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Immunotherapy improves survival, quality of life in rapidly progressing head and neck cancer

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Immunotherapy doubles overall survival and improves quality of life, with fewer side effects, in a treatment-resistant and rapidly progressing form of head and neck carcinoma, reports a large, randomized international trial co-led by investigators at the University of Pittsburgh Cancer Institute (UPCI). The new trial was considered so successful that it was stopped early to allow patients in the comparison group to receive the new drug.

Findings from the international CheckMate-141 phase III clinical trial were presented today at the 52nd annual American Society of Clinical Oncology (ASCO) meeting in Chicago. A subset of the results were previously presented at the American Association for Cancer Research meeting in April of this year.

"These exciting results indicate that there is a new standard of care option for a population of head and neck cancer patients with no other treatment options," said the trial's international 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.

The new drug, 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 trial enrolled 361 patients with recurrent or metastatic head and neck squamous cell carcinoma who had not responded to platinum-based chemotherapy, a rapidly progressing form of the disease with an especially poor prognosis, said Dr. Ferris. Patients were randomized to receive either nivolumab or a single type of standard chemotherapy until tumor progression was observed.

The nivolumab group achieved better outcomes than the standard chemotherapy group by all accounts. After 12 months, 36 percent of the nivolumab group was alive, compared to just 17 percent of the standard chemotherapy group.

Nivolumab treatment also doubled the number of patients whose tumors shrunk, and the number whose disease had not progressed after six months of treatment. Importantly, these benefits were achieved with just one-third the rate of serious adverse events reported in the standard chemotherapy group.

In addition, on average, patients receiving nivolumab reported that their quality of life remained stable or improved throughout the study, while those in the chemotherapy group reported a decline.

While nivolumab improved survival rates in the overall study population, it appeared to be most successful in patients whose tumors were positive for the human papillomavirus (HPV). This is important because the fraction of head and neck cancers attributable to HPV infection has increased by 250 percent over the past several decades, Dr. Ferris explained.

"Unfortunately, most patients in this trial still experienced a progression of their cancer, demonstrating that we still have a lot of work to do. But,

the future appears brighter than ever before because there is a new class of agents, immunotherapies, which we now know can prolong survival and improve quality of life, with few side effects, in head and neck cancer," said Dr. Ferris.

The research team currently is working to identify new biomarkers that will allow them to develop a better understanding of how drug resistance develops, and how to best design effective combinations of medications that may improve patient responses.

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, and Dana-Farber Cancer Institute. 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; and National Cancer Center Hospital East and Kobe University Hospital, both in Japan.

The trial was funded by the drug manufacturer, Bristol-Myers Squibb, who is now seeking FDA approval for the use of nivolumab in head and neck carcinoma.

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