MedicalXpress

Study evaluates pembrolizumab in head and neck cancer

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Immunotherapy with the checkpoint inhibitor pembrolizumab may be a better option than standard treatments for patients whose head and neck cancer has spread, or recurred after an initial round of chemotherapy, according to results of the Keynote-040 trial presented at the ESMO 2017 Congress in Madrid.

Although the 19 percent improvement in overall survival among patients treated with pembrolizumab did not meet the prespecified difference for statistical significance, it was nevertheless a clinically meaningful difference for this population who only lived seven to eight months, on average, after initiating treatment, said lead investigator Dr. Ezra Cohen, from the University of California, San Diego Moores Cancer Center, in La Jolla, California.

"Even though the study did not meet its primary endpoint, I still think it is a positive trial," he said. "It reinforces that pembrolizumab should continue to be offered as an important option for all patients with this devastating disease."

The KEYNOTE-040 trial was a global, open-label, phase 3 study which included patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) after a platinum-based chemotherapy.

Patients were randomised to receive either pembrolizumab (n=247) or standard of care (SOC) treatment (n=248), which was the investigator's choice of either methotrexate, docetaxel, or cetuximab.

Median overall survival (OS) was only marginally higher in the pembrolizumab compared to standard treatment arm (8.4 versus 7.1 months, hazard ratio [HR] 0.81 95 percent CI 0.66-0.99, P= .0204), however for a subset of patients who had PD-L1-expressing tumours, pembrolizumab was associated with dramatic and significantly improved outcomes.

Specifically, among patients with combined tumour and immune cell PD-L1-expression (CPS) of at least 1 percent, median OS was 8.7 months with pembrolizumab versus 7.1 months with standard treatments (HR 0.75; 95 percent CI 0.59-0.95, P=.0078), and among patients with PD-L1-expression in more than 50 percent of their cancer cells, median OS was 11.6 versus 7.9 months respectively (HR 0.54; 95 percent CI 0.35-0.82, P=.0017).

Compared to the other treatments, pembrolizumab measured up well in terms of side-effects.

"In almost every category it had a better side-effect profile, meaning a lower incidence of toxicity, versus standard treatments," said Cohen. "The exception is hypothrodism, which occurred in 13 percent of those treated with pembro versus only 1 percent of those given other treatments."

Overall, Cohen said the KEYNOTE-040 trial reinforces what is already known about anti-PD therapy in head and neck cancer. "From a clinician's perspective I would feel the same in any country. This is a meaningful therapy that improves survival."

Asked to comment for ESMO, Dr. Amanda Psyrri, from the University of Athens Medical School, and Attikon University Hospital in Athens said: "Keynote-040 did not reach its primary endpoint of overall survival; however, pembrolizumab was superior to investigator's choice

in terms of toxicity, an important consideration in treatment decisions for these poor-prognosis patients with recurrent/metastatic platinum-refractory HNSCC. As the authors point out, subsequent immunotherapy in the SOC arm may have confounded OS analysis. The magnitude of treatment effect was greater in patients with PD-L1 combined positive score (CPS) ≥ 1 percent, especially those with CPS ≥50 percent,suggesting that pembrolizumab may represent the preferable treatment option for this subset of patients."

More information: Abstract LBA45_PR 'Pembrolizumab (pembro) vs standard of care (SOC) for recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC): Phase 3 KEYNOTE-040 trial' will be presented by Dr. Cohen during Proffered Paper Session 'Head and neck cancer' on Monday, 11 September 2017, 15:00 to 16:20 (CEST) in Granada Auditorium.

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