

Nivolumab reduces symptoms in relapsed metastatic head and neck cancer

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Nivolumab maintains function and reduces symptoms in treatment of relapsed metastatic head and neck cancer, according to results from the CheckMate 141 trial presented at the ESMO 2016 Congress in Copenhagen and published in the *New England Journal of Medicine*.

CheckMate 141 is a randomised, open label phase III trial in which 361 patients with platinum refractory relapsed head and neck cancer received treatment with nivolumab or standard of care chemotherapy (physician's choice of methotrexate, docetaxel or cetuximab). As previously reported, nivolumab improved overall survival by an average of 2.5 months.

For the first time today the investigators presented the results of patient reported outcomes, including functional capacity and symptoms. The analysis included 129 patients who completed questionnaires³ at baseline, nine weeks and at six week intervals during treatment. Questions covered functional areas, such as their physical ability to perform their role in life (job, etc) and their emotional, cognitive and social wellbeing. They were also asked about symptoms such as fatigue, nausea, pain and shortness of breath. An overall score was calculated for global health.

Within each treatment arm the questionnaire results were tracked from baseline to nine weeks and 15 weeks. The investigators also compared the results between the two treatment arms at nine weeks and 15 weeks using previously defined score differences defining a clinically relevant

gap (for some domains it was a gap of seven points while for others it was a gap of ten points).

For patients receiving nivolumab, both function and symptom burden was maintained or even improved at nine and 15 weeks compared to baseline. In contrast, patients receiving standard of care chemotherapy had worse scores in all areas at nine and 15 weeks compared to baseline.

When the investigators compared the scores between the two treatment arms at nine and 15 weeks, they found that for most of the function and symptom areas, nivolumab gave a clinical significant benefit over standard of care chemotherapy.

"Nivolumab not only prolongs life but it does so while maintaining function and reducing symptoms compared with standard of care chemotherapy," said lead author Professor Kevin Harrington, joint head of the Division of Radiotherapy and Imaging, at the Institute of Cancer Research, London, UK and Consultant Clinical Oncologist at The Royal Marsden NHS Foundation Trust.

"We need to drill down into the data to understand the reasons for these findings," he continued. "The data suggest that the superior clinical activity of nivolumab maintains patient-reported outcomes, but it is also likely that nivolumab is a kinder treatment that is associated with fewer side effects which can have a negative effect on quality of life."

"We're used to the notion that for gain there has to be pain, and that we have to ask patients to accept more toxicity to get better outcomes," said Harrington. "But immunotherapy with nivolumab gives better survival and allows patients to function at work and socially, and experience less pain and fatigue than with chemotherapy. This is a win-win scenario for patients and their doctors."

Commenting on the study, Professor Sandrine Faivre, a medical oncologist at Beaujon University Hospital, Clichy, France said: "This study assessed symptoms and quality of life using several questionnaires, including one specifically designed for patients with head and neck cancer. This is important because these tumours have particular consequences. A tumour mass in the neck, for example, is painful and may impair eating and speaking functions. It is also visible and can lead to social isolation."

"This is the first study to show that an immunotherapy is superior to classical treatment options for improving quality of life and symptoms, on top of prolonging survival," continued Faivre. "I can now explain to my patients that nivolumab may help them to feel and function better in daily life."

She concluded: "Nivolumab works in around one-third of patients with advanced head and [neck cancer](#). We need biomarkers or biological criteria to identify [patients](#) most likely to benefit from this treatment so that unnecessary side effects and costs are avoided."-

Provided by European Society for Medical Oncology

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