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1225P Preliminary efficacy and safety data of nivolumab in never smoker patients with advanced squamous NSCLC: Experience from Italian sites participating in the Expanded Access Programme (EAP)

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Background: Nivolumab is the first checkpoint inhibitor approved for the treatment of squamous non-small cell lung cancer (Sq-NSCLC) to show a survival benefit in a randomised phase III trial. In prior studies nivolumab has shown a better clinical benefit in current and former smokers compared to never smokers. Nevertheless, no data are available from a real world setting. The EAP provided an opportunity to evaluate the feasibility of treatment in this patient population outside of a controlled clinical trial in Italy.

Methods: Nivolumab was available upon physician request for patients (pts) aged ≥18 years who had relapsed after a minimum of one prior systemic treatment for stage IIIB/stage IV Sq-NSCLC. Nivolumab 3 mg/kg is administered intravenously every 2 weeks to a maximum of 24 months. Pts included in the analysis had received ≥ 1 dose of nivolumab and were monitored for adverse events using Common Terminology Criteria for Adverse Events.

Results: Of 372 patients with Sq-NSCLC participating in the EAP in Italy, 38 (10.2%) were never smokers, in line to what observed in the registrational study Checkmate 017 (10%). With a median number of doses 8 (range, 1–22) and a median follow-up of 5.6 months, the disease control rate was 50%, including 9 patients with a partial response and 10 with stable disease. Eight pts were treated beyond RECIST defined progression, with 4 of these pts achieving a disease control. As of April 2016, median progression-free survival and overall survival were 3.5 months and not reached, respectively. Among 38 pts, 17 pts (44.7%) discontinued treatment for any reason except toxicity; 5 out of 38 discontinued due to AE (13.1%).

Conclusions: With the limitation of a small sample size and type of study (EAP), these data seem to suggest that nivolumab might have a similar efficacy in non-smoker patients to that observed in the overall population, warranting further investigation in this area.

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