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# Investigational anticancer drug may benefit subgroup of patients with head and neck cancer

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Patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN), the most common form of head and neck cancer, may benefit from treatment with the investigational drug dacomitinib if their cancer has no defects in a cell signaling pathway called the PI3K pathway and no signs of excessive inflammation, according to results of a phase II clinical trial presented here at the AACR Annual Meeting 2014, April 5-9.

"Patients with recurrent and/or metastatic SCCHN have a very poor prognosis. There are few approved therapies for these patients and their median survival is six to nine months," said Byoung Chul Cho, M.D., Ph.D., an associate professor at Yonsei Cancer Center in Seoul, the Republic of Korea. "Our data show that dacomitinib has promising antitumor activity in heavily treated recurrent and/or metastatic SCCHN in patients without PI3K pathway alteration or overexpression of proinflammatory cytokines.

"Our findings obviously need confirming in phase III clinical trials comparing the efficacy of dacomitinib with other palliative chemotherapy," added Cho. "By using our biomarker data to select those patients who are most likely to benefit from the drug—those without PI3K pathway alteration or overexpression of proinflammatory cytokines—the trial will be more likely to succeed."

Dacomitinib blocks the activity of a protein called epidermal growth factor receptor (EGFR). According to Cho, the rationale for their clinical trial is that most SCCHNs have elevated levels of EGFR, which makes it a potential therapeutic target.

"If our results are confirmed in phase III clinical trials, dacomitinib could provide a new targeted treatment option for a disease for which new therapies are desperately needed," said Cho. "We are conducting further biomarker analysis to better define patients most likely to respond."

Cho and colleagues enrolled 48 patients with recurrent and/or metastatic SCCHN in their phase II clinical trial. All patients received oral dacomitinib once a day. Response Evaluation Criteria In Solid Tumors (RECIST) guidelines, version 1.1, were used to assess patients' responses.

Ten patients had a partial response and 31 patients had stable disease. This meant that the overall response rate, which was the primary endpoint of the study, was 21 percent. In addition, after a median follow-up of 8.4 months, the average time to disease progression was 3.9 months and the average overall survival time was 6.6 months.

The researchers performed genetic analyses of the patients' tumor samples and identified a number of markers associated with response. Patients with tumors containing mutations in either of two genes important for the PI3K pathway, PIK3CA and PTEN, had their disease progress more than twice as quickly as patients with tumors without PIK3CA or PTEN mutations: Average progression-free survival was 2.9 months and 4.9 months, respectively. For two of the patients with tumors lacking PIK3CA and PTEN mutations, the time to disease progression was much longer than the average, 13.1 and 18.9 months.

The researchers also found differences in average progression-free survival between patients with tumors with high and low levels of genes linked to inflammation, including IL6, IL8, PTGS2, and PLA2G2A: Average progression-free survival times were 2.8 months and 9.9 months, respectively.

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