Nivolumab effective treatment for malignant mesothelioma

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Nivolumab monotherapy is an effective treatment option for relapsed malignant mesothelioma (MM), according to research presented today at the International Association for the Study of Lung Cancer World Conference on Lung Cancer.

Malignant mesothelioma is an intractable cancer, and no phase III trial has yet shown an improvement in overall survival following the standard first line chemotherapy doublet comprising pemetrexed and cisplatin or carboplatin since it was licensed in 2004.

Professor Dean Fennell, chair of Thoracic Medical Oncology at the University of Leicester in collaboration with Professor Gareth Griffiths and his team at the Southampton Clinical Trials Unit, University of Southampton, UK, presented results of the Checkpoint Blockade for Inhibition of Relapsed Mesothelioma (CONFIRM) study, funded by Cancer Research UK/Stand Up To Cancer. The investigator-led, placebo-controlled randomized phase III trial involved 24 centers in the United Kingdom.

Nivolumab is a programmed death-1 (PD-1) inhibitor that has shown activity in previously treated malignant mesothelioma in two single-arm phase II clinical trials.

In the CONFIRM trial, 332 adult patients with previously treated, unresectable, histologically confirmed MM (pleural or peritoneal) and Eastern Cooperative Oncology Group performance status 0-1 were randomly assigned to nivolumab (n = 221) or placebo (n = 111).

Participants were stratified by epithelioid vs nonepithelioid histology. The co-primary endpoints were investigator-assessed progression-free survival (PFS) and overall survival (OS); key secondary endpoints included best overall response and safety.

Overall survival was immature but showed significantly longer survival with nivolumab (events 232 [target 291]; median, 9.2 vs 6.6 months; HR, 0.72; 95% CI: 0.55-0.94; P=0.02). Investigator-assessed progression-free survival was longer for nivolumab vs placebo (3.0 vs 1.8 months; HR 0.61; 95% CI, 0.48-0.77; P 1% (in 34% of included patients) and survival. Grade 3-4 treatment-related adverse events were reported in 19% of patients who received nivolumab and in 6.3% who received placebo. Treatment discontinuation due to toxicity occurred in 13.1% (nivolumab) versus 2.7% (placebo).

"CONFIRM met its co-primary endpoints of

improved overall survival and progression-free survival with nivolumab vs placebo in relapsed malignant mesothelioma. The safety profile of nivolumab was consistent with its known profile with no new safety signals. Nivolumab monotherapy is an effective treatment option for [patients with this disease," said Prof. Fennell.

"CONFIRM gives good evidence that this treatment approach should be considered for the new standard of care for these patients," said Prof. Griffiths

"Therapeutic alternatives are always welcome in the contest of a difficult-to-treat diseases such as malignant pleural mesothelioma," said Dr. Giorgio Scagliotti, interim IASLC CSO, "and this study contributes to increase our range of treatment opportunities in the setting of relapsed/recurrent disease."

Provided by International Association for the Study of Lung Cancer