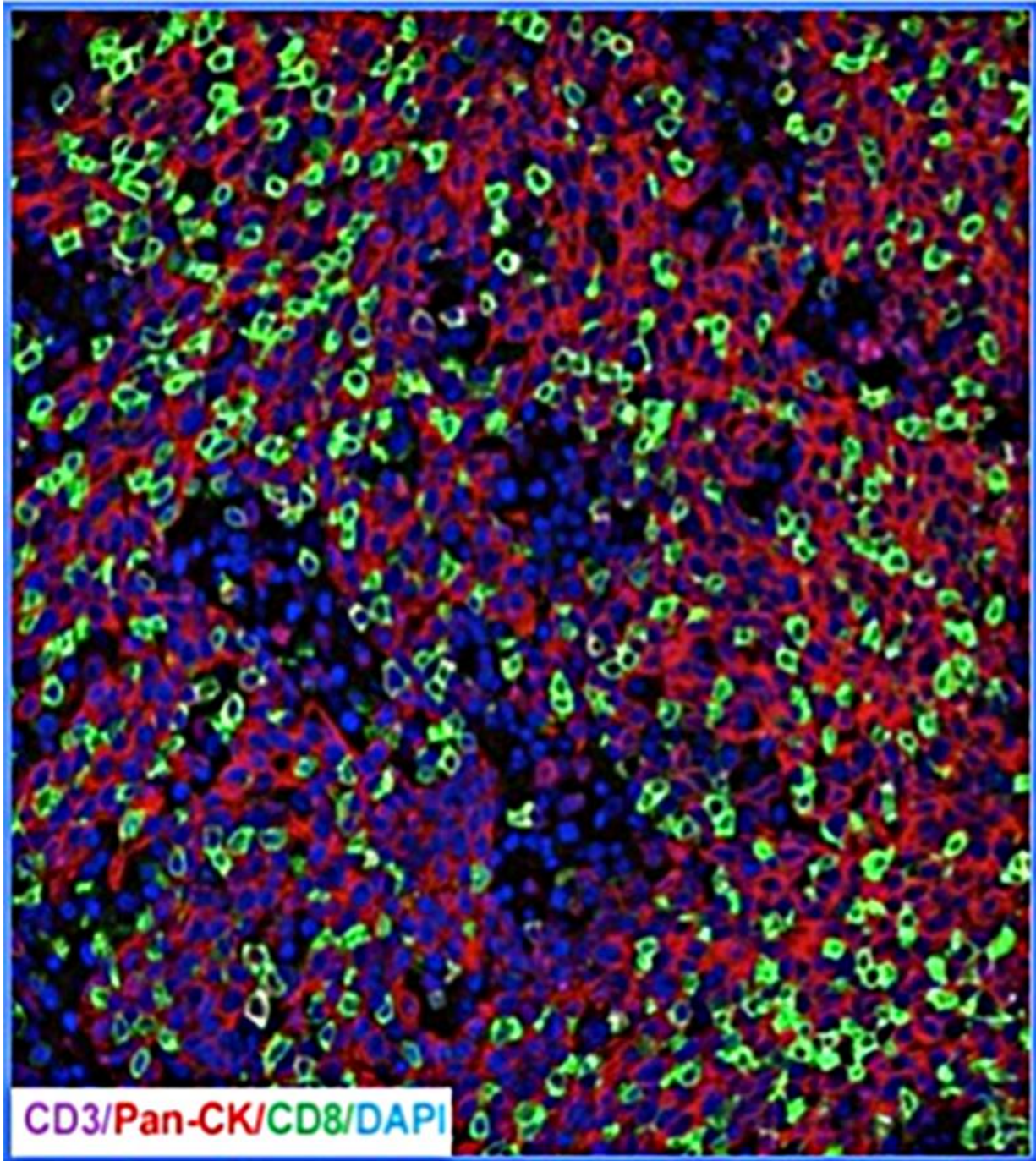


# **Pembrolizumab shows real promise against head and neck cancer**

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The cancer (red and blue) is infiltrated with immune cells (green), which can attack and kill cancer. When cancers hide, medications such as pembrolizumab make the cells visible to the immune system. This can lead to lasting control of the cancer with few side effects. Credit: Tanguy Seiwert Laboratory



Immunotherapy with the anti-PD-1 antibody pembrolizumab (Keytruda) was effective in one out of four patients with recurrent or metastatic head and neck cancer, according to results presented at the 2015 meeting of the American Society for Clinical Oncology (ASCO).

