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Immunotherapy prolongs life, reduces side effects and improves quality of life

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The immunotherapy nivolumab significantly increases survival and causes fewer adverse side-effects in patients with recurrent head and neck cancer, according to a randomized trial co-led by investigators at the University of Pittsburgh Cancer Institute (UPCI), partners with UPMC CancerCenter.

The results of the international CheckMate-141 phase III clinical trial were reported Sunday in the *New England Journal of Medicine*, following preliminary presentations at the annual American Society of Clinical Oncology and American Association for Cancer Research meetings earlier this year. Patients on nivolumab were doing so much better than those receiving standard therapy that the trial was stopped early to allow all patients to receive it.

"Due to our clinical trial, anti-PD-1 therapies like nivolumab are now the recommended treatment for patients with this very difficult, devastating cancer," said lead author and trial co-chair Robert Ferris, M.D., Ph.D., UPMC Endowed Professor, and chief of the Division of Head and Neck Surgery and co-leader of the Cancer Immunology Program at UPCI.

Worldwide, more than 600,000 cases of squamous-cell carcinoma of the head and neck are diagnosed annually, and the cancer recurs in more than half the patients within three years. The cancer typically returns because it has evaded the immune system and become resistant to chemotherapy.

Alcohol and tobacco use are the two main risk factors for head and neck cancers. Infection with the human papillomavirus (HPV) also is a risk factor, and rates of head and neck cancer attributable to HPV infection have increased 250 percent over the past several decades.

Nivolumab, which belongs to a class of drugs known as immunotherapeutics, enables the body's immune system to destroy cancer cells. It currently is approved to treat certain types of cancers, including melanoma and lung cancer.

The CheckMate-141 trial enrolled 361 patients receiving care at 64 locations worldwide for recurrent head and neck cancer that had progressed within six months of chemotherapy. From June 2014 through August 2015, the researchers randomly assigned 240 patients to receive nivolumab and 121 to receive standard therapy, which consisted of one of three chemotherapy drugs.

On average, the patients on nivolumab survived 7.5 months, versus 5.1 months for the patients on standard therapy. At one year, 36 percent of the nivolumab patients were still living, compared with 16.6 percent of the standard-care patients.

Additionally, only 13.1 percent of the patients receiving nivolumab suffered serious, quality-of-life-disrupting side effects of the treatment, compared with 35.1 percent of those receiving standard therapy.

"It is wonderful news that we have a new, better option for patients with recurrent head and neck cancer," said Dr. Ferris. "But for the vast majority of patients, nivolumab isn't a cure and more research is needed to find one. Perhaps even more important, we need to prevent this cancer from ever occurring. We have to help people to stop smoking or chewing tobacco, and encourage them to never start. We also need to continue to encourage children to be vaccinated against HPV."

The trial's other co-chair is Maura Gillison, M.D., Ph.D., from Ohio State University. Additional U.S. institutions that participated in the trial include University of Texas MD Anderson Cancer Center, Stanford Cancer Institute, University of Chicago, University of Michigan, Emory University, Dana-Farber Cancer Institute and Bristol-Myers Squibb.

International collaborators are located at Centre Leon Berard, Centre Antoine Lacassagne, and Institut Gustave Roussy, all in France; Fondazione IRCCS Istituto Nazionale Tumori, in Italy; The Institute of Cancer Research, in the United Kingdom; University Hospital Essen, in Germany; Hospital Universitario 12 de Octubre, in Spain; University Hospital Zurich, in Switzerland; and National Cancer Center Hospital East and Kobe University Hospital, both in Japan.

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