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Activity of OSE-2101 in HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO): Final results of phase III Atalante-1 randomised trial

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Background

OSE2101 (Tedopi®) is an anticancer vaccine (modified epitopes restricted to HLA-A2+ from 5 tumor-associated antigens). Atalante-1 is a randomized phase 3 trial of OSE2101 vs Standard of Care (SoC docetaxel or pemetrexed) in pretreated HLA-A2+ patients with advanced NSCLC, with IO as last treatment.

Methods

EGFR and ALK negative NSCLC patients, ECOG PS 0-1 were randomized 2:1 to receive OSE2101 subcutaneously Q3W for 6 cycles, followed by maintenance Q8W for 1 year and Q12W until progression, versus SoC (docetaxel or pemetrexed Q3W). Primary endpoint was OS (initial hypothesis of HR 0.7 for 401 pts). Secondary endpoints were disease control rate (DCR), quality of life (QoL - EORTC QLQ-C30/LC13), and Progression free survival (PFS). Toxicities were reported using CTCAE 5.0. Positive pre-specified analyses (ESMO 2020 #1260MO) identified a Population of Interest (PoI) comprised by patients with IO secondary resistance defined as failure after a minimum of 12 weeks IO in sequential CT-IO patients. Due to the risk of COVID-19 pandemic on data integrity, the study was stopped prematurely following IDMC recommendations. PoI was chosen as primary population for the final analysis.

Results

219 pts were enrolled: median age 65 years, 29% female, 10% never-smoker, 70% non-squamous. 183 (84%) pts received sequential CT-IO from whom 118 pts (54%) complied with the definition of PoI, with otherwise similar characteristics that the overall population. In PoI, mOS was 11.1 mo for OSE2101 vs 7.5 for SoC [HR 0.59 (0.38-0.91) p= 0.02]. 6 mo-DCR 25% vs 24% (NS), mPFS 2.7 mo vs 3.4 (NS), ORR 8% vs 18% (p=0.07). Post progression survival was 7.7 mo vs 4.6 [HR 0.46 p= 0.004], time to worsening ECOG PS 8.6 mo vs 3.3 [HR 0.45 p= 0.0005]. In the total population, HR for OS was 0.86 (0.62-1.19) p=0.36. QoL Global Health Status was maintained for OSE2101 (p<0.05). Severe Adverse Events were 38% vs 68% (p<0.001). There was no TEAE of concern in the OSE2101 group.

Conclusions

OSE2101 had a favorable benefit/risk of versus SoC in advanced HLA-A2+ NSCLC patients. HR for OS improved from 0.86 to 0.59 in patients with secondary resistance to IO with a meaningful gain of median OS of 3.6 months with OSE2101.

Clinical trial identification

EudraCT 2015-003183-36; NCT02654587.

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