

Pembrolizumab elicits significant antitumor activity in head and neck cancer patients

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Treating head and neck cancer patients with recurrent or metastatic disease with the PD-1 inhibitor pembrolizumab resulted in significant clinical responses in a fifth of the patients from a phase II clinical trial, researchers at the Abramson Cancer Center of the University of Pennsylvania and other institutions reported at the 2016 American Society of Clinical Oncology (ASCO) annual meeting. (Abstract #6011)

The preliminary results from the KEYNOTE-055 trial are being presented by Joshua Bauml, MD, an assistant professor of Hematology/Oncology at the Perelman School of Medicine at the University of Pennsylvania. Robert I. Haddad, MD, of the Dana-Farber Cancer Institute and an associate professor of Medicine at Harvard Medical School, is the senior author.

Pembrolizumab elicited a partial response in 17 percent of the 92 [patients](#) evaluable for a response (171 were treated). An additional 18 patients had stable disease. The overall response rate was 17 percent, more than triple the rate observed with methotrexate, the approved agent for head and [neck cancer](#) resistant to platinum-based chemotherapy and cetuximab. Patients enrolled in the trial had all stopped responding to or did not benefit from treatment with platinum-based drugs and cetuximab. The overall survival was eight months—an encouraging result since many patients who don't respond to chemotherapy or cetuximab die within six months.

The drug seemed to be equally effective in patients who were both

positive and negative for human papillomavirus (HPV), which is now the leading cause of head and neck cancers of the oropharynx. The drug was also well-tolerated.

"Pembrolizumab is a promising therapy for certain patient populations," Bauml said. "This could help potentially fill a treatment void and prolong survival for patients with an aggressive form of head and neck cancer, regardless of their HPV status."

Pembrolizumab is an FDA-approved, anti-PD-1 antibody that serves to lift a brakes on the immune system, allowing T cells to infiltrate and attack tumor cells. It is approved to treat metastatic melanoma and metastatic non-small cell [lung cancer patients](#) whose tumor express PD-1, and is currently being tested in various other disease sites.

There are approximately 54,000 new cases of head and neck cancer every year in the United States, and more than 90 percent are HNSCC, which can start in the mouth, various parts in the throat, or behind the nose. It can spread to other parts of the body, such as the lymph nodes or lungs and become fatal. Only about half of these patients survive more than five years after diagnosis.

"The phase I and phase II trials have shown encouraging data that suggests immunotherapy targeting the PD-1 axis can help this group of patients, who are currently left with few options," Bauml said. "I look forward to seeing results from the ongoing phase III trials investigating pembrolizumab vs. standard-of-care chemotherapy. These trials will be able to show the drug's clinical value earlier in the treatment of head and neck cancer."

More information: The results will be presented during the Clinical Science Symposium "Harnessing the Immune System in Head and Neck Cancer: Evolving Standards in Metastatic Disease" on Monday, June 6,

2016 at 11:30 am in Room S100bc .

Provided by University of Pennsylvania School of Medicine

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