53P Immune-related adverse events correlate with clinical outcomes in non-small cell lung cancer (NSCLC) patients treated with nivolumab in the Italian expanded access programme

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Background: The incidence of any and of severe grade immune-related adverse events (irAEs) with second-line Nivolumab (N) monotherapy is 26% and 6% respectively. While potentially serious and even fatal, in the absence of appropriate therapy, such events might be an indicator of the activation of the immune system and, potentially, of efficacy.

Methods: We collected the records of 1.959 NSCLC patients (pts) including those with Squamous (S) and non-Squamous (non-S) histology, treated with N in the Italian expanded access programme and we recorded the appearance of any and of severe grade

irAEs. We then retrospectively searched for potential correlations between this type of toxicity and efficacy parameters by using cox regression analysis.

Results: A total of 1.585 and 374 pts had non-S and S cell carcinoma respectively and 57% received N as second-third line of therapy. Overall 342 (17.8%) developed an irAE of any grade. We observed that pts developing any grade irAE achieved a significantly higher response rate (RR 27.2% vs 15.2%; $p < 0.0001$), disease control rate (DCR 60.5% vs 40.2%; $p < 0.0001$), median progression-free survival (mPFS 6.0 months [95% CI 4.9-7.1] vs 3.0 [95% CI: 2.8-3.2], $p < 0.0001$) and median overall survival (mOS 16.7 months [95% CI: 13.5-19.9] vs 9.4 [95% CI: 8.4-10.4], $p < 0.00001$) compared to pts who did not. IrAEs correlate with clinical outcomes in both non-S and S histology. At multivariate analysis the development of an irAE remained an independent indicator of N efficacy (HR 1.44[95% CI: 1.22-1.71] $p < 0.0001$).

Conclusions: This is the first report performed in a large series of Caucasian NSCLC pts showing that the activation of the immune system induced by N and documented by the appearance of irAEs correlates with outcome. A careful management of pts with such an event could lead to a maximum clinical benefit.

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