Pembrolizumab decreased the size of tumors by 30 percent or more in 24.8 percent of 132 [patients](#), making it nearly twice as effective as the current preferred treatment using platinum-based chemotherapy plus cetuximab, an epidermal growth factor inhibitor.

The results suggest that pembrolizumab, a checkpoint blocker, may soon begin to fill a large, unmet need for better treatments of this common form of cancer.

"The efficacy was remarkable," said Tanguy Seiwert, MD, assistant professor of medicine and associate program leader for head and neck cancer at the University of Chicago, "roughly twice as good as any drug combination in our arsenal."

"In this study," he said, "pembrolizumab was active across a wide range of patient subgroups including HPV-associated and HPV-negative tumors. Overall, 56 percent of patients experienced a measurable decrease in the size of their tumors."

Unlike epidermal growth factor receptor inhibitors, which appear to be less effective in HPV-positive tumors, pembrolizumab showed similar levels of activity in both HPV-associated and HPV-negative tumors.

"This may have the potential to prolong survival for a large proportion of our patients," Seiwert said. "Immunotherapy has been very well tolerated by our patients and serious side effects have been quite uncommon. We hope this approach will change the way we treat head and neck cancer."



In a related study (abstract #6017), also presented at ASCO, Seiwert and colleagues report that an experimental test—applied to an earlier cohort of head and neck cancer patients treated with pembrolizumab—could predict which patients were not likely to benefit from PD-1/PD-L1 agents, with a negative predictive value of 95 percent.

"This assay is quick and reproducible," Seiwert said. "The high negative predictive value may help us select out patients who may not benefit from immunotherapy."

Head and neck cancer is the sixth most common cancer in the United States and worldwide. Recurrent/metastatic head and neck cancer is currently considered incurable, with a poor prognosis and median overall survival of approximately 10 to 12 months. Standard treatment involves platinum-based doublet chemotherapy with or without cetuximab, the only approved targeted therapy.

Second-line options include methotrexate, docetaxel and cetuximab. Only 10 to 13 percent of patients respond to cetuximab as a single agent, and recent data suggest that efficacy in HPV-positive tumors may differ from HPV-negative tumors. While chemotherapy can be effective, it also causes significant side effects such as hair loss, nausea and vomiting, and increased risk of infection due to low immune function.

In the study presented at ASCO, 132 patients with recurrent or metastatic squamous cell carcinoma of the head and neck received a 200-mg infusion of pembrolizumab every 3 weeks. The objective response rate was 24.8 percent (26.3 percent in HPV-negative patients and 20.6 percent in HPV-positive patients). Fifty-six percent of patients saw their target lesions shrink.

Pembrolizumab was well tolerated. Fewer than 10 percent of patients had serious side effects. The most common were fatigue, rash, and



pruritus. More serious immune-related [side effects](#) such as grade 3 pneumonitis and colitis were observed in a three patients.

Unlike a prior report presented at last year's ASCO Annual Meeting, the current cohort was not selected for PD-L1 expression (a candidate predictive biomarker). Fifty-nine percent of the patients enrolled had already received two or more lines of prior therapy.

"Our 25 percent response rate may underestimate the benefit in patients," Seiwert said. "We know from other disease entities such as lung cancer—where the experience with immunotherapy is broader—that patients who have disease stabilization or even pseudo-progression may benefit in ways that translate into longer survival."

Two ongoing phase III studies are evaluating pembrolizumab vs. standard treatment in patients with recurrent/metastatic [head and neck cancer](#). Additional phase III studies with nivolumab (another anti-PD-1 antibody) and MEDI4736 (an anti-PD-L1 antibody) are underway for head and [neck cancer](#).

Provided by University of Chicago Medical Center

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