial's cohorts, demonstrating statistically significant and clinically meaningful improvements in progression-free survival (PFS).

CABINET is evaluating cabozantinib compared with placebo in patients with either advanced pancreatic neuroendocrine tumors (pNET) or advanced extra-pancreatic neuroendocrine tumors (also referred to as carcinoid tumors) who experienced progression after prior systemic therapy. The DSMB recommended the study stop early due to efficacy and findings will be discussed with the U.S. Food and Drug Administration. Detailed results from the trial will be presented at an upcoming scientific meeting.

"Patients with progressive neuroendocrine tumors have limited treatment options. At present, after progression on previous therapies, the treatment path is unclear, underscoring the need for additional options for this disease that is rising in incidence," said Jennifer Chan, MD, MPH, study chair for the CABINET trial and Clinical Director of the Gastrointestinal Cancer Center and Director of the Program in Carcinoid and Neuroendocrine Tumors at Dana-Farber Cancer Institute.

"These promising findings from the CABINET trial, in which cabozantinib showed an efficacy benefit for patients with pancreatic and extra-pancreatic neuroendocrine tumors, are welcome news and show

the potential for cabozantinib to address important unmet needs for this community."

The safety profile of cabozantinib observed in the trial was consistent with its known safety profile, and no new safety signals were identified.

"The Alliance and NCTN have a long and established history of successful practice changing cancer [clinical trials](#). The results of CABINET add to this important work to further improve the outcomes of patients with the rare tumors of pancreatic and extra-pancreatic NET," said Suzanne George, MD, Interim Group Chair of the Alliance, Associate Professor of Medicine at Harvard Medical School and Clinical Director at the Center for Sarcoma and Bone Oncology at Dana-Farber Cancer Institute.

CABINET (Randomized, double-blinded phase III study of cabozantinib versus placebo in patients with advanced neuroendocrine tumors after progression on prior therapy) is a multicenter, randomized, double-blinded, placebo-controlled phase III pivotal trial that enrolled 290 patients in two separate cohorts (pNET, n=93; extra-pancreatic NET, n=197) in the United States.

Patients were randomized 2:1 into the cabozantinib or placebo arms of the study in each of the two cohorts. Patients must have had measurable disease per RECIST 1.1 criteria and must have experienced disease progression after at least one FDA-approved line of prior therapy other than somatostatin analogs. The primary endpoint was PFS in each cohort. Upon confirmation of disease progression, patients were unblinded, and those receiving placebo were permitted to cross over to open-label therapy with cabozantinib. Secondary endpoints included overall survival, radiographic response rate and safety.

"The CABINET trial is a great example of the importance of the

National Clinical Trials Network, sponsored by the National Cancer Institute, in conducting rigorous, practice changing trials at both academic and community oncology practices throughout the United States, working with industry partners, patient advocacy, and academia," noted Eileen O'Reilly, MD, from Memorial Sloan Kettering Cancer Center and Jeffrey Meyerhardt, MD, MPH, from Dana-Farber Cancer Institute, who co-chair the Gastrointestinal Committee for the Alliance.

Each year, about 12,000 people will be diagnosed with neuroendocrine tumors. These tumors are cancers that develop from cells in the diffuse neuroendocrine system. The cells can be found throughout the body, but the most common places for tumors to develop are in the gastrointestinal tract, lungs, and pancreas. Most NETs grow slowly, but some are more aggressive, growing rapidly and spreading to other parts of the body. There are several types of treatment for neuroendocrine [cancer](#), including surgery, liver-directed therapy, somatostatin analogs, chemotherapy, targeted therapy, and peptide receptor radionuclide therapy.

"This is great news for patients with advanced neuroendocrine tumors! You will now have another weapon in your arsenal against these cancers," said Julie Krause, a GI patient advocate with the Alliance. "If you are progressing on standard care for treatment of pancreatic and extra-pancreatic neuroendocrine tumors, cabozantinib showed amazing results in the CABINET trial. I am very excited about this advance for these patients."

More information: Clinical trial:
clinicaltrials.gov/study/NCT03375320

Provided by Alliance for Clinical Trials in Oncology

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